EXHIBIT 1001

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Albert et al.

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(54) **APPARATUSES AND METHODS FOR NEGATIVE PRESSURE WOUND THERAPY**

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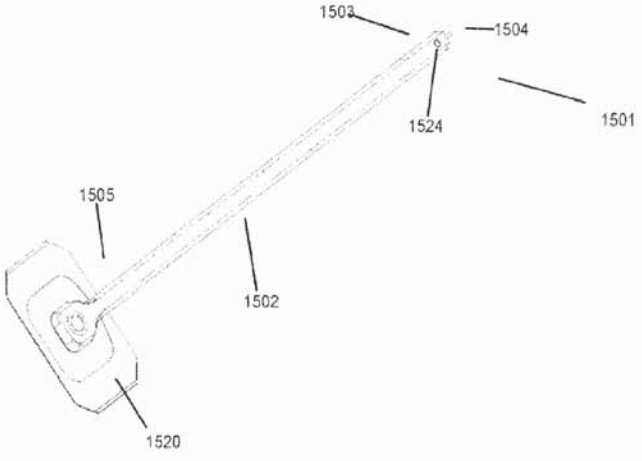
(57) **ABSTRACT**

Disclosed herein are several embodiments of a negative pressure appliance and methods of using the same in the treatment of wounds. Some embodiments are directed to improved fluidic connectors or suction adapters for connecting to a wound site, for example using softer, kink-free conformable suction adapters.

24 Claims, 92 Drawing Sheets



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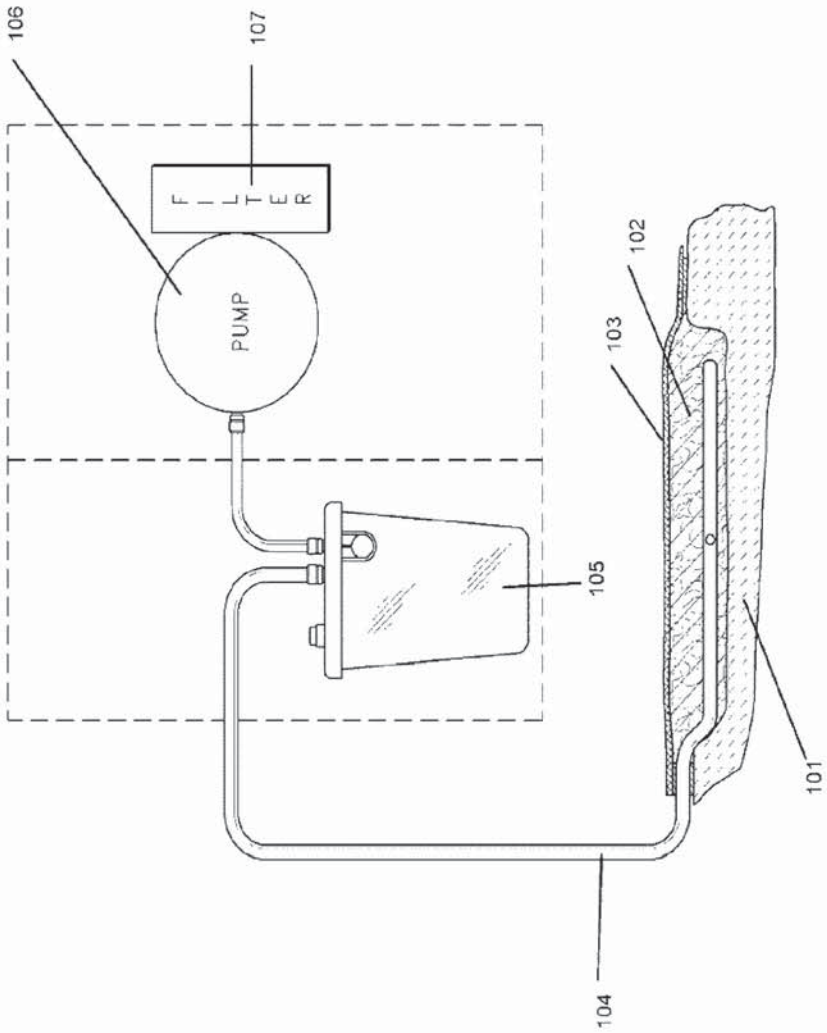

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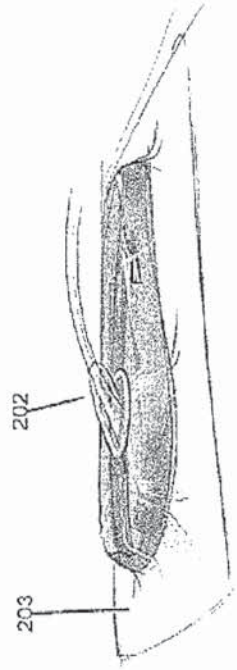

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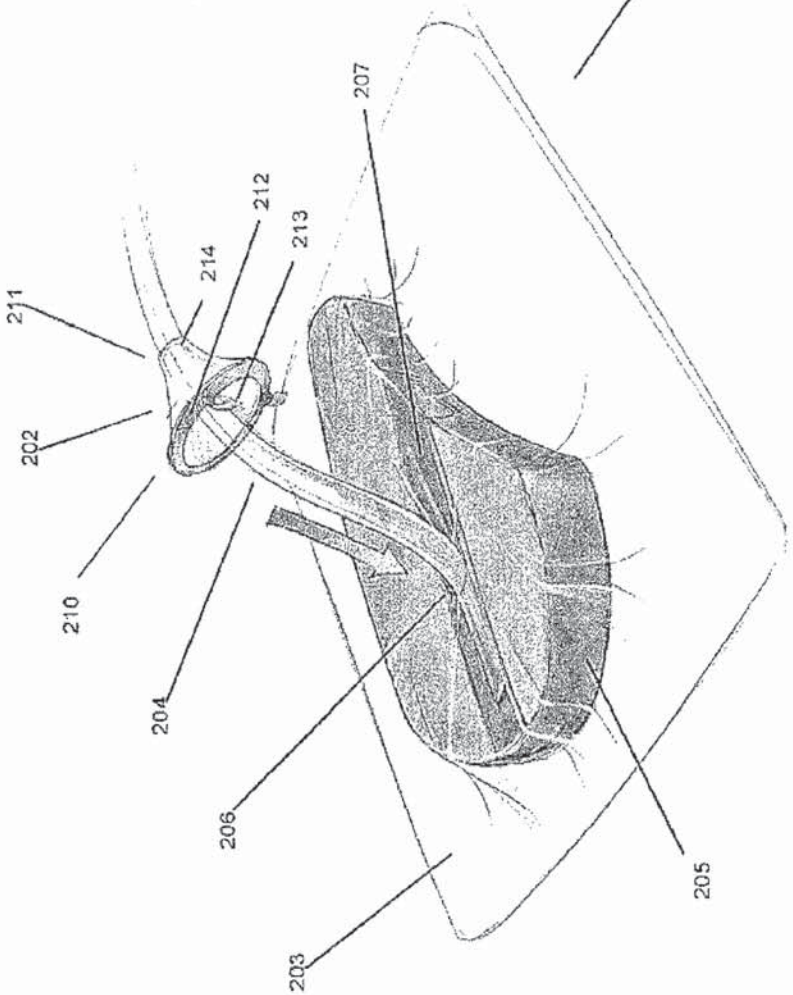

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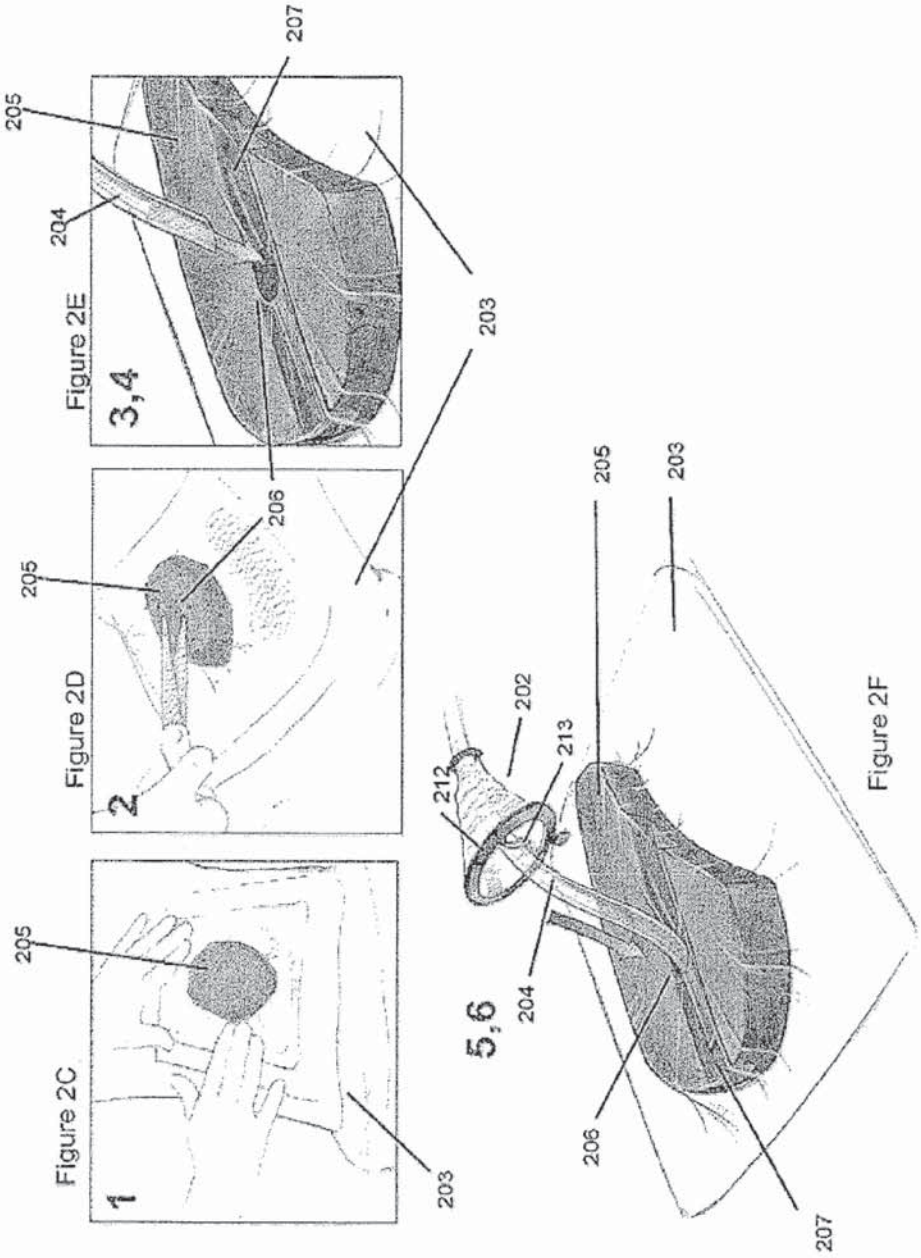
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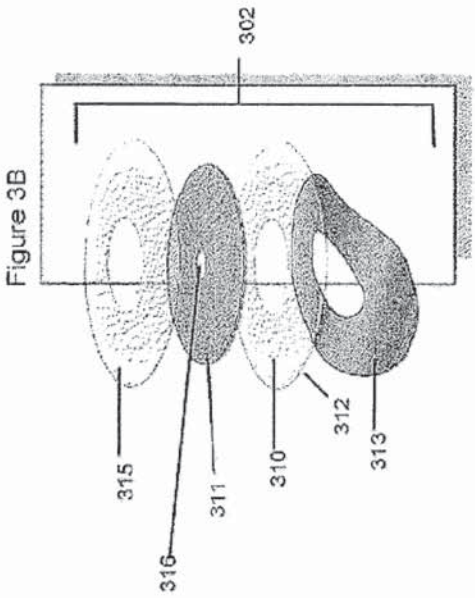

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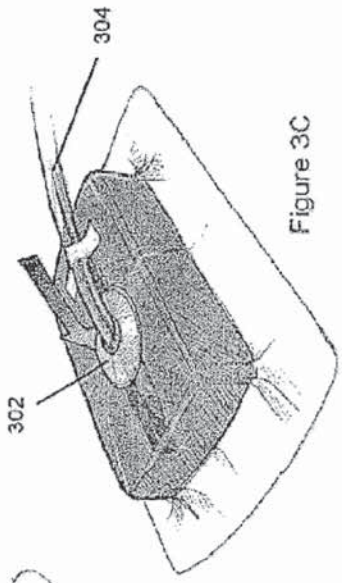
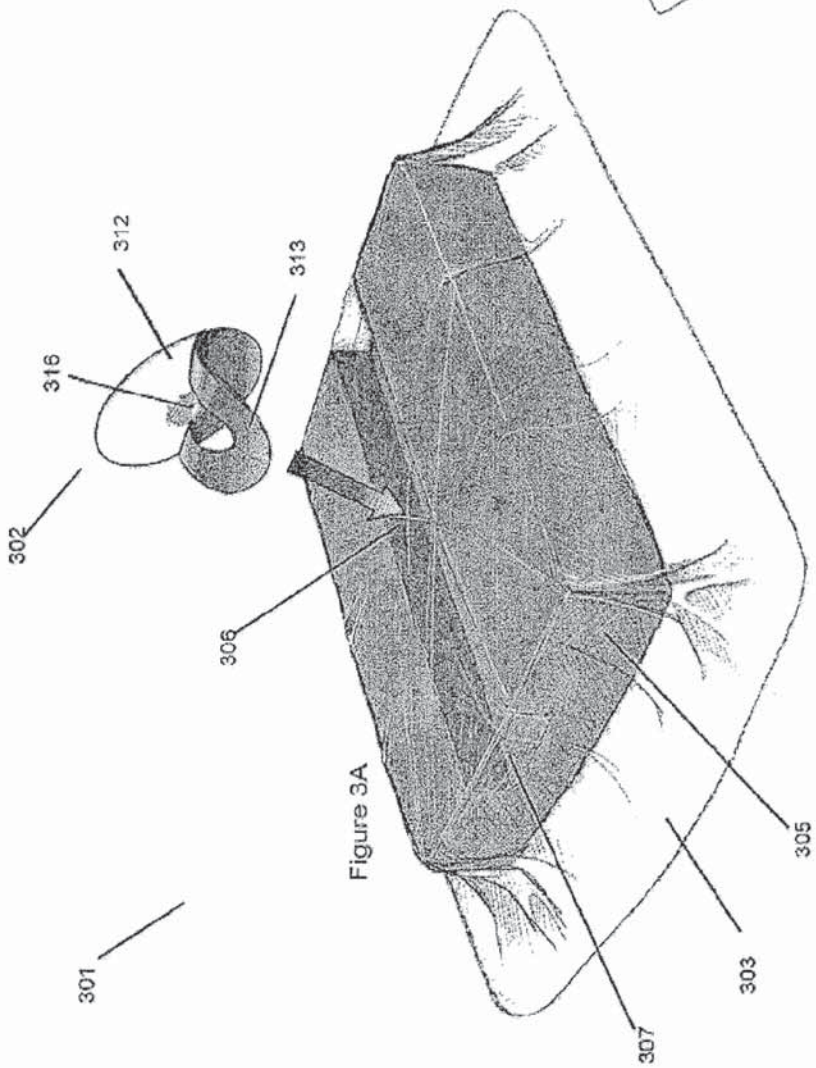


Figure 3C



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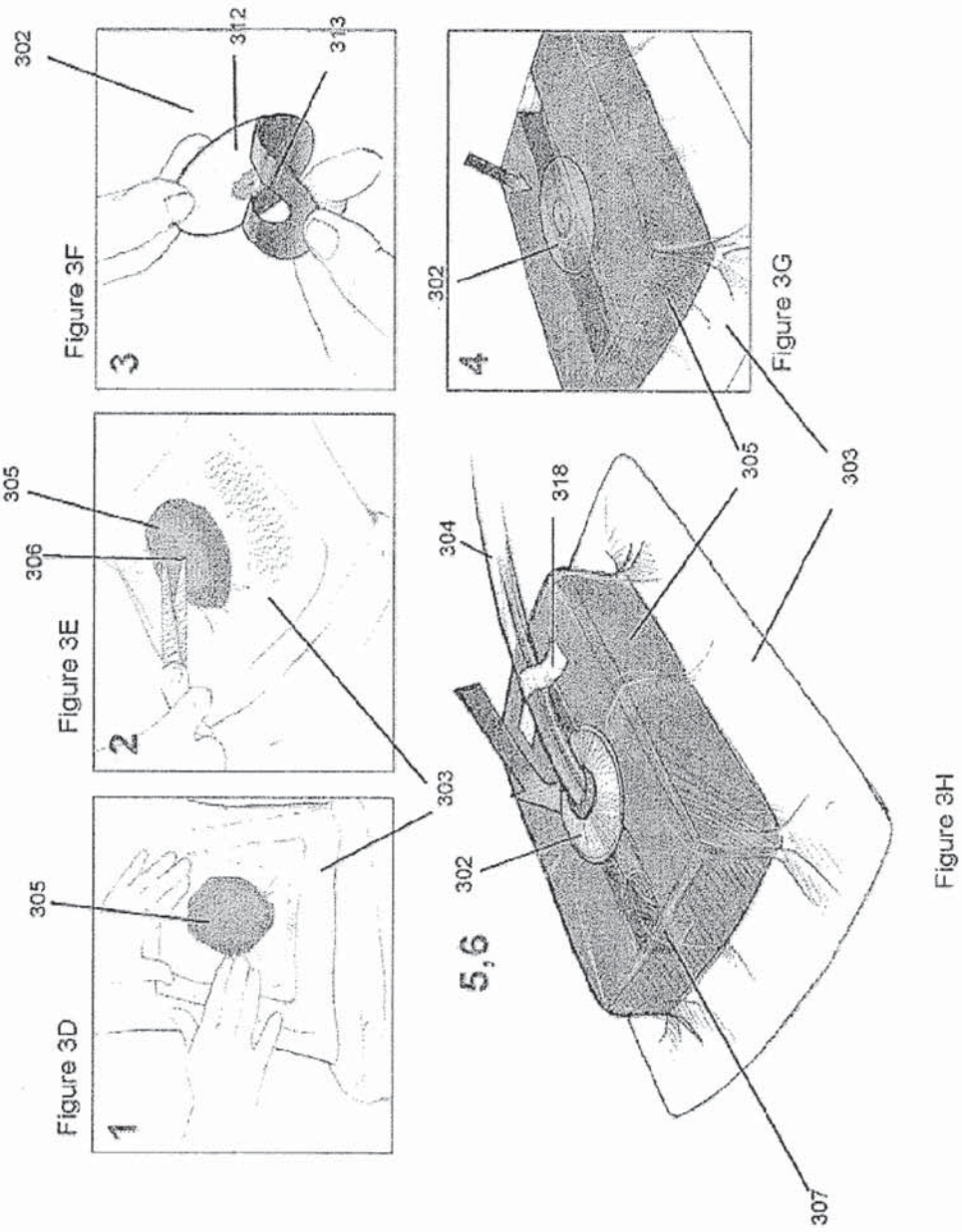
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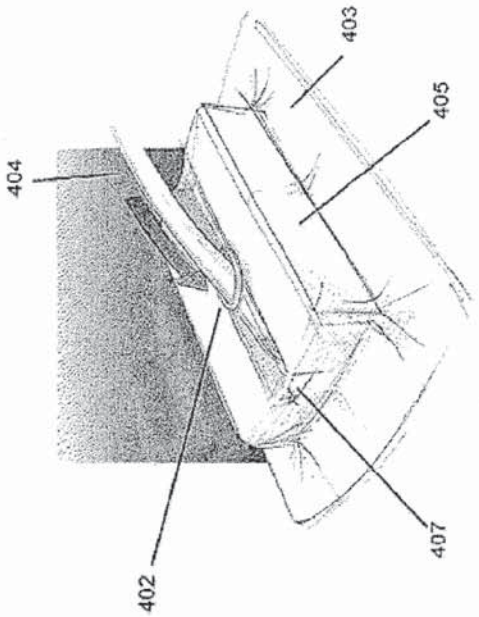
Figure 3H



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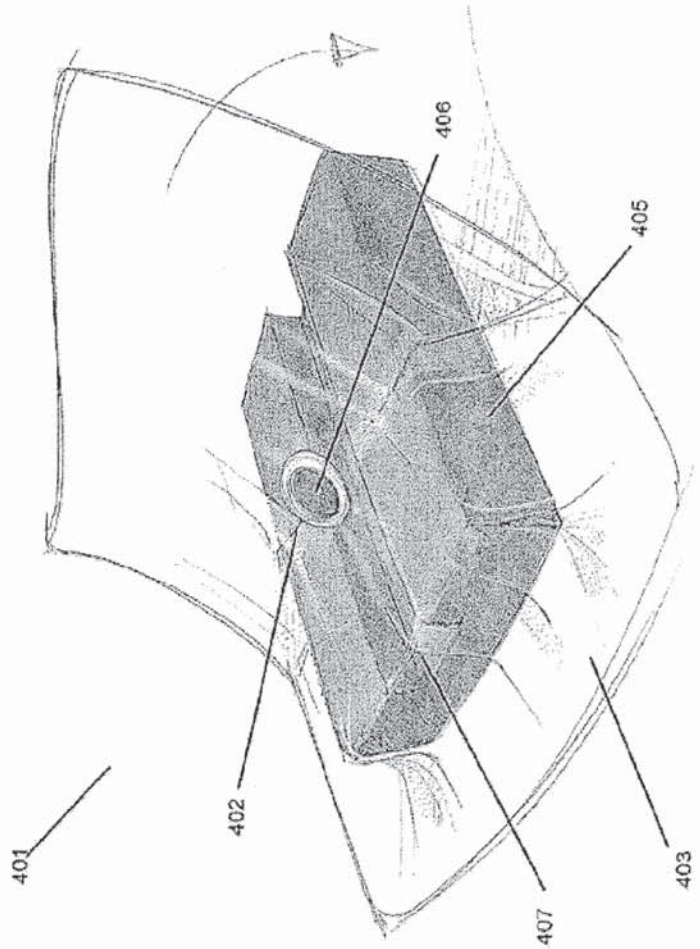

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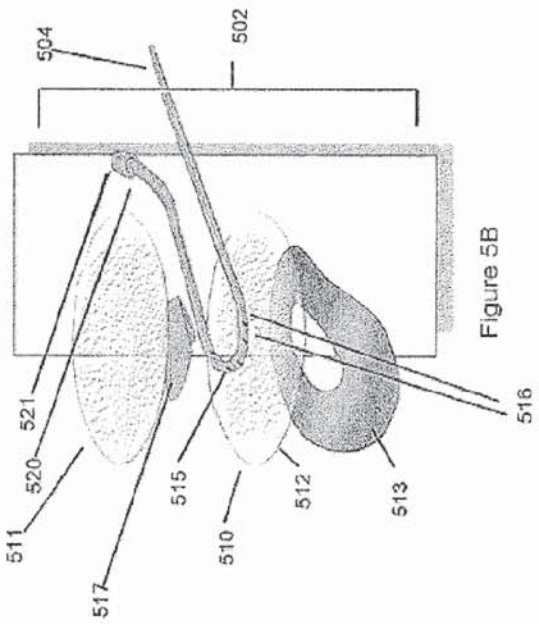

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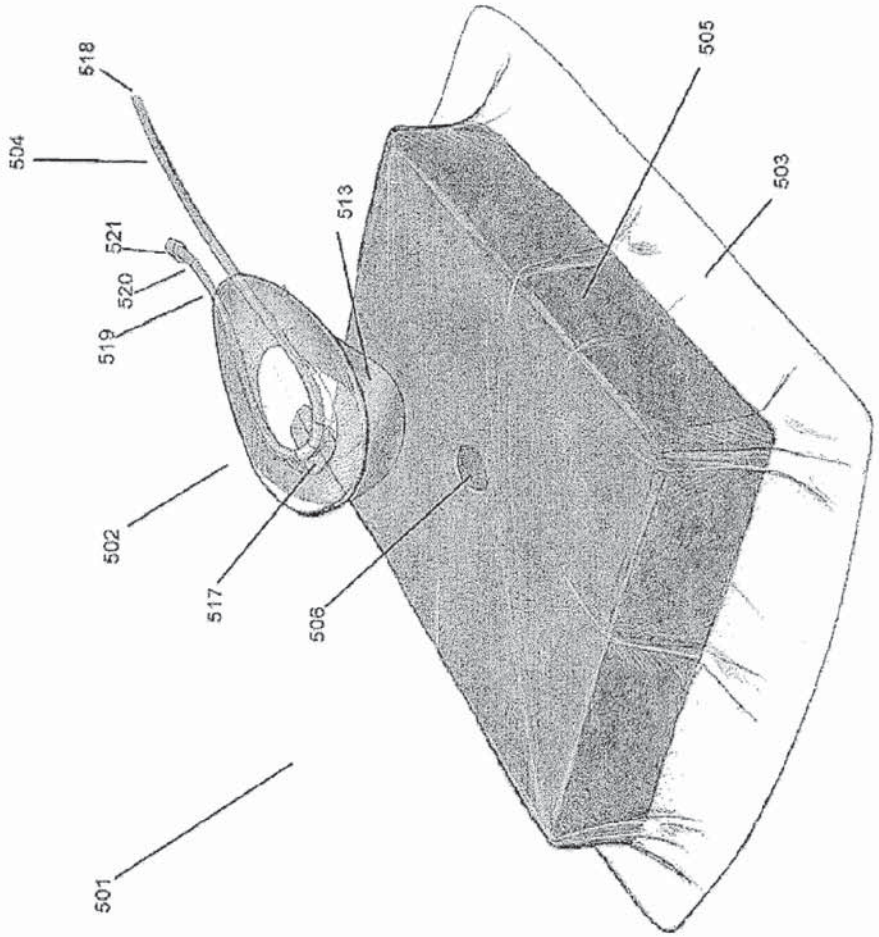

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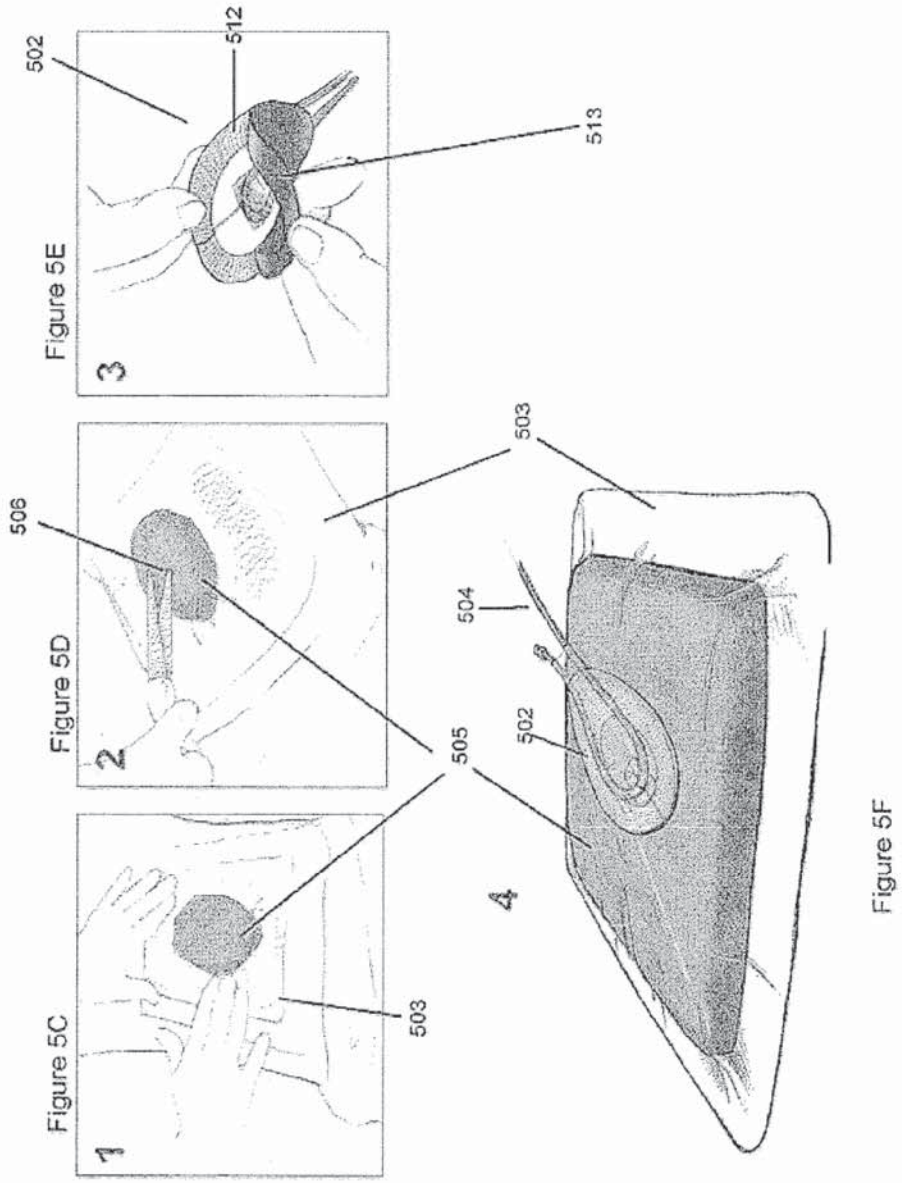
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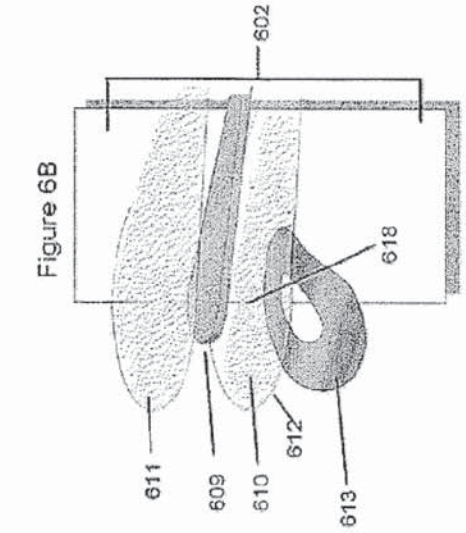

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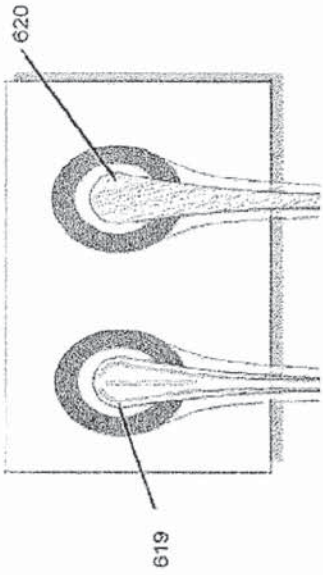
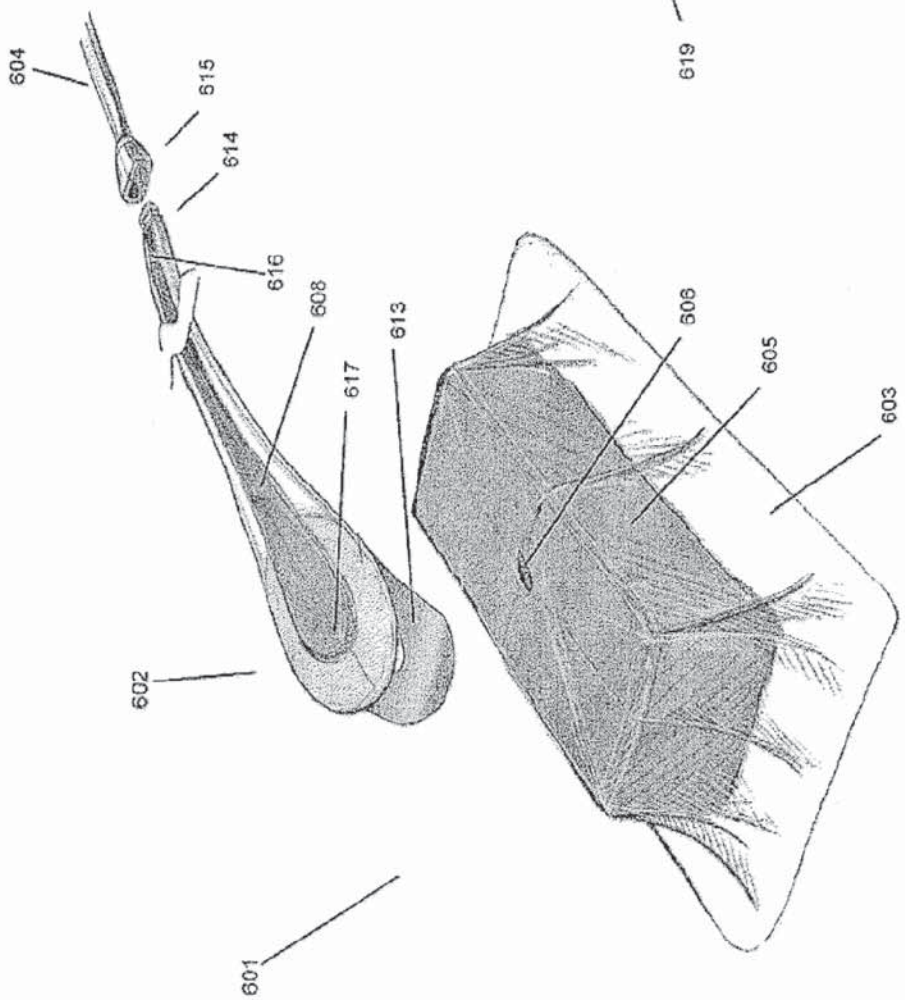


Figure 6C

Figure 6D



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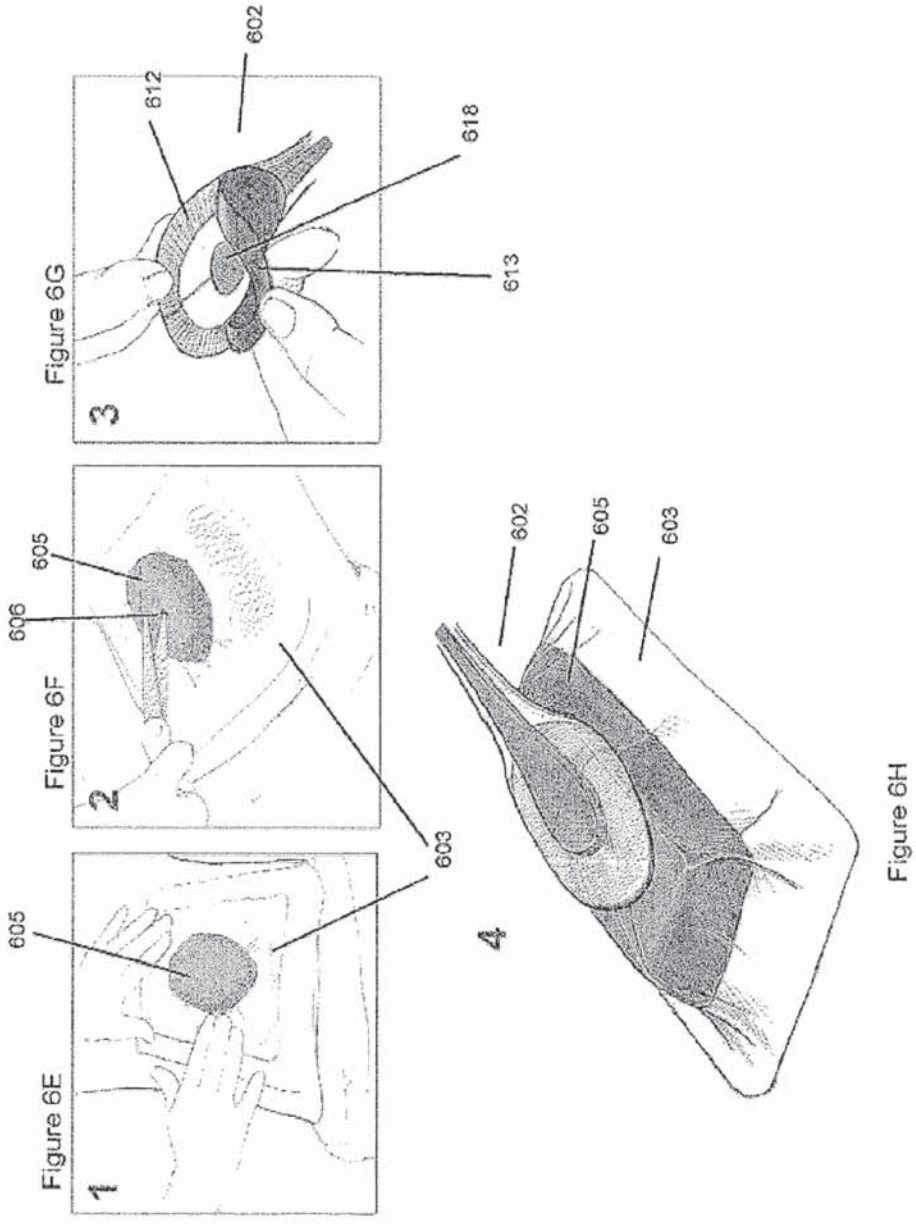
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Figure 6H

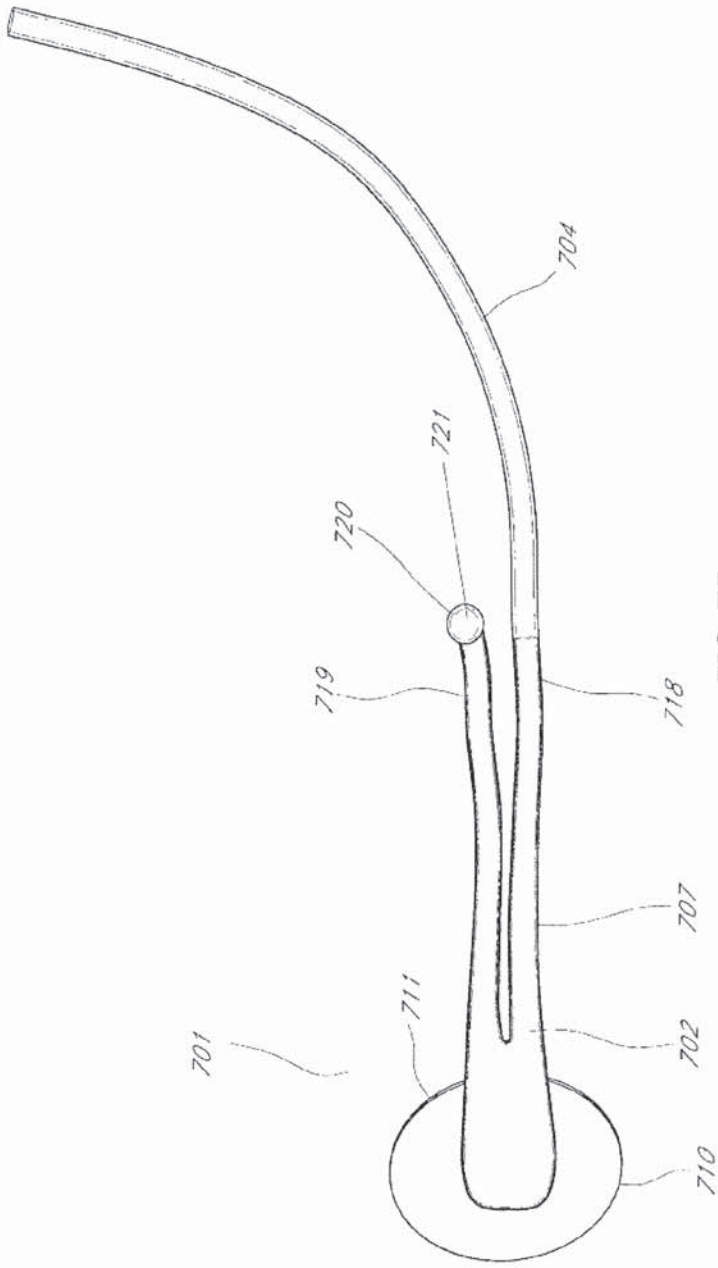


FIG. 7A

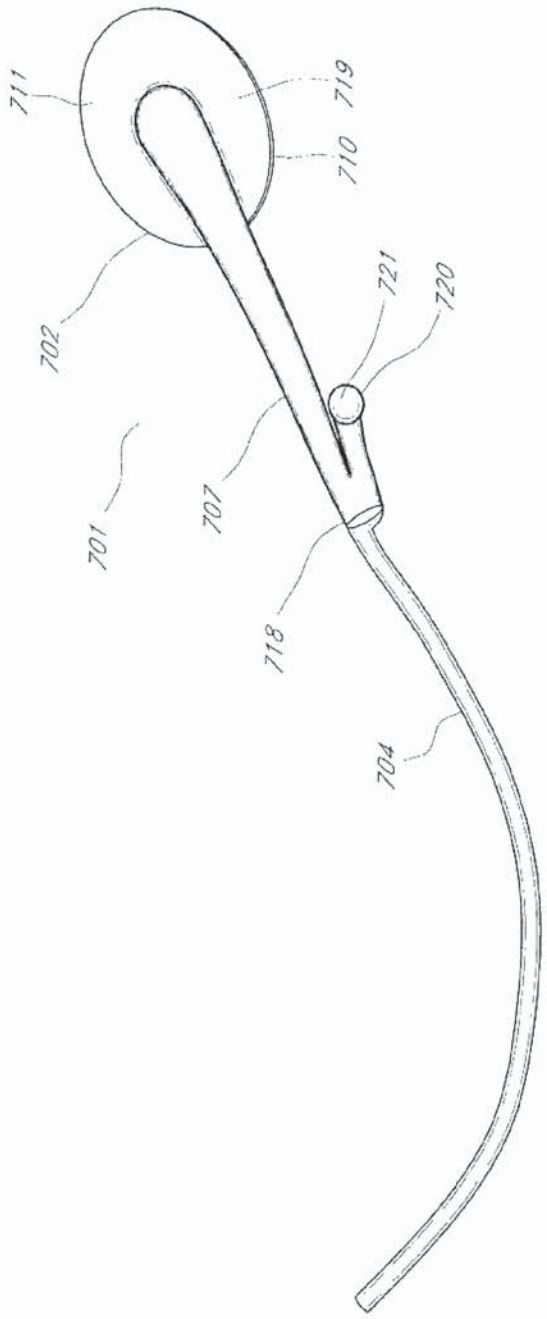


FIG. 7B

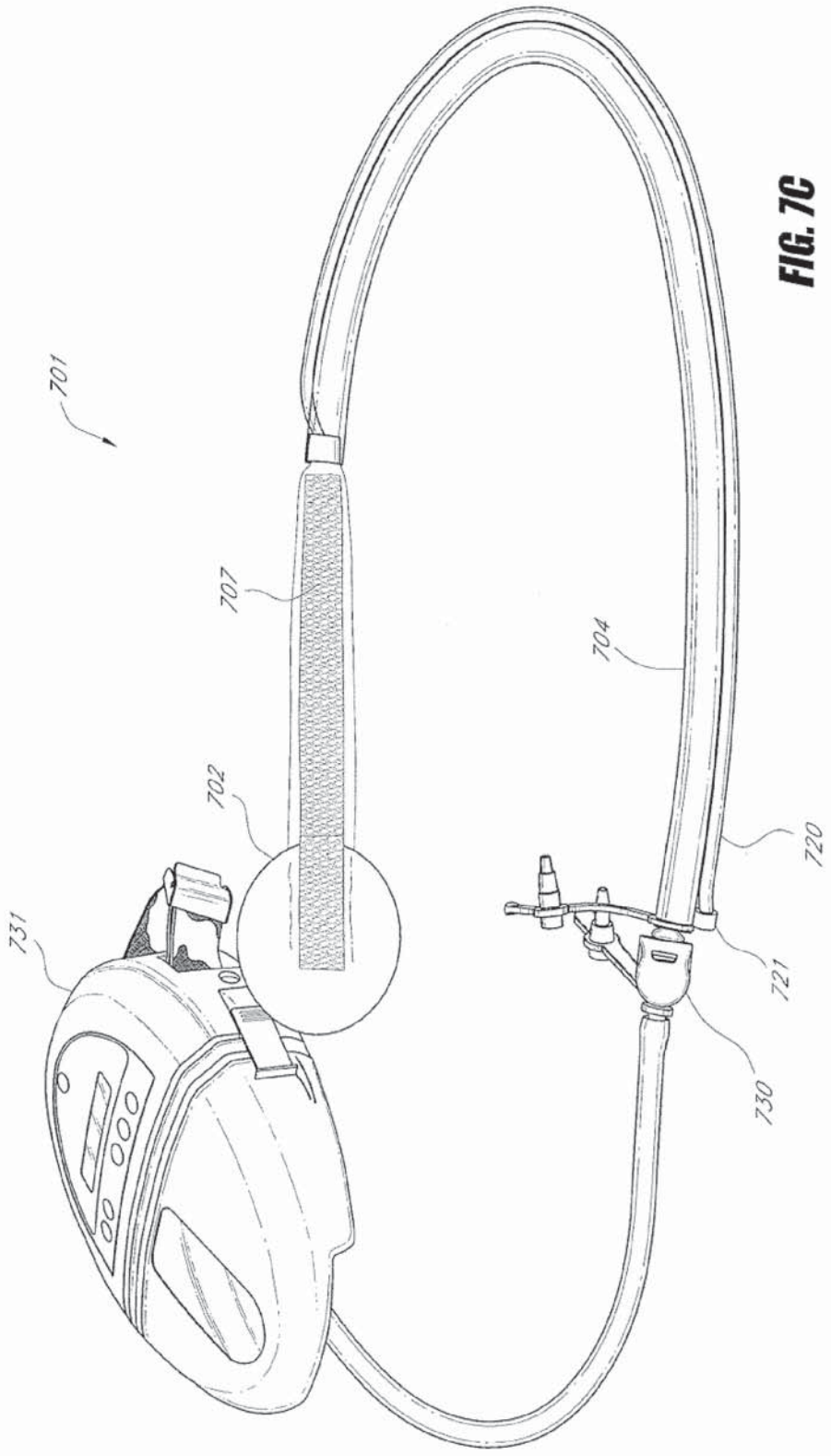


FIG. 7C

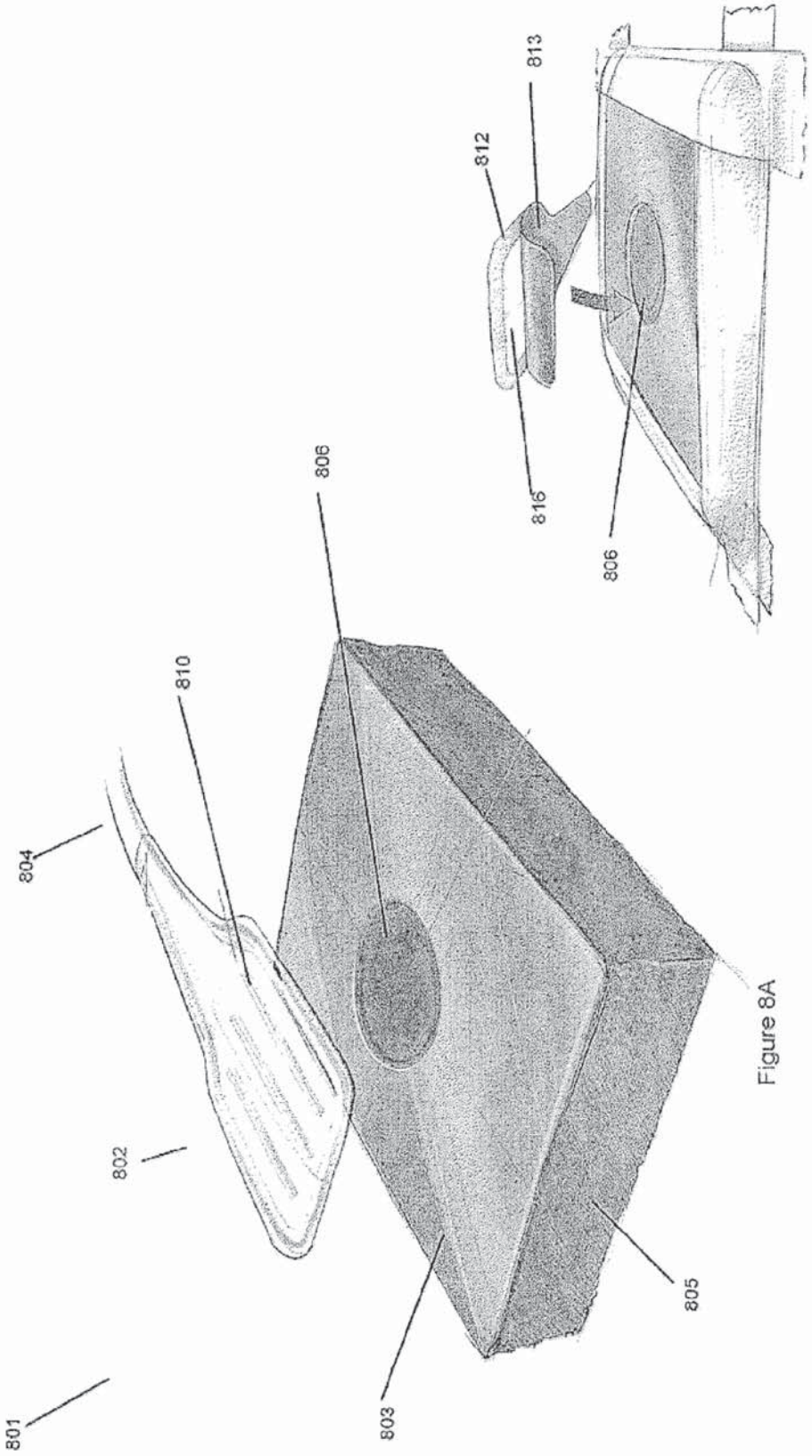


Figure 8A

Figure 8B

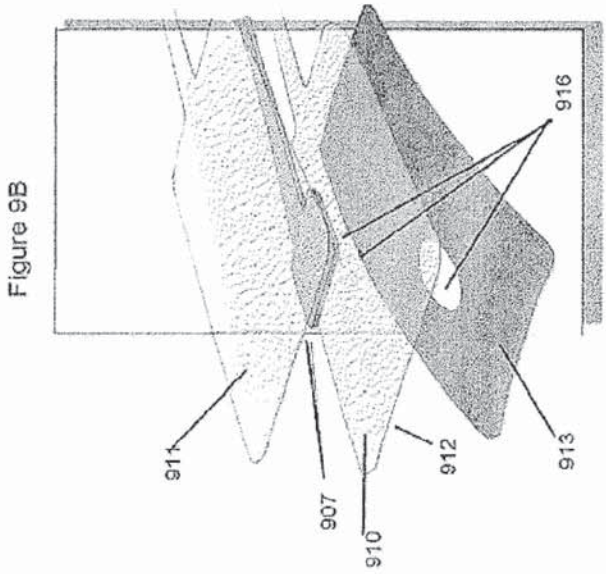
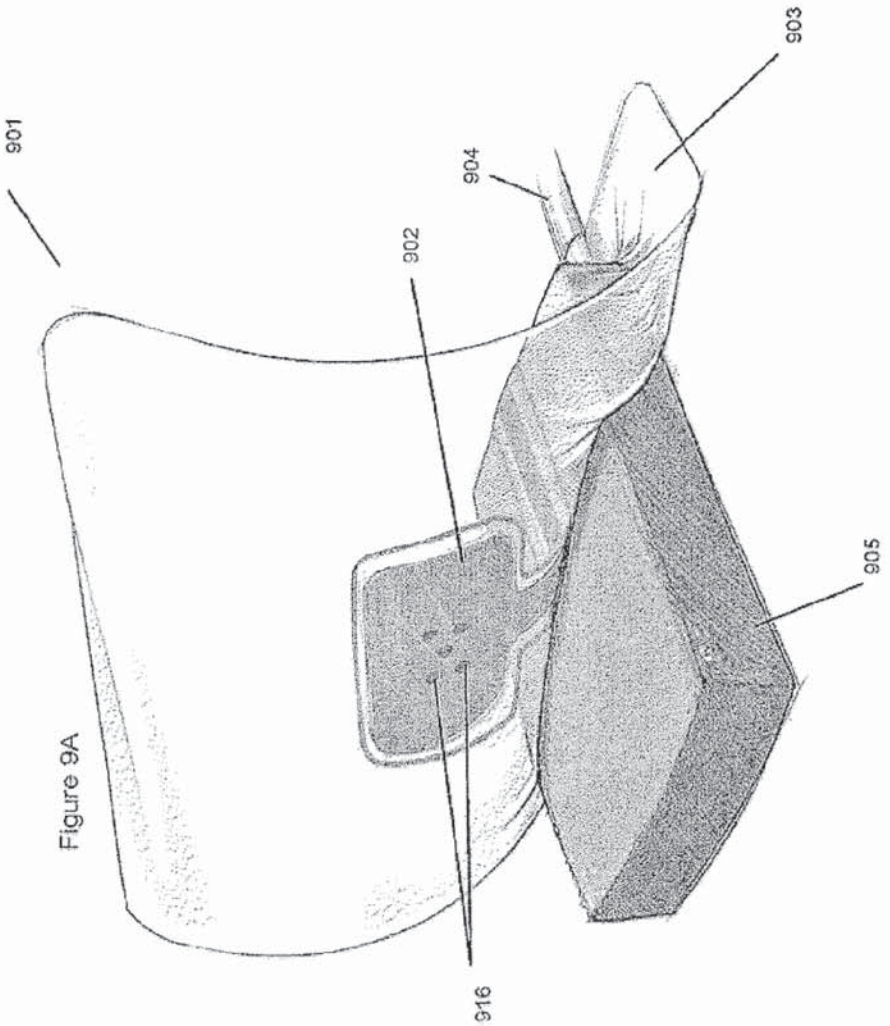


Figure 9B



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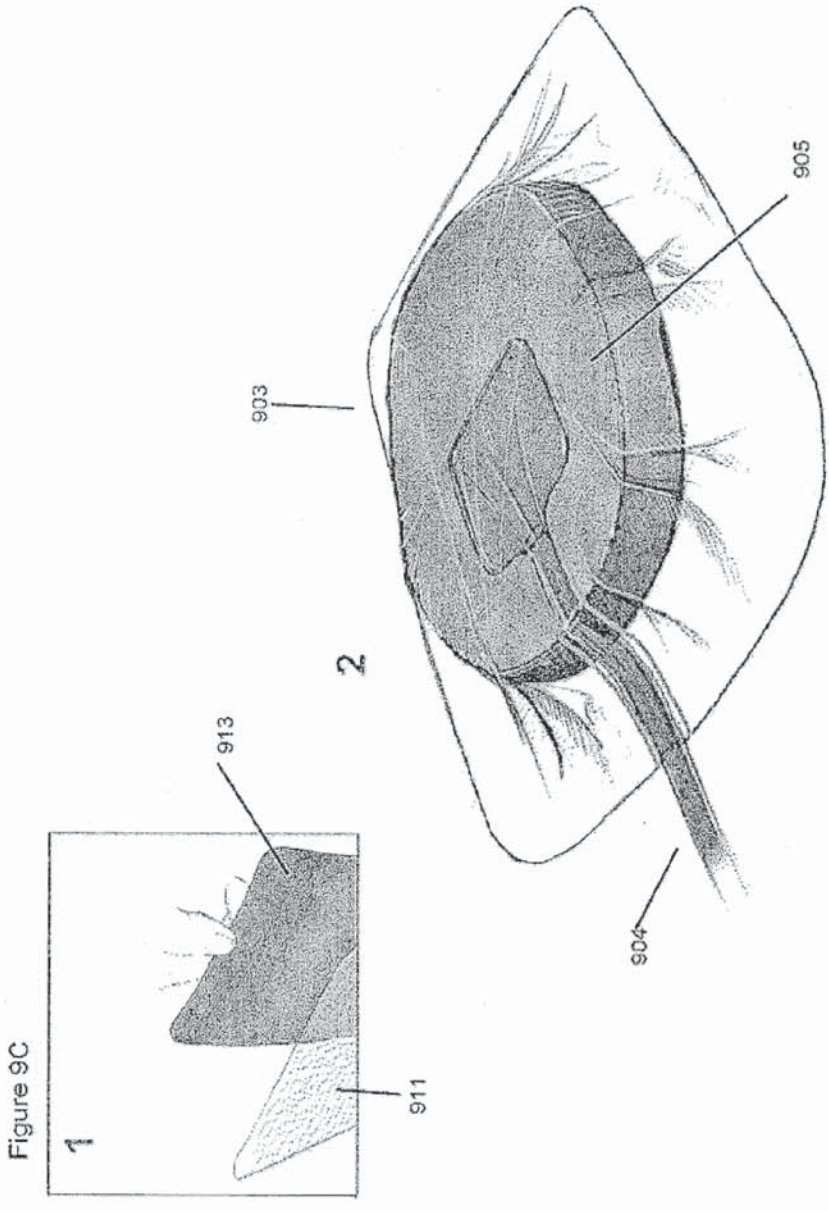
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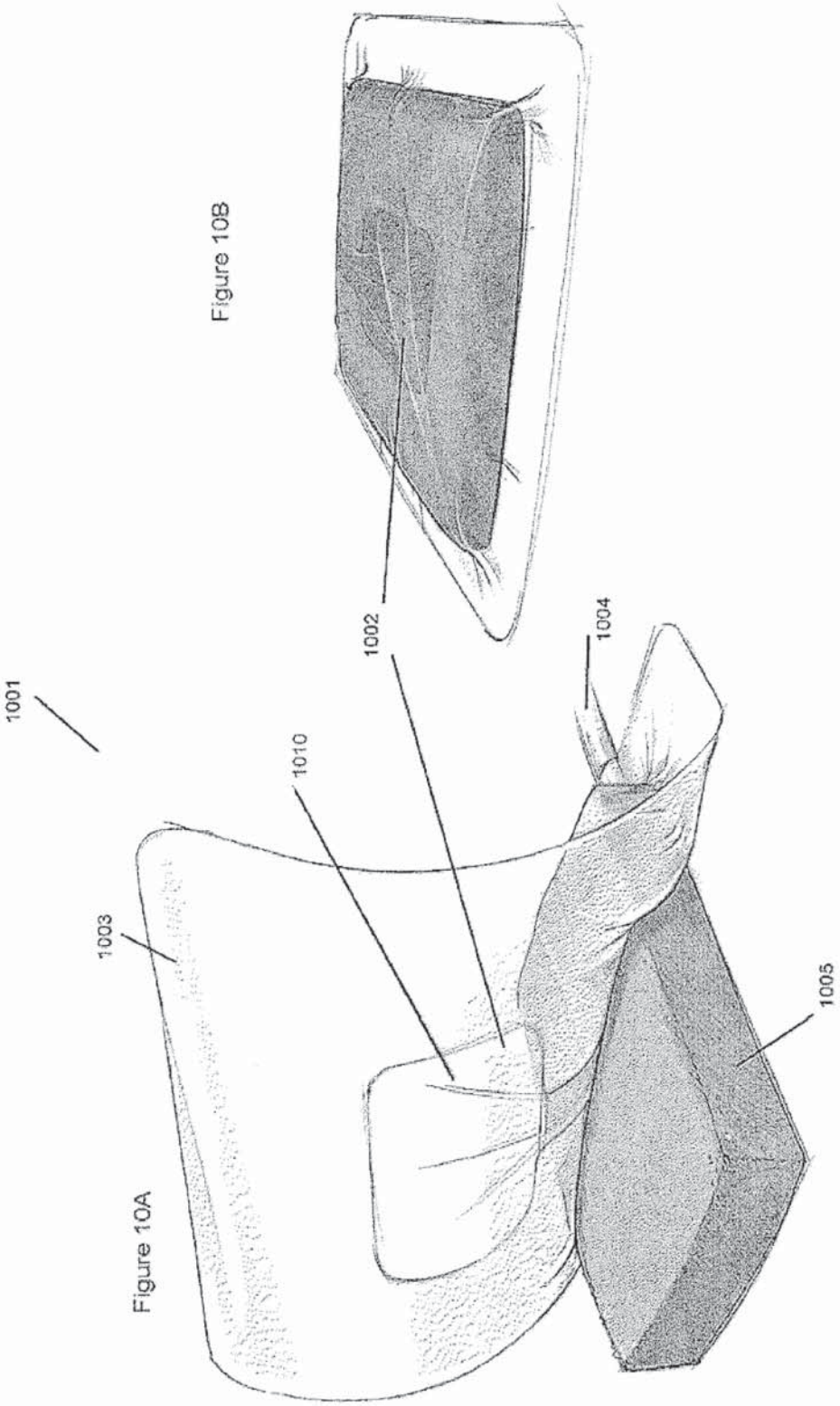


