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(54) **SUBCUTANEOUS IMPLANTABLE DEVICE FOR GRADUALLY ALIGNING A SPINE AND SUBCUTANEOUS IMPLANTABLE DEVICE FOR GRADUALLY LENGTHENING A BONE**

SUBKUTAN IMPLANTIERBARE VORRICHTUNG ZUR STUFENWEISEN AUSRICHTUNG EINER WIRBELSÄULE UND SUBKUTAN IMPLANTIERBARE VORRICHTUNG ZUR STUFENWEISEN VERLÄNGERUNG EINES KNOCHENS

DISPOSITIF IMPLANTABLE SOUS-CUTANÉ POUR ALIGNER PROGRESSIVEMENT UNE COLONNE VERTÉBRALE ET DISPOSITIF IMPLANTABLE SOUS-CUTANÉ POUR ALLONGER PROGRESSIVEMENT UN OS

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(56) References cited:
US-A- 4 262 665
US-A1- 2003 158 557
US-A1- 2007 016 202
US-A1- 2008 023 012
US-A1- 2009 012 565
US-A1- 2009 012 565
US-A1- 2010 063 545
US-A1- 2010 063 545
US-A1- 2014 236 234
US-A1- 2015 196 342
US-A1- 2015 196 342

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Description

FIELD OF THE INVENTION

[0001] The present invention relates to surgical devices, and, more particularly, to orthopedic surgical devices, and, more particularly, to corrective orthopedic surgical 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] Figure 1 is a stylized posterior 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 generates 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 prior art 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.

[0004] 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.

[0005] 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.

[0006] 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, the curve can be considered significant and a brace may be recommended. If the curve is greater than 40 degrees, the curve can be considered severe and surgery may be recommended. Braces are not designed to correct severe spinal curves. They are used to help slow or stop the curve from getting worse. Since surgery is recommended typically only when the curve is considered significant or severe, surgeons are limited to performing surgical procedures on a subset of the population of individuals diagnosed with scoliosis.

[0007] 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 prevents the curve from worsening. However, the rigid column reduces the range of motion available to the patient.

[0008] 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 US 2006/0195090 A1 (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.

[0009] US 6,551,320 B2 (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. US 2009/0112262 A1 (Pool et al.) 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.

[0010] US 5,782,831 A (Sherman et al.) 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.

[0011] US 2014/0236234 A1, US 2009/0012565 A1 and US 2015/0196342 A1 disclose subcutaneous implantable devices for aligning a spine having a plurality of vertebrae with the features of the preamble of claim 1.

[0012] 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. Such corrective systems can be prohibitively expensive. Additionally, typical corrective systems involve the risk of permanent neurological injury caused by stretching the spinal cord. Other typical risks of surgical corrective systems for treating scoliosis involve infection, blood loss, and lung, bowel, and bladder problems. 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.

[0013] What is needed then is a percutaneous 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 techniques can be employed. Additionally, it would be advantageous to access a device for aligning a spine by palpating intact skin to avoid infections.

SUMMARY OF THE INVENTION

[0014] The present invention relates to a subcutaneous implantable device for aligning a spine as claimed hereafter. Preferred embodiments are set forth in the dependent claims. The present invention broadly comprises a subcutaneous implantable device for aligning a spine having a plurality of vertebrae including a first bracing assembly secured to a first vertebra of the spine, a second bracing assembly secured to a second vertebra of the spine, a rod secured by the at least two bracing assemblies, the rod arranged for limited sliding movement within the at least two bracing assemblies, a gear mechanism attached to the rod, a control means attached to the gear mechanism, and a cable fixedly secured to a third vertebra of the spine by an anchor. The third vertebra is located between the first and second vertebrae, and the cable is arranged for pulling the third vertebra towards the rod.

[0015] A bone lengthening apparatus, not forming part of the invention, is disclosed, including a screw shell secured to a distal portion of said bone, a separation rod including a threaded end arranged to engage the screw shell of the distal portion, the separation rod being arranged to be securable to a proximal portion of the bone and extendable from the proximal portion to the distal portion, and where the proximal portion is separated from the distal portion by a gap, a gear mechanism attached to the separation rod, and a control means attached to the gear mechanism and arranged to rotate the separation rod to widen the gap between the distal and proximal portions of the bone.

[0016] A primary object of the invention is to provide a device of spinal alignment in which corrective alignment is achieved "gradually" 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.

[0017] Another object of the invention is to provide a device for aligning a lateral curve in a spine using simple percutaneous methods and minimally invasive techniques, such as endoscopic techniques.

[0018] Still another object of the invention is to provide a device for aligning a lateral curve in the spine which can be resorbed into the body where the alignment device, including the balloon and/or anchor and/or a traction cable, is made of bioabsorbable materials.

[0019] Another object of the invention is to provide a mechanical device for gradually correcting a spine afflicted with scoliosis subcutaneously.

[0020] A still further object of the invention is to provide a device for aligning a lateral curve in a spine using a minimum amount of vertebral drilling sites.

[0021] Yet another object of the invention is to provide a percutaneous device for aligning a spine including a balloon that can be inflated with bioabsorbable liquids capable of being withdrawn or bioabsorbable material, e.g., bone putty.

[0022] Still another object of the invention is to provide a percutaneous device for aligning a spine including a balloon that contains metal vanes which can be deployed against the external cortical surface of a bone to strengthen anchoring capabilities.

[0023] An additional object of the invention is to provide a mechanically, hydraulically or electronically operated device including an expandable anchoring mechanism deployable within or around a bone that can be reliably actuated with a pushing or pulling vector force sufficient to controllably alter the temporary or permanent position of a skeletal structure.

[0024] These and other objects, features and functions of the present invention will become apparent to those having ordinary skill in the art upon the reading of the following detailed description in view of the drawings and appended claims.

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWINGS

[0025] 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 Figures 1 to 18B and 30 to 35 illustrate examples that are useful for understanding the invention:

Figure 1 is a stylized posterior view of a person with a spine afflicted with scoliosis;
Figure 2A is a rear view of a person with scoliosis wearing a full body brace as known in the prior art;
Figure 2B is a rear view similar to that of Figure 2A but showing a lighter prior art brace;
Figure 3 is a cross-sectional view of a hollow bone screw having an outer shell and an inner screw threadably inserted therein, which can be used in the present invention;
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 the assembly of 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-sectional view taken generally along line 5C-5C in Figure 5B;
Figure 6 is side perspective exploded view of the assembly of the present invention 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 an anterior view of a laterally curved spinal column with the alignment assembly in place;
Figure 9 an anterior view showing the assembly holding the spinal column in place after a pulling procedure;
Figure 10 is an anterior view similar to that of Figure 9 showing the spinal column moved to a straighter position relative to the axis after a succeeding pulling procedure;
Figure 10A is an anterior view similar to that of Figure 10 showing 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 an anterior view showing the results of the final pulling procedure in which the lateral curve of the spinal column is significantly reduced if not eliminated;
Figure 12 is an anterior view showing spinal column after the final pulling procedure; Figure 12A is a cross-sectional view similar to Figure 5C showing the 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 a second assembly utilized in the gradual alignment of a spine with one or more lateral curves;
Figure 14A is a cross-sectional 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 in 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 posterior view of the inflatable balloon catheter attached to an external leverage support to form the second embodiment of the present invention;
Figure 17 is a partial cross-sectional view of a bone screw embedded into a 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;
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;
Figure 19 is a top perspective view of an embodiment of the winding means component of the subcutaneous implantable device for performing a gradual lateral spinal alignment of a spine according to the invention;
Figure 20 is a top perspective view of the worm gear enclosed in a housing;
Figure 21A is a top perspective view of a ratchet assembly used as an alternate form of a winding means in the second alternate assembly for perform-

ing gradual spinal alignments;
Figure 21B is a top perspective view of a ratchet assembly used as an alternate form of a winding means in the second alternate assembly for performing gradual spinal alignments;
Figure 22 is a bottom perspective view of the assembly secured to a rigid bracing rod;
Figure 23 is an anterior view of the assembly attached to a curved spinal column;
Figure 24 is the same view as in Figure 23 depicting the spinal column pulled straighter, i.e., closer to the desired anatomical position;
Figure 25 shows the spinal column in the desired anatomical alignment caused by the pulling of the curve of the spine toward the bracing rod;
Figure 26 is an enlarged posterior view of one embodiment of the bracing assembly used to attach the vertebra to the bracing rod;
Figure 27 depicts the second alternate embodiment of the assembly attached to a spinal cord in which an inflatable balloon anchor is extended through a target vertebra and attached to the assembly with a cable;
Figure 28 is the same view as in Figure 27 depicting the spinal column pulled straighter, i.e., closer to the desired anatomical position;
Figure 29 is the same view as in Figure 27 with the spinal column pulled into the desired anatomical alignment using the balloon anchor;
Figure 30 is a longitudinal cross-sectional view of a femur;
Figure 31 is an enlarged cross-sectional view of a femur showing an osteotomy separating the femur into an upper section and a lower section;
Figure 32A is the same longitudinal cross-sectional view of the femur as shown in Figure 31 including a bone lengthening assembly including a worm gear, not forming part of the invention;
Figure 32B is a view similar to that of Figure 32A wherein the gap formed by the osteotomy is widened after the separation rod is turned;
Figure 33 shows bone growth that naturally occurs filling the gap created by the osteotomy;
Figure 34 depicts the completion of the bone growth after the removal of the separation rod and worm gear; and,
Figure 35 is the same view as in Figure 32 showing the use of an electric motor to turn the separation rod.

DETAILED DESCRIPTION OF EMBODIMENTS OF THE INVENTION

[0026] At the outset, it should be appreciated that like drawing numbers 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.

[0027] While the present invention is described according to the invention as defined in independent claim 1. Preferred embodiments of the invention are defined in the dependent claims.

[0028] 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 aspects only, and is not intended to limit the scope of the present invention, which is limited only by the appended claims.

[0029] 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.

[0030] Figure 3 is a cross-sectional view of hollow bone screw **20.** The bone screw is used to secure the assembly of the invention to the vertebrae of the patient, as described *infra.* 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.** It should be understood that threads **22A** and **24A** can be omitted.

[0031] 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** and set screw **37.**

[0032] Figure 5C is a cross-sectional view taken generally 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. Set screw **37** engages threaded through-bore **37A** (shown in Figure 6).

[0033] Figure 6 is a side perspective exploded view of assembly **10** attached to 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**, which can be used in the invention, 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 **36A** of aperture **36.** Persons having ordinary skill in the art recognize that cable **46** may be threaded from distal end point **25** toward the proximal end of lumen **26** with wings **46** deployed at distal end point **25.** In addition, equivalent devices having expanded or expandable components positioned similarly to wings **46** may be used in place of toggle bolt **40** as long as they provide satisfactory support for pulling cable **46** as described below.

[0034] Cable **46** is guided through tube **50** which extends posteriorly through back **BA.** Lip **52** is located at one end of tube **50** and includes internal threads **52A** so that tube **50** can be threadably attached to annular lip **38.** Set screw **54** is screwed into threaded tube aperture **50A** to hold cable **46** in place.

[0035] Figure 7 is a side perspective view of assembly **10** showing pulling tool **60**, not forming part of the invention, 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 is 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 does 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 **BA** so that the lungs and surrounding viscera can be avoided.

[0036] Figure 8 is an anterior 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.

[0037] 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 in 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 having ordinary skill in the art recognize that the length of the alignment period depends 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.

[0038] Figure 10 is an anterior view of 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.

[0039] Figure 11 is the same anterior 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.**

[0040] Figure 12 is an anterior 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.**

[0041] Figure 12A is a cross-sectional view similar to Figure 5C in which set screw 37 is shown screwed within 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 having ordinary skill 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** is fixed to cable **46**, the remaining "tail" of cable **46** which extends beyond set screw **37** can be cut close to or inside aperture **36.** In one embodiment, a cap may be placed over annular lip **38.**

[0042] In an alternate embodiment not forming part of the invention, a percutaneous method of spinal alignment 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.

[0043] 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.

[0044] Figure 13 is a top view of inflatable balloon bone anchor **110** ("anchor **110**") which is a component of assembly **100** (shown in Figure 16) utilized in the gradual alignment of a spine with one or more lateral curves. 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 described below and resorb into the body well after the alignment procedure is completed. In an example embodiment where balloon **114** is inflatable and deflatable, both ports **118A** and **118B** can be utilized to allow fluids to pass in and out of balloon **114.** In an example embodiment where balloon **114** is dissolvable, only a single port **118A** or **118B** is needed to allow fluid to pass into balloon **114.** In that case, the fluid is introduced and sealed until it dissolves.

[0045] Figure 14A is a cross-sectional view of target vertebra **80** in which a Jamshidi needle **102** ("needle **102**"), which can be used in the invention, 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 shown in 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.

[0046] Figures 14C and 14D depict the inflation of balloon **114** through a hydraulic method in which 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 ordinary skill in the art. It should be appreciated that a noncompliant or compliant balloon can be used. If a compliant balloon is used it is made of a hardenable material.

[0047] Figure 15A depicts a second method of attaching anchor **110** to vertebra **80**, which can be used with the invention. Needle **102** is drilled or tapped through vertebra **80** to create a passage extending through opposing sides of vertebra **80.** Similar to the method described above, it can be seen that anchor **110** is carried inside needle **102** during the drilling process or placed later after stylet is removed. 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.**

[0048] Figures 15B-15D depict an alternate embodiment of an 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. Alternatively, when the balloon is inflated, the arms pivotally deploy. 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 is recognized that the mechanical inflation method may be

used to form cavity **82** and embed balloon **114** as seen in Figures 14C and 14D. Conversely, the hydraulic method described above may be used to inflate balloon **114** and draw it toward vertebra **80** as seen in Figures 15C and 15D.

[0049] Figure 16 is a schematic posterior view of anchor **110** attached to external leverage support **B** to form assembly **100.** In the posterior view shown, tube **112** extends through vertebra **80** with inflatable balloon **114** drawn against a 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 rod **30.** Pulling tools such as come-alongs, winches, pliers, etc., attached to proximal end **116** may be used.

[0050] 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 of 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.

[0051] Figure 17 is a cross-sectional view of bone screw **120** embedded into vertebra **80** and attached to strut **122.** Bone screw **120** and strut **122** are components of bone screw-strut construction **130** shown in Figure 18B. This bone screw-strut construction **130** ("construction **130**") can be used to apply a pushing force on the lateral curve by 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 some other polyaxial connection to allow different vector angles of force to be applied to bone screw **120** as it pushes on the lateral curve.

[0052] 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 of bone anchor **110** as well as to the spinal column itself.

[0053] Figure 18B schematically depicts the use of 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 assemblies **100.** It is recognized that brace **B'** may be the same or a different external support than support **B** attached to assemblies **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 and 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 assemblies **100** to multiple points on the spine.

[0054] Assemblies **100** are used in a manner similar to that used for assembly **10** described above. With anchors **110** attached to target vertebra **80**, and proximal ends **116** attached to brace **B**, tubes **112** are pulled toward brace **B** to pull the lateral curve closer to alignment. After the pulling process, tubes **112** are attached to brace **B** in such a way so as to hold anchors **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 anchors **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 assemblies **100** to gradually push the spine into the desired alignment

[0055] Once the desired spinal alignment is 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 dissolved into the body. Alternatively, percutaneous alignment could be maintained until skeletal maturity is reached, potentially obviating the need for surgery entirely.

[0056] Figure 19 is a top perspective view of an embodiment of the winding means component **200** of the subcutaneous implantable device for performing a gradual lateral spinal alignment of a spine according to the invention. In the configuration shown, the winding means is in the form of ratcheting mechanism **202**, for example, a worm gear, which includes screw **204** that interacts with wheel **206.** It should be appreciated that screw **204** could be a worm screw and that wheel **206** could be a worm wheel. Wheel **206** includes stem **210** which holds or retains cable **212.** Control lever **208** acts as a control means and is operatively attached to screw **204** to turn screw **204** a predetermined amount when pressed. By "operatively attached" it is meant that a component or device is connected either directly or indirectly to a second component and causes that second component to function, e.g., turn a predetermined amount. As can be seen in Figure 19, when screw **204** turns, wheel **206** also rotates which in turn rotates stem **210** to wind cable **212.** It should be appreciated that due to the frictional relationship between screw **204** and wheel **206**, wheel **206** can-

not rotate worm screw **204.** Spring means **205A** is provided to enable lever **208** to rebound to its starting position so that lever **208** can only be moved a predetermined amount when pressed. Spring means **205A** is in the form of a torsion spring, for example.

[0057] Figure 20 is a top perspective view of ratcheting mechanism **202** enclosed in housing **203.** It is apparent to those having skill in the art that housing **203** may be a single unit enclosing ratcheting mechanism **202** or may include separately elements that enclose the individual components of ratcheting mechanism **202**, such as housing **203A** enclosing stem **210** as seen in Figure 20. It should be appreciated that housing **203** can be made of any suitable casing for example, a silicone elastomer. Preferably, spring means **205B** is included to enable lever **208** to rebound to its starting position creating a ratchet effect so that lever **208** can only be moved a predetermined amount when pressed. Spring means **205B** can be in the form of a coil spring attached to housing **203** in which lever **208** is caused to return to a starting position. Lever **208** may rebound to a starting position off coil spring **211** attached to rebound board **208A.** Persons having ordinary skill in the art recognize that although Figures 19-20 depict different spring means that act to return lever **208** to a starting position, preferably, only one spring means is utilized in any one particular ratcheting mechanism **202.**

[0058] The winding means may be a ratchet mechanism used to control the rotation of stem **210** through ratcheting mechanism **202** or directly through control of ratchet assembly **216** as shown in Figures 21A and 21B. In Figure 21A, control lever **208** is operatively attached to ratchet gear **216A** which engages ratchet gear **216B** to rotate ratchet gear **216B** in a single direction. In Figure 21B, control lever **208** is operatively attached to a single ratchet gear **216A** and control lever **208** can rotate ratchet gear **216A** in a single direction via pawl **217P.** Pawl **217P** is connected to housing **203** surrounding ratchet assembly **216** (shown in Figure 20). Spring **217** acts to maintain rotational tension in ratchet assembly **216** to return lever **208** to its starting position. Persons having ordinary skill in the art recognize that a worm screw, such as screw **204**, may be attached to ratchet assembly **216** to enable ratcheting mechanism **202** to be rotated a predetermined amount and thus pull cable **212** a predetermined amount with each press of control lever **208.**

[0059] Figure 22 is a bottom perspective view of assembly **200** including rigid bracing rod **220.** The components of ratcheting mechanism **202** are enclosed in housings **203**, **203A**, and **203B.** Figure 22 also includes a posterior schematic view of a spinal column comprising vertebrae **80** and intervertebral disks **70.** Ratcheting mechanism **202** may be attached to rod **220** in different orientations relative to the spinal column. Preferably, ratcheting mechanism **202** is attached in such a way as to enable its longitudinal movement along rod **220** before it is fixed into positon and to allow control lever **208** to be proximate to the external side of surrounding tissue to enable it to be operated, e.g., pressed, from outside the body of a patient. Although not shown in Figure 22, preferably, a spring means such as those discussed above, is included in assembly **200** to ensure cable **212** is wound only a predetermined amount when lever **208** is pressed, once identified by palpation through the skin.

[0060] Figure 23 is an anterior view of assembly **200** attached to a curved spinal column. Axis **A** represents the longitudinal axis of the spinal column when straightened to the ideal anatomical position, while axis **A'** indicates the longitudinal axis of the curved spinal column. Target vertebra **80** may be prepared to receive a vertebra fixture element, in this case toggle bolt **40**, in the manner described above for example. Toggle bolt **40** extends through hole **34** such that the distal end of toggle bolt **40** extends through vertebra **80** with wings **42** extended against the side of vertebra **80.** Cable **212** is attached to the proximal end of toggle bolt **40** and is retained on stem **210** of ratcheting mechanism **202.** Bracing assemblies **222** are slidingly attached to bracing rod **220** above and below assembly **200** to maintain the position of assembly **200** relative to hole **34** and toggle bolt **40** so that cable **212** continues to be wound at a convenient angle, e.g., generally perpendicular to the spinal column. Bracing assemblies **222** are prevented from sliding off of bracing rod **220** via caps **C** and **C'.** It should be appreciated that additional members can be placed along bracing rod **220** to limit the movement of bracing assemblies **222** as shown in Figure 26.

[0061] Figure 24 is the same view as Figure 23 depicting spinal column **1** pulled closer to the desired anatomical position as a result of winding cable **212** on stem **210** of ratcheting mechanism **202** (enclosed in housing **203**). This is seen by the smaller diverting angle between lines **A** and **A'.** As spinal column **1** becomes straighter, it lengthens which is reflected in the decrease in the distance between each of the bracing assemblies **222** and the end of bracing rod **220** demonstrating the pivotal or sliding attachment of bracing assemblies **222** to bracing rod **220** as discussed below. Figure 25 shows spinal column **1** in the desired anatomical alignment caused by the pulling of the curve of the spine toward bracing rod **220.**

[0062] Figure 26 is an enlarged posterior view of one embodiment of bracing assembly **222** attached to a vertebra **80** and bracing rod **220.** Screw **222A** is pivotally attached to body **222B** and is screwed into vertebra **80**, in this case dorsal to the transverse process on the facet of the superior articular process. Holding screw **222C** is threaded onto body **222B** to hold bracing assembly **222** onto bracing rod **220** which passes through body **222B.** The pivotal attachment of screw **222A** to body **222B** enables bracing assembly **222** to remain attached to vertebra **80** and to allow spinal column **1** to be pulled to a straighter alignment. Bracing assembly **222** may be attached in such a way as to enable bracing assembly **222** to slide on bracing rod **220** as spinal column **1** is straightened.

[0063] In an alternate embodiment of assembly **200**, inflatable balloon anchor **214**, which can be used in the invention, having vanes **214B** can act as the vertebra fixture element to pull spinal cord **1** into or closer to the desired alignment. As explained above and depicted in Figures 15A-15D regarding balloon anchor **114**, balloon anchor **214** is deployed through target vertebra **80** and inflated. Balloon anchor **214** is similar to balloon anchor **114**, but includes an attachment to cable **212** at its proximal end.

[0064] Figure 27 depicts assembly **200** connected to spinal cord **1** in which balloon anchor **214** is extended through target vertebra **80** and attached to ratcheting mechanism **202** with cable **212** at its proximal end. Similar to Figure 23, bracing assemblies **222** are pivotally attached to vertebrae of spinal column **1** and attached to bracing rod **220** above and below assembly **200** to maintain the position of assembly **200** relative to hole **34** and balloon anchor **214** so that cable **212** continues to be wound at a convenient angle, e.g., generally perpendicular to spinal column **1.**

[0065] Figure 28 is the same view as Figure 27 depicting spinal column **1** pulled straighter, using balloon anchor **214** as a result of winding cable **212** on stem **210** of ratcheting mechanism **202** (enclosed in housing **203**). This is seen by the smaller diverting angle between lines **A** and **A'.** As spinal column **1** becomes straighter, it lengthens which is reflected in the decrease in the distance between each of the bracing assemblies **222** and the end of bracing rod **220** demonstrating the slidable attachment of bracing assemblies **222** bracing rod **220.** Figure 29 shows spinal column **1** in the desired anatomical alignment caused by the pulling of the curve of the spine toward bracing rod **220.**

[0066] Figure 30 is a longitudinal cross-sectional view of femur **150** including upper extremity **152**, shaft or body **154**, lower extremity **156,** and greater trochanter **158.** Also seen is bone marrow **162.** Figure 31 is an enlarged cross-sectional view of femur **150** showing osteotomy or gap **160** separating femur **150** into upper and lower sections. Passage **164** is created by an intramedullary nail by inserting the nail into a hole drilled through greater trochanter **158** or other region of upper extremity **152** in a controlled manner. An example of a suitable intramedullary nail is supplied by Ellipse Technologies in Aliso Viego, California under its Precice® product line.

