UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Cook Incorporated, Cook Group Incorporated and Cook Medical LLC,

Petitioners

v.

Medtronic Vascular, Inc.,

Patent Owner

Patent No. 7,264,632
Issue Date: September 4, 2007

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 7,264,632

Case No. IPR 2019-00206

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Cook Incorporated, Cook Group Incorporated, and Cook Medical LLC (collectively, "Petitioners") respectfully request *inter partes* review of claims 1-2, 4-5, 7-9, and 12 of U.S. Patent No. 7,264,632 ("the '632 Patent") (Ex. 1001). The USPTO assignment records show that the Patent Owner is Medtronic Vascular, Inc. ("Medtronic" or "Patent Owner").

I. MANDATORY NOTICES (37 C.F.R. § 42.8)

A. Real Parties-in-Interest

Petitioners are the real parties-in-interest.

B. Related Matters

This Petition is being filed and served concurrently with a petition for *inter partes* review in IPR No. 2019-00205, which challenges the patentability of claims 1-4, 7-8 and 12 of the '632 patent.

C. Lead And Back-Up Counsel

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D. Service Information

Service on Petitioners may be made by mail or hand-delivery to the lead and back-up counsel at the addresses specified above. Petitioners also consent to service by email at addresses specified above.

II. ADDITIONAL REQUIREMENTS

A. Timing (37 C.F.R. §§ 42.101 And 42.102)

The '632 patent issued on September 4, 2007. Neither Petitioners, nor any of their privies: (1) own the '632 patent; (2) were served with a complaint alleging infringement of the '632 patent; (3) filed a civil action challenging the validity of any claim of the '632 patent; or (4) are barred or estopped from challenging the claims of the '632 patent.

B. Fee for *Inter Partes* Review (37 C.F.R. § 42.103)

The Office is authorized to charge the filing fees specified by 37 C.F.R. § 42.15(a), as well as any other required fees, to Deposit Account No. 23-1925.

C. Certification of Standing (37 C.F.R. § 42.104(a))

Petitioners certify that the '632 patent is available for *inter partes* review and that Petitioners are not barred or estopped from requesting an *inter partes* review challenging the patent claims on the grounds identified in this petition.

D. Identification of Challenge, Precise Relief Requested, And Specific Art And Statutory Grounds On Which The Challenge Is Based (37 C.F.R. § 42.104(b))

The precise relief requested is that claims 1-2, 4-5, 7-9, and 12 of the '632 patent be found unpatentable, and canceled.

Inter partes review is requested in view of the following references and specific grounds for rejection under 35 U.S.C. §§ 102 and 103:[1]

No.	Grounds
1	Claims 1, 4, 7-8, and 12 are anticipated by Pinchuk (Ex. 1006)[2] Embodiment #1.
2	Claims 1-2, 4, 7-8, and 12 are anticipated by Pinchuk (Ex. 1006) Embodiment #2.
3	Claims 4-5, 7-9, and 12 are obvious in view of Pinchuk (Ex. 1006) Embodiment #1 or Embodiment #2, in combination with Robinson (Ex. 1008)[3]

[1] The '632 patent issued from U.S. Patent Application No. 10/455,978, filed June 5, 2003. The pre-AIA sections of 35 U.S.C. §§ 102 and 103 apply here.

[2] U.S. Patent No. 5,415,664.

[3] European Patent Application No. 0 657 147.

III. BACKGROUND

A. "Background Of The Invention"

The '632 patent is entitled "Controlled Deployment Delivery System." (Ex. 1001 at Title). The '632 patent issued from U.S. Patent Application No. 10/455,978 ("the Wright Application"), filed June 5, 2003, and claims priority to U.S. Provisional Patent Application No. 60/387,278 (Ex. 1003, "Provisional Application"), filed June 7, 2002. (Ex. 1001 at 1:6-8). The '632 patent names as inventors Michael T. Wright, Timothy W. Lostetter, and Alex Ruiz ("the Named Inventors").

The "Field of the Invention" of the '632 patent "relates generally to medical devices and procedures, and more particularly to a method and system of deploying a stent-graft[4] in a vascular system." (Ex. 1001 at 1:12-14). According to the '632 patent, "[p]rostheses for implantation in blood vessels or other similar organs of the living body are, in general, well known in the medical art." (*Id.*,

[4] The specification and claims of the '632 patent use the terms "stent graft" and "stent-graft" interchangeably. (*See, e.g.*, Ex. 1001 at 2:10-12 ("The proximal end of the *stent-graft* is typically designed to fixate and seal the *stent graft* to the wall of the vessel during deployment."), claim 7 ("a retention mechanism attached to the outer tube for retaining a proximal end of *a stent-graft* in a constrained diameter configuration while the end of *the stent graft* is still located within the cap"); Ex. 1015 at ¶28).

1:18-20). These include "prosthetic vascular grafts formed of biocompatible materials," as well as "graft material supported by [a] framework" (*i.e.*, "stent-graft[s] or endoluminal graft[s]"). (*Id.*, 1:20-25). The '632 patent acknowledges that, by the time the application for the '632 patent was filed, "the use of stent-grafts for treatment…[of vascular diseases] [was] well known." (*Id.*, 1: 26-29; Ex. 1015 at ¶¶27-28).

A stent is a device, (typically made from biocompatible materials, such as stainless steel or Nitinol (a nickel titanium alloy)), that is used to hold open a natural vessel (*e.g.*, a blood vessel) or an artificial vessel (*e.g.*, a graft) in the body. (Ex. 1015 at ¶¶29). Stents are capable of transitioning from a collapsed smaller diameter to an expanded larger diameter. A stent or stent graft is introduced into the body in a collapsed, smaller diameter inside of a delivery catheter, through a small puncture at a location remote from the vessel portion to be treated (also referred to as an intraluminal delivery). The stent or stent graft is then guided through the vessel to the portion to be treated, where it is expanded to a larger diameter. (*Id.*; Ex. 1001 at 1:40-65). In general, there are two types of stents: (1) balloon-expandable stents; and (2) self-expanding stents. Balloon-expandable stents cannot expand on their own, and require an external force to expand – typically provided by a balloon. Self-expanding stents, on the other hand, are capable of expanding on their own due to mechanical and/or thermal resilience of

the material from which they are manufactured. (Ex. 1015 at ¶29; Ex. 1001 at 1:29-40).

Prior art delivery catheters include coaxial tubes, "arranged for relative axial movement." (Ex. 1001 at 1:48-50). The coaxial tubes are used to compress and restrain the stent graft during insertion of the stent graft in the body. (*Id.*, 1:50-56). The coaxial tubes are manipulated, by relative axial movement, to release and deploy the stent graft from the delivery catheter within the body. (*Id.*, 1:56-65; Ex. 1015 at ¶30).

According to the '632 patent, "[m]any self expanding stent-graft deployment systems" in the prior art were designed to release the proximal end of the stent graft first, as an outer tube or sheath is withdrawn. (Ex. 1001 at 2:8-10). This is illustrated below, for example, in annotated Figures 3 and 4 of U.S. Patent No. 5,824,041 ("Lenker" (Ex. 1009)) (listed as a cited reference on the cover of the '632 patent (Ex. 1001 at p. 1)).

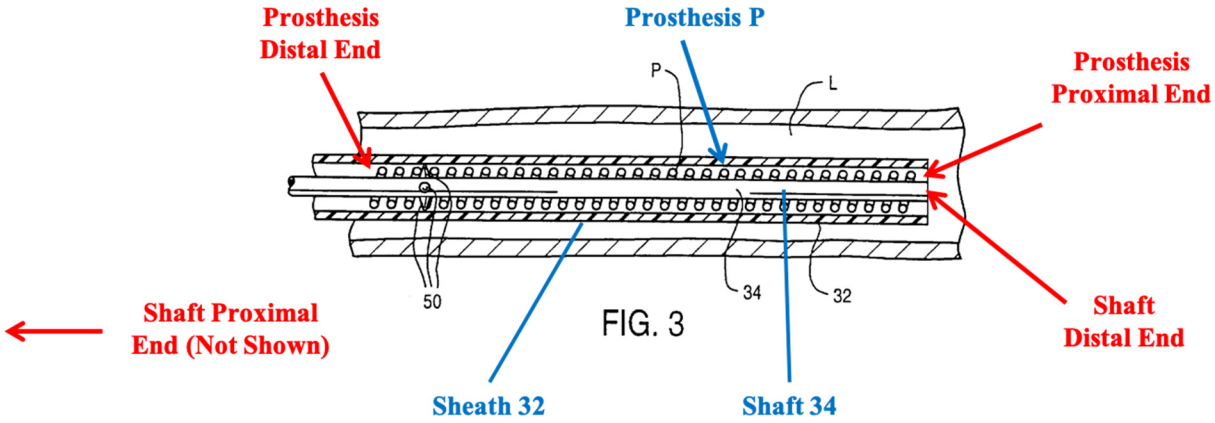


FIG. 3

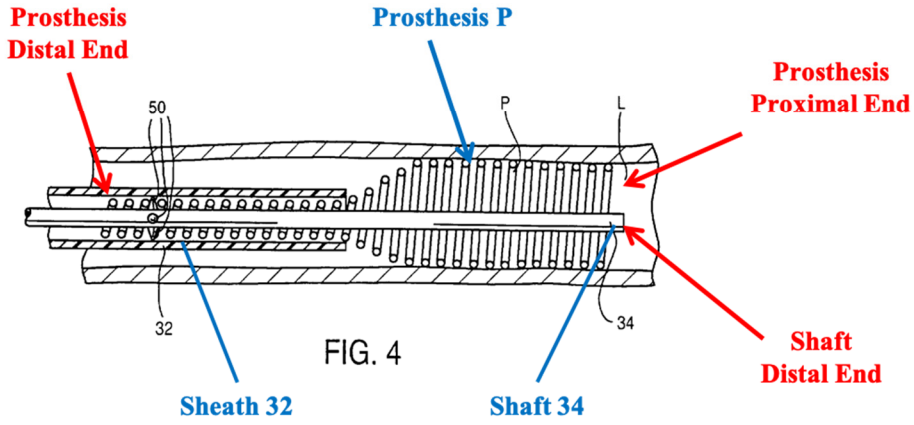


FIG. 4

(Ex. 1015 at ¶31). The annotated figures above depict a delivery catheter 30, including a sheath 32 and coaxial shaft 34 (Ex. 1009 at 7:9-15). The delivery

catheter "receives a radially compressible tubular prosthesis P [(illustrated above as a helical coil)] within the annular space between the outer surface of the shaft 34 and the inner surface of the lumen through sheath 32." (*Id.*, 7:15-23). As shown above, the proximal end of the prosthesis P (the end closest to the heart) expands outwardly from the shaft 34 as the sheath 32 moves proximally (toward the operator) relative to the prosthesis P (from Figure 3 to Figure 4).[5] (Ex. 1015 at ¶31).

The '632 patent describes alleged problems with prior art delivery devices. (Ex. 1001 at 2:8-18). According to the '632 patent, the proximal end of a stent graft "is typically designed to fixate and seal the stent graft to the wall of the vessel during deployment." (*Id.*). Delivery devices that are "configured to have the proximal end of the stent-graft deploy as the outer tube or sheath is pulled back"

[5] The '632 patent defines the proximal end of a stent graft as "the end closest to the heart," and the distal end of the stent graft as "the end furthest away from the heart during deployment." (Ex. 1001 at 1:65-67). *In contrast*, the '632 patent defines the proximal end of the catheter components as "the end nearest the operator," and the distal end of the delivery catheter components as "the end that is farthest from the operator." (*Id.*, 1:67-2:3). As illustrated in annotated Figures 3 and 4 of Lenker, this convention results in seemingly "[in]consistent or opposite" uses of the terms "proximal" and "distal" (*e.g.*, in Figure 3, the *distal* end of the sheath 32 is located at the *proximal* end of the prosthesis P). (*Id.*, 2:3-7).

allegedly "leave[] little room for error in placement since re-positioning the stent-graft after initial deployment, except for a minimal pull down retraction, is usually difficult if possible at all." (*Id.*, 2:8-16). According to the '632 patent, "[d]eploying the proximal end of the stent-graft first makes accurate pre-deployment positioning of the stent-graft critical." (*Id.*, 2:16-18; Ex. 1015 at ¶32).

The '632 patent acknowledges that others in the prior art attempted to overcome this alleged problem in the prior art, by "confin[ing] the proximal end of the stent-graft." (Ex. 1001 at 2:26-27). According to the '632 patent, these prior art attempts "generally fail to provide adequate control in manipulating the stent-graft positioning in both the initial deployment of the stent graft and the re-deployment of the stent-graft (once the stent-graft has been partially deployed)." (*Id.*, 2:26-31). The '632 patent does not identify any of the prior art delivery systems that allegedly "fail to provide adequate control," does not explain why these prior art systems allegedly "fail to provide adequate control," and does not explain what is meant by "*adequate* control"[6] (versus *inadequate* control). (Ex. 1015 at ¶33).

According to the '632 patent, "[a]nother problem encountered with existing systems" is that, during withdrawal of the outer sheath, "frictional forces…can

[6] All emphasis is added unless otherwise noted.

cause the stent-graft to axially compress or bunch up," "increas[ing] the density of the stent-graft within the sheath and…further increas[ing] the frictional drag experienced during deployment." (Ex. 1001, 2:31-38). This allegedly created "a need…for a method and deployment system that enables partial deployment of a stent-graft while constraining a proximal end of the stent-graft." (*Id.*, 2:38-44; Ex. 1015 at ¶34).

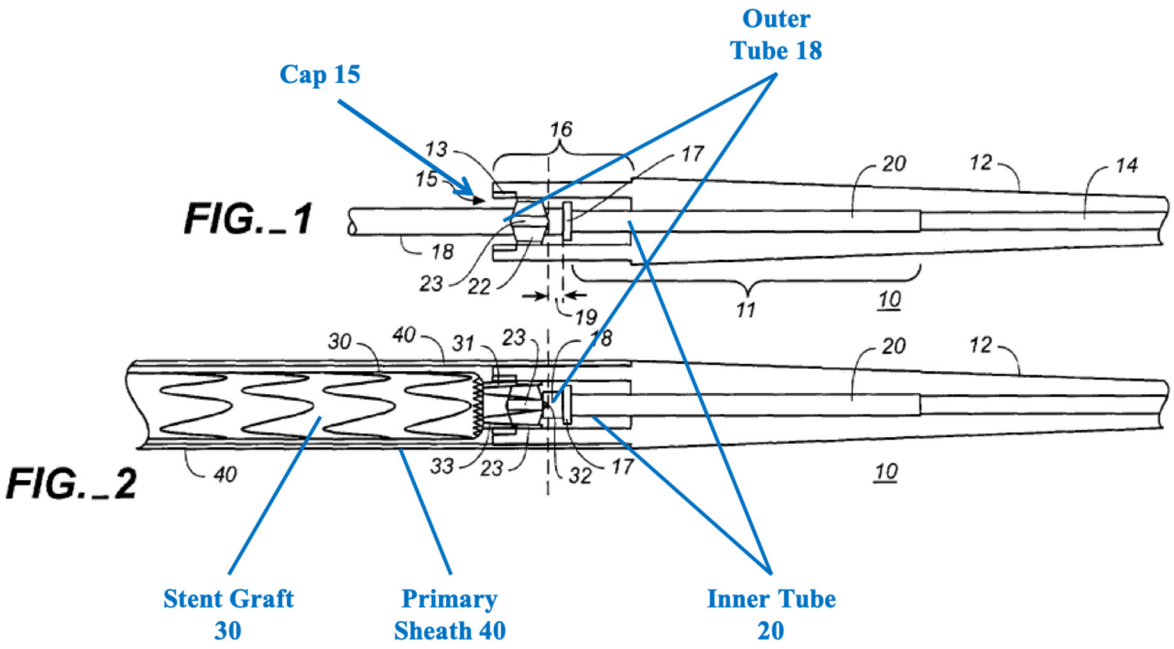
B. "Summary Of The Invention"

The '632 patent discloses as "a first aspect according to the present invention":

> a *stent-graft*, a retractable *primary sheath* containing the stent-graft in a first constrained diameter configuration, an *outer tube* within the retractable primary sheath and within the stent-graft,…an *inner tube* within the outer tube, where the inner tube and the outer tube both move axially relative to the retractable primary sheath and to each other,….[and] *a cap* coupled to a distal end of the inner tube and *configured to retain at least a portion of a proximal end of the stent-graft in a radially compressed configuration*.

(Ex. 1001 at 2:48-58; Ex. 1015 at ¶35).

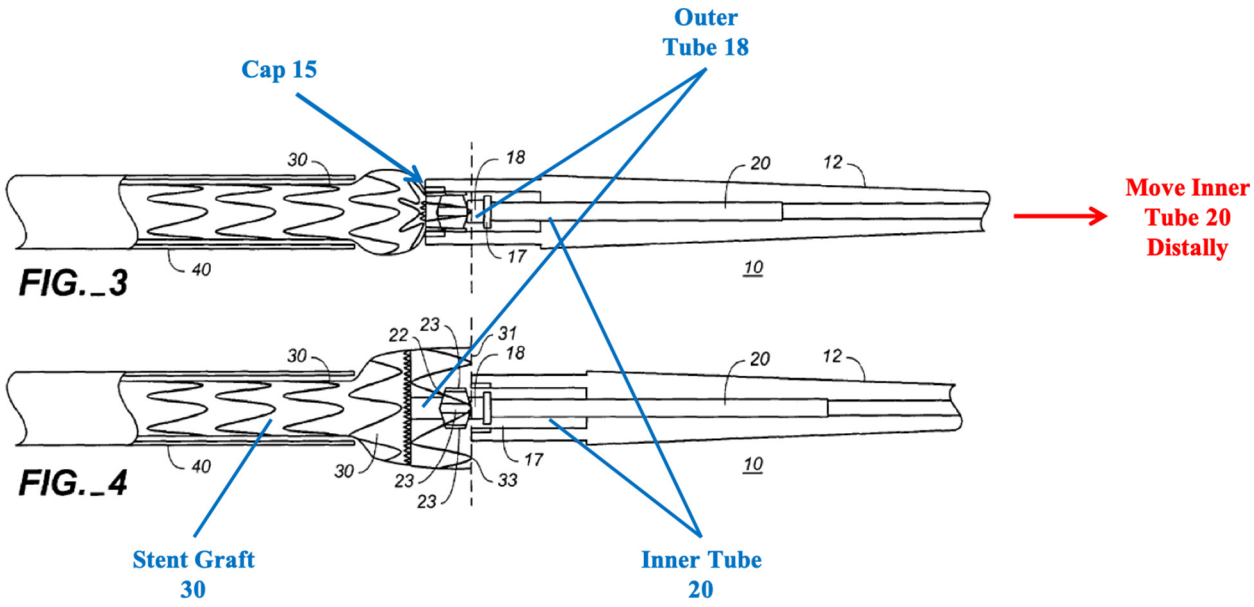
Annotated Figures 1 and 2, below, illustrate an embodiment of the '632 patent including each of these elements of "the present invention."



(Ex. 1015 at ¶35; Ex. 1001 at 3:35-40, 4:12-57). Annotated Figures 1 and 2 illustrate a stent graft 30, a primary sheath 40 containing the stent graft 30 in a constrained diameter configuration, an outer tube 18, an inner tube 20 that moves axially relative to the primary sheath 40 and outer tube 18, and a cap 15 configured to retain a portion of a proximal end of the stent graft 30 in a radially compressed configuration. According to the '632 patent, in this "aspect of the present invention," "[a] controlled relative axial movement between the outer tube and the inner tube releases the proximal end of the stent-graft from the cap and from the

radially compressed configuration." (Ex. 1001 at 2:48-62; *see also id.*, 4:47-53; Ex. 1015 at ¶35).

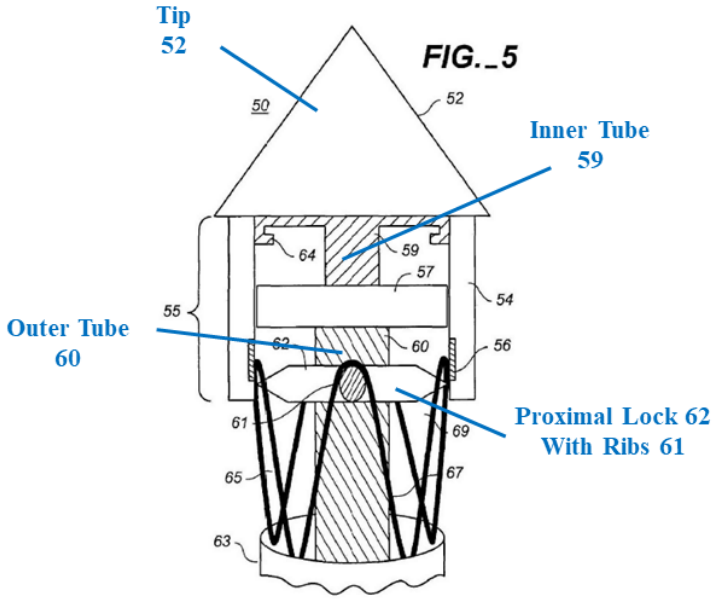
Annotated Figures 3 and 4, below, illustrate movement (from Figure 3 to Figure 4) of the inner tube 20 distally (away from the operator) relative to the proximal end of stent graft 30 (the end closest to the heart), to release the proximal end of stent graft 30 from cap 15.