Figure 10A

Figure 10B

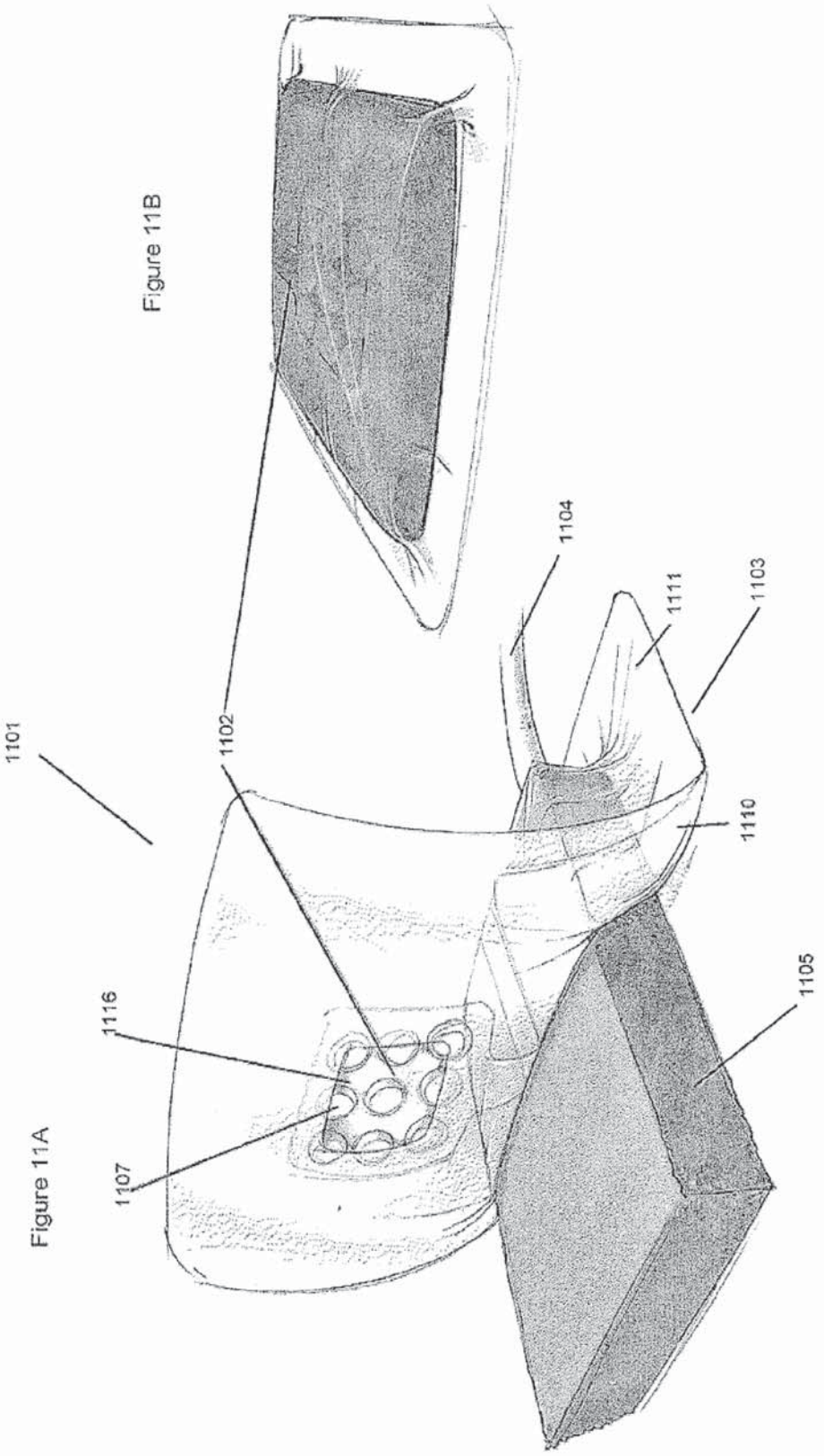


Figure 11A

Figure 11B

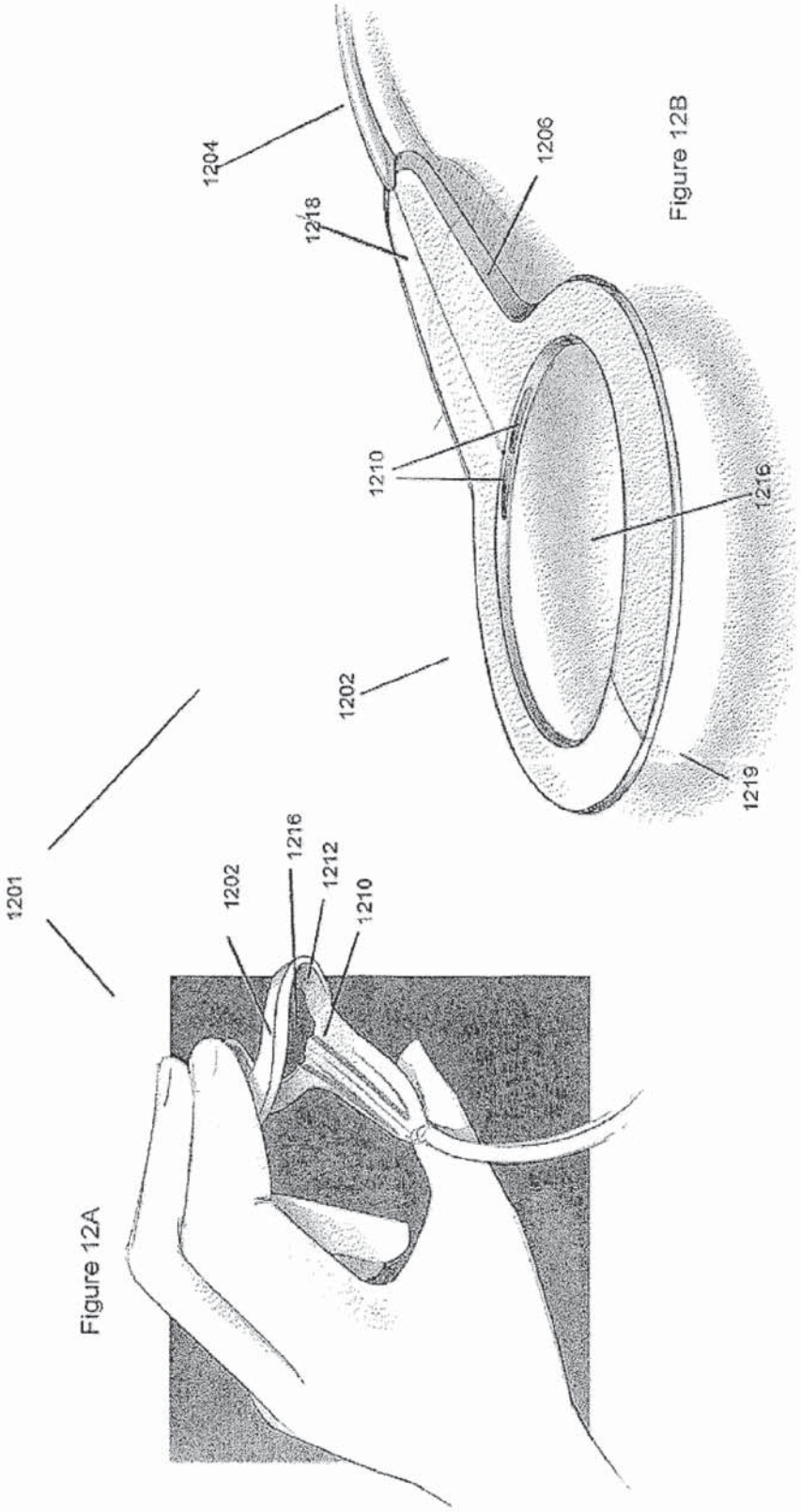
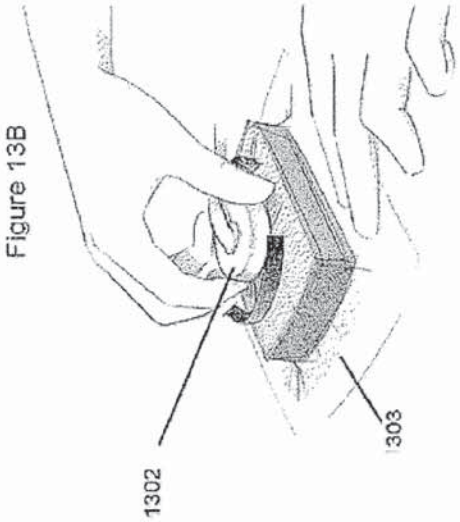


Figure 12A

Figure 12B



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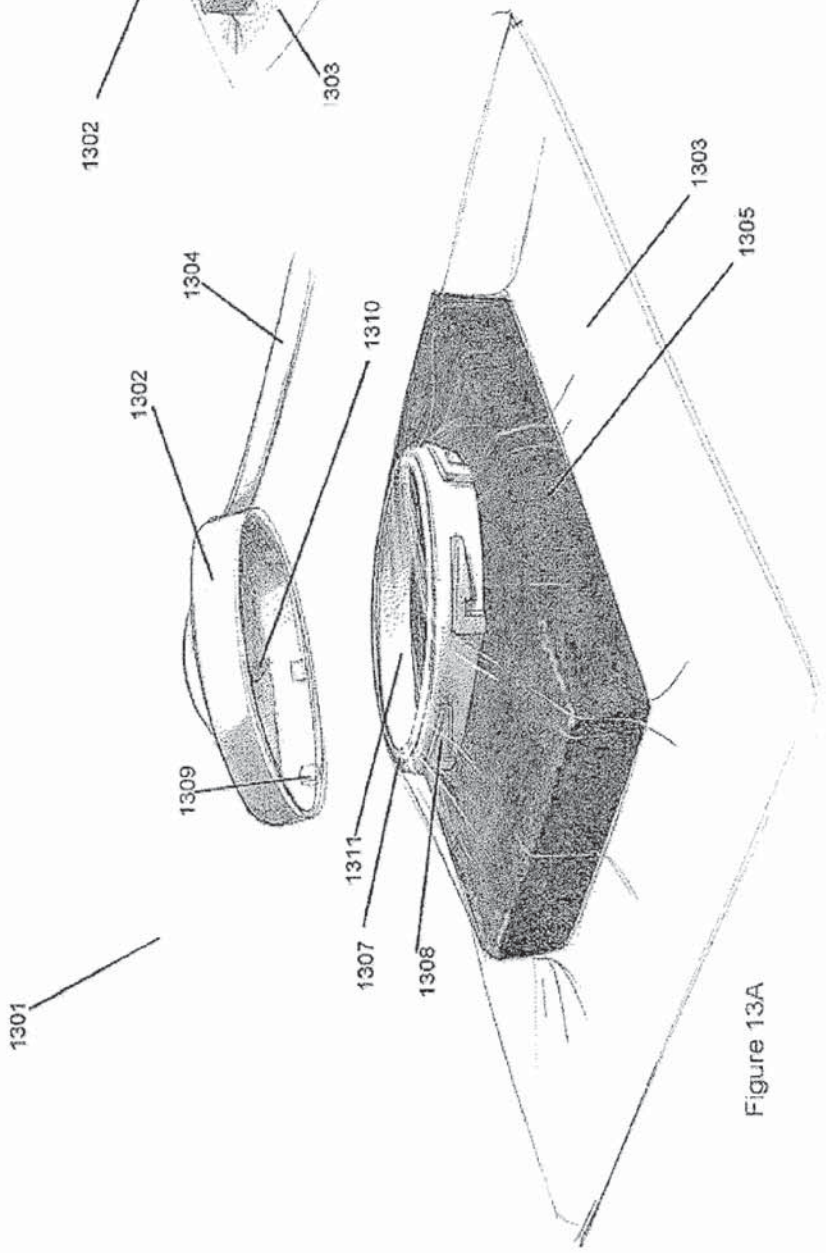

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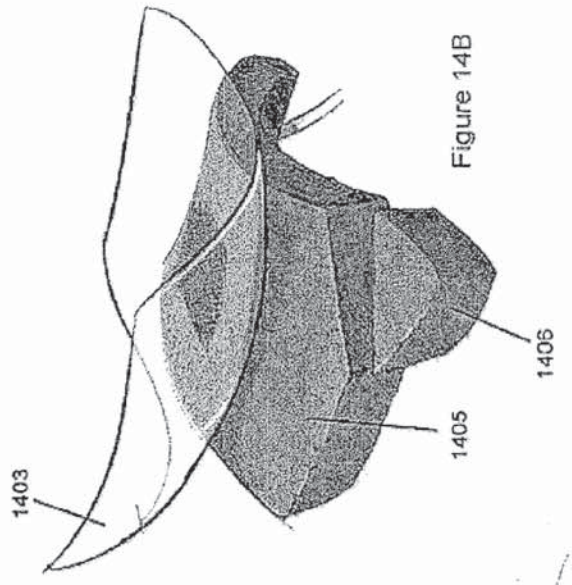

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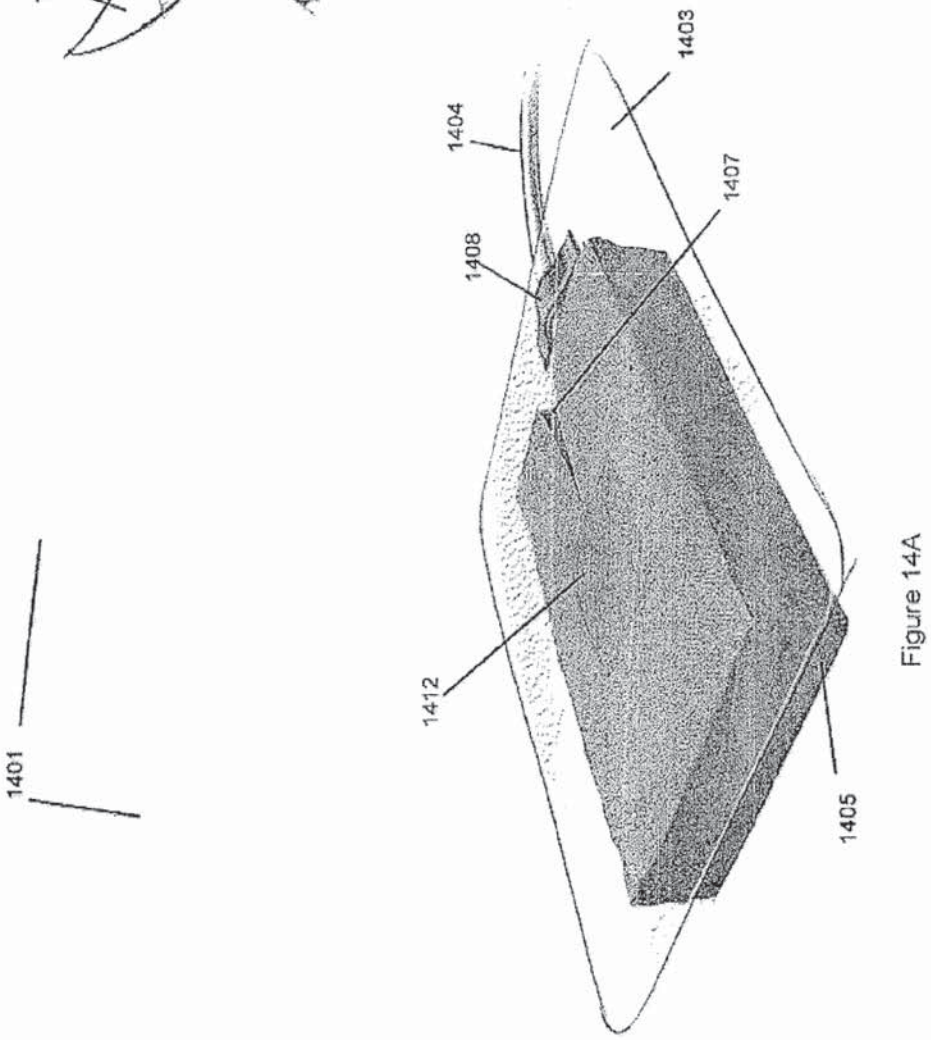

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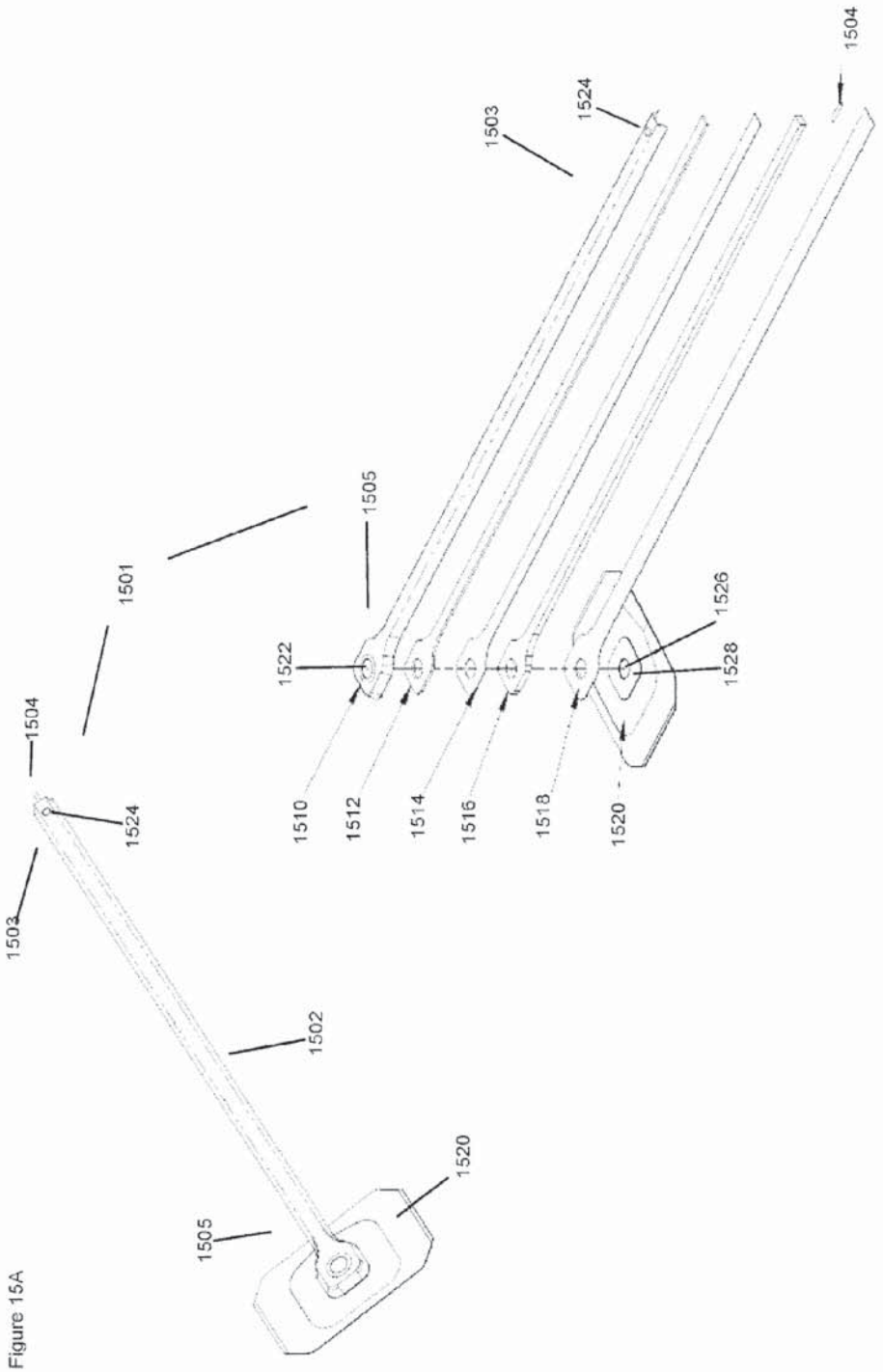


Figure 15A

Figure 15B

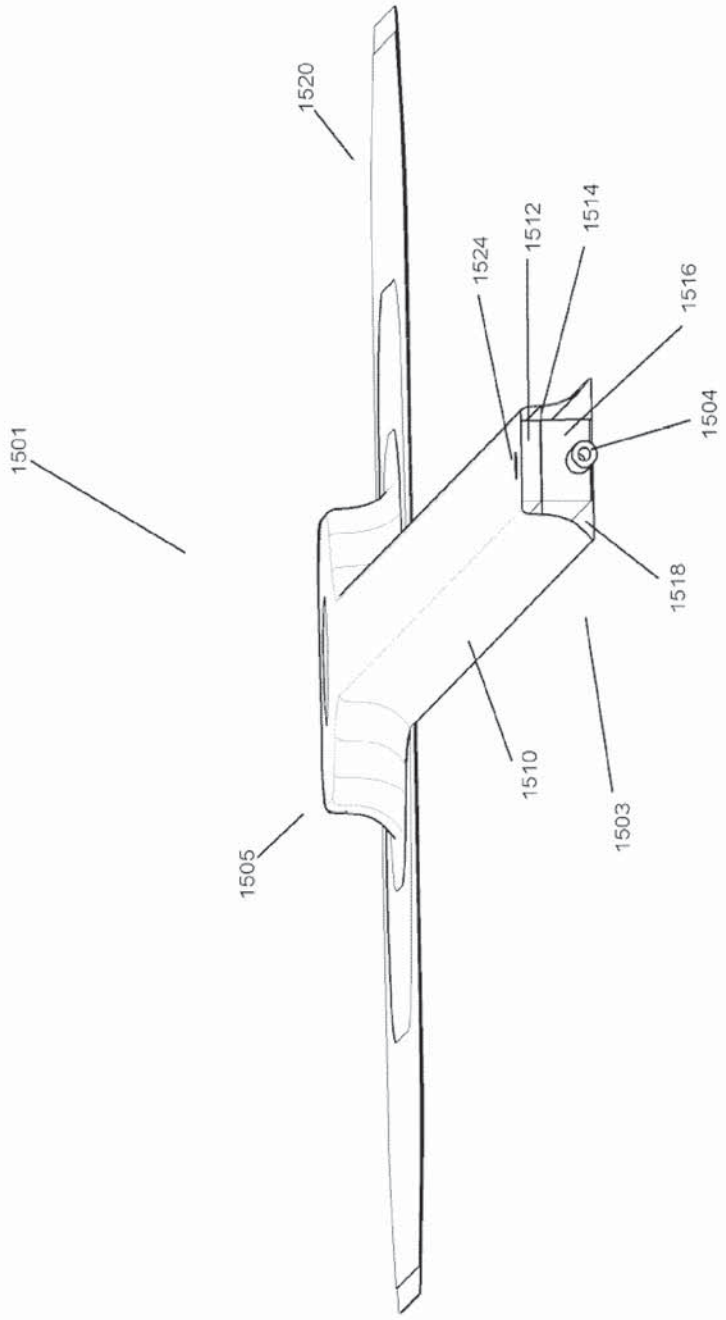
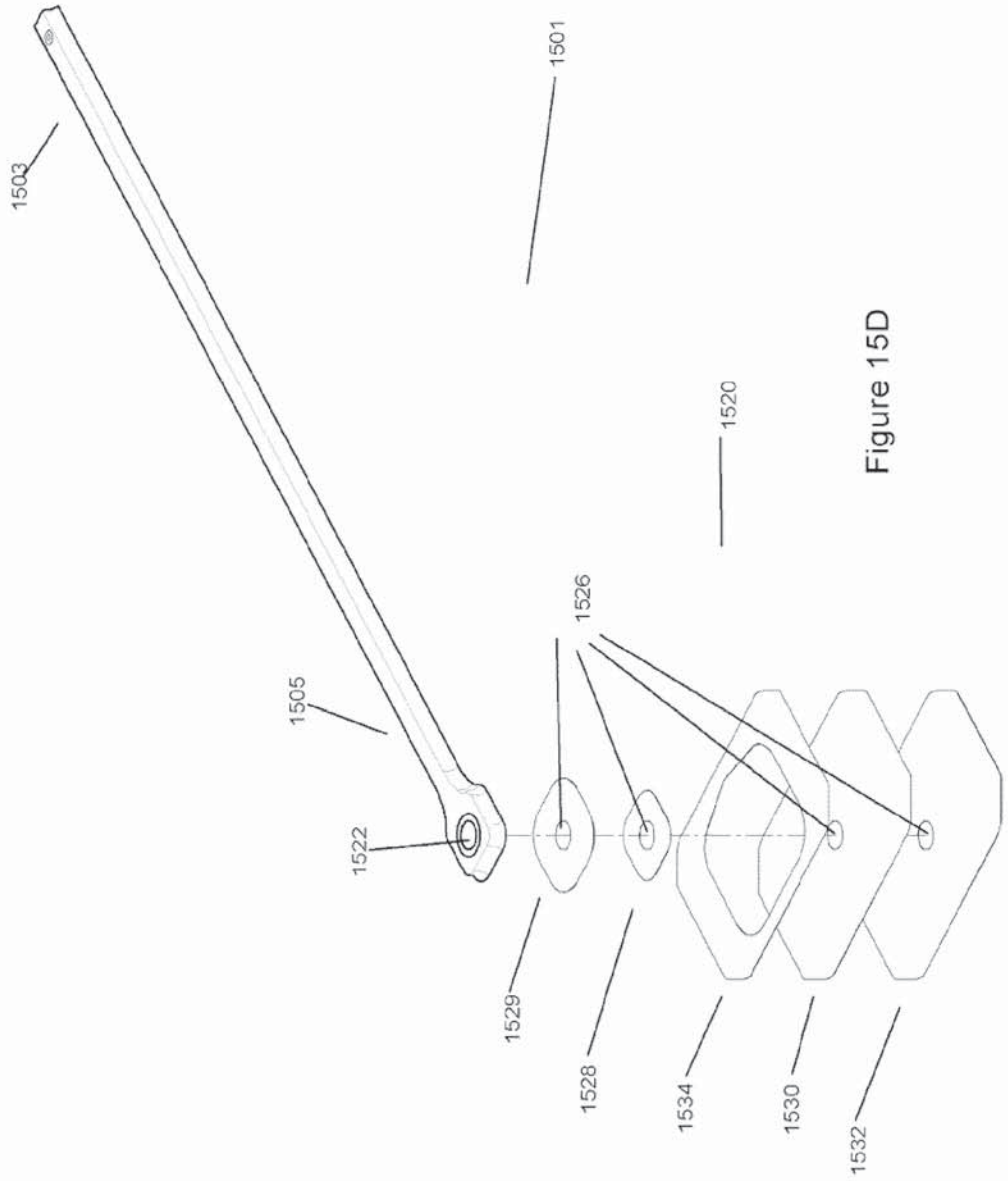


Figure 15C



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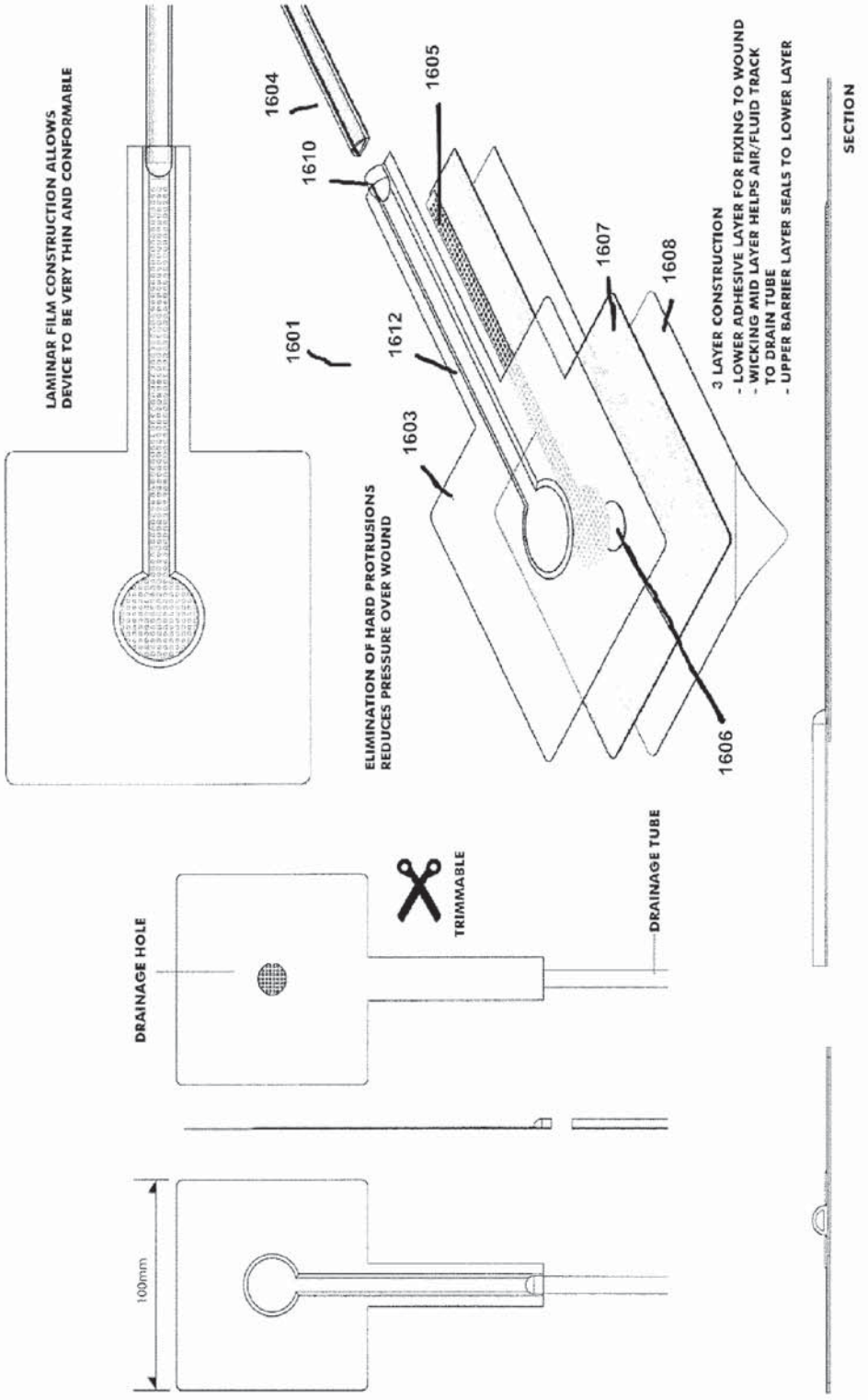
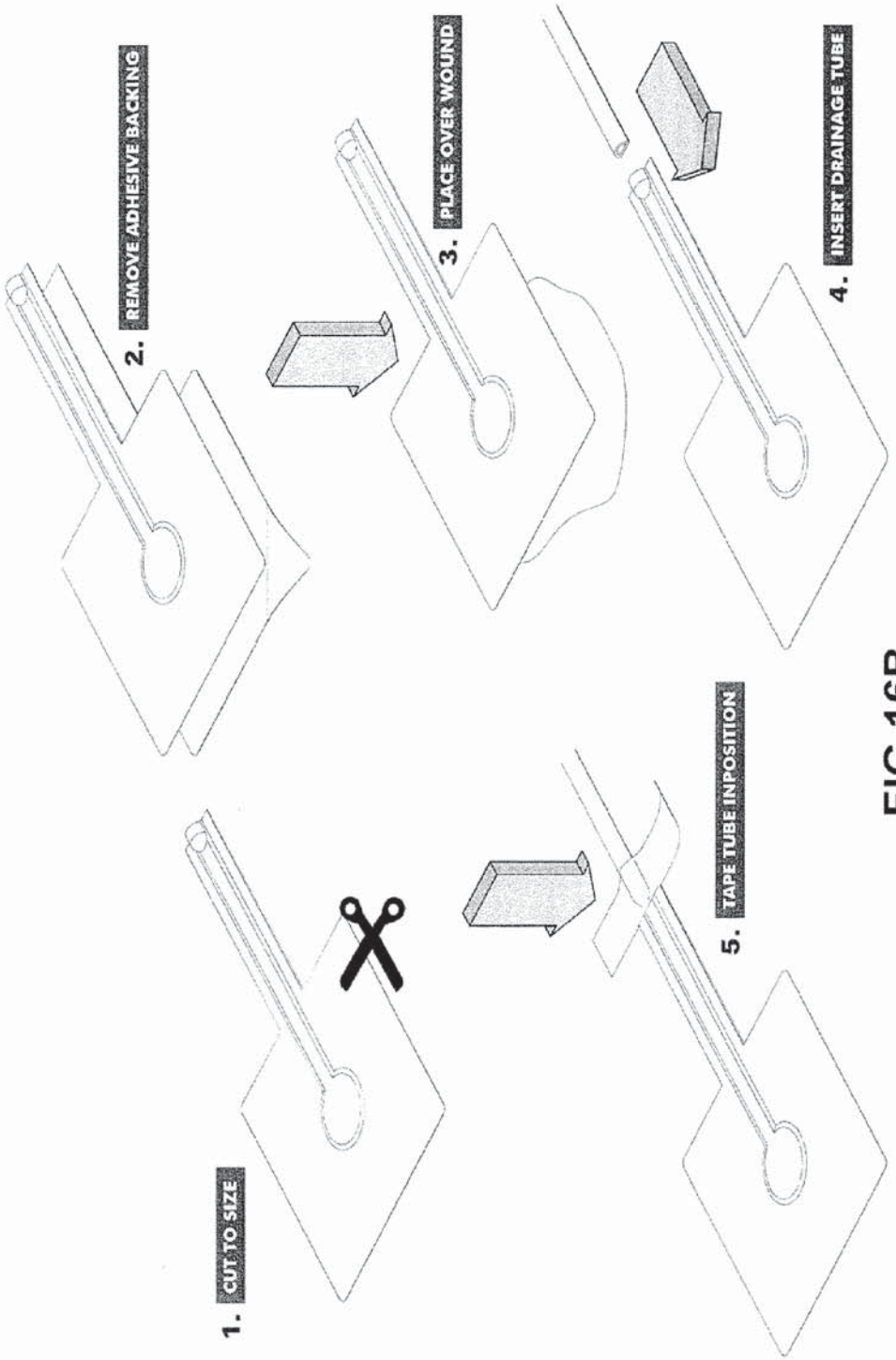

LAMINAR FILM CONSTRUCTION ALLOWS
DEVICE TO BE VERY THIN AND CONFORMABLE
1604
1610
1605
1601
1612
1603
1607
1608
1606
ELIMINATION OF HARD PROTRUSIONS
REDUCES PRESSURE OVER WOUND
3 LAYER CONSTRUCTION
- LOWER ADHESIVE LAYER FOR FIXING TO WOUND
- WICKING MID LAYER HELPS AIR/FLUID TRACK
TO DRAIN TUBE
- UPPER BARRIER LAYER SEALS TO LOWER LAYER
SECTION
DRAINAGE HOLE
TRIMMABLE
DRAINAGE TUBE
100mm

FIG 16A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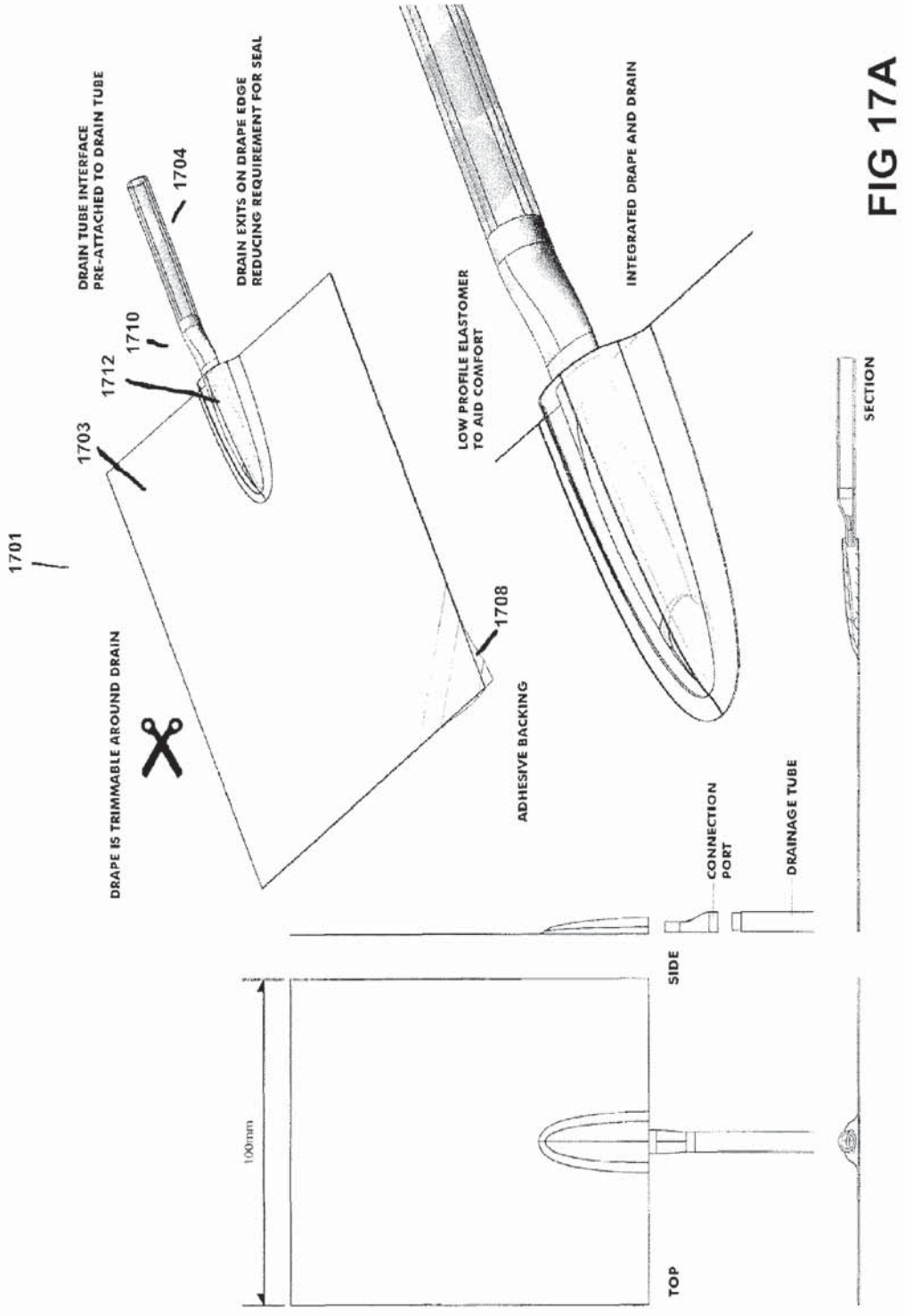
2. REMOVE ADHESIVE BACKING
3. PLACE OVER WOUND
4. INSERT DRAINAGE TUBE
5. TAPE TUBE INPOSITION

FIG 16B


1701
1703
1704
1708
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1712
DRAIN TUBE INTERFACE PRE-ATTACHED TO DRAIN TUBE
DRAIN EXITS ON DRAPE EDGE REDUCING REQUIREMENT FOR SEAL
DRAPE IS TRIMMABLE AROUND DRAIN
ADHESIVE BACKING
LOW PROFILE ELASTOMER TO AID COMFORT
INTEGRATED DRAPE AND DRAIN
CONNECTION PORT
DRAINAGE TUBE
SECTION
SIDE
TOP
100mm

FIG 17A

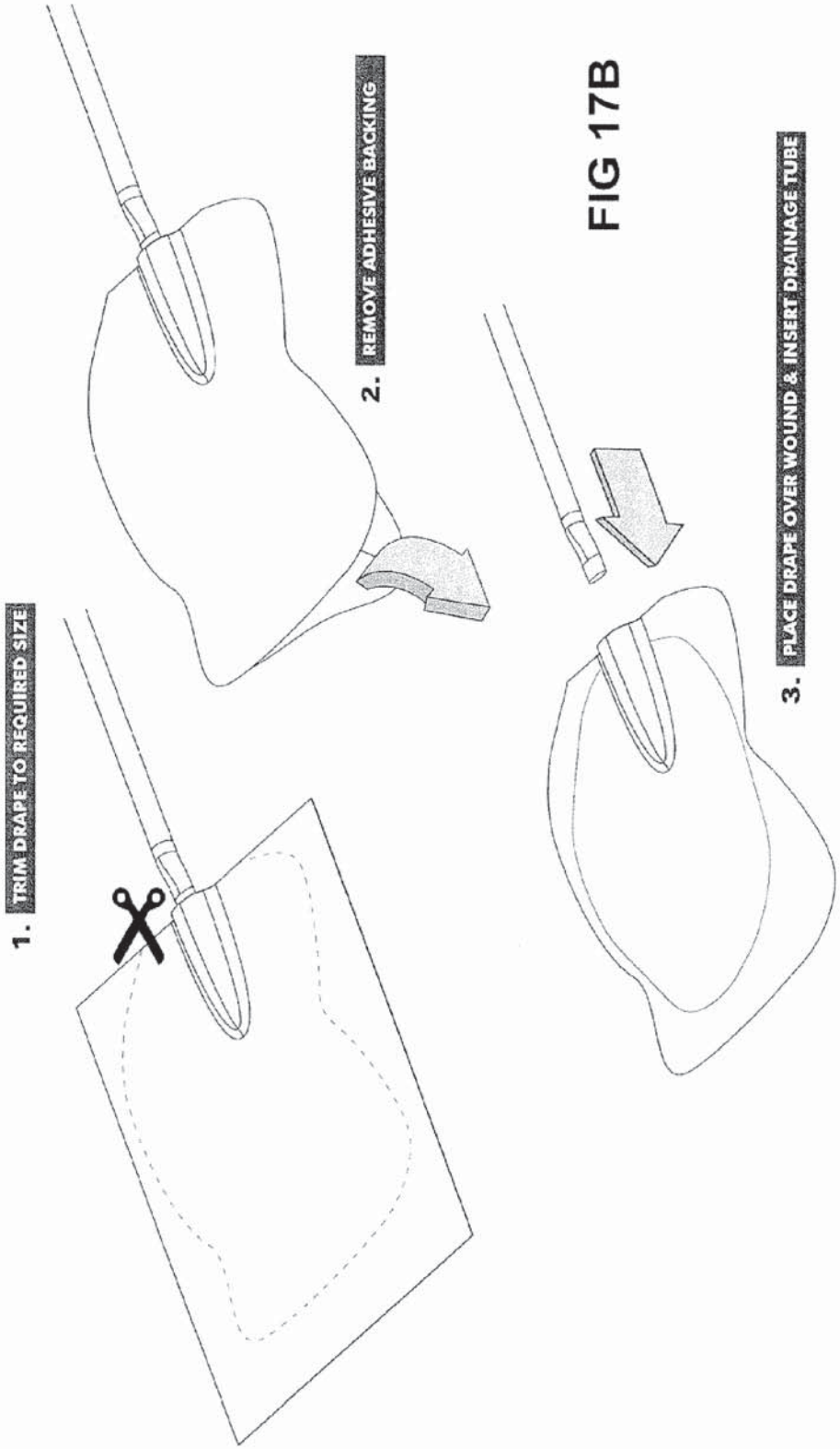

1. TRIM DRAPE TO REQUIRED SIZE
2. REMOVE ADHESIVE BACKING
3. PLACE DRAPE OVER WOUND & INSERT DRAINAGE TUBE

FIG 17B

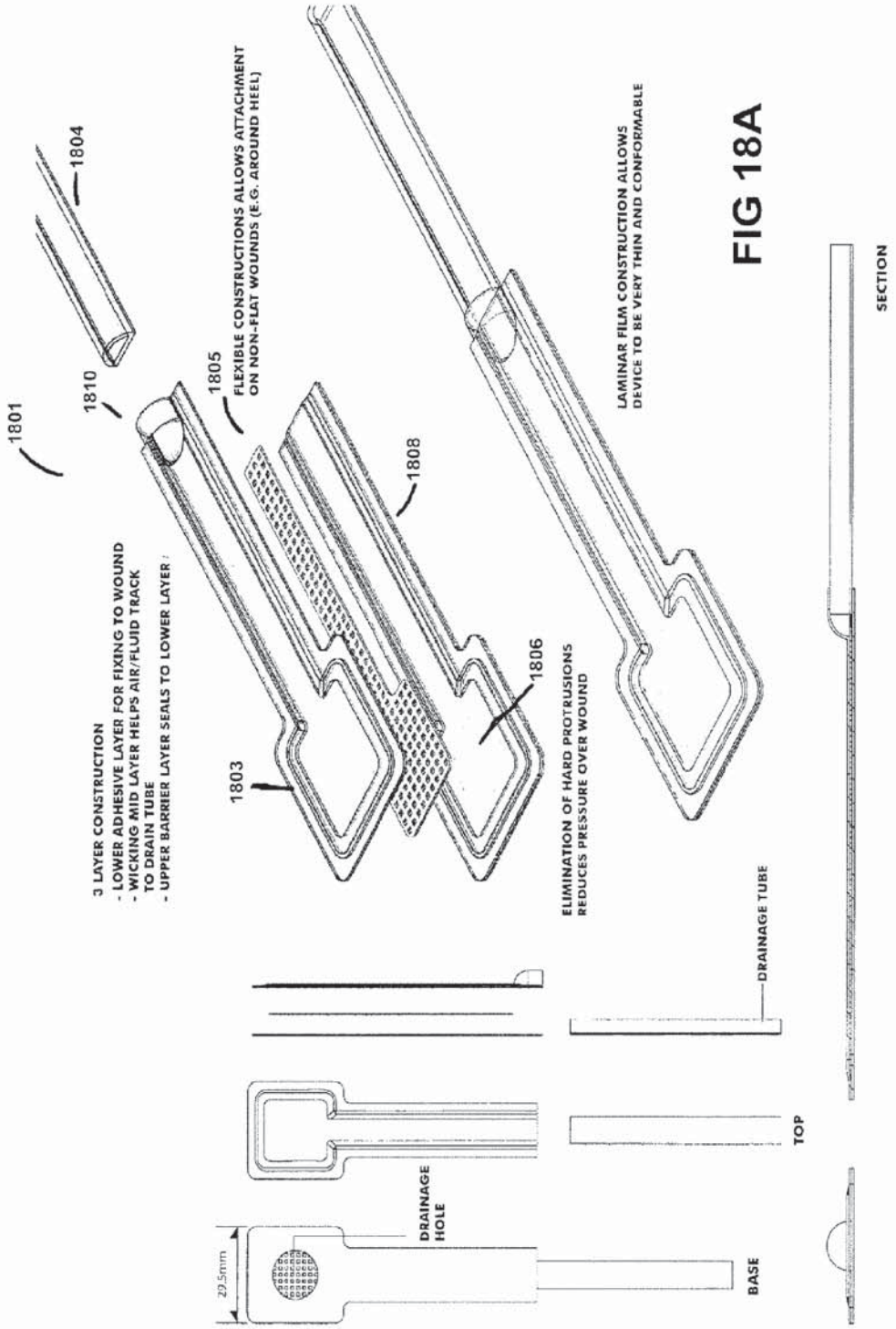

1801
1804
1810
1805
FLEXIBLE CONSTRUCTIONS ALLOWS ATTACHMENT ON NON-FLAT WOUNDS (E.G. AROUND HEEL)
1808
LAMINAR FILM CONSTRUCTION ALLOWS DEVICE TO BE VERY THIN AND CONFORMABLE
3 LAYER CONSTRUCTION
- LOWER ADHESIVE LAYER FOR FIXING TO WOUND
- WICKING MID LAYER HELPS AIR/FLUID TRACK TO DRAIN TUBE
- UPPER BARRIER LAYER SEALS TO LOWER LAYER
1803
1806
ELIMINATION OF HARD PROTRUSIONS REDUCES PRESSURE OVER WOUND
DRAINAGE TUBE
TOP
DRAINAGE HOLE
29.5mm
BASE
SECTION

FIG 18A

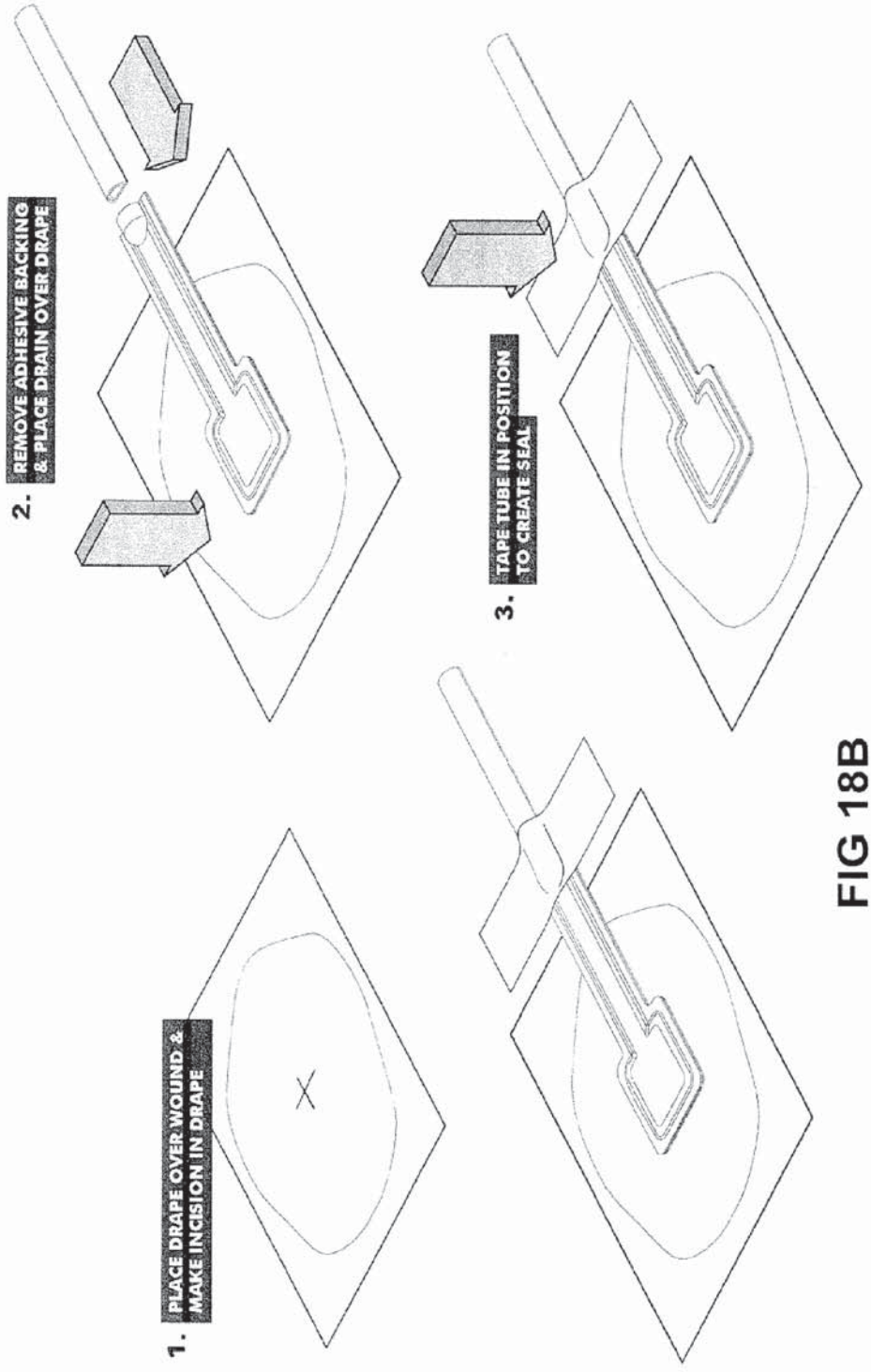

1. PLACE DRAPE OVER WOUND & MAKE INCISION IN DRAPE
2. REMOVE ADHESIVE BACKING & PLACE DRAIN OVER DRAPE
3. TAPE TUBE IN POSITION TO CREATE SEAL

FIG 18B

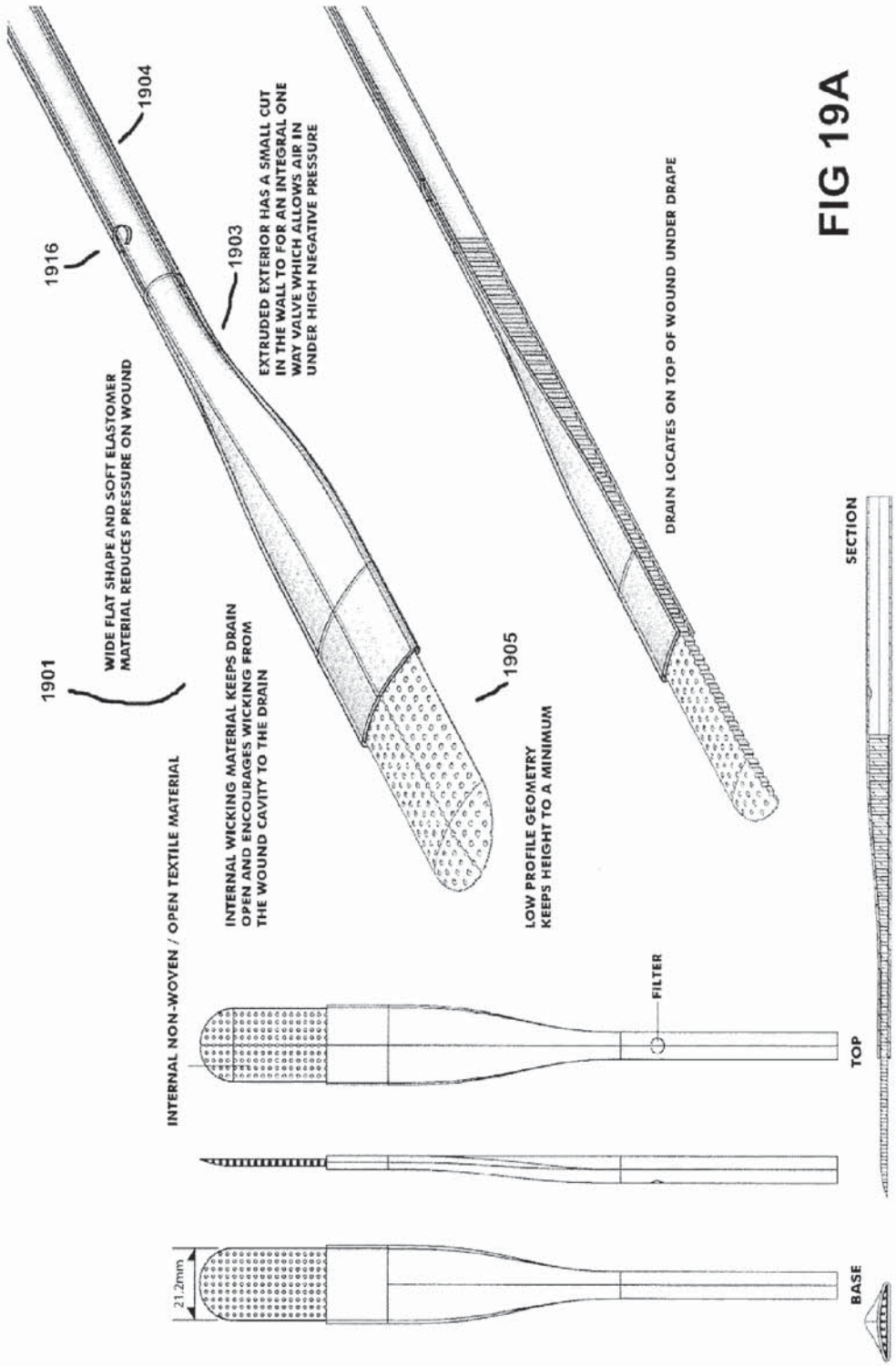
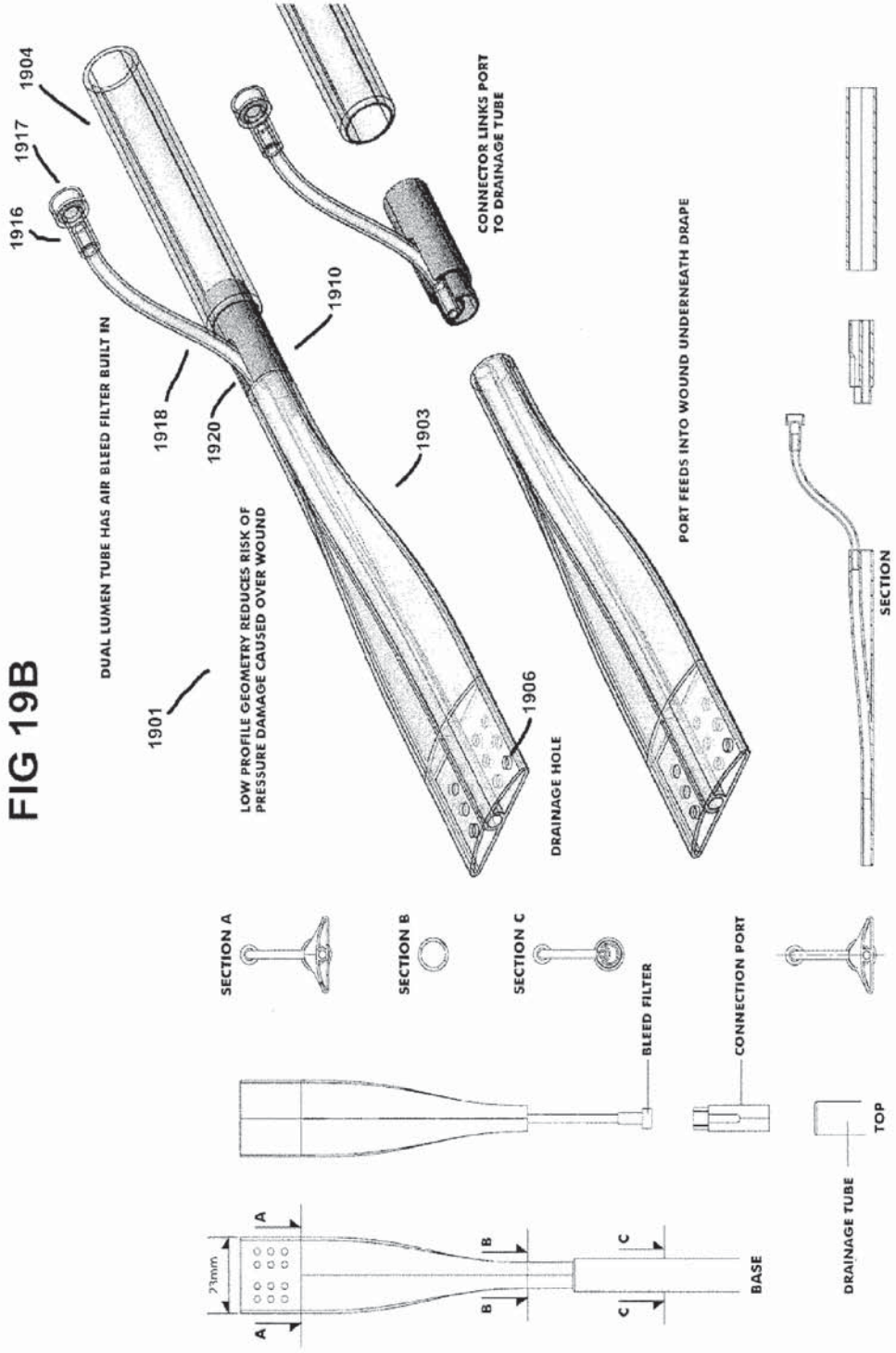

1901
WIDE FLAT SHAPE AND SOFT ELASTOMER MATERIAL REDUCES PRESSURE ON WOUND
1916
1904
1903
EXTRUDED EXTERIOR HAS A SMALL CUT IN THE WALL TO FOR AN INTEGRAL ONE WAY VALVE WHICH ALLOWS AIR IN UNDER HIGH NEGATIVE PRESSURE
DRAIN LOCATES ON TOP OF WOUND UNDER DRAPE
INTERNAL WICKING MATERIAL KEEPS DRAIN OPEN AND ENCOURAGES WICKING FROM THE WOUND CAVITY TO THE DRAIN
1905
LOW PROFILE GEOMETRY KEEPS HEIGHT TO A MINIMUM
INTERNAL NON-WOVEN / OPEN TEXTILE MATERIAL
FILTER
21.2mm
TOP
BASE
SECTION

FIG 19A

FIG 19B


1904
1917
1916
1910
1918
1920
1903
1901
1906
DUAL LUMEN TUBE HAS AIR BLEED FILTER BUILT IN
LOW PROFILE GEOMETRY REDUCES RISK OF PRESSURE DAMAGE CAUSED OVER WOUND
CONNECTOR LINKS PORT TO DRAINAGE TUBE
DRAINAGE HOLE
PORT FEEDS INTO WOUND UNDERNEATH DRAPE
SECTION
SECTION A
SECTION B
SECTION C
BLEED FILTER
CONNECTION PORT
TOP
DRAINAGE TUBE
BASE
A
B
C
23mm

