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(71) Applicant (for all designated States except US): **BHDL HOLDINGS, LLC** [US/US]; 1280 Eugenia Terrace, Lawrenceville, GA 30045 (US).

(72) Inventors; and

(75) Inventors/Applicants (for US only): **HEIGES, Bradley, A.** [US/US]; 71 Wild Thistle Lane, Savannah, GA 31406

(US). **LANE, David, E., II** [US/US]; 1280 Eugenia Terrace, Lawrenceville, GA 30045 (US).

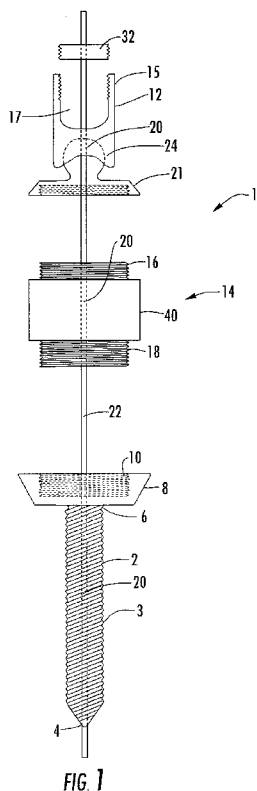
(74) Agents: **SLAVIN, Michael, A.** et al.; McHale & Slavin, P.A., 2855 PGA Boulevard, Palm Beach Gardens, FL 33410 (US).

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(54) Title: MODULAR PEDICLE SCREW WITH TAP AND SCREW DRIVER DEVICE



(57) Abstract: A modular dynamic pedicle screw system including anchoring device having a threaded shank for anchoring within a vertebra, an intermediate element and a head portion configured to receive and secure a rigid or non-rigid stabilization rod. The threaded shank, the intermediate element and the head portion of the anchoring device are configured to permit percutaneous implantation of the device. The intermediate portion is designed to be removable from the threaded shank portion subsequent to implantation of the anchoring device to enable substitution of another intermediate element having different dynamic characteristics. The dynamic stabilization system includes an adjustable torque limiting device that is interchangeable between a tap device and a screw driver. The torque device provides information relative to the patient's bone quality inter-operatively in order to determine the appropriate modulus of elasticity for the dynamic pedicle screw

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MODULAR PEDICLE SCREW SYSTEM WITH TAP AND SCREW DRIVER DEVICE

FIELD OF THE INVENTION

The present invention relates to dynamic spinal stabilization systems. The invention provides a modular pedicle screw attached to the vertebrae to anchor the stabilization system. The modular pedicle screw is configured to have dynamic characteristics of varying degree. The system includes torque limiting wrench that is interchangeable as either a tap or screw driver.

BACKGROUND OF THE INVENTION

The spine is comprised of an intricate system of bones and assorted tissues that support the body and provides protection of the central nervous system including the spinal cord and associated nerves. Within the spinal column are stacked a plurality of vertebrae separated from one another by an intervertebral disc that dampens and cushions the compressive forces exerted upon the spinal column. Located behind the series of alternating vertebrae and discs is the vertebral canal which contains the spinal cord and other associated nerves.

There are more than twenty vertebrae within the spinal column and they are categorized into one of four classifications: cervical, thoracic, lumbar or sacral. The upper seven vertebrae, including the first seven extending downward from the base of the skull are referred to as the cervical vertebrae. The next twelve extending downward from the cervical vertebrae are known as the thoracic vertebrae. Extending downwardly from the thoracic vertebrae are the five lumbar vertebrae. At the base of the spinal column is the sacral bone which also includes the coccyx. The structural and functional relationship of the vertebrae, discs, muscles, ligaments and nerves enables a healthy normal spinal column to move and articulate freely almost without limitation.

The spinal column is comprised of the vertebral body, the pedicle, the spinous process, the transverse process, the facet, the laminar arch, and the vertebral canal. The vertebral body is the generally cylindrically shaped weight bearing structure of the vertebra. The spinous process extends from the rear portion of the vertebra and the transverse processes extend from each side of each vertebra. Both the spinous process and the transverse process connect muscle tissue and ligaments to the spine. The vertebral canal

is formed between the vertebral body and the lamina and houses the spinal cord therein. The pedicle is connected to the vertebral body and supports the lamina.

The spinal column may be subject to numerous abnormalities and disorders which can be caused by trauma, disease, or genetic defect such as ruptured or slipped discs, degenerative disc disease, fractured vertebrae as so forth. Such defects can result in conditions causing extreme pain and reduced or abnormal nerve function. These spinal abnormalities can potentially cause damage to the nervous system and in particular the spinal cord and likewise impair the normal freedom of motion of the spinal column.

It is not uncommon to treat such abnormalities surgically by spinal fusion wherein one or more vertebral bodies are fused together. However, spinal fusion may limit the spinal cord's range of motion in rotation and lateral bending. In addition, spinal fusion may increase the stress placed upon non fused adjacent vertebral bodies thereby diminishing their structural integrity. Moreover, the fusion device or material may become dislodged and move away from the area of implantation.

A wide variety of approaches have been in use to achieve spinal fusion by implanting artificial devices in or on the spinal column to result in immobilization. One approach utilizes an anterior implant where the implant is located on the anterior, or front portion, of the vertebral body. An anterior stabilization can include full or partial disc replacement by a rigid spacer that is approximately the size of the disc that has been removed. A different approach involves the utilization of a posterior implant. Posterior implants include rods that are attached to either the lamina or transverse process by hooks or by pedicle screws. Other posterior implants allow for flexible or dynamic stabilization using pedicle screws connected by rigid or flexible rod member. Prior art posterior pedicle screw based stabilization systems create forces that are often transferred to the anchored pedicle screws. Patients having a relatively brittle bone structure cannot withstand the magnitude of these forces without resulting in the failure of the anchoring system.

DESCRIPTION OF THE PRIOR ART

One example of a dynamic anchoring device is disclosed in US Patent Application Publication 2004/0025289 by Biedermann et al. The device includes an element for anchoring in a bone or vertebra and a head connected to the shank, a receiving part for receiving the head, and a pressure element acting on the head, wherein the pressure

element is resilient so that upon a movement of the element from a first angular position of the shank relative to said receiving part into a second angular position the pressure element exerts a return force onto the head to urge the element towards the first angular position.

Another example of a dynamic anchoring device is disclosed in US Patent Application Publication 2005/014823 to Boyd et al. The dynamic stabilization system disclosed therein includes bone anchors having a flexible portion between the bone engaging and head portions of the anchor.

U.S. Patent Application Publication 2005/0216003 to Biedermann et al discloses a bone anchoring element such as a screw. The screw has a shaft and a first head. A second head is elastically connected to the first head. The second head is arranged in the receiving member such that the second head can pivot or swivel. The second head is fixed in the resting member in an angular resting position. The screw is deflectable from the angular head position relative to the second head. The second head is elastically connected to the first head such that a restoring force returns the screw to the angular resting position. The resting angular position of the shaft relative to the receiving part is adjustable.

U.S. Patent Application Publication 2006/0129147 to Biedermann et al discloses a stabilization device for bones or vertebrae that comprises a substantially cylindrical elastic element. The elastic element has a first end and a second end opposite to the first end. An elastic section extends between the first end and the second end. The elastic section includes at least first and second helical coils. The first and second helical coils are arranged coaxially so that the first helical coil extends at least in a portion between the second helical coil. The elastic element may form, for example, a portion of a rod, bone anchoring element, or plate.

U.S. Patent Application Publication 2007/0055236 to Hudgins et al discloses an apparatus and method for stabilizing the facet joints of the spine. The facet implant may be in the form of a screw or other anchor with the intermediate portion in the form of a polyaxial head, a cord a spring, etc.

