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(54) **METHOD AND APPARATUS FOR FLEXIBLE FIXATION OF A SPINE**

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Related U.S. Application Data

(63) Continuation-in-part of application No. 10/798,014, filed on Mar. 10, 2004, which is a continuation-in-part of application No. 10/728,566, filed on Dec. 5, 2003.

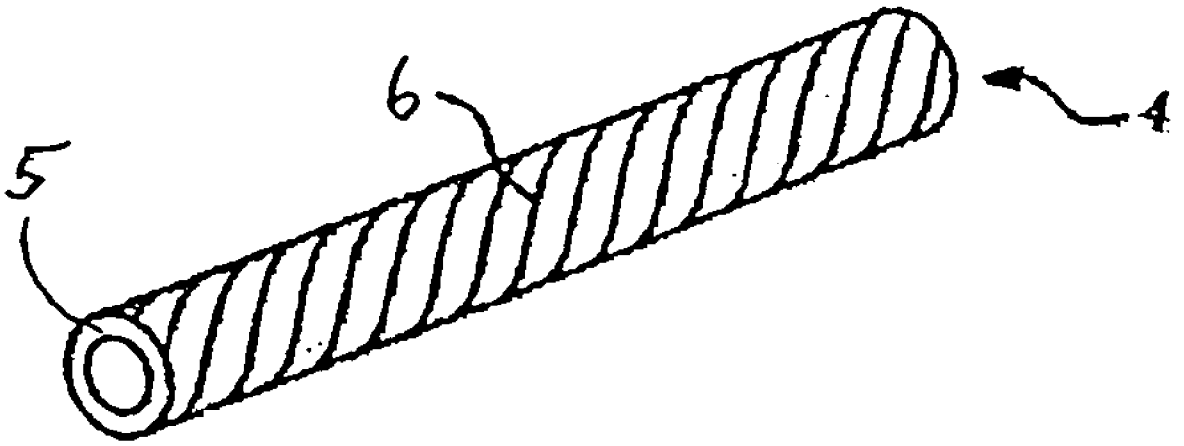
Publication Classification

(51) **Int. Cl.**[7] **A61B 17/56**

(52) **U.S. Cl.** **606/61**

(57) **ABSTRACT**

A flexible spinal fixation device having a flexible connection unit for non-rigid stabilization of the spinal column. In one embodiment, the fixation device includes at least two securing members configured to be inserted into respective adjacent spinal pedicles, each securing member each including a coupling assembly. The fixation device further includes a flexible connection unit configured to be received and secured within the coupling assemblies of each securing member so as to flexibly stabilize the affected area of the spine.



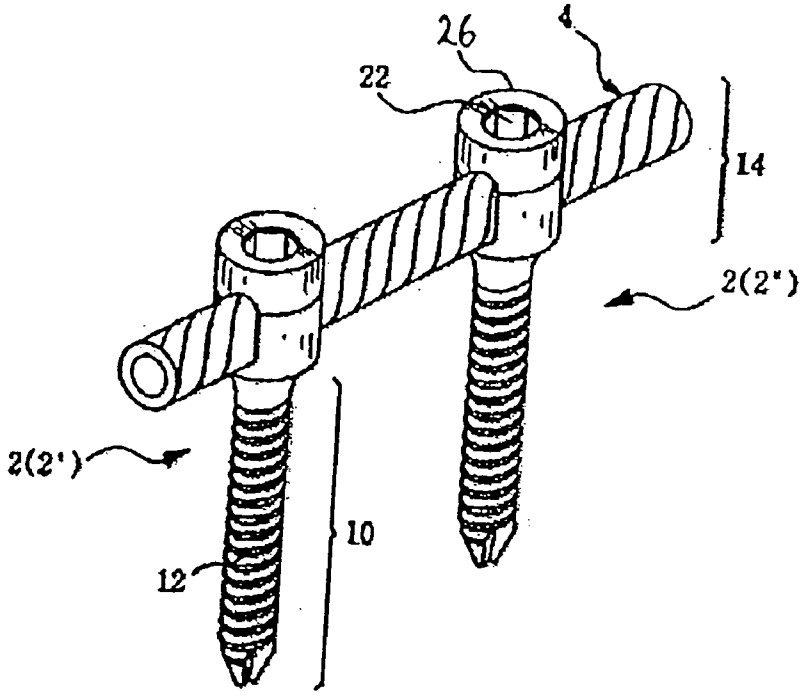


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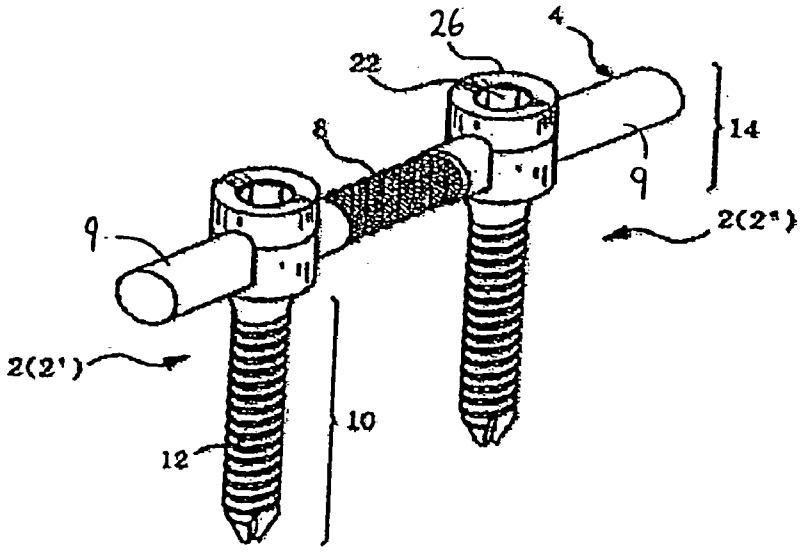


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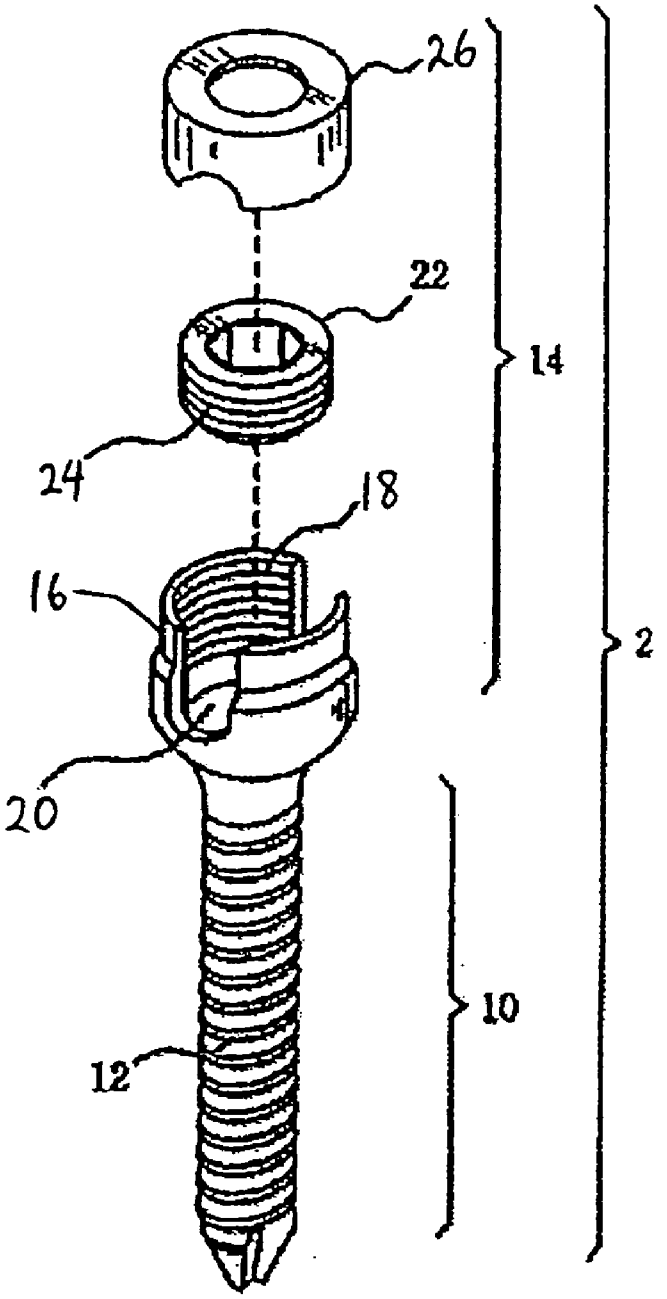


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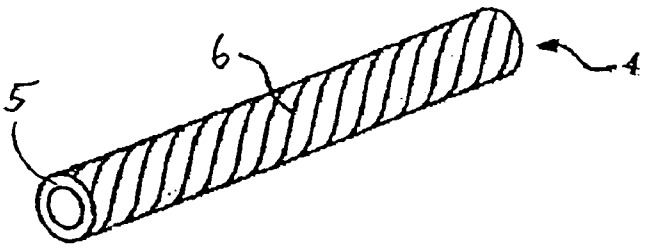


Fig. 4

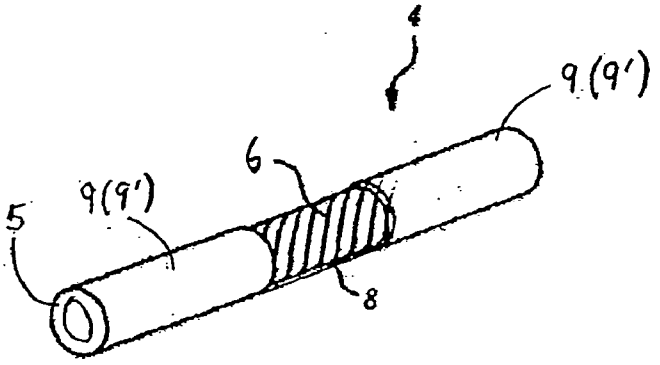


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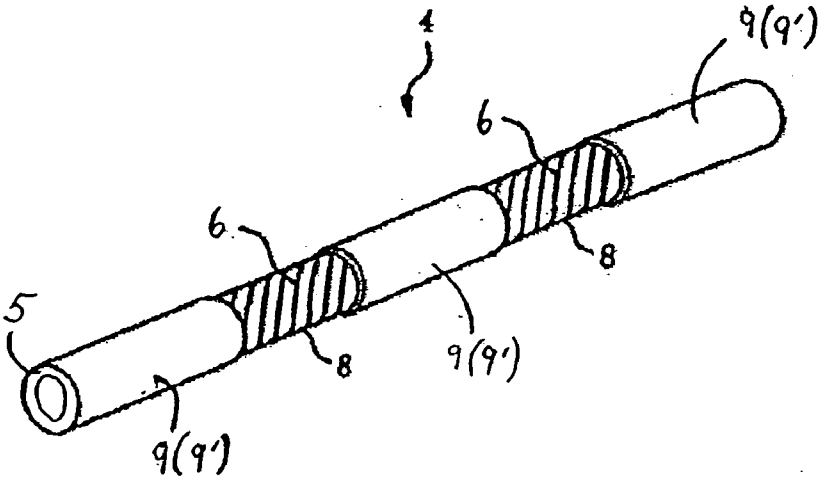


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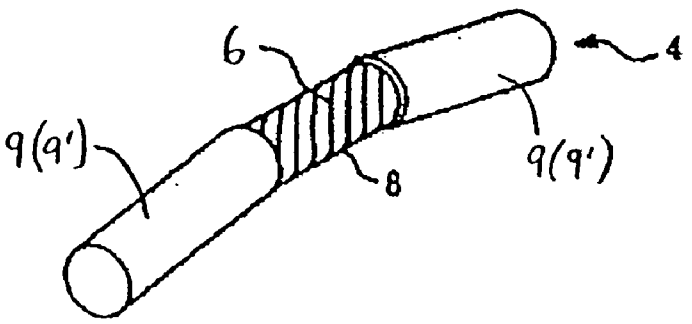


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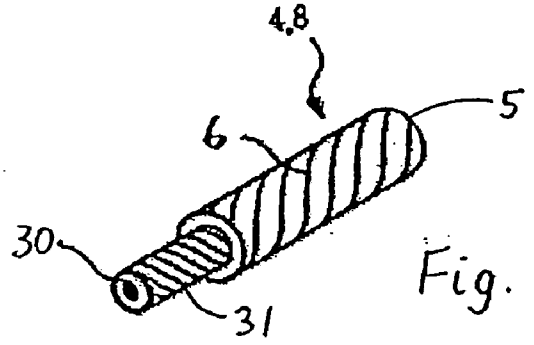


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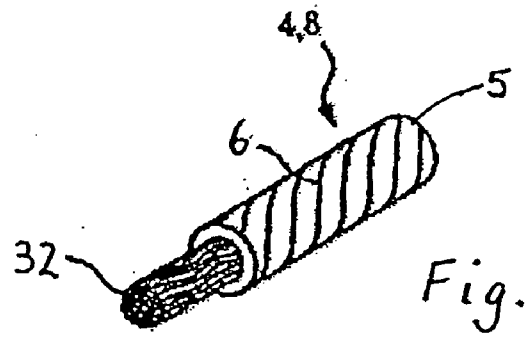


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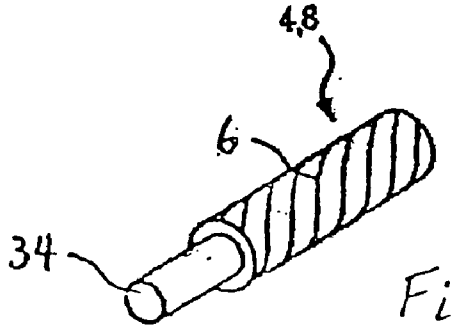


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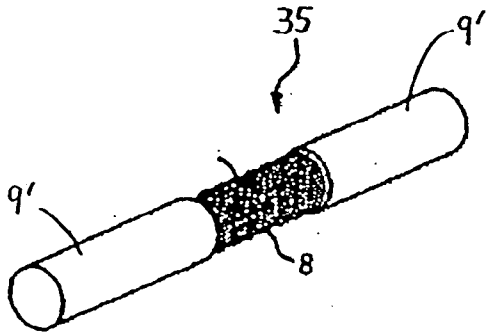


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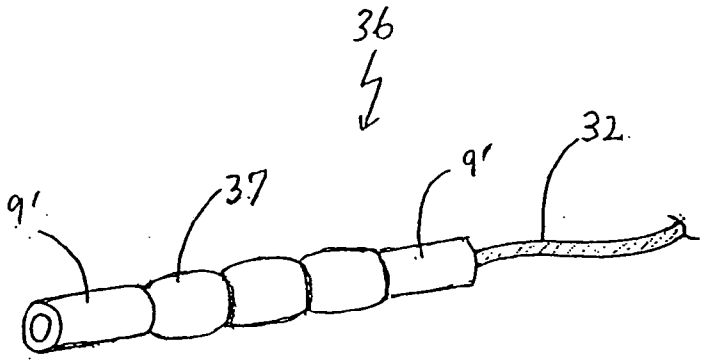


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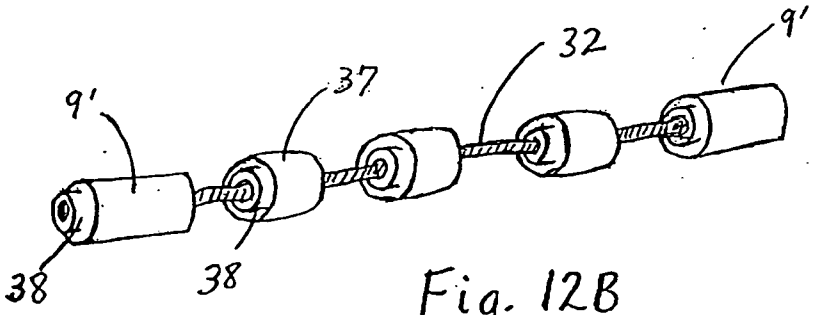


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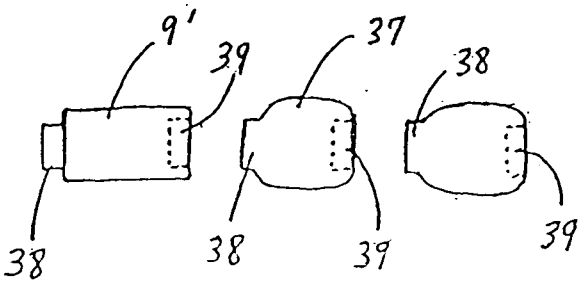