(Ex. 1001 at 3:41-46, 4:58-5:43; Ex. 1015 at ¶36).

The "Summary of the Invention" further describes a "proximal lock" or "retention mechanism" attached to the outer tube, for retaining a proximal end of the stent graft in a constrained configuration while the proximal end of the stent graft is within the cap. (*Id.*, 3:3-21). The lock may include "a plurality of ribs or splines for retaining [a] plurality of apices of [a] proximal spring of [a] stent-graft."

(*Id.*, 3:3-11). Annotated Figure 5, below, illustrates an embodiment of the '632 patent including a "proximal lock" or "retention mechanism."



(*Id.*, 3:56-58, 5:35-43, 5:56-6:59, Figures 3-5, 5A, 6; Ex. 1015 at ¶37). As shown above in annotated Figure 5, the proximal lock is coupled to a distal end of outer tube 60, and includes a plurality of ribs 61 that retain "a plurality of proximal spring apices 65, 67 and 69 (68 is hidden in this view) of a stent-graft 63…within a cap or shroud portion 55 of a tip 52." (Ex. 1001 at 6:14-18; *see also id.*, 5:35-43 ("Additionally, a proximal lock (retainer) 22 is also coupled to a distal portion of the outer tube 18. The proximal lock 22 preferably includes at least one or a plurality of ribs (or splines) 23 that can together with the shroud portion 16 serve as an axial constraint for the end [of] stent-graft 30. The proximal end (or the proximal springs 31, 32, and 33) of the stent-graft 30 cannot deploy until the

proximal end of the ribs of the proximal lock clear the end of the shroud portion 16 of the tip.")).

The "Summary of the Invention" describes another "aspect according to the present invention" as "a method for controlled deployment of a stent-graft includ[ing] the steps of":

- "constraining a proximal end of a stent-graft radially under a cap while partially deploying a remaining portion of the stent graft,"
- "evaluating and adjusting as necessary at least one of the axial and radial positions of the stent-graft after the partial deployment of the remaining portion," and
- "releasing the proximal end of the stent-graft by minimal controlled coaxial movement between the cap and a tube retaining the stent-graft within the cap."

(*Id.*, 3:22-31; Ex. 1015 at ¶38).

As further explained below, each of these aspects of the "invention" was known in the art by the time the application for the '632 patent was filed. (Ex. 1015 at ¶39).

C. Level Of Ordinary Skill In The Art

The person having ordinary skill in the art ("PHOSITA") as of the time of the filing of the applications that became the '632 patent (the 2002-2003 timeframe), would have included a medical device engineer or similar professional with at least an undergraduate degree in engineering and experience with endoluminal devices and methods, or a vascular surgeon or similar physician with at least two years equivalent experience with endoluminal devices and methods, with the understanding that such experience may come from education and/or training. (Ex. 1015 at ¶17).[7]

Petitioners submit the Declaration of Enrique Criado, M.D. (Ex. 1015). Dr. Criado is a vascular surgeon, and Chief of Vascular Surgery at MidMichigan Health, which is affiliated with the health care division of the University of Michigan. (Ex. 1015 at ¶4). As reflected in his *curriculum vitae* (included as Exhibit B to Ex. 1015), Dr. Criado had extensive experience in the 2002-2003 timeframe with vascular surgery and with endoluminal devices and methods. (*Id.*, ¶¶4-12, 18, 28, 30, Exhibit B). Dr. Criado qualified as a PHOSITA in the 2002-

[7] The same definition of a person or ordinary skill in the art, as well as the analysis of the prior art references discussed in this petition, would apply anytime in the 2002-2003 timeframe. (Ex. 1015, ¶19).

2003 timeframe, and his Declaration addresses the '632 patent and prior art from the perspective of a PHOSITA at that time. (*Id.*).

D. Claim Construction (37 C.F.R. § 42.104(b)(3))

A claim subject to *inter partes* review receives the "broadest reasonable construction [("BRI")] in light of the specification of the patent in which it appears." 37 C.F.R. § 42.100(b). *In re Cuozzo Speed Techs., LLC*, 793 F.3d 1268, 1278-79 (Fed. Cir. 2015), *aff'd, Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131 (2016). For the purposes of this *inter partes* review only, Petitioners adopt the following constructions, consistent with the understanding of a PHOSITA.

1. "Proximal" / "Distal"

As explained above in Section III.A., the '632 patent defines the "proximal" end of a stent graft as the end "closest to the heart," and the "distal" end of a stent graft as the end "furthest away from the heart during deployment." (Ex. 1001 at 1:65-67). In other words, when referring to a component of a *stent graft*, the terms "proximal" and "distal" are defined with respect to the *patient*.

In contrast, when referring to a component of a *delivery catheter* (*e.g.*, a sheath, tube, or cap), the '632 patent defines the terms "proximal" and "distal" with respect to the *operator, or physician*. In particular, the term "proximal" is defined as "the end nearest the operator," whereas the term "distal" is defined as "the end that is farthest from the operator." (*Id.*, 1:67-2:3). Each of these conventions has been adopted in this Petition, unless otherwise indicated. (Ex. 1015 at ¶¶41-42).

2. "Second Retention Mechanism For Retaining A Distal End On The Stent-Graft Undeployed While A Remaining Portion Of The Stent-Graft Is Deployed"

Claim 12 recites a retention mechanism "for retaining *a distal end* of the stent-graft undeployed while a remaining portion of the stent-graft is deployed." As shown below in Figure 3A, the '632 patent discloses constraining a distal end of the stent graft (end closest to the operator) within a primary, or outer sheath (*e.g.*, sheath 40).

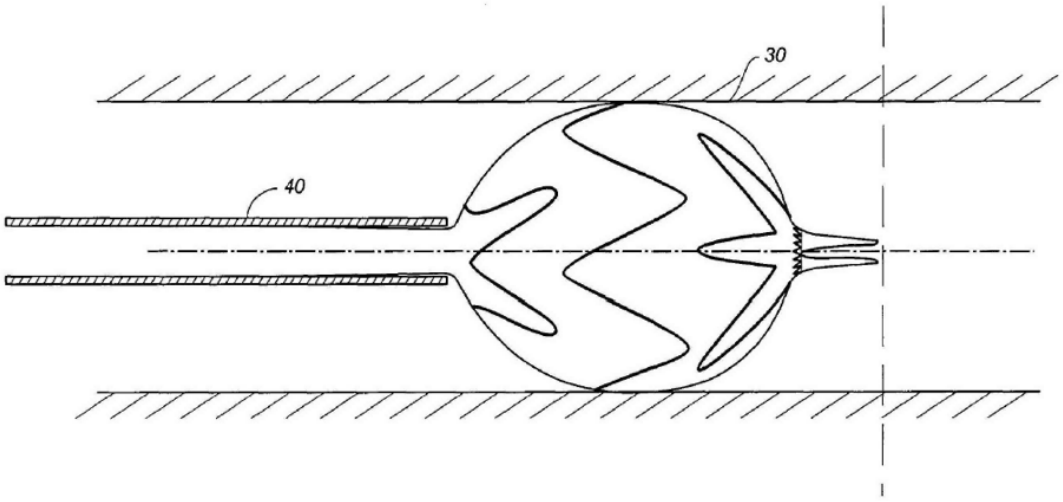


FIG._3A

(Ex. 1015 at ¶43; Ex. 1001 at 2:50-51 ("a retractable primary sheath containing the stent-graft in a first constrained diameter configuration"), 3:41-46 ("FIG. 3 is a close up schematic cross sectional view of [a] deployment system…showing partial deployment of the proximal portion of the stent graft as the proximal end of the stent-graft remains constrained *while the distal end of the stent graft remains*

loaded in its outer sheath."), 3:47-49 ("FIG. 3A is a partial cross sectional view of the stent graft shown in FIG. 3, but without the distal end of the catheter and retaining shaft which is shown in FIG. 3."), 4:55-5:14).

The '632 patent does not disclose any other structure for "retaining" a distal end of the stent graft undeployed, as described in claim 12. Therefore, as explained in the Criado Declaration, the BRI of "second retention mechanism for retaining a distal end of the stent-graft undeployed while a remaining portion of the stent-graft is deployed" includes an outer sheath that retains a distal end of the stent graft, as depicted in Figure 3A and described in the '632 patent. (Ex. 1015 at ¶43).

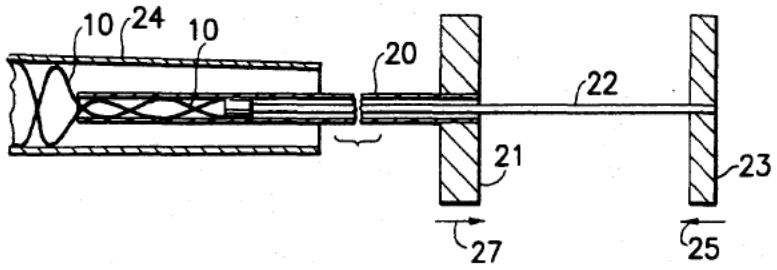
IV. SPECIFIC PRIOR ART REFERENCES FORMING THE BASIS FOR UNPATENTABILITY

A. Pinchuk (Ex. 1006)

Pinchuk published on May 16, 1995 from a U.S. patent application filed on March 30, 1994. (Ex. 1006 at Cover; Ex. 1015 at ¶44). Pinchuk qualifies as prior art under 35 U.S.C. §§ 102(a), 102(b), and 102(e). Pinchuk was not cited during prosecution of the '632 patent. (Ex. 1015 at ¶44).

Pinchuk is entitled "Method And Apparatus For Introducing A Stent Or A Stent-Graft." (Ex. 1006 at Title). Pinchuk describes "the delivery and deployment of a transluminal prosthesis," including stents and stent grafts, and particularly "a method and apparatus for delivery and deploying a flexible tubular prosthesis having a diameter which is variable by axial movement of the ends of the prosthesis." (*Id.*, 1:7-12; Ex. 1015 at ¶45).

Pinchuk describes alleged problems with prior art delivery devices (illustrated below in Figure 3) that include "a flexible catheter 20 having a proximal handle 21 and a flexible plunger 22 having a proximal handle 23," with a "stent 10…partially inserted into the distal end of the catheter 20."



(Ex. 1006, 1:42-63, Figure 3). According to Pinchuk, such devices are "deficient in several respects" including, among other things: (1) the stent or stent graft "can kink or bunch up" during withdrawal of the sheath, "preventing proper deployment of the stent;" and (2) "by releasing the [proximal][8] end of the stent first, the stent can no longer be positioned in the [proximal] direction" because "the ends of the wires of the [proximal] end of the stent will typically lodge themselves in the wall of the artery 24 and prohibit movement of the stent in the [proximal] direction."

[8] Pinchuk universally uses the term "proximal" to refer to a position or direction towards the operator, and the term "distal" to refer to a position or direction away from the operator. To avoid any potential confusion resulting from conflicting definitions between Pinchuk and the '632 patent, the Petition adopts the definitions of "proximal" and "distal" from the '632 patent when describing Pinchuk.

(*Id.*, 1:63-2:8; *see also id.*, 2:8-28). These are the very same problems described in the '632 patent. (*See* Section III.A; Ex. 1001 at 2:8-44; Ex. 1015 at ¶46).

In order to overcome these alleged problems, and provide "a method and apparatus for introducing a stent which allows for precise location of the stent," Pinchuk discloses delivery devices, or "introducers," including "*three concentric tubes*: a *hollow [outer] tube*…; an *inner tubular actuation member*…; and an *outer sheath*." (Ex. 1006 at 3:3-30; *see also id.*, Abstract). The distal end of the inner tubular actuation member (the end furthest from the operator) includes a "cup-like gripping member," which forms "a clamping or gripping mechanism" with the distal end (the end furthest from the operator) of the hollow outer tube. (Ex. 1006, 3:30-39). The proximal ends of the hollow outer tube and the inner actuation member (ends closest to the operator) are "coupled to an actuation device which effects relative movement" between the two tubes. (*Id.*, 3:32-35; *see also id*., 3:40-63; Ex. 1015 at ¶47).

Annotated Figures 5a and 6, below, disclose in a ***first embodiment*** ("Embodiment #1) an introducer 140 for delivering a stent or stent graft,[9] the introducer 140 including a hollow tube 42 (outer tube), a control member 148 (inner tube), and a sheath 70.

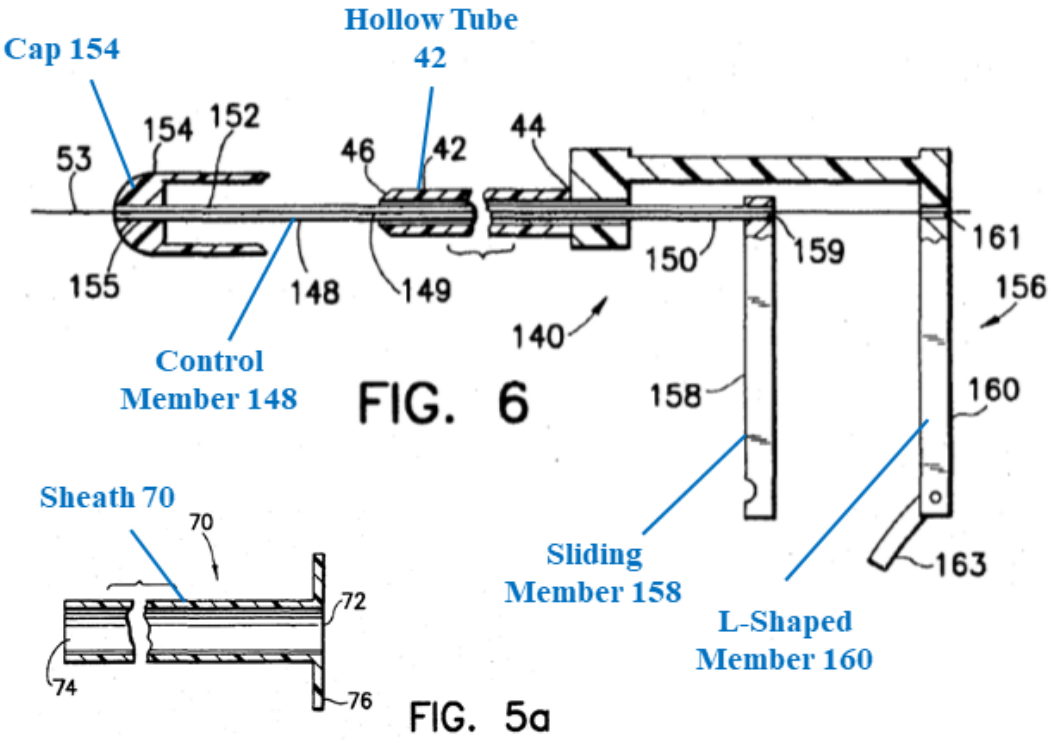


FIG. 6

FIG. 5a

(Ex. 1006 at 4:41-46, 5:57-6:13; *see also id.*, Abstract, 1:7-8, 3:27-63, 7:64-65, 8:39-64, 9:56-60; Ex. 1015 at ¶48). The inner tube (148) extends through the outer

[9] Pinchuk teaches that "while the invention has been disclosed with reference to the delivery and deployment of a stent, it will be understood that the invention is equally useful for the delivery and deployment of a stent-graft or endoluminal graft." (Ex. 1006 at 9:56-60).

tube (42), and includes a cap 154 fixed at its distal end (end furthest from the operator). (*Id.*). The proximal ends (ends closest to the operator) of the outer tube (42) and inner tube (148) are coupled to actuator members (sliding member 158 and L-shaped member 160) and move axially relative to one another. (*Id.*, 3:21-39 ("The proximal ends of the hollow tube and the actuation member are coupled to an actuation device which effects relative movement of the hollow tube and the actuation member."), 3:40-62, 5:57-6:13, 7:64-9:1). "[W]hen the actuator members 158, 160 are squeezed together, the end cap 154 covers and engages the distal end 46 of the tube 42." (*Id.*, 5:68-6:3; Ex. 1015 at ¶48).

Pinchuk discloses, that prior to deployment, the proximal end of the stent or stent graft (the end closest to the heart) is "captured and held between the end cap…and the distal end…of the hollow tube [(the end furthest from the operator)]." (*Id.*, 5:35-40; *see also id.*, 8:2-11 ("The [proximal] end…of a stent 10 is diametrically compressed and inserted into the cylindrical portion…of the cap…as shown in FIG. 9….The cap…is then brought into engagement with the frustroconical [*sic*] tapered locking member 347 as described above, thus capturing the [proximal end] of the stent 10.")). The inner and outer tubes (42, 148) are then inserted into the sheath 70, and the sheath 70 retains the distal end of the stent or stent graft (the end furthest away from the heart) in a compressed state. (*Id.*, 5:43-48 ("With the [proximal end] of a stent captured and held between the end

cap…and the…hollow tube 42, the introducer…is inserted into the proximal end…of a sheath 70….”), 8:14-20 (The inner and outer tubes are “then inserted into the proximal end…of a sheath 70 as [s]hown in FIG. 10….[A]s the introducer…is inserted into the sheath 70, the outer diameter of the stent 10 is compressed….”); *see also id.*, 3:40-62, 7:64-8:28; 9:27-30; Ex. 1015 at ¶49). During deployment, “the introducer…is held stationary while the sheath 70 is partially withdrawn in a proximal direction [(towards the operator)]…, thereby allowing partial diametric expansion” of the stent, or stent graft. (Ex. 1006, 8:41-47). “[T]he [proximal end] of the stent [or stent graft] remains captured between the cap 154” and the proximal end of the hollow tube 42, and “the [distal end] of the stent [or stent graft] remains covered by the sheath 70.” (*Id.*, 8:47-50; Ex. 1015 at ¶49).

Annotated Figure 8, below, depicts in a ***second embodiment***

("Embodiment #2) an introducer 340 for delivering a stent or stent graft, the introducer 340 including a flexible tubular coil[10] 342 (outer tube), a control member 348 (inner tube), and a sheath 170.

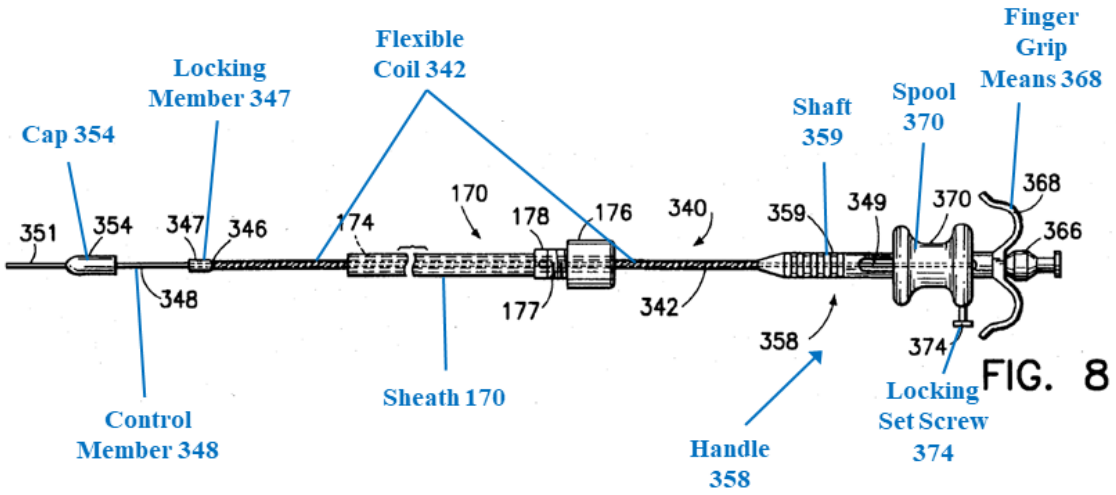


FIG. 8

(Ex. 1006 at 4:53-59, 6:55-55 ("FIGS. 8, 8a and 8b show a presently preferred embodiment of the stent introducer 340 according to the invention. The introducer 340 includes a flexible coil 342 and a coaxial control member 348

[10] Pinchuk refers to metal coils as "tube[s]." (*Id.*, 5:28-34 (explaining that "[s]uitable materials for the *[outer] tube*…include polyethylene, polyurethane, NYLON, TEFLON, metal springs, *coils* or braids, metal tubing, reinforced plastics, or combinations of these.")). Further, a PHOSITA would recognize from Pinchuk's disclosure that the disclosed "flexible coil 342" is formed from a coil either with, or without, an associated polymer sleeve, dip, or coating. (Ex. 1015 at ¶50).

which extends through the coil 342."); *see also id.*, Abstract, 1:7-8, 3:27-63, 6:55-7:65, 8:39-64; Ex. 1015 at ¶50). The inner tube (348) extends through the outer tube (342), and includes a cap 354 fixed at its distal end (end furthest from the operator). (Ex. 1006 at 7:14-21 ("The distal end 352 of the control member 348 is provided with a rigid cap 354 which has a proximal cylindrical portion 353, an interior frustroconical [*sic*] portion 353a, an outer frustroconical [*sic*] portion 356, and a distally extending soft catheter tip 357.")). The outer tube (342) includes a "frustroconical [*sic*] tapered capturing or locking member 347 at its distal end" (end furthest from the operator). (*Id.*, 7:11-14). The proximal end (end closest to the operator) of the outer tube (342) is coupled to a spool 370, and the proximal end of the inner tube (348) is coupled to the handle 358. "[M]ovement of the spool 370 relative to the [handle 358] effects movement of the [outer tube] 342 relative to the [inner tube] 348, and thereby effects movement of the locking member 347 relative to the cap 354." (*Id.*, 7:44-55; Ex. 1015 at ¶50).