[0067] Figure 32A is the same longitudinal cross-sectional view of femur **150** depicting a novel bone lengthening assembly that includes ratcheting mechanism **202** not forming part of the invention. Screw shell **172** is placed in the distal section **150B** of femur **150** below osteotomy **160** to act as an embodiment of a distal base portion of the assembly. This placement may be effected by the intramedullary nail when it is passed into distal section **150B.** Like outer screw shell **22** discussed above, screw shell **172** includes inner threads **172A.** Separation rod **170** ("rod **170**") is an upper proximal adjustable portion of the assembly and includes threaded end **174** ("end **174**") at its distal end. Separation rod **170** is operatively attached to ratcheting mechanism **202.** End **174** extends through osteotomy **160** and is inserted into screw shell **172** so the threads of end **174** threadably interact with inner threads **172A.** When control lever **208** on ratcheting mechanism **202** is activated, separation rod **170** rotates to turn threaded end **174** into shell **172** thereby pushing distal section **150B** of bone **150** away from upper section **150A** widening gap **160.** This is depicted in Figure 32B in which the gap formed by osteotomy **160** is widened after separation rod **170** is turned. In a typical embodiment, ratcheting mechanism **202** is configured to turn rod **170** to widen the gap 1 mm with each movement of control lever **208.** Although not seen, it is understood that ratcheting mechanism **202** includes a spring means such as coil spring **211** with rebound board **208A** and/or torsion spring **205A** discussed above or other spring devices to return control lever **208** to a starting position.

[0068] Figure 33 shows bone growth **165** that naturally occurs to fill the gap created by osteotomy **160.** As can be seen, separation rod **170**, which may include threaded end **174**, spans osteotomy **160** to continue widening gap **160** to a desired width showing that new bone growth occurs while the separation procedure continues. In other words, the bone growth continues as gap **160** is widened to the desired width. Ultimately, as seen in Figure 34, when gap **160** is widened to the target width, separation rod **170** and ratcheting mechanism **202** are withdrawn and bone and marrow growth continues to completely fill in gap 160 until the bone density is the same or almost the same as the rest of femur **150.** It is noted that screw shell **172** remains in femur **150.** Figure 34 also shows bone marrow **162** having filled in passage **164** with femur **150** lengthened by the width of the gap that was lengthened by ratcheting mechanism **202.**

[0069] In the embodiment of the bone lengthening assembly discussed above, similar to assembly **200** discussed above, worm screw **204** is rotated a specific number of degrees in order to rotate separation rod **170** to produce a predetermined distance, e.g., 1 mm. between proximal section **150A** and distal section **150B** of femur **150.** After an established amount of time, ratcheting mechanism **202** is again rotated to separate the two femur sections another 1 mm. As with ratcheting mechanism **202** in the spinal alignment assembly **200** discussed above, control lever **208** is pressed to turn worm screw **204** to rotate separation rod **170** to enable the additional 1 mm separation. Preferably, assembly **200** is configured such that lever **208** only rotates rod **170** enough to widen gap **160** a predetermined distance, e.g., 1 mm, when lever **208** is pressed or activated. It is recognized by persons having skill in the art that ratcheting mechanism **202** may be mounted on greater trochanter **158** or another feature close to the external surface of the surrounding tissue to provide easy access to lever **208** by palpation through the skin.

[0070] In an alternate embodiment, shown in Figure 35, control lever **208** is replaced by motor **M** having a

Bluetooth® receiver capability. A Bluetooth® transmitter may be used to transmit a programmed command to motor **M** to turn worm gear **204** the predetermined amount to rotate separation rod **170.** A similar motor with Bluetooth® receiver capability may be used to turn worm gear **204** when used in spine straightening assembly **200.**

[0071] The use of a worm gear in a bone lengthening assembly provides the advantage of precision in widening the gap between the divided portions of the bone by the same distance each time the rod is rotated by ratcheting mechanism **202.** In addition, the ratchet mechanism described above with respect to the spinal alignment assembly **200**, may be used in the bone lengthening assembly to hold the worm gear in position to prevent possibly slippage of worm screw **204** ensuring the gap continues to be widened to the desired width without the upper section **150A** falling back toward the lower section **150B** of the femur **150.** Persons having ordinary skill in the art recognize that the other bones, such as the humerus or tibia may be targeted in a bone lengthening process, and such rod lengthening can be used to stretch a curved spine if the distal ends of the rod are secured to the spine with pedicle screws.

[0072] Thus, it is seen that the objects of the invention are 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.

REFERENCE NUMBERS

[0073]

P	Person
1	Spinal column
2	Upper curve
3	Lower curve
4	Brace
5	Brace
20	Bone screw
22	Outer screw shell
22A	Threads
22B	Internal threads
24	Inner screw
24A	Threads
24B	Cap
25	Distal end point
26	Lumen
30	Rod
30A	End
32	Receiver
34	Screw hole
34A	Axis
36	Aperture
36A	Wall
37	Set screw
37A	Threaded through-bore for set screw
38	Annular lip
40	Toggle bolt
41	Shaft
42	Deployable wings
44	Pivot attachment
46	Cable
50	Tube
50A	Tube aperture
52	Lip
52A	Threads
54	Set screw
60	Pulling tool
70	Vertebral disc
80	Vertebra
100	Assembly
102	Needle
102A	Stylet
110	Bone anchor
112	Tube
114	Balloon
114A	Anchor tip
114B	Array
116	Proximal end
117	Distal end
118	Fluid conduit
118A	Port
118B	Port
120	Bone screw
122	Strut
130	Bone screw-strut-construction
150	Femur
150A	Upper section
150B	Lower section
152	Upper extremity
154	Body
156	Lower extremity
158	Greater trochanter
160	Gap
162	Bone marrow
164	Passage
165	Bone growth
170	Separation rod
172	Screw shell
172A	Inner threads
174	Threaded end
200	Assembly
202	Winding means, ratcheting mechanism
203	Housing
203A	Housing
203B	Housing
204	Worm screw
205A	Torsion spring
205B	Coil spring
206	Worm wheel
208	Control lever
208A	Rebound board
210	Stem
212	Cable
216	Ratchet assembly

216A	Ratchet gear
216B	Ratchet gear
217	Spring
220	Bracing rod
222	Bracing assembly
222A	Screw
222B	Body
222C	Holding screw
M	Motor
BA	Back
B	Brace
B'	Brace
A	Axis
C	Cap
C'	Cap

Claims

1. A subcutaneous implantable device for aligning a spine (1) having a plurality of vertebrae, comprising:

a first bracing assembly (222) configured to be secured to a first vertebra of said spine (1);
a second bracing assembly (222) configured to be secured to a second vertebra of said spine (1);
a rod (220) secured by said first and second bracing assemblies (222), said rod (220) configured for limited sliding movement within said first and second bracing assemblies (222);
a cable (212) arranged to be secured to a third vertebra (80) of said spine, wherein:

said third vertebra (80) is located between said first and second vertebrae; and,
said cable (212) is arranged for pulling said third vertebra (80) towards said rod (220);

a gear mechanism (204, 206, 210) attached to said rod (220); and
a control means (208) attached to said gear mechanism (204, 206, 210) to wind said cable (212);
characterized by
said gear mechanism including:

a stem (210) arranged to wind said cable (212);
a wheel (206) connected to said stem (210), wherein said wheel (206) includes gear teeth;
a screw (204) operatively arranged to rotate said gear teeth of said wheel (206) in a single direction; and,
said control means being a control lever (208) attached to rotate said screw (204) in said single direction.

2. The implantable device recited in Claim 1, wherein said cable (212) is secured to said third vertebra (80) with an anchor (40, 214).

3. The implantable device recited in Claim 2, wherein said anchor is a molly bolt, or a toggle bolt (40), or a balloon (214).

4. The implantable device recited in Claim 3, wherein said balloon (214) is inflated within said third vertebra (80).

5. The implantable device recited in any of the preceding Claims, wherein said control lever (208) is connected to a fixed surface by a resilient member (205A, 205B, 211, 217) and said control lever (208) is rotatable only to a limited extent, or
said control lever (208) is connected to a resilient member (205A, 205B, 211, 217) to urge said control lever (208) to a starting position after said control lever (208) is pressed, or
said control lever (208) is connected to a first gear (216A) which engages a second gear (216B) to rotate said second gear (216B) in said single direction, or
said control lever (208) is connected to a first gear (216A) having gear teeth and said gear mechanism (204, 206, 210) includes a pawl (217P) arranged to engage said gear teeth of said first gear (216A) to enable said first gear (216A) to rotate in said single direction.

6. The implantable device recited in any of the preceding Claims, wherein said first and second bracing assemblies (222) are pivotable relative to said rod (220).

7. The implantable device recited in any of the preceding Claims, wherein said control lever (208) is arranged to be palpated subcutaneously.

8. The implantable device recited in any of the preceding Claims, wherein the gear mechanism (204, 206, 210) includes a ratcheting mechanism (202), for example, a worm gear, which includes said screw (204) that interacts with said wheel (206);
wherein in an embodiment said screw (204) is a worm screw and said wheel (206) is a worm wheel.

9. The implantable device recited in any of the preceding Claims, comprising a spring means (205A) to enable lever (208) to rebound to its starting position so that lever (208) can only be moved a predetermined amount when pressed, wherein the spring means (205A) is in the form of a torsion spring, for example.

10. The implantable device recited in any of the preceding Claims, wherein said first and second bracing

assemblies (222) are arranged on a first side of the spine (1), said anchor (40, 214) is arranged on a second side of the spine (1), and said cable (46, 212) is arranged for pulling said third vertebra (80) towards said rod (30, 220) and thereby extending at least partially through said third vertebra (80).

Patentansprüche

1. Subkutan implantierbare Vorrichtung zur Ausrichtung einer Wirbelsäule (1), die eine Vielzahl von Wirbeln aufweist, umfassend:

eine erste Verankerungsanordnung (222), die dafür konfiguriert ist, an einem ersten Wirbel der Wirbelsäule (1) befestigt zu werden;
eine zweite Verankerungsanordnung (222), die dafür konfiguriert ist, an einem zweiten Wirbel der Wirbelsäule (1) befestigt zu werden;
ein Stab (220), der durch die erste und die zweite Verankerungsanordnung (222) befestigt wird, wobei der Stab (220) für eine begrenzte Gleitbewegung innerhalb der ersten und der zweiten Verankerungsanordnung (222) konfiguriert ist;
ein Kabel (212), das dafür vorgesehen ist, an einem dritten Wirbel (80) der Wirbelsäule befestigt zu werden, wobei:

der dritte Wirbel (80) sich zwischen dem ersten und dem zweiten Wirbel befindet; und
das Kabel (212) dafür angeordnet ist, den dritten Wirbel (80) in Richtung des Stabs (220) zu ziehen;

einen Getriebemechanismus (204, 206, 210), der an dem Stab (220) angebracht ist; und
ein Steuerungsmittel (208), das an dem Getriebemechanismus (204, 206, 210) angebracht ist, um das Kabel (212) aufzuwickeln,
dadurch gekennzeichnet, dass
der Getriebemechanismus umfasst:

einen Schaft (210), der dafür vorgesehen ist, das Kabel (212) aufzuwickeln;
ein Rad (206), das mit dem Schaft (210) verbunden ist, wobei das Rad (206) eine Verzahnung aufweist;
eine Schraube (204), die funktionell dafür angeordnet ist, die Verzahnung des Rades (206) in eine einzige Richtung zu drehen; und

das Steuerungsmittel ein Steuerungshebel ist (208), der angebracht ist, um die Schraube (204) in diese einzige Richtung zu drehen.

2. Implantierbare Vorrichtung nach Anspruch 1, wobei das Kabel (212) mit einem Anker (40, 214) an dem dritten Wirbel (80) befestigt ist.

3. Implantierbare Vorrichtung nach Anspruch 2, wobei der Anker ein Molly-Bolzen oder ein Klappdübel (40) oder ein Ballon (214) ist.

4. Implantierbare Vorrichtung nach Anspruch 3, wobei der Ballon (214) innerhalb des dritten Wirbels (80) aufgeblasen wird.

5. Implantierbare Vorrichtung nach einem der vorhergehenden Ansprüche, wobei der Steuerungshebel (208) durch ein elastisches Element (205A, 205B, 211, 217) mit einer ortsfesten Oberfläche verbunden ist und der Steuerungshebel (208) nur in einem begrenzten Umfang drehbar ist, oder
der Steuerungshebel (208) mit einem elastischen Element (205A, 205B, 211, 217) verbunden ist, um den Steuerungshebel (208) in eine Ausgangsposition zu treiben, nachdem der Steuerungshebel (208) gedrückt wurde, oder
der Steuerungshebel (208) mit einem ersten Zahnrad (216A) verbunden ist, das in ein zweites Zahnrad (216B) eingreift, um das zweite Zahnrad (216B) in die einzige Richtung zu drehen, oder
der Steuerungshebel (208) mit einem ersten Zahnrad (216A) verbunden ist, das eine Verzahnung aufweist, und der Getriebemechanismus (204, 206, 210) eine Sperrklinke (217P) umfasst, die dafür vorgesehen ist, in die Verzahnung des ersten Zahnrads (216A) einzugreifen, um es dem ersten Zahnrad (216A) zu ermöglichen, sich in die einzige Richtung zu drehen.

6. Implantierbare Vorrichtung nach einem der vorhergehenden Ansprüche, wobei die erste und die zweite Verankerungsanordnung (222) bezüglich des Stabs (220) schwenkbar sind.

7. Implantierbare Vorrichtung nach einem der vorhergehenden Ansprüche, wobei der Steuerungshebel (208) dafür vorgesehen ist, subkutan betastet zu werden.

8. Implantierbare Vorrichtung nach einem der vorhergehenden Ansprüche, wobei der Getriebemechanismus (204, 206, 210) einen Ratschenmechanismus (202) umfasst, beispielsweise ein Schneckengetriebe, das die Schraube (204) umfasst, die mit dem Rad (206) zusammenwirkt;
wobei in einer Ausführungsform die Schraube (204) eine Schneckenschraube ist und das Rad (206) ein Schneckenrad ist.

9. Implantierbare Vorrichtung nach einem der vorhergehenden Ansprüche, die ein Federmittel (205A)

umfasst, um es dem Hebel (208) zu ermöglichen, in seine Ausgangsposition zurückzuspringen, so dass der Hebel (208) nur um einen vorbestimmten Betrag bewegt werden kann, wenn er gedrückt wird, wobei das Federmittel (205A) beispielsweise in Form einer Torsionsfeder vorliegt.

10. Implantierbare Vorrichtung nach einem der vorhergehenden Ansprüche, wobei die erste und die zweite Verankerungsanordnung (222) auf einer ersten Seite der Wirbelsäule (1) angeordnet sind, der Anker (40, 214) auf einer zweiten Seite der Wirbelsäule (1) angeordnet ist und das Kabel (46, 212) angeordnet ist, um den dritten Wirbel (80) in Richtung auf die Stange (30, 220) zu ziehen, wobei es sich zumindest teilweise durch den dritten Wirbel (80) erstreckt.

Revendications

1. Dispositif implantable sous-cutané pour aligner une colonne vertébrale (1) comportant une pluralité de vertèbres, comprenant :

un premier ensemble de renfort (222) configuré pour être arrimé à une première vertèbre de ladite colonne vertébrale (1) ;
un second ensemble de renfort (222) configuré pour être arrimé à une deuxième vertèbre de ladite colonne vertébrale (1) ;
une tige (220) arrimée par lesdits premier et second ensembles de renfort (222), ladite tige (220) étant configurée pour un mouvement coulissant limité au sein desdits premier et second ensembles de renfort (222) ;
un câble (212) agencé pour être arrimé à une troisième vertèbre (80) de ladite colonne vertébrale, dans lequel :

ladite troisième vertèbre (80) est située entre lesdites première et deuxième vertèbres ; et,
ledit câble (212) est agencé pour tirer ladite troisième vertèbre (80) vers ladite tige (220) ;

un mécanisme d'engrenage (204, 206, 210) fixé à ladite tige (220) ; et
un moyen de commande (208) fixé audit mécanisme d'engrenage (204, 206, 210) pour enrouler ledit câble (212) ;
caractérisé par
ledit mécanisme d'engrenage incluant :

un arbre (210) agencé pour enrouler ledit câble (212) ;
une roue (206) raccordée audit arbre (210), dans lequel ladite roue (206) inclut des dents d'engrenage ;
une vis (204) agencée fonctionnellement pour faire tourner lesdites dents d'engrenage de ladite roue (206) dans un seul sens ; et,
ledit moyen de commande étant un levier de commande (208) fixé pour faire tourner ladite vis (204) dans ledit seul sens.

2. Dispositif implantable selon la revendication 1, dans lequel ledit câble (212) est arrimé à ladite troisième vertèbre (80) avec une ancre (40, 214).

3. Dispositif implantable selon la revendication 2, dans lequel ladite ancre est un boulon à gaine d'expansion, ou un boulon à ailettes (40), ou un ballonnet (214).

4. Dispositif implantable selon la revendication 3, dans lequel ledit ballonnet (214) est gonflé au sein de ladite troisième vertèbre (80).

5. Dispositif implantable selon l'une quelconque des revendications précédentes, dans lequel ledit levier de commande (208) est raccordé à une surface fixe par un organe résilient (205A, 205B, 211, 217) et ledit levier de commande (208) ne peut tourner que dans une mesure limitée, ou
ledit levier de commande (208) est raccordé à un organe résilient (205A, 205B, 211, 217) pour pousser ledit levier de commande (208) vers une position de départ après que ledit levier de commande (208) est pressé, ou
ledit levier de commande (208) est raccordé à un premier engrenage (216A) qui met en prise un deuxième engrenage (216B) pour faire tourner ledit deuxième engrenage (216B) dans ledit seul sens, ou ledit levier de commande (208) est raccordé à un premier engrenage (216A) ayant des dents d'engrenage et ledit mécanisme d'engrenage (204, 206, 210) inclut un cliquet (217P) agencé pour mettre en prise lesdites dents d'engrenage dudit premier engrenage (216A) pour permettre audit premier engrenage (216A) de tourner dans ledit seul sens.

6. Dispositif implantable selon l'une quelconque des revendications précédentes, dans lequel lesdits premier et second ensembles de renfort (222) peuvent pivoter par rapport à ladite tige (220).

7. Dispositif implantable selon l'une quelconque des revendications précédentes, dans lequel ledit levier de commande (208) est agencé pour être palpé par voie sous-cutanée.

8. Dispositif implantable selon l'une quelconque des revendications précédentes, dans lequel le mécanisme d'engrenage (204, 206, 210) inclut un mécanis-

me de rochetage (202), par exemple, un engrenage à vis sans fin, qui inclut ladite vis (204) qui interagit avec ladite roue (206) ;
dans lequel dans un mode de réalisation, ladite vis (204) est une vis sans fin et ladite roue (206) est une roue à vis sans fin.

9. Dispositif implantable selon l'une quelconque des revendications précédentes, comprenant un moyen de ressort (205A) pour permettre au levier (208) de rebondir vers sa position de départ de sorte que le levier (208) puisse n'être déplacé que d'une quantité prédéterminée lorsqu'il est pressé, dans lequel le moyen de ressort (205A) se présente sous la forme d'un ressort de torsion, par exemple.

10. Dispositif implantable selon l'une quelconque des revendications précédentes, dans lequel lesdits premier et second ensembles de renfort (222) sont agencés sur un premier côté de la colonne vertébrale (1), ladite ancre (40, 214) est agencée sur un second côté de la colonne vertébrale (1), et ledit câble (46, 212) est agencé pour tirer ladite troisième vertèbre (80) vers ladite tige (30, 220) et ainsi s'étendre au moins partiellement à travers ladite troisième vertèbre (80).

