



US006923819B2

(12) **United States Patent**
Meade et al.

(10) **Patent No.:** US 6,923,819 B2
(45) **Date of Patent:** Aug. 2, 2005

(54) **APPARATUS AND METHOD FOR SURGICAL SUTURING WITH THREAD MANAGEMENT**

(75) Inventors: **John C. Meade**, Mendon, MA (US);
Niall G. Deloughery, Lemerick (IE);
Gerald I. Brecher, North Andover, MA (US);
James H. Bleck, Chelmsford, MA (US)

(73) Assignee: **SuturTek Incorporated**, North Chelmsford, MA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **10/127,254**

(22) Filed: **Apr. 22, 2002**

(65) **Prior Publication Data**

US 2002/0193809 A1 Dec. 19, 2002

Related U.S. Application Data

(60) Provisional application No. 60/298,281, filed on Jun. 14, 2001.

(51) **Int. Cl.**⁷ **A61B 17/04**

(52) **U.S. Cl.** **606/144**; 606/139

(58) **Field of Search** 606/144-148,
606/139, 222-227

(56) **References Cited**

U.S. PATENT DOCUMENTS

2,327,353 A	8/1943	Karle	112/169
3,197,997 A *	8/1965	Kurtz	606/223
3,344,790 A	10/1967	Dorner	128/340
3,910,282 A *	10/1975	Messer et al.	606/226
4,027,608 A	6/1977	Arbuckle	112/169
4,235,177 A	11/1980	Arbuckle	112/169
4,437,465 A	3/1984	Nomoto et al.	128/340
4,557,265 A	12/1985	Andersson	128/340
4,621,640 A	11/1986	Mulhollan et al.	128/340
4,841,888 A	6/1989	Mills et al.	112/169
4,899,746 A	2/1990	Brunk	606/144

5,269,806 A	12/1993	Sardelis et al.	606/222
5,306,281 A	4/1994	Beurrier	606/144
5,318,578 A *	6/1994	Hasson	606/144
5,344,061 A	9/1994	Crainich	227/182
5,437,681 A	8/1995	Meade et al.	606/145
5,540,705 A	7/1996	Meade et al.	606/145
5,643,295 A	7/1997	Yoon	606/151
5,665,096 A	9/1997	Yoon	606/139
5,665,109 A	9/1997	Yoon	606/232
5,709,693 A *	1/1998	Taylor	606/145
5,759,188 A	6/1998	Yoon	606/147

(Continued)

FOREIGN PATENT DOCUMENTS

GB	18602	9/1908	128/340
----	-------	--------	---------

OTHER PUBLICATIONS

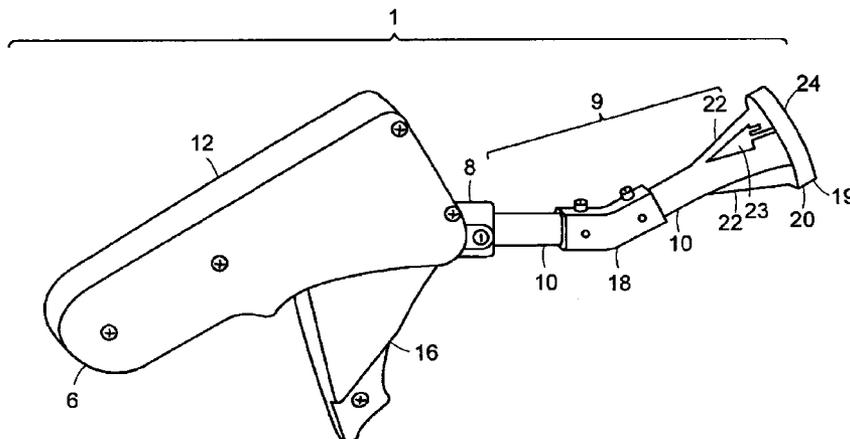
International Search Report based on PCT/US02/12560 dated Mar. 3, 2003.

Primary Examiner—Anhtuan T. Nguyen
Assistant Examiner—Jessica R. Baxter
(74) *Attorney, Agent, or Firm*—Palmer & Dodge, LLP; Richard B. Smith; David J. Dykeman

(57) **ABSTRACT**

An apparatus and a method for surgical suturing with thread management. An apparatus for tissue suturing comprising a cartridge having a suturing needle having a pointed end and a blunt end, the suturing needle capable of rotating about an axis; a pusher assembly comprising a cartridge holder having a needle rotation drive capable of releasably engaging the cartridge and rotating the suturing needle about the axis; and an actuator capable of releasably engaging the needle rotation drive to rotate the needle rotation drive. A method for suturing tissue comprising placing a suturing device having a cartridge containing a suturing needle to span separated tissue segments; activating an actuator to cause rotational movement of the suturing needle through the separated tissue segments; and deactivating the actuator to stop an advancing movement of the suturing needle to cause a suturing material to be pulled through the separated tissue segments forming a stitch.

62 Claims, 18 Drawing Sheets



US 6,923,819 B2

Page 2

U.S. PATENT DOCUMENTS

5,766,186 A	6/1998	Faraz et al.	606/145	6,159,224 A *	12/2000	Yoon	606/147
5,833,695 A *	11/1998	Yoon	606/139	6,261,307 B1 *	7/2001	Yoon et al.	606/205
5,860,992 A	1/1999	Daniel et al.	606/145	6,270,508 B1	8/2001	Klieman et al.	606/147
5,908,426 A *	6/1999	Pierce	606/139	6,322,581 B1	11/2001	Fukuda et al.	606/223
5,954,733 A	9/1999	Yoon	606/147	6,454,777 B1 *	9/2002	Green	606/144
6,053,908 A	4/2000	Crainich et al.	606/1	6,719,763 B2	4/2004	Chung et al.	606/144
6,071,289 A	6/2000	Stefanchik et al.	606/147	6,755,843 B2	6/2004	Chung et al.	606/139