Another device for the dynamic fixation of impaired spinal column segments is disclosed in U.S. Published Patent Application 2007/0233087 to Schlapfer. The device includes an intermediate element for a detachable, lockable, ball joint like connection having an outer wall concentric with the longitudinal axis and an inner wall forming a coaxial

cavity. Either the outer wall or the inner wall comprises one of two contact zones that form the ball joint like connection. The intermediate element is at least partly made of a super elastic material.

U.S. Published Patent Application 2008/0021465 to Shaddock et al discloses
5 a spine implant device for fusion or dynamic stabilization of a spine segment that includes a fixation device with a shaft portion for engaging bone and a proximal end for coupling to a rod that allows for limited flexing of the proximal end relative to the shaft portion.

A further example of a dynamic spinal stabilization system is disclosed in US
10 Published Patent Application 2008/0071273 to Hawkes et al. Disclosed is a system for stabilizing at least one spinal motion segment that includes a fastener having an anchoring portion and a coupling portion and a longitudinal support member couple to the fastener wherein a portion of the system is formed from a super-elastic material.

U.S. Patent 7,363,838 to Abdelgany discloses a method and assembly for
15 tightening a locking element in an orthopedic implant. The assembly is comprised of a ratcheting mechanism that includes a shaft portion and a sleeve portion operatively connected to the shaft portion. The assembly further includes a first handle or wrench operatively connected to the sleeve portion.

U.S. Patent 5,437,524 to Huang discloses a torque adjustment controller for
20 use with a tool to safely adjust and control the torque the tool works on a workpiece. The torque adjustment controller mainly consists of a housing, an output shaft, an input shaft, a stepped ring, a lugged moveable member contacting the stepped ring, a torque spring disposed between the output and the input shafts. The adjusted torque is transmitted from the input shaft to the output shaft to work on the workpiece to safely protect the latter from being damaged due to improper torque applied by the tool.

U.S. Patent 5,626,474 to Kukla et al discloses a manually operated dental
25 implant torque wrench that includes a drive assembly. The drive assembly includes a receptacle end rotatably mounted to the second open end and adapted for attaching a dental tool thereto. An adjustable torque limiting assembly is connected to an elongated shaft for disengaging the elongated shaft assembly from the rotation of a drive assembly when
30 rotation of the elongated shaft assembly has reached an adjustable predetermined torque setting.

U.S. Patent 6,330,845 to Meulink discloses a wrench that guards against displacing an implant or splitting a bone. The wrench assembly includes a handle and a socket shaft depending from the handle in a torque transmitting relation. The socket has an implant engaging portion for engaging the implant to torque transmitting relation. A torque wrench is engageable with a drive shaft to facilitate applying a known torque to the implant. The torque wrench has a handle and a torque indicator responsive to the flexing of the handle to indicate the amount of torque being generated at the engagement end of the torque wrench.

SUMMARY OF THE INVENTION

The present invention relates to a spinal stabilization system that provides for dynamic stabilization using a modular screw in conjunction with a rigid or non-rigid rod that permits load transfer at the pedicle screw rod interface as opposed to the dynamic rod per se. The screw has an elastic segment interposed between a threaded portion of the screw and the screw head portion, also referred to as a "tulip". The amount or degree of motion can be varied based on the rigidity or flexibility of the elastic material as well as the length and diameter of the elastic material. The pedicle screw is designed to be used in a percutaneous dynamic spinal stabilization system. The screw can be used in a single or multi-level construct in combination with a titanium, PEEK or Nitinol rod. The dynamic screw design enables percutaneous delivery of the stabilization system although the dynamic system can be used in an open application as well.

The dynamic spinal stabilization system includes a dynamic modular pedicle screw system which in turn preserves motion in the posterior column of the human spine. The dynamic screws can be used in conjunction with a rigid or non-rigid rod. The dynamic pedicle screw used with a rigid rod will allow for the load transfer to occur at the screw/rod interface as opposed to a non-physiologic load transferred through a dynamic rod alone. Alternatively, the modular pedicle screw can include a rigid segment interposed between a threaded portion of the screw and the screw head portion, also referred to as a "tulip".

The dynamic stabilization system includes an adjustable torque limiting device that is interchangeable between a tap device and a screw driver. The device is initially used as a tap which gives an initial indication of screw insertional torque. This initial indication provides the basis for selecting the dynamic characteristic of the pedicle

screw. The device is additionally used as a screw driver which confirms the initial indication during the screw insertion process. This torque limiting device enables a surgeon to determine in-situ patient information relative to bone quality. This information is required in order to determine the appropriate modulus of elasticity of the intermediate component of the dynamic pedicle screw.

Accordingly, it is an objective of the instant invention to provide a semi dynamic spinal stabilization system that allows for variable customization of the elastic member thereby increasing the ability to specifically address a greater number of pathologies.

It is also an objective of the instant invention to provide a torque limiting device that can interchangeably function as either a tap or screw driver to thereby provide the surgeon with information regarding the in-situ bone quality such that a pedicle screw with an appropriate dynamic characteristic can be selected.

It is a further objective of the instant invention to provide absorption of the dynamic force transmission within the anchoring screw and not at the bone-screw interface.

It is yet another objective of the instant invention to provide a modular pedicle screw that is designed to be used in a percutaneous dynamic stabilization system.

It is a still further objective of the invention to provide a kit of modular anchoring devices for a dynamic spinal stabilization system. The anchoring device is a three part design including a threaded rigid shank, an intermediate component that is an elastic polymer or rigid material, and a rigid multi-axial tulip. The kit would include a plurality of threaded shanks of varying sizes, a plurality of intermediate portions of varying geometries and rigidities, a plurality of tulip heads and a torque related instrument that can interchangeably function as either a tap or screw driver.

It is a further object of the invention to provide an intermediate component that is designed to be removable from the threaded shank portion subsequent to implantation of the pedicle screw should the pathology change thereby necessitating a change in the flexibility of the dynamic system. The ability to change the dynamism of the stabilization system without removing the threaded shank portion allows the surgeon to maintain the original bone purchase in the patient which facilitates the procedure, the healing process and improves the potential for long term success.

Another distinct objective of the system is to provide a more comprehensive yet less invasive method to address more complex spine cases, i.e. spinal deformity cases. Currently, dynamic systems are limited in their applicability and mostly ruled out for use in more complex spine cases. One reason may be due to the limited ability to manipulate the individual spine segments in order to obtain the overall correction/objective. This reinforces a current perception that a more invasive technique is always required. This system may not be applicable in all complex cases however it will be a minimally invasive/percutaneous dynamic screw option for surgeons to consider.

Other objectives and advantages of this invention will become apparent from the following description taken in conjunction with any accompanying drawings wherein are set forth, by way of illustration and example, certain embodiments of this invention. Any drawings contained herein constitute a part of this specification and include exemplary embodiments of the present invention and illustrate various objects and features thereof.

BRIEF DESCRIPTION OF THE FIGURES

Figure 1 is a perspective disassembled view of the dynamic modular pedicle screw.

Figure 2 is a perspective view of the dynamic spine stabilization system showing a multi level construction utilizing a pair of dynamic pedicle screws and a stabilization rod.

Figure 3A is a top view of the elastic intermediate member.

Figure 3B is a side view of the elastic intermediate member.

Figure 3C is a sectional perspective view of the elastic intermediate.

Figure 4A is a top view of a second embodiment for the elastic intermediate member.

Figure 4B is a side view of the second embodiment for the elastic intermediate member.

Figure 4C is a sectional perspective view of the second embodiment for the elastic intermediate member.

Figures 5A and 5B show various configurations for the elastic portion and their relative dynamic properties.

Figures 6A and 6B show a third and fourth embodiment for the elastic intermediate member.