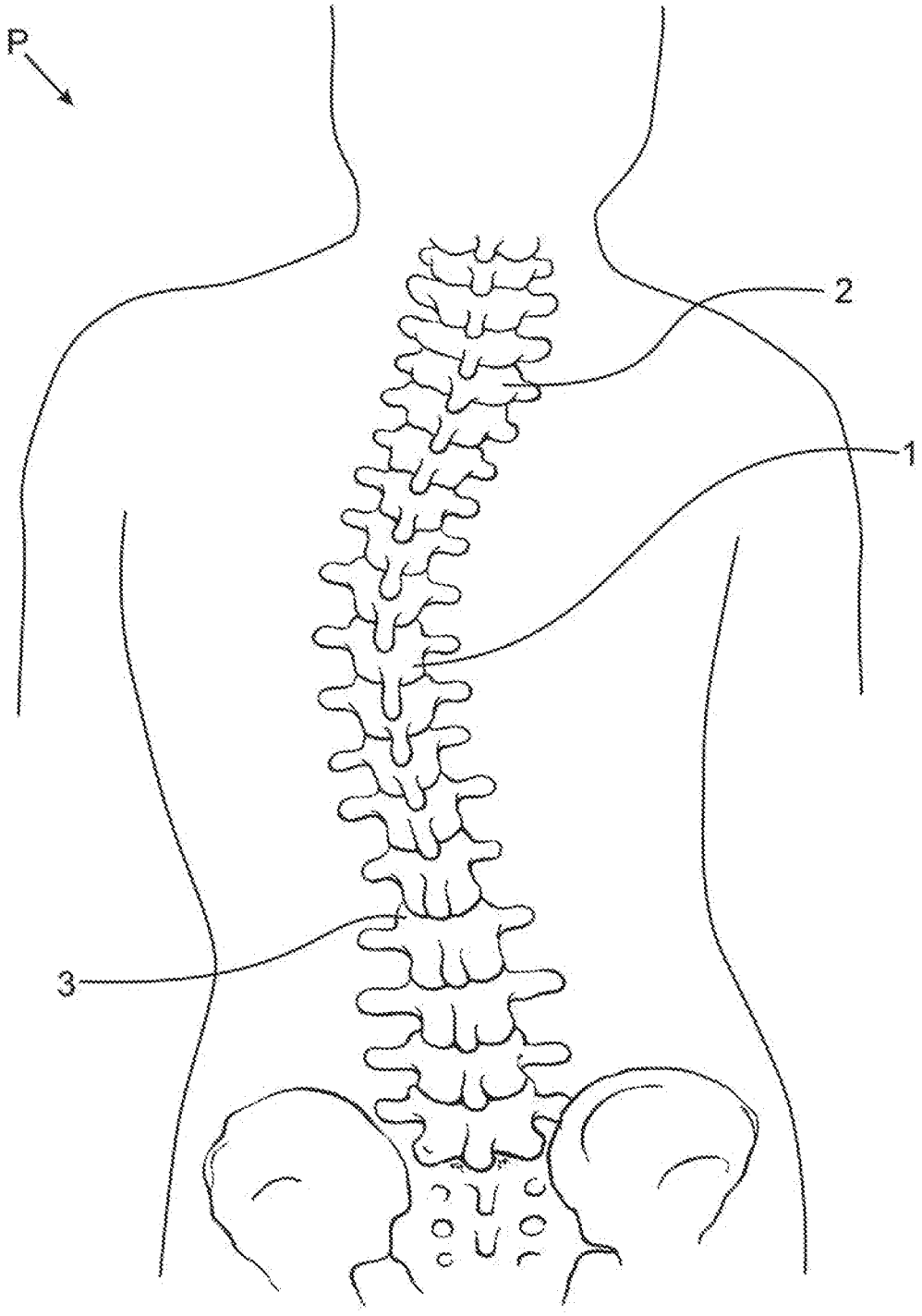


Fig. 1

Prior Art

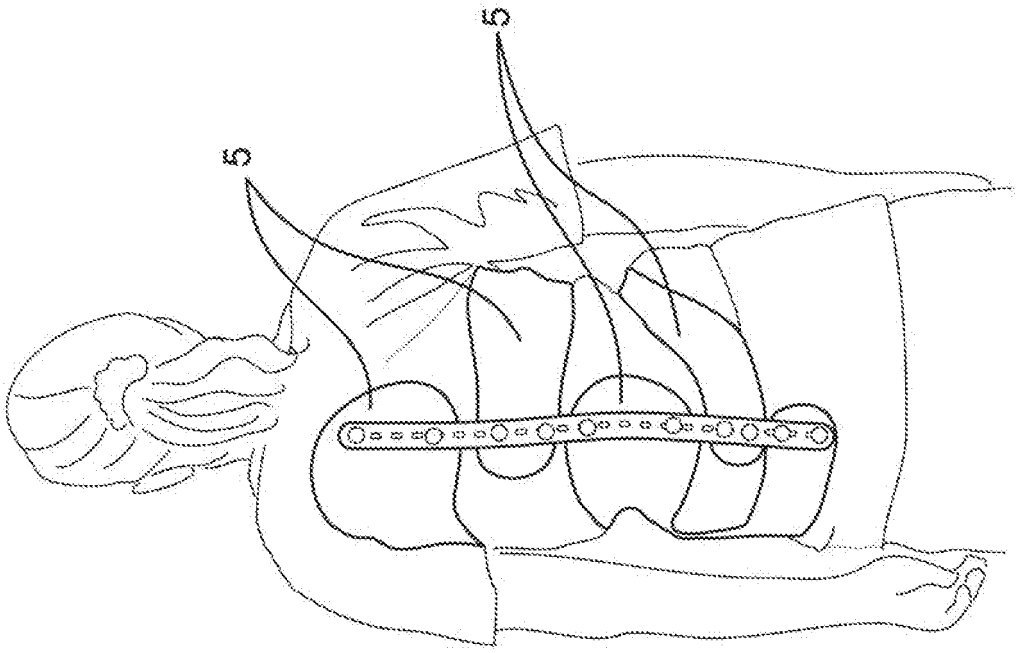


Fig. 2B

Prior Art

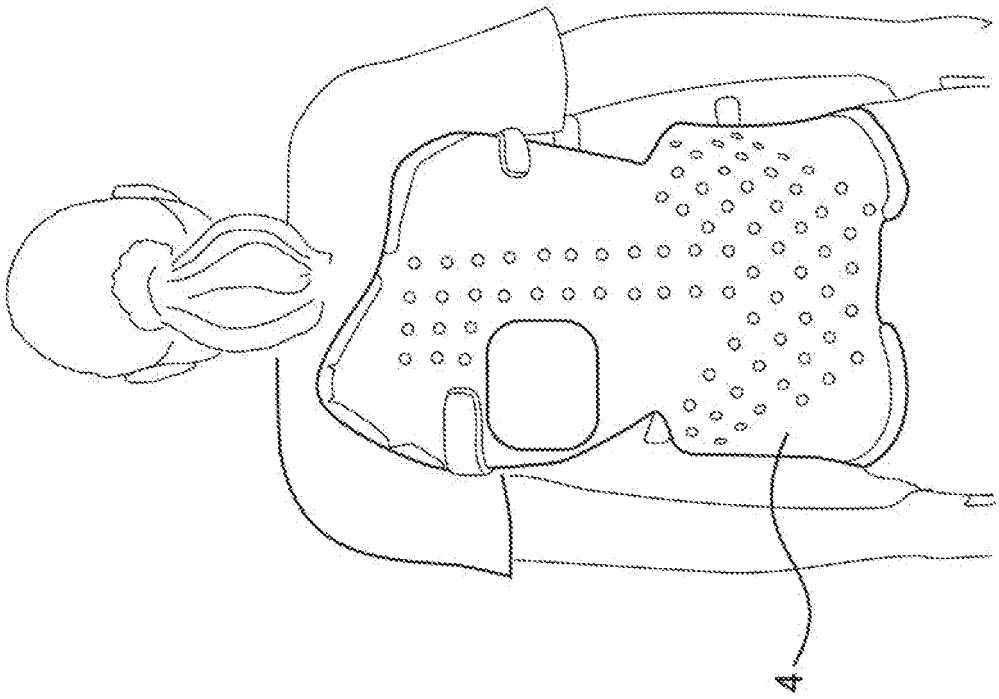


Fig. 2A

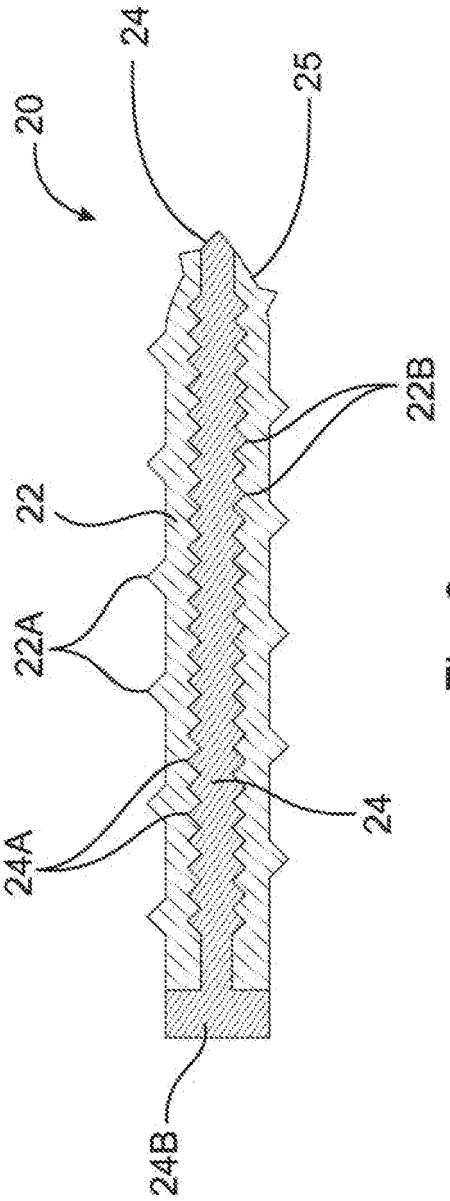


Fig. 3

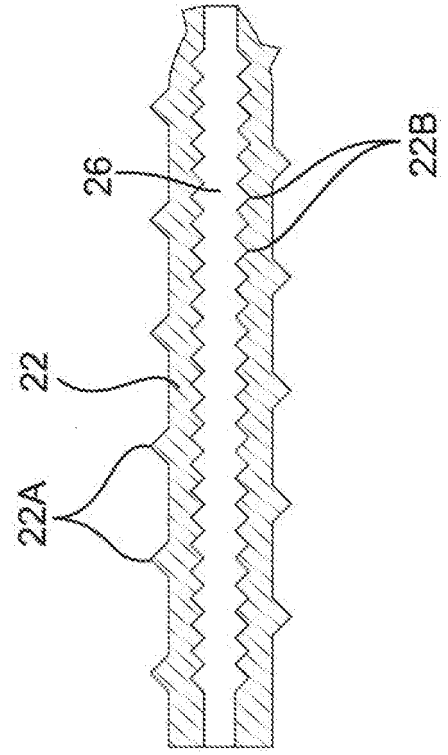


Fig. 4A

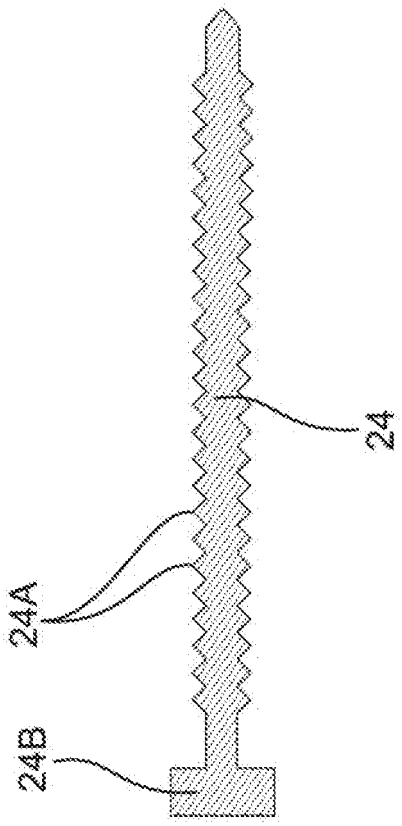
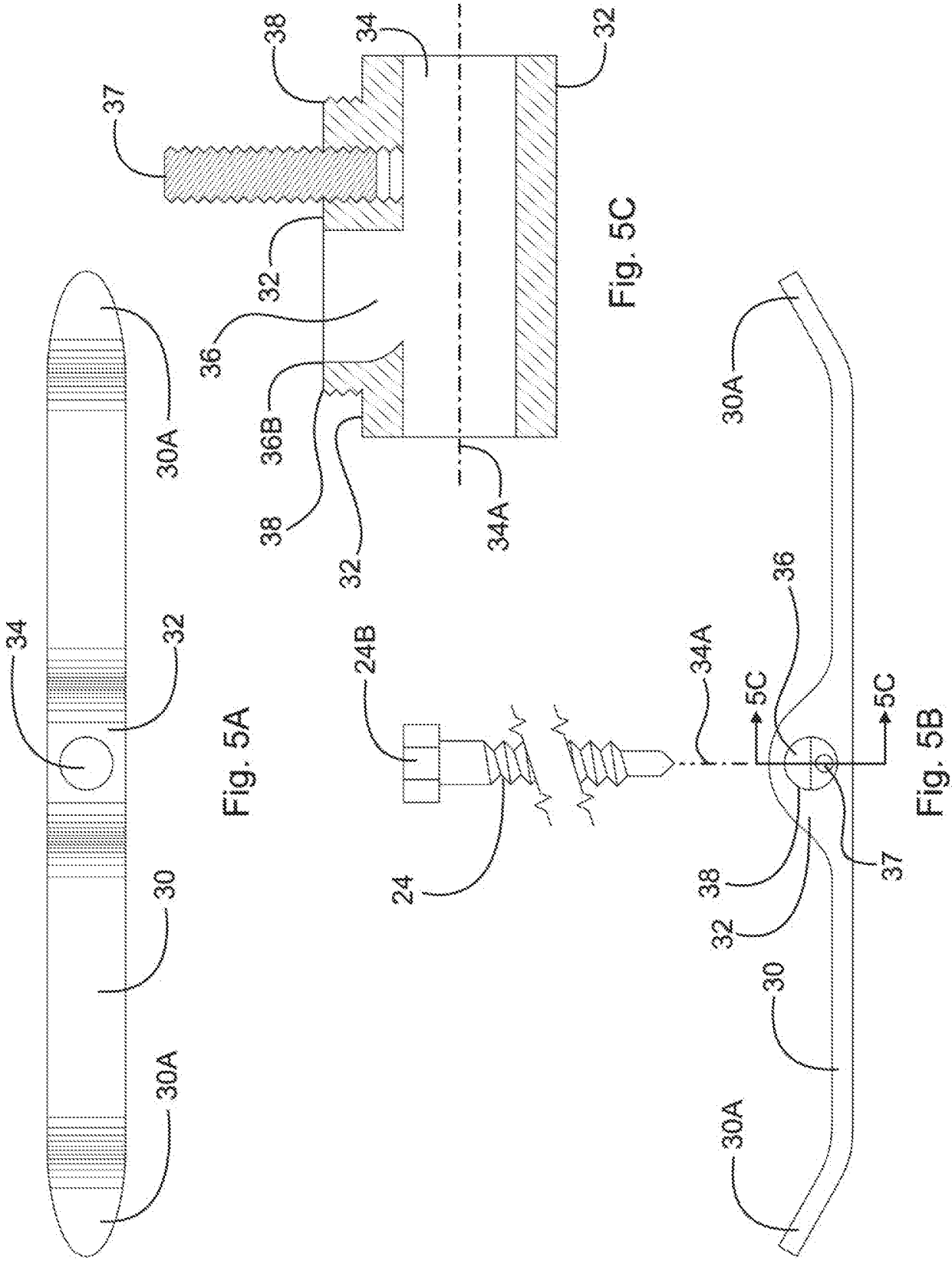


Fig. 4


34
32
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30A
30A
Fig. 5A
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34
32
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32
36
36B
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32
34A
Fig. 5C
24B
24
34A
5C
5C
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37
30A
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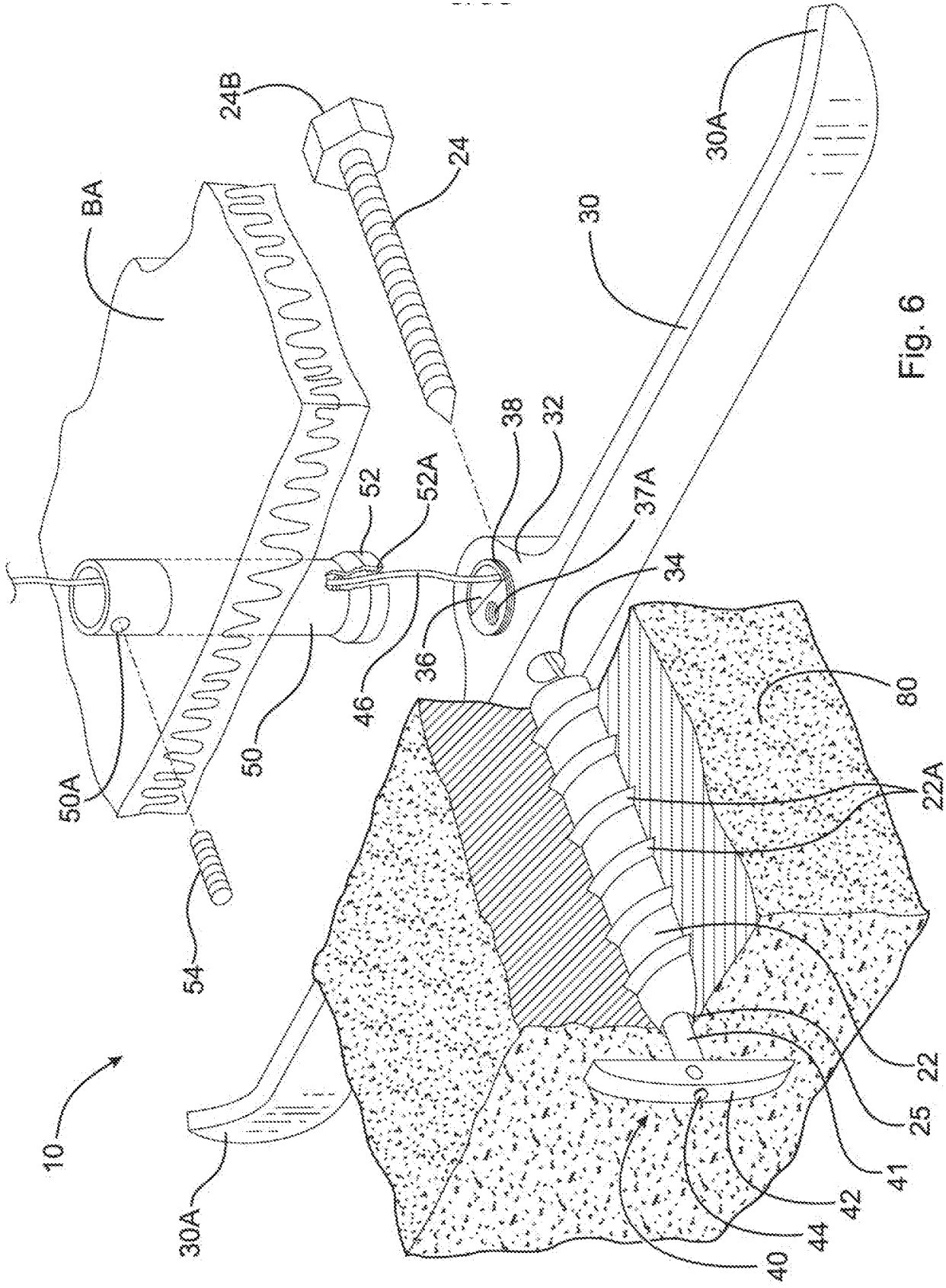
30A
Fig. 5B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30A
10

