Application Data Sheet 37 CFR 1.76	Attorney Docket Number	JAC023-644278
	Application Number	
Title of Invention	TOP NOTCH RECEIVERS HAVING DUAL LEAD IN CLOSURE MATING THREAD FORMS	

The application data sheet is part of the provisional or nonprovisional application for which it is being submitted. The following form contains the bibliographic data arranged in a format specified by the United States Patent and Trademark Office as outlined in 37 CFR 1.76.
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Secrecy Order 37 CFR 5.2:

☐ Portions or all of the application associated with this Application Data Sheet may fall under a Secrecy Order pursuant to 37 CFR 5.2 (Paper filers only. Applications that fall under Secrecy Order may not be filed electronically.)

Inventor Information:

Inventor 1

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Roger	P.	Jackson	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

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Inventor 2

Legal Name

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All Inventors Must Be Listed - Additional Inventor Information blocks may be generated within this form by selecting the **Add** button. Add

Correspondence Information:

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Enter either Customer Number or complete the Correspondence Information section below. For further information see 37 CFR 1.33(a).			
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Application Information:

Title of the Invention	TOP NOTCH RECEIVERS HAVING DUAL LEAD IN CLOSURE MATING THREAD FORMS		
Attorney Docket Number	JAC023-644278	**Small Entity Status Claimed**	☐
Application Type	Nonprovisional		
Subject Matter	Utility		
Total Number of Drawing Sheets (if any)	7	**Suggested Figure for Publication (if any)**	

Filing By Reference:

Only complete this section when filing an application by reference under 35 U.S.C. 111(c) and 37 CFR 1.57(a). Do not complete this section if application papers including a specification and any drawings are being filed. Any domestic benefit or foreign priority information must be provided in the appropriate section(s) below (i.e., "Domestic Benefit/National Stage Information" and "Foreign Priority Information").

For the purposes of a filing date under 37 CFR 1.53(b), the description and any drawings of the present application are replaced by this reference to the previously filed application, subject to conditions and requirements of 37 CFR 1.57(a).

Application number of the previously filed application	Filing date (YYYY-MM-DD)	Intellectual Property Authority or Country

Publication Information:

☐ Request Early Publication (Fee required at time of Request 37 CFR 1.219)

☐ **Request Not to Publish.** I hereby request that the attached application not be published under 35 U.S.C. 122(b) and certify that the invention disclosed in the attached application **has not and will not** be the subject of an application filed in another country, or under a multilateral international agreement, that requires publication at eighteen months after filing.

Representative Information:

Representative information should be provided for all practitioners having a power of attorney in the application. Providing this information in the Application Data Sheet does not constitute a power of attorney in the application (see 37 CFR 1.32).
Either enter Customer Number or complete the Representative Name section below. If both sections are completed the customer Number will be used for the Representative Information during processing.

Please Select One:	◉ Customer Number	○ US Patent Practitioner	○ Limited Recognition (37 CFR 11.9)
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This section allows for the applicant to either claim benefit under 35 U.S.C. 119(e), 120, 121, 365(c), or 386(c) or indicate National Stage entry from a PCT application. Providing benefit claim information in the Application Data Sheet constitutes the specific reference required by 35 U.S.C. 119(e) or 120, and 37 CFR 1.78.
When referring to the current application, please leave the "Application Number" field blank.

Prior Application Status	Pending		Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
	Continuation of	15964502	2018-04-27

Prior Application Status	Patented				Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
15964502	Continuation of	15469076	2017-03-24	9956004	2018-05-01

Prior Application Status	Patented				Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
15469076	Continuation of	14566356	2014-12-10	9636146	2017-05-02

Prior Application Status	Patented				Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
14566356	Continuation of	13694849	2013-01-10	8911479	2014-12-16

Prior Application Status	Expired		Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
13694849	Claims benefit of provisional	61631746	2012-01-10

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Prior Application Status	Expired		Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
13694849	Claims benefit of provisional	61634361	2012-02-28

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Foreign Priority Information:

This section allows for the applicant to claim priority to a foreign application. Providing this information in the application data sheet constitutes the claim for priority as required by 35 U.S.C. 119(b) and 37 CFR 1.55. When priority is claimed to a foreign application that is eligible for retrieval under the priority document exchange program (PDX) the information will be used by the Office to automatically attempt retrieval pursuant to 37 CFR 1.55(i)(1) and (2). Under the PDX program, applicant bears the ultimate responsibility for ensuring that a copy of the foreign application is received by the Office from the participating foreign intellectual property office, or a certified copy of the foreign priority application is filed, within the time period specified in 37 CFR 1.55(g)(1).

Application Number	Country[i]	Filing Date (YYYY-MM-DD)	Access Code[i] (if applicable)

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Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications

☐ This application (1) claims priority to or the benefit of an application filed before March 16, 2013 and (2) also contains, or contained at any time, a claim to a claimed invention that has an effective filing date on or after March 16, 2013.
NOTE: By providing this statement under 37 CFR 1.55 or 1.78, this application, with a filing date on or after March 16, 2013, will be examined under the first inventor to file provisions of the AIA.

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Authorization or Opt-Out of Authorization to Permit Access:

When this Application Data Sheet is properly signed and filed with the application, applicant has provided written authority to permit a participating foreign intellectual property (IP) office access to the instant application-as-filed (see paragraph A in subsection 1 below) and the European Patent Office (EPO) access to any search results from the instant application (see paragraph B in subsection 1 below).

Should applicant choose not to provide an authorization identified in subsection 1 below, applicant **must opt-out** of the authorization by checking the corresponding box A or B or both in subsection 2 below.

NOTE: This section of the Application Data Sheet is **ONLY** reviewed and processed with the **INITIAL** filing of an application. After the initial filing of an application, an Application Data Sheet cannot be used to provide or rescind authorization for access by a foreign IP office(s). Instead, Form PTO/SB/39 or PTO/SB/69 must be used as appropriate.

1. Authorization to Permit Access by a Foreign Intellectual Property Office(s)

A. Priority Document Exchange (PDX) - Unless box A in subsection 2 (opt-out of authorization) is checked, the undersigned hereby **grants the USPTO authority** to provide the European Patent Office (EPO), the Japan Patent Office (JPO), the Korean Intellectual Property Office (KIPO), the State Intellectual Property Office of the People's Republic of China (SIPO), the World Intellectual Property Organization (WIPO), and any other foreign intellectual property office participating with the USPTO in a bilateral or multilateral priority document exchange agreement in which a foreign application claiming priority to the instant patent application is filed, access to: (1) the instant patent application-as-filed and its related bibliographic data, (2) any foreign or domestic application to which priority or benefit is claimed by the instant application and its related bibliographic data, and (3) the date of filing of this Authorization. See 37 CFR 1.14(h)(1).

B. Search Results from U.S. Application to EPO - Unless box B in subsection 2 (opt-out of authorization) is checked, the undersigned hereby **grants the USPTO authority** to provide the EPO access to the bibliographic data and search results from the instant patent application when a European patent application claiming priority to the instant patent application is filed. See 37 CFR 1.14(h)(2).

The applicant is reminded that the EPO's Rule 141(1) EPC (European Patent Convention) requires applicants to submit a copy of search results from the instant application without delay in a European patent application that claims priority to the instant application.

2. Opt-Out of Authorizations to Permit Access by a Foreign Intellectual Property Office(s)

☐ A. Applicant **DOES NOT** authorize the USPTO to permit a participating foreign IP office access to the instant application-as-filed. If this box is checked, the USPTO will not be providing a participating foreign IP office with any documents and information identified in subsection 1A above.

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NOTE: Once the application has published or is otherwise publicly available, the USPTO may provide access to the application in accordance with 37 CFR 1.14.

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Applicant Information:

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

Applicant 1

If the applicant is the inventor (or the remaining joint inventor or inventors under 37 CFR 1.45), this section should not be completed. The information to be provided in this section is the name and address of the legal representative who is the applicant under 37 CFR 1.43; or the name and address of the assignee, person to whom the inventor is under an obligation to assign the invention, or person who otherwise shows sufficient proprietary interest in the matter who is the applicant under 37 CFR 1.46. If the applicant is an applicant under 37 CFR 1.46 (assignee, person to whom the inventor is obligated to assign, or person who otherwise shows sufficient proprietary interest) together with one or more joint inventors, then the joint inventor or inventors who are also the applicant should be identified in this section.

Clear

◉ Assignee	○ Legal Representative under 35 U.S.C. 117	○ Joint Inventor
○ Person to whom the inventor is obligated to assign.	○ Person who shows sufficient proprietary interest	

If applicant is the legal representative, indicate the authority to file the patent application, the inventor is:

Name of the Deceased or Legally Incapacitated Inventor:

If the Applicant is an Organization check here. ☐

Prefix	**Given Name**	Middle Name	**Family Name**	Suffix
	Roger	P.	Jackson	

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Country[i]	US	Postal Code	66207
Phone Number		Fax Number	
Email Address			

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Assignee Information including Non-Applicant Assignee Information:

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Assignee 1

Complete this section if assignee information, including non-applicant assignee information, is desired to be included on the patent application publication. An assignee-applicant identified in the "Applicant Information" section will appear on the patent application publication as an applicant. For an assignee-applicant, complete this section only if identification as an assignee is also desired on the patent application publication.

If the Assignee or Non-Applicant Assignee is an Organization check here. ☐

Prefix	**Given Name**	Middle Name	**Family Name**	Suffix
	Roger	P.	Jackson	

Mailing Address Information For Assignee including Non-Applicant Assignee:

Address 1	4706 W. 86th Street		
Address 2			
City	Prairie Village	**State/Province**	KS
Country [i]	US	Postal Code	66207
Phone Number		Fax Number	
Email Address			

Additional Assignee or Non-Applicant Assignee Data may be generated within this form by selecting the Add button.

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Signature:

NOTE: This Application Data Sheet must be signed in accordance with 37 CFR 1.33(b). **However, if this Application Data Sheet is submitted with the INITIAL filing of the application and either box A or B is not checked in subsection 2 of the "Authorization or Opt-Out of Authorization to Permit Access" section, then this form must also be signed in accordance with 37 CFR 1.14(c).**

This Application Data Sheet **must** be signed by a patent practitioner if one or more of the applicants is a **juristic entity** (e.g., corporation or association). If the applicant is two or more joint inventors, this form must be signed by a patent practitioner, **all** joint inventors who are the applicant, or one or more joint inventor-applicants who have been given power of attorney (e.g., see USPTO Form PTO/AIA/81) on behalf of **all** joint inventor-applicants.

See 37 CFR 1.4(d) for the manner of making signatures and certifications.

Signature	/Milan Vinnola/			Date (YYYY-MM-DD)	
First Name	Milan	Last Name	Vinnola	Registration Number	45979

Additional Signature may be generated within this form by selecting the Add button.

TOP NOTCH RECEIVERS HAVING DUAL LEAD IN CLOSURE MATING THREAD FORMS

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] The present application is a continuation of U.S. Patent Application No. 15/964,502, filed April 27, 2018, now U.S. Patent No. 10,548,641, which is a continuation of U.S. Patent Application No. 15/469,076, filed March 24, 2017, now U.S. Patent No. 9,956,004, which is a continuation of U.S. Patent Application No. 14/566,356, filed December 10, 2014, now U.S. Patent No. 9,636,146, which is a continuation of U.S. Patent Application No. 13/694,849, filed January 10, 2013, now U.S. Patent No. 8,911,479, issued December 16, 2014, which claims the benefit of U.S. Provisional Application No. 61/631,746, filed January 10, 2012 and U.S. Provisional Application No. 61/634,361, filed February 28, 2012, all of which are incorporated by reference herein for all purposes.

BACKGROUND OF THE INVENTION

[0002] The present invention is directed to structure for joining together parts of a medical implant, in particular to closure mechanisms for use with open bone anchors in spinal surgery, and in some embodiments thereof, for use with spinal bone anchors such as polyaxial screws.

[0003] Bone anchors, such as bone screws and hooks are utilized in many types of spinal surgery in order to secure various implants to vertebrae along the spinal column for the purpose of stabilizing and/or adjusting spinal alignment. For example, the most common mechanism for providing vertebral support is to implant bone screws into certain bones which then in turn support a rod or are supported by the rod. Although both closed-ended and open-ended bone anchors are known, open-ended anchors are particularly well suited for connections to longitudinal connecting members such as hard, soft or deformable rods, dynamic or elastic connectors and connector arms, because such rods or other connector members do not need to be passed through a closed bore, but rather can be laid or urged into an open channel within a receiver or head of such a bone anchor. Generally, the anchors must be inserted into the bone as an integral unit or a preassembled unit, in the form of a shank or hook and connected pivotal receiver. In some instances, a portion of such a preassembled unit, such as a shank of a polyaxial

bone screw assembly, may be independently implanted into bone, followed by push- or pop-on assembly of a receiver portion of the unit.

[0004] Typical open-ended bone screws include a threaded shank with a head or receiver having a pair of parallel projecting branches or arms which form a yoke with a U-shaped slot or channel to receive a rod or other longitudinal connecting member. Hooks and other types of connectors, as are used in spinal fixation techniques, may also include similar open ends for receiving rods or portions of other fixation and stabilization structure. The open-ended head or rod receiver portion of such implants typically includes a pair of spaced arms forming a channel closed by a closure member after the rod or other longitudinal connecting member is placed in the channel. Known closures include slide-on types, twist-on varieties that are rotated ninety degrees to a locked in position, and a variety of single start helically wound guide and advancement structures including, for example, thread forms having v-thread, reverse-angle buttress or square thread forms, to name a few, as well as other non-threadlike helically wound forms. Sometimes threaded plugs are utilized with outer threaded nuts to prevent splaying of the receiver arms.

[0005] As indicated above, the force required to press a closure structure down onto a rod or other connector located between arms of an open implant is considerable. Even though a head or receiver portion of an open polyaxial bone anchor may be pivoted in a direction to make it easier for the arms of the open implant to receive a rod or other connector, spinal misalignments, irregularities and the placement of other surgical tools make it difficult to place the rod or other connector between the arms of the implant while a closure structure is mated with the open implant as well as used to push the rod or other connector downwardly into the implant. For example, when the closure is a cylindrical plug having a single start helically wound guide and advancement structure, such structure must be aligned with mating structure on one of the implant arms and then rotated until a portion of the structure is captured by mating guide and advancement structure on both arms of the implant, all the while the closure is being pressed down on the rod while other forces are pushing and pulling the rod back out of the implant. Integral or mono-axial open implants that cannot be pivoted to receive the rod are even more difficult to manipulate during the initial placement of the rod and initial mating rotation of a closure plug between the spaced, open arms of the implant. Therefore, extraordinary forces are

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placed on the implant and closure plug while the surgeon either pushes down on the rod or pulls up on the bone to get the rod in position between the implant arms and to initially push down upon the rod with the closure plug.

SUMMARY OF THE INVENTION

[0006] A closure structure, top or plug of the invention for insertion between spaced arms of an open medical implant includes one or more helically wound guide and advancement features, each feature having a start surface or structure located at or near a bottom surface of the closure plug, each start structure simultaneously engaging and being captured by each of the spaced arms of the open implant upon initial rotation of the closure structure with respect to the open implant arms. According to an aspect of the invention, a double-start closure is disclosed having two helically wound forms thereon, each form having a start structure for simultaneously engaging a mating helical form on a respective open implant arm. Each time the illustrated duel- or double-start closure plug is rotated one turn (three hundred sixty degrees) between the implant arms, the closure plug advances axially into the implant and toward the rod by a width of two helical forms. The helically wound forms of the multi-start closure spiral around a cylindrical plug body thereof to an extent that the closure rotates over ninety degrees to fully or substantially receive the entire closure plug between the arms of the open implant. The illustrated closure is sized for at least one complete rotation (three hundred sixty degrees) of the plug with respect to the open implant to substantially receive the plug between the implant arms. Multi-start closures of the invention may have two or more coarse or fine helical forms, resulting in fewer or greater forms per axial distance spiraling about the closure plug body and thus resulting in plugs that rotate less (when more coarse) or more (when thin or fine) than one complete rotation to be fully received between the implant arms, typically, at least a ninety-one degree rotation is preferred.

[0007] An illustrated multi-start closure and mating open implant is in the form of non-threaded, interlocking flange forms. Also disclosed are multi-start closure structures provided with helically wound forms of other geometry, including, but not limited to helically wound threads such as reverse angle, buttress, square and v-threads. The multi-start closure may be cannulated for minimally invasive surgical applications.

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[0008] Another illustrated multi-start closure embodiment of the invention is shown with a bone screw assembly having an open receiver with a pair of opposed arms, each arm having guide and advancement structure for simultaneous mating engagement with a start of the helically wound multi-start closure. A further embodiment according to the invention includes an open bone anchor receiver having integral upwardly extending break-off tabs that also have the guide and advancement structure for mating with the multi-start closure. A further embodiment includes an attachable/detachable guide tool cooperating with such a multi-start open receiver, the tool having inner guide and advancement structures located near a bottom thereof for rotatably and matingly receiving the multi-start closure and being synchronized with the receiver guide and advancement structure for rotating and driving the multi-start closure downward from the guide tool to the receiver.

[0009] Objects of the invention further include providing apparatus and methods that are easy to use and especially adapted for the intended use thereof and wherein the tools are comparatively inexpensive to produce. Other objects and advantages of this invention will become apparent from the following description taken in conjunction with the accompanying drawings wherein are set forth, by way of illustration and example, certain embodiments of this invention.

[0010] The drawings 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 DRAWINGS

[0011] FIG. 1 is a perspective view of an embodiment of a multi-start closure according to the invention.

[0012] FIG. 2 is another perspective view of the multi-start closure of FIG. 1.

[0013] FIG. 3 is a front elevational view of the closure of FIG. 1 shown with a portion of a receiver of a polyaxial bone screw according to FIG. 8, the receiver shown in partial front elevation with portions broken away to show the detail thereof, and further showing a rod being pressed upon by the closure, the rod also in partial front elevation with portions broken away to show the detail thereof.

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[0014] FIG. 4 is a reduced top plan view of the closure of FIG. 1.

[0015] FIG. 5 is a reduced bottom plan view of the closure of FIG. 1.

[0016] FIG. 6 is an enlarged front elevational view of the closure of FIG. 1 with portions broken away to show the detail thereof.

[0017] FIG. 7 is a reduced cross-sectional view taken along the line 7-7 of FIG. 6.

[0018] FIG. 8 a partial front elevational view of an open bone screw assembly, with portions broken away to show the detail thereof, including a receiver, a shank, a compression insert and also shown in engagement with the closure top of FIG. 1 (in reduced view) and a longitudinal connecting member in the form of a hard rod.

[0019] FIG. 9 is a front elevational view of an alternative closure of an embodiment of the invention, similar to the closure of FIG. 1, but including a break-off head, the alternative closure shown with a portion of a receiver of the polyaxial bone screw of FIG. 8 shown in enlarged and partial front elevation with portions broken away to show the detail thereof, and further showing a rod being pressed upon by the alternative closure, the rod also in partial front elevation with portions broken away to show the detail thereof.

[0020] FIG. 10 is another front elevational view of the closure of FIG. 9 with portions broken away to show the detail thereof.

[0021] FIG. 11 is a front elevational view of an alternative square-thread closure of an embodiment of the invention with portions broken away to show the detail thereof, the closure shown with a portion of a receiver of the polyaxial bone screw of FIG. 8 shown in enlarged and partial front elevation with portions broken away to show the detail thereof, and further showing a rod being pressed upon by the alternative closure, the rod also in partial front elevation with portions broken away to show the detail thereof.

[0022] FIG. 12 is a front elevational view of an alternative reverse angle closure of an embodiment of the invention with portions broken away to show the detail thereof, the closure shown with a portion of a receiver of the polyaxial bone screw of FIG. 8 shown in enlarged and partial front elevation with portions broken away to show the detail thereof, and further showing

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a rod being pressed upon by the alternative closure, the rod also in partial front elevation with portions broken away to show the detail thereof.

[0023] FIG. 13 is a front elevational view of an alternative v-thread closure embodiment of the invention with portions broken away to show the detail thereof, the closure shown with a portion of a receiver of the polyaxial bone screw of FIG. 8 shown in enlarged and partial front elevation with portions broken away to show the detail thereof, and further showing a rod being pressed upon by the alternative closure, the rod also in partial front elevation with portions broken away to show the detail thereof.

[0024] FIG. 14 is a front elevational view of an alternative buttress-thread closure embodiment of the invention with portions broken away to show the detail thereof, the closure shown with a portion of a receiver of the polyaxial bone screw of FIG. 8 shown in enlarged and partial front elevation with portions broken away to show the detail thereof, and further showing a rod being pressed upon by the alternative closure, the rod also in partial front elevation with portions broken away to show the detail thereof.

[0025] FIG. 15 is a partial front elevational view of an embodiment of a multi-start open bone anchor receiver of an embodiment of the invention with portions broken away to show the detail thereof, the receiver including break-off tabs.

[0026] FIG. 16 is an enlarged and partial front elevational view of the receiver of FIG. 15 with portions broken away to show the detail thereof.

[0027] FIG. 17 is a partial front elevational view of an embodiment of a bone anchor receiver having a guide and advancement structure that matingly cooperates with the multi-start closure of FIG. 1, also shown in front elevation, the receiver having portions broken away to show the detail thereof, and further shown with a guide tool, shown in phantom, the guide tool having a multi-start guide and advancement structure receiving inner surface synchronized with the bone anchor receiver guide and advancement structure.

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DETAILED DESCRIPTION OF THE INVENTION

[0028] As required, detailed embodiments of the present invention are disclosed herein; however, it is to be understood that the disclosed embodiments are merely exemplary of the invention, which may be embodied in various forms. Therefore, specific structural and functional details disclosed herein are not to be interpreted as limiting, but merely as a basis for the claims and as a representative basis for teaching one skilled in the art to variously employ the present invention in virtually any appropriately detailed structure. It is also noted that any reference to the words top, bottom, up and down, and the like, in this application refers to the alignment shown in the various drawings, as well as the normal connotations applied to such devices, and is not intended to restrict positioning of the bone attachment structures in actual use.

[0029] Furthermore, the terms lead, pitch and start, as such terms are used to describe helically wound guide and advancement structures, are to be understood as follows: Lead is a distance along the axis of a closure plug that is covered by one complete rotation (360 degrees) of the closure plug with respect to a mating open implant. Pitch is the distance from a crest (or outer point or location) of one guide and advancement structure form to the next. For example in a single-start thread-form, such as a single start, helically wound v-thread closure plug, lead and pitch are the same. Single start means that there is only one ridge or helically wound form wrapped around a cylindrical core, or in the case of the present invention, wrapped around a cylindrical closure plug body and thus there is only one start structure or surface at a base or forward end of the closure body that initially engages a mating structure on the open implant. Each time a single start closure rotates one turn (360 degrees), the closure has advanced axially by a width of one ridge or one helical form. Double-start means that there are two ridges or forms wrapped around a core body and thus there are two starting surfaces or structures on the closure plug. Therefore, each time a double-start body rotates one turn (360 degrees), such a body has advanced axially by a width of two ridges or forms. Multi-start means that there are at least two and may be up to three or more of such ridges or forms wrapped around a core body.

[0030] With reference to FIGS. 1-8, and in particular to FIG. 8, the reference number 1 generally represents an open implant in the form of a polyaxial bone screw apparatus or assembly that cooperates with an illustrated closure structure 18 embodiment of the invention.

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The bone screw assembly 1 is described in detail in U.S. Provisional Patent Application No. 61/631,746 filed Jan. 10, 2012 and incorporated by reference herein (hereafter the '746 application) and therefore will not be described in great detail herein. The description set forth in the '746 application includes a more detailed explanation of all the components referenced in FIG. 8. It is noted that multi-start closure embodiments of the invention, such as the closure 18 may be used with a variety of open implants including, but not limited to a wide variety of polyaxial screws, mono-axial or fixed screws, hooks and other types of open implants requiring a plug or closure mechanism to fix a rod or other implant member to a vertebra or other bone. Thus, the assembly 1 is only one example of how multi-start closures of the invention may be used.

[0031] Briefly, the illustrated assembly 1 includes a shank 4 with an upwardly extending upper portion or capture structure 8; an open receiver 10; a retaining structure or retainer (not shown) that pivots with the shank 4, a compression or pressure insert 14 and the multi-start closure structure or plug 18 in the form of a cylindrical plug having a double-start helically wound flange-form. The closure structure 18 presses against and captures a longitudinal connecting member, for example, a rod 21 which in turn engages the compression insert 14 that presses against the shank upper portion 8 that is attached to the retaining structure that in turn presses against an inner surface of the receiver 10, so as to capture and fix the longitudinal connecting member 21 within the receiver 10 and thus fix the member 21 relative to a vertebra (not shown). The illustrated receiver 10 and the shank 4 cooperate in such a manner that the receiver 10 and the shank 4 can be secured at any of a plurality of angles, articulations or rotational alignments relative to one another and within a selected range of angles both from side to side and from front to rear, to enable flexible or articulated engagement of the receiver 10 with the shank 4 until both are locked or fixed relative to each other near the end of an implantation procedure.

[0032] The illustrated rod 21 is hard, stiff, non-elastic and cylindrical, having an outer cylindrical surface 22. However, in other embodiments, the rod 21 may be elastic, deformable and/or of a different cross-sectional geometry. The rod 21 may be made from a variety of metals, metal alloys and deformable and less compressible plastics, including, but not limited to rods made of elastomeric, polyetheretherketone (PEEK) and other types of materials, such as

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polycarbonate urethanes (PCU) and polyethylenes. Furthermore, in lieu of a rod, longitudinal connecting members for use with the assembly 1 may take a variety of shapes, and/or may include a tensioned cord as described in greater detail in the '746 application that is incorporated by reference herein.

[0033] It is noted that the receiver 10 includes guide and advancement structures 168 that are shown as interlocking flange forms described in greater detail in applicant's U.S. Pat. No. 6,726,689, also incorporated by reference herein. Alternately, when the closure structure includes a different helical form, the receiver cooperating structures (e.g., 168) must also be of a cooperating, mating geometry, such as a square-shaped thread receiving form, a buttress thread receiving form, a reverse angle thread receiving form or other thread-like or non-thread-like helically wound discontinuous advancement structure receiving forms for operably guiding under rotation and advancing a multi-start closure structure downward between the receiver arms 160, as well as eventual torquing when the closure structure abuts against the rod 21 or other connecting member.

[0034] With particular reference to FIGS. 1-7, the illustrated multi-start closure structure 18 is a double start closure having a substantially cylindrical plug body 40 having an axis of rotation that is the same as that of the receiver 10 and including a helically wound guide and advancement structure in the form of a pair of helically wound forms 42 and 43, each illustrated as an interlocking flange form that operably joins with mating flange form guide and advancement structures 168 disposed on the arms of the receiver 10. The form 42 includes a start surface or structure 46 and the form 43 includes a start surface or structure 47. Each helically wound form 42 and 43 may take a variety of forms and geometries, including those described in Applicant's U.S. Pat. No. 6,726,689, which is incorporated by reference herein. It is noted (and also described in greater detail subsequently herein) that each of the closure structure guide and advancement structures or forms 42 and 43 could alternatively be in the form of a buttress thread, a square thread, a reverse angle thread, a v-thread or other thread like or non-thread like helically wound advancement structures, for operably guiding under rotation and advancing the closure structure downward between the arms of the receive 10 and preferably having such a nature as to resist splaying of the receiver arms when the closure structure 18 is advanced into the receiver channel. The specific flange forms 42 and 43 illustrated in FIGS. 1-7, as well as

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acceptable alternative locking forms, are described in detail in Applicant's U.S. Pat. No. 6,726,689, incorporated by reference herein, and thus shall not be discussed further herein. Such interlocking flange forms are preferred as the added strength provided thereby beneficially cooperate with and counter any reduction in strength caused by the any reduced profile of the receiver 10 that may more advantageously engage longitudinal connecting member components.

[0035] The illustrated closure structure 18 also includes a top surface 54 with an internal drive 56 in the form of an aperture that is illustrated as a star-shaped internal drive such as that sold under the trademark TORX, or may be, for example, a hex drive, or other internal drives such as slotted, tri-wing, spanner, two or more apertures of various shapes, and the like. A driving tool (not shown) sized and shaped for engagement with the internal drive 56 is used for both rotatable engagement and, if needed, disengagement of the closure 18 from the receiver 10 at arms 160. A base or bottom surface 58 of the closure is planar and further includes a rim 60 for engagement and penetration into the surface 22 of the rod 21 in certain embodiments of the invention. The closure top 18 further includes a cannulation through bore 62 extending along a central axis thereof and through a drive base surface 63 and the bottom surface 58 thereof. Such a through bore provides a passage through the closure 18 interior for a length of wire (not shown) inserted therein to provide a guide for insertion of the closure top into the receiver arms 160.

[0036] The closure structure 18 helically wound flange form start structures 46 and 47 of the respective forms 42 and 43 are located on opposite sides of the closure plug body 40 and are both located adjacent the bottom surface 58. As illustrated in FIG. 3, for example, when the closure structure 18 is rotated into the receiver 10 between receiver arms 160, each having a guide and advancement structure 168, the start 46 engages mating guide and advancement structure 168 on one arm 160 and the start 47 simultaneously engages guide and advancement structure 168 on the opposing arm 160, both forms 42 and 43 being simultaneously captured by the mating forms 168 on the opposed arms 160. As the structure 18 is rotated, the structure advances axially downwardly between the arms 160 and presses evenly down upon the captured rod 21. Each time the illustrated duel- or double-start closure plug 18 is rotated one complete turn or pass (three hundred sixty degrees) between the implant arms, the closure plug 18 advances axially into the implant and toward the rod by a width of two helical flange forms. The illustrated closure 18 is

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sized for at least one complete rotation (three hundred sixty degree) of the plug 18 with respect to the receiver 10 open arms 160 to substantially receive the plug between the implant arms. Each of the start structures 46 and 47 includes a leading face having at least one curvate surface. The at least one curvate surface includes at least one radius of curvature. In one embodiment, the at least one curvate surface is both concave and convex. Multi-start closures of the invention may have two or more coarse or fine helical forms, resulting in fewer or greater forms per axial distance spiraling about the closure plug body and thus resulting in plugs that rotate less or more than one complete rotation to be fully received between the implant arms. Preferably, helically wound forms of the multi-start closure of the invention are sized so as to spiral around a cylindrical plug body thereof to an extent that the closure rotates at least ninety-one degrees to fully or substantially receive the closure plug between the arms of the bone screw receiver or other open implant. Particularly preferred guide and advancement structures are sized for at least one complete turn or pass (three-hundred sixty degree) of the closure between the receiver 10 arms and as many as two to three rotations to be fully received between implant arms.

[0037] In use, the receiver 10, the retainer 12 and the compression insert 14 are assembled with the shank 4 either before or after the shank is implanted into a vertebra, and the resulting assembly 1 is ultimately attached to the rod 21 or other longitudinal connecting member as described in the '746 application incorporated by reference herein. It is noted that the shank 4 and other bone screw assembly parts, the rod 21 (also having a central lumen in some embodiments) and the closure top 18 having the central bore 62 can be inserted in a percutaneous or minimally invasive surgical manner, utilizing guide wires. After the rod 21 or other longitudinal connecting member is positioned in an open or percutaneous manner in cooperation with the at least two bone screw assemblies 1 (or other open implants), the closure structure 18 is then inserted into and advanced between the arms 160 of each of the receiver 10. The closure structure 18 is rotated, using a tool engaged with the inner drive 56 until a selected pressure is reached at which point the rod 21 engages a U-shaped seating surface of the compression insert 14, further pressing the insert against the shank upper portion 8 and attached retainer into locked frictional engagement with the receiver 10. Prior to locking the insert 14 against the shank head 8, the shank 4 may be pivoted to a plurality of potentially desirable positions with respect to the receiver 10, followed by locking of the polyaxial mechanism by fully mating the multi-start

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closure top 18 with the receiver 10. Different angular or articulated positions of the shank 4 with respect to the receiver 10 are shown in the '746 application incorporated by reference herein.

[0038] With specific reference to FIGS. 3 and 8, as the multi-start closure structure 18 rotates and moves downwardly into the respective receiver 10, the rim 60 engages and penetrates the rod surface 22, the closure structure 18 pressing downwardly against and biasing the rod 21 into compressive engagement with the insert 14 that urges the shank upper portion 8 and attached retainer into locking engagement with the receiver, the retainer outer surface frictionally abutting an inner spherical seating surface of the receiver 10. For example, about 80 to about 120 inch pounds of torque on the closure top may be applied for fixing the bone screw shank 6 with respect to the receiver 10. Also, for example, when the shank 4 is disposed at an angle with respect to the receiver 10, a part of the shank upper portion 8 may also be in frictional engagement with a portion of the receiver spherical seating surface.

[0039] If removal of the rod 21 from any of the bone screw assemblies 1 is necessary, or if it is desired to release the rod 21 at a particular location, disassembly is accomplished by using the driving tool (not shown) that mates with the internal drive 56 on the closure structure 18 to rotate and remove such closure structure from the cooperating receiver 10. Disassembly is then accomplished in reverse order to the procedure described previously herein for assembly.

[0040] With reference to FIGS. 9 and 10, an alternative closure top 18' is shown that is almost identical to the closure top 18. However, the top 18' differs from the top 18 in that the top 18' includes a break-off head 70' that further includes a top surface 72' having tooling notches 73', an outer faceted driving surface 74', illustrated as having a hex-shaped profile, and an inner bore 76'. Otherwise, the closure top 18' includes a body 40', a first helical form 42', a second helical form 43', a body top surface 54', a body internal drive 56', a base 58', a rim 60', a cannulation bore 62' and a drive base surface 63' that is the same or substantially similar to the respective body 40, first helical form 42, second helical form 43, body top surface 54, internal drive 56, base 58, rim 60, cannulation bore 62 and drive base surface 63 previously described herein with respect to the closure top 18. The break-off head 70' is integral with the body 40' at the body top surface 54'. The inner bore 76' communicates with the inner drive 56' and the cannulation bore 62'. The break-off head 70' is designed to allow such head 70' to break from the

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body 40' at or near the top surface 54' at a preselected torque, for example, 70 to 140 inch pounds, when a hex-shaped tool (not shown) engages the outer surfaces 74' and drives the closure structure 18' into the receiver 10 as shown in FIG. 9. The inner drive 56' is used for disassembly or loosening of the closure 18' from the receiver 10, and re-tightening, if needed.

[0041] With reference to FIG. 11, another alternative multi-start closure top 318 is shown that is almost identical to the closure top 18 with the exception that the two flange forms 42 and 43 with respective starts 46 and 47 have been replaced with square threads 342 and 343 with respective starts 346 (not shown) and 347. Otherwise, the dual or double start closure top 318 includes a body 340, a body top surface 354, a body internal drive 356, a base 358, a rim 360', a cannulation bore 362 and a drive base surface 363 that is the same or substantially similar to the respective body 40, body top surface 54, internal drive 56, base 58, rim 60, cannulation bore 62 and drive base surface 63 previously described herein with respect to the closure top 18. In FIG. 11, the closure top 318 is shown partially wound into a polyaxial bone screw receiver 310 having opposed arms 360 with inner surfaces equipped with guide and advancement structures 368 that are sized and shaped to simultaneously closely receive and mate with the square threads 342 and 343 of the double closure structure 318. Otherwise, the receiver 310 is identical or substantially similar to the receiver 10 described in detail in the '746 application incorporated by reference herein.

[0042] With reference to FIG. 12, an alternative multi-start closure top 418 is shown that is almost identical to the closure top 18 with the exception that the two flange forms 42 and 43 with respective starts 46 and 47 have been replaced with reverse angle threads 442 and 443 with respective starts 446 (not shown) and 447. Otherwise, the dual or double start closure top 418 includes a body 440, a body top surface 454, a body internal drive 456, a base 458, a rim 460', a cannulation bore 462 and a drive base surface 463 that is the same or substantially similar to the respective body 40, body top surface 54, internal drive 56, base 58, rim 60, cannulation bore 62 and drive base surface 63 previously described herein with respect to the closure top 18. The closure top 418 is shown partially wound into a polyaxial bone screw receiver 410 having opposed arms 460 with inner surfaces equipped with guide and advancement structures 468 that are sized and shaped to simultaneously closely receive and mate with the reverse angle threads 442 and 443 of the double start closure structure 418. Otherwise, the receiver 410 is identical or

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substantially similar to the receiver 10 described in detail in the '746 application incorporated by reference herein.

[0043] With reference to FIG. 13, another alternative multi-start closure top 518 is shown that is almost identical to the closure top 18 with the exception that the two flange forms 42 and 43 with respective starts 46 and 47 have been replaced with v-threads 542 and 543 with respective starts 546 (not shown) and 547. Otherwise, the dual or double start closure top 518 includes a body 540, a body top surface 554, a body internal drive 556, a base 558, a rim 560', a cannulation bore 562 and a drive base surface 563 that is the same or substantially similar to the respective body 40, body top surface 54, internal drive 56, base 58, rim 60, cannulation bore 62 and drive base surface 63 previously described herein with respect to the closure top 18. The closure top 518 is shown partially wound into a polyaxial bone screw receiver 510 having opposed arms 560 with inner surfaces equipped with guide and advancement structures 568 that are sized and shaped to simultaneously closely receive and mate with the threads 542 and 543 of the double start closure structure 518. Otherwise, the receiver 510 is identical or substantially similar to the receiver 10 described in detail in the '746 application incorporated by reference herein.

[0044] With reference to FIG. 14, another alternative multi-start closure top 618 is shown that is almost identical to the closure top 18 with the exception that the two flange forms 42 and 43 with respective starts 46 and 47 have been replaced with buttress threads 642 and 643 with respective starts 446 and 447 (not shown). Otherwise, the dual or double start closure top 618 includes a body 640, a body top surface 654, a body internal drive 656, a base 658, a rim 660', a cannulation bore 662 and a drive base surface 663 that is the same or substantially similar to the respective body 40, body top surface 54, internal drive 56, base 58, rim 60, cannulation bore 62 and drive base surface 63 previously described herein with respect to the closure top 18. The closure top 618 is shown partially wound into a polyaxial bone screw receiver 610 having opposed arms 660 with inner surfaces equipped with guide and advancement structures 668 that are sized and shaped to simultaneously closely receive and mate with the buttress threads 642 and 643 of the double start closure structure 618. Otherwise, the receiver 610 is identical or substantially similar to the receiver 10 described in detail in the '746 application incorporated by reference herein.

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[0045] With reference to FIGS. 15 and 16, an open receiver 710 is illustrated that is substantially similar to the receiver 10 previously described herein with the exception that the receiver 710 includes opposed arms 760, each having an integral upstanding break-off extension 761. Each receiver arm 760 and integral extension 761 has an inner helically wound guide and advancement structure 768 that is sized and shaped to mate with the flange forms 42 and 43 of the dual start closure 18 previously described herein. The break-off extensions 761 are initially integral with the respective arms 760 and are then broken off by a user after the closure 18 has been rotatingly advanced along the arm extensions 761 and into the channel located between the receiver arms 760. In the illustrated embodiment, in addition to an outer groove or notch 770 located at or near a top surface 769 of each of the arms 760 where the extensions 761 break off from the receiver arms, illustrated inner arm surfaces include a recess or cut 771, best shown in FIG. 16, that runs substantially horizontally. Each recess 771 is curved and elongate and disposed somewhat cross-wise or transverse to the respective flange form 768. For example, with reference to the arm 760 shown in FIG. 16, the recess 771 cuts into a weakened region, generally 780, where the arm 760 joins with the respective attached adjacent extension 761, the curved and elongate recess 771 beginning at a lower portion or location 781 of the flange form recess or segment and terminating at an opposed upper end location of the flange form segment, while otherwise leaving the flange form 768 intact. Stated in another way, the substantially horizontally extending recess 771 cuts into both a lead portion and a trailing portion of each of the flange form segments located near and directly above the opposed arms 760 and substantially opposite the notch 770, thus further weakening the region where the extension and the arm attach, without destroying the flange form path, so that the closure 18 is not derailed by the recess 771 or otherwise prohibited from moving downwardly into the receiver channel formed between the receiver arms 760.