* cited by examiner

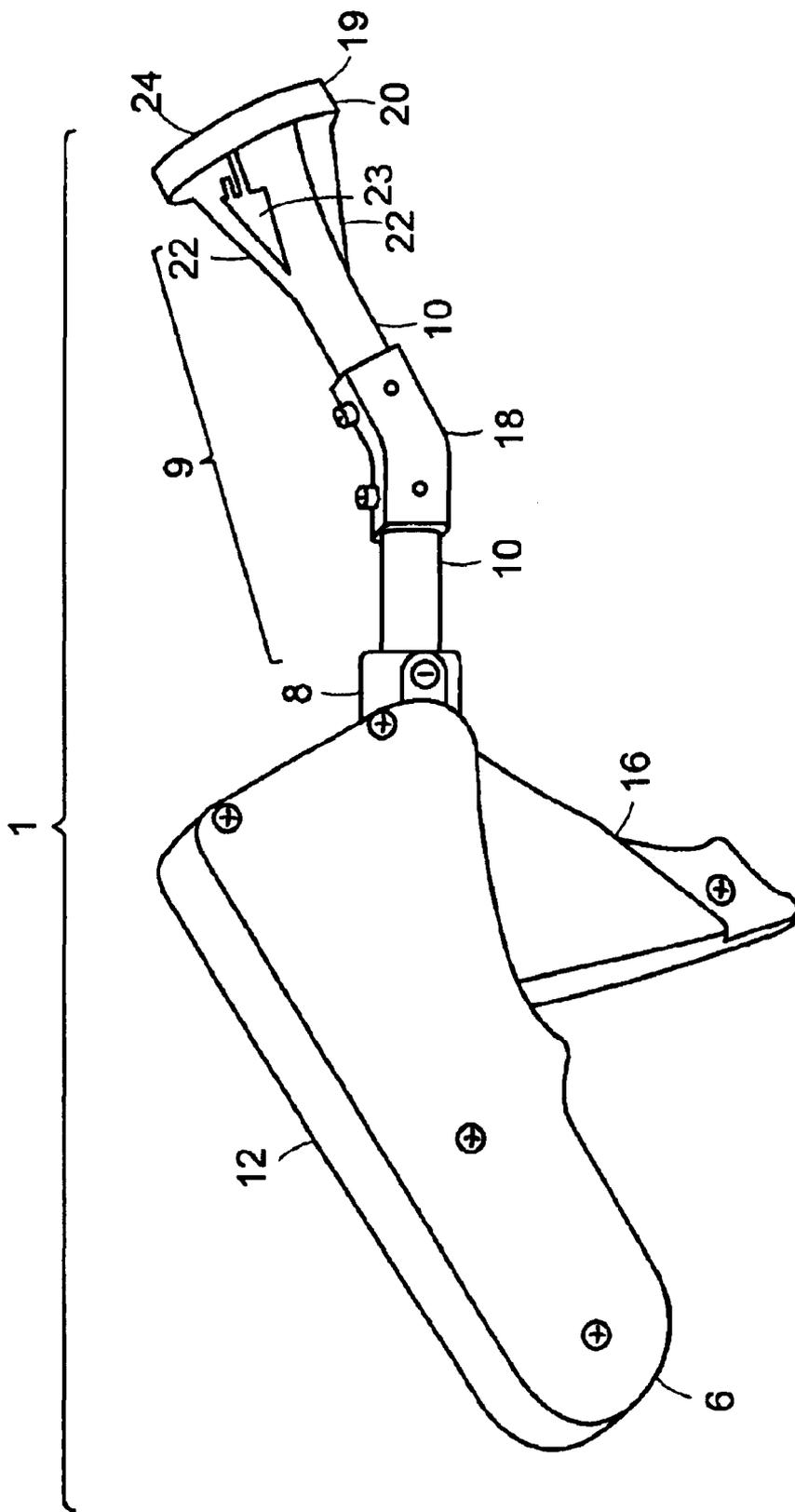


FIG. 1

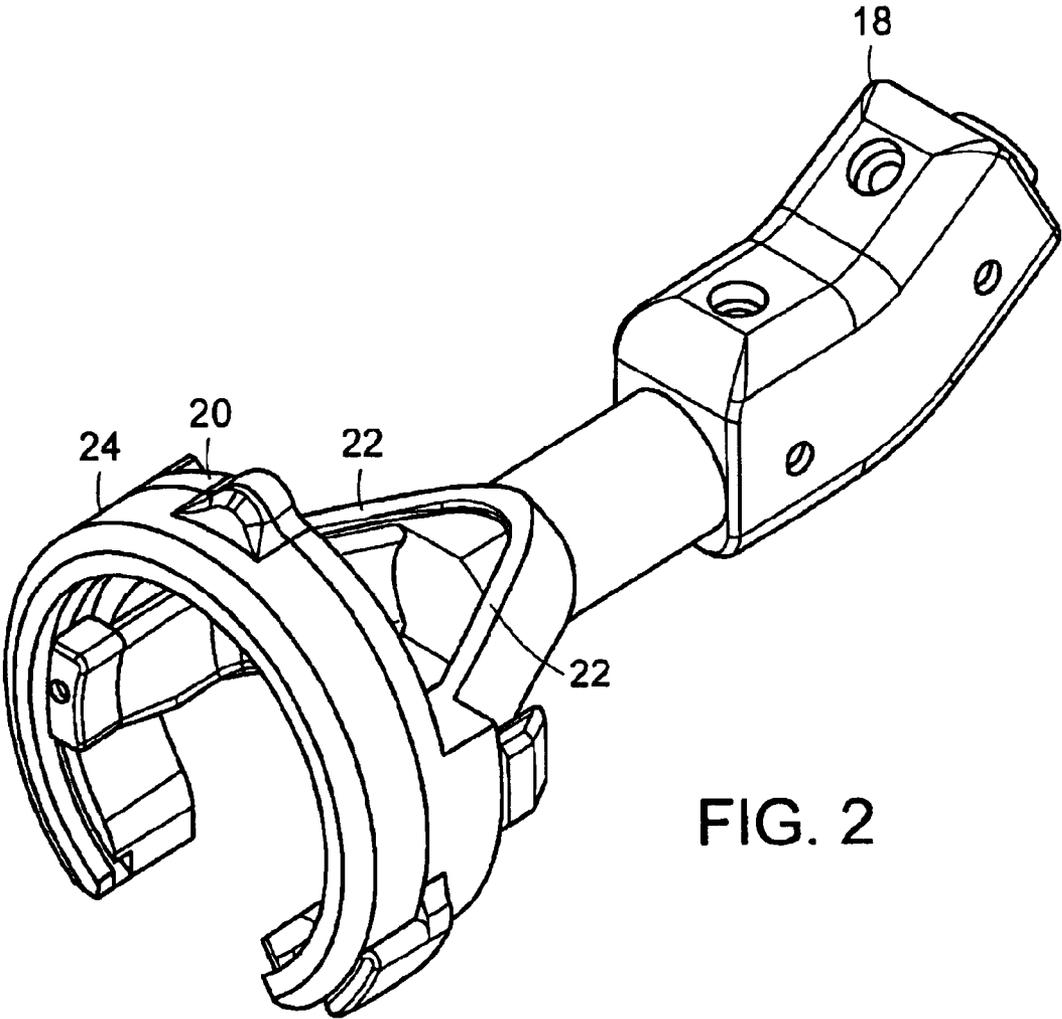


FIG. 2

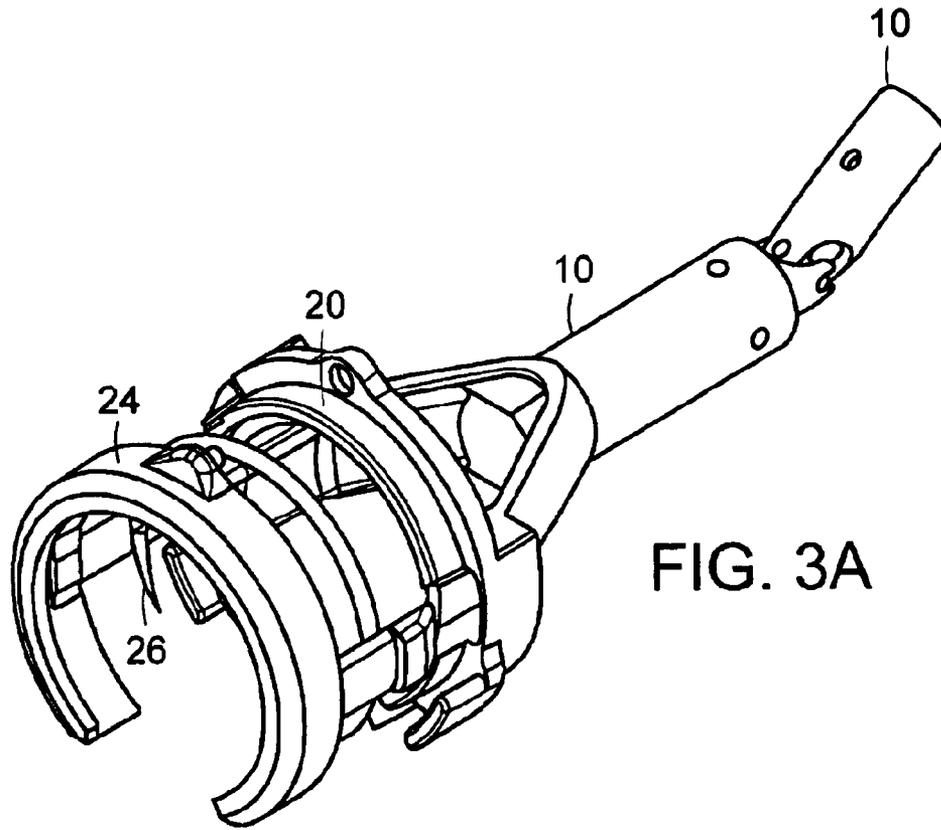


FIG. 3A

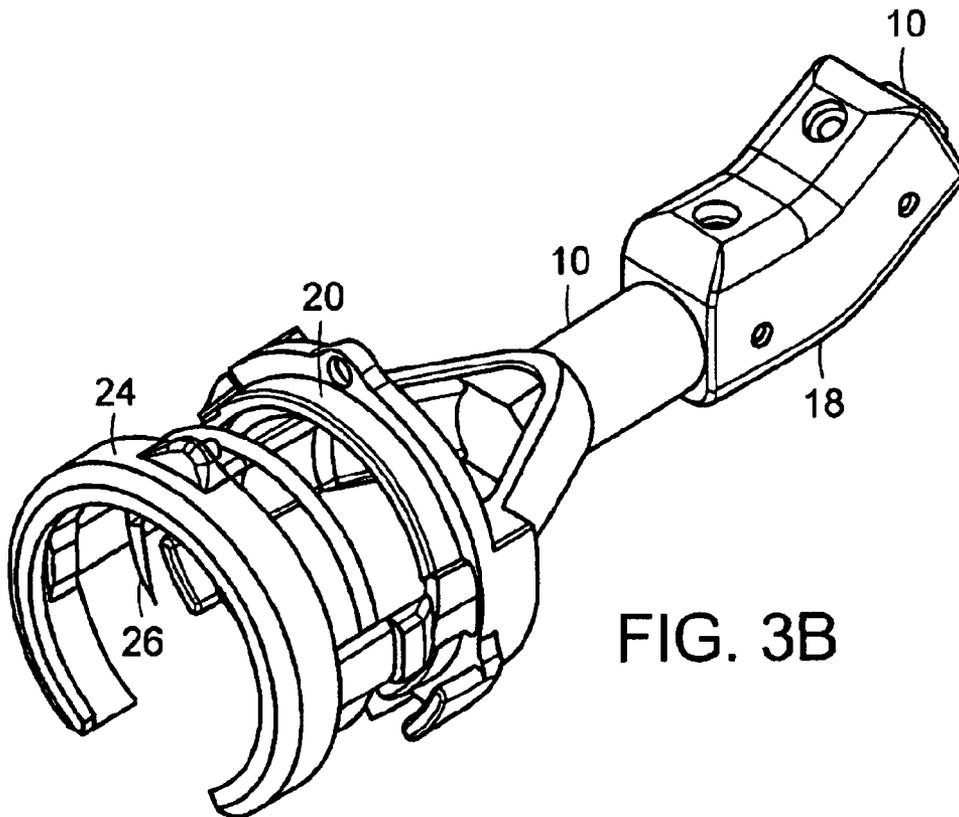


FIG. 3B

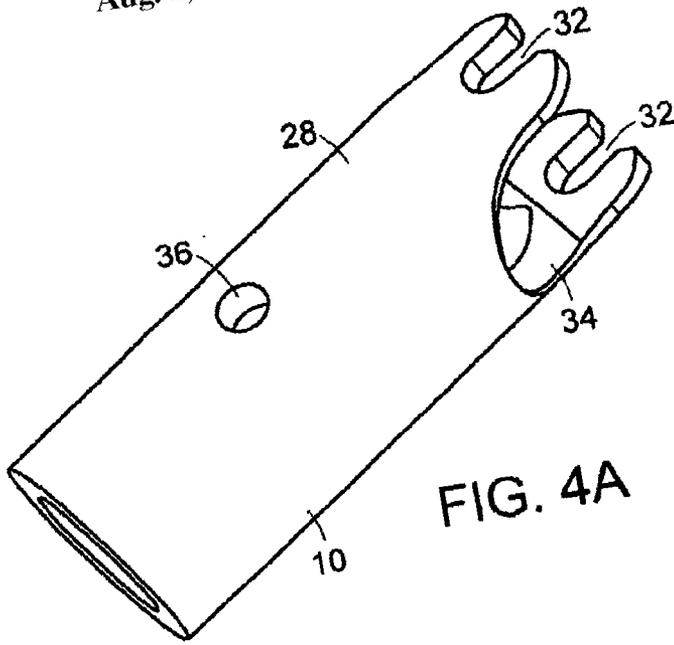


FIG. 4A

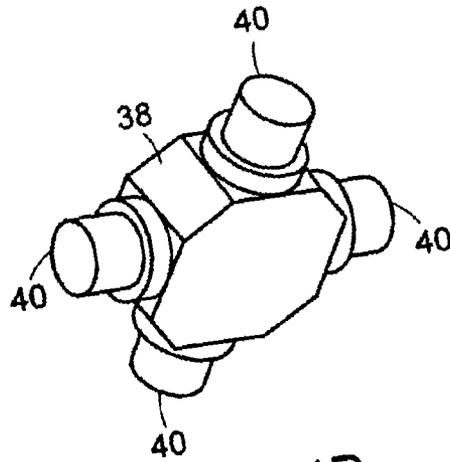


FIG. 4B

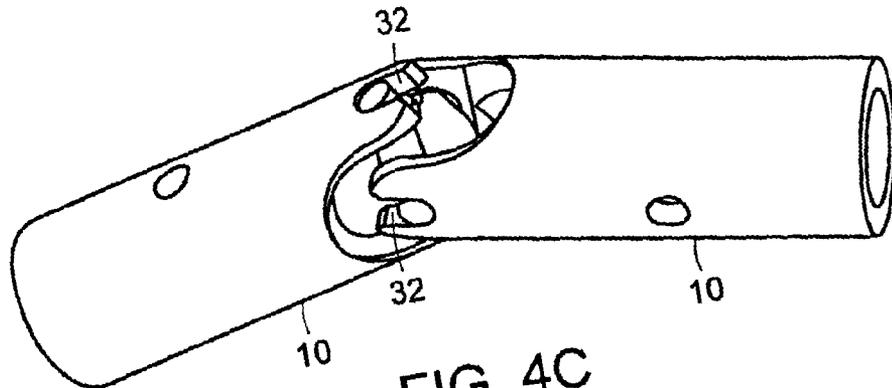


FIG. 4C

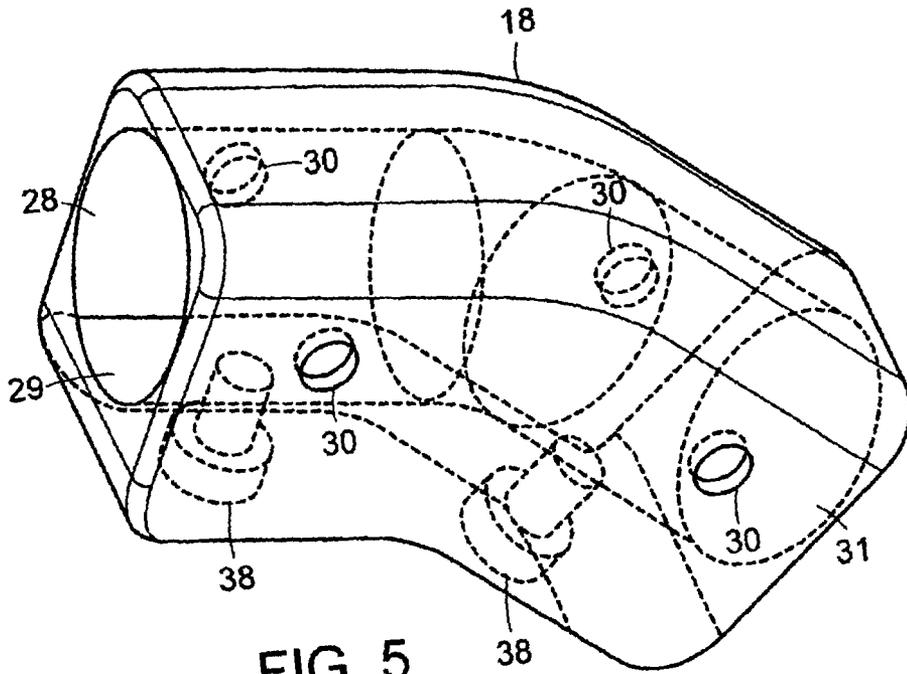


FIG. 5

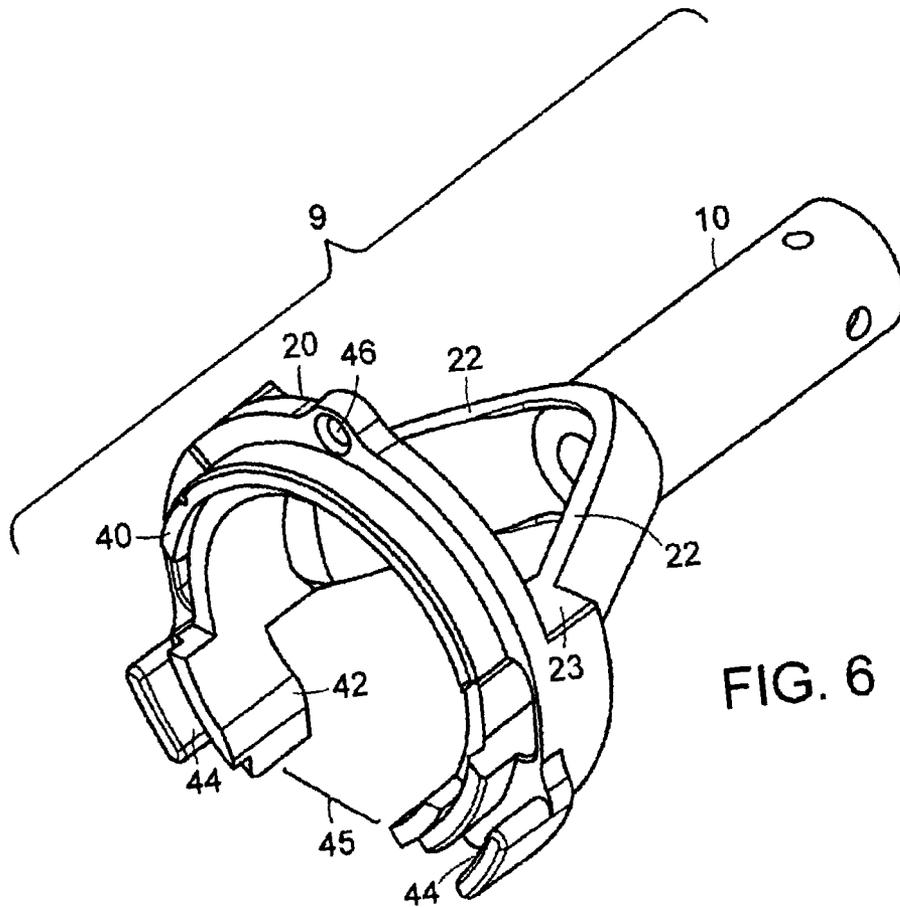


FIG. 6

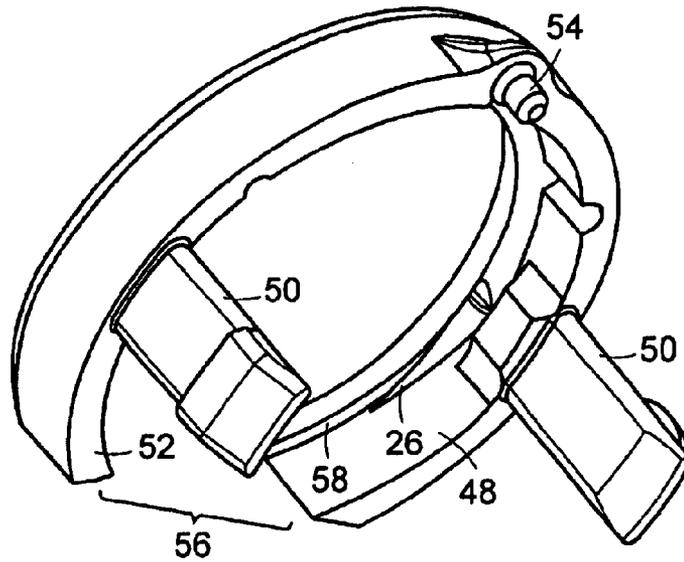


FIG. 7A

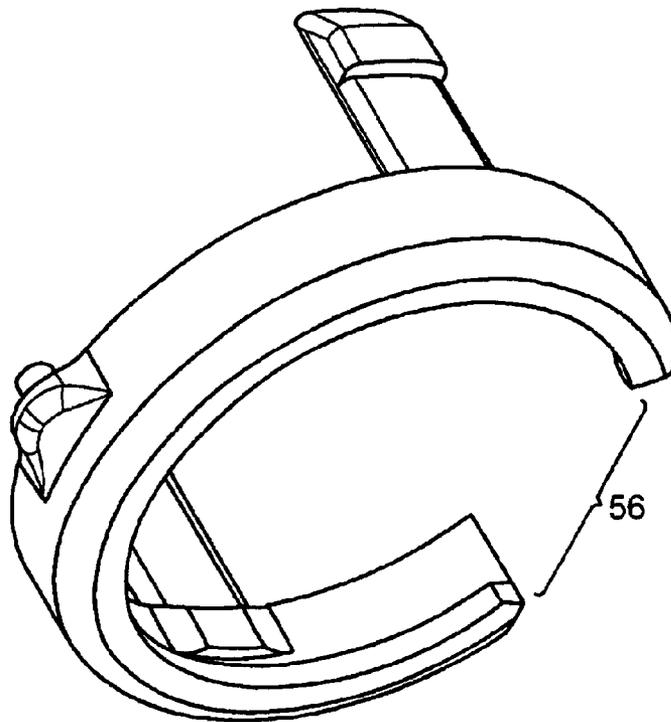


FIG. 7B

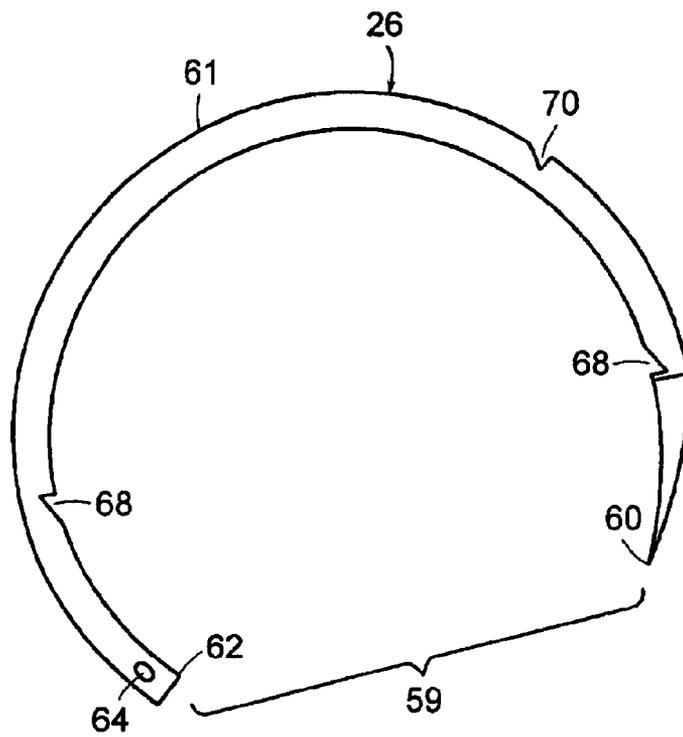


FIG. 8A