Figure 7A is an exploded side view of the lower coupling the intermediate member and the threaded shank.

5 Figure 7B is a top view of the lower coupling member of the intermediate member.

Figure 7C is a top of view of the threaded shank portion.

Figure 8A is a side view of the upper coupling member and the tulip head.

Figure 8B is a top view of the tulip head component.

10 Figure 8C is a top view of the upper coupling member of the intermediate element.

Figure 9 is a perspective view of the torque limiting device with a tap inserted in the driver.

15 Figure 10 is a perspective view of a screw driver shaft that can be selectively substituted for the tap shaft shown in Figure 9.

DETAILED DESCRIPTION OF THE INVENTION

Figure 1 shows a dissembled view of the modular dynamic pedicle screw 1. Screw 1 includes a threaded shank portion 2 having a one end that tapers into a point 4 at one end and has an opposite end 6 that includes a coupling element 8. Coupling element 8 includes internal female threads 10. The pedicle screw 1 has a channel 20 through the entire length of the pedicle screw, including the tulip head 12, the intermediate component.14, and the threaded shank portion 2. This channel 20 allows the pedicle screw 1 to be maneuvered on a Kirschner wire 22, also know as a K-wire. In practice the K-wire is positioned within the patient using fluoroscopy, or other imaging techniques, so as to provide precise positioning of the pedicle screw 1. Once the components are securely positioned the K-wire can be easily removed through the channel 20 which is open at the end of the threaded shank portion and extends through the uppermost portion of the head portion or tulip 12. The threaded shank 2 is externally threaded. The threads 3 can be fenestrated or partially fenestrated. Fenestrated threads are particularly appropriate for osteoporotic patients or patients who require greater assurance of increased pedicle screw purchase based on bone

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quality. The threaded shank 2 of the pedicle 1 are appropriately sized in relation to the patient's pathology and can be formed in different lengths and external threaded diameters.

The head or tulip portion 12 of the pedicle screw 1 includes upwardly extending cylindrical wall 15 wherein grooves 17 are positioned in diametrically opposed relationship. These opposing grooves 18 allow for top loading of either a rigid or non rigid rod 30 into the tulip. The tulip may be fixed or multi axial. The inner portion of the cylindrical wall accepts a threaded lock screw 32 to secure the rod 30 to the pedicle screw 1. The tulip design can accept tulip extension towers, attached to tulip portion 12, which will facilitate the percutaneous passing of the rod 30 through multiple screws based upon the number of spinal segments involved in the overall dynamic spinal stabilization system. The tulip extensions allow for external control of the tulip head during the rod delivery process. The screw extensions that are attached to the tulip portions remain in place until the percutaneous delivery and placement of the rod 30 has been achieved and threaded lock screws 32 have been finally tightened. In addition, the pedicle screw 1 is also configured to receive a shank extension tower. The screw extension tower is a completely rigid device that extends dorsally through the skin incision. This feature enables three dimensional manipulation of the spine segment. Once the rigid manipulation of the segment is complete the screw extension tower is removed and the dynamic member is fully functional. The tulip design allows for top loading of the rod 30 delivered under direct visualization as is possible when the surgery is performed under open conditions. A coupling element 21 having a cylindrical wall with external threads for engagement with the intermediate member 14 is attached to tulip portion 12 with a ball and socket arrangement 24.

The intermediate portion 14 of the dynamic pedicle screw includes an elastic portion 40, an upper coupling member 16 and a lower coupling member 18. As shown in Figures 3A-3C, portion 40 is generally cylindrical in shape and includes a passageway 42 concentric with the longitudinal axis of the cylindrical body. The portion 40 is formed from elastic motion preserving dynamic material which allows for the requisite degree of motion and is capable of standing the mechanical loads associated with the human spine. This provides intraoperative flexibility for the surgeon to choose or customize the construct to address the patient's specific pathology. The portion 40 is available in varying levels, ranges and modes of dynamism, such as dynamic, motion preserving, non-fusion and rigid.

Dynamism can be adjusted based on the type of material used, for example Nitinol or polycarbonate, the length of the cylinder, the diameter and or wall thickness of the cylinder or any combination of the above variables (as shown in figures 5A and 5B). Embedded within the wall of cylindrical portion 40 is a jacket 44 made from a polyester material, or the like, which extends outwardly from each end of the cylinder 40, as shown in Figures 3A through 3C. A second embodiment, shown in Figures 4A through 4C utilizes a polyester, or the like, jacket that surrounds the outer surfaces of cylindrical member 40 and extends outwardly from each end of the cylinder 40. Extending portions 48 of the jacket extend into tabs formed in the upper and lower coupling members, 16 and 18 respectively, to complete the assembly of the intermediate portion 14. Upper coupling member 16 includes a cylindrical wall having an externally threaded surface. Upper coupling member 16 is threadably connected to tulip coupling member 21. Likewise, lower coupling member 18 includes a cylindrical wall having an externally threaded surface. Lower coupling member 18 is screwed on to coupling member 8 positioned on the threaded shank portion 2. As an alternative, cylindrical member 40 can be bonded, glued or molded directly on to the upper and lower coupling members, 16 and 18 respectively, without the utilization of a jacket.

The intermediate portion can also be rigid allowing for rigid fixation. In order to assemble a rigid modular screw a non-elastic intermediate portion 14 is coupled to the threaded shank portion 2 and the tulip head portion 12. In this instance, cylindrical member 40 can be made from the same material as the threaded shank 2 or the tulip head 12 or some other rigid compatible material. The non-elastic cylindrical member 40 can be threaded into upper and lower coupling members or otherwise suitably affixed thereto.

Figures 6A and 6B illustrate a third and fourth embodiment for the intermediate member 54. As shown in Fig. 6A intermediate member 54 includes an upper coupling member 56 that includes a threaded portion 57 which is sized and configured to threadably connect to tulip coupling member 21. Upper coupling member 54 is generally cylindrical in shape. It includes an upper cylindrical portion 51 adjacent the threaded portion 57 having a first diameter. Depending downward from the upper cylindrical portion is a post like cylindrical portion 53 having a center coincident with the upper cylindrical portion diameter 51. Depending downward from the post like cylindrical portion 53 is an interengaging cylindrical portion 55 whose center is coincident with both the upper

cylindrical portion 56 and the post like cylindrical portion 53. The diameter of the interengaging cylindrical portion 55 is greater than the post like cylindrical portion 53 but less than the upper cylindrical portion 51. Intermediate member 54 also includes a lower coupling member 58 having a threaded portion that is sized and configured to threadably engage threads 10 on coupling member 8. The lower coupling member 58 has a lower cylindrical portion 57 having a diameter substantially the same size as the upper cylindrical portion 51 of the upper coupling member 56. Extending upwardly from the lower cylindrical member is a hollow cylindrical wall 70. The upper portion of the hollow cylindrical wall terminates in an annular flange 72 that extends radially inward to form a cylindrical cavity having a reduced diameter aperture. The diameter of the aperture is sufficiently large to allow the interengaging cylindrical portion 55 to pass there through when introduced at an appropriate angle. Once the upper and lower coupling members are properly positioned, with the interengagement cylinder 55 of the upper coupling member 56 located within the cylindrical cavity of the lower coupling member 58, a synthetic material 50, such as a polycarbonate urethane, is injected into the space formed between the upper and lower coupling members. The modulus of elasticity of the injection molded material 50 is variable and can provide a range of stiffness from rigid to flexible. Likewise, the lengths and diameters of the upper and lower coupling members can be changed to allow for varying amounts of synthetic material 50 to be injected between the two members. By varying the length, diameter, or wall thickness of synthetic material 50 the degree of elasticity of intermediate member 54 can be varied. The synthetic material can be appropriately color coded, and or otherwise marked with indicia, to provide a visual indication of the elasticity of the injection molded material. The surfaces of the upper and lower coupling elements are properly surface treated prior to injection of the synthetic material to provide an optimum amount of adhesion between the synthetic material and the upper and lower coupling members. The assembled intermediate member 54, including the upper and lower coupling members and the synthetic material 50 is designed to handle a torque in the range of 80 to 120 inch pounds of force. In addition the intermediate member provides five degrees of motion, including flexion/extension and is capable of handling force in the order of 250 to 400 newtons. The upper and lower coupling members 56 and 58 are made from titanium or any other suitable biocompatible material, either metallic or synthetic. All surface edges of

the upper and lower coupling members are rounded to remove sharp surface edges from the intermediate member.