Pinchuk discloses that, prior to deployment, the proximal end of a stent or stent graft (end closest to the heart) "is diametrically compressed and inserted into the cylindrical portion 353 of the cap 354." (Ex. 1006 at 8:2-4; *see also, id.*, 5:35-40). "The cap 354 is then brought into engagement with the frustroconical [*sic*] tapered locking member 347…, thus capturing the distal end 11 of the stent 10." (*Id.*, 8:8-11). "[T]he cap 354 is then inserted into the proximal end…of a

sheath…as [s]hown in FIG. 10," which retains the distal end of the stent or stent graft (the end furthest away from the heart) in a compressed state. (*Id.*, 8:14-20, Figure 10; *see also id.*, 3:40-62, 5:43-48 ("With the [proximal end] of a stent captured and held between the end cap…and the…hollow tube 42, the introducer…is inserted into the proximal end…of a sheath 70….")). During deployment, "the introducer…is held stationary while the sheath…is partially withdrawn in a proximal direction [(towards the operator)]…, thereby allowing partial diametric expansion" of the stent, or stent graft. (*Id.*, 8:41-47). "[T]he [proximal end] of the stent [or stent graft] remains captured" between the cap 354 and locking member 347, and "the [distal end] of the stent [or stent graft] remains covered by the sheath." (*Id.*, 8:47-50; *see also id.*, 3:50-62; Ex. 1015 at ¶51).

B. Robinson (Ex. 1008)

Robinson published on June 14, 1995. (Ex. 1008 at Cover; Ex. 1015 at ¶52). Robinson qualifies as prior art under 35 U.S.C. §§ 102(a) and 102(b). Robinson was not cited during prosecution of the '632 patent.[11] (Ex. 1015 at ¶52).

Robinson discloses "devices and techniques for placing and securing a vascular graft in a predetermined location in a patient's vascular system." (Ex. 1008 at 1:3-5; *see also id.*, 5:41-52, Figures 13-16). Figure 13 (reproduced below), illustrates a "catheter-like device by which [a stent graft] may be

[11] The '632 patent identifies as a cited reference U.S. Patent No. 6,077,297 (the "'297 patent"). (Ex. 1001 at Cover). The '297 patent appears to disclose figures that are also disclosed in the Robinson reference, (Ex. 1008). Neither the '297 patent, nor Robinson, was substantively addressed on the record during prosecution. (Ex. 1015 at ¶53). Further, the Patent Office never considered Dr. Criado's testimony regarding Robinson, or Dr. Criado's testimony that claims 4-5, 7-9, and 12 would have been obvious in view of Pinchuk and Robinson, as described below in Section V.C.

percutaneously inserted and deployed within the patient's blood vessel." (*Id.*, 10:14-17).

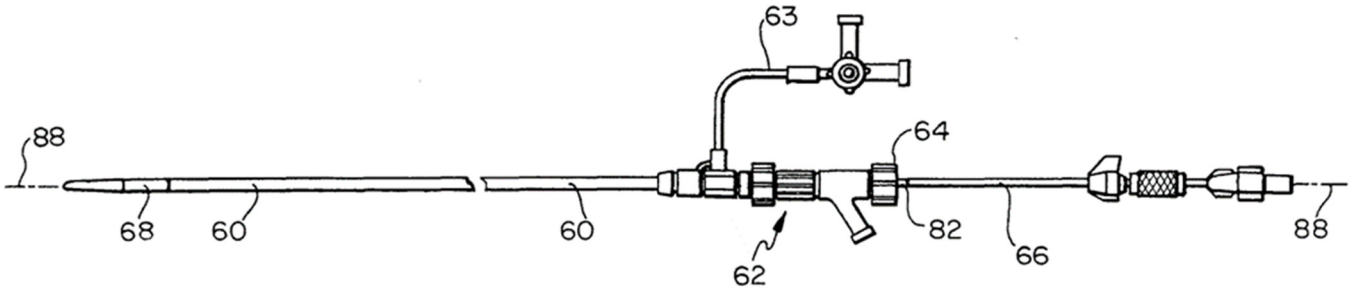


Fig. 13

(*Id.*, 5:41-42). As shown above, the device includes a sheath 60 "adapted to receive a positioning tube 66 that has, at its distal tip, a flexible distally tapered dilator 68." (*Id.*, 10:17-23). Robinson discloses deploying the stent graft (20) by percutaneously advancing the delivery system containing stent graft (20) through the patient's vasculature until the distal end of the delivery system (the end furthest from the operator) is located near an aneurysm. (*See, e.g., id.*, 12:5-35). Robinson discloses maintaining the position of the delivery device while withdrawing the sheath (60) in order to release the stent graft (20). (*Id.*; Ex. 1015 at ¶53).

As shown below in annotated Figures 16a and 16b, the delivery device includes a stay 78 and implant retention device 85, which are "used to maintain the position of the [stent graft] 10 as the sheath 60 is withdrawn." (Ex. 1008 at 11:11-14).

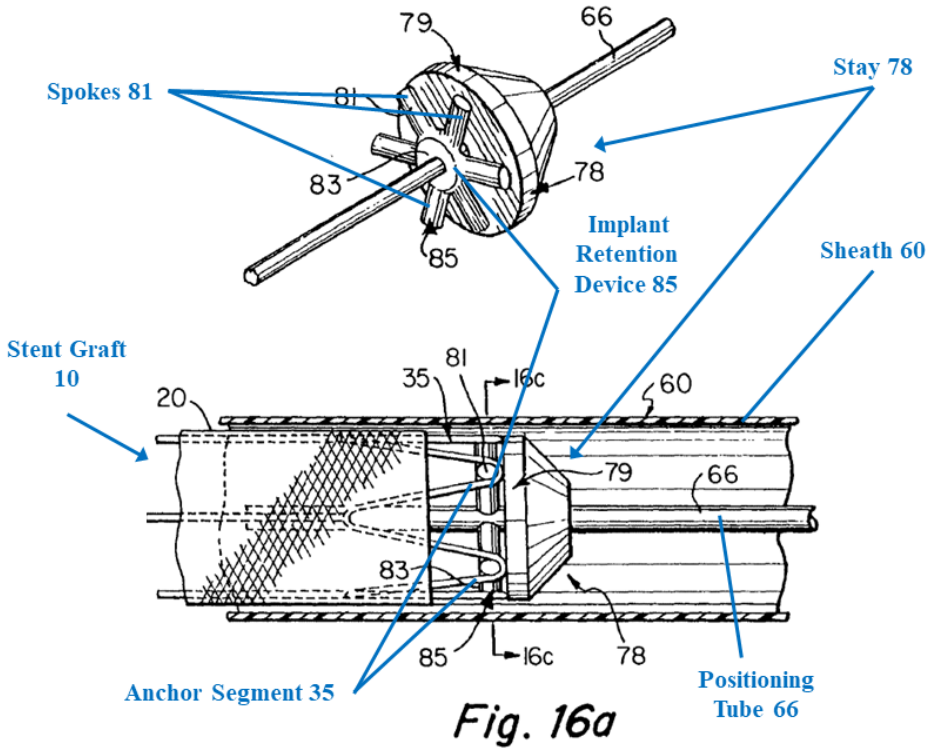


Fig. 16a

(*Id.*, 5:50-52; *see also id.*, 10:54-11:10, 12:26-30, Figures 16a and 16b, and claims 16, 18, and 19; Ex. 1015 at ¶54). The stent graft 10 "is placed over the distal end of the positioning tube 66 in a position such that the proximal bends of anchor segment 35 [of stent graft 10] are disposed against the stay 78." (Ex. 1008 at 10:54-57). The retention device 85 "takes the form of a plurality of radially extending spokes 81 attached to a central hub 83." (*Id.*, 11:14-16). As shown above in Figure 16a, each of the spokes 81 of the retention device 85 engages an

apex of anchor segment 35 of stent graft 10. (*Id.*, 11:19-27; claim 18 ("a plurality of spokes…, each of the spokes adapted to engage a proximal portion of the implant")). As a result, "the anchor, (and thus, the entire [stent graft 10]) is prevented from moving distally relative to the stay," and also "is prevented from moving in the distal direction as the sheath is advanced". (*Id.*, 11:27-35; 1015 at ¶54).

Robinson teaches that the stay 78 and implant retention device 85 provide improved control during deployment of the stent graft, permitting "repositioning of the implant [if] desired," as well as "recapture" of a partially deployed stent graft. (Ex. 1008 at 11:29-32). The stay "maintains engagement with the [distal] end of the anchor…, thereby preventing [distal] movement of the [stent graft] while the sheath is withdrawn" (towards the operator). (*Id.*, 12:26-30). Further, the stay "retain[s] the [stent graft] as the sheath is withdrawn," preventing deployment of the distal end of the stent graft "until the [stent graft] is fully released from the sheath." (*Id.*, claims 16 and 19; Ex. 1015 at ¶55).

V. DETAILED EXPLANATION OF PERTINENCE AND MANNER OF APPLYING CITED PRIOR ART TO THE CHALLENGED CLAIMS (37 C.F.R. §§ 42.104(b)(4) AND (b)(5))

There is a reasonable likelihood that claims 1-2, 4-5, 7-9, and 12 are unpatentable in view of one or more of the grounds identified in Section II.D. Each of these grounds includes prior art references that were not cited during prosecution. As demonstrated below, the challenged claims are unpatentable because they are either anticipated by the prior art or are obvious applications of "known technique[s] to…prior art ready for the improvement," and merely state obvious combinations of "familiar elements according to known methods," which "do[] no more than yield predictable results." *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 416-17 (2007); MPEP § 2143(I). The motivation to combine embodiments would have come from the references themselves, as well as from the knowledge generally available to a PHOSITA.

A. Ground 1: Claims 1, 4, 7-8, And 12 Are Anticipated By Pinchuk (Ex. 1006) Embodiment #1

1. Independent Claim 1

a. *"A controlled stent-graft deployment delivery system, comprising:"*

As shown below in annotated Figure 6, Pinchuk discloses in Embodiment #1 a controlled stent graft deployment delivery system (introducer 140).

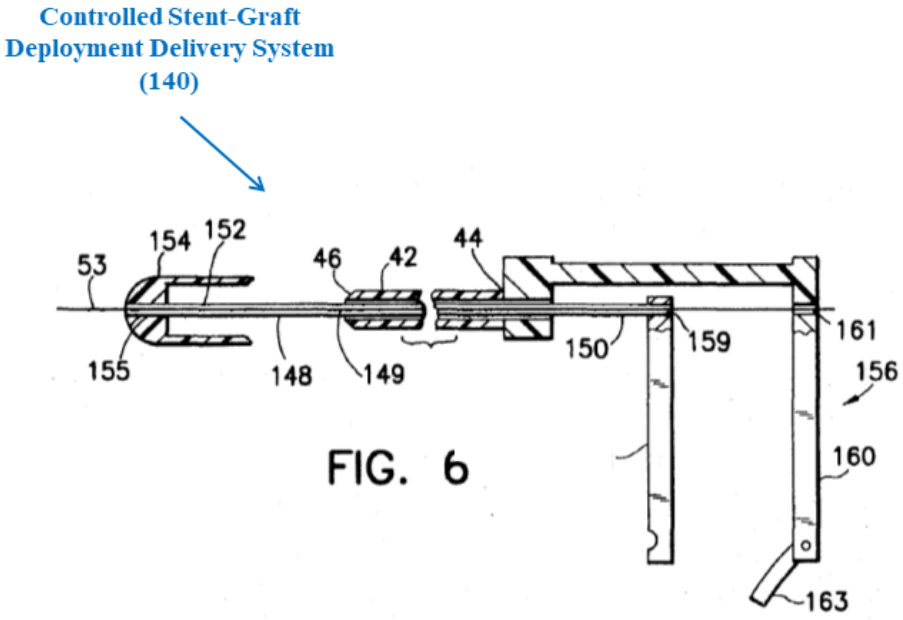


FIG. 6

(Ex. 1006 at Title, Abstract, 3:27-63, 4:44-46, 5:57-6:13, 7:64-65, 8:39-64, 9:56-60; Ex. 1015 at ¶58).

b. *"a stent-graft;"*

Pinchuk Embodiment #1 discloses a stent graft. (Ex. 1006 at Abstract ("A stent, stent graft, or endoluminal graft introducer….The [proximal] end of a…stent-graft is inserted into the cup-like cap…."), Title ("Method And Apparatus For Introducing…A Stent-Graft"), 9:56-60 ("[T]he invention is equally useful for the delivery and deployment of a stent-graft or endoluminal graft."); *see also id.*, 1:14-22, 3:40-45, claims 1, 6, 22, Figures 1, 2; Ex. 1015 at ¶59).

c. *"a retractable primary sheath containing said stent-graft in a first constrained diameter configuration;"*

As shown below in annotated Figures 5a and 6, Pinchuk Embodiment #1 discloses a retractable primary sheath (sheath 70) for containing the stent graft (*e.g.*, stent graft 10 (not shown below)) in a first constrained diameter configuration.

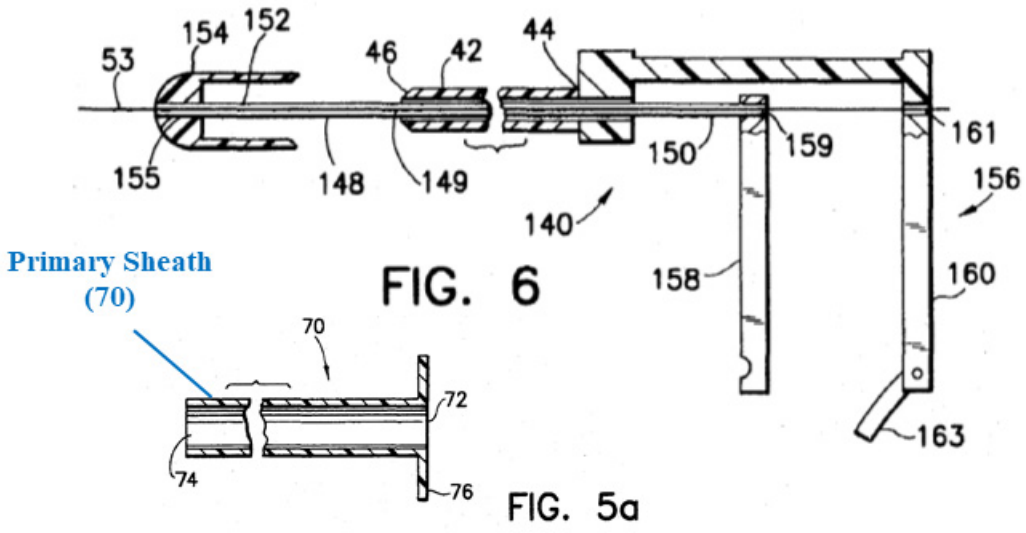


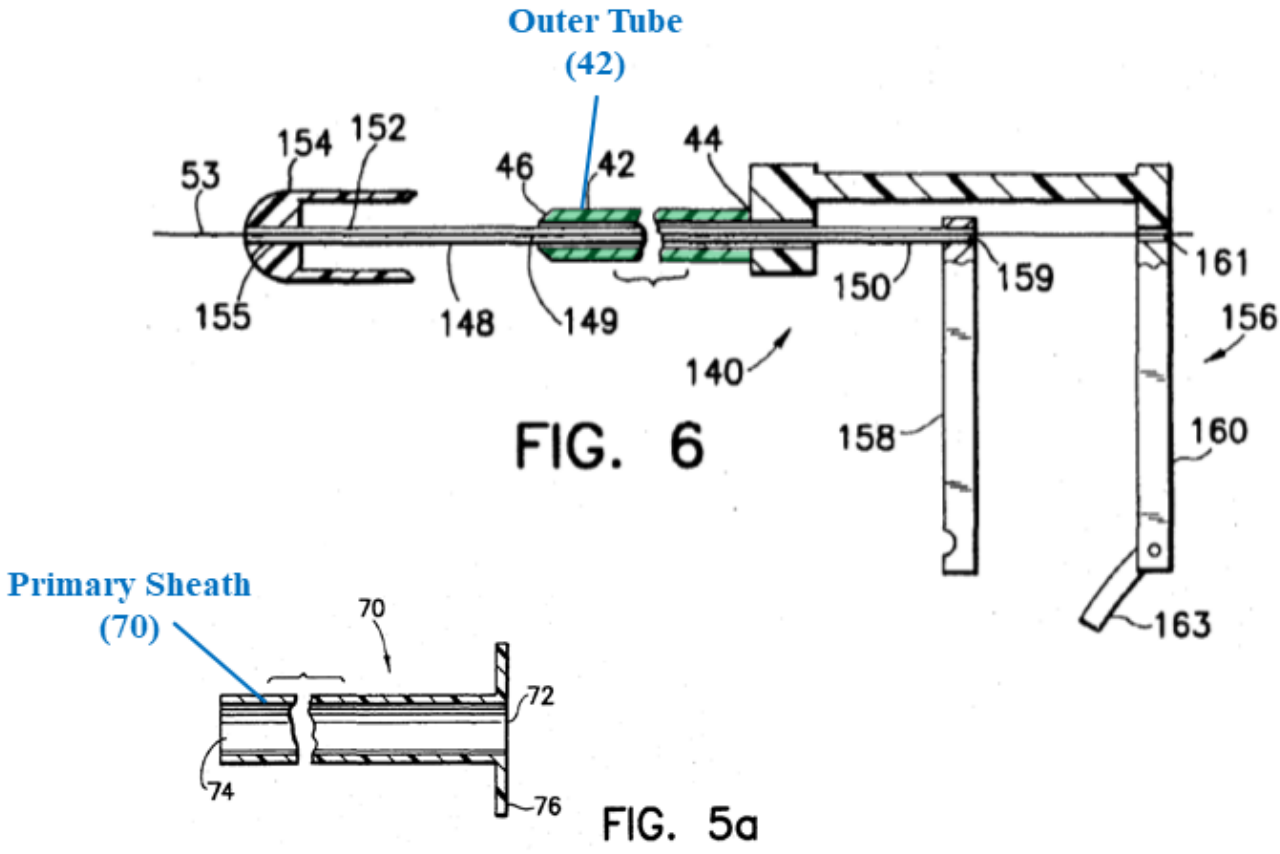
FIG. 6

FIG. 5a

(Ex. 1006 at 4:41-46 ("FIG. 5a is a broken cross sectional view of a sheath for use with the stent introducer according to the invention."), 3:21-32, 3:40-62, 7:64-8:28 (The inner and outer tubes are "inserted into the proximal end…of a sheath 70…. Those skilled in the art will appreciate that as the introducer…is inserted into the sheath 70, the outer diameter of the stent 10 is compressed…."), Figures 5a, 10a; Ex. 1015 at ¶60).

d. ***"an outer tube within the retractable primary sheath and within the stent-graft;"***

As shown below in annotated Figures 5a and 6, Pinchuk Embodiment #1 discloses an outer tube (hollow tube 42 (highlighted in green)), which, in use, is disposed within the retractable primary sheath (sheath 70) and within the stent graft (not shown below).



(Ex. 1006 at 3:21-32, 3:40-62, 8:2-38, 8:41-61, Figures 6, 11; Ex. 1015 at ¶61).

Pinchuk discloses that "[t]he method of the invention is best understood with reference to [Figure 10a]," among others. (Ex. 1006 at 7:64-65). As shown below in annotated Figure 10a, the outer tube (coil 342 (highlighted in green)) is within retractable primary sheath (sheath 70 (highlighted in red)) and within stent graft (10).