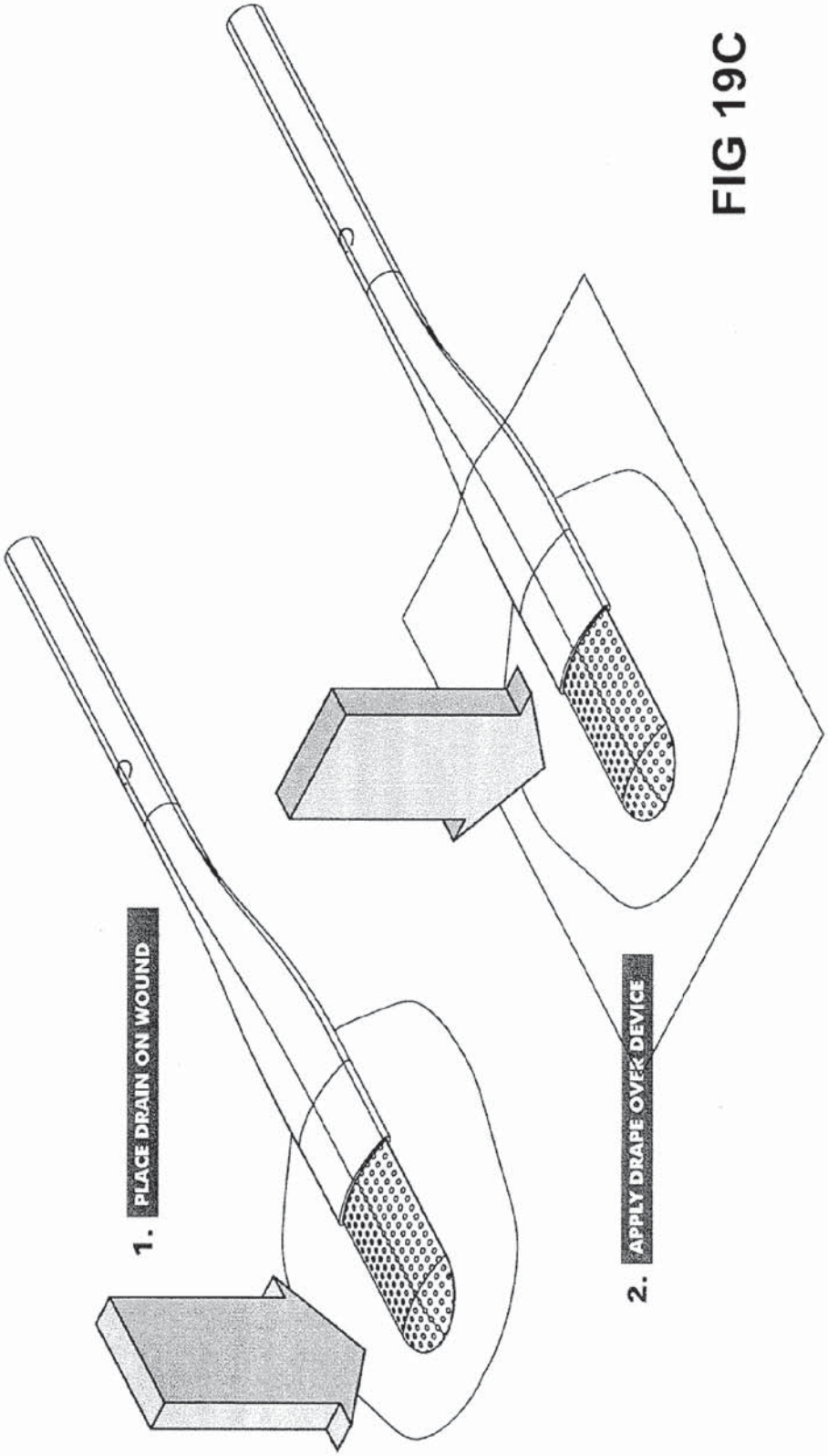


FIG 19C

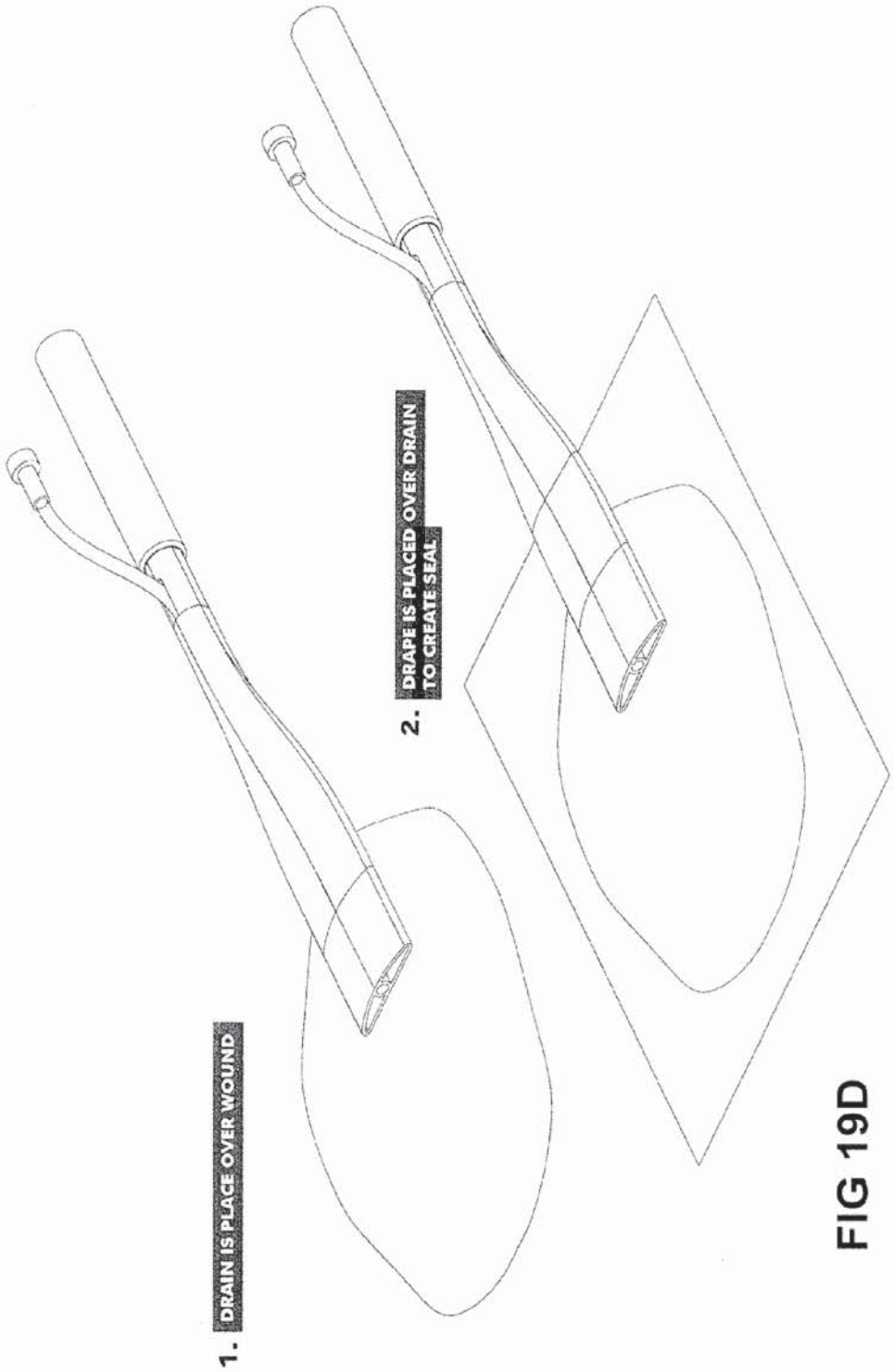

1. DRAIN IS PLACE OVER WOUND
2. DRAPE IS PLACED OVER DRAIN TO CREATE SEAL

FIG 19D

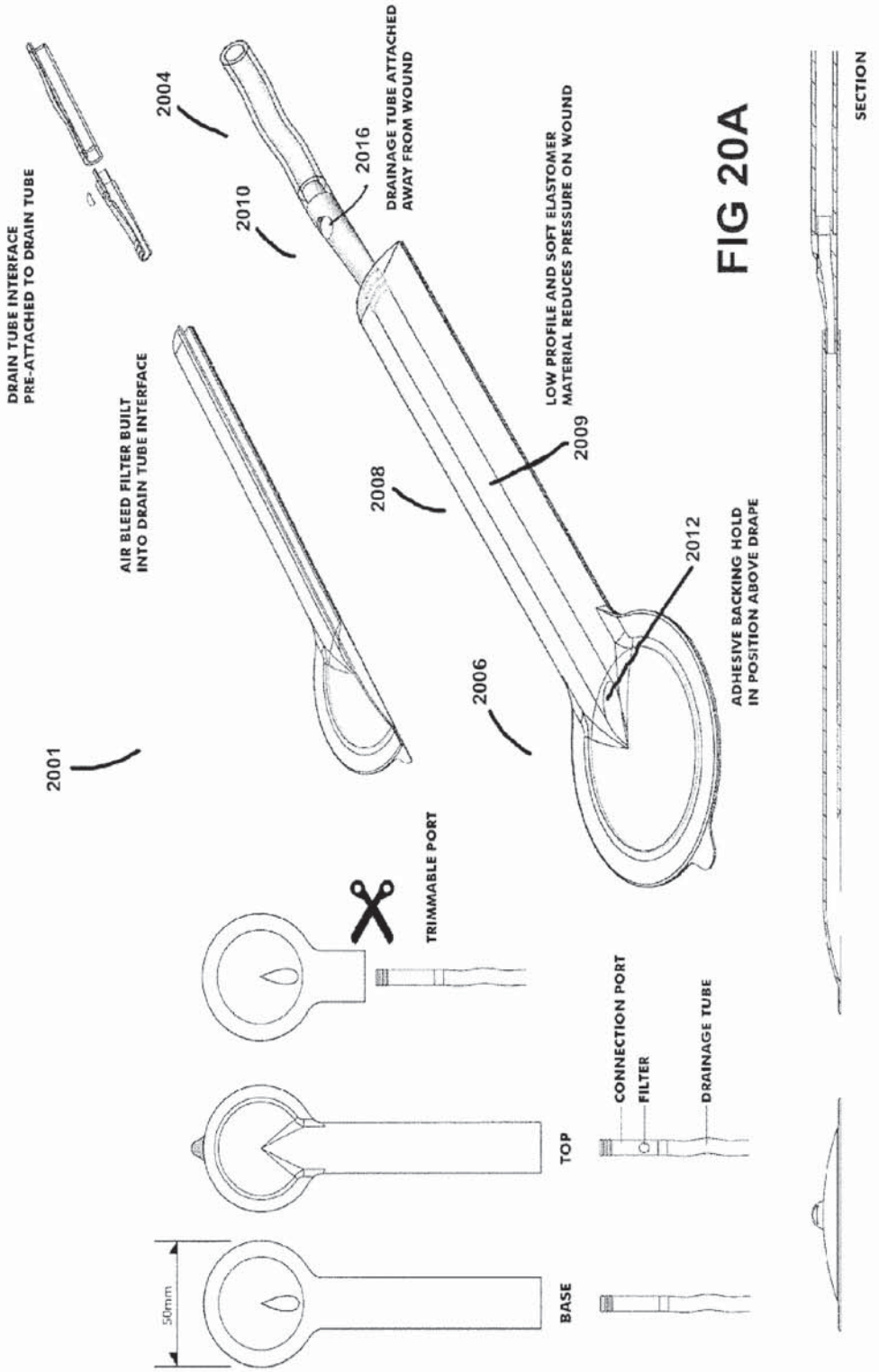

DRAIN TUBE INTERFACE
PRE-ATTACHED TO DRAIN TUBE
AIR BLEED FILTER BUILT
INTO DRAIN TUBE INTERFACE
2001
2004
2010
2016
DRAINAGE TUBE ATTACHED
AWAY FROM WOUND
LOW PROFILE AND SOFT ELASTOMER
MATERIAL REDUCES PRESSURE ON WOUND
2009
2008
2006
2012
ADHESIVE BACKING HOLD
IN POSITION ABOVE DRAPE
TRIMMABLE PORT
50mm
BASE
TOP
CONNECTION PORT
FILTER
DRAINAGE TUBE
SECTION

FIG 20A

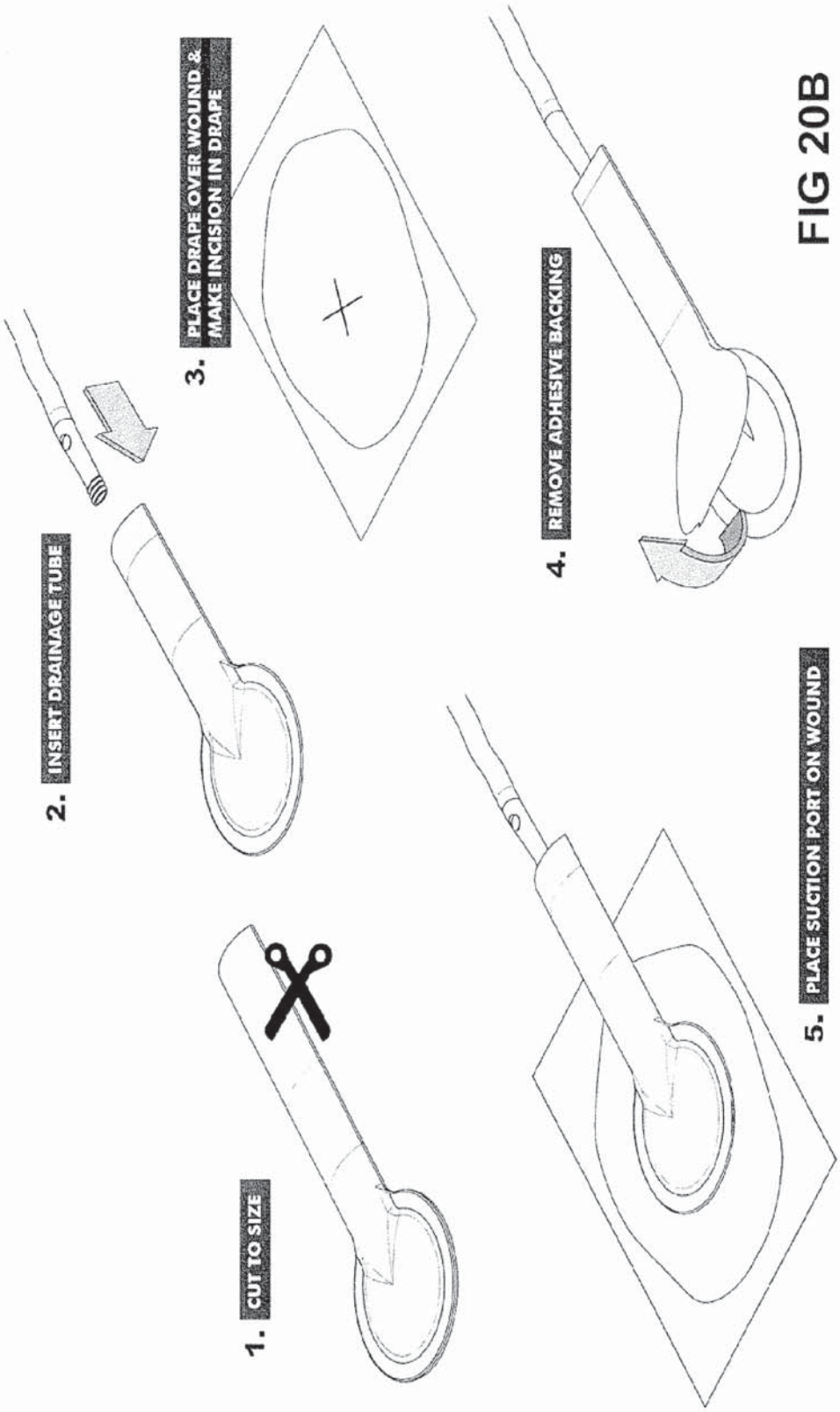

1. CUT TO SIZE
2. INSERT DRAINAGE TUBE
3. PLACE DRAPE OVER WOUND & MAKE INCISION IN DRAPE
4. REMOVE ADHESIVE BACKING
5. PLACE SUCTION PORT ON WOUND

FIG 20B

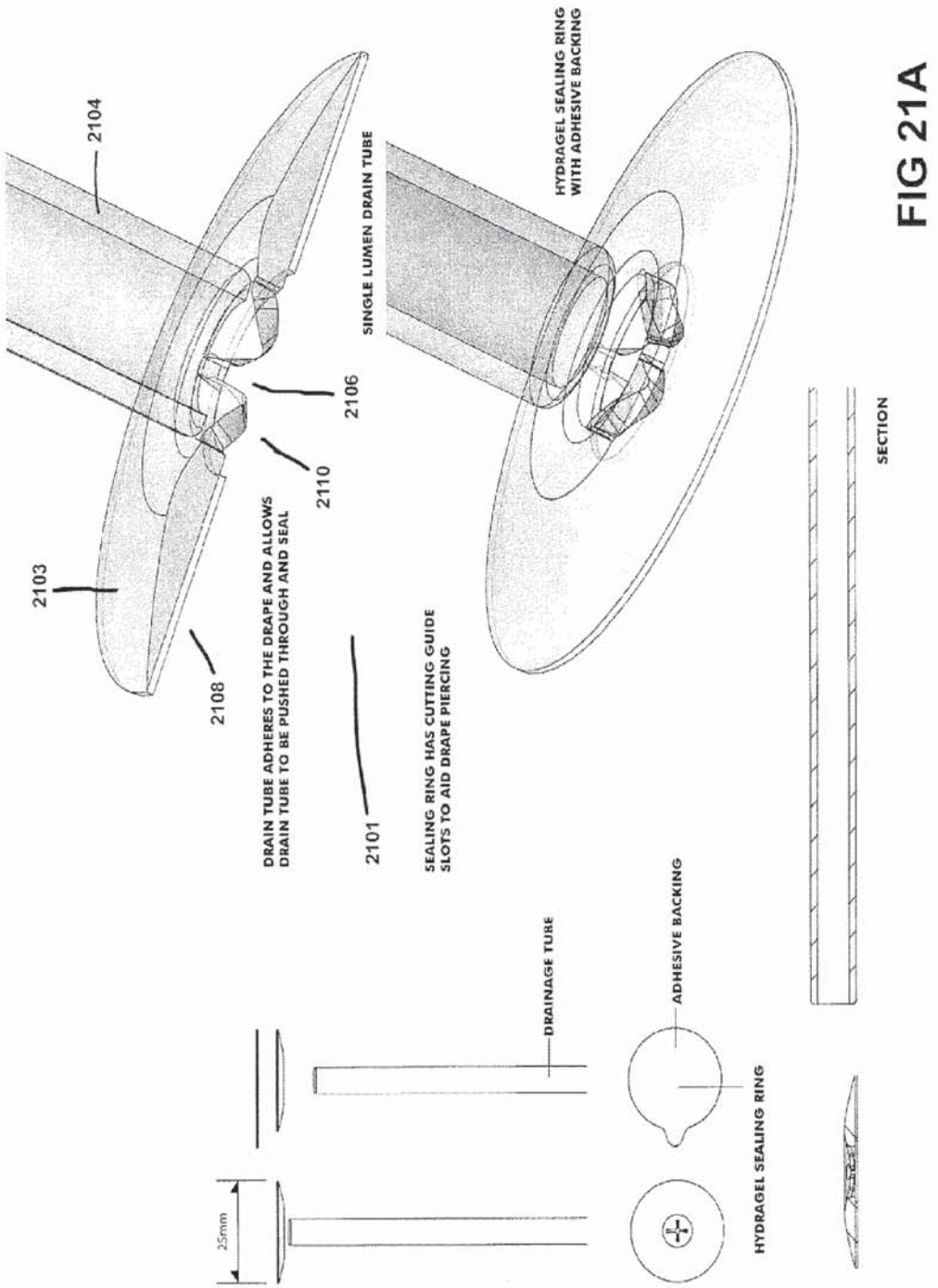

2104
2106
2110
2103
2108
2101
DRAIN TUBE ADHERES TO THE DRAPE AND ALLOWS DRAIN TUBE TO BE PUSHED THROUGH AND SEAL
SEALING RING HAS CUTTING GUIDE SLOTS TO AID DRAPE PIERCING
SINGLE LUMEN DRAIN TUBE
HYDRAGEL SEALING RING WITH ADHESIVE BACKING
SECTION
DRAINAGE TUBE
ADHESIVE BACKING
HYDRAGEL SEALING RING
25mm

FIG 21A

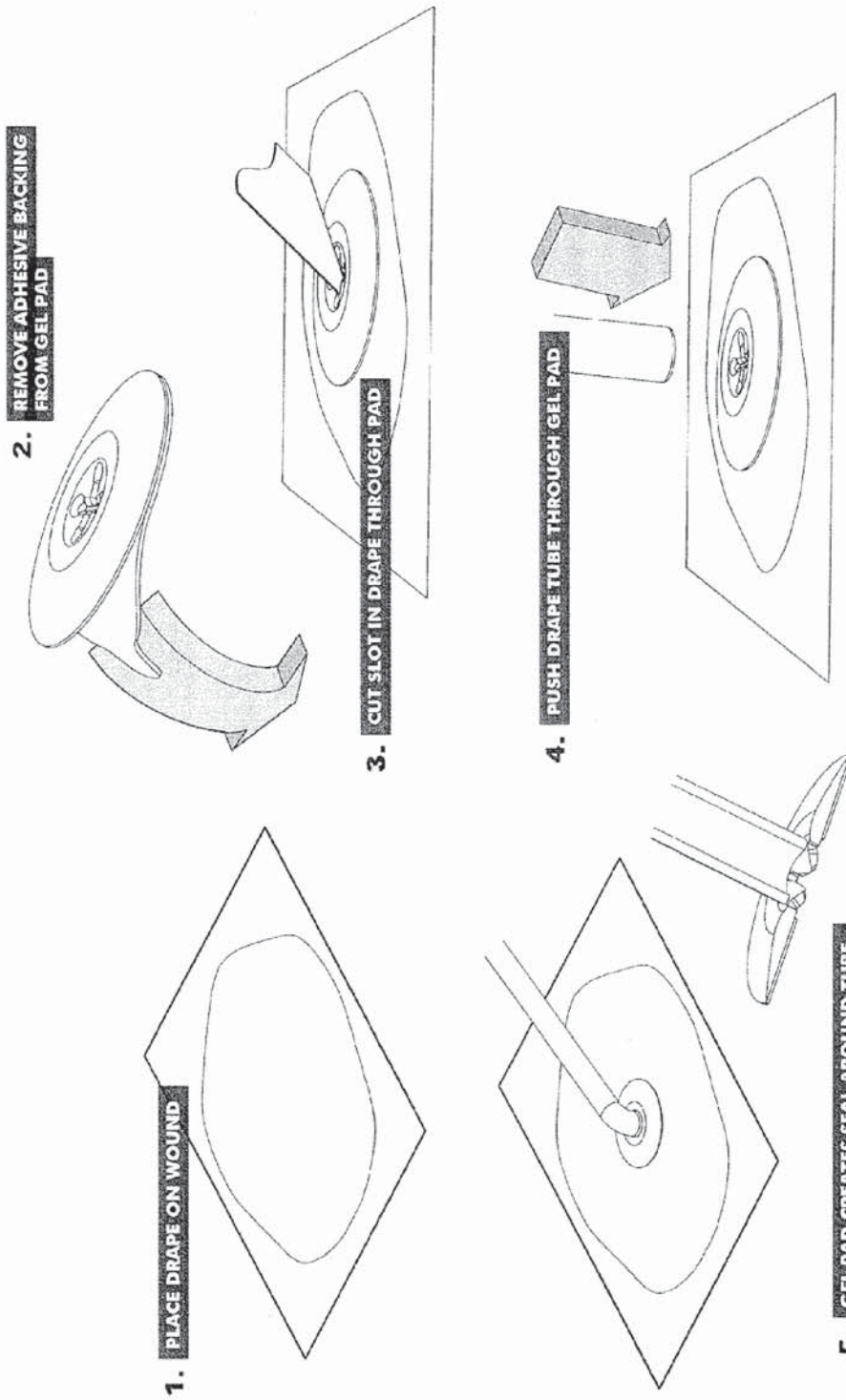

1. PLACE DRAPE ON WOUND
2. REMOVE ADHESIVE BACKING FROM GEL PAD
3. CUT SLOT IN DRAPE THROUGH PAD
4. PUSH DRAPE TUBE THROUGH GEL PAD
5. GEL PAD CREATES SEAL AROUND TUBE

FIG 21B

FIG 22A

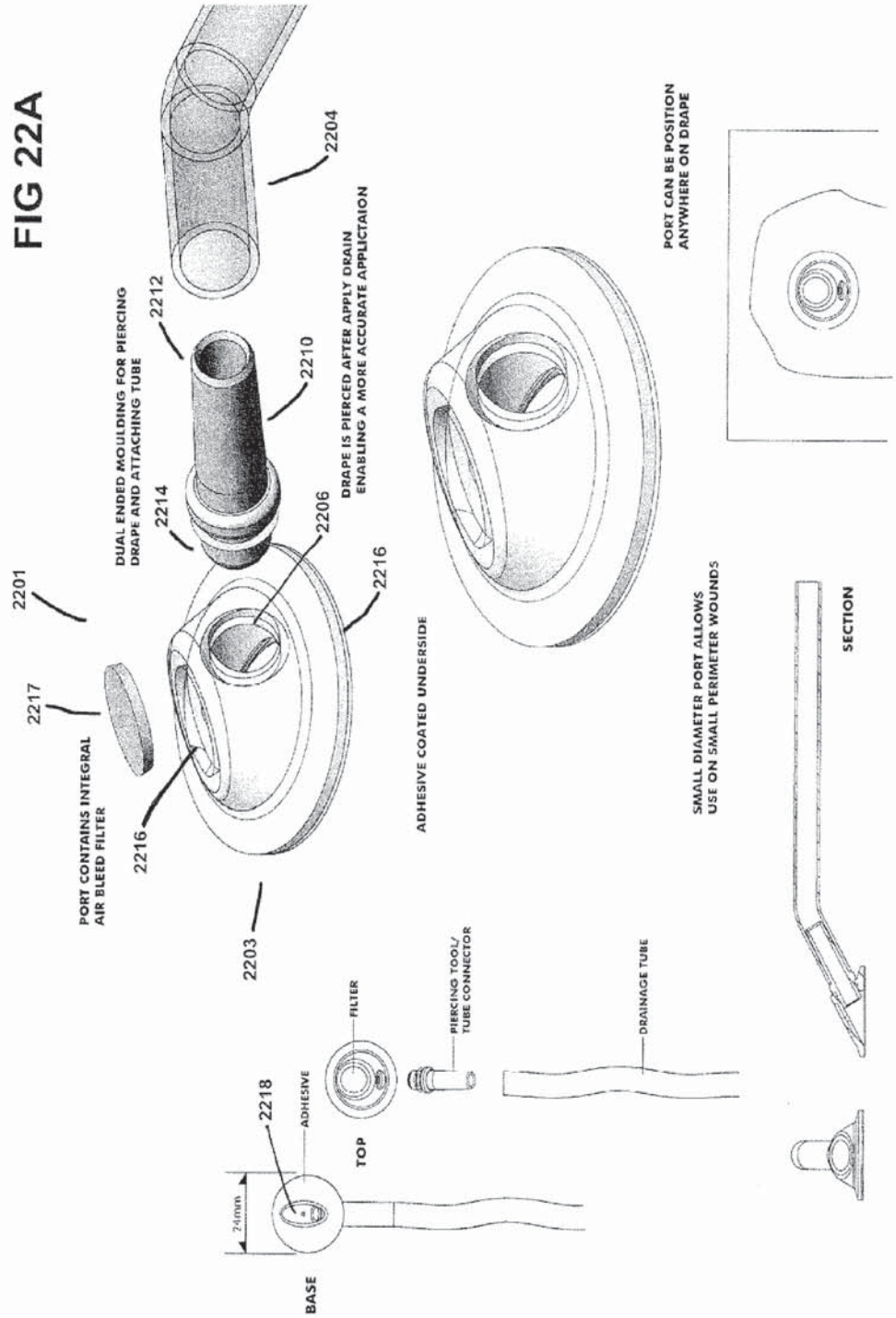
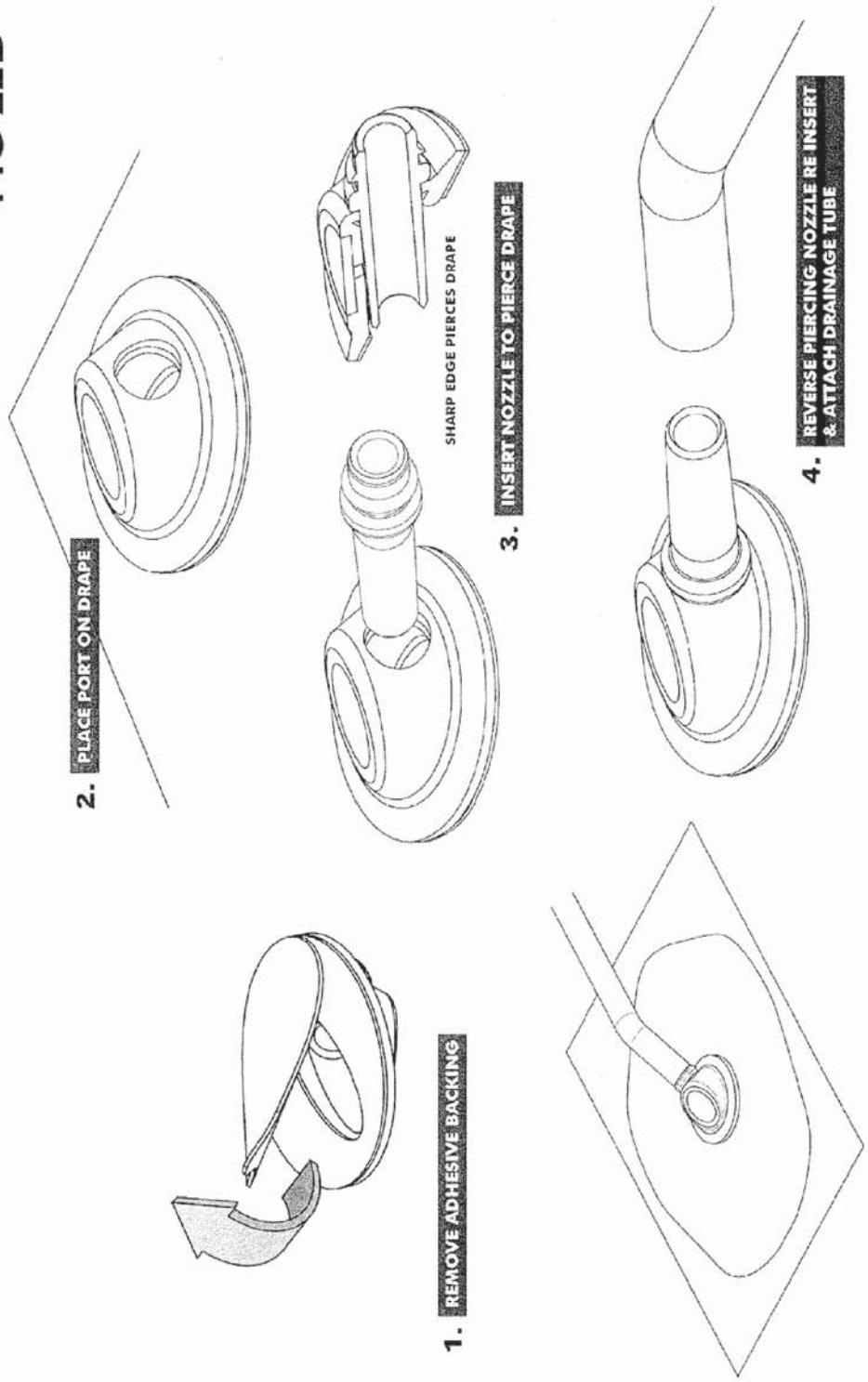

2204
2212
2210
2214
2206
2216
2201
2217
2216
2203
DUAL ENDED MOULDING FOR PIERCING DRAPE AND ATTACHING TUBE
DRAPE IS PIERCED AFTER APPLY DRAIN ENABLING A MORE ACCURATE APPLICTAION
PORT CONTAINS INTEGRAL AIR BLEED FILTER
ADHESIVE COATED UNDERSIDE
PORT CAN BE POSITION ANYWHERE ON DRAPE
SMALL DIAMETER PORT ALLOWS USE ON SMALL PERIMETER WOUNDS
SECTION
2218
ADHESIVE
FILTER
PIERCING TOOL/ TUBE CONNECTOR
DRAINAGE TUBE
24mm
TOP
BASE

FIG 22B


1. REMOVE ADHESIVE BACKING
2. PLACE PORT ON DRAPE
SHARP EDGE PIERCES DRAPE
3. INSERT NOZZLE TO PIERCE DRAPE
4. REVERSE PIERCING NOZZLE RE INSERT & ATTACH DRAINAGE TUBE

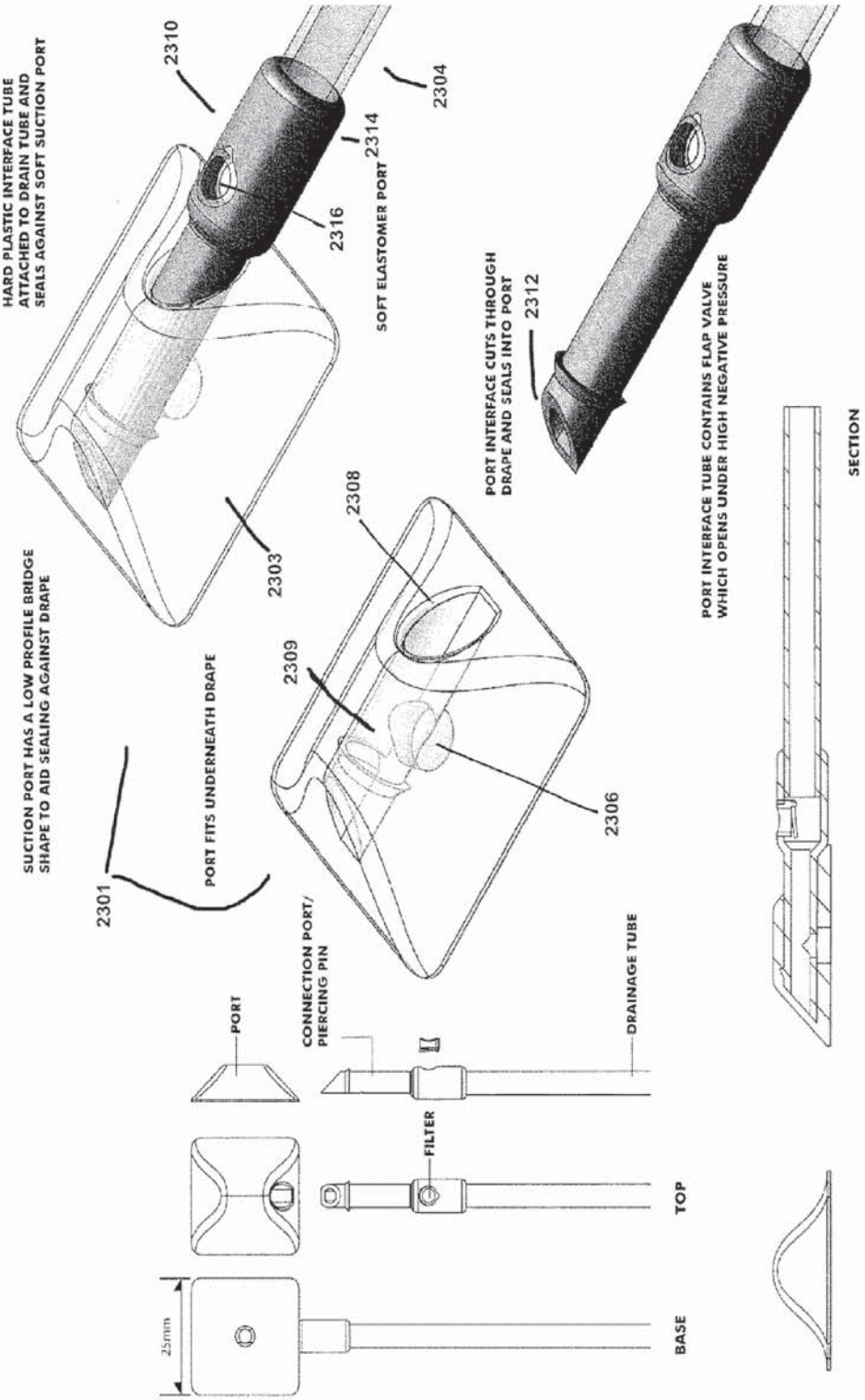
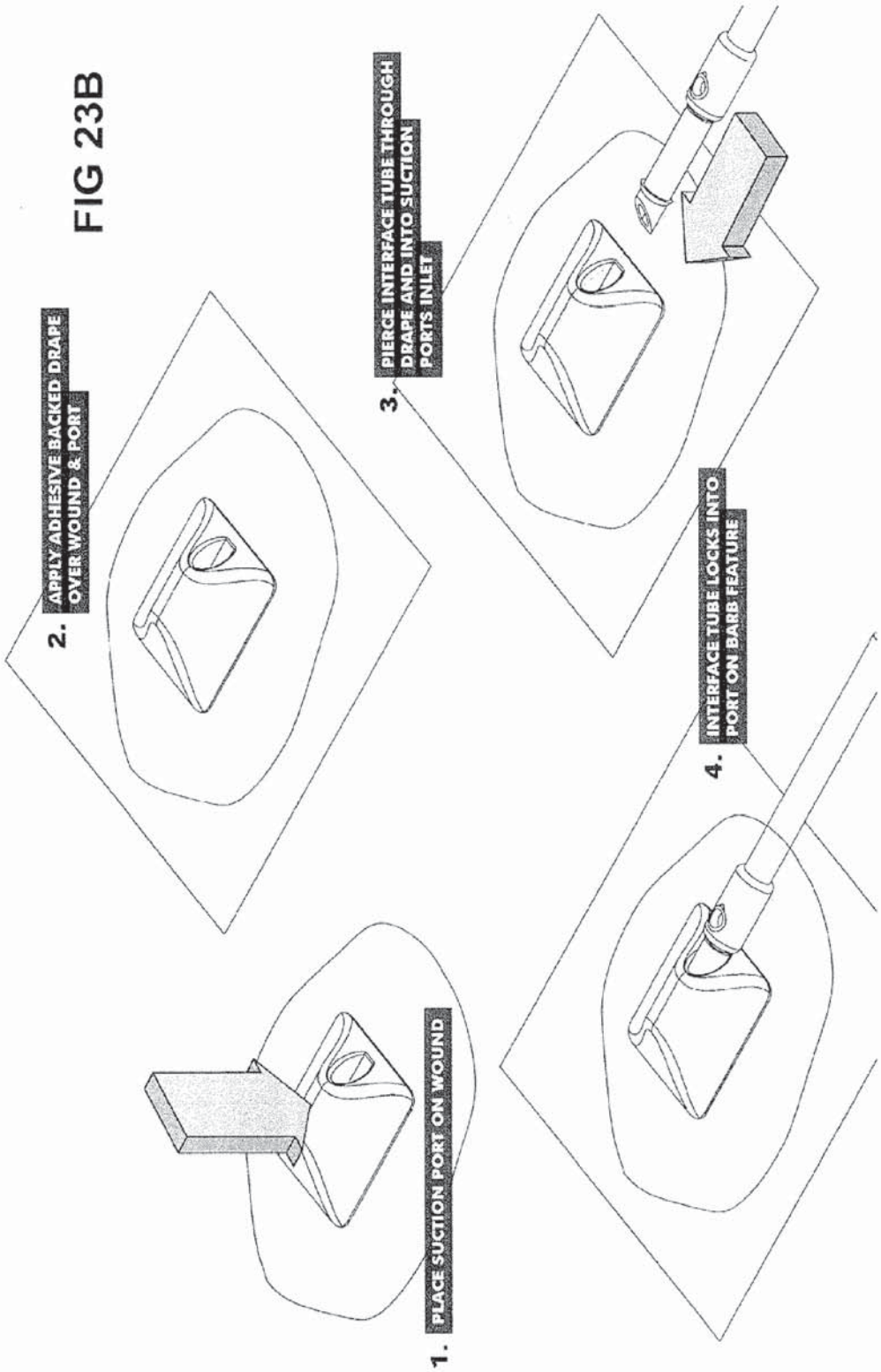

HARD PLASTIC INTERFACE TUBE ATTACHED TO DRAIN TUBE AND SEALS AGAINST SOFT SUCTION PORT
2310
2304
2314
SOFT ELASTOMER PORT
2316
2303
2308
2309
2306
PORT INTERFACE CUTS THROUGH DRAPE AND SEALS INTO PORT
2312
PORT INTERFACE TUBE CONTAINS FLAP VALVE WHICH OPENS UNDER HIGH NEGATIVE PRESSURE
SECTION
SUCTION PORT HAS A LOW PROFILE BRIDGE SHAPE TO AID SEALING AGAINST DRAPE
2301
PORT FITS UNDERNEATH DRAPE
CONNECTION PORT/ PIERCING PIN
DRAINAGE TUBE
PORT
FILTER
TOP
BASE
25mm

FIG 23A

FIG 23B


1. PLACE SUCTION PORT ON WOUND
2. APPLY ADHESIVE BACKED DRAPE OVER WOUND & PORT
3. PIERCE INTERFACE TUBE THROUGH DRAPE AND INTO SUCTION PORTS INLET
4. INTERFACE TUBE LOCKS INTO PORT ON BARB FEATURE

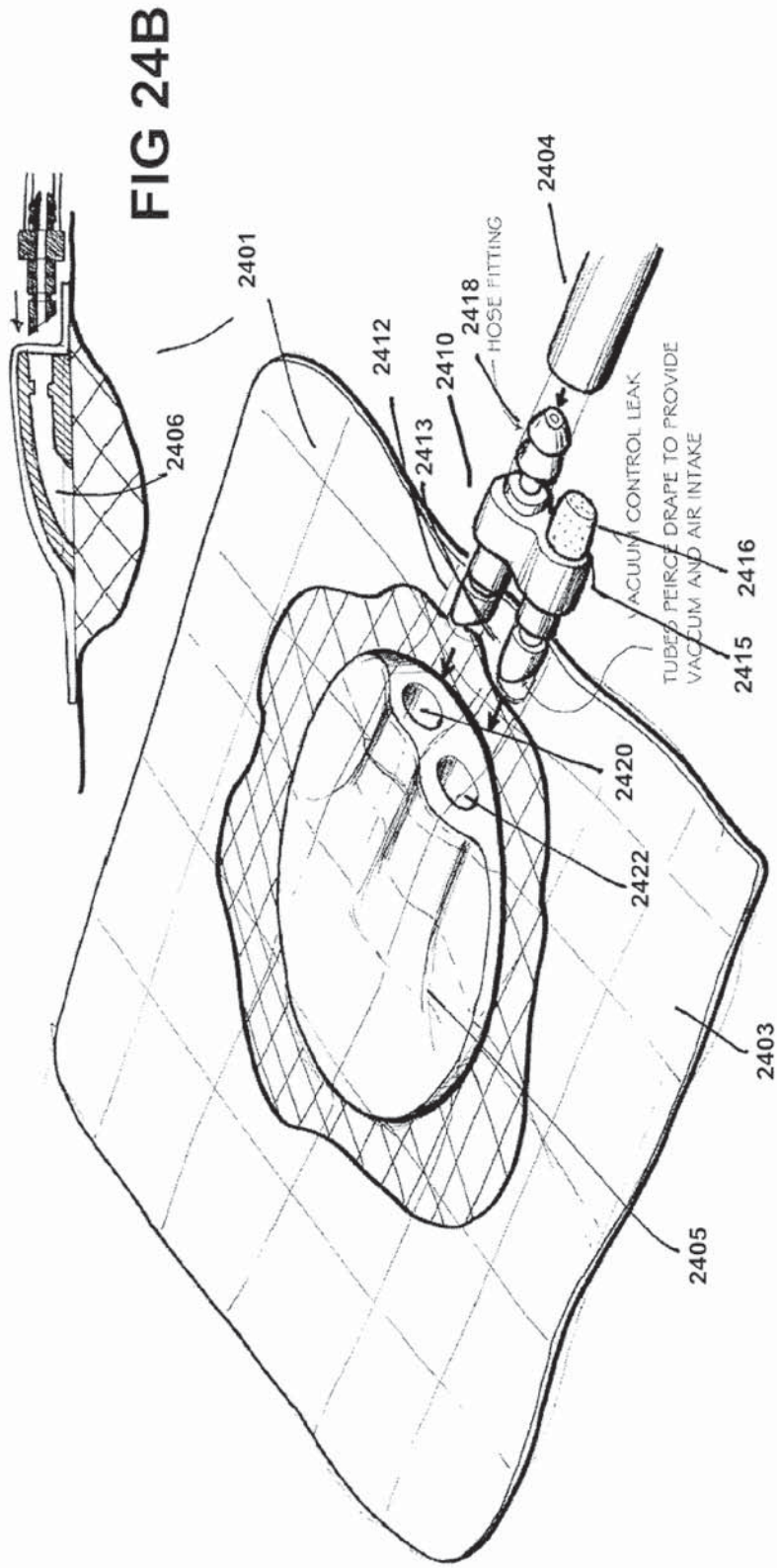


FIG 24B

FIG 24A

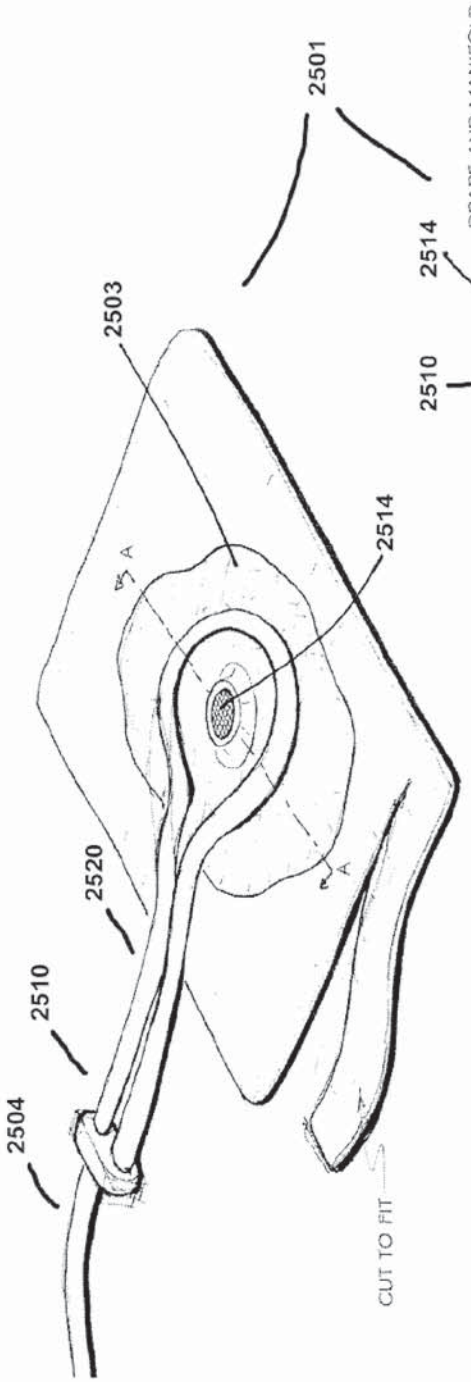


FIG 25A

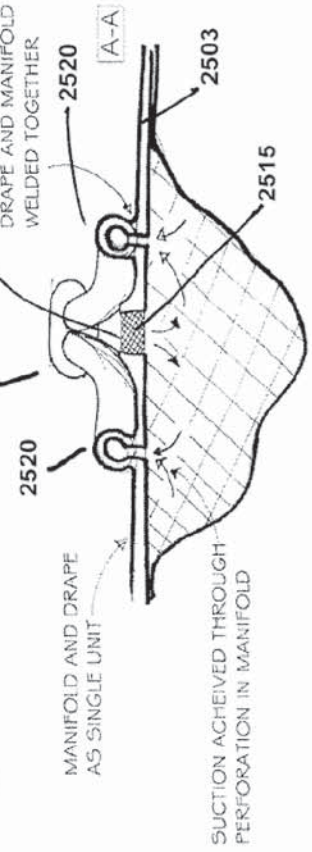


FIG 25B

FIG 26A

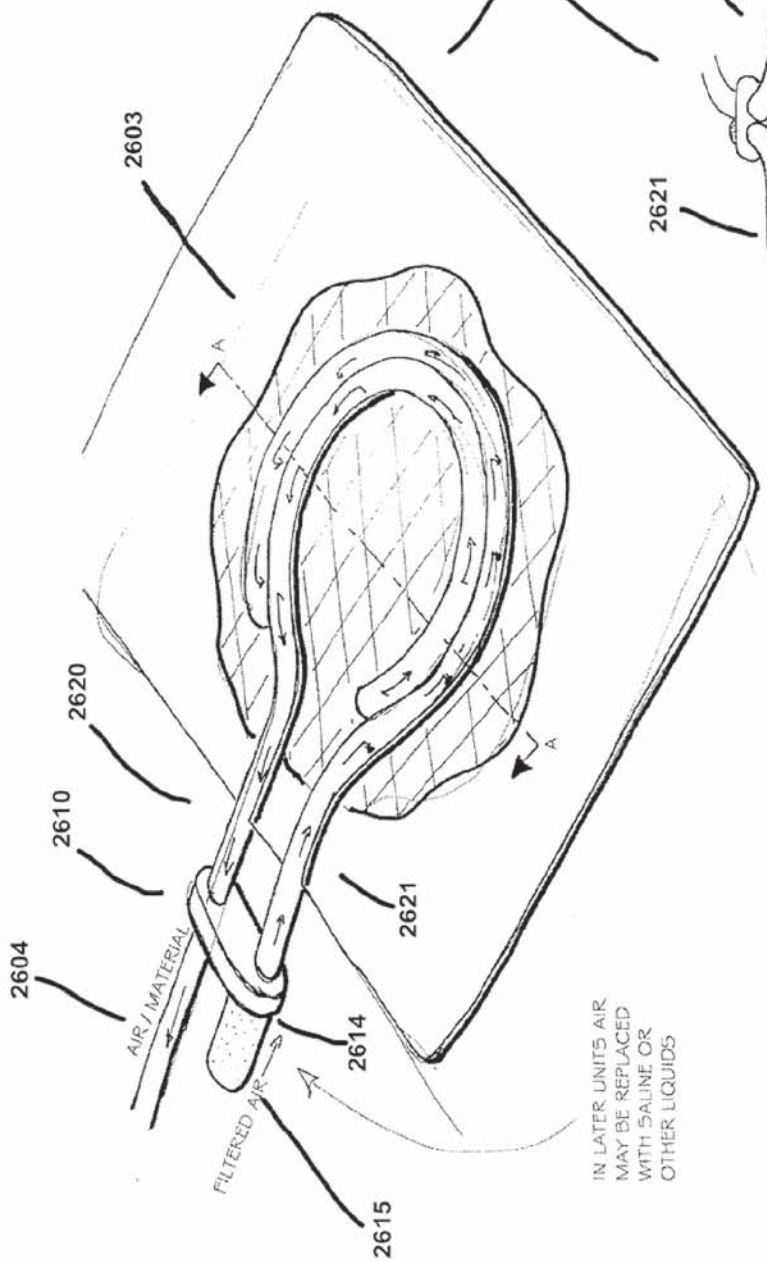
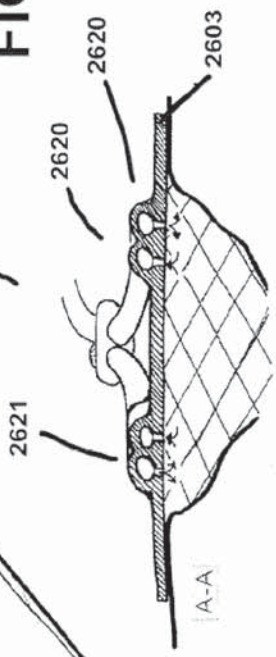