Fig. 12C

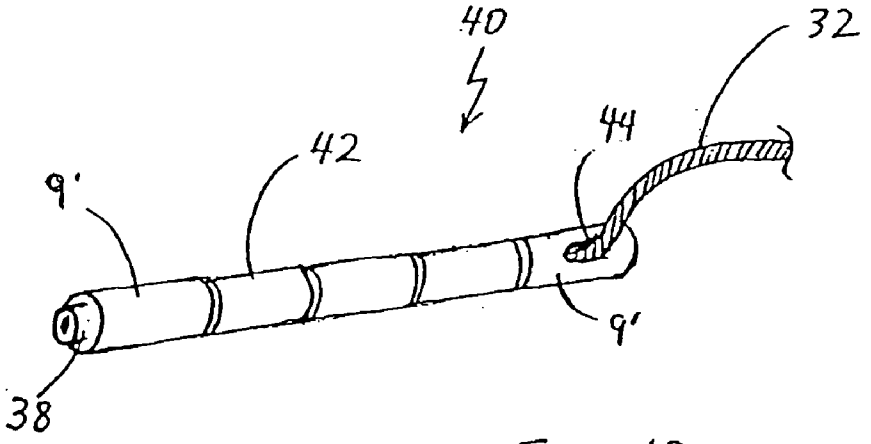


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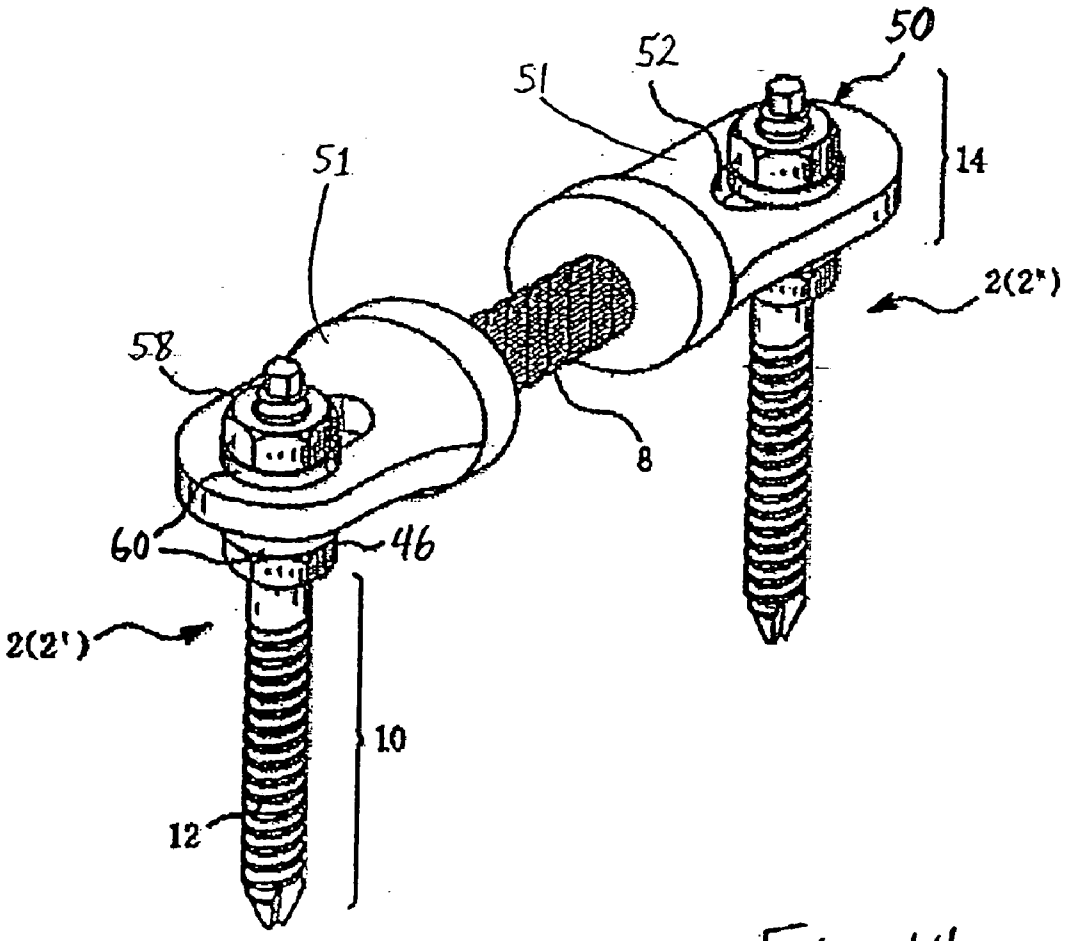


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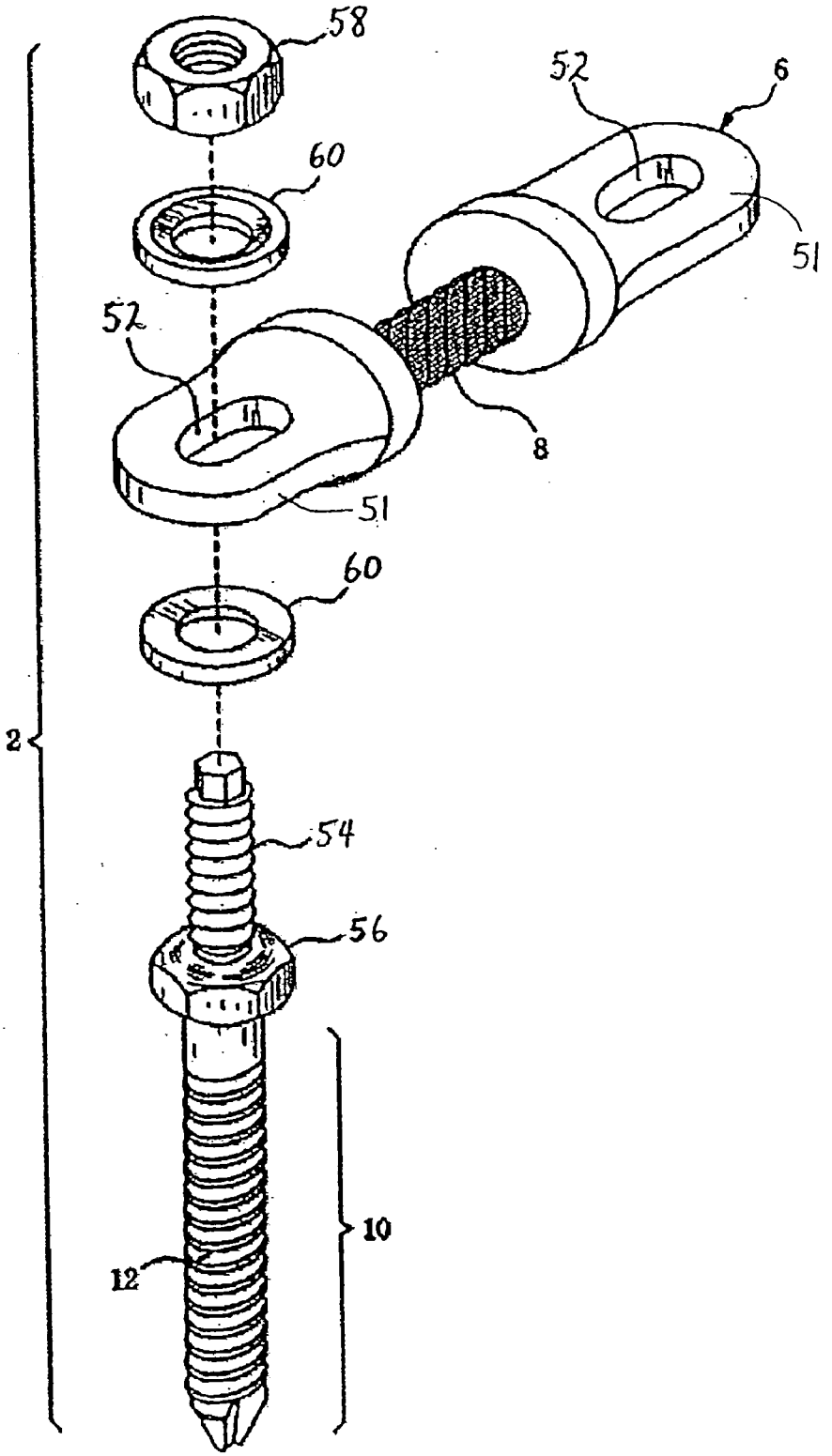


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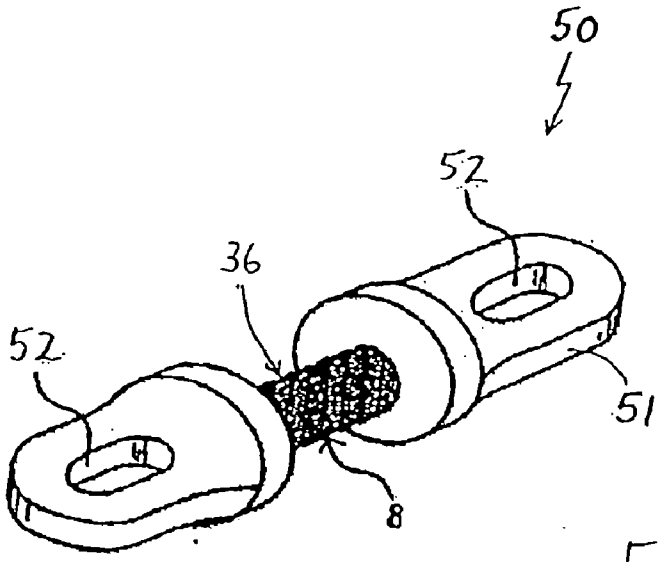


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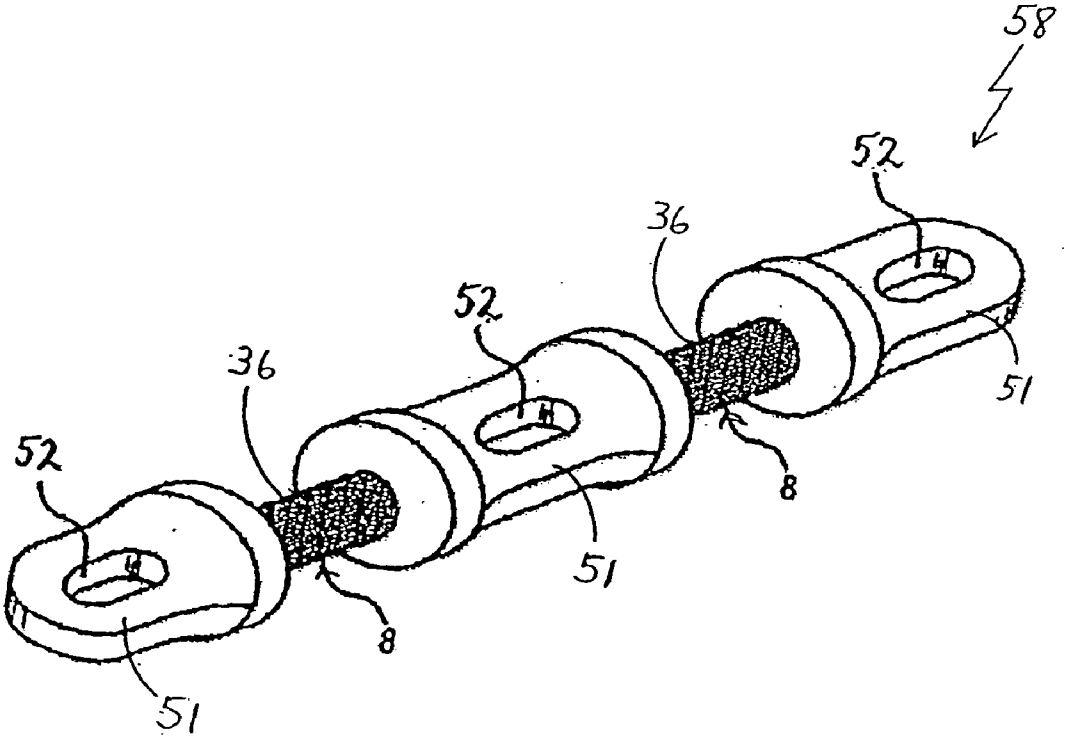


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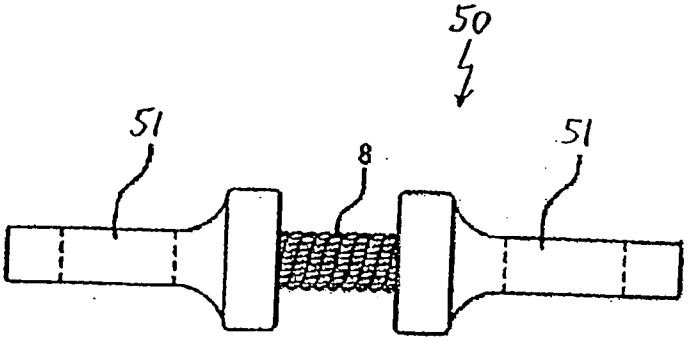


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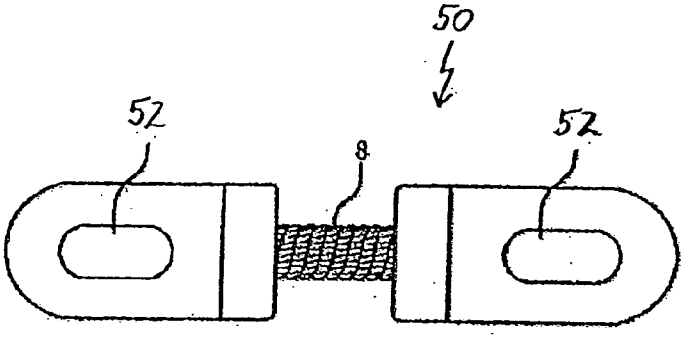


Fig. 16D

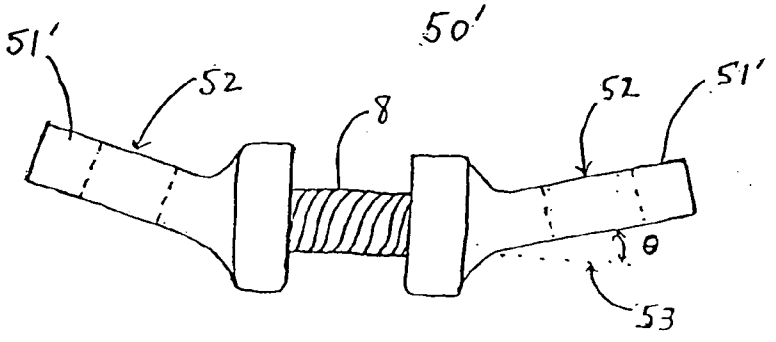


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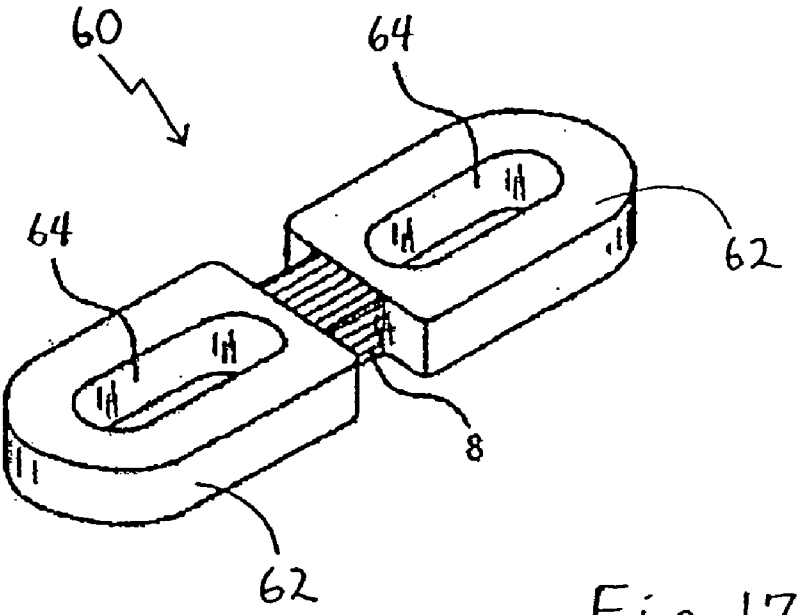


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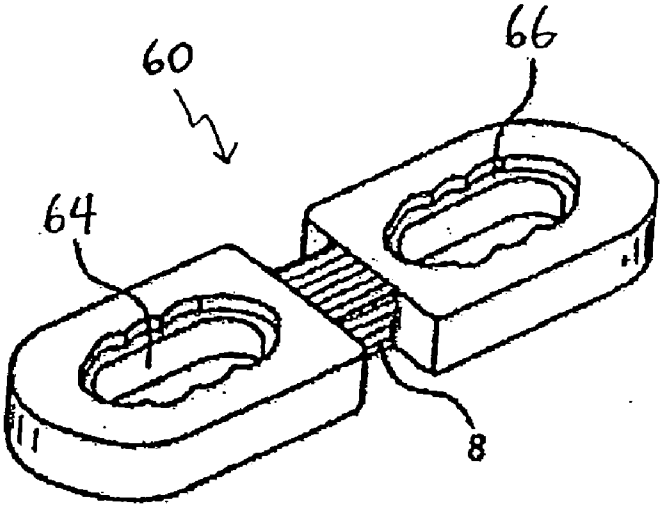


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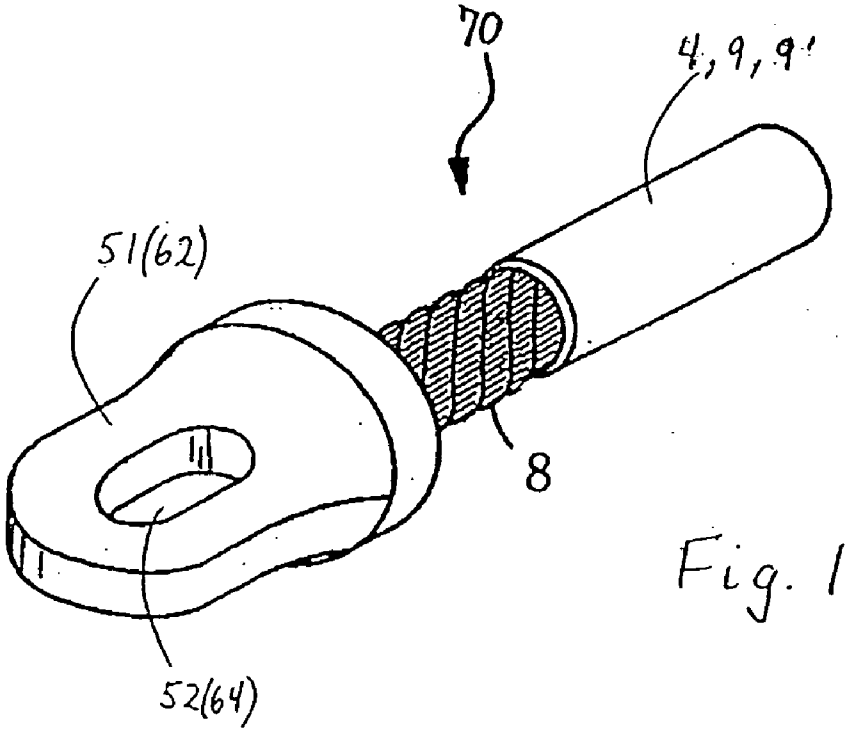


