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(54) METHOD AND ASSOCIATED INSTRUMENTATION FOR INSTALLATION OF SPINAL DYNAMIC STABILIZATION SYSTEM

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(56) References Cited

U.S. PATENT DOCUMENTS

2,248,054 A 7/1941 Joseph

4,526,067 A	7/1985	Gaquere	
4,862,774 A	9/1989	Else	
4,946,458 A	8/1990	Harms	
5,030,220 A	7/1991	Howland	
5,261,913 A	11/1993	Marnay	
5,360,431 A	11/1994	Puno et al.	
5,458,030 A	10/1995	Betts et al.	
5,540,688 A	7/1996	Navas	
5,562,660 A	10/1996	Grob	
	(Continued)		

FOREIGN PATENT DOCUMENTS

CA	2684238 A1	10/2008
EP	0669109 A	8/1995
	(Cont	inued)

OTHER PUBLICATIONS

Zimmer Spine, Dynesys LIS Less Invasive Surgery, The Dynamic Stabilization System, 24 pages, copyright 2005.*

(Continued)

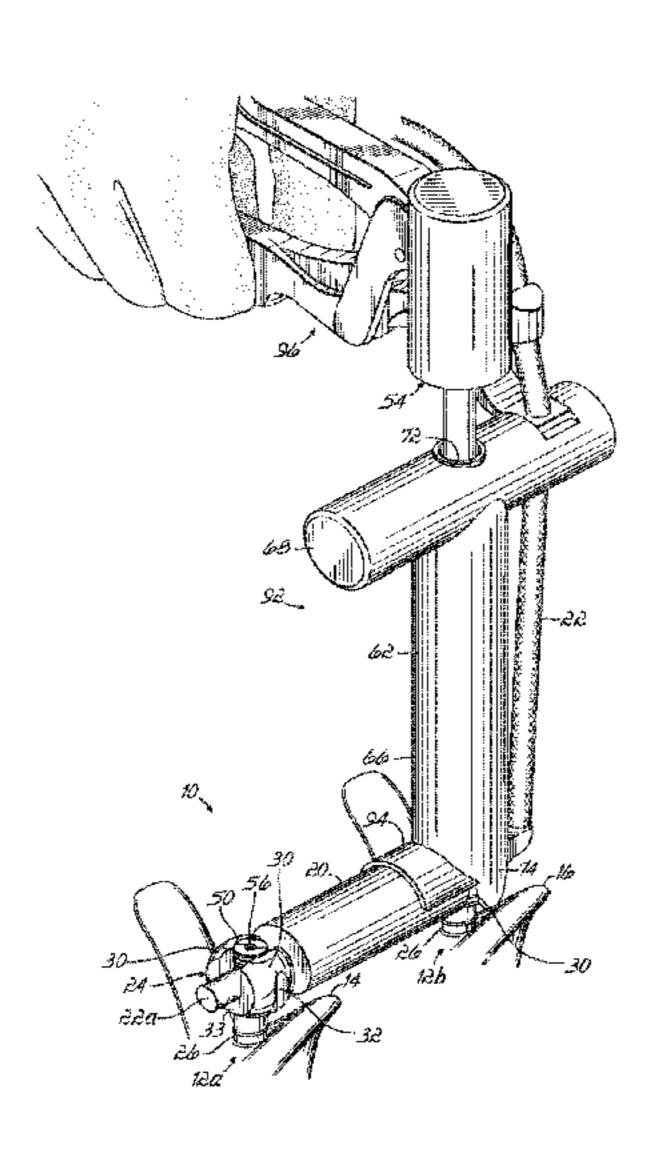
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(57) ABSTRACT

In one embodiment, a spinal stabilization apparatus includes a vertebral anchor having a head portion and a bone attachment portion. An elongate, flexible guide is removably coupled to the head portion of the vertebral anchor and has a channel extending longitudinally thereof and communicating with a slot in the head portion of the anchor. An elongate cord may be received within the channel to facilitate inserting and securing a spacer between pairs of anchors installed into adjacent vertebrae of a person's spine.

