(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) **EP 3 125 795 B1**

(12) **EUROPEAN PATENT SPECIFICATION**

(45) Date of publication and mention of the grant of the patent:
05.06.2019 Bulletin 2019/23

(21) Application number: **15773114.2**

(22) Date of filing: **01.04.2015**

(51) Int Cl.:
A61B 17/70 *(2006.01)* ***A61B 17/66*** *(2006.01)*
A61B 17/00 *(2006.01)* ***A61B 17/56*** *(2006.01)*
A61B 17/68 *(2006.01)* ***A61B 17/86*** *(2006.01)*
A61B 17/88 *(2006.01)*

(86) International application number:
PCT/US2015/023879

(87) International publication number:
WO 2015/153758 (08.10.2015 Gazette 2015/40)

(54) ASSEMBLY FOR ALIGNING A SPINE USING DEPLOYABLE BONE ANCHORS

ANORDNUNG ZUM AUSRICHTEN EINER WIRBELSÄULE ANHAND VON FREISETZBAREN KNOCHENANKERN

ENSEMBLE PERMETTANT D'ALIGNER UNE COLONNE VERTÉBRALE EN UTILISANT DES ANCRAGES OSSEUX DÉPLOYABLES

(84) Designated Contracting States:
AL AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HR HU IE IS IT LI LT LU LV MC MK MT NL NO PL PT RO RS SE SI SK SM TR

(30) Priority: **03.04.2014 US 201414244241**

(43) Date of publication of application:
08.02.2017 Bulletin 2017/06

(73) Proprietor: **Suddaby, Loubert S.**
Orchard Park, NY 14127 (US)

(72) Inventor: **Suddaby, Loubert S.**
Orchard Park, NY 14127 (US)

(74) Representative: **Reichert & Lindner Partnerschaft Patentanwälte**
Bismarckplatz 8
93047 Regensburg (DE)

(56) References cited:
US-A- 5 782 831 **US-A1- 2004 049 202**
US-A1- 2008 051 707 **US-A1- 2009 012 565**
US-A1- 2009 281 575 **US-A1- 2011 054 536**
US-A1- 2013 211 455 **US-B2- 7 842 072**
US-B2- 8 512 343 **US-B2- 8 672 944**

EP 3 125 795 B1

Description

FIELD OF THE INVENTION

[0001] The present invention relates to the field of surgical devices, particularly to orthopedic surgical device, and more particularly to corrective devices related to the spine.

BACKGROUND OF THE INVENTION

[0002] Scoliosis is a disorder that causes an abnormal curve of the spine, or backbone. Patients with scoliosis develop abnormal curves to either side of the body's median line (lateral curve) and the bones of the spine twist on each other like a corkscrew. Scoliosis is about two times more common in girls than boys. It can be seen at any age, but it is most common in those over 10 years old.

[0003] Often, the cause of scoliosis is unknown and is described based on the age when scoliosis develops. If the person is less than 3 years old, it is called infantile idiopathic scoliosis. Scoliosis that develops between 3 and 10 years of age is called juvenile idiopathic scoliosis, and people that are over 10 years old have adolescent idiopathic scoliosis.

[0004] In functional scoliosis, the spine is normal, but an abnormal curve develops because of a problem somewhere else in the body. This could be caused by one leg being shorter than the other or by muscle spasms in the back. In the neuromuscular form, there is a problem during the formation of the bones of the spine. Either the bones of the spine fail to form completely or they fail to separate from each other. This type of scoliosis may develop in people with other disorders including birth defects, muscular dystrophy, cerebral palsy, and Marfan's disease. This type of scoliosis is often much more severe and needs more aggressive treatment than other forms of scoliosis. Degenerative scoliosis occurs in older adults. It is caused by changes in the spine due to arthritis. Weakening of the normal ligaments and other soft tissues of the spine combined with abnormal bone spurs can lead to an abnormal curvature of the spine.

[0005] Adolescent idiopathic scoliosis is the most common form of scoliosis. If the angle of the spinal curve (Cobb's angle) is small when first diagnosed, it can be observed and followed with routine X-rays and measurements. If the curve stays below 25 degrees, no other treatment is usually needed. If the curve is between 25-40 degrees, a brace may be recommended. If the curve is greater than 40 degrees, then surgery may be recommended. Braces are not designed to correct the curve. They are used to help slow or stop the curve from getting worse.

[0006] Spinal fusion is one surgical procedure that may be used to alleviate scoliosis. In this procedure, bone is grafted to the vertebrae to form a rigid column. The rigidity of the column will prevent the curve from worsening. However, the rigid column reduces the range of motion available to the patient.

[0007] Modern surgical procedures attempt to address sagittal imbalance and rotational defects unresolved by the earlier rod systems. They primarily involve a combination of rods, screws, hooks, cables and/or wires fixing the spine and applying forces to the spine to correct the spinal curvature. An example of the use of screws and cables is seen in U.S. Patent Application Publication No. 2006/0195090 to Suddaby ("Suddaby"). Suddaby discloses a system for improving the alignment of a spine by placing a series of screws or pins into the posterior or lateral side of the bodies of individual vertebrae. Hollow spacers are placed between the pins and a cable is extended through the heads of the pins and the spacers and is attached to an expansion sleeve. Tension is applied to the cable by pulling it through the expansion sleeve and then applying tension to the cable to pull the attached pins into an improved alignment. One of a plurality of nodules at the end of the cable is then placed into the passage of the expansion sleeve thereby holding the cable in the new "tensioned" position. The tension discourages movement of the spine.

[0008] U.S. Patent No. 6,551,320 to Lieberman ("Lieberman") discloses an apparatus for aligning a spine that includes a plurality of anchors screwed into adjacent vertebral bodies. A cable or series of cables is strung through or around the anchors and then pulled. The tension applied to the cable(s) is used to pull the spine into a desired alignment. U.S. Patent Application Publication No. 2009/0112262 to Pool, et al. ("Pool") discloses a system in which at least one anchor is screwed or otherwise embedded into an upper vertebra and one or more anchors are similarly placed in lower vertebra(ae). A cable is extended between the anchors and force applied to the cable by a magnetic adjustment device to align the spine. In some cases a second anchor-cable arrangement can be used on the opposite side of the spine.

[0009] U.S. Patent No. 5,782,831 to Sherman, et al. ("Sherman") discloses a system for reducing a displaced vertebra between adjacent vertebrae. The Sherman patent describes a system in which two anchors are screwed into the vertebrae on either side of the displaced vertebra with a rod attached between the anchors. A third anchor is screwed into the displaced vertebra and attached to a cable. A cable tightening device, such as a come-along type device is used to pull the displaced vertebra into alignment after which it is attached to the support rod. However, the attachment of a bar across three adjacent vertebrae prevents pulling a curved spine into a more proper alignment.

[0010] Finally, US 2009/012565 A1 discloses an assembly for performing a gradual spinal alignment which includes an implant fixed to one side of a vertebra and a rod extending along an axis of the spine on a second side of the vertebra. An adjustment member, which may include a reel, is coupled to the rod. A force directing member, such as a cable, extends between the rod and the adjustment member. The force directing member is retractable toward and extendible from the adjustment member.

[0011] In attempting to solve spinal alignment and displacement problems, the prior art relies on multiple vertebral anchors and the application of alignment force through complicated force applicators and cable systems. Often such corrective systems fail to provide complete correction of spinal alignment as full recuperation requires either too much force to correct the curve or sudden, rapid stretching of spinal neural elements resulting in permanent neurological damage. Because direct visualization of the individual spinal elements is often required for the above techniques, lengthy incisions and large spinal dissections are required to expose the spinal segments requiring treatment. Even with these major life threatening surgeries, perfect spinal alignment is rarely, if ever, achieved.

[0012] What is needed then is an apparatus for aligning the spine that possesses few parts and is easy to implant while enabling a gradual restoration of the spinal alignment over a determined period of time so that large and/or sudden forces are not applied to the curved spine. By applying reduced corrective forces over a longer period of time, complications such as bone fracture and nerve damage can be reduced or avoided. Moreover, it would be advantageous in the art of neurosurgery and orthopedic surgery to align a spine with simple percutaneous methods so that endoscopic or minimally invasive technique can be employed.

SUMMARY OF THE INVENTION

[0013] The object of the invention is to provide an assembly for performing a gradual spinal alignment using simple percutaneous methods and minimally invasive techniques, such as endoscopic techniques. This object is solved by the assembly for performing a gradual spinal alignment of claim 1.

[0014] Further examples not forming part of the invention include providing an assembly in which the alignment device may be resorbed into the body, gradually achieving corrective alignment to avoid potential neurological and muscular damage. By gradually it is meant over a period of several weeks to several months depending on the severity of the lateral curve.

[0015] The invention offers an assembly for performing a gradual spinal alignment using a firm support device such as a body brace for leverage support. The invention presents an assembly for performing a gradual spinal alignment by which both sides of the spinal column may be subject to an alignment procedure at the same time. The invention provides an assembly for performing a gradual spinal alignment using a minimum amount of vertebral drilling sites.

[0016] The present invention comprises an assembly for performing a gradual lateral spinal alignment of a spine, the spine to be realigned having a lateral curve, the lateral curve having a convex side and an opposite concave side. The assembly comprises a percutaneous implantable device. The percutaneous implantable device comprises a tube having a proximal end and a distal end. The tube is arranged to extend through a hole in a vertebra of the spine. The percutaneous implantable device also comprises a cable extending within the tube. The cable is secured to the distal end of the tube. The percutaneous implantable device also comprises an anchor tip attached to the cable and an inflatable balloon secured to the distal end of the tube and arranged to inflate against an external surface of the vertebra and completely enclose the anchor tip. The assembly further comprises an external leverage support releasably attached to the proximal end of the tube passing percutaneously with its proximal end to the external leverage support, wherein when the inflatable balloon is inflated, the cable and inflated balloon are arranged for pulling the vertebra towards the external leverage support. This assembly possesses few parts and is easy to implant while enabling a gradual restoration of the spinal alignment over a determined period of time so that large and/or sudden forces are not applied to the curved spine. By applying reduced corrective forces over a longer period of time, complications such as bone fracture and nerve damage can be reduced or avoided.

[0017] In a preferred embodiment, the assembly further comprises a pulling device attached to the proximal end of the tube. The pulling device may include, but is not limited to, a pliers, a winch, a screw jack, or a come-along.

[0018] In an embodiment, the tube is fabricated from polyglycolic acid.

[0019] In further embodiments, the inflatable balloon is inflated hydraulically or mechanically.

[0020] In an example not forming part of the invention, the assembly comprises a hollow bone screw having internal threads and an open proximal end and an open distal end, a second screw threadably inserted into the hollow bone screw, a toggle bolt that includes a shaft having a distal end and a proximal end, wherein the distal end supports a pivotal attachment, and a toggle wing pivotably attached to the pivotal attachment. The assembly also includes a rigid stabilizing rod, the stabilizing rod having two ends and defining a first orifice and a second orifice, such that the axis of the second orifice is perpendicular to the axis of the first orifice and the second orifice is surrounded by an externally threaded annular lip, a cable having a first end and a second end, the first end attached to the proximal end of the toggle bolt and extending through second orifice, and a tube enclosing at least part of the length of the cable and having a first end threadably attached to the externally threaded annular lip, such that one end of the toggle bolt is extended through the distal end of the hollow screw.

[0021] An embodiment not belonging to the invention also broadly comprises a method of gradually laterally aligning a spine having a lateral curve using a spinal alignment assembly the spinal alignment assembly including a hollow bone screw having internal threads and an open proximal end and an open distal end, a second screw threadably inserted into the hollow bone screw; a toggle bolt that includes a shaft having a distal end, a middle section, and a proximal end, wherein the distal end supports a pivotal attachment, and a toggle wing pivotably attached to the pivotal attachment. The assembly also includes a rigid stabilizing rod, the stabilizing rod having two ends and defining a first orifice and a second orifice, wherein the axis of the second orifice is perpendicular to the axis of the first orifice and the second orifice is surrounded by an externally threaded annular lip, a cable having a first end and a second end, the first end attached to the proximal end of the toggle bolt and extending the second orifice, and a tube enclosing at least part of the length of the cable and having a first end threadably attached to the externally threaded annular lip and a second set screw threadably inserted into the tube, such that one end of the toggle bolt is extended through the distal end of the hollow screw. The gradual alignment method comprises the steps of screwing the hollow bone screw into a body of a vertebra of the spine; removing the second inner screw from the hollow bone screw; extending the toggle bolt through the hollow bone screw; placing the stabilizing rod on the hollow bone screw between the spine and the receiver; deploying the toggle wing on a convex side of the lateral curve; aligning the stabilizing rod laterally and longitudinally along the concave side of the lateral curve of the spine; enclosing at least part of the length of the cable in the tube such that the second end of the cable extends out of the back of a user; threadably attaching the tube to the receiver; attaching a cable tightening device at or near the second end of the cable; pulling the cable so as to pull the toggle bolt and the vertebra toward the concave side of the lateral curve; and tightening the second set screw to the cable to hold the pulled toggle bolt in the pulled position.

[0022] An example not claimed comprises an assembly for performing a gradual spinal alignment comprising: a first external leverage support and an inflatable bone anchor attached to the external leverage support, the inflatable bone anchor including a proximal tube having proximal and distal ends and attached to the external leverage support and at least one distal inflatable balloon anchor at the distal end. The tube is attached to the external leverage support at the proximal end. An alternate example further includes a second external leverage support; at least one strut extending from the second external leverage support; and, a bone screw extending from each of the at least one strut.

[0023] An embodiment not belonging to the present invention also broadly comprises a method of gradually aligning a spine having a lateral curve using a spinal alignment assembly, the lateral curve having a concave side and a convex side, the spinal alignment assembly comprising: a first external leverage support; an inflatable bone anchor attached to the external leverage support, the inflatable bone anchor including a tube attached to at least one distal inflatable balloon anchor, a pulling device attached to the proximal end of the tube of the inflatable bone anchor; wherein the proximal tube is attached to the external leverage support; wherein the first external leverage support is a body brace; the method comprising: drilling a hole into a vertebral body on the concave side; inserting the at least one distal inflatable balloon into the hole; inflating the at least one distal balloon to form a cavity within the vertebra body; pulling the bone anchor at the proximal end to pull the lateral curve toward the concave side; and attaching a proximal end of the inflatable bone anchor to the brace.