FIG 26B



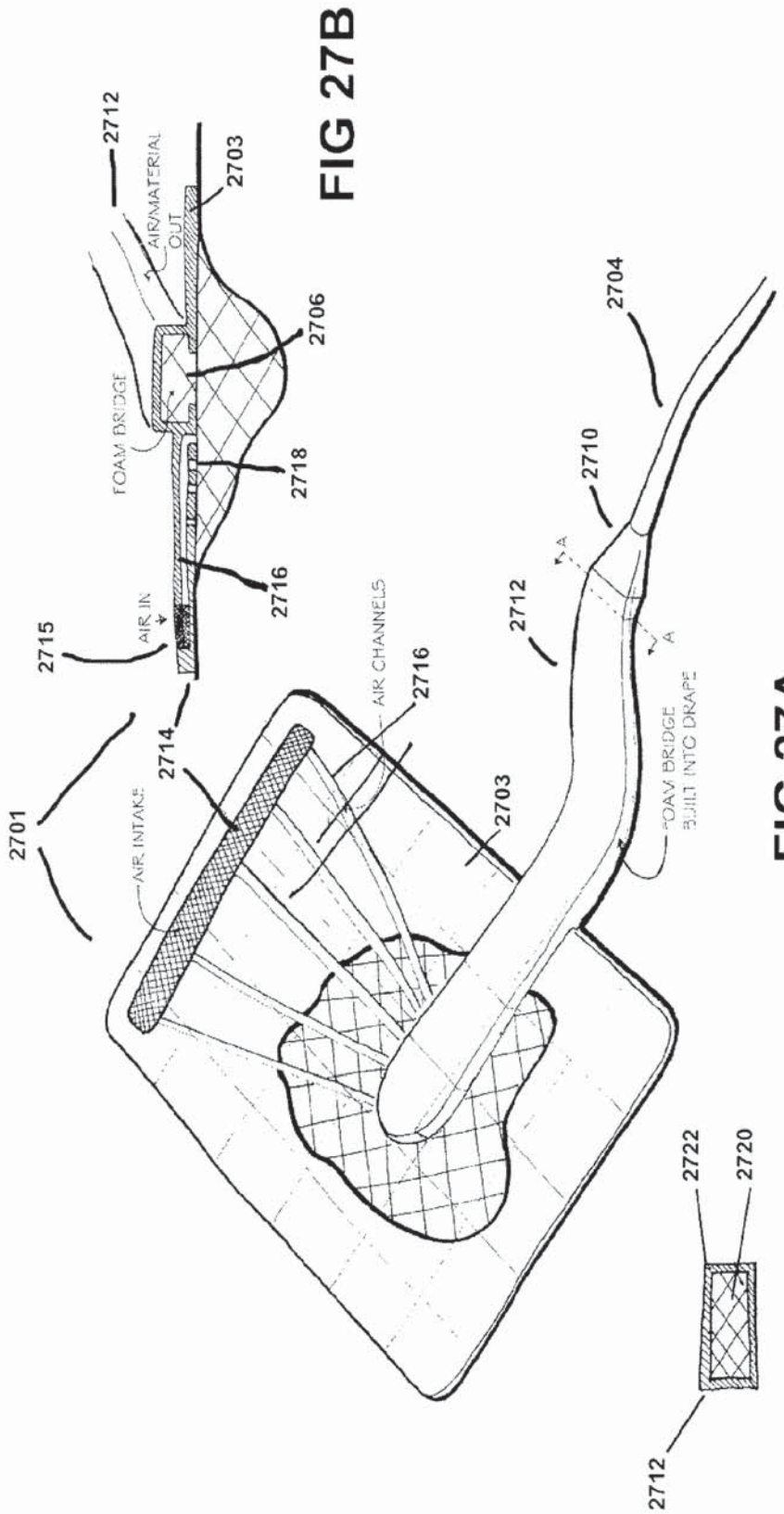


FIG 27B

FIG 27A

FIG 27C

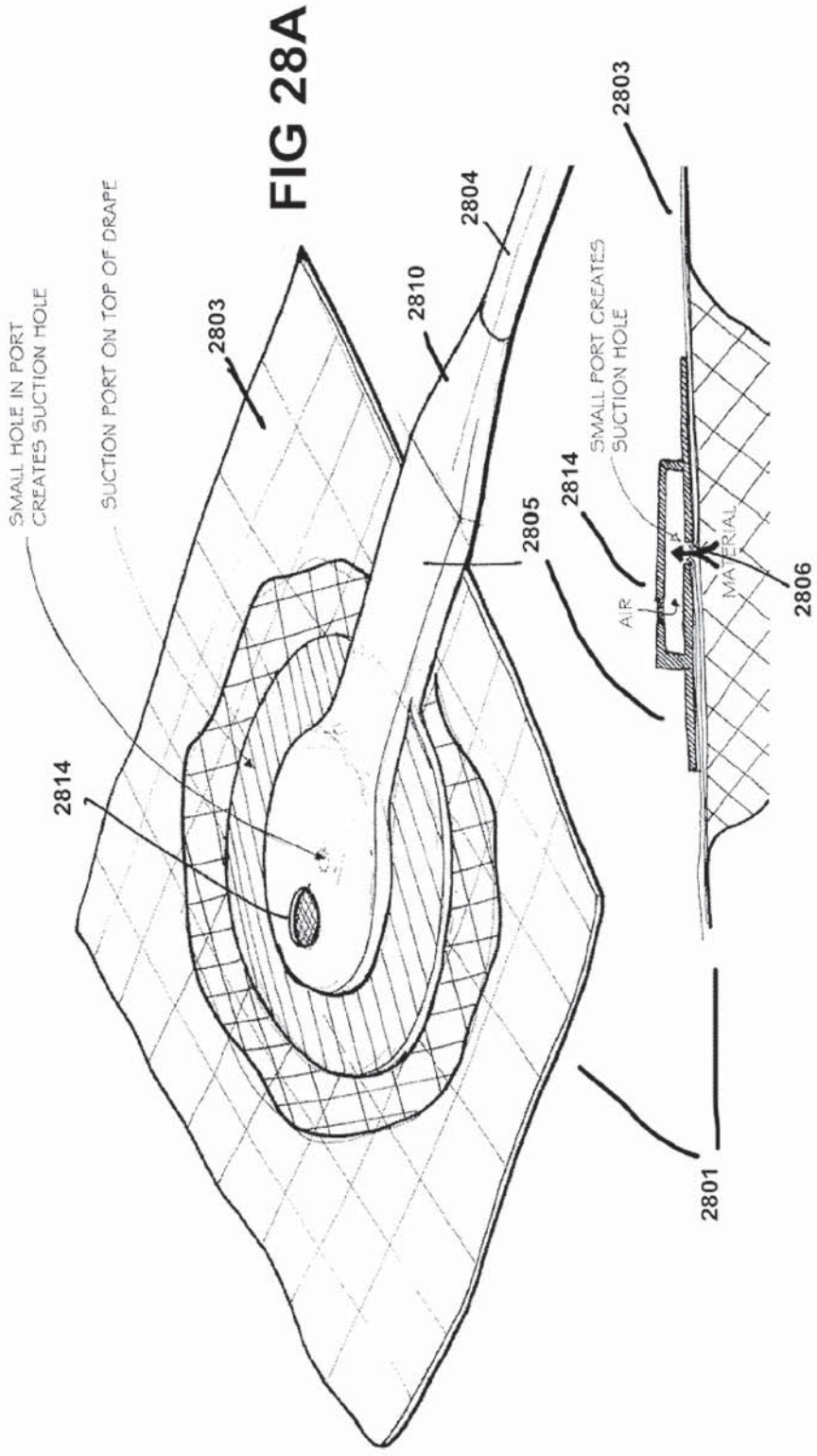


FIG 28A

FIG 28B

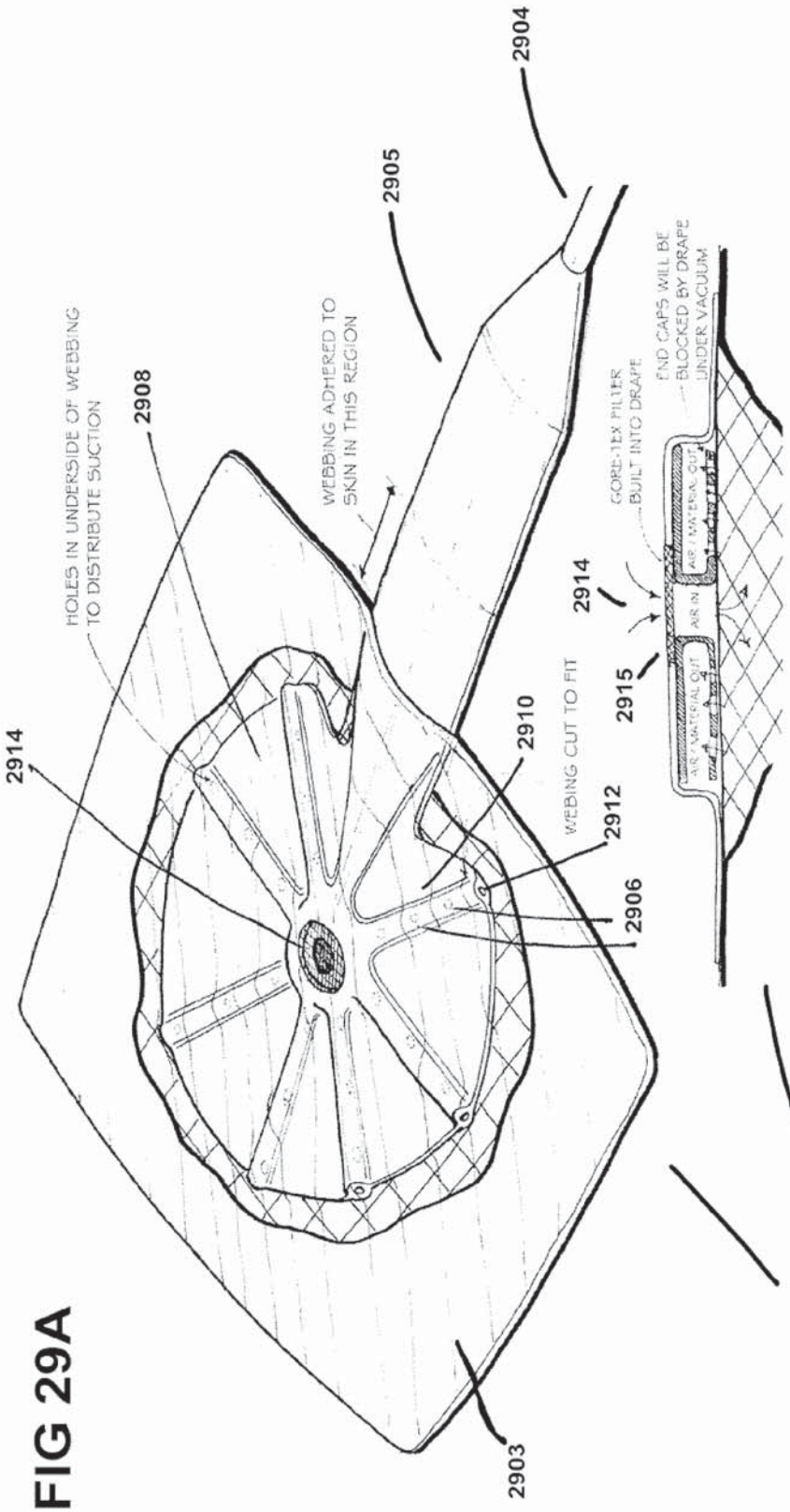


FIG 29A

FIG 29B

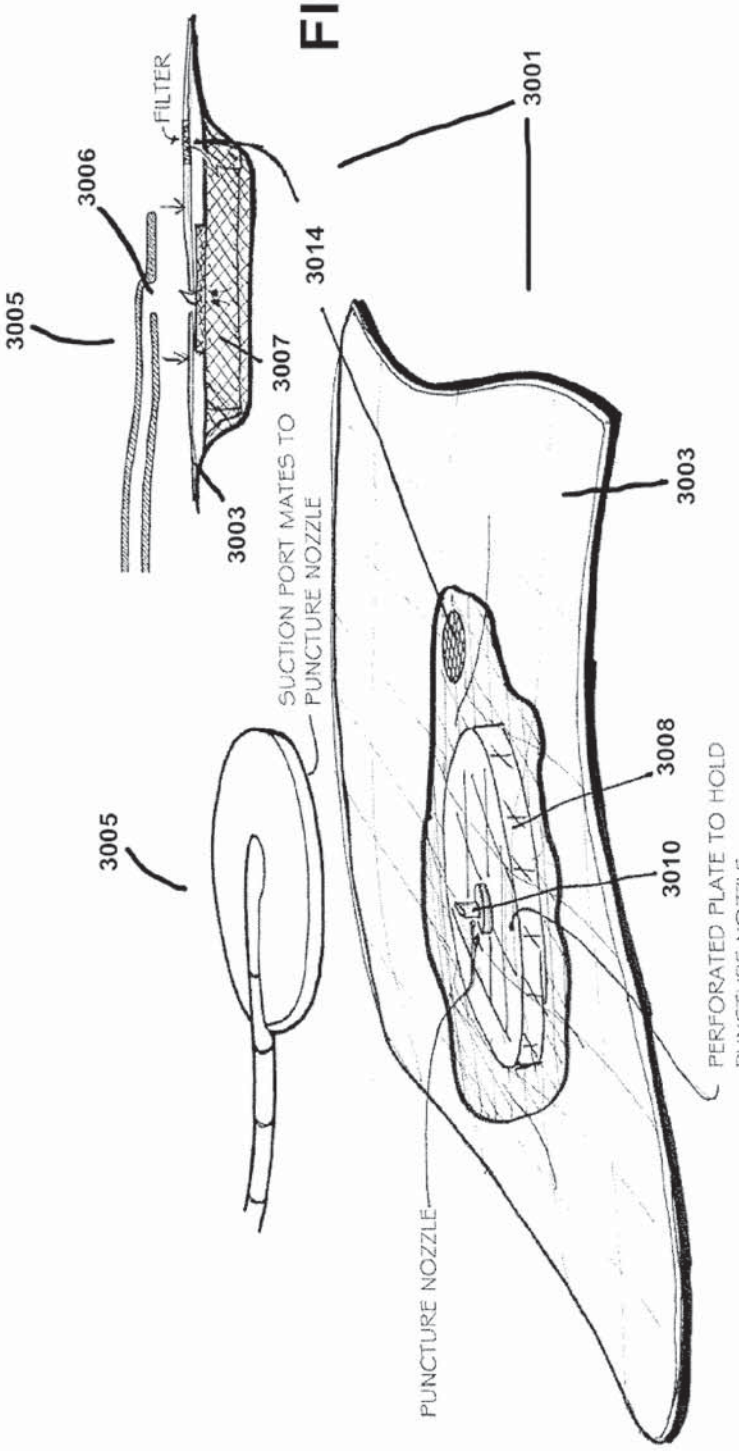


FIG 30B

FIG 30A

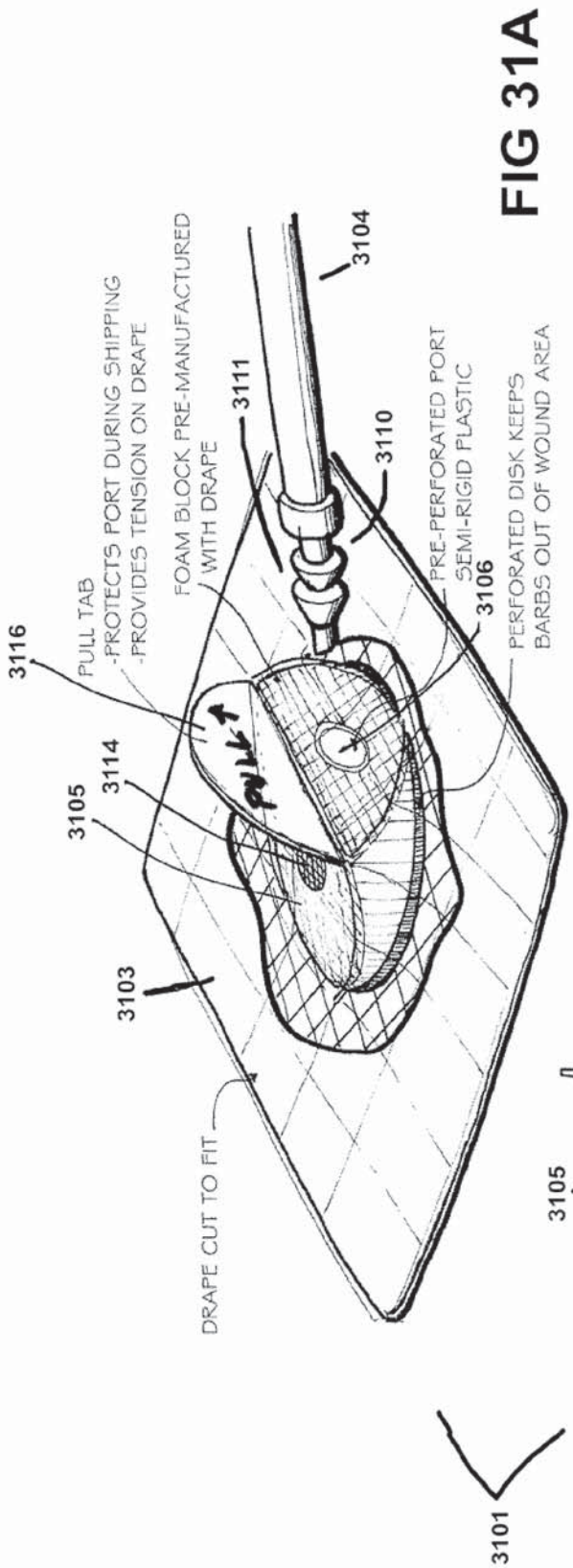


FIG 31A

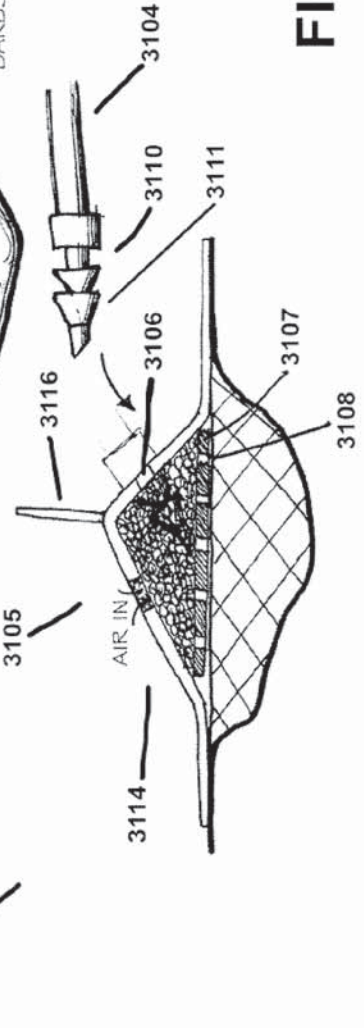


FIG 31B

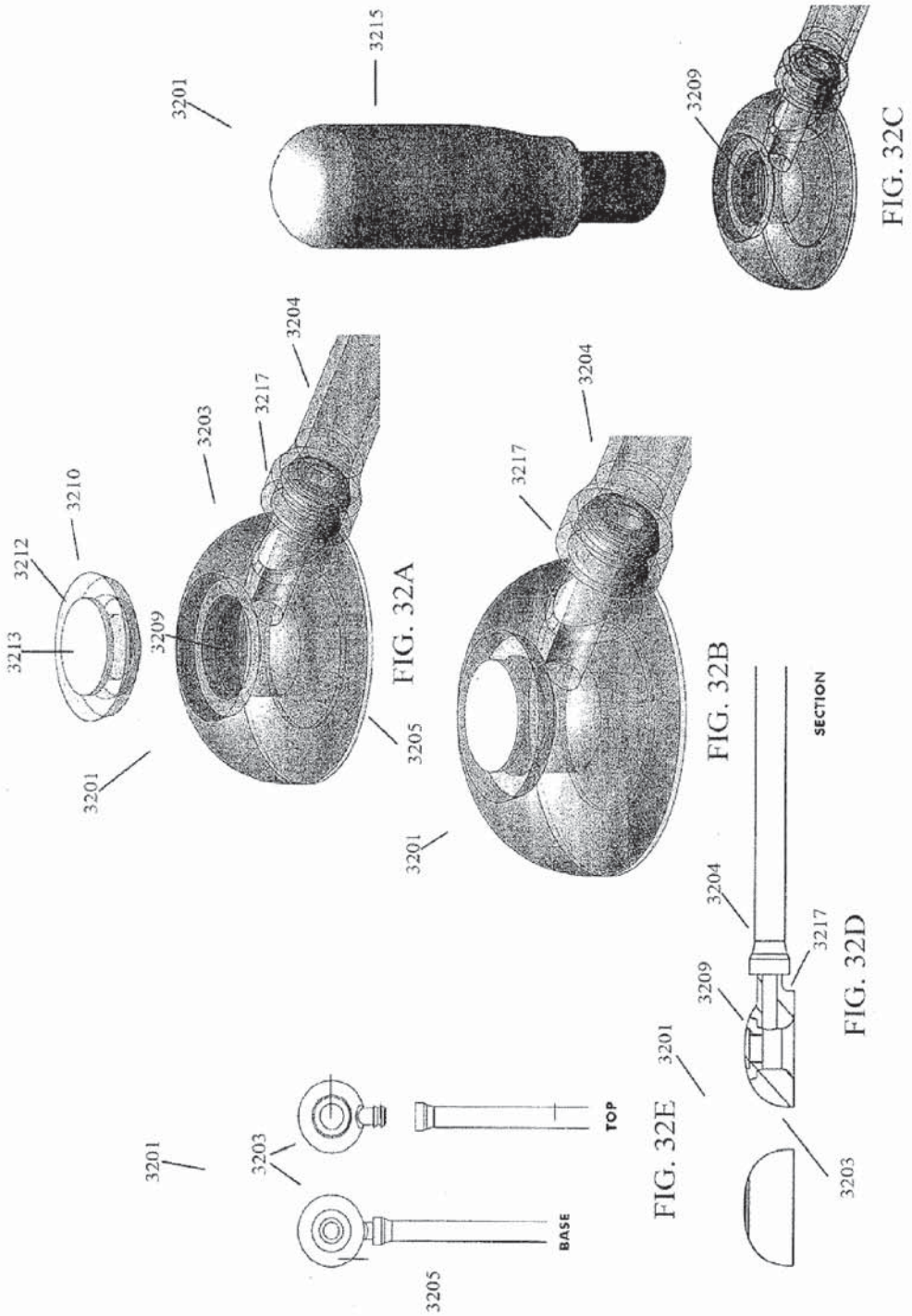


FIG. 32C

FIG. 32A

FIG. 32B

FIG. 32E

FIG. 32D

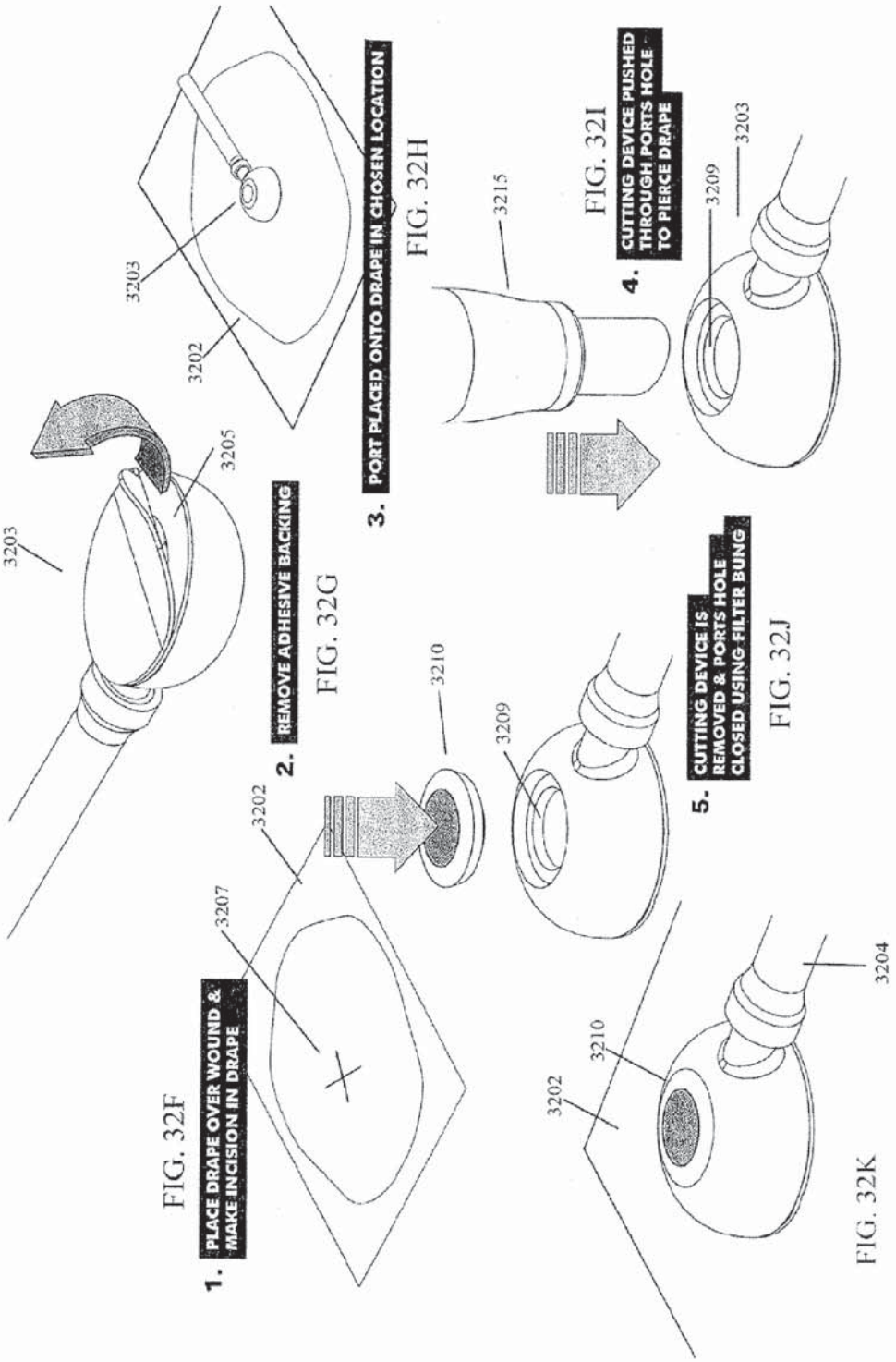


FIG. 32F

FIG. 32G

FIG. 32H

FIG. 32I

FIG. 32J

FIG. 32K

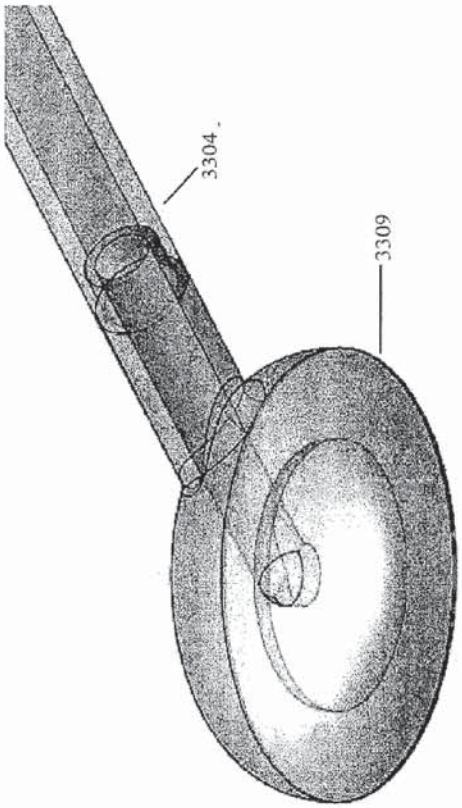
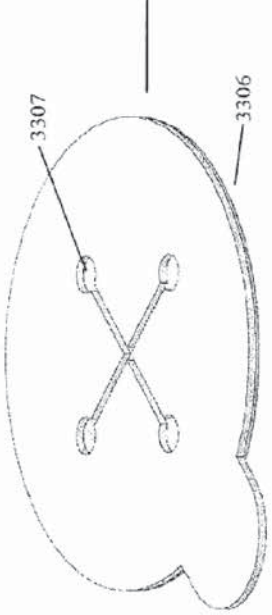