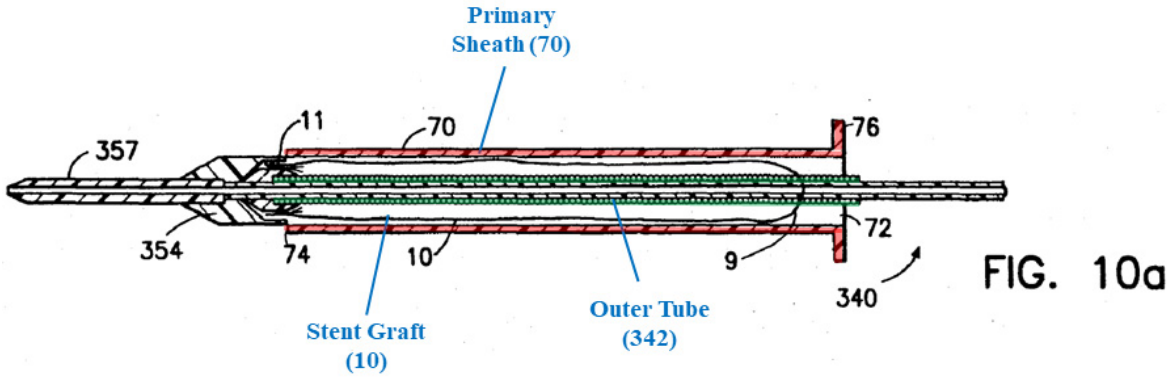
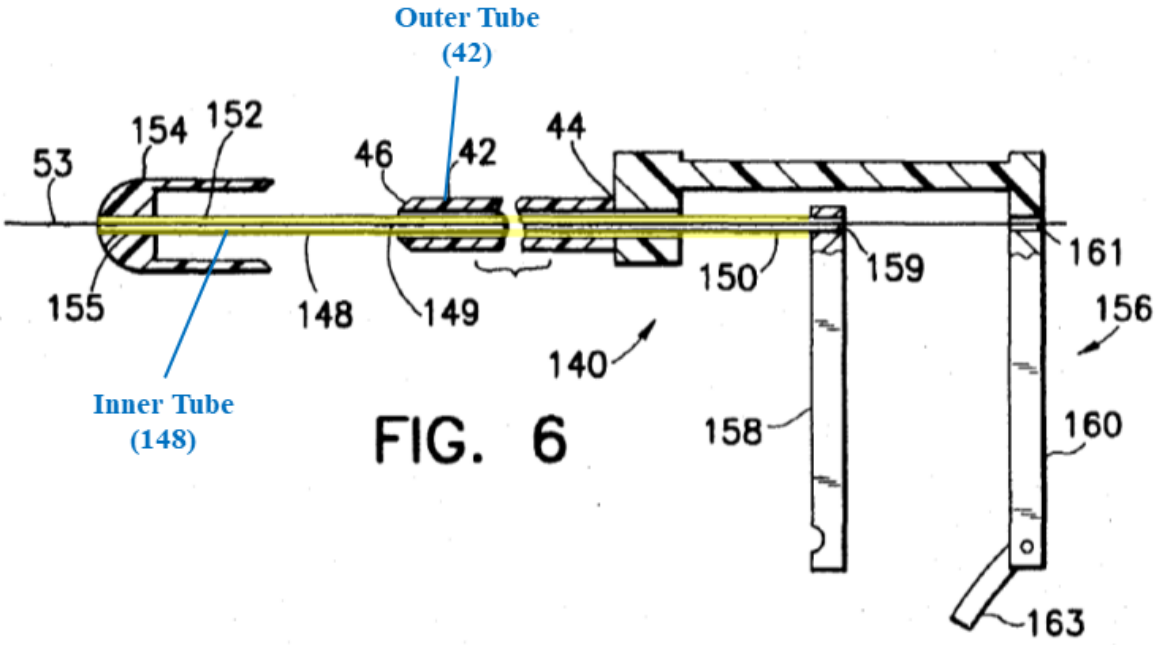


FIG. 10a

(*Id.*, Figure 10a; *see also id.*, 7:65-9:1; Ex. 1015 at ¶62). A PHOSITA would have understood that outer tube (42) in Embodiment #1 is analogous to outer tube (342) in Figure 10A, and that, like outer tube (342) in Figure 10a, outer tube (42) in Embodiment #1 is within the retractable primary sheath (70) and within the stent graft (10). (*Id.*).

e. *"an inner tube within the outer tube,"*

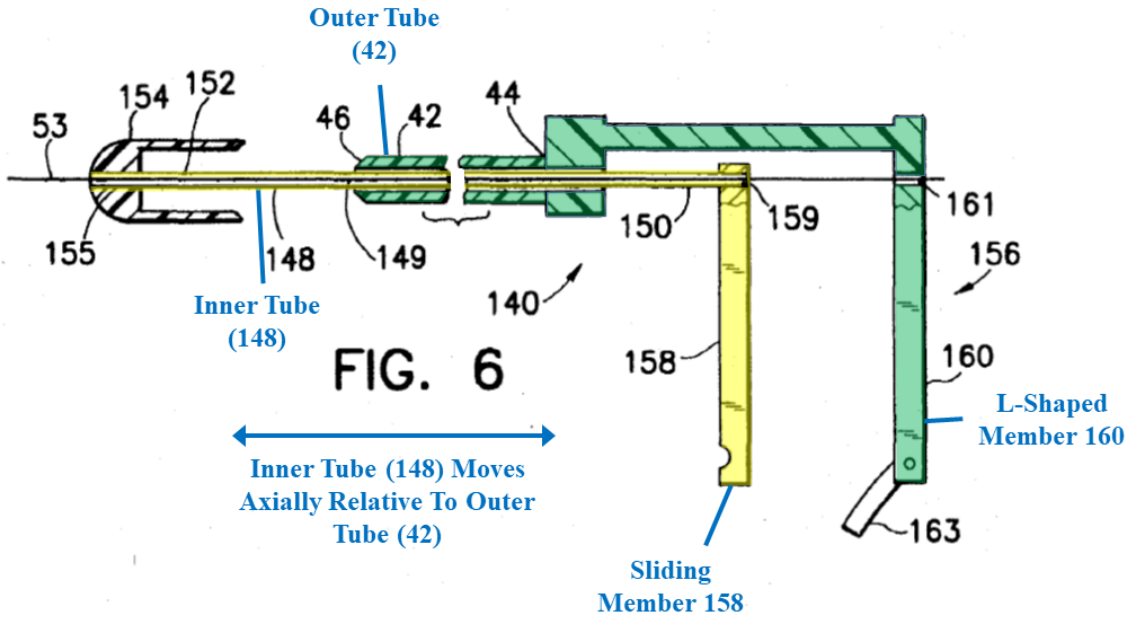
As shown below in annotated Figure 6, Pinchuk Embodiment #1 discloses an inner tube (control member 148 (highlighted in yellow)) within outer tube (42).



(Ex. 1006 at 3:21-32, 5:57-6:13, Figure 6; Ex. 1015 at ¶63).

f. ***"wherein the inner tube and the outer tube both axially can move relative to the retractable primary sheath and to each other;"***

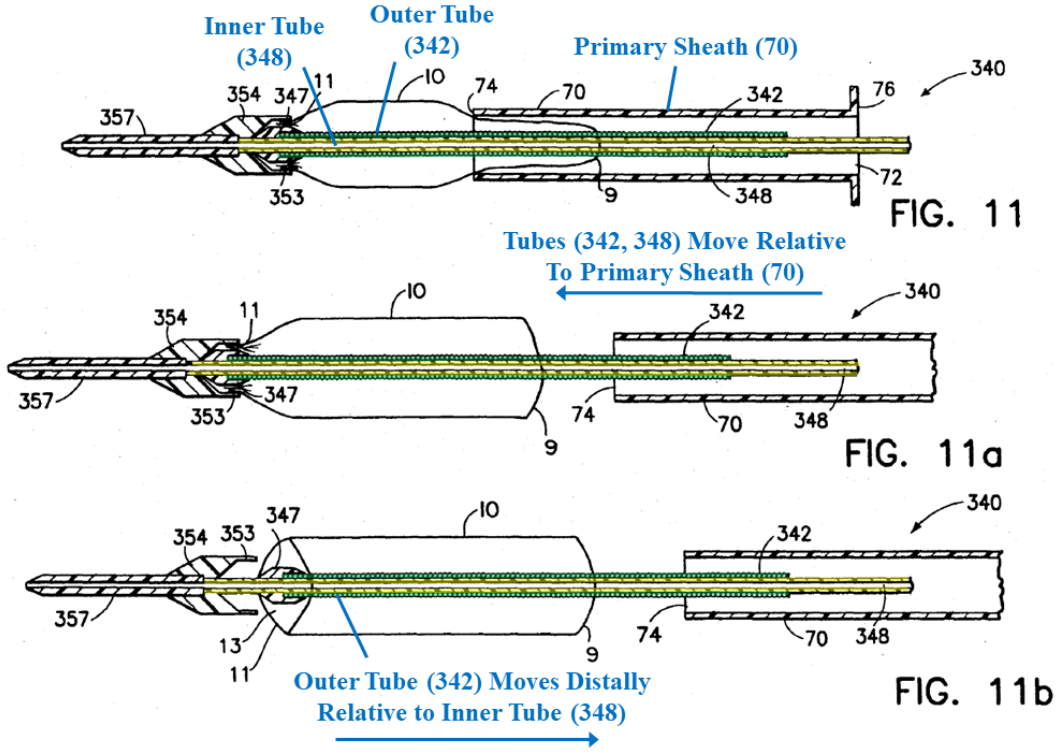
As shown below in annotated Figure 6, Pinchuk Embodiment #1 discloses that inner tube (148) and outer tube (42) both move axially relative to each other, *e.g.*, by moving sliding member 158 towards, or away from, L-shaped member 160.



(Ex. 1006 at 3:21-39, 5:57-6:13; Ex. 1015 at ¶64). As shown above, L-shaped member 160 "is coupled to the proximal end 44 of the [outer tube (42)]" (L-shaped member 160 and outer tube (42) highlighted above in green), and sliding member 158 "is coupled to the proximal end 150 of the [inner tube (148)]" (sliding member 158 and inner tube (148) highlighted above in yellow). (Ex. 1006 at 5:63-68). "[W]hen the actuator members 158, 160 are squeezed together, the end

cap 154 covers and engages the distal end 46 of the tube 42." (*Id.*, 5:58-6:3). The inner tube (148) and outer tube (42) both move axially relative to the retractable primary sheath (70). (*Id.*, 3:40-62; Ex. 1015 at ¶64).

Pinchuk discloses that "[t]he method of the invention is best understood with reference to [Figures 11, 11a, and 11b]," among others. (Ex. 1006 at 7:64-65). As shown below in annotated Figures 11, 11a, and 11b, inner tube (348 (highlighted in yellow)) and outer tube (342 (highlighted in green)) move axially relative to retractable primary sheath (70), and to each other.

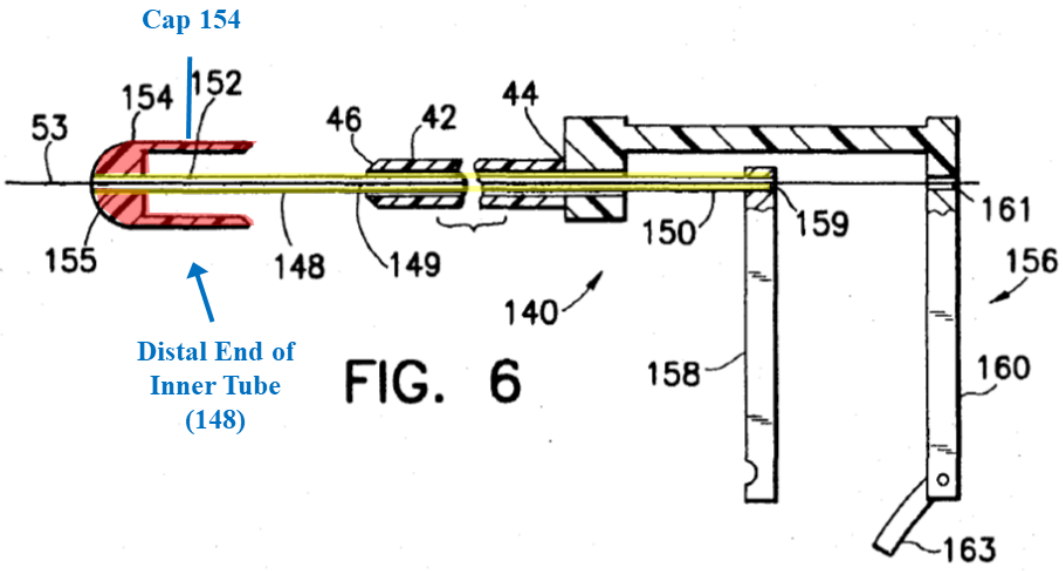


(Ex. 1006 at Figures 11, 11a, 11b; *see also id.,* 7:51-54, 7:64-65, 8:39-61 (During deployment "the introducer 340 is held stationary while the sheath 70 is partially

withdrawn in a proximal direction….When the stent 10 is precisely located, its [distal] end 9 is released by further withdrawal of the sheath 70…The stent 10 is fully deployed when the [proximal] end 11 of the stent is released from the cap 354 and the…locking member 347."); Ex. 1015 at ¶65). A PHOSITA would have understood that Pinchuk Embodiment #1 operates in the same manner as that illustrated in Figures 11, 11a, and 11b. (Ex. 1015 at ¶65).

g. ***"a cap coupled to a distal end of the inner tube and configured to retain at least a portion of a proximal portion of the stent-graft in a radially compressed configuration,"***

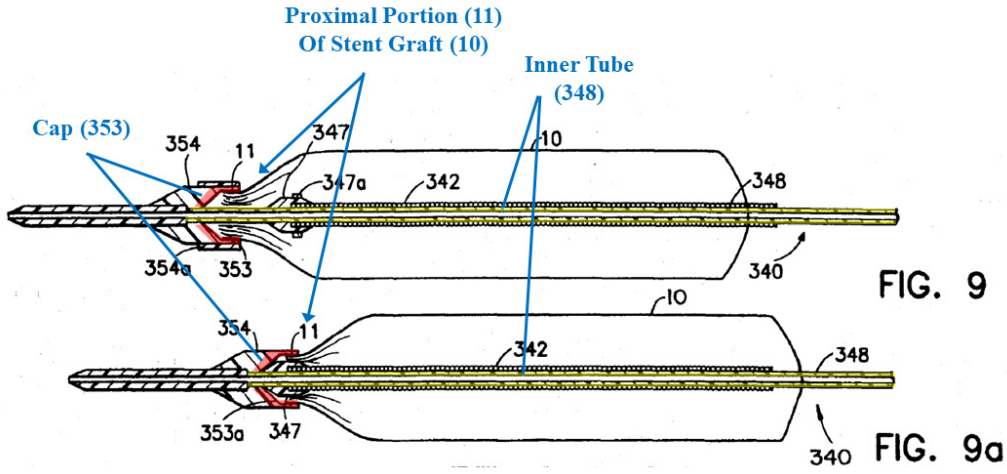
As shown below in annotated Figure 6, Pinchuk Embodiment #1 discloses a cap (cap 154 (highlighted in red)) coupled to a distal end of the inner tube (control member 148 (highlighted in yellow)), which is configured to retain at least a portion of a proximal portion (end 11) of the stent graft (stent graft 10 (not shown below)) in a radially compressed configuration.



(Ex. 1006 at 3:40-45, 5:57-6:13 ("Turning now to FIG. 6….when the actuator members 158, 160 are squeezed together, the end cap 154 covers and engages the distal end 46 of the tube 42."); *see also id.*, 3:30-63, 5:4-13; Ex. 1015 at ¶66).

Pinchuk discloses that "[t]he method of the invention is best understood with reference to [Figures 9 and 9a]," among others. (Ex. 1006 at 7:64-65). As shown

below in annotated Figures 9 and 9a, the cap (cylindrical portion 353 (highlighted in red)) retains at least a portion of a proximal portion of stent graft (10) in a radially compressed configuration.



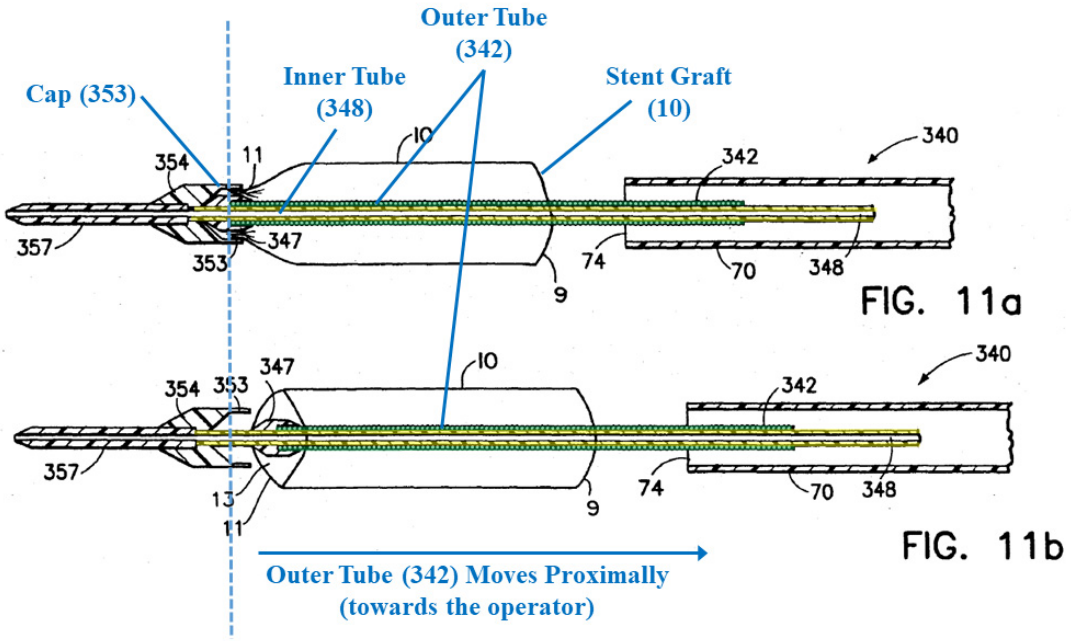
(Ex. 1006 at Figures 9, 9a; *see also id.*, 8:2-28 ("The [proximal] end 11 of a stent 10 is diametrically compressed and inserted into the cylindrical portion 353 of the cap 354 as shown in FIG. 9."); Ex. 1015 at ¶67). A PHOSITA would have understood that Pinchuk Embodiment #1 operates in the same manner as that illustrated in Figures 9 and 9a. (Ex. 1015 at ¶67).

h. ***"wherein a controlled relative axial movement between the outer tube and the inner tube releases the proximal end of the stent-graft from the cap and from the radially compressed configuration."***

Pinchuk Embodiment #1 discloses a controlled relative axial movement between the outer tube (42) and the inner tube (148) releases the proximal end (11) of the stent graft (10) from cap 154 and from the radially compressed configuration. (*See* Ex. 1006 at 3:21-39, 3:40-62 ("[T]he actuation device is manipulated to move the cup-like member and the distal end of the hollow tube together, thereby gripping the [proximal] end of the stent....The actuation device is then manipulated to release the [proximal] end of the stent from the cup-like cap member and the distal end of the hollow tube."), 5:57-6:13, Figure 6; Ex. 1015 at ¶68).

Pinchuk discloses that "[t]he method of the invention is best understood with reference to [Figures 11a and 11b]," among others. (Ex. 1006 at 7:64-65). As shown below in Figures 11a and 11b, controlled relative axial movement (from Figure 11a to Figure 11b) between outer tube (342) (highlighted in green) and inner tube (348) (highlighted in yellow) releases the proximal end of the stent

graft (10) (end closest to the heart) from cap (353) and from the radially compressed configuration.



(Ex. 1006 at 3:56-62, 7:44-63, 8:39-64, Figures 11a, 11b; Ex. 1015 at ¶69). A PHOSITA would have understood that Pinchuk Embodiment #1 operates in the same manner as that illustrated in Figures 11a and 11b. (Ex. 1015 at ¶69).

2. Dependent Claim 4

Claim 4 depends from claim 1 and further states "further comprising a proximal lock attached to the outer tube, wherein the stent-graft has a plurality of proximal spring apices at the proximal end of the stent-graft that remain latched onto the proximal lock in the radially compressed configuration while the plurality of spring apices remain within the cap."

As shown below in annotated Figure 6, Pinchuk Embodiment #1 discloses a proximal lock (including end 46) attached to the outer tube (42).