The embodiment shown in Figure 6B is similar to that shown in Figure 6A except that in this embodiment upper flanges 62 and lower flanges 64 are substituted for the threaded portions 57 and 59 respectively. Flanges 62 and 64 include two or more spaced flange segments (62A,62B and 64A, 64B) that cooperate with complimentary recesses and grooves formed on the tulip coupling member 21 and the threaded shank member 2.

Figure 7A illustrates the lower coupling member 18 and the threaded shank 2 with its coupling member 8. Annular threads 10 on coupling 8 mate with external threads on lower coupling member 18. Figure 7B is a top view of lower coupling member 18 showing a socket 19 that includes a portion of channel 20. Socket 19 is designed to operatively engage an insertion or removal tool which can be inserted through the intermediate portion 14 via channel 20. Should it be necessary to change the dynamic characteristics of the spinal support system the surgeon would remove the rod 30 from the head 12 by first removing threaded lock screw 32. Following removal of the rod 30 the head portion 12 would be unthreaded from the intermediate portion 14 using an appropriate tool. Thereafter, a tool would be inserted through the channel 20 in the intermediate member 14 to engage socket 19 formed in lower coupling member 18. Upon rotation of the tool the lower coupling 18 of the intermediate member will be unthreaded from the second coupling 8 formed on the threaded shank portion 2. The intermediate portion can then be removed from the patient. A new intermediate portion 14 can then be positioned over the existing threaded shank portion 2. Thereafter a tool would be inserted through channel 20 of the intermediate member 14 and engage socket 19 formed in the lower coupling member 8. Upon rotation of the tool the lower coupling 18 of the intermediate member 14 will be threaded into the second coupling formed on the treaded shank 2. The head portion 12 can then be threaded onto the intermediate portion 14 and the rod 30 can be affixed thereto by locking screw 32. The ability to change the dynamism of the stabilization system without removing the threaded shank portion allows the surgeon to maintain the original bone purchase in the patient which facilitates the procedure, the healing process and improves the potential for long term success. Figure 7C is a top view of the threaded shank 2 with channel 20 and coupling threads 10.

Figure 8A is a side view showing tulip head member 12 with cylindrical side walls 15 and groove 17. A coupling element 21 having a cylindrical wall with external threads for engagement with the intermediate member 14 is attached to tulip portion 12 with a ball and socket arrangement 24. Figure 8B is a side view of tulip head member 12. Figure 8C is a top view of the upper coupling member 16.

The rod 30 connects multiple screws based upon the number of segments involved in the overall construct. The rod can be of any compatible material (PEEK, Titanium, Nitinol, etc). This also increases the versatility of the system allowing for more control in defining the rigidity or dynamism of the overall construct. The rod 30 used in conjunction with the dynamic pedicle screw system can be either rigid or non rigid.

Figure 9 is a perspective view of the torque device 70 that can be interchangeably used as either a tap device or screw driver device. The torque device includes a "T" shaped handle 72. Handle 72 is mechanically connected to socket 74 through adjustable clutch mechanism 76. Clutch mechanism 76 includes a collar that can selectively set the slip point of an over load clutch. The set point can be incrementally varied from 10 inch-pounds through 80 in-pounds in 10 inch pound increments. A tap device 78 can be removeably inserted into socket 74. Tap device 78 includes a tap shaft 80 and a plurality of cutting threads 82.

Figure 10 is a perspective view of the screw driver device 84 that is interchangeable with the tap device 78 of Figure 9. Screw driver device 84 is likewise removeably inserted into socket 74. Screwdriver device 84 includes a screw driver shaft 86 and a screw driver head 88.

As noted, the torque device includes an interchangeable tap device 78 as well as a screw driver 84. The dynamic stabilization system includes an adjustable torque device 70 that is interchangeable between a tap device 78 and a screw driver 84. The device is initially used as a tap which gives an initial indication of screw insertional torque. This initial indication provides the basis for selecting the dynamic characteristic of the pedicle screw. The device is additionally used as a screw driver which confirms the initial indication during the screw insertion process. Initially the tap is advanced in a measurable fashion. Starting with a low torque setting, for example 10 inch-lbs, on control collar 76 the tap device 78 is advanced until the overload clutch mechanism 76 slips or until the

appropriate distance of advance through the pedicle into the vertebral body has been achieved which ever occurs first. The visual confirmation of depth is achieved through the use of interoperative fluoroscopy as well as depth markings on the tap shaft 80. Should the clutch mechanism 76 slip prior to the tap device 78 reaching the desired depth the control collar 76 on the device would be rotated to the next higher setting, such as 20 inch-pounds. The process would be repeated, and the torque setting would be progressively increased until the tap threads 82 have reach the desired depth. The device 70, including handle 72, clutch mechanism 76, socket 74, tap device 78 and screw driver 84 are cannulated in design in order to accommodate percutaneous pedicle preparation and screw delivery. The use of the torque device 70 therefore seeks to maximize the dampening effect and minimize the potential of a loosening side-effect.

The utilization of torque device 70 is necessary for optimum selection of the appropriate dynamic screw of any configuration and represents a novel technique with the field of spinal instrumentation. The objective is to provide information relative to the patient's bone quality inter-operatively in order to determine the appropriate modulus of elasticity for the dynamic pedicle screw. For example, if the patient's pedicle tap torque is 40 inch-pounds verses 80 inch-pounds, the patient should receive a less stiff (lower modulus of elasticity) intermediate component in order to transfer load more appropriately or reduce the stress at the bone/screw interface. The ability to provide the patient with varying degrees of physiological dampening/stiffening via the modular aspect of the intermediate component necessitates the ability to have inter-operative determination of the patient's bone quality, or pull out strength, in order to make the most appropriate decision for the patient

The appropriately selected screw should have dynamic characteristics that should absorb the strain within the implant during and particular cycle and should limit any strain transduction to the bone screw interface. If the modulus of elasticity of the screw is too high, the screw will have a higher incidence of loosening. On the other hand, if the screw has a modulus that is too low, the screw will not create the desired effect of physiologic dampening and strain.

The utilization of a torque measuring device such as device 70 is particularly important in matching the dynamic characteristics of the pedicle screw not only to the patient but to the specific level as it relates to the overall bone density and fixation requirements of the patient.

5 Various types and sizes of the components, namely the intermediate members, the threaded shanks, the tulip heads and rods, etc. are individually wrapped and terminally sterilized. They are brought to the operating room as a kit and individually selected by the surgeon based on the case presented to them by the patient. Once the sterilized package is opened the device contained therein is either used or discarded. The
10 components can not be sterilized. The kit also includes a torque limiting wrench that is interchangeable as either a tap or screw driver. The torque limiting wrench including the socket clutch and handle assembly can be sterilized and is therefore reusable however the tap shaft and screw driver attachments may be disposable.

 All patents and publications mentioned in this specification are indicative of
15 the levels of those skilled in the art to which the invention pertains. All patents and publications are herein incorporated by reference to the same extent as if each individual publication was specifically and individually indicated to be incorporated by reference.