Fig. 6

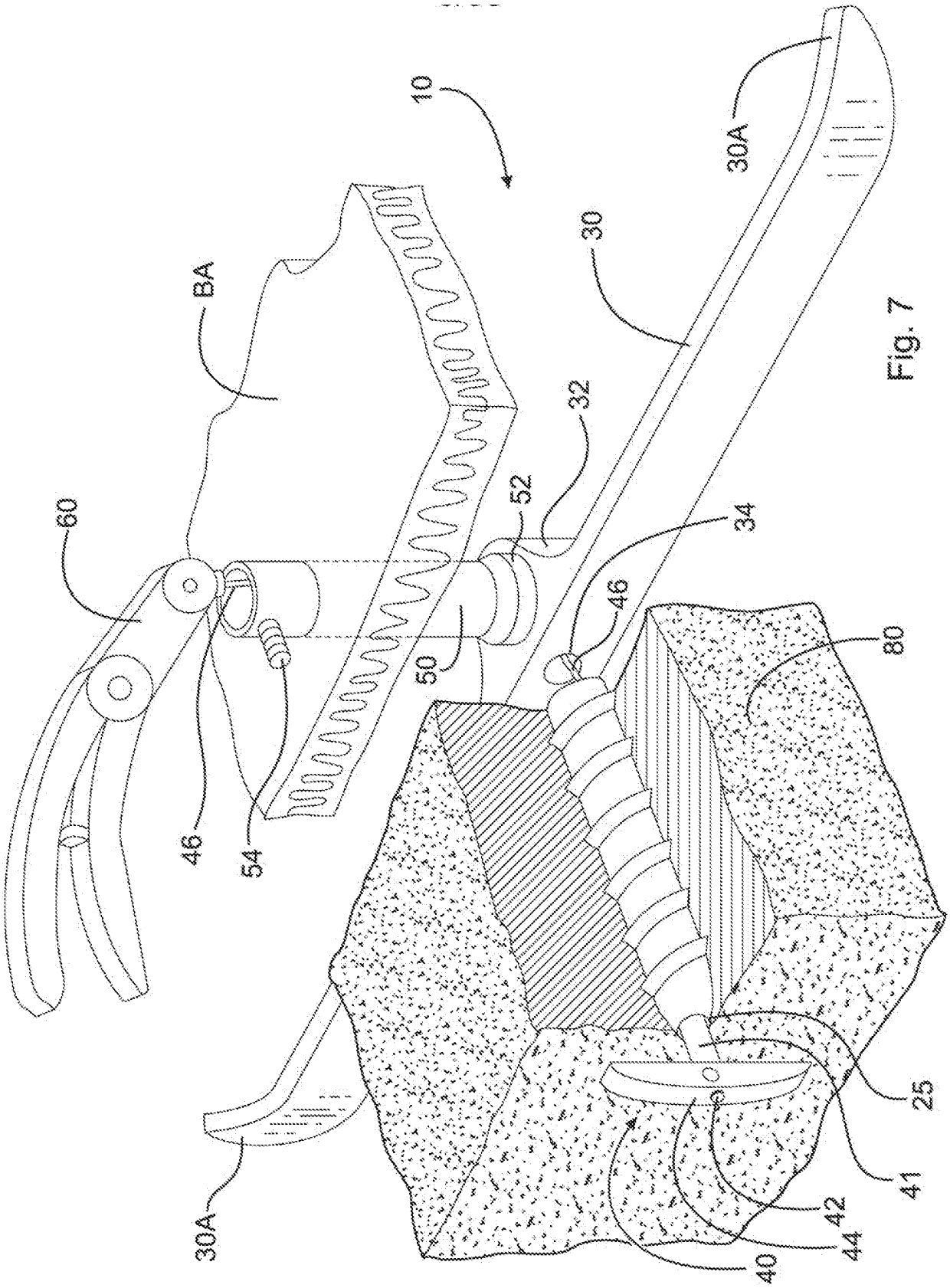


Fig. 7

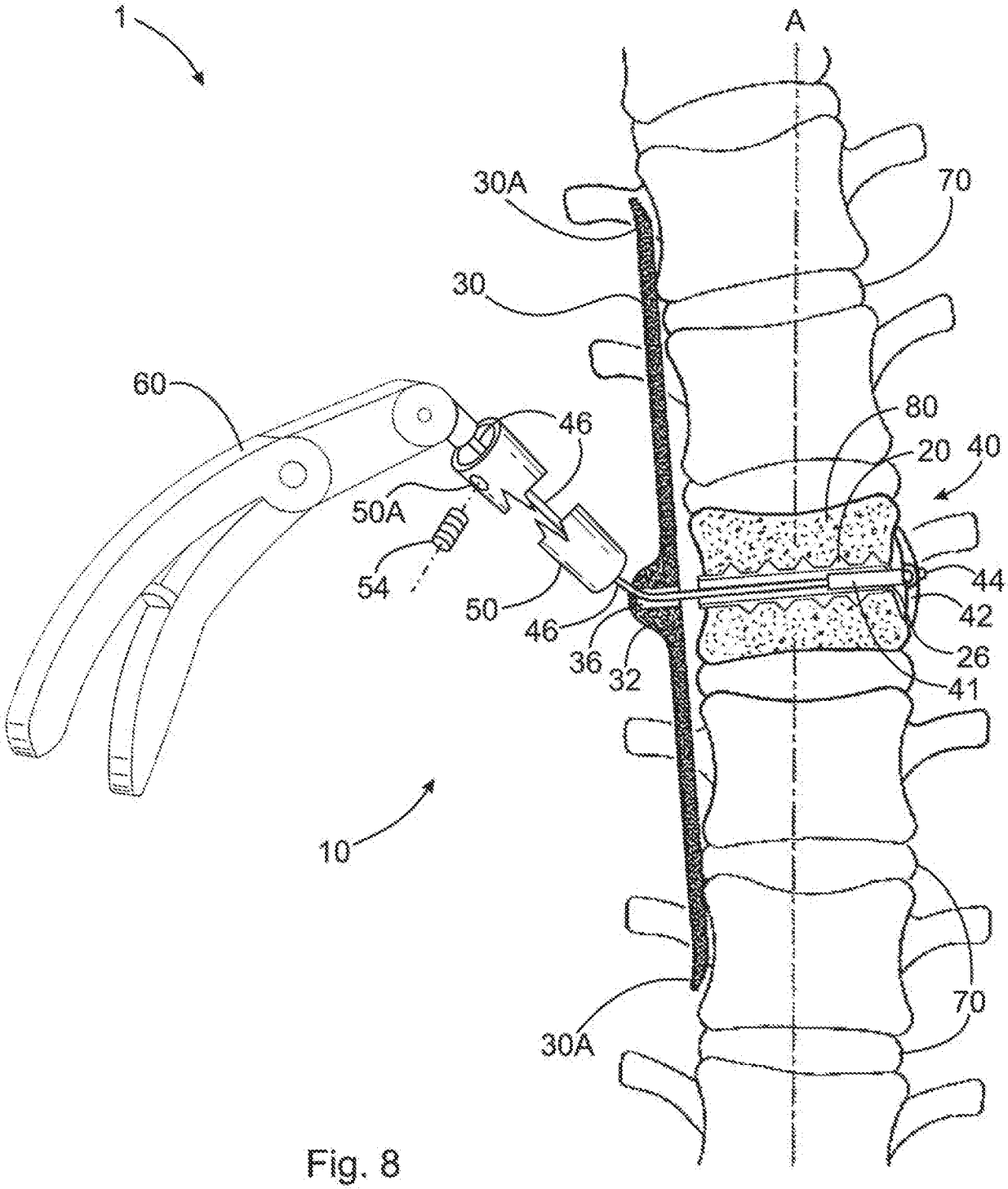


Fig. 8

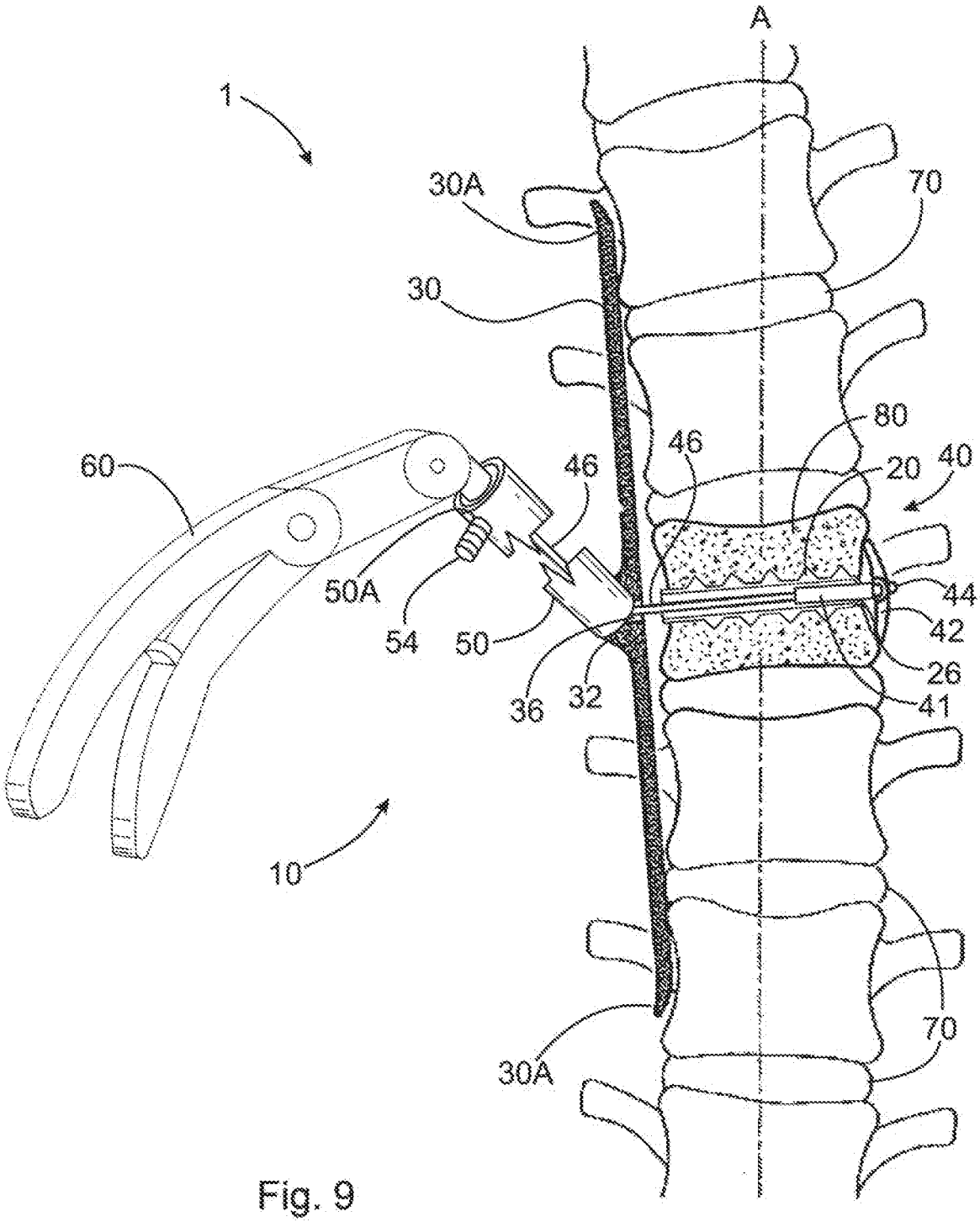


Fig. 9

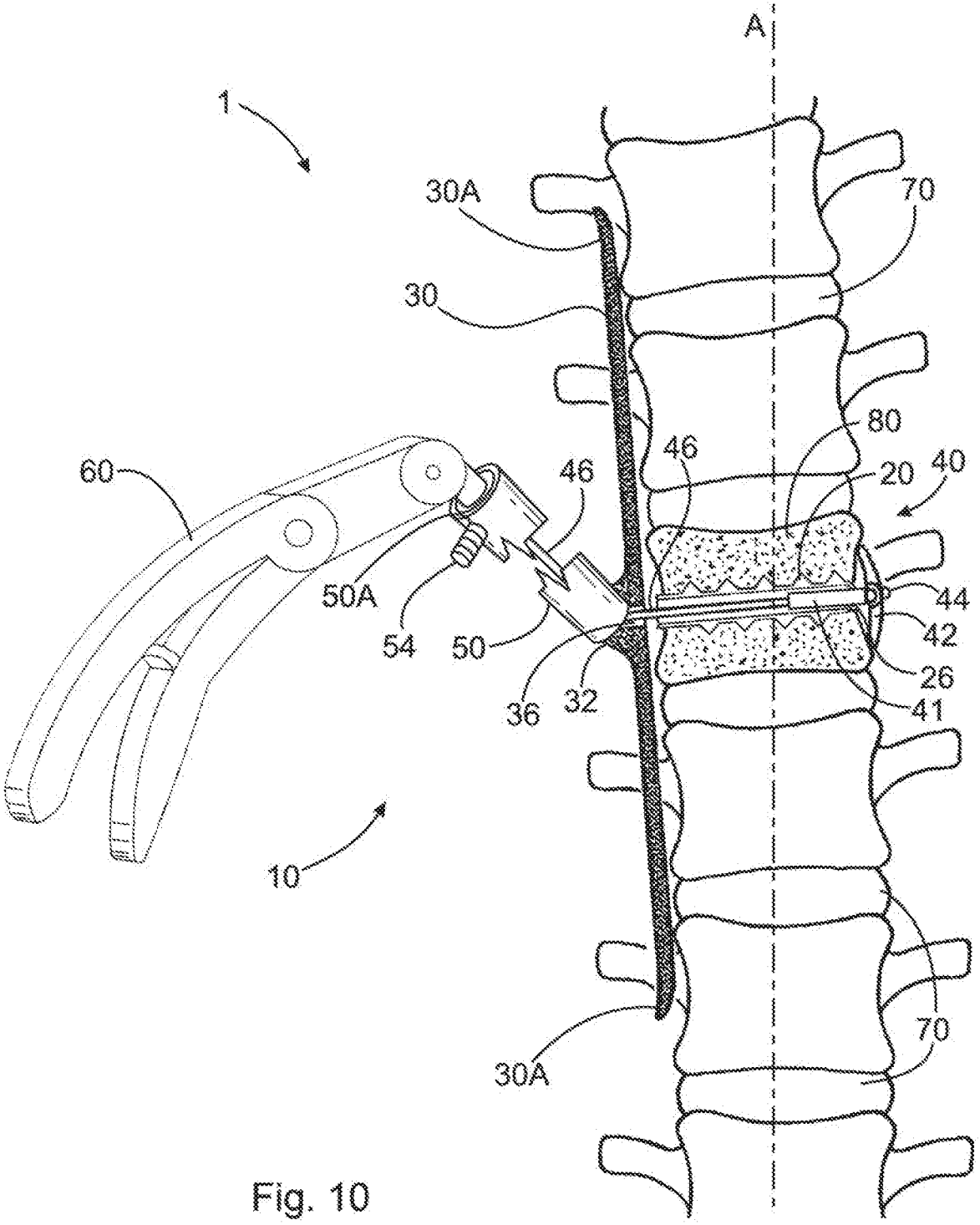


Fig. 10

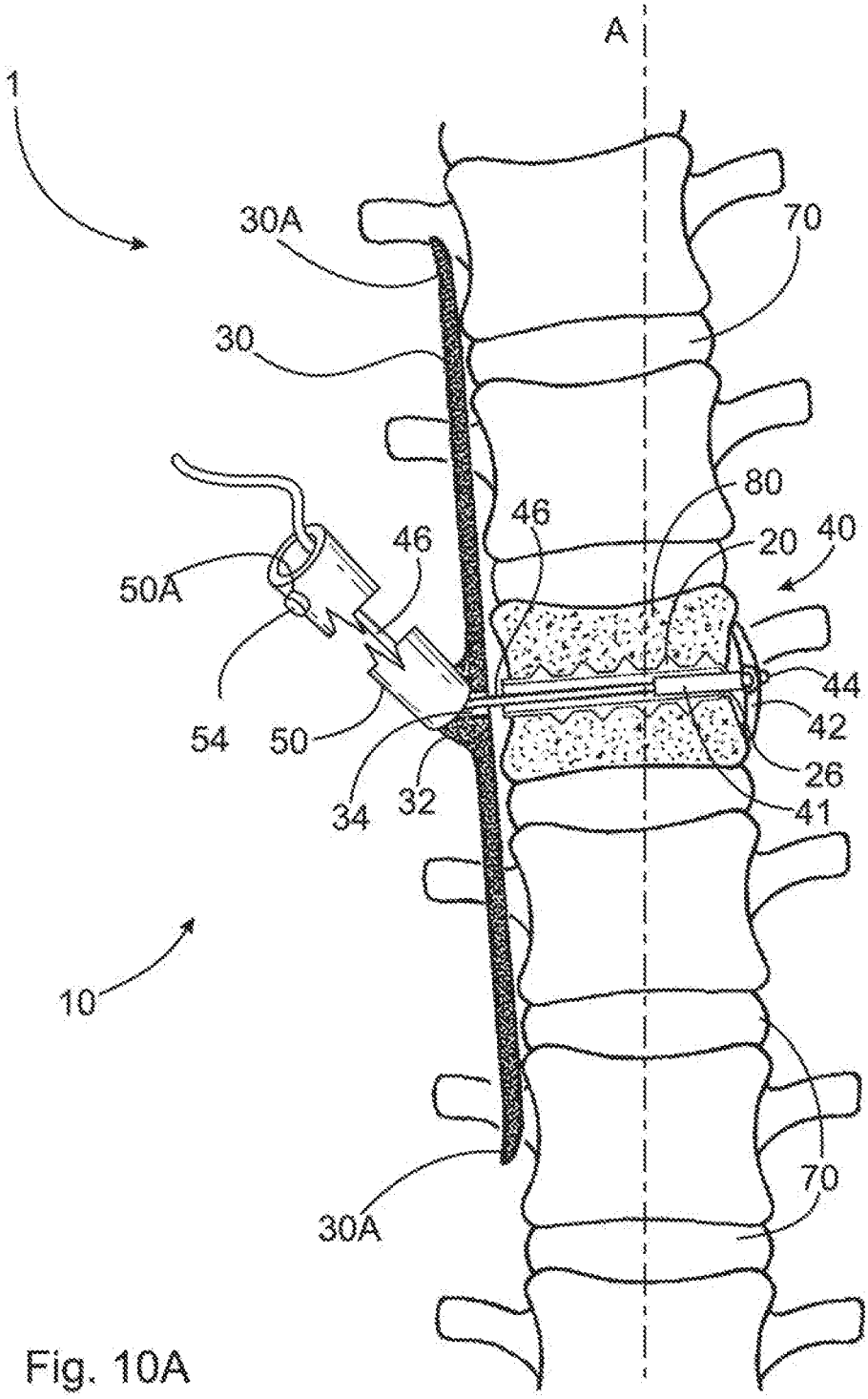


Fig. 10A

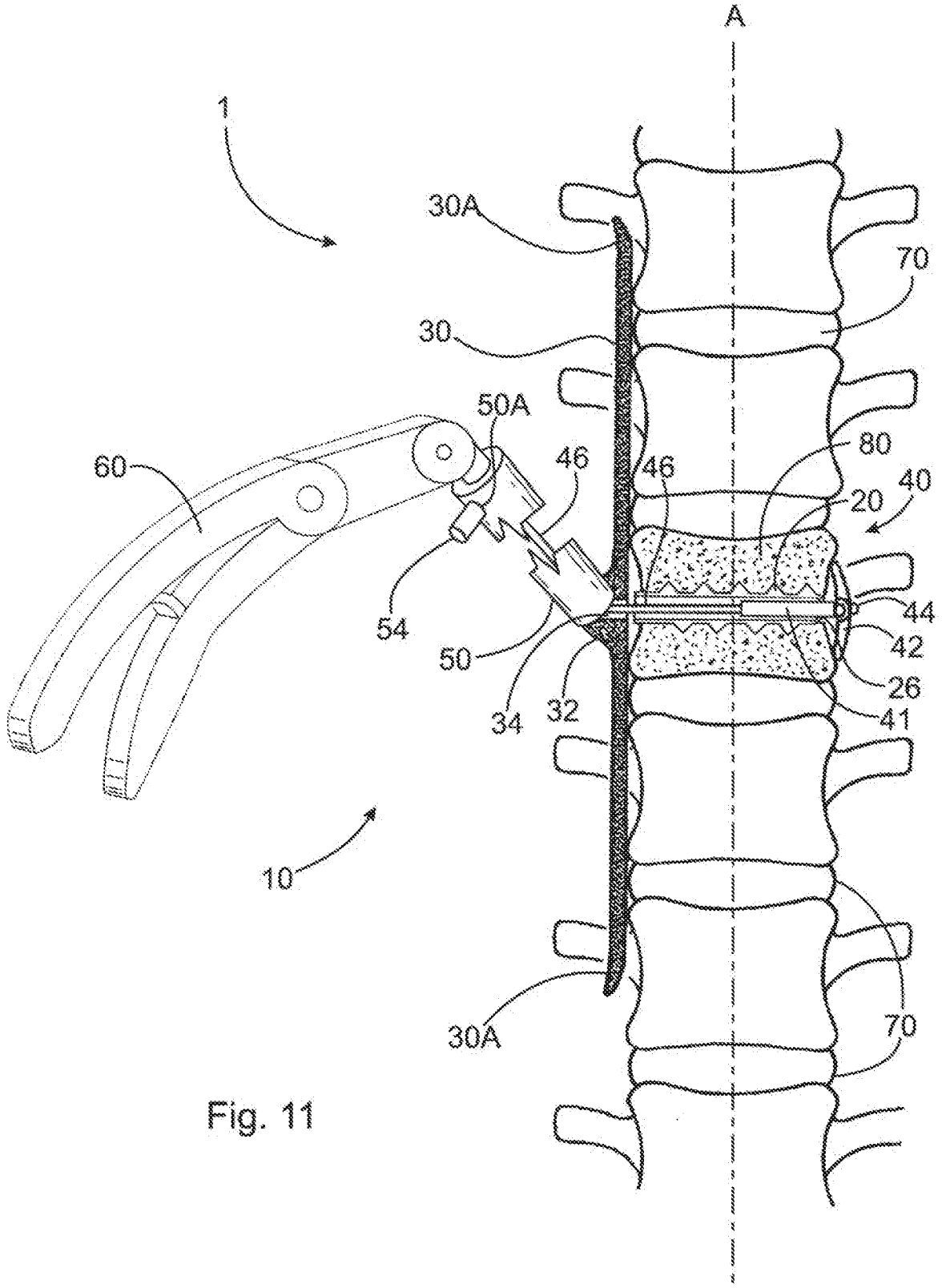


Fig. 11

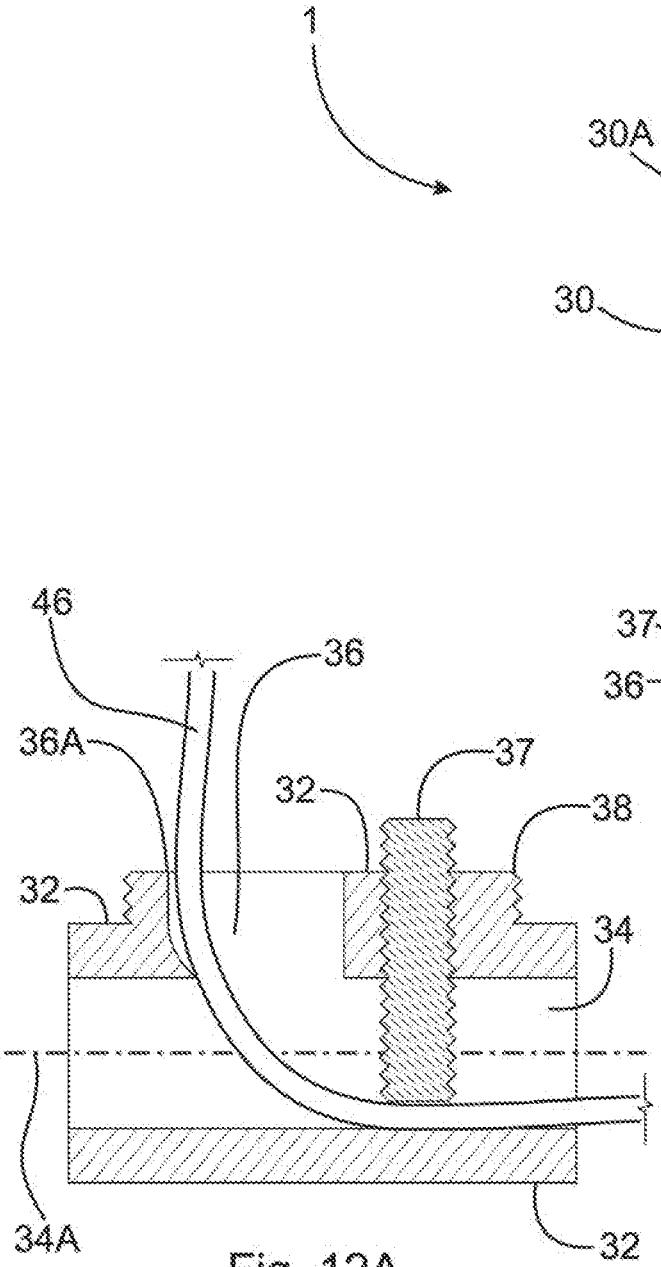


Fig. 12A

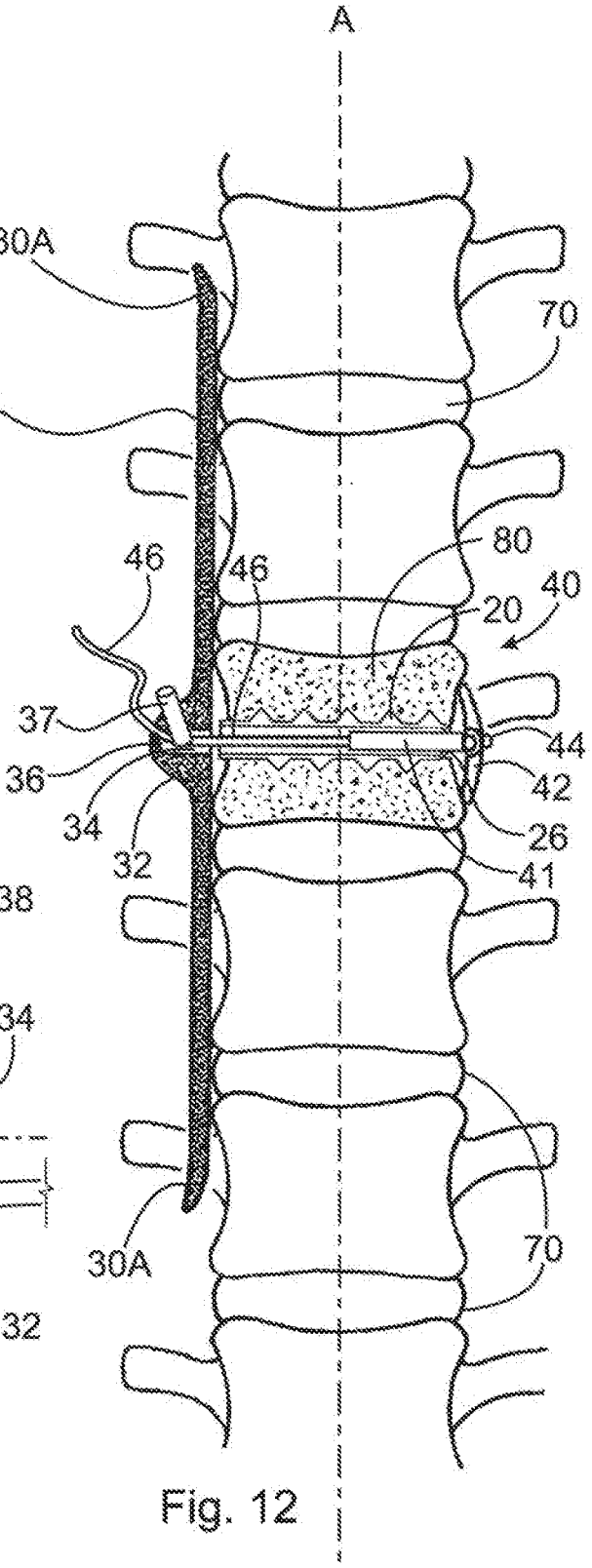


Fig. 12

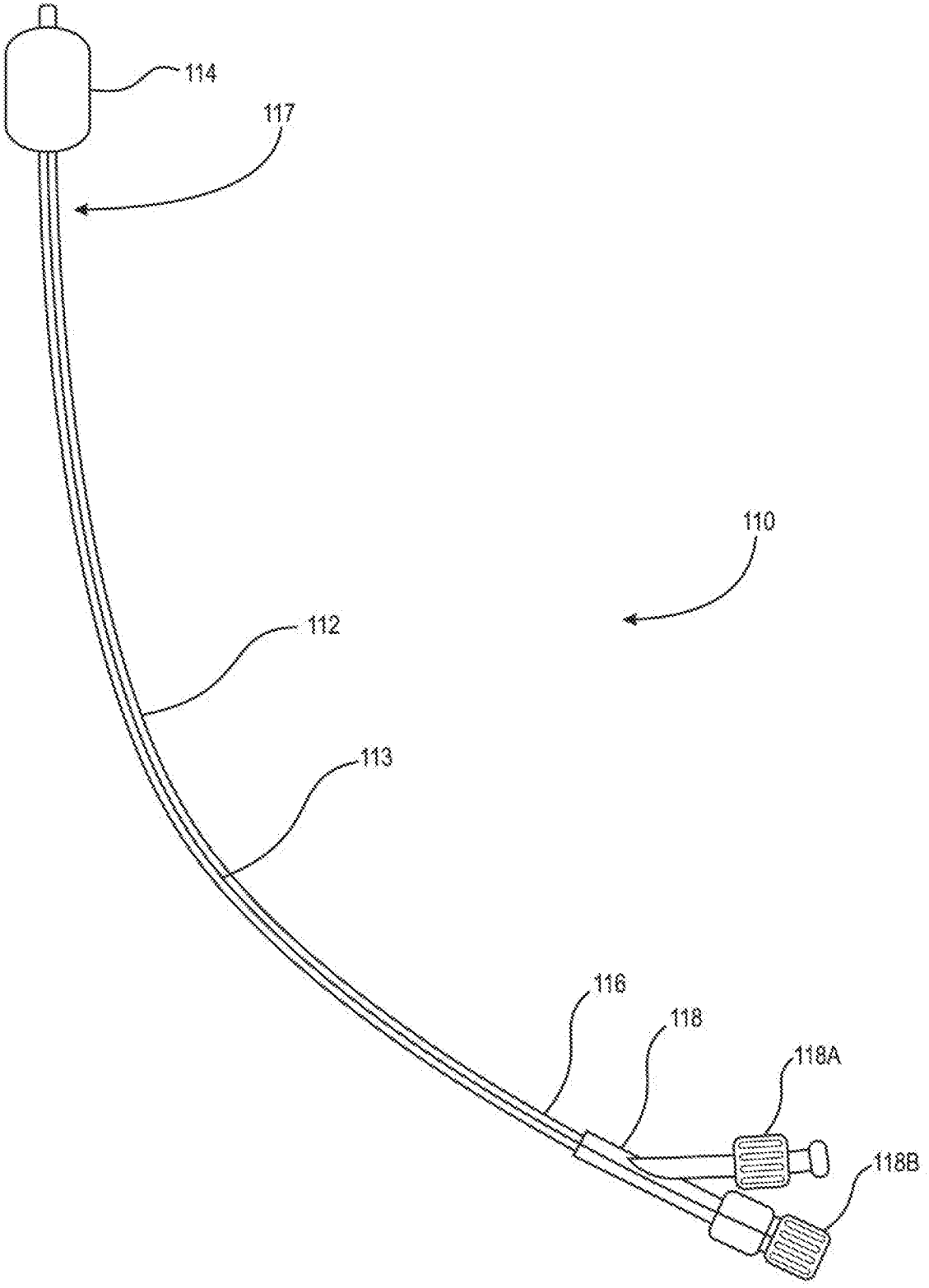


Fig. 13

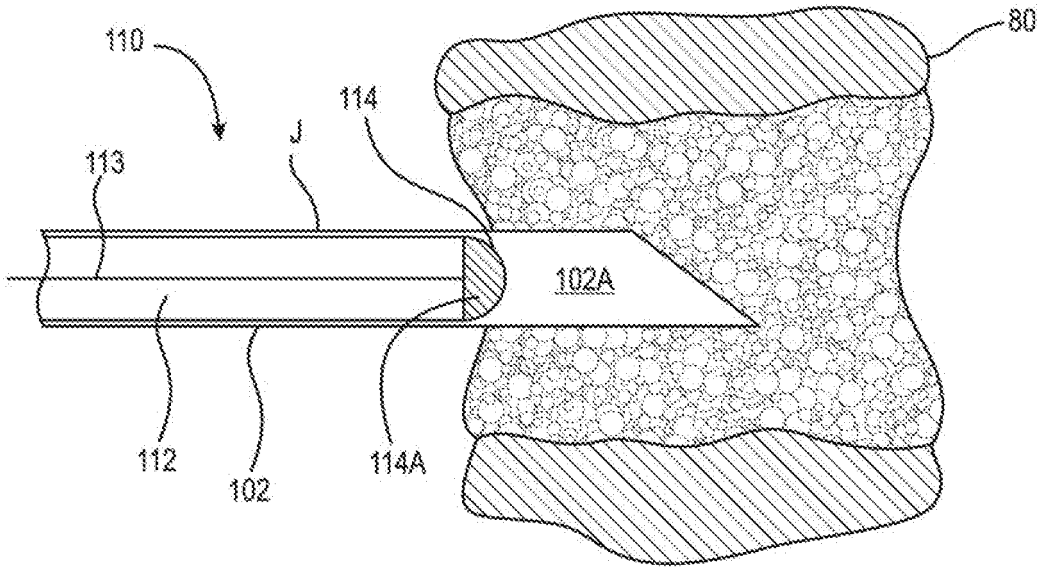