19 Claims, 6 Drawing Sheets



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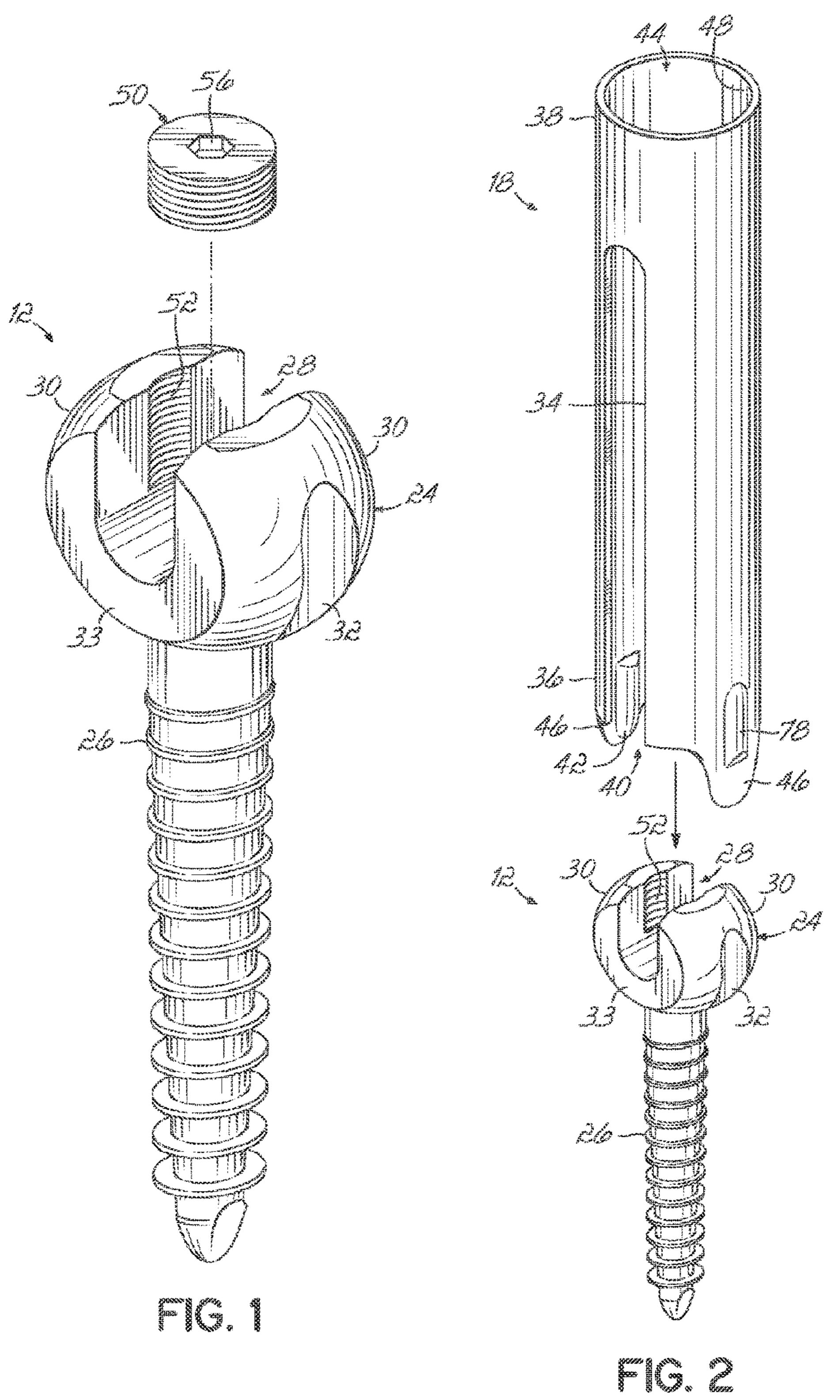
(56)	Referen	ces Cited			55526 A1		Drew et al.
U.S.	PATENT	DOCUMENTS		2005/012	35815 A1 24991 A1	6/2005	
					31408 A1		Sicvol et al.
5,584,831 A	12/1996				31410 A1 31421 A1	6/2005	Lin Anderson et al.
, ,		Biedermann			13737 A1		Pafford et al.
5,681,319 A 5,989,254 A	10/1997	Biedermann Katz			54389 A1		Selover et al.
, ,		Bigand et al.		2005/01:	54390 A1		Biedermann et al.
6,139,549 A	10/2000				71542 A1		Biedermann
6,183,472 B1	2/2001	Lutz			92570 A1		Jackson
, ,		Schmotzer			92579 A1 93513 A1		Jackson Jahng et al.
6,391,030 B1*	5/2002	Wagner			34451 A1		Markworth
6,402,752 B2	6/2002	Schaffler-Wachter	24/134 P		57472 A1		Biedermann
6,471,705 B1		Biedermann		2006/003	36255 A1	2/2006	Pond, Jr. et al.
6,530,929 B1		Justis et al.			84993 A1		Landry et al.
6,616,667 B1*	9/2003	Steiger	A61B 17/8861		34995 A1		Biedermann
			606/103		06383 A1 11712 A1		Biedermann Jackson
6,695,843 B2		Biedermann			11712 A1*		Jackson A61B 17/7037
6,723,100 B2 6,736,820 B2		Biedermann		2000,01		<i>5</i> , 2 0 0	606/914
6,835,196 B2		Biedermann Biedermann		2006/01	11715 A1	5/2006	Jackson A61B 17/861
6,896,677 B1	5/2005						128/897
6,905,500 B2	6/2005	Jeon et al.			12758 A1	6/2006	
6,918,911 B2		Biedermann			12761 A1 55277 A1		Landry et al. Metz-Stavenhagen
6,932,822 B2		Oribe et al.			00132 A1*		Chao A61B 17/708
6,986,771 B2 6,989,011 B2	1/2006 1/2006			2000,02.	70132 111	3,2000	606/86 A
6,994,710 B2		White et al.		2006/02	17738 A1	9/2006	Tanimura
7,008,424 B2		Teitelbaum					Taguchi
7,018,378 B2		Biedermann et al.			16200 A1		Jackson
7,073,415 B2		Casutt et al.			55244 A1 78461 A1		Jackson Shluzas
7,081,116 B1 7,090,679 B2		Saint-Martin et al			29729 A1	6/2007	
7,250,052 B2		Landry et al.	•		98088 A1		Biedermann et al.
7,326,210 B2		Jahng et al.		2007/02	70860 A1	11/2007	Jackson
7,476,240 B2		Raymond et al.				12/2007	
7,758,584 B2 7,918,857 B2		Bankoski et al. Dziedzic et al.		2008/000)9863 A1*	1/2008	Bond A61B 17/025
7,918,857 B2 7,918,858 B2		Stad et al.		2008/004	51797 A1*	2/2008	606/86 A Remineter A61B 17/7005
7,922,725 B2		Darst Rice et al.		2006/00.)1/0/ A1	2/2008	Remington A61B 17/7005 606/279
7,927,360 B2		Pond, Jr. et al.		2008/009	91213 A1	4/2008	Jackson
8,632,572 B2		Darst Rice et al. Strobel et al.		2008/014	40076 A1	6/2008	Jackson
2001/0007074 A1 2001/0012937 A1		Schaffler-Wachter		2008/014	47122 A1	6/2008	Jackson
2002/0035366 A1		Walder			77317 A1		Jackson
2002/0058942 A1	5/2002	Biedermann			33216 A1		Jackson Diagram 1
2002/0082602 A1		Biedermann			52551 A1 56604 A1		Rice et al. Darst Rice et al.
2002/0116001 A1 2002/0133154 A1		Schafer Saint Martin		2011/010	7000 4 A1	7/2011	Darst Rice et al.
2002/0133154 A1 2002/0133159 A1		Jackson			FOREIG	N PATE	NT DOCUMENTS
2002/0138076 A1		Biedermann et al.			rondro		
2002/0143341 A1		Biedermann		\mathbf{EP}	0669	109 B1	5/1999
2002/0161368 A1*	10/2002	Foley		EP		949 A1	4/2005
2003/0018342 A1	1/2003	Oribe et al.	128/898	EP EP		8949 B1 2179 B1	6/2007 2/2010
2003/0016342 A1		Biedermann		EP		2179 B1 2179	4/2015
2003/0100896 A1	5/2003	Biedermann		FR	2715	5057 A1	7/1995
2003/0100904 A1		Biedermann		FR		057 B1	3/1996
2003/0114860 A1 2003/0125741 A1		Cavagna et al. Biedermann		FR		180 A1	3/2004 8/2005
2003/0123/41 A1 2003/0187439 A1		Biedermann		FR FR		1180 B1 7057 A1	8/2005 9/2005
2004/0097933 A1		Lourdel et al.		FR		7057 B1	6/2007
2004/0102781 A1	5/2004			NL)576 A	3/1978
2004/0122425 A1		Suzuki et al.		WO	WO-8900		1/1989
2004/0138662 A1 2004/0143265 A1		Landry et al. Landry et al.		WO WO	WO-9000 WO-9106		1/1990 5/1991
2004/0143203 A1		Biedermann		WO	WO-9100 WO-9116		10/1991
2004/0176766 A1	9/2004	Shluzas		WO	WO-9220		11/1992
2004/0181224 A1		Biedermann Matthia at al		WO	WO-9311		6/1993
2004/0186474 A1 2004/0225289 A1		Matthis et al. Biedermann et al.		WO WO	WO-9414 WO-9414		7/1994 8/1994
2004/0223289 A1 2004/0243193 A1	12/2004			WO	WO-9414 WO-9417		8/199 4 8/1994
2004/0249378 A1	12/2004	Saint Martin et al		WO	WO-9501		1/1995
2005/0010220 A1	1/2005	Casutt et al		WO	WO-9513		5/1995
2005/0055026 A1	3/2005	Biedermann et al.	606/86 A	WO WO	WO-9513 WO-9514		5/1995 6/1995
2005/0055020 A1 2005/0065516 A1	3/2005			WO	WO-9519 WO-9519		7/1995
		_					

(56)	References Cited			
	FOREIGN PATENT DOCUMENTS			
WO	WO-9812977 A1 4/1998			
WO	WO-9905980 A1 2/1999			
WO	WO-0027297 A1 5/2000			
WO	WO-0101873 A1 1/2001			
WO	WO-02069854 A1 9/2002			
WO	WO-2004004549 A2 1/2004			
WO	WO-2004024011 A1 3/2004			
WO	WO-2004041100 A1 5/2004			
WO	2004004549 A8 3/2005			
WO	WO-2005087121 A1 9/2005			
WO	WO-2006066685 A1 6/2006			
WO	WO-2008130728 10/2008			