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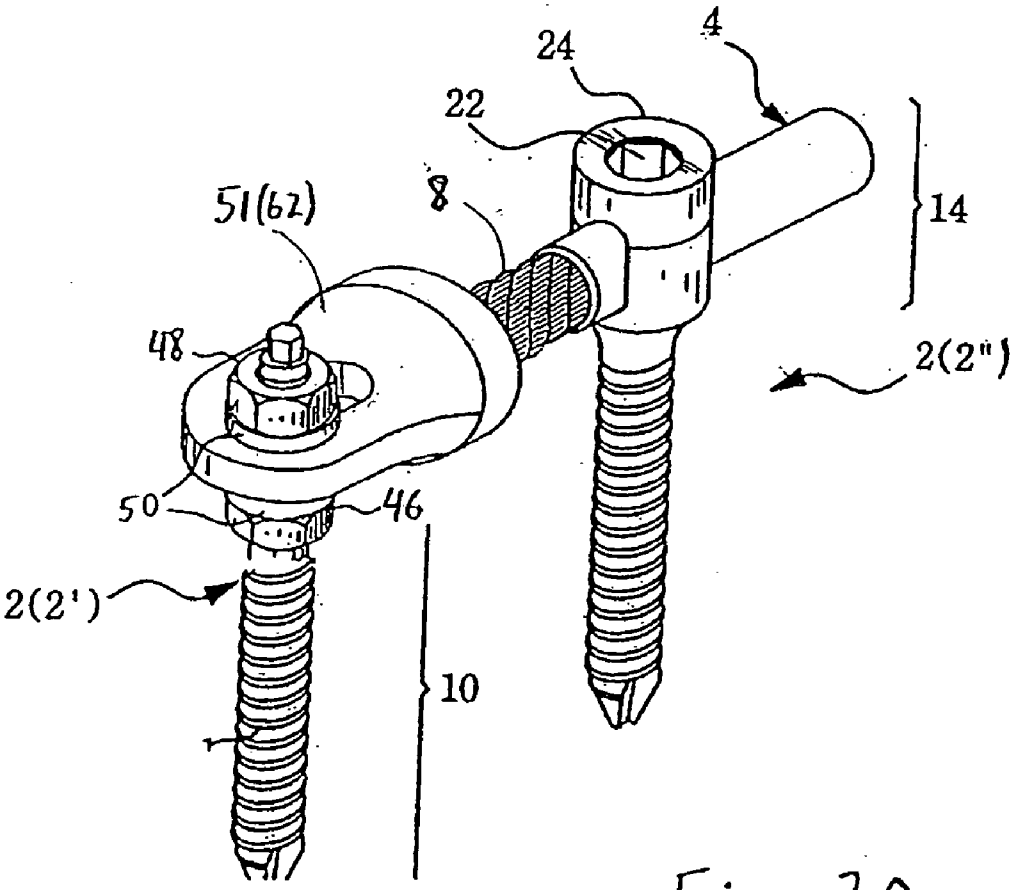


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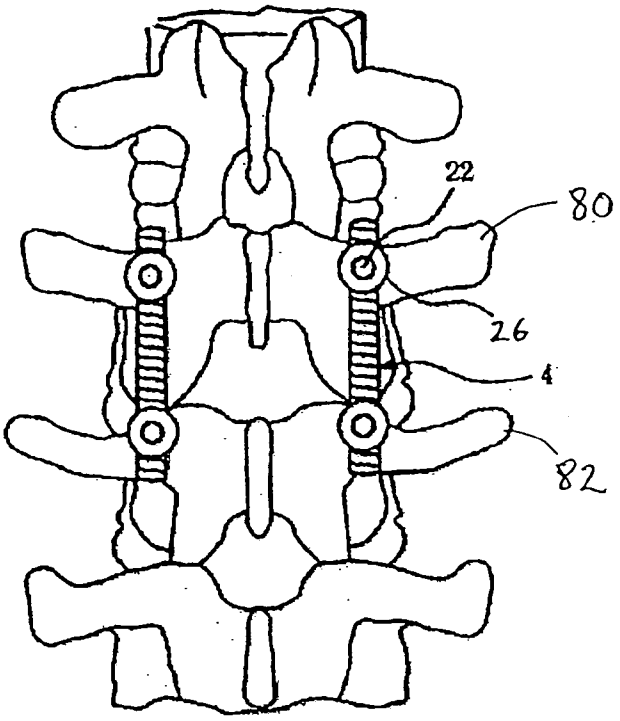


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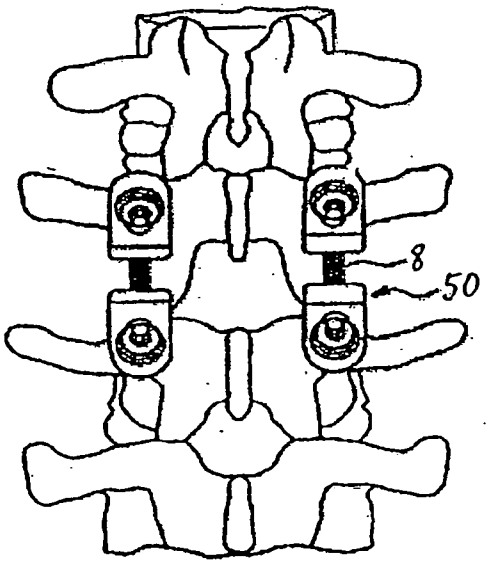


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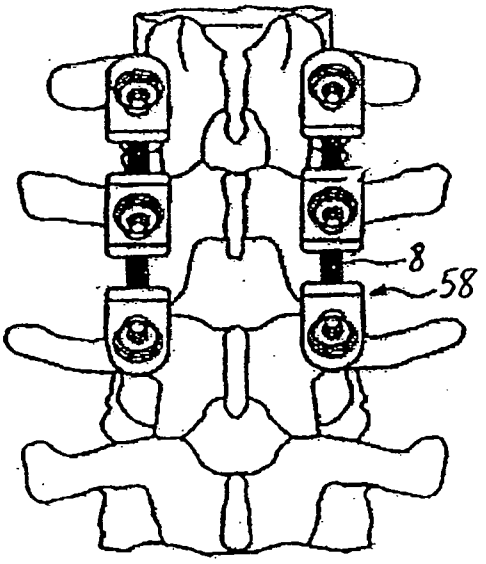


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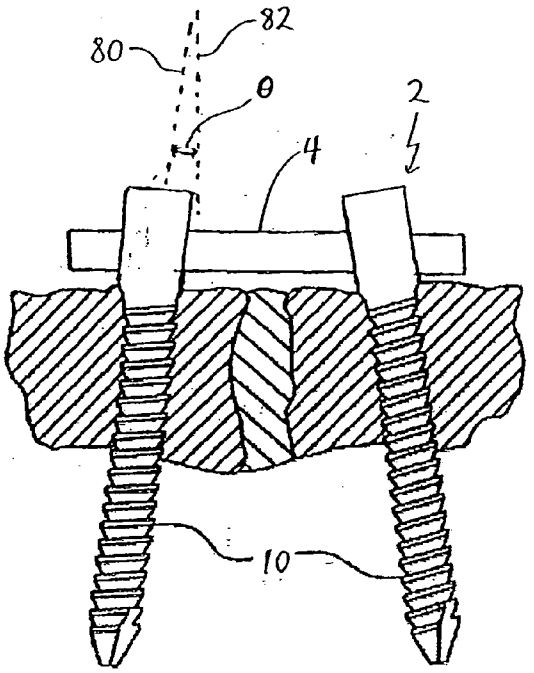


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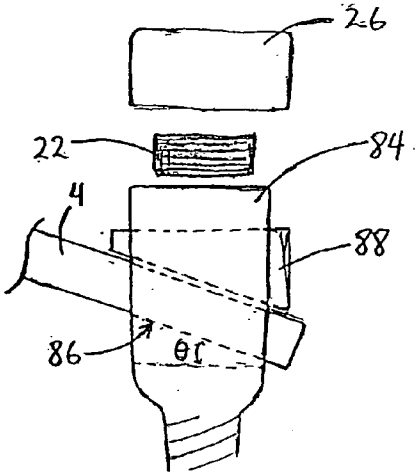


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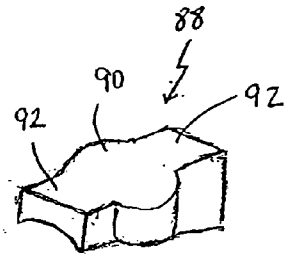


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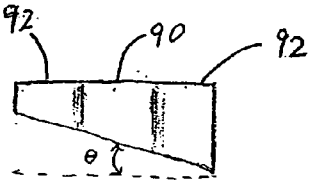


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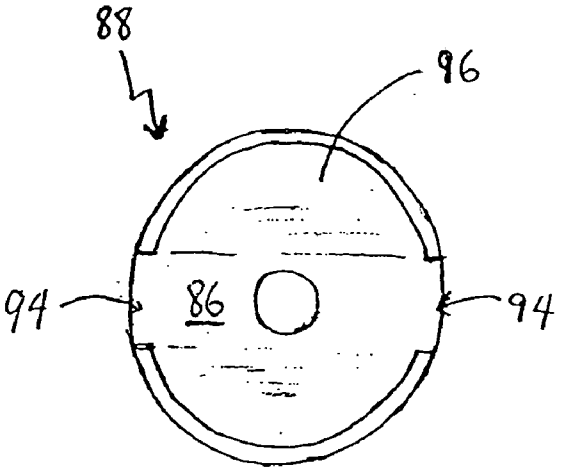


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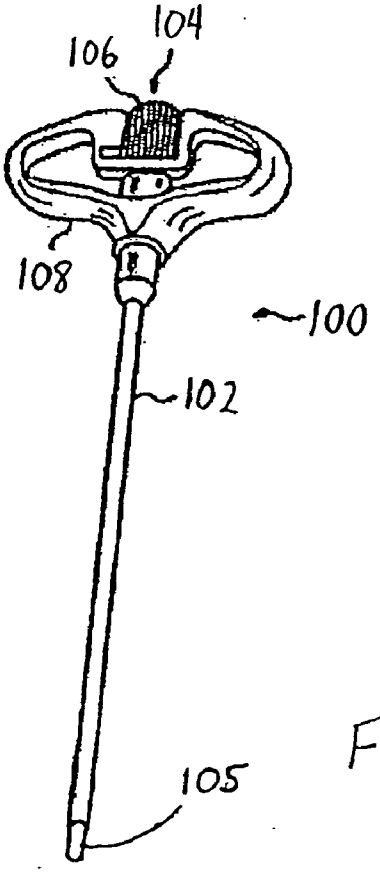


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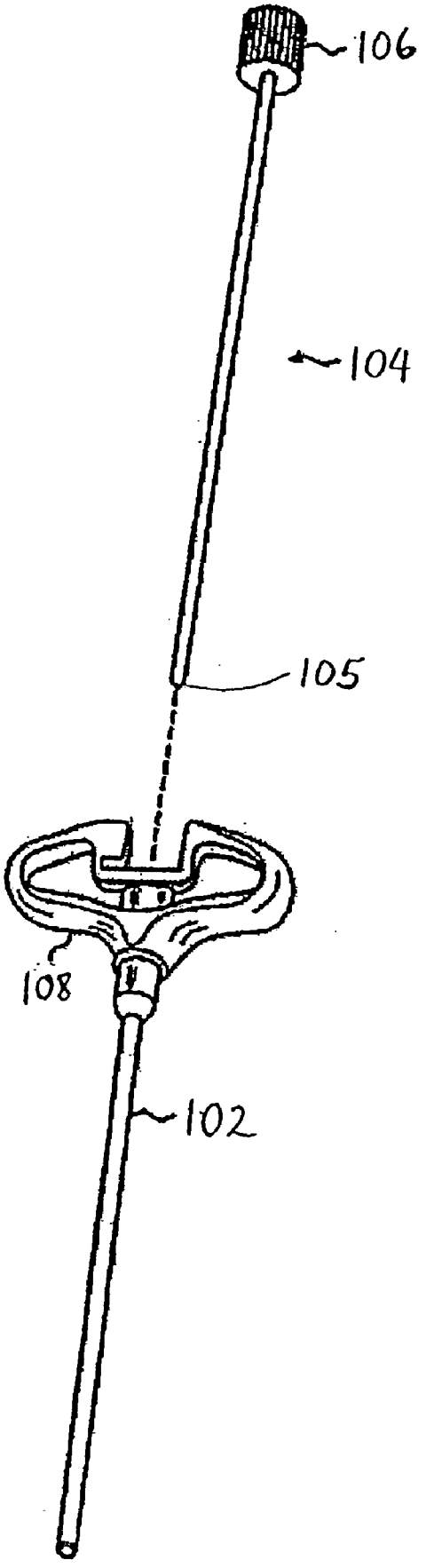


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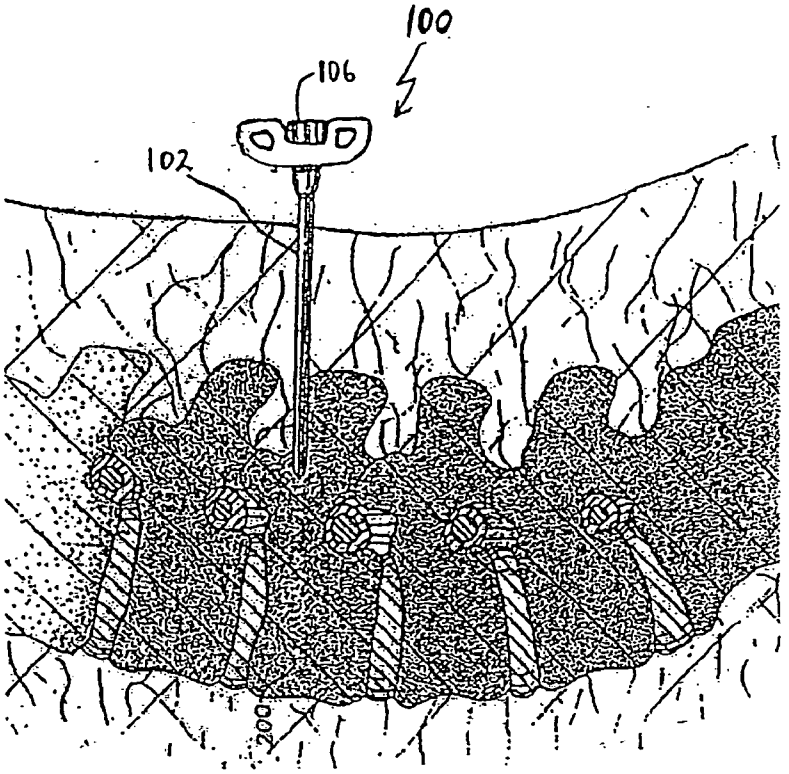


Fig. 26A

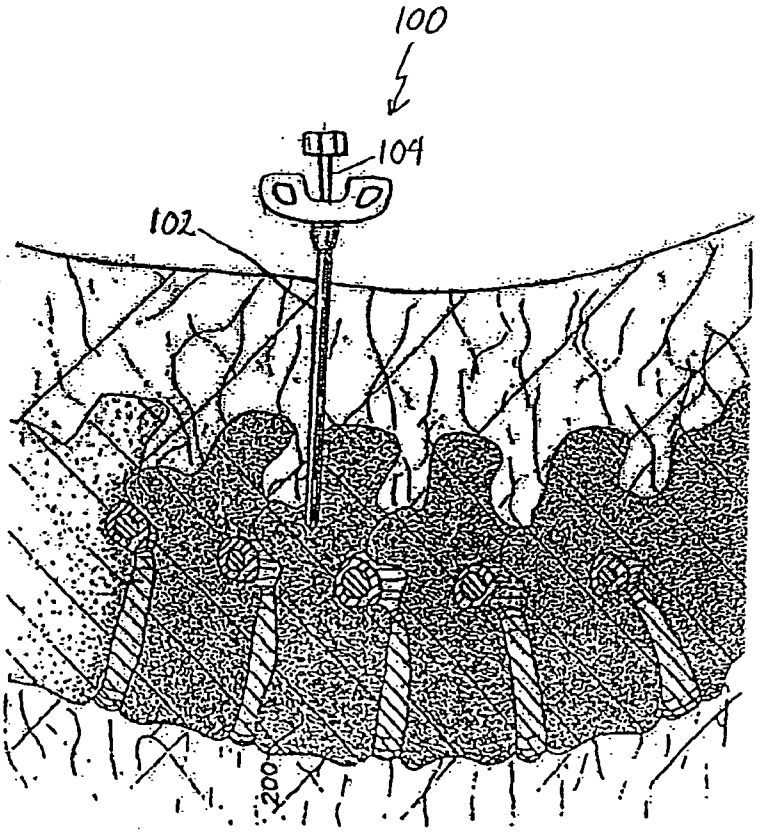


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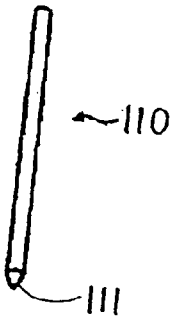


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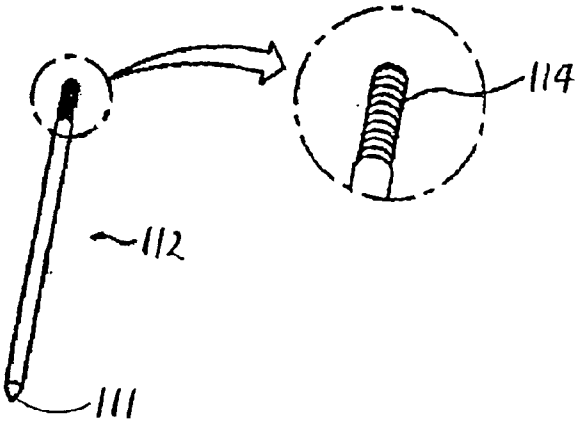


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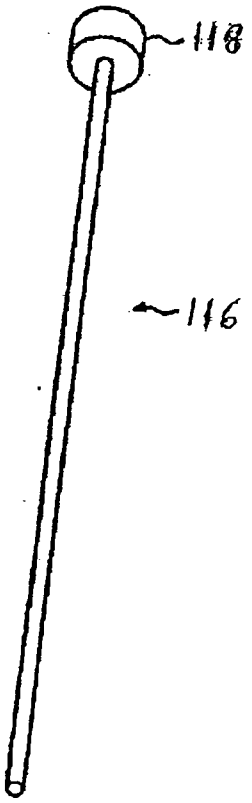