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWINGS

[0024] The nature and mode of the operation of the present invention will now be more fully described in the following detailed description of the invention taken with the accompanying drawing Figures, in which:

Figure 1 is a stylized drawing of person with a spine afflicted with scoliosis;

Figure 2A is a rear view of a full body brace used by scoliosis patients;

Figure 2B is a rear view of a lighter brace used by scoliosis patients;

Figure 3 is a cross section of a hollow bone screw having an outer shell and an inner screw threadably inserted therein;

Figures 4 and 4A demonstrate how the inner screw can be separated from the outer shell leaving a lumen as a hollow space along the length of the outer shell;

Figure 5A is a top view of the stabilizing rod of an assembly not according to the present invention;

Figure 5B is a side view of the stabilizing rod showing the receiver formed into the peak that defines a screw hole;

Figure 5C is a cross section view taken along line 5C-5C in Figure 5B;

Figure 6 is side perspective exploded view of the assembly of Figures 5A-5C attached to a vertebra in the spinal column of the spine to be aligned;

Figure 7 is a side perspective view of the assembly showing a pulling tool attached to the end of the pulling cable;

Figure 8 is a top or posterior view of a laterally curved spinal column with the alignment assembly in place;

Figure 9 a top or posterior view showing the assembly holding the spinal column in place after a pulling procedure;

Figure 10 shows the spinal column moved to a straighter position relative to the axis after a succeeding pulling procedure;

Figure 10A shows the assembly with the pulling tool removed and the tube set screw screwed into the tube aperture to hold the cable in place between pulling procedures;

Figure 11 is the same posterior view showing the results of the final pulling procedure in which the lateral curves of the spinal column is significantly reduced if not eliminated;

Figure 12 is a posterior view showing spinal column after the final pulling procedure;

Figure 12A is a cross section view similar to Figure 5C showing he set screw holding the cable in place to maintain tension of the assembly after the final pulling procedure;

Figure 13 is a top view of the inflatable balloon bone anchor which is a component of an assembly according to the invention utilized in the gradual alignment of a spine with one or more lateral curves;

Figure 14A is a cross section view of a target vertebra in which a Jamshidi needle is used to drill a hole into the target vertebra;

Figure 14B is the same view as Figure 14A depicting the Jamshidi needle withdrawn from around the balloon and tube;

Figure 14C shows the initiation of the inflation of the inflatable balloon inside the cancellous material at the core of the target vertebra;

Figure 14D depicts the withdrawal of the anchor tip resulting in the inflated balloon lining a cavity created within the cancellous bone material;

Figure 15A depicts a second method of attaching the inflatable balloon anchor to a vertebra in which the Jamshidi needle is drilled through the vertebra to create a passage extending through the opposing sides of the vertebra;

Figure 15B shows the Jamshidi needle withdrawn from around the inflatable balloon catheter and the balloon starting to inflate;

Figure 15C shows the inflatable balloon drawn against the side of the target vertebra opposing the side where the balloon bone anchor enters the vertebra (proximal side);

Figure 15D depicts the fully inflated balloon drawn against the vertebra;

Figure 16 is a schematic front view of the inflatable balloon catheter attached to an external leverage support to form an embodiment of the present invention;

Figure 17 is a cross section view of a bone screw embedded into vertebra and attached to a strut;

Figure 18A is a schematic view of the use of two balloon anchor assemblies to pull the spinal column into alignment; and,

Figure 18B depicts schematically the use of the bone screw construction with one or more balloon anchor assemblies to combine both pulling and pushing forces to simultaneously apply corrective pressure on both sides of the lateral curve.

DETAILED DESCRIPTION OF EMBODIMENTS OF THE INVENTION

[0025] At the outset, it should be appreciated that like reference signs on different drawing views identify identical structural elements of the invention. It also should be appreciated that figure proportions and angles are not always to scale in order to clearly portray the attributes of the present invention.

[0026] While the present invention is described with respect to what is presently considered to be the preferred embodiments, it is understood that the invention is not limited to the disclosed embodiments. Furthermore, it is understood that this invention is not limited to the particular methodology, materials and modifications described and as such may, of course, vary. It is also understood that the terminology used herein is for the purpose of describing particular embodiments only, and is not intended to limit the scope of the present invention, which is limited only by the appended claims.

[0027] Unless defined otherwise, all technical and scientific terms used herein have the same meaning as commonly understood to one of ordinary skill in the art to which this invention belongs. Although any methods, devices or materials similar or equivalent to those described herein can be used in the practice or testing of the invention, the preferred methods, devices, and materials are now described.

[0028] Adverting to the drawings, Figure 1 is a stylized view of a person **P** with a spine afflicted with scoliosis. Spinal column **1** is shown to have two lateral curves - upper curve **2** and lower curve **3.** Often the presence of one lateral curve will generate the formation of a second curve to compensate for the reduced spinal support of the body caused by one lateral curve. Figures 2A and 2B depict two different types of braces **4** and **5,** respectively, used to prevent further deterioration of spinal alignment. In some cases, braces such as braces **4** and **5** may improve the condition, but they rarely enable the wearer to achieve a full recovery to a correct spinal alignment.

[0029] Figure 3 is a cross section of hollow bone screw **20.** Outer screw shell **22** is externally threaded with threads **22a** to enable it to be screwed into the body of a vertebra as described below. Inner screw **24** is also externally threaded with threads **24a** to threadably connect with internal threads **22b** of outer screw shell **22.** Preferably cap **24b** is attached to the proximal end of inner screw **24.** Figures 4 and 4A demonstrate how inner screw **24** can be separated from outer shell **22** leaving lumen **26** as a hollow space along the length of outer shell **22.**

[0030] Figure 5A is a top view of stabilizing rod **30** ("rod **30**"). Preferably the ends **30a** of rod **30** are curved to provide the advantage of being able to move more easily along the spine and longitudinal muscles along the spine. Receiver complex **32** ("receiver **32**") extends from the surface of rod **30** to form a peak which defines screw hole **34.** Figure 5B is a side view of rod **30** showing receiver **32** formed into the peak that defines screw hole **34** (not seen in Figure 5B). Also seen is aperture **36,** defined by part of one side of receiver **32,** and set screw **37** set into the same side of receiver **32.**

[0031] Figure 5C is a cross section view taken along line 5C-5C in Figure 5B. Set screw **37** is shown set into receiver **32.** It can be seen that aperture **36** and set screw **37** have parallel longitudinal -axes and both of these axes are substantially perpendicular to the axis **34a** of screw hole **34.** Annular lip **38** surrounds aperture **36** and set screw **37** and is externally threaded.

[0032] Figure 6 is side perspective exploded view of an assembly **10** for performing a gradual spinal alignment not belonging to the invention. In this view, the assembly 10 is attached to a vertebra **80** in the spinal column of the spine to be aligned. Initially, hollow screw **20** is extended into screw hole **34** and is screwed into body **80** of the target vertebra until the distal end point **25** emerges slightly from the distal side, which preferably is at or near the peak of the convex curve of the laterally curved spinal column **1.** Inner screw **24** is then removed from outer shell **22** thereby opening lumen **26.** Toggle bolt **40** having shaft **41** with a distal end and a proximal end (not seen in Figure 6) and deployable wings **42** is guided through lumen **26** from the proximal side of vertebra **80** until it extends past distal end point **25** at the distal end hollow screw **20.** Preferably, toggle bolt **40** includes pivot attachment **44** to which wings **42** are attached. Wings **42** are deployed (opened out) as shown in Figure 6 and pulled against the convex side of vertebra **80.** Cable **46,** attached to the proximal end of shaft **41,** extends out the proximal end of lumen **26** and guided into screw hole **34** and up aperture **36.** This perpendicular turn is preferably guided by curved wall **36b** of aperture **36.** Persons of skill in the art will recognize that cable **46** may be threaded from distal end point **25** toward the proximal end of lumen **26** with wings 42 deployed at distal end point **25.** In addition, equivalent devices having expanded or expandable components positioned similarly to wings 42 may be used in place of toggle bolt **40** as long as they provide satisfactory support for pulling cable **46** as described below.

[0033] Cable **46** is guided through tube **50** which extends posteriorly through back **B.** Lip **52** at one end of tube **50** included internal threads **52a** to enable tube **50** to be threadably attached to annular lip **38.** Set screw **54** is screwed into threaded tube aperture **50a** to hold cable **46** in place.

[0034] Figure 7 is a side perspective view of assembly **10** showing pulling tool **60** attached to the end of cable **46.** Cable **46** has sufficient length to extend from the proximal end of the toggle bolt shaft to outside the back to be attached to pulling tool **60.** Examples of pulling tools are winch or reel-type devices, come-along, pliers, screw jacks, or other suitable devices that are able to repeatedly apply a pulling force to cable **46** which pulls the convex apex of laterally curved spinal column **1** at the point where toggle wing **42** contacts vertebral body **80.** Tube **50** is threadably attached to annular lip **38.** It will be understood that other vertebra are positioned above and below target vertebra **80.** Because rod **30** is placed along the concave curve of the spine, it is possible that it will not contact vertebra **80** during some or all of the alignment process as is shown in Figure 7. The perpendicular turn allows the force vectors on cable **46** to be directed out of back **B** so that the lungs and surrounding viscera can be avoided.

[0035] Figure 8 is a top or posterior view of laterally curved spinal column **1** with alignment assembly **10** in place as shown in Figure 7. Axis **A** represents what the longitudinal axis of spinal column **1** would be when straightened to the ideal anatomical position. Toggle bolt **40** is depicted with deployed wings **42** contacting vertebra **80.** Vertebral discs **70** are shown alternately placed within spinal column **1** between each vertebra. The attachment of tube **50** to annular lip **38** is depicted in cut out form to show cable **46** extending from toggle bolt **40** through lumen **26** and aperture **36** into tube **50.** In a preferred practice, tube **50** would be attached to annular lip **38.** The further or distal end of cable **46** is attached to pulling tool **60.** Rod **30** is placed laterally and longitudinally along spinal column **1.** It can be seen that because rod **30** is preferably on the concave side of the lateral spinal curve, it may not contact curved spinal column **1** where cable **46** emerges from spinal column **1** on the concave or proximal side.

[0036] During the pulling procedure, set screw **54** is loosened or removed from tube aperture **50a.** Pulling tool **60** applies pulling force across spinal column **1** onto wings **42.** This pulls spinal column **1** against stabilizing rod **30** forcing wings **42** and consequently vertebra **80** toward rod **30** thereby reducing the lateral curve. After sufficient movement, tube set screw **54** is threaded into tube aperture **50a** to hold the pulled cable and spinal column in the new straighter position. After a period of time to allow muscles and nerves and spinal column **1** to adjust to the new position, the pulling procedure is repeated with spinal column **1** again being pulled against rod **30** to an even straighter position relative to axis **A.** Figure 9 shows assembly **10** after a pulling procedure with tube **50** attached to rod **30** at annular lip **38** (not shown in Figure 9). By following the sequence of pulling, tightening, and waiting, spinal column **1** is gradually brought closer to proper alignment. By gradual or gradually is meant that alignment may be achieved of a period of as little as one or two days to as long as 6 months, although in mild cases of scoliosis 5-15 minutes to one day may be possible. Normally, an alignment period may range from a week to about three months, but persons of skill in the art will recognize that the length of the alignment period will depend on such factors as the severity of the lateral curve, the age of the patient, and the strength of the surrounding neuromuscular structure as well as other factors.

[0037] Figure 10 shows spinal column **1** moved to a straighter position relative to axis **A** after a succeeding pulling procedure. Rod **30** is shown closer to spinal column **1** as spinal column **1** is pulled straighter. It can also be seen that curved ends **30a** provide an advantage over straight ends in that it allows stabilizing rod **30** to move along spinal column **1** with less if any interference with elements of spinal column **1.** Figure 10A shows assembly **10** with pulling tool removed and tube set screw **54** screwed into tube aperture **50a** holding cable **46** in place between pulling procedures.

[0038] Figure 11 is the same posterior view showing the results of the final pulling procedure in which the lateral curve of spinal column **1** is significantly reduced if not eliminated. It can be seen that the middle section of stabilizing rod **30** is pulled close to vertebra **80** at the insertion point of hollow bone screw **20.**

[0039] Figure 12 is a posterior view showing spinal column **1** after the final pulling procedure. Tube **50** is removed through the back of the patient. Stabilizing rod **30** is left in place holding spinal column **1** in place against toggle bolt wings **42** with the holding force transmitted on cable **46** in lumen **26.**

[0040] Figure 12A is a cross section view similar to Figure 5C in which set screw **37** is shown screwed down into screw hole **34** to hold (fix) cable **46** in place under tension after the final pulling procedure. Set screw **37** is screwed in place before set screw **54** is loosened to constantly maintain tension in cable **46** to enable assembly **10** to hold spinal column **1** in the final position. Set screw **37** may be tightened using appropriate conventional or arthroscopic instruments known to those skilled in the art. Thus, cable **46** is held in place under tension by its attachment to toggle bolt **40** at the distal end and by set screw **37** at the proximal end. After set screw **37** holds cable **46,** the remaining "tail" of cable **46** extending past set screw **37** can be cut close to or inside aperture **38.** In one embodiment, a cap may be placed over annular lip **38.**

[0041] In an **alternate embodiment,** a percutaneous method of spinal alignment, not belonging to the invention, requiring no incisions employs puncture wounds to facilitate the placement of deployable bone anchors into or across chosen spinal elements such that tensile forces can be applied to specific areas of the spine thereby facilitating spinal alignment.

[0042] To achieve these ends, a standard Jamshidi needle, with removable central stylet, is passed across a chosen spinal element, such as a vertebra, from a direct lateral or a posterolateral approach depending on the desirability of avoiding intervening muscles or other structures.

[0043] Figure 13 is a top view of inflatable balloon bone anchor **110** ("anchor **110**") which is a component of assembly **100** for performing a gradual alignment of a spine with one or more lateral curves according to the present invention. Substantially, assembly **100** comprises a percutaneous implantable device (see Figures 13 to 18B) and external leverage support B, B' (see Figures 16, 18A, 18B). The percutaneous implantable device comprises tube 112 having proximal end 116 and distal end 117, tube 112 is arranged to extend through a hole in vertebra 80 of the spine. The percutaneous implantable device also comprises cable 113 extending within tube 112, cable 113 secured to distal end 117 of tube 112. The percutaneous implantable device further comprises anchor tip 114a attached to cable 113 and inflatable balloon 114 secured to distal end 117 of tube 112 and arranged to inflate against an external surface of vertebra 80 and completely enclose anchor tip 114a. According to Figure 13, anchor **110** includes hollow tube **112** with inflatable balloon **114** attached at distal end **117** with fluid conduit **118** ("conduit **118"**) attached to proximal end **116.** Optionally, ports **118a** and **118b** extend from conduit **118** and receive the fluid(s) that may be used to inflate balloon **114** as explained below. Fluids may be introduced into tube **112** and balloon **114** through conduit **118.** Preferably, tube **112** and balloon **114** are fabricated from polyglycolic acid or other similar biologically compatible absorbable material which can withstand the tensile or pulling strain created on anchor **110** as describe below and will also resorb into the body well after the alignment procedure is completed.

[0044] Figure 14A is a cross section view of target vertebra **80** in which a Jamshidi needle **102** ("needle **102**") equipped with removable stylet **102a** is used to drill a hole into vertebra **80.** Inside needle **102** is the distal end **117** of tube **112** with uninflated balloon **114** contacting anchor tip **114a.** Cable **113** is seen extending through tube **112** and attached to anchor tip **114a.** Figure 14B is the same view as Figure 14A with stylet **102a** removed from needle **102** and needle **102** withdrawn over tube **112** and from around balloon **114** and tube **112.** In one embodiment, needle **102** is withdrawn before conduit **118** is attached to proximal end **116.** Figure 14C shows the initiation of the inflation of balloon **114** inside the cancellous material that forms the core of vertebra **80** while Figure 14D depicts the withdrawal of anchor tip **114a** resulting in the inflated balloon **114** creating and lining a cavity **82** to become embedded within the cancellous bone material.

[0045] Figures 14C and 14D depict the hydraulic inflation of balloon **114** wherein fluid is introduced through ports **118a** and/or **118b** and passes into balloon **114** through tube **112.** As fluid volume increases, balloon **114** increases in size to create cavity **82** in the cancellous material. For temporary anchor fixation, water or saline may be used to inflate balloon **114.** Permanent fixation may be achieved with hardenable materials such as bone putty or methyl methylacrylate (MMA) as is known to those having skill in the art.