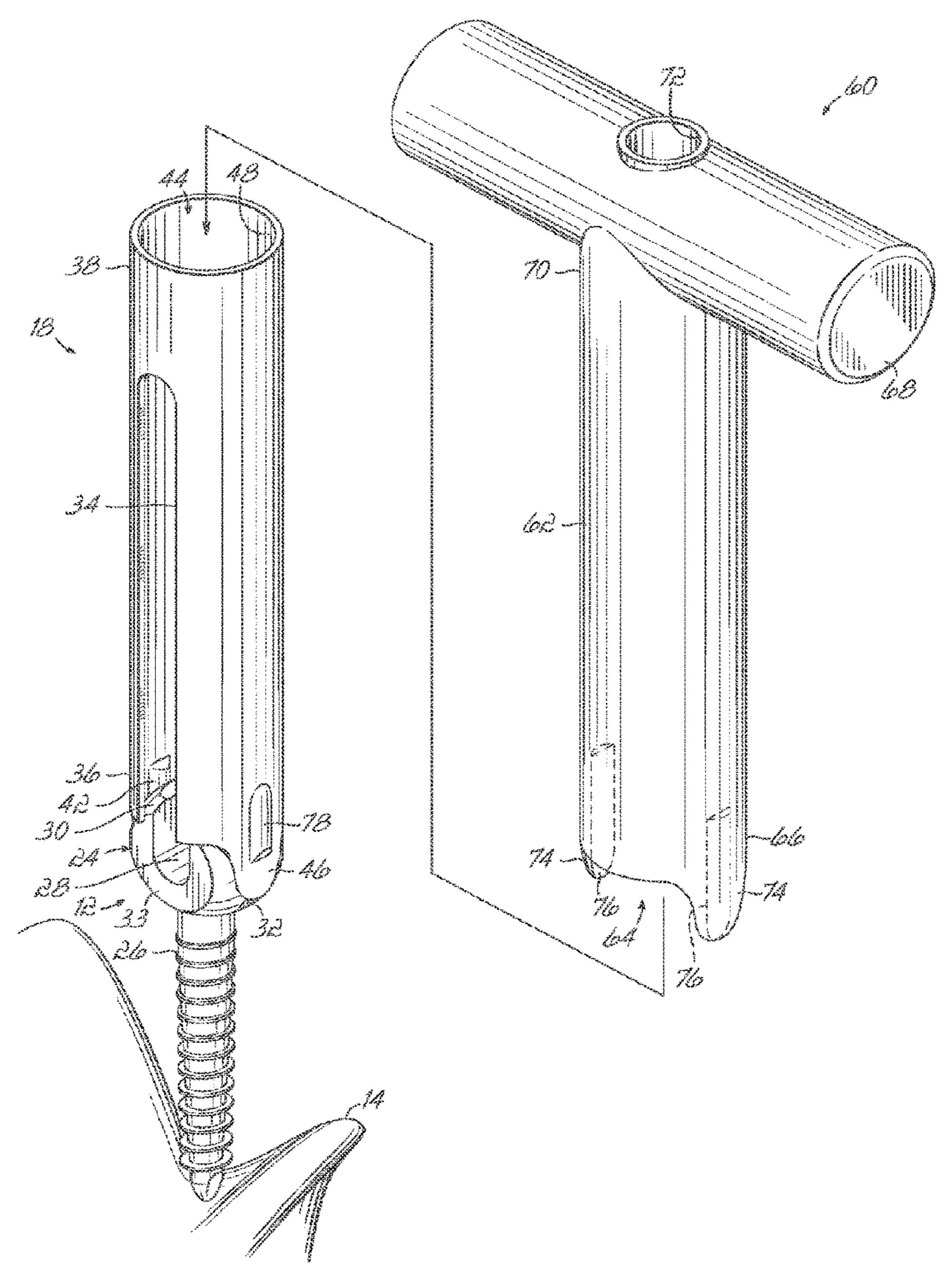
OTHER PUBLICATIONS

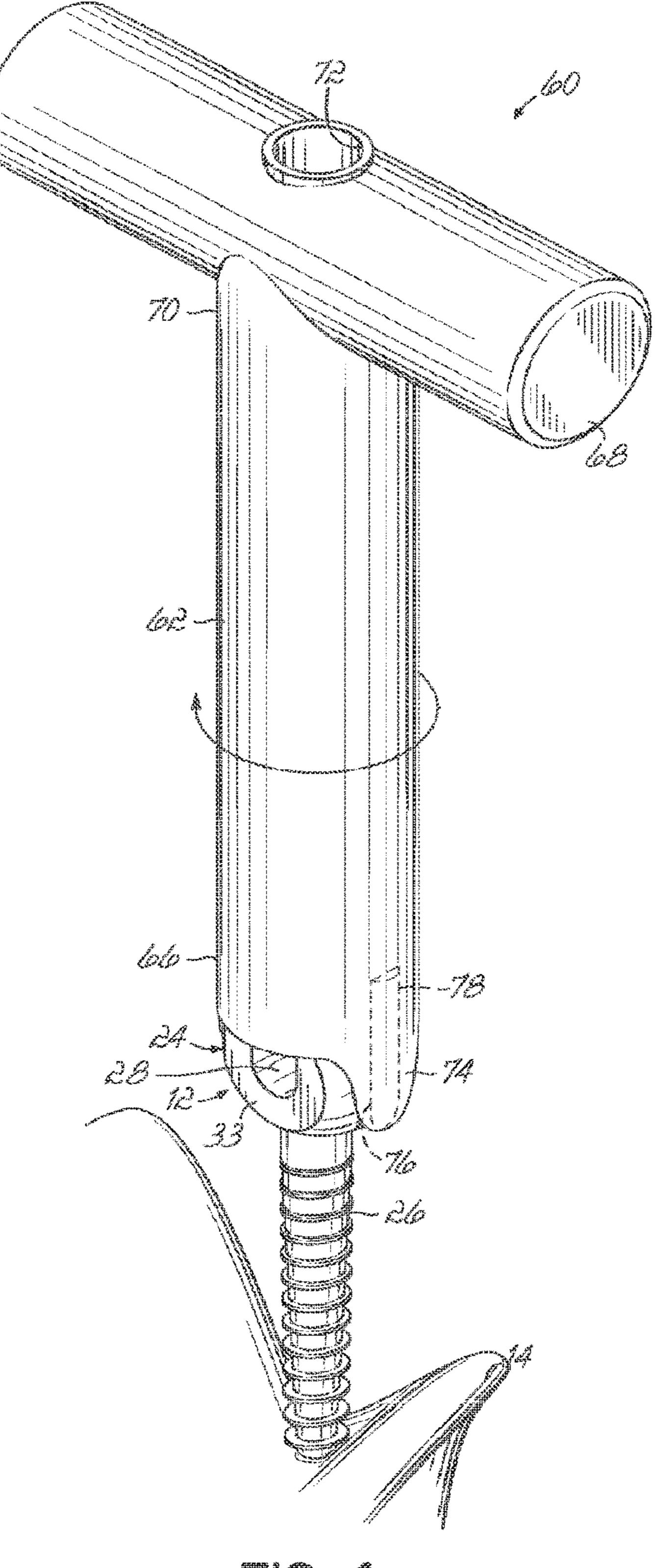
- "U.S. Appl. No. 11/737,151, Non Final Office Action dated Aug. 17, 2010", 13 pgs.
- "U.S. Appl. No. 11/737,151, Notice of Allowance dated Dec. 3, 2010", 4 pgs.
- "U.S. Appl. No. 11/737,151, Response filed Nov. 17, 2010 to Non Final Office Action dated Aug. 17, 2010", 11 pgs.
- "U.S. Appl. No. 13/048,447, Final Office Action dated Jul. 10, 2013", 8 pgs.
- "U.S. Appl. No. 13/048,447, Non Final Office Action dated Mar. 25, 2013", 8 pgs.
- "U.S. Appl. No. 13/048,447, Notice of Allowance dated Sep. 16, 2013", 6 pgs.
- "U.S. Appl. No. 13/048,447, Response filed Jun. 25, 2013 to Non Final Office Action dated Mar. 25, 2013", 10 pgs.
- "U.S. Appl. No. 13/048,447, Response filed Sep. 6, 2013 to Final Office Action dated Jul. 10, 2013", 4 pgs.