 It is to be understood that while a certain form of the invention is illustrated, it is not to be limited to the specific form or arrangement herein described and shown. It
20 will be apparent to those skilled in the art that various changes may be made without departing from the scope of the invention and the invention is not to be considered limited to what is shown and described in the specification and any drawings/figures included herein.

 One skilled in the art will readily appreciate that the present invention is well adapted to carry out the objectives and obtain the ends and advantages mentioned, as well as
25 those inherent therein. The embodiments, methods, procedures and techniques described herein are presently representative of the preferred embodiments, are intended to be exemplary and are not intended as limitations on the scope. Changes therein and other uses will occur to those skilled in the art which are encompassed within the spirit of the invention and are defined by the scope of the appended claims. Although the invention has been
30 described in connection with specific preferred embodiments, it should be understood that the invention as claimed should not be unduly limited to such specific embodiments.

Indeed, various modifications of the described modes for carrying out the invention which are obvious to those skilled in the art are intended to be within the scope of the following claims.

CLAIMS

What is claimed is:

Claim 1. A kit for a modular screw stabilization system comprising; components to assemble a plurality of modular pedicle screws and one or more rods, each modular pedicle screw including a head portion, an intermediate portion, and a threaded shank portion,

said kit including a plurality of said head portions each including a cylindrical wall with diametrically opposed grooves that extend downwards from the top of said cylindrical wall, said grooves are sized and configured to receive said rod within said diametrically opposed grooves, said head portions including a first channel formed coincident with its longitudinal axis and open at the top and the bottom of the head portion, and, a first coupling element connected to each of said head portion,

said kit further including a plurality of intermediate portions each including an elastic portion or a rigid portion directly molded onto an upper coupling member and a lower coupling member, said elastic or rigid portion and said upper and lower coupling being fixedly connected, each of said plurality of intermediate portions including a second channel extending coincident with its longitudinal axis and open at the top and bottom of said intermediate member,

said kit also including a plurality of said threaded shank portions, each including a threaded and tapered outer surface and a second coupling member formed at one end thereof, each said threaded shank portions and each of said second coupling members each having a third channel formed coincident with the longitudinal axis of each of said threaded shank portions and open at the top and bottom of each of said threaded shank portions, said first, second and third channels are configured to be in alignment with one another,

whereby a wire can pass freely from the open bottom end of the threaded shank portion, through the intermediate portion, and out the open top end of the head portion and be completely removed from the pedicle screw and

said kit further including a torque drive device for tapping a hole for said pedicle screws or driving said screws into said hole.

Claim 2. The kit for a dynamic screw stabilization system as set forth in claim 1, wherein said plurality of threaded shank portions is of the same or different lengths and external diameters.

Claim 3. The kit for a dynamic screw stabilization system as set forth in claim 1, wherein at least some of the threaded shank portions have fenestrated and partially fenestrated threads.

Claim 4. The kit for a dynamic screw stabilization system as set forth in claim 1, wherein the plurality of intermediate portions have elastic portions of same or varying rigidity.

Claim 5. The kit for a dynamic screw stabilization system as set forth in claim 4, wherein the elastic portion varies in rigidity from rigid to flexible.

Claim 6. The kit for a dynamic screw stabilization system as set forth in claim 1 said kit including a plurality of lock screws each configured to engage threads formed on an inner surface of said cylindrical wall thereby securing said rod to said head portion.

Claim 7. The kit for a modular screw stabilization system as set forth in claim 1 wherein said torque drive device comprises;

a handle configured to be engaged by a hand and to impart torque thereto;

a clutching mechanism having a first end and a second end, said clutching mechanism operatively connected to said handle at said first end; wherein the torque transmitted through said handle at the first end is selectively transmitted through the clutch mechanism to the second end;

a socket member operatively connected to said clutching mechanism as said second end,

said clutching mechanism including an adjustment member to selectively vary a torque setting wherein said clutch mechanism will slip and the torque entering the first end of the clutch mechanism will not be transmitted to the second end of the clutch mechanism;

said socket member including a socket having a recess configured to removeably receive a tool implement;

said handle, said clutching mechanism, said socket member and tool implement are each cannulated and adapted to be positioned using a wire passing through said cannulations.

Claim 8 The kit for a modular screw stabilization system as set forth in claim 7 wherein said tool implement is a hole tapping device.

Claim 9 The kit for a modular screw stabilization system as set forth in claim 7 wherein said tool implement is a screw driving device.

Claim 10 The kit for a modular screw stabilization system as set forth in claim 7 wherein said adjustment member is a rotatable collar positioned between the first end and second end of said clutch mechanism.

Claim 11 The kit for a modular screw stabilization system as set forth in claim 10 for use in a dynamic pedicle screw wherein said rotatable collar and said clutch mechanism include indicia indicative of the torque level at which said clutch mechanism will slip.

Claim 12 The kit for a modular screw stabilization system as set forth in claim 11 wherein the indicia includes a plurality of markings each representing a calibrated level of torque at which the clutch mechanism will slip.

Claim 13. A torque drive device for use in a dynamic pedicle screw comprising;
a handle configured to be engaged by a hand and to impart torque thereto;
a clutching mechanism having a first end and a second end, said clutching mechanism operatively connected to said handle at said first end; wherein the torque transmitted through said handle at the first end is selectively transmitted through the clutch mechanism to the second end;

a socket member operatively connected to said clutching mechanism as said second end,

said clutching mechanism including an adjustment member to selectively vary a torque setting wherein said clutch mechanism will slip and the torque entering the first end of the clutch mechanism will not be transmitted to the second end of the clutch mechanism;

said socket member including a socket having a recess configured to removeably receive a tool implement;

said handle, said clutching mechanism, said socket member and tool implement are each cannulated and adapted to be positioned using a wire passing through said cannulations.

Claim 14. The torque drive device of claim 13 for use in a dynamic pedicle screw wherein said tool implement is a hole tapping device.

Claim 15 The torque drive device of claim 13 for use in a dynamic pedicle screw wherein said tool implement is a screw driving device.

Claim 16 The torque drive device of claim 13 for use in a dynamic pedicle screw wherein said adjustment member is a rotatable collar positioned between the first end and second end of said clutch mechanism.

Claim 17 The torque drive device of claim 16 for use in a dynamic pedicle screw wherein said rotatable collar and said clutch mechanism include indicia indicative of the torque level at which said clutch mechanism will slip.

Claim 18 The torque drive device of claim 17 for use in a dynamic pedicle screw wherein the indicia includes a plurality of markings each representing a calibrated level of torque at which the clutch mechanism will slip.

Claim 19 A method for selecting and installing a dynamic pedicle screw comprising the steps of :

applying torque to a handle of a torque drive device to impart torque thereto;

connecting said handle to a clutching mechanism having a first and second end, said handle operatively connected to said handle at said first end of said clutching mechanism;

connecting a socket member to said second end of said clutching mechanism; said clutching mechanism including an adjustment member to selectively vary a torque setting wherein said clutch mechanism will slip and the torque entering the first end of the clutch mechanism will not be transmitted to the second end of the clutch mechanism;

attaching a tap device having tap threads into the socket member and positioning said threads adjacent a hole to be tapped;

setting said adjustment member at a low torque setting and advancing said tap device;

applying torque to said handle until the clutch member slips or said tap device has advanced an appropriate distance;

if said tap device has not reached the appropriate distance increasing said torque setting on said adjustment member at incrementally higher values until the tap device has been advanced to said appropriate distance;

selecting a dynamic pedicle screw with a particular modulus of elasticity based upon the final torque setting utilized in advancing the tap device to the appropriate distance.