[0046] With reference to FIG. 17, the multi-start closure 18 is shown cooperating with a spinal implant receiver, such as a bone screw receiver 10' and a discrete, detachable guide tool 801. The elongate guide tool 801, only partially shown in FIG. 17, is typically sized for extending from the bone screw receiver 10' upwardly to a location outside of a patient, the tool providing a guide channel for operably guiding the rod 21 or other longitudinal connecting member from a position exterior of the bone screw receiver 10' toward and into the bone screw receiver 10'. The illustrated guide tool has opposed arms 805, each arm having a helical guide

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and advancement structure 810 thereon that is illustrated as a square thread form, but may be of other geometry, including a flange form the same or similar to the flange forms 168' of the receiver 10' that mates with the flange forms 42 and 43 of the closure structure 18. Thus, the illustrated structures 810 are sized and shaped for receiving and rotating engagement with a dual start closure. The closure 18 is shown partially wound into the receiver 10' that is identical or substantially similar to the receiver 10 with the exception of certain outer arm surface features (not shown). Thus, the receiver 10' includes opposed arms 160' with inner surfaces having guide and advancement structures 168' that are sized and shaped to simultaneously closely receive and mate with the flange forms 42 and 43 of the dual start closure structure 18. The guide tool 801 includes attachment structure for detachable attachment to the receiver 10'(not shown), that may take a variety of forms and methods, including, but not limited to a slide-on, slide-off attachment, a snap-on, rotate off attachment, a rotate-on and rotate-off attachment, to name a few. For example, cooperating attachment structure for both the tool and the receiver may be used that is disclosed in U.S. Pat. No. 7,470,279 and incorporated by reference herein. Returning to the inner helically wound guide and advancement structure 810 formed on each arm 804 of the guide tool 801, the structure 810 is sized and shaped for being aligned with the receiver arms 160' during removable attachment of the tool 801 with the respective bone screw receiver 10' so as to continue the helical pathway for the closure 18, the structures 810 being synchronized with the flange forms 168' to allow for the rotation and driving transfer of the closure 18 from the tool 801 into the receiver 10'.

[0047] It is to be understood that while certain forms of the present invention have been illustrated and described herein, it is not to be limited to the specific forms or arrangement of parts described and shown.

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CLAIMS

1. A medical implant assembly comprising:

a receiver having a first arm and a second arm, the first arm and the second arm each having a top side surface;

a channel formed by the first arm and the second arm and opening between a front outer face and a second outer face of the receiver, the channel adapted to receive a longitudinal connecting member, the channel closeable with a closure having an axis of rotation and a bottom surface that is closed and flat;

a first interior surface of the first arm opposite the first side outer face;

a second interior surface of the second arm opposite the second side outer face;

a first discontinuous helically wound structure on the first interior surface of the first arm, the first discontinuously helically wound structure engageable to a first start of a first continuously helically wound form disposed on the closure; and

a second discontinuous helically wound structure on the second interior surface of the second arm, the second discontinuous helically wound structure engageable to a second start of a second continuous helically wound form disposed on the closure, a rotation of the closure about the axis of rotation between the first arm and the second arm causing a simultaneous mating of the first start with the first discontinuous helically wound structure and the second start with the second discontinuous helically wound structure, the closure rotationally advanceable within the channel until the bottom surface engages and locks the longitudinal connecting member within the channel.

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ABSTRACT

An open implant closure structure includes a helically wound guide and advancement structure having at least two helically wound forms thereon providing a multi-start closing mechanism for use between spaced arms of a cooperating open medical implant having mating helically wound structure thereon. Illustrated structures include interlocking flange forms, v-threads, square threads, reverse angle threads and buttress threads and receivers with break-off extensions and cooperating tooling.

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Fig. 1.

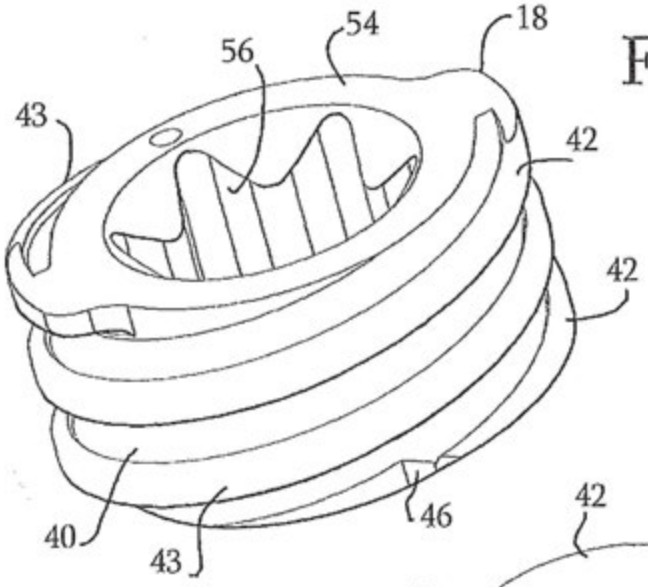


Fig. 2.

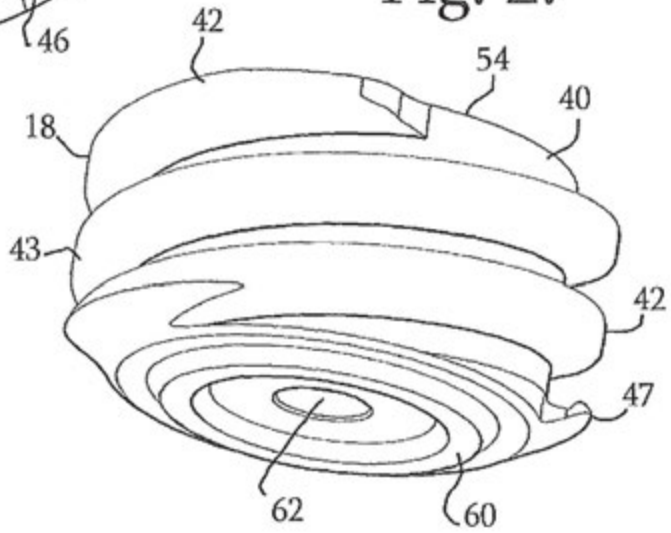
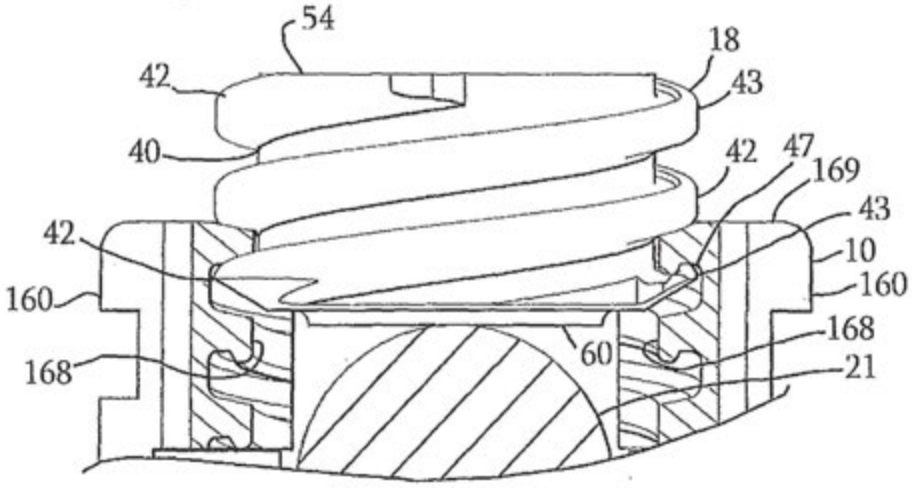


Fig. 3.



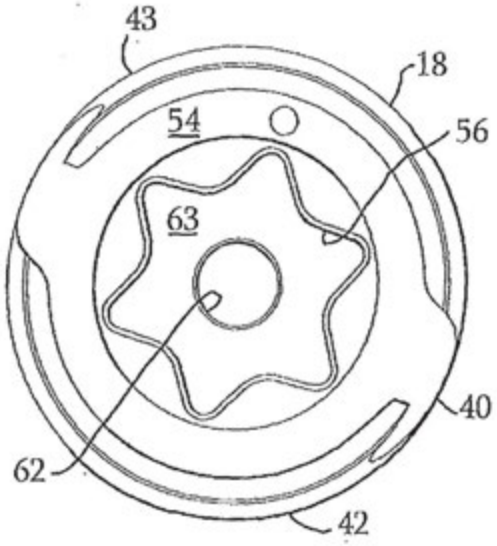


Fig. 4.

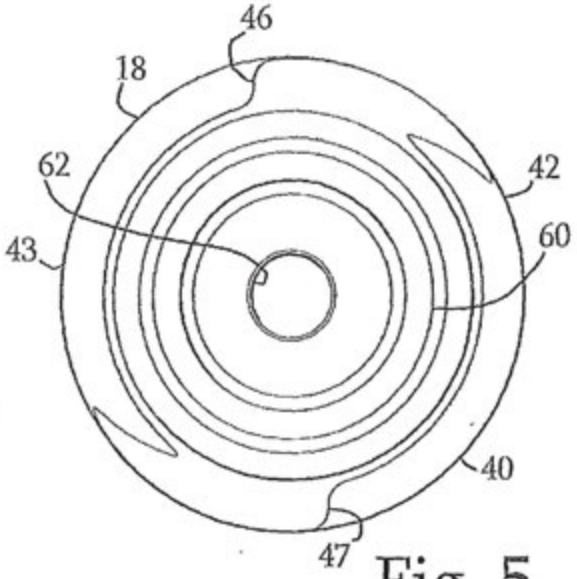


Fig. 5.

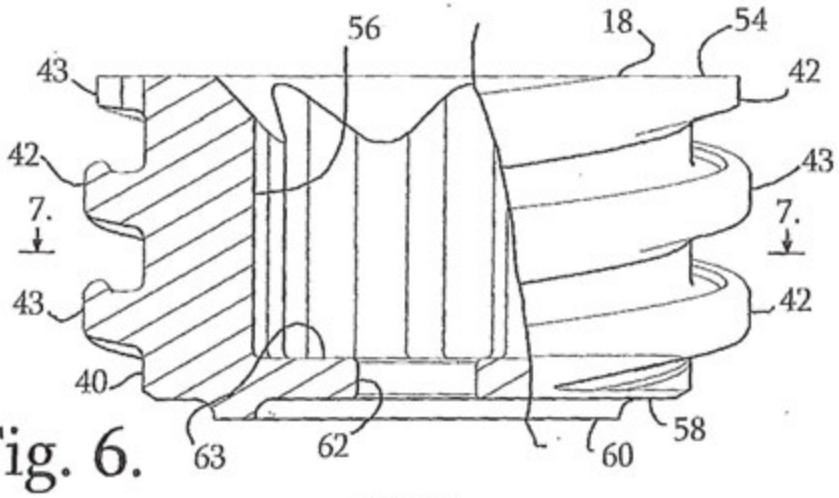


Fig. 6.

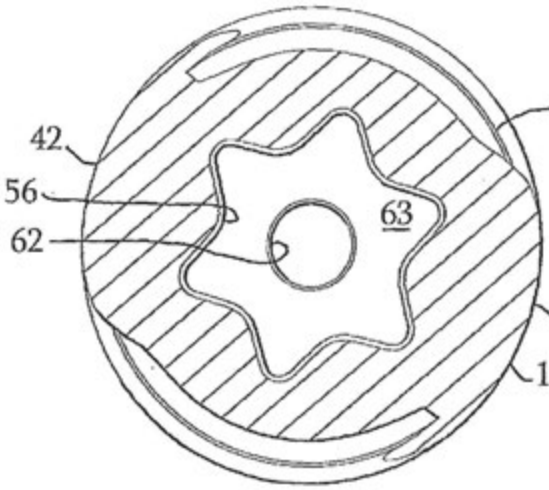


Fig. 7.

Fig. 8.

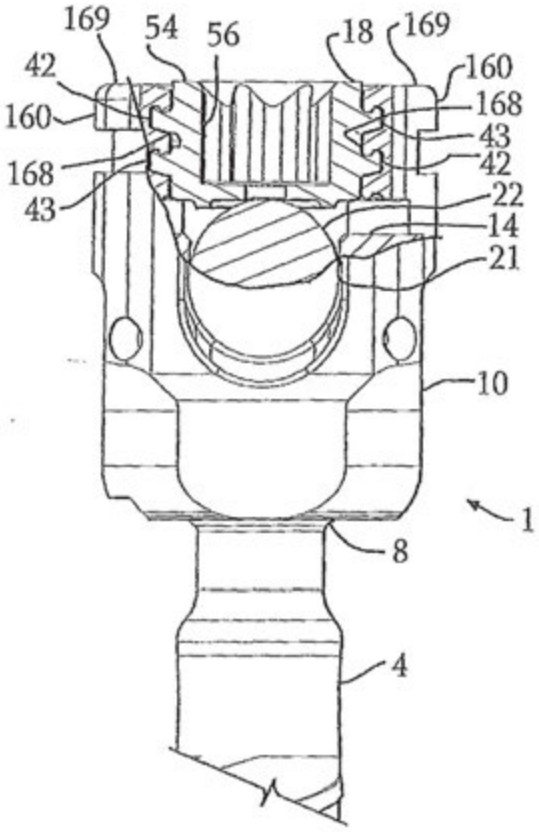


Fig. 9.

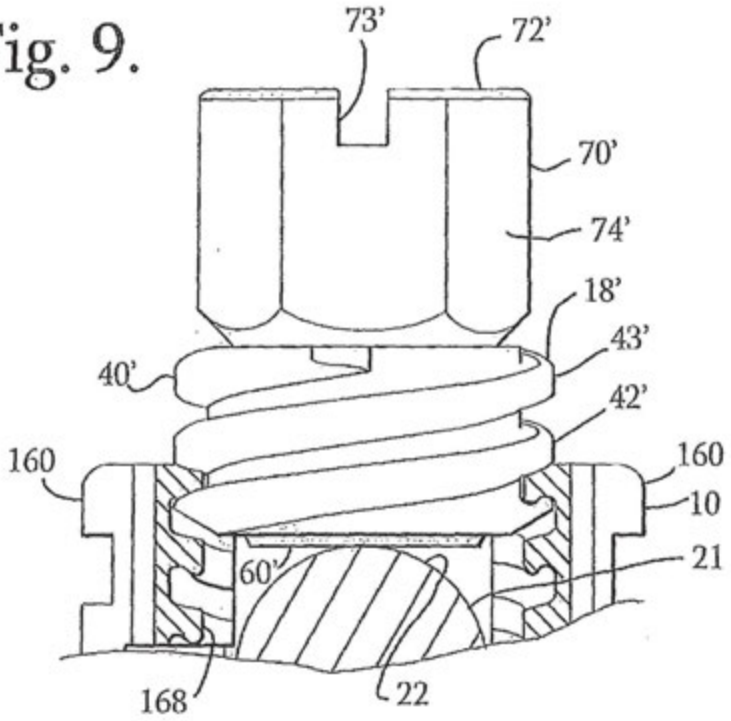

73'
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Fig. 10.

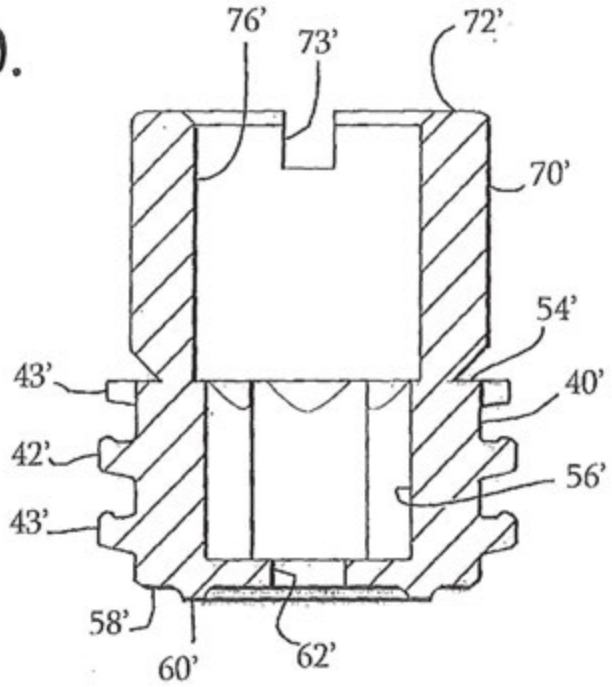

76'
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Fig. 11.

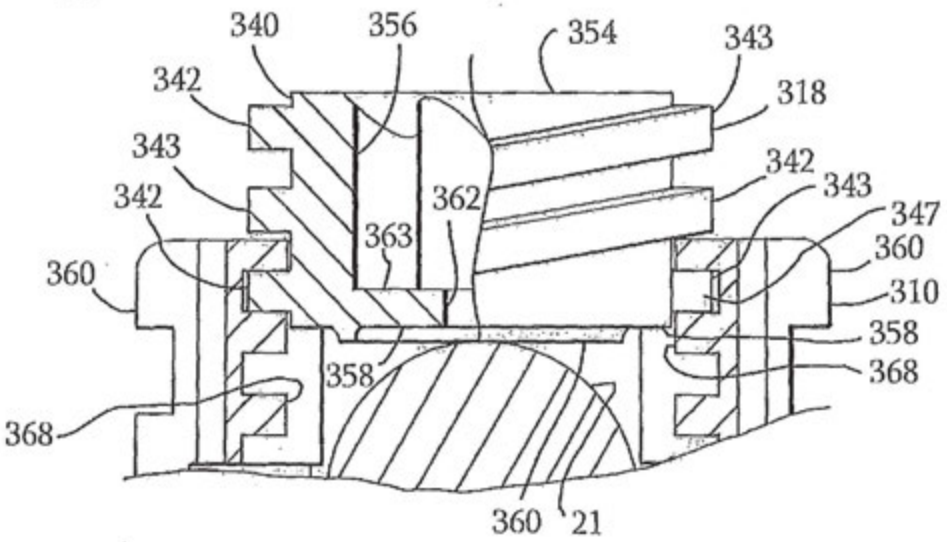

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Fig. 12.

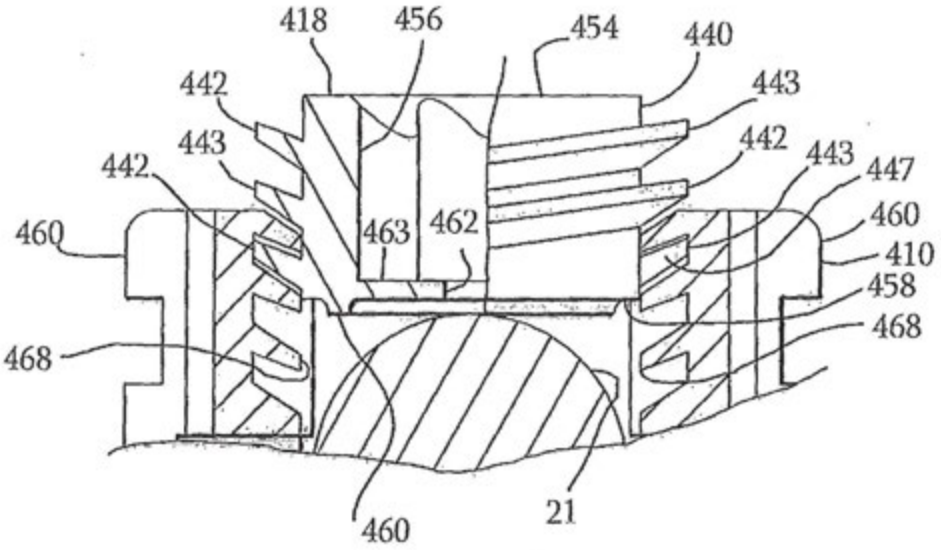

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Fig. 13.

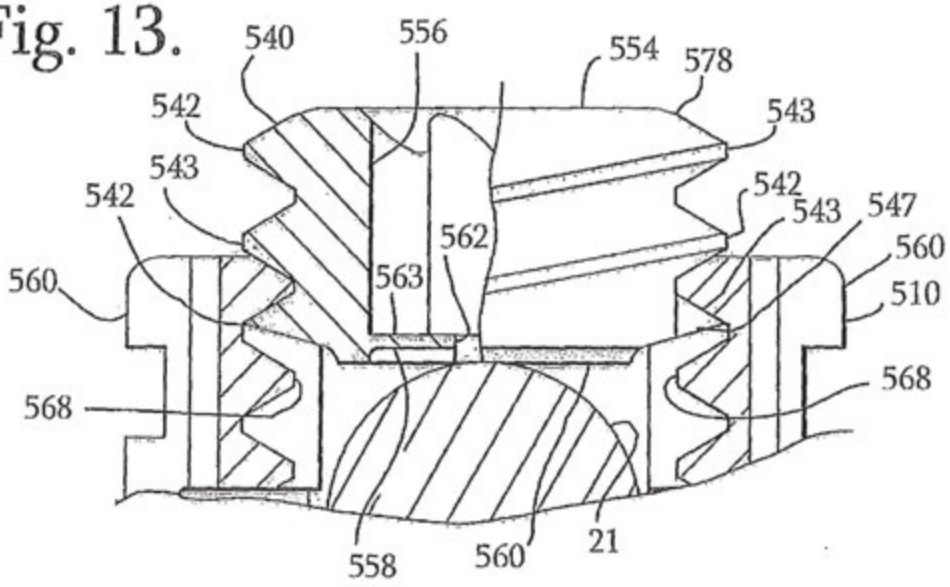

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Fig. 14.

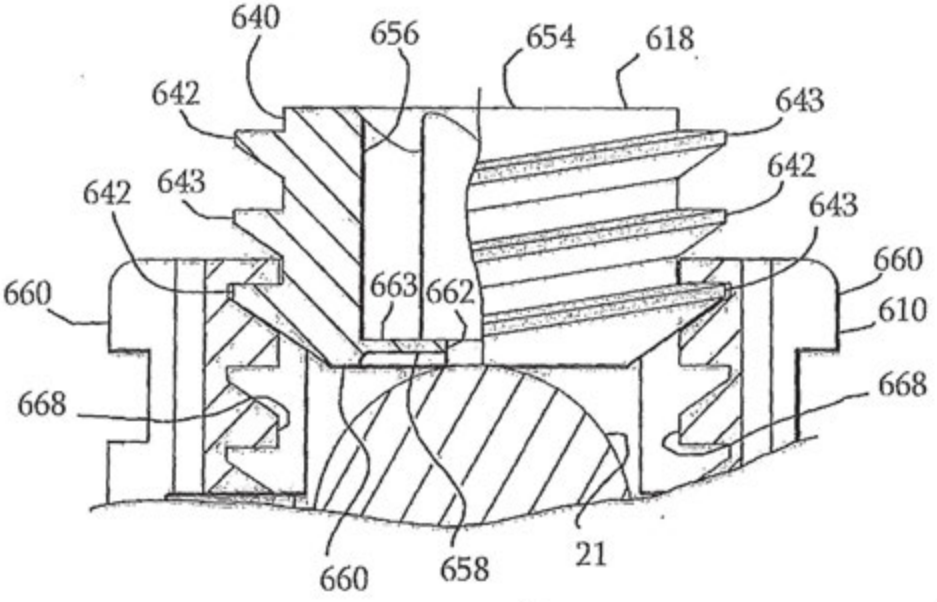
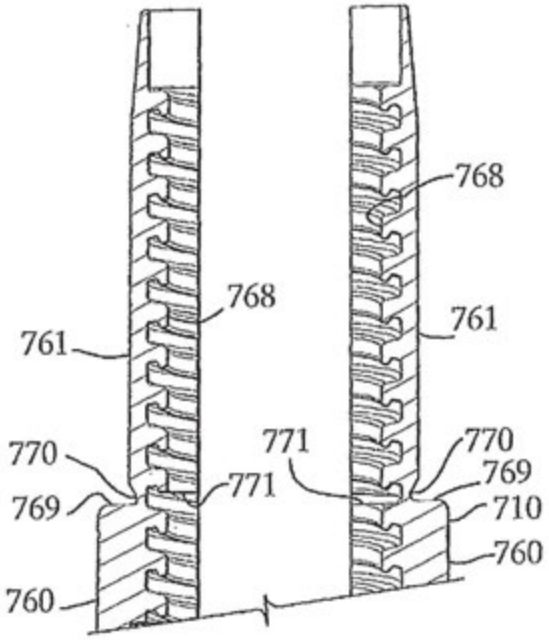

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Fig. 15.



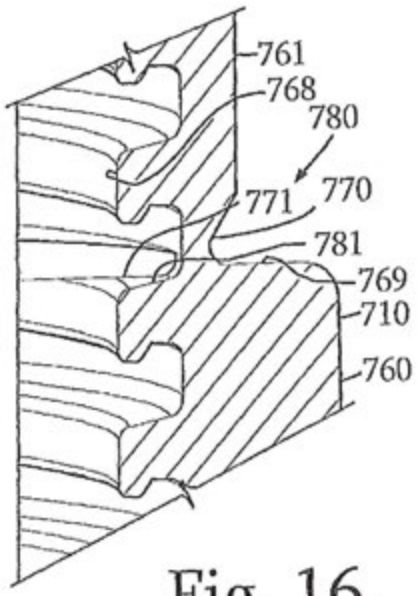


Fig. 16.

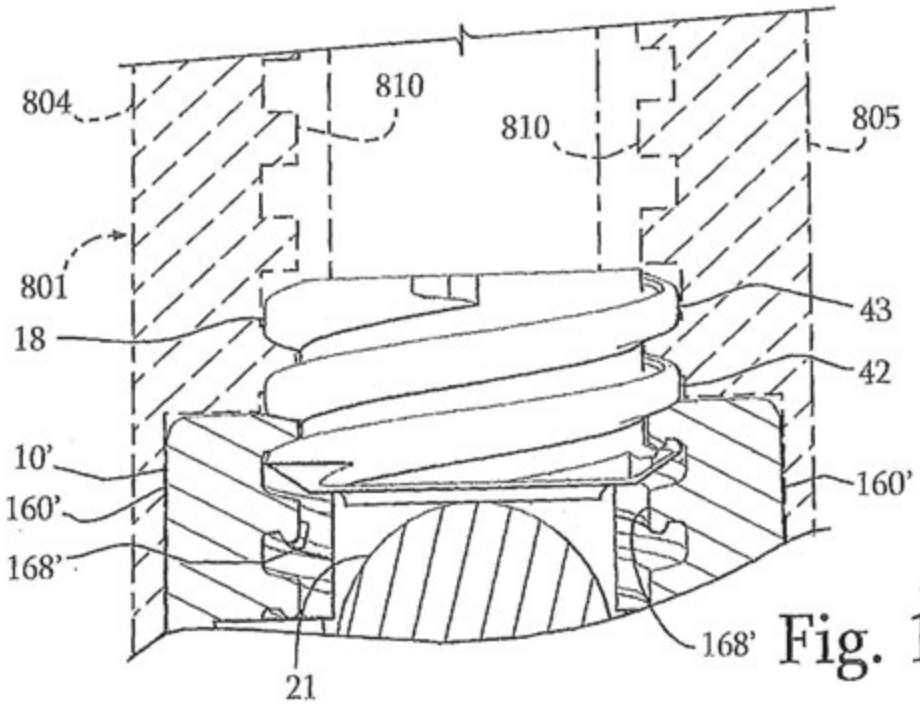


Fig. 17.

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DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN APPLICATION DATA SHEET (37 CFR 1.76)

Title of Invention	MULTI-START CLOSURES FOR OPEN IMPLANTS

As the below named inventor, I hereby declare that:

This declaration is directed to:

- [x] The attached application, or
- [ ] United States application or PCT international application number _____ filed on _____.

The above-identified application was made or authorized to be made by me.

I believe that I am the original inventor or an original joint inventor of a claimed invention in the application.

I hereby acknowledge that any willful false statement made in this declaration is punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both.

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LEGAL NAME OF INVENTOR

Inventor: Roger P. Jackson Date (Optional) : _____

Signature: Roger P. Jackson

Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 form for each additional inventor.

This collection of information is required by 35 U.S.C. 115 and 37 CFR 1.63. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 1 minute to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN APPLICATION DATA SHEET (37 CFR 1.76)

Title of Invention	MULTI-START CLOSURES FOR OPEN IMPLANTS

As the below named inventor, I hereby declare that:

This declaration is directed to:

- [■] The attached application, or
- [ ] United States application or PCT international application number _____ filed on _____.

The above-identified application was made or authorized to be made by me.

I believe that I am the original inventor or an original joint inventor of a claimed invention in the application.

I hereby acknowledge that any willful false statement made in this declaration is punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both.

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LEGAL NAME OF INVENTOR

Inventor: James L. Surber Date (Optional) :_____

Signature: _____

Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 form for each additional inventor.

This collection of information is required by 35 U.S.C. 115 and 37 CFR 1.63. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 1 minute to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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Electronic Patent Application Fee Transmittal	
Application Number:	
Filing Date:	
Title of Invention:	TOP NOTCH RECEIVERS HAVING DUAL LEAD IN CLOSURE MATING THREAD FORMS
First Named Inventor/Applicant Name:	Roger P. Jackson
Filer:	Milan M. Vinnola/Danielle Casteel
Attorney Docket Number:	JAC023-644278
Filed as Large Entity	
Filing Fees for Utility under 35 USC 111(a)	

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
UTILITY APPLICATION FILING	1011	1	300	300
UTILITY SEARCH FEE	1111	1	660	660
UTILITY EXAMINATION FEE	1311	1	760	760
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Miscellaneous:				
		Total in USD ($)		1720

Electronic Acknowledgement Receipt	
EFS ID:	38465921
Application Number:	16779304
International Application Number:	
Confirmation Number:	4759
Title of Invention:	TOP NOTCH RECEIVERS HAVING DUAL LEAD IN CLOSURE MATING THREAD FORMS
First Named Inventor/Applicant Name:	Roger P. Jackson
Customer Number:	24030
Filer:	Milan M. Vinnola/Danielle Casteel
Filer Authorized By:	Milan M. Vinnola
Attorney Docket Number:	JAC023-644278
Receipt Date:	31-JAN-2020
Filing Date:	
Time Stamp:	18:44:17
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	DA
Payment was successfully received in RAM	$1720
RAM confirmation Number	E20201UI44355092
Deposit Account	501662
Authorized User	Danielle Casteel
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows: 37 CFR 1.16 (National application filing, search, and examination fees) 37 CFR 1.17 (Patent application and reexamination processing fees)	

37 CFR 1.19 (Document supply fees)

37 CFR 1.20 (Post Issuance fees)

37 CFR 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Application Data Sheet	WebADS.pdf	146039 ab537002627ad52fd9f2e93b744cac0cd2e5546c	no	8
Warnings:					
Information:					
2		JAC023-644278_Spec.pdf	156267 bdb9546d363d4582a90d34ae241053c309db2a3a	yes	18

Multipart Description/PDF files in .zip description

Document Description	Start	End
Specification	1	16
Claims	17	17
Abstract	18	18

Warnings:					
Information:					
3	Drawings-only black and white line drawings	JAC023-644278_Figures.pdf	723490 1a260a4cf4c0b528cfdc13b76f6cccb56965b3d7e	no	7
Warnings:					
Information:					
4	Oath or Declaration filed	SignedDeclarations.pdf	129885 47394 3df12dc5e500d581a440f63f42b4215cee5	no	2
Warnings:					
Information:					
5	Fee Worksheet (SB06)	fee-info.pdf	34746 23db5cd2e794f7acc0c52954a23b772cc0621d5e	no	2

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National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

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APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
16/779,304	01/31/2020	3773	1720	JAC023-644278	1	1

CONFIRMATION NO. 4759

FILING RECEIPT

24030
POLSINELLI PC
900 WEST 48TH PLACE
SUITE 900
KANSAS CITY, MO 64112-1895

Date Mailed: 02/21/2020

Receipt is acknowledged of this non-provisional utility patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF FIRST INVENTOR, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection.

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Inventor(s)

Roger P. Jackson, Prairie Village, KS;
James L. Surber, Kansas City, KS;

Applicant(s)

Roger P. Jackson, Prairie Village, KS;

Assignment For Published Patent Application

Roger P. Jackson, Prairie Village, KS

Power of Attorney: None

Domestic Priority data as claimed by applicant

This application is a CON of 15/964,502 04/27/2018 PAT 10548641
which is a CON of 15/469,076 03/24/2017 PAT 9956004
which is a CON of 14/566,356 12/10/2014 PAT 9636146
which is a CON of 13/694,849 01/10/2013 PAT 8911479
which claims benefit of 61/631,746 01/10/2012
and claims benefit of 61/634,361 02/28/2012

Foreign Applications for which priority is claimed (You may be eligible to benefit from the **Patent Prosecution Highway** program at the USPTO. Please see http://www.uspto.gov for more information.) - None.
Foreign application information must be provided in an Application Data Sheet in order to constitute a claim to foreign priority. See 37 CFR 1.55 and 1.76.

Permission to Access Application via Priority Document Exchange: Yes

Permission to Access Search Results: Yes

Applicant may provide or rescind an authorization for access using Form PTO/SB/39 or Form PTO/SB/69 as appropriate.

If Required, Foreign Filing License Granted: 02/20/2020

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 16/779,304**

Projected Publication Date: 05/28/2020

Non-Publication Request: No

Early Publication Request: No

Title

TOP NOTCH RECEIVERS HAVING DUAL LEAD IN CLOSURE MATING THREAD FORMS

Preliminary Class

606

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications: No

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Title 37, Code of Federal Regulations, 5.11 & 5.15

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Zimvie_Zimmer Biomet v. Jackson
IPR2023-01432; Petitioners' EX1002
Page 44 of 391

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number: 16/779,304

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY FEE($)
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			N/A	300
SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A			N/A	660
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	760
TOTAL CLAIMS (37 CFR 1.16(i))	1 minus 20 =	*			OR	x 100 =	0.00
INDEPENDENT CLAIMS (37 CFR 1.16(h))	1 minus 3 =	*				x 460 =	0.00
APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).						0.00
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))							0.00
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL			TOTAL	1720

APPLICATION AS AMENDED - PART II

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY ADDITIONAL FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE($)
AMENDMENT A	Total (37 CFR 1.16(i))	*	Minus	**	=	x =		OR	x =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x =		OR	x =	
	Application Size Fee (37 CFR 1.16(s))									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE($)	ADDITIONAL FEE($)		RATE($)	ADDITIONAL FEE($)
AMENDMENT B	Total (37 CFR 1.16(i))	*	Minus	**	=	x =		OR	x =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x =		OR	x =	
	Application Size Fee (37 CFR 1.16(s))									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".
The "Highest Number Previously Paid For" (Total or Independent) is the highest found in the appropriate box in column 1.

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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
16/779,304	01/31/2020	Roger P. Jackson	JAC023-644278

CONFIRMATION NO. 4759

24030
POLSINELLI PC
900 WEST 48TH PLACE
SUITE 900
KANSAS CITY, MO 64112-1895

PUBLICATION NOTICE

OC00000011730008?

Title:TOP NOTCH RECEIVERS HAVING DUAL LEAD IN CLOSURE MATING THREAD FORMS

Publication No.US-2020-0163702-A1
Publication Date:05/28/2020

NOTICE OF PUBLICATION OF APPLICATION

The above-identified application will be electronically published as a patent application publication pursuant to 37 CFR 1.211, et seq. The patent application publication number and publication date are set forth above.

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Office of Data Managment, Application Assistance Unit (571) 272-4000, or (571) 272-4200, or 1-888-786-0101

Doc code : PET.OP.AGE
Description : Petition to make special based on Age/Health

PTO/SB/130 (07-09)

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PETITION TO MAKE SPECIAL BASED ON AGE FOR ADVANCEMENT OF EXAMINATION UNDER 37 CFR 1.102(c)(1)

Application Information

Application Number	16779304	Confirmation Number	2403	Filing Date	31-Jan-2020
Attorney Docket Number (optional)	JAC023-644278	Art Unit	3773	Examiner	EDUARDO ROBERT
First Named Inventor	Roger P. Jackson				
Title of Invention	TOP NOTCH RECEIVERS HAVING DUAL LEAD IN CLOSURE MATING THREAD FORMS				

Attention: Office of Petitions
An application may be made special for advancement of examination upon filing of a petition showing that the applicant is 65 years of age, or more. No fee is required with such a petition. See 37 CFR 1.102(c)(1) and MPEP 708.02 (II).

APPLICANT HEREBY PETITIONS TO MAKE SPECIAL FOR ADVANCEMENT OF EXAMINATION IN THIS APPLICATION UNDER 37 CFR 1.102(c)(1) and MPEP 708.02 (II) ON THE BASIS OF THE APPLICANT'S AGE.

A grantable petition requires one of the following items:
(1) Statement by one named inventor in the application that he/she is 65 years of age, or more; or
(2) Certification by a registered attorney/agent having evidence such as a birth certificate, passport, driver's license, etc. showing one named inventor in the application is 65 years of age, or more.

Name of Inventor who is 65 years of age, or older

Given Name	Middle Name	Family Name	Suffix
Roger	P.	Jackson	

A signature of the applicant or representative is required in accordance with 37 CFR 1.33 and 10.18. Please see 37 CFR 1.4(d) for the format of the signature.

Select (1) or (2) :

○ (1) I am an inventor in this application and I am 65 years of age, or more.

◉ (2) I am an attorney or agent registered to practice before the Patent and Trademark Office, and I certify that I am in possession of evidence, and will retain such in the application file record, showing that the inventor listed above is 65 years of age, or more.

Signature	/Milan M. Vinnola/		
Name	Milan M. Vinnola	Registration Number	45979

EFSWeb 1.0.18

PTO/SB/130 (07-09)
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Fr eedom of Information Act requires disclosure of these records.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about indivi duals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

In re Application of
Roger P. Jackson

Application No. 16779304
Filed: January 31,2020

Attorney Docket No. JAC023-644278

:DECISION ON PETITION TO MAKE SPECIAL
:UNDER 37 CFR 1.102(c)(1)

This is a decision on the electronic petition under 37 CFR 1.102 (c)(1), filed 29-MAY-2020 to make the above-identified application special based on applicant's age as set forth in MPEP § 708.02, Section II.

The petition is **GRANTED**.

A grantable petition to make an application special under 37 CFR 1.102(c)(1), MPEP § 708.02, Section II : Applicant's Age must include a statement by applicant or a registered practitioner having evidence that applicant is at least 65 years of age. No fee is required.

Accordingly, the above-identified application has been accorded "special" status and will be taken up for action by the examiner upon the completion of all pre-examination processing.

Telephone inquiries concerning this electronic decision should be directed to the Electronic Business Center at 866-217-9197.

All other inquiries concerning either the examination or status of the application should be directed to the Technology Center.

Electronic Acknowledgement Receipt

EFS ID:	39578034
Application Number:	16779304
International Application Number:	
Confirmation Number:	4759
Title of Invention:	TOP NOTCH RECEIVERS HAVING DUAL LEAD IN CLOSURE MATING THREAD FORMS
First Named Inventor/Applicant Name:	Roger P. Jackson
Customer Number:	24030
Filer:	Milan M. Vinnola/Danielle Casteel
Filer Authorized By:	Milan M. Vinnola
Attorney Docket Number:	JAC023-644278
Receipt Date:	29-MAY-2020
Filing Date:	31-JAN-2020
Time Stamp:	15:46:37
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Petition automatically granted by EFS	petition-request.pdf	38205 3b9d38cb3c855bcd7b01fbdd729c6141b0d87d59	no	2
Warnings:					

Information:	
Total Files Size (in bytes):	38205

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.
National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.
New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Inventor(s):	Roger P. Jackson		
App. No.:	16/779,304	Con. No.:	4759
Filed:	January 31, 2020	Art Unit:	3773
Title:	MEDICAL IMPLANT RECEIVERS HAVING DUAL LEAD IN CLOSURE MATING THREAD FORMS AND CURVATE EXTENDING INSTRUMENT ENGAGING GROOVES	Examiner:	Not Yet Assigned

PRELIMINARY AMENDMENT

Via EFS-Web
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Commissioner:

Prior to examination, Applicant respectfully requests to amend the above-identified application as follows:

Amendments to the Specification begin on page 2;

Amendments to the Claims begin on page 3; and

Remarks begin on page 6.

Electronic Acknowledgement Receipt	
EFS ID:	39578155
Application Number:	16779304
International Application Number:	
Confirmation Number:	4759
Title of Invention:	TOP NOTCH RECEIVERS HAVING DUAL LEAD IN CLOSURE MATING THREAD FORMS
First Named Inventor/Applicant Name:	Roger P. Jackson
Customer Number:	24030
Filer:	Milan M. Vinnola/Danielle Casteel
Filer Authorized By:	Milan M. Vinnola
Attorney Docket Number:	JAC023-644278
Receipt Date:	29-MAY-2020
Filing Date:	31-JAN-2020
Time Stamp:	17:04:06
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		JAC023-644278_PrelimAmend.pdf	17892 83d576681117f9c57f20ff761941 23e910c989e02c	yes	6

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Applicant Arguments/Remarks Made in an Amendment	6	6
	Claims	3	5
	Specification	2	2
	Preliminary Amendment	1	1
Warnings:			
Information:			
	Total Files Size (in bytes):	17892	

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.
National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.
New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

REMARKS

This Amendment is being submitted prior to the receipt of any office action on the merits. The originally filed disclosure fully supports the claim amendment and new claims. In particular, support for new claims 2-12 can be found, for example, at least in figure 8. Thus, no new matter has been added.

If the Examiner believes a telephone conversation might advance prosecution, then the Examiner is invited to call Applicant's undersigned representative at 303-256-1950.