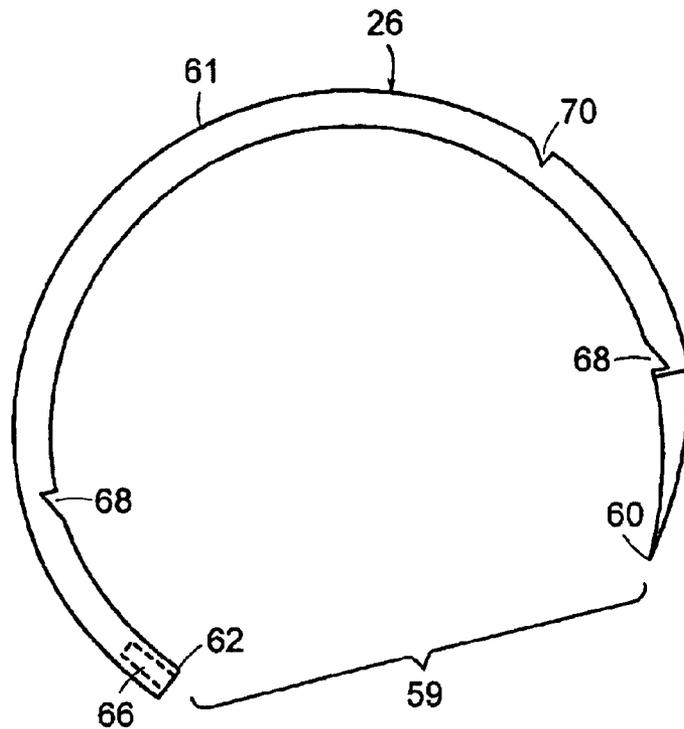


FIG. 8B

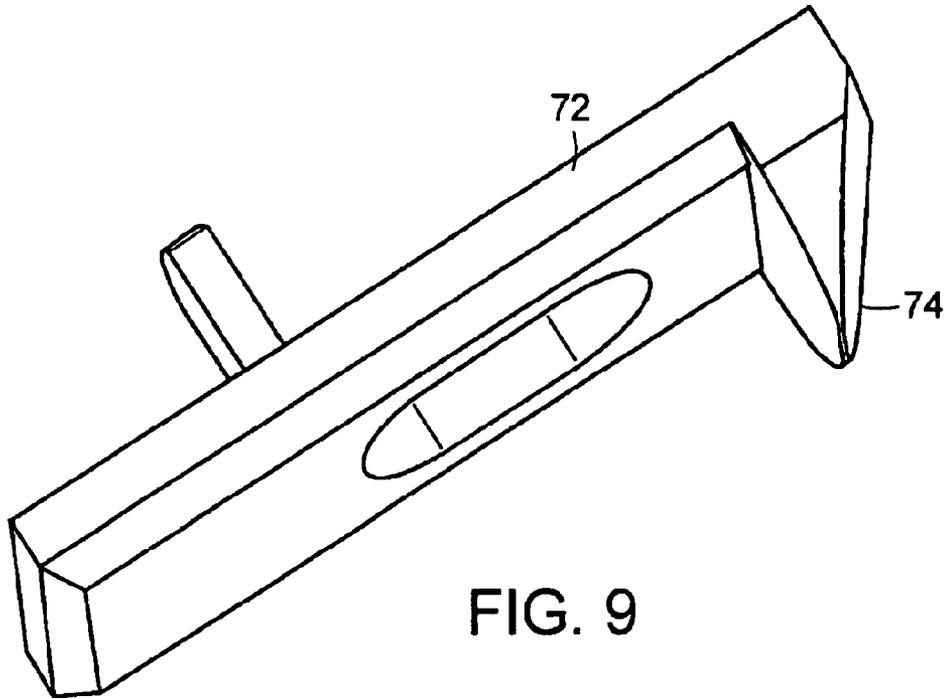


FIG. 9

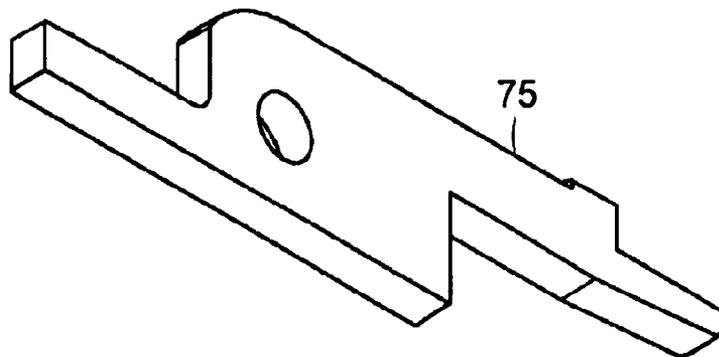


FIG. 10

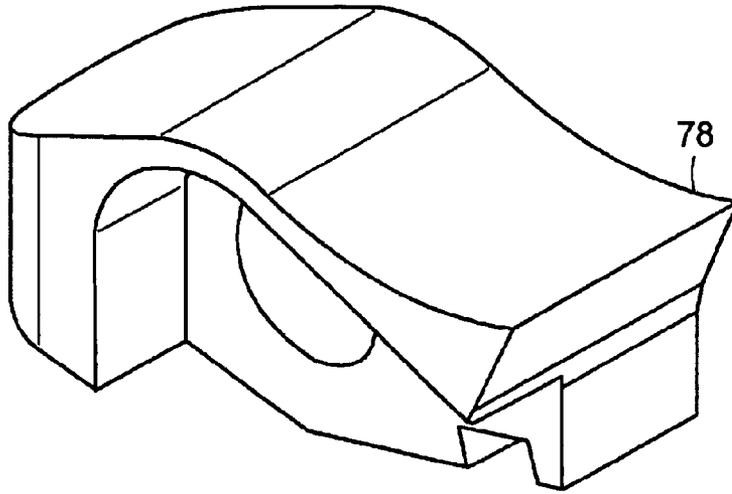


FIG. 11A

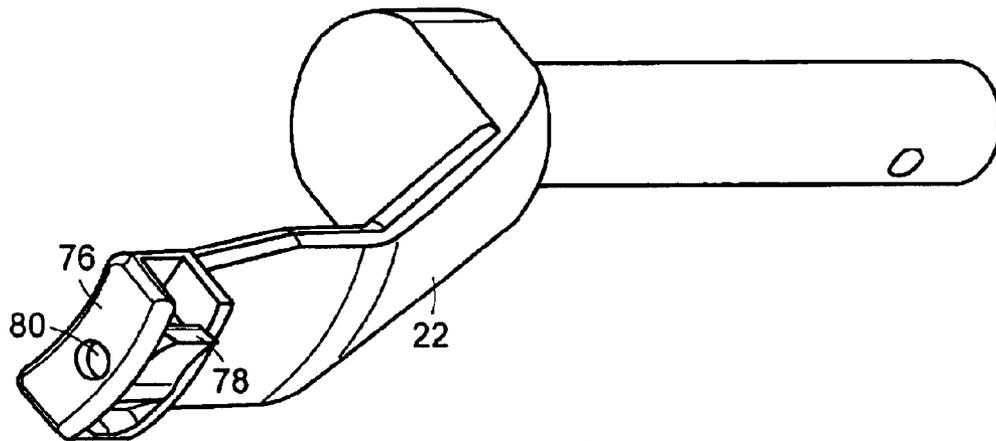


FIG. 11B

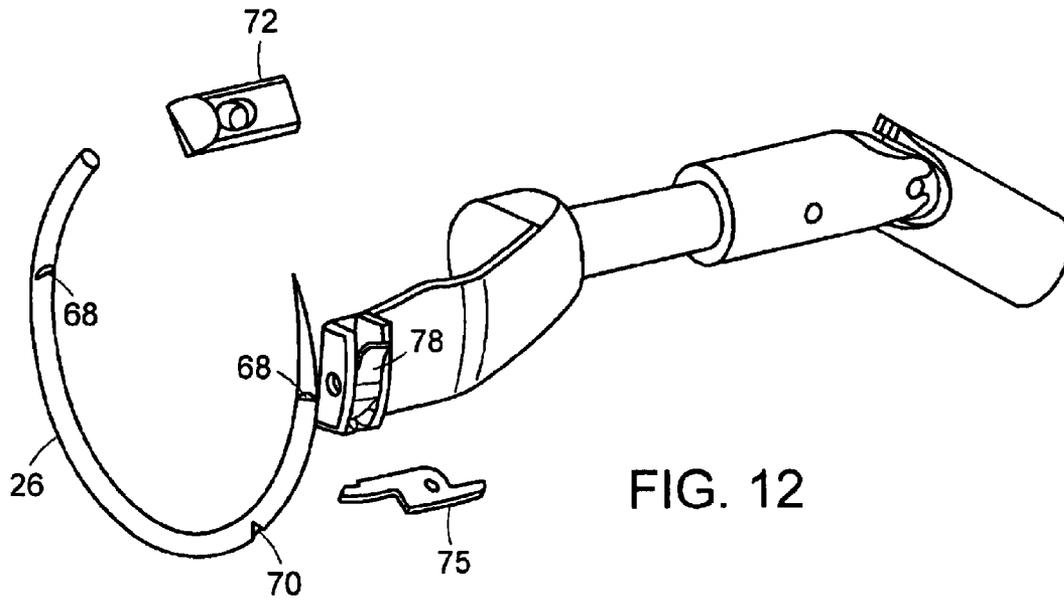


FIG. 12

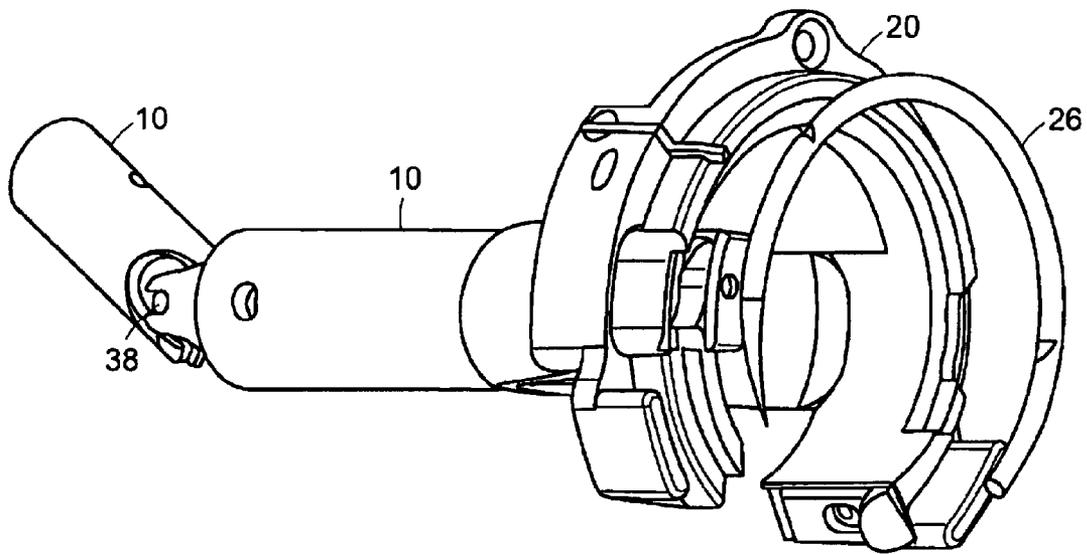


FIG. 13

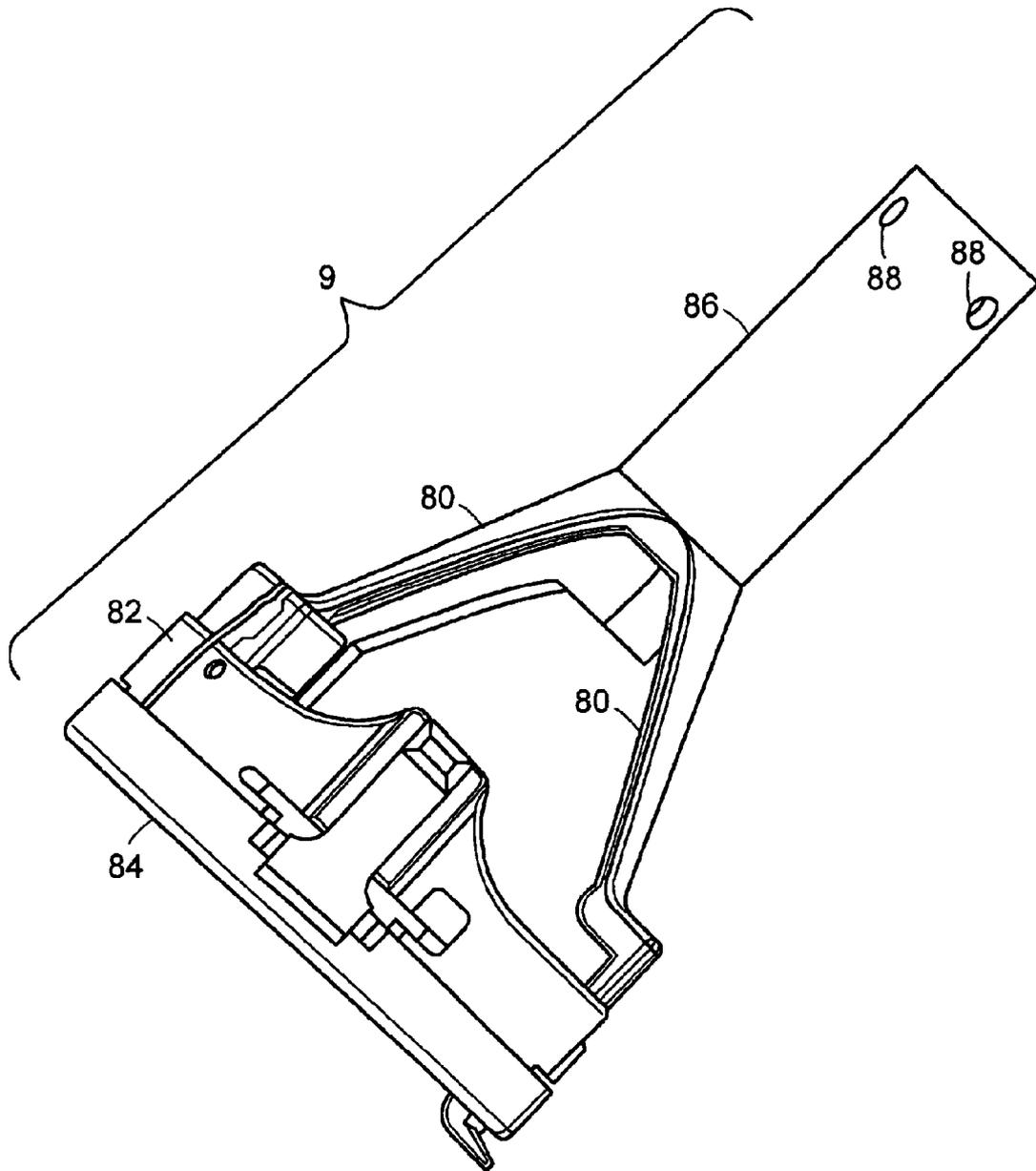


FIG. 14

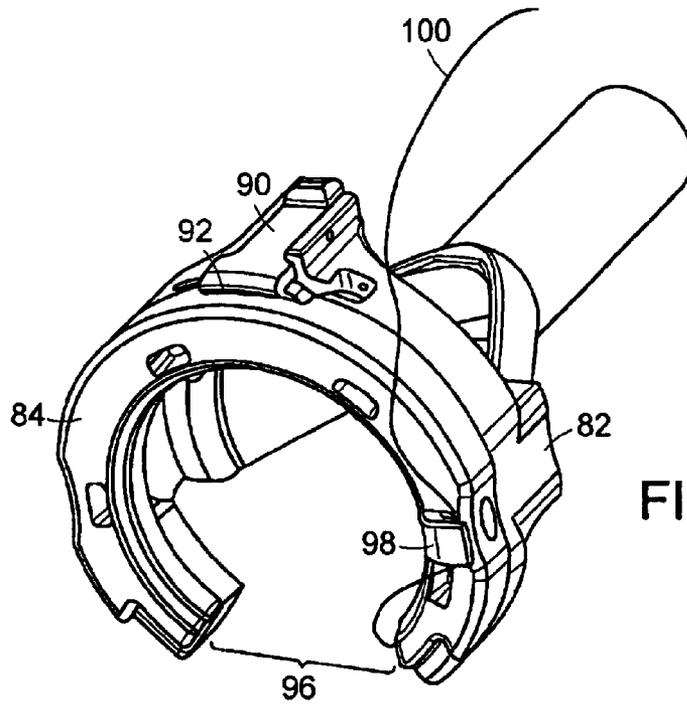


FIG. 15A

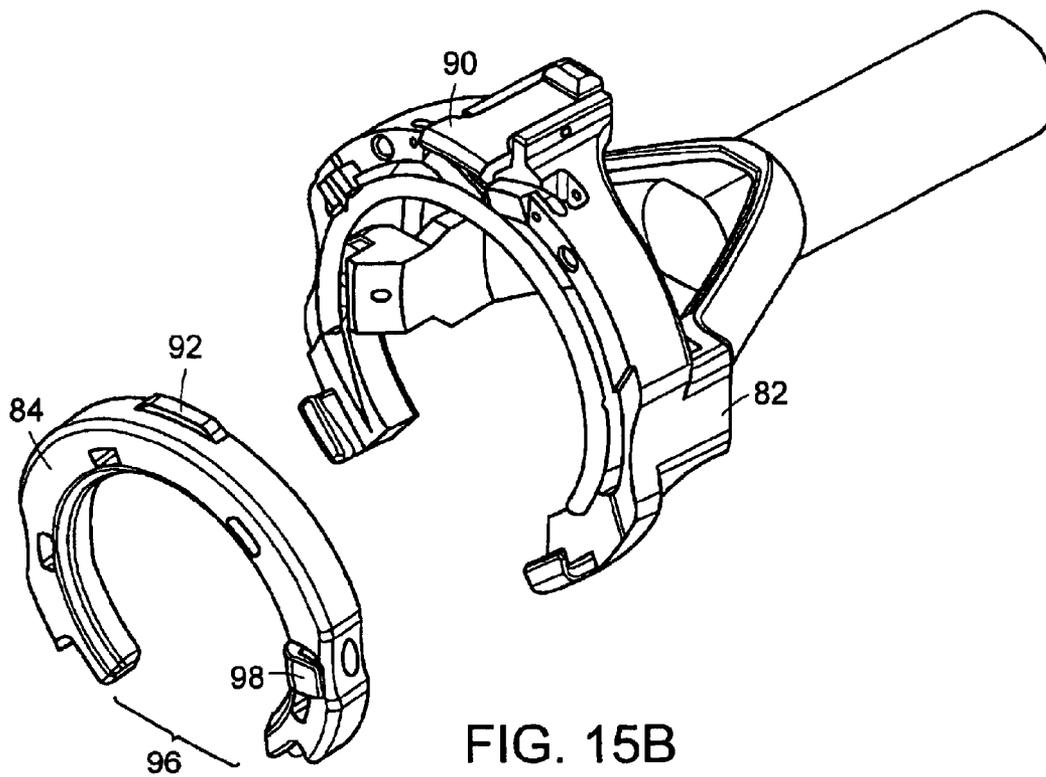


FIG. 15B

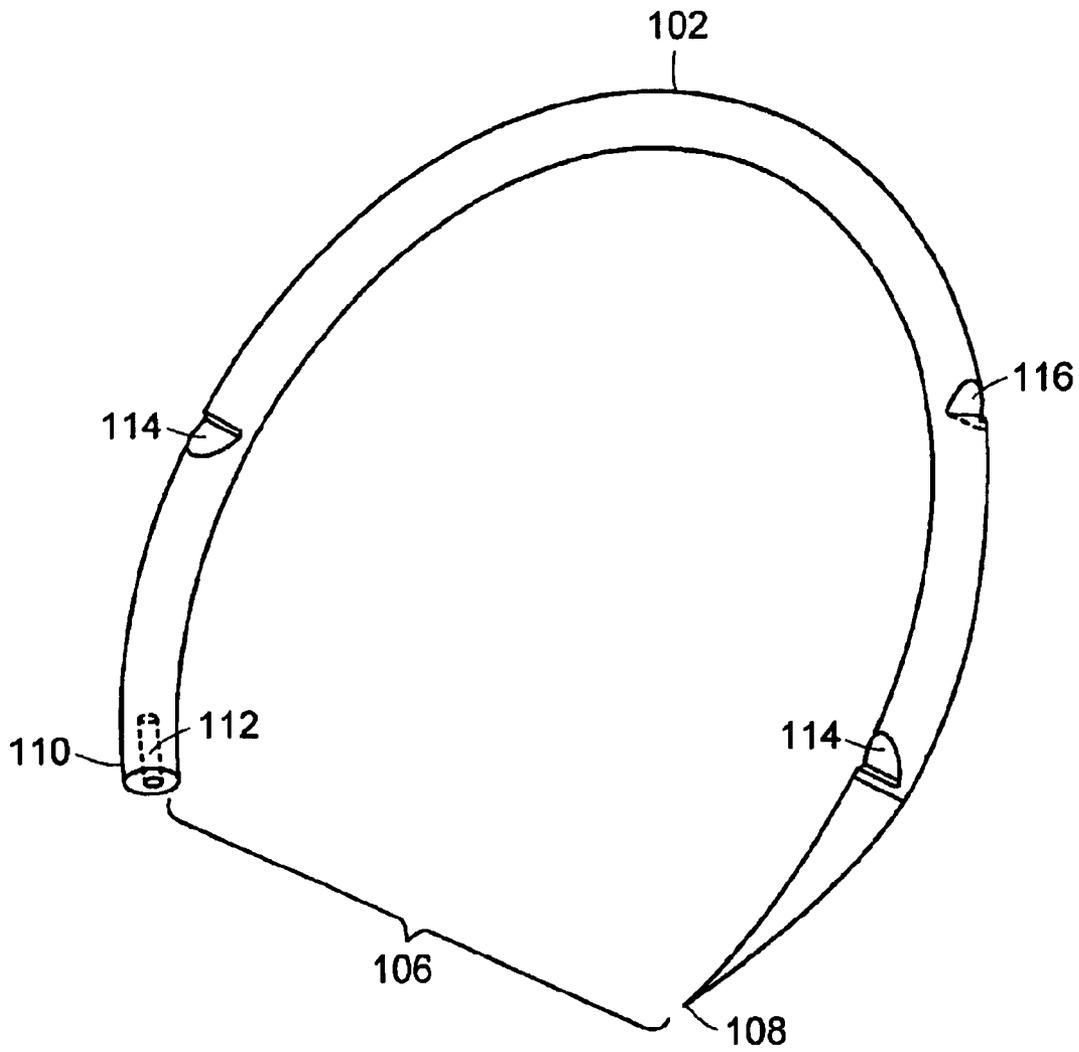


FIG. 16

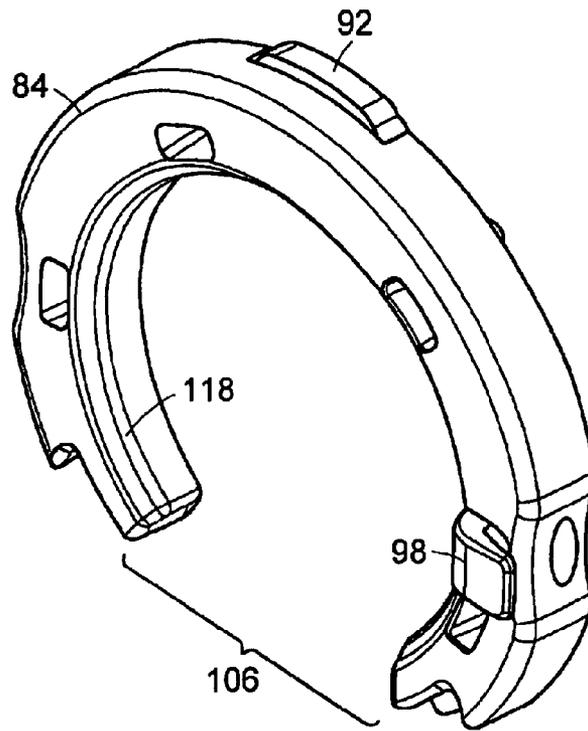


FIG. 17A