FIG. 33A



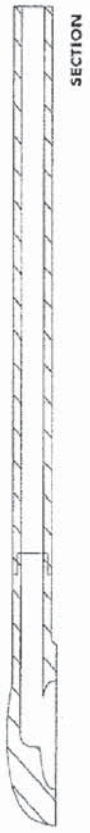


FIG. 33B

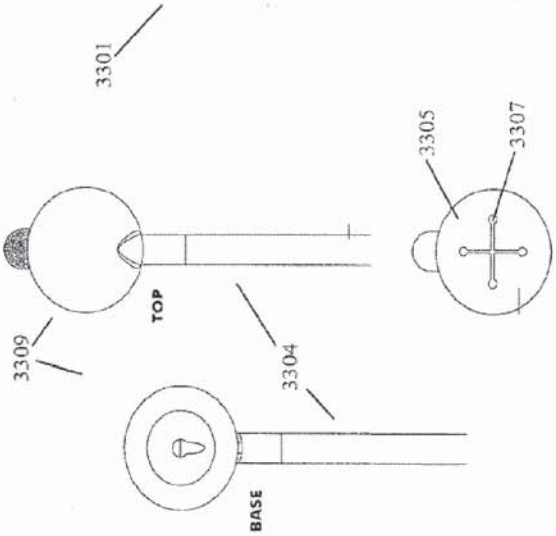


FIG. 33C

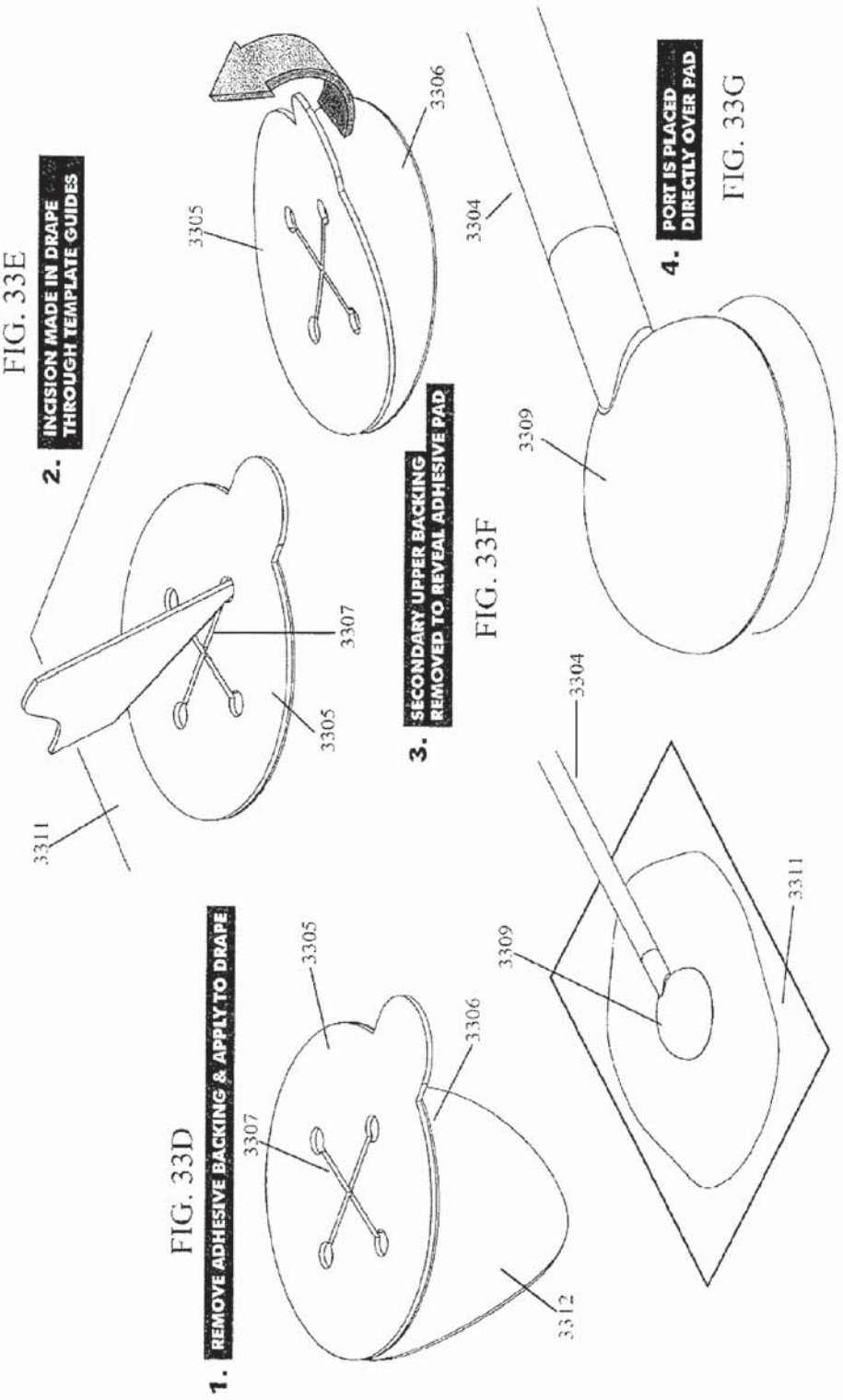


FIG. 33D

FIG. 33E

FIG. 33F

FIG. 33G

FIG. 33H

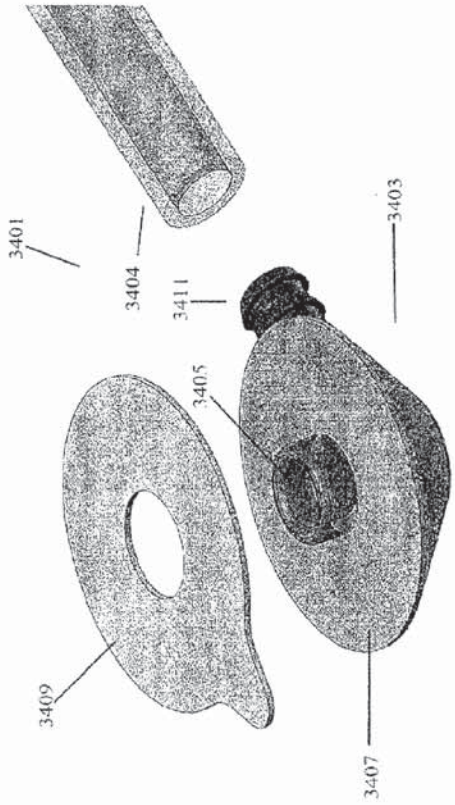


FIG. 34A

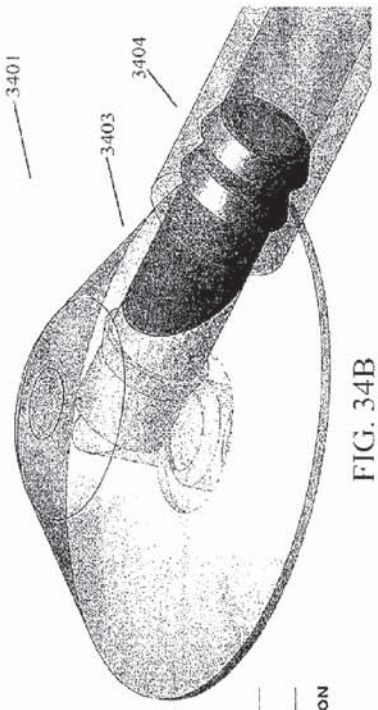


FIG. 34B

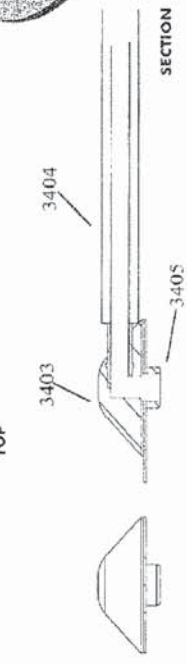


FIG. 34C

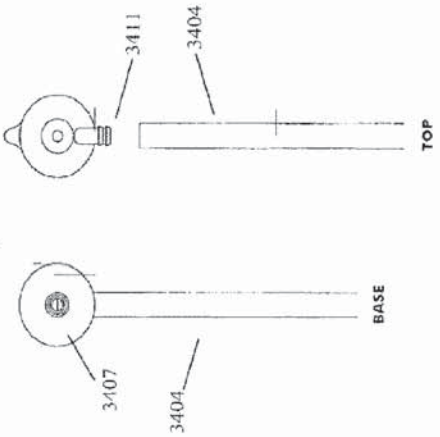


FIG. 34D

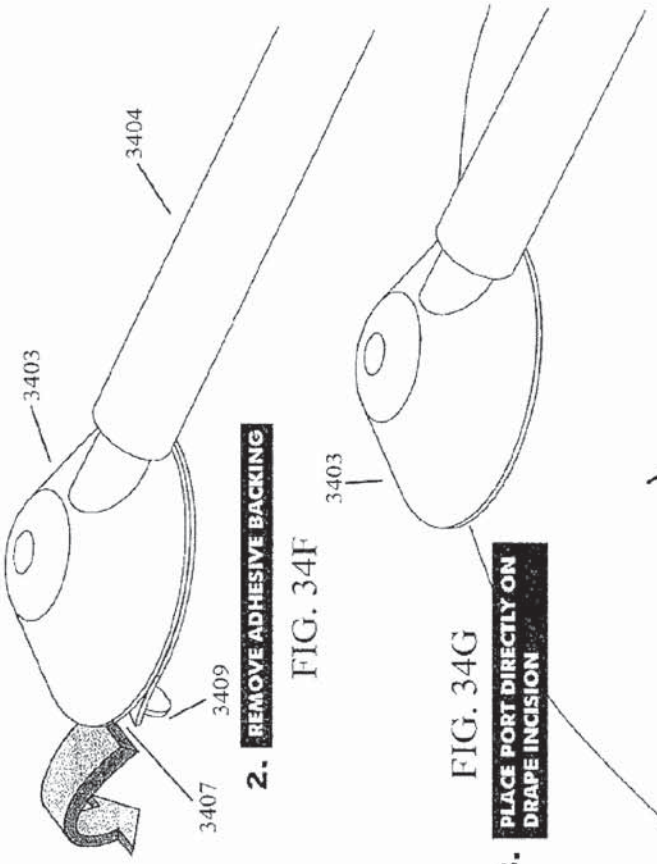


FIG. 34F

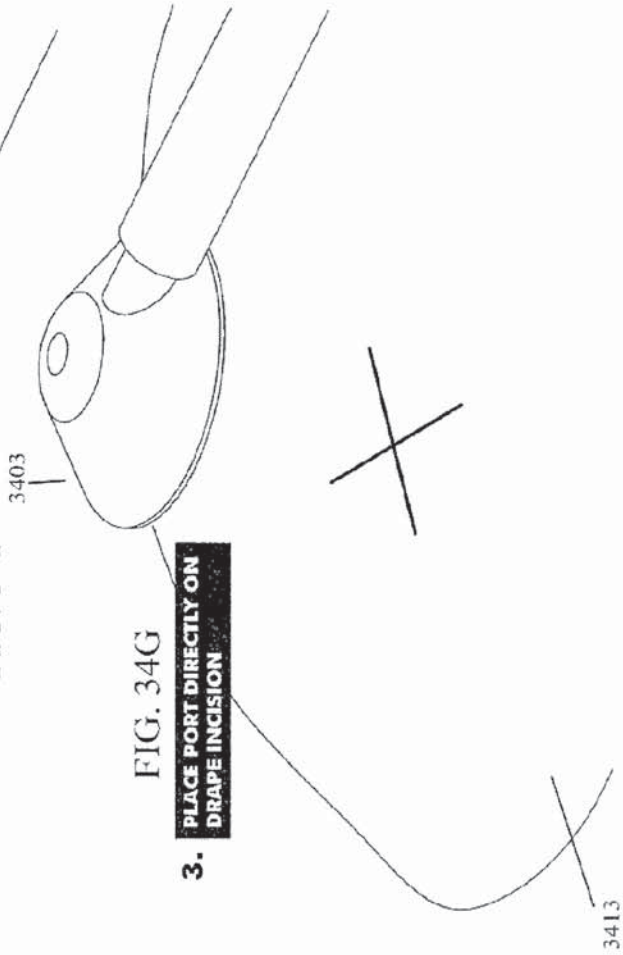


FIG. 34G

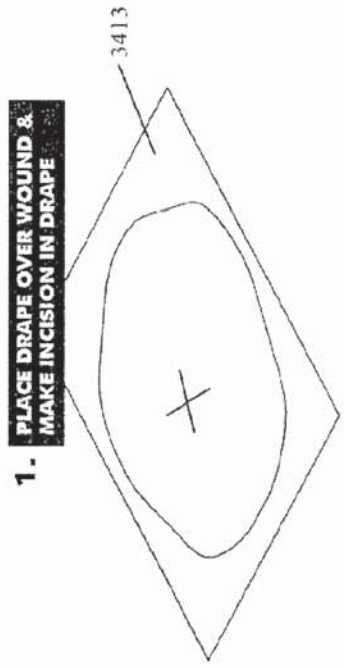


FIG. 34E

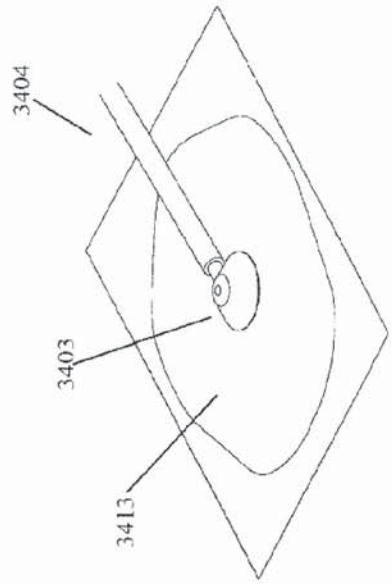


FIG. 34H

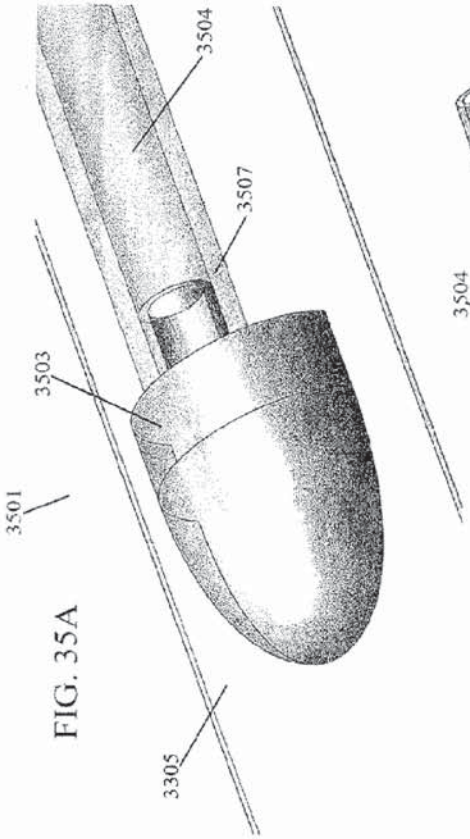


FIG. 35A

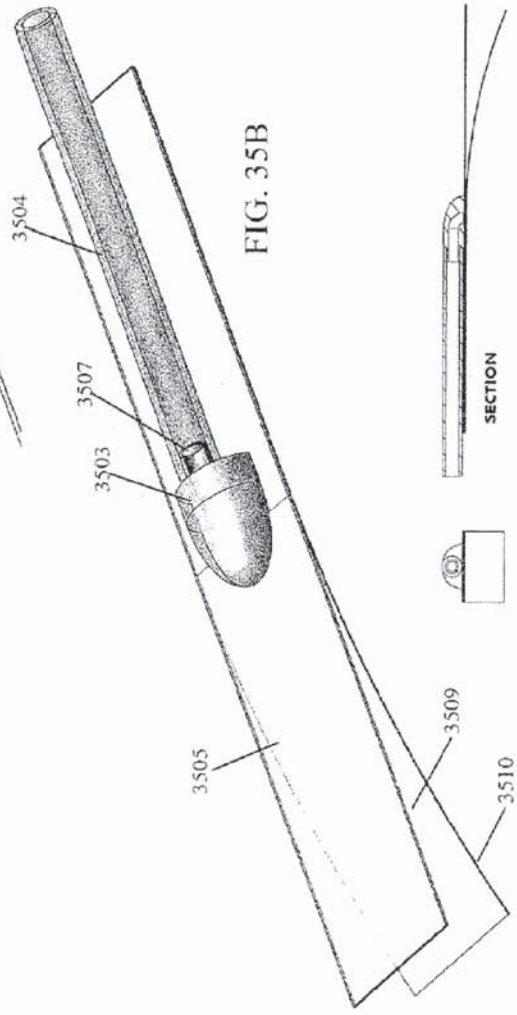


FIG. 35B

FIG. 35C

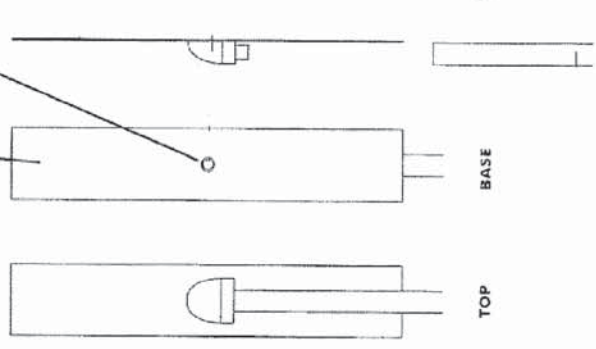


FIG. 35D

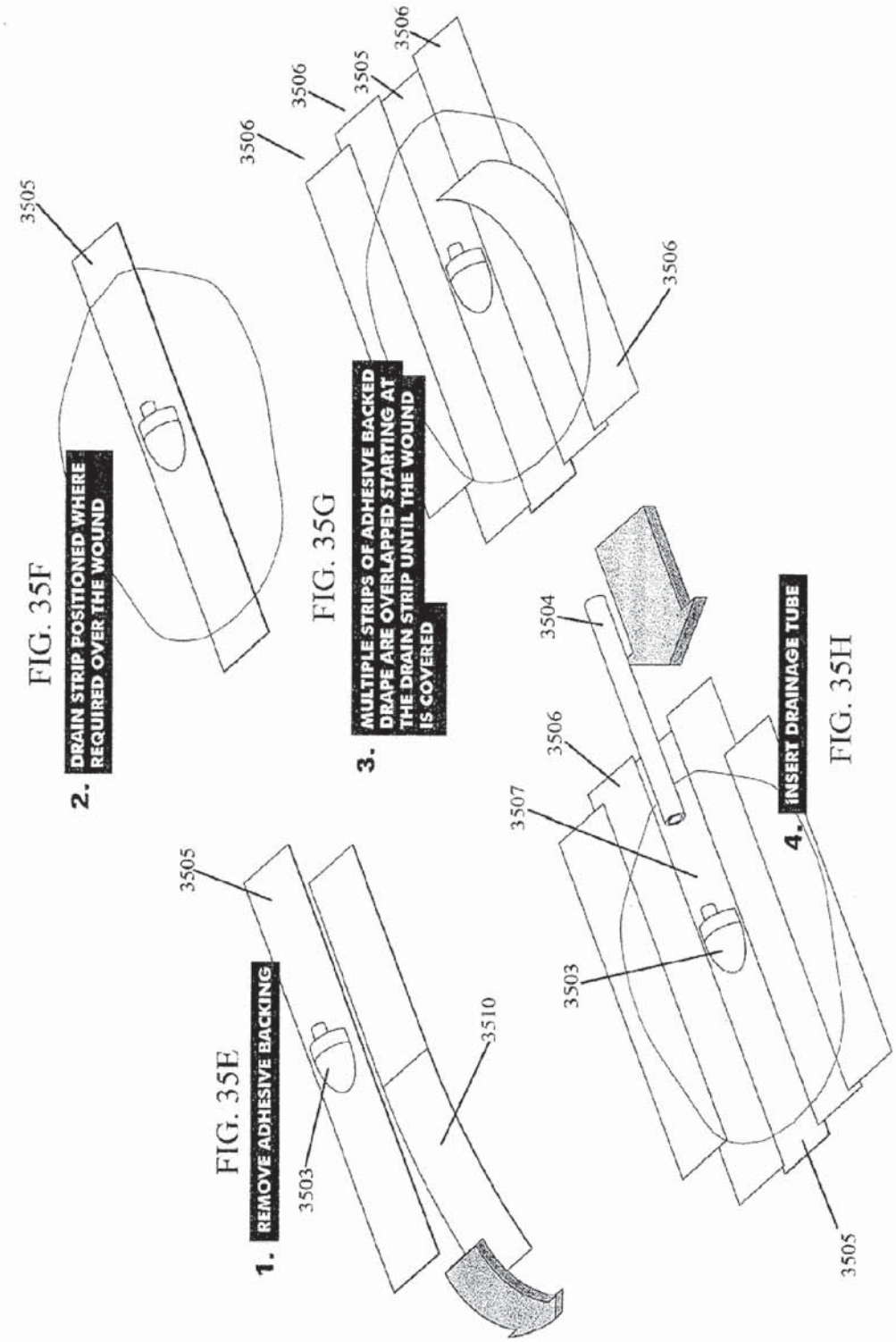


FIG. 35E

FIG. 35F

FIG. 35G

FIG. 35H

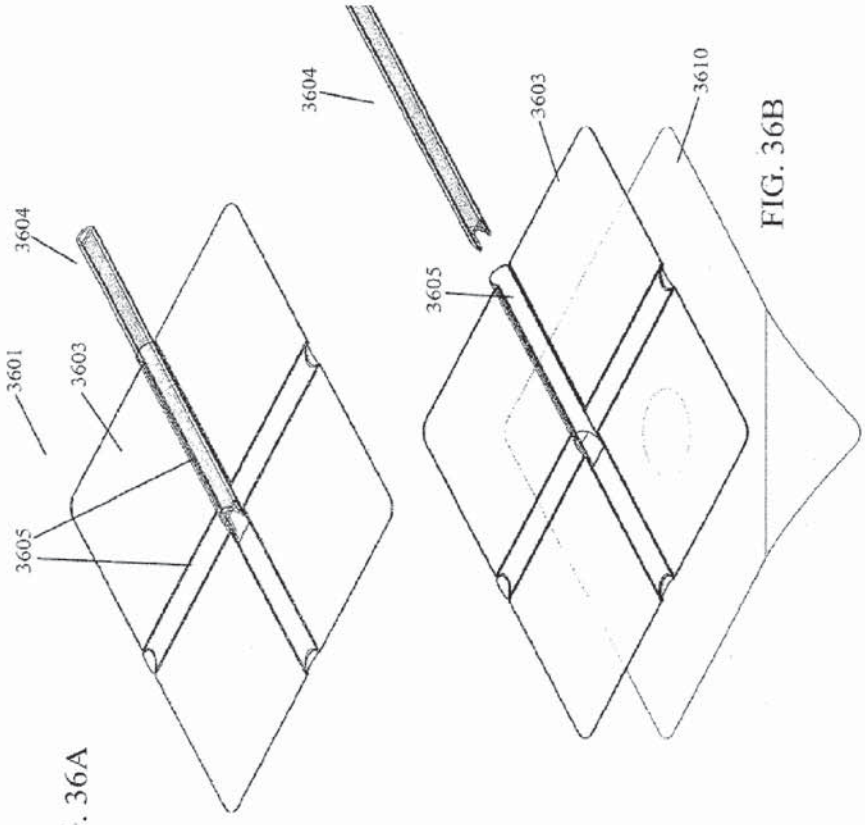


FIG. 36A

FIG. 36B

FIG. 36C

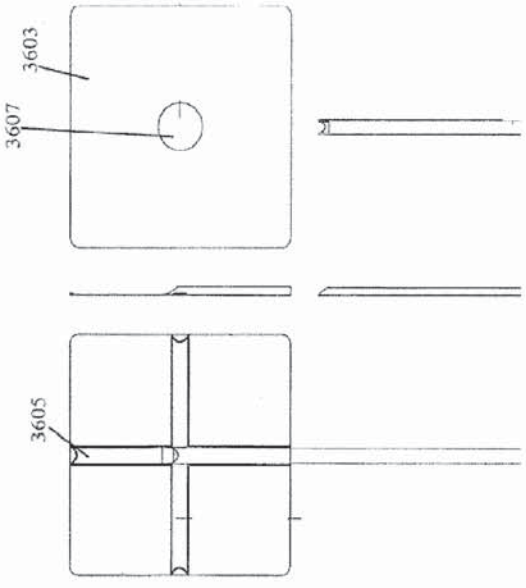


FIG. 36D

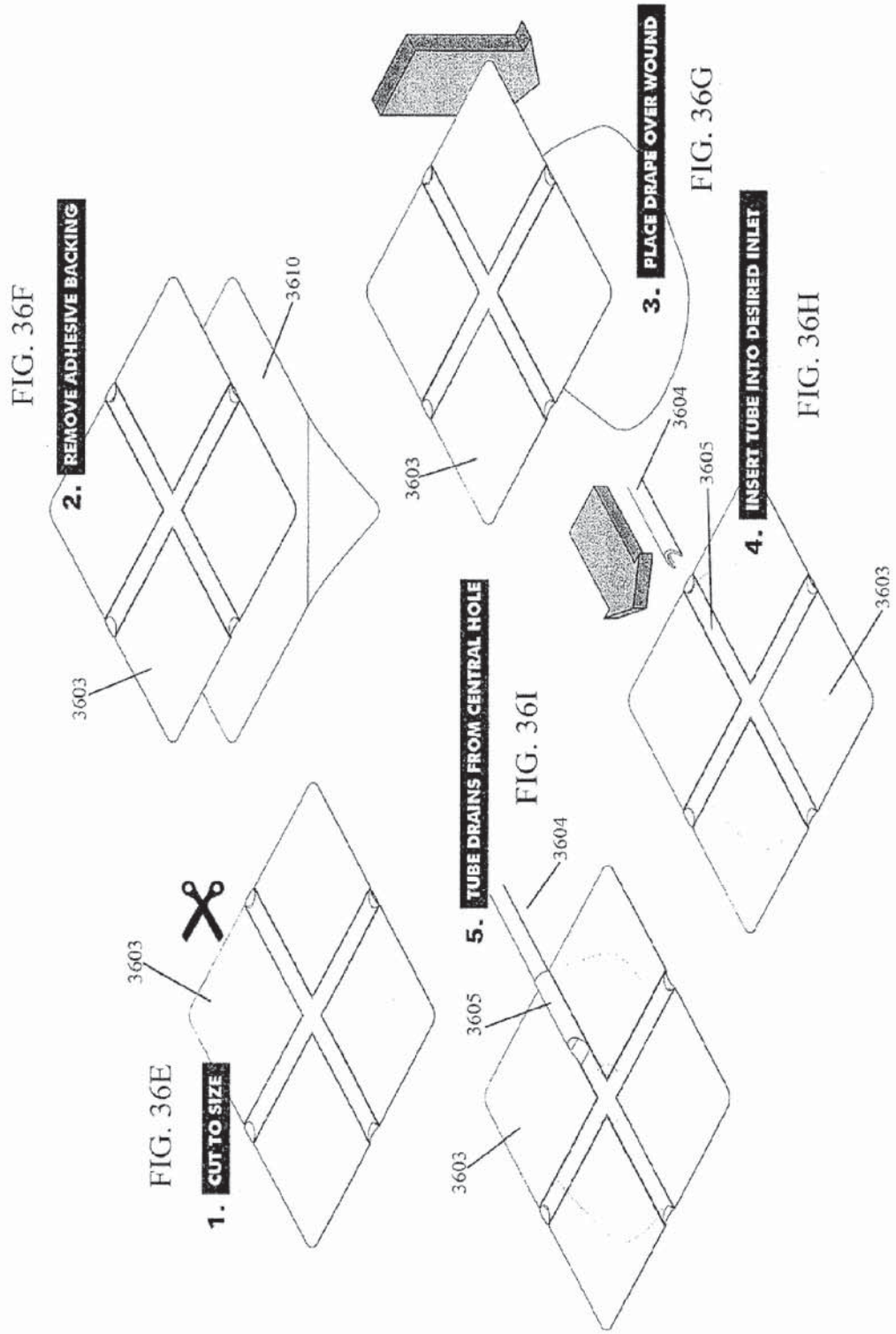


FIG. 36E

FIG. 36F

FIG. 36G

FIG. 36H

FIG. 36I

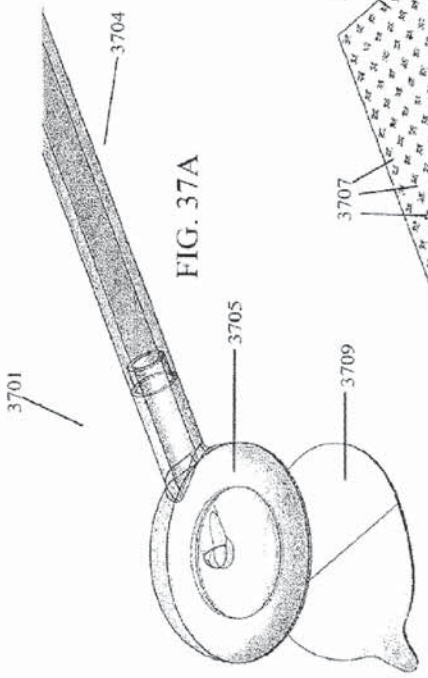


FIG. 37A

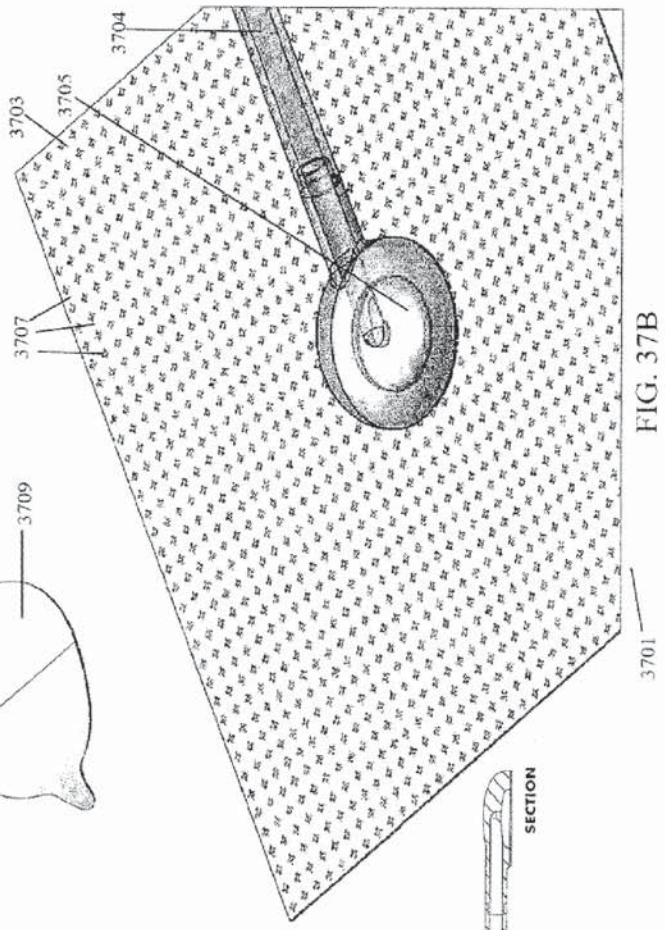


FIG. 37B

FIG. 37C

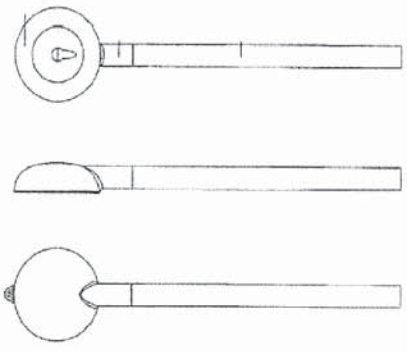


FIG. 37D

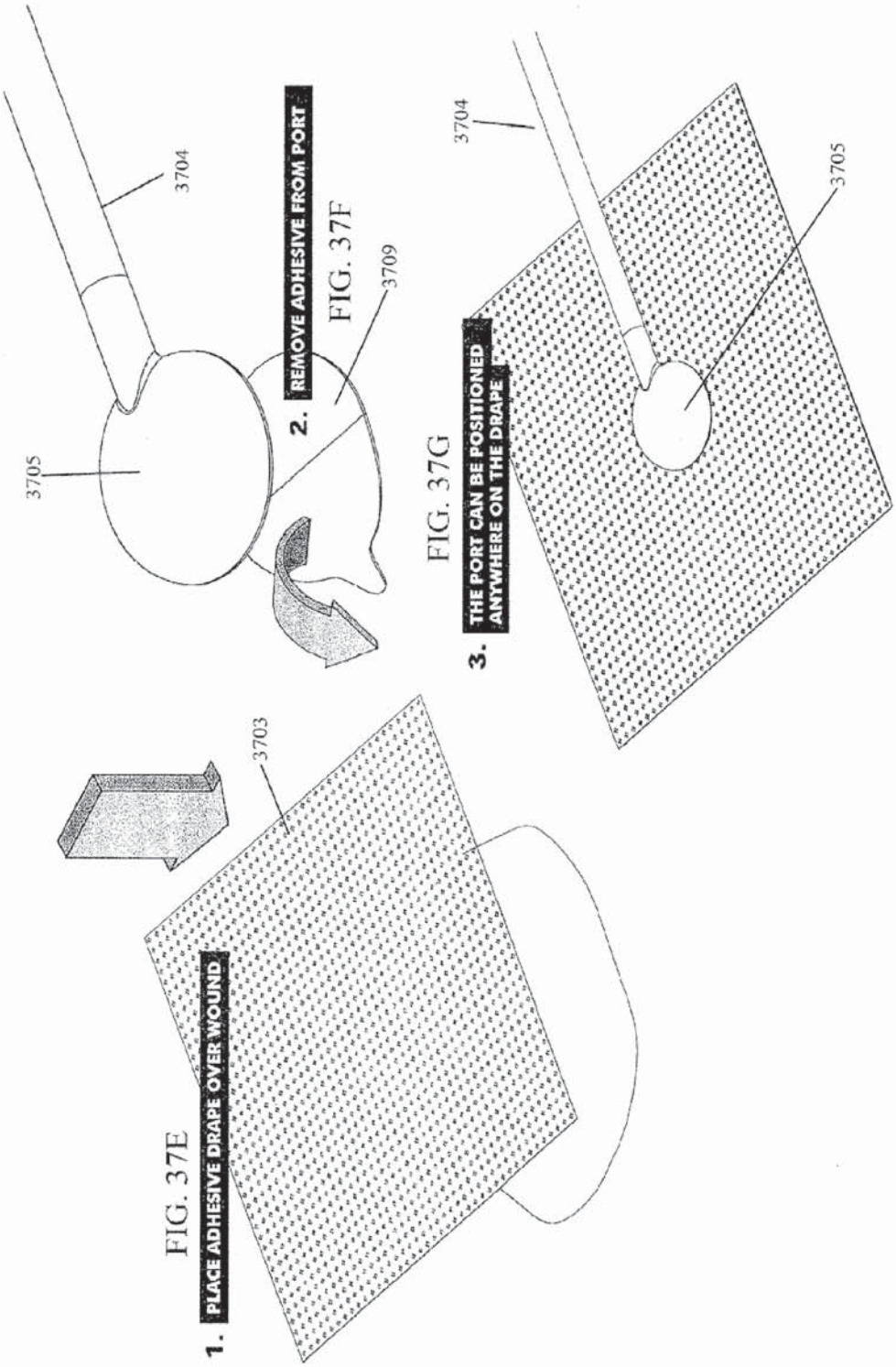


FIG. 37E

FIG. 37F

FIG. 37G

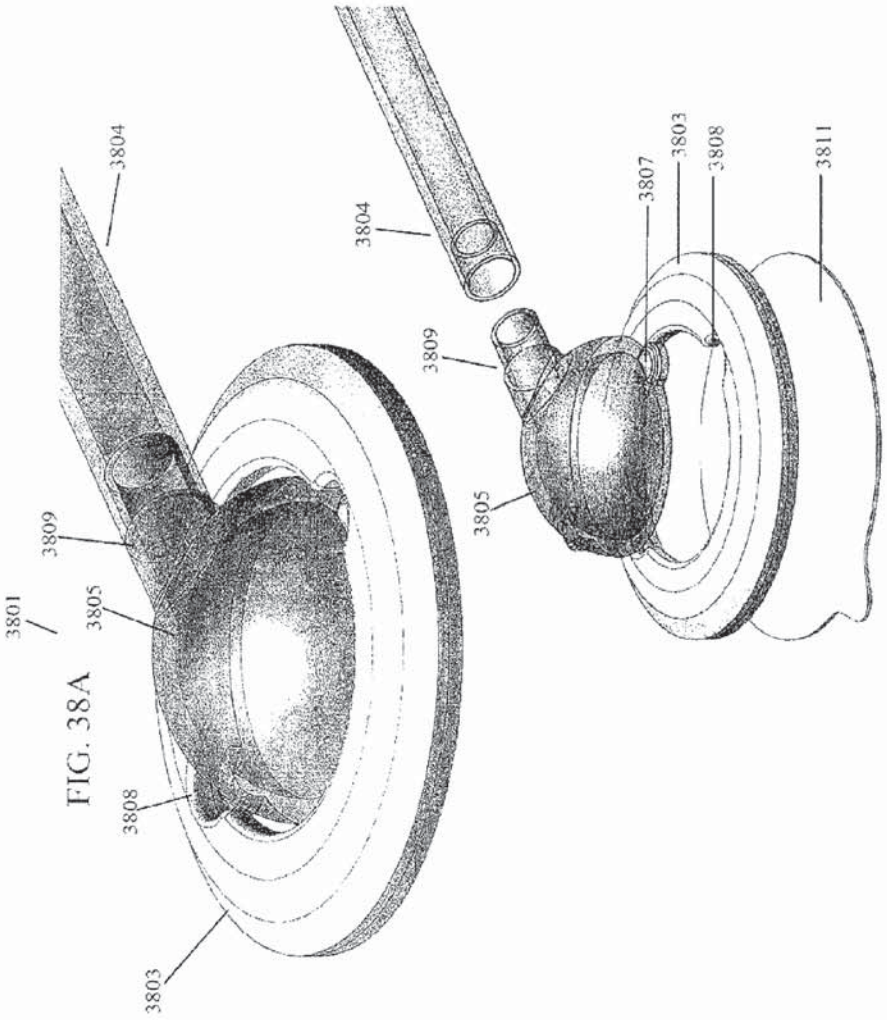


FIG. 38A

FIG. 38B

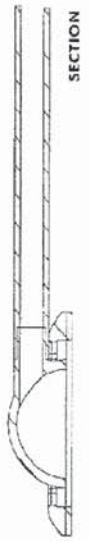


FIG. 38C

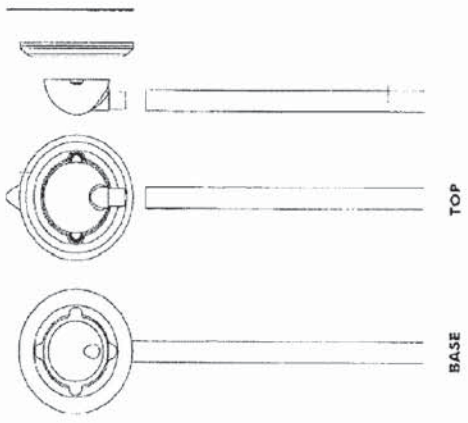


FIG. 38D

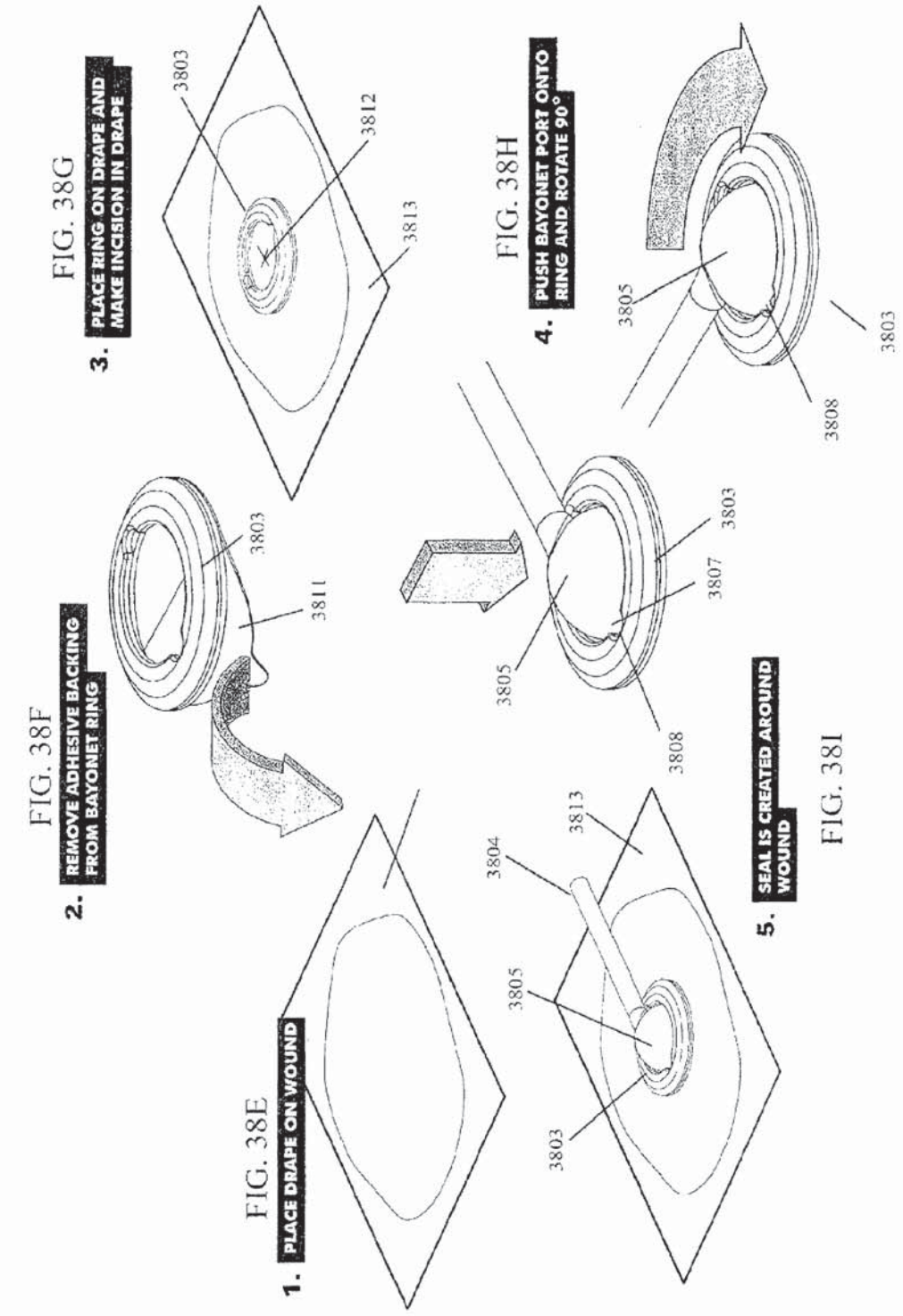


FIG. 38E

FIG. 38F

FIG. 38G

FIG. 38H

FIG. 38I

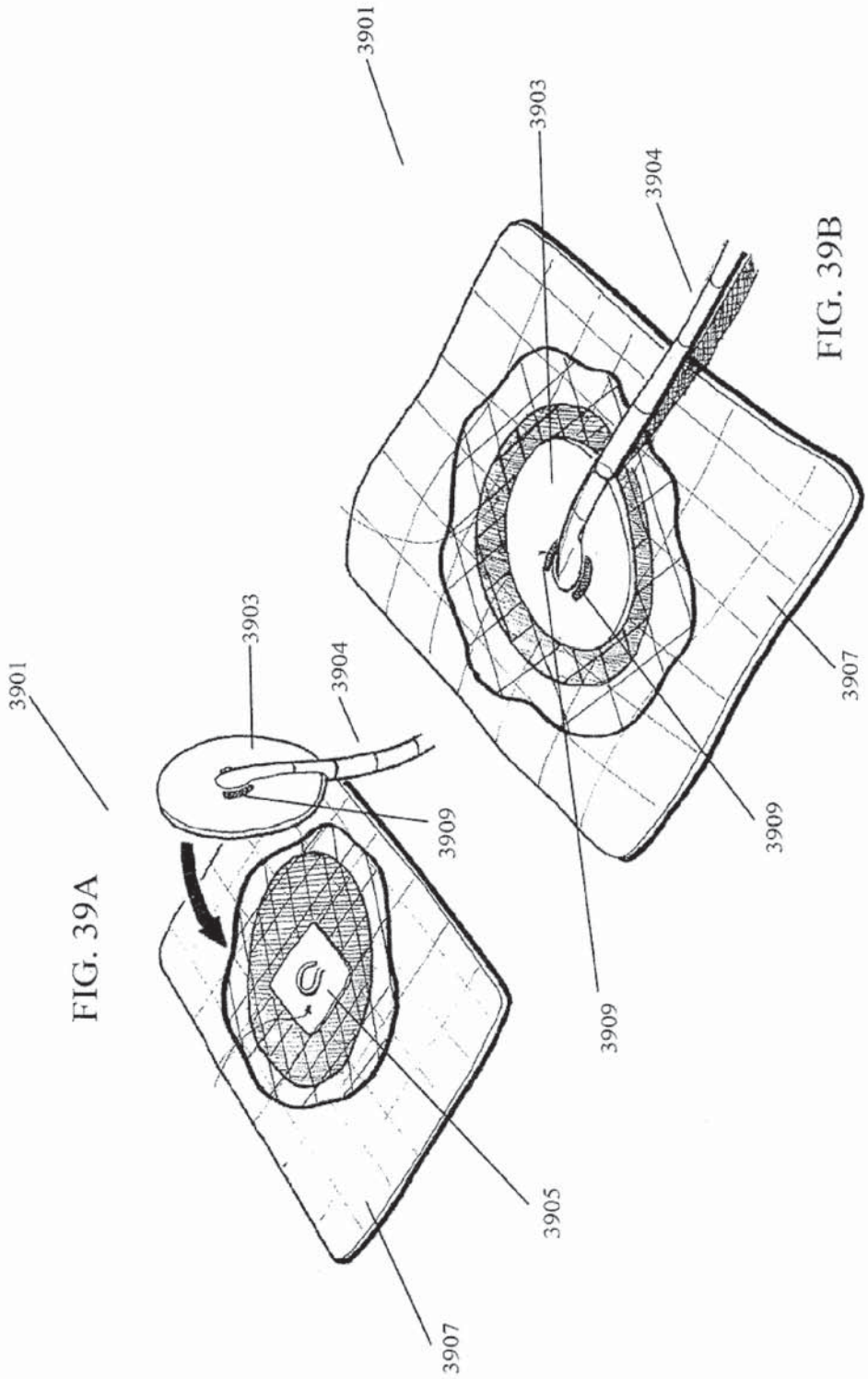


FIG. 39A

FIG. 39B

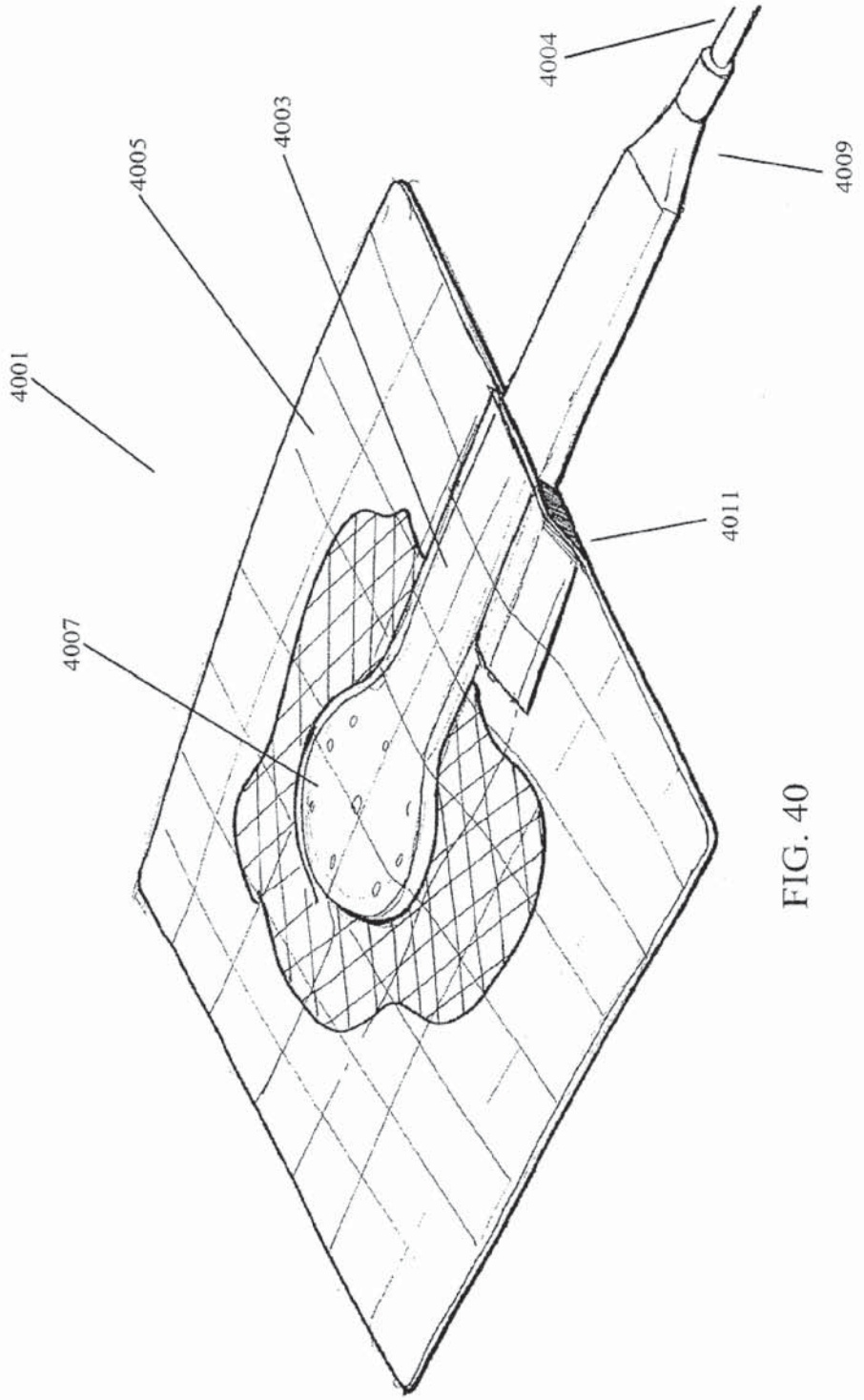


FIG. 40

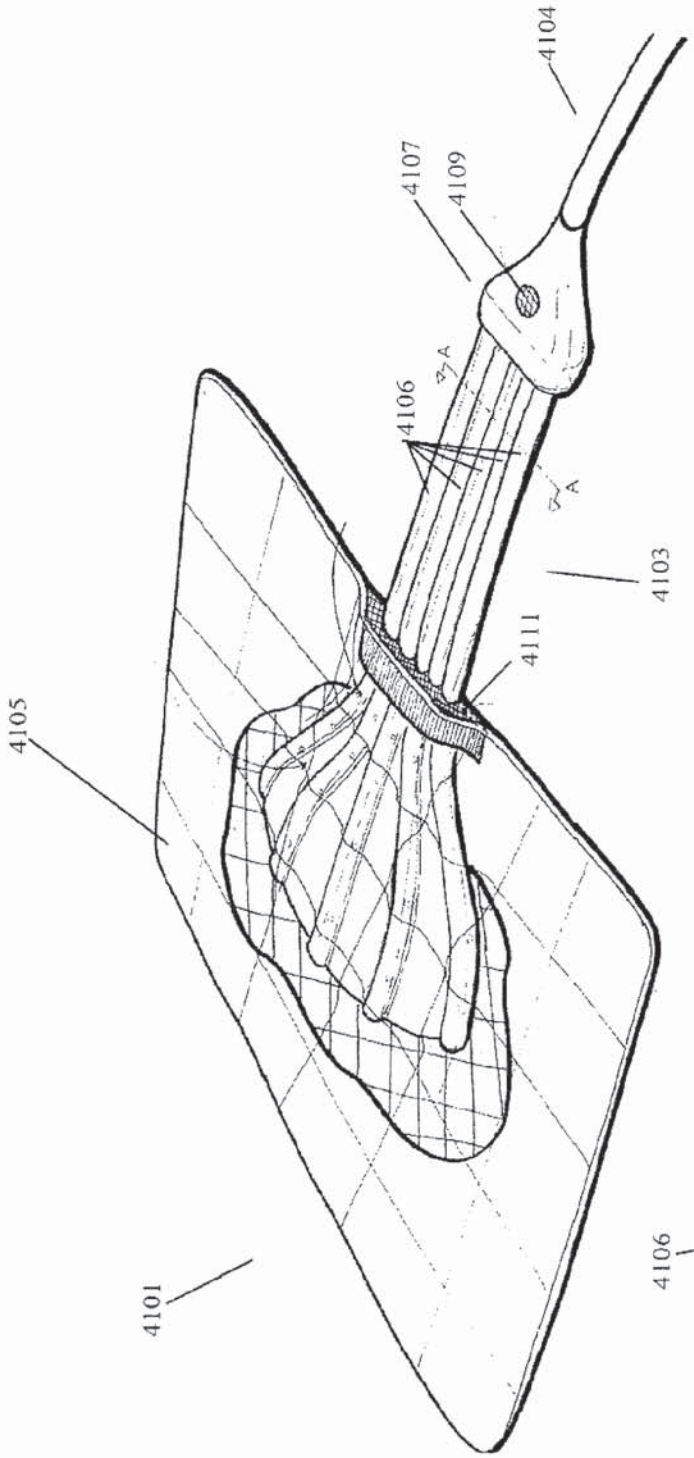


FIG. 41A

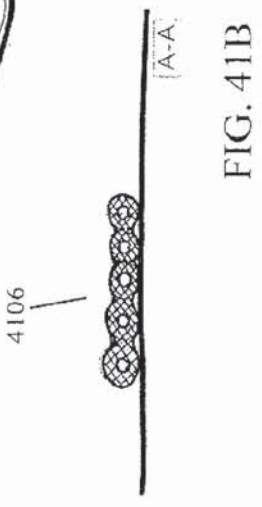


FIG. 41B

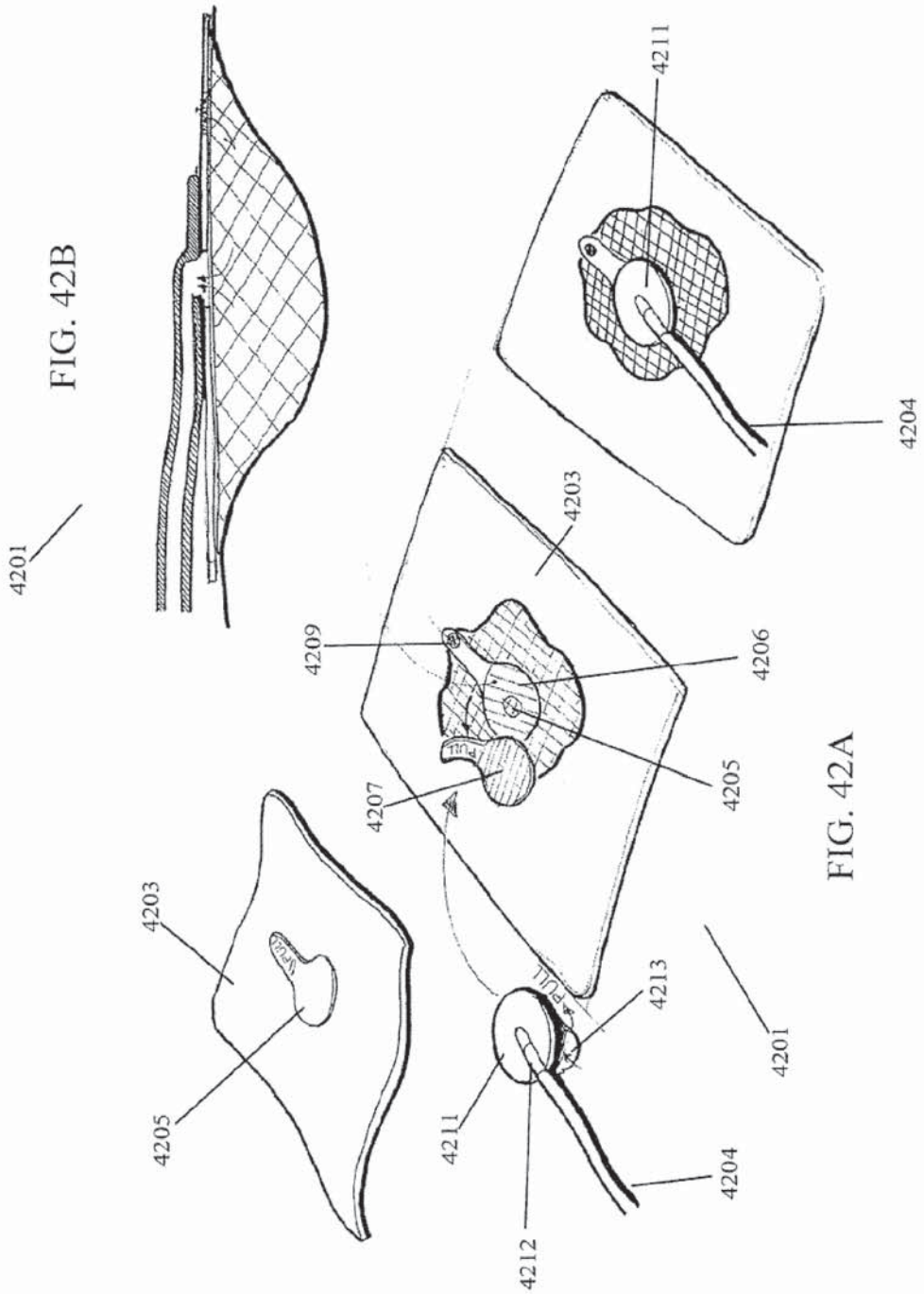


FIG. 42A

FIG. 42B

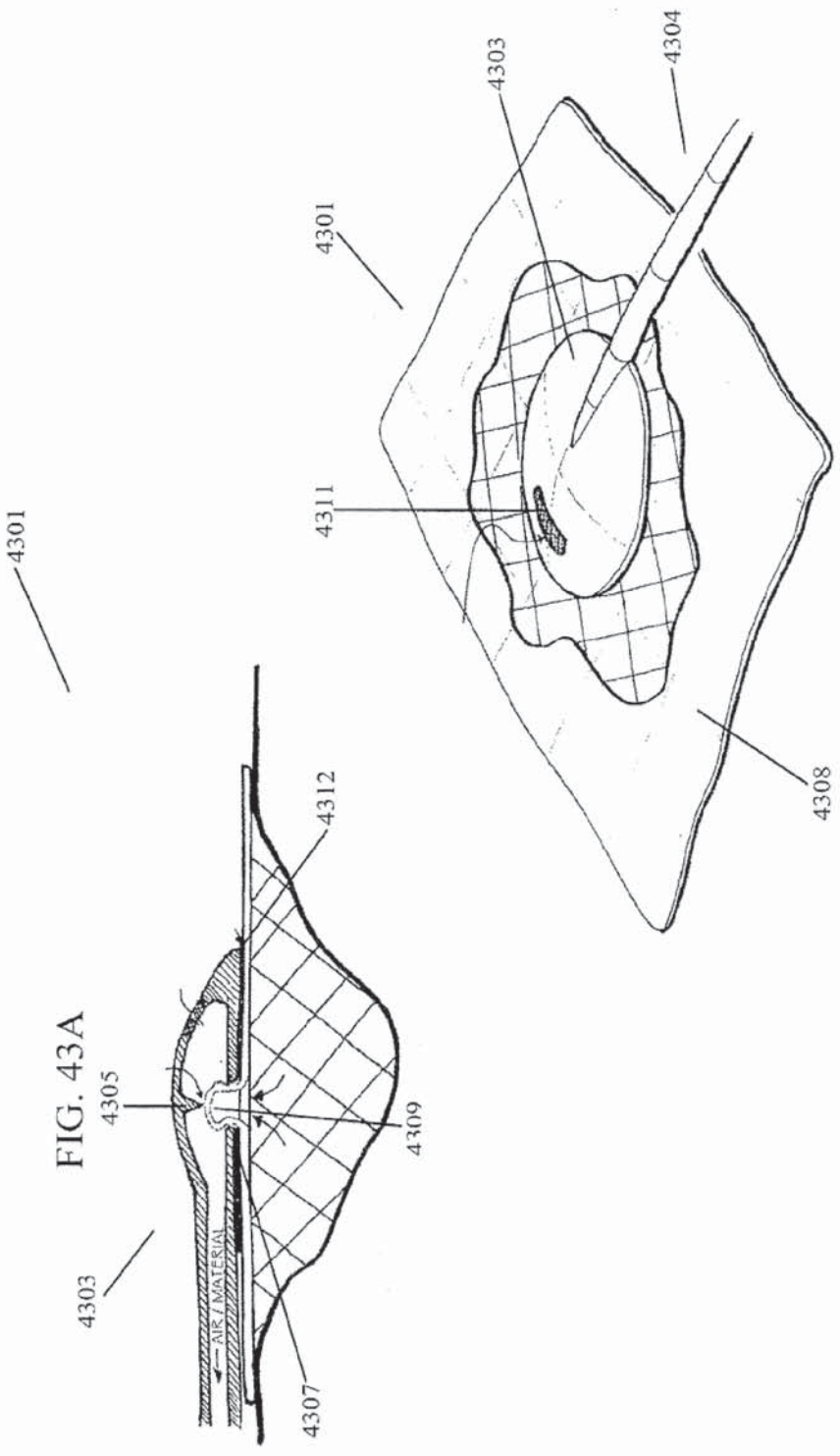


FIG. 43B

FIG. 43A

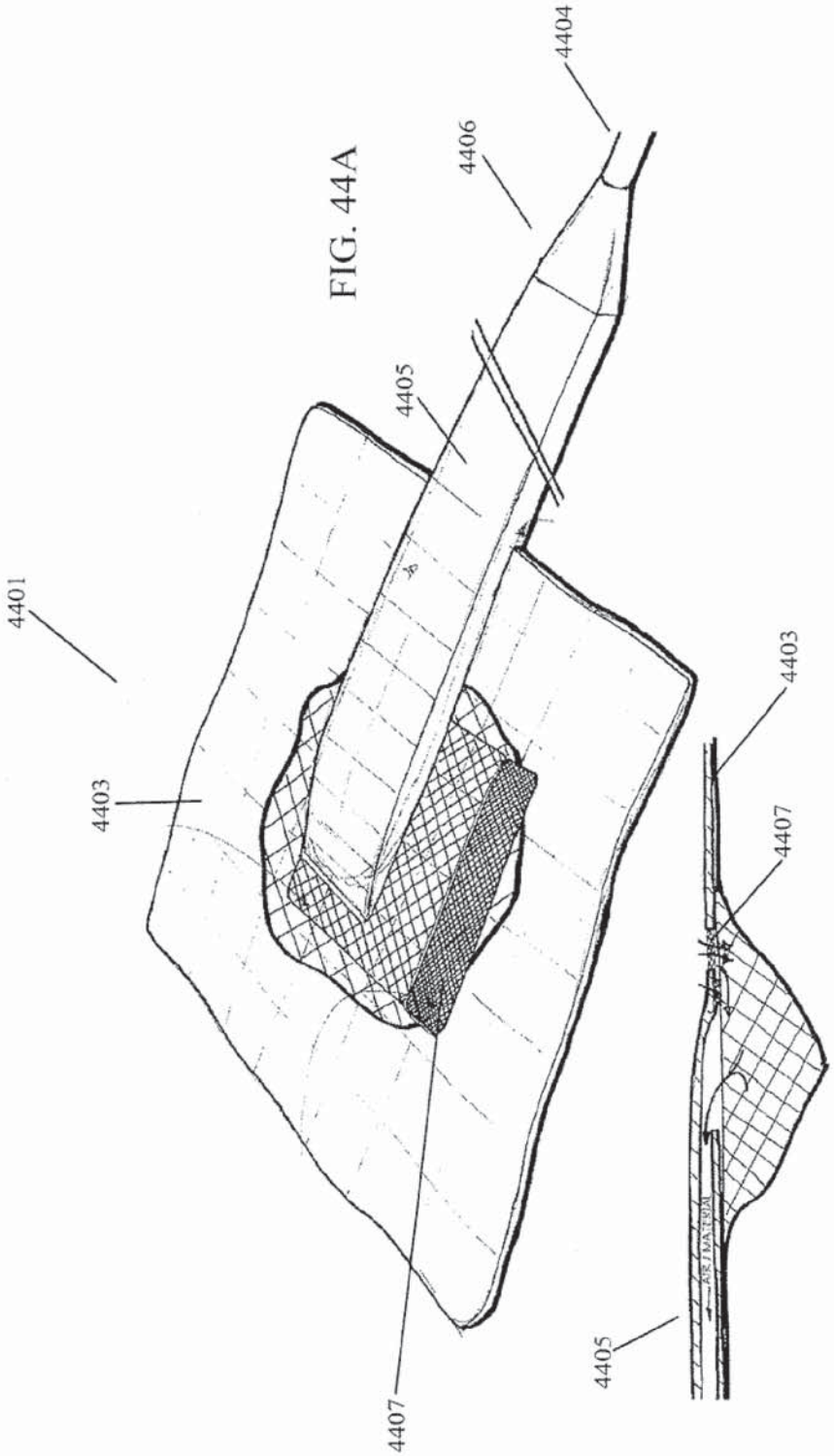


FIG. 44A

FIG. 44B

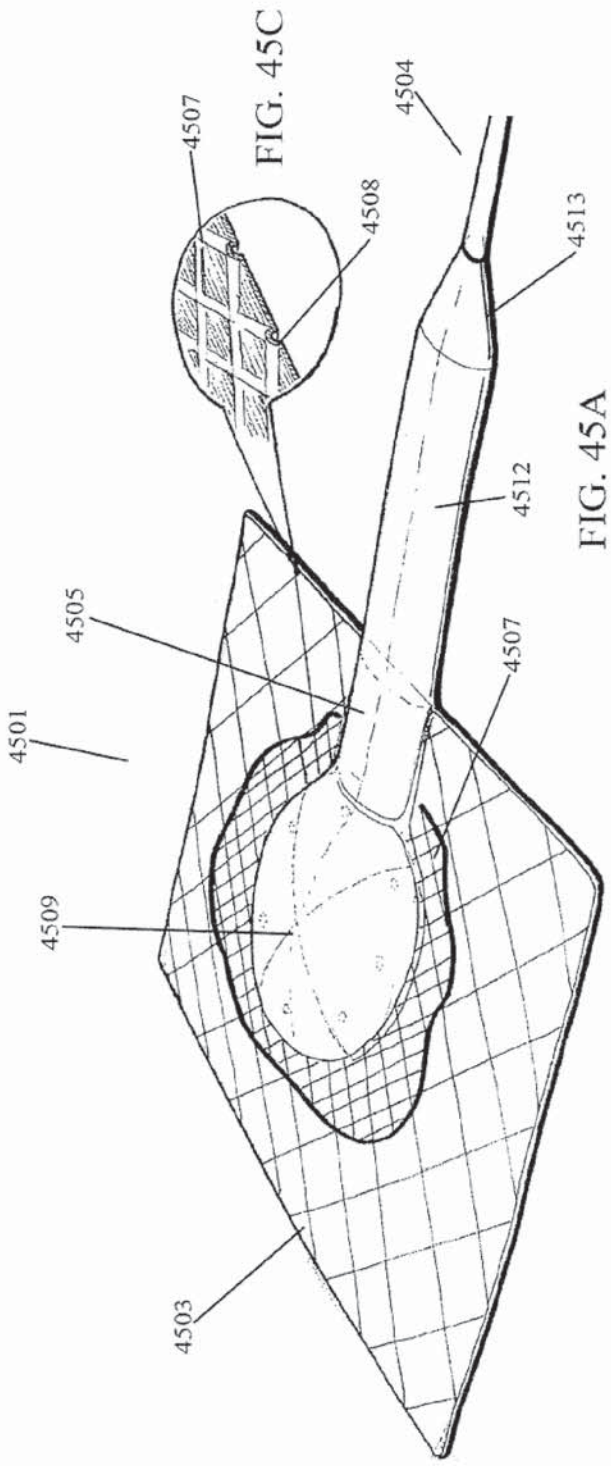


FIG. 45C

FIG. 45A

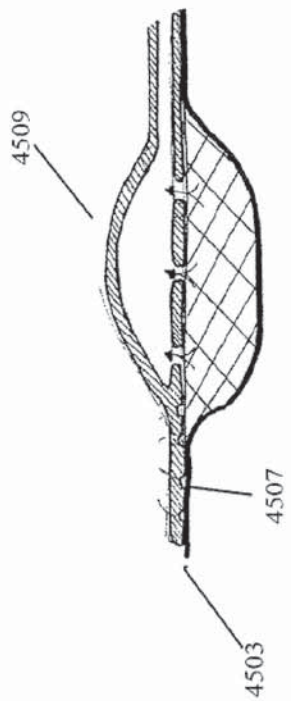


FIG. 45B

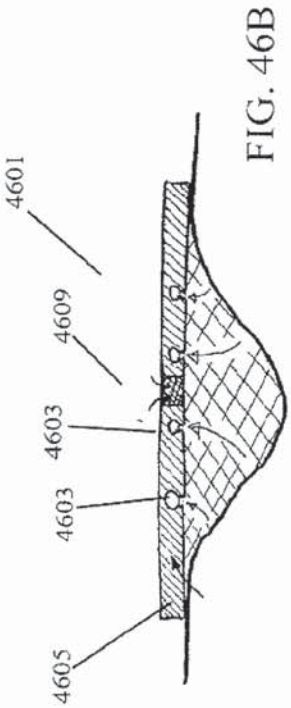


FIG. 46B

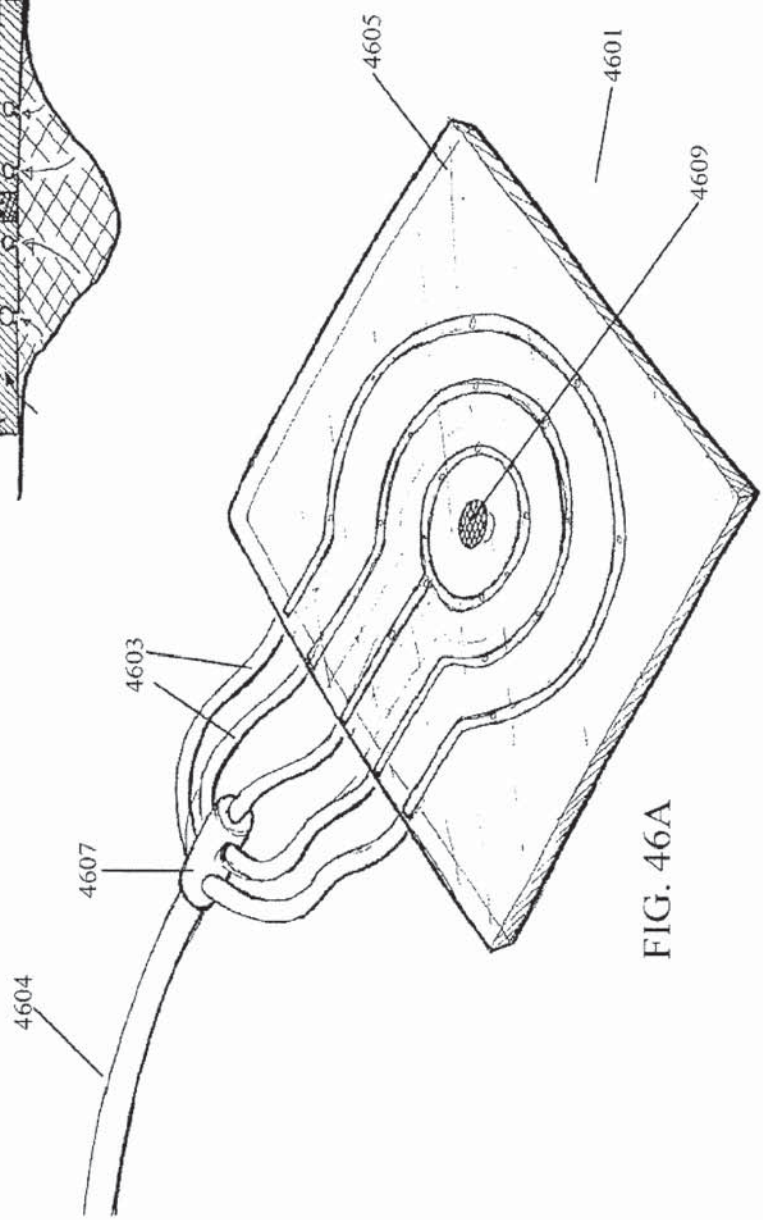


FIG. 46A

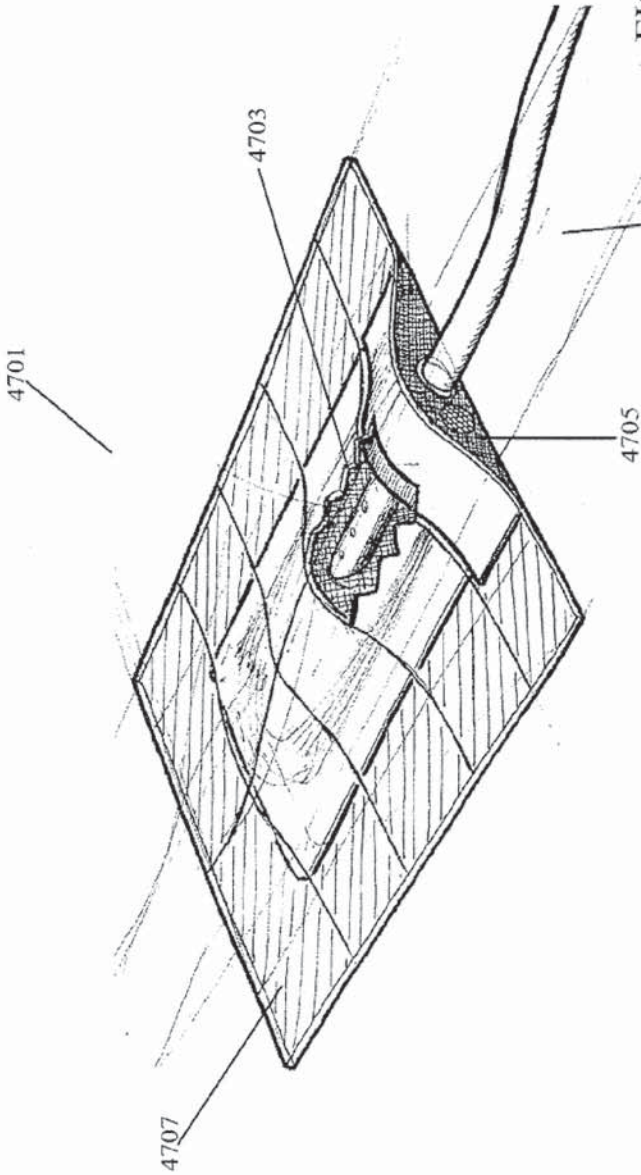


FIG. 47A

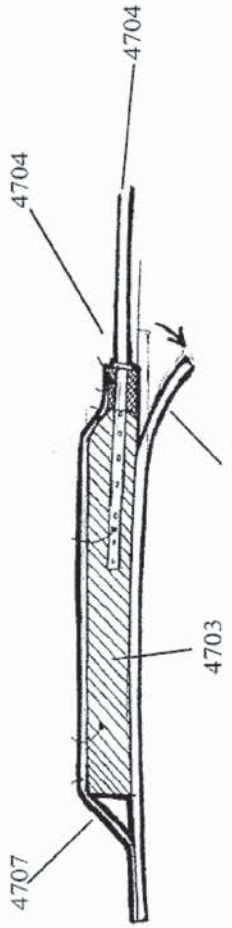


FIG. 47B

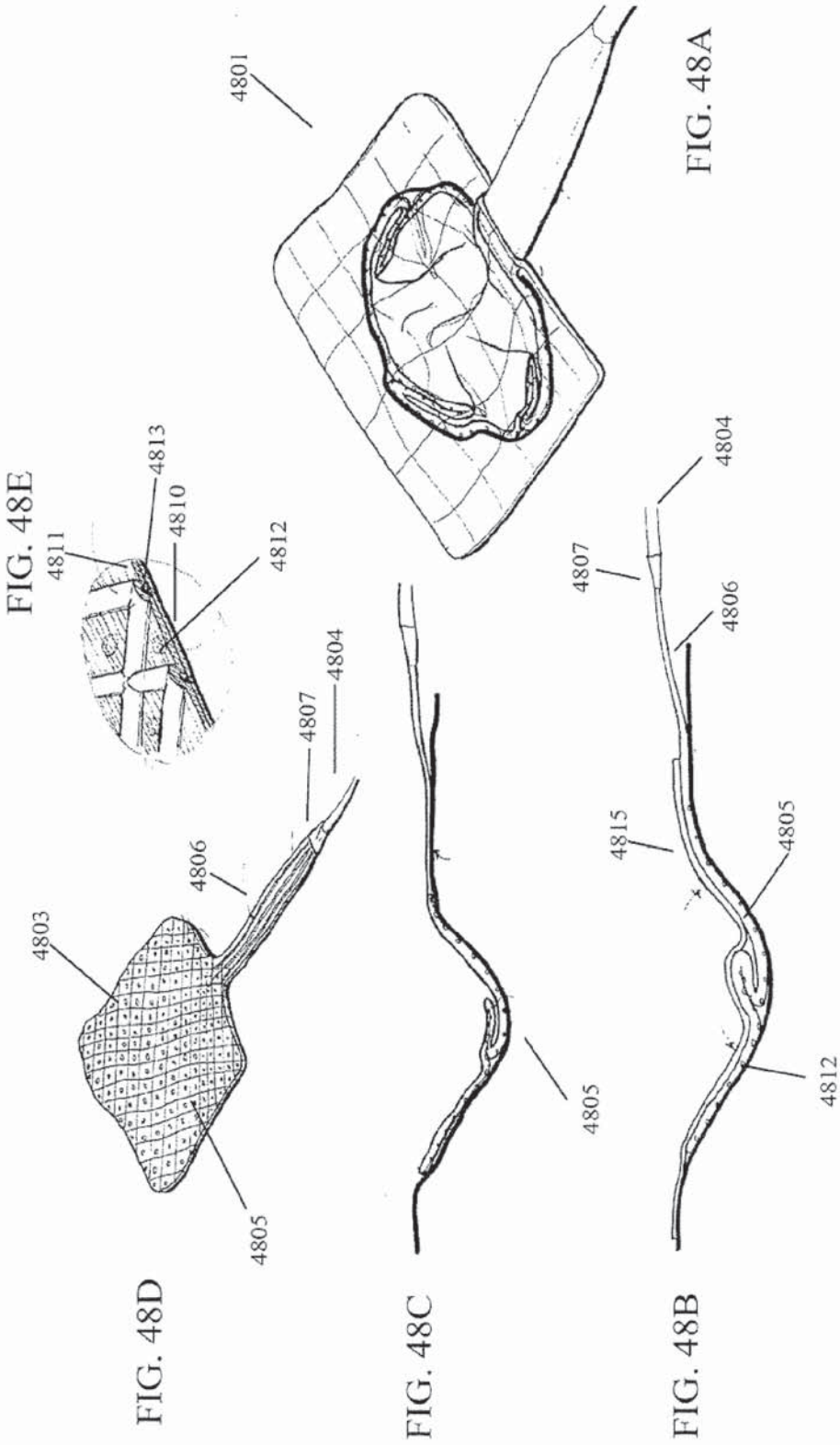


FIG. 48A

FIG. 48E

FIG. 48D

FIG. 48C

FIG. 48B

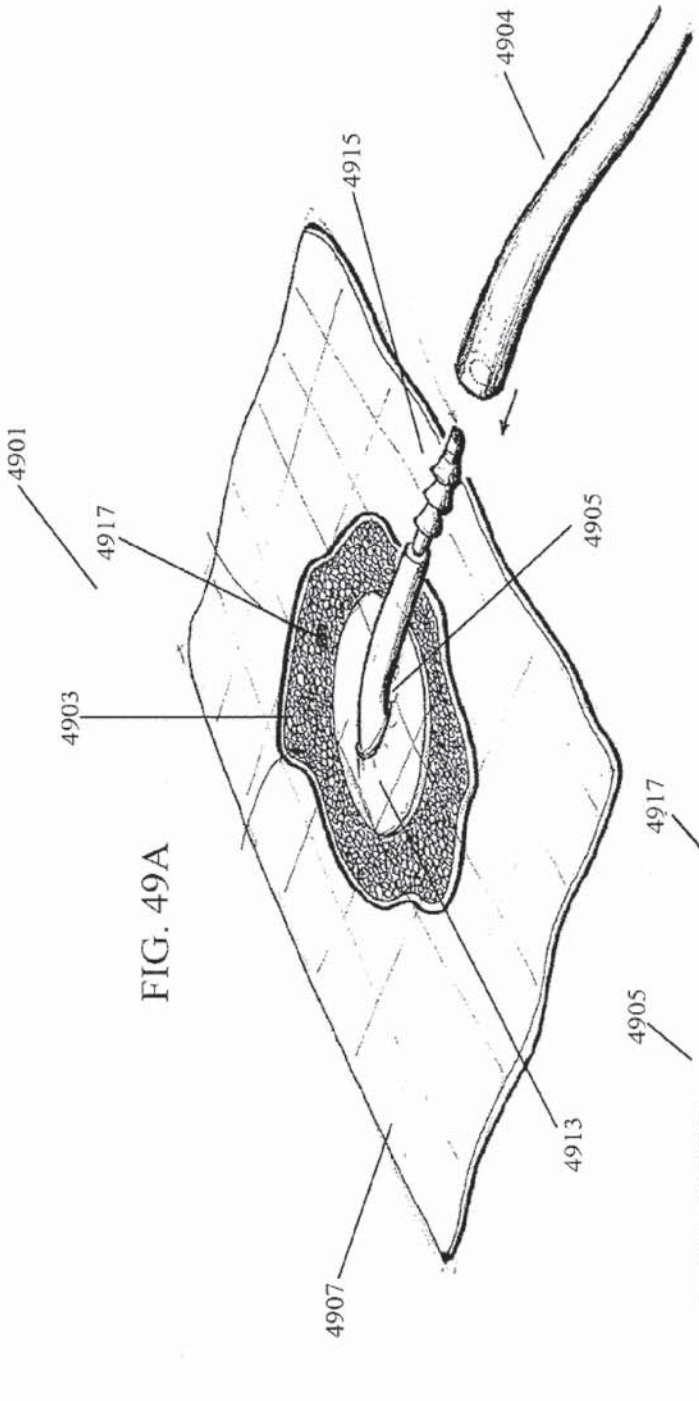


FIG. 49A

FIG. 49B

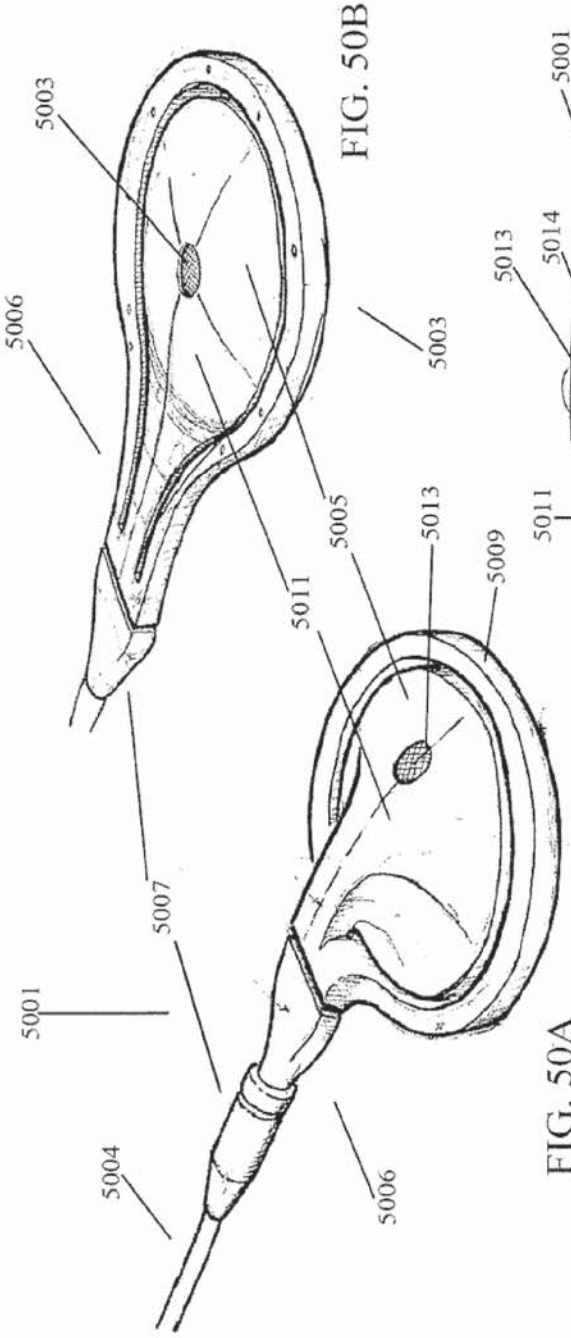


FIG. 50A

FIG. 50B

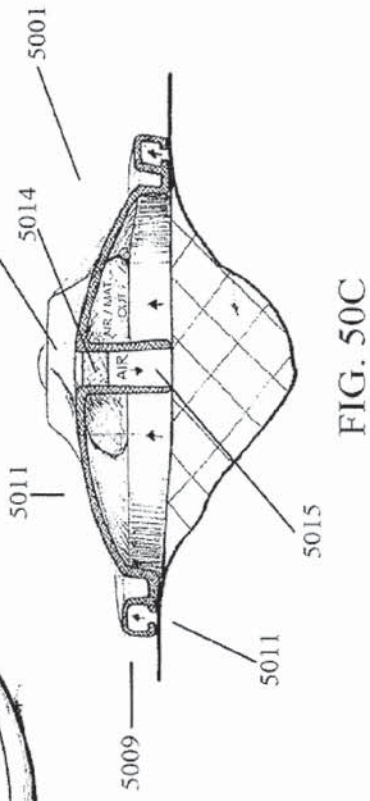


FIG. 50C

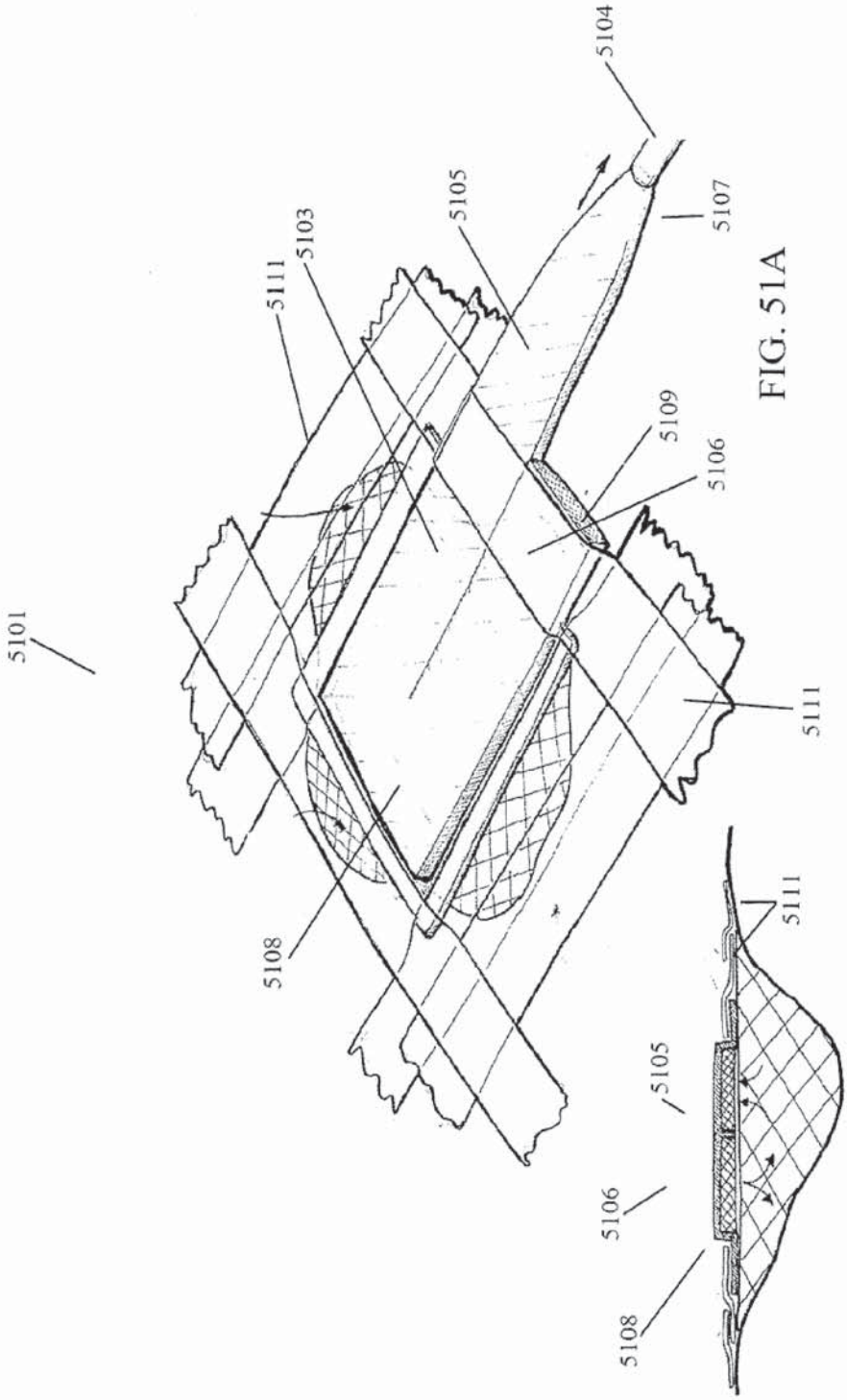


FIG. 51A

FIG. 51B

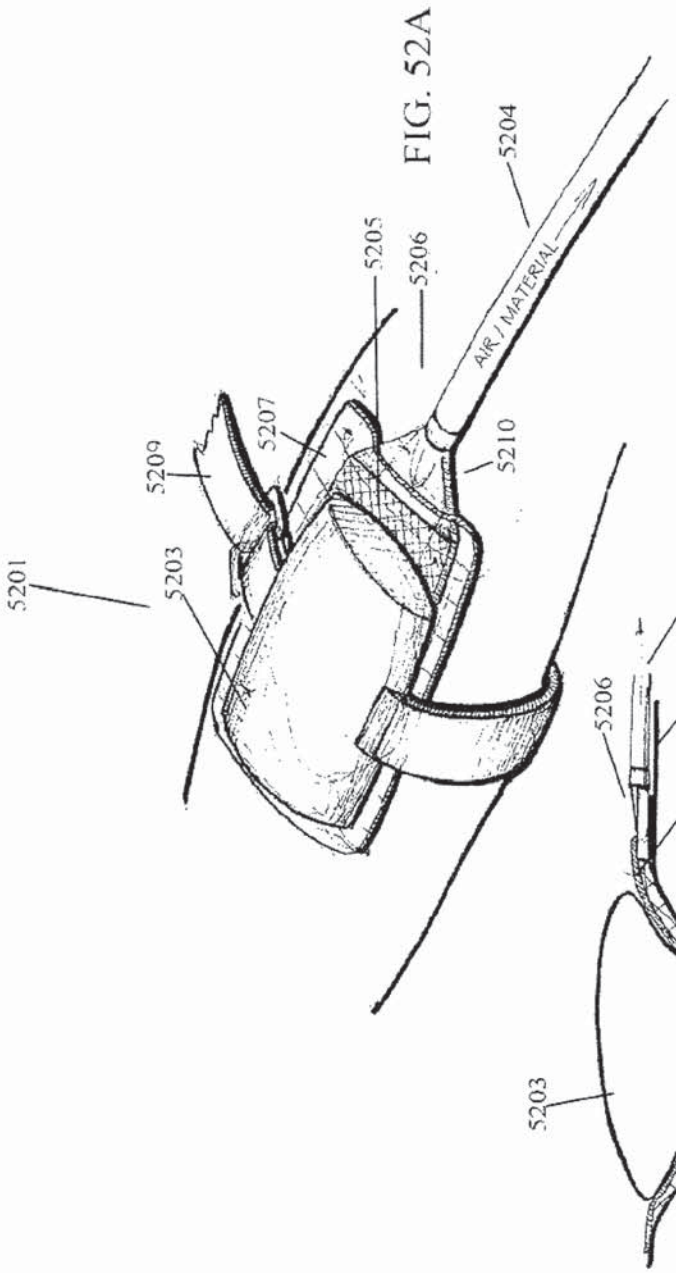


FIG. 52A

FIG. 52B

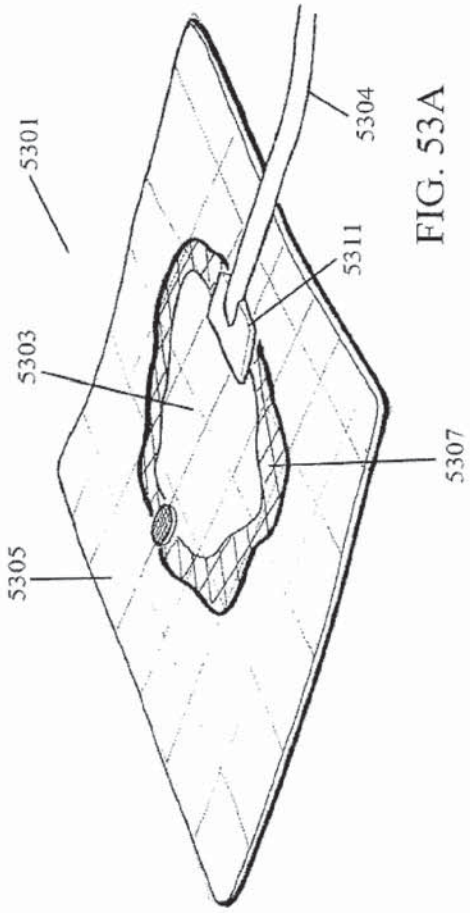


FIG. 53A

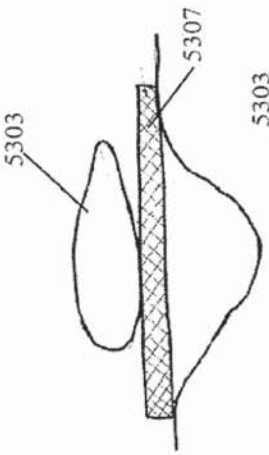


FIG. 53B

FIG. 53C

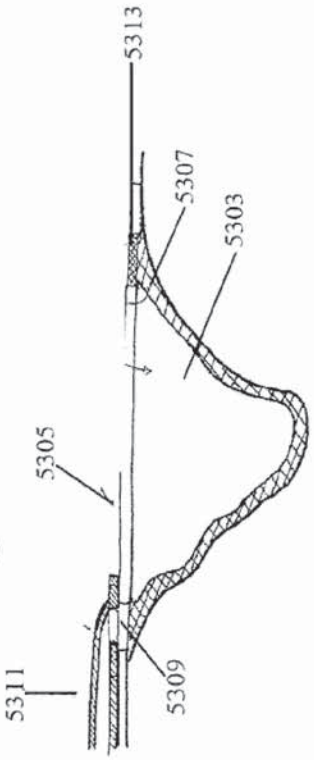


FIG. 53D

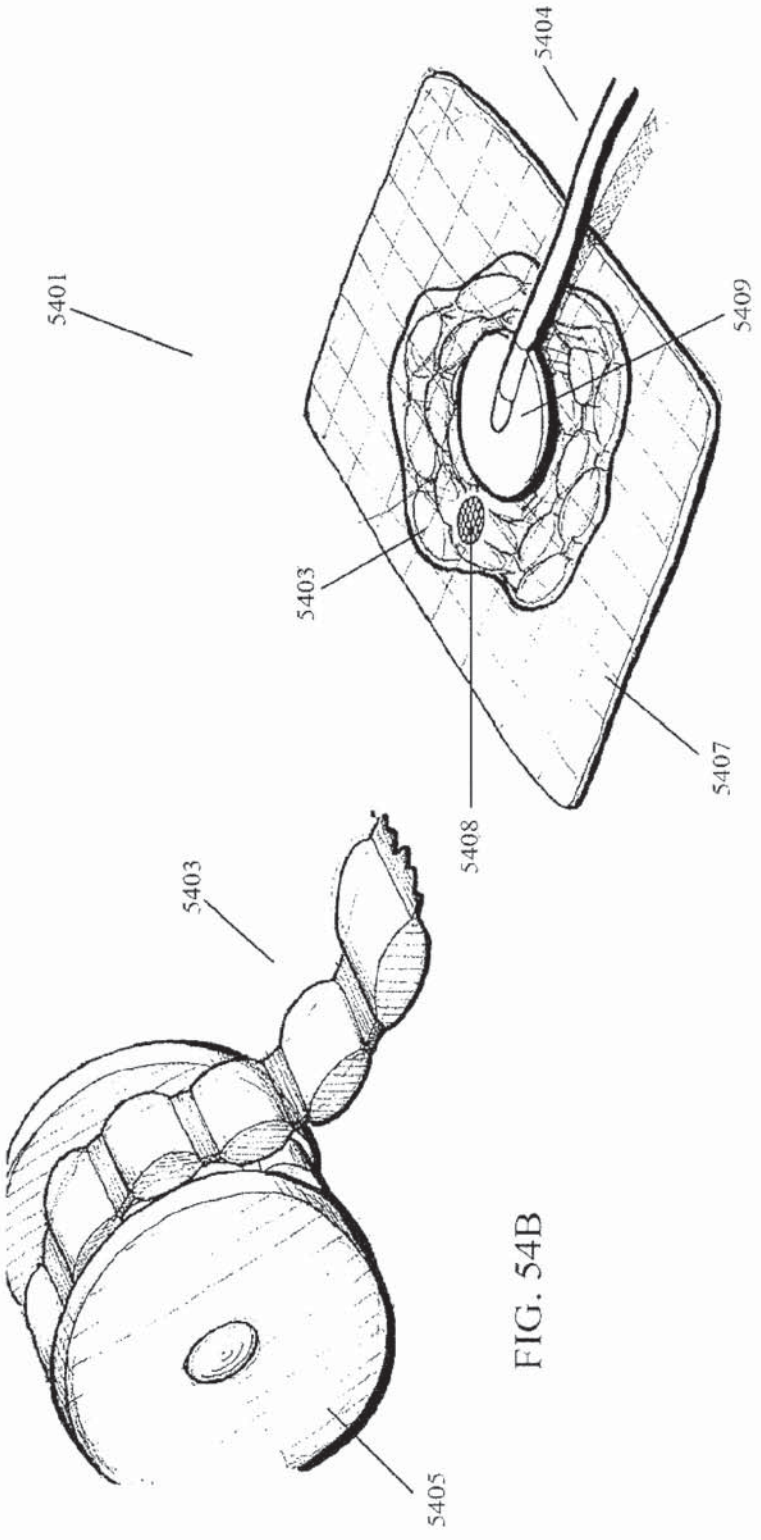


FIG. 54A

FIG. 54B

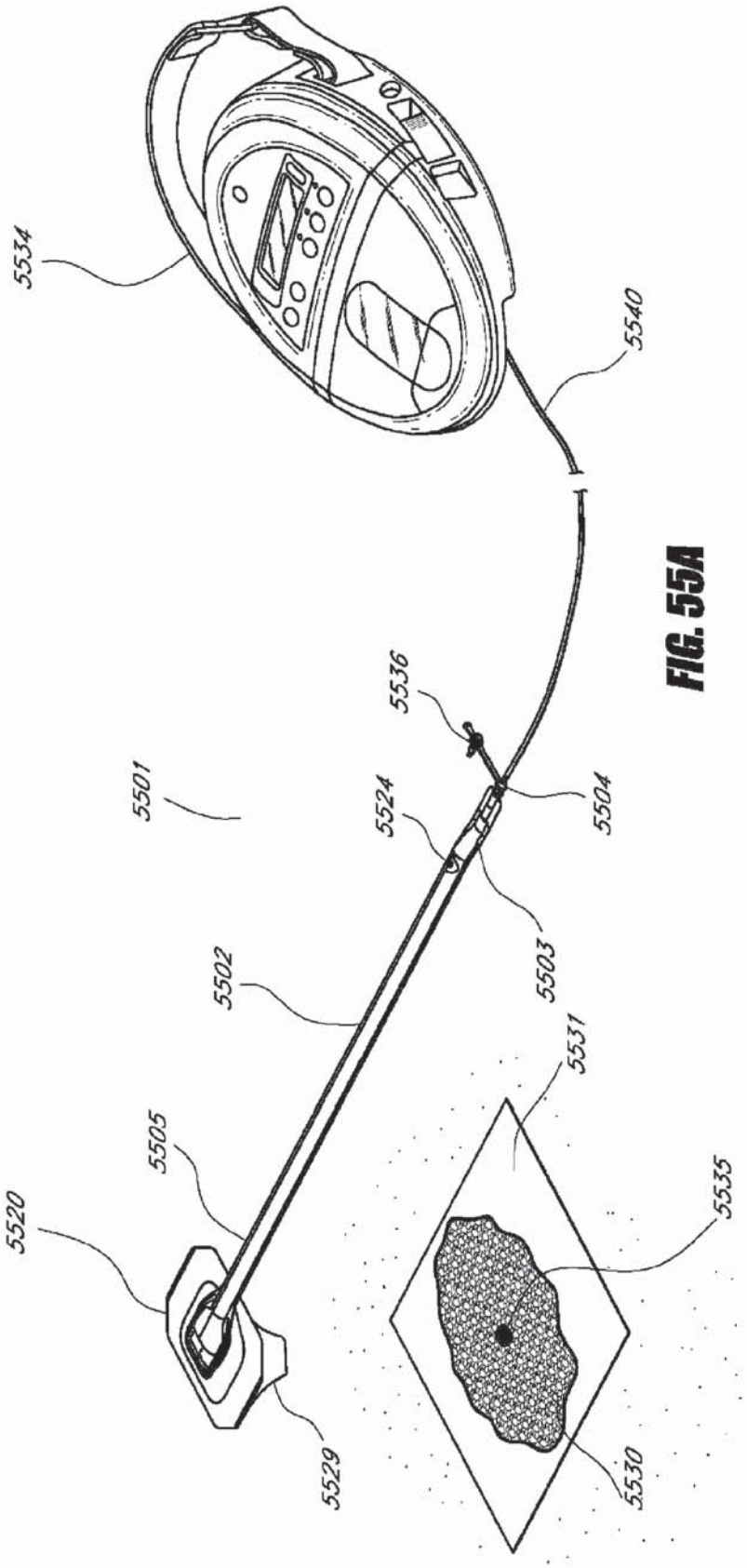

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FIG. 55A

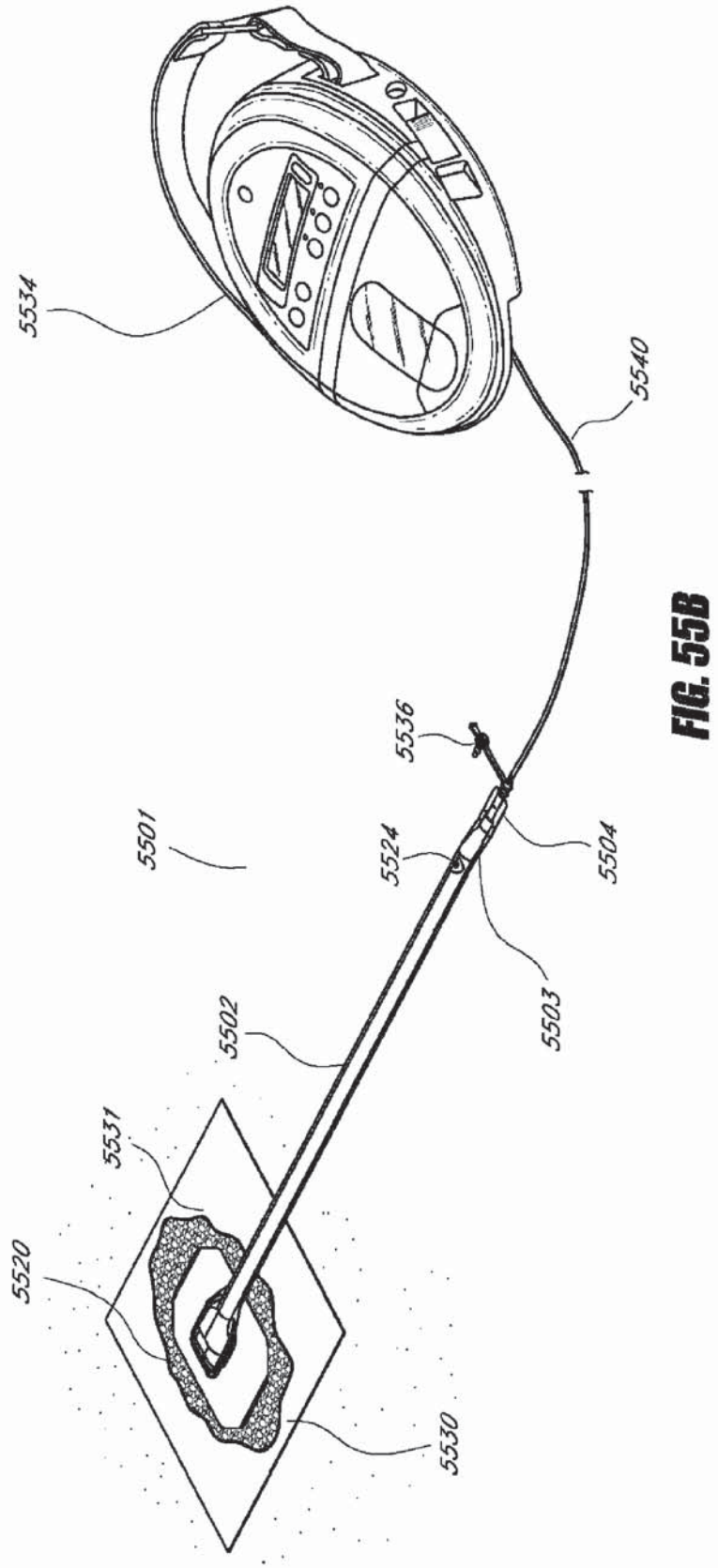

FIG. 55B

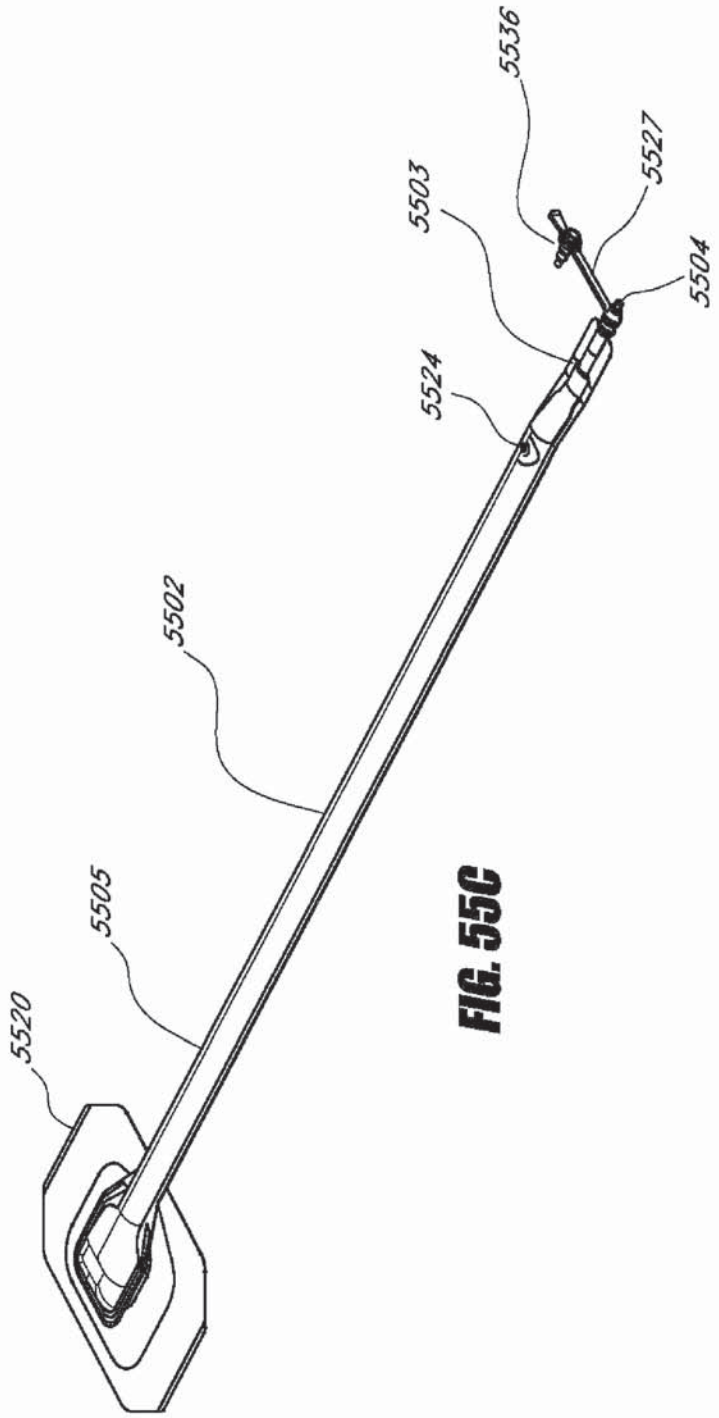

FIG. 55C

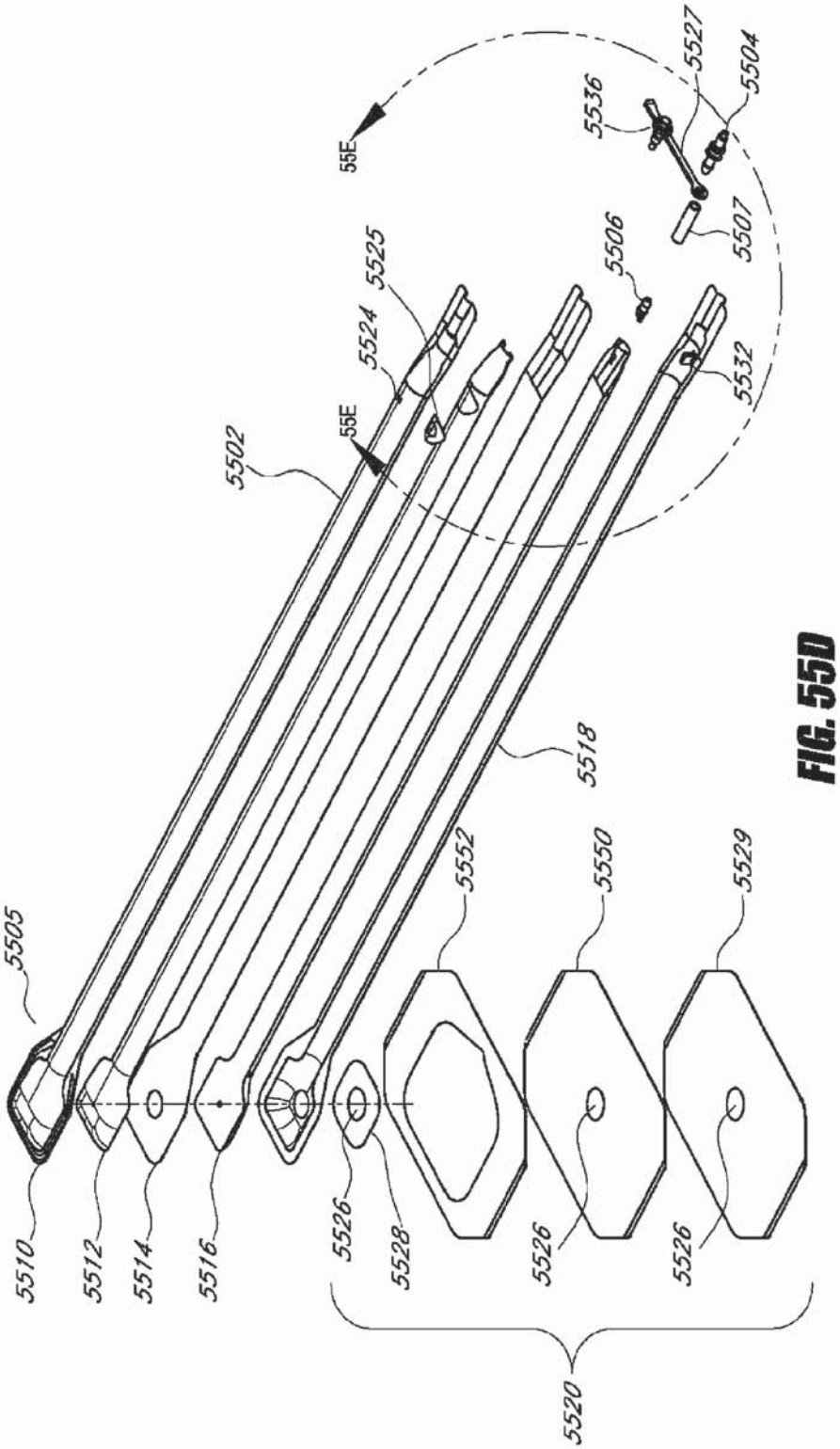
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FIG. 55D