Please grant any extensions of time required to enter this preliminary amendment and charge any additional required fees to our Deposit Account No. No. 50-1662.

Respectfully submitted,

05/29/2020
Date

/Milan M. Vinnola/
Christopher M. Sponheimer, Reg. No. 64,462
Milan M. Vinnola, Reg. No. 45,979

Attorneys for Applicant
Tel: 303-256-1950
USPTO Customer No. 24030

POLSINELLI PC
900 West 48th Place, Suite 900
Kansas City, MO 64112
uspt@polsinelli.com
Tel: 720-931-8134
Fax: 816-753-1536

Amendments to the Claims:

The following listing of claims replaces all prior versions of the claims and all prior listings or the claim in the present application.

1. (Currently Amended) A medical implant assembly comprising:

a receiver having a longitudinal axis, a first arm, and a second arm, the first arm and the second [[arm]] arms each extending in the same direction as the longitudinal axis and having a top side surface and an outer side face surface;

a channel formed by the first arm and the second arm and opening between a front outer face and a back ~~second~~ outer face opposite the front outer face of the receiver, the channel adapted to receive a longitudinal connecting member, the channel ~~closeable~~ configured to be closed with a closure having an axis of rotation and a bottom surface configured to engage the longitudinal connecting member ~~that is closed and flat~~;

a first interior surface of the first arm opposite the ~~first~~ outer side ~~outer~~ face surface thereof;

a second interior surface of the second arm opposite the ~~second~~ outer side ~~outer~~ face surface thereof;

a first discontinuous helically wound structure on the first interior surface of the first arm, the first discontinuously helically wound structure configured ~~engageable~~ to engage a first start of a first continuously helically wound thread form disposed on the closure; ~~and~~

a second discontinuous helically wound structure on the second interior surface of the second arm, the second discontinuous helically wound structure configured ~~engageable~~ to engage a second start of a second continuous helically wound thread form disposed on the closure, a rotation of the closure about the axis of rotation between the first arm and the second arm configured to cause ~~causing~~ a simultaneous mating of the first start with the first discontinuous helically wound structure and the second start with the second discontinuous helically wound structure, the closure configured to be rotationally ~~advanceable~~ advanced within the channel until the bottom surface engages and locks the longitudinal connecting member within the channel; and

the first and second arm outer side face surfaces each having a curvate extending groove configured to be engaged by an instrument, each groove extending horizontally to the front and back outer face of each arm and being located adjacent the top side surface on each arm, wherein an entirety of each groove is configured to be located above a top surface of the longitudinal connecting member when the longitudinal connecting member is received and locked in the channel by the closure.

2. (New) The medical implant of claim 1, wherein each groove includes an outer facing surface.

3. (New) The medical implant of claim 2, wherein the outer facing surfaces of the grooves extend in a direction parallel to the longitudinal axis.

4. (New) The medical implant of claim 1, wherein each groove includes a downward facing surface.

5. (New) The medical implant of claim 4, wherein the downward facing surfaces of the grooves are planar.

6. (New) The medical implant of claim 5, wherein each downward facing surface of the grooves are parallel with one another.

7. (New) The medical implant of claim 1, wherein each groove includes an upward facing surface.

8. (New) The medical implant of claim 7, wherein the upward facing surfaces of the grooves are planar.

9. (New) The medical implant of claim 8, wherein each upward facing surface of the grooves are parallel with one another.

10. (New) The medical implant of claim 1, wherein each groove is interrupted by a vertical slot on the respective side face surface.

11. (New) The medical implant of claim 10, wherein each vertical slot extends to the respective top side surface.

12. (New) The medical implant of claim 10, wherein each vertical slot includes an aperture in communication with the channel.

13. (New) The medical implant of claim 1, wherein the first and second discontinuous helically wound structure comprises one of a reverse angle thread, a square thread, a buttress thread, or a helical flange form.

14. (New) The medical implant of claim 1, wherein the first and second arm each has a breakoff extension.

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01432; Petitioners' EX1002
Page 58 of 391

Amendments to the Specification:

Please replace the TITLE of the as-filed specification with the following replacement title.

MEDICAL IMPLANT ~~TOP NOTCH~~ RECEIVERS HAVING DUAL LEAD IN CLOSURE MATING THREAD FORMS AND CURVATE EXTENDING INSTRUMENT ENGAGING GROOVES

PTO/SB/06 (09-11)
Approved for use through 1/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 16/779,304	Filing Date 01/31/2020	☐ To be Mailed

ENTITY: ☑ LARGE ☐ SMALL ☐ MICRO

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA		RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A		N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (l), or (m))	N/A	N/A		N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*		x $100 =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*		x $460 =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).				
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))					
* If the difference in column 1 is less than zero, enter "0" in column 2.				TOTAL	

APPLICATION AS AMENDED - PART II

AMENDMENT	05/29/2020	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 14	Minus	** 20	= 0		x $100 =	0
	Independent (37 CFR 1.16(h))	* 1	Minus	*** 3	= 0		x $460 =	0
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	0

AMENDMENT		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	*	Minus	**	=		x $0 =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=		x $0 =	
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.	LIE
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".	/DELEACHES M YOUNG/
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".	
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.	

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

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UNITED STATES DEPARTMENT OF COMMERCE
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Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/779,304	01/31/2020	Roger P. Jackson	JAC023-644278	4759

24030 7590 06/12/2020
POLSINELLI PC
900 WEST 48TH PLACE
SUITE 900
KANSAS CITY, MO 64112-1895

EXAMINER	
COMSTOCK, DAVID C	

ART UNIT	PAPER NUMBER
3773	

NOTIFICATION DATE	DELIVERY MODE
06/12/2020	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

uspt@polsinelli.com

Office Action Summary	Application No. 16/779,304	Applicant(s) Jackson et al.	
	Examiner DAVID C COMSTOCK	Art Unit 3773	AIA (FITF) Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on 29 May 2020.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☐ This action is **FINAL.** 2b)☑ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5) ☑ Claim(s) 1-14 is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6) ☐ Claim(s) _____ is/are allowed.

7) ☑ Claim(s) 1-14 is/are rejected.

8) ☐ Claim(s) _____ is/are objected to.

9) ☐ Claim(s) _____ are subject to restriction and/or election requirement

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to **PPHfeedback@uspto.gov.**

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☑ The drawing(s) filed on 31 January 2020 is/are: a)☑ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☑ Notice of References Cited (PTO-892)

2) ☐ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.

4) ☐ Other: _____.

DETAILED ACTION

Notice of Pre-AIA or AIA Status

The present application is being examined under the pre-AIA first to invent provisions.

Drawings

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: 169 (Figs. 3 and 8). Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include reference numerals for the apertures (claim 12), and further, the apertures are not described in the description. Corrected drawing sheets in compliance with 37 CFR 1.121(d), and an appropriate amendment to the specification to add the reference characters, are required in reply to the Office action to avoid abandonment of the application. Any amended

replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required:

The specification should be amended to provide proper antecedent basis for the claimed vertical slot(s) (claims 10-12) and the aperture(s) (claim 12). Applicant is reminded that no new matter beyond what can be properly and reasonably supported by the drawings should be added.

Claim Rejections - 35 USC § 103

In the event the determination of the status of the application as subject to AIA 35 U.S.C. 102 and 103 (or as subject to pre-AIA 35 U.S.C. 102 and 103) is incorrect, any correction of the statutory basis for the rejection will not be considered a new ground of rejection if the prior art relied upon, and the rationale supporting the rejection, would be the same under either status.

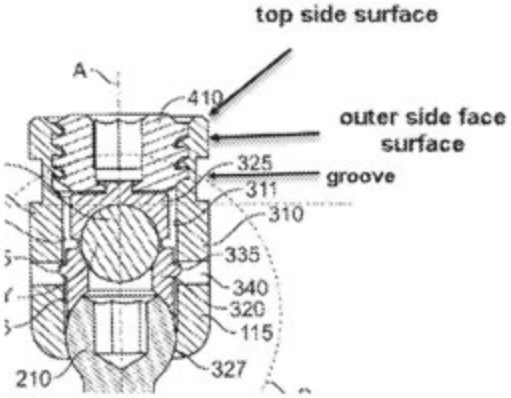
The following is a quotation of pre-AIA 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under pre-AIA 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of pre-AIA 35 U.S.C. 103(c) and potential pre-AIA 35 U.S.C. 102(e), (f) or (g) prior art under pre-AIA 35 U.S.C. 103(a).

Claims 1-9, 13 and 14 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Garamszegi (2008/0045953) in view of Boschert (2005/0277928).

Garamszegi discloses medical implant assembly (Fig. 3) comprising: a receiver (115) having a longitudinal axis **A** and first and second arms (310; Fig. 4) extending in the same direction as the longitudinal axis. The receiver has a top side surface and an outer side face surface (see annotated Fig. 4 below).



A channel (315; Fig. 3) is formed by the first arm and the second arm and opening between a front outer face and a back outer face opposite the front outer face of the receiver. The channel is adapted to receive a longitudinal connecting member (120; Fig. 4). The channel is configured to be closed with a closure (e.g., 410, 325; Fig. 3) having an axis of rotation and a bottom surface (e.g., bottom of portion 325) configured to engage the longitudinal connecting member (Fig. 3). The receiver comprises discontinuous helically wound structure (i.e., the threads) on each of the interior surfaces of the arms opposite the outer side face surfaces thereof (see Fig. 3 and annotated Fig. 4 above). The threads engage threads on the closure. The closure (410, 325) is configured to be rotationally advanced within the channel until the bottom surface (bottom of portion 325) engages and locks the longitudinal connecting member within the channel. The first and second arm outer side face surfaces each have a curvate extending groove (see annotated Fig. 4 above and cf. Fig. 9) capable of being engaged by an instrument. Each groove extends horizontally to the front and back outer face of each arm and is located adjacent the top side surface on each arm (id.). An entirety of each groove is located above a top surface of the longitudinal connecting member when the longitudinal connecting member

is received and locked in the channel by the closure (Fig. 4). Additionally, each arm includes an aperture (340) in communication with the channel (id.).

Thus, Garamszegi discloses the claimed invention except for the closure having a first helically wound thread form and a second continuously helically wound thread form, each with their own starts (i.e., double-start thread), such that rotation of the closure causes simultaneous mating of the threads on each arm with the closure. Boschert also discloses a medical implant assembly (10; Fig. 1) and teaches that "the threads 72 of the setscrew 70 can also be designed with a double lead to allow the setscrew 70 to start more easily than with a single lead" (see para. 0057). It would have been obvious to a person having ordinary skill in the art at the time of the invention to have provided the closure of Garamszegi with double-start (i.e., double lead) threads, in view of Boschert, in order to allow the closure (i.e., setscrew) to start more easily.

Regarding claim 2, each groove includes an outer facing surface (Fig. 4).

Regarding claim 3, the outer facing surfaces of the grooves extend in a direction parallel to the longitudinal axis (i.e., they extend vertically as well as circumferentially)(Fig. 4; cf. Fig. 9).

Regarding claims 4-9, each groove includes a planar downward facing surface (Fig. 4; cf. Fig. 9) that is parallel with one another. Likewise, each groove includes a planar upward facing surface that is parallel with one another (id.).

Regarding claim 13, the discontinuous helically wound structure comprises a reverse angle thread (see, e.g., Fig. 4).

Regarding claim 14, the first and second arm each has a breakoff extension (310; Fig. 3; para. 0080).

Claims 10-12 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Garamszegi (2008/0045953) in view of Boschert (2005/0277928), as applied to claim 1 above, and further in view of Hammill, SR. et al. (2010/0125302; hereinafter "Hammill").

The device of Garamszegi and Boschert discloses the claimed invention except for the vertical slot on the side face surfaces (that would interrupt the groove and include the aperture, as described above). Hammill teaches that vertical slots (90; e.g., Figs. 11 and 12) can be provided on side face surfaces of a receiver to allow a counter-torque tool to apply a counter torque to prevent the receiver from rotating while the closure is being tightened (see also para. 0098). It would have been obvious to a person having ordinary skill in the art at the time of the invention to have provided the receiver of the combination of Garamszegi and Boschert with vertical slots on the side face surfaces (that would interrupt the groove and include the aperture, as described above), in view of Hammill, in order to allow a counter-torque tool to apply a counter torque to prevent the receiver from rotating while the closure is being tightened. In further support of this combination, it is noted that Garamszegi teaches that "other types of drive couplers can be used" (para. 0067).

Regarding claim 11, each vertical slot extends to the respective top side surface (see, e.g., Fig. 2).

Regarding claim 12, it is noted that the vertical slots of Hammill are shown to be centered on each side wall (e.g., the figures show three slots on each side wall with the second slot being centered on each side wall; e.g., Fig. 1). As each aperture is centered on each side wall, and as a vertical slot of the combination is centered on each side wall, each center vertical

slot of the combination would also include the aperture that is in communication with the channel.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Comstock whose telephone number is (571) 272-4710. The examiner can normally be reached Monday-Friday, 9 a.m. - 6 p.m.

If attempts to reach the examiner by telephone are unsuccessful, ***please contact* the examiner's supervisor, SPE, *at* (571) 272-4719**. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/DAVID C COMSTOCK/
Examiner, Art Unit 3773

/EDUARDO C ROBERT/
Supervisory Patent Examiner, Art Unit 3773

Notice of References Cited	Application/Control No. 16/779,304	Applicant(s)/Patent Under Reexamination Jackson et al.	
	Examiner DAVID C COMSTOCK	Art Unit 3773	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	CPC Classification	US Classification
*	A	US-20030100896-A1	05-2003	Biedermann, Lutz	F16B43/02	606/305
*	B	US-20030088248-A1	05-2003	Reed, Gary Jack	A61B17/7041	606/308
*	C	US-20050277928-A1	12-2005	Boschert, Paul F.	A61B17/7037	606/328
*	D	US-20080015596-A1	01-2008	Whipple; Dale E.	A61B17/8685	606/86A
*	E	US-20080045953-A1	02-2008	Garamszegi; Laszlo	A61B17/7032	606/86A
*	F	US-20090221879-A1	09-2009	Gorek; Josef	A61B17/708	600/214
*	G	US-20100004692-A1	01-2010	Biedermann; Lutz	A61B17/7098	606/305
*	H	US-20100036417-A1	02-2010	James; Anthony	A61B17/8605	606/246
*	I	US-20100125302-A1	05-2010	Hammill, SR.; John E.	A61B17/7038	606/308
*	J	US-20110152947-A1	06-2011	KIRSCHMAN; DAVID LOUIS	A61B17/8665	606/302
*	K	US-20110208248-A1	08-2011	Barrus; Michael	A61B17/7037	606/305
*	L	US-20120029578-A1	02-2012	Suh; Sean	A61B17/864	606/309
	M					

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	CPC Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/779,304	Jackson et al.
	Examiner	Art Unit
	DAVID C COMSTOCK	3773

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

CLAIMS

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	06/08/2020								
	1	✓								
	2	✓								
	3	✓								
	4	✓								
	5	✓								
	6	✓								
	7	✓								
	8	✓								
	9	✓								
	10	✓								
	11	✓								
	12	✓								
	13	✓								
	14	✓								

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01432; Petitioners' EX1002
Page 72 of 391

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/779,304	Jackson et al.
	Examiner	Art Unit
	DAVID C COMSTOCK	3773

CPC - Searched*		
Symbol	Date	Examiner
A61B17/7035,7032,863,84,8665,8685	06/08/2020	/DC/
A61B2090/037	06/08/2020	/DC/
A61B2017/8655	06/08/2020	/DC/

CPC Combination Sets - Searched*		
Symbol	Date	Examiner

US Classification - Searched*			
Class	Subclass	Date	Examiner
606	265,266,270,273,275,315	06/08/2020	/DC/

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

Search Notes		
Search Notes	Date	Examiner
Text search--see EAST search history	06/08/2020	/DC/
Inventor name search--see EAST search history	06/08/2020	/DC/

Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner

/DAVID C COMSTOCK/ Examiner, Art Unit 3773	

Zimvie_Zimmer Biomet v. Jackson
IPR2023-01432; Petitioners' EX1002
Page 73 of 391

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
S2	971	((("JACKSON") near3 ("Roger")) OR (("SURBER") near3 ("James"))).INV.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2020/06/07 21:26
S3	10,936	A61B17/7035,7032,863,84,8665,8685.cpc. A61B2090/037.cpc. A61B2017/8655.cpc.	US-PGPUB; USPAT; USOCR	OR	ON	2020/06/07 21:37
S4	1,068	(606/265,266,270,273,275,315).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2020/06/07 21:38
S5	134	S2 and ((dual with start with thread$2) or (dual with lead with thread$2) or (double with thread$2) or (dual with thread$2))	US-PGPUB; USPAT; USOCR	OR	ON	2020/06/07 21:39
S6	579	S2 and (reverse with angle)	US-PGPUB; USPAT; USOCR	OR	ON	2020/06/07 21:43
S7	799	(S3 S4) and ((dual with start with thread$2) or (dual with lead with thread$2) or (double with thread$2) or (dual with thread$2))	US-PGPUB; USPAT; USOCR	OR	ON	2020/06/07 21:48
S8	687	S7 not (jackson.in.)	US-PGPUB; USPAT; USOCR	OR	ON	2020/06/07 21:48
S9	104	(S3 S4) and (((dual with start with thread$2) or (dual with lead with thread$2) or (double with thread$2) or (dual with thread$2)) same (closure or setscrew or "set screw" or cap))	US-PGPUB; USPAT; USOCR	OR	ON	2020/06/07 21:50
S10	61	S9 not jackson.in.	US-PGPUB; USPAT; USOCR	OR	ON	2020/06/07 21:50
S11	626	S8 not S10	US-PGPUB;	OR	ON	2020/06/07 21:58

			USPAT; USOCR			
S17	1,769	A61B17/7035.cpc.	US-PGPUB; USPAT; USOCR	OR	ON	2020/06/07 22:28
S22	4,693	A61B17/7032.cpc.	US-PGPUB; USPAT; USOCR	OR	ON	2020/06/08 00:04
S23	3,399	S22 not (S7 S9 S17 S21)	US-PGPUB; USPAT; USOCR	OR	ON	2020/06/08 00:05
S24	2,229	S23 and @pd<"20150101"	US-PGPUB; USPAT; USOCR	OR	ON	2020/06/08 00:06
S25	2,068	S24 not jackson.in.	US-PGPUB; USPAT; USOCR	OR	ON	2020/06/08 00:07

6/8/2020 9:31:19 AM
C:\Users\dcomstock\Documents\EAST\Workspaces\16779304.wsp

Bibliographic Data

Application No: 16/779,304

Foreign Priority claimed: ○ Yes ◉ No

35 USC 119 (a-d) conditions met: ☐ Yes ☑ No ☐ Met After Allowance

Verified and Acknowledged: /DAVID C COMSTOCK/ (Examiner's Signature) | (Initials)

Title: TOP NOTCH RECEIVERS HAVING DUAL LEAD IN CLOSURE MATING THREAD FORMS

FILING or 371(c) DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
01/31/2020	606	3773	JAC023-644278
RULE			

APPLICANTS

Roger P. Jackson, Prairie Village, KS, UNITED STATES

INVENTORS

Roger P. Jackson Prairie Village, KS, UNITED STATES

James L. Surber Kansas City, KS, UNITED STATES

CONTINUING DATA

This application is a CON of 15964502 04/27/2018 PAT 10548641

15964502 is a CON of 15469076 03/24/2017 PAT 9956004

15469076 is a CON of 14566356 12/10/2014 PAT 9636146

14566356 is a CON of 13694849 01/10/2013 PAT 8911479

13694849 has PRO of 61634361 02/28/2012

13694849 has PRO of 61631746 01/10/2012

FOREIGN APPLICATIONS

IF REQUIRED, FOREIGN LICENSE GRANTED**

02/20/2020

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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 16/779,304	Filing Date 01/31/2020	☐ To be Mailed

ENTITY: ☑ LARGE ☐ SMALL ☐ MICRO

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA		RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A		N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (l), or (m))	N/A	N/A		N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*		x $100 =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*		x $460 =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).				
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))					
* If the difference in column 1 is less than zero, enter "0" in column 2.				TOTAL	

APPLICATION AS AMENDED - PART II

AMENDMENT	09/01/2020	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 20	Minus	** 20	= 0		x $100 =	0
	Independent (37 CFR 1.16(h))	* 1	Minus	*** 3	= 0		x $460 =	0
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	0

AMENDMENT		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	*	Minus	**	=		x $0 =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=		x $0 =	
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.	LIE
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".	/LINDA HUMES/
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".	
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.	

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Inventor(s):	Roger P. Jackson		
App. No.:	16/779,304	Con. No.:	4759
Filed:	January 31, 2020	Art Unit:	3773
Title:	MEDICAL IMPLANT RECEIVERS HAVING DUAL LEAD IN CLOSURE MATING THREAD FORMS AND CURVATE EXTENDING INSTRUMENT ENGAGING GROOVES	Examiner:	COMSTOCK, David C

AMENDMENT AND RESPONSE TO OFFICE ACTION

Via EFS-Web
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Commissioner:

In response to the non-final Office Action dated June 12, 2020, please consider the following remarks and amend the above-identified application as follows:

Amendments to the Specification begin on page 2 of this paper;

Amendments to the Claims begin on page 3;

Amendments to the Drawings begin on page 6; and

Remarks begin on page 7 of this paper.

Fig. 18.

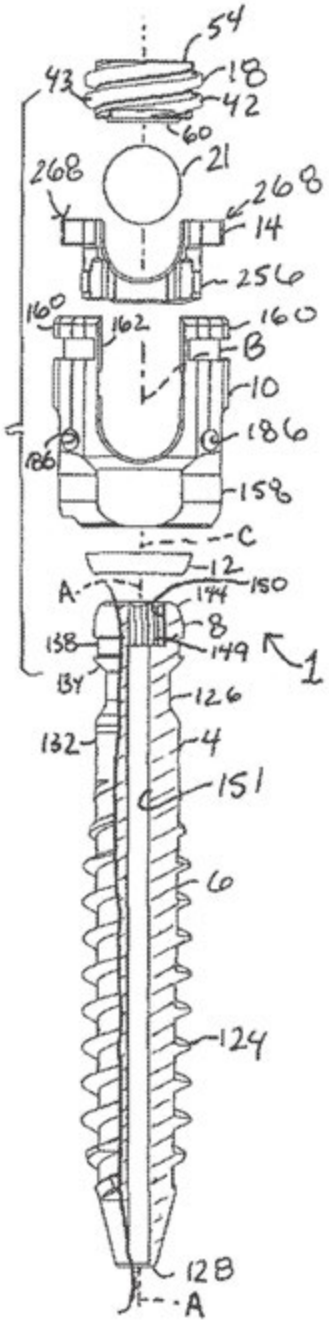


Fig. 19.

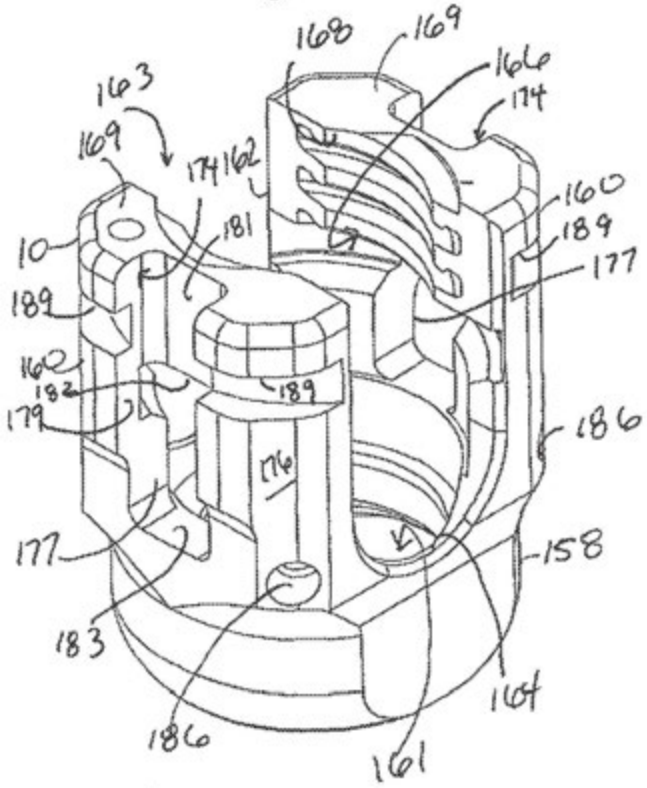


Fig. 20.

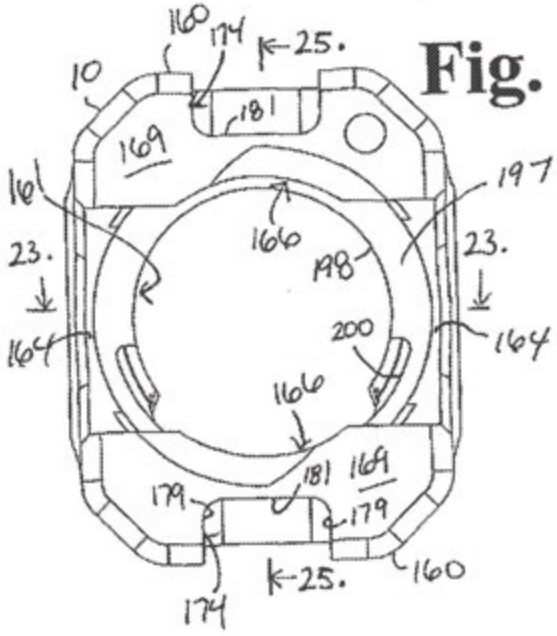


Fig. 21.

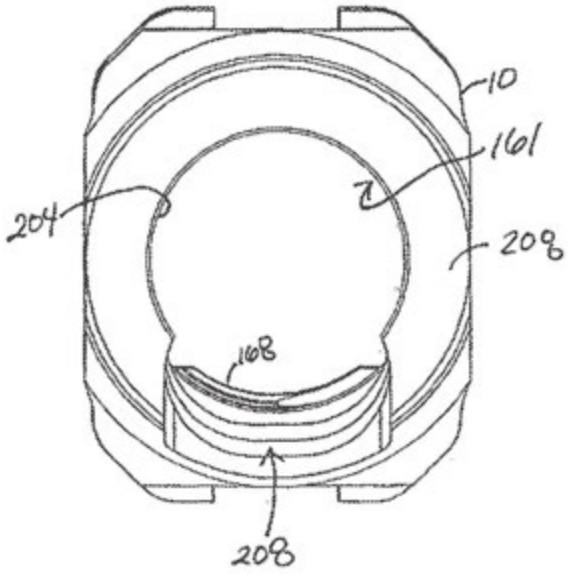


Fig. 22.

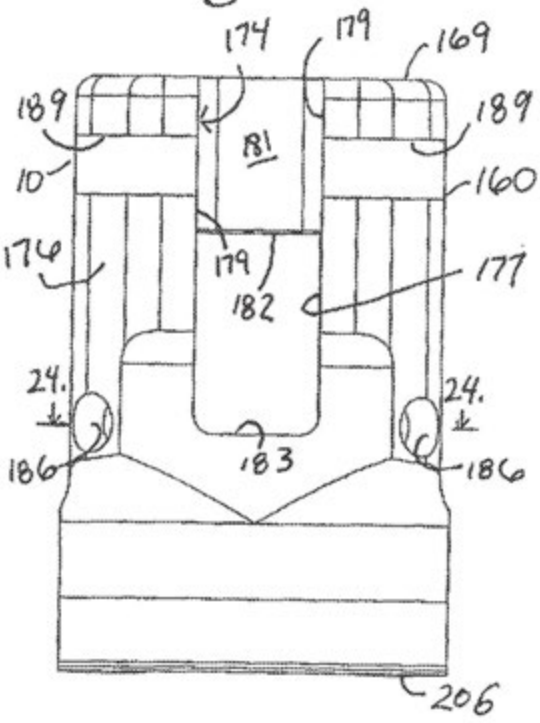


Fig. 23.

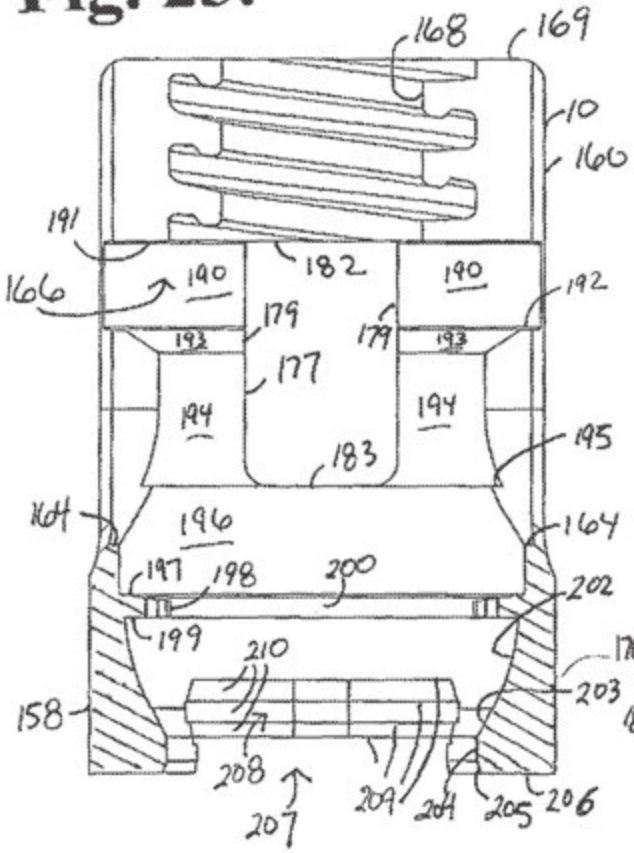


Fig. 24.

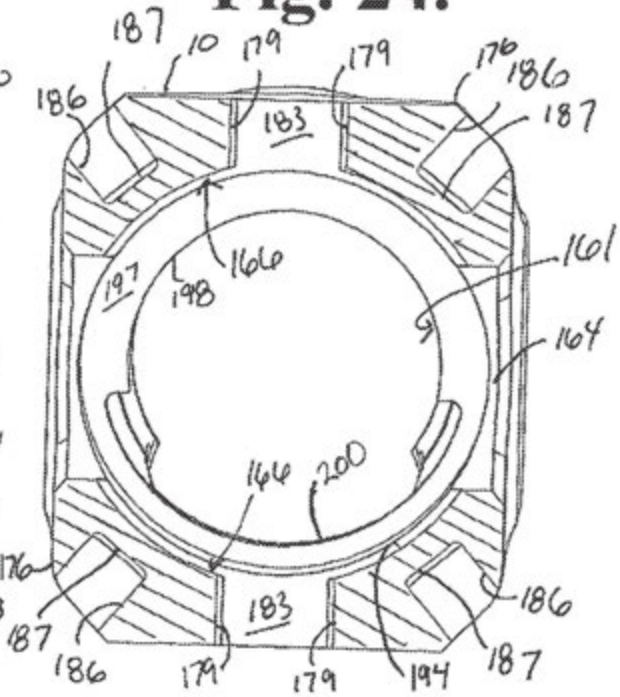


Fig. 25.

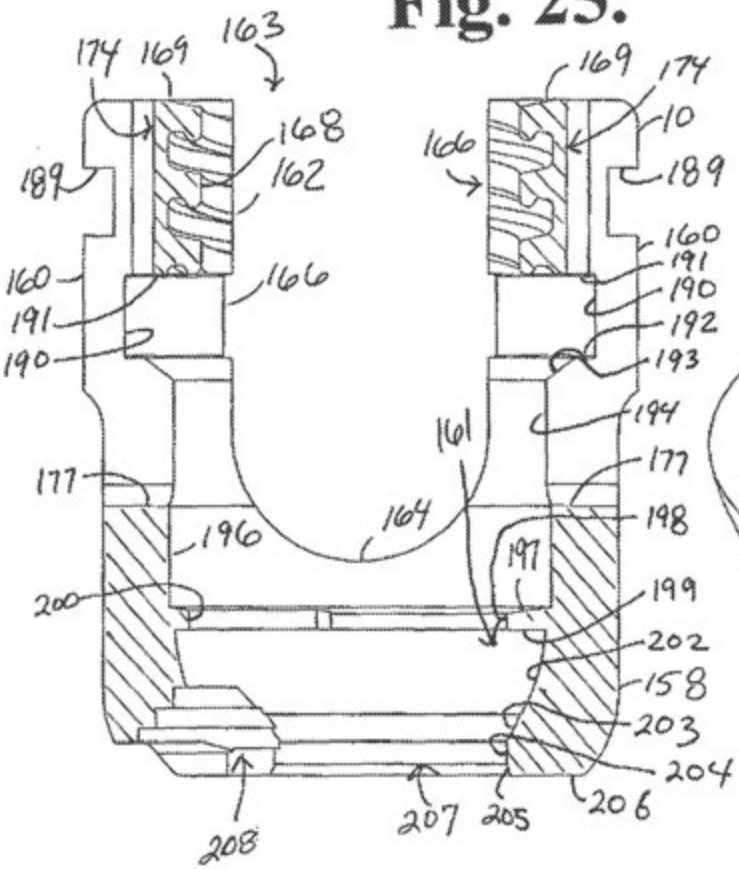


Fig. 26.

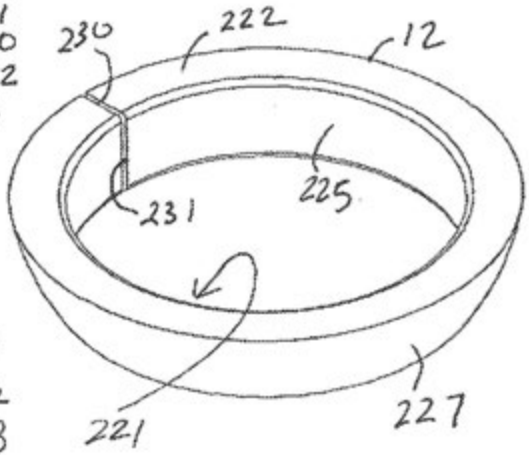
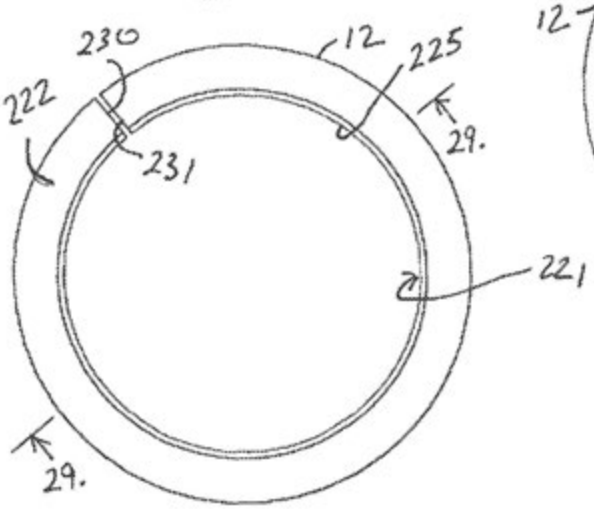


Fig. 27.



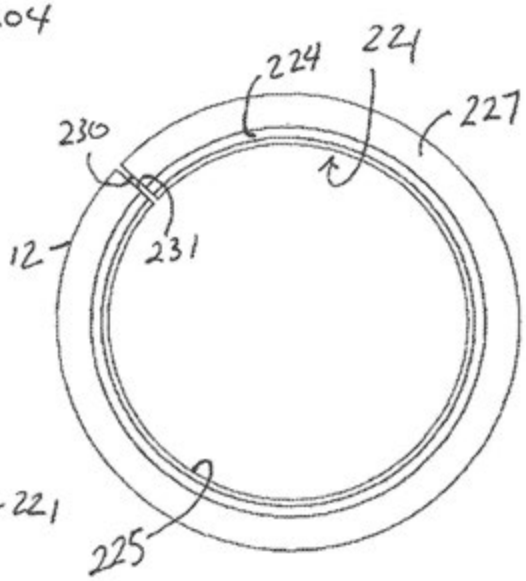


Fig. 28.

Fig. 29.

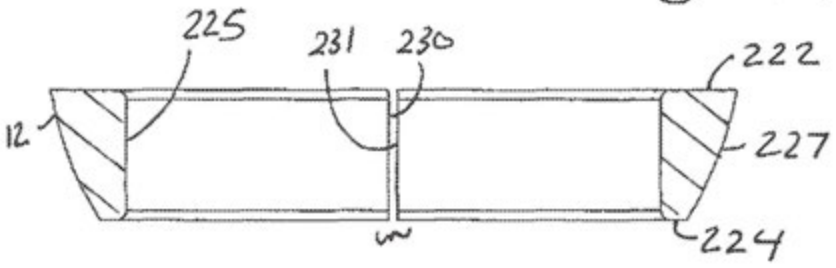


Fig. 30.

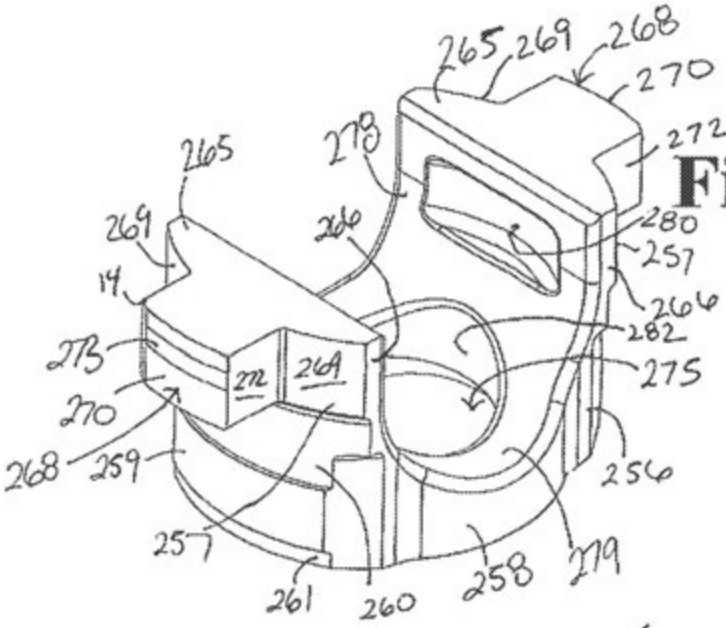


Fig. 31.

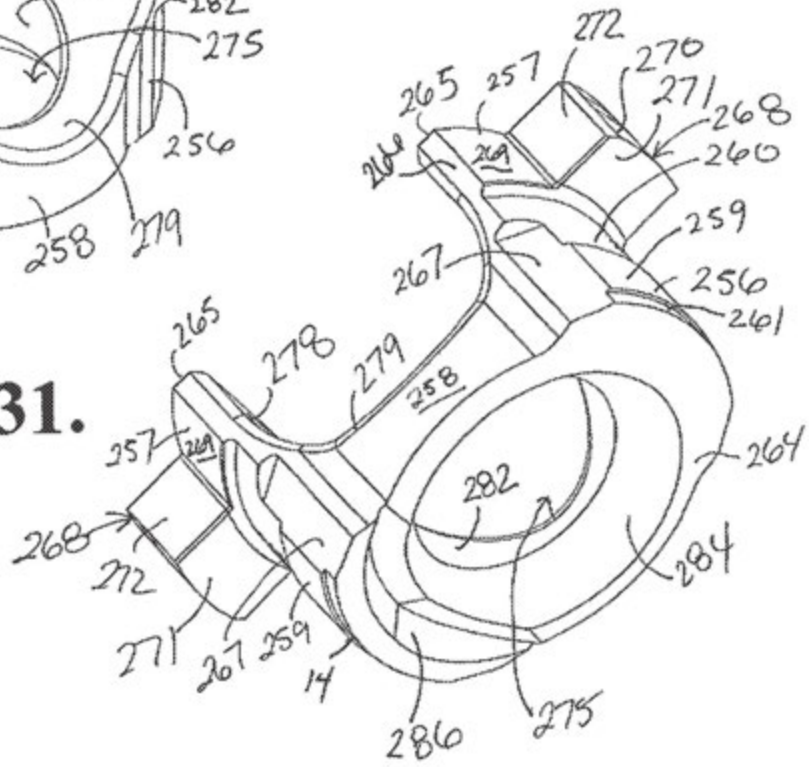


Fig. 32.

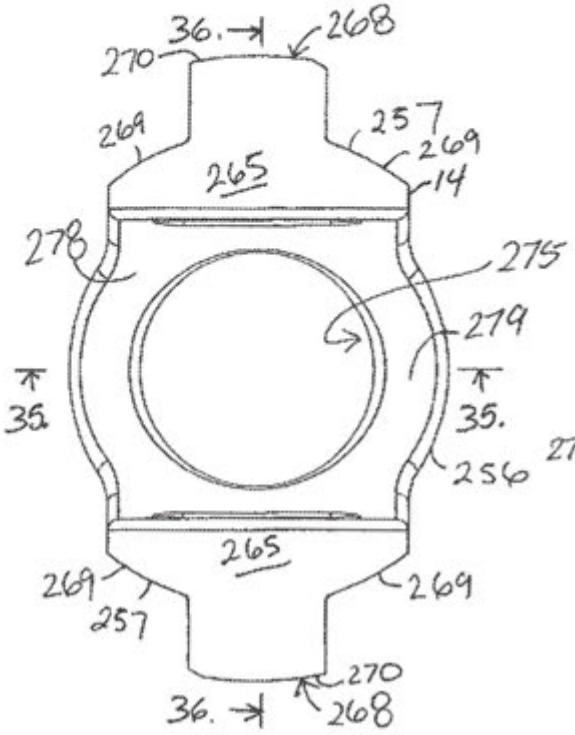


Fig. 33.