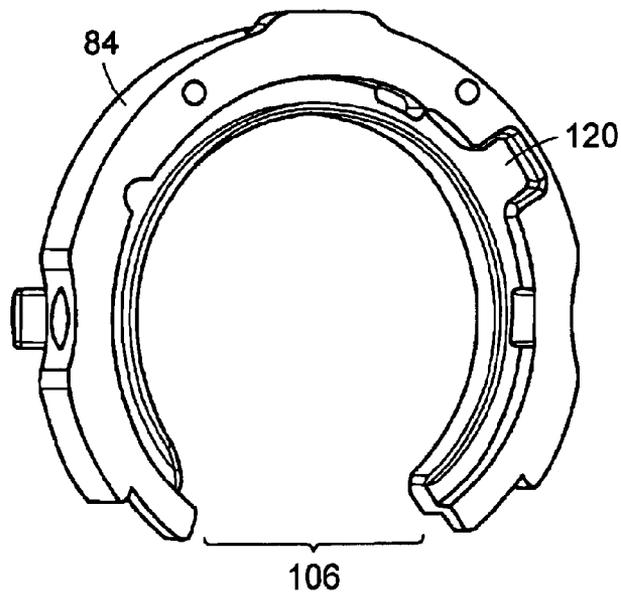


FIG. 17B

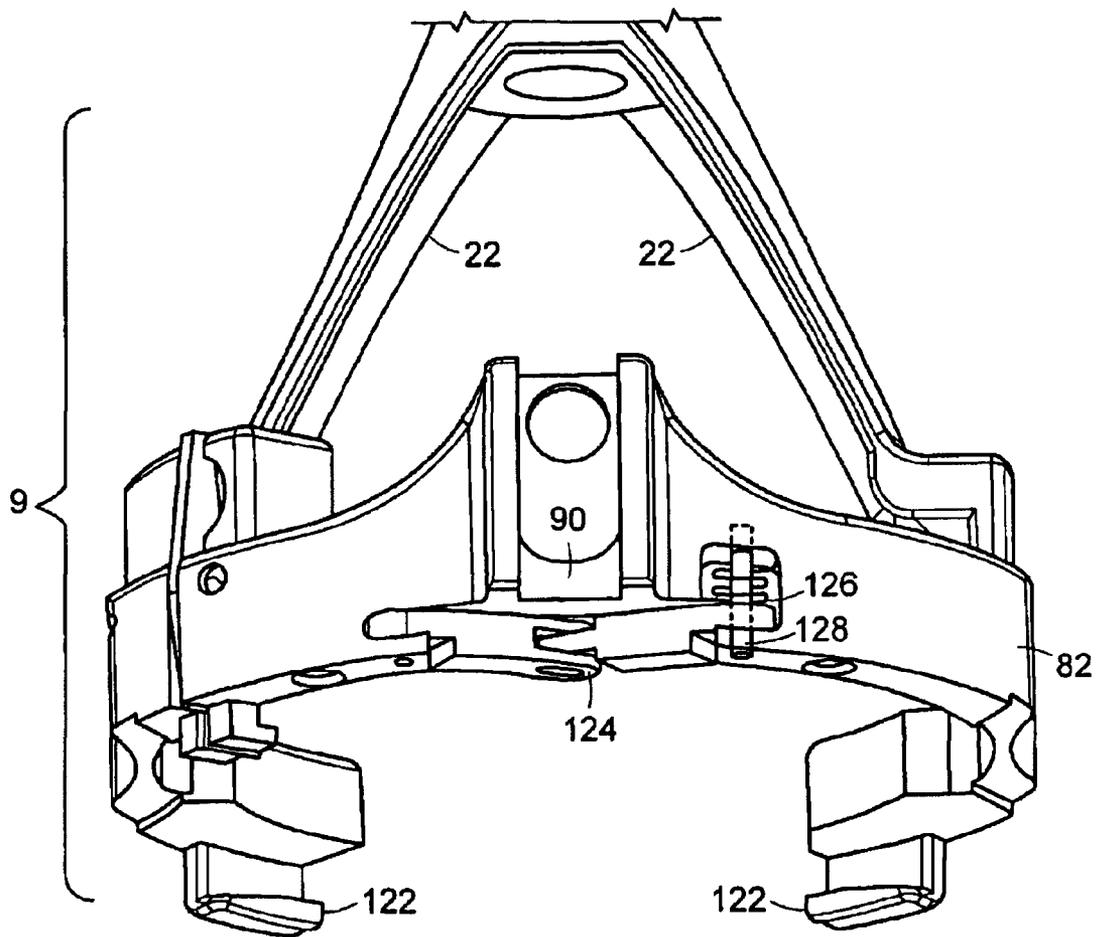


FIG. 18

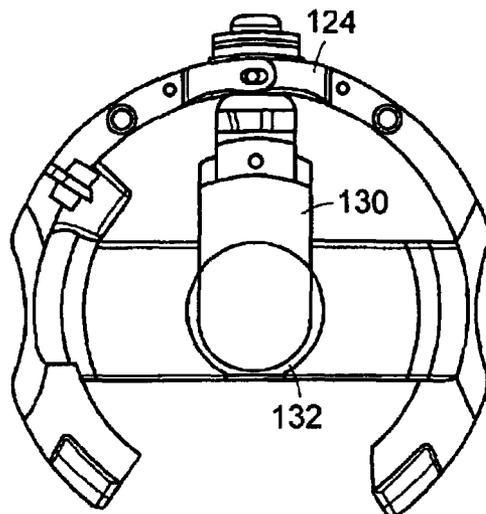


FIG. 19A

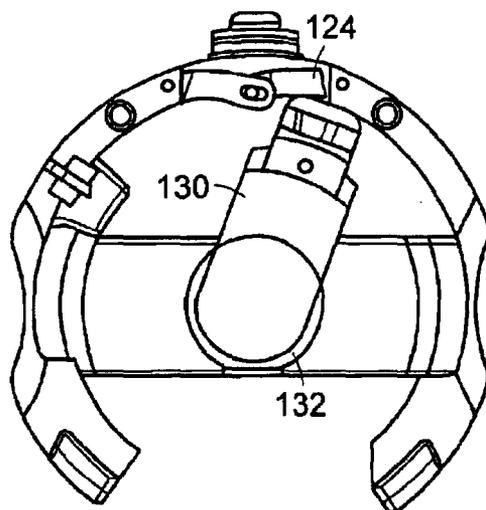


FIG. 19B

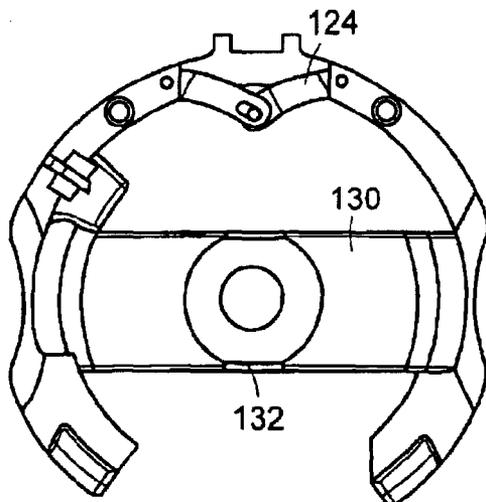


FIG. 19C

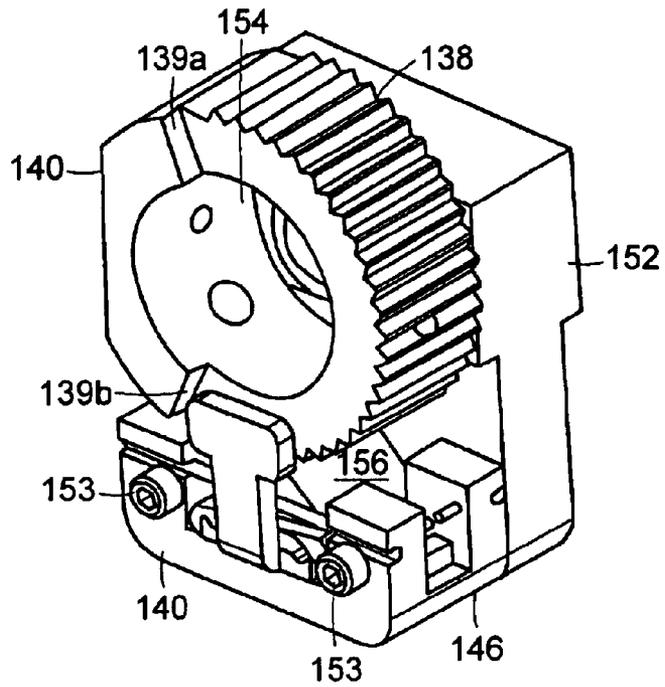


FIG. 20B

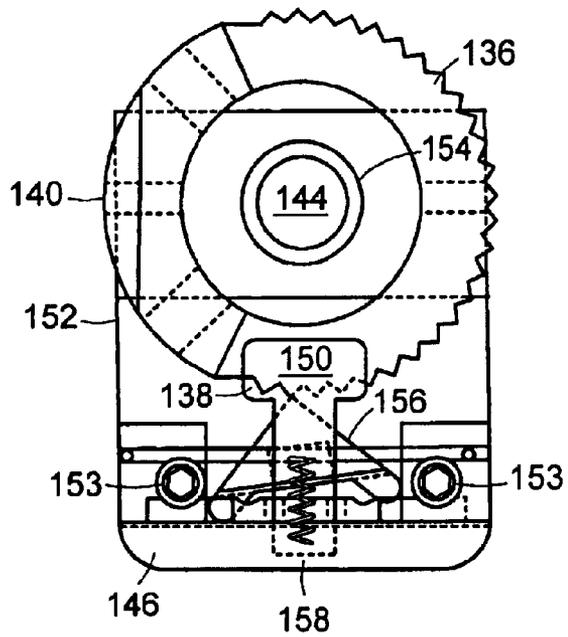


FIG. 20C

APPARATUS AND METHOD FOR SURGICAL SUTURING WITH THREAD MANAGEMENT

RELATED APPLICATIONS

This application claims priority to U.S. Provisional Application Ser. No. 60/298,281, filed on Jun. 14, 2001, for “Surgical Suturing Device with Thread Management” by John Meade and Niall Deloughery.