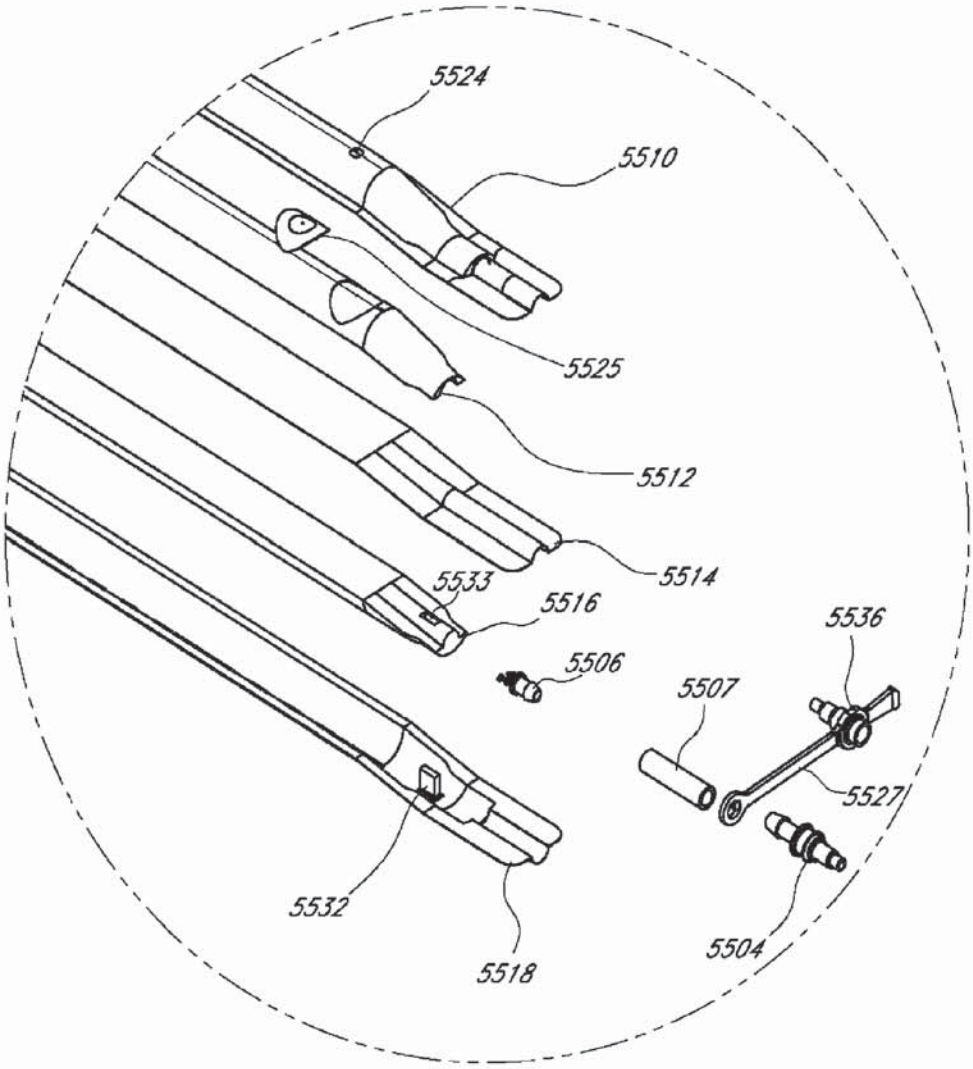
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FIG. 55E

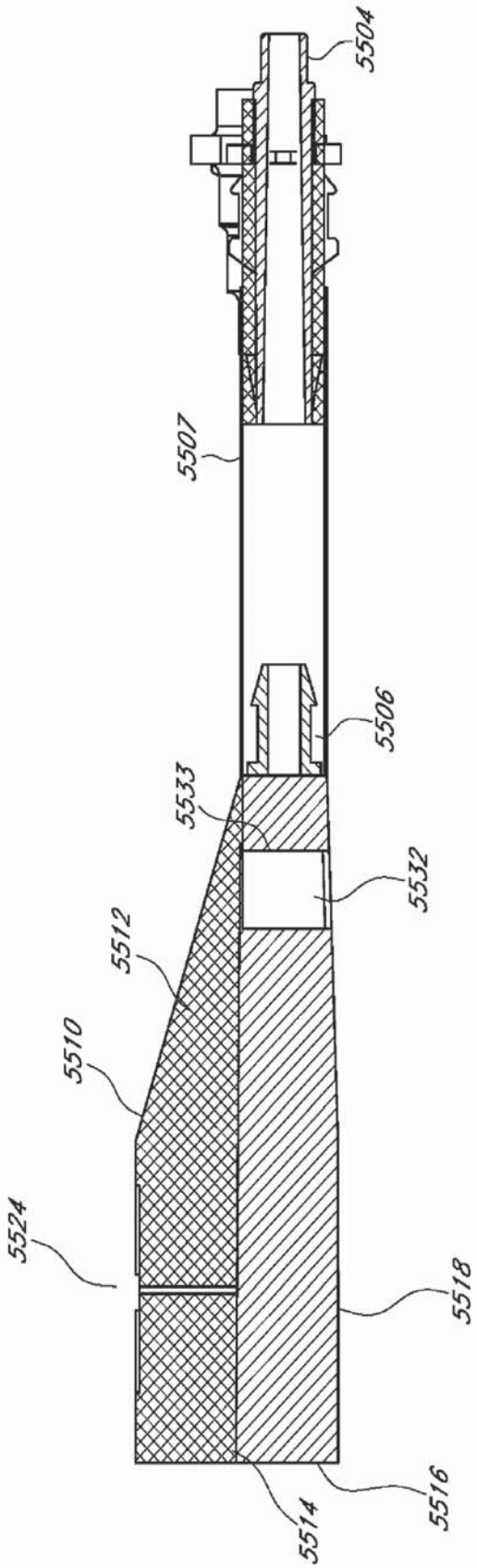

FIG. 55F

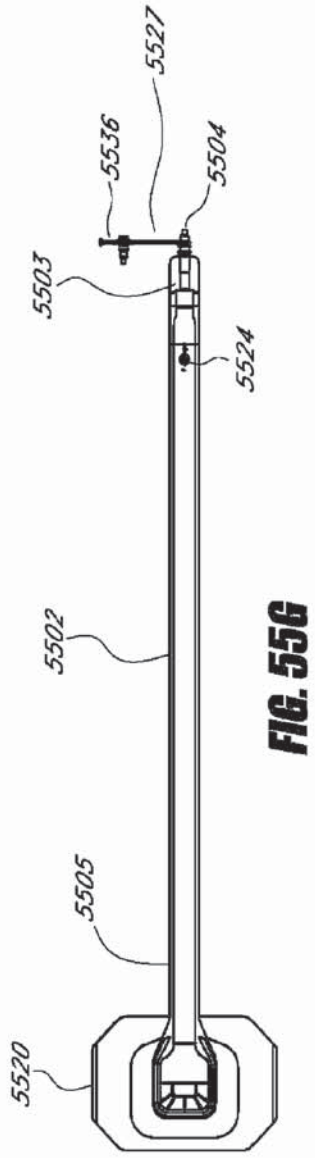

FIG. 55G

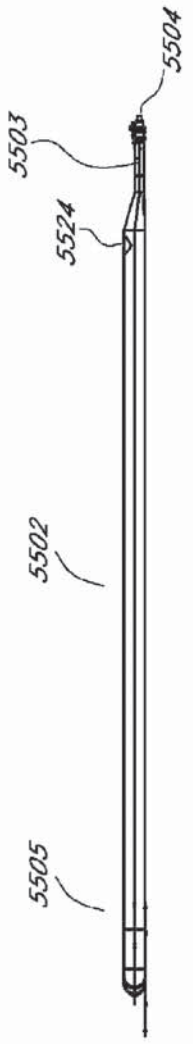

FIG. 55H

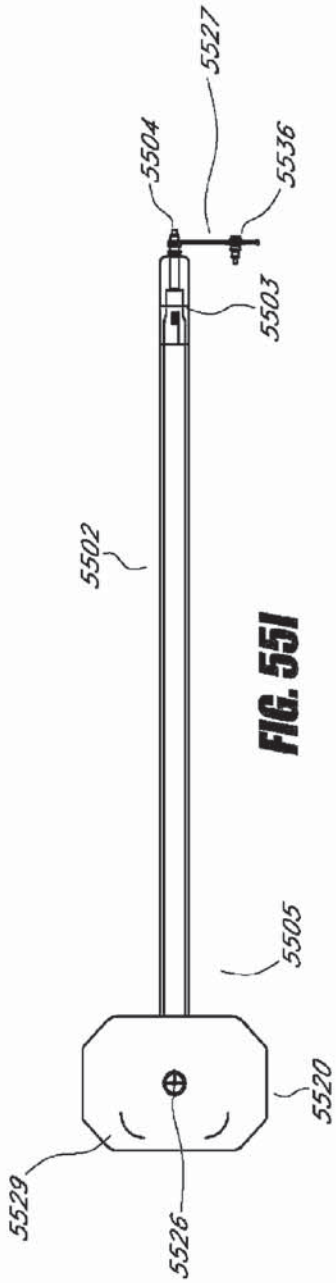

FIG. 55I

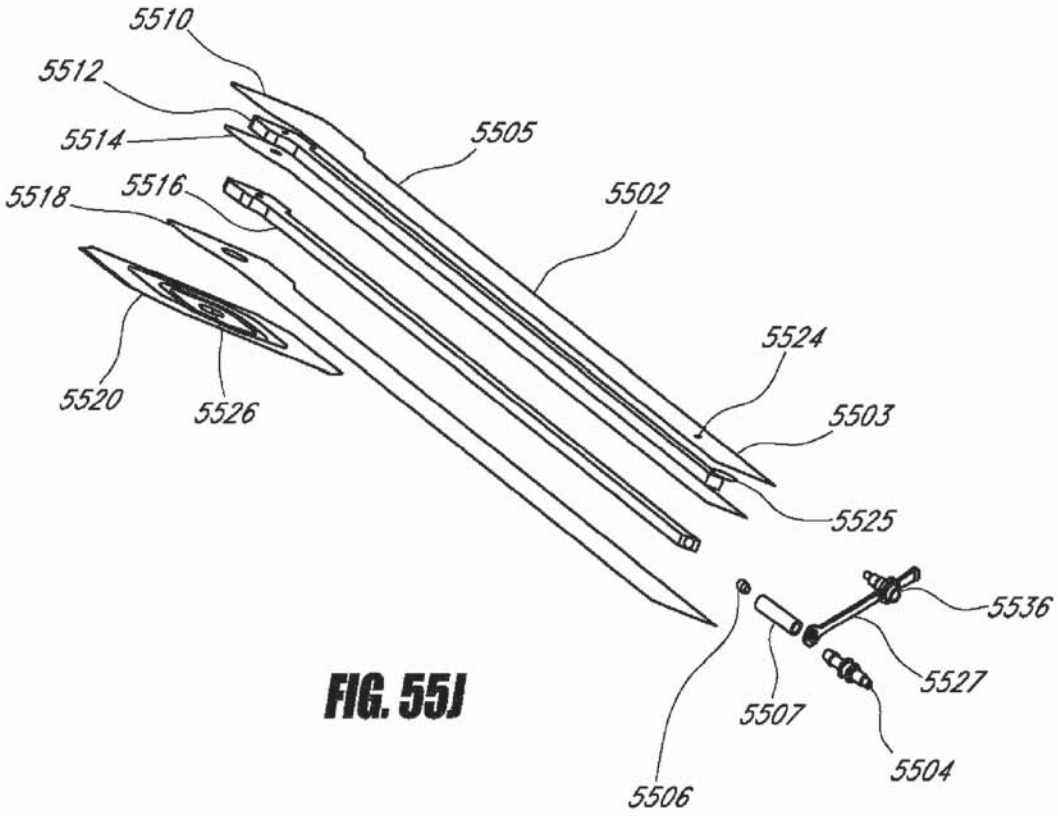
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FIG. 55J

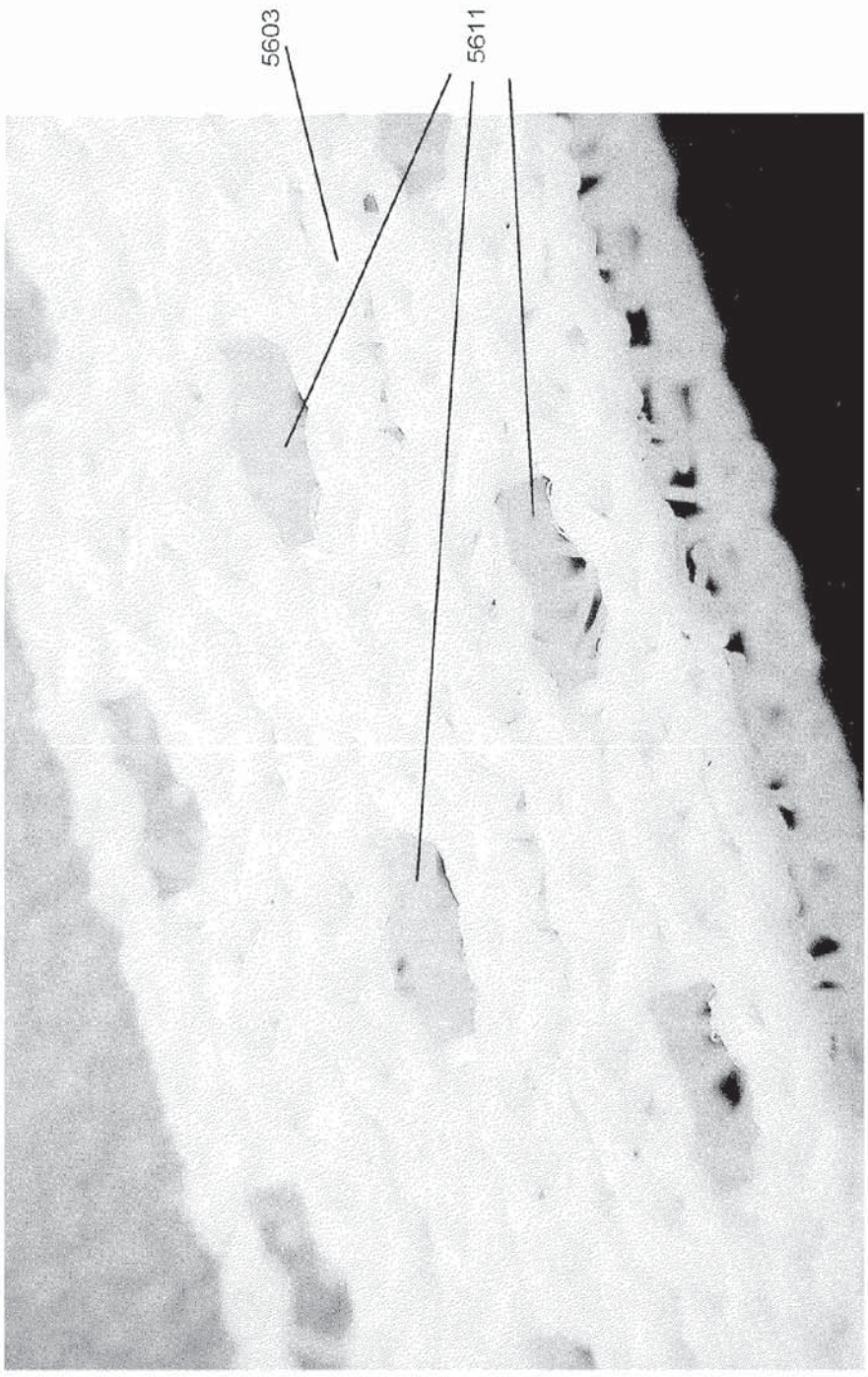

FIG. 56A

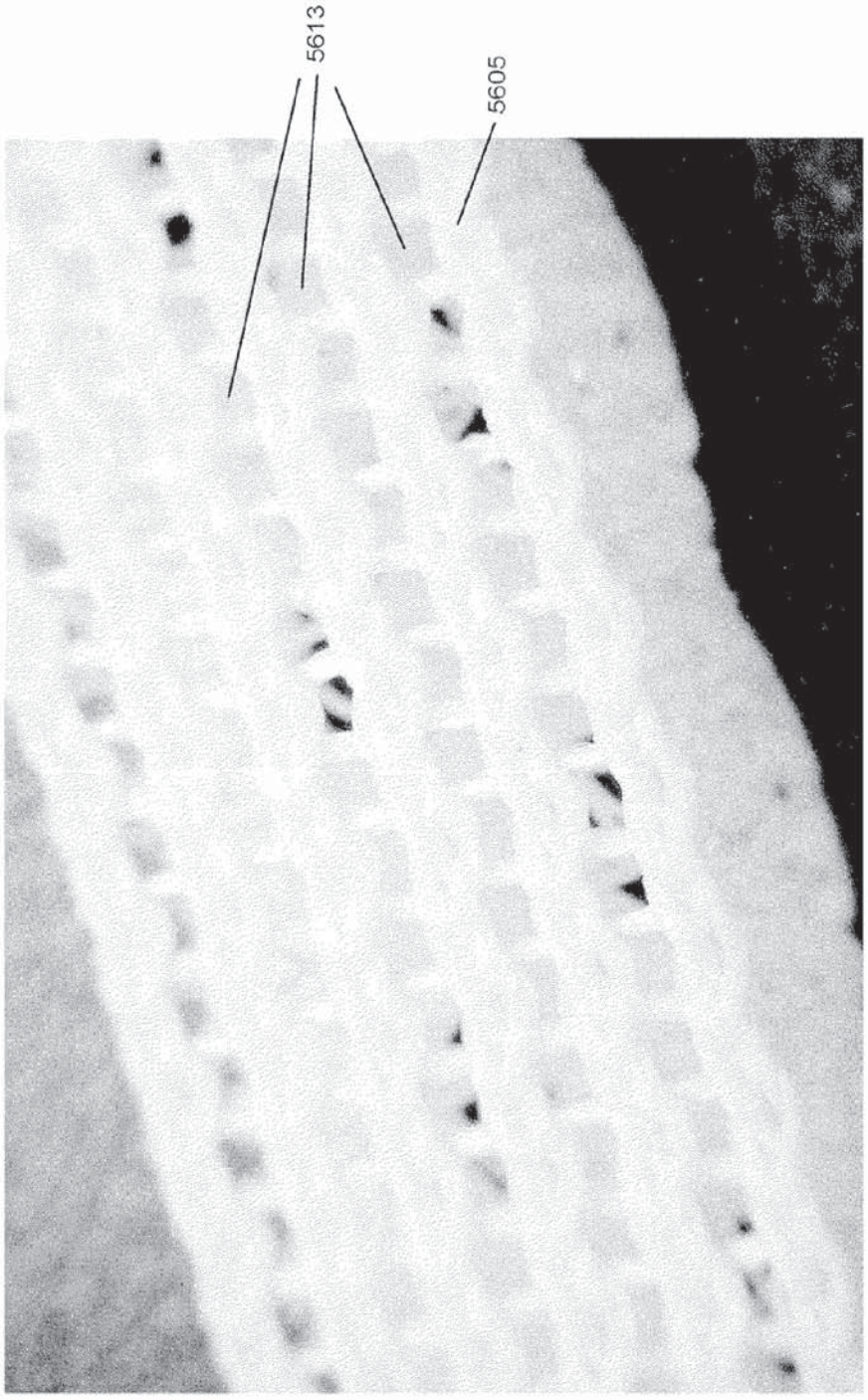

FIG. 56B

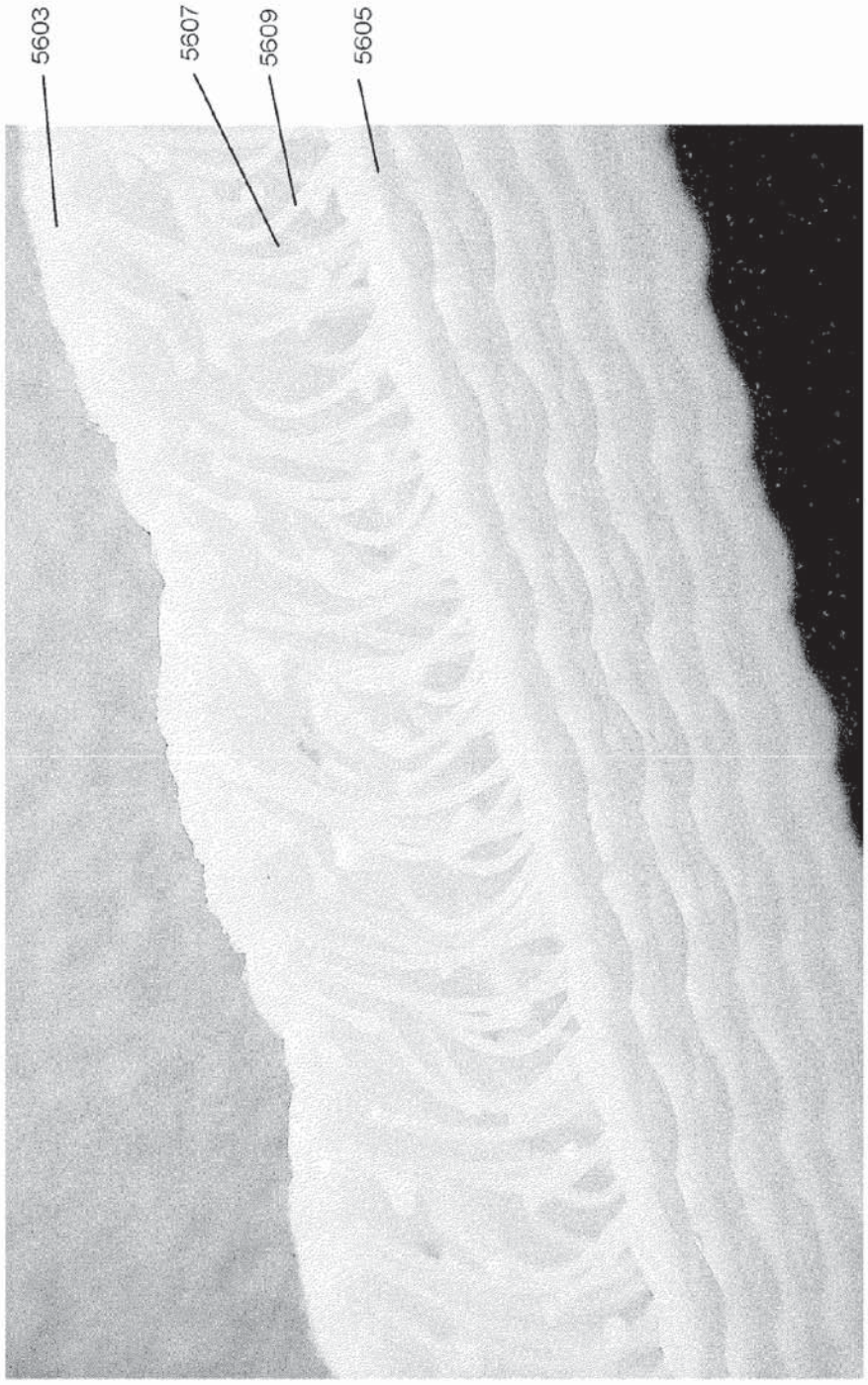

FIG. 56C

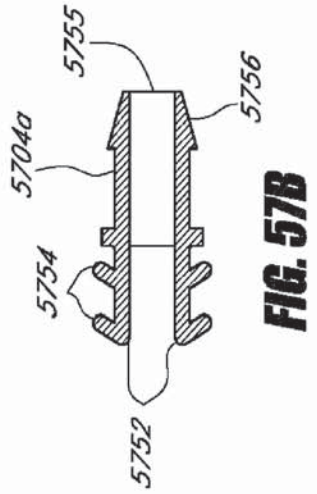

FIG. 57B

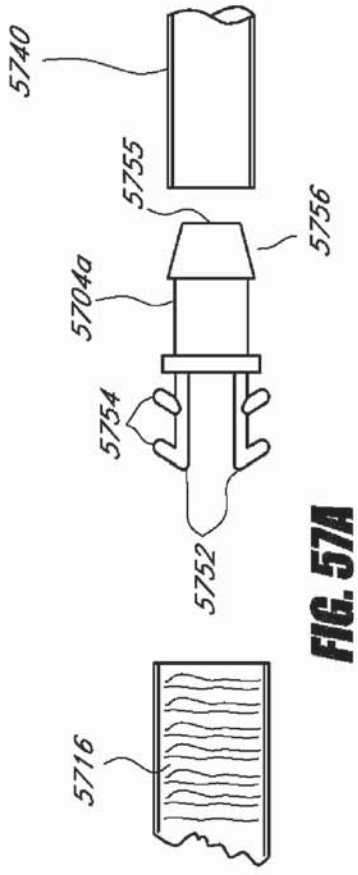

FIG. 57A

APPARATUSES AND METHODS FOR NEGATIVE PRESSURE WOUND THERAPY

CROSS-REFERENCE TO RELATED APPLICATIONS

The present application is a continuation of U.S. patent application Ser. No. 14/267,636, filed on May 1, 2014, which is a continuation of U.S. patent application Ser. No. 13/381,885, filed on Dec. 30, 2011, now U.S. Pat. No. 8,801,685 which is a national phase application under 35 U.S.C. §371 of International Application No. PCT/US2010/061938, filed on Dec. 22, 2010, which claims the benefit of U.S. Provisional Application No. 61/289,358, filed Dec. 22, 2009, U.S. Provisional Application No. 61/332,440, filed May 7, 2010, and U.S. Provisional Application No. 61/369,008, filed Jul. 29, 2010, the entirety of each of which is hereby incorporated by reference.

FIELD OF THE INVENTION

Embodiments of the present invention relate generally to the treatment of wounds using negative pressure wound therapy, and more specifically to an improved apparatus and method thereof.

BACKGROUND OF THE INVENTION

The treatment of open or chronic wounds that are too large to spontaneously close or otherwise fail to heal by means of applying negative pressure to the site of the wound is well known in the art. Negative pressure wound treatment systems currently known in the art commonly involve placing a cover that is impermeable to liquids over the wound, using various means to seal the cover to the tissue of the patient surrounding the wound, and connecting a source of negative pressure (such as a vacuum pump) to the cover in a manner so that an area of negative pressure is created under the cover in the area of the wound.

SUMMARY OF THE INVENTION

Embodiments of the invention disclosed herein are directed to a negative pressure appliance and methods of treatment using a negative pressure appliance, and may be useful in the treatment of wounds using negative pressure.

Certain embodiments of the invention employ fluidic connectors and/or suction adapters for connecting a source of negative pressure to a dressing positioned over a wound site. These fluidic connectors and/or suction adapters offer advantages over the prior art. For example and for illustrative purposes only, some of the embodiments may offer a softer, kink-free fluidic connector for connecting a wound site to a source of negative pressure for treatment. Such a fluidic connector and/or suction adapter is faster to apply, requiring fewer steps compared to prior art connectors, and offers greater patient comfort and safety by being soft and conformable, thereby avoiding pressure ulcers and other complications caused by harder connectors.

Certain embodiments provide for a negative pressure wound treatment system comprising a wound packing material configured to be positioned at a wound, a flexible drape configured to be positioned over the wound and wound packing material and sealed to the skin surrounding the wound, and which further comprises a conduit configured to deliver negative pressure to the wound through an aperture in the drape and through the wound packing material to the wound. Such embodiments further comprise a flexible suction adapter configured to surround the aperture and connect the conduit to the flexible drape and for transmitting negative pressure from the conduit through the aperture.

In one embodiment, a negative pressure wound treatment system is provided comprising a flexible drape configured to be positioned over a wound and sealed to skin surrounding the wound. A conduit is configured to deliver negative pressure to the wound, wherein negative pressure is delivered through an aperture in the drape. A flexible suction adapter is configured to surround the aperture and connect the conduit to the flexible drape, the flexible suction adapter comprising upper and lower layers forming an elongate interior channel having a proximal end and a distal end, the proximal end configured for fluid communication with the conduit and the lower layer including at least one aperture for communicating with the aperture in the drape. An elongated foam spacer is within the interior channel extending between the proximal end and the distal end.

In another embodiment, a negative pressure wound treatment system comprises a flexible drape configured to be positioned over a wound and sealed to skin surrounding the wound. The flexible drape defines an elongate channel extending between upper and lower portions of the flexible drape, wherein the channel extends from an edge of the flexible drape to an interior portion thereof. The lower portion of the flexible drape includes at least one aperture in communication with the elongate channel for transmitting negative pressure through the channel and through the aperture. A conduit is configured to deliver negative pressure to the wound, wherein the conduit is connected to the channel to deliver negative pressure through the channel and the at least one aperture in the lower layer.

In yet another embodiment, a negative pressure wound treatment system comprises a bridge with top, bottom, and intermediate layers sandwiching top and bottom fluid channels, wherein the top channel comprises an air leak, and the bottom channel is connected to a source of negative pressure suitable for drawing exudates from a wound site. The bridge is attached to an applicator portion including at least one aperture and suitable for placement over a wound site, and may also include a visualization window for visualization of the wound site.

Methods of treating wounds with negative pressure are also described. A method of treating a wound with negative pressure may include applying a flexible drape over a wound site, applying a flexible suction adapter over the wound site, where the flexible adapter comprises an applicator and bridge portion provided with an air leak. The suction adapter is then connected to a source of negative pressure, and negative pressure is applied to the wound until it has reached a desired level of healing.

Also disclosed herein are embodiments of an apparatus for providing suction to a wound site comprising a top and bottom layer constructed from a liquid-impermeable material with a 3D knitted or 3D fabric material located between these top and bottom layers. An aperture in the bottom layer is in fluid communication with the 3D knitted or 3D fabric material. An elongate channel extends between the top and bottom layers containing the 3D knitted or 3D fabric material. The top layer, bottom layer, and 3D knitted or 3D fabric material include enlarged distal ends with the elongate channel extending in a proximal direction away from the enlarged distal ends.

In some embodiments, the elongate channel comprises a lower fluid passage, and the apparatus comprises an upper fluid passage disposed above and separate from the 3D

knitted or 3D fabric material that is connected to an air leak. In some cases, the upper fluid passage may contain foam or another compliant spacer material. In other embodiments, an air leak communicates with a wound site through a conduit extending in a proximal direction away form the enlarged distal ends and may in some cases include a looped portion. The enlarged ends of the top and bottom layers may be rectangular or square, or may form a teardrop shape, and the 3D knitted or 3D fabric material may have a circular enlarged end. The 3D knitted or 3D fabric material may also be in fluid communication with a source of negative pressure, such as a pump. The bottom layer may be configured to be attached to a drape, or may be attached to an applicator. The bottom layer may also comprise an adhesive disposed on its wound-facing side, and can in some cases be provided with multiple apertures. In some embodiments, the 3D knitted or 3D fabric material may be in fluid communication with a dual lumen tube that incorporates an air leak at a proximal portion thereof. The air leak may in some cases comprise a plurality of discrete air channels, and may be located on the enlarged distal end of the top layer. The 3D knitted or 3D fabric material can be provided with a flattened distal end.

Embodiments of systems for the treatment of wounds using negative pressure using embodiments of the suction adapters disclosed above are also disclosed. These systems can comprise a suction adapter as described previously, a flexible drape configured to be positioned over a wound and sealed to the skin surrounding the wound, and where the suction adapter is configured to be attached to the drape so as to surround an aperture formed in the drape. A vacuum pump may be connected by at least one conduit to the suction adapter.

In another embodiment of a suction adapter, this adapter has an applicator with an upper and lower surface, with the upper surface connected to the distal end of a bridge. The bridge has a proximal end and a distal end, and has an upper fluid passage connected to an air leak and a lower fluid passage in fluid communication with a source of negative pressure, with the lower fluid passage comprising a 3D knitted or 3D fabric material.

In some embodiments of the suction adapter, the upper fluid passage may comprise foam. The bridge portion may further comprise a top layer, a bottom layer and an intermediate layer, each of the layers having proximal ends and distal ends and elongate portions extending therebetween, where the upper fluid passage extends between the top and intermediate layers, and the lower fluid passage extends between the intermediate and bottom layers. The distal end of the bridge may also have an enlarged shape. The air leak may be disposed at the proximal end of the bridge. The 3D knitted or 3D fabric material may include a top knitted layer, a bottom knitted layer, and a middle area with vertically extending fibers, and may be approximately 1.5 to 6 mm thick. The 3D knitted or 3D fabric material may be constructed so as to resist compression to less than half its original thickness when subjected to a load of 15 psi.

The suction adapter embodiments above may be used in embodiments of a negative pressure wound treatment system comprising a flexible drape configured to be positioned over a wound and sealed to the skin surrounding the wound, and where the suction adapter is configured to be attached to the drape so as to surround at least one aperture formed in the drape. A vacuum pump is preferably connected by at least one conduit to the suction adapter.

Further embodiments of negative pressure wound treatment systems described herein may comprise a flexible drape configured to be positioned over a wound and sealed to skin surrounding the wound, a conduit configured to deliver negative pressure to the wound, wherein negative pressure is delivered through an aperture in the drape, and a flexible suction adapter configured to surround the aperture on the drape and connect the conduit to the flexible drape. The flexible suction adapter can comprise upper and lower layers forming an elongate interior channel with proximal and distal ends, where the proximal end is configured to communicate fluidically with the conduit and wherein the lower layer has at least one aperture for communicating with the aperture in the drape. An elongated spacer extending between the proximal and distal ends may also be placed within the interior channel.

In some embodiments, the elongated spacer may become progressively larger toward the distal end. The interior channel may incorporate a looped portion that extends toward and away from the at least one aperture in the lower layer, and the spacer may be configured similarly. The channel in the suction adapter may also comprise an air leak, which may be disposed between the proximal and distal end of the channel, and may also incorporate a filter. The lower layer of the suction adapter may comprise more than one aperture, for example four apertures. The wound may also be packed with a wound packing material placed under the flexible drape.

Another embodiment of a negative pressure wound treatment system described herein includes a wound packing material configured to be positioned at a wound, a flexible drape configured to be positioned over the wound packing material and over the wound and sealed to skin surrounding the wound, a conduit configured to deliver negative pressure to the wound through an aperture in a drape and through the wound packing material placed in the wound, and a flexible suction adapter configured to surround the aperture and connect the conduit to the flexible drape and for transmitting negative pressure from the conduit through the aperture.

In some embodiments, the suction adapter may be a flexible shroud having a distal end configured to seal with the flexible drape around the aperture and a proximal end configured to seal about the conduit, where the conduit is configured to extend through the flexible shroud into the aperture. The suction adapter may also be a sealing disc sandwiched between annular upper and lower support discs, where the lower support disc is configured to be adhered to the flexible drape around the aperture, and the conduit is configured to extend through openings in the sealing disc and upper and lower support discs into the aperture. In other cases, the flexible suction adapter may be a sealing ring integrated with the aperture in the drape, with the conduit being sized and configured to make a sealing contact with the sealing ring. The flexible suction adapter may also comprise upper and lower support layers sandwiching a looped portion of the conduit, where the lower layer includes at least one aperture and the conduit includes a plurality of apertures so that negative pressure can be transmitted through the plurality of apertures in the conduit through the at least one aperture in the lower layer and through the aperture in the flexible drape. The flexible suction adapter can also have upper and lower support layers sandwiching an elongated foam spacer, where the lower layer includes at least one aperture for transmitting negative pressure from the foam spacer to the aperture in the flexible drape, and the elongated foam spacer includes a proximal end configured to connect to a distal end of the conduit. The suction adapter can also comprise a membrane with elongate parallel channels integrated onto it and configured to be positioned over

the flexible drape around the aperture so as to channel wound exudate. In another embodiment, the flexible drape can define a lower layer and further comprises an upper layer that sandwiches the flexible suction adapter between the upper and lower layers; the flexible suction adapter can comprise a foam spacer.

Yet another embodiment of a negative pressure wound treatment system comprises a flexible drape configured to be positioned over a wound and sealed to skin surrounding the wound, with the flexible drape defining an elongate channel extending between upper and lower portions of the flexible drape, and where the channel extends from an edge of the flexible drape to an interior portion of the flexible drape, the lower portion of the flexible drape including at least one aperture in communication with the elongate channel for transmitting negative pressure through the channel and through the aperture. A conduit is configured to deliver negative pressure to the wound, where the conduit is connected to the channel to deliver negative pressure through the channel and the at least one aperture in the lower layer. In some embodiments, a foam spacer may extend into the channel, and spacer comprising bosses may also be present on in an interior portion of the channel.

Embodiments of a suction adapter described herein can include an applicator with an upper surface and a lower surface, a bridge with a proximal end and a distal end, where the distal end of the bridge is connected to the upper surface of the applicator, and where the bridge comprises a top layer, a bottom layer and an intermediate layer, each of the layers having proximal ends and distal ends and elongate portions extending therebetween. A first channel layer then extends between the top and intermediate layers, where the first channel layer has a proximal end and a distal end and an elongate portion extending therebetween. A second channel layer extends between the intermediate and bottom layers, where the channel layer has a proximal end and a distal end and an elongate portion extending therebetween. An air leak is disposed at the proximal end of the top layer that is configured to provide an air path into the first channel layer.

Another embodiment described herein includes a suction adapter suitable to treat a wound site with negative pressure that includes an applicator with an upper surface and a lower surface, a bridge having a proximal end and a distal end, where the distal end of the bridge is connected to the upper surface of the applicator. The bridge comprises a top layer, a bottom layer and an intermediate layer, with each layer having a proximal end and a distal end and an elongate portion extending therebetween, a first channel layer extending between the top and intermediate layers, the first channel layer having a proximal end and a distal end and an elongate portion extending therebetween and a second channel layer extending between the intermediate and bottom layers, the second channel layer having a proximal end and a distal end and an elongate portion extending therebetween. An air leak is disposed at the proximal end of the top layer, the air leak configured to provide an air path into the first channel layer. One of the first and second channel layers comprises foam and the other of the first and second channel layers comprising a fabric.

Methods of treating a wound with negative pressure are also disclosed herein. A method of treating a wound site with negative pressure comprises applying a flexible drape over a wound site, applying a flexible suction adapter over an opening in the flexible drape, where the flexible suction adapter comprises top and bottom layers constructed from a liquid-impermeable material, a 3D knitted or 3D fabric material located between the top and bottom layers, an aperture in the bottom layer in fluid communication with the wound site through the opening and the 3D knitted or 3D fabric material, and applying negative pressure to the wound, the negative pressure being transmitted to the wound through at least one conduit connected between the source of negative pressure and the flexible suction adapter and passing through the 3D knitted or 3D fabric material through the aperture in the bottom layer and into the opening in the flexible drape.

In some embodiments, the application of negative pressure to the wound may cause air to flow into the wound via an air leak disposed on the flexible suction adapter. The flow rate of air, may, in some embodiments be at least 0.08 liters/minute when negative pressure is applied to the suction adapter, and this flow rate may be maintained while a weight is placed on the suction adapter, for example a 4.75 kg weight. Adhesive may be placed on the suction adapter when adhering the adapter to the drape, or the adapter can be supplied pre-attached to a drape. Otherwise, the method above may comprise cutting an opening into the drape. Wound contact material can also be placed into the wound site prior to applying the drape. A similar method may transmit negative pressure to the wound through at least one conduit connected between the source of negative pressure and the flexible suction adapter and that passes through the 3D knitted material into the opening in the flexible drape.

Yet another method of treating a wound site with negative pressure is disclosed herein. This method comprises applying a flexible drape over a wound site, applying a flexible suction adapter over an opening made in the flexible drape, the flexible suction adapter comprising an applicator having an upper surface and a lower surface and a bridge having a proximal end and a distal end, and where the distal end of the bridge is connected to the upper surface of the applicator, and the bridge comprises a top layer, a bottom layer and an intermediate layer, each of the layers having proximal ends and distal ends and elongate portions extending therebetween, a first channel layer extending between the top and intermediate layers, where the first channel layer has a proximal end and a distal end and an elongate portion extending therebetween, a second channel layer extending between the intermediate and bottom layers, the channel layer having a proximal end and a distal end and an elongate portion extending therebetween, an air leak disposed at the proximal end of the top layer configured to provide an air path into the first channel layer. The flexible suction adapter is connected to a source of negative pressure, and negative pressure is applied to the wound, the negative pressure being transmitted through the second channel layer and drawing in air from the air leak through the first channel layer.

A further method for treating a wound with negative pressure is described herein. This method comprises applying a flexible drape over a wound site, applying a flexible suction adapter over an opening made in the flexible drape, connecting the flexible suction adapter to a source of negative pressure; and applying negative pressure to the wound, the negative pressure being transmitted through the second channel layer and drawing in air from the air leak through the first channel layer. The flexible suction adapter used comprises an applicator having an upper surface and a lower surface and a bridge having a proximal end and a distal end, the distal end of the bridge being connected to the upper surface of the applicator. The bridge comprises a top layer, a bottom layer and an intermediate layer, with each of the layers having proximal ends and distal ends and elongate portions extending therebetween, a first channel layer extending between the top and intermediate layers, the first

channel layer having a proximal end and a distal end and an elongate portion extending therebetween, a second channel layer extending between the intermediate and bottom layers, the channel layer having a proximal end and a distal end and an elongate portion extending therebetween, an air leak disposed at the proximal end of the top layer configured to provide an air path into the first channel layer, and wherein one of the first and second channel layers comprises foam and the other of the first and second channel layers comprising a fabric.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** illustrates a negative-pressure system that can be used in the treatment of wounds.

FIG. **2**A illustrates an embodiment of a negative pressure wound treatment system with a flexible shroud being applied over a flexible drape.

FIG. **2**B illustrates the system of FIG. **2**A with the shroud applied to the flexible drape.

FIGS. **2**C-**2**F illustrates a method of applying the negative pressure wound treatment system of FIGS. **2**A and **2**B to a patient.

FIG. **3**A illustrates an embodiment of a negative pressure wound treatment system with a sealing disc being applied over a flexible drape.

FIG. **3**B is an exploded view of the sealing disc of FIG. **3**A.

FIG. **3**C illustrates the system of FIG. **3**A with the sealing disc applied to the flexible drape.

FIGS. **3**D-**3**H illustrate a method of applying the negative pressure wound treatment system of FIGS. **3**A-**3**C to a patient.

FIG. **4**A illustrates an embodiment of negative pressure wound treatment system with a flexible drape having an integrated sealing ring.

FIG. **4**B illustrates the system of FIG. **4**A with a conduit inserted through the sealing ring.

FIG. **5**A illustrates an embodiment of a negative pressure wound treatment system using a suction adapter with an air leak.

FIG. **5**B is an exploded view of the suction adapter of FIG. **5**A.

FIGS. **5**C-**5**F illustrate a method of applying the negative pressure wound treatment system of FIGS. **5**A-**5**B to a patient.

FIG. **6**A illustrates an embodiment of a negative pressure wound treatment system with a flexible suction adapter.

FIG. **6**B is an exploded view of the flexible suction adapter of FIG. **6**A.

FIGS. **6**C and **6**D are alternative embodiments of the flexible suction adapter of FIGS. **6**A-**6**B.

FIGS. **6**E-**6**H illustrate a method of applying the negative pressure wound treatment system of FIGS. **6**A-**6**D to a patient.

FIGS. **7**A-**7**B illustrate other embodiments of a flexible suction adapter.

FIG. **7**C illustrates a negative pressure wound treatment system using a flexible suction adapter.

FIGS. **8**A and **8**B illustrate another embodiment of a negative pressure wound treatment system with a flexible suction adapter.

FIG. **9**A illustrates an embodiment of a negative pressure wound treatment system with a flexible drape integrating a suction channel therein.

FIG. **9**B is an exploded view of the flexible drape of FIG. **9**A.

FIG. **9**C-**9**D illustrate a method of applying the negative pressure wound treatment system of FIGS. **9**A and **9**B to a patient.

FIGS. **10**A and **10**B illustrate another embodiment of a negative pressure wound treatment system with a flexible drape integrating a suction channel therein.

FIGS. **11**A and **11**B illustrate another embodiment of a negative pressure wound treatment system with a flexible drape integrating a suction channel and spacers comprising bosses therein.

FIGS. **12**A and **12**B illustrate an embodiment of a flexible one-piece suction adapter.

FIGS. **13**A and **13**B illustrate an embodiment of a negative pressure wound treatment system with a drape-piercing suction adapter.

FIGS. **14**A and **14**B illustrate another embodiment of a negative pressure wound treatment system with an integrated drape and wound packing material.

FIGS. **15**A-D illustrate another embodiment of a negative pressure wound treatment system with a flexible suction adapter.

FIGS. **16**A-B illustrate another embodiment of a negative pressure wound treatment system with a flexible drape integrating a suction channel therein.

FIGS. **17**A-B illustrate an embodiment of a negative pressure wound treatment system with a low profile side drain.

FIGS. **18**A-B illustrate an embodiment of a negative pressure wound treatment system comprising a wicking layer.

FIGS. **19**A-D illustrate embodiments of a negative pressure wound treatment system incorporating a flat drain portion.

FIGS. **20**A-B illustrate an embodiment of a negative pressure wound treatment system incorporating a trimmable suction port.

FIGS. **21**A-B illustrate another embodiment of a negative pressure wound treatment system incorporating a sealing ring.

FIGS. **22**A-B illustrate an embodiment of a negative pressure wound treatment system incorporating a piercing attachment for use with a port.

FIGS. **23**A-B illustrate a different embodiment of a negative pressure wound treatment system incorporating a piercing attachment for use with a port.

FIGS. **24**A-B illustrate embodiments of a negative pressure wound treatment system incorporating a piercing connector and a controlled air leak.

FIGS. **25**A-B illustrate embodiments of a negative pressure wound treatment system incorporating a manifold and a central controlled air leak.

FIGS. **26**A-B illustrate embodiments of a negative pressure wound treatment system incorporating two manifolds.

FIGS. **27**A-C illustrate embodiments of a negative pressure wound treatment system comprising a flexible suction adapter with separate controlled air leak paths.

FIGS. **28**A-B illustrate an embodiment of a negative pressure wound treatment system incorporating a controlled air leak in a suction head.

FIGS. **29**A-B illustrate an embodiment of a negative pressure wound treatment system incorporating a starburst negative pressure distribution manifold and a central controlled air leak.

FIGS. **30**A-B illustrate an embodiment of a negative pressure wound treatment system provided with a piercing nozzle.

FIGS. **31**A-B illustrate an embodiment of a negative pressure wound treatment system with a port, a piercing connector, and a controlled air leak.

FIGS. **32**A-K illustrate embodiments of a negative pressure wound treatment system with a port and a piercing tool.

FIGS. **33**A-H illustrate embodiments of a negative pressure wound treatment system incorporating a cutting template.

FIGS. **34**A-H illustrate embodiments of a negative pressure wound treatment system comprising a soft port with a protruding channel.

FIGS. **35**A-H illustrate an embodiment of a negative pressure wound treatment with drape strips provided with a port.

FIGS. **36**A-I illustrate a negative pressure wound treatment system comprising a drape with integrated drainage channels.

FIGS. **37**A-G illustrate a negative pressure wound treatment system incorporating a drape with miniature openings.

FIGS. **38**A-I illustrate an embodiment of a negative pressure wound treatment system comprising a bayonet connector between a ring and a port.

FIGS. **39**A-B illustrate a negative pressure wound treatment system comprising a low-profile port configured to attach to a valve attached to a drape.

FIG. **40** illustrates an embodiment of a negative pressure wound treatment system provided with a low-profile fluidic connector.

FIGS. **41**A-B illustrate an embodiment of a negative pressure wound treatment system provided with a plurality of suction tubes.

FIGS. **42**A-B illustrate an embodiment of a negative pressure wound treatment system incorporating a pre-made aperture onto a drape.

FIGS. **43**A-B illustrate an embodiment of a negative pressure wound treatment system incorporating a piercing connector.

FIGS. **44**A-B illustrate an embodiment of a negative pressure wound treatment system with a drape incorporating an integrated suction port.

FIGS. **45**A-C illustrate an embodiment of a negative pressure wound treatment system incorporating a drape with cross-linked air channels and port integrated thereupon.

FIGS. **46**A-B illustrate an embodiment of a negative pressure wound treatment system comprising suction channels integrated into a wound cover.

FIGS. **47**A-B illustrate an embodiment of a negative pressure wound treatment system incorporating a low-profile suction unit.

FIGS. **48**A-E illustrate an embodiment of a negative pressure wound treatment system comprising a flexible suction adapter sheet.

FIGS. **49**A-B illustrate an embodiment of a negative pressure wound treatment system incorporating a wound packing pouch.

FIGS. **50**A-C illustrate embodiments of a negative pressure wound treatment system comprising a port provided with a sealing ring.

FIGS. **51**A-B illustrate another embodiment of a negative pressure wound treatment system incorporating a low-profile suction adapter.

FIGS. **52**A-B illustrate an embodiment of a negative pressure wound treatment system provided with a bladder.

FIGS. **53**A-D illustrate a different embodiment of a negative pressure wound treatment system provided with a bladder.

FIGS. **54**A-B illustrate an embodiment of a negative pressure wound treatment system using discrete wound packing material portions.

FIG. **55**A illustrates an embodiment of a negative pressure wound treatment system comprising a pump, and illustrating a flexible suction adapter being applied to a wound.

FIG. **55**B illustrates the embodiment of FIG. **55**A, with the flexible suction adapter having been placed over a wound.

FIG. **55**C illustrates an isometric view of a flexible suction adapter that may be used in a negative pressure wound treatment system.

FIG. **55**D illustrates an exploded view of the flexible suction adapter of FIG. **55**C.

FIG. **55**E illustrates a close-up view of the proximal end of the flexible suction adapter of FIG. **55**D.

FIG. **55**F illustrates a close-up cutaway view of the proximal end of the flexible suction adapter of FIG. **55**C.

FIG. **55**G illustrates a top view of the flexible suction adapter of FIG. **55**C.

FIG. **55**H illustrates a side view of the flexible suction adapter of FIG. **55**C.

FIG. **55**I illustrates a bottom view of the flexible suction adapter of FIG. **55**C.

FIG. **55**J illustrates an exploded view of an alternative flexible suction adapter.

FIG. **56**A illustrates a top view of a 3D fabric that may be used in a negative pressure wound treatment system.

FIG. **56**B illustrates a bottom view of the 3D fabric of FIG. **56**A.

FIG. **56**C illustrates a side cutaway view of the 3D fabric of FIG. **56**A.

FIGS. **57**A-B illustrate an embodiment of a connector with two or more projections and that may be connected to a suction adapter illustrated in FIG. **55**.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Preferred embodiments disclosed herein relate to wound therapy for a human or animal body. Therefore, any reference to a wound herein can refer to a wound on a human or animal body, and any reference to a body herein can refer to a human or animal body. The term "wound" as used herein, in addition to having its broad ordinary meaning, includes any body part of a patient that may be treated using negative pressure. Wounds include, but are not limited to, open wounds, pressure sores, ulcers and burns. Treatment of such wounds can be performed using negative pressure wound therapy, wherein a reduced or negative pressure can be applied to the wound to facilitate and promote healing of the wound. It will also be appreciated that the negative pressure systems and methods as disclosed herein may be applied to other parts of the body, and are not necessarily limited to treatment of wounds.

With reference initially to FIG. **1**, treatment of a wound with negative pressure in certain embodiments of the application uses a system as illustrated schematically. In one embodiment, a wound **101** may be partly or completely filled with a wound packing material **102**, such as foam, gauze, or any other suitable material. Alternatively, no wound packing material may be utilized. A flexible drape **103** that is at least partially fluid impermeable, and preferably liquid impermeable, may then be laid over the wound packing material **102** and preferably onto at least part of the surrounding healthy skin surrounding a wound. The drape **103** may be connected via a conduit **104** such as a flexible

tube to a source of negative pressure **106** such as a pump. This conduit **104** may, in some embodiments, comprise one or more tubes. Suitable sources for negative pressure include both powered negative pressure sources such as vacuum pumps, and manually powered negative pressure sources such as suction bulbs. Negative pressure is applied to the wound through the conduit **104** and through the wound packing material **102**, and wound exudate and other secretions are drawn away from the wound, through the wound packing material, and into a canister or other collection unit **105**. The collection unit **105** may be located along the conduit before the negative pressure source, or may be located elsewhere relative to the negative pressure source. In some embodiments, one or more filters **107** may be provided along the vacuum pathway, for example at the outlet of the pump. This filter **107** may be useful for absorbing odors or may be a bacterial filter. Suitable systems for treating wounds in the above manner include the RENASYS-F, RENASYS-G, RENASYS EZ and RENASYS GO systems available from Smith & Nephew.

The application of reduced or negative pressure to a wound in the above manner may be used to promote faster healing, increase blood flow, decrease bacterial burden, increase the rate of granulation tissue formation, remove exudate and slough from the wound, alleviate interstitial edema, stimulate the proliferation of fibroblasts, stimulate the proliferation of endothelial cells, close chronic open wounds, inhibit burn penetration, and enhance flap and graft attachment, among other things. It has also been reported that wounds that have exhibited positive response to treatment by the application of negative pressure include infected open wounds, decubitus ulcers, dehisced incisions, partial thickness burns, and various lesions to which flaps or grafts have been attached.

Suitable drapes such as those used in the embodiments described herein are preferably liquid tight, such that at least partial negative pressure may be maintained at the wound site. The drape may be constructed from, for example, transparent flexible plastics such as polyurethane. Other suitable materials include without limitation synthetic polymeric materials that do not absorb aqueous fluids, including polyolefins, such as polyethylene and polypropylene, polysiloxanes, polyamides, polyesters, and other copolymers and mixtures thereof. The materials used in the drape may be hydrophobic or hydrophilic. Examples of suitable materials include Transeal® available from DeRoyal and OpSite® available from Smith & Nephew. In order to aid patient comfort and avoid skin maceration, the drapes in certain embodiments are at least partly breathable, such that water vapor is able to pass through without remaining trapped under the dressing. Lastly, although several embodiments illustrated herein illustrate an operator cutting an aperture into a drape manually, drapes used in the embodiments disclosed here may also be provided with one or more pre-cut apertures.

The wound is optionally filled with a wound packing material. Preferably, this wound packing material is conformable to the wound bed. This material is preferably soft and resiliently flexible. Examples of suitable forms of such wound fillers are foams formed of a suitable material, e.g. a resilient thermoplastic. Preferred materials for the present wound dressing include reticulated polyurethane foams with small apertures or pores and open-celled foams. Other suitable materials may include gauze. Preferably, such wound packing material will be able to channel wound exudate and other fluids through itself when negative pressure is applied to the wound. Some wound packing materials may include preformed channels or openings for such purposes.

Typically, the negative pressure wound treatment system is operated until a wound has reached a level of healing acceptable to a physician. The treatment system is preferably operated using a negative or reduced pressure ranging from about 40 to 200 mm Hg, though the amount may be lower or higher depending on physician preference. The time period for use of the wound treatment apparatus on a wound is selected by the physician. During the time period that negative pressure is applied, dressing changes and other temporary interruptions to the treatment may occur. Preferably, the negative pressure wound treatment system is able to handle at least 1 L of wound exudate or other fluid per day, or 0.694 ml/min. Some embodiments may handle over 10 L of wound exudate per day.

In preparing a wound site for treatment with the embodiments described herein, the wound is typically cleaned, debrided, and dried in a medically-acceptable manner. Optionally, the wound site may be filled partly or completely with a wound packing material **102** as shown in FIG. **1**, including for example but without limitation gauze or foam. This wound packing material may be trimmed to fit into the wound space. Next, a drape **103** is placed to cover the wound site while overlapping onto the healthy skin surrounding the wound; in some cases, the drape may need to be trimmed to size. Depending on the type of drape, a skin sealant may need to be applied to the skin surrounding the wound prior to placing the drape so that the drape may be adhered to the skin. Preferably, the drape **103** has an adhesive layer on its wound-facing side. Once adhered to the skin, the drape should form an air-tight seal against the skin. In order to treat the wound using negative pressure, some embodiments disclosed herein may require that the drape be pierced (for example to insert a conduit or to communicate with a suction adapter as described below) to create an aperture leading to the wound site. Obviously, some drapes may have an aperture or apertures already pre-cut or preformed into the drape, and some embodiments disclosed herein may not require an aperture to be made (as shown in FIG. **1**). After application of negative pressure to the wound site, wound exudate and other fluids may be drawn away from the wound site and into a suitable receptacle **105**, preferably interposed between the wound site and the source of negative pressure **106**. Application of negative pressure is continued (with intervening dressing changes, if necessary) until the wound has reached a desired level of healing.

With reference to FIGS. **2**A and **2**B, one embodiment of a negative pressure wound treatment system **201** uses a flexible shroud **202** at the interface between a flexible drape **203** and a conduit **204**. In dressing a wound to be treated using negative pressure, a wound packing material **205** as described above may be appropriately sized and placed into the wound cavity. As shown in FIG. **2**A, the wound packing material **205** may be a foam having an elongate groove or channel **207** for receiving conduit **204**. The drape **203** may be placed over the wound and over the wound packing material **205**, with one or more apertures **206** formed through the drape that permit wound exudate to be evacuated from the wound through tube **204** leading to a negative pressure source. In order to effectively evacuate wound exudate from the wound, these drape apertures are preferably made fluid-tight. In the illustrated embodiment of FIGS. **2**A and **2**B, the flexible shroud **202** is placed over the aperture in the drape and around the tube **204**, permitting a

fluid-tight connection to be made without the use of cumbersome tape, paste, or other such sealing materials typically used.