Fig. 14A

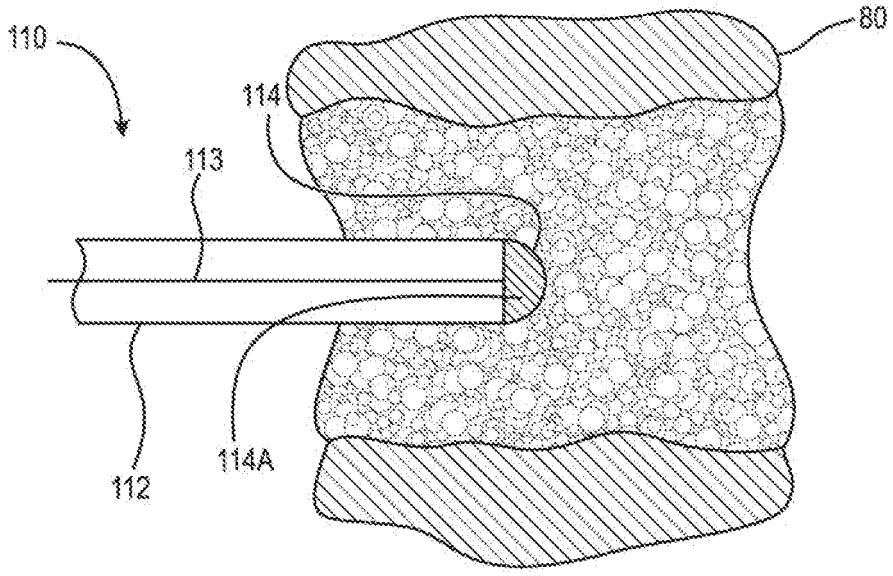


Fig. 14B

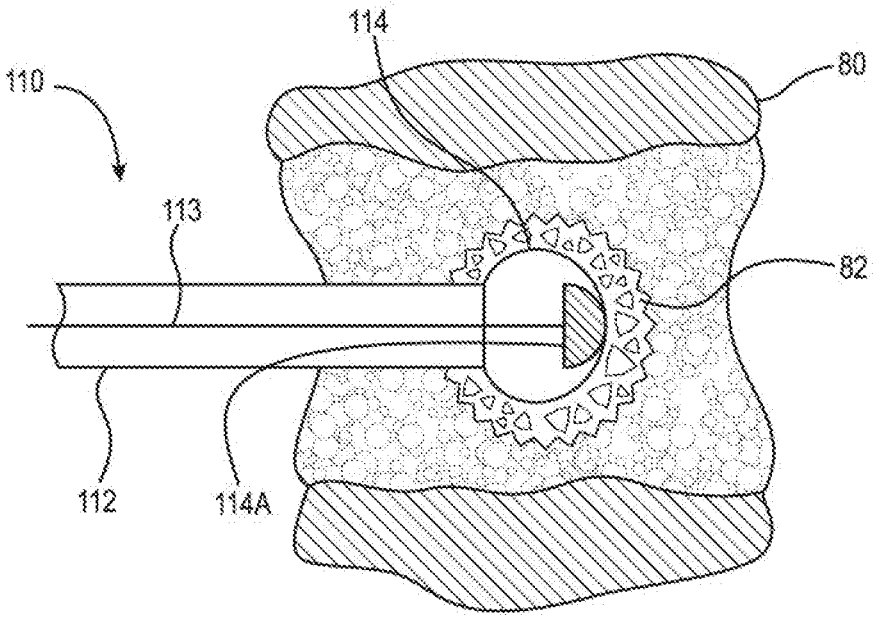


Fig. 14C

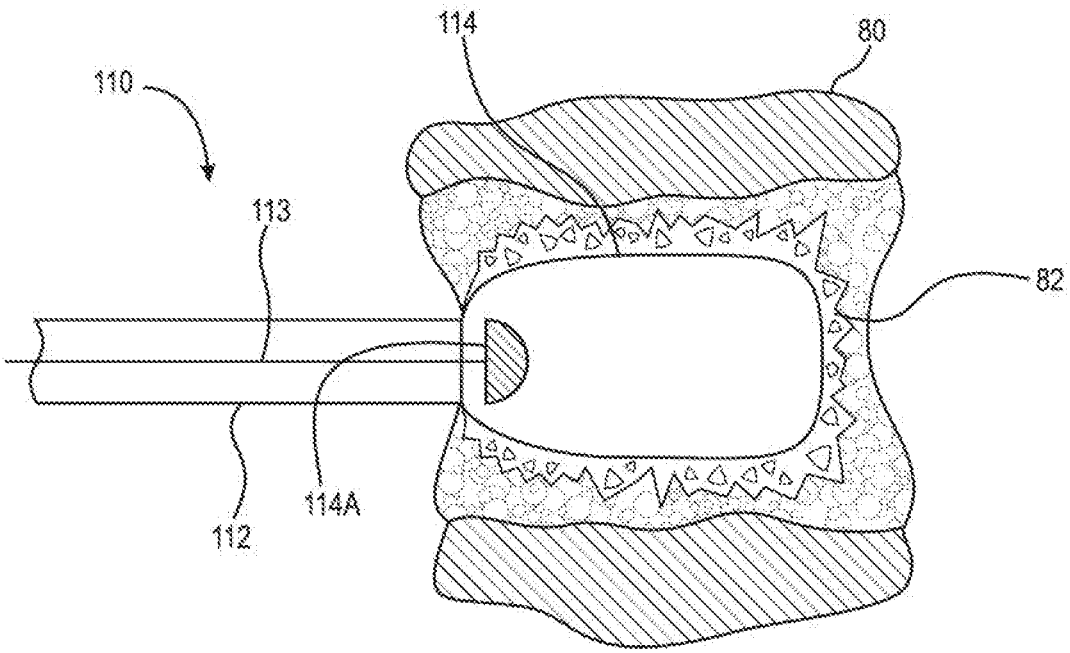


Fig. 14D

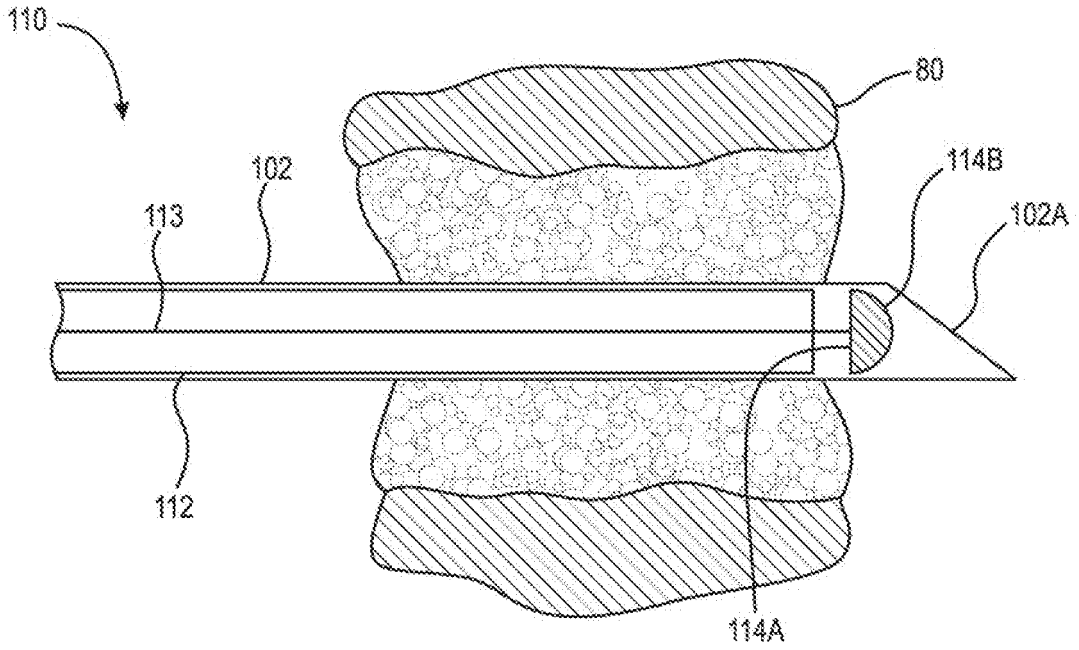


Fig. 15A

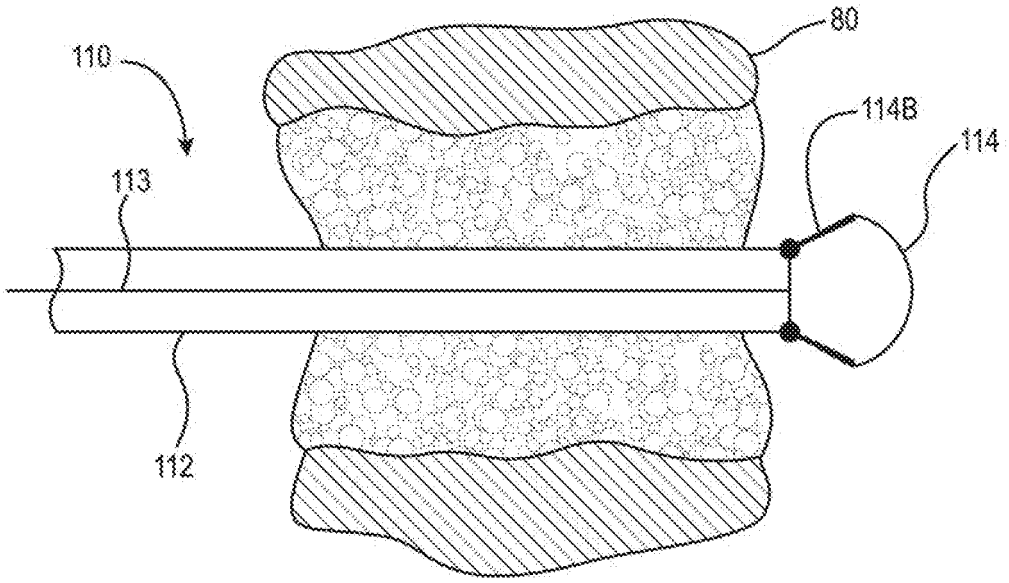


Fig. 15B

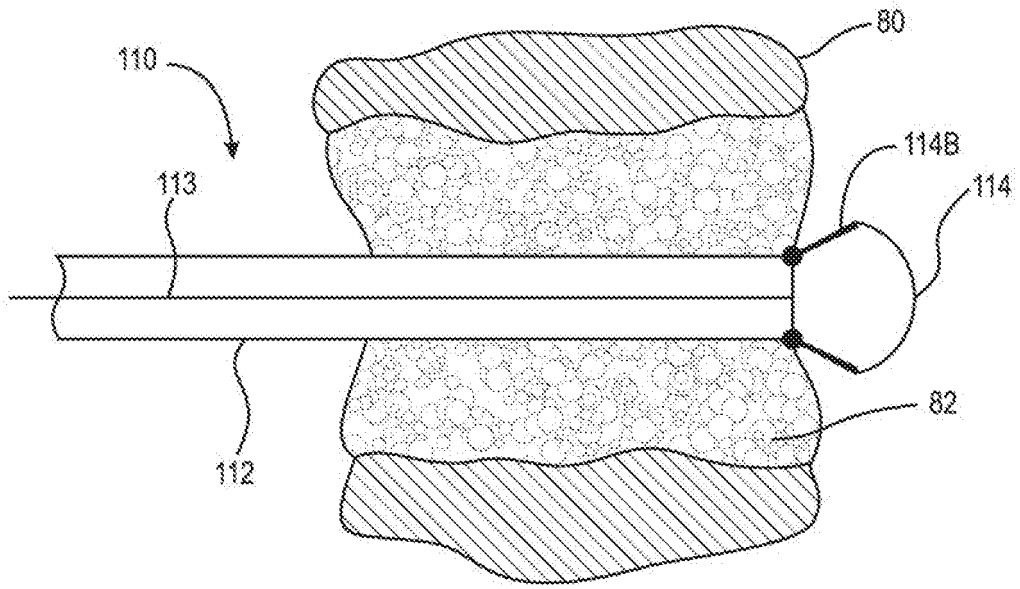


Fig. 15C

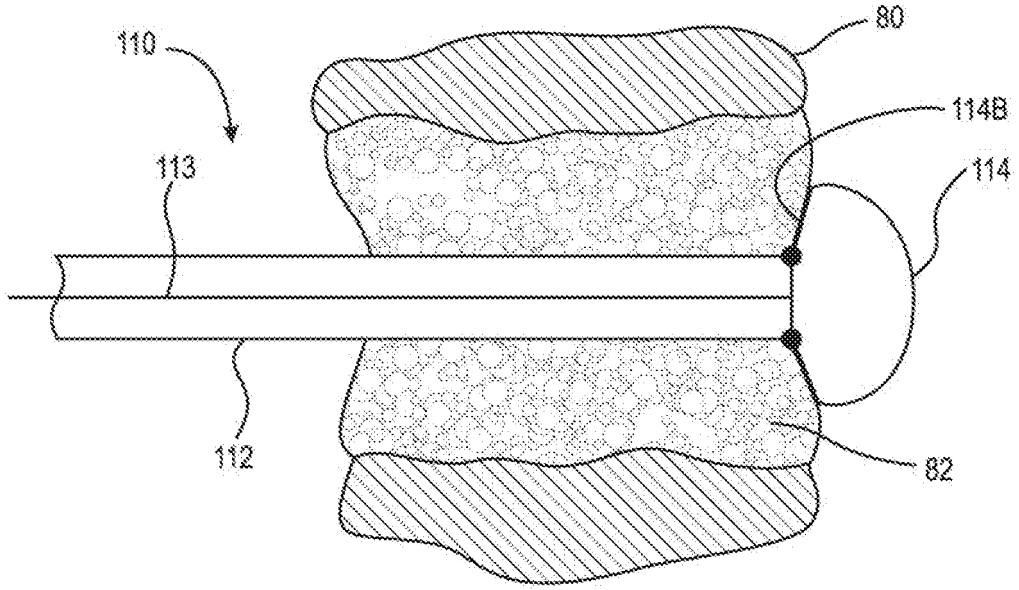
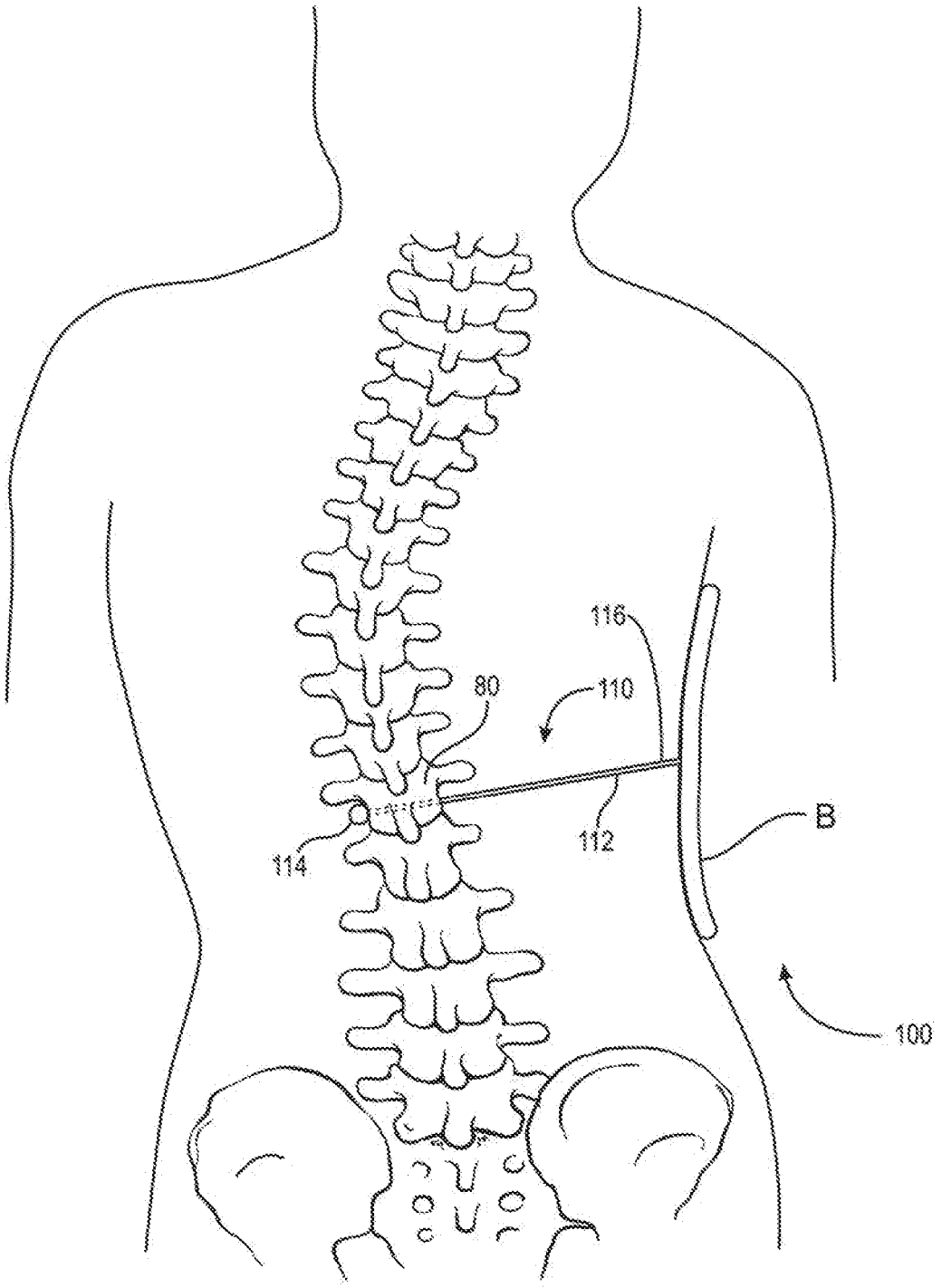


Fig. 15D



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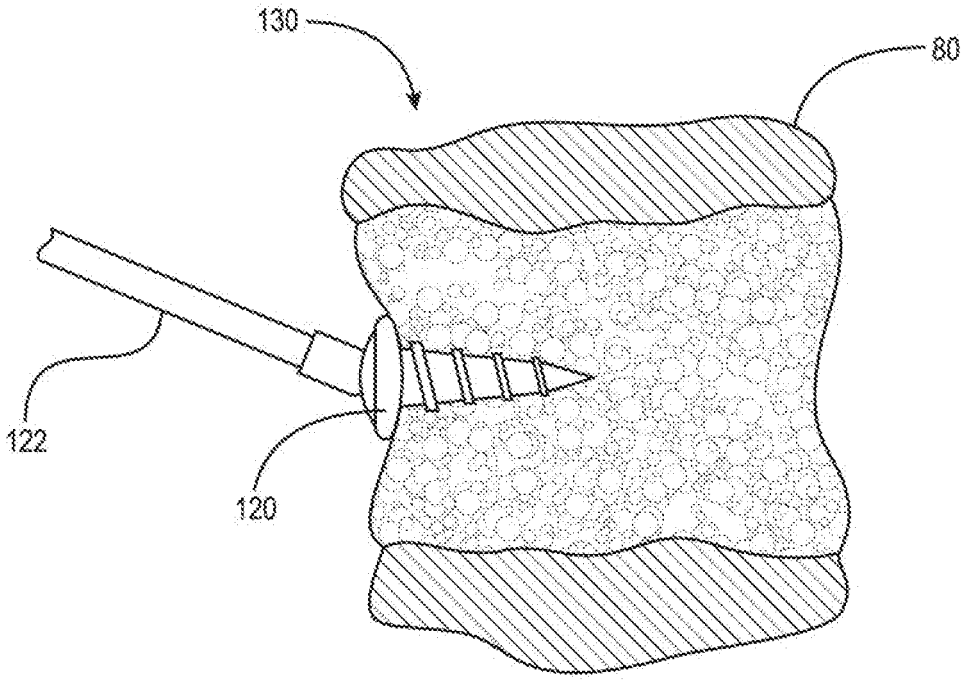