FIELD OF THE INVENTION

The present invention relates to a surgical device for suturing tissue. More particularly, the present invention relates to a suturing device that enables the manipulation and control of the suturing needle and suturing material during operation, and methods for using such a device for suturing tissue.

BACKGROUND OF THE INVENTION

Sutures are used in a variety of surgical applications including closing ruptured or incised tissue, soft tissue attachment, anastomosis, attachment of grafts, etc. Conventionally, suturing of ruptured or incised tissues, for example, is accomplished by the surgeon passing the sharpened tip of a curved suturing needle with a suture attached to the opposite blunt end of the needle through the incised tissue segments to be sutured such that the needle tip penetrates the tissue segments causing the needle to span the incision. The needle is then pulled through the tissue segments manually causing the attached suture to follow the curved path of the needle. Usually a knot is tied at the trailing end of the suture to anchor the first stitch. This action is performed repetitively with application of tension to the needle to pull the entire suture through the tissue segments through subsequent stitches until the entire incised segments are sutured together with a plurality of stitches.

For example, conventional, open abdominal surgery, including OB-Gyn procedures such as Cesarean delivery, creates a substantial incision (typically eight or more inches in length) in the fascia. In major orthopedic surgery, such as total hip replacement, even longer incisions in two layers of fascia must be closed. The closure of fascia must be done carefully at the conclusion of the surgical procedure, prior to skin closure. Closing fascia by hand suturing is a routine, repetitive, and time-consuming procedure. Typical abdominal incisions may take as long as twenty minutes, while in the case of hip replacement surgery, fascia closure can take even longer. Alternative mechanical suturing devices, as well as staplers, bone anchors, and suture-based arterial closure devices have been used as alternatives to hand suturing in other applications, since manual suturing is a tedious and the speed of the procedure is mostly dependent on skill of the surgeon. Moreover, manual suturing involves the handling and manipulation of a sharp suturing needle with an instrument such as a needle forceps, which can result in slipping and inadvertent, accidental needle pricks through a surgeon’s or nurse’s gloves, posing a potential risk of infection for the surgeon, nurse, staff, and patient. Furthermore, the direct handling of the needle can cause the needle to become contaminated with pathogenic bacteria that can cause onset of infection at the site of the sutures. There is also a risk of the needle penetrating the bowel and causing a serious, and often fatal infection.

Suturing devices described in the art designed to overcome these limitations are, however, either unduly complex design and economically non-viable or relatively difficult to

use and unsuited for precise manipulation for suturing areas that are not easily accessible. For example, the device disclosed in U.S. Pat. No. 4,557,265 has to be held sideways in relation to the direction of the incision being closed.

Another limitation of prior art suturing devices is their inability to provide positive control over the needle and suture during the suturing process. This can result in non-uniform sutures with either overly loose or overly tight stitches, which can cause excessive bleeding and risk tearing the repaired tissue in the patient.

A suturing device that maintains a positive control over the suturing needle and is capable of providing uniform stitches is disclosed in U.S. Pat. Nos. 5,437,681 and 5,540,705. The disclosed device requires a “scissors-like” grip and is operated by the surgeon’s thumb that provides articulation of the drive mechanism that causes rotation of a linear drive shaft encased in a barrel, which in turn causes a suturing needle encased in a disposable cartridge mounted at the distal end of the barrel to rotate in an advancing motion through the tissue. The device is, however, limited in its efficient operability in the following ways: (1) the rotational direction of the needle and the drive shaft is in a direction that is perpendicular to the device actuating handles, thereby rendering the device relatively difficult to manipulate and control, (2) does not allow the user to view the needle and its progress through the tissue during the suturing operation, since the barrel containing the drive shaft leading to the needle cartridge does not have an open construction to permit such observation, because the action of the needle is blocked from user’s view by the nature of the instrument design, thereby making it difficult for the user to position the advancing needle with high accuracy along the junction of the incised tissue segments and (3) the rate of needle advancement and, therefore, the size and uniformity of the stitches is essentially controlled by the user by the extent to which the articulation mechanism is depressed, thereby rendering the process of obtaining uniform needle rotation, tissue penetration and suture advancement difficult and entirely dependent on the skill of the user.

SUMMARY OF THE INVENTION

The present invention provides a suturing device that closely emulates or replicates the manual suturing actions carried out by a surgeon. The suturing device of the present invention provides greater ease of use and allows better visualization for the user during its operation than present mechanical suturing methods, while maintaining control over needle movement, advancement and suturing thread management during all phases of the suturing process, thereby preventing entanglement of the suturing thread material during needle movement.

A benefit provided the suturing device of the present invention is that it enables maneuvering a suturing material through a tissue incision in a manner substantially similar to the way a surgeon would do so by hand. In particular, the suturing device first pushes a suturing needle from the tail of the needle and drives the point of the needle through the tissue. The device then picks up the point of the needle after it has been driven through the tissue, and pulls the remainder of the suturing needle and the suture attached to the suturing needle through the tissue. The suturing needle thus consistently follows the arc of its own curve, which is the preferred method of suturing, in the most non-traumatic way of passing a needle through tissue. A benefit provided by the suturing device of the present invention is the ability of the suturing needle to pull the suturing thread entirely through the tissue segments being closed, following each stitch. The

present invention also relates to a suturing device comprising a suturing needle that is protected by a housing cartridge, whereby the suturing needle is not exposed to or handled directly by the user, thereby precluding inadvertent needle sticks. The configuration of the suturing device of the present invention also protects against inadvertent penetration of a bowel by the needle, since the cartridge acts as a shield between the bowel and the needle.

The suturing needle of the present invention is configured to fit into a cartridge, which in turn, is removably attached to the distal end of the suturing device. The present invention further provides an actuating means and a shaft and drive assembly that provides a torquing force to the suturing needle to cause the needle to advance through tissue during a suturing process without inadvertent retraction.

The suturing device of the present invention offers several advantages over conventional methods used by surgeons for suturing tissue in that it provides a hand-held suturing instrument of relatively simple mechanical construction and which requires no external motive source. The present invention provides relative ease of operation for the surgeon with only one hand, thereby enabling the surgeon to move obstructing tissue, debris and biological fluids from the suturing site with a free hand, while eliminating the need for needle holders, pick-up forceps, and other tools normally required for suturing by hand. Furthermore, the suturing device of the present invention can be configured as to length, tip, needle, suture, and needle cartridge size for use in conventional open surgery as well as in minimally invasive surgery (MIS) and in "less-invasive" surgery, such as through natural orifices or through small incisions. Additionally, the suturing head can be oriented in any preferred direction and either fixed in a particular orientation, or rendered movable in a variety of orientations by an articulation means.

These and other advantages of the present invention will be obvious through the embodiments described hereinafter. The present invention accordingly comprises the features of construction, combination of elements and arrangement of parts that will be exemplified in the following detailed description.

The surgical suturing device of the present invention is configured to provide a "pistol like" grip for the user that includes a barrel assembly and a handgrip that extends from the proximal end of the barrel. The barrel assembly has either a linear or non-linear configuration, including but not limited to, straight, curved and angled configurations. The barrel assembly comprises a plurality of hollow segments capable of being coupled together by one or more universal joints that do not require a permanent connection between the segments, enabling segments to be pulled apart individually and separated. A cartridge holder is removably attached to the distal end of the barrel assembly by a plurality of support arms to which is releasably mounted a disposable cartridge that is capable of accommodating a suturing needle and a suturing thread material.

The disposable cartridge has a generally cylindrical housing with an aperture in the sidewall of the housing at the distal or working end thereof. An arcuate suturing needle having a sharp, pointed tip at one end of the needle is slidably mounted in a circular track at the distal end of the housing and opposite to the location of the aperture. The needle is connected to a terminal end of a suturing material or thread with a suturing thread source, such as for example, a spool assembly that is contained either entirely within, or remains external the cartridge. The radius of the arc defining

the arcuate suturing needle is approximately equal to the circumference to the cartridge housing at the aperture therein. The needle normally resides in a "home" position in its track such that the gap in the arcuate suturing needle is in alignment with the aperture in the cartridge housing. The sharp, pointed end of the needle is situated on one side and entirely within the confines of the housing aperture; the pointed end is, therefore, always shielded by the cartridge housing. The blunt end of the suturing needle that is attached to the suturing thread is located at the opposite side of the aperture. The sharp, pointed end of the needle is, therefore, wholly contained within the cartridge and does not protrude and be exposed to the user.

In accordance with the present invention, the needle may be releasably engaged by a driving means that is rotatably mounted within the barrel assembly so that the needle can be rotated from its home position by about 360° about the central vertical axis of the cartridge. Such a rotatory action of the needle causes its sharp tip to advance across the cartridge housing so as to span the aperture. Thus, when the device is positioned such that the incised tissue segments to be sutured are situated at the housing aperture, the needle penetrates the tissue segments and spans the incision between them. A continued rotatory movement of the needle causes it to return it to its original "home" position, and thereby causes the suturing thread attached to the needle to be pulled into and through the tissue in an inward direction on one side of the tissue incision, and upwards and out through the tissue on the opposite side of the incision. Thus, the suture follows the curved path of the needle to bind the tissues together with a stitch of thread across the incision in a manner identical to that of a surgeon suturing manually, wherein the needle is "pushed" from the tail and then "pulled" from the point by the drive mechanism. Preferably, an anchoring means is provided at the trailing terminal end of the suturing material to prevent the material from being pulled completely through and out of the tissue segments. For example, the anchoring means can be a pre-tied or a welded loop, a knot wherein the suture is simply tied, or a double-stranded, looped suture is that attached to the suturing needle.

The rotatory movement of the needle within the needle cartridge is accomplished by a needle driver that may be operated by the user by holding the suturing device with one hand in a pistol-like grip around the handle, and using at least one finger of that hand to activate a triggering lever. The suturing device includes a finger operated trigger lever located proximally to the handle, which when actuated, operates a drive shaft encased within the universal joint barrel assembly through a drive mechanism so as to cause the drive shaft to undergo a rotatory motion, thereby causing the suturing needle to advance in a circular motion. Thus, by placement of the device with the needle cartridge aperture spanning the incised tissue segments and actuating the trigger lever, the suturing device enables the user to lay down a running stitch or interrupted stitch to close the tissue incision in a time efficient manner.

The needle cartridge of the present invention is disposably mounted on a cartridge holder assembly that is removably attached to the distal end of the universal joint barrel assembly. The cartridge holder assembly is supported by a plurality of support arms that extend from the distal end of the universal joint barrel assembly. The minimalized structural design of the support arms enables the user to have a clear, unobstructed view of the suturing needle as it advances through the tissue segments during the course of a suturing operation, thereby enabling precise placement of

5

the suturing device to provide uniform sutures and precluding the risk of tearing tissue by its placement too close to the edge of the incision. The suturing device of the invention is then advanced a short distance along the incision and the aforementioned operation is repeated to produce another stitch comprising the suturing material. The suturing device of the invention can either pull the entire suture material through the tissues automatically under controlled tension thereby replicating the actions of a surgeon suturing manually so as to tighten the formed stitches without tearing tissue. Alternatively, the surgeon simply pulls the thread by hand to tighten the stitch placed over the incised tissue segments by passage of the suturing needle of the suturing device of the invention.

The user may continue to manipulate the suturing device, alternately advancing and actuating rotation of the needle about an axis that is generally parallel to the direction of advancement to create a continuous suture which may extend through the entire length of the incision or a series of interrupted stitches. After each individual stitch is laid down, it is tightened by exerting a pull on the suturing material so that the resultant suture is neat and tensioned uniformly along the length of the incised tissue segments. Therefore, a tight closure of the segments is accomplished and bleeding and tearing of tissue are minimized.

As will be described in greater detail below, the needle driver may be operated by the surgeon holding the instrument with one hand, and using at least one finger of that hand. The suturing device includes a finger-operated lever that is functionally coupled with internal gearing and forms part of a handgrip that is located at one terminal end of the device, that enables the surgeon to efficiently and effectively lay down a running stitch, or a series of interrupted or uninterrupted stitches, to close a tissue incision in a minimum amount of time.

The suturing device of the present invention can additionally include an associated thread management system, which operates in conjunction with the needle driver to control or handle the suturing material or thread during rotation of the suturing needle. For example, the thread management roller pushes the thread away from the track so the suture does not get pinched by the needle as the needle re-enters the track. Thus, there is minimal probability of the thread becoming tangled or hung up during the suturing operation. The thread management system can also include a mechanism whereby the suturing material or thread is controllably "paid out" during the suturing process.

When using the suturing device of the present invention, no ancillary instruments or tools such as needle holders, pick-up forceps or the like are needed to complete the suture. Also, the suturing device may be configured in different ways with respect to length and angle of the universal joint barrels, the angle between barrel segments and the number and shape of the support arms. The size of the needle, needle cartridge, cartridge aperture and aperture position may also be varied for use in open surgery to perform procedures such as closing of the fascia, skin closure, soft tissue attachment, anastomosis, fixation of mesh, grafts and other artificial materials. The suturing device or the present invention may also be designed with a very small working end or tip at the end of a long rigid shaft or a flexible shaft that can be oriented in any preferred direction so that the instrument may be used for MIS, such as suturing in the course of endoscopic surgery, including laparoscopy, thoracoscopy and arthroscopy, as well as less-invasive surgical procedures.

In addition to offering all of the advantages discussed above, the suturing device of the present invention is rela-

6

tively simple and cost efficient to manufacture. Therefore, the suturing device should find widespread suturing applications that include single stitches or continuous stitches, e.g. spiral, mattress, purse string, etc., that are required to close tissue incisions, attach grafts, or the like.

BRIEF DESCRIPTION OF THE DRAWINGS

The present invention will be further explained with reference to the attached drawings, wherein like structures are referred to by like numerals throughout the several views. The drawings shown are not necessarily to scale, with emphasis instead generally being placed upon illustrating the principles of the present invention.

FIG. 1 shows a pictorial view of the suturing device of the present invention including the main components of a cartridge, a cartridge holder assembly, drive shaft segments, a universal coupling joint assembly and a sleeve, an actuator handle with an actuating trigger.