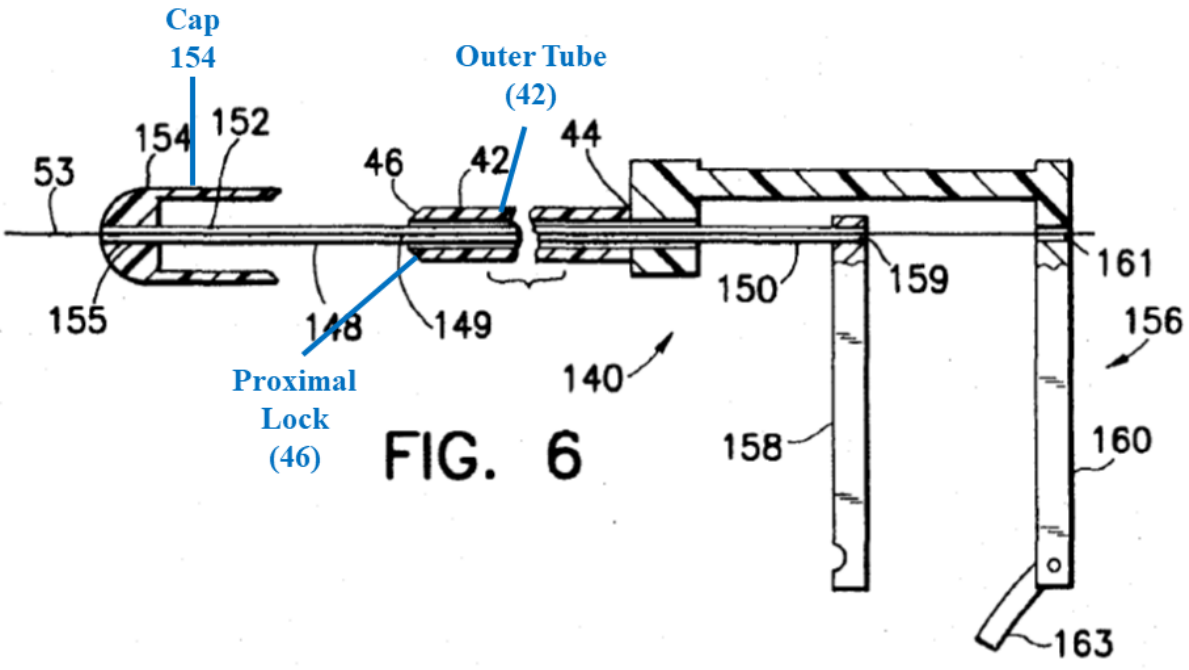
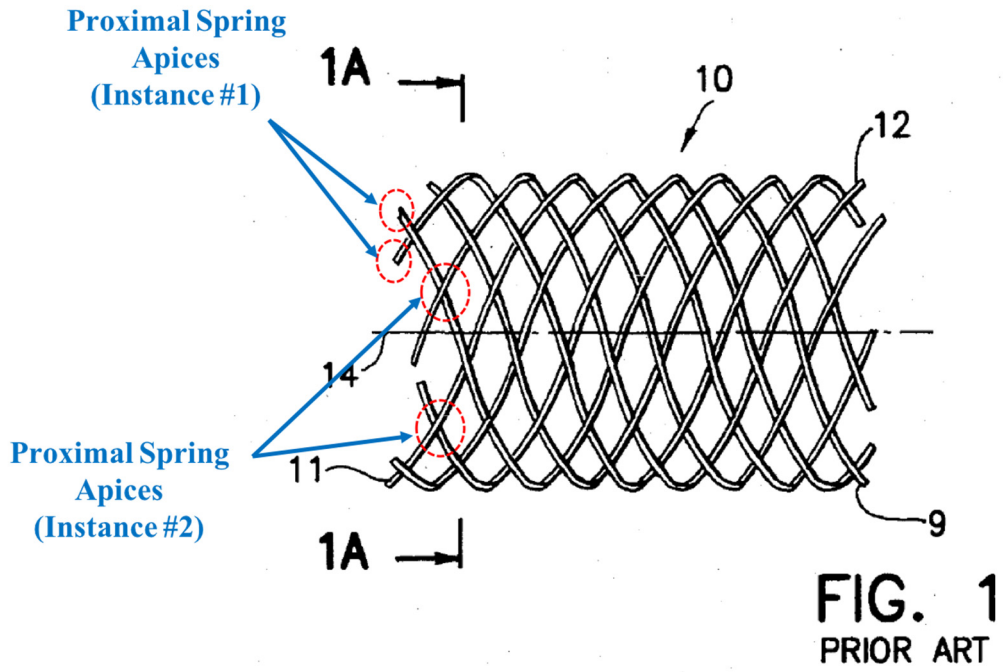


FIG. 6

(Ex. 1006 at 5:57-6:13; Ex. 1015 at ¶71). In use, the proximal lock (including 46) engages cup 154 to constrain and retain the proximal end (end closest to the heart) of the stent graft. (Ex. 1006, at 3:21-39, 3:40-62 ("According to the method of the invention…the actuation device is manipulated to move the cup-like member and

the distal end of the hollow tube together, thereby gripping the [proximal] end of the stent."), 5:35-48 ("[A]ccording to the method of the invention, the [proximal] end of the stent is captured and held between the end cap 54 and the distal end 46 of the hollow tube 42 when the handle and lever members are squeezed together…."), 5:57-6:3; Ex. 1015 at ¶71).

Pinchuk Embodiment #1 discloses a stent graft, for the reasons in Section V.A.1.b., above. Figure 1 (annotated and reproduced below) depicts a stent configuration for a stent graft, including a plurality of proximal spring apices at the proximal end (end 11) of the stent graft (10).



(Ex. 1006 at Figure 1; *see also id.*, 1:14-41, Figure 2; Ex. 1015 at ¶72). As shown above, the stent configuration includes proximal spring apices in at least two

instances. In the first instance, the stent configuration includes proximal spring apices formed by the proximal ends of each of the wires. That is, each proximal end of a wire is a proximal spring apex. In the second instance, the stent configuration includes proximal spring apices formed by the crossings of adjacent wires at the proximal end of the stent. That is, each of the wire crossings at the proximal end of the stent is a proximal spring apex. When the stent graft configuration depicted above is used in Embodiment #1, each of the proximal spring apices illustrated above is disposed within cap 154 in a radially compressed configuration, and each is retained in the cap by gripping (latching) onto the proximal lock (including end 46). (Ex. 1006 at 3:21-39, 3:40-62, 5:35-48, 5:57-6:3, 7:64-8:11, 8:39-64; Ex. 1015 at ¶72).

The plurality of proximal spring apices remain latched onto the proximal lock (including 46) in a radially compressed configuration while the plurality of spring apices remain within the cap. (Ex. 1006 at 3:21-39, 3:40-62, 5:35-48, 5:57-6:3). When the cap 154 and proximal lock (including 46) are subsequently moved apart, the spring apices are released from the lock and allowed to expand. (*Id.*; *see also id.*, Figures 6, 8a, 11, Abstract, 3:59-62 ("The actuation device is then manipulated to release the [proximal] end of the stent from the cup-like cap member and the distal end of the hollow tube."), 8:41-9:1; Ex. 1015 at ¶73).

3. Independent Claim 7

a. *"A controlled stent-graft deployment delivery system, comprising:"*

Pinchuk Embodiment #1 discloses this preamble for the reasons in Section V.A.1.a. (Ex. 1015 at ¶74).

b. *"a retractable primary sheath;"*

Pinchuk Embodiment #1 discloses this limitation for the reasons in Section V.A.1.c. (Ex. 1015 at ¶75).

c. *"an outer tube within the retractable primary sheath;"*

Pinchuk Embodiment #1 discloses this limitation for the reasons in Section V.A.1.d. (Ex. 1015 at ¶76).

d. *"an inner tube within the outer tube,"*

Pinchuk Embodiment #1 discloses this limitation for the reasons in Section V.A.1.e. (Ex. 1015) at ¶77).

e. *"wherein the inner tube can move axially relative to the outer tube;"*

Pinchuk Embodiment #1 discloses this limitation for the reasons in Section V.A.1.f. (Ex. 1015 at ¶78).

f. *"a cap axially fixed to a distal end of the inner tube;"*

Pinchuk Embodiment #1 discloses this limitation for the reasons in Section V.A.1.g. (Ex. 1015 at ¶79).

g. ***"and a retention mechanism attached to the outer tube for retaining a proximal end of a stent-graft in a constrained diameter configuration while the end of the stent graft is still located within the cap while still enabling axial and radial movement of the stent-graft, wherein the retention mechanism comprises a proximal lock fixed to the outer tube."***

Pinchuk Embodiment #1 discloses this limitation for the reasons in Section V.A.2. In particular, Pinchuk Embodiment #1 discloses a retention mechanism comprising a proximal lock (including end 46) fixed to the outer tube (42) for retaining a proximal end (end 11) of stent graft (10) in a constrained diameter configuration while the end (11) of the stent graft (10) is still located within the cap (154). (Ex. 1015 at ¶80).

Pinchuk Embodiment #1 further discloses that the retention mechanism still enables axial and radial movement of the stent graft (10). (*See* Ex. 1006 at 7:64-9:7; Ex. 1015 at ¶81). Pinchuk discloses that "[t]he method of the invention is best understood with reference to [Figure 11]," among others. (Ex. 1006 at 7:64-65). According to Pinchuk, "[t]he stent 10 is deployed at the deployment site…in a sequence of operations," including holding stationary the introducer while "the sheath 70 is partially withdrawn in a proximal direction as shown in FIG. 11

[(reproduced below)], thereby allowing partial diametric expansion of the stent 10."

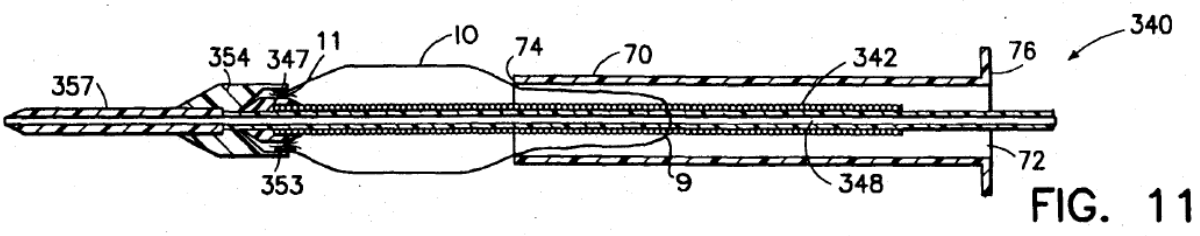


FIG. 11

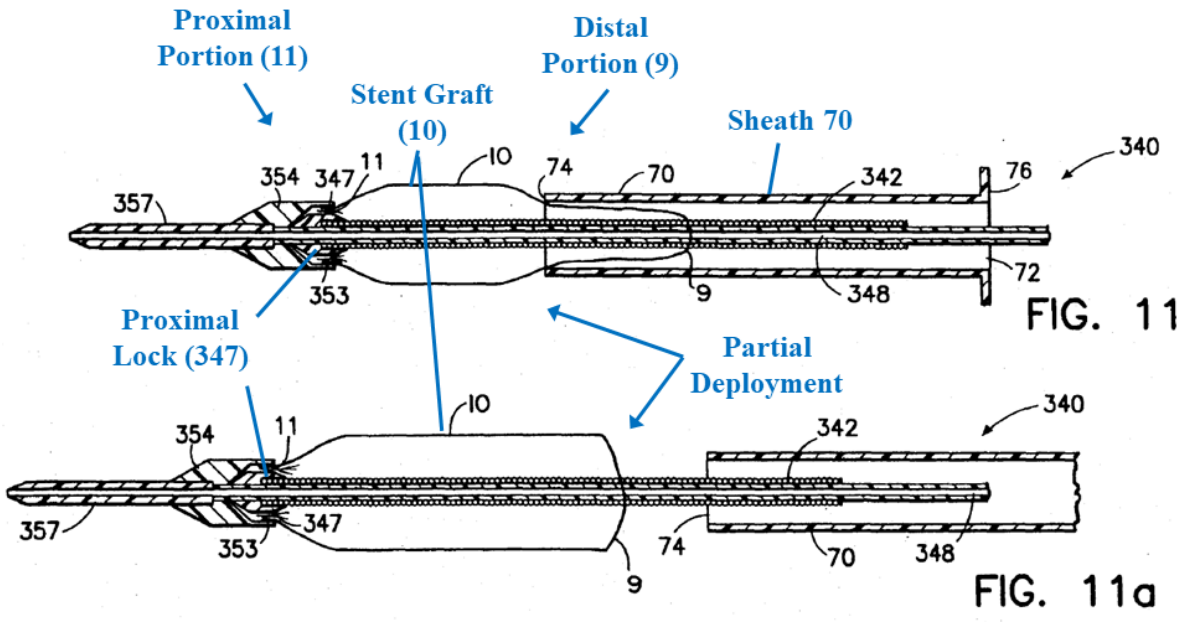
(*Id.*, 8:39-47; Ex. 1015 at ¶81).

In the configuration depicted above in Figure 11, "the [proximal] end 11 of the stent 10 remains captured between the cap 354 and the tapered locking member 347 and the [distal] end 9 of the stent remains covered by the sheath 70," so that "[t]he stent is therefore *movable proximally and distally* by moving the sheath 70 and the introducer 340 together since the wire ends of the stent are prevented from lodging into the organ wall at the deployment stent." (Ex. 1006 at 8:47-54; *see also id.*, Figure 11a, 8:54-61). A PHOSITA would have understood that in the configuration depicted above in Figure 11, the stent graft also is capable of radial movement. (*Id.*, 8:47-9:7; *see also id.*, Figures 11, 11a, 11b, Abstract; Ex. 1015 at ¶82). A PHOSITA would have understood that Pinchuk Embodiment #1 operates in the same manner as Illustrated in Figure 11. (Ex. 1015 at ¶82).

4. Dependent Claim 8

Claim 8 depends from Claim 7 and further states "wherein the retention mechanism enables a partial deployment of a remaining distal portion of the stent-graft while maintaining the proximal end of the stent-graft in the constrained diameter configuration."

As shown below in annotated Figures 11 and 11a, and for the reasons in Section V.A.3.g., above, Pinchuk Embodiment #1 discloses that the retention mechanism (including the proximal lock (46 in Embodiment #1; 347 in Figure 11)) enables a partial deployment of a remaining distal portion (9) of stent graft (10) while maintaining the proximal end (11) of stent graft (10) in the constrained diameter configuration.



(Ex. 1006 at 8:39-9:7, Abstract; Ex. 1015 at ¶84).

Figure 11 discloses a partial deployment of a remaining distal end portion (9), where the stent graft (10) is partially deployed, and a portion of the distal end portion (9) remains constrained within the sheath (70). (Ex. 1006 at 3:10-12, 3:16-18, 8:39-9:7, Abstract).

Figure 11a discloses a further partial deployment of a remaining distal end portion (9), where the stent graft (10) is partially deployed, and the distal end portion (9) is fully released from the sheath. (*Id.*).

A PHOSITA would have understood that Pinchuk Embodiment #1 operates in the same manner as illustrated in Figures 11 and 11a, and likewise enables a partial deployment via the proximal lock (including 46) and primary sheath (70). (Ex. 1015 at ¶84).

5. Independent Claim 12

a. *"A controlled stent-graft deployment delivery system, comprising:"*

Pinchuk Embodiment #1 discloses this preamble for the reasons in Section V.A.1.a. (Ex. 1015 at ¶85).

b. *"a retractable primary sheath;"*

Pinchuk Embodiment #1 discloses this limitation for the reasons in Section V.A.1.c. (Ex. 1015 at ¶86).

c. *"an outer tube within the retractable primary sheath;"*

Pinchuk Embodiment #1 discloses this limitation for the reasons in Section V.A.1.d. (Ex. 1015 at ¶87).

d. *"an inner tube within the outer tube,"*

Pinchuk Embodiment #1 discloses this limitation for the reasons in Section V.A.1.e. (Ex. 1015 at ¶88).

e. *"wherein the inner tube can move axially relative to the outer tube;"*

Pinchuk Embodiment #1 discloses this limitation for the reasons in Section V.A.1.f. (Ex. 1015 at ¶89).

f. *"a cap axially fixed to a distal end of the inner tube;"*

Pinchuk Embodiment #1 discloses this limitation for the reasons in Section V.A.1.g. (Ex. 1015 at ¶90).

g. ***"a retention mechanism attached to the outer tube for retaining a proximal end of a stent-graft in a constrained diameter configuration while the end of the stent graft is still located within the cap while still enabling axial and radial movement of the stent-graft;"***

Pinchuk Embodiment #1 discloses this limitation for the reasons in Sections V.A.2 and V.A.3.g. (Ex. 1015 at ¶91).

h. ***"and a second retention mechanism for retaining a distal end on the stent-graft undeployed while a remaining portion of the stent-graft is deployed."***

As shown below in annotated Figure 11, Pinchuk Embodiment #1 discloses a second retention mechanism (sheath 70) that retains a distal portion of stent graft (10) undeployed, while a remaining portion of stent graft (20) is deployed.

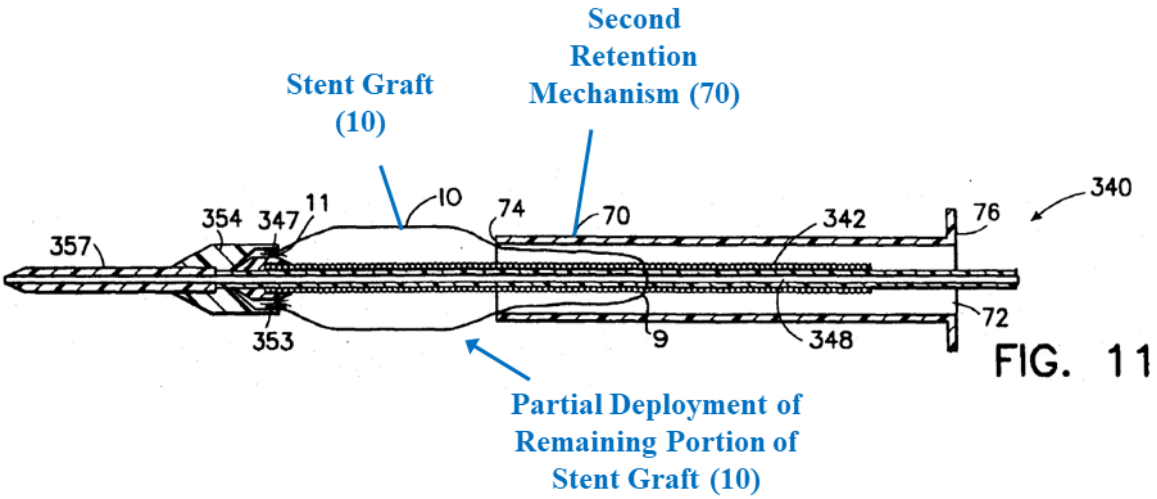


FIG. 11

(Ex. 1006 at 8:39-9:7, Figures 11, 11a, Abstract). Sheath 70 qualifies as a "retention mechanism," for the reasons in Section III.D.2. (Ex. 1015 at ¶92).

B. Ground 2: Claims 1-2, 4, 7-8, And 12 Are Anticipated By Pinchuk (Ex. 1006) Embodiment #2

1. Independent Claim 1

a. *"A controlled stent-graft deployment delivery system, comprising:"*

As shown below in annotated Figure 8, Pinchuk discloses in Embodiment #2 a controlled stent graft deployment delivery system (introducer 340).

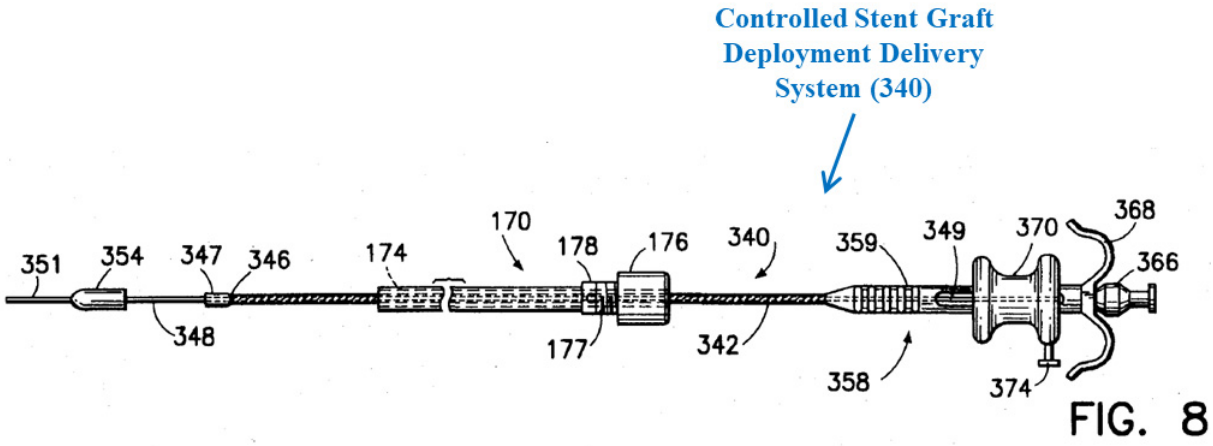


FIG. 8

(Ex. 1006 at Title, Abstract, 1:7-8, 3:27-63, 6:55-59, 6:65-7:63, 8:39-64, 9:56-60; Ex. 1015 at ¶93).

b. *"a stent-graft;"*

Pinchuk Embodiment #2 discloses a stent graft. (Ex. 1006 at Abstract ("A stent, stent graft, or endoluminal graft introducer….The [proximal] end of a…stent-graft is inserted into the cup-like cap…."), Title ("Method And Apparatus For Introducing…A Stent-Graft"), 9:56-60 ("[T]he invention is equally useful for the delivery and deployment of a stent-graft or endoluminal graft."); *see also id.*, 1:14-22, 3:40-45, Claims 1, 6, 22, Figures 1, 2; Section V.A.1.b.; Ex. 1015 at ¶94).

c. *"a retractable primary sheath containing said stent-graft in a first constrained diameter configuration;"*

As shown below in annotated Figure 8, Pinchuk Embodiment #2 discloses a retractable primary sheath (sheath 170 (highlighted red)) for containing the stent graft (e.g., stent graft 10 (not shown below)) in a first constrained diameter configuration.