[0046] Figure 15A depicts a second arrangement for attaching anchor **110** to vertebra **80.** Needle **102** is drilled through vertebra **80** to create a passage extending through opposing sides of vertebra **80.** Similar to the arrangement described above, it can be seen that anchor **110** is carried inside needle **102** during the drilling process. Figure 15B shows stylet **102a** removed and needle

102 withdrawn from around anchor **110** with balloon **114** starting to inflate. Figure 15C shows balloon **114** drawn against the side of vertebra **80** (distal side) opposing the side where tube **112** enters vertebra **80** (proximal side). Figure 15D depicts fully inflated balloon **114** drawn against vertebra **80.**

[0047] Figures 15B-15D depict an alternate embodiment apparatus for mechanically deploying balloon **114.** Array **114b** comprises a plurality of arms or vanes operatively attached to the inner surface of balloon **114** and pivotally attached to cable **113.** By operatively attached is meant that a component or device is connected either directly or indirectly to a second component and causes that second component to function. For example, each of the plurality of arms in array **114b** is operatively attached to the inner surface of balloon **114** and causes balloon **114** to open. When cable **113** is pulled, the arms of array **114b** each open causing balloon **114** to inflate. Array **114b** may be used to open balloon **114** when greater pulling or traction forces are necessary during the aligning process as explained below. It will be recognized that the mechanical inflation arrangement may be used to form cavity **82** and embed balloon **114** as seen in Figures 14C and 14D. Conversely, the

hydraulic arrangement described above may be used to inflate balloon **114** and draw it toward vertebra **80** as seen in Figures 15C and 15D.

[0048] Figure 16 is a schematic front view of anchor **110** attached to an external leverage support **B** to form assembly **100** according to the invention. Assembly 100 for performing a gradual spinal alignment according to the present invention also comprises external leverage support B, B' (see also Figures 18A, 18B) releasably attached to proximal end 116 of tube 112 passing percutaneously with its proximal end 116 to external leverage support B, B', wherein when inflatable balloon 114 is inflated, cable 113 and inflated balloon 114 are arranged for pulling vertebra 80 towards external leverage support B, B'. According to Figure 16, in the front view shown, tube **112** extends through vertebra **80** with inflatable balloon **114** drawn against side of vertebra **80** on the convex side of the lateral curve of the spinal column. After balloon **114** is inflated, tube **112** is releasably attached to external leverage support B, in this case external body brace ("brace **B"**) similar to that seen in Figure 1 and otherwise described above. Proximal end **116** is attached to brace **B.** To effect the attachment outside the body, a small incision may be made to pass tube **112** through the skin and releasably attach it to brace **B.** Attachment may be made similar to that seen above with assembly **10** in which cable **46** is pulled and tied against stabilizing bar **30.** Pulling tools such as come alongs, winches, pliers, etc. attached to proximal end **116** may be used.

[0049] Because the attachment to vertebra **80** is percutaneous and reversible, multiple points of attachment can be selected to resolve multiple curve issues as well as to spread corrective force over more than target vertebra **80** so that excessive force on a single cable is not required. Partial external braces **B** may be used opposite each series assemblies **100** to direct the required pulling force more precisely. This provides the advantage of obviating the need for the large external braces presently in use. In a preferred embodiment, the braces may have movable pads or points of contact to prevent applying the pulling force at the same site on the skin.

[0050] Figure 17 is a cross section view of bone screw **120** embedded into vertebra **80** and attached to strut **122.** This bone screw-strut construction **130** ("construction **130**") can be used to apply pushing force on the lateral curve by being turning strut **122,** which is attached to brace **B',** toward embedded bone screw **120,** thereby pushing the lateral curve into alignment. Preferably, bone screw **120** is attached to strut **122** by a hinge or other polyaxial connection to allow different vector angles of force to be applied to bone screw **120** as is pushes on the lateral curve.

[0051] Figure 18A is a schematic view of the use of two assemblies **100** to pull the spinal column into alignment. It can be seen that anchors **110** are attached to vertebrae **80** with balloons **114** contacting vertebrae **80** on the convex side of the lateral curve. This arrangement provides the advantage of reducing the forces applied to the components bone anchor **110** as well as to the spinal column itself.

[0052] Figure 18B depicts schematically the use of the bone screw construction **130** with one or more assemblies **100** to combine both pulling and pushing forces to apply corrective forces on both sides of the lateral curve. Construction **130** is attached to brace **B'** on the opposite side of the spine from assembly **100.** It will be recognized that brace **B'** may be the same or a different external support than support **B** attached to assembly **100.** Bone screw **120** may be used to push the lateral curve into alignment by screwing strut **122,** threadably attached to brace **B',** toward the convex side of the lateral curve thereby pushing it into alignment. Figure 18B also shows two assemblies **100** pulling two portions of the same lateral curve into alignment demonstrating the attachment of assembly **100** to multiple points on the spine.

[0053] Assembly(ies) **100** are used in a manner similar to that used for assembly **10** described above. With anchor **110** attached to target vertebra **80,** and proximal end **116** attached to brace **B,** tube **112** is pulled toward brace **B** to pull the lateral curve closer to alignment. After the pulling process, tube **112** is attached to brace **B** in such a way as to hold catheter **110** in the pulled position, thereby holding the lateral curve in its new position closer to the desired alignment. The pulling process and the results of the pulling process can be observed with MRI, x-rays, etc. to determine how much to pull catheter **110** each time. By repeating the "pull-tie off' process, the lateral curve can gradually be brought into or closer to alignment without disrupting surrounding tissue and nerves. Similarly, bone construction **130** may supplement assembly(ies) **100** to gradually push the spine into the desired alignment

[0054] Once the desired spinal alignment had been achieved over a period of time, much like braces are used to align teeth, the spine can be fused using endoscopic techniques and the deployed anchors can be contracted and removed or dissolve into the body. Alternatively, percutaneous alignment could be maintained until skeletal maturity is reached, potentially obviating the need for surgery entirely.

[0055] Thus it is seen that the object of the invention is efficiently obtained, although changes and modifications to the invention should be readily apparent to those having ordinary skill in the art, which changes would not depart from the scope of the invention as claimed.

Claims

1. An assembly (100) for performing a gradual spinal alignment comprising:

   a percutaneous implantable device comprising:

   a tube (112) having a proximal end (116) and a distal end (117), the tube (112) arranged to extend through a hole in a vertebra (80) of the spine;
   a cable (113) extending within the tube (112), the cable (113) secured to the distal end (117) of the tube (112);
   an anchor tip (114a) attached to the cable (113); and
   an inflatable balloon (114) secured to the distal end (117) of the tube (112) and arranged to inflate against an external surface of the vertebra (80) and completely enclose the anchor tip (114a);

   the assembly (100) further comprising:
   an external leverage support (B, B') releasably attached to the proximal end (116) of the tube (112) passing percutaneously with its proximal end (116) to the external leverage support (B, B'), wherein when the inflatable balloon (114) is inflated, the cable (113) and inflated balloon (114) are arranged for pulling the vertebra (80) towards the external leverage support (B, B').

2. The assembly (100) recited in Claim 1, further comprising a pulling device (60) attached to the proximal end (116) of the tube (112).

3. The assembly (100) recited in Claim 2, wherein the pulling device (60) is pliers.

4. The assembly (100) recited in Claim 2, wherein the pulling device (60) is a winch.

5. The assembly (100) recited in Claim 2, wherein the pulling device (60) is a screw jack.

6. The assembly (100) recited in Claim 2, wherein the pulling device (60) is a come-along.

7. The assembly (100) recited in Claim 1, wherein the tube (112) is fabricated from polyglycolic acid.

8. The assembly (100) recited in Claim 1, wherein the inflatable balloon (114) is inflated hydraulically.

9. The assembly (100) recited in Claim 1, wherein the inflatable balloon (114) is inflated mechanically.

Patentansprüche

1. Eine Anordnung (100) zum Durchführen einer allmählichen Wirbelsäulenausrichtung, umfassend:

   ein Rohr (112), das ein proximales Ende (116) und ein distales Ende (117) aufweist, wobei das Rohr (112) so angeordnet ist, dass es durch ein Loch in einem Wirbel (80) der Wirbelsäule verläuft;
   ein Seil (113), das im Rohr (112) verläuft, wobei das Seil (113) am distalen Ende (117) des Rohrs (112) sicher befestigt ist;
   eine Ankerspitze (114a), die am Seil (113) befestigt ist; und
   einen aufblasbaren Ballon (114), der am distalen Ende (117) des Rohrs (112) sicher befestigt ist und so angeordnet ist, dass er sich gegen eine Außenfläche des Wirbels (80) aufbläst und die Ankerspitze (114a) vollständig umschließt;
   wobei die Anordnung (100) ferner aufweist:
   eine externe Gestängestütze (B, B'), die am proximalen Ende (116) des Rohrs (112), das mit seinem proximalen Ende (116) perkutan zur externen Gestängestütze (B, B') verläuft, lösbar befestigt ist, wobei, wenn der aufblasbare Ballon (114) aufgeblasen ist, das Seil (113) und der aufgeblasene Ballon (114) so angeordnet sind, dass sie den Wirbel (80) zur externen Gestängestütze (B, B') hin ziehen.

2. Die Anordnung (100) nach Anspruch 1, ferner aufweisend eine Zugvorrichtung (60), die am proximalen Ende (116) des Rohrs (112) befestigt ist.

3. Die Anordnung (100) nach Anspruch 2, wobei die Zugvorrichtung (60) eine Zange ist.

4. Die Anordnung (100) nach Anspruch 2, wobei die Zugvorrichtung (60) eine Winde ist.

5. Die Anordnung (100) nach Anspruch 2, wobei die Zugvorrichtung (60) eine Schraubenwinde ist.

6. Die Anordnung (100) nach Anspruch 2, wobei die Zugvorrichtung (60) ein Greifzug ist.

7. Die Anordnung (100) nach Anspruch 1, wobei das Rohr (112) aus Polyglykolsäure hergestellt ist.

8. Die Anordnung (100) nach Anspruch 1, wobei der aufblasbare Ballon (114) hydraulisch aufgeblasen wird.

9. Die Anordnung (100) nach Anspruch 1, wobei der aufblasbare Ballon (114) mechanisch aufgeblasen wird.

Revendications

1. Un assemblage (100) pour effectuer un alignement progressif de la colonne vertébrale comprenant:

un tube (112) ayant une extrémité proximale (116) et une extrémité distale (117), le tube (112) étant agencé pour traverser un trou dans une vertèbre (80) de la colonne vertébrale;
un câble (113) s'étendant à l'intérieur du tube (112), le câble (113) étant fixé à l'extrémité distale (117) du tube (112);
une pointe d'ancrage (114a) fixée au câble (113); et
un ballon gonflable (114) fixé à l'extrémité distale (117) du tube (112) et agencé pour se gonfler contre une surface externe de la vertèbre (80) et envelopper complètement la pointe d'ancrage (114a);
l'assemblage (100) comprenant en outre:
un support de levier externe (B, B') fixé de manière amovible à l'extrémité proximale (116) du tube (112) passant par voie percutanée avec son extrémité proximale (116) au support de levier externe (B, B'), le câble (113) et le ballon gonflé (114) étant disposés pour tirer la vertèbre (80) vers le support externe (B, B') lorsque le ballon gonflable est gonflé.

2. L'assemblage (100) selon la revendication 1, comprenant en outre un dispositif de traction (60) fixé à l'extrémité proximale (116) du tube (112).