As shown in FIG. **2**A, the flexible shroud **202** has a distal end **210** facing toward the wound, and a proximal end **211** facing away from the wound. The distal end is enlarged relative to the proximal end to surround the aperture **206**, giving the shroud in one embodiment the shape of a skirt. The distal end **210** preferably has a flat, distally facing surface, with a layer of adhesive **212** and a release layer **213** disposed on the distal end of the flexible shroud. The adhesive may be chosen from any adhesive able to create a fluid-tight seal, including pressure-sensitive adhesives such as silicone adhesives. In some embodiments, an adhesive layer is not necessary, and the flexible shroud **202** is self-sealing against the drape, for example when suction is applied. In order to seal the flexible shroud **202** against the conduit **204**, a flexible grommet **214** may be provided at the proximal end **211**, although some embodiments may have the flexible shroud be sealed or molded to the conduit **204** without the use of a grommet. The flexible shroud **202** may be fixed to a single location on the conduit **204**, or it may slide freely along it. If the flexible shroud **202** is fixed to a single location on the conduit **204**, it may be adhered to the conduit with any suitable means, including adhesives such as cyanoacrylates, light-activated adhesives, or welding.

In a preferred embodiment, the flexible shroud **202** is constructed from a pliable plastic material such as polyurethane. Preferably, the material chosen for the flexible shroud **202** is soft and at least partially conformable to the skin of a patient to avoid causing pressure ulcers or other complications due to prolonged pressure onto patient skin or the wound site.

One method for using the negative pressure treatment system of FIGS. **2**A and **2**B is illustrated in FIGS. **2**C-**2**F. An operator may first debride and clean a wound in a typical manner known to a medical professional of ordinary skill in the art. As shown in FIG. **2**C, a wound packing material **205**, as previously described, may then be placed into the wound; in some cases, the wound packing material may extend above the level of the skin in the wound. As also illustrated in FIG. **2**C, a drape **203** may be placed over the wound and the wound packing material **205**, preferably overlapping onto the healthy skin adjacent the wound. Preferably, the drape is adhered to the skin and/or wound packing material. An aperture **206** is then made into the drape as shown in FIG. **2**D, preferably in proximity to the wound packing material **205** and along the groove **207** formed in the wound packing material **205**. Although FIG. **2**D demonstrates an aperture **206** being made into the drape **203** with a pair of scissors, an aperture may be made by any suitable means, and in some embodiments, the drape **203** may be provided with an aperture pre-cut into the drape. As shown in FIG. **2**E, a conduit **204** as described above is inserted through the aperture **206** and into the groove **207**. In some cases, trimming or cutting of the tube may be necessary.

To apply the flexible shroud **202**, as illustrated in FIG. **2**F, release sheet **213** is removed to expose the adhesive layer **212** of the flexible shroud, and the flexible shroud is then adhered over and around the aperture **206** in order to create a fluid-tight seal. In certain embodiments, the shroud **202** may slide freely over the conduit **204**; in such cases, the shroud **202** is slid down and adhered around the aperture **206**. In other embodiments where the shroud **202** is attached to and does not slide freely over the conduit **204**, the conduit **204** may need to be trimmed as needed to fit into the wound space under the drape **203**. Preferably, the conduit **204** is slid into a groove **207** in the wound packing material **205**. Subsequently, the conduit **204** may be connected to a negative pressure source. When activated, the negative pressure source will collapse the flexible shroud **202** (as shown in FIG. **2**B) and draw wound exudate and other fluids from the wound area.

Turning to FIGS. **3**A-**3**C, another embodiment of a negative pressure wound treatment system **301** uses a sealing disc **302** to seal the interface between the drape **303** and a conduit **304** in a fashion similar to what is described above. In this embodiment, the sealing disc **302** comprises an annular lower support disc **310** preferably constructed from an at least partly-flexible material, such as a polyurethane layer, with a hole through its center. On the bottom side of the lower support disc **310**, an adhesive layer **312** may be disposed with an optional protective release layer **313** covering the adhesive layer, where the protective release layer may be removed prior to use. This adhesive layer **312** may be used to adhere the sealing disc **302** to the drape **303**.

Preferably, the sealing disc **302** further comprises a seal **311** placed above the lower support disc **310**, where the seal is able to create a fluid-tight seal between itself and a conduit **304**. The seal **311** is preferably constructed from a flexible, conformable material such as silicone and comprises a central hole **316** that is preferably smaller than the central hole in the support disc. The exact size of the seal **311**, and its relation in size to the support disc is not important, as long as the seal is able to create a fluid-tight seal between itself and the conduit **304**. Some embodiments may comprise a lower support disc **310** with a central seal **311** integrated into the middle of sealing disc **310** (instead of above it), to create a one-piece unit construction.

Preferably, the sealing disc **302** also comprises an upper support disc **315** placed above the other components of the sealing disc, such that the seal **311** is sandwiched between the upper support disc **315** and lower support disc **310**. The top disc may be constructed from the same material as the support disc, or it may be of a different material. Preferably, the top disc, the seal, and the support disc are secured together to form a single sealing disc **302**, for example using means such as adhesives or welding.

To use the suction disc **302** described above, and with reference to FIG. **3**D-**3**H, an operator will typically prepare the wound as described previously. Once the wound is prepared and a drape **303** placed over the wound (FIG. **3**D), the drape **303** is pierced (FIG. **3**E) and the sealing disc's adhesive protective layer **313** is removed (FIG. **3**F) and placed over the resulting aperture **306** (FIG. **3**G). Preferably, the sealing disc **302** is placed with its central hole **316** aligned with an aperture **306** made through the drape **303**. Subsequently, as shown in FIG. **3**H, the conduit **304**, which may be cut to size, is inserted through the sealing disc **302** and into the drape **303**, and connected to a source of negative pressure. In some embodiments, a channel **307** may be formed in the wound packing material **305**, such that the conduit **304** may be slid into this channel **307**. If necessary, a strip of tape or other adhesive **318** may be used to secure the conduit **304** to the drape **303** to prevent the conduit **304** from undesired movement. The wound is then treated until it has reached a desired level of healing.

FIGS. **4**A-**4**B illustrate another embodiment of a negative pressure wound treatment system **401**. As illustrated, a flexible drape **403** includes an integrated sealing ring **402** surrounding a pre-made aperture **406** in the flexible drape. The integrated sealing ring **402** (which may be similar to the embodiment discussed in FIGS. **3**A-C) should be of a diameter large enough to permit passage of a conduit **404**,

but small enough so that a substantially fluid-tight seal is maintained once the conduit **404** is inserted therein. The sealing ring **402** is preferably constructed from a compliant material such a silicone or urethane. Here, rather than using an adhesive layer to attach the sealing disc to the drape as shown in FIGS. **3**A-C, the sealing ring **402** is pre-attached to the drape **403**, for example by molding the ring **402** onto the drape **403**.

In use and after preparation of the wound as described previously, and with reference to FIG. **4**B, a drape **403** is trimmed, if necessary, and sealed over a wound site optionally filled with a wound packing material **405**. A conduit **404** is inserted through the aperture **406** of the integrated sealing ring **402**. The tube **404**, which may be cut to size, is connected to a source of negative pressure, and the wound is treated until it has reached a desired level of healing.

In FIGS. **5**A and **5**B, another embodiment of a negative pressure wound treatment system **501** is shown with a suction adapter **502** comprising an integrated air leak. The suction adapter **502** comprises upper and lower layers **511** and **510**, which may be annular and/or disc shaped as shown, and formed of a flexible plastic material. As illustrated in FIG. **5**B, the conduit **504** is preferably sandwiched between the upper and lower layers **511**, **510** and forms a loop within the upper and lower layers **511**, **510**. The conduit **504** includes a plurality of apertures **515** in the looped portion, and the lower layer **510** is provided with an aperture or apertures **516** enabling it to serve as a conduit for removing wound exudate from the wound through the drape aperture or apertures **506** and into the apertures **515** of the conduit **504** sandwiched in the suction adapter **502**. Preferably, a layer of adhesive **512** is placed on the lower portion **510** to provide for securing of the suction adapter to the drape. A protective release layer **513** removable by an operator may also be placed on the adhesive layer to protect it during handling.

In some embodiments, the conduit **504** may be secured to the upper and/or lower layers **511**, **510** using, for example, a strip of adhesive, clip, or other fixative **517**. In some embodiments, the fixative **517** may serve as a targeting or visual indicator to aid in the placement of the suction adapter **502** over the aperture **506**. Preferably, the upper and lower layers **511**, **510** of the suction adapter are sealed together with the conduit **504** to form a substantially fluid-tight suction adapter **502**. The sealing may be accomplished through any appropriate means, such as adhesives or welding.

The conduit **504** has a proximal end **518** leading toward a source of negative pressure and a distal portion inserted into the suction adapter with its distal end **519** extending past the loop to form a controlled air leak **520**. This air leak **520** provides a constant source of air entering into the suction adapter **502** and may aid in the removal of wound exudate. Additionally, this air leak **520**, due to the constant rate at which air enters the negative pressure system, may be used in a feedback mechanism to the pump control circuitry and may be useful in detecting blockages occurring in the system, for example in the conduit **504**. Preferably, a filter **521** is placed at the end of the air leak **520** to prevent outside contaminants, such as microorganisms, dust, or other foreign matter from entering the wound area. In some embodiments, the filter **521** may be designed so that a patient may use the system **501** in a shower or other similar environment without occluding the air leak **520**. The filter may be hydrophobic and/or oleophobic. Preferably, the air leak **520** supports a flow rate of air of at least 0.08 L/min. Some embodiments may support an air leak of at least 0.16 L/min.

In use, and as illustrated in FIGS. **5**C-**5**F, an operator would prepare a wound site in an acceptable manner as previously described. As shown in FIG. **5**C, an optional wound packing material **505** may then be placed into the wound site, which would then be covered by a drape **503**, appropriately sized and sealed. After piercing the drape **503** (FIG. **5**D), the adhesive protective layer **513** is removed from the suction adapter **502** (FIG. **5**E), placed over the drape aperture **506** (FIG. **5**F), and connected to a source of negative pressure (not illustrated). The wound is then treated substantially as described previously. Note that in this embodiment, because the conduit **504** does not need to be inserted through the drape **503**, no groove or channel in the wound packing material **505** (which was preferably included in certain other embodiments disclosed herein) is needed in using this suction adapter **502**.

FIGS. **6**A-**6**D show another embodiment of a negative pressure wound treatment system **601**. The system comprises a wound packing material **605** and flexible drape **603** as described above. A flexible suction adapter **602** is further provided for connecting an aperture **606** in the drape to a conduit **604**. Here, the suction adapter **602** is preferably formed of a relatively compliant and pliable material to avoid causing patient discomfort and injury, which may include pressure sores or ulcerations. The suction adapter **602** is connected via connectors **614**, **615** to a source of negative pressure via the conduit **604**. The connectors **614**, **615** may be constructed from a semi-rigid material, including for example but without limitation plastics such as acrylonitrile butadiene styrene (ABS). In some embodiments, end caps (not illustrated) may be provided to seal off one or more of the connectors **614**, **615** when they are disconnected from each other, so as to prevent wound exudate from leaking out of the system.

The flexible suction adapter **602** comprises an upper layer or sheet **611**, a lower layer or sheet **610**, and an elongate channel **608** extending between the upper and lower sheets having a proximal end **616** and a distal end **617**. As illustrated, the channel preferably enlarges toward its distal end, and may form an elongated teardrop shape so as to permit negative pressure to be applied to a larger wound area at the distal end **617** while maintaining a smaller size at the proximal end **616** for connecting with the conduit **604**. Additionally, the teardrop shape aids the suction adapter **602** in conforming to different wound sizes and shapes. The channel **608** as illustrated includes a spacer **609** extending between the proximal and distal ends, and at least one aperture **618** is formed on the lower sheet near the distal end **617** that permits fluid to be evacuated from a wound area (in a manner similar to what has been previously described). In some embodiments, there may be multiple apertures **618** to permit efficient transfer of fluid from the wound. For example, there may be four smaller apertures instead of one larger aperture. The spacer **609** is preferably constructed from a compliant material that is flexible and that also permits fluid to pass through it if the spacer is kinked or folded over. Preferably, the spacer **619** is sandwiched between the upper and lower layers **611** and **610**, for example using adhesives or heat-sealing. In order to secure the suction adapter **602** over an aperture **606** on a drape, lower layer **610** may be provided with a layer of adhesive **612** disposed on its underside, and with an optional protective release sheet **613**.

Suitable materials for the spacer **609** include without limitation foams, including open-cell foams such as polyethylene or polyurethane foam, meshes, 3D knitted fabrics, non-woven materials, and fluid channels. Advantageously,

such materials used in the spacer **609** not only permit greater patient comfort, but may also provide greater kink resistance, such that the spacer **609** is still able to transfer fluid from the wound toward the source of negative pressure while being kinked or bent. In some embodiments, the fluid channels may simply comprise folds created when the upper sheet is wider than the lower sheet, or vice versa, such that application of negative pressure causes the wider sheet to collapse and form folds or wrinkles suitable to channel fluids from the wound to the source of negative pressure. An example of such an embodiment is illustrated in FIG. **8**A described below, where a suction adapter may be constructed from a flexible and non-rigid material such as a film.

In other embodiments, and as illustrated in FIG. **6**C, fluid channels may comprise one or more solid channels **619**, and may not require the use of the spacer **609** described above. In some embodiments, these solid channels are molded into either or both the upper and lower sheets; alternatively, these may be constructed separately and inserted in the space between the upper and lower sheets. If possible, such channels are at least partly compliant and non-rigid, thereby avoiding patient discomfort and other complications. FIG. **6**D illustrates another embodiment where the spacer **609** comprises a thin mesh **620**.

FIGS. **6**E-**6**H illustrate a method of using and applying the suction adapter **602** described above. The wound is prepared in an acceptable manner as described above, and a drape **603** is fitted and sealed over the wound site (which may contain an optional wound packing material **605**) (FIG. **6**E). An aperture **606** is then cut into the drape **603** (although some drapes may be provided with an aperture **606** already pre-cut) (FIG. **6**F). The release layer **613**, if present, is removed to expose the adhesive layer **612** on the underside of the suction adapter **602** (FIG. **6**G). The suction adapter **602** is then placed such that the apertures **618** on its underside are substantially aligned with the aperture **606** on the drape **603**. The suction adapter **602** is then connected to a source of negative pressure, and the treatment is applied until the wound has reached an acceptable level of healing.

FIGS. **7**A-**7**B illustrate embodiments of the wound treatment system **701** with an air leak provided, where the conduit used in FIGS. **5**A-H is replaced with a compliant material, for example foam. The compliant material aspect of these two embodiments will be described in further detail below. FIG. **7**A demonstrates a suction adapter **702** similar in design to FIG. **5**A, but which uses a compliant material. Here, the compliant spacer channel **707**, preferably constructed from a compliant material such as foam able to transmit fluid through itself, is connected at its proximal end **718** to a conduit **704**, which is then connected directly or indirectly to a source of negative pressure. At the distal end **719** an air leak **720** is provided, optionally with a filter **721**. This air leak provides a constant source of air entering the suction adapter **702**, and (as described previously in FIGS. **5**A-B) may be useful in detecting blockages in the system (for example the conduit **704**) and may aid in the removal of wound exudate. Preferably, the filter **721** is constructed from a thin membrane, which may be hydrophobic or oleophobic. The filter **721** is preferably able to filter microorganisms and foreign particles from entering the wound site. In some embodiments, the filter **721** is able to be wetted, for example when a patient enters a shower. The filter **721** may be die-punched from a membrane stock and attached to the air leak **720** by any suitable means, such as welding or adhesives. This compliant spacer channel **707** is sandwiched between an upper layer **711** and a lower layer **710**, with the lower layer **710** preferably being provided with a layer of adhesive optionally covered with a release layer in a similar fashion to the embodiments illustrated in FIGS. **5**A-B. The lower layer **710** has one or more apertures permitting it to be fluidically connected to an aperture on a drape used to cover a wound (not illustrated). The apertures on the lower layer **710** are also fluidically connected to the compliant spacer channel **707**, such that upon the application of negative pressure, wound exudate and other such fluids may be evacuated from the wound site through the aperture in the drape, through the aperture in the lower layer **710**, and into the compliant spacer channel **707**. Preferably, the section of the compliant spacer channel **707** situated over the apertures in the lower layer **710** is larger to permit more effective removal of wound exudate from the wound site, and may form an elongated teardrop shape.

Focusing on the air leak aspect of these embodiments, FIG. **7**B illustrates an embodiment with a controlled air leak **720** on the suction adapter **702** that is provided at the proximal end **718** of the compliant spacer channel **707**, instead of being provided at the distal end as described above. A filter **721** is optionally provided at the air leak site. The proximal end **718** is joined to a conduit **704**. In a proximal air leak design, the air leak may be disposed at a "T"-junction between the apertures near the distal end and the proximal end of the spacer channel **707** connected to the negative pressure source. Of course, although FIG. **7**B illustrates a proximal air leak using a foam fluid transfer material, such an embodiment could also be realized using other materials, for instance the conduit used in FIG. **5**A.

FIG. **7**C illustrates an embodiment joining a compliant suction adapter **702** and short compliant spacer channel **707** connected to a dual lumen tube **704** incorporating an air leak **720** at the proximal portion **718**. Here, one lumen in the tube **704** is fluidically connected through connector **730** to a source of negative pressure **731** at its proximal end **718**, and the other lumen is open at the proximal end **718** to form an air leak **720**. This open end may optionally include an air filter **721**. At the distal end of the dual lumen tube, both lumens are fluidically connected to the compliant spacer channel **707** to permit the application of negative pressure to the wound site through the suction head **702**, in a manner similar to the other embodiments discussed above. In some embodiments, a compliant spacer channel **707** may not be necessary, and the dual lumen tube **704** may be directly connected to the suction head.

FIGS. **8**A-B illustrate a suction adapter **802** of a similar design to the embodiments described in FIGS. **6**A-H. Here, however, the suction adapter **802** is not filled with any material, and instead comprises a flat portion comprising elongate parallel channels **810** integrated onto the underside of suction adapter **802**. These channels **810** may be molded integrally or attached separately onto the suction adapter **802**. The suction adapter **802** preferably comprises one or more apertures **816** that would permit a fluidic connection to be made between an aperture **806** made in a drape **803**, such that wound exudate from a wound site can be drawn through optional wound packing means **805**, through the aperture **806**, and into the suction adapter **802** through its aperture **816**. The wound exudate is then drawn off through the conduit **804**. An adhesive layer **812** is preferably provided on the underside of the suction adapter **802** to permit it to be secured to the drape **803**, and preferably includes a release layer **813** that is removed prior to adhesion of the suction adapter **802**.

FIGS. **9**A and **9**B illustrate an embodiment of the wound treatment system **901** using a drape **903** with a suction channel **902** integrated therein. In this embodiment, the

drape **903** typically used to cover the wound and the optional wound packing material **905** that may be disposed in the wound also serves as a suction channel **902** to transfer fluids such as wound exudate away from the wound using a source of negative pressure, connected to the drape **903** through conduit **904**. The drape **903** includes at least one aperture **916** suitable for the passage of wound exudate. A spacer **907** is preferably placed over the apertures **916**, the spacer **907** being preferably composed of the same types of materials as the spacer **609** used in FIG. **6**A, such as foam. The drape **903** comprises a top layer **911** and a bottom layer **910**. In order to create a fluid-tight seal, the top layer **911** is attached to the bottom layer **910**, sandwiching the spacer **907** between it. This top layer **911** should cover at least the spacer **907**, and may be dimensioned to be as large or larger than the bottom layer **910** situated below it. The bottom and the top layers **910**, **911** may be attached together using any suitable means, for example adhesives or welding.

An adhesive layer **912** with an optional release sheet **913** is preferably disposed on the wound-facing side of the bottom layer **910**, as well as on the wound-facing side of the top sheet **911**, if the top sheet is larger than the drape. The adhesive layer **912** preferably covers the entire wound-facing side of the drape **903**, and may in some embodiments incorporate a multi-part release sheet **913** rather than a single release sheet **913**. In this case, the release sheet **913** may be removable in several parts, for example to permit only a portion of the adhesive to be exposed for initial placement on the wound site, followed by removal of another portion of the release sheet **913** once the drape placement is finalized. The components of the assembled drape **903**, including the drape itself, the spacer, and the top layer, may also comprise markings or other indicators, including visual or tactile indicators, to aid an operator in aligning, positioning, and deploying the drape.

In order to use the wound treatment system **901** described above and illustrated in FIGS. **9**C-D, a medical professional would to prepare a wound site and optionally place wound packing material **905** inside the wound substantially in the manner described previously. Advantageously, instead of having to then place a drape over the wound site and create an aperture into the drape, a medical professional using a drape **903** with an integrated suction channel would only have to position the drape over the wound site, trim the drape **903** (if necessary), remove any adhesive release layer **913** (FIG. **9**C), and seal the wound by attaching the drape **903** over the wound site (FIG. **9**D). The drape **903** would then be connected to a conduit **904**. This drape **903** would thus save time and avoid complications and difficulties in having to size and cut a hole in a drape that the prior art and some of the other embodiments presently employ.

In some embodiments, illustrated in FIGS. **10**A and **10**B (which is similar to the embodiment illustrated in FIG. **9**A), the wound treatment system **1001** incorporates a drape without a separate spacer. Instead, the suction channel **1002** may comprise one or more ridges or folds **1010** present on the underside of the suction channel **1002**, the ridges **1010** serving to maintain patency of the negative pressure connection from the wound to the source of negative pressure. In some cases, the ridges **1010** may be molded into either the top layer or the bottom layer of the drape **1003**. Preferably, such ridges **1010** are substantially compliant and pliable to avoid causing patient discomfort and other complications.

FIGS. **11**A-B demonstrate a variation of the embodiment illustrated in FIG. **9**A, where wound treatment system **1101** uses a drape **1103** incorporating a spacer comprised of bosses **1107** serving to keep the top layer **1111** and bottom layer **1110** of the drape **1103** separate in order to form a suction channel **1102** for removal of wound exudate from a wound site at the aperture **1116**. These bosses **1107** may be molded into the top or bottom layer of drape **1103**, or else may be constructed separately and attached thereto. In some embodiments, the bosses **1107** are solid; in other embodiments they may be hollow. Preferably, the bosses **1107** are at least partially compliant and flexible, and may be formed from any suitable material, such as flexible plastics including polyurethane. The bottom layer **1110** optionally includes an adhesive layer and release sheet.

FIGS. **12**A-B illustrate a wound treatment system **1201** comprising a flexible one-piece suction adapter. Here, the suction adapter **1202** may be manufactured from a compliant, flexible material such as plastic, including for example silicone, and comprises a proximal portion **1218** and a distal portion **1219**, where the distal portion **1219** comprises a central aperture **1216** for placement around a wound site. The edges of the suction adapter may be chamfered (for example at chamfer **1206**) to help seal the suction adapter against the edges of the wound site, and also minimize the risk of the suction adapter snagging or catching on other tubes, dressings, or other materials that may be in proximity to the wound site. Suction channels **1210** are also provided that serve to draw fluid away from the wound site through a conduit **1204** and toward a source of negative pressure connected thereto. In some embodiments, illustrated in FIG. **12**B, the suction channels **1210** are formed through the proximal portion **1219** of the suction head, and are thus connected to a source of negative pressure. In other embodiments, illustrated in FIG. **12**A, the suction channels **1210** may not be enclosed on all or part of the skin-facing portion. Optionally, a layer of adhesive **1212** is present on the wound-facing side of the suction head, although some embodiments may instead be self-sealing, for example if the suction head is constructed entirely or in part from silicone.

In use, once a wound site is cleaned, prepared in accordance with typical medical protocols, and optionally filled with a wound packing material, a first drape is placed over the wound and an aperture made thereon. Next, the suction adapter **1202** is placed over the drape aperture, with the central aperture **1216** being placed over the drape aperture. Subsequently, a second drape is placed over the wound site and suction adapter **1202**. After connecting the suction adapter to a source of negative pressure through the conduit **1204**, wound exudate is removed from the wound and the wound may then progress to a desired stage of healing.

FIGS. **13**A and **13**B illustrate another embodiment of a wound treatment system **1301** using a piercing cap **1302**. Here, the piercing cap **1302** is provided with a bayonet or other piercing element **1310** suitable for perforating a drape **1303** placed over a wound site. On the wound-facing side of the drape is a suction base **1307** adapted to fit together with the piercing cap **1302**, typically with a drape **1303** in between. The suction base **1307** is provided with a central aperture **1311** to be placed over the wound site. In order to fit together, the piercing cap **1302** and suction base **1307** are preferably each provided with portions that lock and fit together, for example locking tabs or screw-like engagement mechanisms **1308** and **1309**. In certain preferred embodiments (illustrated in FIG. **13**B), the piercing cap **1302** rotationally engages with the suction base **1307**, thereby minimizing the force applied to the wound. Some embodiments may also include a sealing gasket to prevent air leaks between the interface of the piercing cap **1302** and the suction base **1307**, although the drape **1303** may in some cases provide a sufficient seal.

In use, a wound site is prepared substantially in the manner that has been described previously above, but with a suction base **1307** being provided under the drape **1303** at the site over which a fluidic connection is to be made. After the drape **1303** has been sealed over the wound site (which may optionally include a wound packing material **1305**), a piercing cap **1302** pierces the drape and attaches to the suction base **1307**, thereby creating a fluidic connection enabling wound exudate to be conveyed from the wound site to the source of negative pressure through a conduit **1304**. The wound site may then be maintained as such until it has reached a desired stage of healing.

FIGS. **14**A-B illustrate an embodiment of a wound treatment system **1401** comprising a drape **1403** provided with a wound-packing material **1405** integrated thereon. In this embodiment, a drape **1403** substantially of same material used in the other embodiments described herein is provided with a wound packing material **1405**, for example foam, attached to the wound-facing side of the drape **1403**. Preferably, the adhesive does not attach the entire portion of the wound packing material to the wound-facing side of the drape, thus permitting a medical professional using the drape to easily trim the wound packing material to size. Optionally, precut or preformed detachable sections **1406** of wound packing material may be provided. The drape may be secured to the wound-facing material by a patch of adhesive **1412** disposed in the center of the drape **1403**. In some embodiments, a channel **1407** may be provided through the wound packing material **1405**, preferably through the center, so as to facilitate the placement of a conduit **1404** into the wound treatment system **1401**. Optionally, the wound treatment system **1401** may be provided with such a conduit **1404** pre-attached or adhered into the channel **1407**. Such an arrangement may be advantageous in providing optimal application of negative pressure to the wound site through the conduit **1404**. Optionally, a seal bridge **1408** may be provided at the junction where the conduit **1404** exits the drape **1403**, thereby sealing the wound site and preventing air leaks that may affect the application of negative pressure to the wound site. Preferably, the drape **1403** is provided with a further adhesive layer (not illustrated here) surrounding the adhesive patch **1412** and extending to the edges of the drape **1403**, which is preferably covered with a release sheet (not illustrated here). Such a configuration permits an operator to accurately place the wound treatment system **1401** over a wound site and seal the drape **1403** against the skin surrounding the wound site by removing the release sheet once the drape **1403** and wound packing material **1405** have been positioned and sized appropriately. In some embodiments, additional adhesives, for example sealing tape, may be provided to aid in sealing the drape **1403** to the skin of a patient.

In order to use the wound treatment system **1401** described above, a wound site is cleaned and prepared in any suitable manner. Next, the wound packing material **1405** attached to the drape **1403** is fitted into the wound site, by trimming the wound packing material and/or by removing precut or preformed sections **1406** (if so provided) as necessary as well as by trimming the drape **1403** if necessary. A conduit **1404** is then inserted into a channel **1407**, and after trimming (if necessary) and sealing the drape **1403** against the skin of the patient, the conduit **1404** is connected to a source of negative pressure and the wound is treated until it reaches a desired level of healing. In some embodiments, the conduit **1404** is provided pre-inserted into the channel **1407**.

FIGS. **15**A-D illustrate an embodiment of a negative pressure wound treatment system **1501** comprising a flexible suction adapter. This system may be combined with other components as described elsewhere in this application, for example the components illustrated in FIG. **7**C, and particularly the source of negative pressure **731**, tubing and a connector **730**. Here, the system **1501** may comprise a bridge **1502** having a proximal end **1503** and a distal end **1505** and an applicator **1520** at the distal end **1505** of the bridge **1502**. In some embodiments, the bridge **1502** may comprise an upper channel layer **1512** sandwiched between an upper layer **1510** and an intermediate layer **1514**, with a lower channel layer **1516** sandwiched between the intermediate layer **1514** and a bottom layer **1518**. Preferably, the layers **1510**, **1514**, and **1518** have elongate portions extending between proximal and distal ends and may be comprised of a material that is fluid-impermeable, for example polymers such as polyurethane. It will of course be appreciated that the layers **1510**, **1514**, and **1516** may each be constructed from different materials, including semi-permeable materials. Similarly to the embodiment described in FIG. **6** with regards to the spacer **609**, the upper and lower channel layers **1512** and **1516** are preferably elongate layers extending from the proximal end **1503** to the distal end **1505** and may each preferably comprise a porous material, including for example open-celled foams such as polyethylene or polyurethane. In some embodiments, one or more of the upper and lower channel layers **1512** and **1516** may be comprised of a wicking fabric, for example a knitted or woven spacer fabric (such as a knitted polyester 3D fabric, Baltex 7970®, or Gehring 8790) or a nonwoven fabric. These materials selected are preferably suited to channeling wound exudate away from the wound and for transmitting negative pressure and/or vented air to the wound site, and may also confer a degree of kinking or occlusion resistance to the channel layers **1512** and **1516**. In some embodiments, the wicking fabric may have a three-dimensional structure, which in some cases may aid in wicking fluid or transmitting negative pressure. To prevent the channels **1512** and/or **1516** from being displaced or twisted while encased in the system **1501**—which may impair performance of the respective channels under negative pressure—it may in some embodiments be preferable to adhere or otherwise secure the channels **1512** and/or **1516** to one or more of the layers **1510**, **1514**, and **1518**. In certain embodiments, including wicking fabrics, these materials remain open and capable of communicating negative pressure to a wound area under the typical pressures used in negative pressure therapy, for example between 80 to 150 mmHg. In some embodiments, the wicking fabric may comprise several layers of material stacked or layered over each other, which may in some cases be useful in preventing the channel **1516** from collapsing under the application of negative pressure. In other embodiments, the wicking fabric used in channel **1516** may be between 1.5 mm and 6 mm; more preferably, the wicking fabric may be between 3 mm and 6 mm thick, and may be comprised of either one or several individual layers of wicking fabric. In other embodiments, the channel **1512** may be between 1.2-3 mm thick, and preferably thicker than 1.5 mm. Additionally, and as described previously, the materials used in the system **1501** are preferably conformable and soft, which may help to avoid pressure ulcers and other complications which may result from a wound treatment system being pressed against the skin of a patient.

Preferably, the distal ends of the layers **1510**, **1514**, and **1518** and the channels **1512** and **1516** are enlarged at the distal end (to be placed over a wound site), and may form a

"teardrop" or other enlarged shape. Preferably, and with additional reference to FIG. **15**C, a connector **1504** is provided at the proximal end **1503** which may be used to connect the lower channel layer **1516** to a source of negative pressure. The connector **1504** may for example be embedded into the lower channel layer **1516**, and preferably extends sufficiently away from the assembled bridge **1502** so as to permit a fluidic connector, for example a tube, to be connected to it so as to permit wound exudate to be suctioned away from the wound and for negative pressure to be applied to the wound site. The upper layer **1510** may comprise additional material extending downward, preferably at least of the thickness of the bridge **1502**. During assembly, the upper layer **1510** is preferably attached, for example by melting, welding, or with adhesives, to the lower layer **1518** so as to form a fluid-tight seal (with the exception of the apertures at the distal and proximal ends). Preferably, the middle layer **1514** is attached to the top layer **1510** and the bottom layer **1518**. Note that FIG. **15**C is intended to illustrate the various materials and components at the proximal end **1503**, and that a system **1501** constructed accordingly will preferably not have the proximal end **1503** open and unsealed. In some embodiments, it will be preferable to attach or bond the connector **1504** to at least one of the layers **1510**, **1514**, **1518** so as to create a fluid-tight connection.

In certain embodiments, a controlled air leak **1524** may be disposed on the bridge portion **1502**, for example at the proximal end thereof. This air leak **1524** may comprise an opening or channel extending through upper layer **1510**, such that the air leak **1524** is in fluidic communication with the upper channel **1512**. Upon the application of suction to the system **1501**, air will enter through the air leak **1524** and move from the proximal end **1503** to the distal end **1505** along the upper channel **1512**. The air will then be suctioned into the lower channel **1516** by passing through the apertures through the distal ends of the layers **1512**, **1514**, **1516** and **1518**. The air leak **1524** preferably comprises a filter (not illustrated), which may be similar in function to the filter **521** illustrated in FIG. **5**A. Preferably, the air leak **1524** is located at the proximal end of the bridge portion **1502** so as to minimize the likelihood of wound exudate or other fluids coming into contact and possibly occluding or interfering with the air leak **1524** or its filter. In some embodiments, this filter is a microporous membrane capable of excluding microorganisms and bacteria, and which may be able to filter out particles larger than 45 μm.

Advantageously, some embodiments may provide for a filter that is at least partially chemically-resistant, for example to water, common household liquids such as shampoos, and other surfactants. In some embodiments, reapplication of vacuum to the system **1501** and/or wiping of the outside portion of the filter may be sufficient to clear any foreign substance occluding the filter. The filter may be composed of a suitably-resistant polymer such as acrylic, polyethersulfone, or polytetrafluoroethylene, and may be oleophobic and/or hydrophobic. In some embodiments, the filter may also comprise a supporting backing layer, for example a nonwoven polyester support. Preferably, the air leak **1524** will supply a relatively constant air flow that does not appreciably increase as additional negative pressure is applied to the system **1501**. In embodiments of the system **1501** where the air flow through the air leak **1524** increases as additional negative pressure is applied, preferably this increased air flow will be minimized and not increase in proportion to the negative pressure applied thereto.

The system **1501** is preferably constructed so as to provide a consistent fluid flow even if the system **1501** is kinked or weighted down. For example, in use on a patient, the bridge portion **1502** may become folded over itself, or else the patient may roll over, thus placing his or her weight over at least a portion of the system **1501**. Typically, prior art dressings and fluidic connectors become blocked or ineffective in such situations. Here, however, certain embodiments provide for improved blockage resistance if kinked or weighed down. Preferably, the system **1501** is able to maintain a flow rate through the air leak **1524** of at least 0.08 L/min, and preferably 0.12 L/min while negative pressure is applied through a source of negative pressure. Further embodiments also provide for the system **1501** to be able to handle fluid exudate drainage from the wound site through the lower channel **1516** of at least 10 L/day, or 6.9 ml/min. Certain embodiments provide for the system **1501** to maintain these flow rates with a weight, for example a 12 kg weight pressing down on the bridge portion through a rod with a 1 in. diameter. In some embodiments, these flow rates are also maintained while the bridge portion **1502** is kinked over itself with the same weight, or for example with a 4.75 kg weight placed directly on the folded region. It is preferable that the system **1501** be able to withstand being folded or kinked over even during an extended period of time, for example over 40 hours. Preferably, embodiments of the system **1501** are also able to transmit and maintain a negative pressure at the wound that is close to the negative pressure level at the source of negative pressure. For example, an acceptable level of pressure maintained at the wound may be within .+−0.25 mmHg of the negative pressure set at the source of negative pressure, with this pressure being preferably maintained at this level within for example 95% of the time that the system **1501** has negative pressure applied to it. Acceptable pressure levels may include pressure ranges between 40-120 mmHg, although levels of 200 mmHg have successfully been used.

With additional reference to FIG. **15**D, the system **1501** also comprises an applicator **1520** designed for placement over a wound site. Preferably, the applicator **1520** comprises a flexible layer **1530**, for example polyethylene or polyurethane, with a layer of adhesive on its lower (wound-facing) side. Optionally, a protective release layer **1532** may be placed on the adhesive layer, which is removable before use. In some embodiments, a more rigid removable backing layer **1534** may be provided to facilitate handling of the applicator **1520** due to its flexible adhesive-backed layer **1530**. The applicator **1520** preferably comprises an attachment point for the bridge **1502** at the distal end **1505**, for example using a section of double-sided adhesive tape **1528**. The double-sided adhesive tape **1528** may be protected by an additional protective release layer **1529**, which is removed prior to adhering the bridge **1502** to the applicator **1520**. It will be understood that different attachment methods are also contemplated, for example heat sealing, welding, or suitable adhesives. Some embodiments may also permit the manufacture of the bridge **1502** and the applicator **1520** as a single unit that does not require separate attachment means. The applicator **1520** preferably comprises at least one aperture **1526** through itself and designed to be placed over a wound site, and which can serve to fluidically connect the wound site to the source of negative pressure and to the air leak while also serving as a conduit to draw out wound exudate from the wound site. Additionally, certain embodiments may provide for the aperture **1526** to be used in a viewing window **1522** described below.

With continued reference to FIGS. **15**A-B, certain embodiments may also provide for a viewing window **1522** that permits targeting and visualization of the wound site

prior to placement of the system **1501** as well as ongoing monitoring of the wound site during the course of treatment. Preferably, a set of apertures are created or formed through the distal portions of layers **1510**, **1512**, **1514**, **1516**, and **1518** in alignment with aperture **1526** through the applicator **1520**. Although FIG. **15**B illustrates a set of apertures with a circular cross-section, other cross-sections are possible, for example with a polygonal or rectangular cross-section. Preferably, a viewing window **1522** which is at least partially transparent is provided to cover the first aperture through the top layer **1510** to shield the wound from contamination.

The filter provided in the controlled air leak **1524** in certain embodiments may be useful in a system **1501** for use with more ambulatory and active patients. For example, a chemically-resistant filter may permit a patient to bathe or shower without damaging the filter's functionality when reconnected to a source of negative pressure. Any occlusion or fluid blocking the air leak **1524** could then be cleared by, for example, wiping off the filter or re-applying negative pressure to the system **1501**. Such a system would also have the advantage that the system **1501** and any assorted wound dressing materials, if present, would not need to be removed and then re-applied should a patient need to be disconnected from the source of negative pressure, for example incidental to bathing. This would entail significant advantages in improving the cost-effectiveness and ease of use of the present treatment system.

In use, the system **1501** may be used in a similar fashion to the other embodiments previously disclosed herein. A wound site is preferably cleaned and prepared in a suitable fashion, and a wound packing material, if necessary, placed into the wound site, followed by a drape. An opening through the drape to the wound site is then created, although some embodiments may have a pre-made aperture. Subsequently, an operator may situate the applicator portion **1520** over the aperture, optionally using the viewing window **1522** as a positioning aid. After removing the backing layer (if present) from the adhesive layer on the underside of the applicator portion **1520**, the applicator is sealed to the drape, and the support layer (if present) is also removed from the applicator portion **1520**. A fluidic conduit such as a tube may then be connected to the connector **1504**. After the fluidic conduit is connected to a source of negative pressure, preferably with a container suitable for containing wound exudate interposed therebetween, the application of negative pressure may then be effectuated to the wound site until the wound site progresses to a desired level of healing.

During use of the system **1501**, wound exudate is drawn by the negative pressure through the lower channel layer **1516**. The air leak **1524** allows air to pass through the upper channel layer **1512** into the apertures through the distal ends of the layers **1512**, **1514**, **1516** and **1518**. The negative pressure draws air passing through the upper channel layer into the lower channel layer **1516** back toward the source of negative pressure or pump. In some embodiments, the controlled air leak **1524** provides a constant flow of air through the system **1501**, which then may be used to determine whether blockage or leakage is present. Causes of blockage can include, for example, situations where the lower channel **1516** becomes occluded with wound debris. Leakage causes can include, for example, improper sealing of the drape over the wound site, or physical damage to the system **1501** leading to excess air leaking into the system. The blockage or leakage may be determined, in certain embodiments, by measuring the speed of the pump while the pump works to maintain a constant negative pressure. Pump speed may also be measured indirectly by measuring the amount of voltage or signal sent to the pump.

FIG. **16**A illustrates a wound treatment system **1601** similar to the embodiment described in FIG. **9**. Here, a top layer **1603** (illustrated with a square or rectangular shape) is preferably constructed from a liquid-impermeable material, although it is preferably at least partially gas and water vapor permeable. A bottom layer **1607** (illustrated with a square or rectangular shape) may then be attached or bonded to the top layer **1603**, for example using adhesives or welding, while sandwiching a wicking layer **1605** between these two layers. The bottom layer preferably has a layer of adhesive (not illustrated) disposed on at least part of the wound-facing side, which may be protected by an optional protective layer **1608** (illustrated in FIG. **16**B). Preferably, at least the layers **1603**, **1607**, and **1608** are constructed of a material that is easily cut, for example with scissors, so that the system **1601** may be sized as appropriate for placement over a wound site.

The bottom layer **1607** preferably has at least one aperture **1606** capable of creating a fluidic connection between a wound site disposed under the aperture and the wicking layer **1605**. This wicking layer **1605** is preferably an elongate layer placed between the layers **1603** and **1607**, constructed from a material capable of wicking or transporting fluid from a wound site, especially while under suction. Suitable materials include but are not limited to foams as described above, woven materials, 3D knitted materials, materials constructed of from either or both hydrophilic materials (such as cotton), hydrophobic materials (such as polyethylene), or a mixtures of both. Either or both the top or bottom layers may have a channel **1612** suitable for containing the wicking layer **1605**, and this channel and wicking layer are preferably enlarged at the distal end closest to the aperture **1606**. As illustrated, the wicking layer **1605** has an enlarged end with a circular shape place over the aperture **1606**. Preferably, a fluidic connector **1610** is attached to the top layer **1603** to permit a suction tube or other conduit **1604** to create a fluidic connection between the wound space, the wound treatment system **1601**, and a source of negative pressure.

FIG. **16**B illustrates a method of using the system **1601**, where the system **1601** is cut to size and secured to the wound. In some embodiments, a strip of tape or other fixative may be used to secure the tube **1604** to the connector **1610**.

FIG. **17**A illustrates an embodiment of a negative pressure wound treatment system **1701**. The system **1701** preferably has a low-profile port **1712** integrated into a drape **1703** (illustrated with a square or rectangular shape), where the port **1712** preferably situated along one side of the drape **1703**. The port **1712** is preferably sized to permit one side of a fluidic connector **1710** to be connected to it. The other side of the connector **1710** is preferably sized to permit a conduit or tube **1704** to be connected, although some embodiments may permit the conduit **1704** to be connected directly to the port **1712** without the use of a connector **1710**. Preferably, the port **1712** is attached over an aperture through the drape **1703**, permitting a fluidic connection to be made from the wound site through the port **1712**, through the fluidic connector **1710**, and into the conduit **1704**, which is preferably connected to a source of negative pressure. A layer of adhesive may also be provided on all or some of the wound facing side of the drape **1703**, and which may be protected by a release layer **1708**.

FIG. **17**B illustrates a method of using the system **1701** described above, where the drape **1703** is cut to size and applied to the wound.

FIG. **18**A illustrates an embodiment of a negative pressure treatment system **1801** similar to FIG. **6**A. In a preferred embodiment, a flexible wicking layer **1805** is sandwiched between a top layer **1803** and a bottom layer **1808**, where the bottom layer **1808** is preferably provided with at least one aperture **1806** to expose the wicking layer to a wound site. Similarly to other embodiments, an adhesive layer and an optional protective layer may be disposed on the wound-facing side of the bottom layer **1808**. A fluidic connector **1810** may be disposed at the proximal end of the system **1801** so as to create a fluidic connection between the wound site and a source of negative pressure through a conduit **1804**. Preferably, the system **1801**, and in particular the layers **1803**, **1805**, and **1808**, are flexible and conformable to aid in the placement over a wound site located on, for example, a non-flat or difficult to access area of the body, such as a heel.

FIG. **18**B illustrates a method of using the system **1801**. As illustrated the system **1801** is applied to a drape having an incision or hole extending through the drape. In some embodiments, a strip of tape or other fixative may be used to secure the tube **1804** to the connector **1810**.

FIGS. **19**A-B illustrate embodiments of a negative pressure treatment system **1901**. With reference to FIG. **19**A, the system **1901** comprises an exposed wicking layer **1905** extending from a flat drain portion **1903**. The drain portion **1903** is preferably integrated with a tube or conduit **1904**, and tapers down to become wider and flatter at its distal end. Preferably, the drain portion **1903** and the conduit **1904** are formed together as a single unit. The drain portion **1903** is also preferably constructed from a soft elastomeric material, including for example silicone, polyurethane, polyethylene, and/or polyvinylchloride, and which is able to conform to a wound site and spread out any pressure over a larger area. The wicking portion **1905** is preferably constructed from a soft material able to transmit fluid along itself, for example a nonwoven, open textile material (such as cotton gauze or XD spacer fabric (Baltex®)), thereby permitting it to be placed over or into a wound site so as to drain wound exudate and transmit negative pressure to the wound site. Some embodiments of the system **1901** may also provide for a controlled air leak **1916**, similar to the air leak **1524** described in FIG. **15**A. In certain embodiments, this air leak **1916** may be in the form of a one-way valve which opens and permits air to enter the system when high negative pressure is applied.

FIG. **19**B illustrates another embodiment of the negative pressure treatment system **1901**. Here, the drain portion **1903** may be partly bifurcated to permit a lumen **1918** attached to a controlled air leak **1916** to reach the area close to the wound site. This air leak **1916** preferably includes a filter element **1917** to prevent particulates and other contaminants from entering the wound site. The drain **1903** is preferably flat and tapered so as to present a low profile on the wound, and is preferably constructed of a soft elastomeric material of the type described above. To facilitate drainage of exudate from the wound, an aperture or apertures **1906** may be provided along the wound-facing portion of the drain. Turning back to the air leak **1916**, certain embodiments provide for the proximal end of the air leak **1916** (closest to the air filter **1917**) to be accommodated on a suction adapter **1910**, for example in a notch **1920** made in the adapter **1910**. The suction adapter **1910** is preferably designed to receive a tube or conduit **1904** and connect it to the drain **1903**.

FIGS. **19**C-D illustrate methods of using embodiments of the system **1901** described above.

FIG. **20**A illustrates an embodiment of a negative pressure wound treatment **2001** comprising a trimmable suction port. A suction head **2006** is attached to a tail **2008** (although the head **2006** and tail **2008** may be formed as a single unit), where the tail **2008** comprises a channel **2009** disposed longitudinally inside to create a channel leading from the wound site, through at least one aperture **2012** disposed on the wound-facing side of the suction head **2006**, and to a source of negative pressure. Preferably, this channel **2009** is sized to accommodate the insertion or attachment of a suction adapter **2010** and/or a conduit or tube **2004**. The head **2006**, although illustrated as being round, may be of any suitable shape, and preferably comprises a layer of adhesive disposed on its wound-facing side for attachment to a drape. Similar to previously-described embodiments, this adhesive layer is preferably protected by a removable backing layer.

The suction adapter **2010** may be sized to taper from a shorter, wider cross-section at its distal end inserted into the channel **2009** to a rounder profile at its proximal end to permit insertion or attachment of a tube **2004**. Some embodiments may provide for a controlled air leak **2016** similar in design to other examples previously illustrated.

The tail **2008** is preferably constructed from a flexible, conformable material capable of being trimmed or cut, for example during sizing of the system **2001** for placement over a wound site. Accordingly, an operator may trim the tail **2008** as appropriate for the size and location of the wound site, followed by the insertion of, preferably, the suction adapter **2010** into the channel **2009**, although some embodiments provide for the insertion of a tube **2004** directly into the channel **2009** without necessitating the use of a suction adapter **2010**.

FIG. **20**B illustrates a method of using the system **2001** described above.

FIG. **21**A illustrates another embodiment of a negative pressure wound treatment system **2101** comprising a sealing ring similar to the system **301** illustrated in FIG. **3**A. Here, a sealing disc **2103** is preferably constructed from a flexible, resilient material able to seal against a tube or conduit **2104** that is inserted through the sealing disc **2103**'s central aperture **2106** so as to create a fluid-tight seal. A preferred material may include silicone or polyurethane, although hydrogels may be used as well. Preferably, an adhesive layer **2108** is disposed on the wound-facing side of the disc **2103**, optionally protected by a removable backing layer.

In use, and with further reference to FIG. **21**B, the sealing disc **2103** is positioned over a drape covering a wound site, and the adhesive layer of the disc adhered to the drape. Flaps **2110** may also be provided to form a template or cutting guide for cutting a hole through the drape, in addition to serving as additional sealing means against the tube **2104**. In some embodiments, the flaps **2110** may be arranged, for example, to form a cross or "X" shape, such that a cutting implement such as a scalpel can be used to form a correspondingly-sized aperture in the underlying drape. Subsequently, a conduit **2104** may be pushed through the aperture created through the drape. After verifying that the conduit **2104** has formed a fluid-tight seal against the disc **2103** and/or the flaps **2110**, negative pressure therapy may be applied until the wound has reached a desired stage of healing.

FIG. **22**A illustrates an embodiment of a negative pressure wound treatment system **2201** incorporating a suction port with a piercing attachment. The system **2201** comprises a port **2203** adapted for placement over a wound site, and more preferably over a drape situated over a wound site

prepared substantially in the same manner as previously described. The port **2203** preferably comprises an aperture **2218** for placement over a wound site, and this side of the port **2203** preferably comprises an adhesive layer **2216**, optionally protected with a backing layer and adapted to adhere to a drape or to patient skin. The port **2203** preferably also comprises a side aperture **2206** sized to permit a fluidic connector **2210** to be connected to it. Advantageously, some embodiments permit for the port **2203** to be of a relatively small size, such that smaller wounds may be effectively treated. In some embodiments, the connector **2210** may comprise a piercing end **2212**, where this piercing tip **2212** is sharpened or otherwise adapted to perforate a drape positioned over a wound site when pushed through the aperture **2206** so that the tip **2212** extends past the lower aperture **2218**. This tip **2212** may also be adapted to create a fluidic connection between a tube or conduit **2204** connected to it. The other side of the fluidic connector **2210** is preferably a blunter and shorter end **2214**. This end **2214** is preferably able to create a fluid-tight seal between the fluidic connector **2210** and the aperture **2206**, and preferably does not extend past the aperture **2218** when inserted into the aperture **2206**. Preferably, the port **2203** also comprises a controlled air leak **2216** similar to the embodiments previously described, and which may be provided with a filter **2217**.

In use, and with further reference to FIG. **22**B, a wound site may be prepared substantially in a manner previously described and sealed with a drape. The port **2203** may then be situated over an appropriate position over the drape, and then adhered to the drape. The piercing tip **2212** of the fluidic connector **2210** may then be pushed through the side aperture **2206** and past the bottom aperture **2218** so as to create an aperture in the drape positioned over the wound site. The connector **2210** may then be pulled out from the wound site and reversed so that the blunt end **2214** may then create a fluid-tight seal to the aperture **2206**. The piercing tip **2212** may then be connected to a tube **2204**, for example by slipping the end of the tube **2204** over the end **2212**, although other connection means are possible. A suction source may then be activated, and negative pressure is applied to the wound and wound exudates and other materials suctioned from the wound site until the wound has reached a desired level of healing.

FIG. **23**A illustrates a fluidic connector used in a negative pressure wound treatment system **2301**. This system **2301** preferably comprises a port **2303**, which may be shaped in a low-profile bridge shape with a flat side against a wound site. The port **2303** is preferably placed under a drape, with the drape sealed over it. Preferably, the port **2303** comprises at least one aperture **2306** on its wound-facing side, adapted to convey fluid away from a wound site and negative pressure to a wound site. The port **2303** may also be provided with a side aperture **2308** leading into a channel **2309**, where the channel **2309** connects to the aperture **2306**. The aperture **2308** and channel **2309** are preferably sized to receive a piercing fluidic connector **2310**. This connector **2310** may be provided with a piercing tip **2312** at its distal end, where the piercing tip **2312** is sharpened or otherwise designed to create an aperture through a drape placed over the port **2303** to permit a fluidic connection to be made between the connector **2310** and the port **2303**. Preferably, the port **2303** is constructed from a softer, more conformable material which may also serve to seal against the connector **2310** to aid in creating a fluid-tight seal. Some embodiments may provide for the connector **2310** to have a controlled air leak **2316**, which may also be provided with a filter or a one-way valve. The one-way valve may be designed to open only under high negative pressure. The connector **2310** preferably comprises an aperture on its underside (not illustrated) so as to create a fluidic connection between itself and the aperture **2306**. The proximal side **2314** of the fluidic connector is preferably constructed so as to be able to attach or connect a tube or conduit **2304** to it, where the tube **2304** is connected to a source of negative pressure.

FIG. **23**B illustrates a method of using the system **2301** described above.

FIGS. **24**A-B illustrate an embodiment of a negative pressure wound treatment system **2401** which comprises a port **2405** situated under a drape **2403** pierceable by a piercing fluidic connector **2410**. The port **2405** is preferably situated over a wound site in need of treatment, and sealed under a drape **2403**, although certain embodiments may instead provide for this port **2405** to be provided with adhesive means enabling it to be situated over an aperture made in a drape **2403**. The port **2405** preferably contains at least one large aperture **2406** on its wound-facing side permitting the application of negative pressure to the wound and the removal of exudate from the wound site, in addition to two side ports **2420**, **2422**. The system **2401** preferably comprises a piercing fluidic connector **2410** provided with piercing tips **2412**, **2413** able to pierce through the drape **2403** so as to fluidically connect to apertures **2420**, **2422**. One tip, illustrated for example here as tip **2412**, may be used to create a fluidic connection from a tube or conduit **2404** through to the aperture **2420**, where the tube **2404** is connected to the fluidic connector **2410** through hose fitting **2418**. Another tip, illustrated for example as tip **2413**, may serve as to create a conduit suitable for a controlled air leak **2415** through the aperture **2422** similar to those previously described. An air filter **2416** may optionally be provided.

FIGS. **25**A-B illustrate an embodiment of a wound treatment system **2501** comprising a drape **2503** with a manifold **2520** integrated therein. In certain embodiments of the system **2501**, a drape **2503** is provided which is trimmable and may be sealed over a wound site. A manifold **2520** may integrated or attached over a portion of the drape **2503** preferably the section of the drape **2503** which is to be placed over a wound site to be treated—and the manifold **2520** may contain multiple apertures or perforations suitable for channeling suction to the wound site and for suctioning away exudate and other fluids from the wound site. Preferably, a controlled air leak **2514** is provided that is in fluid communication with the wound site, and may for example be located in the middle of a loop that may be formed with the manifold **2520** around a wound site. This air leak preferably comprises a filter **2515**. The manifold **2520** is preferably connected to a fluidic connector **2510**, which may be used to connect to a tube or conduit **2504**.

FIGS. **26**A-B illustrate an embodiment of a negative pressure wound treatment system **2601** of a similar construction to the embodiments illustrated in FIGS. **25**A-B, but with an air leak **2614** provided on a fluidic connector **2610** rather than being formed in a central aperture. A manifold **2620** is preferably integrated or attached to the drape **2603**, preferably in a semi-circular or looped configuration, with perforations or apertures suitable for conveying negative pressure and/or exudate from the wound site. This manifold **2620** is preferably connected to the fluidic connector **2610** so as to fluidically connect the wound site with a tube or conduit **2604** connected to a source of negative pressure. A second manifold **2621**, connected to the air leak **2614**, is preferably arranged in a similar semi-circular or looped arrangement around the manifold **2620**, and permits air from

the outside environment to enter into the wound site. Preferably, the air leak **2614** is protected with a filter **2615** to prevent outside contaminants from entering the wound site. In a similar fashion to the embodiment described in FIGS. **25**A-B, the drape **2603** may be trimmable for sizing purposes and may be sealed over a wound site.

FIGS. **27**A-C illustrate an embodiment of a negative pressure wound treatment system **2701** comprising a conformable wound drainage device with separate controlled air leak paths. In a preferred embodiment, a drape **2703** is provided with a conformable suction bridge **2712** preferably constructed from a fluid-impermeable material **2722**. The bridge **22712** is preferably filled with a fluid-channeling material **2720**, for example open-celled foam, that is at least partly resistant to occlusion due to pressure or kinking. The bridge **2712** may be bonded to or integrated with the drape **2703**, or may be attached using any suitable means. The bridge **2712** is preferably provided with one or more apertures on its wound-facing side to permit wound exudate to be drawn away from the wound site using a source of negative pressure. The source of negative pressure is connected to the system **2701** through a conduit **2704** attached to a fluidic connector **2710** connected to the bridge **2712**. A controlled air leak **2714** may also be provided at a location separate from the bridge **2712**, with one or more air channels **2716** connecting to one or more apertures **2718** located near the wound site. Preferably, the air leak **2714** is provided with a filter **2715**.

FIGS. **28**A-B illustrate embodiments of a negative pressure wound treatment system **2801** comprising a controlled air leak **2814** integrated into a portion of a suction head **2805**. The air leak **2814** causes air to be drawn into the suction head **2805**, aiding in suctioning exudate from the wound site through the aperture or apertures **2806** disposed on the wound-facing side of the suction head **2805**. Similarly to other embodiments, a fluidic connector **2810** provides a connection between a tube or conduit **2804** leading to a source of negative pressure and the suction head **2805**. Preferably, the suction head **2805** has a layer of adhesive on its wound-facing side to permit attachment over an aperture made on a drape **2803** situated over a wound site. Other embodiments may instead provide for the drape **2803** to be integrated or attached to the suction head **2805** with a pre-formed aperture to be situated over the wound site.

FIGS. **29**A-B illustrate embodiments of a negative pressure wound treatment system **2901** comprising a distributed negative pressure manifold. The system **2901** comprises a suction tail **2905** connected or attached to a suction head **2908**, where the head **2908** comprises one or more projections **2910** extending outwardly from the center of the head **2908**. As illustrated in this particular embodiment, several projections **2910** may form a web or starburst configuration, although other configurations are also possible, and may include further interlinking of the projections **2910**. Each projection **2910** preferably comprises a central channel **2912** extending along the length of the projection **2910** and connected in the center of the suction head **2908**. The channel **2912** is preferably connected to one or more apertures **2906** disposed along its length and suitable for suctioning wound exudate from a wound site. Preferably, a centrally-located controlled air leak **2914** communicating with the wound site is present, with a filter **2915** to keep particulates and other contaminants from entering the wound site. The filter **2915** may be constructed from any suitable material, for example Gore-Tex®. In some embodiments, at least a portion of the tail **2905** may be provided with a layer of adhesive on its wound-facing side, which can serve to better adhere to patient skin and seal the wound site.

In use, and with continued reference to FIGS. **29**A-B, a wound site is prepared and cleaned in substantially the same way as described previously. The suction head **2908** is then trimmed as necessary to fit the wound site; the trimming may include cutting through the projections **2910**. If so provided, an adhesive protective layer may be removed from the wound-facing side of the tail **2905** to adhere against the patient skin. Subsequently, a drape **2903** may be placed over the suction head **2908** and sealed to the skin surrounding the wound. A conduit **2904** connected to a source of negative pressure is then connected to the tail **2905**, thus applying negative pressure to the wound site. When used, the head **2908** may be designed so that the drape **2903** seals against all or part of the open ends of the channels **2912** in the projections **2910** when the head **2908** is trimmed.

FIGS. **30**A-B illustrate an embodiment of a wound treatment system **3001** provided with a piercing nozzle **3010**. Here, certain embodiments provide for the piercing nozzle **3010** to be mounted or attached to a plate **3008**, where the plate **3008** is preferably perforated so as to effectively serve as a distribution manifold for negative pressure to the wound site and as a conduit to channel exudates away from the wound site. In certain embodiments, multiple piercing nozzles **3010** may be provided, and which may be distributed over the plate **3008**. The piercing nozzle is preferably designed to have a sharp edge suitable for piercing a drape, for example a drape **3003** placed over a wound site and over the piercing nozzle **3010** and plate **3008**, and the nozzle **3010** is also preferably comprises a conduit or channel therein suitable for conveying fluid and/or negative pressure. In a preferred embodiment, a suction head **3005** is provided with at least one aperture **3006** disposed on its wound-facing side. In some embodiments, an adhesive layer may be provided on the wound-facing side of the head **3005** suitable for securing the head **3005** to the drape **3003**. In additional embodiments, the drape **3003** may be mechanically fastened to the head **3005** by means of features incorporated on the wound-facing side of the head **3005** suitable for mechanical fastening of the head **3005** to the drape **3003**. The aperture **3006** may be designed so as to receive at least part of the piercing nozzle **3010**, so as to create a fluidic connection between a wound site and a source of negative pressure connected to the head **3005** through the piercing nozzle **3010** and the aperture **3006**. Some embodiments may also provide a controlled air leak **3014** optionally provided with a filter and integrated into the drape **3003**; preferably, this air leak **3014** is located in a region in close proximity to the plate **3008**.

With continued reference to FIGS. **30**A-B, in use a wound site is prepared substantially as described previously. The plate **3008** is preferably placed over the wound site area, with the piercing nozzles **3010** facing upward. The drape **3003** is then placed over the wound site and over the plate **3008**, and then sealed to the skin surrounding the wound site. Subsequently, the suction head **3005** is pressed over the nozzles **3010**, causing the nozzles **3010** to pierce the drape **3003** and be received into the aperture **3006**. The wound site is then connected to a source of negative pressure and treated until the wound has attained a selected stage of healing.

FIGS. **31**A-B illustrate an embodiment of a negative pressure treatment system **3101** comprising a suction port which shares some similarities with the embodiments described in FIG. **22**. In a preferred embodiment, the system **3101** comprises a suction port **3105** integrated with a drape **3103**. The port **3105** is preferably constructed from a section

of foam or other porous material, with its outside surface surrounded by a semi-rigid plastic. In some embodiments, the drape **3103** may be provided pre-attached to the port **3105**, for example by adhering the port **3105** onto the top side of the drape **3103**, or by attaching the port **3105** to the around and to bottom side of the drape **3103**. The port **3105** preferably comprises a controlled air leak **3114** which communicates to the interior of the port **3105**. The port **3105** may also comprise an aperture **3106** able to receive a connector **3110** and/or a tube or conduit **3104**. Preferably, this aperture **3106** is sealed with, for example, a thin layer of plastic that can be perforated with a connector **3110**. The connector **3110** is preferably designed with a sharp tip able to pierce a layer of plastic disposed over the aperture **3106**, and is able to create a fluid-tight seal between itself and the aperture **3106**, for example by means of barbs **3111**. A removable flap **3116** may also be attached to the port **3105** and made to overlay the aperture **3106** so as to protect the aperture **3106** from damage during handling. The flap **3116** may also be pulled during insertion of the connector **3110** to as to place the drape **3103** under tension and facilitate its perforation. To prevent the connector **3110** and/or tube **3104** from projecting past the port **3105** and possibly disturbing the wound site, a plate **3107** may be attached or formed with the port **3105**. The plate **3107** is preferably constructed from a resilient, harder material such as a plastic and capable of resisting piercing when pushed by the connector **3110**. In order to channel wound exudate from the wound site, the plate **3107** preferably comprises one or more apertures **3108**.