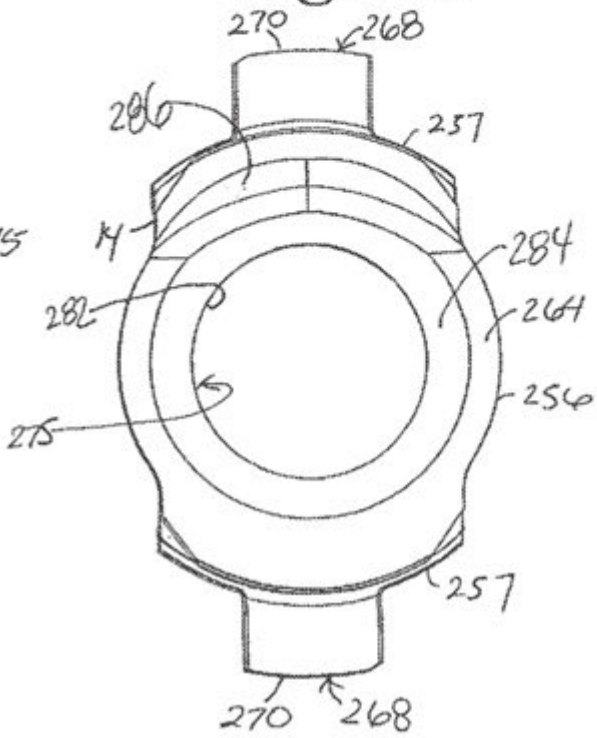


Fig. 34.

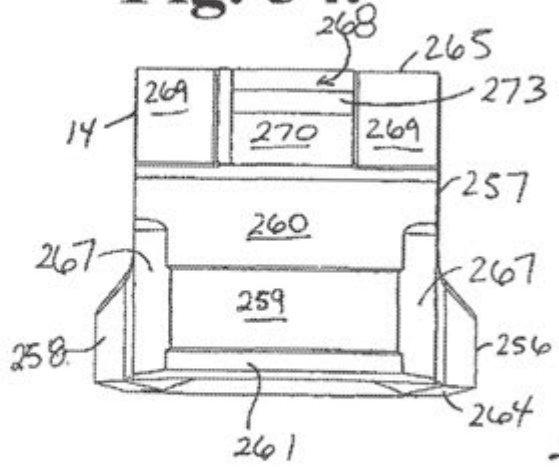
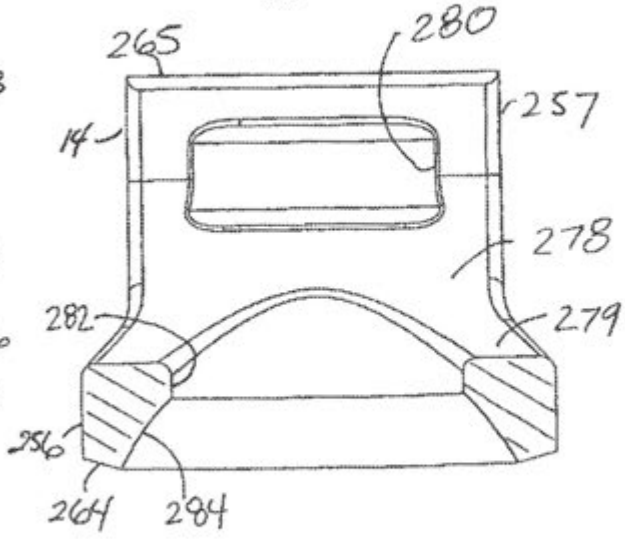


Fig. 35.



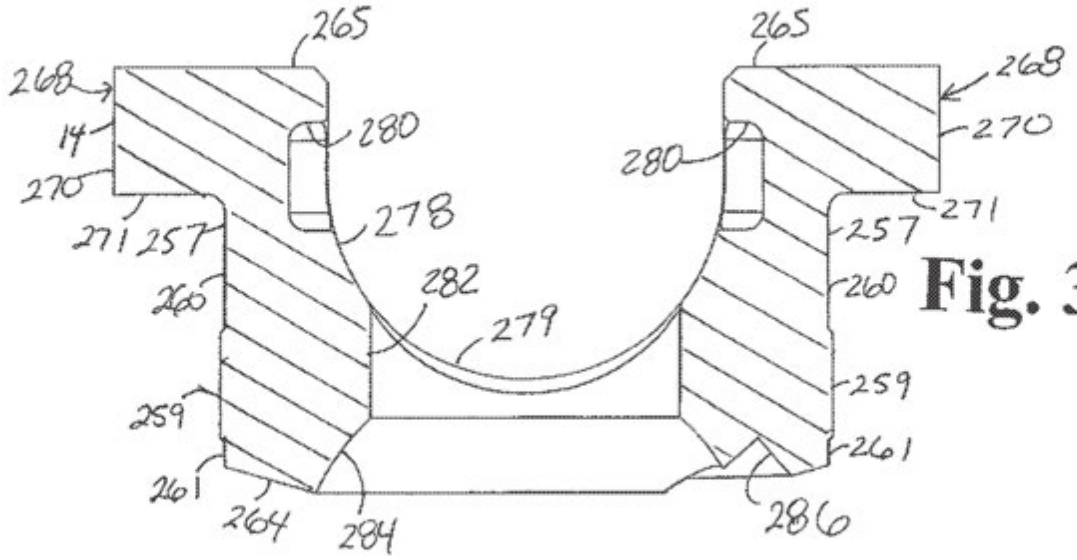


Fig. 36.

Fig. 37.

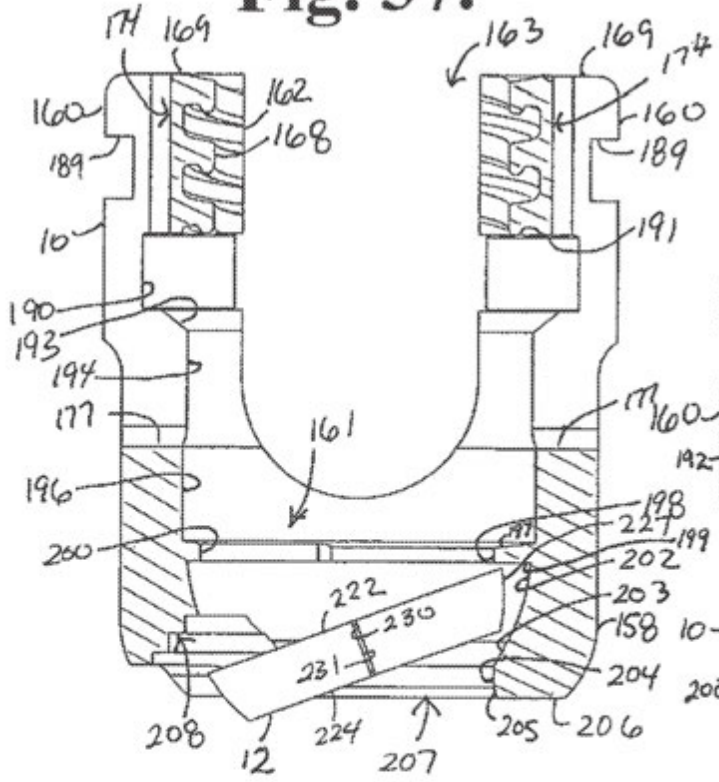


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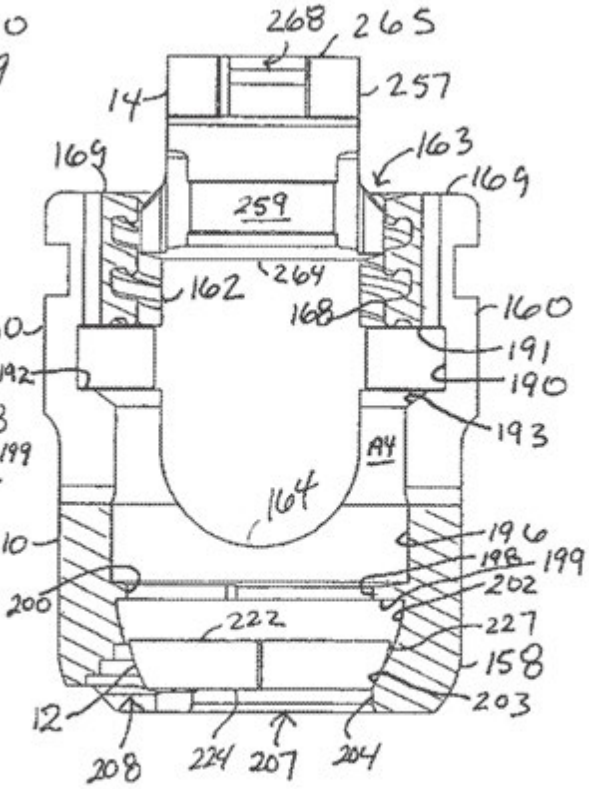


Fig. 39.

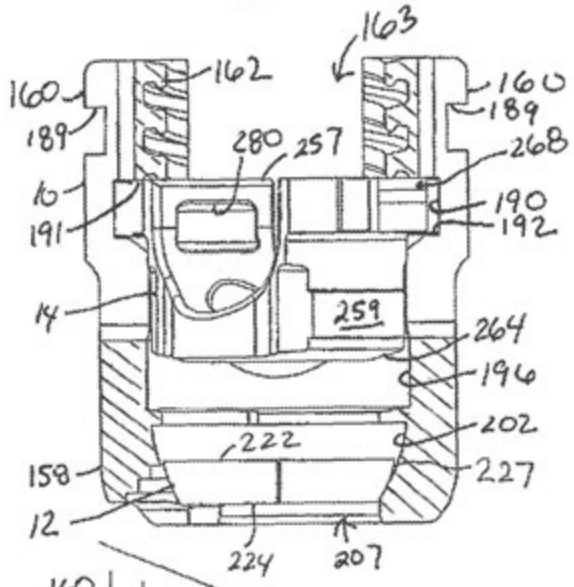


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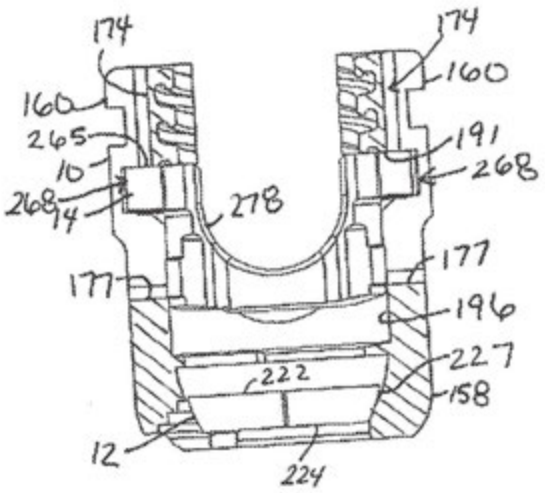


Fig. 41.

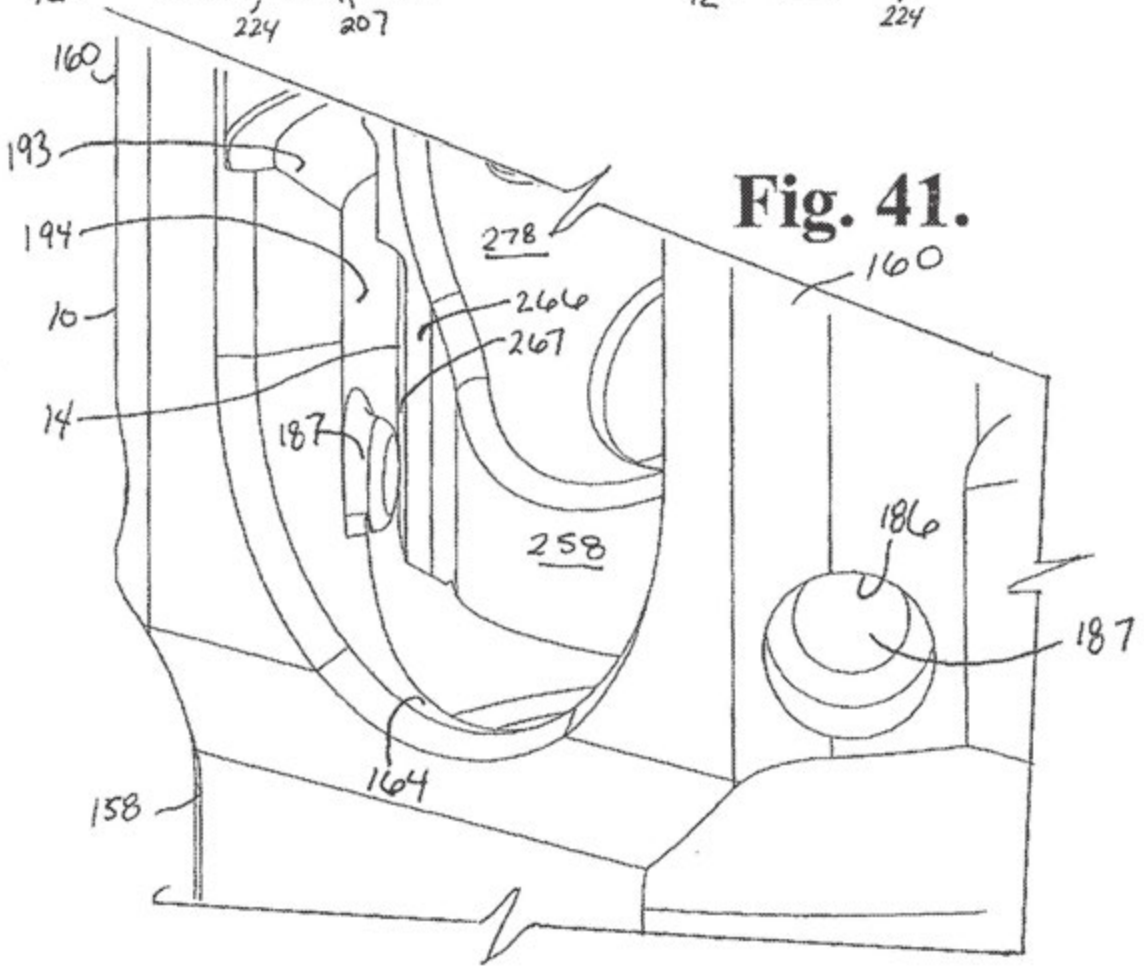


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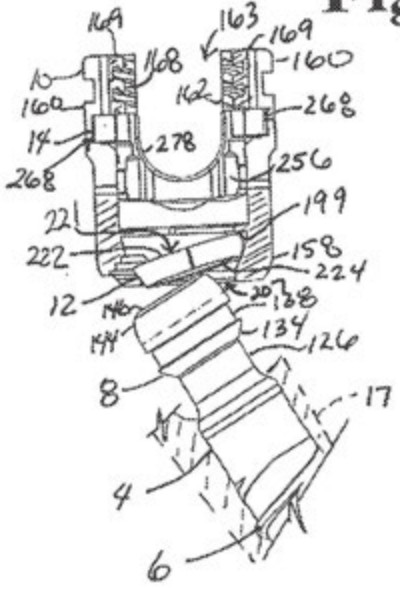


Fig. 43.

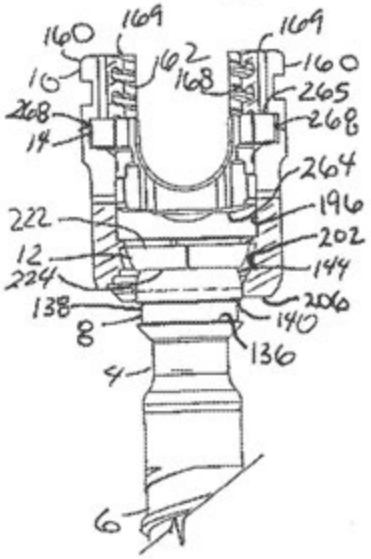


Fig. 44.

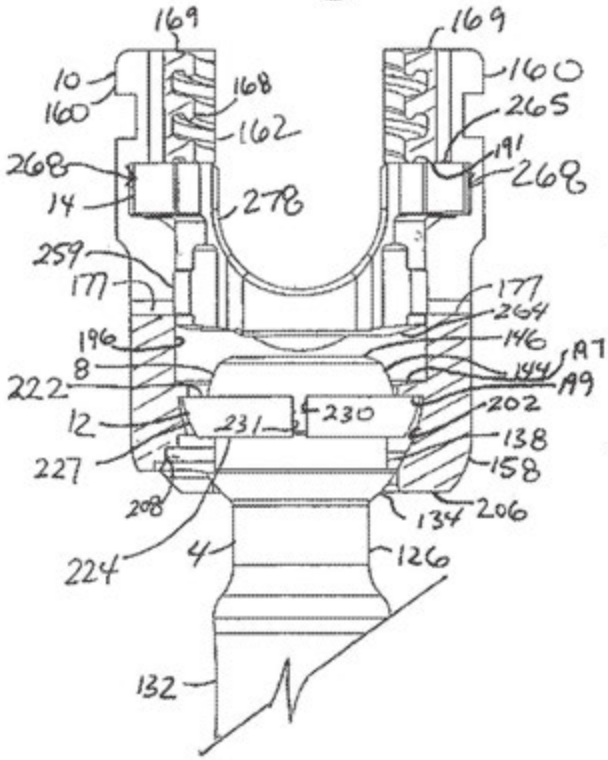


Fig. 45.

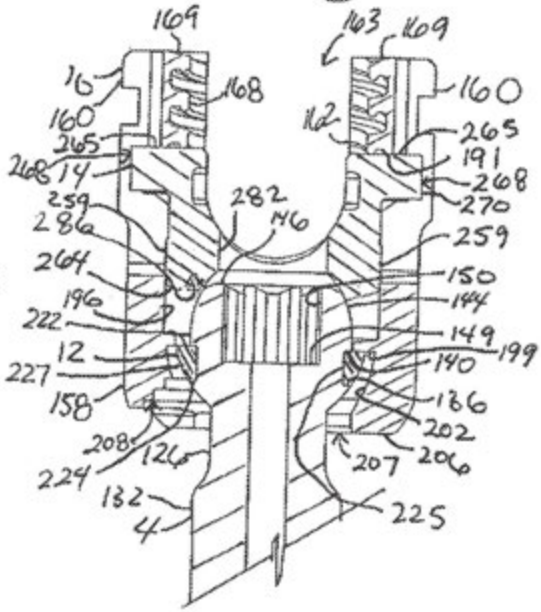


Fig. 46.

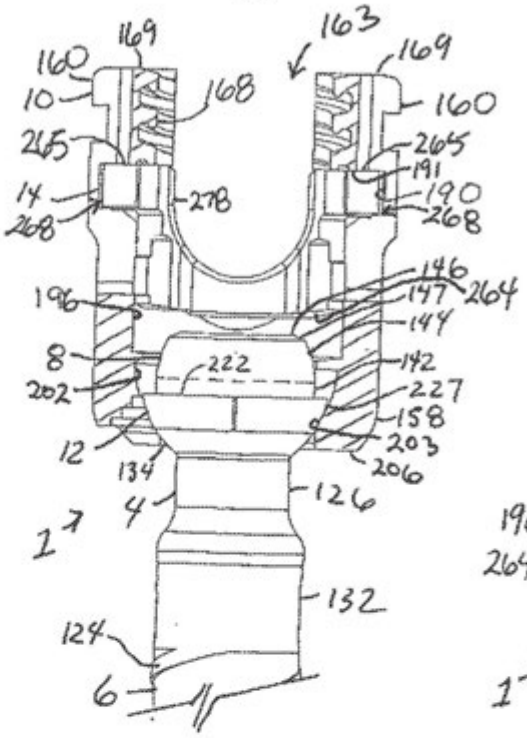


Fig. 47.

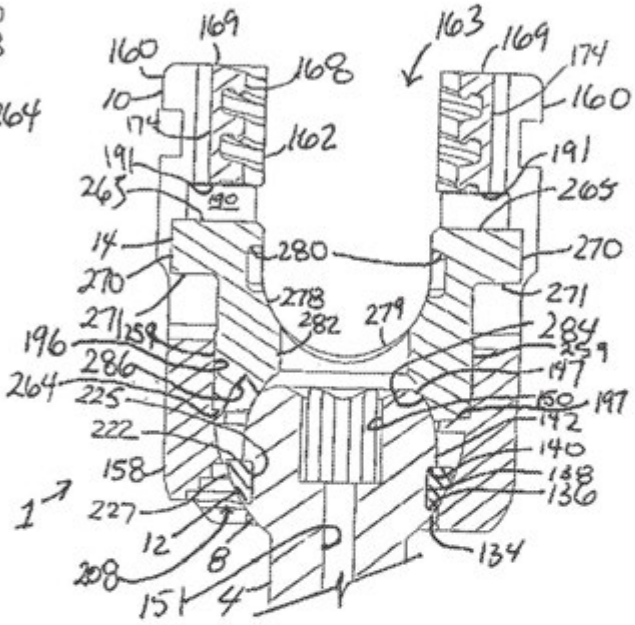


Fig. 48.

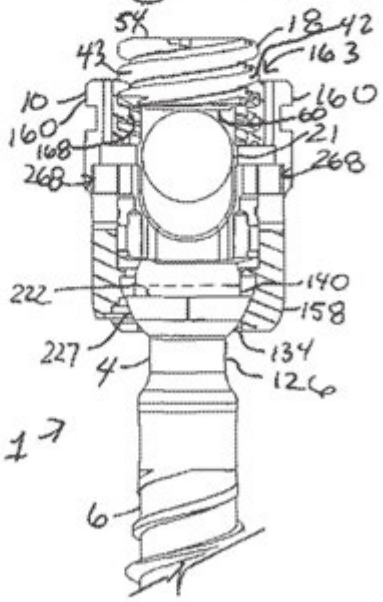


Fig. 49.

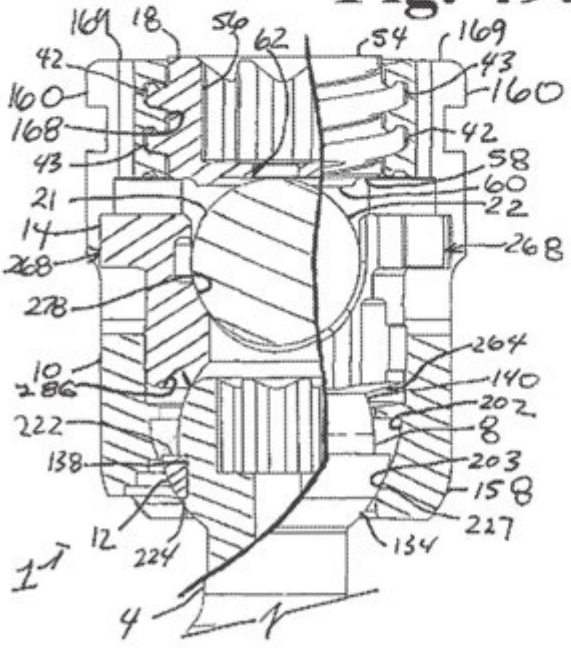


Fig. 50.

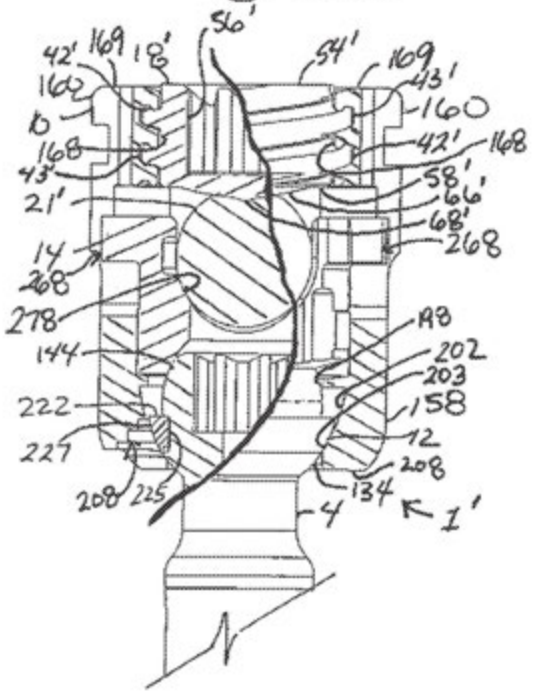


Fig. 51.

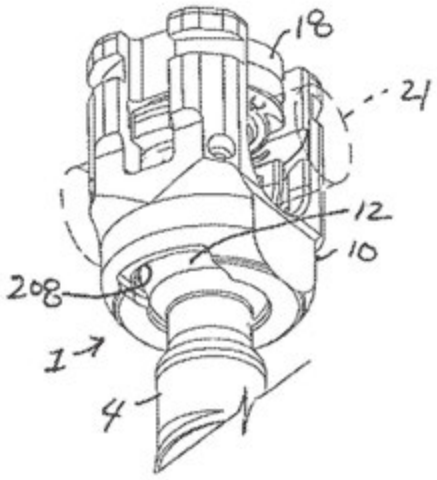


Fig. 52.

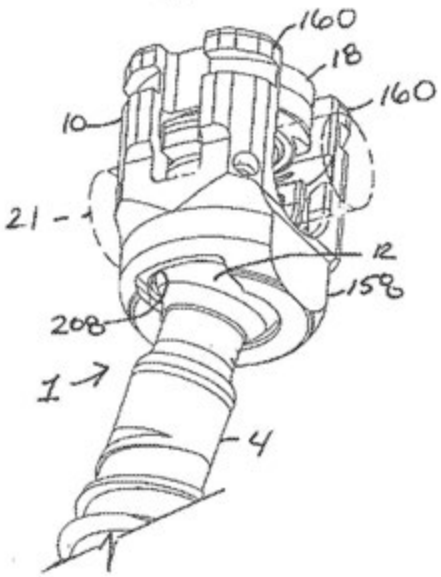


Fig. 53.

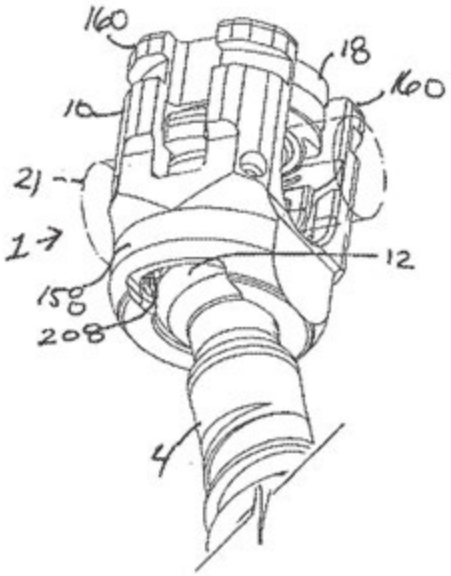


Fig. 54.

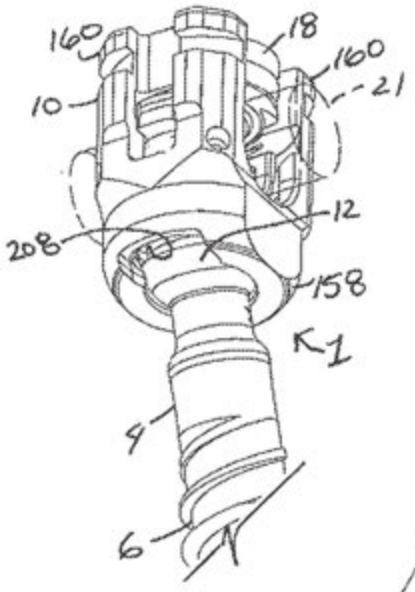


Fig. 55.

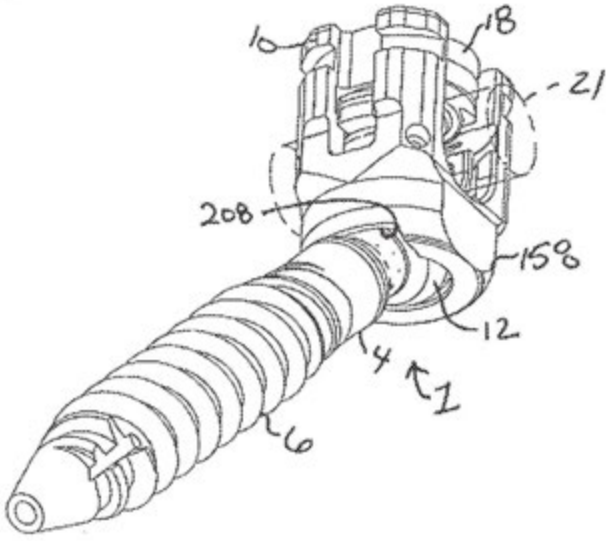


Fig. 56.

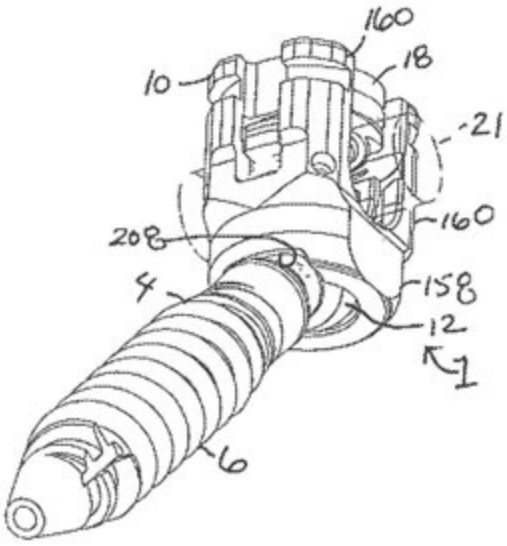


Fig. 57.

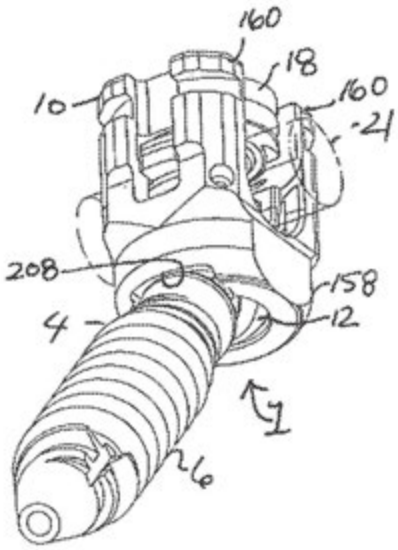
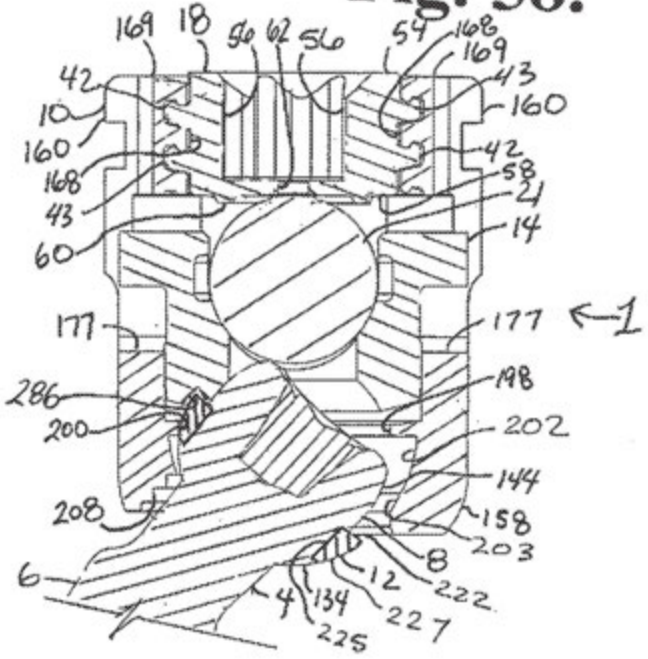


Fig. 58.


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SUBSTITUTE SPECIFICATION – CLEAN VERSION

MEDICAL IMPLANT RECEIVERS HAVING DUAL LEAD IN CLOSURE MATING THREAD FORMS AND CURVATE EXTENDING INSTRUMENT ENGAGING GROOVES

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] The present application is a continuation of U.S. Patent Application No. 15/964,502, filed April 27, 2018, now U.S. Patent No. 10,548,641, which is a continuation of U.S. Patent Application No. 15/469,076, filed March 24, 2017, now U.S. Patent No. 9,956,004, which is a continuation of U.S. Patent Application No. 14/566,356, filed December 10, 2014, now U.S. Patent No. 9,636,146, which is a continuation of U.S. Patent Application No. 13/694,849, filed January 10, 2013, now U.S. Patent No. 8,911,479, issued December 16, 2014, which claims the benefit of U.S. Provisional Application No. 61/631,746, filed January 10, 2012 and U.S. Provisional Application No. 61/634,361, filed February 28, 2012, all of which are incorporated by reference herein for all purposes.

BACKGROUND OF THE INVENTION

[0002] The present invention is directed to structure for joining together parts of a medical implant, in particular to closure mechanisms for use with open bone anchors in spinal surgery, and in some embodiments thereof, for use with spinal bone anchors such as polyaxial screws.

[0003] Bone anchors, such as bone screws and hooks are utilized in many types of spinal surgery in order to secure various implants to vertebrae along the spinal column for the purpose of stabilizing and/or adjusting spinal alignment. For example, the most common mechanism for providing vertebral support is to implant bone screws into certain bones which then in turn support a rod or are supported by the rod. Although both closed-ended and open-ended bone anchors are known, open-ended anchors are particularly well suited for connections to longitudinal connecting members such as hard, soft or deformable rods, dynamic or elastic connectors and connector arms, because such rods or other connector members do not need to be passed through a closed bore, but rather can be laid or urged into an open channel within a receiver or head of such a bone anchor. Generally, the anchors must be inserted into the bone as

an integral unit or a preassembled unit, in the form of a shank or hook and connected pivotal receiver. In some instances, a portion of such a preassembled unit, such as a shank of a polyaxial bone screw assembly, may be independently implanted into bone, followed by push- or pop-on assembly of a receiver portion of the unit.

[0004] Typical open-ended bone screws include a threaded shank with a head or receiver having a pair of parallel projecting branches or arms which form a yoke with a U-shaped slot or channel to receive a rod or other longitudinal connecting member. Hooks and other types of connectors, as are used in spinal fixation techniques, may also include similar open ends for receiving rods or portions of other fixation and stabilization structure. The open-ended head or rod receiver portion of such implants typically includes a pair of spaced arms forming a channel closed by a closure member after the rod or other longitudinal connecting member is placed in the channel. Known closures include slide-on types, twist-on varieties that are rotated ninety degrees to a locked in position, and a variety of single start helically wound guide and advancement structures including, for example, thread forms having v-thread, reverse-angle buttress or square thread forms, to name a few, as well as other non-threadlike helically wound forms. Sometimes threaded plugs are utilized with outer threaded nuts to prevent splaying of the receiver arms.

[0005] As indicated above, the force required to press a closure structure down onto a rod or other connector located between arms of an open implant is considerable. Even though a head or receiver portion of an open polyaxial bone anchor may be pivoted in a direction to make it easier for the arms of the open implant to receive a rod or other connector, spinal misalignments, irregularities and the placement of other surgical tools make it difficult to place the rod or other connector between the arms of the implant while a closure structure is mated with the open implant as well as used to push the rod or other connector downwardly into the implant. For example, when the closure is a cylindrical plug having a single start helically wound guide and advancement structure, such structure must be aligned with mating structure on one of the implant arms and then rotated until a portion of the structure is captured by mating guide and advancement structure on both arms of the implant, all the while the closure is being pressed down on the rod while other forces are pushing and pulling the rod back out of the implant. Integral or mono-axial open implants that cannot be pivoted to receive the rod are even more

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difficult to manipulate during the initial placement of the rod and initial mating rotation of a closure plug between the spaced, open arms of the implant. Therefore, extraordinary forces are placed on the implant and closure plug while the surgeon either pushes down on the rod or pulls up on the bone to get the rod in position between the implant arms and to initially push down upon the rod with the closure plug.

SUMMARY OF THE INVENTION

[0006] A closure structure, top or plug of the invention for insertion between spaced arms of an open medical implant includes one or more helically wound guide and advancement features, each feature having a start surface or structure located at or near a bottom surface of the closure plug, each start structure simultaneously engaging and being captured by each of the spaced arms of the open implant upon initial rotation of the closure structure with respect to the open implant arms. According to an aspect of the invention, a double-start closure is disclosed having two helically wound forms thereon, each form having a start structure for simultaneously engaging a mating helical form on a respective open implant arm. Each time the illustrated duel- or double-start closure plug is rotated one turn (three hundred sixty degrees) between the implant arms, the closure plug advances axially into the implant and toward the rod by a width of two helical forms. The helically wound forms of the multi-start closure spiral around a cylindrical plug body thereof to an extent that the closure rotates over ninety degrees to fully or substantially receive the entire closure plug between the arms of the open implant. The illustrated closure is sized for at least one complete rotation (three hundred sixty degrees) of the plug with respect to the open implant to substantially receive the plug between the implant arms. Multi-start closures of the invention may have two or more coarse or fine helical forms, resulting in fewer or greater forms per axial distance spiraling about the closure plug body and thus resulting in plugs that rotate less (when more coarse) or more (when thin or fine) than one complete rotation to be fully received between the implant arms, typically, at least a ninety-one degree rotation is preferred.

[0007] An illustrated multi-start closure and mating open implant is in the form of non-threaded, interlocking flange forms. Also disclosed are multi-start closure structures provided with helically wound forms of other geometry, including, but not limited to helically wound

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threads such as reverse angle, buttress, square and v-threads. The multi-start closure may be cannulated for minimally invasive surgical applications.

[0008] Another illustrated multi-start closure embodiment of the invention is shown with a bone screw assembly having an open receiver with a pair of opposed arms, each arm having guide and advancement structure for simultaneous mating engagement with a start of the helically wound multi-start closure. A further embodiment according to the invention includes an open bone anchor receiver having integral upwardly extending break-off tabs that also have the guide and advancement structure for mating with the multi-start closure. A further embodiment includes an attachable/detachable guide tool cooperating with such a multi-start open receiver, the tool having inner guide and advancement structures located near a bottom thereof for rotatably and matingly receiving the multi-start closure and being synchronized with the receiver guide and advancement structure for rotating and driving the multi-start closure downward from the guide tool to the receiver.

[0009] Objects of the invention further include providing apparatus and methods that are easy to use and especially adapted for the intended use thereof and wherein the tools are comparatively inexpensive to produce. Other objects and advantages of this invention will become apparent from the following description taken in conjunction with the accompanying drawings wherein are set forth, by way of illustration and example, certain embodiments of this invention.

[0010] The drawings 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 DRAWINGS

[0011] FIG. 1 is a perspective view of an embodiment of a multi-start closure according to the invention.

[0012] FIG. 2 is another perspective view of the multi-start closure of FIG. 1.

[0013] FIG. 3 is a front elevational view of the closure of FIG. 1 shown with a portion of a receiver of a polyaxial bone screw according to FIG. 8, the receiver shown in partial front

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elevation with portions broken away to show the detail thereof, and further showing a rod being pressed upon by the closure, the rod also in partial front elevation with portions broken away to show the detail thereof.

[0014] FIG. 4 is a reduced top plan view of the closure of FIG. 1.

[0015] FIG. 5 is a reduced bottom plan view of the closure of FIG. 1.

[0016] FIG. 6 is an enlarged front elevational view of the closure of FIG. 1 with portions broken away to show the detail thereof.

[0017] FIG. 7 is a reduced cross-sectional view taken along the line 7-7 of FIG. 6.

[0018] FIG. 8 a partial front elevational view of an open bone screw assembly, with portions broken away to show the detail thereof, including a receiver, a shank, a compression insert and also shown in engagement with the closure top of FIG. 1 (in reduced view) and a longitudinal connecting member in the form of a hard rod.

[0019] FIG. 9 is a front elevational view of an alternative closure of an embodiment of the invention, similar to the closure of FIG. 1, but including a break-off head, the alternative closure shown with a portion of a receiver of the polyaxial bone screw of FIG. 8 shown in enlarged and partial front elevation with portions broken away to show the detail thereof, and further showing a rod being pressed upon by the alternative closure, the rod also in partial front elevation with portions broken away to show the detail thereof.

[0020] FIG. 10 is another front elevational view of the closure of FIG. 9 with portions broken away to show the detail thereof.