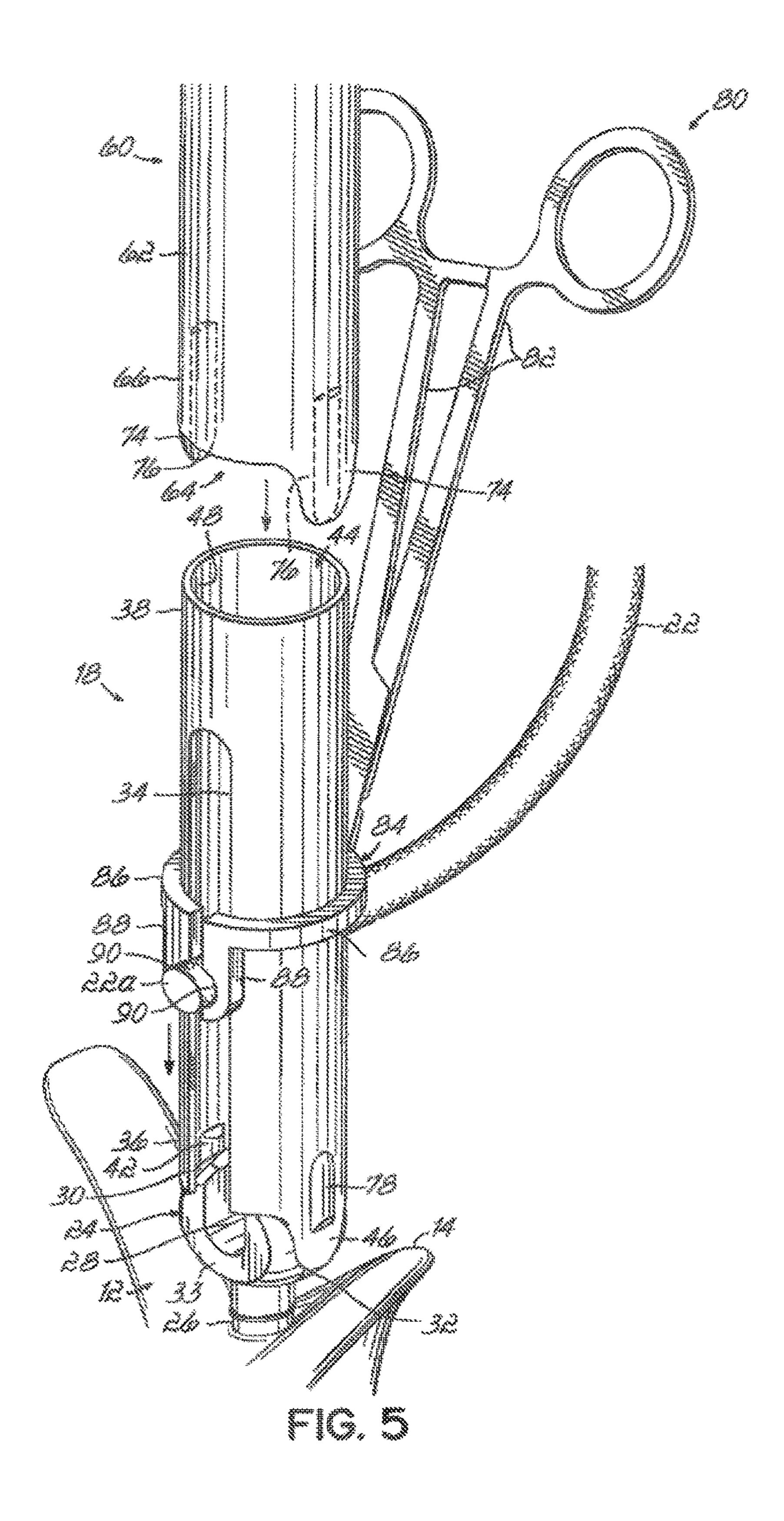
- "U.S. Appl. No. 15/619,948, Non Final Office Action dated Mar. 15, 2018", 27 pgs.
- "U.S. Appl. No. 15/619,948, Preliminary Amendment dated Jun. 12, 2017", 6 pgs.
- "U.S. Appl. No. 15/619,948, Response filed Jul. 13, 2018 to Non Final Office Action dated Mar. 15, 2018", 9 pgs.
- "Canadian Application Serial No. 2,684,238, Voluntary Amendment filed Oct. 15, 2009", 5 pgs.
- "European Application Serial No. 08728645.6, Communication Pursuant to Article 94(3) EPC mailed Jan. 27, 2014", 4 pgs.
- "European Application Serial No. 08728645.6, Communication Pursuant to Article 94(3) EPC mailed Mar. 7, 2013", 5 pgs.
- "European Application Serial No. 08728645.6, Decision to grant mailed Mar. 26, 2015", 2 pgs.
- "European Application Serial No. 08728645.6, Extended European Search Report mailed Jul. 10, 2012", 8 pgs.
- "European Application Serial No. 08728645.6, Intention to Grant mailed Nov. 5, 2014", 35 pgs.
- "European Application Serial No. 08728645.6, Response filed Feb. 5, 2013 to Extended European Search Report mailed Jul. 10, 2012", 23 pgs.
- "European Application Serial No. 08728645.6, Response filed Jun. 5, 2014 to Communication Pursuant to Article 94(3) EPC mailed Jan. 27, 2014", 11 pgs.
- "European Application Serial No. 08728645.6, Response filed Jul. 16, 2013 to Communication Pursuant to Article 94(3) EPC mailed Mar. 7, 2013", 12 pgs.
- "International Application Serial No. PCT/US2008/052576, International Preliminary Report on Patentability mailed Oct. 20, 2009", 6 pgs.
- "International Application Serial No. PCT/US2008/052576, International Search Report mailed Jul. 28, 2008", 1 pg.
- "International Application Serial No. PCT/US2008/052576, Written Opinion mailed Jul. 28, 2008", 5 pgs.
- * cited by examiner