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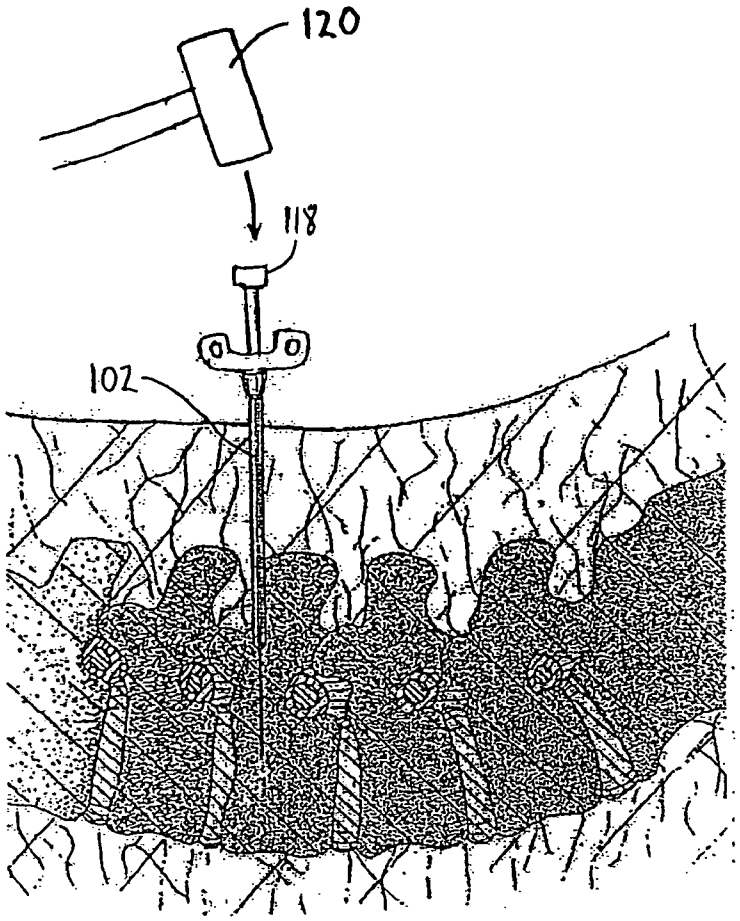


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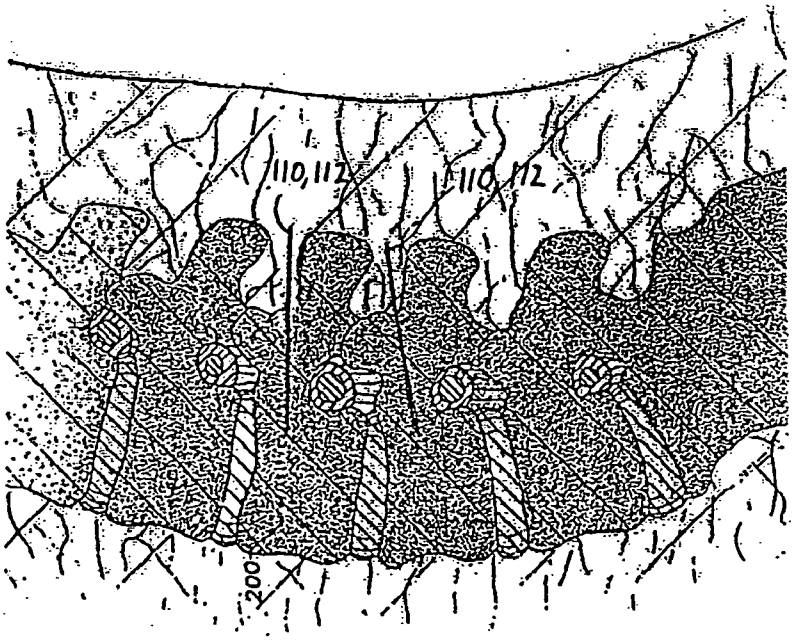


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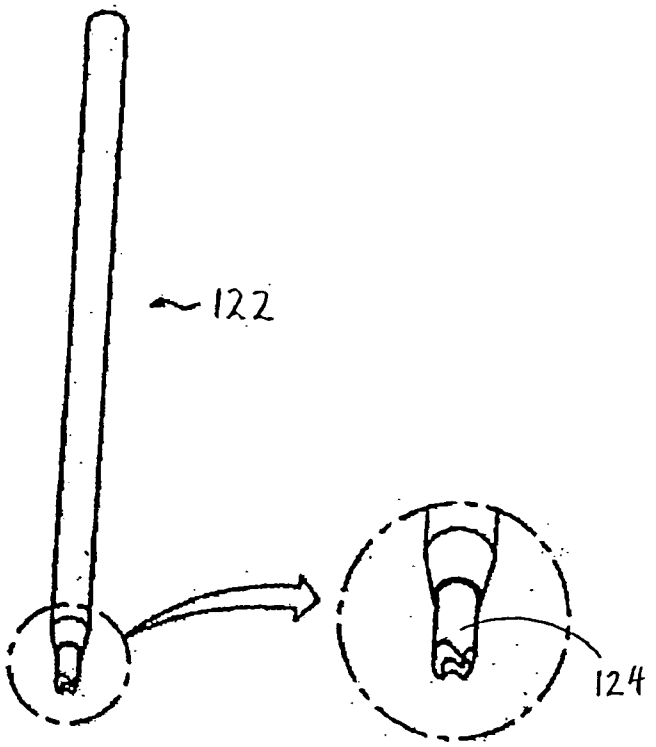


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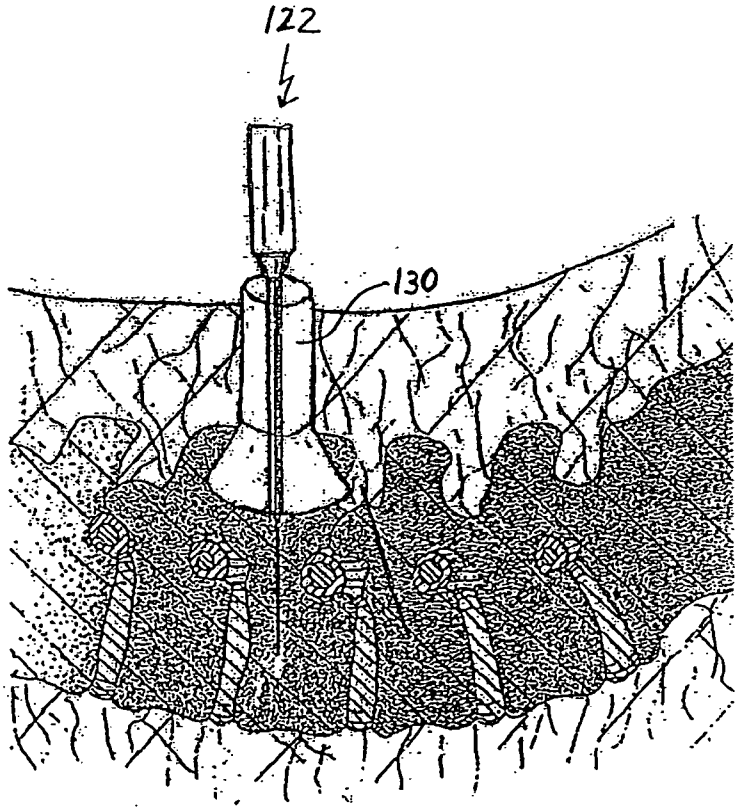


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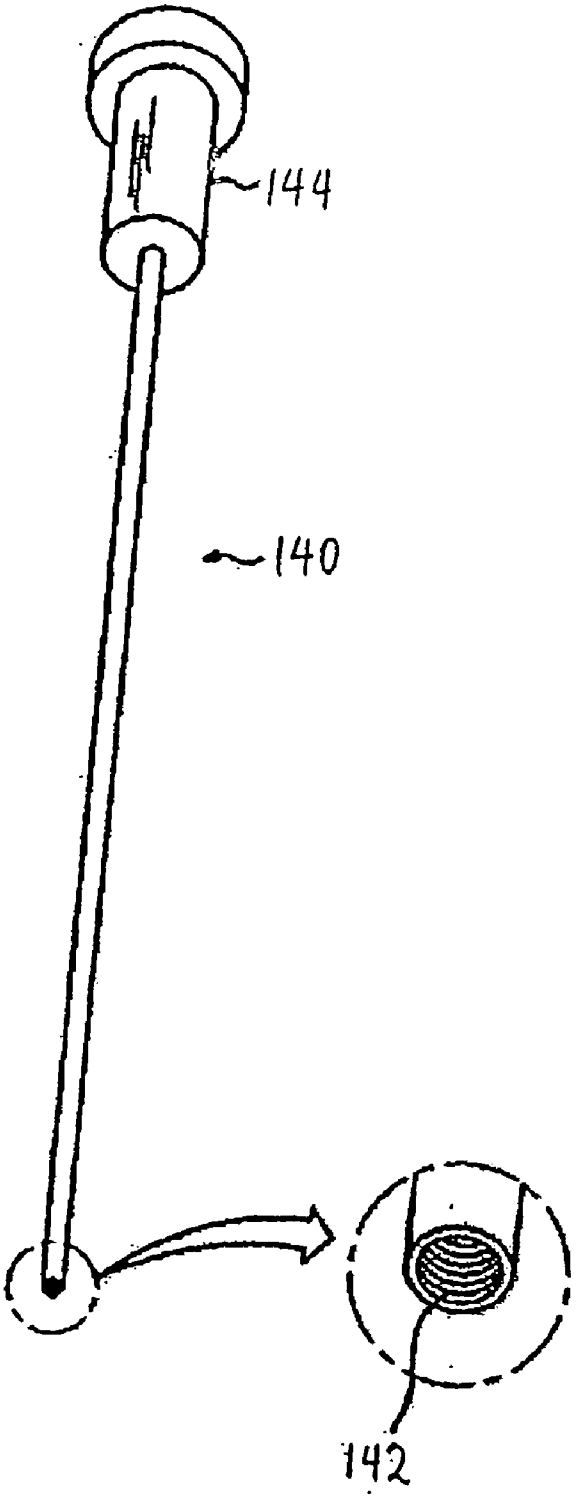


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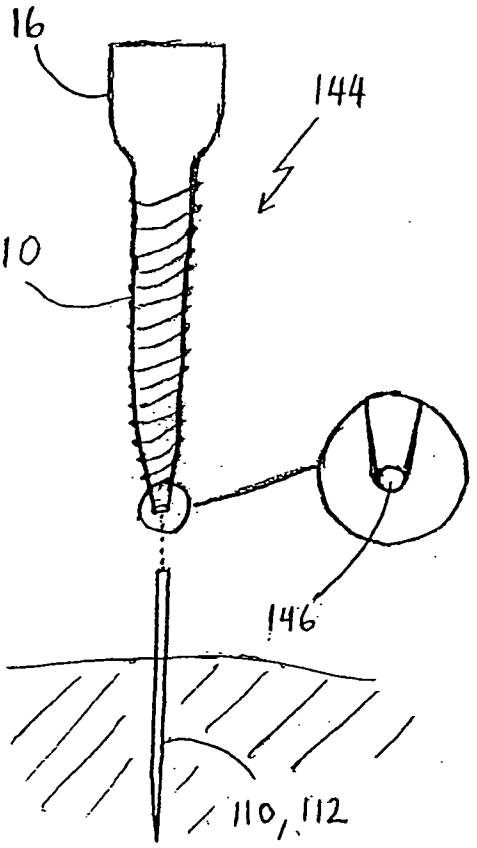


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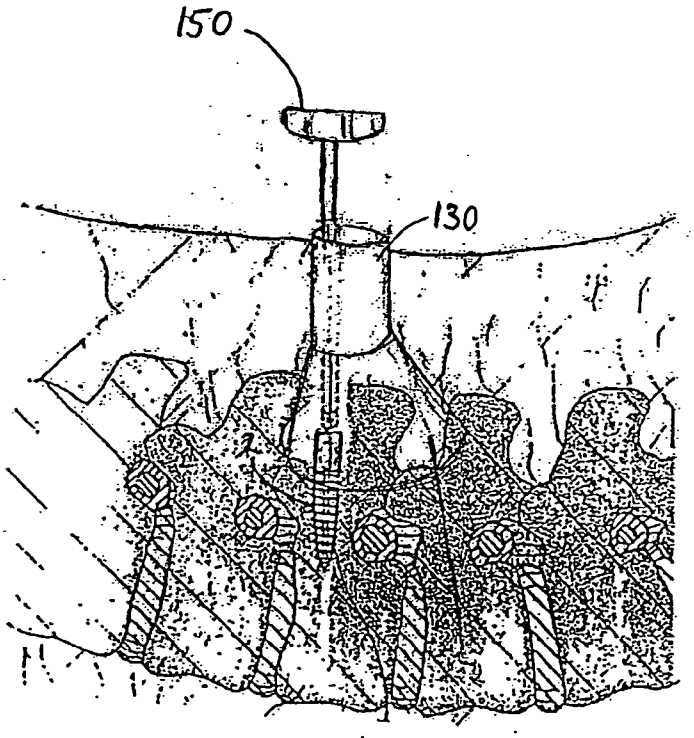


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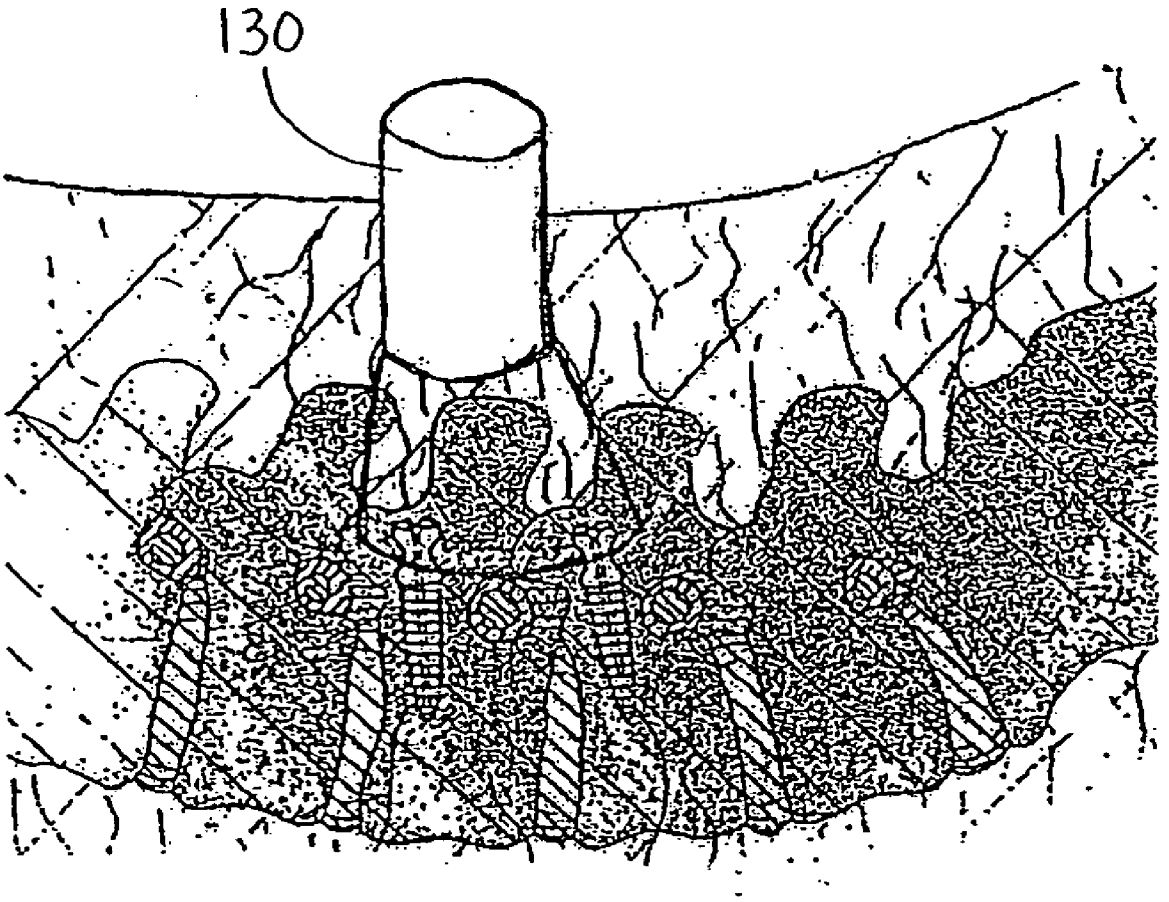


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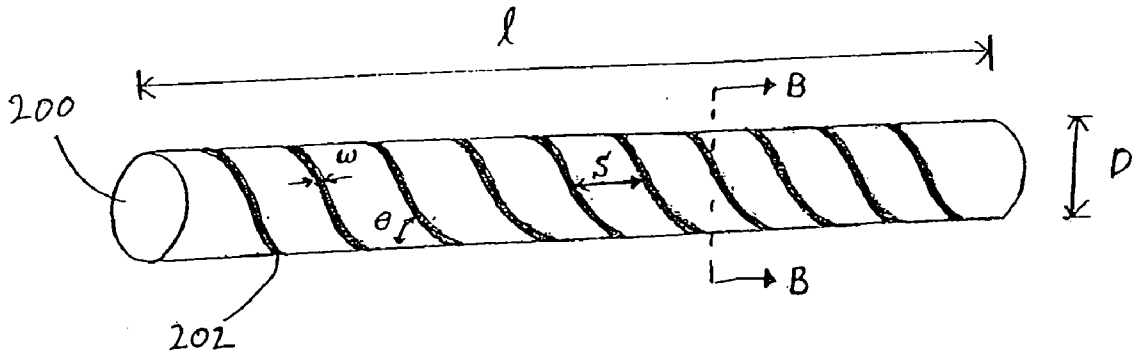