[0021] FIG. 11 is a front elevational view of an alternative square-thread closure of an embodiment of the invention with portions broken away to show the detail thereof, the closure shown with a portion of a receiver of the polyaxial bone screw of FIG. 8 shown in enlarged and partial front elevation with portions broken away to show the detail thereof, and further showing a rod being pressed upon by the alternative closure, the rod also in partial front elevation with portions broken away to show the detail thereof.

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[0022] FIG. 12 is a front elevational view of an alternative reverse angle closure of an embodiment of the invention with portions broken away to show the detail thereof, the closure shown with a portion of a receiver of the polyaxial bone screw of FIG. 8 shown in enlarged and partial front elevation with portions broken away to show the detail thereof, and further showing a rod being pressed upon by the alternative closure, the rod also in partial front elevation with portions broken away to show the detail thereof.

[0023] FIG. 13 is a front elevational view of an alternative v-thread closure embodiment of the invention with portions broken away to show the detail thereof, the closure shown with a portion of a receiver of the polyaxial bone screw of FIG. 8 shown in enlarged and partial front elevation with portions broken away to show the detail thereof, and further showing a rod being pressed upon by the alternative closure, the rod also in partial front elevation with portions broken away to show the detail thereof.

[0024] FIG. 14 is a front elevational view of an alternative buttress-thread closure embodiment of the invention with portions broken away to show the detail thereof, the closure shown with a portion of a receiver of the polyaxial bone screw of FIG. 8 shown in enlarged and partial front elevation with portions broken away to show the detail thereof, and further showing a rod being pressed upon by the alternative closure, the rod also in partial front elevation with portions broken away to show the detail thereof.

[0025] FIG. 15 is a partial front elevational view of an embodiment of a multi-start open bone anchor receiver of an embodiment of the invention with portions broken away to show the detail thereof, the receiver including break-off tabs.

[0026] FIG. 16 is an enlarged and partial front elevational view of the receiver of FIG. 15 with portions broken away to show the detail thereof.

[0027] FIG. 17 is a partial front elevational view of an embodiment of a bone anchor receiver having a guide and advancement structure that matingly cooperates with the multi-start closure of FIG. 1, also shown in front elevation, the receiver having portions broken away to show the detail thereof, and further shown with a guide tool, shown in phantom, the guide tool having a

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multi-start guide and advancement structure receiving inner surface synchronized with the bone anchor receiver guide and advancement structure.

[0028] FIG. 18 is an exploded perspective view of the polyaxial bone screw assembly of FIG. 8.

[0029] FIG. 19 is an enlarged perspective view of the receiver of FIG. 18.

[0030] FIG. 20 is a top plan view of the receiver of FIG. 19.

[0031] FIG. 21 is a bottom plan view of the receiver of FIG. 19.

[0032] FIG. 22 is a side elevational view of the receiver of FIG. 19.

[0033] FIG. 23 is an enlarged cross-sectional view taken along the line 23-23 of FIG. 20.

[0034] FIG. 24 is an enlarged cross-sectional view taken along the line 24-24 of FIG. 22.

[0035] FIG. 25 is an enlarged cross-sectional view taken along the line 25-25 of FIG. 20.

[0036] FIG. 26 is an enlarged perspective view of the retainer of FIG. 18.

[0037] FIG. 27 is a top plan view of the retainer of FIG. 16.

[0038] FIG. 28 is a bottom plan view of the retainer of FIG. 26.

[0039] FIG. 29 is an enlarged cross-sectional view taken along the line 29-29 of FIG. 27.

[0040] FIG. 30 is an enlarged perspective view of the compression insert of FIG. 18.

[0041] FIG. 31 is another perspective view of the insert of FIG. 30.

[0042] FIG. 32 is a top plan view of the insert of FIG. 30.

[0043] FIG. 33 is a bottom plan view of the insert of FIG. 30.

[0044] FIG. 34 is a reduced side elevational view of the insert of FIG. 30.

[0045] FIG. 35 is an enlarged cross-sectional view taken along the line 35-35 of FIG. 32.

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[0046] FIG. 36 is an enlarged cross-sectional view taken along the line 36-36 of FIG. 32.

[0047] FIG. 37 is an enlarged front elevational view of the receiver and retainer of FIG. 18 with portions of the receiver broken away to show the detail thereof and shown in an early stage of assembly with the retainer.

[0048] FIG. 38 is a front elevational view with portions broken away of the receiver and retainer, similar to FIG. 37, further showing the retainer and also the compression insert of FIG. 18 in a later stage of assembly, the compression insert shown in side elevation.

[0049] FIG. 39 is a reduced front elevational view with portions broken away, similar to FIG. 38, showing the insert in a stage of being rotated into a desired position within the receiver.

[0050] FIG. 40 is a reduced front elevational view with portions broken away, similar to FIG. 39 showing the insert being rotated into the desired position.

[0051] FIG. 41 is an enlarged and partial perspective view of the assembly as shown in FIG. 40, further showing portions of the receiver pressed or crimped toward the insert to prohibit further rotation of the insert with respect to the receiver.

[0052] FIG. 42 is an enlarged and partial, partially exploded front elevational view of the shank of FIG. 18 and also the receiver, retainer and compression insert of FIG. 18 as assembled as in FIG. 32, with portions broken away to show the detail thereof, the shank being shown implanted in a vertebra, shown in phantom, as the shank may be assembled with the receiver either before or after implantation.

[0053] FIG. 43 is a partial front elevational view, similar to FIG. 42, with portions broken away to show the detail thereof and showing the shank in a stage of assembly with the retainer.

[0054] FIG. 44 is an enlarged partial front elevational view, similar to FIG. 43, with portions broken away to show the detail thereof and showing the shank in a subsequent stage of assembly with the retainer wherein the retainer is at maximum expansion with the receiver cavity.

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[0055] FIG. 45 is a reduced and partial front elevational view, similar to FIG. 44, with portions broken away to show the detail thereof wherein the shank is fully assembled with the retainer.

[0056] FIG. 46 is a partial front elevational view, similar to FIG. 45, with portions broken away to show the detail thereof and showing the retainer dropped down to a seated position within the receiver.

[0057] FIG. 47 is an enlarged and partial front elevational view with portions broken away, similar to FIG. 46 and further showing the insert after being pressed downwardly into friction fit engagement with the shank.

[0058] FIG. 48 is an enlarged and partial front elevational view with portions broken away of the assembly of Fig. 18, shown with the closure top partially assembled as also shown in FIG. 3.

[0059] FIG. 49 is an enlarged and partial front elevational view with portions broken away, similar to FIG. 48 and further showing the closure fully assembled between arms of the receiver.

[0060] FIG. 50 a reduced and partial front elevational view with portions broken away of the assembly of FIG. 49, but with the rod and closure top thereof removed and replaced with an alternative deformable rod and an alternative multi-start closure of the invention, the insert remaining locked against the receiver and thus keeping the shank locked in place during removal and replacement of the rod and closure top.

[0061] FIG. 51 is a reduced and partial perspective view of the assembly of FIG. 49.

[0062] FIG. 52 is a partial perspective view, similar to FIG. 51, but showing the shank disposed at an eighteen degree angle (cephalic) with respect to the receiver.

[0063] FIG. 53 is a partial perspective view, similar to FIG. 52, but showing the shank disposed at an eighteen degree angle (caudal) with respect to the receiver.

[0064] FIG. 54 is a partial perspective view, similar to FIG. 53, but showing the shank disposed at an eighteen degree angle (lateral) with respect to the receiver.

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[0065] FIG. 55 is a partial perspective view, similar to FIG. 54, but showing the shank disposed at a forty-two degree (medial) by eight degree (cephalic) angle with respect to the receiver.

[0066] FIG. 56 is a partial perspective view, similar to FIG. 55, but showing the shank disposed at a forty-two degree (medial) angle with respect to the receiver.

[0067] FIG. 57 is a partial perspective view, similar to FIG. 56, but showing the shank disposed at a forty-two degree (medial) by eight degree (caudal) angle with respect to the receiver.

[0068] FIG. 58 is an enlarged front elevational view of the assembly of FIG. 57 with portions broken away to show the detail thereof.

DETAILED DESCRIPTION OF THE INVENTION

[0069] As required, detailed embodiments of the present invention are disclosed herein; however, it is to be understood that the disclosed embodiments are merely exemplary of the invention, which may be embodied in various forms. Therefore, specific structural and functional details disclosed herein are not to be interpreted as limiting, but merely as a basis for the claims and as a representative basis for teaching one skilled in the art to variously employ the present invention in virtually any appropriately detailed structure. It is also noted that any reference to the words top, bottom, up and down, and the like, in this application refers to the alignment shown in the various drawings, as well as the normal connotations applied to such devices, and is not intended to restrict positioning of the bone attachment structures in actual use.

[0070] Furthermore, the terms lead, pitch and start, as such terms are used to describe helically wound guide and advancement structures, are to be understood as follows: Lead is a distance along the axis of a closure plug that is covered by one complete rotation (360 degrees) of the closure plug with respect to a mating open implant. Pitch is the distance from a crest (or outer point or location) of one guide and advancement structure form to the next. For example in a single-start thread-form, such as a single start, helically wound v-thread closure plug, lead and pitch are the same. Single start means that there is only one ridge or helically wound form wrapped around a cylindrical core, or in the case of the present invention, wrapped around a

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cylindrical closure plug body and thus there is only one start structure or surface at a base or forward end of the closure body that initially engages a mating structure on the open implant. Each time a single start closure rotates one turn (360 degrees), the closure has advanced axially by a width of one ridge or one helical form. Double-start means that there are two ridges or forms wrapped around a core body and thus there are two starting surfaces or structures on the closure plug. Therefore, each time a double-start body rotates one turn (360 degrees), such a body has advanced axially by a width of two ridges or forms. Multi-start means that there are at least two and may be up to three or more of such ridges or forms wrapped around a core body.

[0071] With reference to FIGS. 1-8 and 18-58, and in particular to FIGS. 8 and 18, the reference number 1 generally represents an open implant in the form of a polyaxial bone screw apparatus or assembly that includes a shank 4, that further includes a body 6 integral with an upwardly extending upper portion or capture structure 8; a receiver 10; a retaining structure or retainer 12, a compression or pressure insert 14, and a multi-start closure structure or plug 18 of the invention in the form of a cylindrical plug having a double start helically wound flange-form. It is noted that multi-start closure embodiments of the invention, such as the closure 18 may be used with a variety of open implants including, but not limited to a wide variety of polyaxial screws, mono-axial or fixed screws, hooks and other types of open implants requiring a plug or closure mechanism to fix a rod or other implant member to a vertebra or other bone. Thus, the assembly 1 is only one example of how multi-start closures of the invention may be used.

[0072] The closure structure 18 presses against and captures a longitudinal connecting member, for example, a rod 21 which in turn engages the compression insert 14 that presses against the shank upper portion 8 that is attached to the retaining structure that in turn presses against an inner surface of the receiver 10, so as to capture and fix the longitudinal connecting member 21 within the receiver 10 and thus fix the member 21 relative to a vertebra (not shown). The illustrated receiver 10 and the shank 4 cooperate in such a manner that the receiver 10 and the shank 4 can be secured at any of a plurality of angles, articulations or rotational alignments relative to one another and within a selected range of angles both from side to side and from front to rear, to enable flexible or articulated engagement of the receiver 10 with the shank 4 until both are locked or fixed relative to each other near the end of an implantation procedure.

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[0073] The illustrated rod 21 is hard, stiff, non-elastic and cylindrical, having an outer cylindrical surface 22. However, in other embodiments, the rod 21 may be elastic, deformable and/or of a different cross-sectional geometry. The rod 21 may be made from a variety of metals, metal alloys and deformable and less compressible plastics, including, but not limited to rods made of elastomeric, polyetheretherketone (PEEK) and other types of materials, such as polycarbonate urethanes (PCU) and polyethylenes. Furthermore, in lieu of a rod, longitudinal connecting members for use with the assembly 1 may take a variety of shapes, and/or may include a tensioned cord as described in greater detail herein.

[0074] It is noted that the receiver 10 includes guide and advancement structures 168 that are shown as interlocking flange forms described in greater detail in applicant's U.S. Pat. No. 6,726,689, also incorporated by reference herein. Alternately, when the closure structure includes a different helical form, the receiver cooperating structures (e.g., 168) must also be of a cooperating, mating geometry, such as a square-shaped thread receiving form, a buttress thread receiving form, a reverse angle thread receiving form or other thread-like or non-thread-like helically wound discontinuous advancement structure receiving forms for operably guiding under rotation and advancing a multi-start closure structure downward between the receiver arms 160, as well as eventual torqueing when the closure structure abuts against the rod 21 or other connecting member.

[0075] With particular reference to FIGS. 1-7, the illustrated multi-start closure structure 18 is a double start closure having a substantially cylindrical plug body 40 having an axis of rotation that is the same as that of the receiver 10 and including a helically wound guide and advancement structure in the form of a pair of helically wound forms 42 and 43, each illustrated as an interlocking flange form that operably joins with mating flange form guide and advancement structures 168 disposed on the arms of the receiver 10. The form 42 includes a start surface or structure 46 and the form 43 includes a start surface or structure 47. Each helically wound form 42 and 43 may take a variety of forms and geometries, including those described in Applicant's U.S. Pat. No. 6,726,689, which is incorporated by reference herein. It is noted (and also described in greater detail subsequently herein) that each of the closure structure guide and advancement structures or forms 42 and 43 could alternatively be in the form of a buttress thread, a square thread, a reverse angle thread, a v-thread or other thread like or non-thread like

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helically wound advancement structures, for operably guiding under rotation and advancing the closure structure downward between the arms of the receive 10 and preferably having such a nature as to resist splaying of the receiver arms when the closure structure 18 is advanced into the receiver channel. The specific flange forms 42 and 43 illustrated in FIGS. 1-7, as well as acceptable alternative locking forms, are described in detail in Applicant's U.S. Pat. No. 6,726,689, incorporated by reference herein, and thus shall not be discussed further herein. Such interlocking flange forms are preferred as the added strength provided thereby beneficially cooperate with and counter any reduction in strength caused by the any reduced profile of the receiver 10 that may more advantageously engage longitudinal connecting member components.

[0076] The illustrated closure structure 18 also includes a top surface 54 with an internal drive 56 in the form of an aperture that is illustrated as a star-shaped internal drive such as that sold under the trademark TORX, or may be, for example, a hex drive, or other internal drives such as slotted, tri-wing, spanner, two or more apertures of various shapes, and the like. A driving tool (not shown) sized and shaped for engagement with the internal drive 56 is used for both rotatable engagement and, if needed, disengagement of the closure 18 from the receiver 10 at arms 160. It is also foreseen that the closure structure 18 may alternatively include a break-off head designed to allow such a head to break from a base of the closure at a preselected torque, for example, 70 to 140 inch pounds. Such a closure structure would also include a body surface having an internal drive to be used for closure removal. A base or bottom surface 58 of the closure is planar and further includes a rim 60 for engagement and penetration into the surface 22 of the rod 21 in certain embodiments of the invention. The closure top 18 further includes a cannulation through bore 62 extending along a central axis thereof and through a drive base surface 63 and the bottom surface 58 thereof. Such a through bore provides a passage through the closure 18 interior for a length of wire (not shown) inserted therein to provide a guide for insertion of the closure top into the receiver arms 160.

[0077] The closure structure 18 helically wound flange form start structures 46 and 47 of the respective forms 42 and 43 are located on opposite sides of the closure plug body 40 and are both located adjacent the bottom surface 58. As illustrated in FIG. 3, for example, when the closure structure 18 is rotated into the receiver 10 between receiver arms 160, each having a guide and advancement structure 168, the start 46 engages mating guide and advancement structure 168 on

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one arm 160 and the start 47 simultaneously engages guide and advancement structure 168 on the opposing arm 160, both forms 42 and 43 being simultaneously captured by the mating forms 168 on the opposed arms 160. As the structure 18 is rotated, the structure advances axially downwardly between the arms 160 and presses evenly down upon the captured rod 21. Each time the illustrated duel- or double-start closure plug 18 is rotated one complete turn or pass (three hundred sixty degrees) between the implant arms, the closure plug 18 advances axially into the implant and toward the rod by a width of two helical flange forms. The illustrated closure 18 is sized for at least one complete rotation (three hundred sixty degree) of the plug 18 with respect to the receiver 10 open arms 160 to substantially receive the plug between the implant arms. Each of the start structures 46 and 47 includes a leading face having at least one curvate surface. The at least one curvate surface includes at least one radius of curvature. In one embodiment, the at least one curvate surface is both concave and convex. Multi-start closures of the invention may have two or more coarse or fine helical forms, resulting in fewer or greater forms per axial distance spiraling about the closure plug body and thus resulting in plugs that rotate less or more than one complete rotation to be fully received between the implant arms. Preferably, helically wound forms of the multi-start closure of the invention are sized so as to spiral around a cylindrical plug body thereof to an extent that the closure rotates at least ninety-one degrees to fully or substantially receive the closure plug between the arms of the bone screw receiver or other open implant. Particularly preferred guide and advancement structures are sized for at least one complete turn or pass (three-hundred sixty degree) of the closure between the receiver 10 arms and as many as two to three rotations to be fully received between implant arms.

[0078] An alternative closure top, such as the top 18' shown in FIG. 50 for use with a deformable rod, such as a PEEK rod 21', for example, includes a bottom surface 58' that has a domed portion 66' with a central nub 68' in lieu of the flat and rimmed surfaces of the closure top 18. Otherwise, the closure top 18' includes a guide and advancement structures 42' and 43', a top surface 54' and an internal drive feature 56' the same or substantially similar to the respective guide and advancement structures 42 and 43, top surface 54 and internal drive feature 56 of the closure top 18.

[0079] The shank 4, best illustrated in FIGS. 18 and 42-49, is elongate, with the shank body 6 having a helically wound bone implantable thread 124 (single or dual lead thread form)

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extending from near a neck 126 located adjacent to the upper portion or capture structure 8, to a tip 128 of the body 6 and extending radially outwardly therefrom. During use, the body 6 utilizing the thread 124 for gripping and advancement is implanted into the vertebra 17 leading with the tip 128 and driven down into the vertebra with an installation or driving tool (not shown), so as to be implanted in the vertebra to near the neck 126, as more fully described in the paragraphs below. The shank 4 has an elongate axis of rotation generally identified by the reference letter A.

[0080] The neck 126 extends axially upward from the shank body 6. The neck 126 may be of the same or is typically of a slightly reduced radius as compared to an adjacent upper end or top 132 of the body 6 where the thread 124 terminates. Further extending axially and outwardly from the neck 126 is the shank upper portion 8 that provides a connective or capture apparatus disposed at a distance from the upper end 132 and thus at a distance from the vertebra 17 when the body 6 is implanted in such vertebra.

[0081] The shank upper portion 8 is configured for a pivotable connection between the shank 4 (with attached retainer 12) and the receiver 10 prior to fixing of the shank 4 in a desired position with respect to the receiver 10. The shank upper portion 8 has an outer, convex and substantially spherical lower surface 134 that extends outwardly and upwardly from the neck 126 and terminates at a substantially planar ledge or shelf 136 that is annular and disposed perpendicular to the shank axis A. The spherical lower surface 134 has an outer radius that is the same or substantially similar to an outer radius of the retainer 12 as will be described in greater detail below, the surface 134 as well as the retainer 12 outer surface participating in the ball and socket joint formed by the shank 4 and attached retainer 12 within the partially spherical surface defining an inner cavity of the receiver 10. Extending upwardly from the ledge 136 is a cylindrical surface 138, the surface 138 having a radius that is smaller than the radius of the lower spherical surface 134. Extending outwardly from the cylindrical surface 138 is another annular surface or upper ledge 140 that faces toward the ledge 136 and is also substantially perpendicular to the axis A. As will be discussed in greater detail below, the lower ledge 136, cylindrical surface 138 and upper ledge 140 cooperate to capture and fix the resilient open retainer 12 to the shank upper portion 8, prohibiting movement of the retainer 12 along the axis A once the retainer 12 is located between the ledges 136 and 140. Extending upwardly from the

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upper ledge 140 is a cylindrical surface 142 having a radius smaller than the radius of the spherical surface 134 but larger than the radius of the cylindrical surface 138. Extending upwardly from the surface 142 is an upper partially spherical or domed surface 144. The spherical surface 144 has an outer radius configured for sliding cooperation and ultimate frictional mating with a substantially spherical concave surface of the compression insert 14 that has the same or substantially similar radius as the surface 144. The radius of the surface 144 is smaller than the radius of the lower spherical surface 134. Located near or adjacent to the surface 144 is an annular top surface 146. In the illustrated embodiment a bevel 147 extends about the spherical surface 144 and is located between the spherical surface 144 and the annular planar top surface 146.

[0082] A counter sunk substantially planar base or seating surface 149 partially defines an internal drive feature or imprint 150. The illustrated internal drive feature 150 is an aperture formed in the top surface 146 and has a multi-lobular or star-shaped aperture, such as those sold under the trademark TORX, the aperture designed to receive a tool (not shown)of an Allen wrench type, into the aperture for rotating and driving the bone screw shank 4. It is foreseen that such an internal tool engagement structure may take a variety of tool-engaging forms and may include one or more apertures of various shapes, such as a pair of spaced apart apertures or hex shape, or other geometric shape. The seat or base 149 of the drive feature 150 is disposed perpendicular to the axis A with the drive feature 150 otherwise being coaxial with the axis A. In operation, a driving tool is received in the internal drive feature 150, being seated at the base 149 and engaging the faces of the drive feature 150 for both driving and rotating the shank body 6 into the vertebra 17, either before the shank 4 is attached to the receiver 10 as shown in FIG. 42 or after the shank 4 is attached to the receiver 10, with the shank body 6 being driven into the vertebra 17 with the driving tool extending into the receiver 10.

[0083] The shank 4 shown in the drawings is cannulated, having a small central bore 151 extending an entire length of the shank 4 along the axis A. The bore 151 is defined by an inner cylindrical wall of the shank 4 and has a circular opening at the shank tip 128 and an upper opening communicating with the internal drive 150 at the surface 149. The bore 151 is coaxial with the threaded body 6 and the upper portion 8. The bore 151 provides a passage through the shank 4 interior for a length of wire (not shown) inserted into the vertebra 17 prior to the

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insertion of the shank body 6, the wire providing a guide for insertion of the shank body 6 into the vertebra 17.

[0084] To provide a biologically active interface with the bone, the threaded shank body 6 may be coated, perforated, made porous or otherwise treated. The treatment may include, but is not limited to a plasma spray coating or other type of coating of a metal or, for example, a calcium phosphate; or a roughening, perforation or indentation in the shank surface, such as by sputtering, sand blasting or acid etching, that allows for bony ingrowth or ongrowth. Certain metal coatings act as a scaffold for bone ingrowth. Bio-ceramic calcium phosphate coatings include, but are not limited to: alpha-tri-calcium phosphate and beta-tri-calcium phosphate ($Ca_3(PO_4)_2$), tetra-calcium phosphate ($Ca_4P_20_9$), amorphous calcium phosphate and hydroxyapatite ($Ca_{10}(PO_4)_6(OH)_2$). Coating with hydroxyapatite, for example, is desirable as hydroxyapatite is chemically similar to bone with respect to mineral content and has been identified as being bioactive and thus not only supportive of bone ingrowth, but actively taking part in bone bonding.

[0085] With particular reference to FIGS. 18-25, the receiver 10 has a generally U-shaped appearance with a partially discontinuous substantially cylindrical inner profile and a partially cylindrical and partially faceted outer profile. The receiver 10 has an axis of rotation B that is shown in FIG. 18 as being aligned with and the same as the axis of rotation A of the shank 4, such orientation being desirable, but not required during assembly of the receiver 10 with the shank 4. After the receiver 10 is pivotally attached to the shank 4, either before or after the shank 4 is implanted in a vertebra 17, the axis B is typically disposed at an angle with respect to the axis A, as shown, for example, in FIGS. 54-58.

[0086] The receiver 10 includes a substantially cylindrical base 158 integral with a pair of opposed upstanding arms 160. A cavity, generally 161, is located within the base 158. The arms 160 form a cradle and define a U-shaped channel 162 with an upper opening, generally 163, and a U-shaped lower seat 164, the channel 162 having a width for operably snugly receiving the rod 21 between the arms 160. The channel 164 communicates with the base cavity 161. Each of the arms 160 has an interior surface, generally 166 that has a cylindrical profile and further includes a partial helically wound guide and advancement structure 168 extending radially inwardly from

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the surface 166 and located adjacent top surfaces 169 of each of the arms 160. In the illustrated embodiment, the guide and advancement structures 168 are each in the form of a partial helically wound interlocking flange form configured to mate under rotation with the dual start closure structure 18. Thus, unlike single start advancement structures, the helical forms 168 on the opposing arm surfaces 166 that are configured to mate with the dual start closure top 18 are reverse or flipped images of one another, the structures 168 on each arm 160 being aligned with respect to the receiver axis B, so that each closure structure start and are simultaneously engaged and captured at each arm 160 at the same time.

[0087] The arms 160 further include an opposed pair of vertically extending outer grooves, generally 174, running substantially parallel to the receiver axis B that are centrally formed in outer curved (illustrated as faceted, both curved and planar) surfaces 176. Each groove 174 runs centrally from the respective arm top surface 169 and terminates at a through aperture 177. Each aperture 177 extends through the respective arm surface 176 and also through the respective interior arm surface 166 and is located spaced from the receiver base 158. Each groove 174 has an upper opening partially defined by a pair of opposed surfaces 179 and a substantially planar outer wall surface 181 extending between the surfaces 179. The planar wall surface 181 terminates at the top arm surface 169 and at a lower surface 182 partially defining the aperture 177. The illustrated opposed surfaces 179 are parallel and extend below the lower surface 182, partially defining the through aperture 177. The opposed surfaces 179 are sized to receive portions of an elongate tool (not shown) for locking and unlocking the insert 14 with respect to the receiver as will be described in greater detail below. In some embodiments, the surfaces 179 may be disposed at a slight angle with respect to each other, forming a dovetail-like space for maintaining a close relationship between an elongate tool (not shown) that enters into the groove 174 at the arm top surface 169 and is slidingly received between the surfaces 179. The surfaces 179 terminate at a lower surface 183 that also partially defines the through aperture 177. The surface 183 is substantially perpendicular to the surfaces 179. Thus, the illustrated through aperture 177 located below each of the grooves 174 is substantially the same width as the groove 174 there-above, resulting in the aperture 177 having a substantially rectangular profile. The through apertures 177 are sized and shaped for receiving tooling and portions of the compression insert 14 as will be described in greater detail below.

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[0088] With particular reference to FIGS. 19, 22, 24, and 41, formed in the arm surfaces 176 and located on either side of the through apertures 177 are lateral crimping apertures 186. The four crimping apertures 186 are substantially circular in profile and do not extend completely through the respective arms 160, but rather terminate at a location between the arm outer surface 176 and the interior surface 166 to provide a crimping portion or wall 187. The crimping portions or walls 187 are sized and shaped for pressing or crimping some or all of the wall material inwardly onto front and rear surfaces of the insert 14 to prohibit rotation and misalignment of the insert 14 with respect to the receiver 10 as will be described in greater detail below.

[0089] The receiver 10 is a one-piece or integral structure and is devoid of any spring tabs or collet-like structures. Preferably the insert and/or receiver are configured with structure for blocking rotation of the insert with respect to the receiver, such as the crimp walls 187, but allowing some up and down movement of the insert with respect to the receiver during the assembly and implant procedure. Also formed in each outer arm surface 176 near the top surface 169 is an undercut tool receiving and engaging groove 189. Some or all of the apertures and grooves described herein, including, but not limited to grooves 174, apertures 177, and grooves 189 may be used for holding the receiver 10 during assembly with the insert 14, the retainer 12 and the shank 4; during the implantation of the shank body 6 into a vertebra when the shank is pre-assembled with the receiver 10; during assembly of the bone anchor assembly 1 with the rod 21 and the closure structure 18; and during lock and release adjustment of inserts according to the invention with respect to the receiver 10, either into or out of frictional engagement with the inner surfaces of the receiver 10 as will be described in greater detail below. It is foreseen that tool receiving grooves or apertures may be configured in a variety of shapes and sizes and be disposed at other locations on the receiver arm 160 outer surfaces 176 and/or inner surfaces 166 as well as surfaces defining the base 158.

[0090] Returning to the interior arm surfaces, generally 166, of the receiver arms 160, located below the discontinuous guide and advancement structure 168 is a discontinuous cylindrical surface 190 partially defining a run-out feature for the guide and advancement structure 168. Adjacent to and above the surface 190 is a discontinuous upper annular ceiling surface 191. The upper annular surface 191 includes the surface 182 that partially defines the

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aperture 177 and also includes bottom surfaces of the guide and advancement structure 168. Also adjacent to and below the surface 190 is a discontinuous annular surface or step 192 that in turn is adjacent to a discontinuous frusto-conical surface 193 that extends from the surface 192 inwardly toward the receiver central axis B. Adjacent the surface 193 is another substantially cylindrical discontinuous surface 194 that may in some embodiments run frusto-conical either toward or away from the axis B, depending upon, for example, clearance requirements for the top loading of assembly components, such as the retainer and a compression insert or inserts and also modifying (enlarging or reducing) a thickness for the crimping walls 187, if desired. In the current embodiment, the surface 194 terminates at a small discontinuous ledge or lip 195 directed inwardly toward the axis B. The through apertures 177 extend through both the cylindrical surfaces 190 and the surfaces 193 and 194. A cylindrical surface 196 is adjacent to and runs downwardly from the lip 195 towards the base cavity 161. A lower portion of the cylindrical surface 196 is continuous and thus partially defines the base cavity 61. The cylindrical surface 196 has a diameter smaller than a diameter of the cylindrical surface 190, but larger than a diameter of the surface 194. The receiver inner arm surfaces 166 may further include other sloped, stepped or chamfered surfaces between the cylindrical surfaces 190, 194, and 196 as desired for ease in assembly of the other top loaded components.

[0091] With particular reference to FIGS. 23-25, the continuous portion of the inner cylindrical surface 96 terminates at a downwardly sloping, annular ledge surface 197 that extends from the surface 196 and runs inwardly toward the receiver axis B. The surface 197 terminates at a substantially cylindrical surface 198. The surface 198 terminates at another annular surface 199 that faces a lower portion of the receiver cavity 161. The surfaces 197, 198, and 199 form an abutment or ceiling stop for the retainer 12 as will be described in greater detail below. The ceiling surface 199 runs substantially perpendicular to the axis B. Cut or otherwise formed into the surfaces 197, 198, and 199 under one of the arms 160 is a curved c-shaped notch, creating a substantially cylindrical surface 200 having a radius greater than a radius of the surface 198, the opening partially defined by the surface 200 providing clearance within the assembly 1, allowing the retainer 12 to move above the surface 197 when the shank 4 and attached retainer 12 are pivoted at a favored angle, for example, as shown in FIG. 58 and discussed in more detail below.

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[0092] As stated above, the surface 199 is substantially annular and defines an upper ceiling or stop of a retainer 12 expansion portion or chamber of the inner cavity 161 that is further defined by a substantially spherical surface 202 that is adjacent to the surface 199. The surface 202 partially defines a recess that is sized and shaped to receive the retainer 12 as it expands around the shank upper portion 8 as the shank 8 is moved upwardly toward the channel 162 during assembly. Located below and adjacent to the spherical surface 202 is another curved surface 203 extending downwardly and inwardly toward the axis B. The surface 203 is illustrated as spherical, but in some embodiments the surface may be frusto-conical. The surface 203 is a seating surface for the retainer 12, the surface 203 slidingly receiving the retainer 12 until the retainer is frictionally locked against the surface 203 when downward pressure is placed on the shank 4 by the insert 14. A cylindrical surface 204 is adjacent the spherical surface 203 and an outwardly flaring surface 205, illustrated as frusto-conical, spans between the cylindrical surface 204 and a bottom surface 206 of the receiver 10. The surface 205 communicating with the bottom surface 206 to define a lower opening, generally 207 into the receiver base inner cavity 161. The cylindrical surface 204, as well as the frusto-conical surface 203 are sized and shaped to be smaller than an upper outer radial dimension of the retainer 12 when the retainer 12 is fixed to the shank upper portion 8, so as to form a restriction to prevent the structure 12 and attached shank portion 8 from passing through the cavity 161 and out the lower exterior 206 of the receiver 10 during operation thereof.

[0093] In various embodiments of the invention, a cut-out or aperture made of one or more notches or curved, cupped or stepped surfaces may be cut into or otherwise formed in a portion of the base surface 206, as well as in portions of the surfaces 202, 203, 204, and 205, the cupped or stepped surfaces being typically located substantially centrally and directly below one of the arm 160. Such a cupped or stepped surface or surfaces may be sized and shaped for providing clearance for an increased angle of articulation between the shank 4 and the receiver 10 in a particular or desired direction. In the present embodiment, one such arrangement of stepped surfaces, generally 208 is illustrated. In particular, the cut-out portion 208 includes a plurality of graduated, partially annular surfaces 209 connecting with a plurality of graduated partially planar and partially curved surfaces 210, the surfaces 209 and 210 defining edges for gripping the shank 4 as shown, for example in FIG. 58. The cut-out 208 is located directly below the cut-out portion

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200 that provides clearance for the retainer 12 during such a favored angle pivoting of the shank 4 and attached retainer 12.

[0094] With particular reference to FIGS. 18 and 26-29, the open retainer 12 that operates to capture the shank upper portion 8 within the receiver 10 has a central axis C that is operationally the same as the axis A associated with the shank 4 when the shank upper portion 8 and the retainer 12 are installed within the receiver 10. The retainer 12 is made from a resilient material, such as a stainless steel or titanium alloy, so that the retainer 12 may be expanded during assembly as will be described in greater detail below. However, because there is little or no need to compress the retainer 12 during assembly, the opening or slit that allows for expansion of the retainer 12 is designed to be very narrow, advantageously providing substantial or almost full surface contact between the retainer and the shank upper portion 8 and also between the retainer and the receiver seating surface 203.

[0095] The retainer 12 has a central channel or hollow through bore, generally 221, that passes entirely through the structure 12 from a top surface 222 to a bottom surface 224 thereof. The bore 221 is primarily defined by a discontinuous inner cylindrical surface 225 that runs from the top surface 222 to the bottom surface 224. In some embodiments of the invention, notches or grooves may be formed in the inner and/or bottom surfaces to more evenly distribute stress across the entire retainer during expansion thereof. The retainer 12 further includes an outer substantially spherical surface 227 running between the top surface 222 and the bottom surface 224, the surface 227 has an identical or substantially similar radius as the receiver seating surface 203 and also the shank lower spherical surface 134. The resilient retainer 12 further includes first and second end surfaces, 230 and 231 disposed in spaced relation to one another when the retainer is in a neutral state. Both end surfaces 230 and 231 are disposed substantially perpendicular to the top surface 222 and the bottom surface 224. The embodiment shown in FIGS. 26-29 illustrates the surfaces 230 and 231 as substantially parallel, however, it is foreseen that it may be desirable to orient the surfaces obliquely or at a slight angle to the top and bottom surfaces.

[0096] With particular reference to FIGS. 18 and 30-36, the locking compression insert 14 is illustrated that is sized and shaped to be received by and down-loaded into the receiver 10 at the

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upper opening 166. The compression insert 14 has an operational central axis that is the same as the central axis B of the receiver 10. In operation, the insert advantageously frictionally engages the bone screw shank upper portion 8 as well as engaging the receiver 10 in an interference fit engagement, locking the shank 4 in a desired angular position with respect to the receiver 10 that remains in such locked position even if, for example, a rod and closure top are later removed and the rod is replaced with another rod or other longitudinal connecting member or member component, such as a sleeve of a tensioned cord connecting member. Such locked position may also be released by the surgeon if desired with insert engaging tools (not shown). In some embodiments of the invention, an alternative insert is provided that does not have the receiver interference fit feature, but is otherwise substantially similar to the insert 14. Such an insert includes outer surfaces that are slidingly received along the receiver 10 surfaces defining the arms 160 and the cavity 161. The locking insert 14 (as well as the non-locking alternative insert not shown) is preferably made from a solid resilient material, such as a stainless steel or titanium alloy, so that portions of the insert 14 may be grasped, pinched or pressed, if necessary, and un-wedged from the receiver 10 with a release tool (not shown).

[0097] The locking compression insert 14 includes a body 256.with cylindrical surfaces of a variety of diameters as well as planar surfaces and chamfers and cut-outs to provide clearance between the insert 14 and the retainer 12 during various steps of assembly as well as when the assembly 1 is in a final locked position. The body 256 is integral with a pair of upstanding arms 257. Located between the arms 257, the body 256 has an outer partial cylindrical surface 258. Each arm outer surface is substantially cylindrical in profile but is made from a variety of facets or faces as well as cut-outs to provide for clearance with other components of the assembly 1. Located on the body 256 below each upstanding arm 257 is a substantially cylindrical interference fit surface or band 159 that extends outwardly from and between an upper cylindrical surface 260 and a lower cylindrical surface 261. The lower surface 261 is adjacent to an annular bottom surface 264 of the insert 14. Each upper cylindrical surface 260 partially defines one of the insert arms 257. The interference fit band 159 runs substantially parallel to the bottom surface 264. A diameter of the insert 14 measured at the band surface 259 is larger than a diameter measured at surfaces 260 or 261. As best shown in FIG. 36, in the illustrated embodiment, the bottom surface 264 is disposed at an angle with respect to the lower surface 261, but may be perpendicular to the lower surface 261 in other embodiments. The insert 14

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further includes substantially planar arm top surfaces 265 located opposite the bottom surface 264. The arms 257 are each further defined by substantially planar front and rear surfaces 266 that run from the top surfaces 265 to the bottom surface 264. At the bottom surface 264, the front and rear surfaces 266 are narrow due to clearance cut-outs 267 located at each corner of the insert 14. Each arm 257 also includes an outwardly extending wing, generally 268 located centrally on and extending outwardly from an upper cylindrical surface 269 of the arm 257, the surface 269 being adjacent to the arm top surface 265. Each arm top surface 265 also extends along the respective wing 268 to a substantially cylindrical outer surface 270. Each wing is also defined by a lower surface 271 and opposed planar side surfaces 272, the upper surfaces 265 and the lower surfaces 271 being substantially parallel to one another. The juncture between the planar side surfaces 272 and the cylindrical surface 270 may include one or more chamfered, planed, or otherwise angled or curved surface to aid in rotational assembly of the insert 14 within the receiver 10. The opposed side surfaces 272 generally span between top and bottom surfaces 265 and 271 respectively, of each wing 268, the side surfaces 272 being substantially perpendicular to adjacent top and bottom surfaces 265 and 271. The cylindrical surfaces 270 are sized and shaped for sliding rotation within the receiver arm cylindrical surfaces 190 during assembly of the insert 14 with the receiver 10 as will be described in greater detail below. The illustrated wings 268 include indicator stripes 273 that provide a surgical staff with an indication of the location of the insert 14 with respect to the receiver 10 during surgery. For example, the location of the stripe 273 with respect to the receiver 10 indicates whether the insert 14 is in a non-floppy, but movable, frictional engagement with the shank head 8 or whether the insert 14 is fully locked down on the shank head 8. The indicator stripes 273 are conveniently located on the wing cylindrical surface 270 that is visible when the wings 268 are extending through the receiver apertures 177.

[0098] Returning to the inner surfaces of the insert 14, a through bore, generally 275, is disposed primarily within and through the body 256 and communicates with a generally U-shaped through channel formed by a saddle surface 278 that is substantially defined by the upstanding arms 257. Near the top surfaces 265, the saddle surface 278 is substantially planar. The saddle 278 has a curved lower seat 279 sized and shaped to closely, snugly engage the rod 21 or other longitudinal connecting member. It is foreseen that an alternative embodiment may be configured to include planar holding surfaces that closely hold a square or rectangular bar as

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well as hold a cylindrical rod-shaped, cord, or sleeved tensioned cord longitudinal connecting member. A pair of opposed, inwardly facing grooves or apertures 280 are located in the saddle 278 beginning near a juncture of the substantially planar upper portion of the saddle 278 and extending toward the curved lower seat 279. The grooves 280 are sized and shaped to receive tooling for rotation, locking, unlocking and other manipulation of the insert 14.

[0099] The bore, generally 275, is substantially defined at the body 256 by an inner cylindrical surface 282 that communicates with the seat 279 and also communicates with a lower concave, radiused or otherwise curved portion 284, that in some embodiments may include shank gripping surfaces or ridges, the surface portion 284 generally having a radius for closely mating with the surface 144 of the shank upper portion 8. The portion 284 terminates at the base surface 264. It is foreseen that the lower shank engaging portion 284 may additionally or alternatively include a roughened or textured surface or surface finish, or may be scored, knurled, or the like, for enhancing frictional engagement with the shank upper portion 8. Formed in a portion of the surface 284 and in a portion of the bottom surface 264 is a notch 286 sized and shaped to receive a portion of the retainer 12 when the shank 4 and attached retainer 12 are pivoted into a favored angle position as shown, for example, in FIG. 58. The notch 286 is located directly beneath one of the arms 257 and has a geometry for receiving a portion of the top 222 and outer spherical surface 227 of the retainer 12 when the shank upper portion 8 is fully locked into place by the insert surface 284 and the shank 4 is pivoted toward the receiver cut-out 208.