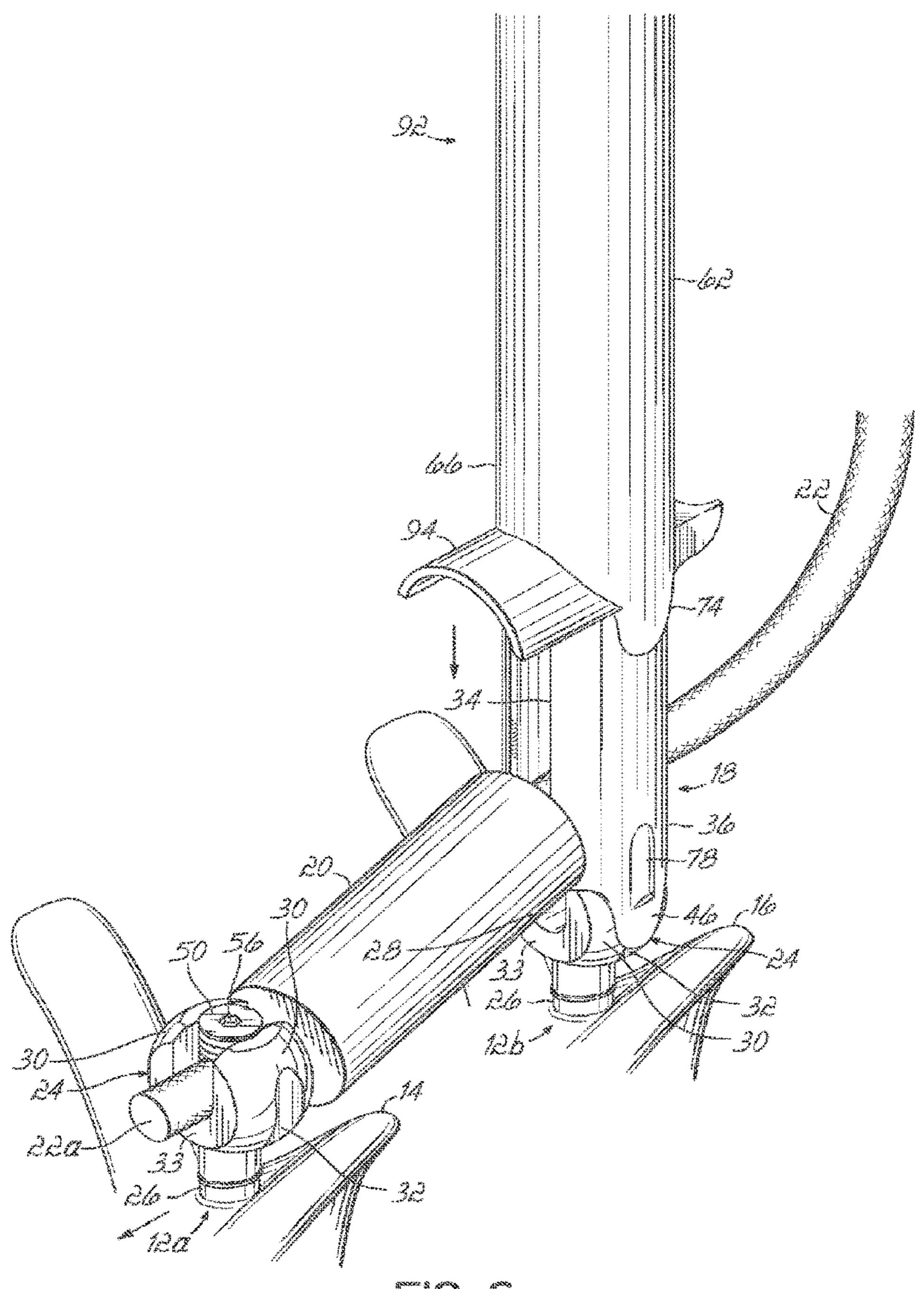


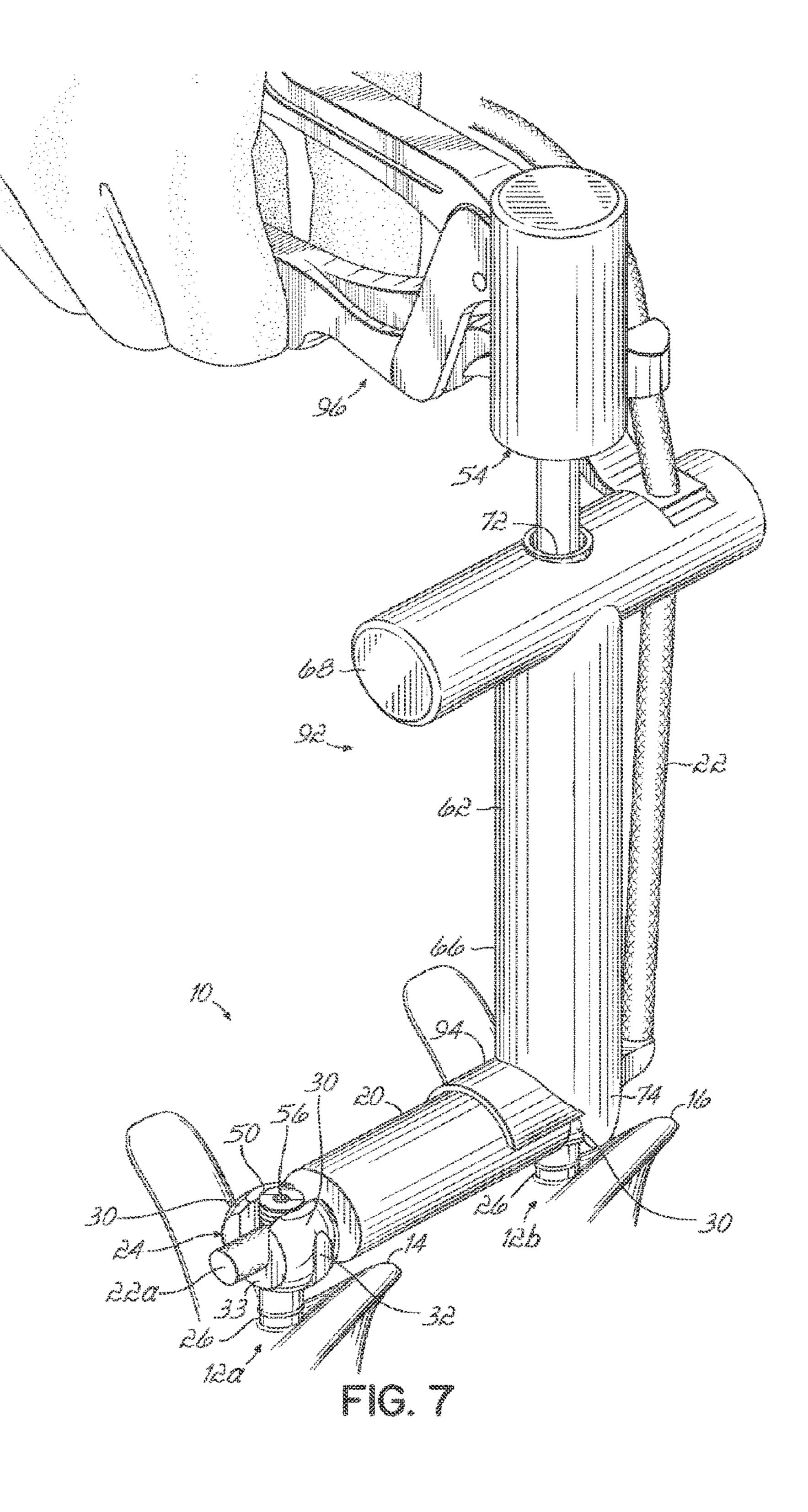
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METHOD AND ASSOCIATED INSTRUMENTATION FOR INSTALLATION OF SPINAL DYNAMIC STABILIZATION **SYSTEM**

Matter enclosed in heavy brackets [] appears in the original patent but forms no part of this reissue specification; matter printed in italics indicates the additions made by reissue; a claim printed with strikethrough 10 indicates that the claim was canceled, disclaimed, or held invalid by a prior post-patent action or proceeding.

REFERENCE TO RELATED APPLICATIONS

This application More than one application has been filed for the reissue of U.S. Pat. No. 8,632,572. The reissue applications are U.S. application Ser. No. 14/995,435 (the present application) and U.S. application Ser. No. 15/619, 948, filed on Jun. 12, 2017, all of which are divisional 20 neous access to the vertebral anchor when mounted thereon. reissues of U.S. Pat. No. 8,632,572. The present application is a reissue of U.S. application Ser. No. 13/048,447, filed on Mar. 15, 2011, now U.S. Pat. No. 8,632,572, which is a continuation of U.S. patent application Ser. No. 11/737,151, filed Apr. 19, 2007, now U.S. Pat. No. 7,922,725 B2, which 25 one of the sleeves when mounted on the associated vertebral is incorporated herein by reference.

TECHNICAL FIELD

This invention relates generally to spinal support devices, and more particularly to methods and devices that facilitate installing an implantable system for providing dynamic stability of a person's spine.

BACKGROUND OF THE INVENTION

The treatment of acute and chronic spinal instabilities or deformities of the thoracic, lumbar, and sacral spine has traditionally involved the implantation of rigid rods to secure the vertebrae of a patient. More recently, flexible 40 materials have been utilized in connection with securing elements, such as pedicle screws, to provide a dynamic stabilization of the spine. Such dynamic stabilization systems typically include a flexible spacer positioned between pedicle screws installed in adjacent vertebrae of a person's 45 spine. Once the spacer is positioned between the pedicle screws, a flexible cord is threaded through eyelets formed in the pedicle screws and an aperture through the spacer. The flexible cord retains the spacer between the pedicle screws while cooperating with the spacer to permit mobility of the 50 spine. Traditional implantation of such dynamic stabilization systems may require relatively large surgical sites to permit threading the cord through the screws and spacer once the spacer has been positioned between the screws.

While some dynamic stabilization systems have been 55 proposed for permitting the top loading of a spacer and cord between pedicle screws, these systems also require added instrumentation and procedures to distract the pedicle screws for placement of the spacer.

A need therefore exists for a spinal dynamic stabilization 60 system and associated installation tools and techniques that overcome these and other drawbacks of the prior art.

SUMMARY OF THE INVENTION

This invention overcomes the foregoing and other shortcomings and drawbacks of spinal stabilization systems here-

tofore known for use in suitable various commercial and industrial environments. While various embodiments will be described herein, the invention is not limited to these embodiments. On the contrary, the invention includes all alternatives, modifications and equivalents as may be included within the spirit and scope of this invention.

In one embodiment, a system for stabilizing a patient's spine includes a pair of vertebral anchors adapted to be anchored to first and second vertebrae, respectively. Each vertebral anchor has an upwardly open channel. A connecting element that may be in the form of a flexible cord extends between the vertebral anchors and is seated in the channels. An annular spacer is positioned between the channels of the vertebral anchors with the connecting element passing there through. A pair of fasteners is each mated with the one of the channels of the vertebral anchors to secure the connecting element thereto. A pair of access members in the form of sleeves is mounted on the vertebral anchors and each sleeve has a cannula to provide percuta-

A slot in each of the sleeves is in communication with the associated channel when mounted on the vertebral anchor. The system includes one tool having a tubular member with a cannula extending there through and configured to fit over anchor. The tool is used by the surgeon to advance the connecting member along the slot and into the channel of one of the vertebral anchors and to position the spacer between the vertebral anchors. In alternative embodiments, the tool may have an arcuate flange on its distal end to cradle the spacer for distraction during insertion between the vertebral anchors.