Claim 20 The method for selecting and installing a dynamic pedicle screw set forth in claim 19 further including the additional steps of:

positioning the dynamic pedicle screw adjacent said tapped hole;

removing said tap device from said socket member;

attaching a screw driving device having a screw driving head into said socket member;

positioning said screw driving head into operative engagement with said dynamic pedicle screw;

setting said adjustment member at a low torque setting and advancing said screw driving device;

applying torque to said handle until the clutch member slips or said screw driving device has advanced an appropriate distance;

if said screw driving device has not reached the appropriate distance, increasing said torque setting on said adjustment member at incrementally higher values until the tap device has been advanced to said appropriate distance; and

confirming the selection of said dynamic pedicle screw with a particular modulus of elasticity based upon the final torque setting utilized in advancing the screw driving device to the appropriate distance.

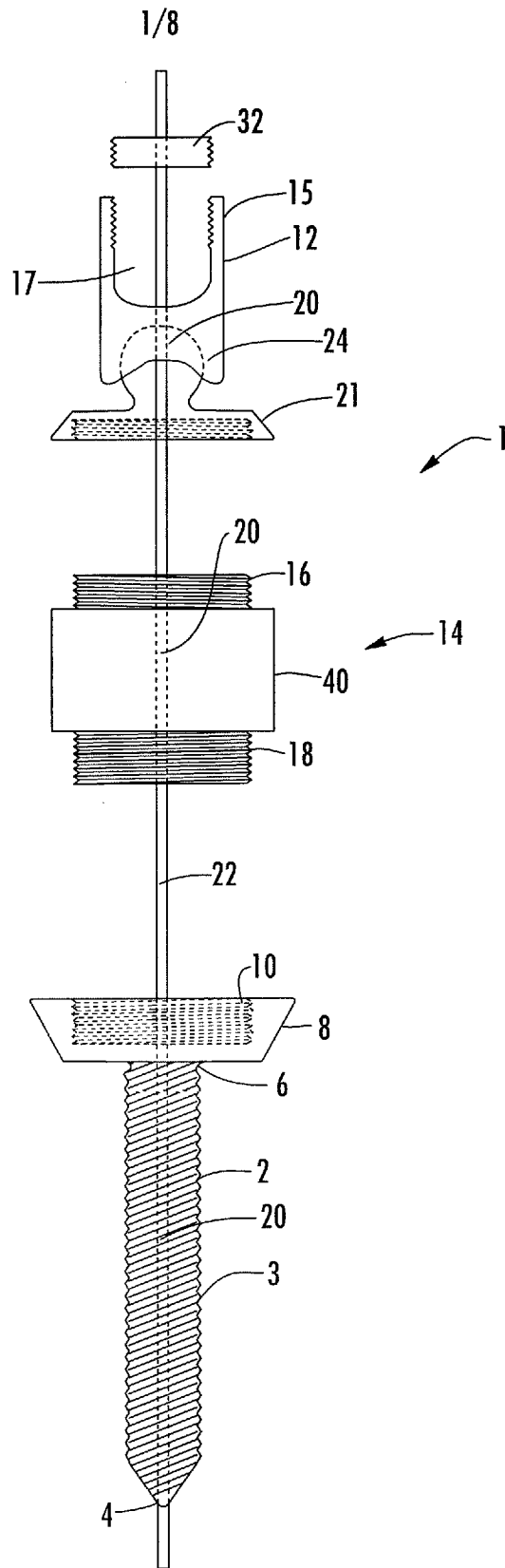


FIG. 1

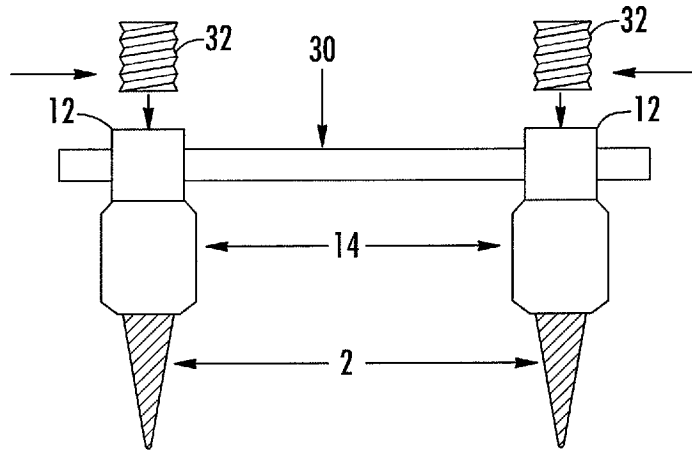


FIG. 2

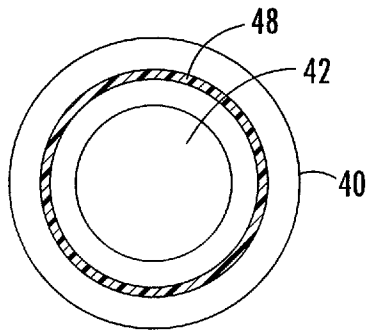


FIG. 3A

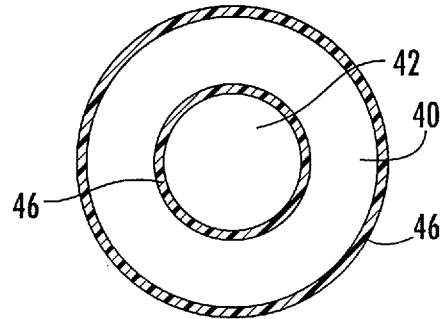


FIG. 4A

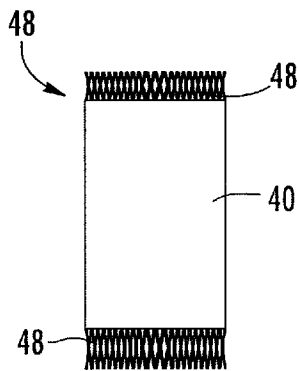


FIG. 3B

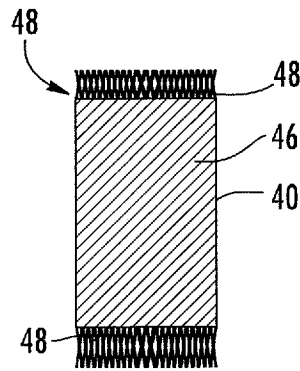


FIG. 4B

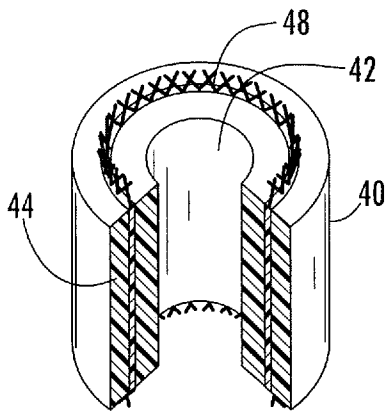


FIG. 3C

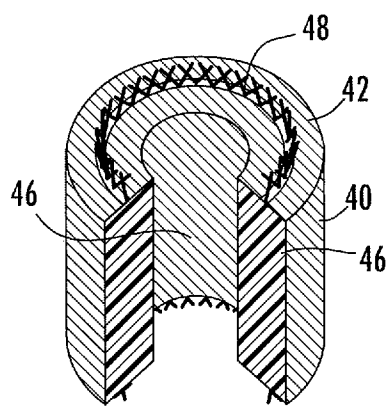


FIG. 4C

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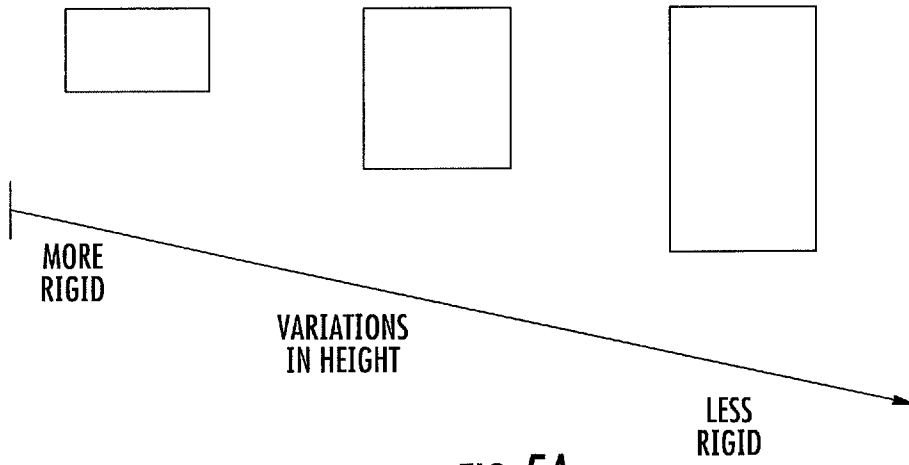