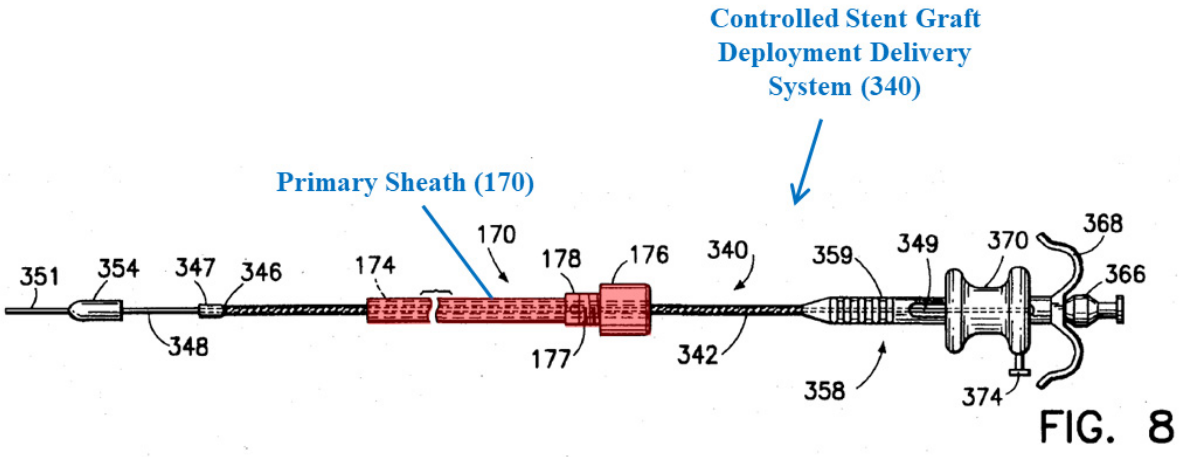


FIG. 8

(Ex. 1006 at 3:21-32 ("[T]he stent delivery and deployment apparatus of the present invention includes an introducer….includ[ing] three concentric tubes: a hollow tube having a proximal end and a distal end; an inner tubular actuation member having a proximal end and a distal end; and an outer sheath."), 3:40-62, 6:65-7:8, 7:64-8:28, 8:41-57, 9:27-30, Figures 8, 10a, *see also id.*, 8:2-28; Section V.A.1.c.; Ex. 1015 at ¶95).

As shown below, Pinchuk alternatively discloses using introducer 340 with retractable primary sheath (70 (highlighted red)).

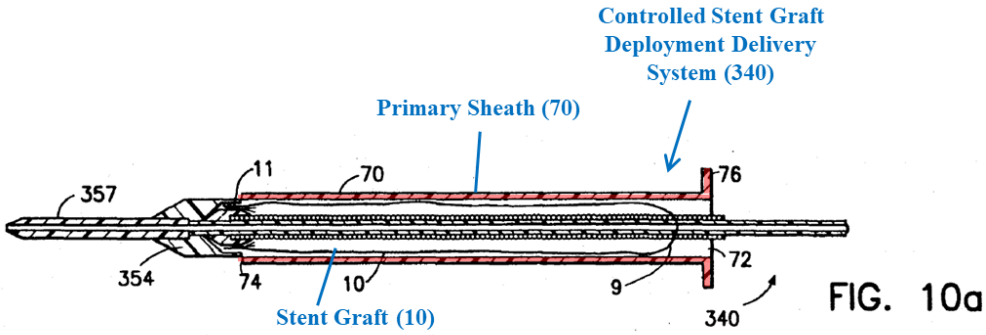


FIG. 10a

(Ex. 1006 at Figure 10a, 7:64-8:38 ("The distally extending soft catheter tip 357 of the cap 354 is then inserted into the proximal end 72 of a sheath 70 as [s]hown in FIG.10."); *see also id.*, 4:52-64; Ex. 1015 at ¶96). As shown above in annotated Figure 10a, the retractable primary sheath (70) contains the stent graft (10) in a first constrained diameter configuration. (*Id.*; *see also id.*, 8:14-46 ("When the stent 10, sheath 70, and introducer 340 are assembled in the configuration shown in FIG. 10a, the entire assembly is ready for delivery to the stent deployment site."); Ex. 1015 at ¶96).

d. ***"an outer tube within the retractable primary sheath and within the stent-graft;"***

As shown below in annotated Figure 10a, Pinchuk Embodiment #2 discloses an outer tube (coil 342 (highlighted green)) within the retractable primary sheath (70) and within the stent graft (10).

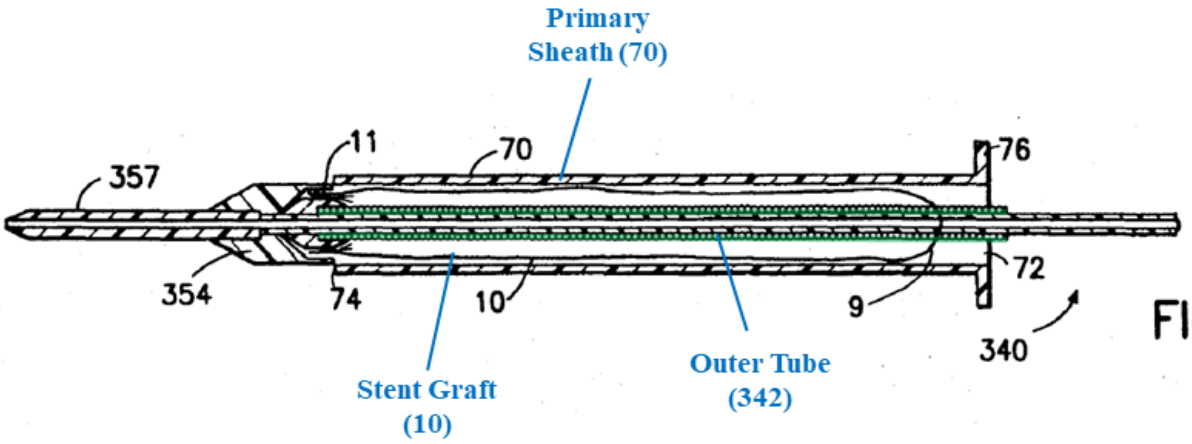


FIG. 10a

(Ex. 1006 at 3:21-32, 3:40-62, 8:2-38, 8:41-61, Figures 10a, 11; Section V.A.1.d.; Ex. 1015 at ¶97). A PHOSITA would recognize from Pinchuk's disclosure that the disclosed "flexible coil 342" is formed from a tubular coil either with, or without, an associated polymer sleeve, dip, or coating. (Ex.1006 at 5:23-34; Section IV.A.; Ex. 1015 at ¶97).

As explained above in Section IV.A., Pinchuk describes "coils" as "tubes." (*Id.*, 5:28-34). This is consistent with a PHOSITA's understanding that the word "tube" encompasses cylindrical coil structures. (Ex. 1015 at ¶98; *see also* Ex. 1010 (defining "tube" as "a hollow cylindrical structure or canal"); Ex. 1011

(U.S. 5,800,520 to Medtronic, Inc.) at 5:4-23 ("[T]he *tubular* member comprises a sheet of biocompatible material which is *coiled* concentrically."), 4:54-64; Ex. 1012 (U.S. 6,024,763 to Medtronic, Inc.) at 12:41-56 (describing a "flexible *tube* preferably compris[ing] a tightly wound *coil*")).

e. *"an inner tube within the outer tube,"*

As shown below in annotated Figure 10a, Pinchuk Embodiment #2 discloses an inner tube (control member 348 (highlighted in yellow)) within an outer tube (342 (highlighted in green)).

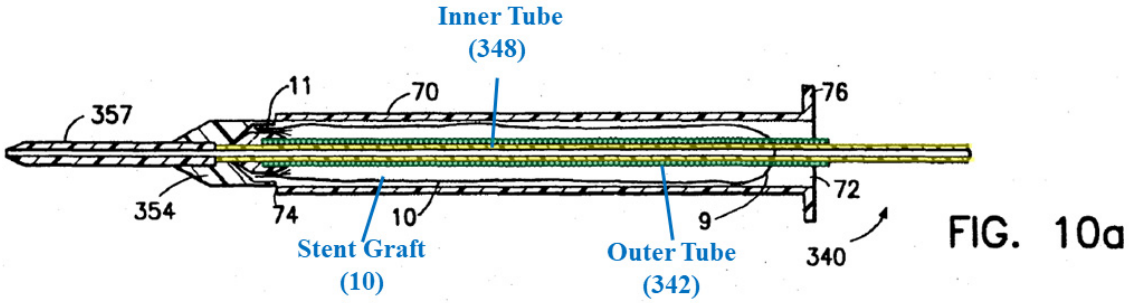


FIG. 10a

(Ex. 1006 at 3:21-32, 6:57-59 ("The introducer 340 includes a flexible coil 342 and a coaxial control member 348 which extends through the coil 342."), Figure 10a; *see also* Section V.A.1.e.; Ex. 1015 at ¶99).

f. ***"wherein the inner tube and the outer tube both axially can move relative to the retractable primary sheath and to each other;"***

As shown below in annotated Figures 11, 11a, and 11b, Pinchuk Embodiment #2 discloses the inner tube (348 (highlighted in yellow)) and outer tube (342 (highlighted in green)) both move axially relative to the retractable primary sheath (70) (Figure 11 to Figure 11a), and to each other (Figure 11a to Figure 11b).

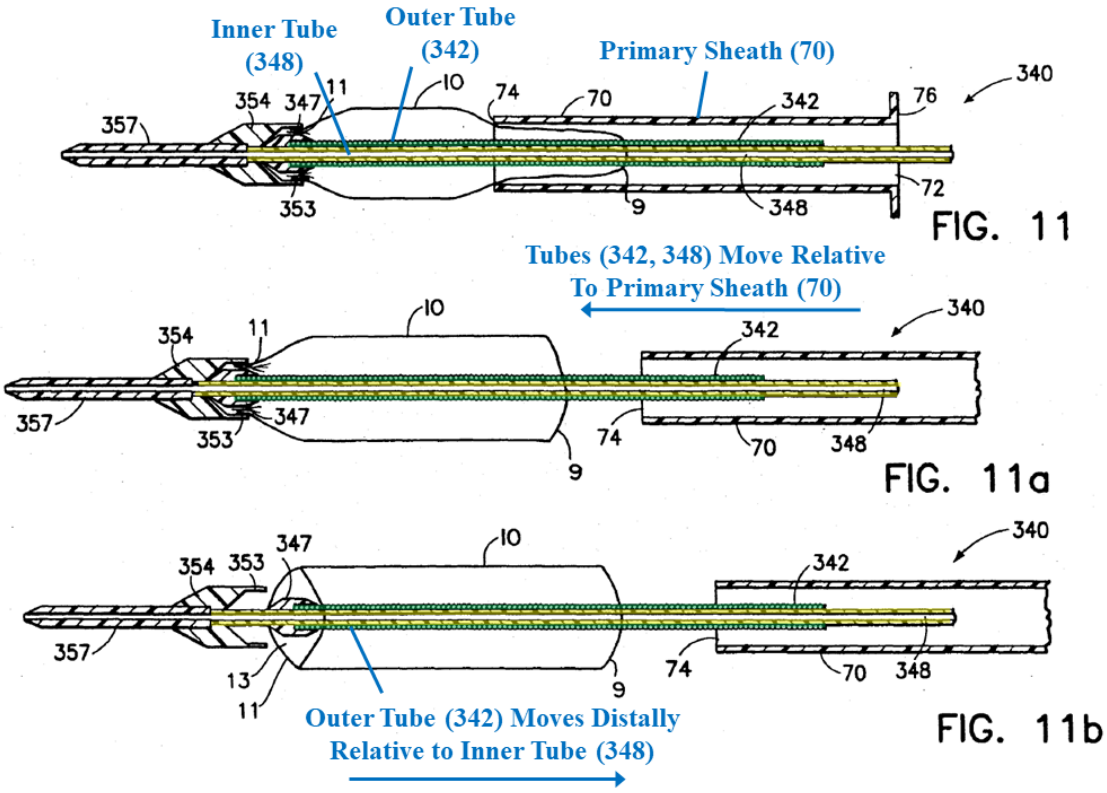


FIG. 11

FIG. 11a

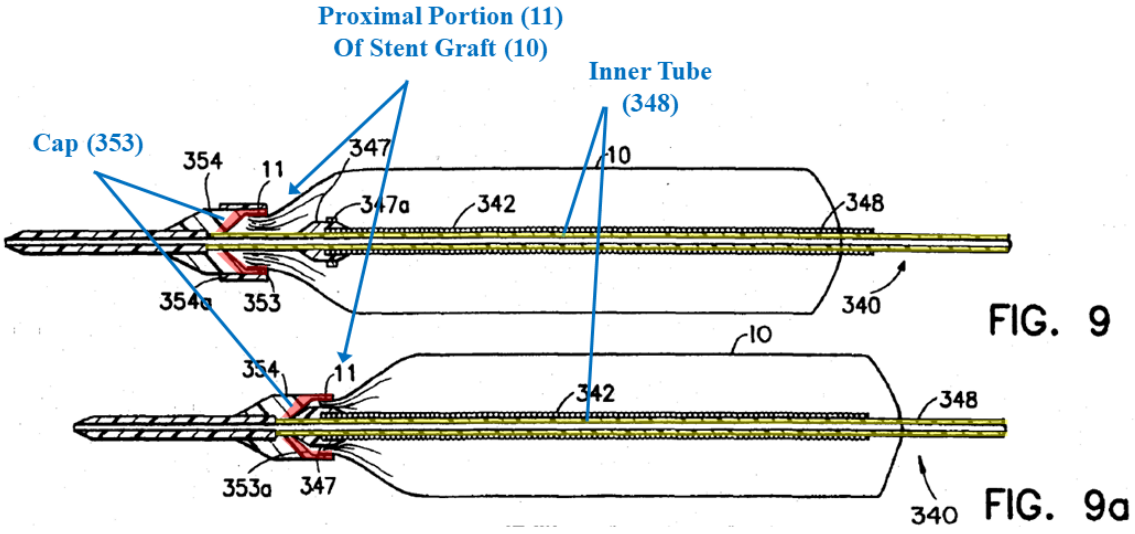
FIG. 11b

(Ex. 1006 at 3:21-39, 3:40-62, 8:39-61 (During deployment "the introducer 340 is held stationary while the sheath 70 is partially withdrawn in a proximal direction….When the stent 10 is precisely located, its [distal] end 9 is released by

further withdrawal of the sheath 70…The stent 10 is fully deployed when the [proximal] end 11 of the stent is released from the cap 354 and the…locking member 347."); *see also id.*, Figures 11, 11a, 11b, 7:51-54; Section V.A.1.f.; Ex. 1015 at ¶100).

g. ***"a cap coupled to a distal end of the inner tube and configured to retain at least a portion of a proximal portion of the stent-graft in a radially compressed configuration,"***

As shown below in annotated Figures 9 and 9a, Pinchuk Embodiment #2 discloses a cap (cylindrical portion 353 (highlighted in red)) coupled to a distal end of the inner tube (control member 348 (highlighted in yellow)) and configured to retain at least a portion of the proximal portion (end 11) of the stent graft (10) in a radially compressed configuration.

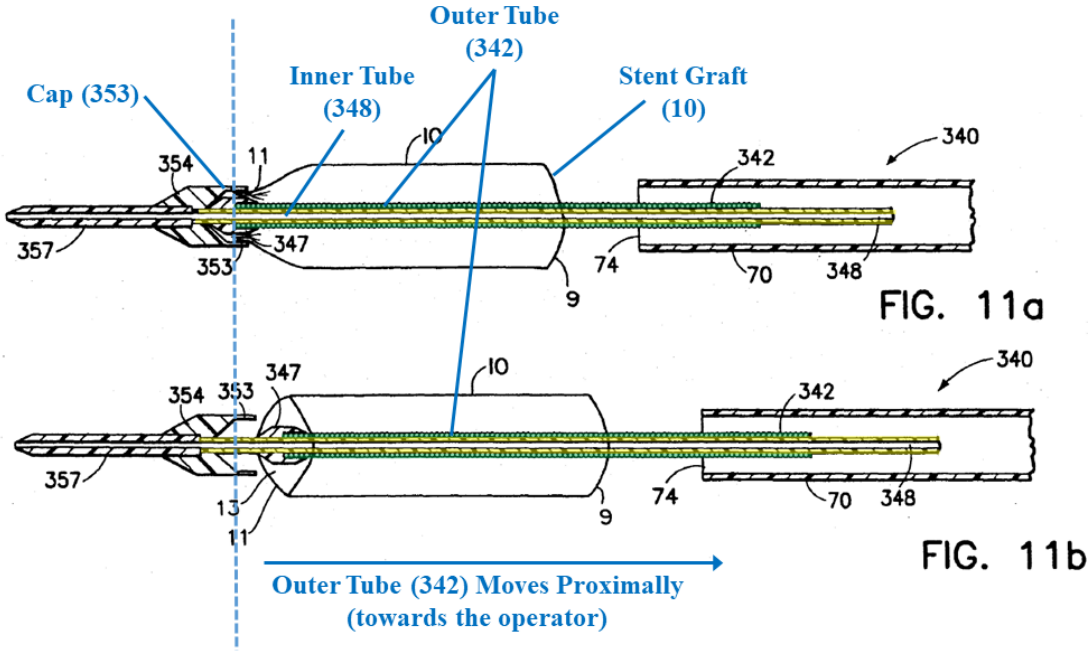


(Ex. 1006 at 3:30-63, 7:64-8:39, 8:2-28 ("The [proximal] end 11 of a stent 10 is diametrically compressed and inserted into the cylindrical portion 353 of the cap 354 as shown in FIG. 9."); Section V.A.1.g.; Ex. 1015 at ¶101).

h. ***"wherein a controlled relative axial movement between the outer tube and the inner tube releases the proximal end of the stent-graft from the cap and from the radially compressed configuration."***

Pinchuk Embodiment #2 discloses that a controlled relative axial movement between the outer tube (342) and the inner tube (348) releases the proximal end (11) of the stent graft (10) from cap 154 and from the radially compressed configuration. (*See* Ex. 1006 at 3:21-39, 3:40-62 ("[T]he actuation device is manipulated to move the cup-like member and the distal end of the hollow tube together, thereby gripping the [proximal] end of the stent….The actuation device is then manipulated to release the [proximal] end of the stent from the cup-like cap member and the distal end of the hollow tube."), Figures 11a-11b, 7:64-9:1; *see also*, Section V.A.1.h.). In particular, Pinchuk discloses releasing the proximal end (11) of the stent (end closest to the heart) by sliding the outer tube (342) proximally (toward the operator) relative to the inner tube (348). (*Id.*; Ex. 1015 at ¶102).

As shown below in Figures 11a and 11b, controlled relative axial movement (from Figure 11a to Figure 11b) between outer tube (342 (highlighted green)) and inner tube (348 (highlighted yellow)) releases the proximal end of the stent graft (10) from cap (353) and from the radially compressed configuration.



(Ex. 1006 at 3:56-62, 8:39-64, Figures 11a, 11b; Ex. 1015 at ¶103).

2. Dependent Claim 2

Claim 2 depends from claim 1 and further states "wherein the cap is a shroud portion of a flexible tapered tip fixed to the distal end of the inner tube."

As shown below in annotated Figure 8a, Pinchuk Embodiment #2 discloses that the cap (cylindrical portion 353) is a shroud portion of a flexible tapered tip ("cap 354") fixed to the distal end of the inner tube (control member 348 (highlighted yellow)).

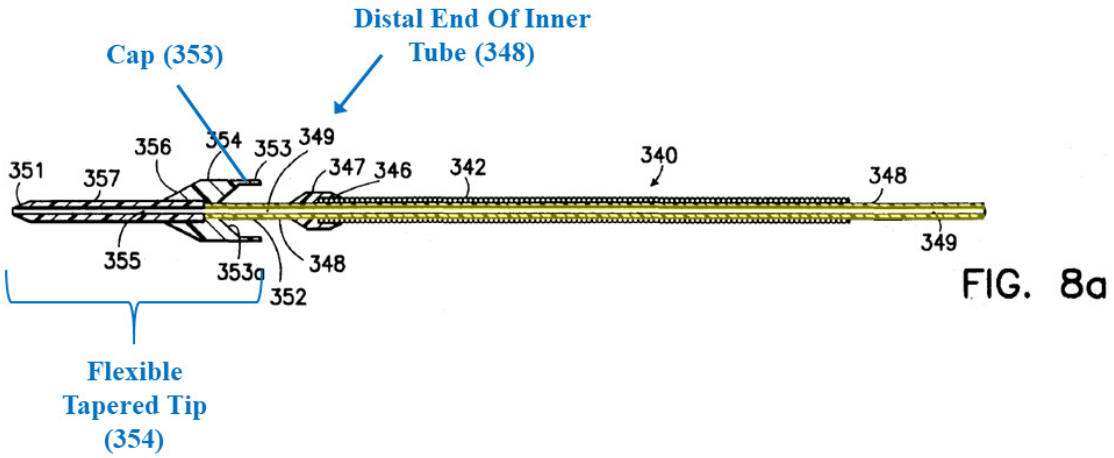


FIG. 8a

(Ex. 1006 at Figures 8a, 11, 7:17-25 ("The distal end 352 of the control member 348 is provided with a rigid cap 354 which has a proximal cylindrical portion 353, an interior frustroconical [*sic*] portion 353a, an [o]uter frustroconical [*sic*] portion 356, and a distally extending soft catheter tip 357."); Ex. 1015 at ¶105).