[0100] The compression insert 14 through bore 275 is sized and shaped to receive a driving tool (not shown) therethrough that engages the shank drive feature 146 when the shank body 6 is driven into bone with the receiver 10 attached. Also, in some locking embodiments of the invention, the bore receives a manipulation tool (not shown) used for releasing the insert 14 from a locked position with the receiver 10, the tool pressing down on the shank head 8 and also gripping the insert 14 at the apertures 280, or with other tool engaging features. Each of the arms 257 and the insert body 256 may include more surface features, such as cut-outs notches, bevels, etc. to provide adequate clearance for inserting the insert 14 into the receiver and cooperating with the retainer 12 during the different assembly steps as will be described in greater detail below.

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[0101] The insert body 256 cylindrical surface 258 has a diameter slightly smaller than a diameter between crests of the guide and advancement structure 168 of the receiver 10, allowing for top loading of the compression insert 14 into the receiver opening 163, with the arms 257 of the insert 14 being located between the receiver arms 160 during insertion of the insert 14 into the receiver 10 as shown, for example, in FIG. 38. Once the arms 257 of the insert 14 are generally located beneath the guide and advancement structure 168, the insert 14 is rotated into place about the receiver axis B with the wings 268 entering the receiver groove formed by the cylindrical surface 190, the adjacent upper annular surface 191 and the adjacent lower annular surface 192 until the wings 268 are located in the apertures 177 as will be described in greater detail below.

[0102] With reference to FIGS. 18 and 48-50, the illustrated elongate rod or longitudinal connecting member 21 (of which only a portion has been shown) can be any of a variety of implants utilized in reconstructive spinal surgery, but is typically a cylindrical, elongate structure having the outer substantially smooth, cylindrical surface 22 of uniform diameter. The rod 21 may be made from a variety of metals, metal alloys and deformable and less compressible plastics, including, but not limited to rods made of elastomeric, polyetheretherketone (PEEK) and other types of materials, such as polycarbonate urethanes (PCU) and polyethylenes.

[0103] Longitudinal connecting members for use with the assembly 1 may take a variety of shapes, including but not limited to rods or bars of oval, rectangular or other curved or polygonal cross-section. The shape of the insert 14 may be modified so as to closely hold the particular longitudinal connecting member used in the assembly 1. Some embodiments of the assembly 1 may also be used with a tensioned cord. Such a cord may be made from a variety of materials, including polyester or other plastic fibers, strands or threads, such as polyethylene-terephthalate. Furthermore, the longitudinal connector may be a component of a longer overall dynamic stabilization connecting member, with cylindrical or bar-shaped portions sized and shaped for being received by the compression insert 14 of the receiver having a U-shaped, rectangular- or other- shaped channel, for closely receiving the longitudinal connecting member. The longitudinal connecting member may be integral or otherwise fixed to a bendable or damping component that is sized and shaped to be located between adjacent pairs of bone screw assemblies 1, for example. A damping component or bumper may be attached to the longitudinal

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connecting member at one or both sides of the bone screw assembly 1. A rod or bar (or rod or bar component) of a longitudinal connecting member may be made of a variety of materials ranging from deformable plastics to hard metals, depending upon the desired application. Thus, bars and rods of the invention may be made of materials including, but not limited to metal and metal alloys including but not limited to stainless steel, titanium, titanium alloys and cobalt chrome; or other suitable materials, including plastic polymers such as polyetheretherketone (PEEK), ultra-high-molecular weight-polyethylene (UHMWP), polyurethanes and composites, including composites containing carbon fiber, natural or synthetic elastomers such as polyisoprene (natural rubber), and synthetic polymers, copolymers, and thermoplastic elastomers, for example, polyurethane elastomers such as polycarbonate-urethane elastomers.

[0104] Preferably, the receiver 10, the retainer 12 and the compression insert 14 are assembled at a factory setting that includes tooling for holding, alignment and manipulation of the component pieces, as well as crimping a portion of the receiver 10 toward the insert 14. In some circumstances, the shank 4 is also assembled with the receiver 10, the retainer 12 and the compression insert 14 at the factory. In other instances, it is desirable to first implant the shank 4, followed by addition of the pre-assembled receiver, retainer and compression insert at the insertion point (see, e.g., FIG. 42). In this way, the surgeon may advantageously and more easily implant and manipulate the shanks 4, distract or compress the vertebrae with the shanks and work around the shank upper portions or heads without the cooperating receivers being in the way. In other instances, it is desirable for the surgical staff to pre-assemble a shank of a desired size and/or variety (e.g., surface treatment of roughening the upper portion 8 and/or hydroxyapatite on the shank 6), with the receiver, retainer and compression insert. Allowing the surgeon to choose the appropriately sized or treated shank 4 advantageously reduces inventory requirements, thus reducing overall cost.

[0105] Pre-assembly of the receiver 10, retainer 12 and compression insert 14 is shown in FIGS. 37-41. With particular reference to FIG. 37, first the retainer 12 is inserted into the lower receiver opening 207, leading with the outer surface 227, the top surface 222 slightly angled to face upwardly and toward one arm 160 that is located above the stepped, cut-out 208. The retainer 12 is then moved upwardly and at an angle toward the annular ceiling surface 199 located opposite the cut-out surface 200 and then past the stepped cut-out 298 in such an angled

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and upward manner into the chamber 161, followed by tilting the retainer 12 such that the top surface 222 is moved into a position within the receiver cavity 161 axially aligned with the receiver axis B and spaced from the surface 199. Then the retainer 12 is allowed to drop until the retainer spherical surface 227 is seated on the receiver spherical surface 203 as shown in FIG. 38.

[0106] Also with reference to FIG. 38 and with further reference to FIGS. 39 and 40, the. compression insert 14 is then downloaded into the receiver 10 through the upper opening 163 with the bottom surface 264 initially facing the receiver arm top surfaces 169 and the insert arms 257 located between the opposed receiver arms 160. The insert 14 is then lowered toward the channel seat 164 until the insert 14 arm upper surfaces 265 are adjacent the receiver arm inner surfaces located below the guide and advancement structures 168. Thereafter, the insert 14 is rotated in a clockwise or counter-clockwise manner about the receiver axis B until the upper arm surfaces 265 are directly below the guide and advancement structure 168 of each arm as illustrated in FIG. 40 with the U-shaped channel 278 of the insert 14 aligned with the U-shaped channel 162 of the receiver 10. In some embodiments, the insert arms 257 may need to be compressed slightly during rotation to clear inner surfaces of the receiver arms 160. As the insert 14 is rotated about the axis B, the insert wings, generally 268 slidingly rotate within the circular groove formed by the receiver surfaces 190, 191, and 192.

[0107] With particular reference to FIGS. 40 and 41, at this time, the four crimping wall portions 187 are pressed inwardly towards the insert 14 and crimping wall material thus engages the insert near front and rear surfaces 266 thereof, specifically at the four surfaces or facets 267 as best shown in FIG. 41. The crimping wall material of the wall 187 pressing against the insert 14 at a total of four locations thereby prohibits the insert 14 from rotating with respect to the receiver axis B. At this time, there can be some upward and downward movement of the insert 14, but such movement is limited as the upper wall 182 defining the receiver aperture 177 (that is also the surface 191) stops further upward movement of the insert wings 268. Downward movement of the insert 14 is prohibited by the bands 259 resting on receiver ledge surface 195 adjacent the cylindrical surface 196. The retainer 12 and the insert 14 are now in a desired position for shipping as an assembly along with the separate shank 4 and also ready for assembly with the shank 4 either at the factory, by surgery staff prior to implantation, or directly upon an implanted shank 4 as will be described herein.

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[0108] As illustrated in FIG. 42, the bone screw shank 4 or an entire assembly 1 made up of the assembled shank 4, receiver 10, retainer 12 and compression insert 14, is screwed into a bone, such as the vertebra 17, by rotation of the shank 4 using a suitable driving tool (not shown) that operably drives and rotates the shank body 6 by engagement thereof at the internal drive 150. Specifically, the vertebra 17 may be pre-drilled to minimize stressing the bone and have a guide wire (not shown) inserted therein to provide a guide for the placement and angle of the shank 4 with respect to the vertebra. A further tap hole may be made using a tap with the guide wire as a guide. Then, the bone screw shank 4 or the entire assembly 1 is threaded onto the guide wire utilizing the cannulation bore 151 by first threading the wire into the opening at the bottom 128 and then out of the top opening at the drive feature 150. The shank 4 is then driven into the vertebra using the wire as a placement guide. It is foreseen that the shank and other bone screw assembly parts, the rod 21 (also having a central lumen in some embodiments) and the closure top 18 having the central bore 62 can be inserted in a percutaneous or minimally invasive surgical manner, utilizing guide wires. When the shank 4 is driven into the vertebra 17 without the remainder of the assembly 1, the shank 4 may either be driven to a desired final location or may be driven to a location slightly above or proud to provide for ease in assembly with the pre-assembled receiver, compression insert and retainer.

[0109] With further reference to FIG. 42, the pre-assembled receiver, insert and retainer are placed above the shank upper portion 8 until the shank upper portion is received within the opening 207. With particular reference to FIGS. 43-45, as the shank upper portion 8 is moved into the interior 161 of the receiver base, the shank upper portion 8 presses upwardly against the retainer 12 in the recess partially defined by the spherical surface 202. As the portion 8 continues to move upwardly toward the channel 162, the shank surface 144 forces outward movement of the retainer 12 towards the surface 202 in the receiver expansion chamber or area as the shank 4 presses the retainer 12 up against the receiver annular ledge surface or ceiling 199. The retainer 12 initially expands about the shank upper spherical surface 144 and then slides along the cylindrical surface 142, and finally snapping or popping into the recessed cylindrical surface 138, the surface 225 of the retainer 12 fully contacting and frictionally engaging the cylindrical surface 138 between the shank lower ledge 136 and the upper ledge 140. At this time, the retainer 12 is in a neutral or slightly expanded state, fully snapped onto the shank upper portion 8 with both the retainer 12 and shank upper portion 8 in pivotal relation with the receiver 10.

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[0110] With reference to FIG. 46, the shank 4 and attached retainer 12 are then moved downwardly into a desired position with the retainer seated on the surface 203. With reference to FIG. 47, the insert 14 may be pressed downwardly by a tool (not shown) entering at the receiver grooves 174, for example, and pressing down on the insert wings 268, to result in a frictional engagement between the insert inner spherical surface 284 and the shank upper domed surface 144 to an extent that the shank is pivotable with respect to the receiver, but in a non-floppy manner. The insert 14 remains in such position due to interference fit engagement between the insert outer band surfaces 259 and the receiver cylindrical surfaces 196. Alternatively, the insert 14 may be pushed into such interference fit by a rod 21 and closure top 18. Typically, tools are first used to provide the non-floppy arrangement between the insert 14 and the shank head 8, followed by performing a locking engagement utilizing the rod 21 and closure top 18 as shown in FIG. 48. In some embodiments, when the receiver 10 is pre-assembled with the shank 4, the entire assembly 1 may be implanted after the insert 14 is pressed into non-floppy frictional engagement with the shank head 8 by inserting the driving tool (not shown) into the receiver and the shank drive 150 and rotating and driving the shank 4 into a desired location of the vertebra 17.

[0111] Again, with reference to FIG. 48 and also FIG. 49, the rod 21 is eventually positioned in an open or percutaneous manner in cooperation with the at least two bone screw assemblies 1. The closure structure 18 is then inserted into and advanced between the arms 160 of each of the receivers 10. The closure structure 18 is rotated, using a tool engaged with the inner drive 56 until a selected pressure is reached at which point the rod 21 engages the U-shaped seating surface 278 of the compression insert 14, further pressing the insert spherical surface 284 against the shank spherical surface 144, pressing the shank upper portion 8 and attached retainer 12 into locked frictional engagement with the receiver 10. With specific reference to FIGS. 3, 48, and 49, as the multi-start closure structure 18 rotates and moves downwardly into the respective receiver 10, the rim 60 engages and penetrates the rod surface 22, the closure structure 18 pressing downwardly against and biasing the rod 21 into compressive engagement with the insert 14 that urges the shank upper portion 8 and attached retainer 12 into locking engagement with the receiver, the retainer 12 spherical surface 227 frictionally abutting the spherical seating surface 203 of the receiver 10. For example, about 80 to about 120 inch pounds of torque on the closure top may be applied for fixing the bone screw shank 6 with respect to the receiver 10.

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Also, for example, with reference to FIGS. 52-58, when the shank 4 is disposed at an angle with respect to the receiver 10, the lower spherical surface 134 of the shank upper portion 8 may also be in frictional engagement with a portion of the receiver spherical seating surface 203. The retainer 12 may also expand slightly upon locking, providing a full and secure frictional locking engagement with the receiver at the surface 203.

[0112] If removal of the rod 21 from any of the bone screw assemblies 1 is necessary, or if it is desired to release the rod 21 at a particular location, disassembly is accomplished by using the driving tool (not shown) that mates with the internal drive 56 on the closure structure 18 to rotate and remove such closure structure from the cooperating receiver 10. Disassembly is then accomplished in reverse order to the procedure described previously herein for assembly.

[0113] With further reference to FIG. 49 and also with reference to FIG. 50, at this time, the closure top 18 may be loosened or removed and/or the rod 21 may be adjusted and/or removed and the frictional engagement between the insert 14 and the receiver 10 at the receiver surface 196 will remain locked in place, advantageously maintaining a locked angular position of the shank 4 with respect to the receiver 10. Thus, at this time, another rod, such as the deformable rod 21' and cooperating alternative multi-start closure top 18' may be loaded onto the already locked-up assembly to result in an alternative assembly. It is noted that the closure drive 56' may advantageously be made smaller than the drive of the closure 18, such that the deformable rod 21' is not unduly pressed or deformed during assembly since the polyaxial mechanism is already locked.

[0114] With reference to FIGS. 51-58, prior to locking the insert 14 against the shank head 8, the shank 4 may be pivoted to a plurality of potentially desirable positions with respect to the receiver 10, followed by locking of the polyaxial mechanism by fully mating the multi-start closure top 18 with the receiver 10. For example, different angular or articulated positions of the shank 4 with respect to the receiver 10 are shown, some making full use of the stepped cut-out 208 and the c-shaped groove forming the surface 200 of the receiver and/or the notch 286 of the insert 14. For reference, FIG. 51 illustrates a zero degree relationship between the shank 4 and the receiver 10. In other words, the axis A of the shank is aligned with the axis B of the receiver. FIG. 52 shows the shank 4 pivoted laterally of the receiver cut-out portion 208 in an eighteen

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degree cephalic relationship. FIG. 53 shows the shank 4 pivoted away from the receiver cut-out portion 208 in an eighteen degree caudal relationship. FIG. 54 illustrates the shank 4 being pivoted with respect to the receiver 10 at an eighteen degree lateral relationship. FIG. 55 shows the shank 4 pivoted toward the receiver cut-out portion 208 at a forty-two degree medial by eight degree cephalic relationship. FIG. 56 shows the shank 4 pivoted toward the receiver cut-out portion 208 at a forty-two degree medial relationship. FIGS. 57 and 58 show the shank 4 pivoted toward the receiver cut-out portion 208 at a forty-two degree medial by eight degree caudal relationship. FIG. 58 also shows that in such a pivoted relationship between the shank 4 and the receiver 10, a portion of the retainer 12 moves past the receiver surface 200 and is received by the notch 286 in the insert 14.

[0115] With reference to FIGS. 9 and 10, an alternative closure top 18' is shown that is almost identical to the closure top 18. However, the top 18' differs from the top 18 in that the top 18' includes a break-off head 70' that further includes a top surface 72' having tooling notches 73', an outer faceted driving surface 74', illustrated as having a hex-shaped profile, and an inner bore 76'. Otherwise, the closure top 18' includes a body 40', a first helical form 42', a second helical form 43', a body top surface 54', a body internal drive 56', a base 58', a rim 60', a cannulation bore 62' and a drive base surface 63' that is the same or substantially similar to the respective body 40, first helical form 42, second helical form 43, body top surface 54, internal drive 56, base 58, rim 60, cannulation bore 62 and drive base surface 63 previously described herein with respect to the closure top 18. The break-off head 70' is integral with the body 40' at the body top surface 54'. The inner bore 76' communicates with the inner drive 56' and the cannulation bore 62'. The break-off head 70' is designed to allow such head 70' to break from the body 40' at or near the top surface 54' at a preselected torque, for example, 70 to 140 inch pounds, when a hex-shaped tool (not shown) engages the outer surfaces 74' and drives the closure structure 18' into the receiver 10 as shown in FIG. 9. The inner drive 56' is used for disassembly or loosening of the closure 18' from the receiver 10, and re-tightening, if needed.

[0116] With reference to FIG. 11, another alternative multi-start closure top 318 is shown that is almost identical to the closure top 18 with the exception that the two flange forms 42 and 43 with respective starts 46 and 47 have been replaced with square threads 342 and 343 with respective starts 346 (not shown) and 347. Otherwise, the dual or double start closure top 318

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includes a body 340, a body top surface 354, a body internal drive 356, a base 358, a rim 360', a cannulation bore 362 and a drive base surface 363 that is the same or substantially similar to the respective body 40, body top surface 54, internal drive 56, base 58, rim 60, cannulation bore 62 and drive base surface 63 previously described herein with respect to the closure top 18. In FIG. 11, the closure top 318 is shown partially wound into a polyaxial bone screw receiver 310 having opposed arms 360 with inner surfaces equipped with guide and advancement structures 368 that are sized and shaped to simultaneously closely receive and mate with the square threads 342 and 343 of the double closure structure 318. Otherwise, the receiver 310 is identical or substantially similar to the receiver 10.

[0117] With reference to FIG. 12, an alternative multi-start closure top 418 is shown that is almost identical to the closure top 18 with the exception that the two flange forms 42 and 43 with respective starts 46 and 47 have been replaced with reverse angle threads 442 and 443 with respective starts 446 (not shown) and 447. Otherwise, the dual or double start closure top 418 includes a body 440, a body top surface 454, a body internal drive 456, a base 458, a rim 460', a cannulation bore 462 and a drive base surface 463 that is the same or substantially similar to the respective body 40, body top surface 54, internal drive 56, base 58, rim 60, cannulation bore 62 and drive base surface 63 previously described herein with respect to the closure top 18. The closure top 418 is shown partially wound into a polyaxial bone screw receiver 410 having opposed arms 460 with inner surfaces equipped with guide and advancement structures 468 that are sized and shaped to simultaneously closely receive and mate with the reverse angle threads 442 and 443 of the double start closure structure 418. Otherwise, the receiver 410 is identical or substantially similar to the receiver 10.

[0118] With reference to FIG. 13, another alternative multi-start closure top 518 is shown that is almost identical to the closure top 18 with the exception that the two flange forms 42 and 43 with respective starts 46 and 47 have been replaced with v-threads 542 and 543 with respective starts 546 (not shown) and 547. Otherwise, the dual or double start closure top 518 includes a body 540, a body top surface 554, a body internal drive 556, a base 558, a rim 560', a cannulation bore 562 and a drive base surface 563 that is the same or substantially similar to the respective body 40, body top surface 54, internal drive 56, base 58, rim 60, cannulation bore 62 and drive base surface 63 previously described herein with respect to the closure top 18. The

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closure top 518 is shown partially wound into a polyaxial bone screw receiver 510 having opposed arms 560 with inner surfaces equipped with guide and advancement structures 568 that are sized and shaped to simultaneously closely receive and mate with the threads 542 and 543 of the double start closure structure 518. Otherwise, the receiver 510 is identical or substantially similar to the receiver 10.

[0119] With reference to FIG. 14, another alternative multi-start closure top 618 is shown that is almost identical to the closure top 18 with the exception that the two flange forms 42 and 43 with respective starts 46 and 47 have been replaced with buttress threads 642 and 643 with respective starts 446 and 447 (not shown). Otherwise, the dual or double start closure top 618 includes a body 640, a body top surface 654, a body internal drive 656, a base 658, a rim 660', a cannulation bore 662 and a drive base surface 663 that is the same or substantially similar to the respective body 40, body top surface 54, internal drive 56, base 58, rim 60, cannulation bore 62 and drive base surface 63 previously described herein with respect to the closure top 18. The closure top 618 is shown partially wound into a polyaxial bone screw receiver 610 having opposed arms 660 with inner surfaces equipped with guide and advancement structures 668 that are sized and shaped to simultaneously closely receive and mate with the buttress threads 642 and 643 of the double start closure structure 618. Otherwise, the receiver 610 is identical or substantially similar to the receiver 10.

[0120] With reference to FIGS. 15 and 16, an open receiver 710 is illustrated that is substantially similar to the receiver 10 previously described herein with the exception that the receiver 710 includes opposed arms 760, each having an integral upstanding break-off extension 761. Each receiver arm 760 and integral extension 761 has an inner helically wound guide and advancement structure 768 that is sized and shaped to mate with the flange forms 42 and 43 of the dual start closure 18 previously described herein. The break-off extensions 761 are initially integral with the respective arms 760 and are then broken off by a user after the closure 18 has been rotatingly advanced along the arm extensions 761 and into the channel located between the receiver arms 760. In the illustrated embodiment, in addition to an outer groove or notch 770 located at or near a top surface 769 of each of the arms 760 where the extensions 761 break off from the receiver arms, illustrated inner arm surfaces include a recess or cut 771, best shown in FIG. 16, that runs substantially horizontally. Each recess 771 is curved and elongate and

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disposed somewhat cross-wise or transverse to the respective flange form 768. For example, with reference to the arm 760 shown in FIG. 16, the recess 771 cuts into a weakened region, generally 780, where the arm 760 joins with the respective attached adjacent extension 761, the curved and elongate recess 771 beginning at a lower portion or location 781 of the flange form recess or segment and terminating at an opposed upper end location of the flange form segment, while otherwise leaving the flange form 768 intact. Stated in another way, the substantially horizontally extending recess 771 cuts into both a lead portion and a trailing portion of each of the flange form segments located near and directly above the opposed arms 760 and substantially opposite the notch 770, thus further weakening the region where the extension and the arm attach, without destroying the flange form path, so that the closure 18 is not derailed by the recess 771 or otherwise prohibited from moving downwardly into the receiver channel formed between the receiver arms 760.

[0121] With reference to FIG. 17, the multi-start closure 18 is shown cooperating with a spinal implant receiver, such as a bone screw receiver 10' and a discrete, detachable guide tool 801. The elongate guide tool 801, only partially shown in FIG. 17, is typically sized for extending from the bone screw receiver 10' upwardly to a location outside of a patient, the tool providing a guide channel for operably guiding the rod 21 or other longitudinal connecting member from a position exterior of the bone screw receiver 10' toward and into the bone screw receiver 10'. The illustrated guide tool has opposed arms 805, each arm having a helical guide and advancement structure 810 thereon that is illustrated as a square thread form, but may be of other geometry, including a flange form the same or similar to the flange forms 168' of the receiver 10' that mates with the flange forms 42 and 43 of the closure structure 18. Thus, the illustrated structures 810 are sized and shaped for receiving and rotating engagement with a dual start closure. The closure 18 is shown partially wound into the receiver 10' that is identical or substantially similar to the receiver 10 with the exception of certain outer arm surface features (not shown). Thus, the receiver 10' includes opposed arms 160' with inner surfaces having guide and advancement structures 168' that are sized and shaped to simultaneously closely receive and mate with the flange forms 42 and 43 of the dual start closure structure 18. The guide tool 801 includes attachment structure for detachable attachment to the receiver 10'(not shown), that may take a variety of forms and methods, including, but not limited to a slide-on, slide-off attachment, a snap-on, rotate off attachment, a rotate-on and rotate-off attachment, to name a

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few. For example, cooperating attachment structure for both the tool and the receiver may be used that is disclosed in U.S. Pat. No. 7,470,279 and incorporated by reference herein. Returning to the inner helically wound guide and advancement structure 810 formed on each arm 804 of the guide tool 801, the structure 810 is sized and shaped for being aligned with the receiver arms 160' during removable attachment of the tool 801 with the respective bone screw receiver 10' so as to continue the helical pathway for the closure 18, the structures 810 being synchronized with the flange forms 168' to allow for the rotation and driving transfer of the closure 18 from the tool 801 into the receiver 10'.

[0122] It is to be understood that while certain forms of the present invention have been illustrated and described herein, it is not to be limited to the specific forms or arrangement of parts described and shown.

Doc Code: PA..
Document Description: Power of Attorney

PTO/AIA/82A (07-13)
Approved for use through 03/31/2021. OMB 0651-0035
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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TRANSMITTAL FOR POWER OF ATTORNEY TO ONE OR MORE REGISTERED PRACTITIONERS

NOTE: This form is to be submitted with the Power of Attorney by Applicant form (PTO/AIA/82B) to identify the application to which the Power of Attorney is directed, in accordance with 37 CFR 1.5, unless the application number and filing date are identified in the Power of Attorney by Applicant form. If neither form PTO/AIA/82A nor form PTO/AIA82B identifies the application to which the Power of Attorney is directed, the Power of Attorney will not be recognized in the application.

Application Number	16/779,304
Filing Date	01/31/2020
First Named Inventor	Roger P. Jackson
Title	MEDICAL IMPLANT RECEIVERS HAVING DUAL LEAD IN CLOSURE MATING THREAD FORMS AND CURVATE EXTENDING INSTRUMENT ENGAGING GROOVES
Art Unit	3773
Examiner Name	David C. Comstock
Attorney Docket Number	JAC023-644278

SIGNATURE of Applicant or Patent Practitioner

Signature	/Christopher M. Sponheimer/	Date (Optional)	09/01/2020
Name	Christopher M. Sponheimer	Registration Number	64,462
Title (if Applicant is a juristic entity)	Attorney for Applicant		
Applicant Name (if Applicant is a juristic entity)	Roger P. Jackson		

NOTE: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4(d) for signature requirements and certifications. If more than one applicant, use multiple forms.

☑ *Total of one forms are submitted.

This collection of information is required by 37 CFR 1.131, 1.32, and 1.33. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 3 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Doc Code: PA..
Document Description: Power of Attorney

PTO/AIA/82B (07-13)
Approved for use through 11/30/2014. OMB 0651-0051
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number

POWER OF ATTORNEY BY APPLICANT

I hereby revoke all previous powers of attorney given in the application identified in either the attached transmittal letter or the boxes below.

Application Number	Filing Date

(Note: The boxes above may be left blank if information is provided on form PTO/AIA/82A.)

☑ I hereby appoint the Patent Practitioner(s) associated with the following Customer Number as my/our attorney(s) or agent(s), and to transact all business in the United States Patent and Trademark Office connected therewith for the application referenced in the attached transmittal letter (form PTO/AIA/82A) or identified above: 24030

OR

☐ I hereby appoint Practitioner(s) named in the attached list (form PTO/AIA/82C) as my/our attorney(s) or agent(s), and to transact all business in the United States Patent and Trademark Office connected therewith for the patent application referenced in the attached transmittal letter (form PTO/AIA/82A) or identified above. (Note: Complete form PTO/AIA/82C.)

Please recognize or change the correspondence address for the application identified in the attached transmittal letter or the boxes above to:

☑ The address associated with the above-mentioned Customer Number

OR

☐ The address associated with Customer Number:

OR

Firm or Individual Name					
Address					
City		State		Zip	
Country					
Telephone		Email			

I am the Applicant (if the Applicant is a juristic entity, list the Applicant name in the box):

☑ Inventor or Joint Inventor (title not required below)

☐ Legal Representative of a Deceased or Legally Incapacitated Inventor (title not required below)

☐ Assignee or Person to Whom the Inventor is Under an Obligation to Assign (provide signer's title if applicant is a juristic entity)

☐ Person Who Otherwise Shows Sufficient Proprietary Interest (e.g., a petition under 37 CFR 1.46(b)(2) was granted in the application or is concurrently being filed with this document) (provide signer's title if applicant is a juristic entity)

SIGNATURE of Applicant for Patent

The undersigned (whose title is supplied below) is authorized to act on behalf of the applicant (e.g., where the applicant is a juristic entity).

Signature	Roger P. Jackson	Date (Optional)	12-3-13
Name	Roger P. Jackson		
Title			

NOTE: Signature - This form must be signed by the applicant in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications. If more than one applicant, use multiple forms.

☐ Total of forms are submitted.

This collection of information is required by 37 CFR 1.131, 1.32, and 1.33. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 3 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Privacy Act Statement

The **Privacy Act of 1974 (P.L. 93-579)** requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these records.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.	:	16/779,304	Confirmation No.	:	4759
First Applicant	:	Roger P. Jackson	Art Unit	:	3773
Filed	:	01/31/2020	Examiner	:	David C. Comstock
Title		MEDICAL IMPLANT RECEIVERS HAVING DUAL LEAD IN CLOSURE MATING THREAD FORMS AND CURVATE EXTENDING INSTRUMENT ENGAGING GROOVES			
Docket No.	:	JAC023-644278			

INFORMATION DISCLOSURE STATEMENT
PURSUANT TO 37 C.F.R. §§ 1.56, 1.97, AND 1.98

Commissioner:

The Examiner is respectfully requested to consider the patents, patent applications, publications, or other information cataloged on the enclosed Form PTO/SB/08A during examination of the above-identified patent application. The order of presentation of the references should not be construed as an indication of importance. These references are submitted for the Examiner's consideration and are submitted pursuant to an Applicant's duty of disclosure under 37 C.F.R. § 1.56.

Copies of all of the cited documents

☐ are enclosed unless otherwise indicated on the enclosed Form PTO/SB/08a.

☐ have been previously furnished to the Office in prior application No. _____, filed _____, which the present application relies upon for an earlier effective filing date under 35 U.S.C. § 120. Therefore, no copies of the cited documents are included herewith pursuant to 37 C.F.R. § 1.98(d); MPEP § 609(III)(A)(2).

☒ are enclosed unless they are U.S. patents or U.S. patent application publications pursuant to 37 C.F.R. § 1.98(a).

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I
BASIS

This information disclosure statement is filed pursuant to

☐ 37 C.F.R. § 1.97(b).
This information disclosure statement is filed either (1) within three months of the filing date of a national application other than a continued prosecution application under 37 C.F.R. § 1.53(d); (2) within three months of the date of entry of the national stage as set forth in 37 C.F.R. § 1.491 in an international application; (3) before the mailing date of a first Office action on the merits; or (4) before the mailing of a first Office action after the filing of a request for continued examination under 37 C.F.R. § 1.114, whichever event occurs last.

Accordingly, this information disclosure statement requires no fee and no certification.

☒ 37 C.F.R. § 1.97(c).
This information disclosure statement is filed after the period specified in 37 C.F.R. § 1.97(b), but before the mailing date of any of (1) a final action under 37 C.F.R. § 1.113; (2) a notice of allowance under 37 C.F.R. § 1.311; or (3) an action that otherwise closes prosecution in the application.

Accordingly, this information disclosure statement requires either the fee specified in 37 C.F.R. § 1.17(p) for submission of an information disclosure statement under 37 C.F.R. § 1.97(c), or a statement under 37 C.F.R. § 1.97(e).

☐ 37 C.F.R. § 1.97(d).
This information disclosure statement is filed after the period specified in 37 C.F.R. § 1.97(c) since a

- ☐ final action under 37 C.F.R. § 1.113
- ☐ notice of allowance under 37 C.F.R. § 1.311

was mailed to the Applicant(s) on _____. The issue fee has not been paid herein.

Accordingly, this information disclosure statement requires the fee set forth in 37 C.F.R. § 1.17(p) to consider an information disclosure statement under 37 C.F.R. § 1.97(d), and a statement under 37 C.F.R. § 1.97(e).

If this statement crosses in the mail with an Office action, or is otherwise not in the indicated category of 37 C.F.R. § 1.97, it is respectfully requested that this statement be treated in the next appropriate category and made of record. To the extent required, please treat this paper as a conditional petition for acceptance of the information disclosure statement.

II
FEES

Any required fee is being paid as indicated below by an enclosed check or our deposit account.

☐ No fee is due.

☒ The fee specified in 37 C.F.R. § 1.17(p) for submission of an information disclosure statement under 37 C.F.R. § 1.97(c) or (d) is due.

☐ A check is enclosed for the required fee.

☐ Payment by credit card is submitted simultaneously herewith for the required fee.

☒ Please charge the required fee to our deposit account no. 50-1662.

☒ The Commissioner is hereby authorized to charge any additional required fees or credit any overpayments associated with this information disclosure statement to our deposit account no. 50-1662.

III
CERTIFICATION

Pursuant to 37 C.F.R. § 1.97(e), I state as follows:

☒ No statement is necessary.

☐ Each item of information contained in this information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this information disclosure statement. 37 C.F.R. § 1.97(e)(1).

☐ No item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to my knowledge after making reasonable inquiry, no item of information contained in this information disclosure statement was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this information disclosure statement. 37 C.F.R. § 1.97(e)(2).

Pursuant to 37 C.F.R. § 1.704(d), I state as follows:

☐ Each item of information contained in this information disclosure statement was first cited in any communication from a foreign patent office in a counterpart application, and this communication was not received by any individual designated in 37 C.F.R. § 1.56(c) more than thirty days prior to the filing of this information disclosure statement.

IV
FOREIGN LANGUAGE REFERENCES

Pursuant to 37 C.F.R. § 1.98(a)(3)(i), any information disclosure statement filed under 37 C.F.R. § 1.97 shall include a concise explanation of the relevance, as it is presently understood by the individual designated in § 1.56(c) most knowledgeable about the content of the information, of each patent, publication, or other information listed that is not in the English language. The concise explanation may be either separate from the specification or incorporated therein. In compliance with the rules, the Applicant states as follows:

☒ No concise explanation is required since all cited references are in English.

☐ A concise explanation of the relevance of one or more foreign language references is attached.

☐ No English language version was available for one or more foreign language references.

☐ According to the procedural policy adopted by the PTO with regard to disclosure requirements, the Applicant is satisfying the disclosure requirement pursuant to MPEP § 609.04(a)(III) by submitting herewith the following:

- ☐ An English language version of one or more non-English language documents.
- ☐ An English language equivalent application or patent of one or more non-English language applications or patents.
- ☐ An English language version of one or more search reports or other actions by one or more foreign patent offices in one or more counterpart foreign applications, which indicate the degree of relevance found by the foreign office(s).
- ☐ An English language abstract of one or more non-English language references.

The Applicant has not analyzed these documents and, therefore, declines to comment on their relevance at this time.

V
REMARKS

☐ Pursuant to the doctrines established by the Court of Appeals for the Federal Circuit in *McKesson Information Solutions, Inc. v. Bridge Medical, Inc.*, 487 F.3d 897 (Fed. Cir. 2007) and *Dayco Products, Inc. v. Total Containment, Inc.*, 329 F.3d 1358 (Fed. Cir. 2003), Applicant(s) submit documents herewith reflecting the prosecution history of applications that Applicant(s) believe may be considered related to the present application.

☒ In satisfaction of the duty of disclosure under 37 C.F.R. § 1.56, and as required by M.P.E.P. § 2001.06(b), the Examiner is requested to consider the pending U.S. patent applications listed in "Attachment A," which are owned by the Assignee of the present

application. The pending patent applications may include subject matter similar to that of the present application.

It is respectfully requested that

(1) the Examiner sign the enclosed Form PTO/SB/08a to evidence that the cited information has been fully considered by the Patent and Trademark Office during the examination of this application; and

(2) the citations for the cited information be printed on any patent that issues from this application.

The submission of this information disclosure statement by the Applicant(s) shall not be construed as a representation that a search has been performed or that no other material information under 37 C.F.R. § 1.56 exists. See 37 C.F.R. § 1.97(g).

The submission of this information disclosure statement by the Applicant(s) shall not be construed as an admission that any information cited or referred to herein is, or is considered to be, material to the patentability of one or more of the pending claims in this application pursuant to 37 C.F.R. § 1.56(b), unless specifically designated by the Applicant(s) as such. See 37 C.F.R. § 1.97(h).

The submission of this information disclosure statement by the Applicant(s) shall not be construed as an admission that any information cited or referred to herein is, or is considered to be, or even qualifies as "prior art" under 35 U.S.C. § 102 with respect to this invention, unless specifically designated by the Applicant(s) as such.

Notwithstanding any statements by the Applicant(s), the Examiner is urged to form his or her own conclusion regarding the relevance of the cited information.

VI
CONCLUSION

The Examiner is encouraged to contact the undersigned attorney to discuss any questions concerning this information disclosure statement or any of the information cited or referred to herein.

Respectfully submitted 09/01/2020

/Christopher M. Sponheimer/

Christopher M. Sponheimer, Reg. No. 64,462
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Polsinelli PC
1401 Lawrence Street, Suite 2300
Denver, CO 80202
Phone: (303) 583-8253
Fax: (720) 294-0187

ATTACHMENT A
APPLN. NO. 16/779,304
INFORMATION DISCLOSURE STATEMENT
FOR
STATEMENT UNDER MPEP § 2001.06(b)

U.S. PATENT DOCUMENTS			
Examiner Initials	**Patent No.**	**Issue Date**	**Name of Patentee or Applicant of Cited Document**
	8,377,100	02/19/2013	Jackson
	9,636,146	5/02/2017	Jackson et al.
	9,717,533	8/01/2017	Jackson et al.
	9,743,957	8/29/2014	Jackson
	9,861,394	1/09/2018	Jackson
	10,004,541	6/26/2018	Jackson
	10,206,716	02/19/2019	Jackson et al.

U.S. PUBLICATION DOCUMENTS			
Examiner Initials	**Publication No.**	**Publication Date**	**Name of Patentee or Applicant of Cited Document**
	2014/0214097	7/31/2014	Jackson et al.
	2015/0119942	4/30/2015	Jackson et al.
	2015/0148846	5/28/2015	Jackson
	2015/0164558	6/18/2015	Jackson et al.
	2016/0038188	2/11/2016	Jackson et al.
	2016/0242818	8/25/2016	Jackson
	2017/0189073	7/06/2017	Jackson et al.
	2017/0333083	11/23/2017	Jackson et al.
	2017/0354443	12/14/2017	Jackson
	2017/0354441	12/14/2017	Jackson et al.
	2018/0243013	08/30/2018	Jackson et al.
	2018/0296249	10/18/2018	Jackson
	2019/0231400	08/01/2019	Jackson et al.
	2019/0175225	06/13/2019	Jackson et al.
	2019/0274734	09/12/2019	Jackson et al.
	2019/0298415	10/03/2019	Jackson et al.
	2020/0179014	06/11/2020	Jackson

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U.S. APPLICATION DOCUMENTS			
Examiner Initials	Application No.	Filing Date	Name of Patentee or Applicant of Cited Document
EXAMINER		DATE CONSIDERED	
EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.			

PTO/SB/08A (08-03) U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE Substitute for Form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT *(Use as many sheets as necessary)*	APPLICATION NO.: 16/684,236	FILING DATE: 11/14/2019
	INVENTOR(S): Roger P. Jackson	ART UNIT: 3773
	EXAMINER NAME: David C. Comstock	ATTY. DOCKET NO.: JAC023-644278

U.S. PATENT DOCUMENTS

EXAMINER INITIALS*	Cite No.[1]	PATENT NUMBER Number – Kind Code[2] (if known)	ISSUE DATE MM-DD-YYYY	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	A1.	2,005,348	06-1935	Michell	
	A2.	2,833,325	05-1958	Laisy	
	A3.	3,963,322	06-1976	Gryctko	
	A4.	4,600,225	07-1986	Blose	
	A5.	5,067,955	11-1991	Cotrel	
	A6.	5,092,635	03-1992	DeLange et al.	
	A7.	5,234,430	08-1993	Huebner	
	A8.	5,334,203	08-1994	Wagner	
	A9.	5,605,458	02-1997	Bailey et al.	
	A10.	5,607,304	03-1997	Bailey et al.	
	A11.	5,672,176	09-1997	Biedermann et al.	
	A12.	5,797,911	08-1998	Sherman et al.	
	A13.	6,006,930	12-1999	Dreyer et al.	
	A14.	6,010,502	01-2000	Bagby	
	A15.	6,063,090	05-2000	Schlapfer	
	A16.	6,077,262	06-2000	Schlapfer et al.	
	A17.	6,077,267	06-2000	Huene	
	A18.	6,254,146	07-2001	Church	
	A19.	6,296,642	10-2001	Morrison et al.	
	A20.	6,412,831	07-2002	Noel et al.	
	A21.	6,520,962	02-2003	Taylor et al.	
	A22.	6,554,834	04-2003	Crozet et al.	
	A23.	6,730,089	05-2004	Jackson	
	A24.	6,835,196	12-2004	Biedermann et al.	
	A25.	6,997,927	02-2006	Jackson	
	A26.	7,204,838	04-2007	Jackson	
	A27.	7,717,942	05-2010	Schumacher	
	A28.	7,591,839	09-2009	Biedermann et al.	
	A29.	7,794,477	09-2010	Melkent et al.	
	A30.	7,972,364	07-2011	Biedermann et al.	
	A31.	8,382,809	02-2013	Kaufman et al.	
	A32.	8,814,913	08-2014	Jackson	
	A33.	8,911,479	12-2014	Jackson et al.	
	A34.	9,068,587	06-2015	Sage et al.	