FIG. 5A

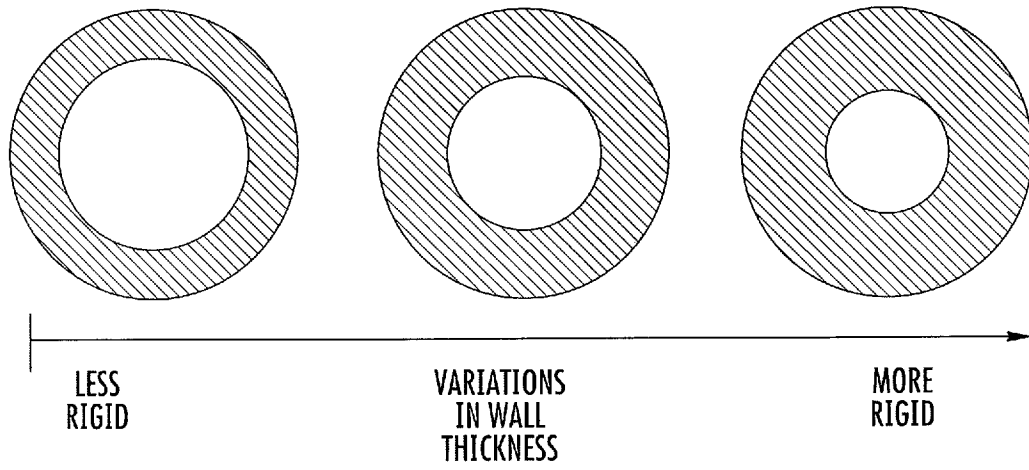
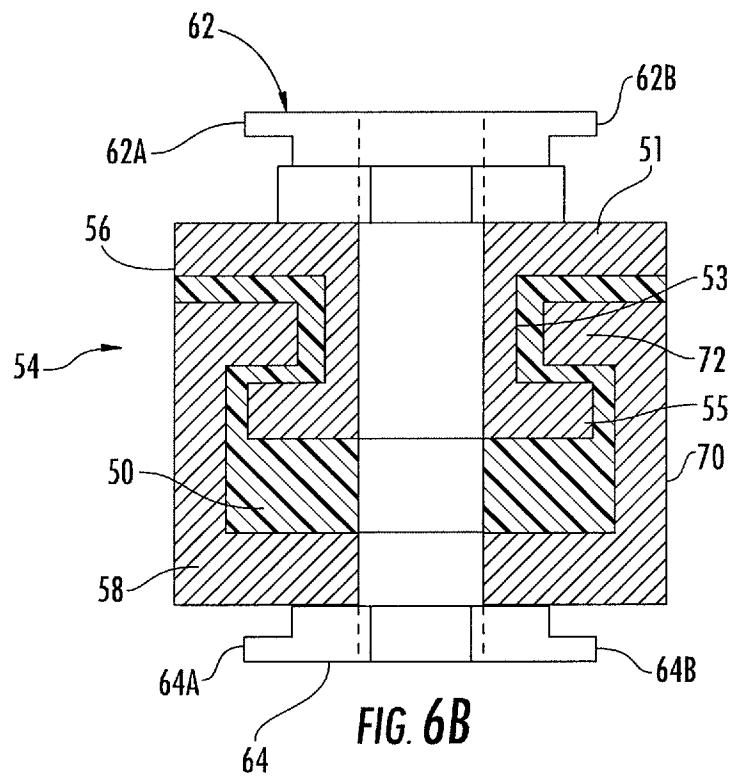
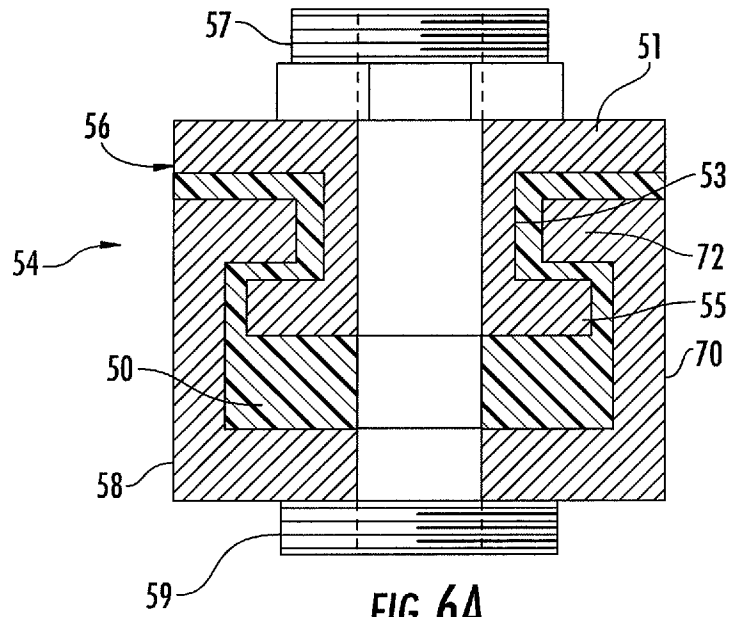


FIG. 5B

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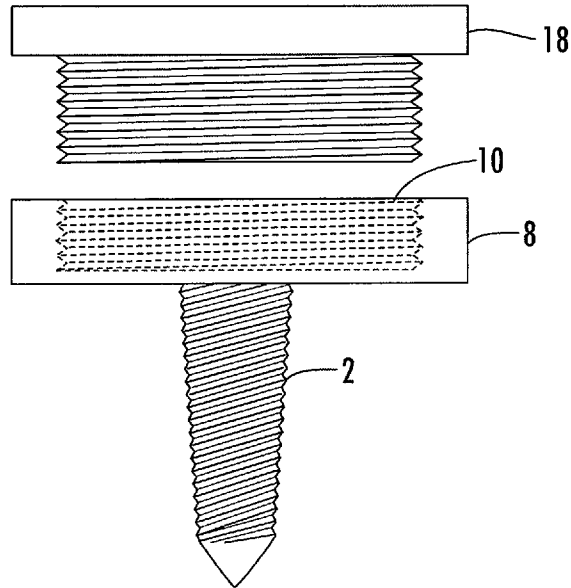