3. L'assemblage (100) selon la revendication 2, dans lequel le dispositif de traction (60) est une pince.

4. L'assemblage (100) selon la revendication 2, dans lequel le dispositif de traction (60 est un treuil.

5. L'assemblage (100) selon la revendication 2, dans lequel le dispositif de traction (60) est un vérin à vis.

6. L'assemblage (100) selon la revendication 2, dans lequel le dispositif de traction (60) est un tirfor.

7. L'assemblage (100) selon la revendication 1, dans lequel le tube (112) est fabriqué à partir d'acide polyblycolique.

8. L'assemblage (100) selon la revendication 1, dans lequel le ballon gonflable (114) est gonflé hydrauliquement.

9. L'assemblage (100) selon la revendication 1, dans lequel le ballon gonflable (114) est gonflé mécaniquement.

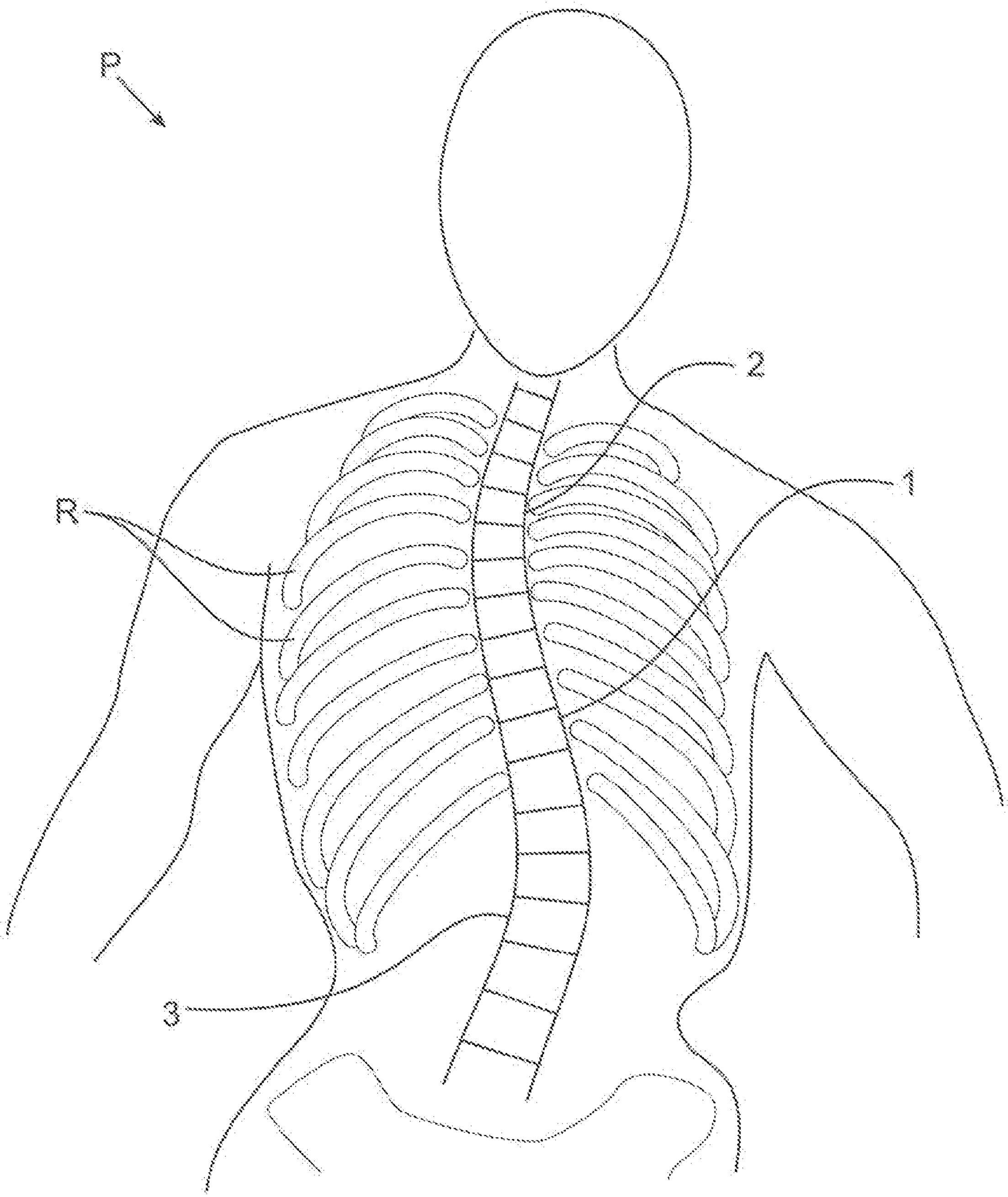

Fig. 1

Prior Art

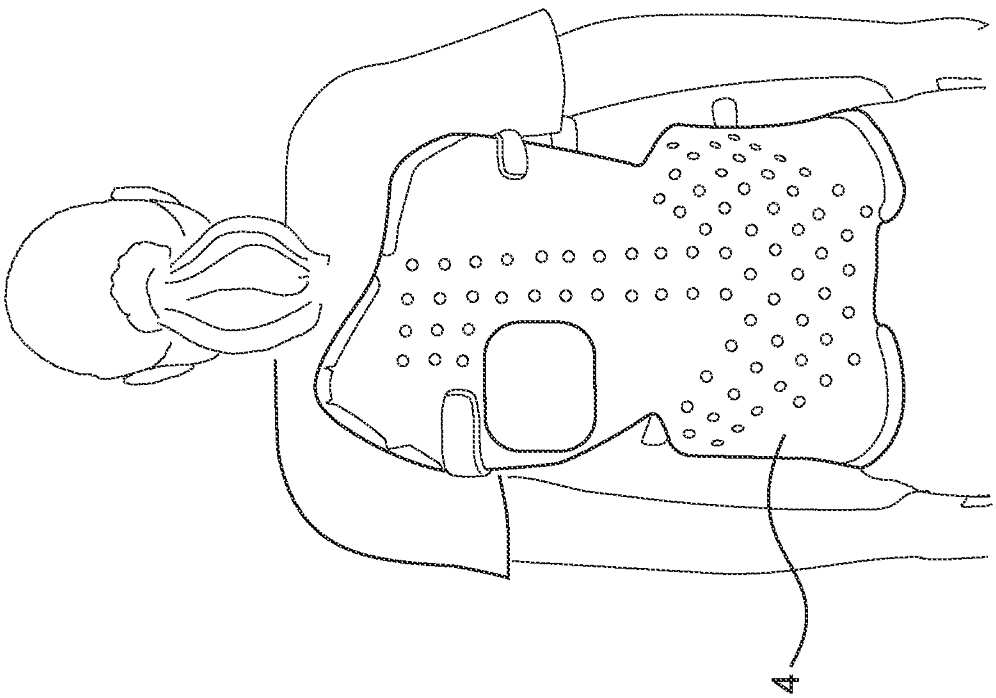

Fig. 2A

Prior Art

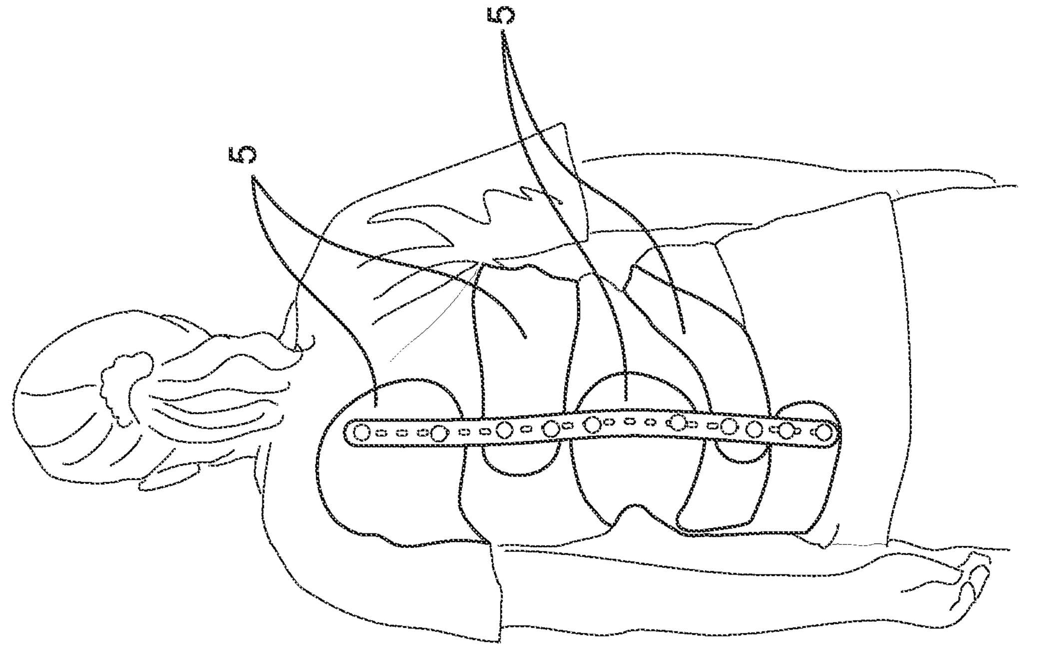

Fig. 2B

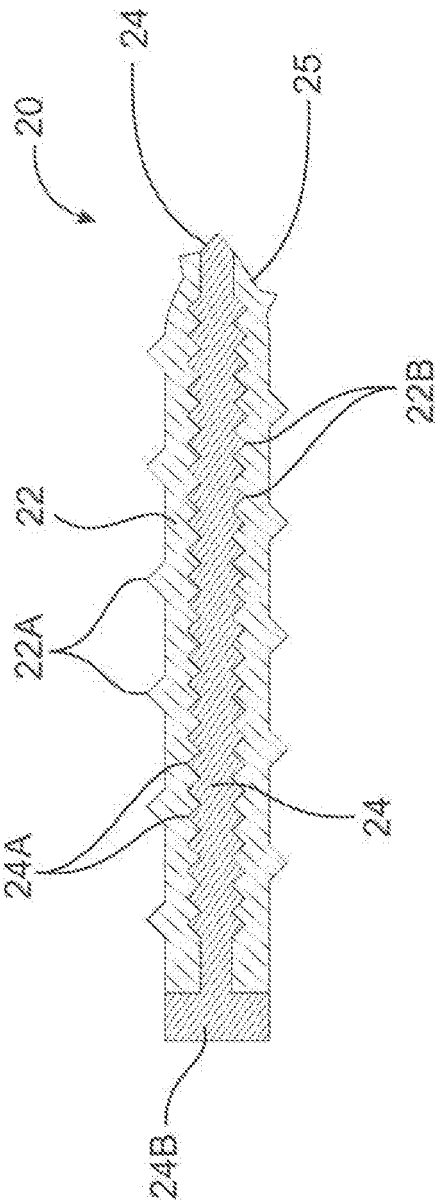

Fig. 3

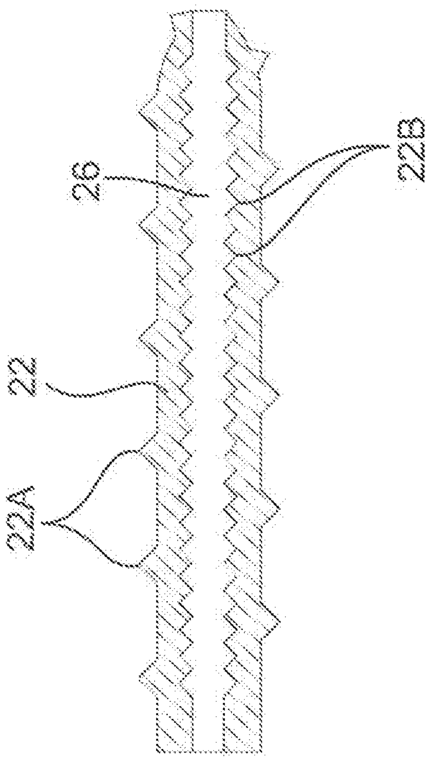

Fig. 4A

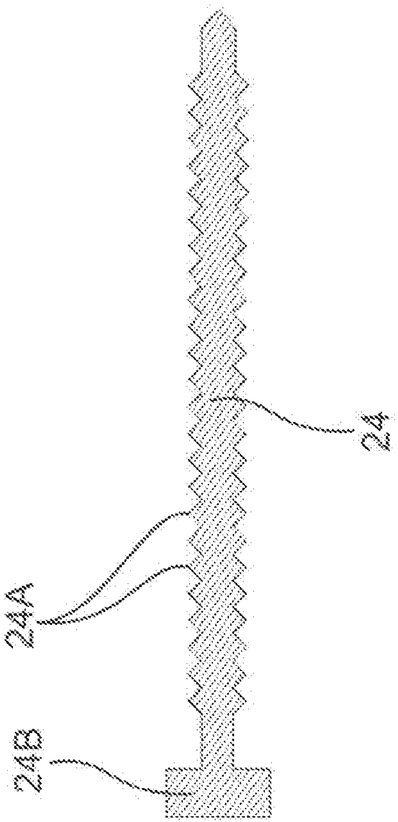

Fig. 4

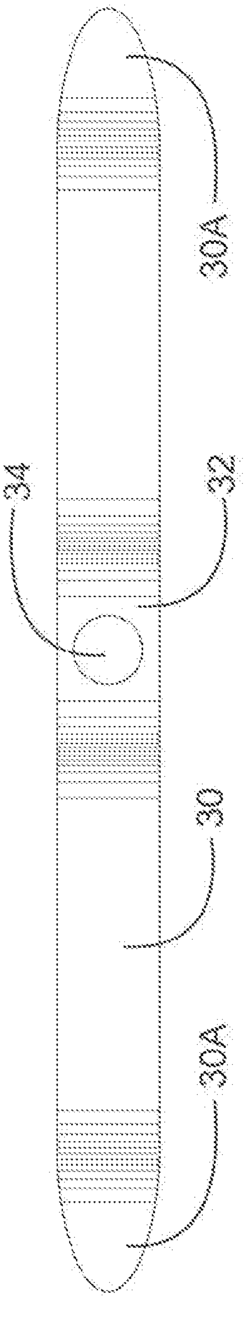

Fig. 5A

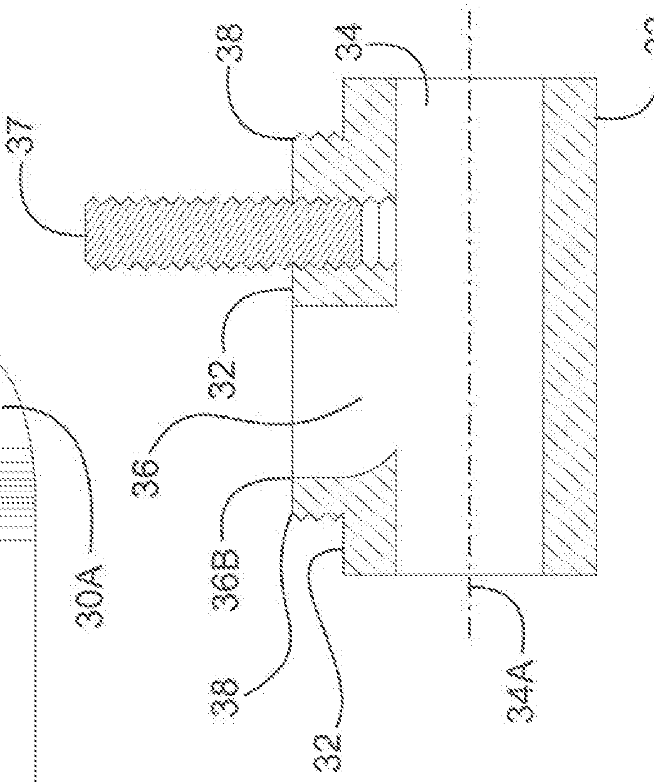

Fig. 5C

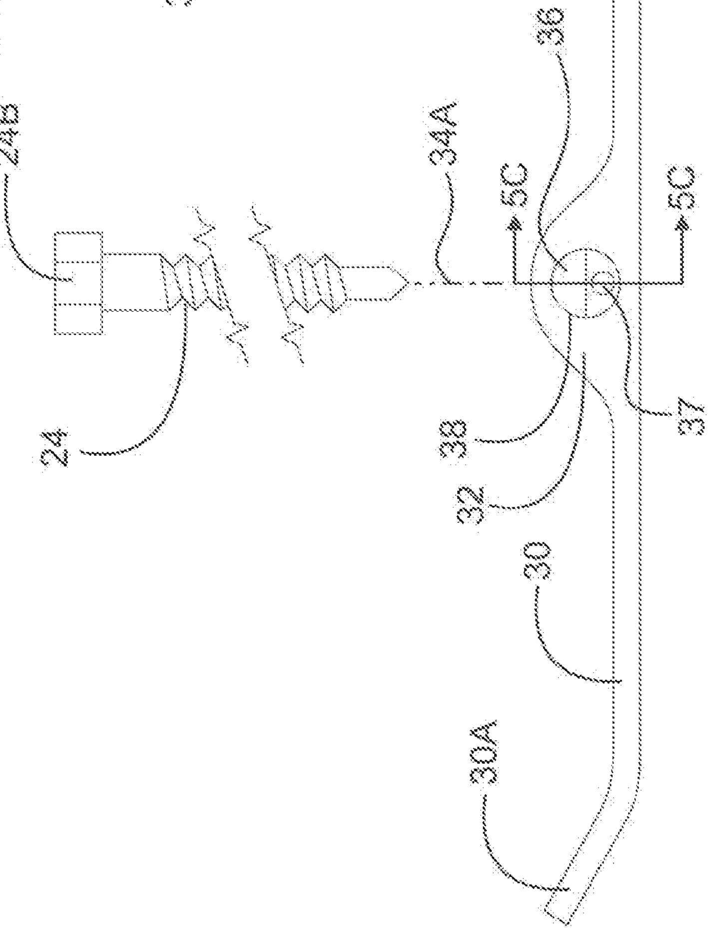

Fig. 5B

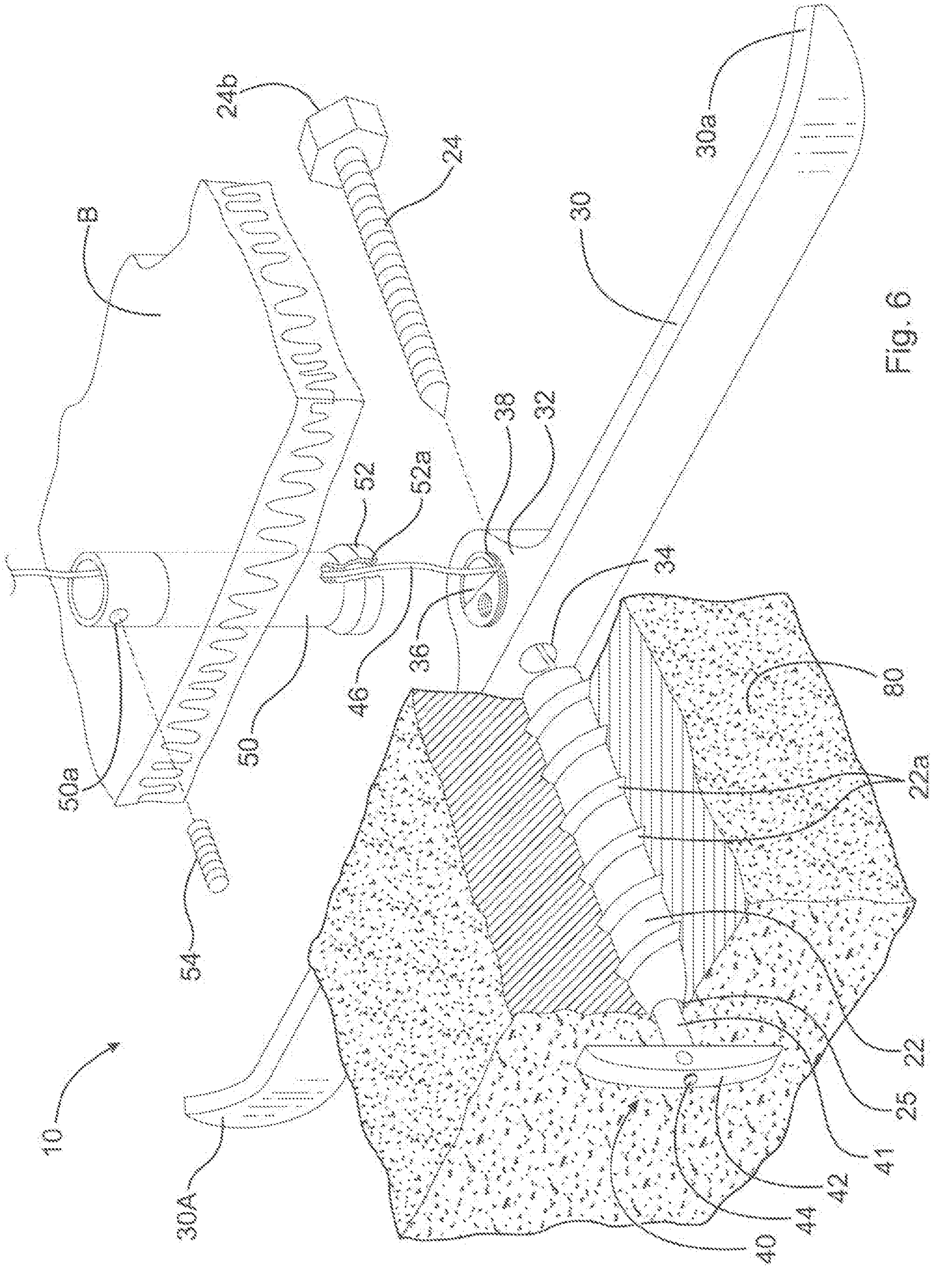
10
30A
54
50a
B
50
46
36
52
52a
38
32
34
24
24b
30
30a
80
22a
22
25
41
42
44
40