FIG. 2 shows a sectional view of the shaft-universal joint assembly attached to one embodiment of the suturing device functional end comprising the pusher, cartridge assembly and cartridge operable by a side drive mechanism.

FIG. 3A shows a segmented sectional view of suturing device functional end comprising a universal joint assembly without and with the universal joint sleeve. FIG. 3B shows an identical view with the universal joint sleeve.

FIGS. 4A, 4B and 4C show enlarged views of a single universal joint, joint coupler and a pair of coupled universal joints respectively.

FIG. 5 shows an expanded view of the universal joint sleeve configured at a 30° angle.

FIG. 6 shows a detailed view of one embodiment of a cartridge mount assembly comprising pair of supporting arms and a shaft segment.

FIGS. 7A and 7B show two different views of one embodiment of the needle cartridge.

FIGS. 8A and 8B show two embodiments of the curved suturing needle with suture material ports that are operable by a side drive mechanism.

FIG. 9 shows an expanded view of the thread management roller housed in the cartridge.

FIG. 10 shows an expanded view of the "anti-rotate" pin housed in the cartridge assembly.

FIG. 11A shows an expanded view of the pawl. FIG. 11B shows an expanded view of the pusher comprising a cartridge holder support arm with the pawl in place.

FIG. 12 shows a cut-away segment view showing interaction points of a suturing needle with a cartridge holder and support arm components.

FIG. 13 shows a segmented view of the relative configuration of a suturing needle with respect to the cartridge holder.

FIG. 14 shows a segmented sectional view of the functional end of a second embodiment of the suturing device operable by a rear drive mechanism comprising a shaft segment, the pusher, cartridge holder and cartridge (shown sectionally in FIGS. 15-19).

FIG. 15A shows a perspective view of a pusher with a cartridge holder assembly comprising an attached cartridge with a suture threading mechanism for restraining a suture material.

FIG. 15B shows a pusher comprising the cartridge holder assembly and a cut-away section of a cartridge comprising the curved suture needle that is operable by a rear drive mechanism.

7

FIG. 16 shows an expanded view of a curved suturing needle with suture material port that is operable by a rear drive mechanism.

FIGS. 17A and 17B show front and rear views of the cartridge.

FIG. 18 shows a cut-away sectional top view of a pusher comprising a cartridge holder assembly with a locking gate.

FIGS. 19A, 19B and 19C shows the operation of the pusher arm in a cartridge assembly operating in a rear drive mode. The pusher arm traverses radially by opening the gate (FIG. 19A), which springs to the closed position (FIGS. 19B and 19C) after its passage.

FIGS. 20A, 20B and 20C show a three-dimensional, a sectional and a cross-sectional view, respectively, of a ratchet assembly of the present invention that is driven by a drive shaft and activates a pusher arm upon device actuation.

While the above-identified drawings set forth preferred embodiments of the present invention, other embodiments of the present invention are also contemplated, as noted in the discussion. This disclosure presents illustrative embodiments of the present invention by way of representation and not limitation. Numerous other modifications and embodiments can be devised by those skilled in the art which fall within the scope and spirit of the principles of the present invention.

DETAILED DESCRIPTION

The suturing device of the present invention is shown generally at 1 in FIG. 1. Referring to FIG. 1, the suturing device 1 of the present invention can be used to produce a continuous or interrupted stitch or suture so as to enable closure of the segments of an incised tissue. The suturing device 1 includes an actuator handle 12 comprising a proximal end 6 and a distal end 8, that allows the device 1 to be held in a pistol grip by the user, and a trigger lever 16. The actuator handle 12 is attached to a pusher 9 at the distal end of handle 12. The pusher 9 comprises a shaft barrel assembly 10 comprising a plurality of shaft segments capable of housing a drive shaft (not shown) that extend outwardly from a housing 14 at the distal end 8 of the actuator handle 12. The shaft barrel assembly 10 is comprised of at least two segments with symmetric coupling assemblies that are coupled to one another with a universal joint coupler (not shown). The coupled assembly is enclosed within a universal joint sleeve 18 such that the universal joint barrel is configured at an angle of about 30° from horizontal. The shaft segment 10 distal from the actuator handle 12 is attached removably to a support arm assembly 22 that is comprised of a pair of "skeletalized" arms extending along mutually divergent axes so as to provide an opening 23 to view the device working end 19 during its operation. The working end 19 of the suturing device 1 comprises a cartridge holder assembly 20 that is removably attached to the support arm assembly 22, to which the needle cartridge 24 is disassemblably attached.

FIGS. 2–13 provide detailed views of the various components of one embodiment of the suturing device 1 and the manner in which the components are configured in the final assembled device to enable its operation via a "side-drive" mechanism in the manner described.

FIG. 2 shows the working end 19 of the suturing device 1 including the universal joint coupling sleeve 18, the universal joint segment distal to the actuator handle (not shown) a "pusher" 9 comprising a support arm assembly 22 and a cartridge holder assembly 20 with an attached disposable needle cartridge 24, and a universal joint assembly (hidden) encased in a joint sleeve 18.

8

FIGS. 3A and 3B provide detailed segmental views of the suturing device working-end 19 showing the disposable needle cartridge 24 in a disengaged mode and a curved suturing needle 26 separated from the needle cartridge 24 to illustrate the relative configuration of these segments with respect to the cartridge holder assembly 20, the pusher 9 comprising the support arm assembly 22 and the universal joint segments. FIG. 3A shows the coupled junction mode involving coupling of the shaft segments 10 comprising a universal joint coupler (hidden), while FIG. 3B shows the coupled shaft segments 10 encased in a coupling joint sleeve or "sweep" 18 that aligns the cartridge mount 20 from the stem to the actuator handle at about 30°. The sweep 18 can be either pre-configured to provide a pre-determined fixed angle for the cartridge mount (relative to actuator handle), or can be configured to be adjustable to provide the user with the ability to vary the cartridge mount angle to a setting optimal for a particular procedure.

FIGS. 4A–C show expanded views of the hollow universal joint segment and the manner in which two identical segments are coupled. As shown in FIG. 4A, the shaft segment 10 comprises a hollow cylindrical barrel 28 with two open ends, and two pairs of arcuate slots 32 and 34 at one end, wherein one pair of arcuate slots is narrower than the other. Additionally, the joint segment contains a plurality of circular openings 36 located on the cylinder surface to accommodate a corresponding number of restraining pins in the universal joint sleeve ("sweep") 18 that are identical in diameter. Two shaft segments 10 having identical arcuate slot configurations 32 and 34 may be coupled together using a universal joint coupler 38 (FIG. 4B) comprising a plurality of pins 40 such that the coupler engages the pair of narrow slots 32 of the adjoining joint segments 32, thereby providing a junction connecting the two shaft segments 10 that is non-rigid (FIG. 4C). The angle between coupled segments 10 can, therefore, be varied. The coupled segments 10 provide a conduit for passage of a drive shaft (not shown) for activating needle movement.

FIG. 5 shows a "transparent" view of the universal joint sleeve or "sweep" 18, which comprises of a hollow tubular segment with two open ends 28 whose tubular axis bends over a predetermined angle. The sleeve 18 additionally comprises a plurality of slots 30 positioned along its side wall that are capable of engaging the corresponding slots 36 on the shaft segments 10 that are positioned appropriately by means of restraining bolts on pins 38. The sweep 18 therefore, enables the angle of the coupled shaft segments 10 to be "locked" in a preferred angle. The sleeve 18 can be configured to have either a fixed angle, or to have the capability to provide the user the ability to adjust the angle to a preferred setting. In one embodiment, the sweep 18 provides an angle of about 30° from horizontal. The angle for the coupled universal joint segments 10 determined by the sweep in turn, determines the angle of the cartridge holder assembly 20 which is attached to the shaft segment 10 at the distal end 8 of the actuator handle 12 (via the support arm assembly 22). The cartridge holder angle relative to actuator handle 12, in turn, determines the accessibility of the suturing device 1 at the site of the suturing procedure which is critical, depending on whether it is open and planar, or non-planar and narrow.

FIG. 6 shows a detailed view of the pusher 9 that includes a cartridge holder assembly 20 that is attached to a support arm assembly comprising a pair of "skeletalized" support arms 22 which in turn, is attached to the terminal end of shaft segment 10. The open configuration of the "skeletalized" support arms 22 that are minimal in bulk is an essential

feature of suturing device **1** that provides a relatively wide opening **23** that allows the user to directly view the aperture in the needle cartridge and cartridge (not shown) holder assembly **20**, the incision in the tissue and needle advancement through the incised tissue segments during operation of suturing device **1**. Although the embodiment shown in FIG. **6** has a plurality of support arms **22**, other variants include a support arm assembly comprising a single support arm as illustrated in FIG. **11B**. The improved viewing ability offered by the shape and configuration of the support arm assembly **22** enables precise device placement over the incision, and uniform advancement of the suturing device after every stitch to provide a uniform and symmetric suture, thereby minimizing the risk of tearing tissue and bleeding due to a stitch being positioned too close to the edge of the incised tissue. The cartridge holder assembly **20** is composed of a sterilizable medical grade material which can either be a metallic material such as stainless steel to enable its reuse subsequent to sterilization following a prior use, or a sterilizable medical grade plastic material, in which case, it may be discarded and disposed after a single use. The cartridge holder assembly **20** has a cylindrical configuration with a distal edge **40** and a proximal edge **42** with respect to the device actuator handle (not shown), with an aperture **45** that corresponds in dimension and location to coincide with a substantially similar aperture located in the disposable needle cartridge. The cartridge holder assembly **20** additionally comprises a plurality of slots **44** located along on the distal edge **40** in that are located diametrically opposite to one another, and are capable of engaging the same plurality of retaining clips correspondingly located in the needle cartridge housing (not shown). The cartridge holder assembly **20** further comprises a cylindrical slot **46** located on the distal edge **40** that is capable of engaging a positioning pin of identical diameter correspondingly located on the needle cartridge housing (not shown). The proximal edge **42** of the cartridge holder assembly is attached to the shaft segment **10** distal to the actuator handle **12** via a support assembly comprising at least one "skeletalized" support arm **22**.

FIGS. **7A** and **7B** show two different views of an embodiment of a disposable suturing needle cartridge **24** of the present invention, which is preferably offered in a sterilized sealed package. The cartridge **24** comprises a circular housing **48** that may be formed of a suitable rigid medical grade sterilizable metal or plastic material. The housing may be releasably retained by the cartridge holder assembly **20** at the distal end **19** of suturing device **1** (working end) by known means, such as a plurality of clips **50** (shown in FIG. **7A**) located along on the edge of an inner lip **52** in diametrically opposite positions that are capable of engaging the same plurality of slots correspondingly located in the cartridge holder assembly **20**. The cartridge **24** further comprises a cylindrical positioning pin **54** located on the edge of the inner lip **52** that is capable of engaging a cylindrical slot of identical diameter correspondingly located on the cartridge holder assembly **20**. While the retaining clips **50** when engaged enable the cartridge to be retained by the cartridge holder assembly **20**, the positioning pin **54** when engaged in the slot causes the aperture in the cartridge **24** to be aligned with the corresponding aperture in the cartridge holder assembly **20**. The needle cartridge **24** further comprises an aperture **56** and a circular groove or "track" **58** that is inscribed in the inside surface of the housing **48**, which lies in a plane that is perpendicular to the longitudinal axis of both the housing **48** and that of the suturing device **1**. As shown in FIG. **7A**, the cartridge-housing aperture **56** interrupts the track **58**. An arcuate

surgical suturing needle **26** composed of medical grade stainless steel or similar material is slidably positioned in the track **58**.

FIGS. **8A** and **8B** show embodiments of the arcuate suturing needle **26** of the present invention. In one embodiment (FIG. **8A**), the needle **26** is formed as a circular split ring with a gap **59**, a sharp, pointed end **60**, and a blunt end **62**. The needle **26** further comprises an opening to accommodate the leading end of the suturing material. In one embodiment, the opening is the form of an eye **64** through which the leading end of the suturing material may be passed through for attaching it to the needle **26**. In the illustrated needle (FIG. **8A**), the eye **64** is located adjacent to the blunt end **62**. The eye **64** however, can be positioned anywhere along the arc or the needle **26** between its apex **61** and the blunt end **62**. In a preferred embodiment (FIG. **8B**), the needle **26** comprises an opening in the form of a cylindrical bore **66** aligned axially with respect to the needle **26**, located at the blunt end **62** (FIG. **8B**). The leading end of the suturing material is inserted into the bore and restrained by mechanically crimping. To enable the needle **26** to penetrate tissue to the required depth, the needle preferably has an arcuate extent between about 280° and about 330°, and more preferably, greater than about 270°. The needle **26** comprises two symmetric notches **68** along the radially inner edge ("inner notches") that are positioned proximally to the sharp, pointed end **60** and the blunt end **62** of the needle **26**. The notches **68** are located directly opposite to each other, each having a perpendicular (about 90°) segment and an angular segment that makes an angle of about 60° with the perpendicular segment. The inner notches **68** are engaged by the drive mechanism in the cartridge holder assembly **20** and enable the needle **26** to undergo a rotatory movement upon actuation of the drive mechanism, thereby causing it to penetrate into and advance through tissue. A similar triangular notch **70** is located on the radially outer edge ("outer notch") of the needle proximally to the inner notch **68** closer to the sharp, pointed end **60**. The outer notch **70** engages with an "anti-rotate" pin located in the cartridge holder assembly **20**, whereby rotation of the needle **26** in a direction opposite to the advancing direction or "needle backing-up" is prevented. The positive engagement of the needle outer notch **70** during operation of the suturing device **1**, and thereby precludes needle **26** from straying out of sequence during the suturing process.

The width of the aperture **56** in the cartridge housing **48** is comparable to and corresponds with the width of the gap in the needle **26** so that when the needle **26** is in the "home" position (as shown in FIG. **7A**) it does not project materially into the aperture **56**. Such an alignment causes the needle to reside entirely within the cartridge holder **20**, thereby preventing inadvertent contact of the sharp pointed end **60** with the user's fingers during handling of the disposable needle cartridge **24** for its placement on the cartridge holder **20** or its disposal after use, and while operating the suturing device **1**. Such protection of the needle **26** in the suturing device of the present invention prevents accidental "needle-pricks" from occurring, thereby substantially reducing the risk of infection caused by pathogenic bacteria or viruses that may contaminate the needle during or after its use prior to its disposal. The needle **26** may be rotated in its curved track **58** about the longitudinal axis of the suturing device **1** to advance the pointed needle tip **60** so that the needle first spans the aperture and then return to its original or home position. Since the suturing material is attached to the needle **26**, it follows the path of the needle **26**. The terminal end of the suturing material may contain a knot or button to prevent

11

it from pulling through the sutured tissue during placement of the first stitch. The suturing material or thread may be stored in an enclosed packaging either externally or internally with respect to the needle cartridge housing 48, and be pulled out of that packaging prior to placement of the first stitch in the suturing process. In a preferred embodiment, the cartridge housing 48 comprise the suturing needle 26 attached to the terminal end suturing material or thread, and an appropriate length of suturing material are all packaged in a terminally sterilizable medical packaging material.

FIG. 9 shows a thread management roller 72 of the present invention which acts to push the thread away from the track so the suture does not get pinched by the needle as the needle re-enters the track. The thread management roller 72 comprises a spring operated stop pin 74 that maintains a positive pressure against the suturing material or thread, thereby preventively retaining the suturing material in the thread retaining slot of the suturing needle, while keeping the thread out of the needle track to preclude the thread from jamming needle movement. The stop pin 74, therefore, prevents jamming of needle movement by an inadvertent entry of the suturing material into the needle slot within the needle cartridge 24 when the material is pulled forward by the advancing movement of the needle 26.