3. Dependent Claim 4

Claim 4 depends from claim 1 and further states "further comprising a proximal lock attached to the outer tube, wherein the stent-graft has a plurality of proximal spring apices at the proximal end of the stent-graft that remain latched onto the proximal lock in the radially compressed configuration while the plurality of spring apices remain within the cap."

As shown below in annotated Figure 11, Pinchuk Embodiment #2 discloses a proximal lock (including locking member 347 (highlighted in red)) attached to outer tube (342 (highlighted in green)), where the stent graft (10) is latched onto the proximal lock (including 347) in the radially compressed configuration.

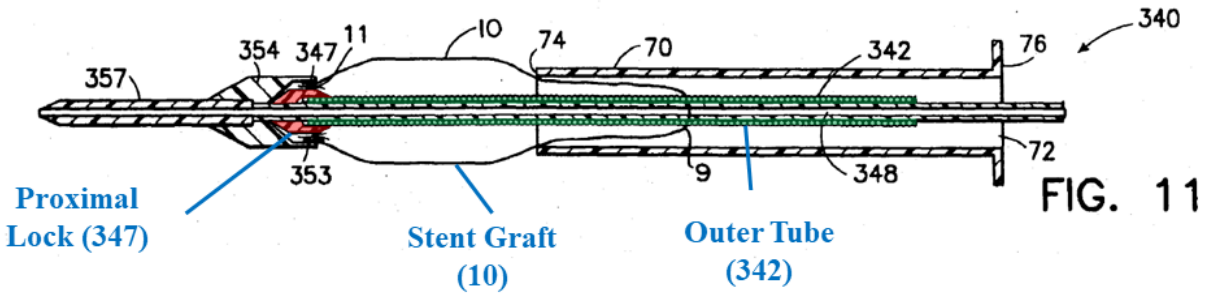


FIG. 11

(Ex. 1006 at 3:21-39, 3:40-62 ("[T]he actuation device is manipulated to move the cup-like member and the distal end of the hollow tube together, thereby gripping the [proximal] end of the stent."), 7:17-21, 8:2-28 ("The [proximal] end 11 of a stent 10 is diametrically compressed and inserted into the cylindrical portion 353 of the cap 354…."), 8:41-9:1; Ex. 1015 at ¶107).

Pinchuk Embodiment #2 discloses a stent graft including a plurality of proximal spring apices at the proximal end of the stent graft, for the reasons in Sections V.B.1.b. and V.A.2., above. (*See also* Ex. 1006 at Figures 1 and 2, 1:14-41). When the stent graft is used with Embodiment #2, the proximal spring apices are disposed within cap (353) in a radially compressed configuration, and are retained in the cap by gripping (latching) onto proximal lock (including 347). (Ex. 1006 at 3:21-39, 3:40-62; *see also id.*, 7:65-8:11; Ex. 1015 at ¶108; Sections V.A.2 and V.B.1.g., above).

The plurality of proximal spring apices remain latched onto the proximal lock (including 347) in a radially compressed configuration while the plurality of spring apices remain within cap (353). (Ex. 1006 at 3:21-39, 3:40-62, 7:65-8:11; Ex. 1015 at ¶109). When cap (353) and proximal lock (including 347) are subsequently moved apart, the spring apices are released from the lock and allowed to expand. (*Id.*; *see also* Ex. 1006 at Figures 8a, 11, Abstract, 3:59-62, 8:58-9:1 ("[S]o long as the [proximal] end 11 of the stent 10 remains captured by the cap 354 and the tapered locking member 347, the stent can be relocated in the [proximal] direction. The stent 10 is fully deployed when the distal end 11 of the stent is released from the cap 354 and the tapered locking member 347 as described above. In this position, which is shown in FIG. 11b, the stent 10 is

diametrically self-exp[a]nded to engage the organ wall at the deployment site (not shown)…."), 8:41-58).

4. Independent Claim 7

a. *"A controlled stent graft deployment delivery system, comprising:"*

Pinchuk Embodiment #2 discloses this preamble for the reasons in Section V.B.1.a. (Ex. 1015 at ¶110).

b. *"a retractable primary sheath;"*

Pinchuk Embodiment #2 discloses this limitation for the reasons in Section V.B.1.c. (Ex. 1015 at ¶111).

c. *"an outer tube within the retractable primary sheath;"*

Pinchuk Embodiment #2 discloses this limitation for the reasons in Section V.B.1.d. (Ex. 1015 at ¶112).

d. *"an inner tube within the outer tube,"*

Pinchuk Embodiment #2 discloses this limitation for the reasons in Section V.B.1.e. (Ex. 1015 at ¶113).

e. *"wherein the inner tube can move axially relative to the outer tube;"*

Pinchuk Embodiment #2 discloses this limitation for the reasons in Section V.B.1.f. (Ex. 1015 at ¶114).

f. *"a cap axially fixed to a distal end of the inner tube;"*

Pinchuk Embodiment #2 discloses this limitation for the reasons in Sections V.B.1.g. and V.B.2. (Ex. 1015 at ¶115).

g. ***"and a retention mechanism attached to the outer tube for retaining a proximal end of a stent-graft in a constrained diameter configuration while the end of the stent graft is still located within the cap while still enabling axial and radial movement of the stent-graft, wherein the retention mechanism comprises a proximal lock fixed to the outer tube."***

Pinchuk Embodiment #2 discloses this limitation for the reasons in Section V.B.3. In particular, Pinchuk Embodiment #2 discloses a retention mechanism comprising a proximal lock (including 347) fixed to the outer tube (342) for retaining a proximal end (11) of a stent graft (10) in a constrained diameter configuration while the end (11) of the stent graft (10) is still located within the cap (353). (Ex. 1015 at ¶116; Section V.B.3.).

Pinchuk Embodiment #2 further discloses that the retention mechanism still enables axial and radial movement of the stent graft (10). (*See* Ex. 1006, 7:64-9:1; Ex. 1015 at ¶117). As shown below in annotated Figure 11, Pinchuk Embodiment #2 discloses the stent graft (10) "is deployed at the deployment site…in a sequence of operations," including holding stationary the introducer while "the sheath 70 is partially withdrawn in a proximal direction as shown in

FIG. 11 [(reproduced below)], thereby allowing partial diametric expansion of the [stent graft (10)]." (Ex. 1006 at 8:39-47).

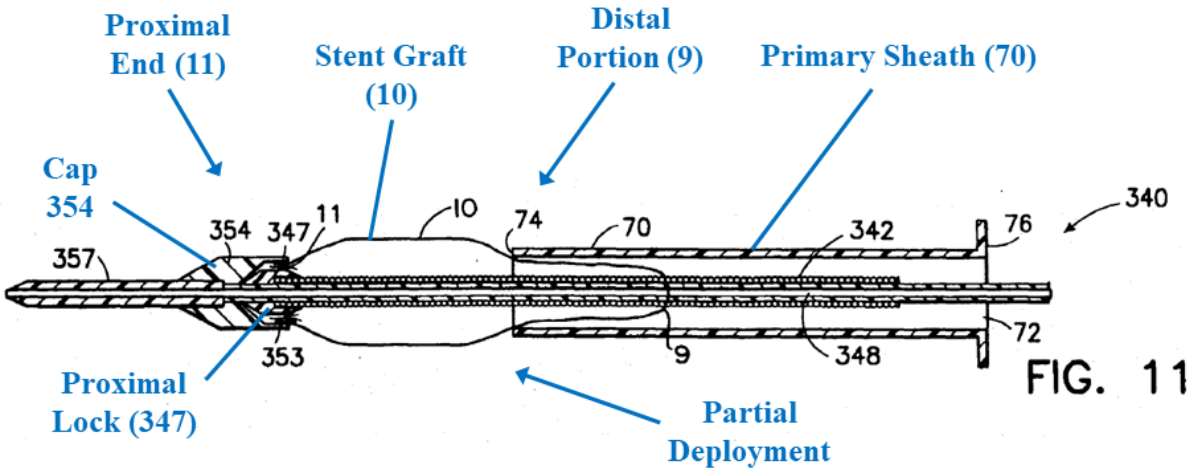


FIG. 11

(Ex. 1015 at ¶117). In the configuration depicted above in annotated Figure 11, "the [proximal] end 11 of the [stent graft (10)] remains captured between the cap 354 and the tapered locking member 347 and the [distal] end 9 of the [stent graft (10)] remains covered by the sheath 70," so that the stent graft (10) is "*movable proximally and distally* by moving the sheath 70 and the introducer 340 together since the wire ends of the [stent graft] are prevented from lodging into the organ wall at the deployment site." (Ex. 1006 at 8:47-54; *see also id.*, Figure 11a, 8:54-61 ("[S]o long as the distal end 11 of the stent remains captured by the cap 354 and the tapered locking member 347, the stent can be relocated in the distal direction.")). A PHOSITA would have understood that in the configuration depicted above in Figure 11, the stent graft also is capable of radial movement.

(Ex. 1006 at 8:47-9:7; *see also id.*, Figures 11, 11a, 11b, Abstract; Ex. 1015 at ¶117).

5. Dependent Claim 8

Claim 8 depends from Claim 7 and further states "wherein the retention mechanism enables a partial deployment of a remaining distal portion of the stent-graft while maintaining the proximal end of the stent-graft in the constrained diameter configuration."

As shown below in annotated Figures 11 and 11a, and for the reasons in Section V.B.4.g., above, Pinchuk Embodiment #2 discloses that the retention mechanism (347) enables a partial deployment of a remaining distal portion (9) of the stent graft (10) while maintaining the proximal end (11) of the stent graft (10) in the constrained diameter configuration.

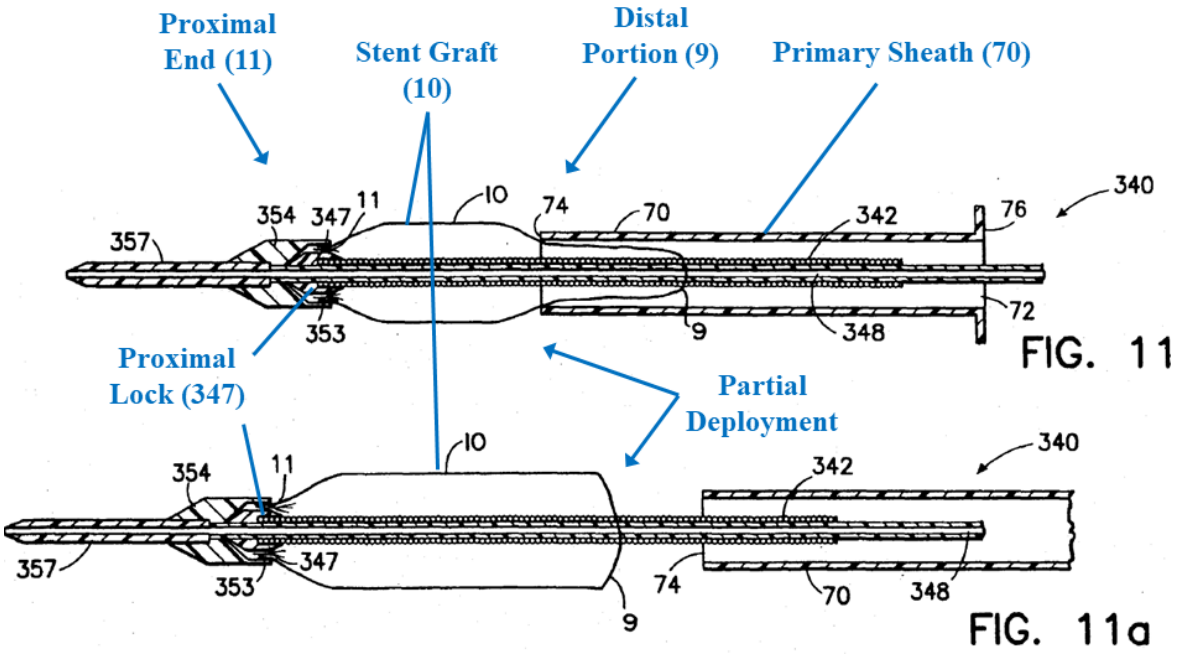


FIG. 11

FIG. 11a

(Ex. 1006 at Figures 11, 11a, Abstract, 8:39-9:7; Ex. 1015 at ¶119).

Figure 11 discloses a partial deployment of a remaining distal end portion (9), where the stent graft (10) is partially deployed, and a portion of the distal end portion (9) remains constrained within the sheath (70). (*Id.*).

Figure 11a discloses a further partial deployment of a remaining distal end portion (9), where the stent graft (10) is partially deployed, and the distal end portion (9) is released from the sheath. (*Id.*).

6. Independent Claim 12

a. *"A controlled stent-graft deployment delivery system, comprising:"*

Pinchuk Embodiment #2 discloses this preamble for the reasons in Section V.B.1.a. (Ex. 1015 at ¶120).

b. *"a retractable primary sheath;"*

Pinchuk Embodiment #2 discloses this limitation for the reasons in Section V.B.1.c. (Ex. 1015 at ¶121).

c. *"an outer tube within the retractable primary sheath;"*

Pinchuk Embodiment #2 discloses this limitation for the reasons in Section V.B.1.d. (Ex. 1015 at ¶122).

d. *"an inner tube within the outer tube,"*

Pinchuk Embodiment #2 discloses this limitation for the reasons in Section V.B.1.e. (Ex. 1015 at ¶123).

e. *"wherein the inner tube can move axially relative to the outer tube;"*

Pinchuk Embodiment #2 discloses this limitation for the reasons in Section V.B.1.f. (Ex. 1015 at ¶124).

f. *"a cap axially fixed to a distal end of the inner tube;"*

Pinchuk Embodiment #2 discloses this limitation for the reasons in Sections V.B.1.g. and V.B.2. (Ex. 1015) at ¶125).

g. ***"a retention mechanism attached to the outer tube for retaining a proximal end of a stent-graft in a constrained diameter configuration while the end of the stent graft is still located within the cap while still enabling axial and radial movement of the stent-graft;"***

Pinchuk Embodiment #2 discloses this limitation for the reasons in Sections V.B.3 and V.B.4.g. (Ex. 1015 at ¶126).

h. ***"and a second retention mechanism for retaining a distal end on the stent-graft undeployed while a remaining portion of the stent-graft is deployed."***

As shown below in annotated Figure 11, Pinchuk Embodiment #2 discloses a second retention mechanism (sheath 70) that retains a distal portion of stent graft (10) undeployed, while a remaining portion of stent graft (10) is deployed.

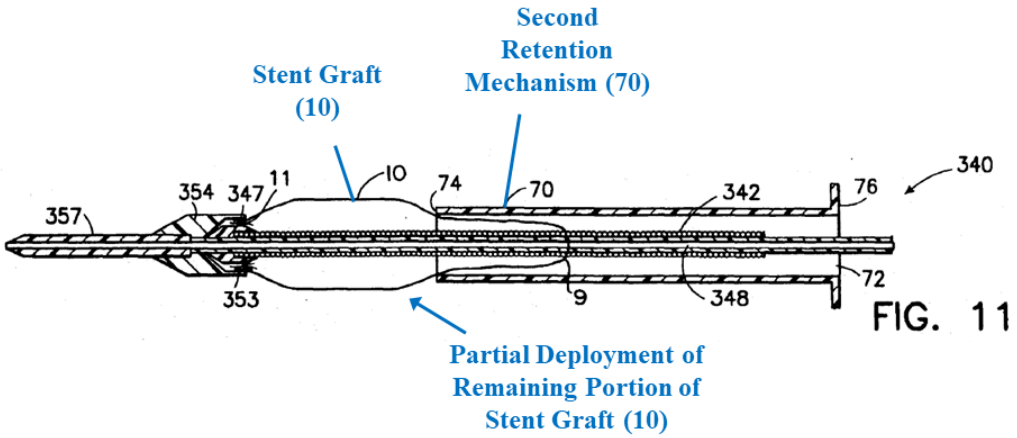


FIG. 11

(Ex. 1006 at 8:39-9:7, Figures 11, 11a, Abstract). Sheath 70 qualifies as a "retention mechanism," for the reasons in Section III.D.2. (Ex. 1015 at ¶127)

C. Ground 3: Claims 4-5, 7-9, And 12 Are Obvious In View Of Pinchuk (Ex. 1006) Embodiment #1 or Embodiment #2 In Combination With Robinson (Ex. 1008)

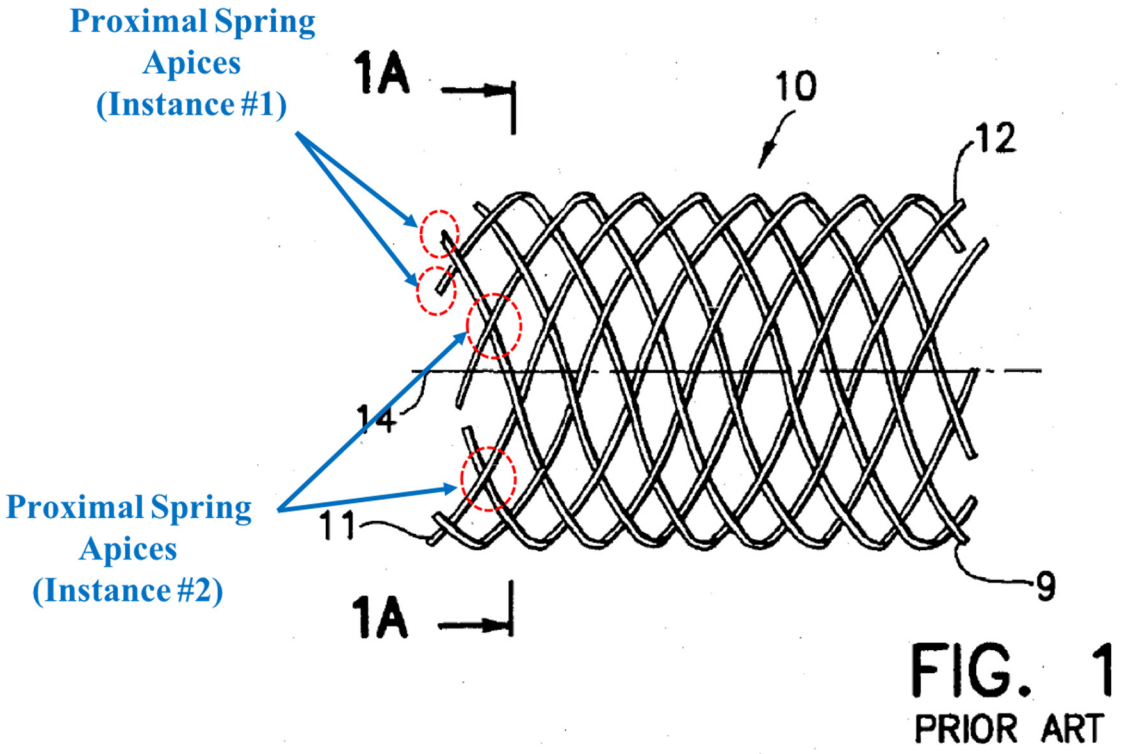
1. Dependent Claim 4

Claim 4 depends from claim 1. Pinchuk Embodiments #1 and #2 each disclose the limitations of claim 1 for the reasons in Sections V.A.1. and V.B.1., respectively. (Ex. 1015 at ¶128).

Claim 4 further states "further comprising a proximal lock attached to the outer tube, wherein the stent-graft has a plurality of proximal spring apices at the proximal end of the stent-graft that remain latched onto the proximal lock in the radially compressed configuration while the plurality of spring apices remain within the cap." Pinchuk Embodiments #1 and #2 each disclose the limitations of claim 4, for the reasons in Sections V.A.2. and V.B.3., respectively. (Ex. 1015 at ¶129).

a. It Would Have Been Obvious to Use Stent Grafts With Self-Expanding Zig-Zag Stents

As shown below in annotated Figure 1, Pinchuk describes stent grafts including self-expanding braided stents, which a PHOSITA would have recognized as Wallstent-type stents.[12] (*See* Ex. 1006 at 1:22-25 (citing U.S. Pat. No. 4,655,771 "to Wallstén"); Ex. 1015 at ¶130).