Fig. 6

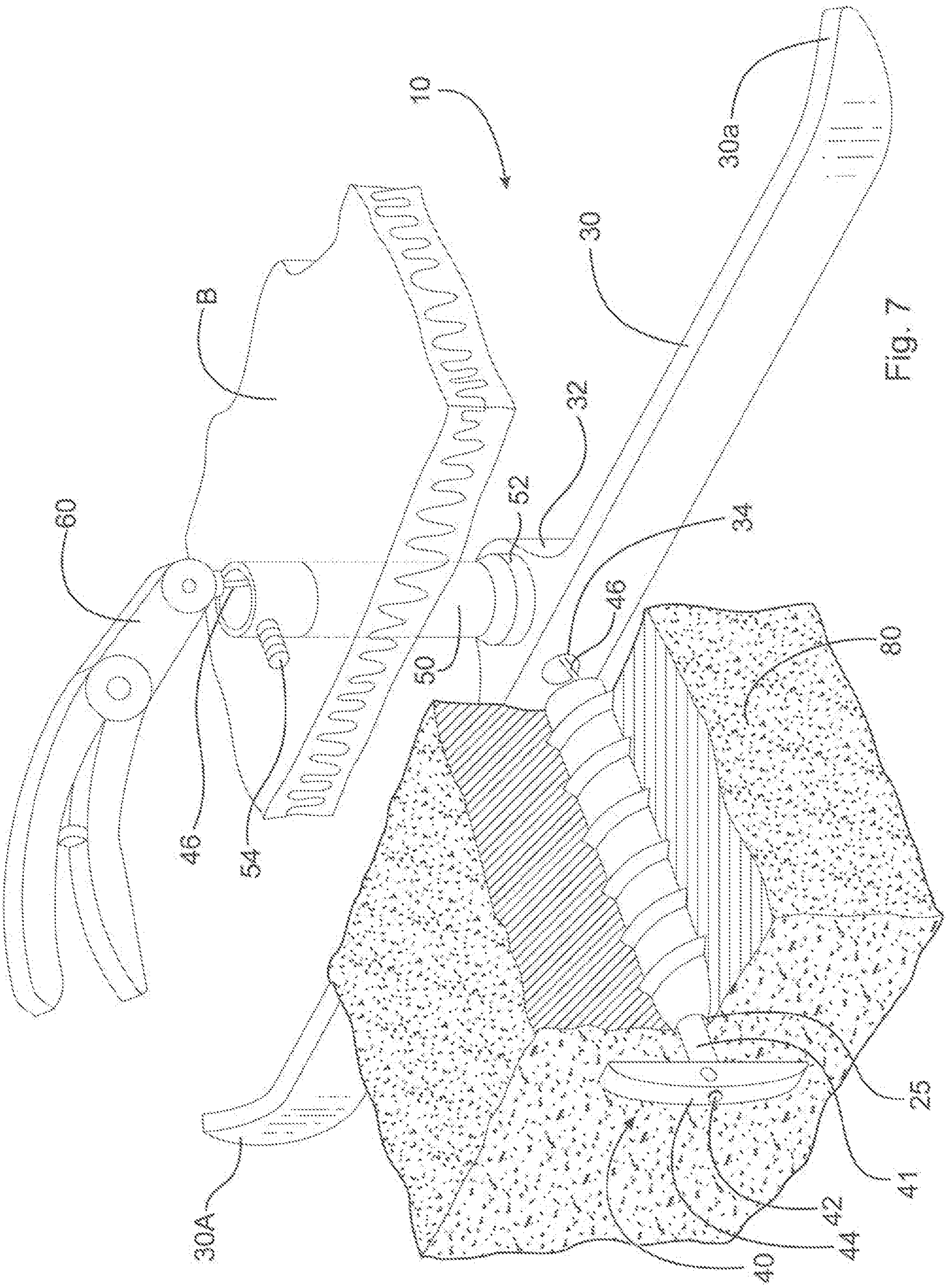

Fig. 7

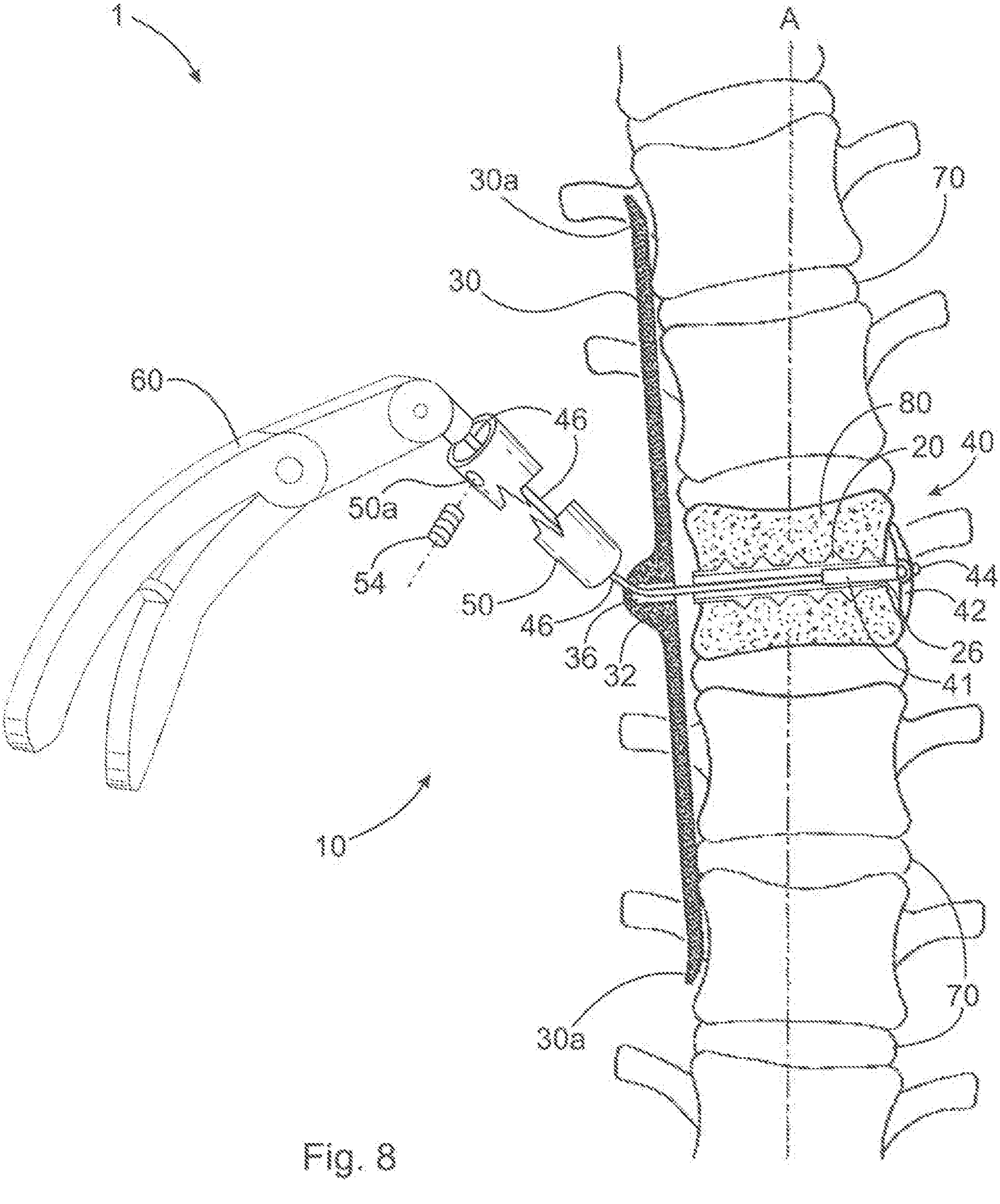

Fig. 8

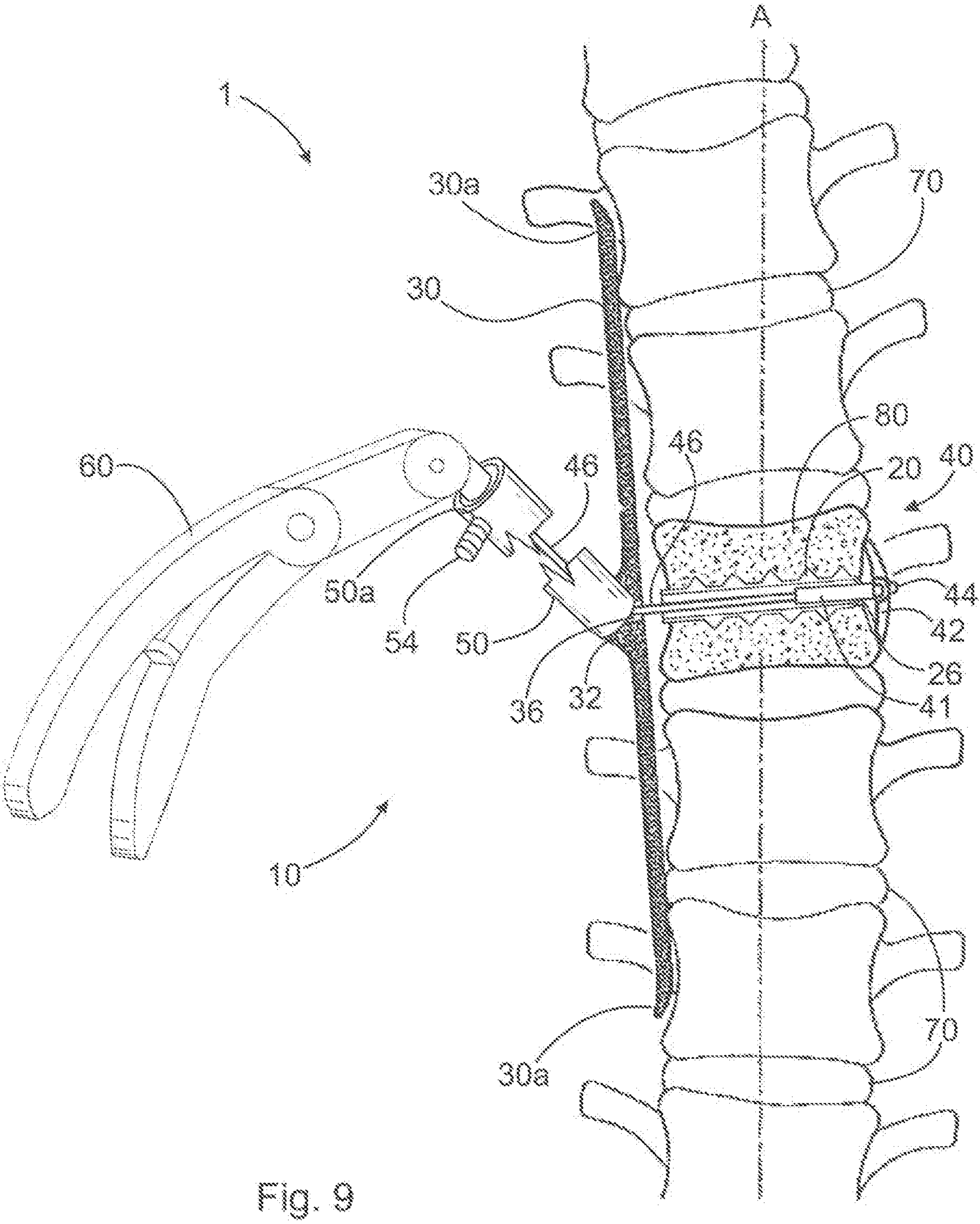

Fig. 9

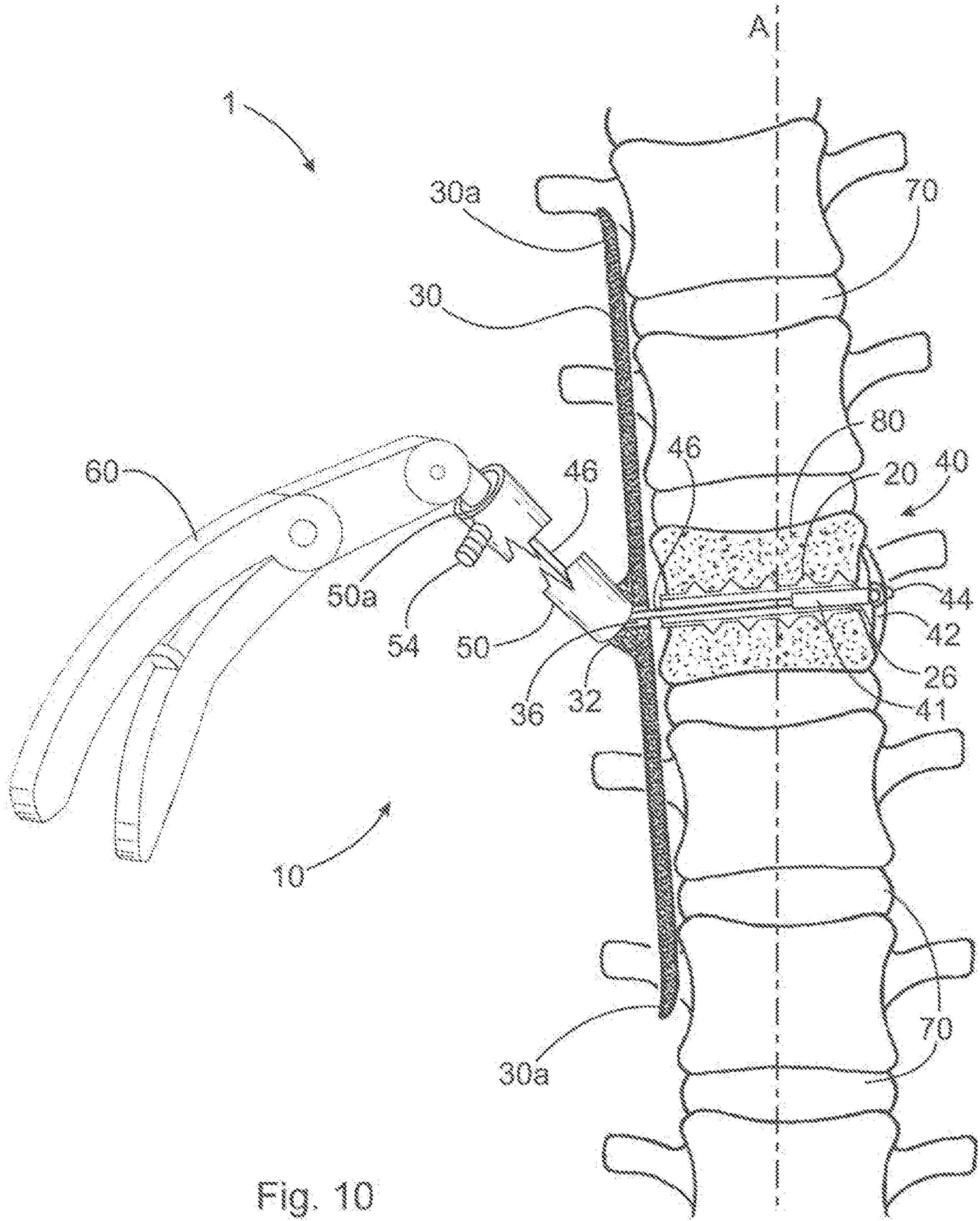

Fig. 10

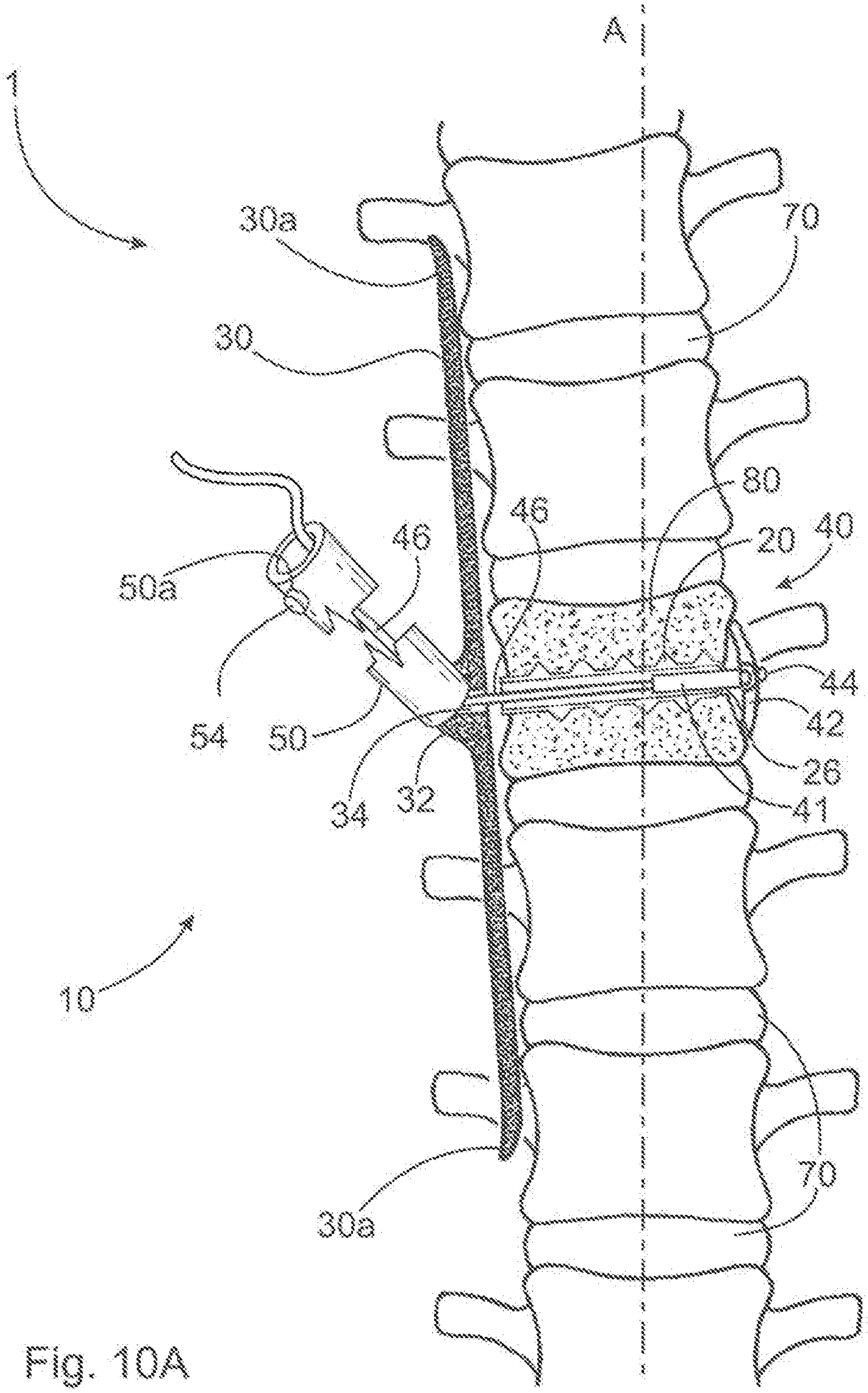

Fig. 10A

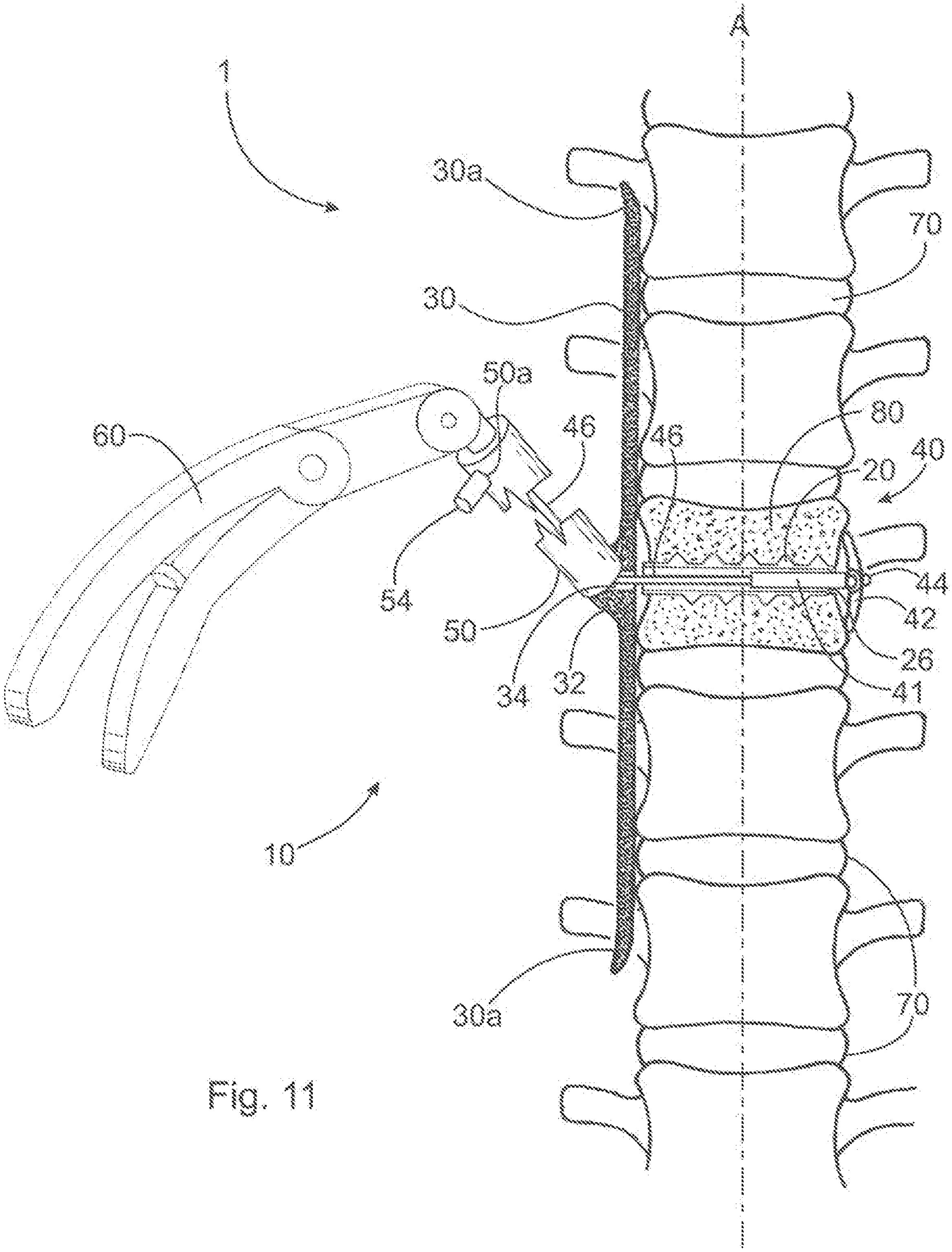

Fig. 11

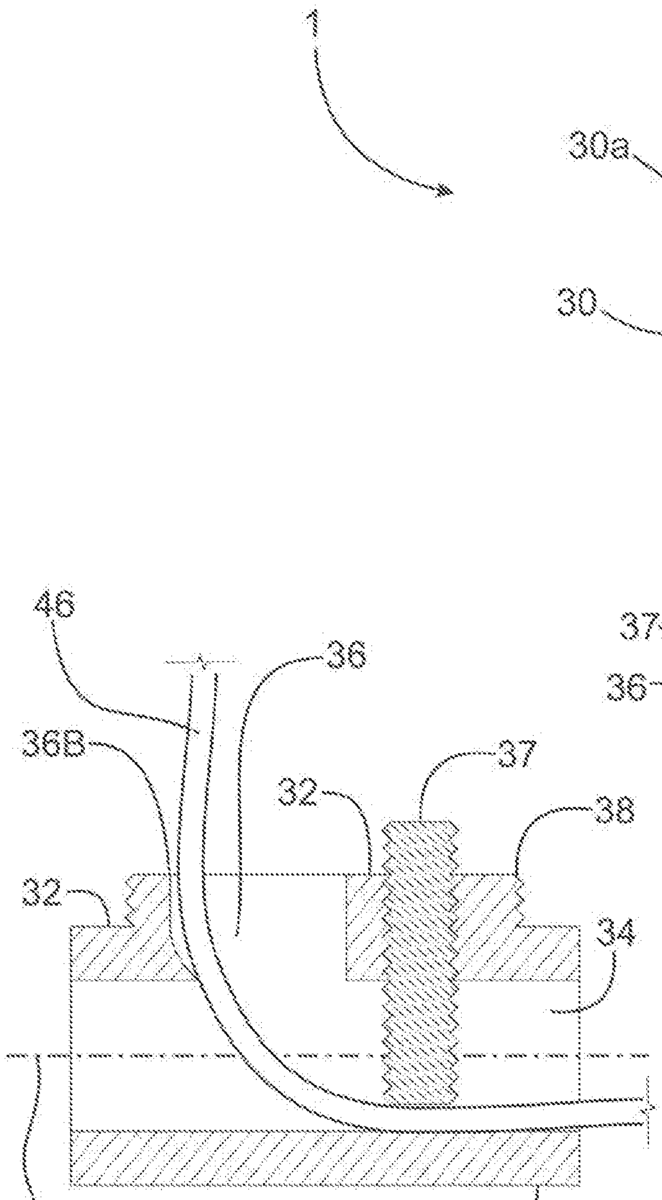

Fig. 12A

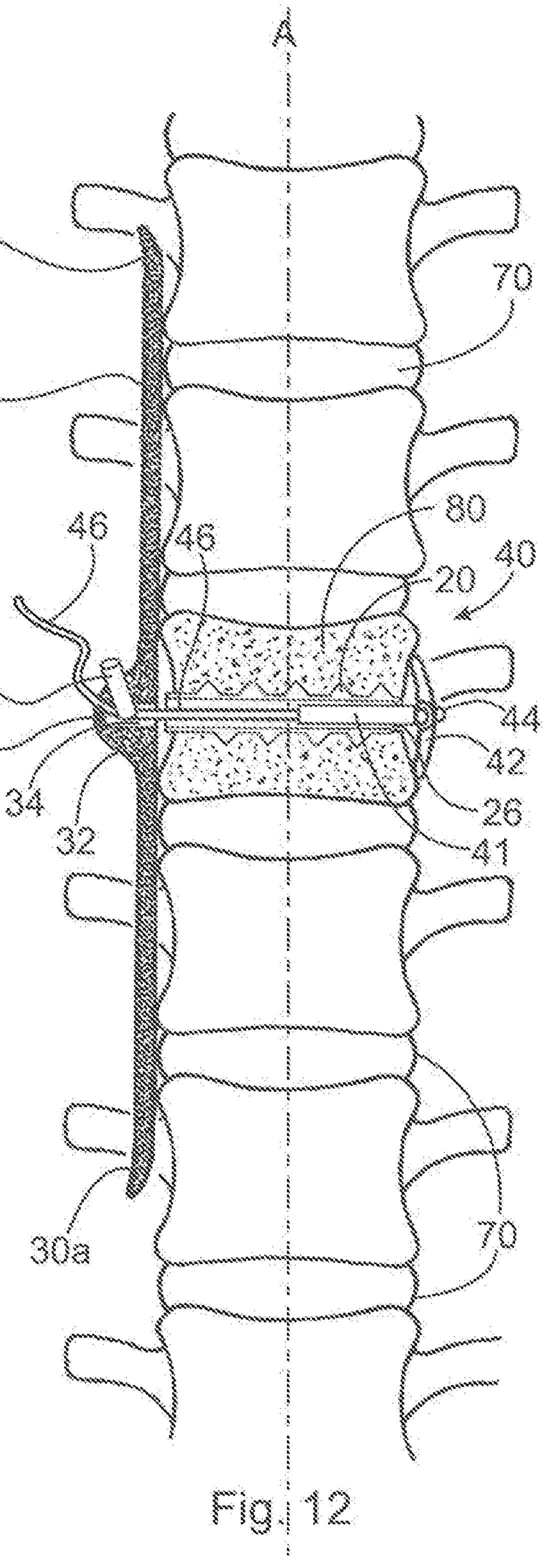