FIG. 10 shows an expanded view of the anti-rotate pin 75 that is capable of engaging the outer notch of the needle 26 to prevent rotation of the needle 26 and prevent “needle backing-up” and thereby precluding the needle 26 from straying out of sequence.

FIG. 11B shows an expanded view of a pusher assembly comprising pusher 76 and a pawl 78 (FIG. 11A) located at its tip, which resides in a corresponding slot in the support arm 22 of the pusher assembly, and is connected the support arm 22 by a pivot pin 80. The needle 26 is driven in a circular path by a rigid arm (“pusher”) that extends from a hub located in the center of the suturing device 1. The pawl 78 at the tip of the pusher 76 is capable of interfitting with the wedge shaped notches located along the radially inner edge of the needle. The pusher 76 is activated by the user upon operation of the actuator trigger in the actuator handle 12, and is capable of sweeping back and forth in an arc spanning about 280°. The outer surface of the pusher 76 is shaped to accommodate a C-shaped spring (not shown) that causes the wedge-shaped pawl 78 to push up against the needle 26 and thereby remain in intimate contact. The advancing movement of needle 26 during its operation causes the triangular slots 68 along the radially inner edge of needle 26 align with the wedge-shaped pawl 78 in the pusher 76, thereby causing the pawl 78 to engage the slots 68 due to a positive pressure exerted on the pin by the C-shaped spring, and to “lock” into the slots 68. The rotatory advancing movement of the needle 26 is therefore controlled to occur sequentially through about 280° each time it is actuated.

FIG. 12 shows a cut-away segmental view of the needle 26 in the home position inside the cartridge (not shown) with respect to the stem cartridge holder assembly (not shown). The relative locations of the pawl 78 that engages the notches 68 in the radially inner edge of the needle 26, the thread management roller 72 and the anti-rotate pin 75 that engages the notch 70 in the radially outer edge of the needle 26 are shown in FIG. 12.

FIG. 13 shows a cut-away view of the needle 26 within the cartridge (not shown) in the “home” position, the alignment of the needle aperture with the corresponding aperture in the needle cartridge holder 20, the relative position of the

12

needle 26 and cartridge holder 20 and aperture location with respect to the coupled shaft segments 10 that are coupled by universal joint coupler 38 and maintained at a fixed angle by the restraining coupling sleeve or “sweep” (not shown).

FIGS. 14–20 show detailed component views of a preferred embodiment of the suturing device of the present invention and the manner in which the components are configured to enable its operation as described herein.

FIG. 14 shows the working end of a preferred embodiment of the suturing device of the present invention, comprising a “pusher” 9 having a support arm assembly 80 and a cartridge holder assembly 82 with the attached disposable needle cartridge 84. The “pusher” 9 is connected to the drive mechanism via shaft segment 86 that is coupled via a universal joint coupling comprising a universal joint assembly encased in a sleeve (not shown) to a second shaft segment distal to the actuator handle 12. The shaft segment 86 is attached to the universal joint assembly by pins that engage slots 88 with corresponding slots in the coupling assembly.

FIG. 15A shows segmental views of the pusher assembly comprising a needle cartridge 84 engaged with cartridge holder assembly 82. The cartridge 84 attaches to cartridge holder assembly 82 via a mounting clip 90 located at the apex of the arc of the cartridge holder assembly 82 that slidably “locks” into position with a complementary slot 92 located correspondingly on the apex of cartridge 84. Both cartridge holder assembly 82 and cartridge 84 comprise an aperture 94 that are of similar dimension, and aligned with one another in the “locked” position. The cartridge 84 further comprises a suturing material management cleat 98 which is capable of restrictively maintaining suturing material 100 in a manner so as to preclude its entanglement as it travels into cartridge 84 during operation of the suturing device.

FIG. 15B shows a cut-away view of the pusher assembly exposing a suturing needle 102 residing within cartridge 84 (not shown) in the “home” position, wherein the alignment of the needle aperture corresponds with apertures of both needle cartridge holder assembly 82, and the cartridge 84. The needle 102 is placed in the “home” position by engaging cartridge 84 with cartridge holder assembly 82 in a “locked” position, whereupon it is restrained by clip 104 in a manner causing it to be engaged with notches located along the radially rear edge of the needle (not shown) that is proximal to cartridge holder assembly 82 by correspondingly located pins in a drive arm located in the cartridge holder assembly 82 that is part of a “rear-drive” needle rotation drive operating mechanism.

FIG. 16 shows a preferred embodiment of the curved suturing needle 102 of the invention. The needle 102 is formed as a circular split ring with an aperture (or gap) 106, as sharp, pointed end 108 and the opposite end 110. A cylindrical bore 112 aligned axially with respect to the needle, located at the blunted 110. The leading end of the suturing material is inserted into the bore and restrained by mechanically crimping. Alternatively, the opening for accommodating the suture material can be in the form of an “eye” wherein the leading end of the suturing material may be passed through for attaching it to the needle 102. To enable the needle 102 to penetrate tissue to the required depth, the needle 102 preferably has an arcuate extent between about 280° and about 330°, and more preferably, greater than about 270°. Needle 26 comprises two symmetric notches (“rear notches”) 114 along the radially rear edge, i.e. the edge proximal to the cartridge holder 82, that are

13

positioned proximally to the sharp pointed end **108** and the opposite blunt end **110** of the needle **102**, respectively. The rear notches **114** are located directly opposite to one another, each having a perpendicular (about 90°) segment and an angular segment that makes an angle of about 60° with the perpendicular segment. The rear notches **114** are engaged by the drive mechanism in the cartridge holder assembly and enable the needle to undergo a rotational movement upon actuation of the drive mechanism, thereby causing it to penetrate and advance through tissue. A similar triangular notch **116** is located on the radially outer edge (“outer notch”) of the needle proximally to the rear notch **114** that is closer to the sharp, pointed end **108**. The outer notch **116** engages with an “anti-rotate” pin located in the cartridge holder assembly, whereby rotation of the needle in a direction opposite to the advancing direction or “needle backing-up” is prevented. The positive engagement of the needle outer notch **116** during operation, therefore, precludes the needle from straying out of sequence during the suturing process.

FIGS. **17A** and **17B** show the outer and inner views, respectively, of the cartridge **84**. The outer surface of the cartridge **84** (FIG. **17A**) comprises a suturing material management cleat **98** which is capable of restrictively maintaining the suturing material in a manner to preclude its entanglement. The cartridge **84** further comprises a slot **92** located at the apex of an actuate edge that slidably engages a complementarily located pin on the cartridge holder assembly to “lock” it in position. The inner surface of the cartridge **84** comprises a track **118** that permits the suturing needle (not shown) housed within to travel in a rotational motion from its “home position” so as to span aperture **106** during operation. A slot **120** located radially on the inner surface of cartridge **84** engages with a complementarily located pin on the cartridge holder assembly such that when the pin is engaged slidably in slot **120**, the needle is constrained to remain in and move along track **118**.

FIG. **18** shows a top sectional view of a preferred embodiment of a “pusher” **9** comprising a cartridge holder assembly **82** and support arms **22**. The cartridge holder assembly **82** comprises a plurality of mounting clips **122** that are capable of receiving the cartridge **84**, and a mounting clip **90** at the apex of the radial edge and slidably engaging a complementarily located slot in the cartridge that engages cartridge holder assembly **82**, thereby causing the drive mechanism in the assembly **82** to engage the suturing needle housed within the cartridge. The cartridge holder assembly **82** further comprises a gate assembly **124** that prevents needle **102** from leaving its track and falling out into the back of the cartridge holder assembly **82**. The gate assembly **124** is maintained in a closed “home” position by a torque force exerted by a spring **126** to which it is coupled via a pin **128**, thereby restricts lateral movement of needle **102**. The gate assembly **124** opens during each actuation of the suturing device to permit a circular movement of the drive mechanism that engages needle **102**, and closes to the home position immediately after passage of the drive mechanism to preclude lateral movement and dislocation of needle **102** within cartridge holder assembly **82**.

FIGS. **19A**, **19B** and **19C** show serial views of the “rear-drive” needle operating drive mechanism operating within the cartridge holder **82** of the pusher assembly (not shown). The “rear-drive” mechanism comprises a driver arm **130** connected to a drive shaft **132** that is capable of circular motion so as to “sweep” along the circular inner edge of the cartridge holder **82** comprising the gate assembly **124**. Actuation of the device causes the drive shaft **132** to rotate

14

in a clockwise direction, thereby causing driver arm **130** to move circularly from its “home” rest position and move up to and the past gate assembly **124**, causing it to open in the process (FIGS. **19A** and **19B**). The driver arm **130** continues to move circularly until it comes to rest once again in the “home” position (FIG. **19C**). The gate assembly **124** returns to its closed home position after passage of the driver arm **130**, thereby allowing driver arm **130** to “drive” needle **102** in a circular motion, while preventing the needle **102** from becoming dislocated from track **118**. Thus, each time suturing device **1** is actuated, driver arm **130** moves past the gate assembly **124**, opening the gate assembly **124** in the process. Since the gate assembly **124** moves back into its closed “home” position after passage of the driver arm **130**, it precludes lateral movement of the needle **102**, thereby preventing needle **102** from jamming due to misalignment during operation.

FIGS. **20A**, **20B** and **20C** show the dimensional, sectional and transparent sectional views, respectively, of a ratchet assembly **134** of the present invention that is part of the drive mechanism for the suturing device **1**. FIG. **20A** shows the ratchet assembly **134** comprises a ratchet ring **136** with a predominantly arcuate outer surface segment **138** having a plurality of teeth **138**, and an arcuate flat segment **140** that having a planar surface. The ratchet ring **136** includes a central circular bore (not shown) that fits slidably over and attaches immovably to a pinion gear **142** comprising a shaft **144**. The ratchet ring **136** further comprises a plurality of wedged surfaces **139a** and **139b** that are proximal to the flat segment **140**. The ratchet assembly **134** is mounted on a base **146** comprising a housing **148** that accommodates a pawl (hidden) that is activated by a coil spring (not shown) and a shuttle **150**, that is attached to a support bracket **152** by a plurality of screws **153**. FIG. **20B** shows a detailed sectional view of the ratchet ring **136** comprising a circular bore **154** that is capable of slidably receiving and attaching to the shaft **144** of the pinion gear **142** (not shown). The ratchet ring **136** is mounted on the base **146** so that the teeth **138** of the ratchet ring **136** are interactively meshed with the pawl **156**. The pawl **156** is activated by a coil spring (not shown) that exerts a positive pressure on the pawl **156** causing it to remain in intimate contact with the teeth **138** of the ratchet ring **136**. The shuttle **150** is attached to the base so that it allows the ratchet ring **136** to rotate in a unidirectional (such as, for example, clockwise) until the circular movement is arrested by contact between the shuttle **150** and a first wedge **139a** in the ratchet ring **136**. Movement of the shuttle **150** after contacting the first wedge **139a** permits the ratchet ring **136** to rotate in a direction opposite to the initial direction of rotation (such as, for example, counter-clockwise) until the movement is stopped by contact of shuttle **150** with the second wedge **139b**. FIG. **20C** shows a transparent sectional view of the ratchet ring **136** where the teeth **138** of the ratchet ring **136** are enmeshed with the pawl **156**, which is maintained in intimate contact with the teeth **138** by a positive pressure exerted by the action of a coil spring **158**.

The ratchet assembly **134** of the present invention may be suitably located within the handle **12** of the suturing device **1**. In a preferred embodiment, the ratchet assembly **134** is located at the distal end **8** of the actuator handle **12**, whereby the shaft **144** of the ratchet assembly **134** is a part of a shaft segment **10** that is terminally attached to a triggering mechanism of the suturing device **1**. Activation of the suturing device **1** by actuating the triggering mechanism (not shown) via the trigger **16** in the actuator handle **12** causes the shaft **144** and the attached ratchet ring **136** and the pinion gear **142** in the ratchet mechanism **134** to rotate unidirectionally, the

15

pinion gear **142** to drive the shaft segment **10** coupled to the driver arm **130** of the rear-drive mechanism in the pusher **9**, which in turn, causes the engaged needle **102** to rotate in the same direction to effectuate penetration of incised tissue by the needle **102** pulling the suturing thread material with it. The rotation of the shaft **144** is arrested after travelling about 280° upon contact by a first wedge **139a** with the shuttle **150**, which in turn, terminates the first actuation step. The shuttle **150** then permits the shaft **144** with the attached ratchet ring **136** and the pinion gear **142** to rotate through an equal distance in the opposite direction until the movement is stopped once again by the contact by the shuttle **150** with the second wedge **139b**. An advantage offered by the ratchet mechanism **134** of the present invention is that the actuation step of the suturing device **1** is pre-determined, that is, the ratchet assembly **134** prevents the user from performing an incomplete actuating event that could result in an improper or incomplete suture by causing the needle **102** to snag in the tissue. Furthermore, the ratchet assembly **134** is capable of operation by the trigger **16** in a manner independent of its orientation with respect to the trigger **16** and actuator handle **12**, such as for example, when it is oriented in an upside down or sideways configuration.

The actuating means of the suturing device **1** of the present invention may comprise of a triggering mechanism that is known in the art, such as for example, the triggering mechanisms disclosed in U.S. Pat. Nos. 6,053,908 and 5,344,061, both of which are hereby incorporated by reference. Alternatively, the actuating means can be either a manually operable button or switch, or a mechanically operable by an automated electrical or a fuel driven device, such as for example, an electrical, electromagnetic or pneumatic motor powered by electrical, electromagnetic, compressed air, compressed gas, hydraulic, vacuum or hydrocarbon fuels.

To commence suturing, any embodiment of the suturing device **1** of the present invention is placed at the site of the wound or tissue incision such that it spans the wound or the two tissue segments created by the incision, following which it is actuated by operation of the actuator trigger **16** on the actuator handle **12**. The detailed operation of the suturing device **1** of the present invention is described with reference to the preferred embodiment, and is equally applicable to all other embodiments of the invention described and contemplated herein. The pawl **156** in the pusher mechanism of the suturing device **1** engages the notch **114** located radially rear edge proximal to the blunt end or "tail" of the suturing needle **102** and pushes the needle in a circular path in an arc spanning about 280°. The sharp, pointed end **108** of the needle **102** crosses the aperture **96** defined by the cartridge **84** and the cartridge holder **82**, and penetrates the first tissue segment located within the aperture **96**, traverses the tissue segment to penetrate the second tissue segment, and re-enters the device on the opposite side of the aperture **96**. The pusher **9** then returns to its original location, whereupon the pawl **156** engages the notch located radially rear edge **114** proximal to the sharp, pointed end of the needle **102**. The needle **102** with the attached suturing material or thread is consequently pulled in a circular path through an arc of about 280°. The blunt end **110** of the needle **102** and the suturing material therefore, pass through the tissue segments and across the wound or incision so as to span the wound or incision. The needle **102** comes to rest at its original "home" position within the track in cartridge holder **82**, having advanced through a complete circular arc of about 360°. The needle **102** including the sharp, pointed end **102** remains entirely contained within the cartridge **84**. The suturing

16

material or thread may then be cut and secured by an appropriate method, such as for example, by tying, or additional stitches may be placed along the entire wound or incision by repeating the aforementioned process. Every stitch, whether a single, interrupted stitch, or one of a series of continuous, running stitches may be placed in like manner. The suturing device **1** of the present invention, therefore, may be used to insert either a single stitch, or to insert a suture comprising a plurality of continuous stitches as a replacement method for a more tedious and time-consuming manual suturing process.

While a suturing device **1** having the separable suture cartridge **84** containing the suturing needle **102**, a pusher **9** comprising a cartridge holder **82** with the support arms **80**, a drive shaft assembly comprising the driver arm **130**, and an actuator handle **12** comprising the actuating trigger **16** and drive mechanism has been described, the entire suturing device **1** can be designed as a single unit which may be either reusable or disposed in its entirety after a single use.