Fig. 17

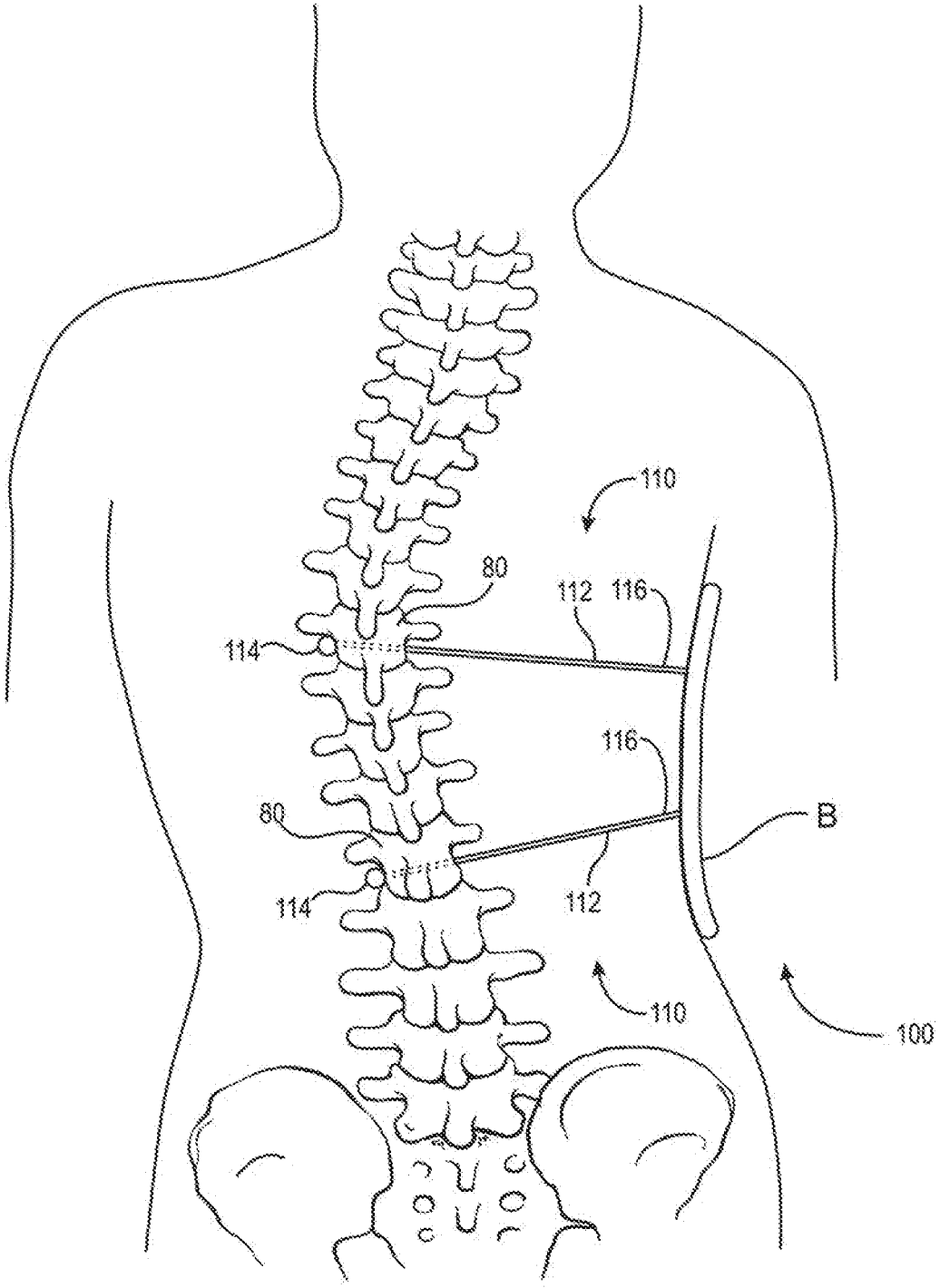


Fig. 18A

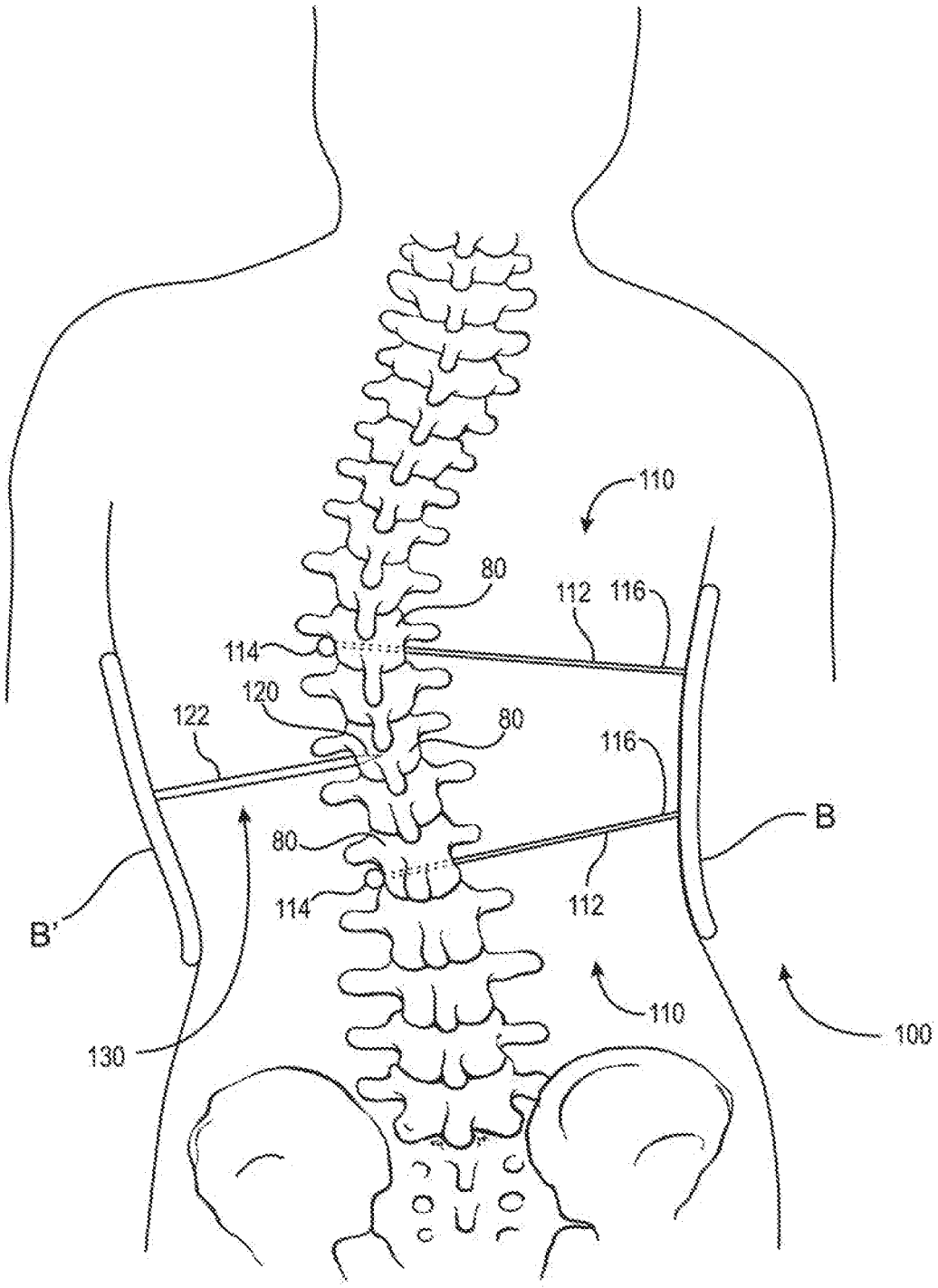
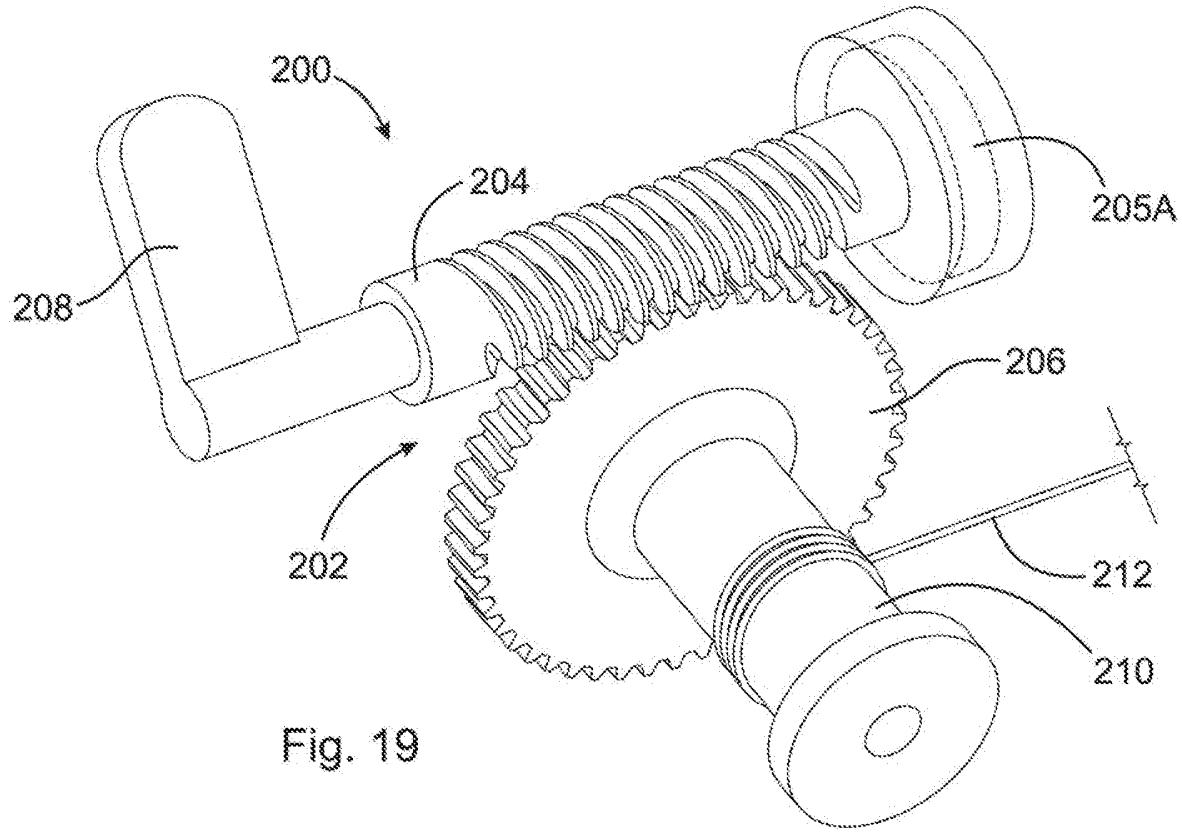


Fig. 18B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205A
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Fig. 19

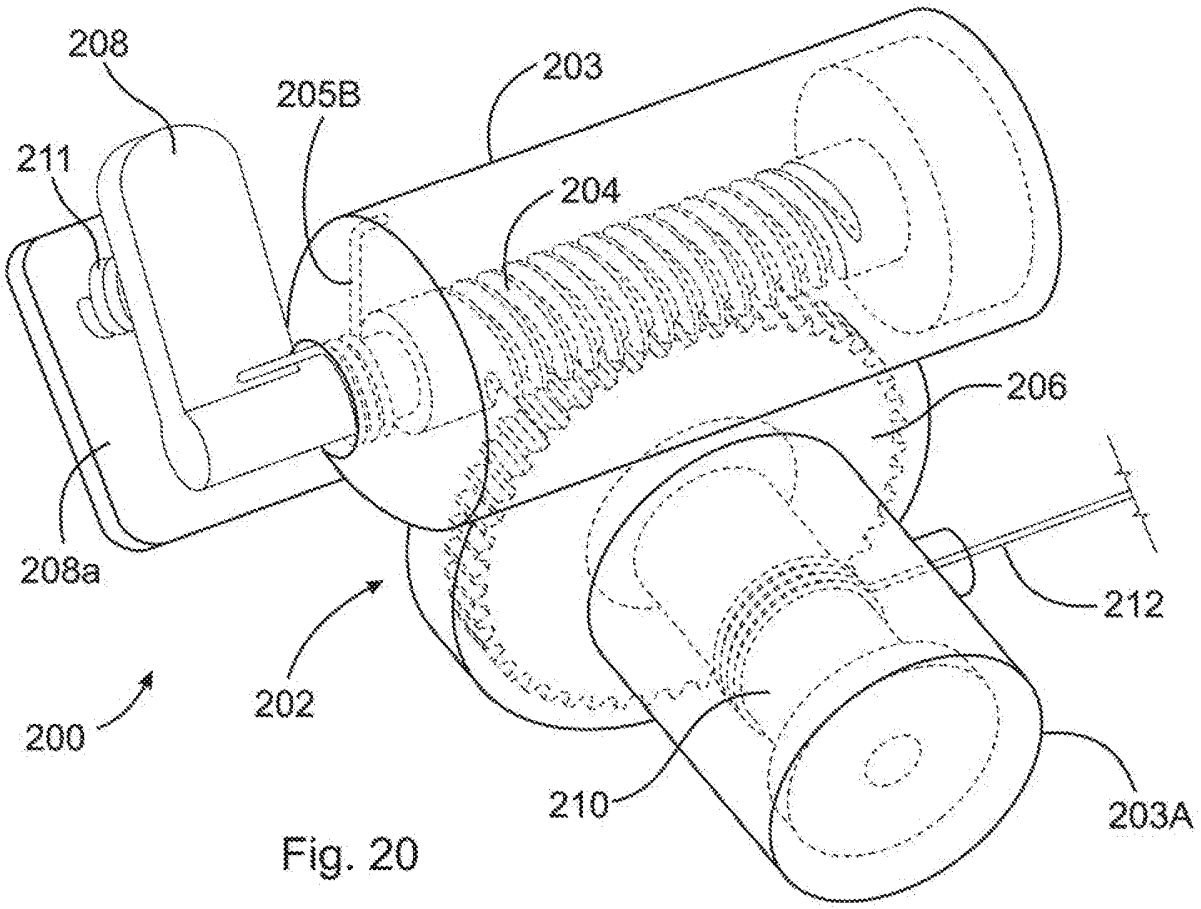
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Fig. 20

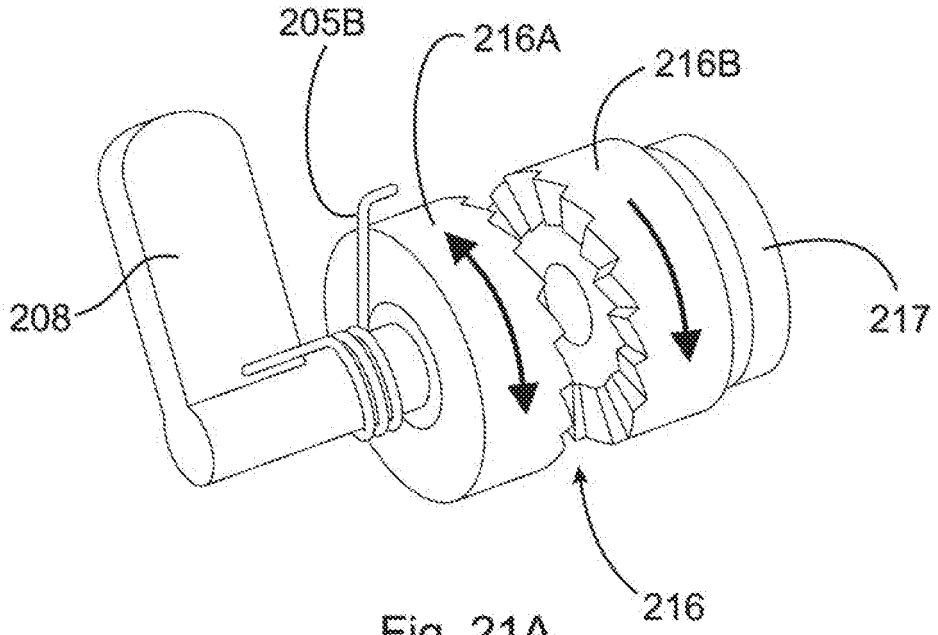


Fig. 21A

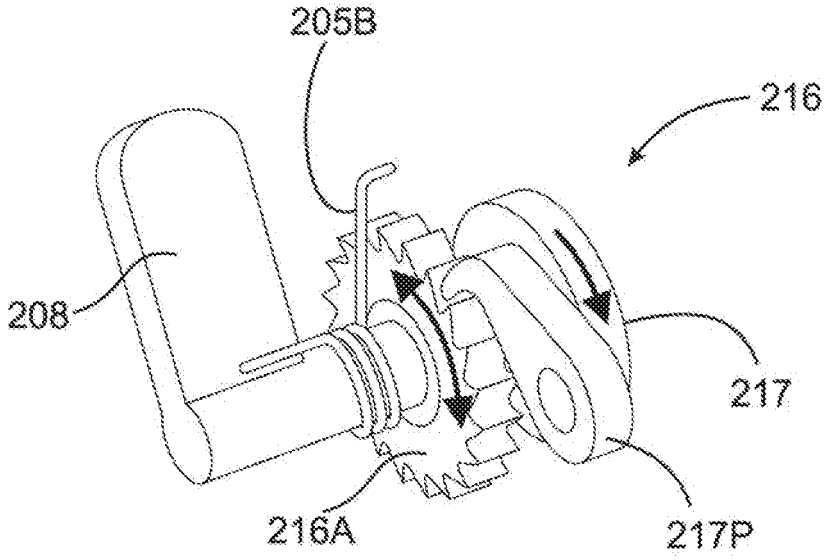


Fig. 21B

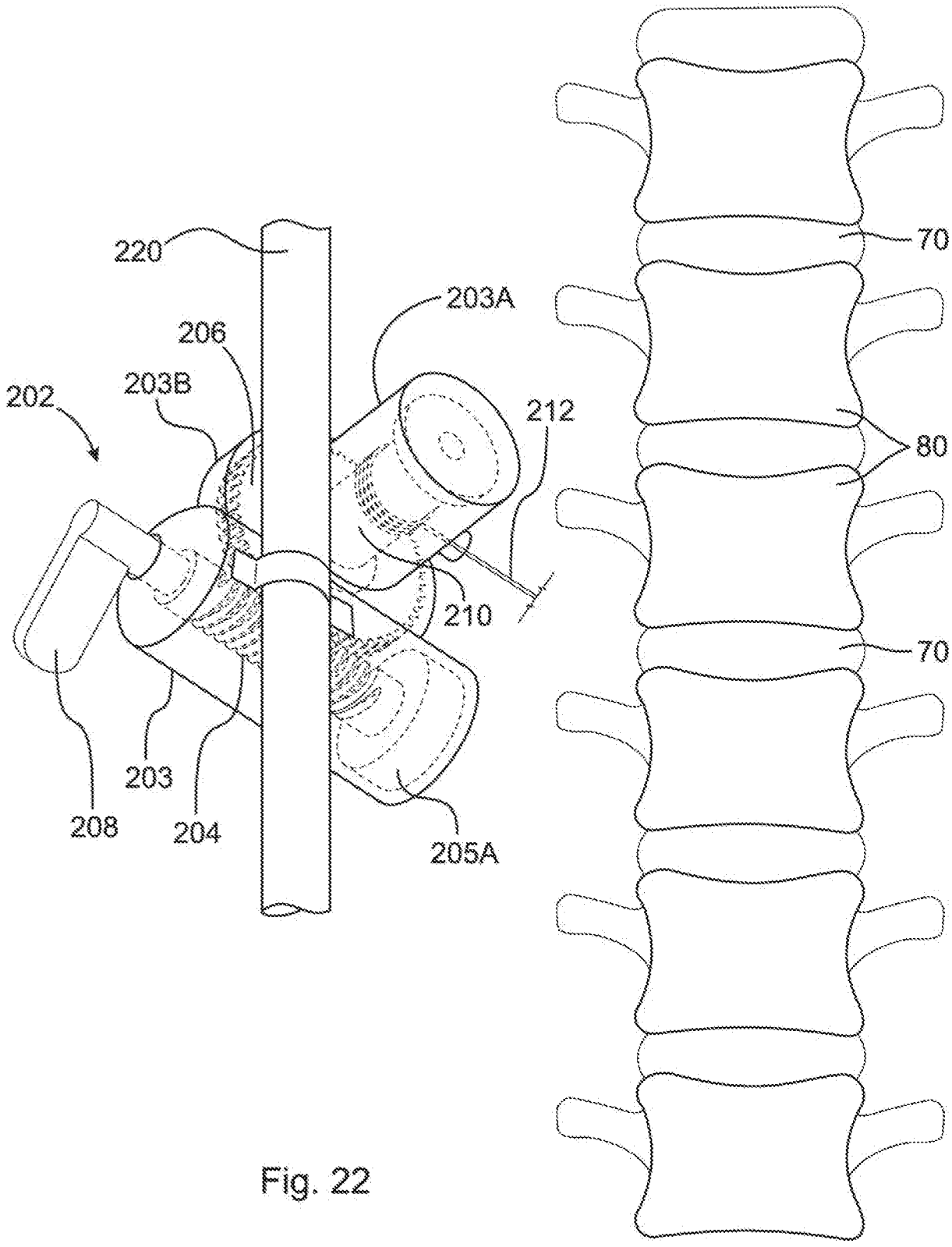
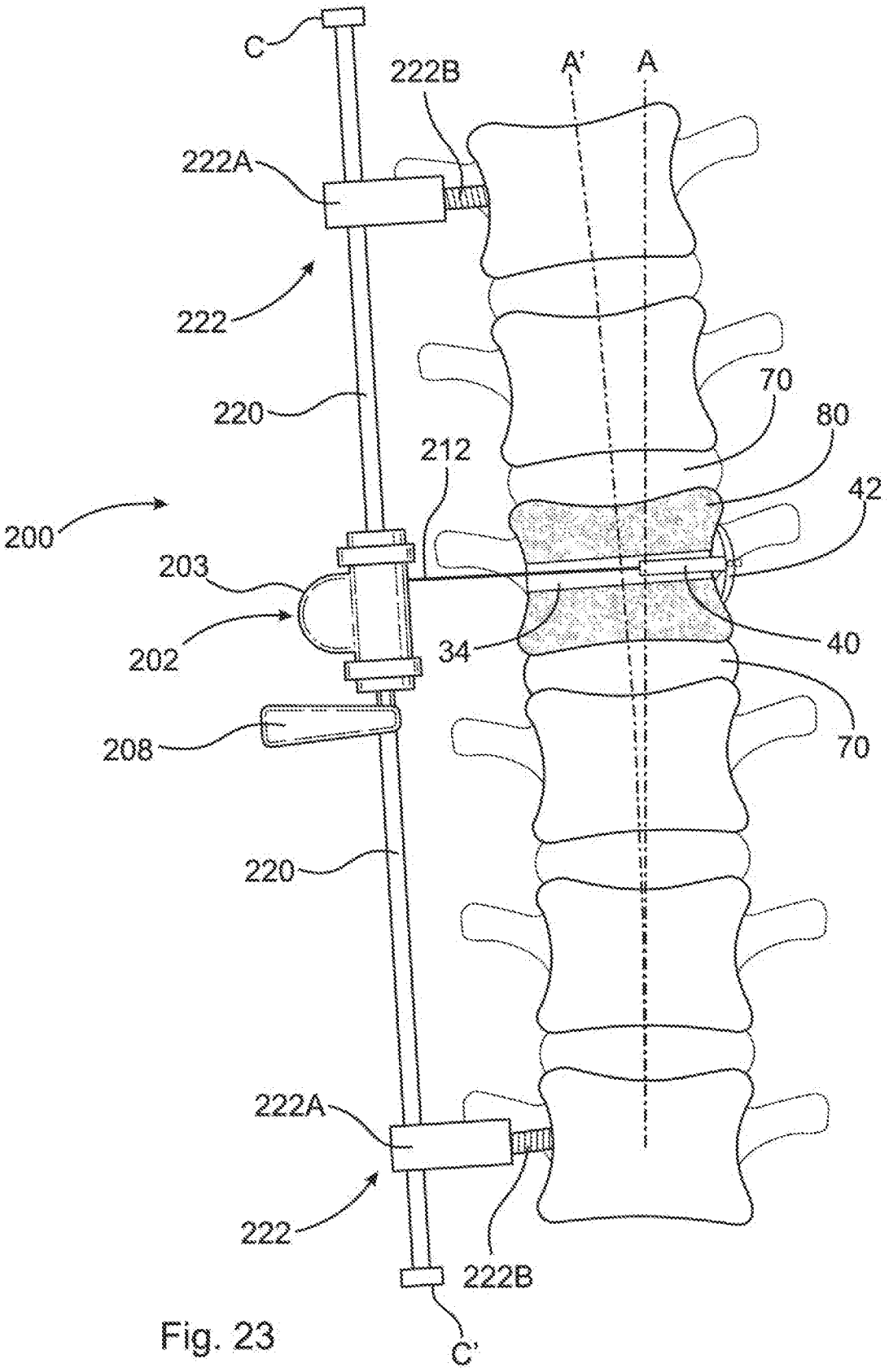


Fig. 22


C
222B
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202
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70
220
222A
222
222B
C'