FIG. 7A

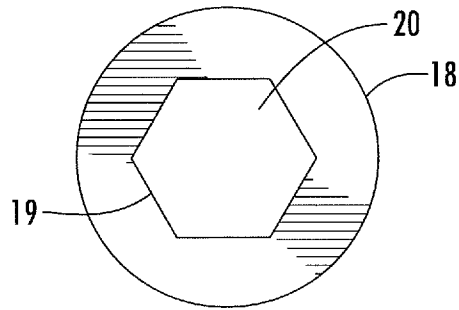


FIG. 7B

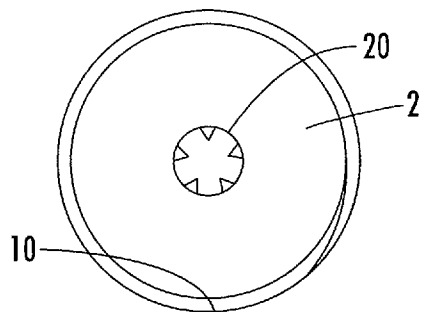


FIG. 7C

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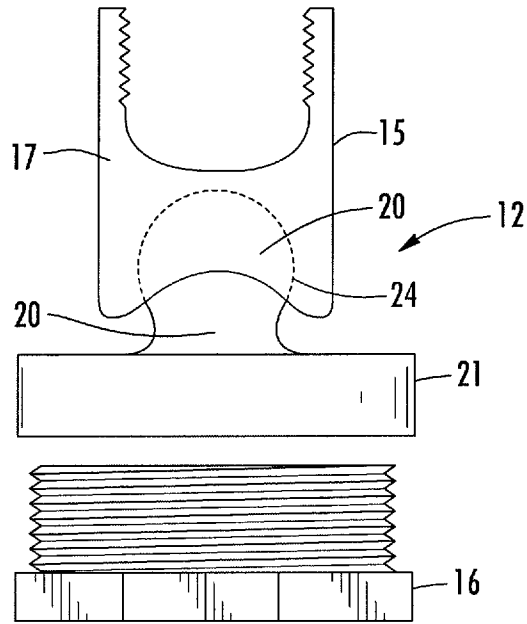


FIG. 8A

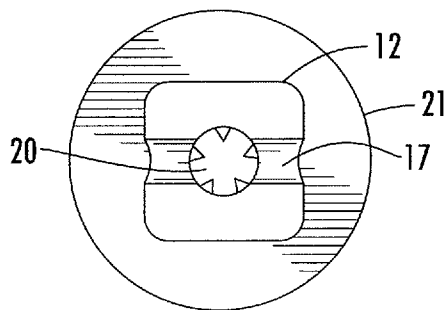


FIG. 8B

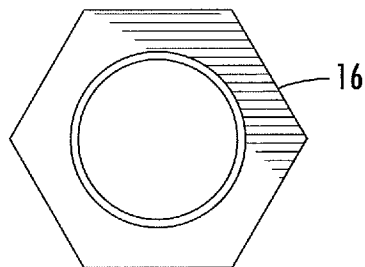


FIG. 8C

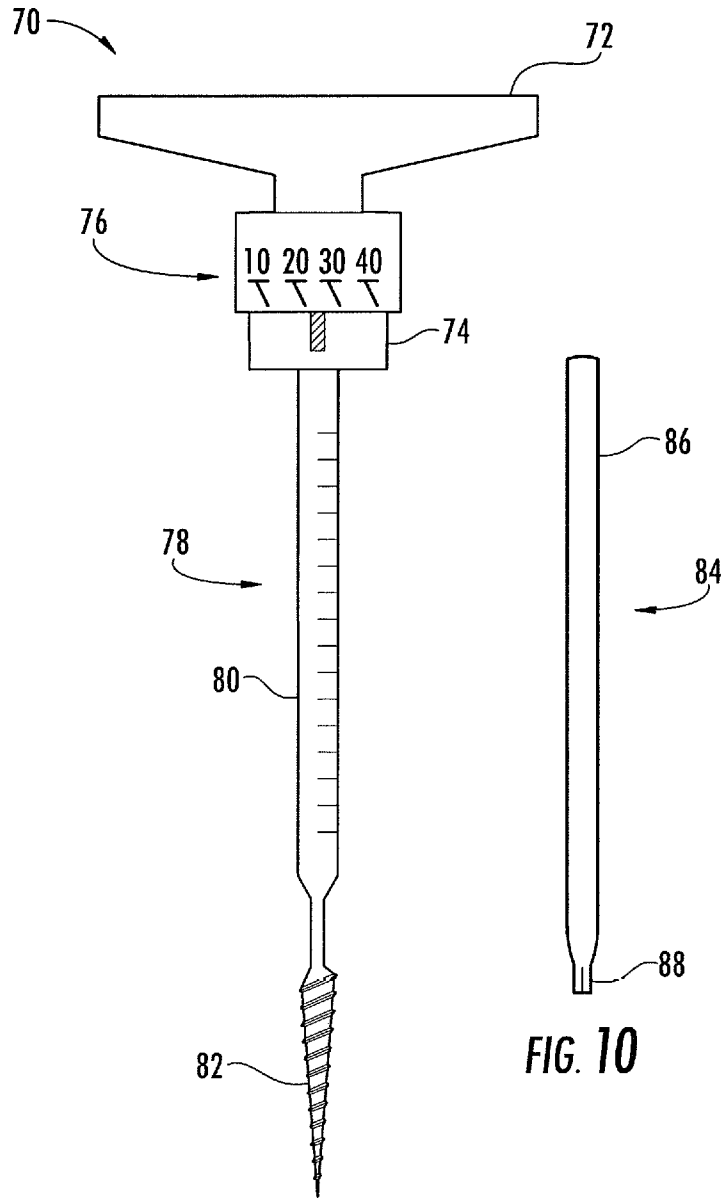


FIG. 9

FIG. 10

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2010/025536

A. CLASSIFICATION OF SUBJECT MATTER INV. A61B17/16 A61B17/86 A61B17/88 A61B17/70		
According to International Patent Classification (IPC) or to both national classification and IPC		
B. FIELDS SEARCHED		
Minimum documentation searched (classification system followed by classification symbols) A61B		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched		
Electronic data base consulted during the international search (name of data base and, where practical, search terms used) EPO-Internal		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2006/241593 A1 (SHERMAN MICHAEL C [US] ET AL) 26 October 2006 (2006-10-26) paragraph [0028] - paragraph [0032]; figure 7 -----	1
A	US 2008/021465 A1 (SHADDUCK JOHN H [US] ET AL) 24 January 2008 (2008-01-24) paragraph [0029]; figure 3 -----	1
A	US 2007/093826 A1 (HAWKES DAVID T [US] ET AL) 26 April 2007 (2007-04-26) abstract; figure 9 figure 6A -----	1
A	US 2005/059972 A1 (BISCUP ROBERT S [US]) 17 March 2005 (2005-03-17) figure 1 ----- -/--	1
<input checked="" type="checkbox"/> Further documents are listed in the continuation of Box C. <input checked="" type="checkbox"/> See patent family annex.		
* Special categories of cited documents : "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier document but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art. "&" document member of the same patent family		
Date of the actual completion of the international search 23 April 2010		Date of mailing of the international search report 11/06/2010
Name and mailing address of the ISA/ European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016		Authorized officer Ducreau, Francis

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2010/025536

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2004/172022 A1 (LANDRY MICHAEL E [US] ET AL) 2 September 2004 (2004-09-02) paragraph [0180] - paragraph [0185]; figures 24,25 -----	1

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2010/025536

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. Claims Nos.: 19, 20
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2. Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.
3. As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

see annex

Remark on Protest

- The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-12

A kit for a modular screw stabilization system

2. claims: 13-18

A torque drive device

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No PCT/US2010/025536

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2006241593 A1	26-10-2006	WO 2006110796 A1	19-10-2006
US 2008021465 A1	24-01-2008	NONE	
US 2007093826 A1	26-04-2007	WO 2007041698 A1	12-04-2007
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		EP 1663030 A2	07-06-2006
		WO 2005032402 A2	14-04-2005
US 2004172022 A1	02-09-2004	NONE	