Fig. 36 A

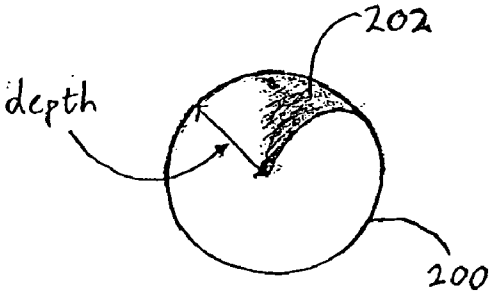


Fig. 36B

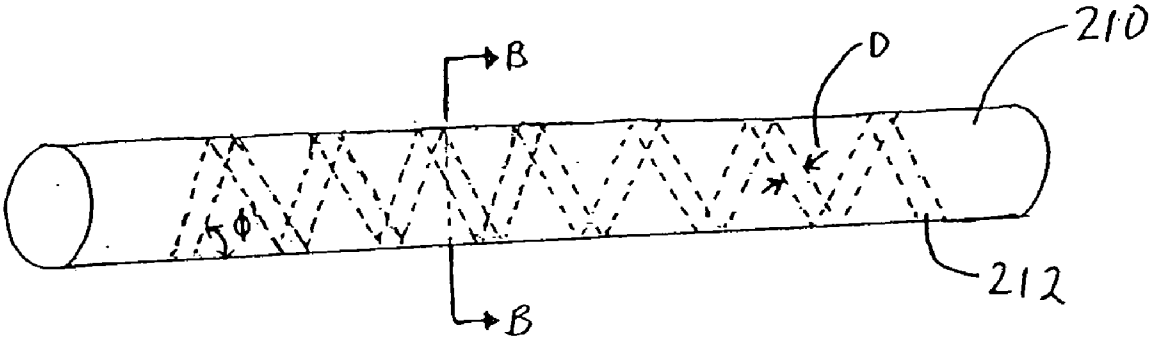


Fig. 37A

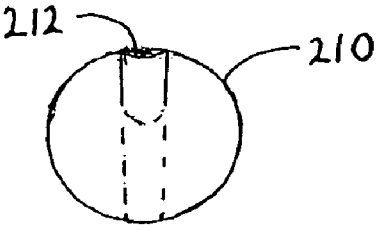


Fig. 37B

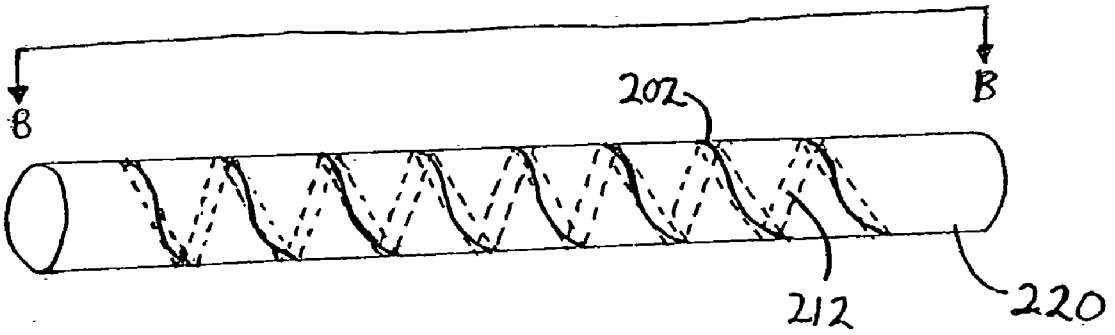


Fig. 38A

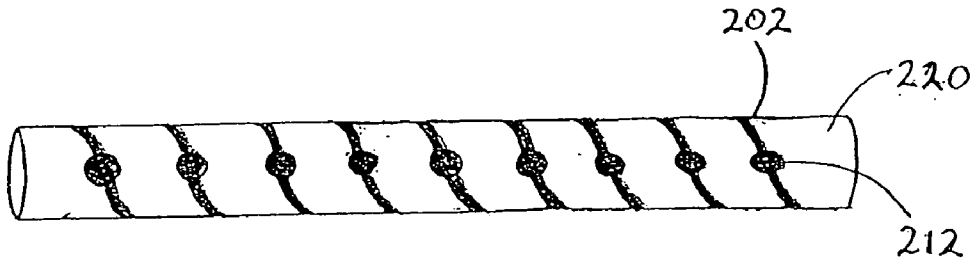


Fig. 38B

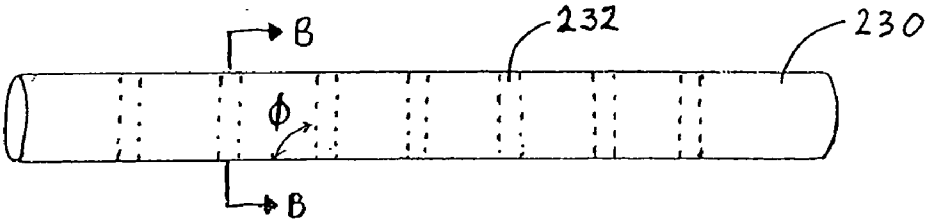


Fig. 39A

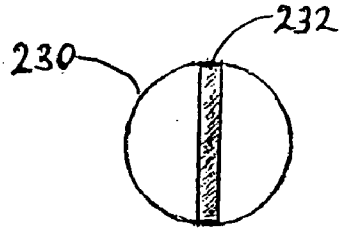


Fig. 39B

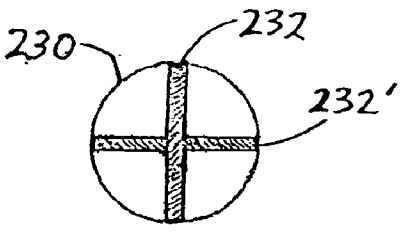


Fig. 39C

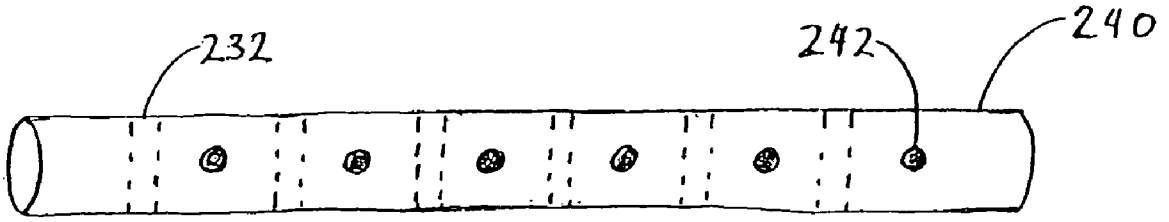


Fig. 40A

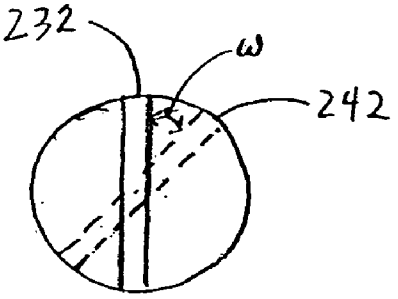


Fig. 40B

METHOD AND APPARATUS FOR FLEXIBLE FIXATION OF A SPINE

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] The present application is a continuation of U.S. application Ser. No. 10,798,014, filed Mar. 10, 2004, which is a continuation-in-part of U.S. patent application Ser. No. 10/728,566, filed Dec. 5, 2003.

BACKGROUND OF THE INVENTION

[0002] 1. Field of the Invention

[0003] The present invention relates to a method and system for fixing and stabilizing a spinal column and, more particularly, to a method and system of spinal fixation in which one or more screw type fixing members are implanted and fixed into a portion of a patient's spinal column and flexible, semi-rigid rods or plates are connected and fixed to the upper ends of the fixing members to provide dynamic stabilization of the spinal column.

[0004] 2. Description of the Related Art

[0005] Degenerative spinal column diseases, such as disc degenerative diseases (DDD), spinal stenosis, spondylolisthesis, and so on, need surgical operation if they do not take a turn for the better by conservative management. Typically, spinal decompression is the first surgical procedure that is performed. The primary purpose of decompression is to reduce pressure in the spinal canal and on nerve roots located therein by removing a certain tissue of the spinal column to reduce or eliminate the pressure and pain caused by the pressure. If the tissue of the spinal column is removed the pain is reduced but the spinal column is weakened. Therefore, fusion surgery (e.g., ALIF, PLIF or posterolateral fusion) is often necessary for spinal stability following the decompression procedure. However, following the surgical procedure, fusion takes additional time to achieve maximum stability and a spinal fixation device is typically used to support the spinal column until a desired level of fusion is achieved. Depending on a patient's particular circumstances and condition, a spinal fixation surgery can sometimes be performed immediately following decompression, without performing the fusion procedure. The fixation surgery is performed in most cases because it provides immediate postoperative stability and, if fusion surgery has also been performed, it provides support of the spine until sufficient fusion and stability has been achieved.

[0006] Conventional methods of spinal fixation utilize a rigid spinal fixation device to support an injured spinal part and prevent movement of the injured part. These conventional spinal fixation devices include: fixing screws configured to be inserted into the spinal pedicle or sacral of the backbone to a predetermined depth and angle, rods or plates configured to be positioned adjacent to the injured spinal part, and coupling elements for connecting and coupling the rods or plates to the fixing screws such that the injured spinal part is supported and held in a relatively fixed position by the rods or plates.

[0007] U.S. Pat. No. 6,193,720 discloses a conventional spinal fixation device, in which connection members of a rod or plate type are mounted on the upper ends of at least one or more screws inserted into the spinal pedicle or sacral of the backbone. The connection units, such as the rods and plates, are used to stabilize the injured part of the spinal column which has been weakened by decompression. The connection units also prevent further pain and injury to the patient by substantially restraining the movement of the spinal column. However, because the connection units prevent normal movement of the spinal column, after prolonged use, the spinal fixation device can cause ill effects, such as "junctional syndrome" (transitional syndrome) or "fusion disease" resulting in further complications and abnormalities associated with the spinal column. In particular, due to the high rigidity of the rods or plates used in conventional fixation devices, the patient's fixed joints are not allowed to move after the surgical operation, and the movement of the spinal joints located above or under the operated area is increased. Consequently, such spinal fixation devices cause decreased mobility of the patient and increased stress and instability to the spinal column joints adjacent to the operated area.

[0008] It has been reported that excessive rigid spinal fixation is not helpful to the fusion process due to load shielding caused by rigid fixation. Thus, trials using load sharing semi-rigid spinal fixation devices have been performed to eliminate this problem and assist the bone fusion process. For example, U.S. Pat. No. 5,672,175, U.S. Pat. No. 5,540,688, and U.S. Pub No 2001/0037111 disclose dynamic spine stabilization devices having flexible designs that permit axial load translation (i.e., along the vertical axis of the spine) for bone fusion promotion. However, because these devices are intended for use following a bone fusion procedure, they are not well-suited for spinal fixation without fusion. Thus, in the end result, these devices do not prevent the problem of rigid fixation resulting from fusion.

[0009] To solve the above-described problems associated with rigid fixation, non-fusion technologies have been developed. The Graf band is one example of a non-fusion fixation device that is applied after decompression without bone fusion. The Graf band is composed of a polyethylene band and pedicle screws to couple the polyethylene band to the spinal vertebrae requiring stabilization. The primary purpose of the Graf band is to prevent sagittal rotation (flexion instability) of the injured spinal parts. Thus, it is effective in selected cases but is not appropriate for cases that require greater stability and fixation. See, Kanayama et al, Journal of Neurosurgery 95(1 Suppl): 5-10, 2001, Markwalder & Wenger, Acta Neurochrgica 145(3): 209-14.). Another non-fusion fixation device called "Dynesys" has recently been introduced. See Stoll et al, European Spine Journal 11 Suppl 2: S170-8, 2002, Schmoelz et al, J of spinal disorder & techniques 16(4): 418-23, 2003. The Dynesys device is similar to the Graf band except it uses a polycarburethane spacer between the screws to maintain the distance between the heads of two corresponding pedicle screws and, hence, adjacent vertebrae in which the screws are fixed. Early reports by the inventors of the Dynesys device indicate it has been successful in many cases. However, it has not yet been determined whether the Dynesys device can maintain long-term stability with flexibility and durability in a controlled study. Because it has polyethylene components and interfaces, there is a risk of mechanical failure. Furthermore, due to the mechanical configuration of the device, the surgical technique required to attach the device to the spinal column is complex and complicated.

[0010] U.S. Pat. Nos. 5,282,863 and 4,748,260 disclose a flexible spinal stabilization system and method using a plastic, non-metallic rod. U.S. patent publication no. 2003/0083657 discloses another example of a flexible spinal stabilization device that uses a flexible elongate member. These devices are flexible but they are not well-suited for enduring long-term axial loading and stress. Additionally, the degree of desired flexibility vs. rigidity may vary from patient to patient. The design of existing flexible fixation devices are not well suited to provide varying levels of flexibility to provide optimum results for each individual candidate. For example, U.S. Pat. No. 5,672,175 discloses a flexible spinal fixation device which utilizes a flexible rod made of metal alloy and/or a composite material. Additionally, compression or extension springs are coiled around the rod for the purpose of providing de-rotation forces on the vertebrae in a desired direction. However, this patent is primarily concerned with providing a spinal fixation device that permits "relative longitudinal translational sliding movement along [the] vertical axis" of the spine and neither teaches nor suggests any particular designs of connection units (e.g., rods or plates) that can provide various flexibility characteristics. Prior flexible rods such as that mentioned in U.S. Pat. No. 5,672,175 typically have solid construction with a relatively small diameter in order to provide a desired level of flexibility. Because they are typically very thin to provide suitable flexibility, such prior art rods are prone to mechanical failure and have been known to break after implantation in patients.

[0011] Therefore, conventional spinal fixation devices have not provided a comprehensive and balanced solution to the problems associated with curing spinal diseases. Many of the prior devices are characterized by excessive rigidity, which leads to the problems discussed above while others, though providing some flexibility, are not well-adapted to provide varying degrees of flexibility. Additionally, existing flexible fixation devices utilize non-metallic components that are not proven to provide long-term stability and durability. Therefore, there is a need for an improved dynamic spinal fixation device that provides a desired level of flexibility to the injured parts of the spinal column, while also providing long-term durability and consistent stabilization of the spinal column.

[0012] Additionally, in a conventional surgical method for fixing the spinal fixation device to the spinal column, a doctor incises the midline of the back to about 10-15 centimeters, and then, dissects and retracts it to both sides. In this way, the doctor performs muscular dissection to expose the outer part of the facet joint. Next, after the dissection, the doctor finds an entrance point to the spinal pedicle using radiographic devices (e.g., C-arm flouroscopy), and inserts securing members of the spinal fixation device (referred to as "spinal pedicle screws") into the spinal pedicle. Thereafter, the connection units (e.g., rods or plates) are attached to the upper portions of the pedicle screws in order to provide support and stability to the injured portion of the spinal column. Thus, in conventional spinal fixation procedures, the patient's back is incised about 10~15 cm, and as a result, the back muscle, which is important for maintaining the spinal column, is incised or injured, resulting in significant post-operative pain to the patient and a slow recovery period.

[0013] Recently, to reduce patient trauma, a minimally invasive surgical procedure has been developed which is capable of performing spinal fixation surgery through a relatively small hole or "window" that is created in the patient's back at the location of the surgical procedure. Through the use of an endoscope, or microscope, minimally invasive surgery allows a much smaller incision of the patient's affected area. Through this smaller incision, two or more securing members (e.g., pedicle screws) of the spinal fixation device are screwed into respective spinal pedicle areas using a navigation system. Thereafter, special tools are used to connect the stabilizing members (e.g., rods or plates) of the fixation device to the securing members. Alternatively, or additionally, the surgical procedure may include inserting a step dilator into the incision and then gradually increasing the diameter of the dilator. Thereafter, a tubular retractor is inserted into the dilated area to retract the patient's muscle and provide a visual field for surgery. After establishing this visual field, decompression and, if desired, fusion procedures may be performed, followed by a fixation procedure, which includes the steps of finding the position of the spinal pedicle, inserting pedicle screws into the spinal pedicle, using an endoscope or a microscope, and securing the stabilization members (e.g., rods or plates) to the pedicle screws in order to stabilize and support the weakened spinal column.

[0014] One of the most challenging aspects of performing the minimally invasive spinal fixation procedure is locating the entry point for the pedicle screw under endoscopic or microscopic visualization. Usually anatomical landmarks and/or radiographic devices are used to find the entry point, but clear anatomical relationships are often difficult to identify due to the confined working space. Additionally, the minimally invasive procedure requires that a significant amount of the soft tissue must be removed to reveal the anatomy of the regions for pedicle screw insertion. The removal of this soft tissue results in bleeding in the affected area, thereby adding to the difficulty of finding the correct position to insert the securing members and causing damage to the muscles and soft tissue surrounding the surgical area. Furthermore, because it is difficult to accurately locate the point of insertion for the securing members, conventional procedures are unnecessarily traumatic.

[0015] Radiography techniques have been proposed and implemented in an attempt to more accurately and quickly find the position of the spinal pedicle in which the securing members will be inserted. However, it is often difficult to obtain clear images required for finding the corresponding position of the spinal pedicle using radiography techniques due to radiographic interference caused by metallic tools and equipment used during the surgical operation. Moreover, reading and interpreting radiographic images is a complex task requiring significant training and expertise. Radiography poses a further problem in that the patient is exposed to significant amounts of radiation.

[0016] Although some guidance systems have been developed which guide the insertion of a pedicle screw to the desired entry point on the spinal pedicle, these prior systems have proven difficult to use and, furthermore, hinder the operation procedure. For example, prior guidance systems for pedicle screw insertion utilize a long wire that is inserted through a guide tube that is inserted through a patient's back muscle and tissue. The location of insertion of the guide tube

is determined by radiographic means (e.g., C-arm flouroscope) and driven until a first end of the guide tube reaches the desired location on the surface of the pedicle bone. Thereafter, a first end of the guide wire, typically made of a biocompatible metal material, is inserted into the guide tube and pushed into the pedicle bone, while the opposite end of the wire remains protruding out of the patient's back. After the guide wire has been fixed into the pedicle bone, the guide tube is removed, and a hole centered around the guide wire is dilated and retracted. Finally, a pedicle screw having an axial hole or channel configured to receive the guide wire therethrough is guided by the guide wire to the desired location on the pedicle bone, where the pedicle screw is screw-driven into the pedicle.

[0017] Although the concept of the wire guidance system is a good one, in practice, the guide wire has been very difficult to use. Because it is a relatively long and thin wire, the structural integrity of the guide wire often fails during attempts to drive one end of the wire into the pedicle bone, making the process unnecessarily time-consuming and laborious. Furthermore, because the wire bends and crimps during insertion, it does not provide a smooth and secure anchor for guiding subsequent tooling and pedicle screws to the entry point on the pedicle. Furthermore, current percutaneous wire guiding systems are used in conjunction with C-arm flouroscopy (or other radiographic device) without direct visualization with the use of an endoscope or microscope. Thus, current wire guidance systems pose a potential risk of misplacement or pedicle breakage. Finally, because one end of the wire remains protruding out of the head of the pedicle screw, and the patient's back, this wire hinders freedom of motion by the surgeon in performing the various subsequent procedures involved in spinal fixation surgery. Thus, there is a need to provide an improved guidance system, adaptable for use in minimally invasive pedicle screw fixation procedures under endoscopic or microscopic visualization, which is easier to implant into the spinal pedicle and will not hinder subsequent procedures performed by the surgeon.