U.S. PATENT DOCUMENTS					
EXAMINER INITIALS*	Cite No.[1]	PATENT NUMBER Number – Kind Code[2] (if known)	ISSUE DATE MM-DD-YYYY	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	A35.	9,445,847	09-2016	Biedermann et al.	
	A36.	7,250,052	07-2007	Landry et al.	
	A37.	7,766,945	08-2010	Nilsson et al.	
	A38.	8,162,989	04-2012	Khalili	
	A39.	8,828,060	09-2014	Biedermann et al.	
	A40.	8,998,956	04-2015	George	
	A41.	4,528,874	07-1985	Dunn	
	A42.	5,171,279	12-1992	Mathews	
	A43.	2,244,046	06-1941	Bradshaw	
	A44.	6,443,953	09-2002	Perra et al.	
	A45.	5,961,517	10-1999	Biedermann et al.	
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[0001]
Kassel, the 16th May 2002 hz / st lawyer's file 19405

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[0006]

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Anchoring element for fastening a rod of a

[0007]
Device for setting up a human or animal spine on a vertebral bone

[0008]
The present invention relates to an anchoring element for fixing a rod of a device for establishing a human or animal spine on a vertebral bone, comprising a substantially U-shaped and two substantially parallel holding webs comprehensive holder, in which a receiving slot for receiving the rod is, and with a counter to the received in the receiving slot rod securing element.

[0009]

f?

X K i "

[0010]

From DE 94 02 839 a pedicle screw is known, which is anchored with its threaded shaft in a vertebral body and having at its protruding from the vertebral bone end of a U-shaped holder with two parallel aligned holding webs.

In this case, a receiving slot for receiving a distraction or compression rod is formed between the

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retaining webs, which can be secured and fixed by means of a fastened to the free ends of the retaining webs securing element.

This securing element is composed in a first embodiment of a hexagonal, annular element with a locking screw inserted therein, wherein the entire securing element can be inserted into a corresponding groove in the retaining webs. The securing element spans the receiving slot, so that the locking screw acts directly on the rod to fix it.

[0011]
In another embodiment, the securing element consists of a sleeve enclosing the retaining element with internal thread, wherein the shell can be screwed onto a corresponding, provided on the outer sides of the retaining webs thread, so that provided on the end face of the shell locking screw can engage in the receiving slot to fix the rod.

[0012]

In such a device, therefore, the pedicle screw must first be anchored in the vertebral body, in order to then insert the rod in the receiving slot.

Thereafter, the securing element is either inserted into the grooves or screwed onto the holder before the vortex or the rod is brought by tightening the locking screw in the desired position. This has proven to be very difficult in practice, since either the insertion of the fuse element into the grooves or the screwing of the fuse element on the holder requires a lot of tact, while at the same time must be taken to ensure that

[0013]
Vertebral body and / or the rod meanwhile does not slip.

[0014]

From DE 297 10 484 an anchoring element is known in which a sawtooth thread for receiving the locking screw is provided on the inner sides of the holding webs.

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This ensures that the forces acting radially on the retaining webs in a normal thread accounts and attack only axially acting forces on the retaining web. As a result, a bending apart of the holding webs is prevented, so that even the holding webs comprehensive ring element can be omitted. Again, it has proven in practice to be very tedious to screw the respective locking screw in the corresponding sawtooth while keeping the spine and / or the rod as long in the desired position until the locking screw holds the rod independently.

[0015]
Based on this, the present invention seeks to provide an anchoring element, wherein the securing element reliably absorbs the forces occurring and in which the securing element is easy and quick to install.

[0016]
As a technical solution to this problem is proposed according to the invention, the above-mentioned anchoring element in that the securing element comprises a locking element and a ring member, wherein the ring member is attachable by means of a Renkverbindung at the free end of the holding webs.

[0017]

A trained according to this technical teaching anchoring element has the advantage that the ring element only needs to be placed axially on the free end of the holding webs and can be brought by a slight pivoting in its final, secured position.

Such a secured ring element holds in the receiving slot

[0018]
already located provisionally in the desired position, so that the operating doctor can now screw in the locking element in order to adjust the rod and fix.

[0019]

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It has proven to be advantageous to form the Renkverbindung as a bayonet lock, with a radially projecting gripper and a slot or groove-like recording, wherein the gripper engages in the receptacle to fix the ring member of the holding webs.

Such a bayonet closure is inexpensive to implement and allows a quick and easy attachment of the ring member to the holder of the anchoring element.

[0020]
The configuration of the receptacle with an axial introduction and a radial holding element has the advantage that the gripper can be brought into the introduction in a simple manner and passes by rotation in the holding element to remain there and form a positive bayonet closure.

[0021]
It is understood that the rod may be formed, for example, as a distraction, compression or connecting rod.

[0022]

In a preferred embodiment, the ring element is insertable into the receiving slot and attachable between the retaining webs, wherein the gripper is mounted externally on the ring member, while the receptacle is arranged in the retaining webs.

This has the advantage that hereby the ring element is also integrated in the receiving slot, so that the entire anchoring element can be made very small.

[0023]

In another preferred embodiment, the ring element surrounds the retaining webs, wherein the receptacle is arranged in the ring element, while the gripper is attached to the retaining webs.

This has the

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[0024]
Advantage that also by this the radial forces emanating from the locking element are absorbed by the ring member, without causing the holding webs are pressed in an undesirable manner.

[0025]

In yet another preferred embodiment, the insertion is V-shaped.

This has the advantage that the introduced into this introduction gripper need only be placed roughly on the introduction and then properly performed by the V-shaped configuration to the transversely oriented support member to be subsequently introduced by pivoting the ring member in this.

As a result, the placement of the ring element on the retaining webs is further simplified.

[0026]

In a further preferred embodiment, the Halteelemet is formed rising upward, whereby the ring member must perform not only a rotating, but in addition an axial movement in order to be solved. By such a Zusatzerfordenis when loosening the ring element unintentional release of the ring element is difficult. Anloges applies to a broadening of the end of the retaining element.

[0027]

In yet another preferred embodiment of the gripper is designed as a pin edge. The flank advantageously rests against the holding element with a larger area, so that unintentional detachment of the ring element is tempered by the correspondingly higher friction.

[0028]
In yet another preferred embodiment, the gripper extends through and out of the receptacle and is curved or inclined, preferably in the direction of the forces on the securing element, such that the

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retaining strut faces inwards

[0029]

is pressed.

Hierdruch the holding webs are pressed inward due to the effective holding forces of the anchoring elements and it is ensured that the ring member is reliably held in the retaining webs. A jumping out of the fuse element due to bending retaining webs is prevented.

[0030]

In a preferred embodiment, a thread for receiving the locking element is provided in the ring element. In addition to the above-mentioned advantage that thereby a small size is achieved, this also has the advantage that the radial forces emanating from the locking element are completely absorbed by the ring element, without deformations occur as in the prior art.

[0031]

Further advantages of the anchoring element according to the invention will become apparent from the accompanying drawings and the embodiments described below. Likewise, according to the invention, the features mentioned above and those which are still further can be used individually or in any desired combinations with one another. The mentioned embodiments are not to be understood as exhaustive enumeration, but rather have exemplary character. Show it:

[0032]
Fig. 1 is an exploded view of a first Ausführngsform an anchoring element according to the invention with a rod;

[0033]
FIG. 2 shows a plan view of the ring element according to FIG. 1; FIG. 3 shows a partially sectioned side view of the anchoring element according to FIG. 1, cut along line IM-IM in FIG. 1;

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[0034]
4 shows an exploded view of a second embodiment of an anchoring element according to the invention with a rod;

[0035]
Fig. 5 is a plan view of the ring member of FIG. 4; Fig. 6 is a side view of the anchoring element of FIG. 4; 7 is an exploded view of a third embodiment of a

[0036]
anchoring element according to the invention with a rod;

[0037]
FIG. 8 shows a plan view of the ring element according to FIG. 7; FIG.

[0038]
9 shows a partially sectioned side view of the anchoring element according to FIG. 7, cut along line IX - IX in FIG. 7; 10 is an exploded view of a fourth embodiment of an anchoring element according to the invention with a rod;

[0039]
11 shows a plan view of the ring element according to FIG. 10; FIG. 12 shows a side view of the anchoring element according to FIG. 10; FIG. 13 is an exploded view of a fifth embodiment of an anchoring element according to the invention with a rod; FIG. 14 shows a plan view of the ring element according to FIG. 13; FIG. FIG. 15 shows a side view of the anchoring element according to FIG. 13; FIG. 16 shows an exploded view of a sixth embodiment of an anchoring element according to the invention with a rod; 17 shows a plan view of the ring element according to FIG. 16;

[0040]
FIG. 18 is a partially sectioned side view of the anchoring element according to FIG. 16, cut along line XVIII-XVIII in FIG. 16; FIG.

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[0041]

19 is an exploded view of a seventh embodiment of an anchoring element according to the invention; FIG. 20 shows a plan view of the ring element according to FIG. 19; FIG. Fig. 21 is a side view of the anchoring element according to Flg.

19.

[0042]

FIGS. 1 to 3 show a first embodiment of an anchoring element embodied as a pedicle screw, wherein the anchoring element for insertion into the vertebral bone has a threaded shaft 10 and a U-shaped holder 12 with two retaining struts 14, 16, substantially parallel, a ring element 18 and designed as a grub screw locking element 20 includes.

In this case, a receiving slot 22 for receiving a rod 24 is provided in the holder 12, which over which from the locking element

[0043]
and the ring member 18 composed fuse element is fixed.

[0044]

In this embodiment, two bayonet pins 26, 28 are radially projecting on the ring member 18 on opposite sides, which in a entssprechende, formed on the inside of the holding webs 14, 16 insertion 30 and a holding member 32 are used.

In this case, the ring member 18 is inserted with its two pins 26, 28 from above into the upwardly open insertion 30, and brought to the bottom of the introduction 30 before the ring member 18 is pivoted by a few degrees, so that the pins 26, 28th be performed to the end of the holding element 32.

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Arrived in this position, the ring member 18 is released and remains reliably in this position.

[0045]
As can be clearly seen in FIG. 3, the insertion 30 is V-shaped to form a large catching area for insertion of the pins 26, 28.

[0046]

In the ring member 18, an internal thread 34 is provided for receiving the locking screw 20 formed as a locking element.

In this case, the locking member 20 is screwed in so far into the ring member 18 that the locking member 20 presses on the rod 24 and fixes it in the desired position.

[0047]

FIGS. 4 to 6 show a second embodiment of an anchoring element according to the invention, also embodied as a pedicle screw.

Again, the anchoring element is composed of a threaded shaft 40 for attachment of the anchoring element in the vertebral bone, a U-shaped bracket 42 with two substantially parallel retaining webs 44, 46, a ring member 48 and a lock screw designed as a Madame 50th

[0048]

together.

In this embodiment, on the respective inner sides of the holding webs 44, 46, an internal thread 52 is formed for receiving the locking element designed as a set screws 50.

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In order that in this embodiment the radial forces acting on the holding webs 44, 46 do not lead to a bending of the holding webs 44, 46, in this case the ring element 48 is placed around the holding webs 44, 46 on the outside.

[0049]
Also in this embodiment, a receiving slot 54 of a rod 24 is formed in the holder 42, which is determined by the locking element 50 in the desired position.

[0050]

On the outwardly facing sides of the holding webs 44, 46 each have a radially projecting pin 56, 58 is provided, which are inserted into corresponding, provided on the inside ring element 48 leads 61, which also here at the introduction 60, 61 correspondingly perpendicular corresponding holding elements 62, 63 connect.

Again, the introducers 60, 61 are V-shaped to realize a large catch area.

[0051]

FIGS. 7 to 9 show a third embodiment of an anchoring element according to the invention, also designed as a pedicle screw.

This third embodiment differs from the first embodiment according to FIGS. 1 to 3 in that on the inside of the holding webs 14, 16, then a slightly upwardly rising support member 66 is formed on the introduction 30, at the end of a widening 68 is provided is.

The broadening 68 is designed substantially circular.

In this holding element 66 of the pin 26, 28 can be inserted and clamped at a corresponding rotation of the ring member 18 in the upwardly extending support member 66, so that in this way a clamping protection is achieved. In this case, the holding element 66 increases in the direction of

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the forces acting on the securing element.

[0052]

The broadening 68 at the end of the holding element 66 also causes that during rotation of the ring member 18 between pin 26, 28, and Ring member 18 on the one hand and the holding webs 14, 16 on the other hand built-up voltage is at least partially degraded again, since the widening 68 extends partially in the direction of the holding force and thus partially abolishes the pressure between the fuse element and rod 24. At the same time thereby a reliable and permanent securing of the ring member 18 is achieved, since to release the ring member 18 just this pressure must be rebuilt, which is not possible without external, targeted force. This means that the ring member 18 can not solve by itself.

[0053]

FIGS. 10 to 12 show a fourth embodiment of an anchoring element according to the invention, also embodied as a pedicle screw. This fourth embodiment differs from the second embodiment according to FIGS. 4 to 6 in that on the inside of the ring element 48, a slightly upwardly rising holding element 70 is then formed on the introduction 61. In this holding element 70, the pin 56, 58 can be inserted and clamped at a corresponding rotation of the ring member 48 in the upwardly extending support member 70, so that in this way a clamping protection is achieved.

[0054]
In an embodiment not shown here, the end of the holding element 70, analogous to the holding element 66 of FIG. 9, widened.

[0055]

A fifth embodiment of an anchoring element according to the invention, also designed as a pedicle screw, is shown in FIGS. 13 to 15.

This fifth embodiment differs from the second embodiment according to FIGS. 4 to 6 in that here the gripper

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[0056]
· & Idigr;

[0057]

As a bayonet edge 72, 74 is formed, which is insertable into a corresponding insertion 76, 77 and retaining element 78 on the ring member 48.

By the broad edge 72, 74 creates a large contact surface between the ring member 48 and retaining web 44, 46, which leads to a large friction as soon as the ring member 48 is placed properly. This friction, in turn, hinders the unintentional release of the ring element 48, so that in this way a safeguard against unintentional release of the ring element 48 is achieved.

[0058]

FIGS. 16 to 18 show a sixth embodiment of an anchoring element according to the invention, also designed as a pedicle screw. This sixth embodiment differs from the first embodiment according to FIGS. 1 to 3 in that here too the pins have been replaced by flanks 80, 82, which engage in a corresponding insertion 84 and retaining element 86. Otherwise the same applies to the fifth embodiment.

[0059]

The illustrated in FIGS. 19 to 21 seventh embodiment of an anchoring element according to the invention substantially corresponds to the first embodiment shown in FIGS. 1 to 3, only the gripper of the bayonet closure is formed differently here. As can be seen from FIG. 19, the gripper of the bayonet closure is designed as a radially projecting, upwardly inclined pin 90, 92. This pin 90, 92 is longer than the comparable pin 26, 28 in FIG. 1.

[0060]

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After the rod 24 has been inserted into the receiving slot 22, the ring member 18 is also inserted into the receiving slot 22 in the axial direction. The pins 90, 92 are aligned so that they reach the introduction 30. Now, the operating surgeon must press the ring member 18 with appropriate force on the rod 24, so that the latter is pushed deeper into the receiving slot 22, and so

[0061]

that the pins 90, 92 reach the bottom of the introduction 30. Arrived in this position, the ring member 18 can be pivoted by an angular width, so that the pins 90, 92 reach the holding member 32. Since the rod 24 is biased in this case, the latter presses permanently on the ring member 18th That is, as shown in FIGS. 19 to 21, the ring member 18 is pushed upward. The pins 90, 92 are now made so long that they protrude from the support member 32 and are also inclined according to the force acting on the ring member 18 force upwards. Due to this inclination of the pins 90, 92, the forces acting on the pins 90, 92 by the rod 24 are decomposed into an axial and a radial component. The radial component causes the retaining webs 14, 16 are pressed inwards. This ensures that the ring member 18 is reliably fixed in the holding webs 14, 16 even with large, occurring forces.

[0062]
In another embodiment, not shown here, the pins are curved, also to push the holding webs inwards.

[0063]
It goes without saying that the flank 80, 82 according to FIGS. 60 to 80 can also be inclined or curved.

[0064]
The rod 24 may be formed, for example, as a connection, distraction or compression rod depending on the purpose.

[0065]
LIST OF REFERENCE NUMBERS

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[0066]
10 threaded shaft

[0067]
12 holder

[0068]
14 holding web

[0069]
16 holding web

[0070]
18 ring element

[0071]
20 Fixing element

[0072]
22 receiving slot

[0073]
24 Rod

[0074]
26 pen

[0075]
28 pen

[0076]

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30 introduction

[0077]
32 retaining element

[0078]
34 inner thread

[0079]
40 threaded shaft

[0080]
42 holder

[0081]
44 holding web

[0082]
46 holding web

[0083]
48 rings element

[0084]
50 Fixing element

[0085]
52 inner thread

[0086]
54 receiving slot

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[0087]
56 pen

[0088]
58 pen

[0089]
61 introduction

[0090]
62 retaining element

[0091]
63 Holding element 66 holding element 68 widening 70 holding element 72 flank

[0092]
74 flank

[0093]
76 introduction

[0094]
77 introduction

[0095]
78 Retaining element 80 flank

[0096]
82 flank

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[0097]
84 introduction

[0098]
86 retaining element

[0099]
90 pen

[0100]
92 pen

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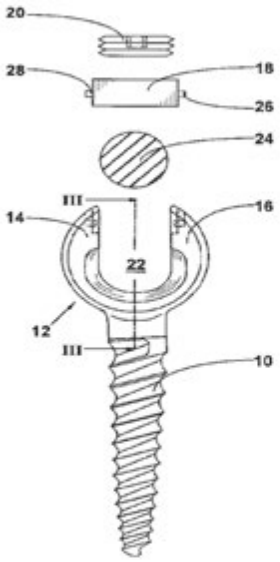
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(54) Verankerungselement zur Befestigung eines Stabes einer Vorrichtung zum Einrichten einer menschlichen oder tierischen Wirbelsäule an einem Wirbelknochen

(57) Verankerungselemente zur Befestigung eines Stabes einer Vorrichtung zum Einrichten einer menschlichen oder tierischen Wirbelsäule an einem Wirbelknochen, mit einer im wesentlichen U-förmig ausgebildeten und zwei im wesentlichen parallel angeordnete Haltestege (14, 16, 44, 46) umfassenden Halterung (12, 42), in dem ein Aufnahmeschlitz (22, 54) zur Aufnahme des Stabes (24) ausgebildet ist, und mit einem gegen den im Aufnahmeschlitz (22, 54) aufgenommenen Stab (22) wirkenden Sicherungselement, dadurch gekennzeichnet, dass das Sicherungselement ein Feststellelement (20, 50) und ein Ringelement (18, 48) umfasst, wobei das Ringelement (18, 48) mittels einer Renkverbindung am freien Ende der Haltestege (14, 16, 44, 46) anbringbar ist.



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VERANKERUNGSELEMENT ZUR BEFESTIGUNG EINES STABES EINER VORRICHTUNG ZUM EINRICHTEN EINER MENSCHLICHEN ODER TIERISCHEN WIRBELSÄULE AN EINEM WIRBELKNOCHEN

Die vorliegende Erfindung betrifft ein Verankerungselement zur Befestigung eines Stabes einer Vorrichtung zum Einrichten einer menschlichen oder tierischen Wirbelsäule an einem Wirbelknochen, mit einern im wesentlichen U-förmig ausgebildeten und zwei im wesentlichen parallel angeordnete Haltestege umfassenden Halterung, in dem ein Aufnahmeschlitz zur Aufnahme des Stabes ausgebildet ist, und mit einem gegen den im Aufnahmeschlitz aufgenommenen Stab wirkenden Sicherungselement.

DE 202 07 850 U1

Aus dem DE 94 02 839 ist eine Pedikelschraube bekannt, die mit ihrem Gewindeschaft in einem Wirbelkörper verankerbar ist und die an ihrem aus dem Wirbelknochen herausragenden Ende eine U-förmig gebildete Halterung mit zwei parallel ausgerichteten Haltestegen aufweist. Dabei ist zwischen den Haltestegen ein Aufnahmeschlitz zur Aufnahme eines Distraktions- oder Kompressionsstabes ausgebildet, der mittels einem an den freien Enden der Haltestege befestigbaren Sicherungselement gesichert und fixiert werden kann. Dieses Sicherungselement setzt sich in einer ersten Ausführungsform aus einem sechseckigen, ringförmigen Element mit einer darin eingelassenen Feststellschraube zusammen, wobei das gesamte Sicherungselement in eine entsprechende Nut in den Haltestegen einschiebbar ist. Das Sicherungselement überspannt den Aufnahmeschlitz, so dass die Feststellschraube direkt auf den Stab wirkt, um diesen zu fixieren.

In einer anderen Ausführungsform setzt sich das Sicherungselement aus einem das Halteelement umschließenden Hülle mit Innengewinde zusammen, wobei die Hülle auf ein entsprechendes, auf den Außenseiten der Haltestege vorgesehenes Gewinde aufschraubbar ist, so dass die auf der Stirnseite der Hülle vorgesehene Feststellschraube in den Aufnahmeschlitz eingreifen kann, um den Stab zu fixieren.

Bei einer derartigen Vorrichtung muss also zunächst einmal die Pedikelschraube im Wirbelkörper verankert werden, um anschließend den Stab in den Aufnahmeschlitz einzulegen. Danach wird das Sicherungselement entweder in die Nuten eingeführt oder aber auf die Halterung aufgeschraubt, bevor der Wirbel bzw. der Stab durch Anziehen der Feststellschraube in die gewünschte Position gebracht wird. Dies hat sich in der Praxis als sehr schwierig herausgestellt, da entweder das Einführen des Sicherungselementes in die Nuten oder das Aufschrauben des Sicherungselementes auf die Halterung sehr viel Fingerspitzengefühl erfordert, wobei gleichzeitig darauf geachtet werden muss, dass der

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Wirbelkörper und/oder der Stab währenddessen nicht verrutscht.

Aus dem DE 297 10 484 ist ein Verankerungselement bekannt, bei dem an den Innenseiten der Haltestege ein Sägezahngewinde zur Aufnahme der Feststellschraube vorgesehen ist. Hierdurch wird erreicht, dass die bei einem normalen Gewinde radial auf die Haltestege wirkenden Kräfte entfallen und lediglich axial wirkende Kräfte am Haltesteg angreifen. Hierdurch wird ein Auseinanderbiegen der Haltestege verhindert, so dass auch das die Haltestege umfassende Ringelement entfallen kann. Auch hier hat es sich in der Praxis als sehr mühsam herausgestellt, die jeweilige Feststellschraube in das entsprechende Sägezahngewinde einzuschrauben und dabei gleichzeitig die Wirbelsäule und/oder den Stab so lange in der gewünschten Position zu halten, bis die Feststellschraube den Stab selbständig hält.

Davon ausgehend liegt der vorliegenden Erfindung die Aufgabe zugrunde, ein Verankerungselement zu schaffen, bei dem das Sicherungselement die auftretenden Kräfte zuverlässig aufnimmt und bei dem das Sicherungselement einfach und schnell anzubringen ist.

Als technische Lösung dieser Aufgabe wird erfindungsgemäß vorgeschlagen, das eingangs genannte Verankerungselement dadurch weiterzubilden, dass das Sicherungselement ein Feststellelement und ein Ringelement umfasst, wobei das Ringelement mittels einer Renkverbindung am freien Ende der Haltestege anbringbar ist.

Ein nach dieser technischen Lehre ausgebildetes Verankerungselement hat den Vorteil, dass das Ringelement lediglich axial auf die freien Ende der Haltestege aufgesetzt werden braucht und durch ein leichtes Verschwenken in seine endgültige, gesicherte Position gebracht werden kann. Ein derart gesichertes Ringelement hält den im Aufnahmeschlitz

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befindlichen Stab bereits provisorisch in der gewünschten Position, so dass der operierende Arzt nun in Ruhe das Feststellelement einschrauben kann, um den Stab zu justieren und zu fixieren.

Dabei hat es sich als vorteilhaft erwiesen, die Renkverbindung als Bajonettverschluss, mit einem radial abstehenden Greifer und einer schlitz- oder nutartigen Aufnahme auszubilden, wobei der Greifer in die Aufnahme eingreift, um das Ringelement der Haltestege zu fixieren. Ein solcher Bajonettverschluss ist kostengünstig realisierbar und erlaubt eine schnelle und einfache Anbringung des Ringelementes an der Halterung des Verankerungselementes.

Die Ausgestaltung der Aufnahme mit einer axialen Einführung und einem radialen Halteelement hat den Vorteil, dass der Greifer in einfacher Weise in die Einführung gebracht werden kann und durch Verdrehen in das Halteelement gelangt, um dort zu verharren und einen formschlüssigen Bajonettverschluss zu bilden.

Es versteht sich, dass der Stab beispielsweise als Distraktions-, Kompressions- oder Verbindungsstab ausgebildet sein kann.

In einer bevorzugten Ausführungsform ist das Ringelement in den Aufnahmeschlitz einführbar und zwischen den Haltestegen anbringbar, wobei der Greifer außen am Ringelement angebracht ist, während die Aufnahme in den Haltestegen angeordnet ist. Dies hat den Vorteil, dass hiermit das Ringelement ebenfalls im Aufnahmeschlitz integriert ist, so dass das gesamte Verankerungselement sehr klein ausgeführt werden kann.

In einer anderen, bevorzugten Ausführungsform umgreift das Ringelement die Haltestege, wobei die Aufnahme im Ringelement angeordnet ist, während der Greifer an den Haltestegen angebracht ist. Dies hat den

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Vorteil, dass auch hierdurch die vom Feststellelement ausgehenden radialen Kräfte vom Ringelement aufgenommen werden, ohne dass dabei die Haltestege in unerwünschter Weise auseinandergedrückt werden.

In noch einer anderen, bevorzugten Ausführungsform ist die Einführung V-förmig ausgebildet. Dies hat den Vorteil, dass der in diese Einführung einzuführende Greifer lediglich grob auf die Einführung aufgesetzt werden braucht und anschließend durch die V-förmige Ausgestaltung dennoch korrekt bis zum quer ausgerichteten Halteelement geführt wird, um anschließend durch Verschwenken des Ringelementes in dieses eingeführt zu werden. Hierdurch wird das Aufsetzen des Ringelementes auf die Haltestege weiter vereinfacht.

In einer weiteren bevorzugten Ausführungsform ist das Halteelemet nach oben ansteigend ausgebildet, wodurch das Ringelement nicht nur eine drehende, sondern zusätzlich eine axiale Bewegung vollziehen muß, um gelöst zu werden. Durch solch ein Zusatzerfordenis beim Lösen des Ringelementes wird ein unbeabsichtigtes Lösen des Ringelementes erschwert. Anloges gilt für eine Verbreiterung des Endes des Halteelementes.

In wieder einer anderen, bevorzugten Ausführungsform ist der Greifer als Stift als Flanke ausgebildet. Die Flanke liegt vorteilhafterweise mit einer größeren Fläche an dem Halteelement an, so dass über die dem-entsprechend höhere Reibung ein unbeabsichtigte Lösen des Ringelementes erwschwert wird.

In noch einer anderen bevorzugten Ausführungsform reicht der Greifer durch die Aufnahme hindurch und aus dieser heraus und ist derart gekrümmt oder geneigt, vorzugsweise in Richtung der auf das Sicherungselement weilenden Kräfte, so dass den Haltesteg nach innen

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gedrückt wird. Hierdruch werden die Haltestege aufgrund der wirkenden Haltekräfte des Verankerungselementees nach innen gedrückt und es ist gewährleistet, dass das Ringelement zuverlässig in den Haltestegen gehalten wird. Ein Herausspringen des Sicherungselementes aufgrund sich aufbiegenden Haltestegen wird so verhindert.

In einer bevorzugten Weiterbildung ist im Ringelement ein Gewinde zur Aufnahme des Feststellelementes vorgesehen. Neben dem oben genannten Vorteil, dass hierdurch eine geringe Baugröße erreicht wird, hat dies weiterhin den Vorteil, dass die vom Feststellelement ausgehenden radialen Kräfte vollständig vom Ringelement aufgenommen werden, ohne dass hierbei Verformungen wie im Stand der Technik auftreten.

Weitere Vorteile des erfindungsgemäßen Verankerungselementes ergeben sich aus der beigefügten Zeichnung und den nachfolgend beschriebenen Ausführungsformen. Ebenso können die vorstehend genannten und die noch weiter ausgeführten Merkmale erfindungsgemäß jeweils einzeln oder in beliebigen Kombinationen miteinander verwendet werden. Die erwähnten Ausführungsformen sind nicht als abschließende Aufzählung zu verstehen, sondern haben vielmehr beispielhaften Charakter. Es zeigen:

Fig. 1 eine Explosionsdarstellung einer ersten Ausführngsform eines erfindungsgemäßen Verankerungselementes mit einem Stab;

Fig. 2 eine Draufsicht auf das Ringelement gemäß Fig. 1;

Fig. 3 eine teilweise geschnittene Seitenansicht des Verankerungselementes gemäß Fig. 1, geschnitten entlang Linie III - III in Fig. 1;

Fig. 4 eine Explosionsdarstellung einer zweiten Ausführungsform eines erfindungsgemäßen Verankerungselementes mit einem Stab;

Fig. 5 eine Draufsicht auf das Ringelement gemäß Fig. 4;

Fig. 6 eine Seitenansicht des Verankerungselementes gemäß Fig. 4;

Fig. 7 eine Explosionsdarstellung einer dritten Ausführungsform eines

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erfindungsgemäßen Verankerungselementes mit einem Stab;

Fig. 8 eine Draufsicht auf das Ringelement gemäß Fig. 7;

Fig. 9 eine teilweise geschnittene Seitenansicht des Verankerungselementes gemäß Fig. 7, geschnitten entlang Linie IX - IX in Fig. 7;

Fig. 10 eine Explosionsdarstellung einer vierten Ausführungsform eines erfindungsgemäßen Verankerungselementes mit einem Stab;

Fig. 11 eine Draufsicht auf das Ringelement gemäß Fig. 10;

Fig. 12 eine Seitenansicht des Verankerungselementes gemäß Fig. 10;

Fig. 13 eine Explosionsdarstellung einer fünften Ausführungsform eines erfindungsgemäßen Verankerungselementes mit einem Stab;

Fig. 14 eine Draufsicht auf das Ringelement gemäß Fig. 13;

Fig. 15 eine Seitenansicht des Verankerungselementes gemäß Fig. 13;

Fig. 16 eine Explosionsdarstellung einer sechsten Ausführungsform eines erfindungsgemäßen Verankerungselementes mit einem Stab;

Fig. 17 eine Draufsicht auf das Ringelement gemäß Fig. 16;

Fig. 18 eine teilweise geschnittene Seitenansicht des Verankerungselementes gemäß Fig. 16, geschnitten entlang Linie XVIII - XVIII in Fig. 16;

Fig. 19 einer Explosionsdarstellung einer siebten Ausführungsform eines erfindungsgemäßen Verankerungselementes;

Fig. 20 eine Draufsicht auf das Ringelement gemäß Fig. 19;

Fig. 21 eine Seitenansicht des Verankerungselementes gemäß Fig. 19.

In den Figuren 1 bis 3 ist eine erste Ausführungsform eines als Pedikelschraube ausgebildeten Verankerungselementes dargestellt, wobei das Verankerungselement zur Einbringung in den Wirbelknochen einen Gewindeschaft 10, sowie eine U-förmig ausgebildete Halterung 12 mit zwei im Wesentlichen parallel angeordneten Haltestegen 14, 16, ein Ringelement 18 und ein als Madenschraube ausgeführtes Feststellelement 20 umfasst. Dabei ist in der Halterung 12 ein Aufnahmeschlitz 22 zur Aufnahme eines Stabes 24 vorgesehen, welcher über das sich aus dem Feststellelement 20

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und dem Ringelement 18 zusammensetzenden Sicherungselement fixiert wird.

In dieser Ausführungform sind am Ringelement 18 an sich gegenüberliegenden Seiten zwei Bajonett-Stifte 26, 28 radial abstehend ausgebildet, welche in eine entssprechende, an der Innenseite der Haltestege 14, 16 ausgebildete Einführung 30 und ein Halteelement 32 einsetzbar sind. Dabei wird das Ringelement 18 mit seinen beiden Stiften 26, 28 von oben in die nach oben offene Einführung 30 eingeführt, und bis an den Grund der Einführung 30 gebracht, bevor das Ringelement 18 um einige Winkelgrade verschwenkt wird, so dass die Stifte 26, 28 bis ans Ende des Halteelementes 32 geführt werden. In dieser Position angekommen, wird das Ringelement 18 losgelassen und verbleibt zuverlässig in dieser Position.

Wie aus Figur 3 gut ersichtlich ist, ist die Einführung 30 V-förmig ausgebildet, um einen großen Fangbereich zum Einführen der Stifte 26, 28 zu bilden.

Im Ringelement 18 ist ein Innengewinde 34 zur Aufnahme des als Madenschraube ausgebildeten Feststellelementes 20 vorgesehen. Dabei wird das Feststellelement 20 so weit in das Ringelement 18 hereingeschraubt, dass das Feststellelement 20 auf den Stab 24 drückt und diesen in der gewünschten Position fixiert.

In den Fig. 4 bis 6 ist eine zweite Ausführungsform eines erfindungsgemäßen, ebenfalls als Pedikelschraube ausgeführten Verankerungselementes dargestellt. Auch hier setzt sich das Verankerungselement aus einem Gewindeschaft 40 zur Anbringung des Verankerungselementes im Wirbelknochen, einer U-förmig ausgebildeten Halterung 42 mit zwei im Wesentlichen parallel angeordneten Haltestegen 44, 46, einem Ringelement 48 und einem als Madeschraube ausgeführten Feststellelement 50

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zusammen. In dieser Ausführungsform ist an den jeweiligen Innenseiten der Haltestege 44, 46 ein Innengewinde 52 zur Aufnahme des als Madenschrauben ausgebildeten Feststellelementes 50 ausgebildet. Damit in dieser Ausführungsform die auf die Haltestege 44, 46 wirkenden, radialen Kräfte nicht zu einem Aufbiegen der Haltestege 44, 46 führen, wird hierbei das Ringelement 48 außen um die Haltestege 44, 46 herumgelegt.

Auch in dieser Ausführungsform ist in der Halterung 42 ein Aufnahmeschlitz 54 eines Stabes 24 ausgebildet, welcher durch das Feststellelement 50 in der gewünschten Position festgestellt wird.

An den nach außen weisenden Seiten der Haltestege 44, 46 ist jeweils ein radial abstehender Stift 56, 58 vorgesehen, die in entsprechende, innenseitig am Ringelement 48 vorgesehene Einführungen 61 einführbar sind, wobei sich auch hier an die Einführung 60, 61 quasi rechtwinklig entsprechende Halteelemente 62, 63 anschließen. Auch hier sind die Einführungen 60, 61 V-förmig ausgeführt, um einen großen Fangbereich zu realisieren.

In den Fig. 7 bis 9 ist eine dritte Ausführungsform eines erfindungsgemäßen, ebenfalls als Pedikelschraube ausgeführten Verankerungselementes dargestellt. Diese dritte Ausführungsform unterscheidet sich von der ersten Ausführungsform gemäß Fig. 1 bis 3 dadurch, dass an der Innenseite der Haltestege 14, 16, sich an die Einführung 30 anschließend eine leicht nach oben ansteigendes Halteelement 66 ausgebildet ist, an dessen Ende eine Verbreiterung 68 vorgesehen ist. Dabei ist die Verbreiterung 68 im Wesentlichen kreisförmig gestaltet. In dieser Halteelement 66 ist der Stift 26, 28 einführbar und verklemmt sich bei entsprechendem Verdrehen des Ringelementes 18 in dem nach oben laufenden Halteelement 66, so dass hierdurch eine Klemmsicherung erreicht wird. Dabei steigt das Halteelement 66 in Richtung der auf das Sicherungselement wirkenden Kräfte.

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Die Verbreiterung 68 am Ende des Halteelementes 66 bewirkt auch, dass die beim Verdrehen des Ringelementes 18 zwischen Stift 26, 28, bzw. Ringelement 18 einerseits und den Haltestegen 14, 16 andererseits aufgebaute Spannung zumindest teilweise wieder abgebaut wird, da die Verbreiterung 68 teilweise in Richtung der Haltekraft erstreckt und somit den Druck zwischen Sicherungselement und Stab 24 zumimdest teilweise aufhebt. Gleichzeitig wird hierdurch eine zuverlässige und dauerhafte Sicherung des Ringelementes 18 erreicht, da zum Lösen des Ringelementes 18 eben dieser Druck wieder aufgebaut werden muß, was ohne externe, gezielte Krafteinwirkung nicht möglich ist. Dies bedeutet, dass sich das Ringelement 18 nicht von alleine lösen kann.

In den Fig. 10 bis 12 ist eine vierte Ausführungsform eines erfindungsgemäßen, ebenfalls als Pedikelschraube ausgeführten Verankerungselementes dargestellt. Diese vierte Ausführungsform unterscheidet sich von der zweiten Ausführungsform gemäß Fig. 4 bis 6 dadurch, dass an der Innenseite des Ringelementes 48, sich an die Einführung 61 anschließend eine leicht nach oben ansteigendes Halteelement 70 ausgebildet ist. In dieses Halteelement 70 ist der Stift 56, 58 einführbar und verklemmt sich bei entsprechendem Verdrehen des Ringelementes 48 in dem nach oben laufenden Halteelement 70, so dass hierdurch eine Klemmsicherung erreicht wird.

In einer hier nicht dargestellten Ausführungsform ist das Ende des Halteelementes 70, analog zum Halteelement 66 gemäß Fig. 9, verbreitert ausgebildet.

In den Fig. 13 bis 15 ist eine fünfte Ausführungsform eines erfindungsgemäßen, ebenfalls als Pedikelschraube ausgeführten Verankerungselementes dargestellt. Diese fünfte Ausführungsform unterscheidet sich von der zweiten Ausführungsform gemäß Fig. 4 bis 6 dadurch, dass hier der Greifer

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als Bajonett-Flanke 72, 74 ausgebildet ist, die in eine entsprechende Einführung 76, 77 und Halteelement 78 am Ringelement 48 einführbar ist. Durch die breite Flanke 72, 74 entsteht eine große Anlagefläche zwischen Ringelement 48 und Haltesteg 44, 46, was zu einer großen Reibung führt, sobald das Ringelement 48 vorschriftsmäßig aufgesetzt ist. Diese Reibung widerum erschwert das unbeabsichtigte Lösen des Ringelementes 48, so dass hierdurch eine Sicherung gegen unbeabsichtigtes Lösen des Ringelementes 48 erreicht wird.

In den Fig. 16 bis 18 ist eine sechste Ausführungsform eines erfindungsgemäßen, ebenfalls als Pedikelschraube ausgeführten Verankerungselementes dargestellt. Diese sechste Ausführungsform unterscheidet sich von der ersten Ausführungsform gemäß Fig. 1 bis 3 dadurch, dass auch hier die Stifte durch Flanken 80, 82 ersetzt wurden, die in eine entsprechende Einführung 84 und Halteelement 86 eingreifen. Im übrigen gilt das zur fünften Ausführungsform gesagte analog.

Die in den Fig. 19 bis 21 dargestellte siebte Ausführungsform eines erfindungsgemäßen Verankerungselementes entspricht im wesentlichen der in den Fig. 1 bis 3 gezeigten ersten Ausführungsform, einzig der Greifer des Bajonettverschlusses ist hier anders ausgebildet. Wie Fig. 19 zu entnehmen ist, ist der Greifer des Bajonettverschlusses als ein radial abstehender, nach oben geneigter Stift 90, 92 ausgebildet. Dieser Stift 90, 92 ist länger als der vergleichbare Stift 26, 28 in Fig. 1.