The system may include another tool also having a tubular member with a cannula extending there through and con-35 figured to fit over one of the sleeves when mounted on the associated vertebral anchor. This tool is adapted to advance the connecting member along the slot and into the channel of the vertebral anchors. This tool may include a mating feature proximate the distal end and complementary to a mating feature on either the vertebral anchor or the sleeve to thereby couple the tool thereto. The complementary mating features may include a recess on the distal end of the tool, a recess on the head of the pedicle screw, an outwardly directed protrusion proximate a distal end of the sleeve, and an inwardly directed protrusion proximate the distal end of the sleeve. The recesses are configured to mate with the protrusions to releasably secure the tool to the pedicle screw and allow the surgeon to use the tool to screw the pedicle screws into the vertebrae.

Other embodiments of this invention involve the installation procedures for a spinal stabilization construct and include installing the vertebral anchors onto the vertebrae and mounting access members, which in one embodiment are sleeves, onto the vertebral anchors. Each sleeve has a cannula to provide percutaneous access to the channel of the respective vertebral anchor. The connecting element is inserted through a slot in one of the sleeves and is advanced from the slot into the channel in the associated vertebral anchor. The connecting element is secured to the channel of the vertebral anchor with a fastener and an annular spacer is positioned on the connecting element adjacent the vertebral anchor.

The connecting element is inserted through a slot in the other sleeve and advanced into the channel in the second of vertebral anchor. The spacer distracts against the first vertebral anchor and positions the spacer between the vertebral anchors. The connecting element is secured to the channel of

the second vertebral anchor with a second fastener. The connecting element may be a flexible cord that is tensioned between the vertebral anchors. The respective fasteners may be passed through the sleeves percutaneously to the respective channels in conjunction with the tensioning of the cord or connecting element.

These and other features, objects and advantages of the invention will become more readily apparent to those skilled in the art in view of the following detailed description, taken in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

The accompanying drawings, which are incorporated in and constitute a part of this specification, illustrate embodi- 15 ments of the invention and, together with the general description of the invention given above, and the detailed description given below, serve to explain the principles of the invention.

FIG. 1 is a perspective view of a vertebral anchor in the 20 form of a pedicle screw and an associated fastener in the form of a set screw according to one aspect of this invention;

FIG. 2 is a perspective view of the vertebral anchor of FIG. 1 being coupled to an access sleeve according to one aspect of this invention;

FIG. 3 is a perspective view of the components of FIG. 2 being coupled to a tool according to another aspect of this invention;

FIG. 4 is a perspective view of the components of FIG. 3 being used to screw a first vertebral anchor into a vertebra 30 of a patient;

FIG. 5 is a perspective view of a connecting element of a dynamic stabilization system being installed on the first vertebral anchor of FIG. 4;

dynamic stabilization system being installed relative to a pair of vertebral anchors installed on respective vertebrae of the patient; and

FIG. 7 is a perspective view of the connecting element of the dynamic stabilization system being tensioned between 40 the vertebral anchors and the anchors being distracted during the tensioning process.

DETAILED DESCRIPTION

FIGS. 1-2 and 6-7 depict some of the components of one embodiment of a spinal stabilization system 10 according to this invention. Specifically, vertebral anchors 12 are adapted to be installed into adjacent vertebrae 14,16 of the spine using removable access members 18 inserted through an 50 incision formed through the patient's skin. The incision may be sized for minimally invasive percutaneous or retractor based techniques or may be used in open procedures. In the embodiment shown, at least two anchors 12, shown here in the form of pedicle screws, are fixedly installed into the 55 pedicle area of adjacent vertebrae 14,16 and a flexible spacer 20 is disposed there between to control motion of the spine, while otherwise leaving the spinal segment mobile. Alternatively, the two anchors can be placed in a patient in combination with a fusion device located between the vertebral bodies.

The spacer 20 and pedicle screws 12 are coupled together by a connecting element 22 which in one embodiment is a flexible member coupled to or passed through the spacer 20 and secured to the heads **24** of the screws **12**. Such spacers 65 20 and flexible members 22 may be similar to those used in the Dynesys® Dynamic Stabilization System available from

Zimmer Spine of Minneapolis, Minn. In one embodiment, the spacer 20 may be formed from polycarbonate urethane and the flexible member 22 is a cord that may be formed from polyethylene-terephthalate, although it will be recognized that various other materials suitable for implantation within the human body and for providing stabilization of the spine while maintaining flexibility may be used.

In one embodiment, the anchor 12 is a pedicle screw having a threaded shank 26 configured to be screwed into the pedicle area of a vertebra 14,16. The head 24 of the screw is configured to receive and secure the flexible member 22. In the embodiment shown, the head **24** includes an upwardly open channel 28 formed between upwardly directed arms 30 and extending generally transverse to the longitudinal axis of the shank **26** and having an open end opposite the shank 26 for receiving the flexible member 22 into the channel 28 of the head 24 in a top loading fashion. Accordingly, the channel 28 alleviates the need to thread the flexible member 22 through an eyelet of the head 24 of the anchor 12 after the anchor 12 has been installed into the vertebral body 14, 16 of a patient's spine. The head **24** may have a pair of spaced, generally flat faces 33 for juxtaposition to the spacer 20.

In this embodiment, the head 24 of the pedicle screw 12 has receiving channels, such as recesses 32, provided on oppositely disposed sides of the arms 30 of the head 24 to facilitate screwing the anchor 12 into a vertebra 14,16 of a patient's spine using a tool as described later herein. In one embodiment, the pedicle screw 12 is formed from a titanium alloy, but it will be recognized that various other materials suitable for implantation within the human body and having sufficient strength to be securely attached to the bone and to secure the flexible member 22 may be used. While a uniaxial pedicle screw is shown and described herein, it will be recognized that the anchor 12 may alternatively comprise a FIG. 6 is a perspective view of the components of the 35 hook, a polyaxial pedicle screw, or various other structure suitable to be secured to a vertebral body.

> An elongate access member 18 is removably secured to the head **24** of the pedicle screw **12** and is formed substantially from a resilient, flexible material that permits deformation or bending of the access member 18 along its length without transmitting significant force to the pedicle screw 12. For example, the access member 18 may be formed from polymeric material such as nylon, polyethylene, polyurethane, or various other polymeric materials that are biocom-45 patible and provide sufficient flexibility to permit the guides to bend in flexure along their length without transmitting significant force to the pedicle screw 12. In other exemplary embodiments, the access members 18 may be configured as a rigid or a composite structure, comprising a portion formed from a substantially rigid material and a portion comprising a flexible material or wholly of a rigid material.

In the embodiment shown in FIG. 2, the access member 18 includes a pair of diametrically opposed, longitudinal slots 34 extending from a first, distal end 36 toward a second, proximal end 38 of the access member 18. Each slot 34 has an opening 40 at the first end 36 that is shaped to mate with the head 24 of the pedicle screw 12 such that the slot 34 communicates with the channel 28 formed in the head 24 of the pedicle screw 12. In this arrangement, the longitudinally extending slot 34 may be used to guide the flexible member 22 from the slots 34 of the access member 18, along its length, and into the channel 28 formed in the head 24 of the pedicle screw 12.