[0018] As discussed above, existing methods and devices used to cure spinal diseases are in need of much improvement. Most conventional spinal fixation devices are too rigid and inflexible. This excessive rigidity causes further abnormalities and diseases of the spine, as well as significant discomfort to the patient. Although some existing spinal fixation devices do provide some level of flexibility, these devices are not designed or manufactured so that varying levels of flexibility may be easily obtained to provide a desired level of flexibility for each particular patient. Additionally, prior art devices having flexible connection units (e.g., rods or plates) pose a greater risk of mechanical failure and do not provide long-term durability and stabilization of the spine. Furthermore, existing methods of performing the spinal fixation procedure are unnecessarily traumatic to the patient due to the difficulty in finding the precise location of the spinal pedicle or sacral of the backbone where the spinal fixation device will be secured.

BRIEF SUMMARY OF THE INVENTION

[0019] The invention addresses the above and other needs by providing an improved method and system for stabilizing an injured or weakened spinal column.

[0020] To overcome the deficiencies of conventional spinal fixation devices, in one embodiment, the inventor of the present invention has invented a novel flexible spinal fixation device with an improved construction and design.

[0021] In one embodiment of the present invention, a flexible connection unit for use in a spinal fixation device includes a rod having at least one groove formed along at least a portion of the rod so as to provide flexibility to rod.

[0022] In another embodiment, a flexible connection unit for use in a spinal fixation device includes a solid rod and at least one transverse tunnel formed within the solid rod so as to provide flexibility to the rod.

[0023] As a result of long-term studies to reduce the operation time required for minimally invasive spinal surgery, to minimize injury to tissues near the surgical area, in another embodiment, the invention provides a method and device for accurately and quickly finding a position of the spinal column in which securing members of the spinal fixation device will be inserted. A novel guidance/marking device is used to indicate the position in the spinal column where the securing members will be inserted.

BRIEF DESCRIPTION OF THE DRAWINGS

[0024] **FIG. 1** illustrates a perspective view of a spinal fixation device in accordance with one embodiment of the invention.

[0025] **FIG. 2** illustrates a perspective view of spinal fixation device in accordance with another embodiment of the invention.

[0026] **FIG. 3** illustrates an exploded view of the coupling assembly **14** of the pedicle screw **2** of **FIGS. 1 and 2**, in accordance with one embodiment of the invention.

[0027] **FIG. 4** illustrates a perspective view of a flexible rod connection unit in accordance with one embodiment of the invention.

[0028] **FIG. 5** illustrates a perspective view of a flexible rod connection unit in accordance with another embodiment of the invention.

[0029] **FIG. 6** illustrates a perspective view of a flexible rod connection unit in accordance with a further embodiment of the invention.

[0030] **FIG. 7** illustrates a perspective view of a pre-bent flexible rod connection unit in accordance with one embodiment of the invention.

[0031] **FIG. 8** illustrates a perspective, cross-sectional view of a flexible portion of connection unit in accordance with one embodiment of the invention.

[0032] **FIG. 9** illustrates a perspective, cross-sectional view of a flexible portion of connection unit in accordance with another embodiment of the invention.

[0033] **FIG. 10** illustrates a perspective, cross-sectional view of a flexible portion of connection unit in accordance with a further embodiment of the invention.

[0034] **FIG. 11** illustrates a perspective view of a flexible rod connection unit in accordance with one embodiment of the invention.

[0035] **FIG. 12A** illustrates a perspective view of a flexible connection unit having one or more spacers in between two end portions, in accordance with one embodiment of the invention.

[0036] **FIG. 12B** illustrates an exploded view of the flexible connection unit of **FIG. 12A**.

[0037] **FIG. 12C** provides a view of the male and female interlocking elements of the flexible connection unit of **FIGS. 12A and 12B**, in accordance with one embodiment of the invention.

[0038] **FIG. 13** shows a perspective view of a flexible connection unit, in accordance with a further embodiment of the invention.

[0039] **FIG. 14** illustrates a perspective view of a spinal fixation device in accordance with another embodiment of the invention.

[0040] **FIG. 15** illustrates an exploded view of the spinal fixation device of **FIG. 14**.

[0041] **FIG. 16A** shows a perspective view of a flexible plate connection unit in accordance with one embodiment of the invention.

[0042] **FIG. 16B** illustrates a perspective view of a flexible plate connection unit in accordance with a further embodiment of the invention.

[0043] **FIG. 16C** shows a side view of the flexible plate connection unit of **FIG. 16A**.

[0044] **FIG. 16D** shows a top view of the flexible plate connection unit of **FIG. 16A**.

[0045] **FIG. 16E** illustrates a side view of the flexible plate connection unit of FIG. **16A** having a pre-bent configuration in accordance with a further embodiment of the invention.

[0046] **FIG. 17** is a perspective view of a flexible plate connection unit in accordance with another embodiment of the invention.

[0047] **FIG. 18** illustrates a perspective view of a flexible plate connection unit in accordance with another embodiment of the invention.

[0048] **FIG. 19** illustrates a perspective view of a hybrid rod-plate connection unit having a flexible middle portion according to a further embodiment of the present invention.

[0049] **FIG. 20** is a perspective view of a spinal fixation device that utilizes the hybrid rod-plate connection unit of **FIG. 19**.

[0050] **FIG. 21** illustrates a perspective view of the spinal fixation device of **FIG. 1** after it has been implanted into a patient's spinal column.

[0051] **FIGS. 22A and 22B** provide perspective views of spinal fixation devices utilizing the plate connection units of **FIGS. 16A and 16B**, respectively.

[0052] **FIG. 23A** illustrates a perspective view of two pedicle screws inserted into the pedicles of two adjacent vertebrae at a skewed angle, in accordance with one embodiment of the invention.

[0053] **FIG. 23B** illustrates a structural view of a coupling assembly of a pedicle screw in accordance with one embodiment of the invention.

[0054] **FIG. 23C** provides a perspective view of a slanted stabilizing spacer in accordance with one embodiment of the invention.

[0055] **FIG. 23D** illustrates a side view of the slanted stabilizing spacer of **FIG. 23C**.

[0056] **FIG. 23E** is a top view of the cylindrical head of the pedicle screw of **FIG. 23**.

[0057] **FIG. 24** illustrates a perspective view of a marking and guiding device in accordance with one embodiment of the invention.

[0058] **FIG. 25** is an exploded view of the marking and guidance device of **FIG. 24**.

[0059] **FIG. 26A** provides a perspective, cross-section view of a patient's spine after the marking and guiding device of **FIG. 24** has been inserted during surgery.

[0060] **FIG. 26B** provides a perspective, cross-section view of a patient's spine as an inner trocar of the marking and guiding device of **FIG. 24** is being removed.

[0061] **FIGS. 27A and 27B** illustrate perspective views of two embodiments of a fiducial pin, respectively.

[0062] **FIG. 28** is a perspective view of a pushing trocar in accordance with a further embodiment of the invention.

[0063] **FIG. 29A** illustrates a perspective, cross-sectional view of a patient's spine as the pushing trocar of **FIG. 28** is used to drive a fiducial pin into a designate location of a spinal pedicle, in accordance with one embodiment of the invention.

[0064] **FIG. 29B** illustrates a perspective, cross-sectional view of a patient's spine after two fiducial pins have been implanted into two adjacent spinal pedicles, in accordance with one embodiment of the invention.

[0065] **FIG. 30** is a perspective view of a cannulated awl in accordance with one embodiment of the invention.

[0066] **FIG. 31** is a perspective, cross-sectional view of a patient's spine as the cannulated awl of **FIG. 30** is being used to enlarge an entry hole for a pedicle screw, in accordance with one embodiment of the invention.

[0067] **FIG. 32** provides a perspective view of fiducial pin retrieving device, in accordance with one embodiment of the invention.

[0068] **FIG. 33** is a perspective view of a pedicle screw having an axial cylindrical cavity for receiving at least a portion of a fiducial pin therein, in accordance with a further embodiment of the invention.

[0069] **FIG. 34** is a perspective, cross-sectional view of a patient's spine after one pedicle screw has been implanted into a designated location of a spinal pedicle, in accordance with one embodiment of the invention.

[0070] **FIG. 35** is a perspective, cross-sectional view of a patient's spine after two pedicle screws have been implanted into designated locations of two adjacent spinal pedicles, in accordance with one embodiment of the invention.

[0071] **FIG. 36A** is perspective view of a flexible rod for spinal fixation having a spiral groove cut therein, in accordance with one embodiment of the present invention.

[0072] **FIG. 36B** provides a cross-sectional view of the flexible rod of **FIG. 36A**, taken along lines B-B of **FIG. 36A**.

[0073] **FIG. 37A** illustrates a perspective view of a flexible rod for spinal fixation having transverse tunnels within the body of the rod, in accordance with one embodiment of the invention.

[0074] **FIG. 37B** is a cross-sectional view of the flexible rod of **FIG. 37A**, taken along lines B-B of **FIG. 37A**.

[0075] **FIG. 38A** is a perspective view of a flexible rod for spinal fixation having a spiral groove cut therein and transverse tunnels in the body of the rod, in accordance with a further embodiment of the invention.

[0076] **FIG. 38B** is a top view of the flexible rod of **FIG. 38A**, from the perspective of lines B-B of **FIG. 38A**.

[0077] **FIG. 39A** is a perspective view of a flexible rod for spinal fixation having transverse tunnels within the body of the rod, in accordance with another embodiment of the invention.

[0078] **FIG. 39B** is a cross-sectional view of the flexible rod of **FIG. 39A**, taken along lines B-B of that figure.

[0079] **FIG. 39C** is an alternative cross-sectional view of the flexible rod of **FIG. 39A**, taken along lines B-B of that figure, having substantially orthogonal transverse tunnels in the body of the rod, in accordance with a further embodiment of the invention.

[0080] **FIG. 40A** illustrates a perspective view of a flexible rod for spinal fixation, in accordance with a further embodiment of the invention.

[0081] **FIG. 40B** illustrates a cross-sectional view of a flexible rod for spinal fixation in accordance with a further embodiment of the invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0082] The invention is described in detail below with reference to the figures wherein like elements are referenced with like numerals throughout.

[0083] **FIG. 1** depicts a spinal fixation device in accordance with one embodiment of the present invention. The spinal fixation device includes two securing members **2** (designated as **2'** and **2"**), and a flexible fixation rod **4** configured to be received and secured within a coupling assembly **14**, as described in further detail below with respect to **FIG. 3**. Each securing member **2** includes a threaded screw-type shaft **10** configured to be inserted and screwed into a patient's spinal pedicle. As shown in **FIG. 1**, the screw-type shaft **10** includes an external spiral screw thread **12** formed over the length of the shaft **10** and a conical tip at the end of the shaft **10** configured to be inserted into the patient's spinal column at a designated location. Other known forms of the securing member **2** may be used in connection with the present invention provided the securing member **2** can be inserted and fixed into the spinal column and securely coupled to the rod **4**.

[0084] As described above, the spinal fixation device is used for surgical treatment of spinal diseases by mounting securing members **2** at desired positions in the spinal column. In one embodiment, the rod **4** extends across two or more vertebrae of the spinal column and is secured by the securing members **2** so as to stabilize movement of the two or more vertebrae.

[0085] **FIG. 2** illustrates a perspective view of a spinal fixation device in accordance with a further embodiment of the present invention. The spinal fixation device of **FIG. 2** is similar to the spinal fixation device of **FIG. 1** except that the rod **4** comprises a flexible middle portion **8** juxtaposed between two rigid end portions **9** of the rod **4**.

[0086] **FIG. 3** provides an exploded view of the securing member **2** of **FIGS. 1 and 2** illustrating various components of the coupling assembly **14**, in accordance with one embodiment of the invention. As shown in **FIG. 3**, the coupling assembly **14** includes: a cylindrical head **16** located at a top end of the screw-type shaft **10**, a spiral thread or groove **18** formed along portions of the inner wall surface of the cylindrical head **16**, and a U-shaped seating groove **20** configured to receive the rod **4** therein. The coupling assembly **14** further comprises an outside-threaded nut **22** having a spiral thread **24** formed on the outside lateral surface of the nut **22**, wherein the spiral thread **24** is configured to mate with the internal spiral thread **18** of the cylindrical head **16**. In a further embodiment, the coupling assembly **14** includes a fixing cap **26** configured to be mounted over a portion of the cylindrical head **16** to cover and protect the outside-threaded nut **22** and more securely hold rod **4** within seating groove **20**. In one embodiment an inner diameter of the fixing gap **26** is configured to securely mate with the outer diameter of the cylindrical head **16**. Other methods of securing the fixing cap **26** to the cylindrical head, such as correspondingly located notches and groove (not shown), would be readily apparent to those of skill in the art. In preferred embodiments the components and parts of the securing member **2** may be made of highly rigid and durable bio-compatible materials such as: stainless steel, iron steel, titanium or titanium alloy. Such materials are known in the art. As also known in the art, and used herein, "bio-compatible" materials refers to those materials that will not cause any adverse chemical or immunological reactions after being implanted into a patient's body.

[0087] As shown in **FIGS. 1 and 2**, in preferred embodiments, the rod **4** is coupled to the securing means **2** by seating the rod **4** horizontally into the seating groove **20** of the coupling means **14** perpendicularly to the direction of the length of the threaded shaft **10** of securing member **2**. The outside threaded nut **22** is then received and screwed into the cylindrical head **16** above the rod **4** so as to secure the rod **4** in the seating groove **20**. The fixing cap **26** is then placed over the cylindrical head **16** to cover, protect and more firmly secure the components in the internal cavity of the cylindrical head **16**. **FIGS. 4-7** illustrate perspective views of various embodiments of a rod **4** that may be used in a fixation device, in accordance with the present invention. **FIG. 4** illustrates the rod **4** of **FIG. 1** wherein the entire rod is made and designed to be flexible. In this embodiment, rod **4** comprises a metal tube or pipe having a cylindrical wall **5** of a predefined thickness. In one embodiment, in order to provide flexibility to the rod **4**, the cylindrical wall **5** is cut in a spiral fashion along the length of the rod **4** to form spiral cuts or grooves **6**. As would be apparent to one of ordinary skill in the art, the width and density of the spiral grooves **6** may be adjusted to provide a desired level of flexibility. In

one embodiment, the grooves **6** are formed from very thin spiral cuts or incisions that penetrate through the entire thickness of the cylindrical wall of the rod **4**. As known to those skilled in the art, the thickness and material of the tubular walls **5** also affect the level of flexibility.

[**0088**] In one embodiment, the rod **4** is designed to have a flexibility that substantially equals that of a normal back. Flexibility ranges for a normal back are known by those skilled in the art, and one of ordinary skill can easily determine a thickness and material of the tubular walls **5** and a width and density of the grooves **6** to achieve a desired flexibility or flexibility range within the range for a normal back. When referring to the grooves **6** herein, the term "density" refers to tightness of the spiral grooves **6** or, in other words, the distance between adjacent groove lines **6** as shown in **FIG. 4**, for example. However, it is understood that the present invention is not limited to a particular, predefined flexibility range. In one embodiment, in addition to having desired lateral flexibility characteristics, the rigidity of the rod **4** should be able to endure a vertical axial load applied to the patient's spinal column along a vertical axis of the spine in a uniform manner with respect to the rest of the patient's natural spine.

[**0089**] **FIG. 5** illustrates the rod **4** of **FIG. 2** wherein only a middle portion **8** is made and designed to be flexible and two end portions **9** are made to be rigid. In one embodiment, metal end rings or caps **9'**, having no grooves therein, may be placed over respective ends of the rod **4** of **FIG. 4** so as make the end portions **9** rigid. The rings or caps **9'** may be permanently affixed to the ends of the rod **4** using known methods such as pressing and/or welding the metals together. In another embodiment, the spiral groove **6** is only cut along the length of the middle portion **8** and the end portions **9** comprise the tubular wall **5** without grooves **6**. Without the grooves **6**, the tubular wall **5**, which is made of a rigid metal or metal hybrid material, exhibits high rigidity.

[**0090**] **FIG. 6** illustrates a further embodiment of the rod **4** having multiple sections, two flexible sections **8** interleaved between three rigid sections **9**. This embodiment may be used, for example, to stabilize three adjacent vertebrae with respect to each other, wherein three pedicle screws are fixed to a respective one of the vertebrae and the three rigid sections **9** are connected to a coupling assembly **14** of a respective pedicle screw **2**, as described above with respect to **FIG. 3**. Each of the flexible sections **8** and rigid sections **9** may be made as described above with respect to **FIG. 5**.

[**0091**] **FIG. 7** illustrates another embodiment of the rod **4** having a pre-bent structure and configuration to conform to and maintain a patient's curvature of the spine, known as "lordosis," while stabilizing the spinal column. Generally, a patient's lumbar is in the shape of a 'C' form, and the structure of the rod **4** is formed to coincide to the normal lumbar shape when utilized in the spinal fixation device of **FIG. 2**, in accordance with one embodiment of the invention. In one embodiment, the pre-bent rod **4** includes a middle portion **8** that is made and designed to be flexible interposed between two rigid end portions **9**. The middle portion **8** and end portions **9** may be made as described above with respect to **FIG. 5**. Methods of manufacturing metallic or metallic-hybrid tubular rods of various sizes, lengths and pre-bent configurations are well-known in the art. Additionally, or alternatively, the pre-bent structure and design of the rod **4** may offset a skew angle when two adjacent pedicle screws are not inserted parallel to one another, as described in further detail below with respect to **FIG. 23A**.