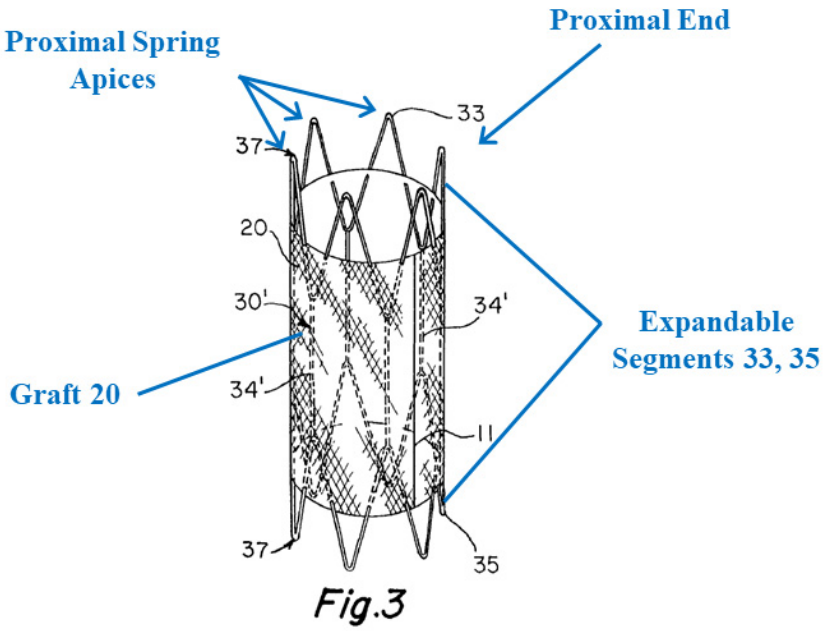
(Ex. 1006 at Figures 1, 2, 1:14-41). As shown above, the Wallstent-type stent includes a plurality of helically wound wires, the wires forming a plurality of

[12] Wallstent-type stents are named after Hans Wallstén, who patented this design in the 1980s. (Ex. 1013 (U.S 4,655,771)).

proximal spring apices in two instances. (*Id.*; *see also* Sections V.A.2. and V.B.3.).

A PHOSITA would have recognized that the Pinchuk delivery systems are not limited to delivering and deploying stent grafts with self-expanding braided stents, however. (Ex. 1006 at 9:56-60 ("[W]hile the invention has been disclosed with reference to the delivery and deployment of a stent, it will be understood that the invention is equally useful for the delivery and deployment of a stent-graft or endoluminal graft."), 10:2-6; Ex. 1015 at ¶131). It would have been obvious to a PHOSITA to use the delivery systems disclosed in Pinchuk Embodiments #1 and #2 for delivering and deploying stent grafts with other prior art self-expanding stent designs. (Ex. 1015 at ¶131).

As shown below in annotated Figure 1, for example, Robinson (Ex. 1008) discloses a prior art stent graft including self-expanding zig-zag type stents (expandable segments 33, 35).



(Ex. 1008, at Figure 3, 7:48-8:33; Ex. 1015 at ¶132). As shown above, the stent graft includes a plurality of spring apices formed at proximal and distal ends of the stent graft. Robinson discloses that the graft 20 portion of the stent graft may extend only partially along the length of the stent frame, such that the plurality of proximal spring apices are uncovered by the graft 20 portion. (Ex. 1008 at 7:48-8:33, Figure 3; Ex. 1015 at ¶132).

It would have been obvious to a PHOSITA to use either of the Pinchuk delivery system embodiments to deliver and deploy stent grafts including self-

expanding zig-zag type stents, as disclosed in Robinson. In the 2002-2003 timeframe, self-expanding zig-zag type stents were one of a finite number of types of self-expanding stents available. As Dr. Criado explains, there were only two types of commercially-available self-expanding stents for treating vascular diseases in the 2002-2003 timeframe: (1) self-expanding zig-zag stents; and (2) self-expanding braided stents. Self-expanding zig-zag type stents would have been an obvious first choice for use in a stent graft in the 2002-2003 timeframe. In that timeframe, for example, all of the commercially-available stent graft devices for treating abdominal aortic aneurysms included self-expanding zig-zag type stents. On the other hand, *none* of these commercially-available stent graft devices included Wallstent-type stents. (Ex. 1015 at ¶133).

Thus, it would have been obvious and common sense in the 2002-2003 timeframe to use the delivery devices disclosed in Pinchuk Embodiment #1 and #2 to deliver and deploy stent grafts including self-expanding zig-zag type stents, as disclosed in Robinson. It would have been particularly obvious to a PHOSITA interested in delivering and deploying a stent graft for treating abdominal aortic aneurysms, as self-expanding zig-zag type stents were the only stent type used in commercial stent grafts for this application. At most, this would have been a simple and routine substitution of simple, well-known mechanical components disclosed in Pinchuk and Robinson. Each of the resulting delivery devices would

include a stent graft with a plurality of proximal spring apices at the proximal end of the stent graft, as disclosed in Robinson. In each of the modified embodiments, the plurality of apices would be latched, and remain latched, onto Pinchuk's proximal lock (including 46 (Embodiment #1); including 347 (Embodiment #2)) in the radially compressed configuration while the plurality of spring apices remained within the cap (154 (Embodiment #1); 353 (Embodiment #2)), for the reasons in Sections V.A.2. and V.B.3., above. (Ex. 1015 at ¶134).

Thus, each of the modified embodiments would include "a proximal lock attached to the outer tube, wherein the stent-graft has a plurality of proximal spring apices at the proximal end of the stent-graft that remain latched onto the proximal lock in the radially compressed configuration while the plurality of spring apices remain within the cap," as described in claim 4. (Ex. 1015) at ¶135).

b. Additionally, Or Alternatively, It Would Have Been Obvious to Modify The Shape Of Pinchuk's Proximal Locks, As Disclosed In Robinson

As explained below, it also would have been obvious to modify the shape of Pinchuk's proximal locks in view of Robinson. The modifications described below would have been obvious to make, either in addition to, or instead of, the modifications described above in Section V.C.1.a. (Ex. 1015 at ¶136).

As explained above in Sections V.A.2. and V.B.3., Pinchuk Embodiments #1 and #2 each disclose a proximal lock coupled to the distal end (end furthest from the operator) of an outer tube. (Ex. 1006 at 3:40-48, 5:35-40, 5:57:6:13, 7:9-31, 7:64-8:14). In each embodiment, the proximal lock locks the proximal end (end closest to the heart) of the stent graft in place to prevent the proximal end from moving distally (toward the operator) when the outer sheath is withdrawn. (*See id.*). Pinchuk discloses that the proximal lock may include a frustoconical shape, for example, that mates with a frustoconical inner surface of the cap. (*Id.*, 3:64-4:4, 7:9-31, 8:4-11, 9:64-68). Pinchuk teaches that the cap and lock may include other shapes, however, stating that "while the preferred end cap and taper lock have been disclosed as having mating frustroconical [*sic*] surfaces, it will be understood that different configurations can achieve the same or similar function as disclosed herein." (*Id.*, 9:64-68; Ex. 1015 at ¶137).

A PHOSITA would have been familiar with other simple lock shapes disclosed in the prior art for locking in place the end of a stent graft during delivery. (Ex. 1015 at ¶138). As shown below in annotated Figures 16a and 16b, for example, Robinson discloses a locking mechanism (implant retention device 85) for locking and retaining an end of a stent graft in a constrained diameter configuration.

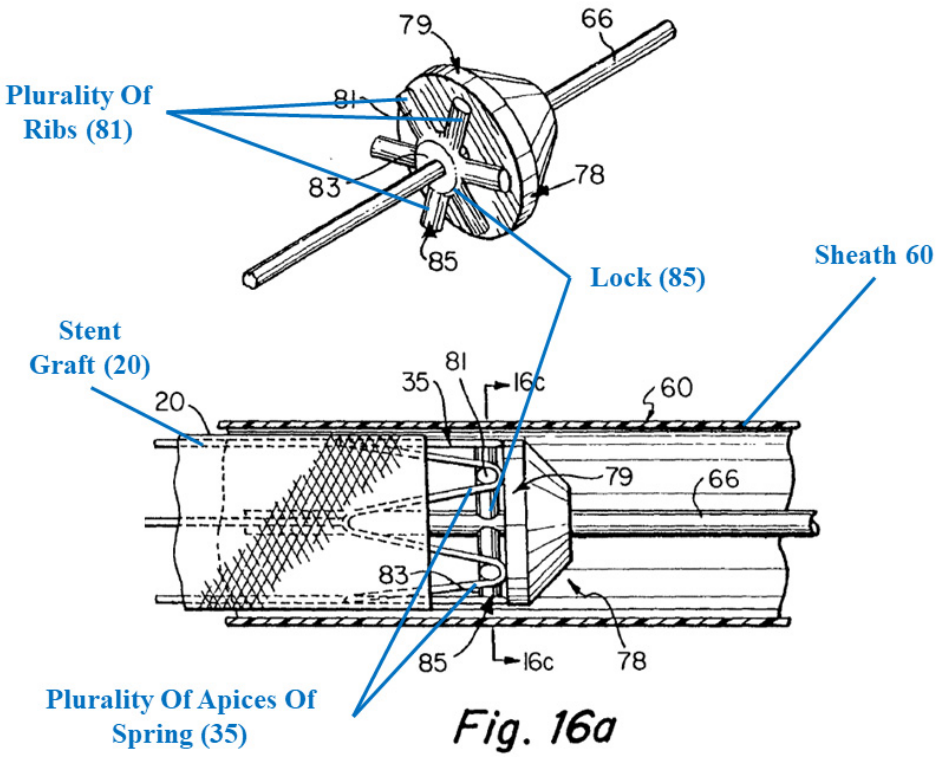


Fig. 16a

(Ex. 1008 at 11:11-44, 10:54-11:10, 12:26-30, claims 16, 18, and 19; Ex. 1015 at ¶138). As shown above, Robinson's lock (85) comprises a plurality of ribs (radially extending spokes 81) for retaining a plurality of spring apices (expandable segments 35) at the end of stent graft (graft 20). (Ex. 1008 at 11:11-44 ("The

retention device 85 takes the form of a plurality of radially extending spokes 81 attached to a central hub 83….[I]n extending radially, the spokes 81 of the retention device 85 engage the [distal]-most ends of the anchor 30, 30' when the [distal] portion of the anchor is compressed within the sheath 60. The engagement is achieved by a distal portion of each spoke which becomes seated in the space on the interior of the bends at the [distal] end of the anchor. The result is that the anchor, (and thus, the entire implant), is prevented from moving distally relative to the stay [(away from the operator)]….Since the [distal]-most bends of the implant assembly are retained by the radial spokes 81, the implant is prevented from moving in the distal direction [(away from the operator)] as the sheath is advanced."); *see also id.*, 10:54-11:10, 12:26-30, claims 16, 18, and 19). The lock (85) is "used to maintain the position of the [stent graft] 10 as the sheath 60 is withdrawn." (*Id.*, 11:11-14, 12:26-30). Lock (85) provides improved control during deployment of the stent graft, permitting "repositioning of the implant [if] desired," as well as "recapture" of a partially deployed stent graft, (*id.*, 11:29-32), and prevents deployment of the end of the stent graft "until the [stent graft] is *fully* released from the sheath." (*Id.*, claims 16 and 19; Ex. 1015 at ¶138).

It would have been obvious to modify the shape of the locks disclosed in Pinchuk Embodiment #1 (end 46) and Pinchuk Embodiment #2 (locking member 347) to include radially-extending spokes, as described in Robinson. A

PHOSITA would have been motivated to modify the shape of each of Pinchuk's locks, to provide the advantages disclosed in Robinson (described above). In addition, a PHOSITA would have been motivated to modify the shape of Pinchuk's locks, in view of Pinchuk's teaching that different lock shapes and configurations "can achieve the same or similar function as disclosed herein." (Ex. 1006 at 9:64-68). While Pinchuk discloses using the locks to retain a *proximal* end of a stent graft, and Robinson discloses using the locks to retain a *distal* end of a stent graft, a PHOSITA would have recognized that Robinson's lock performs essentially the same function as Pinchuk's locks. That is, both types of locks retain the end of a stent graft in place and prevent the end from moving when a constraining tube is moved relative to the stent graft.[13] Therefore, a PHOSITA would have recognized that the Robinson lock shape could be applied to Pinchuk, and would have expected the modification to achieve "the same or similar function as disclosed [in Pinchuk]." (Ex. 1006, 9:64-68; Ex. 1015) at ¶139).

[13] The constraining tube in Robinson is a sheath 60 that is moved relative to the stent graft. Likewise, Pinchuk discloses a constraining tube in the form of a sheath (70) that is moved relative to the stent graft, as well as a constraining tube in the form of a cap (154 (Embodiment #1); 353 (Embodiment #2)) that is moved relative to the stent graft. (Ex. 1015 at ¶139).

A PHOSITA would have expected that the modifications would improve the Pinchuk retention mechanisms. For example, a PHOSITA would have understood that Pinchuk's retention mechanisms operate by gripping and clamping the proximal end of the stent graft between the inner surface of a cap, and the outer surface of a lock. A PHOSITA also would have recognized that modifying the shape of Pinchuk's locks to include ribs would permit the retention mechanism to positively engage openings in the stent grafts (*i.e.*, the proximal apices of the stent graft), as described in Robinson. A PHOSITA would have recognized that a retention mechanism that relies on positive engagement would be an improvement over a retention mechanism that relies only on frictional engagement, for example. A PHOSITA would have expected that modifying the shape of Pinchuk's locks to include ribs would improve the locking function of Pinchuk's retention mechanisms, thereby potentially reducing the risk of premature or inadvertent deployment of the stent graft. (Ex. 1015 at ¶140).

The proposed modifications to Embodiments #1 and #2 would have been simple, and a matter of routine skill to a PHOSITA, involving simple mechanical components described in Pinchuk and Robinson, to yield predictable results. The resulting modified devices each would include "a proximal lock attached to the outer tube, wherein the stent-graft has a plurality of proximal spring apices at the proximal end of the stent-graft that remain latched onto the proximal lock in the

radially compressed configuration while the plurality of spring apices remain within the cap," as described in claim 4. (Ex. 1015 at ¶141).

2. Dependent Claim 5

Claim 5 depends from claim 4 and further requires "the proximal lock further comprises a plurality of ribs for retaining a plurality of apices of the proximal spring of the stent graft." Modified Pinchuk Embodiments #1 and #2 each disclose this limitation, for the reasons in Section V.C.1. (Ex. 1015 at ¶142).

In particular, as explained above in Section V.C.1, it would have been obvious to modify the locks in Pinchuk Embodiments #1 and #2 to include a plurality of ribs (radially extending spokes 81) for retaining a plurality of spring apices (apices formed in either a braided, or self-expanding zig-zag type stent). (*Id.*).

3. Independent Claim 7

a. *"A controlled stent graft deployment delivery system, comprising:"*

Pinchuk Embodiments #1 and #2 each disclose this preamble for the reasons in Sections V.A.1.a. and V.B.1.a., respectively. (Ex. 1015 at ¶143).

b. *"a retractable primary sheath;"*

Pinchuk Embodiments #1 and #2 each disclose this limitation for the reasons in Sections V.A.1.c. and V.B.1.c., respectively. (Ex. 1015 at ¶144).

c. *"an outer tube within the retractable primary sheath;"*

Pinchuk Embodiments #1 and #2 each disclose this limitation for the reasons in Sections V.A.1.d and V.B.1.d., respectively. (Ex. 1015 at ¶145).

d. *"an inner tube within the outer tube,"*

Pinchuk Embodiments #1 and #2 each disclose this limitation for the reasons in Sections V.A.1.e. and V.B.1.e., respectively. (Ex. 1015 at ¶146).

e. *"wherein the inner tube can move axially relative to the outer tube;"*

Pinchuk Embodiments #1 and #2 each disclose this limitation for the reasons in Sections V.A.1.f. and V.B.1.f., respectively. (Ex. 1015 at ¶147).

f. *"a cap axially fixed to a distal end of the inner tube;"*

Pinchuk Embodiments #1 and #2 each disclose this limitation for the reasons in Sections V.A.1.g. and V.B.1.g., respectively. (Ex. 1015 at ¶148).

g. ***"and a retention mechanism attached to the outer tube for retaining a proximal end of a stent-graft in a constrained diameter configuration while the end of the stent graft is still located within the cap while still enabling axial and radial movement of the stent-graft, wherein the retention mechanism comprises a proximal lock fixed to the outer tube."***

Pinchuk Embodiments #1 and #2 each disclose this limitation for the reasons in Sections V.A.3.g. and V.B.4.g., respectively. Alternatively, modified Pinchuk Embodiments #1 and #2 each disclose this limitation, for the reasons in Section V.C.1. (Ex. 1015 at ¶149).

4. Dependent Claim 8

Claim 8 depends from claim 7 and further states "wherein the retention mechanism enables a partial deployment of a remaining distal portion of the stent-graft while maintaining the proximal end of the stent-graft in the constrained diameter configuration." Pinchuk Embodiments #1 and #2 each disclose this limitation for the reasons in Sections V.A.4. and V.B.5., respectively. Alternatively, modified Pinchuk Embodiments #1 and #2 each disclose this limitation, for the reasons in Section V.C.1. (Ex. 1015 at ¶151).

5. Dependent Claim 9

Claim 9 depends from claim 8 and further states "wherein the proximal lock includes a plurality of ribs for retaining a plurality of apices of the proximal spring of the stent-graft." Modified Pinchuk Embodiments #1 and #2 each disclose this limitation for the reasons in Section V.C.1. (Ex. 1015 at ¶152).

6. Independent Claim 12

a. *"A controlled stent-graft deployment delivery system, comprising:"*

Pinchuk Embodiments #1 and #2 each disclose this preamble for the reasons in Sections V.A.1.a. and V.B.1.a., respectively. (Ex. 1015 at ¶153).

b. *"a retractable primary sheath;"*

Pinchuk Embodiments #1 and #2 each disclose this limitation for the reasons in Sections V.A.1.c. and V.B.1.c., respectively. (Ex. 1015 at ¶154).

c. *"an outer tube within the retractable primary sheath;"*

Pinchuk Embodiments #1 and #2 each disclose this limitation for the reasons in Sections V.A.1.d. and V.B.1.d., respectively. (Ex. 1015 at ¶155).

d. *"an inner tube within the outer tube,"*

Pinchuk Embodiments #1 and #2 each disclose this limitation for the reasons in Sections V.A.1.e. and V.B.1.e., respectively. (Ex. 1015 at ¶156).

e. *"wherein the inner tube can move axially relative to the outer tube;"*

Pinchuk Embodiments #1 and #2 each disclose this limitation for the reasons in Sections V.A.1.f. and V.B.1.f., respectively. (Ex. 1015 at ¶157).

f. *"a cap axially fixed to a distal end of the inner tube;"*

Pinchuk Embodiments #1 and #2 each disclose this limitation for the reasons in Sections V.A.1.g. and V.B.1.g., respectively. (Ex. 1015 at ¶158).

g. ***"a retention mechanism attached to the outer tube for retaining a proximal end of a stent-graft in a constrained diameter configuration while the end of the stent graft is still located within the cap while still enabling axial and radial movement of the stent-graft;"***

Pinchuk Embodiments #1 and #2 each disclose this limitation for the reasons in Sections V.A.5.g. and V.B.6.g., respectively. Alternatively, modified Pinchuk Embodiments #1 and #2 each disclose this limitation, for the reasons in Section V.C.1. (Ex. 1015 at ¶159).

h. ***"and a second retention mechanism for retaining a distal end on the stent-graft undeployed while a remaining portion of the stent graft is deployed."***

Pinchuk Embodiments #1 and #2 each disclose this limitation for the reasons in Sections V.A.5.h. and V.B.6.h., respectively. (Ex. 1015 at ¶160).

VI. SECONDARY CONSIDERATIONS OF NONOBVIOUSNESS

Petitioners reserve the right to address any secondary considerations of nonobviousness that Patent Owner may assert.

VII. CONCLUSION

There is a reasonable likelihood that at least one of the challenged claims is unpatentable. Therefore, Petitioners respectfully request that the PTAB grant this petition for *inter partes* review.

Dated: November 12, 2018

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

The undersigned certifies that this brief complies with the type-volume limitations of 37 C.F.R. § 42.24(a)(1)(i). This brief contains 13,996 words as calculated by the "Word Count" feature of Microsoft Word, the word processing program used to create it.

The undersigned further certifies that this brief complies with the typeface requirements of 37 C.F.R. § 42.6(a)(2)(ii) and typestyle requirements of 37 C.F.R. § 42.6(a)(2)(iii). This brief has been prepared in a proportionally spaced typeface using Microsoft Word in Times New Roman 14 point font.

Dated: November 12, 2018

Respectfully submitted,

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Lead Attorney for Petitioners

CERTIFICATE OF SERVICE

I hereby certify that a true copy of the foregoing Petition for *Inter Partes* Review of U.S. Patent No. 7,264,632, as well as the accompanying Power of Attorney, and Exhibits 1001-1003, 1006, 1008-1013, and 1015 have been served in their entirety on November 12, 2018, by Federal Express (Overnight Delivery) on:

MEDTRONIC VASCULAR, INC. IP Legal Department 3576 Unocal Place Santa Rosa, California 95403
Counsel of Record for Medtronic Vascular, Inc. at the U.S. Patent & Trademark Office with respect to U.S. Patent No. 7,264,632

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