It will thus be seen that the examples set forth above among those made apparent from the preceding description are efficiently attained in the suturing device of the present invention. Also, since certain changes may be made in the above description without departing from the scope of the invention, it is intended that all matter contained in the above description or shown in the accompanying drawings shall be interpreted as illustrative, and not in a limiting sense.

What is claimed is:

1. A suturing device comprising:

- a cartridge having a protective housing and a suturing needle having a pointed end and a blunt end, the suturing needle capable of rotating about an axis, wherein the pointed end of the suturing needle is positioned within the protective housing after a complete rotation of the suturing needle about the axis;
- a pusher assembly comprising a cartridge holder assembly having a needle rotation drive, the cartridge holder assembly capable of releasably engaging the cartridge to bring the needle rotation drive into operational contact with the suturing needle wherein the needle rotation drive releasably engages the suturing needle to rotate the suturing needle; and
- an actuator capable of engaging the needle rotation drive to rotate the needle rotation drive and the suturing needle.

2. The suturing device of claim 1 wherein the cartridge further comprises:

- a curved lip covering an arc greater than about 180° and less than about 330°;
- a track in a wall whereby the suturing needle follows a curved path along the track during needle rotation; and
- an aperture in the curved lip which intercepts the track whereby the pointed end of the suturing needle traverses the aperture during each revolution of the suturing needle along the path.

3. The suturing device of claim 2 wherein the cartridge further comprises a suturing material dispenser containing a suturing material.

4. The suturing device of claim 2 wherein the cartridge further comprises a thread management system.

5. The suturing device of claim 1 wherein the cartridge further comprises at least one mounting clip whereby the cartridge is releasably engaged with the cartridge holder assembly having the needle rotation drive.

6. The suturing device of claim 1 wherein the suturing needle covers an arc greater than about 180° and less than

17

about 330° having an aperture located adjacent to the blunt end for engaging a suturing material.

7. The suturing device of claim 1 wherein the suturing needle comprises an aperture between the pointed end and blunt end.

8. The suturing device of claim 1 further comprising an interlocking mechanism capable of releasably locking the suturing needle with the needle rotation drive whereby rotational movement of the needle rotation drive causes the suturing needle to rotate.

9. The suturing device of claim 8 wherein the interlocking mechanism further comprises a plurality of engagement notches that interfit with the needle rotation drive whereby the suturing needle is rotated by said needle rotation drive in a direction which advances the pointed end of the suturing needle.

10. The suturing device of claim 9 wherein the interlocking mechanism engages at least one notch on a surface of the suturing needle.

11. The suturing device of claim 1 wherein the pusher assembly comprises:

the cartridge holder assembly having a distal end and a proximal end, the distal end capable of engaging the cartridge and the proximal end releasably attached to a support arm assembly having at least one arm; and a drive shaft having at least one segment attached to the proximal end of the cartridge holder assembly.

12. The suturing device of claim 11 wherein the support arm assembly has two arms that are spatially configured to provide visual access between the support arms.

13. The suturing device of claim 1 wherein the cartridge holder assembly further comprises:

a curved ring having a lip covering an arc greater than about 180° and less than about 330°;

a track in the lip whereby the suturing needle follows a curved path along the track during needle rotation;

an aperture in a wall which intercepts the track whereby the pointed end of the suturing needle traverses the aperture during each revolution of the suturing needle along the curved path wherein the needle rotation drive capable of rotation about an axis that releasably engages the suturing needle whereby rotation of the needle rotation drive in a curved path causes a corresponding rotation of the needle;

a pawl capable of controlling the direction of rotation of the suturing needle; and

at least one segment of a drive shaft that is releasably attached to the needle rotation drive.

14. The suturing device of claim 13 wherein the cartridge holder assembly further comprises a releasably locking gate assembly.

15. The suturing device of claim 1 wherein the cartridge holder assembly further comprises at least one mounting clip whereby the cartridge holder assembly releasably engages the cartridge having the suturing needle.

16. The suturing device of claim 1 wherein the needle rotation drive comprises:

a rotatable needle driver mounted in a terminally located housing capable of coupling to a cartridge capable of releasably engaging a suturing needle contained therein whereby rotation of the rotatable needle driver causes rotation of the suturing needle; and

a drive shaft attaching to an end of the housing capable of rotating the rotatable needle driver.

17. The suturing device of claim 16 wherein the drive shaft couples the needle driver to an actuator to rotate the needle driver about an axis.

18

18. The suturing device of claim 16 wherein the drive shaft comprises a plurality of separable shaft segments that are coupled by a universal joint assembly that allows said plurality of segments to rotate together.

19. The suturing device of claim 18 wherein the universal joint assembly comprises at least one universal coupler that enables said drive shaft coupled by said universal coupler to rotate when the plurality of shaft segments are configured non-linearly with respect to each other and with respect to a longitudinal axis of the drive shaft.

20. The suturing device of claim 18 wherein the plurality of separable shaft segments are configured linearly or non-linearly with respect to one another and are coupled by at least one universal joint assembly.

21. The suturing device of claim 18 wherein the universal joint assembly comprises a sleeve capable of releasably enclosing the joint assembly in an angular rigid configuration with respect to the longitudinal axis of the drive shaft.

22. The suturing device of claim 16 wherein the drive shaft comprises a ratchet assembly capable of restrictably controlling the extent and direction of rotation of the drive shaft and the needle driver attached to the drive shaft upon actuation of the drive shaft by the actuator.

23. The suturing device of claim 22 wherein the ratchet assembly comprises:

a ratchet ring comprising a central bore capable of allowing the passage of a drive shaft segment therethrough and a plurality of grooves covering at least part of an external surface mounted in a housing;

a locking mechanism capable of releasably locking the ratchet ring to the drive shaft whereby rotational movement of the drive shaft causes a similar rotation of the ratchet ring;

a plurality of wedges symmetrically located on a surface of the ratchet ring;

a pawl that engages the grooves of the ratchet ring;

a shuttle attached to the housing capable of contacting the wedges and controlling the rotation of the ratchet ring; and

a pinion gear comprising a substantially cylindrical grooved segment attached to a terminal end of the drive shaft segment.

24. The suturing device of claim 23 wherein the locking mechanism is selected from the group consisting of a screw, a pin and a bolt.

25. The suturing device of claim 1 wherein the needle rotation drive causes rotation of the suturing needle comprising a blunt end and a sharp pointed end by providing a pushing force adjacent to said blunt end and a pulling force adjacent to said sharp pointed end.

26. The suturing device of claim 1 wherein the actuator is a manually operable trigger, button or switch.

27. The suturing device of claim 1 wherein the actuator is mechanically operable by an electrical device or a fuel driven device.

28. The suturing device of claim 1 wherein the actuator is activated by automation using a power source selected from the group consisting of electrical, electromagnetic, compressed air, compressed gas, hydraulic, vacuum and hydrocarbon fuels.

29. The suturing device of claim 1 further comprising a curved track on an inner surface of the cartridge wherein the suturing needle moves in the curved track during rotation of the suturing needle.

30. The suturing device of claim 1 further comprising a curved track on an inner surface of the cartridge that

19

contains the pointed end of the suturing needle prior to and after rotation of the suturing needle.

31. The suturing device of claim **1** wherein the suturing needle is slidably positioned in a curved track of the cartridge.

32. A surgical device for suturing mammalian tissue comprising:

an actuator handle having an attachment end;

an elongated drive shaft having a distal end, a proximal end attached to the attachment end of the actuator handle, and a longitudinal axis extending between the distal end and the proximal end;

a support arm assembly having a proximal end and a distal end releasably attached to a cartridge holder assembly having a needle rotation drive capable of engaging and rotating a suturing needle about a rotational axis, the proximal end of the support arm assembly releasably attached to the distal end of the drive shaft to fix the support arm assembly relative to the drive shaft;

a cartridge having a protective housing and the suturing needle, the cartridge extending from a distal end of the cartridge holder assembly and releasably attached to the cartridge holder assembly whereby the suturing needle releasably engages the needle rotation drive in the cartridge holder assembly, wherein a pointed end of the suturing needle is positioned within the protective housing after a complete rotation of the suturing needle about the rotational axis; and

an actuator attached to the actuator handle for causing rotation of the drive shaft and the needle rotation drive, thereby rotating the suturing needle about the rotational axis of the needle rotation drive.

33. The surgical device of claim **32** wherein the suturing needle is arcuate having a radius commensurate with a rotational radius of the needle rotation drive of the cartridge holder assembly, the needle rotation drive releasably engaging the suturing needle so the suturing needle is oriented around the longitudinal axis of the drive shaft.

34. The surgical device of claim **32** wherein the actuator is selected from the group consisting of a trigger, a push button, a lever, a pedal and a mechanically driven switch.

35. The surgical device of claim **32** wherein the actuator is operated by applying a manual or an automated mechanical force.

36. The surgical device of claim **35** wherein the automated mechanical force is a power source selected from the group consisting of electrical, electromagnetic, compressed air, compressed gas, hydraulic, vacuum and hydrocarbon fuels.

37. The surgical device of claim **32** further comprising a curved track on an inner surface of the cartridge wherein the suturing needle moves in the curved track during rotation of the suturing needle.

38. The surgical device of claim **32** further comprising a curved track on an inner surface of the cartridge that contains the pointed end of the suturing needle prior to and after rotation of the suturing needle.

39. The surgical device of claim **32** wherein the suturing needle is slidably positioned in a curved track of the cartridge.

40. A method for suturing tissue comprising the steps of: releasably engaging a cartridge to a cartridge holder assembly of a suturing device;

placing a the suturing device having a the cartridge with a protective housing and a suturing needle to cause an aperture in the cartridge to span a plurality of separated tissue segments, wherein a pointed end of the suturing

20

needle is positioned within the protective housing after a complete rotation of the suturing needle about a rotational axis;

activating an actuator coupled to a needle rotation drive that releasably engages the suturing needle to cause rotational movement of the suturing needle across the aperture and advance the suturing needle through the plurality of separated tissue segments; and

deactivating the actuator to stop an advancing movement of the suturing needle to cause a suturing material attached to the suturing needle to be pulled through the plurality of separated tissue segments forming a stitch.

41. The method of claim **40** wherein the surgical device comprises:

an actuator handle having an attachment end;

an elongated drive shaft having a distal end, a proximal end attached to the attachment end of the actuator handle, and a longitudinal axis extending between the distal end and the proximal end;

a support arm assembly having a proximal end and a distal end releasably attached to the cartridge holder assembly having the needle rotation drive capable of engaging and rotating the suturing needle, the proximal end of the support arm assembly releasably attached to the distal end of the drive shaft to fix the support arm assembly relative to the drive shaft;

the cartridge having the suturing needle, the cartridge releasably attached to the cartridge holder assembly whereby the suturing needle is capable of engaging the needle rotation drive in the cartridge holder assembly, wherein the cartridge extends from a distal end of the cartridge holder assembly; and

an actuator attached to the actuator handle for causing rotation of the drive shaft and the needle rotation drive, thereby rotating the suturing needle about the longitudinal axis of the drive shaft.

42. The method of claim **41** wherein the suturing needle is arcuate having a radius commensurate with a rotational radius of the needle rotation drive of the cartridge holder assembly, the needle rotation drive releasably engaging the suturing needle so the suturing needle is oriented around a rotational axis of said needle rotation drive.

43. The method of claim **41** wherein the actuator is selected from the group consisting of a trigger, a push button, a lever, a pedal and a mechanically driven switch.

44. The method of claim **41** wherein the actuator is operated by applying a manual or automated mechanical force.

45. The method of claim **44** wherein the automated mechanical force is a power source selected from the group consisting of electrical, electromagnetic, compressed air, compressed gas, hydraulic, vacuum and hydrocarbon fuels.

46. The method of claim **40** wherein the needle rotation drive causes rotation of the suturing needle comprising a blunt end and a sharp pointed end by providing a pushing force adjacent to said blunt end and a pulling force adjacent to said sharp pointed end.

47. The method of claim **40** wherein the tissue is mammalian tissue.

48. The method of claim **40** further comprising moving the suturing needle in a curved track on an inner surface of the cartridge during rotation of the suturing needle.

49. The method of claim **40** further comprising positioning the pointed end of the suturing needle within a curved track of the cartridge prior to and after rotation of the suturing needle.

50. The method of claim 40 further comprising slidably positioning the suturing needle in a curved track of the cartridge.

51. A method for suturing tissue at a wound or incision site comprising the steps of:

- (a) releasably engaging a cartridge to a cartridge holder assembly of a suturing device;
- (b) placing a suturing device having a cartridge with a protective housing and a suturing needle at the wound site or incision site to cause an aperture in the cartridge to span a tissue of the wound or incision site, wherein a pointed end of the suturing needle is positioned within the protective housing after a complete rotation of the suturing needle about a rotational axis;
- (c) activating an actuator coupled to a needle rotation drive that releasably engages the suturing needle to cause rotational movement of the suturing needle across the aperture and advance the suture needle through the tissue of the wound or incision site;
- (d) deactivating the actuator at the completion of advancing movement of the suturing needle to cause a suturing material attached to the suturing needle to be pulled through the tissue of the wound or incision site; and repeating steps B through D to cause a plurality of stitches to be placed through the tissue of the wound or incision site.

52. The method of claim 51 for obtaining a series of continuous sutures to close the wound or incision site.

53. The method of claim 51 wherein the surgical device comprises:

- an actuator handle having an attachment end;
- an elongated drive shaft having a distal end, a proximal end attached to the attachment end of the actuator handle, and a longitudinal axis extending between the distal end and the proximal end;
- a support arm assembly having a proximal end and a distal end releasably attached to the cartridge holder assembly having the needle rotation drive capable of engaging and rotating the suturing needle, the proximal end of the support arm assembly releasably attached to the distal end of the drive shaft to fix the support arm assembly relative to the drive shaft;

the cartridge having the suturing needle, the cartridge releasably attached to the cartridge holder assembly whereby the suturing needle is capable of engaging the needle rotation drive in the cartridge holder assembly, wherein the cartridge extends from a distal end of the cartridge holder assembly; and

an actuator attached to the actuator handle for causing rotation of the drive shaft and the needle rotation drive, thereby rotating the suturing needle about the longitudinal axis of the drive shaft.

54. The method of claim 53 wherein the needle rotation drive causes rotation of the suturing needle comprising a blunt end and a sharp pointed end by providing a pushing force adjacent to said blunt end and a pulling force adjacent to said sharp pointed end.

55. The method of claim 53 wherein the suturing needle is arcuate having a radius commensurate with a rotational radius of the needle rotation drive of the cartridge holder assembly, the needle rotation drive releasably engaging the suturing needle so the suturing needle is oriented around the longitudinal axis of the drive shaft.

56. The method of claim 53 wherein the actuator is selected from the group consisting of a trigger, a push button, a lever, a pedal and a mechanically driven switch.

57. The method of claim 53 wherein the actuator is operated by applying a manual or automated mechanical force.

58. The method of claim 57 wherein the automated mechanical force is a power source selected from the group consisting of electrical, electromagnetic, compressed air, compressed gas, hydraulic, vacuum and hydrocarbon fuels.

59. The method of claim 51 wherein the tissue is mammalian tissue.

60. The method of claim 51 further comprising moving the suturing needle in a curved track on an inner surface of the cartridge during rotation of the suturing needle.

61. The method of claim 51 further comprising positioning the pointed end of the suturing needle within a curved track of the cartridge prior to and after rotation of the suturing needle.

62. The method of claim 51 further comprising slidably positioning the suturing needle in a curved track of the cartridge.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 6,923,819 B2
DATED : August 2, 2005
INVENTOR(S) : John C. Meade et al.

Page 1 of 1

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 19,

Line 64, delete the “a” between “placing” and “the”; and delete the “a” between “having” and “the”.

Signed and Sealed this

Fourth Day of October, 2005

A handwritten signature in black ink on a light gray dotted background. The signature reads "Jon W. Dudas" in a cursive style.

JON W. DUDAS

Director of the United States Patent and Trademark Office