Fig. 23

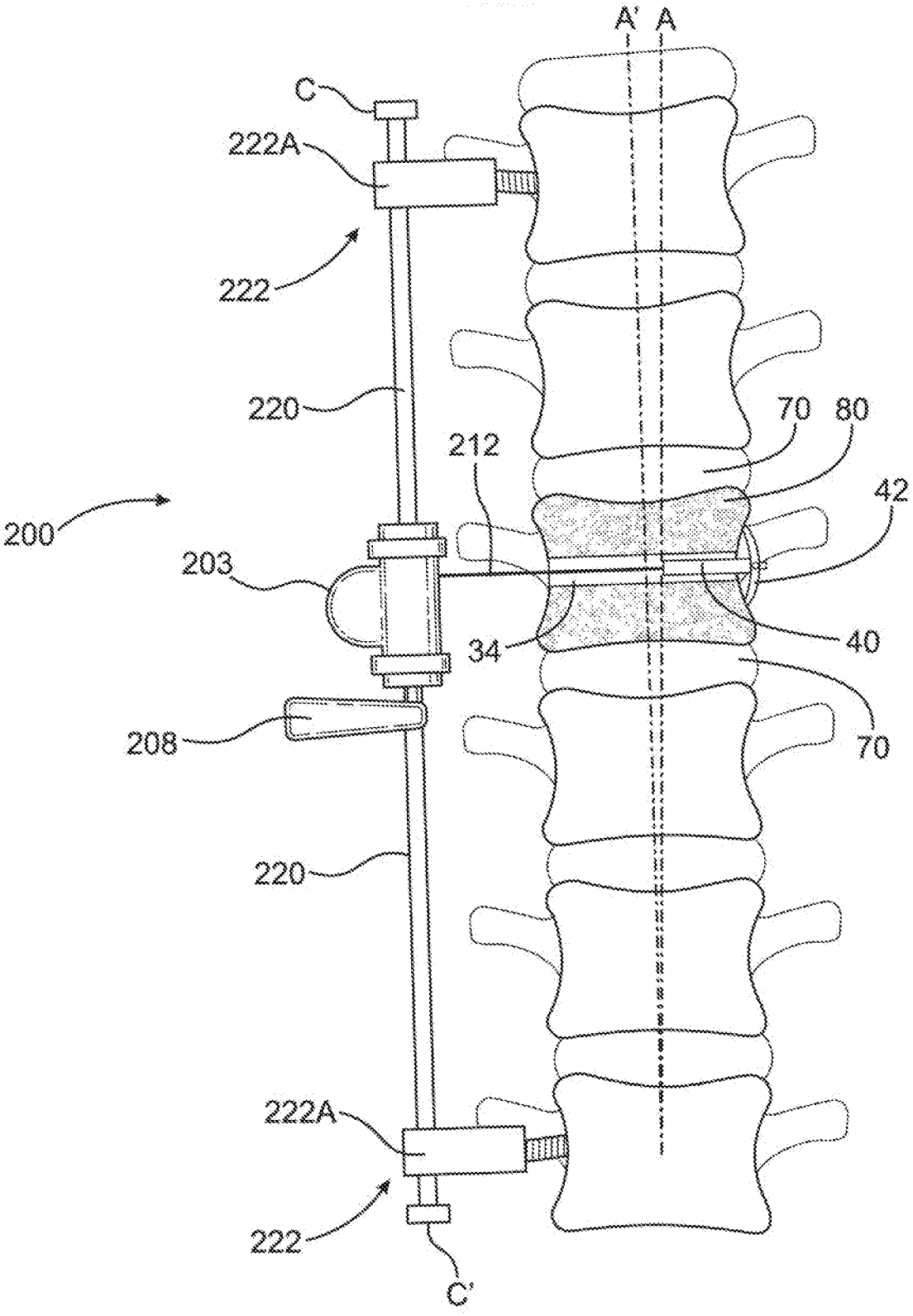


Fig. 24

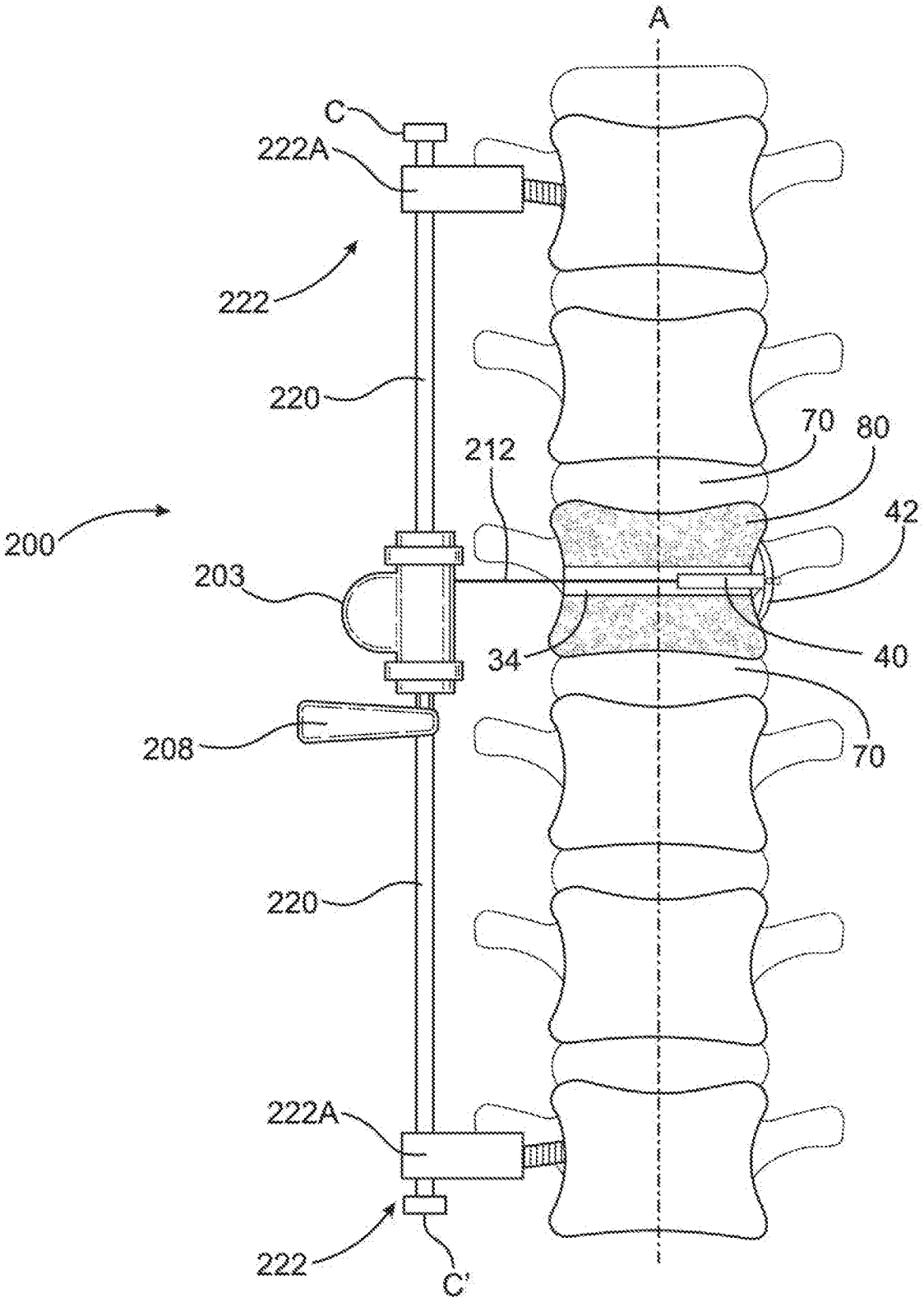


Fig. 25

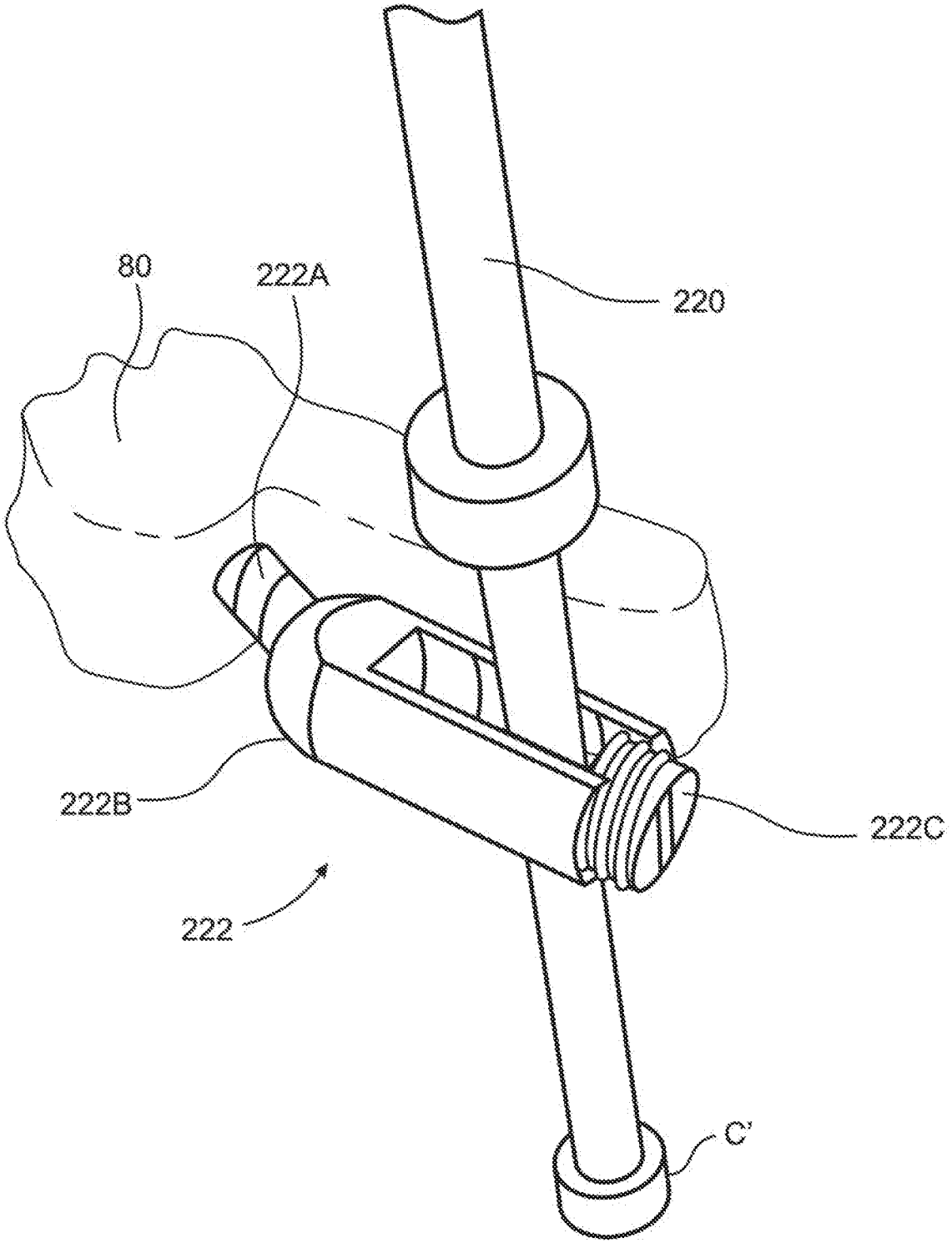


Fig. 26

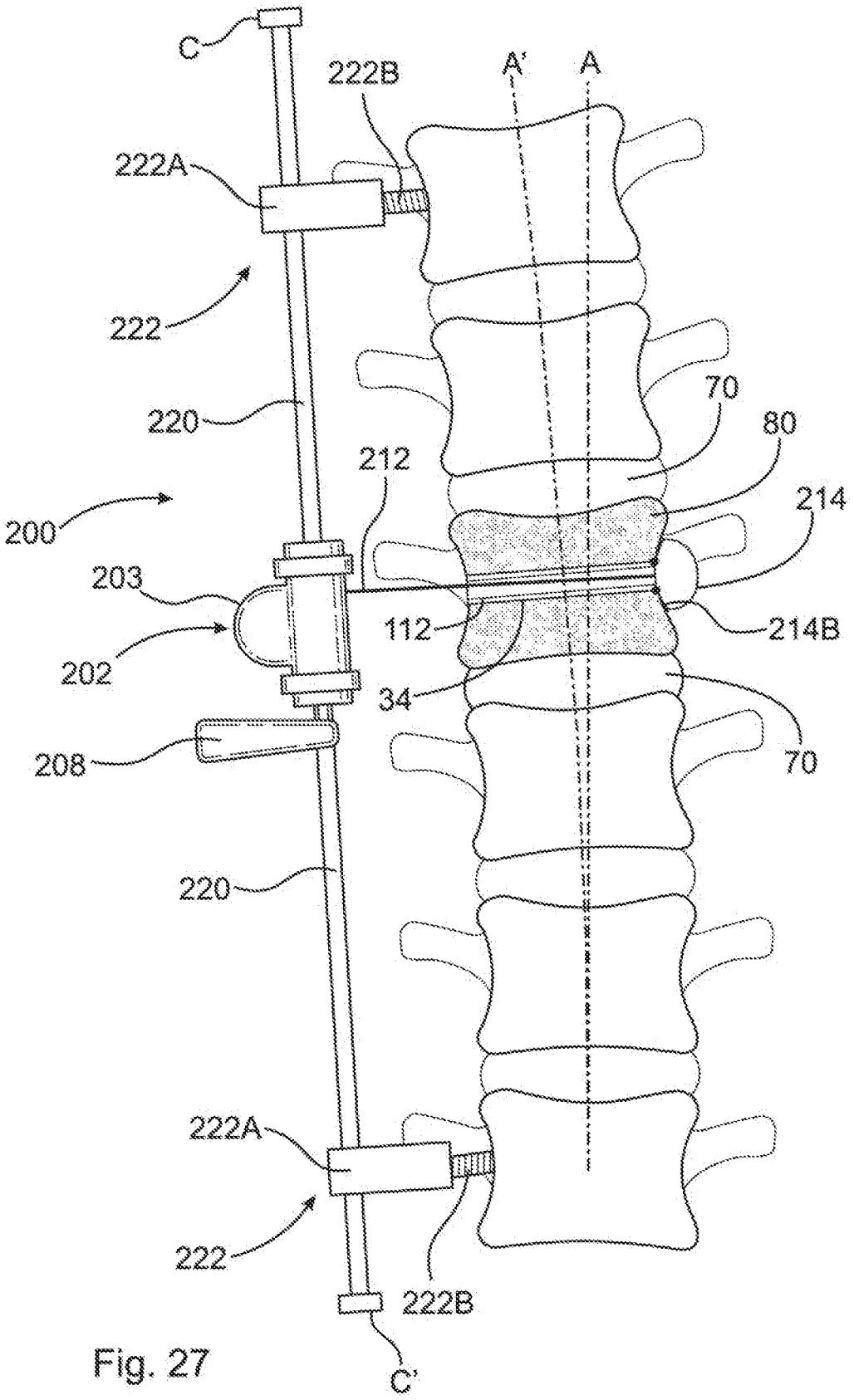
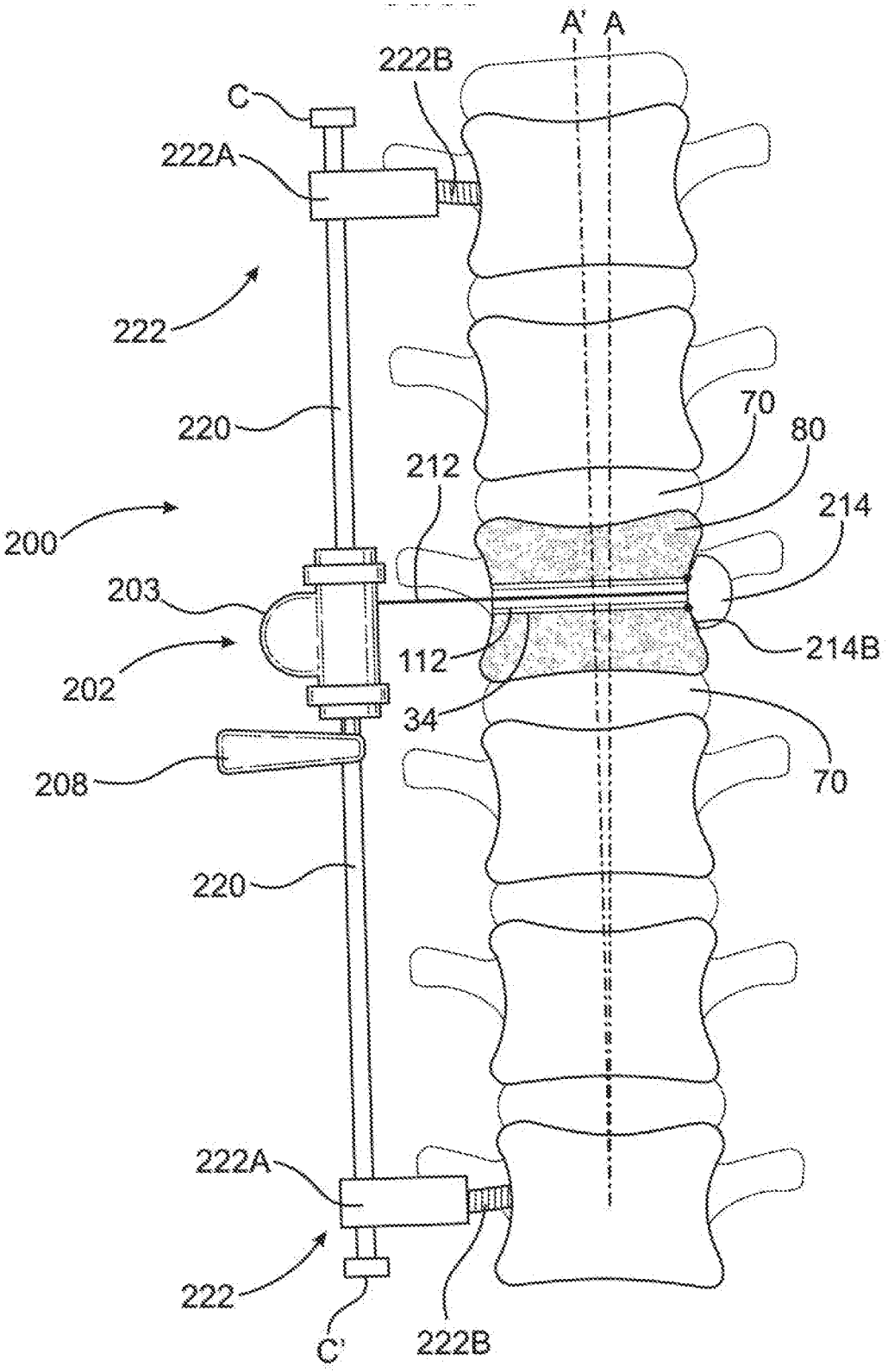

C
222B
A'
A
222A
222
220
70
80
212
214
200
203
112
214B
202
34
208
70
220
222A
222
222B
C'

Fig. 27


A'
A
222B
C
222A
222
220
70
80
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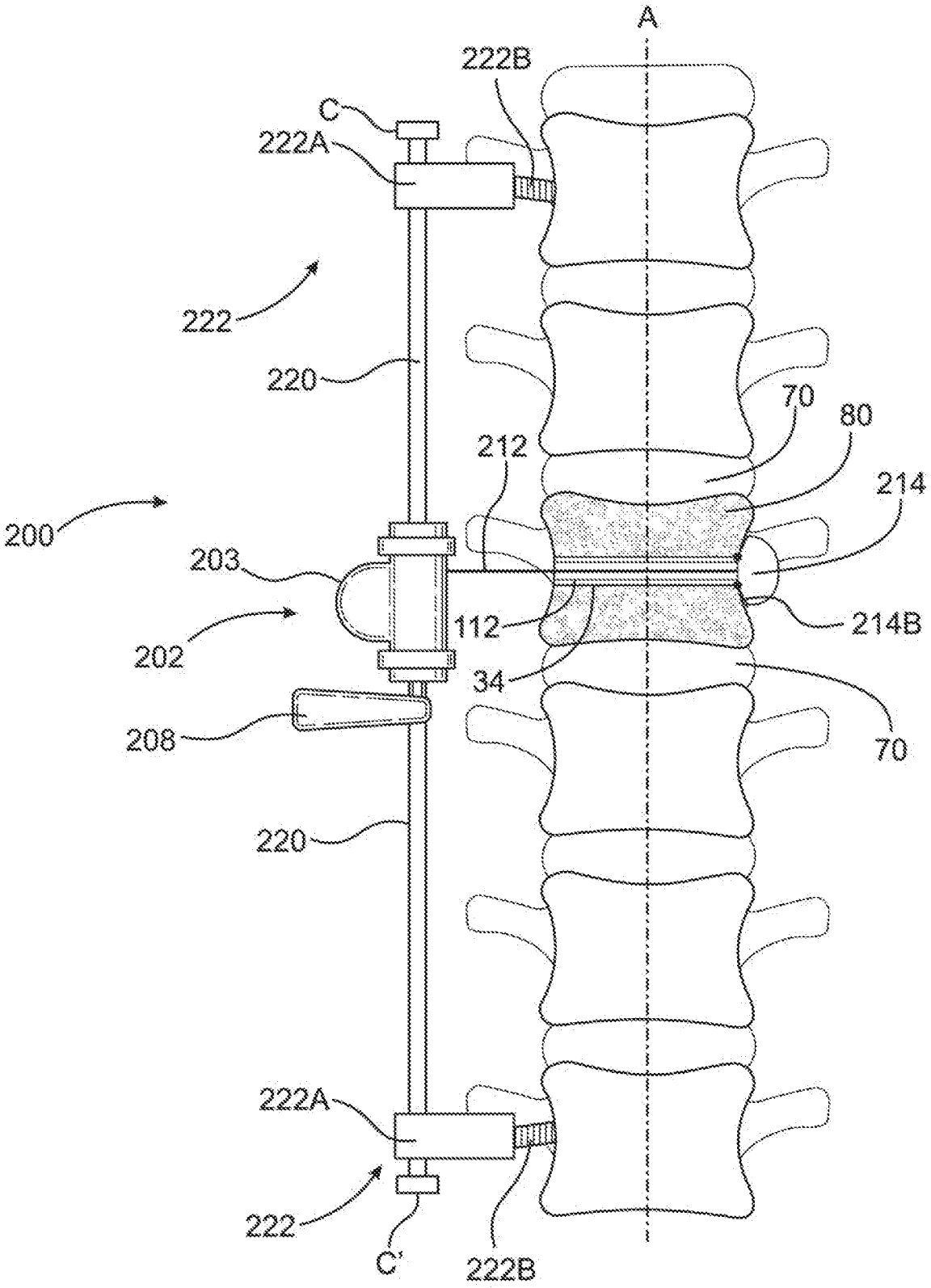
214
200
203
214B
112
202
34
208
70
220
222A
222
C'
222B

Fig. 28


A
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C
222A
222
220
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80
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214
200
203
202
112
214B
34
208
70
220
222A
222
C'
222B