[**0092**] Additional designs and materials used to create a flexible tubular rod **4** or flexible middle portion **8** are described below with respect to **FIGS. 8-10**. **FIG. 8** illustrates a perspective, cross-sectional view of a flexible tubular rod **4**, or rod portion **8** in accordance with one embodiment of the invention. In this embodiment, the flexible rod **4**, **8** is made from a first metal tube **5** having a spiral groove **6** cut therein as described above with respect to **FIGS. 4-7**. A second tube **30** having spiral grooves **31** cut therein and having a smaller diameter than the first tube **5** is inserted into the cylindrical cavity of the first tube **5**. In one embodiment, the second tube **30** has spiral grooves **31** which are cut in an opposite spiral direction with respect to the spiral grooves **6** cut in the first tube **5**, such that the rotational torsion characteristics of the second tube **30** offset at least some of the rotational torsion characteristics of the first tube **5**. The second flexible tube **30** is inserted into the core of the first tube to provide further durability and strength to the flexible rod **4**, **8**. The second tube **30** may be made of the same or different material than the first tube **5**. In preferred embodiments, the material used to manufacture the first and second tubes **5** and **30**, respectively, may be any one or combination of the following exemplary metals: stainless steel, iron steel, titanium, and titanium alloy.

[**0093**] **FIG. 9** illustrates a perspective, cross-sectional view of a flexible rod **4**, **8** in accordance with a further embodiment of the invention. In this embodiment, the flexible rod **4**, **8** includes an inner core made of a metallic wire **32** comprising a plurality of overlapping thin metallic yarns, such as steel yarns, titanium yarns, or titanium-alloy yarns. The wire **32** is encased by a metal, or metal hybrid, flexible tube **5** having spiral grooves **6** cut therein, as discussed above. The number and thickness of the metallic yarns in the wire **32** also affects the rigidity and flexibility of the rod **4**, **8**. By changing the number, thickness or material of the yarns flexibility can be increased or decreased. Thus, the number, thickness and/or material of the metallic yarns in the wire **32** can be adjusted to provide a desired rigidity and flexibility in accordance with a patient's particular needs. Those of ordinary skill in the art can easily determine the number, thickness and material of the yarns, in conjunction with a given flexibility of the tube **5** in order to achieve a desired rigidity v. flexibility profile for the rod **4**, **8**.

[**0094**] **FIG. 10** shows yet another embodiment of a flexible rod **4** wherein the flexible tube **5** encases a non-metallic, flexible core **34**. The core **34** may be made from known biocompatible shape memory alloys (e.g., NITINOL), or biocompatible synthetic materials such as: carbon fiber, Poly Ether Ether Ketone (PEEK), Poly Ether Ketone Ketone Ether Ketone (PEKKEK), or Ultra High Molecular Weight Poly Ethylene (UHMWPE).

[**0095**] **FIG. 11** illustrates a perspective view of another embodiment of the flexible rod **35** in which a plurality of metal wires **32**, as described above with respect to **FIG. 9**, are interweaved or braided together to form a braided metal wire rod **35**. Thus, the braided metal wire rod **35** can be made from the same materials as the metal wire **32**. In addition to the variability of the rigidity and flexibility of the

wire **32** as explained above, the rigidity and flexibility of the braided rod **35** can be further modified to achieve desired characteristics by varying the number and thickness of the wires **32** used in the braided structure **35**. For example, in order to achieve various flexion levels or ranges within the known flexion range of a normal healthy spine, those of ordinary skill in the art can easily manufacture various designs of the braided wire rod **35** by varying and measuring the flexion provided by different gauges, numbers and materials of the wire used to create the braided wire rod **35**. In a further embodiment each end of the braided metal wire rod **35** is encased by a rigid metal cap or ring **9'** as described above with respect to **FIGS. 5-7**, to provide a rod **4** having a flexible middle portion **8** and rigid end portions **9**. In a further embodiment (not shown), the metal braided wire rod **35** may be utilized as a flexible inner core encased by a metal tube **5** having spiral grooves **6** cut therein to create a flexible metal rod **4** or rod portion **8**, in a similar fashion to the embodiments shown in **FIGS. 8-10**. As used herein the term "braid" or "braided structure" encompasses two or more wires, strips, strands, ribbons and/or other shapes of material interwoven in an overlapping fashion. Various methods of interweaving wires, strips, strands, ribbons and/or other shapes of material are known in the art. Such interweaving techniques are encompassed by the present invention. In another exemplary embodiment (not shown), the flexible metal rod **35** includes a braided metal structure having two or more metal strips, strands or ribbons interweaved in a diagonally overlapping pattern.

[**0096**] **FIG. 12A** illustrates a further embodiment of a flexible connection unit **36** having two rigid end portions **9'** and an exemplary number of rigid spacers **37**. In one embodiment, the rigid end portions **9'** and spacers can be made of bio-compatible metal or metal-hybrid materials as discussed above. The connection unit **36** further includes a flexible wire **32**, as discussed above with respect to **FIG. 9'**, which traverses an axial cavity or hole (not shown) in each of the rigid end portions **9'** and spacers **37**. **FIG. 12B** illustrates an exploded view of the connection unit **36** that further shows how the wire **32** is inserted through center axis holes of the rigid end portions **9'** and spacers **37**. As further shown in **FIG. 12B**, each of the end portions **9'** and spacers **37** include a male interlocking member **38** which is configured to mate with a female interlocking cavity (not shown) in the immediately adjacent end portion **9'** or spacer **37**. **FIG. 12C** illustrates an exploded side view and indicates with dashed lines the location and configuration of the female interlocking cavity **39** for receiving corresponding male interlocking members **38**.

[**0097**] **FIG. 13** shows a perspective view of a flexible connection unit **40** in accordance with another embodiment of the invention. The connection **40** is similar to the connection unit **36** described above, however, the spacers **42** are configured to have the same shape and design as the rigid end portions **9'**. Additionally, the end portions **9'** have an exit hole or groove **44** located on a lateral side surface through which the wire **32** may exit, be pulled taut, and clamped or secured using a metal clip (not shown) or other known techniques. In this way, the length of the flexible connection unit **36** or **40** may be varied at the time of surgery to fit each patient's unique anatomical characteristics. In one embodiment, the wire **32** may be secured using a metallic clip or stopper (not shown). For example, a clip or stopper may include a small tubular cylinder having an inner diameter that is slightly larger than the diameter of the wire **32** to allow the wire **32** to pass therethrough. After the wire **32** is pulled to a desired tension through the tubular stopper, the stopper is compressed so as to pinch the wire **32** contained therein. Alternatively, the wire **32** may be pre-secured using known techniques during the manufacture of the rod-like connection units **36, 40** having a predetermined number of spacers **37, 42** therein.

[**0098**] **FIG. 14** depicts a spinal fixation device according to another embodiment of the present invention. The spinal fixation device includes: at least two securing members **2** containing an elongate screw type shaft **10** having an external spiral thread **12**, and a coupling assembly **14**. The device further includes a plate connection unit **50**, or simply "plate **50**," configured to be securely connected to the coupling parts **14** of the two securing members **2**. The plate **50** comprises two rigid connection members **51** each having a planar surface and joined to each other by a flexible middle portion **8**. The flexible middle portion **8** may be made in accordance with any of the embodiments described above with respect to **FIGS. 4-11**. Each connection member **51** contains a coupling hole **52** configured to receive therethrough a second threaded shaft **54 (FIG. 15)** of the coupling assembly **14**.

[**0099**] As shown in **FIG. 15**, the coupling assembly **14** of the securing member **2** includes a bolt head **56** adjoining the top of the first threaded shaft **10** and having a circumference or diameter greater than the circumference of the first threaded shaft **10**. The second threaded shaft **54** extends upwardly from the bolt head **56**. The coupling assembly **14** further includes a nut **58** having an internal screw thread configured to mate with the second threaded shaft **54**, and one or more washers **60**, for clamping the connection member **51** against the top surface of the bolt head **56**, thereby securely attaching the plate **50** to the pedicle screw **2**.

[**0100**] **FIGS. 16A and 16B** illustrate two embodiments of a plate connection unit **40** having at least two coupling members **51** and at least one flexible portion **8** interposed between and attached to two adjacent connection members **51**. As shown in **FIGS. 16A and 16B**, the flexible middle portion **8** comprises a flexible metal braided wire structure **36** as described above with respect to **FIG. 11**. However, the flexible portion **8** can be designed and manufactured in accordance with any of the embodiments described above with respect to **FIGS. 4-11**, or combinations thereof. **FIGS. 16C and 16D** illustrate a side view and top view, respectively, of the plate **50** of **FIG. 16A**. The manufacture of different embodiments of the flexible connection units **50** and **58** having different types of flexible middle portions **8**, as described above, is easily accomplished using known metallurgy manufacturing processes.

[**0101**] **FIG. 16E** illustrate a side view of a pre-bent plate connection unit **50'**, in accordance with a further embodiment of the invention. This plate connection unit **50'** is similar to the plate **50** except that connection members **51'** are formed or bent at an angle θ from a parallel plane **53** during manufacture of the plate connection unit **50'**. As discussed above with respect to the pre-bent rod-like connection unit **4** of **FIG. 7**, this pre-bent configuration is designed to emulate and support a natural curvature of the spine (e.g., lordosis). Additionally, or alternatively, this

pre-bent structure may offset a skew angle when two adjacent pedicle screws are not inserted parallel to one another, as described in further detail below with respect to **FIG. 23A**.

[0102] **FIG. 17** illustrates a perspective view of a plate connection unit **60** having two planar connection members **62** each having a coupling hole **64** therein for receiving the second threaded shaft **44** of the pedicle screw **2**. A flexible middle portion **8** is interposed between the two connection members **62** and attached thereto. In one embodiment, the flexible middle portion **8** is made in a similar fashion to wire **32** described above with respect to **FIG. 9**, except it has a rectangular configuration instead of a cylindrical or circular configuration as shown in **FIG. 9**. It is understood, however, that the flexible middle portion **8** may be made in accordance with the design and materials of any of the embodiments previously discussed.

[0103] **FIG. 18** illustrates a perspective view of a further embodiment of the plate **60** of **FIG. 17** wherein the coupling hole **64** includes one or more nut guide grooves **66** cut into the top portion of the connection member **62** to seat and fix the nut **58** (**FIG. 15**) into the coupling hole **64**. The nut guide groove **66** is configured to receive and hold at least a portion of the nut **58** therein and prevent lateral sliding of the nut **58** within the coupling hole **64** after the connection member **62** has been clamped to the bolt head **56** of the pedicle screw **2**.

[0104] **FIG. 19** illustrates a perspective view of a hybrid plate and rod connection unit **70** having a rigid rod-like connection member **4**, **9** or **9'**, as described above with respect to **FIGS. 4-7**, at one end of the connection unit **70** and a plate-like connection member **51** or **62**, as described above with respect to **FIGS. 14-18**, at the other end of the connection unit **70**. In one embodiment, interposed between rod-like connection member **9** (**9'**) and the plate-like connection member **52** (**64**) is a flexible member **8**. The flexible member **8** may be designed and manufactured in accordance with any of the embodiments discussed above with reference to **FIGS. 8-13**.

[0105] **FIG. 20** illustrates a perspective view of a spinal fixation device that utilizes the hybrid plate and rod connection unit **70** of **FIG. 19**. As shown in **FIG. 20**, this fixation device utilizes two types of securing members **2** (e.g., pedicle screws), the first securing member **2'** being configured to securely hold the plate connection member **42**(**64**) as described above with respect to **FIG. 15**, and the second securing member **2"** being configured to securely hold the rod connection member **4**, **9** or **9'**, as described above with respect to **FIG. 3**.

[0106] **FIG. 21** illustrates a perspective top view of two spinal fixation devices, in accordance with the embodiment illustrated in **FIG. 1**, after they are attached to two adjacent vertebrae **80** and **82** to flexibly stabilize the vertebrae. **FIGS. 22A and 22B** illustrate perspective top views of spinal fixation devices using the flexible stabilizing members **50** and **58** of **FIGS. 16A and 16B**, respectively, after they are attached to two or more adjacent vertebrae of the spine.

[0107] **FIG. 23A** illustrates a side view of a spinal fixation device after it has been implanted into the pedicles of two adjacent vertebrae. As shown in this figure, the pedicle screws **2** are mounted into the pedicle bone such that a center axis **80** of the screws **2** are offset by an angle θfrom a parallel plane **82** and the center axes **80** of the two screws **2** are offset by an angle of approximately 2θ from each other. This type of non-parallel insertion of the pedicle screws **2** often results due to the limited amount of space that is available when performing minimally invasive surgery. Additionally, the pedicle screws **2** may have a tendency to be skewed from parallel due to a patient's natural curvature of the spine (e.g., lordosis). Thus, due to the non-parallel nature of how the pedicle screws **2** are ultimately fixed to the spinal pedicle, it is desirable to offset this skew when attaching a rod or plate connection unit to each of the pedicle screws **2**.

[0108] **FIG. 23B** illustrates a side view of the head of the pedicle screw in accordance with one embodiment of the invention. The screw **2** includes a cylindrical head **84** which is similar to the cylindrical head **16** described above with respect to **FIG. 3** except that the cylindrical head **84** includes a slanted seat **86** configured to receive and hold a flexible rod **4** in a slanted orientation that offsets the slant or skew θ of the pedicle screw **2** as described above. The improved pedicle screw **2** further includes a slanted stabilizing spacer **88** which is configured to securely fit inside the cavity of the cylindrical head **84** and hold down the rod **4** at the same slant as the slanted seat **86**. The pedicle screw **2** further includes an outside threaded nut **22** configured to mate with spiral threads along the interior surface (not shown) of the cylindrical head **84** for clamping down and securing the slanted spacer **88** and the rod **4** to the slanted seat **86** and, hence, to the cylindrical head **84** of the pedicle screw **2**.

[0109] **FIG. 23C** shows a perspective view of the slanted spacer **88**, in accordance with embodiment of the invention. The spacer **88** includes a circular middle portion **90** and two rectangular-shaped end portions **92** extending outwardly from opposite sides of the circular middle portion **90**. **FIG. 23D** shows a side view of the spacer **88** that further illustrates the slant from one end to another to compensate or offset the skew angle θ of the pedicle screw **2**. **FIG. 23E** illustrates a top view of the cylindrical head **84** configured to receive a rod **4** and slanted spacer **88** therein. The rod **4** is received through two openings or slots **94** in the cylindrical walls of the cylindrical head **84**, which allow the rod **4** to enter the circular or cylindrical cavity **96** of the cylindrical head **84** and rest on top of the slanted seat **86** formed within the circular or cylindrical cavity **94**.

[0110] After the rod **4** is positioned on the slanted seat **86**, the slanted stabilizing spacer **88** is received in the cavity **96** such that the two rectangular-shaped end portions **92** are received within the two slots **94**, thereby preventing lateral rotation of the spacer **88** within the cylindrical cavity **96**. Finally, the outside threaded nut **22** and fixing cap **26** are inserted on top of the slanted spacer **88** to securely hold the spacer **88** and rod **4** within the cylindrical head **84**.

[0111] **FIG. 24** illustrates a perspective view of a marking and guidance device **100** for marking a desired location on the spinal pedicle where a pedicle screw **2** will be inserted and guiding the pedicle screw **2** to the marked location using a minimally invasive surgical technique. As shown in **FIG. 24**, the marking device **100** includes a tubular hollow guider **52** which receives within its hollow an inner trocar **104** having a sharp tip **105** at one end that penetrates a patient's muscle and tissue to reach the spinal pedicle. the inner trocar **104** further includes a trocar grip **106** at the other end for easy insertion and removal of the trocar **104**. In one embodi-

ment, the marking and guidance device **100** includes a guider handle **108** to allow for easier handling of the device **100**.

[**0112**] As shown in **FIG. 25**, the trocar **104** is in the form of a long tube or cylinder having a diameter smaller than the inner diameter of the hollow of the guider **102** so as to be inserted into the hollow of the tubular guider **102**. The trocar **104** further includes a sharp or pointed tip **105** for penetrating the vertebral body through the pedicle. The trocar **104** further includes a trocar grip **106** having a diameter larger than the diameter of the hollow of the guider tube **102** in order to stop the trocar **104** from sliding completely through the hollow. The trocar grip **106** also allows for easier handling of the trocar **104**.

[**0113**] **FIGS. 26A and 26B** provide perspective views of the marking and guidance device **100** after it has been inserted into a patient's back and pushed through the muscle and soft tissue to reach a desired location on the spinal pedicle. The desired location is determined using known techniques such as x-ray or radiographic imaging for a relatively short duration of time. After the marking and guidance device **100** has been inserted, prolonged exposure of the patient to x-ray radiation is unnecessary. As shown in **FIG. 26B**, after the guidance tube **102** is positioned over the desired location on the pedicle, the inner trocar **104** is removed to allow fiducial pins (not shown) to be inserted into the hollow of the guidance tube **102** and thereafter be fixed into the pedicle.

[**0114**] **FIGS. 27A and 27B** illustrate perspective views of two embodiments of the fiducial pins **110** and **112**, respectively. As mentioned above, the fiducial pins **110** and **112** according to the present invention are inserted and fixed into the spinal pedicle after passing through the hollow guider **102**. The pins **110** and **112** have a cylindrical shape with a diameter smaller than the inner diameter of the hollow of the guider tube **102** in order to pass through the hollow of the guider **102**. An end of each fiducial pin is a sharp point **111** configured to be easily inserted and fixed into the spinal pedicle of the spinal column. In one embodiment, as shown in **FIG. 27B**, the other end of the fiducial pin incorporates a threaded shaft **114** which is configured to mate with an internally threaded tube of a retriever (not shown) for extraction of the pin **112**. This retriever is described in further detail below with respect to **FIG. 32**.

[**0115**] The fiducial pins **110**, **112** are preferably made of a durable and rigid biocompatible metal (e.g., stainless steel, iron steel, titanium, titanium alloy) for easy insertion into the pedicle bone. In contrast to prior art guide wires, because of its comparatively shorter length and more rigid construction, the fiducial pins **110**, **112** are easily driven into the spinal pedicle without risk of bending or structural failure. As explained above, the process of driving in prior art guidance wires was often very difficult and time-consuming. The insertion of the fiducial pins **110**, **112** into the entry point on the spinal pedicle is much easier and convenient for the surgeon and, furthermore, does not hinder subsequent procedures due to a guide wire protruding out of the patient's back.