In one embodiment, the access member 18 includes mating tabs 42 to mate with the receiving channels or recesses 32 on the head 24 of the pedicle screw 12. In the exemplary embodiment shown, the mating tabs 42 are

inwardly directed protrusions. Mating surfaces between the pedicle screw and the access member 18 are configured to provide a mechanical interlock that is sufficient to withstand forces applied to the access member 18 during installation of the pedicle screws 12 into the vertebrae 14,16 and installa- 5 tion of the spacer 20 between adjacent pedicle screws 12. However, the access members 18 may be removed from the heads 24 of the pedicle screws 12, for example, by application of an appropriate force or by manipulating the access member 18 relative to the pedicle screw 12, to cause the 10 mating tabs 42 on the access member 18 to dislodge from the recesses 32 on the head 24 of the pedicle screw 12. The access member 18 may be formed in a molding process in the form of a sleeve having a longitudinally extending the pedicle screw 12 by mechanically interlocking the sleeve 18 onto the head 24 of the pedicle screw 12 with the mating tabs 42 and receiving channels or recesses 32.

With continued reference to FIGS. 1-2, the sleeve 18 includes an aperture 48 proximate the second end 38 for 20 receiving various components including a fastener 50, such as a set screw, for securing the flexible member 22 to the head 24 of the pedicle screw 12, as will be described more fully below. The aperture **48** leads to the cannula **44** of the access member 18 to provide percutaneous access to the 25 head 24 of the pedicle screw 12.

Longitudinally extending and laterally oriented threads 52 are formed on the inwardly facing surfaces of the arms 30 in the channel **28** of the head **24**. The threads **52** are sized for engagement with the fastener 50 when it is desired to secure 30 the flexible member 22 to the head 24 of the pedicle screw 12. In one embodiment, a driver 54 (FIG. 7) or other tool suitable for engaging a socket **56** in a top face of the fastener, or set screw, 50 may be inserted through the cannula 44.

herein as comprising a set screw, it will be recognized that various other types of securing members may alternatively be used to secure the flexible member 22 to the head 24 of the anchor 12. Likewise, the sleeve 18 may be configured to accommodate these various other types of fasteners and to 40 percutaneously provide access for them to the anchor 12.

Referring now to FIG. 3, use of a tool 60 to install components of the spinal stabilization system 10 to the vertebrae 14,16 of a spine will now be described. Vertebral anchor 12 and sleeve 18 mated together have been inserted 45 through a minimally invasive incision formed in a patient's skin to be threadably secured into the pedicle areas of a vertebra 14,16. The tool 60 in one embodiment as shown includes a tubular member 62 extending longitudinally and defines a central cannula **64** extending from a distal end **66** 50 of the tool 60. The tool 60 includes a handle 68 at the proximal end 70 of the tubular member 62, and the handle **68** and tubular member **62** in combination form a generally T-shaped configuration according to one embodiment of the tool **60**. In one embodiment, the T-shaped handle configu- 55 ration of handle 68 can be incorporated into the sleeve 18. The proximal end 70 of the cannula 64 in the tubular member 62 is accessed through a port 72 in the handle 68 as shown in FIGS. 3 and 4. The port 72 is sized to receive a fastener **50**. The handle **68** provides a convenient grip for a 60 surgeon to grasp the tool 60 for manipulation during installation of the spinal stabilization system 10. The distal end 66 of the tubular member 62 includes a pair of diametrically opposed fingers 74 projecting downwardly. Tool receiving channels, such as recesses 76, are formed on an inner face 65 of each finger 74 and extend longitudinally toward the body portion of the tubular member 62. The cannula 64 and

tubular member 62 are sized and configured to fit over the access member 18 and pedicle screw 12 combination as shown in FIG. 3.

Referring to FIG. 4, with the tool 60 installed onto and over the access member 18 and pedicle screw 12 in a generally telescopic arrangement, the recesses 76 at the distal end 66 of the tubular member 62 mate with outwardly directed tool mating tabs 78 on the distal end of the access member 18. As a result, the tool 60 is mated with the vertebral anchor 12 and access member 18. The mating interaction of the mating tabs 42, 78 and recesses 32, 76 allow the T-shaped tool 60 to drive the pedicle screw 12 as well as act as an anti-torque instrument. The surgeon rotates the tool 60 mated with the vertebral anchor 12 and access cannula 44, and may thereafter be joined to the head 24 of 15 member 18 to screw the vertebral anchor 12 into the vertebra **14,16**. The tool **60** can then be uncoupled from the access member 18 by dislodging the tool mating tabs 78 from the recess 76, thereby leaving the access member 18 mounted on the pedicle screw 12 installed on the vertebra 14,16.

The above-described description of the installation of the pedicle screw 12 may be performed on each of the pedicle screws 12 utilized in the stabilization system 10 as appropriate. In FIG. 5, the attachment of the connecting member, such as the exemplary flexible member 22 in the form of a flexible cord, to one of the pedicle screws 12 is shown. The pedicle screw 12 installed in the vertebra 14 has the access member 18 mounted thereto as shown in FIG. 5. A terminal end 22a of the connecting element 22 is inserted through the slots **34** of the access member **18** and this is likely performed at a portion of the slots **34** and access member **18** extending from the patient's body and above the incision. A forceps 80 having a pair of elongate handle members 82 pivotally coupled together can be utilized to stabilize and maneuver the flexible member 22 in the access member slots 34. The While the fastener 50 has been shown and described 35 forceps 80 include cooperating jaws 84, each of which has an arcuate portion 86 and a downwardly depending leg 88 with a notch 90 proximate the distal end of the leg 88 as shown in FIG. 5. In combination, the jaws 84 of the forceps 80 surround the access member 18 and the notches 90 clamp the end 22a of the flexible member 22 projecting through the slot 34. Any excess portion of the flexible member 22 that overhangs the notches 90 may be severed or trimmed as desired.

With the flexible member 22 clamped by the forceps 80 and projecting through the slots 34 in the access member 18 as shown in FIG. 5, the flexible member 22 may be passed through the slots 34 and down to the channel 28 of the pedicle screw 12. The forceps 80 clamped onto the flexible member 22 and around the access member 18 may be utilized to push the flexible member 22 from the slots 34 and into the channel 28. Alternatively, the tubular member 62 of the tool 60 may be used in combination with the forceps 80 to advance the flexible member 22 from the slots 34 downwardly and into the upwardly open channel 28 of the pedicle screw 12 as shown in FIG. 5.

With the flexible member 22 seated in the channel 28 and secured therein by the forceps 80, the fastener or set screw 50 may be percutaneously introduced through the cannula 44 of the access member 18 for securing the flexible member 22 to the pedicle screw 12. A driver 54 or similar tool may be utilized to threadably secure the set screw 50 to the head 24 of the pedicle screw 12 thereby securing the flexible member 22 to the pedicle screw 12. The tubular member 62 and T-shaped tool 60 may continue to be mounted telescopically on the access member 18 and pedicle screw 12 or removed for easier access and installation of the set screw **50**.

Referring to FIGS. 6 and 7, the adjacent pedicle screw 12a has been placed in the associated vertebra 14 with the procedure as previously described. The spacer 20 is then put over the flexible member 22 and slid into contact with the head 24 of the first pedicle screw 12a as shown in FIG. 6. 5 The tool **62** can be used to create distraction between the vertebral anchors 12a, 12b to allow for easier placement of the spacer 20 between the vertebral anchors 12a, 12b. Alternatively, a distractive force can be generated by the placement of the spacer 20 between the vertebral anchors 10 12a, 12b. As the tool 62 shown in FIG. 6 is forced into engagement with the spacer 20, the spacer 20 then generates a force against the vertebral anchors 12a, 12b thus creating distraction of the vertebrae.

The flexible member 22 is then inserted through the slots 15 34 of the access member 18 on the second pedicle screw 12b and a connecting element guide tool **92** can be slid over the access member 18 on the second pedicle screw 12b as shown in FIGS. 6 and 7. The cord guide tool 92 is similar to the T-shaped tool 60 previously described in FIGS. 3 and 4 with 20 like reference numerals identifying similar features. The flexible member guide tool 92 also includes at least one arcuate flange 94 projecting generally perpendicularly from the axis of the tubular member 62. The arcuate flange 94 is sized and configured to cradle a portion of the spacer 20 as 25 the tool 92 is pushed downwardly over the access member 18. The arcuate flange 94 contacts the end of the spacer 20 adjacent the second pedicle screw 12b and downward pressure on the tool **92** forces the spacer **20** downwardly and into position between the adjacent pedicle screw heads 24. As the 30 cord guide tool 92 slides downwardly over the access member 18, the arcuate flange 94 translates the spacer 20 downward and outward to create distraction by reacting to the force of the flexible member guide tool 92 and pushing against the access member 18 on the second pedicle screw 35 12b and the head 24 of the first pedicle screw 12a. Simultaneously, the flexible member 22 advances from the slots 34 of the access member 18 on the second pedicle screw 12b and into the channel 28 of the head 24 of the second pedicle screw 12b.