Fig. 12

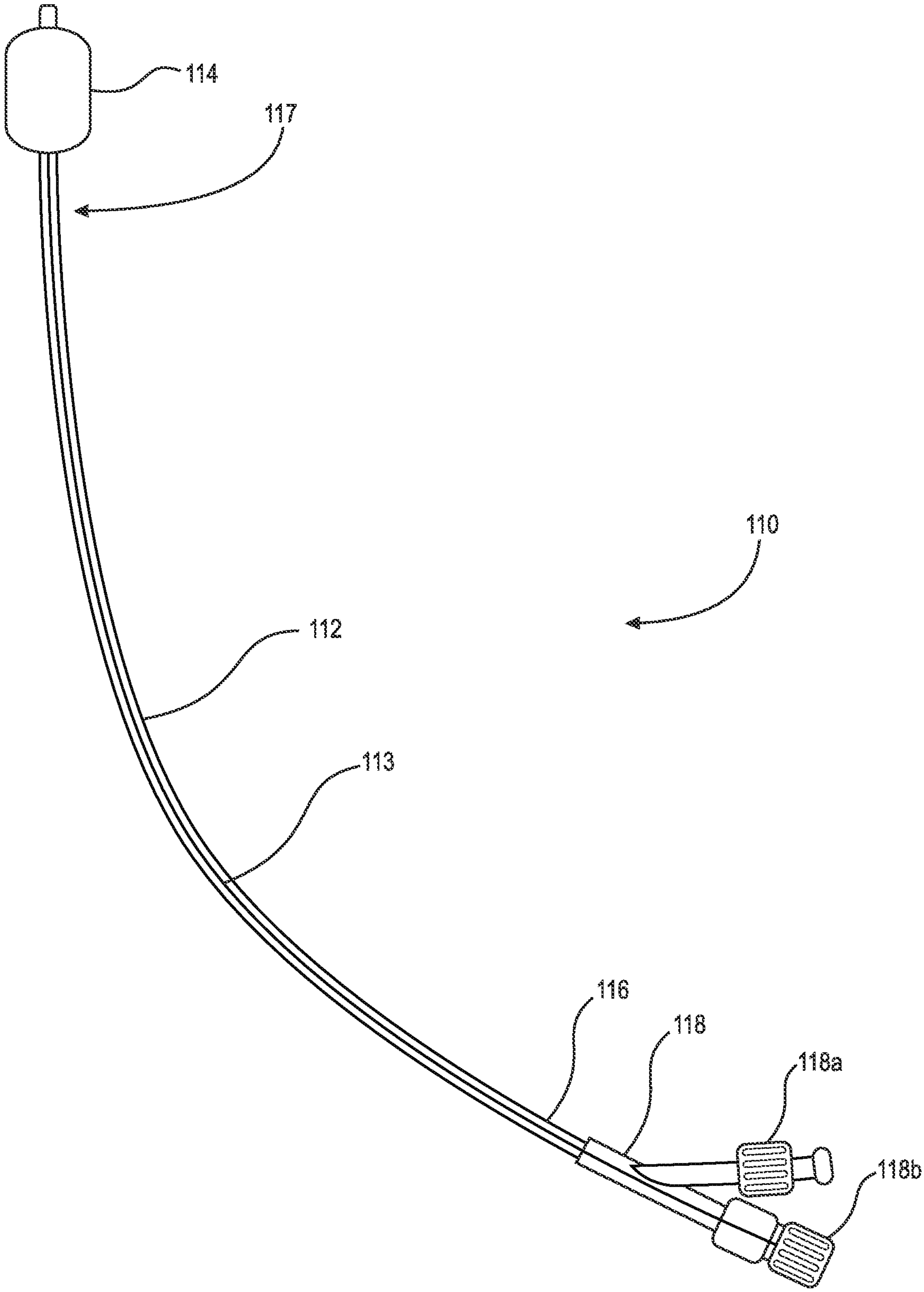

Fig. 13

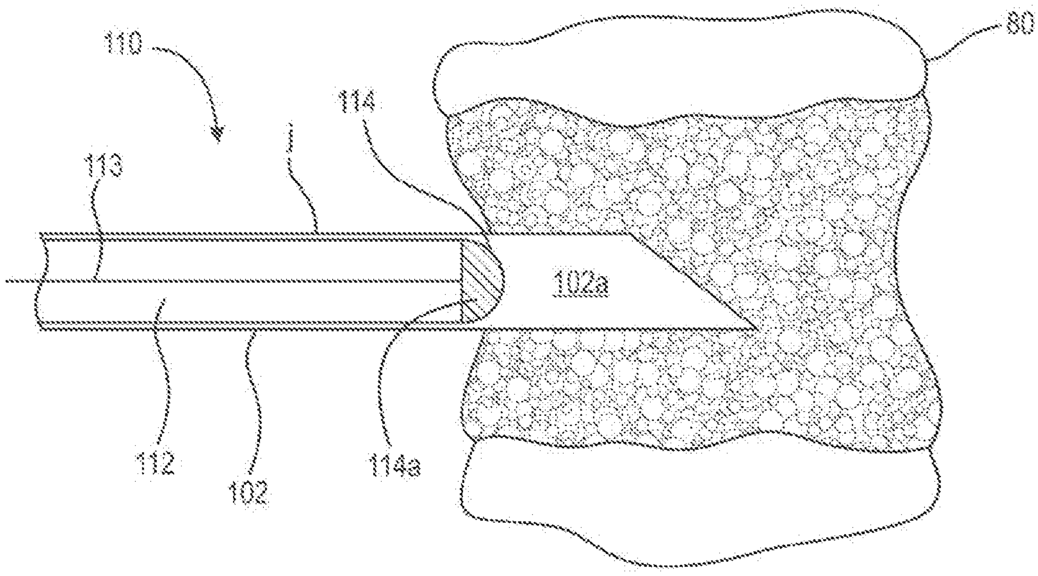

Fig. 14A

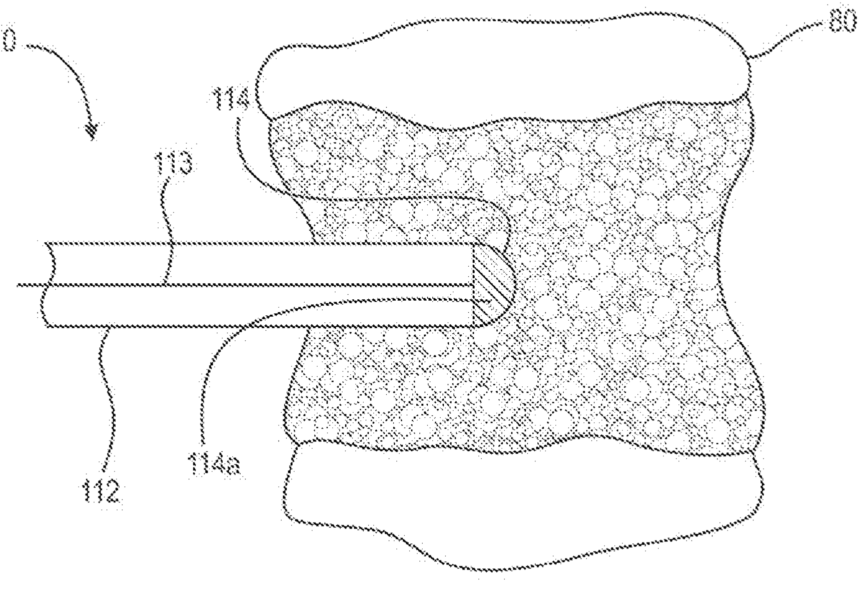

Fig. 14B

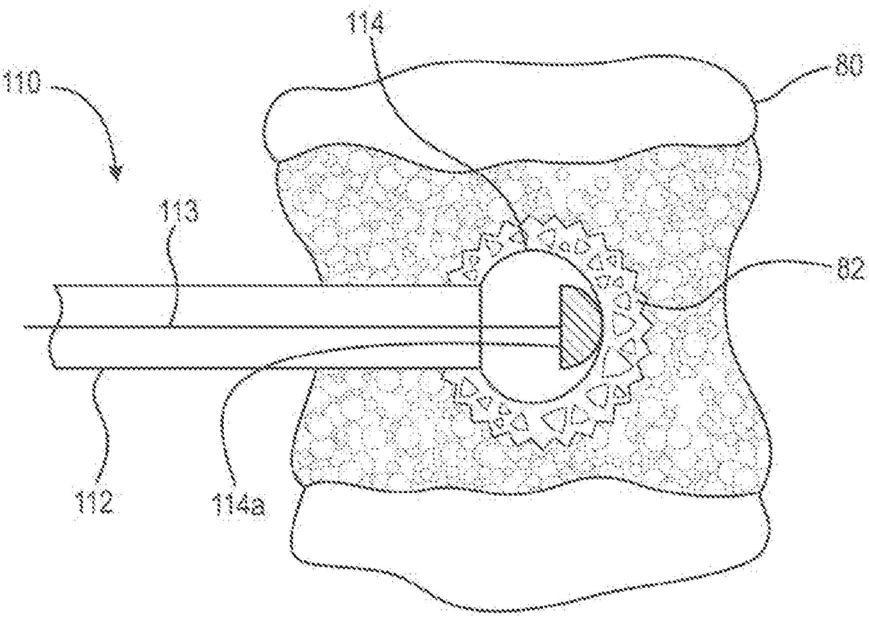

Fig. 14C

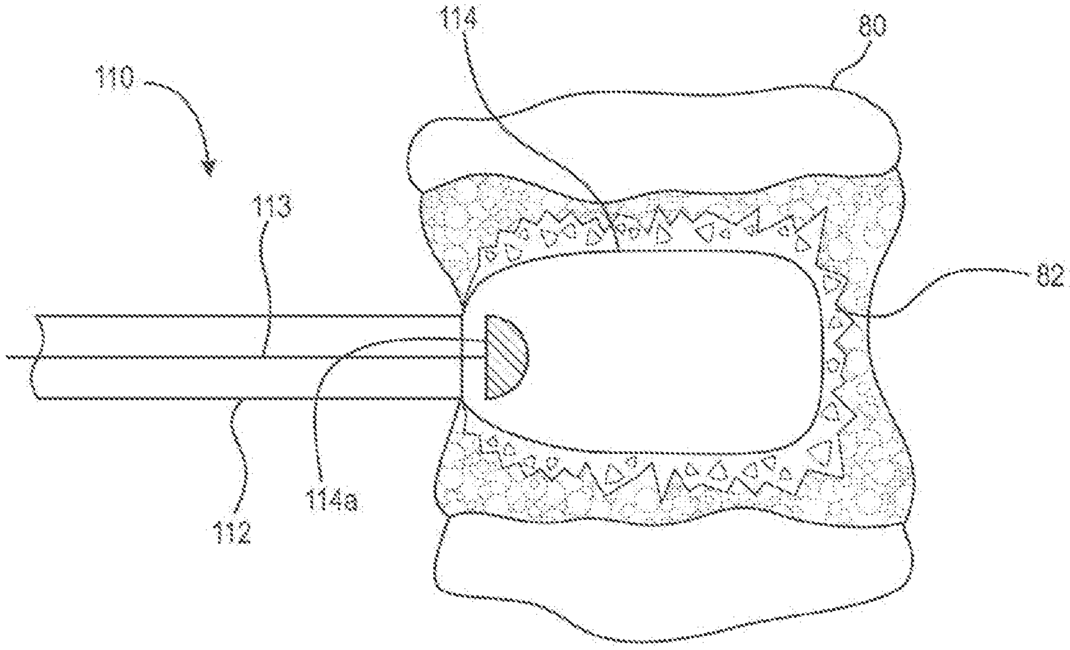

Fig. 14D

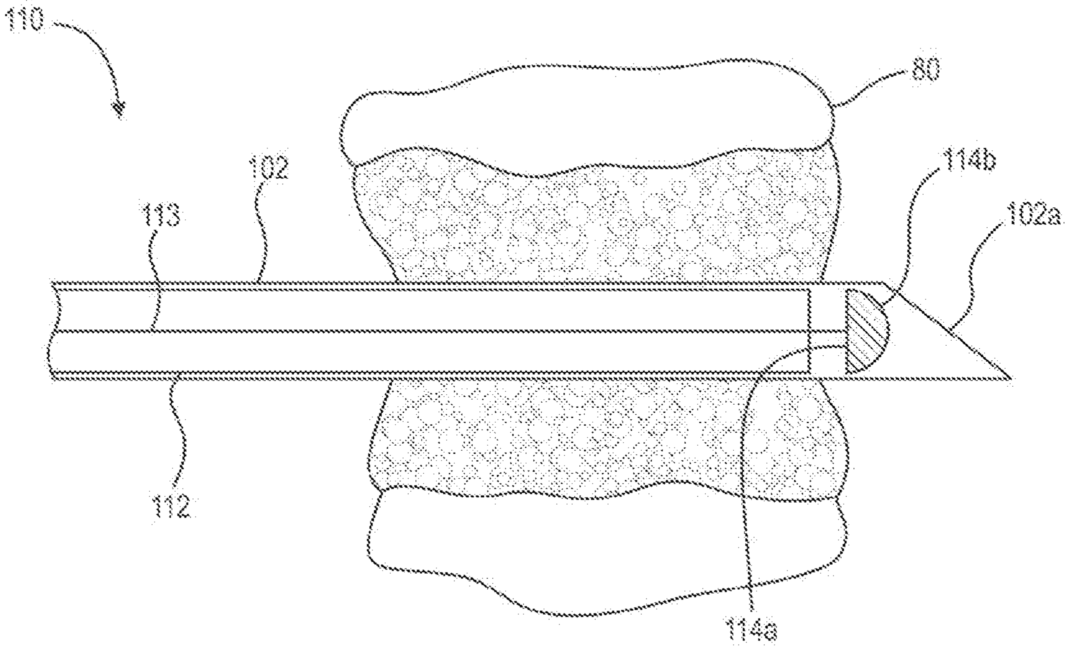

Fig. 15A

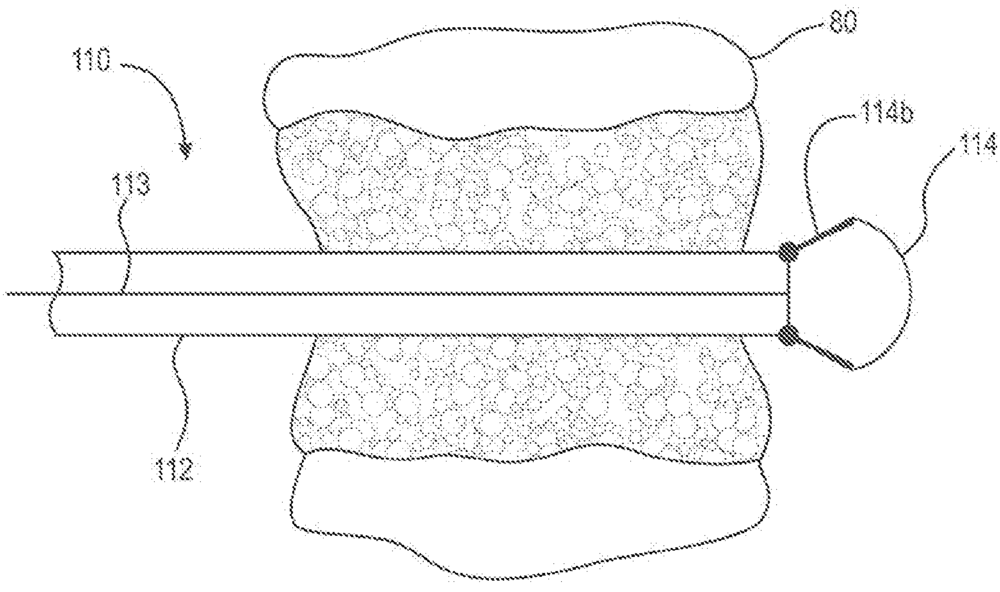

Fig. 15B

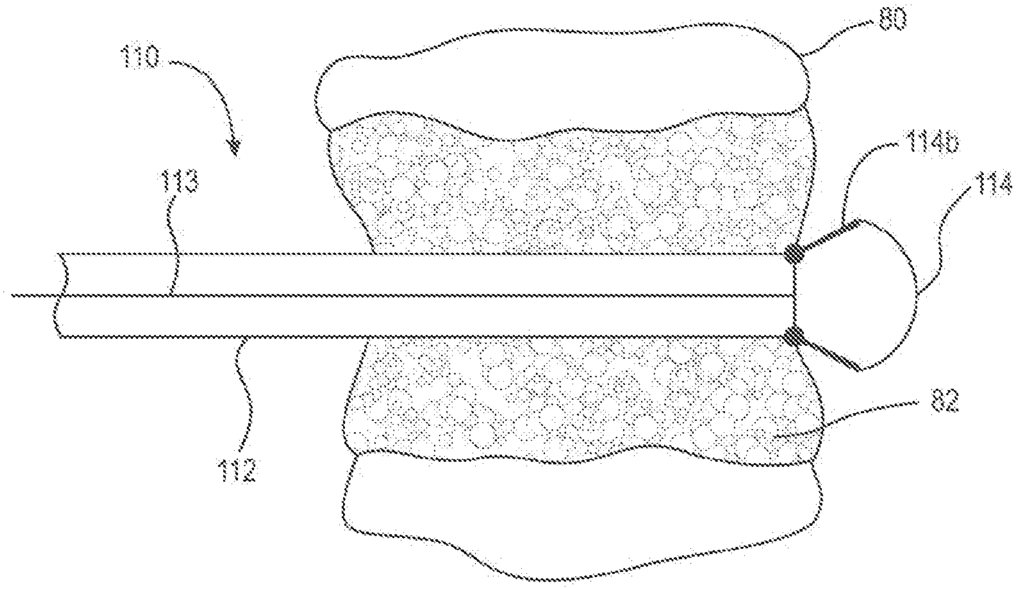