[**0116**] **FIG. 28** shows a cylindrical pushing trocar **116** having a cylindrical head **118** of larger diameter than the body of the pushing trocar **116**. The pushing trocar **116**, according to the present invention, is inserted into the hollow of the guider **102** after the fiducial pin **110** or **112** has been inserted into the hollow of the guider **102** to drive and fix the fiducial pin **110** or **112** into the spinal pedicle. During this pin insertion procedure, a doctor strikes the trocar head **118** with a chisel or a hammer to drive the fiducial pin **110** and **112** into the spinal pedicle. In preferred embodiments, the pushing trocar **116** is in the form of a cylindrical tube, which has a diameter smaller than the inner diameter of the hollow of the guider tube **112**. The pushing trocar **116** also includes a cylindrical head **118** having a diameter larger than the diameter of the pushing trocar **116** to allow the doctor to strike it with a chisel or hammer with greater ease. Of course, in alternative embodiments, a hammer or chisel is not necessarily required. For example, depending on the circumstances of each case, a surgeon may choose to push or tap the head **118** of the pushing trocar **116** with the palm of his or her hand or other object.

[**0117**] **FIG. 29A** illustrates how a hammer or mallet **120** and the pushing trocar **116** may be used to drive the pin **110**, **112** through the hollow of the guider tube **102** and into the designated location of the spinal pedicle. **FIG. 29B** illustrates a perspective cross-sectional view of the spinal column after two fiducial pins **110**, **112** have been driven and fixed into two adjacent vertebrae.

[**0118**] After the fiducial pins **110** or **112** have been inserted into the spinal pedicle as discussed above, in one embodiment, a larger hole or area centered around each pin **110**, **112** is created to allow easer insertion and mounting of a pedicle screw **2** into the pedicle bone. The larger hole is created using a cannulated awl **122** as shown in **FIG. 30**. The cannulated awl **122** is inserted over the fiducial pin **110**, **112** fixed at the desired position of the spinal pedicle. The awl **122** is in the form of a cylindrical hollow tube wherein an internal diameter of the hollow is larger than the outer diameter of the fiducial pins **110** and **112** so that the pins **110**, **112** may be inserted into the hollow of the awl **122**. The awl **122** further includes one or more sharp teeth **124** at a first end for cutting and grinding tissue and bone so as to create the larger entry point centered around the fiducial pin **110**, **112** so that the pedicle screw **2** may be more easily implanted into the spinal pedicle. **FIG. 31** illustrates a perspective cross-sectional view of a patient's spinal column when the cannulated awl **122** is inserted into a minimally invasive incision in the patient's back, over a fiducial pin **110**, **112** to create a larger insertion hole for a pedicle screw **2** (not shown). As shown in **FIG. 31**, a retractor **130** has been inserted into the minimally invasive incision over the surgical area and a lower tubular body of the retractor **130** is expanded to outwardly push surrounding tissue away from the surgical area and provide more space and a visual field for the surgeon to operate. In order to insert the retractor **130**, in one embodiment, the minimally invasive incision is made in the patient's back between and connecting the two entry points of the guide tube **102** used to insert the two fiducial pins **110**, **112**. Before the retractor **130** is inserted, prior expansion of the minimally invasive incision is typically required using a series of step dilators (not shown), each subsequent dilator having a larger diameter than the previous dilator. After the last step dilator is in place, the retractor **130** is inserted with its lower tubular body in a retracted, non-expanded state. After the retractor **130** is pushed toward the spinal pedicle to a desired depth, the lower tubular portion is then expanded as shown in **FIG. 31**. The use of step dilators and retractors are well known in the art.

[0119] After the cannulated awl **122** has created a larger insertion hole for the pedicle screw **2**, in one embodiment, the fiducial pin **110**, **112** is removed. As discussed above, if the fiducial pin **112** has been used, a retrieving device **140** may be used to remove the fiducial pin **112** before implantation of a pedicle screw **2**. As shown in **FIG. 32**, the retriever **140** comprises a long tubular or cylindrical portion having an internally threaded end **142** configured to mate with the externally threaded top portion **114** of the fiducial pin **112**. After the retriever end **142** has been screwed onto the threaded end **114**, a doctor my pull the fiducial pin **112** out of the spinal pedicle. In another embodiment, if the fiducial pin **110** without a threaded top portion has been used, appropriate tools (e.g., specially designed needle nose pliers) may be used to pull the pin **110** out.

[0120] In alternate embodiments, the fiducial pins **110**, **112** are not extracted from the spinal pedicle. Instead, a specially designed pedicle screw **144** may be inserted into the spinal pedicle over the pin **110**, **112** without prior removal of the pin **110**, **112**. As shown in **FIG. 33**, the specially designed pedicle screw **144** includes an externally threaded shaft **10** and a coupling assembly **14** (**FIG. 3**) that includes a cylindrical head **16** (**FIG. 3**) for receiving a flexible rod-shaped connection unit **4** (**FIGS. 4-13**). Alternatively, the coupling assembly **14** may be configured to receive a plate-like connection unit as shown in **FIGS. 14-20**. The pedicle screw **144** further includes a longitudinal axial channel (not shown) inside the threaded shaft **10** having an opening **146** at the tip of the shaft **10** and configured to receive the fiducial pin **110**, **112** therein.

[0121] **FIG. 34** illustrates a perspective cross-sectional view of the patient's spinal column after a pedicle screw **2** has been inserted into a first pedicle of the spine using an insertion device **150**. Various types of insertion devices **150** known in the art may be used to insert the pedicle screw **2**. As shown in **FIG. 34**, after a first pedicle screw **2** has been implanted, the retractor **130** is adjusted and moved slightly to provide space and a visual field for insertion of a second pedicle screw at the location of the second fiducial pin **110**, **112**.

[0122] **FIG. 35** provides a perspective, cross sectional view of the patient's spinal column after two pedicle screws **2** have been implanted in two respective adjacent pedicles of the spine, in accordance with the present invention. After the pedicle screws **2** are in place, a flexible rod, plate or hybrid connection unit as described above with respect to **FIGS. 4-20** may be connected to the pedicle screws to provide flexible stabilization of the spine. Thereafter, the retractor **130** is removed and the minimally invasive incision is closed and/or stitched.

[0123] **FIG. 36A** illustrates a perspective view of a flexible rod **200** for spinal fixation, in accordance with a further embodiment of the invention. The rod **200** is configured to be secured by securing members **2** as described above with reference to **FIGS. 1-3**. In preferred embodiments, the rod **200**, and rods **210**, **220**, **230** and **240** described below, are comprised of a solid cylindrically-shaped rod made of known bio-compatible materials such as: stainless steel, iron steel, titanium, titanium alloy, NITINOL, and other suitable materials or compositions. As shown in **FIG. 36A**, spiral grooves **202** are cut or formed along at least a portion of the length of the cylindrical body of the rod **200**. In an exemplary embodiment, the length of the rod "l" may be between 4 and 8 centimeters (cm), and its cylindrical diameter "D" is between 4-8 millimeters (mm). The spiral grooves **202** have a width "w" between 0.1 and 0.5 mm and a spiral angle θ between 50 and 85 degrees from horizontal. The distance between spiral grooves **202** can be between 3 and 6 mm. However, as understood by those skilled in the art, the above dimensions are exemplary only and may be varied to achieve desired flexibility, torsion and strength characteristics that are suitable for a particular patient or application.

[0124] **FIG. 36B** illustrates a cross-sectional view of the flexible rod **200**, taken along lines B-B of **FIG. 36A**. As shown, spiral groove **202** is cut toward the center longitudinal axis of the cylindrical rod **200**. In one embodiment, the depth of the groove **202** is approximately equal to the cylindrical radius of the rod **200**, as shown in **FIG. 36B**, and penetrates as deep as the center longitudinal axis of the cylindrical rod **200**. However, the depth and width of the groove **202** can be varied to adjust the mechanical and structural characteristics of the rod **200** as desired.

[0125] **FIG. 37A** illustrates a flexible rod **210** for spinal fixation in accordance with another embodiment of the invention. The rod **210** includes a plurality of transverse holes or tunnels **212** drilled or formed within the body of the rod **210**. In one embodiment, the tunnels **212** pass through a center longitudinal axis of the cylindrical rod **210** at an angle Φ from horizontal. The openings for each respective tunnel **212** are located on opposite sides of the cylindrical wall of the rod **210** and adjacent tunnels **212** share a common opening on one side of the cylindrical wall, forming a zigzag pattern of interior tunnels **212** passing transversely through the central longitudinal axis of the rod **210**, as shown in **FIG. 37A**. In one embodiment, the diameter D of each tunnel **212** may be varied between 0.2 to 3 mm, depending the desired mechanical and structural characteristics (e.g., flexibility, torsion and strength) of the rod **210**. However, it is understood that these dimensions are exemplary and other diameters D may be desired depending on the materials used and the desired structural and mechanical characteristics. Similarly, the angle from horizontal Φ may be varied to change the number of tunnels **212** or the distance between adjacent tunnels **212**.

[0126] **FIG. 37B** illustrates a cross-sectional view of the flexible rod **210** taken along lines B-B of **FIG. 37A**. The tunnel **212** cuts through the center cylindrical axis of the rod **210** such that openings of the tunnel **212** are formed at opposite sides of the cylindrical wall of the rod **210**.

[0127] **FIG. 38A** illustrates a perspective view of a flexible rod **220** for spinal fixation, in accordance with a further embodiment of the invention. Rod **220** incorporates the spiral grooves **202** described above with reference to **FIGS. 36A and 36B** as well as the transverse tunnels **212** described above with respect to **FIGS. 37A and 37B**. The spiral grooves **202** are cut into the surface of the cylindrical wall of the rod **220** toward a center longitudinal axis of the rod **220**. As discussed above, the dimensions of the spiral grooves **202** and their angle from horizontal θ (**FIG. 36A**) may be varied in accordance with desired mechanical and structural characteristics. Similarly, the dimensions of the transverse tunnels **212** and their angle from horizontal Φ (**FIG. 37A**) may be varied in accordance with desired mechanical and structural characteristics. In one embodi-

ment, the angles θ and Φ are substantially similar such that the openings of the tunnels **212** substantially coincide with the spiral grooves **202** on opposite sides of the cylindrical wall of the rod **220**.

[**0128**] **FIG. 38B** shows a top view of the flexible rod **220** taken along the perspective indicated by lines B-B of **FIG. 38A**. As shown in **FIG. 38B**, the openings of the tunnels **212** coincide with the spiral grooves **202**. By providing both spiral grooves **202** and transverse tunnels **212** within a solid rod **220**, many desired mechanical and structural characteristics that are suitable for different patients, applications and levels of spinal fixation may be achieved.

[**0129**] **FIG. 39A** illustrates a flexible rod **230** for spinal fixation, in accordance with another embodiment of the invention. The rod **230** includes a plurality of transverse tunnels **232** formed in the body of the rod **230**. The tunnels **232** are substantially similar to the tunnels **212** described above with respect to **FIGS. 37A and 37B**, however, the tunnels **232** are not linked together in a zigzag pattern. Rather, each tunnel **232** is substantially parallel to its immediate adjacent tunnels **232** and the openings of one tunnel **232** do not coincide with the openings of adjacent tunnels **232**. As shown in **FIG. 39A**, the angle from horizontal Φ in this embodiment is approximately 90 degrees. However, it is understood that other angles Φ may be incorporated in accordance with the present invention. It is further understood that the dimensions, size and shape of the tunnels **232** (as well as tunnels **212**) may be varied to achieve desired mechanical and structural characteristics. For example, the cross-sectional shape of the tunnels **212** and **232** need not be circular. Instead, for example, they may be an oval or diamond shape, or other desired shape.

[**0130**] **FIG. 39B** illustrates a cross-sectional view of the rod **230** taken along lines B-B of **FIG. 39A**. As shown in **FIG. 39B**, the transverse tunnel **232** travels vertically and transversely through the center longitudinal axis of the rod **230**. **FIG. 39C** illustrates a cross-sectional view of a further embodiment of the rod **230**, wherein an additional transverse tunnel **232'** is formed substantially orthogonal to the first transverse tunnel **232** and intersects the first transverse tunnel **232** at the center, cylindrical axis point. In this way, further flexibility of the rod **230** may be provided as desired.

[**0131**] **FIG. 40A** illustrates a perspective view of a flexible rod **240**, in accordance with a further embodiment of the invention. The rod **240** includes a plurality of interleaved transverse tunnels **232** and **242** which are substantially orthogonal to each other and which do not intersect, as shown in **FIG. 40A**. In another embodiment, a cross-sectional view of which is shown in **FIG. 40B**, adjacent tunnels **232** and **242** need not be orthogonal to one another. Each tunnel **232**, **242** can be offset at a desired angle co from its immediately preceding adjacent tunnel **232**, **242**. As can be verified by those of skill in the art, without undue experimentation, by varying the dimensions of the tunnels, their numbers, and their angular directions with respect to one another, various desired mechanical and structural characteristics for flexible rods used in spinal fixation devices may be achieved.

[**0132**] Various embodiments of the invention have been described above. However, those of ordinary skill in the art will appreciate that the above descriptions of the preferred embodiments are exemplary only and that the invention may be practiced with modifications or variations of the devices and techniques disclosed above. Those of ordinary skill in the art will know, or be able to ascertain using no more than routine experimentation, many equivalents to the specific embodiments of the invention described herein. Such modifications, variations and equivalents are contemplated to be within the spirit and scope of the present invention as set forth in the claims below.

What is claimed is:

1. A flexible connection unit for use in a spinal fixation device, the flexible connection unit comprising a longitudinal member having at least one groove formed along at least a portion of the longitudinal member thereby providing additional flexibility to the longitudinal member.

2. The flexible connection unit of claim 1 wherein the longitudinal member comprises a solid rod.

3. The flexible connection unit of **2** wherein the solid rod comprises a solid metal rod.

4. The flexible connection unit of claim 1 wherein the at least one groove has a depth between 1 and 5 millimeters and a width between 0.1 and 2.0 millimeters.

5. The flexible connection unit of claim 1 wherein the at least one groove is formed in a spiral configuration along a longitudinal axis of the longitudinal member.

6. The flexible connection unit of claim 5 wherein the at least one groove is formed at a spiral angle θ from horizontal between 30 and 89 degrees.

7. The flexible connection unit of claim 1 further including at least one transverse tunnel formed within at least a portion of the longitudinal member.

8. The flexible connection unit of claim 7 wherein the longitudinal member comprises a solid rod cylindrical in shape and the at least one transverse tunnel passes through the cylindrical rod such that respective openings for the at least one transverse tunnel are located on opposing side surfaces of the cylindrical rod.

9. The flexible connection unit of claim 8 wherein the at least one transverse tunnel comprises a plurality of transverse tunnels and each transverse tunnel passes through a center longitudinal axis of the cylindrical rod at a predetermined angle Φ and wherein adjacent transverse tunnels share a common opening on one side of a cylindrical wall, forming a zigzag pattern of interior tunnels passing transversely through the central longitudinal axis of the rod.

10. The flexible connection unit of claim 9 wherein the location of the common openings intersect with respective portions of the at least one groove at an exterior surface of the rod.

11. The flexible connection unit of claim 1 wherein the longitudinal member comprises a cylindrical tube.

12. The flexible connection unit of **11** wherein the cylindrical tube comprises a metal cylindrical tube.

13. The flexible connection unit of claim 11 further comprising a rod having a smaller diameter than the cylindrical tube such that the rod is configured to fit inside a longitudinal axial channel of the cylindrical tube.

14. The flexible connection unit of claim 13 wherein the rod comprises a solid rod.

15. The flexible connection unit of claim 14 wherein the solid rod is made from a flexible core material selected from a group consisting of: carbon graphite, PEEK, PEEKEK, NITINOL, and UHMWPE.

16. The flexible connection unit of claim 14 wherein the solid rod comprises a second groove formed thereon for providing additional flexibility to the solid rod.

17. The flexible connection unit of claim 13 wherein the rod comprises a second tube.

18. The flexible connection unit of claim 17 wherein the second tube is made from a flexible core material selected from a group consisting of: carbon graphite, PEEK, PEEKEK, NITINOL, and UHMWPE.

19. The flexible connection unit of claim 17 wherein the second tube comprises a second groove formed thereon for provided additional flexibility to the second tube.

20. The flexible connection unit of claim 1 wherein the longitudinal member is configured in the shape of a cylindrical rod.

21. The flexible connection unit of claim 20 wherein the cylindrical rod has a substantially uniform outer diameter along its longitudinal axis.

22. The flexible connection unit of claim 1 wherein the portion of the longitudinal member having at least one groove has a cross-sectional area that is different from respective end portions of the longitudinal member.

23. A flexible connection unit for use in a spinal fixation device comprising a solid longitudinal member and at least one transverse tunnel formed within the solid longitudinal member so as to provide flexibility to the longitudinal member.

24. The flexible connection unit of claim 23 wherein the solid longitudinal member comprises a cylindrical rod and the at least one transverse tunnel passes through a center longitudinal axis of the cylindrical rod such that respective openings for the at least one transverse tunnel are located on opposite sides of a cylindrical wall of the rod.

25. The flexible connection unit of claim 23 wherein the at least one transverse tunnel comprises a plurality of transverse tunnels, each transverse tunnel intersecting a center longitudinal axis of the longitudinal member at a predetermined angle Φ and wherein adjacent transverse tunnels share a common opening at a lateral surface of the longitudinal member, forming a zigzag pattern of interior tunnels intersecting the center longitudinal axis of the longitudinal member.

26. A flexible connection unit for use in a spinal fixation device comprising:

a longitudinal member configured to be secured to a patient's spine using at least three securing members;

wherein a first portion of the longitudinal member is configured to be located between a first pair of securing members and a second portion of the longitudinal member is configured to be located between a second pair of securing members; and

wherein at least one of the first and second portions comprises a groove formed therein for providing flexibility to the at least one of the first and second portions.

27. The flexible connection unit of claim 26 wherein the longitudinal member comprises a cylindrical rod and the groove comprises a spiral groove formed along a longitudinal axis of the at least one of the first and second portions.

28. The flexible connection unit of claim 26 wherein each of the first and second portions comprises a groove formed therein for providing flexibility thereto.

29. The flexible connection unit of claim 28 wherein the grooves formed in the first and second portions each comprise a spiral groove formed around a respective longitudinal axis of the first and second portions.

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