Fig. 29

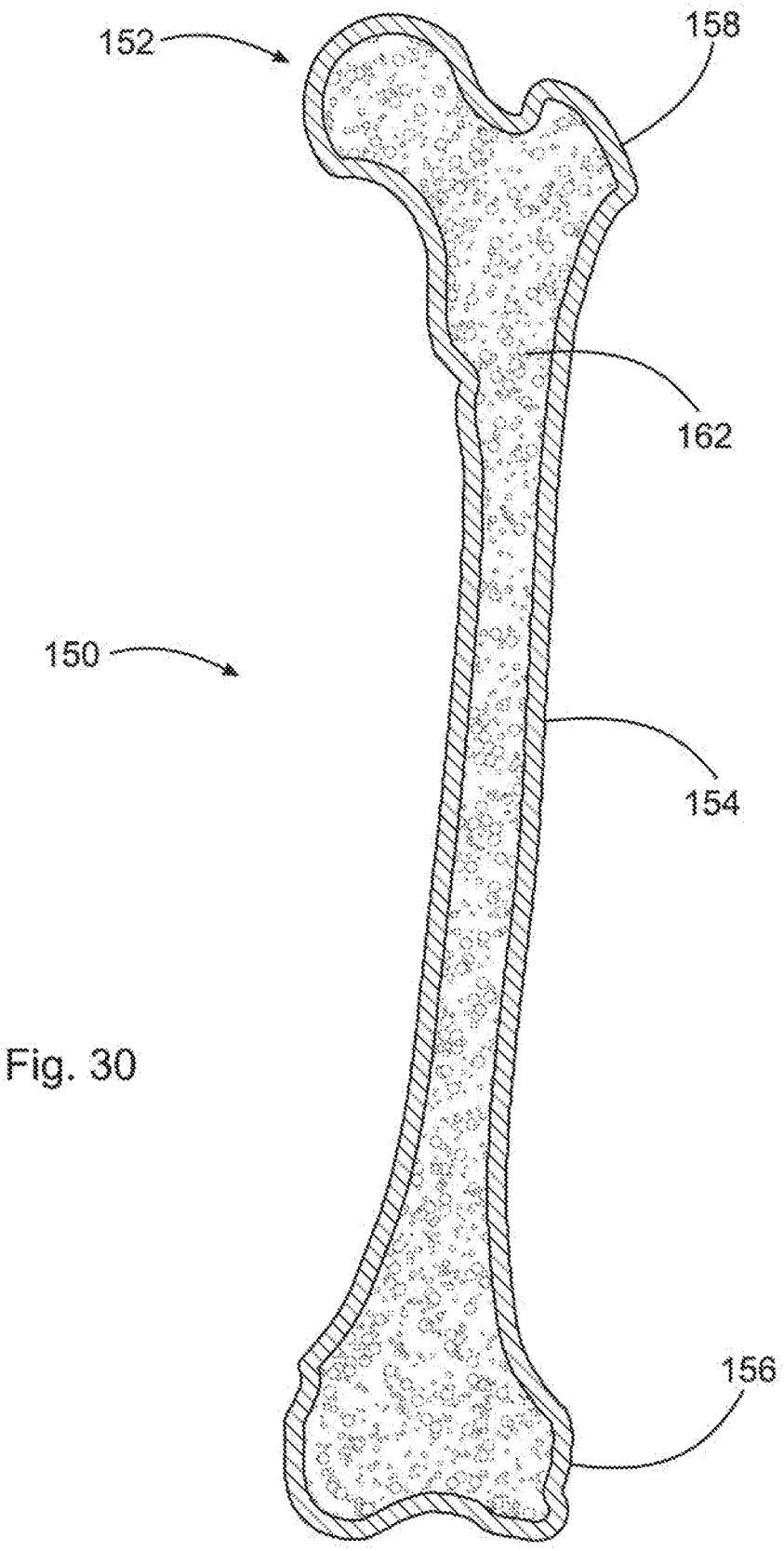


Fig. 30

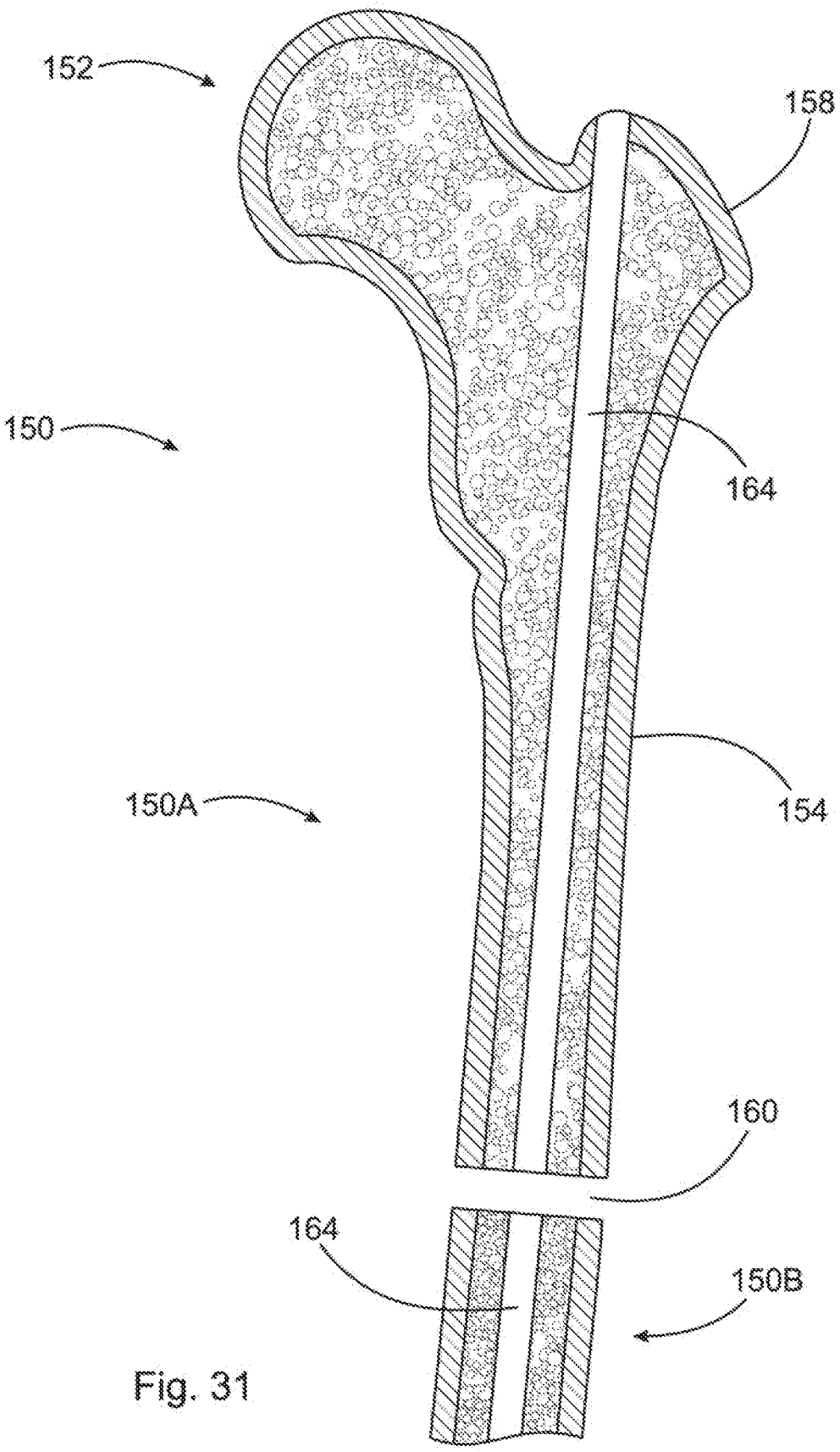
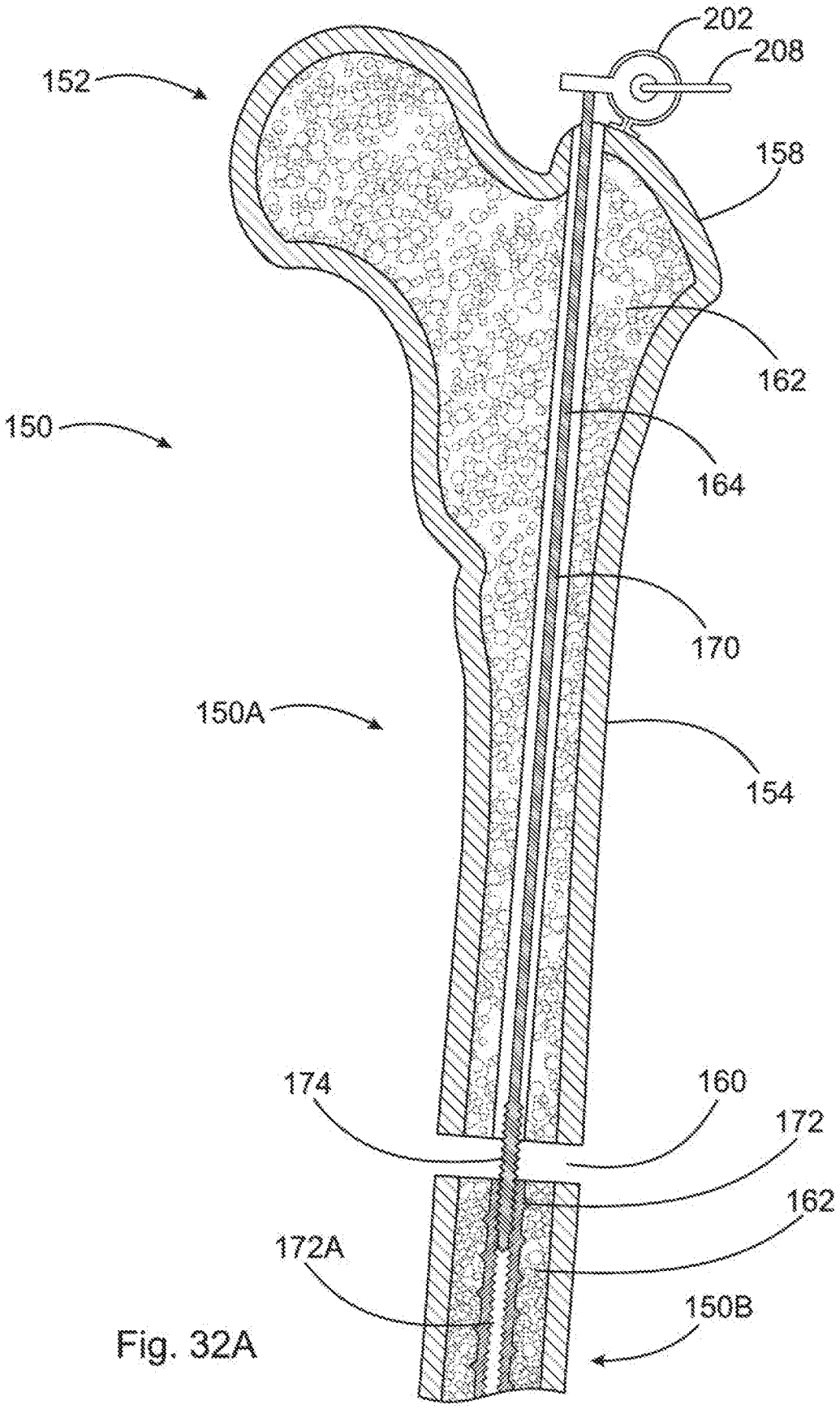


Fig. 31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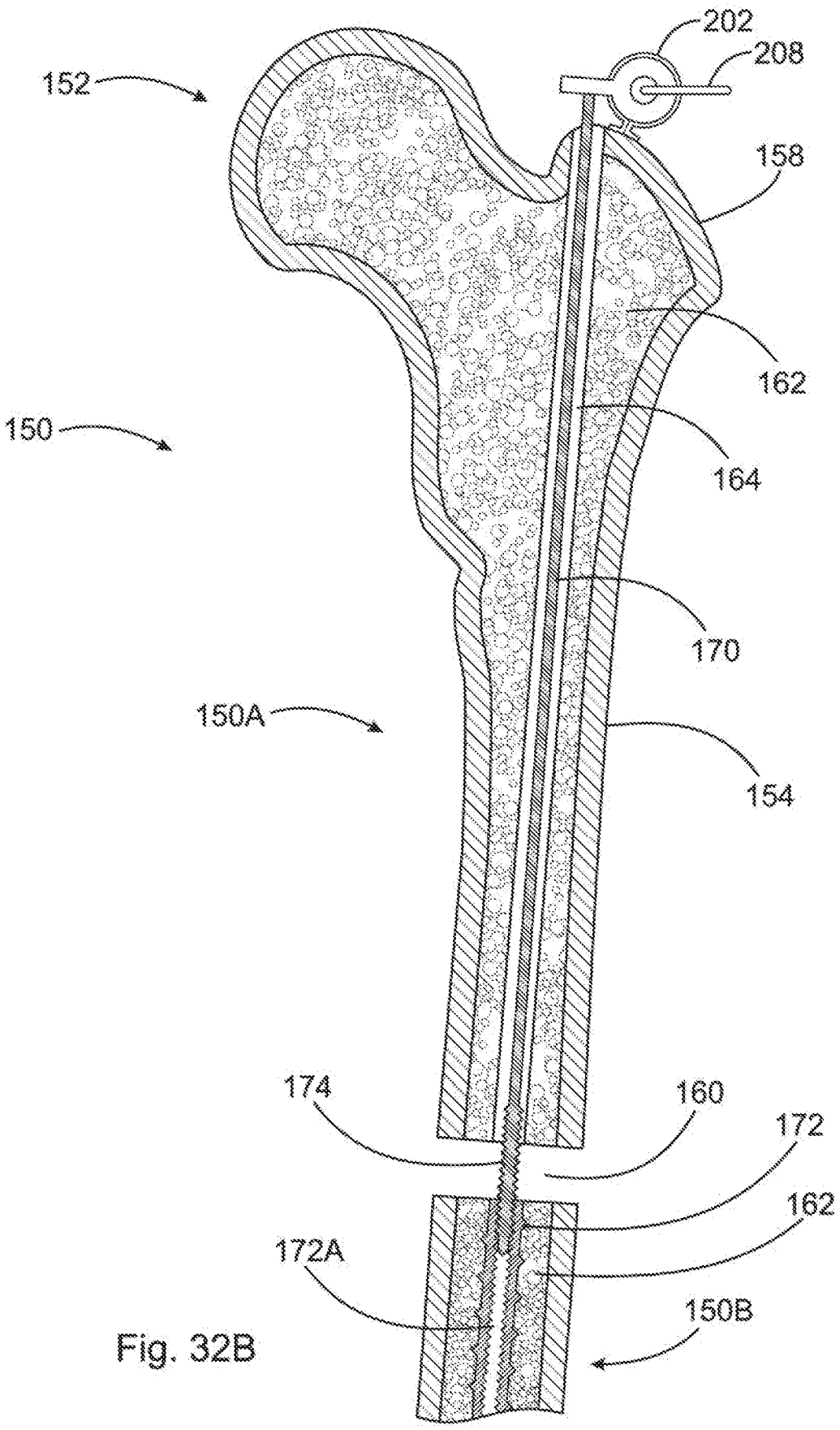
208
152
158
162
150
164
170
150A
154
174
160
172
162
172A
150B

Fig. 32A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150A
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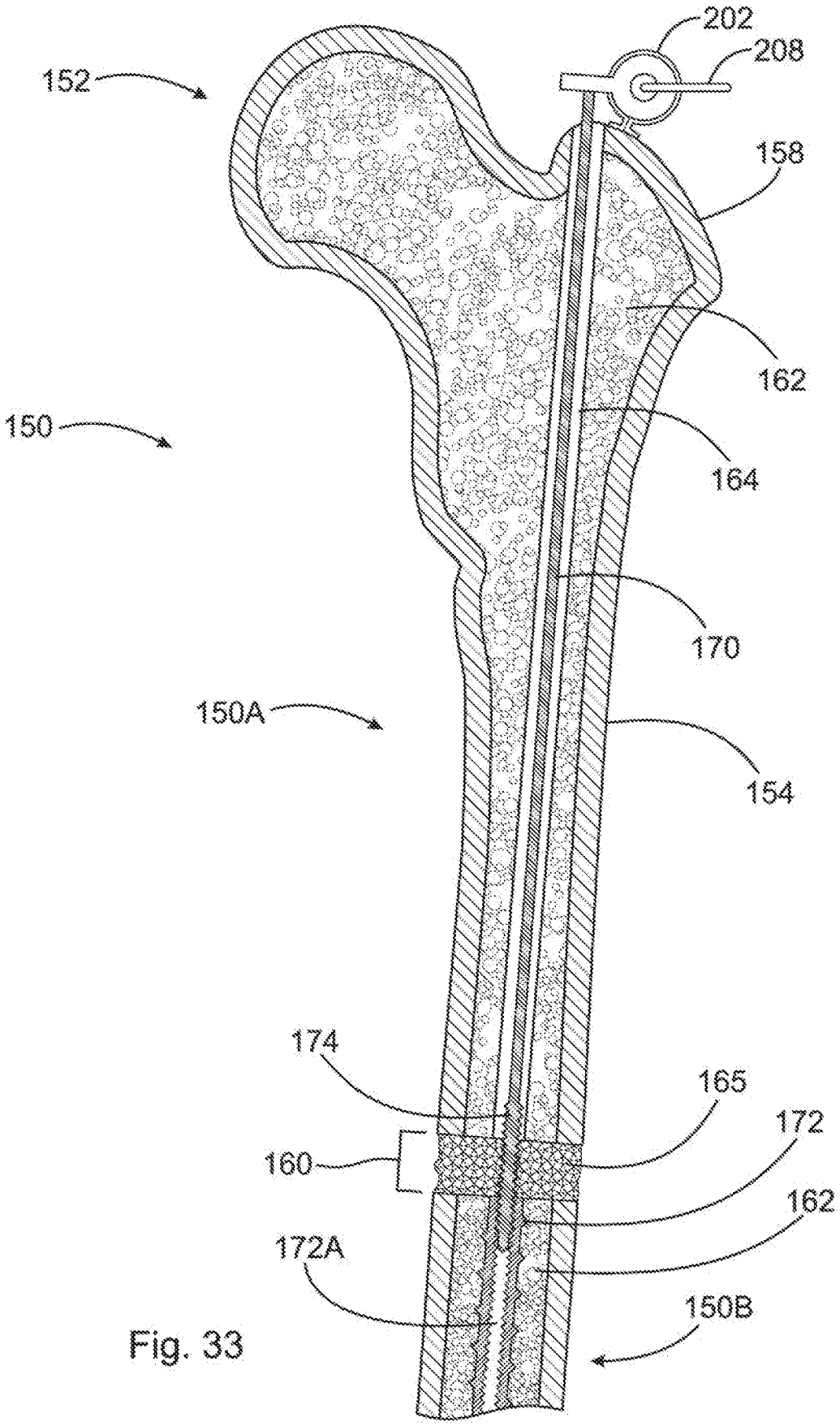
172A
150B

Fig. 32B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150A
154
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165
172
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162
172A
150B

Fig. 33

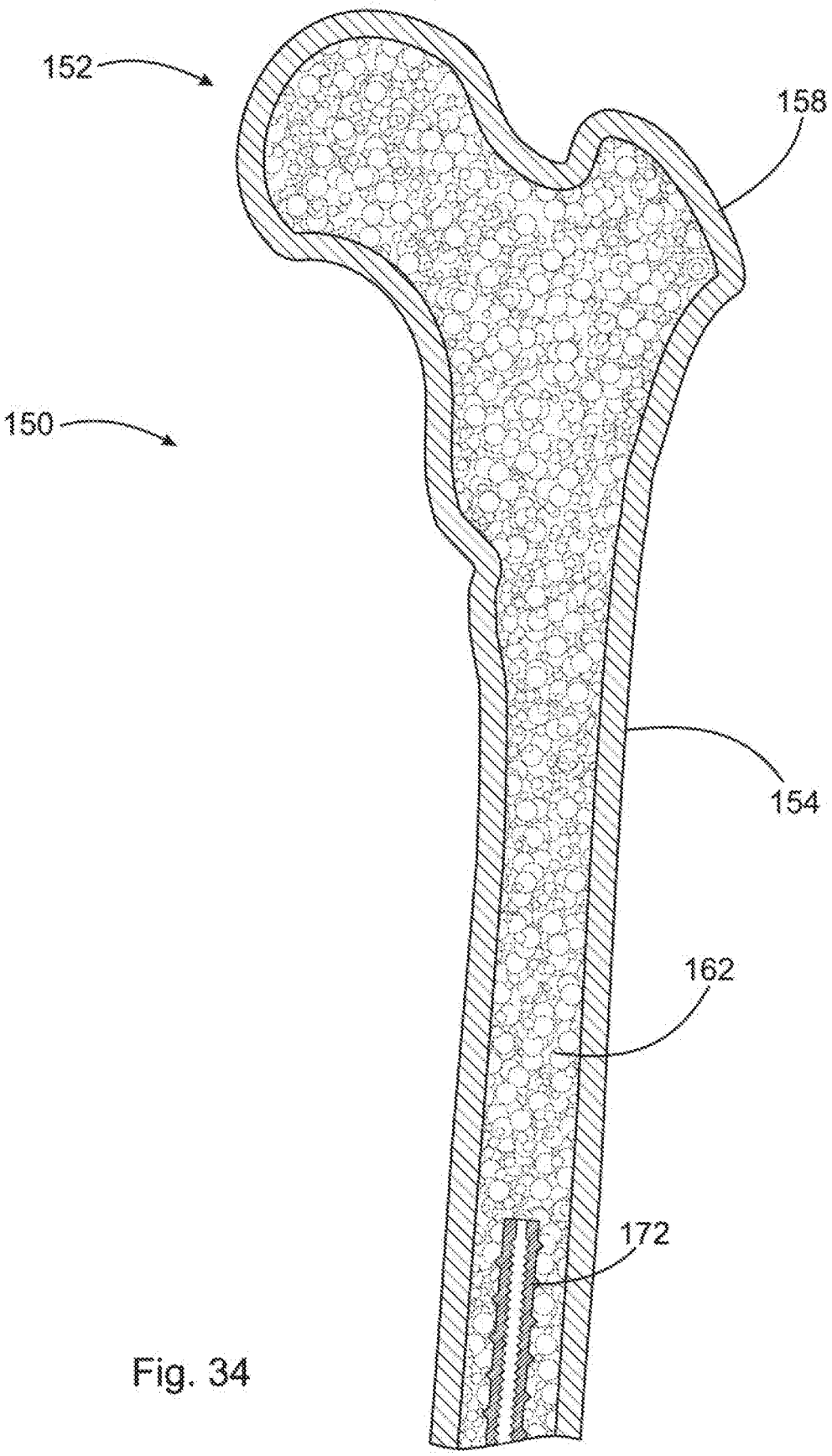

Fig. 34

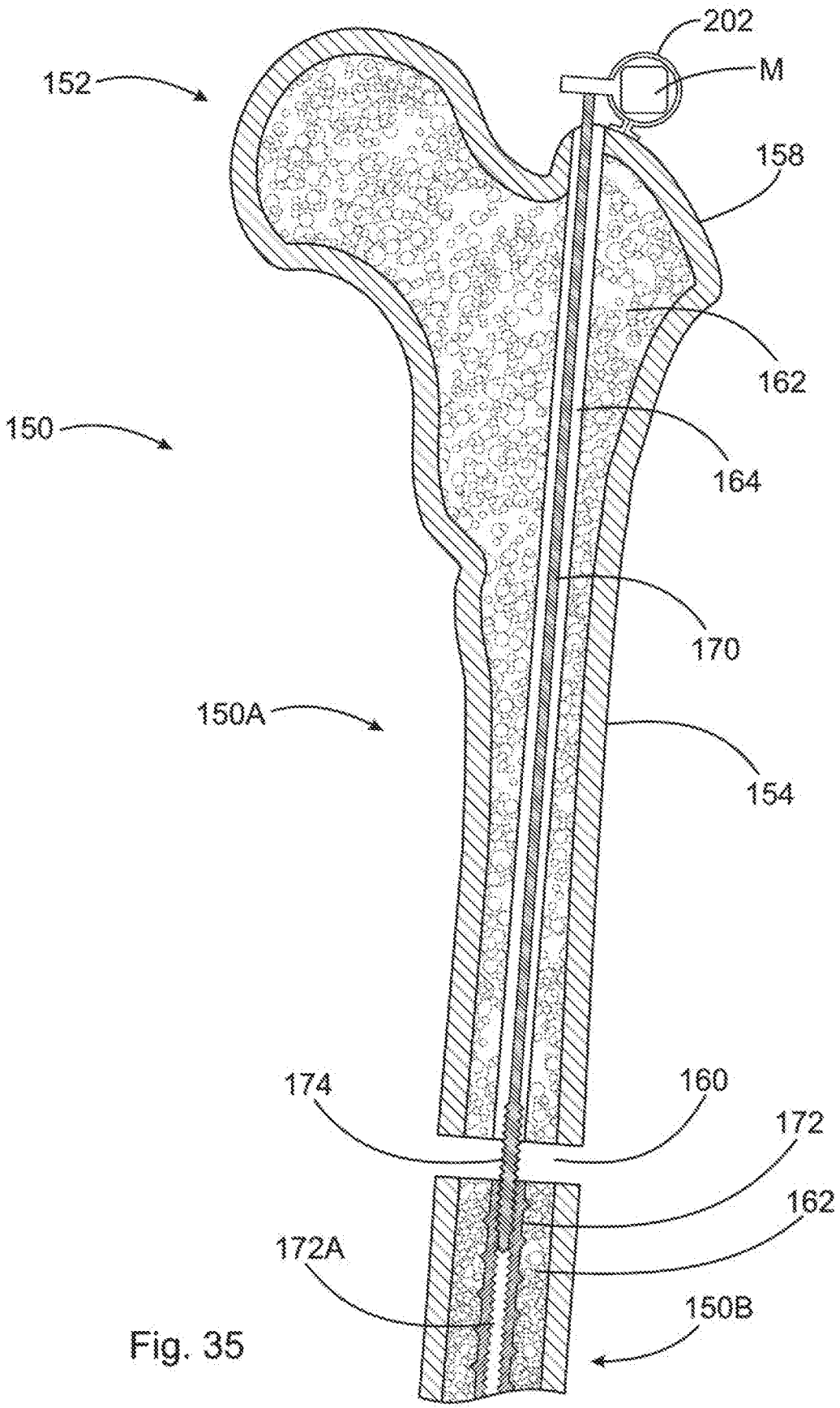

Fig. 35

REFERENCES CITED IN THE DESCRIPTION

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Patent documents cited in the description

- US 20060195090 A1, Suddaby **[0008]**
- US 6551320 B2, Lieberman **[0009]**
- US 20090112262 A1, Pool **[0009]**
- US 5782831 A, Sherman **[0010]**
- US 20140236234 A1 **[0011]**
- US 20090012565 A1 **[0011]**
- US 20150196342 A1 **[0011]**