Fig. 15C

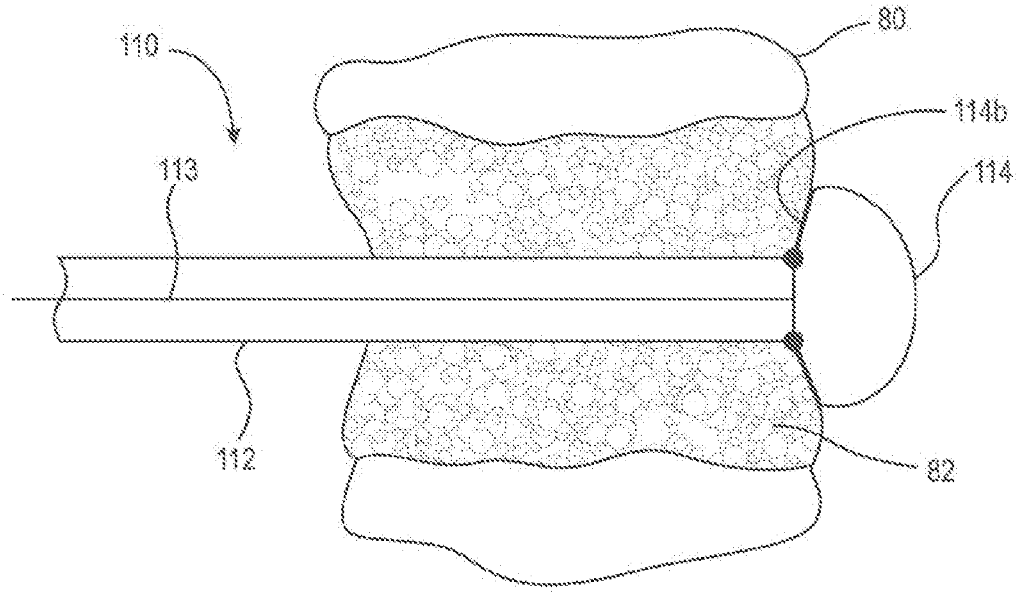

Fig. 15D

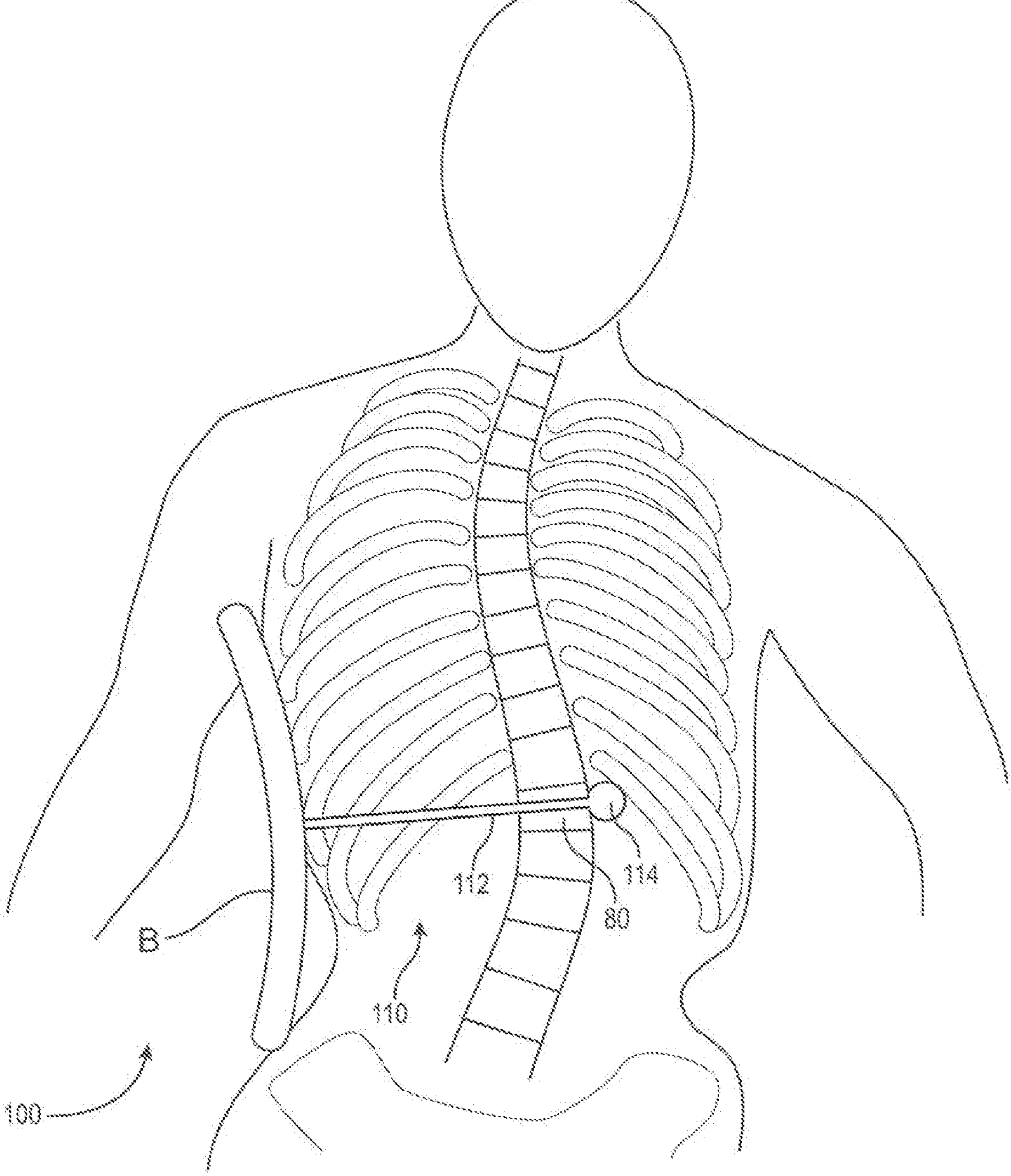

Fig. 16

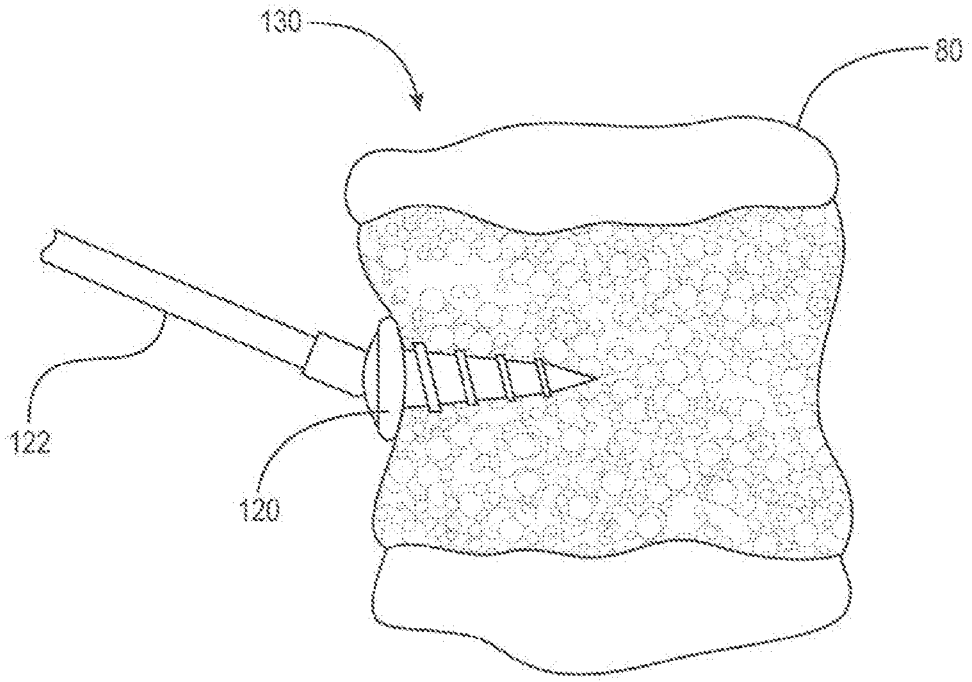

Fig. 17

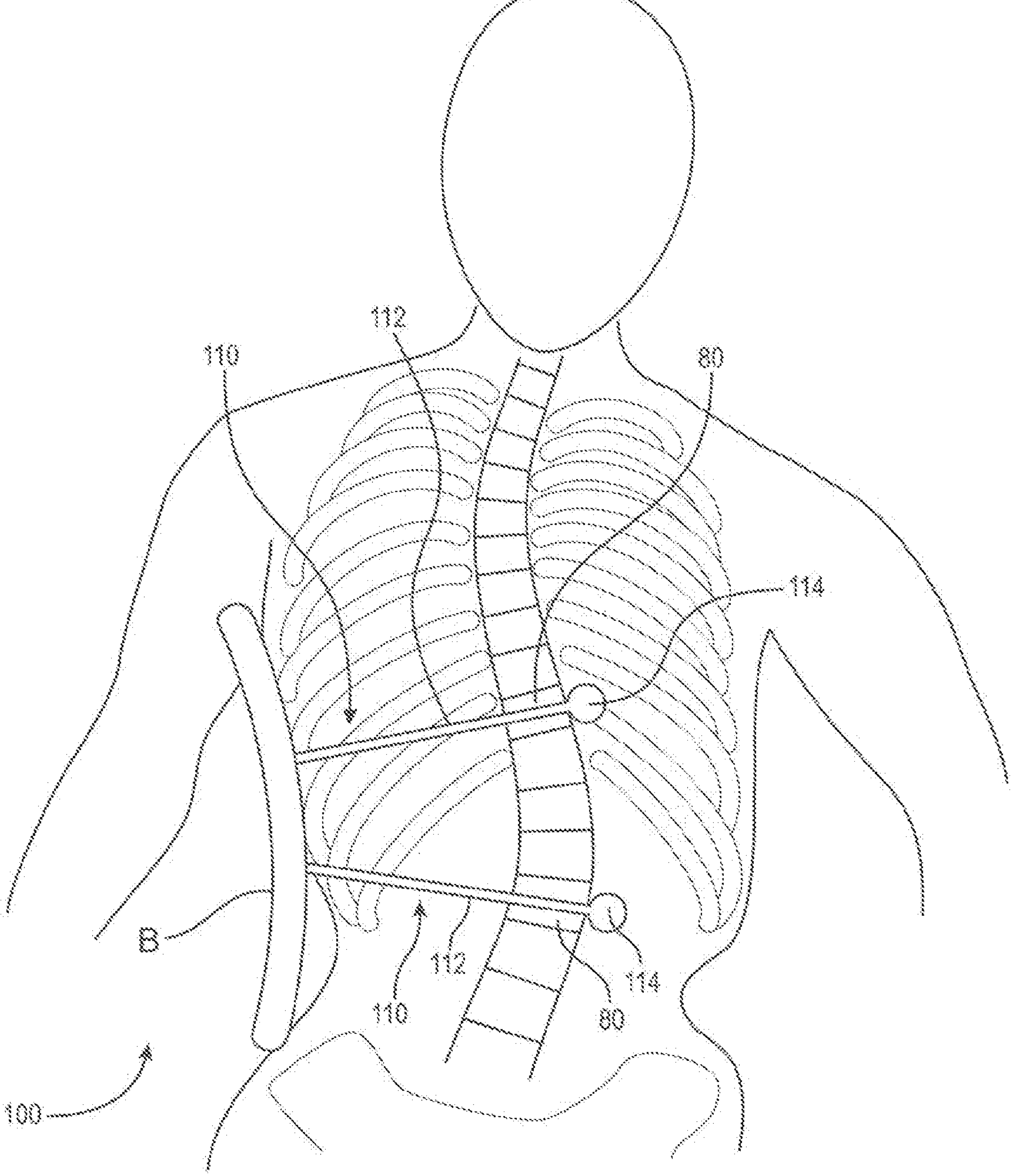

Fig. 18A

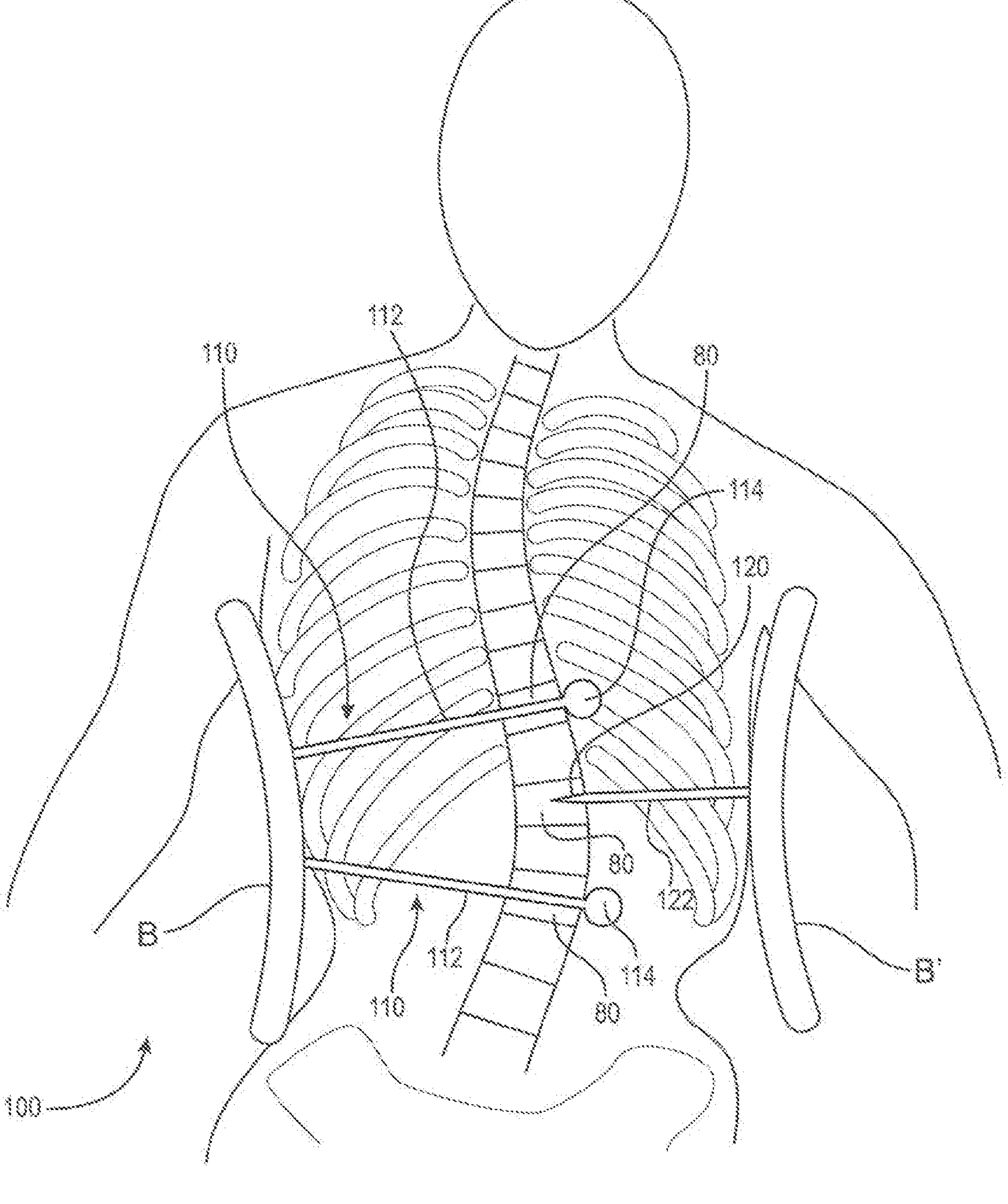

Fig. 18B

REFERENCES CITED IN THE DESCRIPTION

This list of references cited by the applicant is for the reader's convenience only. It does not form part of the European patent document. Even though great care has been taken in compiling the references, errors or omissions cannot be excluded and the EPO disclaims all liability in this regard.

Patent documents cited in the description

- US 20060195090 A **[0007]**
- US 6551320 B, Lieberman **[0008]**
- US 20090112262 A, Pool **[0008]**
- US 5782831 A, Sherman **[0009]**
- US 2009012565 A1 **[0010]**