Advantageously, this invention utilizes the tools and spacer to create distraction between the pedicle screw heads 24 and avoids threading the flexible member 22 through an eyelet in the head of the pedicle screw and any over distraction caused by the thickness of the flexible member 45 when pulled into position.

Once the spacer 20 is positioned between the pedicle screw heads 24 and the flexible member 22 is seated in the channel 28 of the second pedicle screw 12b, the flexible member 22 may be tensioned utilizing a tensioning tool 96 50 as shown in FIG. 7. After the flexible member 22 is appropriately tensioned, the set screw 50 may be passed through the port 70 in the handle 68 of the cord guide tool 92 and seated in the channel 28 of the pedicle screw head 24. The driver **54** is then utilized through the cannula **64** of the 55 contacts an outer surface of the spacer. tool **92** and the access member **18** to mate with the set screw **50** and rotate the set screw **50** into secure engagement in the channel 28 and thereby clamp the tensioned flexible member 22. The driver 54, cord guide tool 92, access member 18 and tensioning tool **96** may then be removed from the patient and 60 the flexible member 22 trimmed to length. Alternatively, if a multi-level spinal dynamic stabilization system 10 is to be installed, the process is repeated on subsequent vertebrae as appropriate and the incision closed to complete the installation.

While this invention has been illustrated by the description of one or more embodiments thereof, and while the

embodiments have been described in considerable detail, they are not intended to restrict or in any way limit the scope of the appended claims to such detail. Additional advantages and modifications will readily appear to those skilled in the art. The invention in its broader aspects is therefore not limited to the specific details, representative apparatus and method and illustrative examples shown and described. Accordingly, departures may be made from such details without departing from the scope or spirit of the general inventive concept.

What is claimed is:

1. A method of installing a spinal stabilization construct, comprising:

installing first and second vertebral anchors onto first and second vertebrae, respectively, each vertebral anchor having an upwardly open channel adapted to receive a flexible connecting element extending between the first and second vertebrae;

mounting first and second access members onto the first and second vertebral anchors, respectively, each access member having a cannula to provide access to the channel of the respective vertebral anchor;

inserting the connecting element through a slot in the first access member;

advancing the flexible connecting element from the slot in the first access member into the channel of the first vertebral anchor;

securing the flexible connecting element [to] within the channel of the first vertebral anchor with a first fastener;

positioning a spacer on the connecting element adjacent the first vertebral anchor;

inserting the flexible connecting element through a slot in the second access member;

translating a tool along an exterior of the second access member without rotation to advance the flexible connecting element along the slot in the second access member into the channel in the second vertebral anchor;

positioning the spacer between the vertebral anchors; and securing the flexible connecting element [to] within the channel of the second vertebral anchor with a second fastener.

2. The method of claim 1, wherein positioning the spacer between the vertebral anchors includes:

pushing the spacer into position between the vertebral anchors with the tool.

- 3. The method of claim 2, wherein the tool includes a lateral portion extending transverse to a longitudinal axis of the tool for contacting the spacer.
- 4. The method of claim 3, wherein the lateral portion is a flange including an arcuate surface.
- 5. The method of claim 4, wherein the arcuate surface
- 6. The method of claim 1, wherein the tool is a tubular member slidably disposed around the second access member.
 - 7. The method of claim 1, further comprising:
 - tensioning the connecting element after securing the flexible connecting element to the channel of the first vertebral anchor and prior to securing the flexible connecting element to the channel of the second vertebral anchor.
 - **8**. The method of claim **1**, further comprising:

distracting the first and second vertebrae during positioning of the spacer between the vertebral anchors.

- 9. The method of claim 1, wherein securing the flexible connecting element to the channel of the first vertebral anchor with the first fastener includes passing the first fastener through the first access member percutaneously to the first vertebral anchor, and securing the flexible connecting element to the channel of the second vertebral anchor with the second fastener includes passing the second fastener through the second access member percutaneously to the second vertebral anchor.
- 10. A method for performing spinal stabilization surgery, comprising:

creating at least one access opening in a patient;

implanting, through the at least one access opening, a plurality of vertebral anchors into a plurality of corresponding vertebrae, each vertebral anchor having an upwardly open channel defined between upwardly directed arms, the channel configured to receive a flexible cord in a top loading manner;

top loading the cord into the channel of a first vertebral 20 anchor of the plurality of vertebral anchors using a cord guide tool having a cord guide feature and a vertebral anchor feature;

securing a first end portion of the cord to the first vertebral anchor;

engaging a second vertebral anchor of the plurality of vertebral anchors with the cord guide tool through the at least one access opening;

using the cord guide tool to advance the cord distally into the channel of the second vertebral anchor subsequent ³⁰ to engagement with the second vertebral anchor and prior to fixation of the cord in the second vertebral anchor;

engaging a tensioning tool to the cord guide tool;

translating the second vertebral anchor implanted into a ³⁵ second vertebra relative to the first vertebral anchor implanted into a first vertebra using vertebral anchor feature of the cord guide tool;

applying a tension to the cord using the tensioning tool; and

securing the cord to the second vertebral anchor by rotating a set screw into securement in the channel of the second vertebral anchor with a driver;

wherein the securing step is performed while the cord guide tool is engaged with the second vertebral anchor ⁴⁵ at the vertebral anchor feature after being slid over an access tool coupled to the second vertebral anchor.

11. The method of claim 10, further comprising:

positioning the driver through a lumen of the cord guide tool to rotate the set screw.

12. The method of claim 11, wherein the tensioning tool is engaged at a proximal end region of the cord guide tool and

the cord passes through an opening in the cord guide tool at least partially defining the cord guide feature to reach the tensioning tool.

13. The method of claim 12, wherein the driver is positioned in the lumen of the cord guide tool while the tensioning tool is engaged at a proximal end region of the cord guide tool.

14. The method of claim 13, wherein the tensioning tool is offset from the lumen of the cord guide.

15. The method of claim 10, wherein a portion of the cord extends from the second vertebral anchor to the tensioning tool.

16. A method for performing spinal stabilization surgery, comprising:

implanting first and second vertebral anchors into first and second vertebral bodies, respectively, each vertebral anchor having an upwardly open channel defined between upwardly directed arms, the channel configured to receive a flexible cord in a top loading manner; advancing the cord distally into the channel the first vertebral anchor;

securing a first end portion of the cord to the first vertebral anchor;

engaging the second vertebral anchor with a cord guide tool:

using the cord guide tool to both advance the cord distally into the channel of the second vertebral anchor with a cord guide feature and translate the second vertebral anchor relative to the first vertebral anchor with a vertebral anchor feature prior to fixation of the cord in the second vertebral anchor, wherein translating the second vertebral anchor involves application of force to the cord guide tool to manipulate the position of the second vertebral body;

engaging a tensioning tool to a proximal end of the cord guide tool;

applying a tension to the cord using the tensioning tool; positioning a driver through a lumen of the cord guide tool; and

securing the cord to the second vertebral anchor while the cord guide tool is engaged with the second vertebral anchor at the vertebral anchor feature after being slid over an access tool coupled to the second vertebral anchor.

17. The method of claim 16, wherein the driver is positioned in the lumen of the cord guide tool while the tensioning tool is engaged with the cord guide tool.

18. The method of claim 17, wherein the tensioning tool is offset from the lumen of the cord guide tool.

19. The method of claim 18, wherein a portion of the cord extends from the second vertebral anchor to the tensioning tool.

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