FIGS. **32**A-K illustrate embodiments of a negative pressure system **3201**. Here, the system **3201** comprises a port **3203** with a layer of adhesive **3205** disposed on its underside. This adhesive layer **3205** may be placed over an aperture **3207** on a drape **3202** placed over a wound to secure the port **3203**. Alternatively, the port **3203** may be adhered or welded to a smaller drape, optionally provided with a further adhesive layer. In some embodiments, this port **3203** may be relatively small, for example 17 mm across, although other sizes may also be appropriate. The port **3203** may be provided with a through opening **3209**, preferably located on a vertical axis; this opening **3209** may also be provided with a removable cover **3210**, which can in turn also function as a controlled air leak **3212**. Preferably, the air leak **3212** comprises a filter **3213** to prevent contaminants from entering the wound. The opening **3209**, preferably when in a vertical configuration, can be designed to accommodate a cutting tool **3215** designed to pierce an underlying drape. The port **3203** is also provided with a connection port **3217** to which a tube **3204** may be connected. In some embodiments, the tube **3204** is pre-assembled to the connection port **3217**.

In use, after adhering the port **3203** over a drape placed over a wound, the removable cover **3210** is removed, and the cutting tool **3215** is pushed through the opening **3209** so as to pierce the drape. The cover **3210** is replaced and the tube **3204** is connected (if necessary) to the port **3203** and then connected at its downstream end to the source of negative pressure.

FIGS. **33**A-H illustrate embodiments of a negative pressure treatment system **3301** provided with a template **3305**. This template **3305** is preferably provided with a double-sided adhesive layer **3306** on its bottom-facing side, and comprises one or more cutting guides **3307**. These guides **3307** may, for example, be in the shape of a cross as illustrated, or may take other forms. The system **3301** also comprises a port **3309** which is preferably of a similar size and shape to the template **3305**, and which may have a tube **3304** pre-attached to itself. Obviously, some embodiments may instead provide for detachable tube **3304**. In one non-limiting embodiment, the port **3309** measures approximately 25 mm across.

In use, the template **3305** is used to guide and control the size of the drape incision. It is placed over a drape **3311**, preferably by adhering the bottom-facing side of the double-sided adhesive layer **3306** to the drape **3311** (an optional release layer **3312** may also be present). Subsequently, an incision is made through the cutting guides **3307** into the drape **3311** to create an aperture sufficient for a fluidic connection. Subsequently, the template **3305** is peeled away from the double-sided adhesive layer **3306** (optionally with the aid of a tab **3313**) to reveal a top-facing layer of adhesive upon which the port **3309** may then be attached. Optionally, the double-sided adhesive layer **3306** may be pigmented to allow the user to easily align the port **3309** on the adhesive layer **3306**. Alternatively, the port **3309** may be adhered or welded to a smaller drape, optionally provided with a further adhesive layer, and which may then be placed over the aperture formed under the adhesive **3306**. Treatment of the wound then proceeds in a similar fashion as to the other embodiments previously described. An advantage of this cutting template **3303** is that the drape aperture size may be controlled so as to permit the use of a smaller port **3309**, and which may be advantageous in treating smaller wounds.

FIGS. **34**A-H illustrate embodiments of a negative pressure treatment system **3401** comprising a port **3403** including a protruding channel **3405** disposed on its underside. The channel **3405**, and optionally part or the remainder of the port **3403** may be constructed from a soft and pliable material, including gels, foams, and combinations thereof such as silicone, polyurethane, polyethylene, polyvinyl chloride, and other plastics. The protruding channel **3405** may be useful in properly positioning the port **3403** over an aperture made into a drape **3413**, and the preferably soft and conformable material used to construct it minimizes pressure damage caused by the port and/or channel pressing onto the wound. In some embodiments, the port **3403** measures approximately 17 mm across, although larger or smaller sizes may be used. A layer of adhesive **3407** with an optional release layer **3409** are preferably provided on the underside of the port for attachment to a drape, and the port **3403** should also comprise an opening **3411** so as to permit connection of a tube **3404**. In an alternative embodiment, the port **3403** may be adhered or welded to a smaller drape, optionally provided with a further adhesive layer.

In FIGS. **35**A-H, embodiments of a negative pressure system **3501** comprise a port **3503** attached to a drape strip **3505**. The port **3503** is preferably constructed from a soft, conformable material, and includes an attachment port **3507** for a tube **3504** to be connected thereto. The underside of the drape strip **3505** has a layer of adhesive **3509**, optionally covered by a release layer **3510**. In use, the drape strip **3505** is adhered directly over a prepared wound, without the use of an additional drape, but with the wound preferably filled with a wound-packing material. If no wound packing material is used, then the adhesive **3509** is preferably chosen to be minimally adherent to wound tissue but sufficiently adherent to the skin surrounding the wound, for example a water-soluble acrylic adhesive, such that a fluid-tight seal may be made. After placing the initial drape strip **3505** over the wound, additional drape strips **3506** (typically not provided with a port) are placed in an overlapping fashion over the wound so as to create a fluid-tight seal over the entire wound. If necessary, the drape strips **3505** and **3506** are trimmed to fit. Subsequently, the tube **3504** is connected to

a source of negative pressure and treated in a fashion as previously described, with wound exudate being carried through an aperture **3508** situated on the underside of the drape strip **3505** and communicating with the port **3503**. In some embodiments, the drape strip **3505** and/or the additional drape strips **3506** measure approximately 20 mm across, although other sizes may be used.

FIGS. **36**A-I illustrate embodiments of a negative pressure treatment **3601**. Here, a drape **3603** is provided with one or more premade drainage channels **3605** leading to a drainage hole **3607** preferably centrally-located on and going through the drape **3603**. The drape **3603** is provided with a layer of adhesive on its underside, optionally protected by a release layer **3610**. In one non-limiting embodiment, the drape measures approximately 100 mm on one side. The drainage channels **3605** run from the edge of the drape **3603** to the drainage hole **3607**, and are dimensioned so as to permit a tube **3604** to be slid into them so as to create a fluidic connection with the drainage hole **3607**. Preferably, several drainage channels **3605** are provided, with these channels **3605** facing different directions on the drape **3603** so as to permit a tube **3604** to be connected from different directions. For example, four drainage channels **3605** may be provided at right angles to each other as illustrated. Of course, other arrangements are possible, such as a "starburst" configuration with more drainage channels **3605**. Preferably, the drainage channels are constructed so as to remain sealed until a tube **3604** is inserted into them.

In FIGS. **37**A-G, embodiments of a negative pressure treatment system **3701** are shown, the system **3701** comprising a drape **3703** and a port **3705** connected to a tube **3704**. Here, the drape **3703** is preferably constructed from a material provided with miniature, self-sealing openings **3707**. These openings **3707** may be molded or cut into the drape **3703**, and are ordinarily fluid-tight. The underside of the drape **3703** as well as the underside of the port **3705** may be provided with a layer of adhesive covered by an optional release layer **3709**. In an alternative embodiment, the port **3705** may be adhered or welded to a smaller drape, optionally provided with a further adhesive layer. Under the application of negative pressure, for example through the port **3705**, these openings **3707** open so as to permit the transmission of negative pressure from the port to the wound space beneath the drape. In other embodiments, the openings **3707** may act as one-way valves. This drape **3703** has several advantages, such as not requiring a separate aperture to be cut into the drape **3703**, while also permitting the port **3705** to be positioned at any appropriate location on the drape **3703**. In some embodiments, the port **3705** measures approximately 25 mm across.

FIGS. **38**A-I illustrate embodiments of a negative pressure treatment system **3801** which comprise a bayonet connection between a ring **3803** and a port **3805**. The port **3805** has one or more tabs **3807** which mate into a corresponding recess **3808** located on the ring **3803**, which in some embodiments may have a diameter of approximately 35 mm. The ring **3803** also includes a groove (not illustrated) adjoining the recess **3808** and configured to receive the tab(s) **3807** and thus create a fluid-tight connection. The ring **3803** preferably comprises an adhesive layer disposed on its underside (optionally protected by a release layer **3811**), which may be used to secure it to a drape. In an alternative embodiment, the ring **3803** may be adhered or welded to a smaller drape, optionally provided with a further adhesive layer. The port **3805** has a connector **3809** configured to connect to a tube **3804**. In use, the ring **3803** is placed and preferably adhered over an incision **3812** made on a drape **3813** placed over a wound. Subsequently, the port **3805** is positioned over the ring **3803** so that the tab **3807** may fit into the recess **3808**. Once so positioned, the port is rotated, for example by from 30 to 90.degree., so that the tab **3807** slides into the groove adjoining the recess **3808** so as to create a fluidic seal. The user may therefore choose the orientation in which the tube connector **3809** points irrespective of the orientation of the ring **3803**.

Turning now to FIGS. **39**A-B, one embodiment of a negative pressure treatment system **3901** uses a low-profile port **3903** configured to attach to a one-way valve **3905** (which can for example be a reed or flap valve) attached to a drape **3907**. In some embodiments, the one-way valve **3905** may be pre-attached to the drape **3907** prior to placing it over a wound. In other embodiments, the valve **3905** is attached onto the drape **3907** after the drape has been placed over the wound and an incision or aperture made into it, or else the valve **3905** in incorporated into a port that is provided pre-attached or welded to a drape. The port **3903** preferably comprises one or more air leaks **3909**, which are of a similar design to those illustrated in other embodiments herein. A tube **3904** may be attached to the port **3903**.

FIG. **40** illustrates an embodiment of a negative pressure treatment system **4001** that is somewhat similar in operation to the embodiment illustrated in FIGS. **24**A-B. Here, a low-profile fluidic connector **4003** may be slid under a drape **4005** situated over a wound. The connector **4003** comprises a suction head **4007** at its distal end, and has an adaptor **4009** at its proximal end configured to connect to a tube **4004**. At the boundary of the drape an air leak filter **4011** may be placed next to the connector **4003** to permit for controlled air flow into the wound space. The filter **4011** may either be attached to the connector **4003** to allow for air flow into the interior channel of the connector **4003** or else may be configured to let air into the wound space without going through the connector **4003**. In an alternative embodiment, the fluidic connector **4003** may be adhered or welded to the drape **4005** prior to use.

FIG. **41**A illustrates an embodiment of a negative pressure treatment system **4101** comprising a suction adapter **4103** placed underneath a drape **4105**. The suction adapter **4103** comprises a plurality of tubes **4106** so as to create a suction manifold that may be useful in distributing negative pressure while reducing the overall height of the adapter **4103**, a useful aspect for low-profile conformable suction adapters. At the proximal end of the adapter **4103**, a converging point **4107** connects to all of the tubes **4106** and connects to a single tube **4104** connected to a source of negative pressure. In some embodiments, an air leak **4109** may be provided on the adapter **4103**, for example over the converging point **4107**. Preferably, a seal **4111** can be provided at the junction where the tubes **4106** meet the drape **4105**. Such a seal **4111** may be either integrated onto the tubes **4106**, either in a fixed or slideable configuration, or else placed separately. The material used for the seal **4111** may be a closed-cell foam wedge, but any material capable of creating a fluid tight seal can be used. FIG. **41**B illustrates a section taken along the line A-A illustrating how in some embodiments, the tubes **4106** can be of a very low height, which may be advantageous for example in minimizing patient discomfort. In some embodiments, the seal **4111** and the tubes **4106** are attached or welded to the drape **4105** to form a single unit.

In FIGS. **42**A-B, an embodiment of a negative pressure treatment system **4201** comprises a drape **4203** with an aperture **4205** integrated into it. The aperture **4205** has an area **4206** coated with a layer of adhesive and may optionally be protected by a release layer **4207**. The aperture **4205**

may also comprise a controlled air leak **4209**, preferably provided with a filter to prevent entry of pathogens and contaminants. A port **4211** is also part of the system **4201**, and may comprise a connector **4212** to connect to a tube **4204**. On the underside of port **4211**, an adhesive layer optionally protected by a release layer **4213** may also be present. In use, the drape **4203** is placed over a wound with the aperture **4205** preferably located in a central position. Subsequently, the release layer **4207** is removed to expose an adhesive layer. Next, the port **4211**, optionally following the removal of a release layer **4213**, is adhered to the area **4206** so as to create a fluidic connection between the port **4211** and the aperture **4205**.

FIGS. **43**A-B illustrate an embodiment with a piercing point sharing some similarities to the embodiment described in FIGS. **13**A-B. Here, an embodiment of a negative pressure treatment system **4301** comprises a port **4303** provided with one or more piercing tips **4305**. Preferably, this piercing tip **4305** is located on the top inner surface of the port **4303** over an aperture **4307**. In use, the application of vacuum through a tube **4304** to the port **4303** draws a portion **4309** of a drape **4308** placed over a wound into the aperture **4307**. The piercing tip **4305** then pierces the drape portion **4309** so as to create a fluidic connection between the wound space and the source of negative pressure so as to permit wound exudate to be removed from the wound. Other aspects of the port **4303** are similar to embodiments described elsewhere herein, and the port may comprise a controlled air leak **4311** and a layer of adhesive **4312** disposed on the underside of the port **4303**.

FIGS. **44**A-B illustrate an embodiment of a negative pressure treatment system **4401** comprising a drape **4403** with an integrated suction port **4405**. Here, the suction port **4405** is preferably constructed of a soft, conformable material which may in some embodiments be the same as the material used in the drape **4403**. There is preferably a layer of adhesive disposed on the underside of the drape **4403** so as to permit adherence to the skin surrounding the wound. The port **4405** may be constructed separately and adhered or welded to the drape **4403**, or in other embodiments the port **4405** may comprise a channel integrated onto the drape **4403** so as to form a single unit. At the proximal end of the port **4405**, a connector **4406** is preferably provided so as to permit the connection of a tube **4404** to the system **4401**. The drape **4403** may also comprise an air channel **4407** to permit air to enter the dressing, preferably at a controlled rate. This air channel **4407** can also comprise a filter to prevent contaminants from entering the wound.

In FIGS. **45**A-C, an embodiment of a negative pressure treatment system **4501** comprises a drape **4503** with a port **4505** integrated thereto. The drape **4503** may also comprise cross-linked air channels **4507**; such channels **4507** communicate with the wound space below the drape **4503** (for example via through holes **4508**) so as to permit a controlled air flow rate to the wound. The edges of the drape **4503** provide openings for the cross-linked air channels **4507**, and the drape **4503** may be cut to size without significantly interfering with the function of the air channels **4507**. In some embodiments, however, it may be advantageous to use a filter or filtering element in conjunction with the air channels **4507** to prevent contaminants from entering the wound space. Preferably, an adhesive layer is disposed underneath the drape **4503**. In one embodiment, the port **4505** comprises a domed portion **4509** approximately centered on the drape **4503**. This domed portion **4509** forms a channel for the evacuation of wound exudate together with an elongated portion **4512**, which communicates to a fluidic adapter portion **4513** connecting to a tube **4504**. As with other embodiments described herein, the port **4505** is preferably constructed from a soft, conformable material (while being able to maintain patency sufficient to draw out fluid under negative pressure), and may be either integrated to the drape **4503** as a single unit (e.g., by molding) or constructed from multiple pieces later attached or joined together.

FIGS. **46**A-B illustrate an embodiment of a negative pressure wound treatment system **4601** that comprises one or more suction channels **4603** integrated into an impermeable cover **4605**. The one or more suction channels **4603** may enter into the cover **4605** to form a network of conduits surrounding a central air leak **4609**, preferably provided with a filter. Of course, alternative configurations are possible, such as a fan- or net-shaped system of channels **4603**, and the air leak **4609** may in some embodiments be omitted or placed in a different location. The channels **4603** converge onto a central collector **4607**, which connects to a tube **4604** that may be connected to a source of negative pressure. The cover **4605** is preferably constructed of a fluid-impermeable material, and is preferably sufficiently thick so as to be able to integrate the channels **4603** within itself. Preferably, a layer of adhesive is disposed on its underside. An example of a suitable material for the cover **4605** may include a closed-cell foam. In some embodiments, spaces may be made into the cover **4605** into which the channels **4603** connect to. In other embodiments, the channels **4603** continue into the cover **4605** and the cover **4605** is, for example, molded around the channels **4603**. In use, the system **4601**'s cover **4605** may be trimmed to size if necessary (while avoiding cutting through the channels **4603**) and placed over a wound site, optionally filled with a wound packing material, and adhered to the skin surrounding the site. Subsequently, a source of suction may be applied to the wound and exudates removed through the channels **4603**.

Turning now to FIGS. **47**A-B, an embodiment of a negative pressure treatment system **4701** comprises a low-profile suction unit **4703** covered with a membrane **4707**. In some embodiments, the suction unit **4703** may be constructed from open-cell foam. Embedded within the suction unit **4703** is a tube **4704**. This tube **4704** may be fenestrated or perforated so as to help prevent clogging and apply suction over a larger area. The tube **4704** passes through an impermeable section **4705**. This impermeable section **4705** may be constructed, for example, from a closed-cell foam, and is attached to the suction unit **4703**. In some embodiments, the impermeable section **4705** may be molded around the tube **4704**. Although the tube **4704** may be connected directly to a source of negative pressure, it may in some embodiments be advantageous to provide a connector situated proximally to the tube **4704** to permit connection of another tube in communication with a source of negative pressure. The membrane **4707** may be constructed in several parts, or may be one large sheet. Preferably, it is provided with a layer of adhesive on its underside, optionally protected by a release layer **4709** which covers the portions of adhesive not secured to the suction unit **4703** and/or the impermeable section **4705**. In use, the system **4701** may be positioned over a wound, optionally filled with packing material. Then, the release layer **4709** is removed so as to permit the membrane **4707** to be adhered to the skin surrounding the wound. Negative pressure is then applied to the wound through the tube **4704**.

FIGS. **48**A-E illustrate an embodiment of a negative pressure treatment system **4801** comprising a flexible suction adapter sheet **4803** capable of being packed into a wound space. The sheet **4803** preferably comprises a larger,

planar section **4805** at its distal end, connected to a tail portion **4806** at its proximal end. At the proximal end of the tail portion **4806**, a connector **4807** may be provided to permit a tube **4804** to be connected thereto. The planar section **4805** may be comprised of two layers: a bottom layer **4810** and a top layer **4811**. The bottom layer **4810** comprises one or more perforations **4812** that face toward the wound so as to collect wound exudate and distribute negative pressure to the wound. The top layer **4811** comprises a network of channels **4813** communicating with the perforations **4812**, and fluidically link to the source of negative pressure so as to channel wound exudate to the source of negative pressure. In some embodiments, the channels **4813** form an interconnected network (such as in a grid configuration), which may be advantageous in preventing clogging and permitting negative pressure to be distributed to the entire bottom layer **4810** in spite of folding that may occur when the portion **4805** is placed within a wound. In some embodiments, the tail portion **4806** can comprise a layer of adhesive on its wound-facing side, which may be useful in forming a seal with the underlying skin. The sheet **4803** may also be covered with a flexible drape **4815** to provide an additional, substantially air-tight seal over the wound.

In use, a wound is cleaned, and the planar section **4805** is inserted into the wound so as to function as a wound packing material. Preferably, the bottom layer **4810** is placed facing into the wound. Subsequently, the tail portion **4806** may be adhered to the skin surrounding the wound. A drape **4815** is then placed and sealed over the entire wound, followed by connecting the tube **4804** to a source of negative pressure.

In FIGS. **49**A-B, a negative pressure treatment system **4901** may comprise a wound packing pouch **4903** used with a port **4905** and a drape **4907**. The pouch **4903** is a flexible pouch that may be filled with a conformable filler **4909**, for example granular beads, and may be placed into the wound space as a filler. The pouch **4903** also comprises a semi-permeable or perforated membrane **4910** containing the filler **4909**. In use, different size pouches **4903** may be supplied, or multiple pouches **4903** may be used to fill the wound space as desired. The port **4905** is similar to other ports described herein, and comprises a distal head portion **4913** designed to be placed in contact with the pouch **4903** so as to evacuate wound exudate and communicate negative pressure to the pouch **4903**. In an alternative embodiment, this port **4905** may be adhered or welded to a smaller drape, optionally provided with a further adhesive layer. At the proximal end of the port **4905** is a connector **4915** configured to connect to a tube **4904**. In some embodiments, this connector **4915** may comprise a piercing or chisel tip configured to pierce through the drape **4907**, which may be advantageous in making an easier connection to the tube **4904**. The drape **4907** may be provided with an adhesive layer on its wound-facing side, and provides an essentially fluid-tight seal over the wound space and over the pouch **4903**. In some embodiments, the drape **4907** may be provided with a controlled air leak **4917**, optionally protected with a filter, designed to permit a controlled amount of air into the wound.

FIGS. **50**A-C illustrate embodiments of a negative pressure treatment system **5001** comprising a sealing port **5003**. Here, the port **5003** comprises a distal head portion **5005** and a proximal tail portion **5006**. The tail portion **5006** includes a connector **5007** configured to connect to a tube **5004**. The head portion **5005** comprises an outer vacuum ring **5009**; this ring **5009** may in some embodiments be used to seal the port **5003** against the skin surrounding a wound, and may be useful in smaller-sized wounds that the ring **5009** is able to circumscribe. In other embodiments and for larger wounds, a drape may be used in a manner similar to other embodiments described herein. In use, a slot **5011**, or a series of apertures on the underside of the ring **5009** permits negative pressure transmitted into the ring **5009** to seal the ring **5009**—and thus the entire port **5003**—against the skin of a patient. The head portion **5005** also comprises a central region **5011** that applies a portion of the vacuum from the vacuum source to the wound and evacuates wound exudate (the remainder of the vacuum is applied to the skin surrounding the wound by the ring **5009**). Here, the region **5011** may also comprise an air leak **5013**, for example disposed centrally and with an optional air filter **5014**. In some embodiments, a separate channel **5015** may be present to channel the air drawn into the wound and port **5003** downward and into the wound space. Preferably, such a channel **5015** is configured to make contact with any wound packing material placed into the wound.

FIGS. **51**A-B illustrates an embodiment of a negative pressure wound treatment system **5101** comprising a low-profile suction adapter **5103** configured to be placed over a wound. The suction adapter **5103** preferably comprises a vacuum portion **5105** and a controlled air leak portion **5106**, wherein both of these portions **5105**, **5106** are preferably constructed of a flexible, soft material capable of transmitting air and fluid flow through themselves. Examples of such materials may include open-cell foams. The entire suction adapter **5103**, including the portions **5105**, **5106**, is preferably covered on its upper portions with a liquid-impermeable membrane **5108**. The vacuum portion comprises at its proximal end a connector **5107** for connecting to a tube **5104**. The controlled air leak portion **5106** preferably comprises an open end **5109** not covered by membrane **5108** so as to permit a flow of air into the adapter **5103**. Preferably, a filter is disposed over this end **5109** to prevent the entry of contaminants into the wound space. In this embodiment, strips of tape **5111** are used to seal the edges of the membrane **5108** against the skin of a patient. In other embodiments, some or all of the underside of the **5108** may be covered in a layer of adhesive. Preferably, the system **5101** is used on a wound that has been filled with a wound packing material such as foam or gauze.

In FIGS. **52**A-B, a negative pressure treatment system **5201** comprises a bladder **5203** in combination with a suction adapter sheet **5205** and a drape **5207**. The bladder **5203** may be filled with a fluid such as air or water, and may be secured to the wound for example by straps **5209**, although other means sufficient to apply positive pressure on the wound may be used. Under the bladder **5203** is the drape **5207**, which is preferably liquid-impermeable and coated with a layer of adhesive on its wound-facing side. The suction adapter sheet **5205** is below the drape, and may be of a type similar to the embodiment described in FIG. **48**A. Preferably, this sheet **5205** comprises one or more conduits configured to channel wound exudate toward a source of negative pressure while distributing negative pressure over the entire wound area. The proximal portion **5206** of the sheet **5205** may comprise a connector **5210** suitable for connecting to a tube **5204**. Optionally, the space below the suction adapter sheet **5205** is filled with a wound packing material such as an open-cell foam. Such a wound treatment system **5201** may be beneficial for use on wounds that require additional positive pressure upon the wound bed. Additionally, use of an embodiment with the straps **5209** may be beneficial for use in particular on the legs and arms of a patient.

FIGS. **53**A-D show variations of the bladder system described in FIG. **52**A. Here, the negative pressure wound treatment system **5301** comprises a bladder **5303** placed underneath a drape **5305**. The bladder **5303** may be filled with a fluid such as saline solution, although other fluids such as air may be used. In some embodiments, a layer of wound contacting material **5307** may be placed in contact with the wound. This wound contacting material **5307** may be foam, gauze, or other suitable materials. Preferably, this material **5307** forms a thin layer and is pushed into contact with the wound. Subsequently, the bladder **5303** is placed into the wound so as to fill the remainder of the wound space. The drape **5305** is then placed over the bladder **5303** and wound contacting material **5307** and sealed to the skin surrounding the wound. An aperture **5309** may then be made into the drape **5305** (although the drape may be provided with an aperture already made into it) over a portion of the wound where the wound contacting material **5307** is in contact with the drape **5305**, and a suction adapter **5311** placed over the aperture **5309**. Alternatively, the suction adapter **5311** may be adhered or welded to the drape **5305** or a smaller drape, optionally provided with a further adhesive layer. The adapter **5311** may be connected to a source of negative pressure via a tube **5304** connected to its proximal end. In some embodiments, the drape **5305** may also be provided with a controlled air leak **5313**, which is in some cases covered with a filtration element to prevent contaminants from entering the wound.

In FIG. **54**A, an embodiment of a negative pressure wound treatment system **5401** is illustrated that uses a wound packing material **5403** provided in discrete portions. The wound packing material **5403** may be supplied in the form of a roll **5405**, for example as illustrated in FIG. **54**B, and dispensed as necessary to fill a wound space; individual sections may be detached, or long sections may be packed into the wound. The wound packing material **5403** may be comprised of a porous material such as open-cell foam, or any other material capable of transmitting negative pressure to the wound site. The form of the wound packing material **5403** may be achieved by molding or heat-forming the material. Alternatively, it may be fabricated using nets or films to join the individual sections. In a further embodiment, the wound packing material **5403** may be molded from solid polymers, and channels may be formed onto the surface to allow removal of fluids from the wound tissue. After a wound is filled with the wound packing material **5403**, a drape **5407** (optionally provided with an integrated air leak **5408** similar to those previously described herein) is placed over the wound and sealed to the skin surrounding the wound. An aperture is then made into the drape **5407** sufficient to permit a port **5409** to be placed over it so that wound exudate may be removed from the wound site through a tube **5404** connected to the port **5409**. Alternatively, the port **5409** may be adhered or welded to a smaller drape, optionally provided with a further adhesive layer or else the drape **5407**.

FIGS. **55**A-J illustrate embodiments of a negative pressure wound treatment system **5501** similar to the embodiments illustrated in FIG. **15**A. Here, the system **5501** may comprise a bridge **5502** having a proximal end **5503** and a distal end **5505** and an applicator **5520** at the distal end **5505** of the bridge **5502** forming a flexible suction adapter. Preferably, the system **5501** is constructed in a similar fashion to the system **1501**, and may comprise a bridge **5502** constructed from a similar dual layer arrangement as previously described. A connector **5504** is preferably disposed at the proximal end **5503** of the bridge **5502**, so as to connect to at least one of the channels **5512** and/or **5516**, as shown in FIG. **55**D. A cap **5536** may be provided with the system **5501** (and can in some cases, as illustrated, be attached to the connector **5504**). The cap **5536** can be useful in preventing fluids from leaking out of the proximal end **5503**. The system **5501** may include a source of negative pressure such as a pump or negative pressure unit **5534** capable of supplying negative pressure. The pump also preferably comprises a canister or other container for the storage of wound exudates and other fluids that may be removed from the wound. In some embodiments, this pump **5534** can be a RENASYS GO pump, as sold by Smith & Nephew. The pump **5534** may be connected to the connector **5504** via a tube **5540**. In use, the applicator **5520** is placed over an aperture **5535** formed in a drape **5531** that is placed over a suitably-prepared wound **5530**, which may in some cases be filled with a wound packing material such as foam or gauze. Subsequently, with the pump **5534** connected via the tube **5540** to the connector **5504**, the pump is activated, thereby supplying negative pressure to the wound. Application of negative pressure may be applied until a desired level of healing of the wound **5530** is achieved.

Here, and with particular reference to FIGS. **55**C-D, the system **5501** may comprise a bridge **5502** having a proximal end **5503** and a distal end **5505** and an applicator **5520** at the distal end **5505** of the bridge **5502**. In some embodiments, the bridge **5502** may comprise an upper channel layer **5512** positioned between an upper layer **5510** and an intermediate layer **5514**, with a lower channel layer **5516** positioned between the intermediate layer **5514** and a bottom layer **5518**. Preferably, the layers **5510**, **5514**, and **5518** have elongate portions extending between proximal and distal ends and may be comprised of a material that is fluid-impermeable, for example polymers such as polyurethane. It will of course be appreciated that the layers **5510**, **5514**, and **5518** may each be constructed from different materials, including semi-permeable materials. As illustrated in FIG. **55**D, the upper and lower layers **5510** and **5518** may be curved, rounded or outwardly convex over a majority of their lengths. During assembly, for example, the layers **5510**, **5514**, and **5518** may be pinched together to weld or adhere the layers together. In doing so, the proximal ends of the channels **5512** and **5516** may be sandwiched between these layers, thus partially compressing the proximal ends of the channels **5512**, **5516** and stretching the layers **5510**, **5514**, **5518** over these aforementioned proximal ends. Of course, the proximal ends of the materials used in the bridge section **5502** may not necessarily be rounded or curved; as shown in FIG. **55**J, they can remain substantially squared off and straight.

Similarly to the embodiment described in FIG. **6** with regards to the spacer **609**, the upper and lower channel layers **5512** and **5516** are preferably elongate layers extending from the proximal end **5503** to the distal end **5505** and may each preferably comprise a porous material, including for example open-celled foams such as polyethylene or polyurethane. In some embodiments, one or more of the upper and lower channel layers **5512** and **5516** may be comprised of a fabric, for example a knitted or woven spacer fabric (such as a knitted polyester 3D fabric, Baltex 7970®, or Gehring 879®) or a nonwoven material. Suitable materials may also include terry-woven or loop-pile materials. The fibers may not necessarily be woven, and can include felted and flocked (including materials such as Flotex®) fibrous materials. The materials selected are preferably suited to channeling wound exudate away from the wound and for transmitting negative pressure and/or vented air to the

wound site, and may also confer a degree of kinking or occlusion resistance to the channel layers **5512** and **5516** as described below. In one embodiment, the upper channel layer **5512** may comprise an open-celled foam such as polyurethane, and the lower channel layer may comprise a fabric as described herein. In another embodiment, the upper channel layer is optional, and the system may instead be provided with an open upper channel. In the embodiment illustrated in FIG. **55**D, the upper channel layer **5512** may have a curved, rounded or upwardly convex upper surface and a substantially flat lower surface, and the lower channel layer **5516** may have a curved, rounded or downwardly convex lower surface and a substantially flat upper surface.

In some embodiments, the fabric may have a three-dimensional (3D) structure, where one or more types of fibers form a structure where the fibers extend in all three dimensions. Such a fabric may in some cases aid in wicking, transporting fluid, and/or transmitting negative pressure. To prevent the channels **5512** and/or **5516** from being displaced or twisted while encased in the system **5501**—which may impair performance of the respective channels under negative pressure—it may in some embodiments be preferable to adhere or otherwise secure the channels **5512** and/or **5516** to one or more of the layers **5510**, **5514**, and **5518**. In certain embodiments, these materials remain open and capable of communicating negative pressure to a wound area under the typical pressures used in negative pressure therapy, for example between 40 to 150 mmHg, although higher and lower values are possible. In some embodiments, the fabric may comprise several layers of material stacked or layered over each other, which may in some cases be useful in preventing the channel **5516** from collapsing under the application of negative pressure. In other embodiments, the fabric used in channel **5516** may be between 1.5 mm and 6 mm; more preferably, the fabric may be between 3 mm and 6 mm thick, and may be comprised of either one or several individual layers of fabric. In other embodiments, the channel **5512** may be between 1.2-3 mm thick, and preferably thicker than 1.5 mm. Additionally, and as described previously, the materials used in the system **5501** are preferably conformable and soft, which may help to avoid pressure ulcers and other complications which may result from a wound treatment system being pressed against the skin of a patient. Further examples of 3D fabrics are discussed below in FIGS. **56**A-C.

Preferably, the distal ends of the layers **5510**, **5514**, and **5518** and the channel layers **5512** and **5516** are enlarged at their distal ends (to be placed over a wound site), and may form a "teardrop" or other enlarged shape. The distal ends of at least the layers **5512**, **5514**, **5516**, and **5518** may also be provided with at least one through aperture. This aperture may be useful not only for the drainage of wound exudate and for applying negative pressure to the wound, but also during manufacturing of the device, as these apertures may be used to align these respective layers appropriately.

With additional reference to FIGS. **55**D-E and J, a channel connector **5506** is provided at the proximal end **5503** of the bridge **5502**, the channel connector **5506** preferably being configured so as to be embedded into the lower channel layer **5516** so as to create a secure fluidic connection. The channel connector **5506** may in some embodiments be inserted into a pre-made cavity formed into the channel **5516**; as illustrated in FIG. **55**J, this cavity can be cut out or can be in the form of a rabbet joint. In some embodiments, the channel connector **5506** may be one of the connectors described in FIGS. **57**A-B below. With one end of the channel connector **5506** being embedded into the lower channel layer **5516**, the other end of the channel connector **5506** may be connected or in communication with, in one embodiment, a connector tube **5507**, although in some embodiments the channel connector **5506** may be connected directly to the connector **5504**, or else connected directly to a tube **5540** connected to a source of negative pressure. When using a connector tube **5507**, the resulting assembly can permit a connector **5504** to be attached thereto. A cap **5536**, which may be secured to the suction adapter for example via a cap leash **5527** secured with a ring disposed on the outer surface of the connector tube **5507**. The cap **5536** may be used to cover the end of the suction adapter, for example at the connector **5504**, so as to prevent exudate and other wound fluids from leaking out. The connector **5504** is preferably configured to connect with a tube **5540** connected to a source of negative pressure. The connector **5504** may for example comprise a lip or other such structure to aid in securing the connector **5504** to a tube **5540** and/or cap **5536**, although it will be understood that other connector types are possible, including quick-disconnect couplings, luer locks, Christmas-tree, and other such connectors.

The upper layer **5510** may comprise additional material extending downward, preferably at least of the thickness of the bridge **5502**; this material may then be used to bond or weld to the other layers so to form a fluid-tight seal. More specifically, during assembly, the upper layer **5510** may be attached, for example by melting, welding, or with adhesives, to the lower layer **5518** so as to form a fluid-tight seal (with the exception of the apertures at the distal and proximal ends). Preferably, the middle layer **5514** is attached to the top layer **5510** and the bottom layer **5518**. In some embodiments, it may be preferable to attach or bond the connectors **5504** and/or **5506**, as well as the tube **5507** to at least one of the layers **5510**, **5514**, **5518** so as to create a fluid-tight connection. To provide for a more secure connection, some embodiments may also be provided with a weld **5532** made onto the lower layer **5518**. The lower channel **5516** may have a hole or aperture made through it, which may be used to weld it, via the weld **5532**, to the lower layer **5518**. This welding of the lower channel **5516** to the lower layer **5518** via the weld **5532** made through the hole **5533** may thus aid in preventing the various layers and channels from shifting or being displaced. Obviously, it will be understood that other securement means may be used, for example adhesives and the like, and that such arrangements may be also be used in the upper channel **5512**.

In certain embodiments, for example as illustrated in FIGS. **55**C-J, a controlled air leak **5524** may be disposed on the bridge portion **5502**, for example at the proximal end thereof. This air leak **5524** may comprise an opening or channel extending through upper layer **5510**, such that the air leak **5524** is in fluidic communication with the upper channel **5512**. Upon the application of suction to the system **5501**, air will enter through the air leak **5524** and move from the proximal end **5503** to the distal end **5505** along the upper channel **5512**. The air will then be suctioned into the lower channel **5516** by passing through the apertures through the distal ends of the layers **5512**, **5514**, **5516** and **5518**. The air leak **5524** preferably comprises a filter **5525**, which may be similar in function to the filter **521** illustrated in FIG. **5**A. Preferably, the air leak **5524** is located at the proximal end of the bridge portion **5502** so as to minimize the likelihood of wound exudate or other fluids coming into contact and possibly occluding or interfering with the air leak **5524** or its filter **5525**. In some embodiments, this filter **5525** is a microporous membrane capable of excluding microorganisms and bacteria, and which may be able to filter out

particles larger than 45 .mu.m. Preferably, the filter **5525** can exclude particles larger than 1.0 .mu.m, and more preferably, particles larger than 0.2 .mu.m. Advantageously, some embodiments may provide for a filter **5525** that is at least partially chemically-resistant, for example to water, common household liquids such as shampoos, and other surfactants. In some embodiments, reapplication of vacuum to the system **5501** and/or wiping of the exposed outer portion of the filter **5525** may be sufficient to clear any foreign substance occluding the filter **5525**. The filter **5525** may be composed of a suitably-resistant polymer such as acrylic, polyethersulfone, or polytetrafluoroethylene, and may be oleophobic and/or hydrophobic. In some embodiments, the filter **5525** may also comprise a supporting backing layer, for example a nonwoven polyester support. Preferably, the air leak **5524** will supply a relatively constant air flow that does not appreciably increase as additional negative pressure is applied to the system **5501**. In embodiments of the system **5501** where the air flow through the air leak **5524** increases as additional negative pressure is applied, preferably this increased air flow will be minimized and not increase in proportion to the negative pressure applied thereto.

The filter **5525** provided in the controlled air leak **5524** in certain embodiments may be useful in a system **5501** for use with more ambulatory and active patients. For example, a chemically-resistant filter may permit a patient to bathe or shower without damaging the filter's functionality when reconnected to a source of negative pressure. Any occlusion or fluid blocking the air leak **5524** could then be cleared by, for example, wiping off the filter **5525** or re-applying negative pressure to the system **5501**. Such a system would also have the advantage that the system **5501** and any assorted wound dressing materials, if present, would not need to be removed and then re-applied should a patient need to be disconnected from the source of negative pressure, for example incidental to bathing. This would entail significant advantages in improving the cost-effectiveness and ease of use of the present treatment system.

The system **5501** is preferably constructed so as to provide a consistent fluid flow even if the system **5501** is kinked or weighted down. For example, in use on a patient, the bridge portion **5502** may become folded over itself, or else the patient may roll over, thus placing his or her weight over at least a portion of the system **5501**. Typically, prior art dressings and fluidic connectors become blocked or ineffective in such situations and in some cases may contribute to complications such as pressure ulcers. Here, however, certain embodiments provide for improved blockage resistance if kinked or weighed down. Preferably, by employing channel layers **5512** and **5516** as described above, and more preferably by employing a foam channel layer **5512** and a fabric channel layer **5516**, the system **5501** is able to maintain a flow rate through the air leak **5524** of at least 0.08 L/min, and preferably 0.12 L/min while negative pressure is applied through a source of negative pressure. Further embodiments also provide for the system **5501** to be able to handle fluid exudate drainage from the wound site through the lower channel **5516** of at least 10 L/day, or 6.9 ml/min. Certain embodiments provide for the system **5501** to maintain these flow rates with a weight, for example a 12 kg weight, pressing down on the bridge portion through a rod with a 1 in. diameter. In some embodiments, these flow rates are also maintained while the bridge portion **5502** is kinked over itself with the same weight, or for example with a 4.75 kg weight placed directly on the folded region. It is preferable that the system **5501** be able to withstand being folded or kinked over even during an extended period of time, for example over 40 hours, and not show any degradation in performance (e.g., flow rates) compared to its performance prior to being folded or kinked over. Preferably, embodiments of the system **5501** are also able to transmit and maintain a negative pressure at the wound that is close to the negative pressure level at the source of negative pressure. For example, an acceptable level of pressure maintained at the wound may be within .+−0.25 mmHg of the negative pressure set at the source of negative pressure, with this pressure being preferably maintained at this level within 95% of the time that the system **5501** has negative pressure applied to it. Acceptable pressure levels may include pressure ranges between 40-120 mmHg, although levels of 200 mmHg have successfully been used.

With additional reference to FIGS. **5**A-D, G-J, the system **5501** also comprises an applicator **5520** designed for placement over a wound site. Preferably, the applicator **5520** comprises a flexible layer **5550**, for example polyethylene or polyurethane, with a layer of adhesive on its lower (wound-facing) side. Optionally, a protective release layer **5529** may be placed on the adhesive layer, which is removable before use. In some embodiments, a more rigid removable backing layer **5552** may be provided on the upper side of the applicator **5520** to facilitate handling of the applicator **5520** due to the flexibility of the layer **5550**. The applicator **5520** preferably comprises an attachment point for the bridge **5502** at the distal end **5505**, for example using a section of double-sided adhesive tape **5528**. The double-sided adhesive tape **5528** may be protected by an additional protective release layer, which is removed prior to adhering the bridge **5502** to the applicator **5520**. It will be understood that different attachment methods are also contemplated, for example heat sealing, welding, or suitable adhesives. Some embodiments may also permit the manufacture of the bridge **5502** and the applicator **5520** as a single unit that does not require separate attachment means. The applicator **5520** preferably comprises at least one aperture **5526** through itself and designed to be placed over a wound site, and which can serve to fluidically connect the wound site to the source of negative pressure and to the air leak while also serving as a conduit to draw out wound exudate from the wound site.

In use, and with reference to FIGS. **5**A-B, the system **5501** may be used in a similar fashion to the other embodiments previously disclosed herein. A wound site **5530** is preferably cleaned and prepared in a suitable fashion, and a wound packing material, if necessary, placed into the wound site, followed by a drape **5531**. An aperture **5535** through the drape to the wound site is then created, although some embodiments may have a pre-made aperture **5535**. Subsequently, an operator may situate the applicator portion **5520** over the aperture **5535**. After removing the backing layer **5529** (if present) from the adhesive layer on the underside of the applicator portion **5520**, the applicator is sealed to the drape **5531**, and the backing layer **5552** (if present) is also removed from the applicator portion **5520**. A fluidic conduit such as a tube **5540** may then be connected to the connector **5504**. The tube **5540** may also be connected to connector **5504** prior to applying the applicator to the wound site. The fluidic conduit is connected to a source of negative pressure **5534**, preferably with a container suitable for containing wound exudate interposed therebetween. The application of negative pressure may then be effectuated to the wound site **5530** until the wound site progresses to a desired level of healing.

During use of the system **5501**, wound exudate from the wound site **5530** is drawn by the negative pressure through the lower channel layer **5516**. The air leak **5524** allows air

to pass through the upper channel layer **5512** into the apertures through the distal ends of the layers **5512**, **5514**, **5516** and **5518**. The negative pressure draws air passing through the upper channel layer into the lower channel layer **5516** back toward the source of negative pressure or pump. In some embodiments, the controlled air leak **5524** provides a constant flow of air through the system **5501**, which then may be used to determine whether blockage or leakage is present. Causes of blockage can include, for example, situations where the lower channel **5516** becomes occluded with wound debris. Leakage causes can include, for example, improper sealing of the drape over the wound site, or physical damage to the system **5501** leading to excess air leaking into the system. The blockage or leakage may be determined, in certain embodiments, by measuring the speed of the pump while the pump works to maintain a constant negative pressure. Pump speed may also be measured indirectly by measuring the amount of voltage or signal sent to the pump.

FIGS. **56**A-C illustrate views of a 3D fabric that may be used in various embodiments described herein, for example the bridge **5502** of the suction adapter illustrated in FIGS. **55**A-J. Although other porous materials such as foam may be used in the embodiments described herein, for example in the upper and lower channels **5512** and/or **5516** illustrated in FIGS. **55**A-C, the use of 3D fabrics may be advantageous in some circumstances. Certain 3D fabrics have been found to perform well in conveying negative pressure to and wound exudate from a fluidic suction adapter, even while under compression—for example when a patient's weight is placed directly upon the suction adapter, or when negative pressure is applied and/or when the fluidic suction adapter is kinked or folded. Some 3D fabrics that have been found to perform acceptably include knitted polyester 3D fabric, Baltex 7970®, Gehring 879®, or Coolmax®. Of course, other fibers and fabric types may be used in part or in whole to make 3D fabrics, and include without limitation polyamides such as nylon, viscose, cotton, as well as other synthetic microfibers. 3D fabrics may also be constructed at least in part from fibers such as Nomex® and Kevlar®. Other types of fabrics and materials disclosed elsewhere herein may also be used.

In one embodiment, as illustrated in FIGS. **56**A-C, the 3D fabric may comprise a bottom side **5603**, a top side **5605**, and an open middle area **5607**. FIG. **56**A illustrates the bottom (wound-facing) side **5603** of a 3D fabric, which may be woven so as to create oblong or ovoid openings **5611** extending lengthwise across the fabric. In one embodiment, the oblong or ovoid openings **5611** represent or provide an open area of between 10 and 45% (or about 10% to about 45%) of the surface area of the bottom layer, more preferably 10% to 30% (or about 10% to about 30%). Here, fibers are knitted (for example by warp knitting) so as to also include these larger openings or pores that permit bulk transport of wound fluids in addition to wound fluids carried along the fibers by capillary action of the fibers. Apertures that are optionally formed in the distal end of the 3D fabric (as illustrated in FIGS. **55**D and J) may also aid in the bulk evacuation of wound debris and fluids.

FIG. **56**B illustrates the top side **5605** of a 3D fabric that may be used as described herein. This top side **5605** in one embodiment does not have the larger ovoid apertures **5611** of the bottom side **5603**, but may have openings **5613** defined by fibers extending lengthwise and generally transversely or at an angle across the width of the fabric. As illustrated, these openings are generally rhombus-shaped. In one embodiment, these openings **5613** may represent or provide an open area greater than that of the bottom layer, for example between 30% and 50% (or about 30% and about 50%). Of course, it will be understood that the fabric presented here is a non-limiting example, and different fabric configurations and orientations are possible, for example with the top side **5605** being placed downward so as to face the wound and with the bottom side **5603** facing upward.

FIG. **56**C illustrates a cross-section of a 3D fabric (the bulb-like projections on the vertical fibers in the fabric are an artifact of the cutting process). The vertically extending fibers **5609** may be woven so as to extend through the middle open area **5607** while also being connected to the bottom and top layers **5603** and **5605**. Preferably, the fibers **5609** present in the open middle layer **5607** will have sufficient stiffness so as to help prevent compression of the fabric. As illustrated in this figure, and without wishing to be bound by theory, 3D fabrics that have been found to perform well will often include a larger open area **5607** in the middle portion that may permit exudates and other fluids to be effectively transported away from a wound site while under the application of negative pressure, while more densely-woven outer layers **5603**, **5605** may aid in providing additional tensile strength and capillary wicking action. For example, the middle layer may include an open volume of greater than 50% (or greater than about 50%). Obviously, the resulting fabric cannot be too thick or composed of fibers that are too stiff, as the resulting suction adapter and system may not remain sufficiently flexible for comfortable usage with a patient.

It will often be advantageous to tailor the performance characteristics of the 3D fabric while in use to account for various requirements of the suction adapter. In particular, the flow rate of exudate through the fabric, for example when under compression, may be simplified by considering the porosity of the fabric. In such situations, and again without wishing to be bound by theory, the porosity of the fabric, and thus the space that will be available for fluids to travel through, may be determined in part by the knit pattern of the fibers used in creating the 3D fabric, the thickness of the fibers used therein, and their respective stiffness and hardness (especially when under compression). Fibers may also be modified by surface properties (the fibers can be flat or textured) and the number of fibers or filaments used in the resulting fabric. Compression resistance may be affected by the choice of fiber or monofilament used in the vertical axis of the fabric, and generally, a stiffer material will improve compression resistance on this axis. Other materials properties, such as hydrophobicity, may play a role. In some cases, it may be beneficial to treat the fabric to be hydrophilic, for example with a hydrophilic polymer, so as to improve wicking of fluids. Preferred embodiments of the 3D fabric used with certain suction adapters have been found to work well when Baltex® fabric is treated in such a fashion. Other possible treatments may include lipophilic coatings to prevent proteins from adhering and building up during use, which may cause clogging and loss of pressure to the wound site.

The flow rate through the 3D fabric while under the application of negative pressure may be approximated by considering each opening as a separate orifice plate subject to Bernoulli's principle while under laminar flow. To simplify calculations, the area of openings for a given area of 3D fabric may be used. Thus, the 3D fabric may be optimized to achieve a good balance between factors such as the compression resistance required and the resulting flow rate under the application of negative pressure. Further optimi-

zation will also take place with the stiffness and flow rate of the 3D fabric being tailored to application in the embodiments described herein. Optimization of the properties and dimensions of the 3D fabric will also preferably take into account a balancing between the flow rate and stiffness required and the conformability of the fabric, as a fabric that is too stiff may not bend appropriately and may also be uncomfortable on the patient. The 3D fabric should preferably be designed so as to yield when compressed against tissue, thereby preventing tissue compression (for example against bony prominences in the patient) and the discomfort and damage, such as pressure ulcers, that may follow. For example, the dimensions of the fabric may be tailored for the ultimate use of the suction adapter—smaller in the case of distal extremities such as fingers, and larger for abdominal and burn wounds. A fabric that is too stiff may also cause pressure ulcers and other such complications, although it may function acceptably in larger dimensions.

In practice, and as also described previously herein, flow rates through embodiments of the suction adapter using 3D fabrics are at least 0.08 L/min, preferably up to 10 L/min during the application of negative pressure, and should be able to handle fluid exudate drainage of at least 10 L/day. Some embodiments of the suction adapter may be configured to handle much larger wounds, including abdominal wounds, and which in some cases may exude at least 0.5 L/hr, or 12 L/day. In more extreme cases, the pump used (for example, the RENASYS EZ) may be able to evacuate up to 16 L/min, thereby evacuating a large wound to a negative pressure level of 120 mmHg in less than a minute. The pressure drop calculated due to the 3D fabric should be minimal, and the level of negative pressure measured at a wound site is preferably within 25 mmHg of the pressure level measured at the source of negative pressure. Although the pressure drop increases as the negative pressure applied increases (thus rendering the 25 mmHg target more difficult to reach), embodiments of the wound treatment system are preferably able to maintain this target pressure to at least a negative pressure of 200 mmHg. The suction adapter and system are preferably able to function within pressure ranges required for negative pressure, which are estimated to be from around 40 mmHg to 200 mmHg. Pressure ranges greater than 200 mmHg are possible, but these may in some circumstances cause patient discomfort. The apparatus may also function at lower pressure ranges, such as 20 mmHg, although at such low pressure levels the therapeutic effects resulting from negative pressure may be diminished, with the device acting more as a drainage device. Preferably, embodiments of a negative pressure treatment system are able to maintain these target pressures at the wound site within 95% of the time that negative pressure is being applied to the wound. In some embodiments, the fabric may comprise several layers of material stacked or layered over each other, which may in some cases be useful in preventing the channel **5516** from collapsing under the application of negative pressure. In other embodiments, the fabric used in channel **5516** may be between 1.5 mm and 6 mm; more preferably, the fabric may be between 3 mm and 6 mm thick, and may be comprised of either one or several individual layers of fabric. In other embodiments, the channel **5512** may be between 1.2-3 mm thick, and preferably thicker than 1.5 mm. Preferably, the 3D fabric is able to withstand a load of at least 5.3 psi with a compression of not more than 10% of the fabric's original thickness. Further, the 3D fabric may also be able to resist compression to less than half of its original thickness when subjected to a load of 15 psi.

In a preferred embodiment, a 3D fabric may be woven from 100% polyester using yarns of 150 and 225 Denier, to yield a fabric weighing approximately 23 to 25 oz per square yard. In these cases, the fabric may be approximately 5.8-6.8 mm thick. The bottom portion of the fabric may also have several openings or pores **5611** similar to those illustrated in FIG. **56**A, which may be elongated, rectangular or ovoid in shape and oriented with their long axis lengthwise along the fabric. The openings **5611** may be arranged in a plurality of rows extending lengthwise across the fabric, for example 2 to 5 rows, or more preferably 3 rows as illustrated in FIG. **56**A. The openings **5611** may be spaced equidistantly from each other in each of the rows, and may form a staggered pattern from one row to another. In one embodiment, each row may have approximately 6-10 openings, more preferably 8 openings, per 2 inches (or about 50 mm). Along a given width or transverse dimension of the fabric, the transverse rows formed by the openings may have a spacing of approximately 6-10 openings, more preferably 8 openings, per 2⅛ inches (or about 54 mm). In one embodiment, the openings may have a length of between about 1/16" to about 1" lengthwise, and a width of between about 1/32" and ½" widthwise. In one example, the openings measure approximately ⅛" (or about 3.2 mm) lengthwise and 1/32" (or about 0.79 mm) across. The 3D fabric in one embodiment may have an overall length of between about 50 and 100 mm, more preferably about 60 mm, a width between about 5 and 15 mm, more preferably about 9 mm, and a thickness of about 6 mm.

Embodiments of the systems described herein have been tested and found to perform satisfactorily. Such testing was performed by constructing suction adapters from embodiments described herein. The distal ends of the suction adapters were then placed over an aperture made onto a drape placed over a simulated wound cavity provided with a source of simulated wound fluid, which was controllable and which can vary the flow rate of the wound fluid. The simulated wound cavity was also in some cases packed with foam or some other wound packing material. In some tests, the simulated wound fluid was a 5:1 water to glycerol mix, and in others filtered horse serum (available from Oxoid, United Kingdom) was used. The proximal end of the suction adapter was then connected to a source of negative pressure, in this case a pump. Flow rate tests and other measurements were then conducted at various negative pressure ranges and simulated exudate flow rates and air leak rates.

FIGS. **57**A-B illustrate embodiments of a connector **5704**, similar to the connectors **1504** and **5506** described previously, and which may be used to securely connect a source of negative pressure to a channel **5716** of a suction adapter such as the ones described herein. For example, this channel **5716** may be the upper channel **1512** or, more preferably, the lower channel **1516** illustrated in FIGS. **15**A-D, as well as the channels **5512** and **5516** in FIGS. **55-56**. Generally, such connectors **5704** may be useful in providing a more secure connection from the source of negative pressure to a negative pressure treatment system. The use of these connectors **5704** is optional, and may not be necessary in all embodiments described herein. In use, a tube **5740** connected to the connector **5704** may pull, or other external forces may somehow disengage the connector **5704** away from the channel **5716** to which it is attached. In such situations, application of negative pressure to the wound may be reduced or stopped. Further means to secure the connector **5704** to the remainder of the system may, as described above, include bonding or attaching other layers of the treatment system, if present, to the connector **5704**. For

example, in the case of the embodiments described in FIGS. **15**A-D, this may include bonding at least one of the layers **1510**, **1514**, **1518** to the connector **5704**. The connectors **5704** may be designed so as to create a secure connection with a fabric or material used in a channel; when 3D fabrics or 3D knitted materials are used, some embodiments of the connector **5704** are configured to engage with or attach to a portion of the material or fibers of the material to create a more secure connection. Preferably, embodiments of the connector **5704** are able to withstand a pulling force of up to 20 kg before disconnection and/or failure of the connector occurs, preferably such that the connector disengages from the channel it is connected to. It will be understood that other embodiments may be configured to withstand a lower pulling force, and may be tailored to release so to prevent injury to a patient (for example, constriction of the suction adapter and/or drainage tubes around a limb).

FIGS. **57**A-B illustrate an embodiment of the connector **5704***a* comprising two or more projections **5752** extending distally lengthwise from the preferably cylindrical main body of the connector **5704***a*. The main body also comprises a central channel **5755** extending lengthwise through the main body of the connector **5704***a*. The projections **5752** may additionally comprise one or more barbs **5754** attached thereto. Preferably, these barbs **5754** are angled proximally so as to act as anchors when pushed or inserted into the channel **5716**. When the channel **5716** is a 3D fabric or knitted material, the barbs **5754** are configured to engage to the fibers therein, creating a more secure connection. At the proximal end of the connector **5704***a*, a lip **5756**, which may be provided in a frustoconical form, may also be provided for connection to a tube **5740**. The tube **5740** may be connected to the connector **5704***a* (as well as the other connectors described herein) for example by press-fitting, although other connections means are possible. The tube **5740** may be the same as tube **5507** in FIG. **55**J, or it may be any other tube used to provide fluid communication with a source of negative pressure. It will also be appreciated that the features of these connectors, particularly at the distal ends, can be incorporated onto the ends of tubes used to communicate negative pressure, such that those tubes can be directly connected to the suction adapter system.

While the above detailed description has shown, described, and pointed out novel features as applied to various embodiments, it will be understood that various omissions, substitutions, and changes in the form and details of the device or process illustrated may be made without departing from the spirit of the disclosure. Additionally, the various features and processes described above may be used independently of one another, or may be combined in various ways. All possible combinations and subcombinations are intended to fall within the scope of this disclosure. Many of the embodiments described above include similar components, and as such, these similar components can be interchanged in different embodiments.

Although the invention has been disclosed in the context of certain embodiments and examples, it will be understood by those skilled in the art that the invention extends beyond the specifically disclosed embodiments to other alternative embodiments and/or uses and obvious modifications and equivalents thereof. Accordingly, the invention is not intended to be limited by the specific disclosures of preferred embodiments herein.

What is claimed is:

1. An apparatus to provide suction to a wound site comprising:

a suction adapter configured to be sealed to a wound cover covering a wound site, the suction adapter comprising:

an applicator configured to be positioned over an opening in the wound cover, the applicator comprising at least one aperture; and

a bridge portion connected to the applicator and comprising at least a first channel and a second channel extending parallel to an upper surface of the applicator, wherein at least one of the first channel and second channel is configured to provide suction to the wound site through the aperture in the applicator from a source of negative pressure;

a visualization window provided in an upper surface of the bridge portion over the at least one aperture in the applicator that provides unobstructed visualization from outside of the suction adapter, through the visualization window and through the aperture in the applicator;

wherein the bridge portion comprises material extending downwardly from the upper surface of the bridge portion to thereby connect the bridge portion to the applicator; and

an intermediate wall extending perpendicularly from the downwardly extending material to partition the first channel from the second channel.

2. The apparatus of claim **1**, wherein the visualization window comprises an at least partially transparent material.

3. The apparatus of claim **1**, wherein the visualization window is configured to permit visualization of the wound site prior to sealing the suction adapter to the wound cover.

4. The apparatus of claim **1**, wherein the visualization window is configured to permit monitoring of the wound site while the apparatus is providing suction to the wound site.

5. The apparatus of claim **1**, wherein the visualization window comprises polyurethane.

6. The apparatus of claim **1**, wherein the visualization window is positioned at a distal end of the bridge portion.

7. The apparatus of claim **1**, wherein the intermediate wall is positioned at the distal end of the bridge portion.

8. The apparatus of claim **1**, wherein the first channel is configured to provide suction to the wound site and the second channel is configured to provide vented air to the wound site.

9. The apparatus of claim **1**, wherein the first channel and the second channel are formed as side by side conduits.

10. The apparatus of claim **1**, wherein the bridge portion comprises a proximal end configured to provide fluid communication with the source of negative pressure and an enlarged distal end provided over the applicator, wherein the first and second channels extend between the proximal and distal ends.

11. The apparatus of claim **10**, wherein the applicator has an area that is larger than an area of the enlarged distal end of the bridge.

12. The apparatus of claim **10**, wherein the visualization window is provided at the enlarged distal end.

13. The apparatus of claim **10**, wherein the enlarged distal end of the bridge portion comprises an aperture positioned over the aperture in the applicator and configured to be positioned over the wound site to fluidically connect the wound site to the source of negative pressure.

14. The apparatus of claim **1**, wherein the applicator further comprises an adhesive provided on a lower surface

of the applicator, and wherein the adhesive is configured to seal the applicator to the drape.

15. The apparatus of claim **1**, further comprising a wound cover for covering the wound site.

16. The apparatus of claim **15**, wherein the wound cover comprises a drape.

17. The apparatus of claim **1**, wherein the intermediate wall extends substantially parallel to the first and second channels.

18. A suction device for a negative pressure wound therapy system, said suction device comprising an attachment portion adapted to be attached to a wound cover member, said suction device comprising a fluid inlet being at least partially circumscribed by said attachment portion, said suction device also comprising a fluid outlet, said suction device further comprising a connection portion adapted to, at least during one operation condition of said suction device, provide a fluid communication between said fluid inlet and said fluid outlet, said connection portion comprising an inspection portion that is transparent to thereby facilitate the positioning of said suction device relative to said wound cover member, wherein said connection portion comprises a duct wall at least partially defining a connection duct from said inlet to said outlet, said duct wall comprising said inspection portion, said connection portion comprising a partition wall extending at least partially from said duct wall.

19. The suction device of claim **18**, wherein the duct wall comprises a portion extending downwardly from an upper surface of the connection portion to thereby connect the connection portion to the attachment portion.

20. The suction device of claim **19**, wherein the partition wall extends perpendicularly from the downwardly extending portion of the duct wall.

21. The suction device according to claim **18**, wherein said fluid outlet extends in a longitudinal direction (L), said partition wall extending in a partition wall extension (E_{PW}) that is substantially parallel to said longitudinal direction (L).

22. A kit for a negative pressure wound therapy system, said kit comprising:

a suction device according to claim **18**;

a wound cover member adapted to be attached over a wound.

23. The kit according to claim **22**, wherein said wound cover member comprises a wound cover film.

24. The kit according to claim **22**, wherein said kit further comprise fluid communication means adapted to provide a fluid communication between said fluid outlet and a negative pressure source.

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