Nachdem der Stab 24 in den Aufnahmeschlitz 22 eingelegt wurde, wird das Ringelement 18 ebenfalls in axialer Richtung in den Aufnahmeschlitz 22 eingeführt. Dabei sind die Stifte 90, 92 so ausgerichtet, dass sie in die Einführung 30 gelangen. Nun muss der operierende Chirurg das Ringelement 18 mit angemessener Kraft auf den Stab 24 aufdrücken, so das letzterer tiefer in den Aufnahmeschlitz 22 hineingedrückt wird, und so

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dass die Stifte 90, 92 bis auf den Grund der Einführung 30 gelangen. In dieser Position angekommen, kann das Ringelement 18 um eine Winkelbreite verschwenkt werden, so dass die Stifte 90, 92 in das Halteelement 32 gelangen. Da der Stab 24 hierbei vorgespannt wird, drückt letzterer dauerhaft auf das Ringelement 18. Das heißt gemäß den Fig. 19 bis 21 wird das Ringelement 18 nach oben gedrückt. Die Stifte 90, 92 sind nun so lang ausgeführt, dass diese aus dem Halteelement 32 herausragen und entsprechend der auf das Ringelement 18 wirkenden Kraft ebenfalls nach oben geneigt sind. Durch diese Neigung der Stifte 90, 92 werden die durch den Stab 24 auf die Stifte 90, 92 wirkenden Kräfte in einer Axial- und einer Radialkomponente zerlegt. Dabei bewirkt die Radialkomponente, dass die Haltestege 14, 16 nach innen gedrückt werden. Hierdurch wird gewährleistet, dass das Ringelement 18 auch bei großen, auftretenden Kräften zuverlässig in den Haltestegen 14, 16 fixiert wird.

In einer anderen, hier nicht dargestellten Ausführungsform sind die Stifte gekrümmt ausgebildet, ebenfalls um die Haltestege nach innen zu drücken.

Es versteht sich, dass die Flanke 80, 82 gemäß Fig. 60 bis 80 ebenfalls geneigt oder gekrümmt ausgebildet sein kann.

Der Stab 24 kann je nach Verwendungszweck beispielsweise als Verbindungs-, Distraktions- oder Kompressionsstab ausgebildet sein.

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Bezugszeichenliste:

10	Gewindeschaft	61	Einführung
12	Halterung	62	Halteelement
14	Haltesteg	63	Halteelement
16	Haltesteg	66	Halteelement
18	Ringelement	68	Verbreiterung
20	Feststellelement	70	Halteelement
22	Aufnahmeschlitz	72	Flanke
24	Stab	74	Flanke
26	Stift	76	Einführung
28	Stift	77	Einführung
30	Einführung	78	Haltelement
32	Halteelement	80	Flanke
34	Innengewinde	82	Flanke
40	Gewindeschaft	84	Einführung
42	Halterung	86	Halteelement
44	Haltesteg	90	Stift
46	Haltesteg	92	Stift
48	Ringeelement		
50	Feststellelement		
52	Innengewinde		
54	Aufnahmeschlitz		
56	Stift		
58	Stift		

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Ansprüche:

1. Verankerungselemente zur Befestigung eines Stabes einer Vorrichtung zum Einrichten einer menschlichen oder tierischen Wirbelsäule an einem Wirbelknochen, mit einer im wesentlichen U-förmig ausgebildeten und zwei im wesentlichen parallel angeordnete Haltestege (14, 16, 44, 46) umfassenden Halterung (12, 42), in dem ein Aufnahmeschlitz (22, 54) zur Aufnahme des Stabes (24) ausgebildet ist, und mit einem gegen den im Aufnahmeschlitz (22, 54) aufgenommenen Stab (22) wirkenden Sicherungselement, dadurch gekennzeichnet, dass das Sicherungselement ein Feststellelement (20, 50) und ein Ringelement (18, 48) umfasst, wobei das Ringelement (18, 48) mittels einer Renkverbindung am freien Ende der Haltestege (14, 16, 44, 46) anbringbar ist.

2. Verankerungselement nach Anspruch 1, dadurch gekennzeichnet, dass die Renkverbindung als Bajonettverschluß ausgebildet ist, wobei der Bajonettverschluß eine schlitz- oder nutartige Aufnahme und einen in die Aufnahme eingreifenden Greifer umfasst.

3. Verankerungselement nach Anspruch 2, dadurch gekennzeichnet, dass die Aufnahme eine axiale Einführung (30, 61, 76, 77, 84) und ein tangentiales Halteelement (32, 62,63, 66, 70, 78, 86) umfasst.

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4. Verankerungselement nach wenigstens einem der Ansprüche 2 oder 3, dadurch gekennzeichnet, dass das Ringelement (18) axial in den Aufnahmeschlitz (22) einführbar und zwischen den Haltestegen (14, 16) anbringbar ist, wobei der Bajonettgreifer aussen am Ringelement (18) angebracht ist, während die Aufnahme in den Haltestegen (14, 16) angeordnet ist.

5. Verankerungselement nach wenigstens einem der Ansprüche 2 oder 3, dadurch gekennzeichnet, dass das Ringelement (48) die Haltestege (44, 46) umgreift, wobei die Aufnahme im Ringelement (48) angeordnet ist, während der Greifer an den Haltestegen (44, 46) angebracht ist.

6. Verankerungselement nach wenigstens einem der Ansprüche 3 bis 5, dadurch gekennzeichnet, dass die Einführung (30, 61, 76, 77, 84) V-förmig ausgebildet ist.

7. Verankerungselement nach wenigstens einem der Ansprüche 3 bis 6, dadurch gekennzeichnet, dass das Halteelement (66, 70) leicht nach oben steigend ausgebildet ist.

8. Verankerungselement nach wenigstens einem der Ansprüche 3 bis 7, dadurch gekennzeichnet, dass sich das Halteelement (66) am Ende verbreitert.

9. Verankerungselement nach wenigstens einem der Ansprüche 2 bis 8, dadurch gekennzeichnet, dass der Greifer als Stift (26, 28, 56, 58, 90, 92) oder Flanke (72, 74, 80, 82) ausgebildet ist.

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10. Verankerungselement nach wenigstens einem der Ansprüche 2 bis 9, dadurch gekennzeichnet, dass der im wesentlichen radial abstehende Greifer durch die Aufnahme hindurch und aus dieser heraus reicht, wobei der Greifer derart gekrümmt oder geneigt ist, dass der im Bereich des Halteelementes (32) am Haltesteg (14, 16) zur Anlage kommende Greifer diesen nach Innen drückt.

11. Verankerungselement nach Anspruch 10, dadurch gekennzeichnet, dass der Greifer in Richtung der auf das Sicherungselement wirkenden Kräfte gekrümmt oder geneigt ist.

12. Verankerungselement nach einem der vorangehenden Ansprüche, dadurch gekennzeichnet, dass im Ringelement (18, 48) ein Gewinde (34, 52) zur Aufnahme des Feststellelementes (20, 50) vorgesehen ist.

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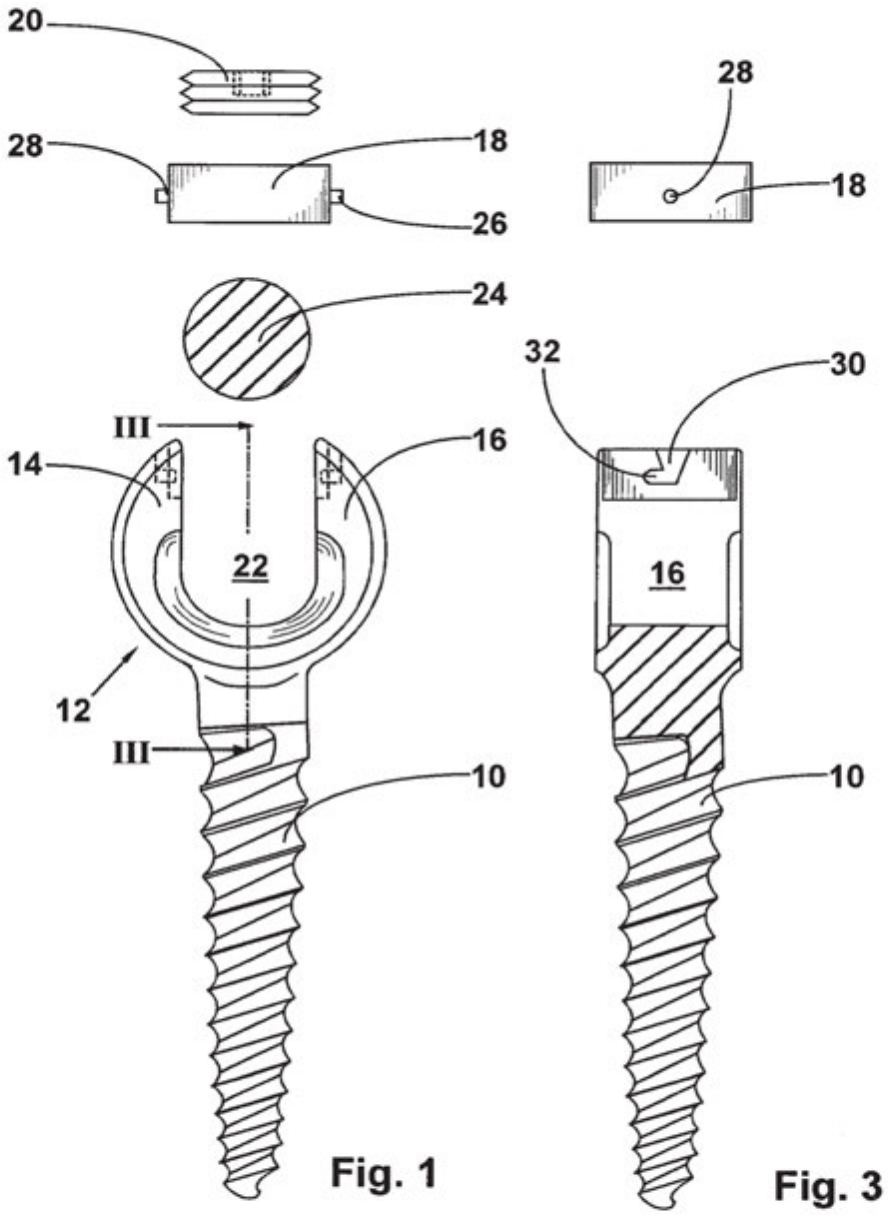


Fig. 1

Fig. 3

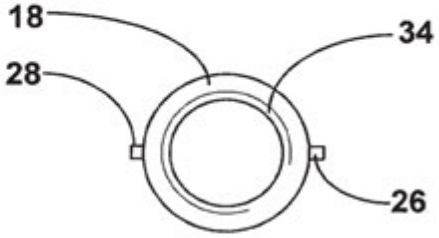


Fig. 2

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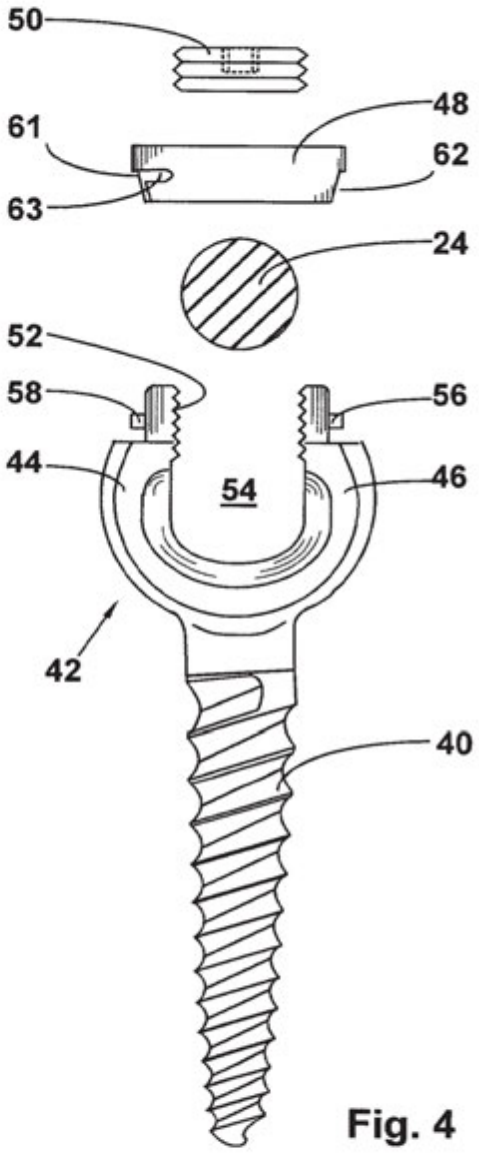


Fig. 4

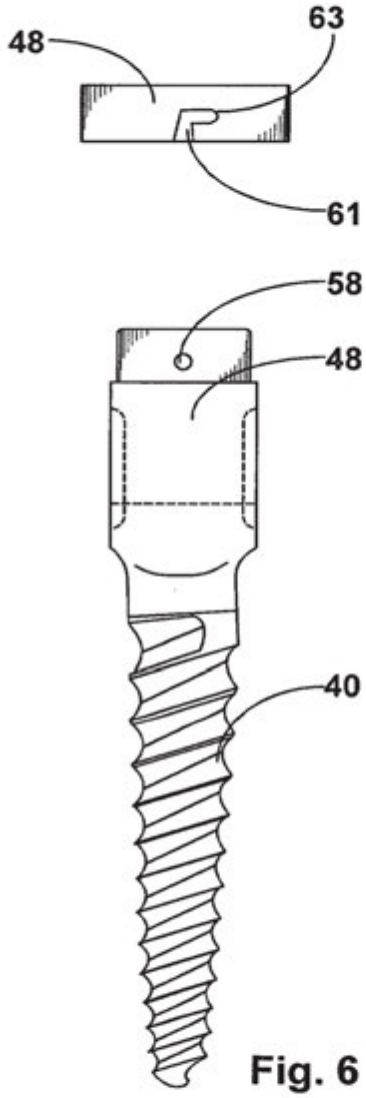


Fig. 6

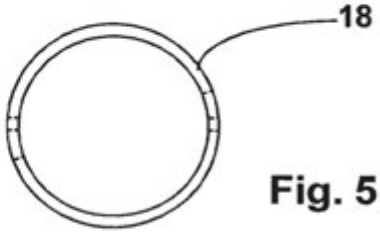


Fig. 5

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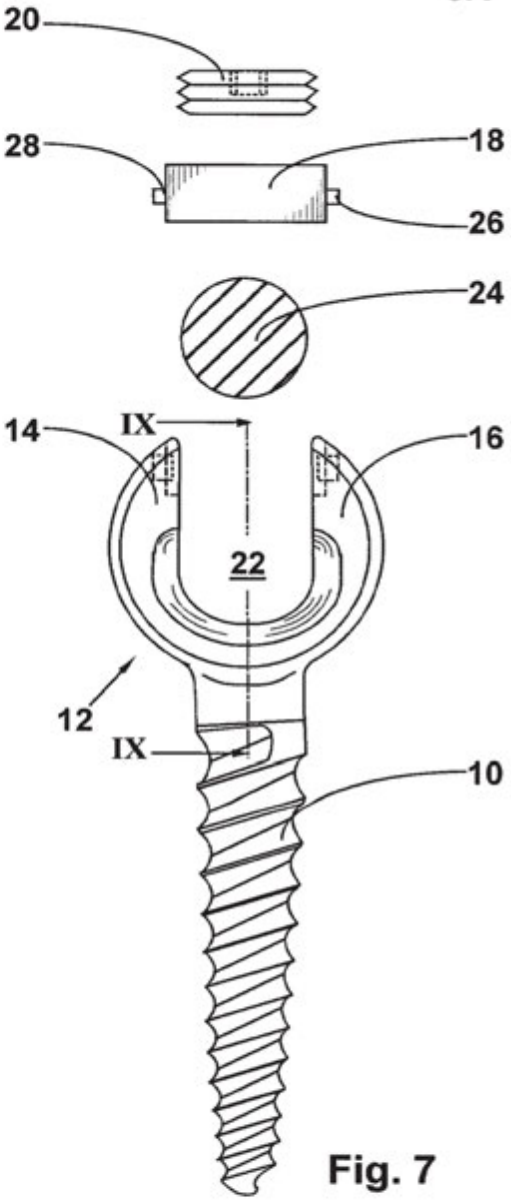


Fig. 7

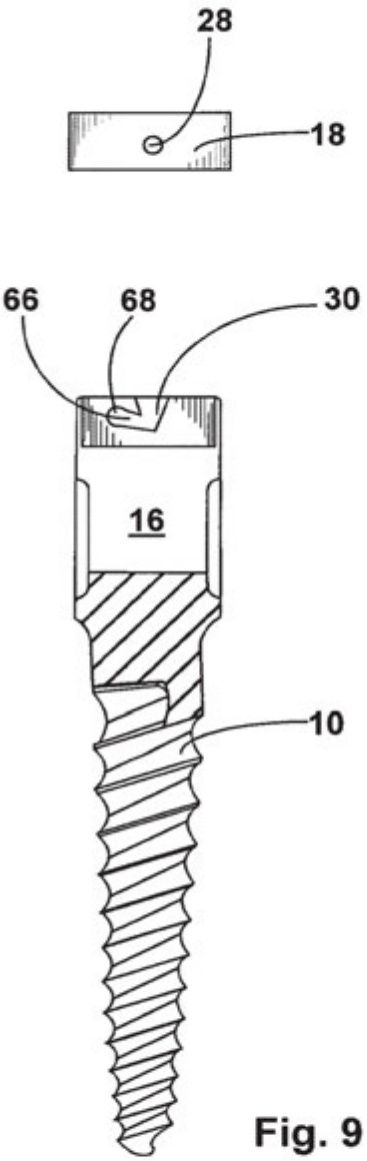


Fig. 9

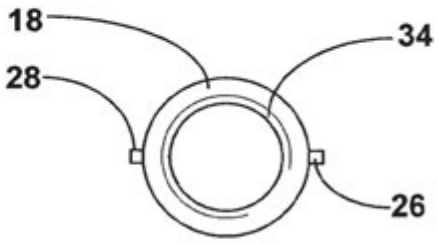


Fig. 8

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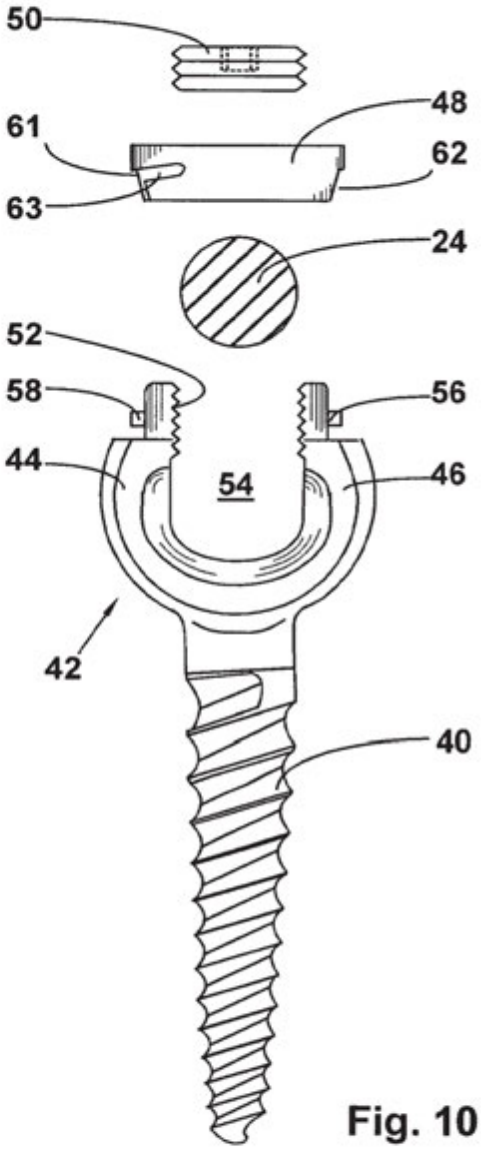


Fig. 10

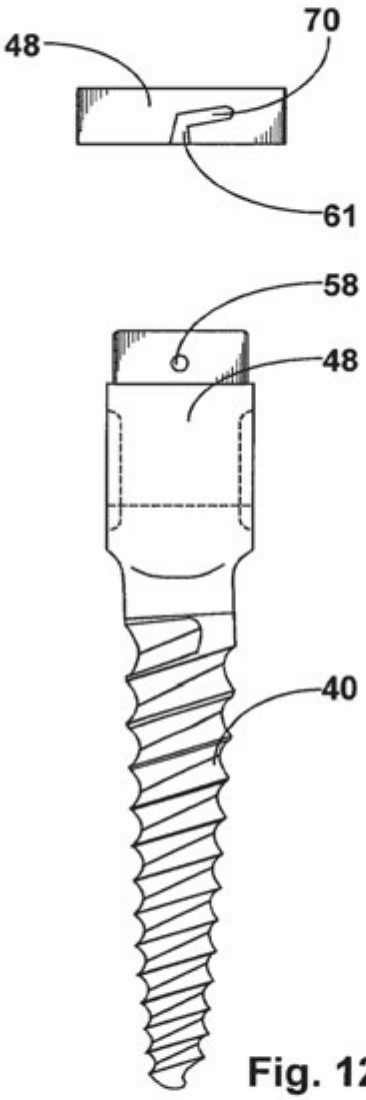


Fig. 12

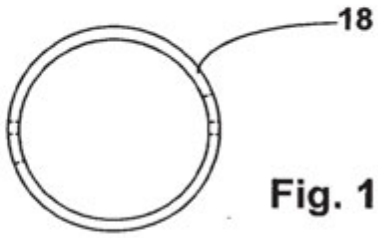


Fig. 11

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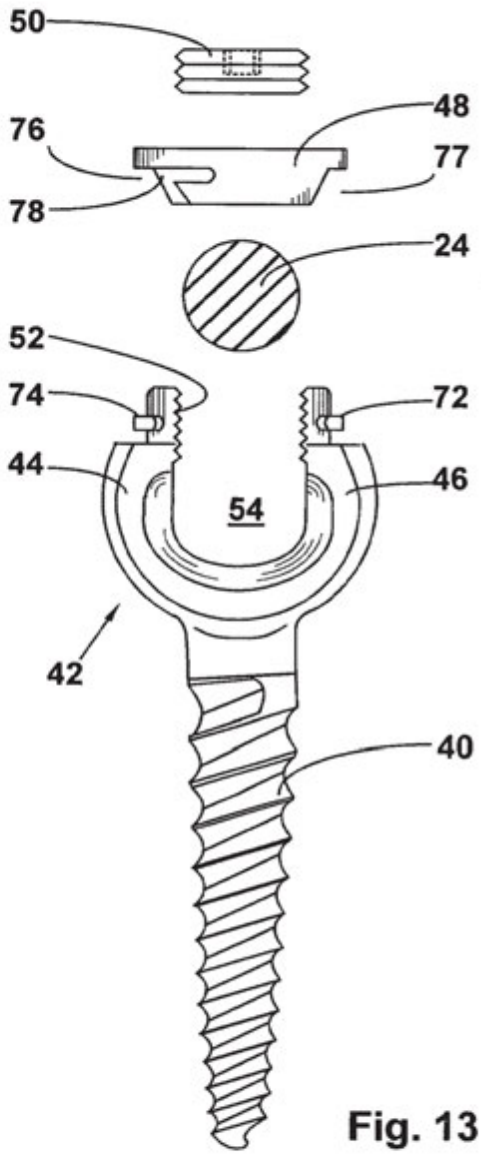


Fig. 13

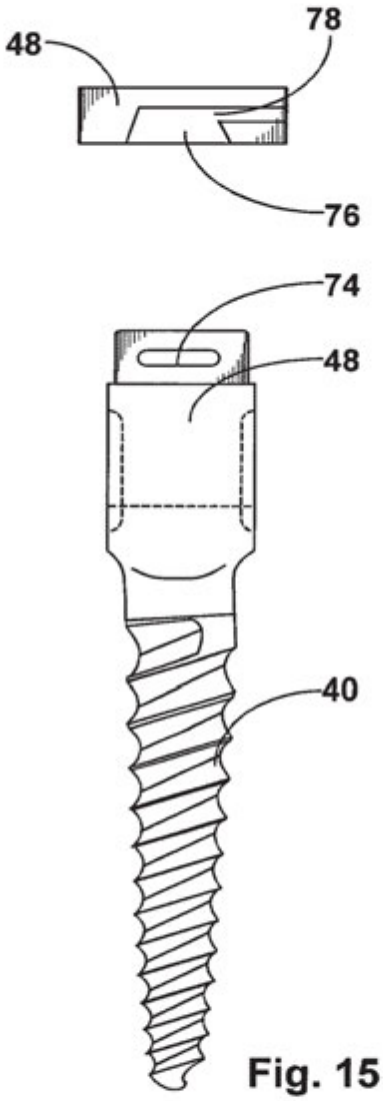


Fig. 15

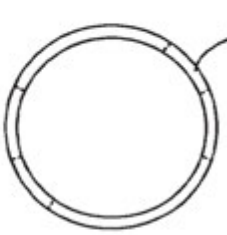


Fig. 14

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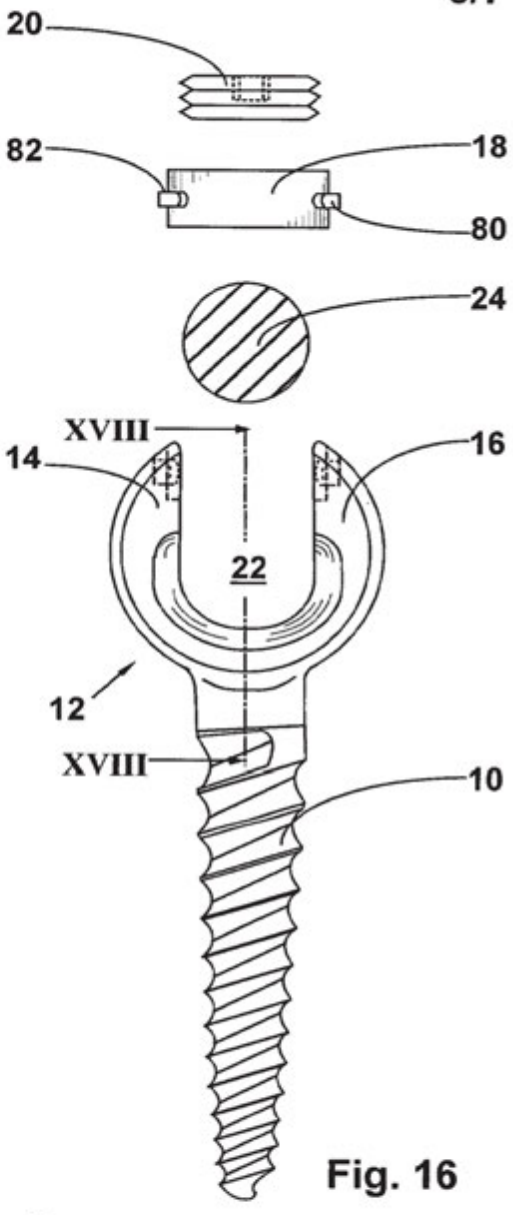


Fig. 16

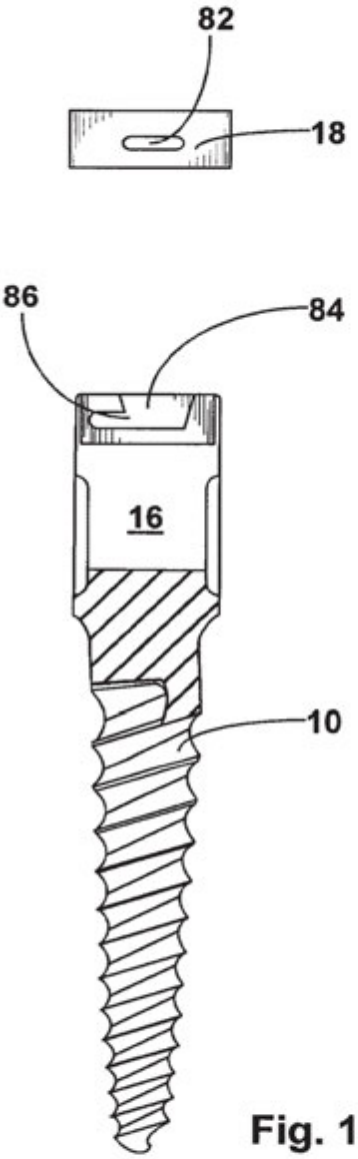


Fig. 18

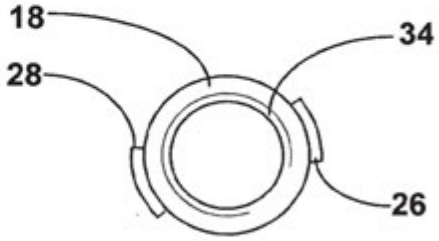


Fig. 17

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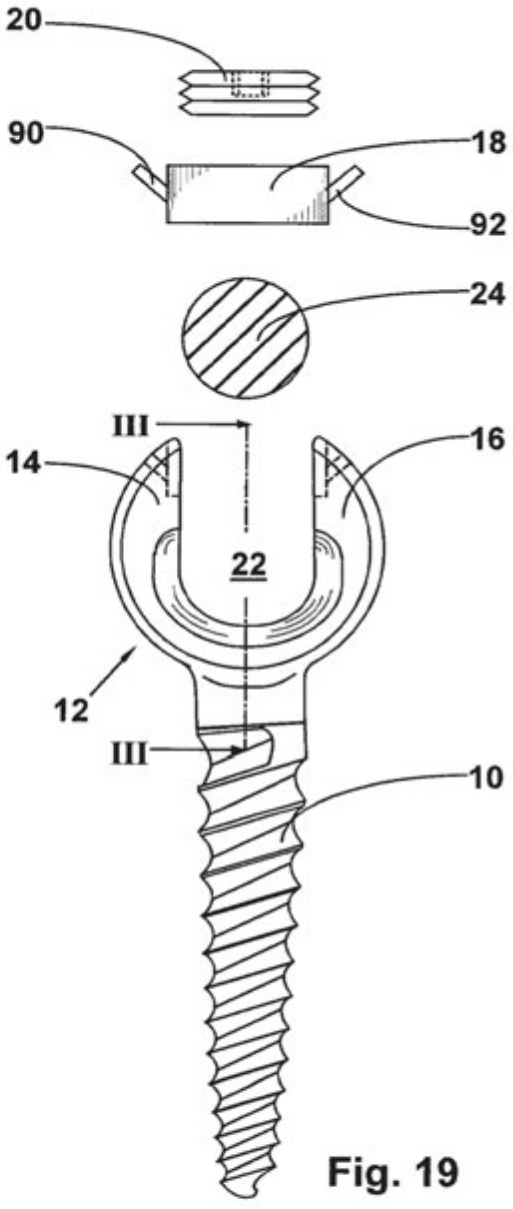


Fig. 19

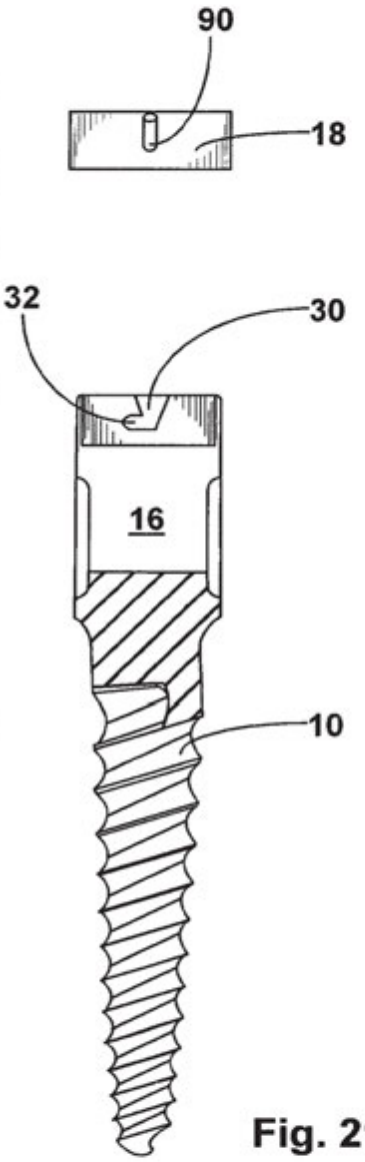


Fig. 21

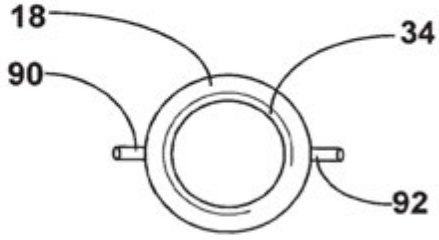


Fig. 20

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Espacenet

EP1316294A2 Fastener assembly for securing a rod-shaped element in a retaining element connected to a shaft

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Inventors: BIEDERMANN LUTZ [DE]

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CPC **A61B17/7032 (EP);A61B17/7035 (EP);A61B17/7049 (EP);**

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Abstract: Fastener assembly for securing a rod-shaped element in a retaining element connected to a shaft
A slit (14) extends in axial direction through a locking component (8) having a hollow cylindrical shape, with an axis of rotation, an outer thread (9) and an inner thread (10).

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(54) **Verschlusseinrichtung zum Sichern eines stabförmigen Elements in einem mit einem Schaft verbundenen Halteelement**

Fastener assembly for securing a rod-shaped element in a retaining element connected to a shaft

Dispositif de fixation pour sécuriser un élément en forme de barre dans un élément de retenue relié à une tige

(84) Benannte Vertragsstaaten:
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US-A- 6 074 391

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Beschreibung

[0001] Die Erfindung betrifft eine in der Wirbelsäulen- bzw. Unfallchirurgie zu verwendende Verschlußeinrichtung zum Sichern eines stabförmigen Elements in einem mit einem Schaft verbundenen Halteelement. Ferner betrifft die Erfindung ein Element mit einem Schaft und einem damit verbundenen Halteelement zum Verbinden mit einem Stab mit einer derartigen Verschlußeinrichtung.

[0002] Aus der WO 95/01132 und der US 6,224,598 B1 ist jeweils ein Wirbelsäulenimplantat mit einem Aufnahmeteil mit einer U-förmigen Ausnehmung zur Aufnahme eines Stabes bekannt, wobei die durch die U-förmige Ausnehmung gebildeten freien Schenkel ein Innengewinde aufweisen. Zur Fixierung des Stabes ist ein zwischen die Schenkel einschraubbares Verschlußelement mit einem Außengewinde, einer zentralen Bohrung mit Innengewinde und eine in das Verschlußelement einschraubbare Innenschraube vorgesehen. Bei der aus der WO 95/01132 bekannten Vorrichtung wird zum Vermeiden des Aufspreizens der Schenkel eine die Schenkel von außen umfassende Sicherheitshülse verwendet.

[0003] Aufgabe der Erfindung ist es, eine Verschlußeinrichtung der eingangs beschriebenen Art zu schaffen, welche eine verbesserte Sicherung gegen Lockerung oder Lösen der Verschlußelemente gewährleistet und gleichzeitig kompakt gebaut und einfach herzustellen ist.

[0004] Diese Aufgabe wird durch die in Patentanspruch 1 gekennzeichnete Verschlußeinrichtung bzw. durch das in Patentanspruch 5 gekennzeichnete Element gelöst. Weiterbildungen der Erfindung sind in den Unteransprüchen gegeben.

[0005] Die Erfindung ist sowohl für monoaxiale als auch für polyaxiale Knochenschrauben geeignet, da sie es erlaubt, daß die Fixierung des Stabes bzw. des Stabes und des Kopfes der Knochenschraube im endgültigen Zustand so zusammenwirken, daß ein sicheres Verblokken gegen Lockern oder Lösen des Verschlußmechanismus besteht.

[0006] Weitere Merkmale und Zweckmäßigkeiten der Erfindung ergeben sich aus der Beschreibung von Ausführungsbeispielen anhand der Figuren. Von den Figuren zeigen:

Fig. 1: eine erste Ausführungsform in perspektivischer Explosionsdarstellung;

Fig. 2a: eine schematische Darstellung der auf das Verschlußelement von Fig. 1 wirkenden Kräfte vor dem Einschrauben der Innenschraube;

Fig. 2b: eine schematische Darstellung der auf das Verschlußelement von Fig. 1 wirkenden Kräfte nach dem Einschrauben der Innenschraube;

Fig. 3: eine Schnittansicht einer zweiten Ausführungsform;

Fig. 4: eine Schnittansicht einer dritten Ausführungsform;

Fig. 5: eine Schnittansicht eines Details einer vierten Ausführungsform;

Fig. 6: eine Schnittansicht eines Details einer fünften Ausführungsform;

Fig. 7: eine Schnittansicht eines Details einer sechsten Ausführungsform; und

Fig. 8: eine Schnittansicht eines Details einer siebten Ausführungsform.

[0007] Das erfindungsgemäße Element ist in der in der in den Figuren Fig. 1 dargestellten Ausführungsform als Monoaxial-Knochenschraube ausgebildet. Diese weist einen Schaft 1 mit einem Knochengewindeabschnitt und ein damit starr verbundenes Aufnahmeteil 2 zur Aufnahme eines die Knochenschraube mit weiteren Knochenschrauben verbindenden Stabes 100 auf. Hierzu ist das Aufnahmeteil mit einer Ausnehmung 3 mit einem U-förmigen Querschnitt versehen, die gerade so groß bemessen ist, daß der Stab 100 einlegbar ist und in den Grund der Ausnehmung passt. Durch die U-förmige Ausnehmung 3 sind zwei freie Schenkel 4, 5 mit jeweils einem freien Ende 6 gebildet, welches den oberen Rand des Aufnahmeteils 2 bildet. Angrenzend an das freie Ende 6 weisen die Schenkel 4, 5 ein Innengewinde 7 auf.

[0008] Zum Verschließen des Stabes 100 in der Ausnehmung 3 ist ein zwischen die Schenkel 4, 5 einschraubbares muffen- bzw. mutterartiges Verschlußelement 8 mit einem mit dem Innengewinde 7 der Schenkel zusammenwirkenden Außengewinde 9 und einem Innengewinde 10 vorgesehen. Das Verschlußelement 8 weist ein erstes stirnseitiges Ende 11 und diesem gegenüberliegend ein zweites Ende 12 auf. Zum Ineingriffbringen mit einem Einschraubwerkzeug sind an dem ersten stirnseitigen Ende 11 radial verlaufende Einschnitte 13 vorgesehen. Einer der Einschnitte erstreckt sich durch das gesamte Verschlußelement 8 in axialer Richtung und bildet somit einen Schlitz 14 derart, daß das Verschlußelement nach Art eines Spannrings eine gewisse Elastizität aufweist. Die Länge des Verschlußelements 8 in axialer Richtung ist derart bemessen, daß das Verschlußelement vollständig zwischen die Schenkel 4, 5 einschraubbar ist.

[0009] Ferner ist eine in das Verschlußelement einschraubbare Innenschraube bzw. Klemm- oder Setzschraube 15 vorgesehen, deren Außengewinde 16 mit dem Innengewinde 10 des Verschlußelements 8 zusammenwirkt. Die Innenschraube 15 weist an ihrem einen Ende eine Ausnehmung 17 zum Ineingriffbringen mit einem Schraubwerkzeug auf.

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[0010] Bei der in Fig. 1 gezeigten Ausführungsform sind das Innengewinde 7 der Schenkel, daß Außengewinde 9 des Verschlußelements, sowie das Innengewinde 10 des Verschlußelements und das Außengewinde 16 der Innenschraube 15 als metrische Gewinde ausgebildet.

[0011] Im Betrieb wird die Knochenschraube zuerst in den Knochen eingeschraubt und anschließend der Stab 100 eingelegt. Dann wird das Verschlußelement 8 mit bereits eingeschraubter, aber noch nicht mit ihrer Unterseite den Stab berührender Innenschraube 15 eingeschraubt, wodurch der Stab zunächst nur am Herauskippen gehindert wird, aber noch verschiebbar ist. Beim Einschrauben des Verschlußelements 8 kommt es aufgrund der geschlitzten und damit elastischen Ausbildung desselben nicht zu einem Aufspreizen der Schenkel 4, 5, sondern, wie in Fig. 2a gezeigt ist, setzen die Schenkel dem geschlitzten Verschlußelement einen Widerstand entgegen, der es versucht zusammenzudrücken, was durch die nach innen gerichteten Pfeile veranschaulicht ist. Anschließend wird die Innenschraube 15 so eingeschraubt bis sie mit ihrer Unterseite auf den Stab drückt und diesen fixiert. Durch das Festziehen der Innenschraube 15 wirkt auf das Verschlußelement 8 wie in Fig. 2b durch die Pfeile dargestellt ist, eine nach radial nach außen gerichtete Kraftkomponente, wodurch das Außengewinde 9 des Verschlußelements in das Innengewinde 7 der Schenkel gedrückt wird und sich dort verblockt. Damit ist ein gegen Lockerung gesicherter Verschluß gewährleistet.

[0012] In der in Fig. 3 gezeigten Ausführungsform ist das erfindungsgemäße Element als Polyaxialschraube ausgebildet, die ein Schraubenelement mit einem Gewindeschaft 1 mit einem Knochengewinde und einem kugelsegmentförmigen Kopf 20 aufweist, der mit einem Aufnahmeteil 21 verbunden ist Das Aufnahmeteil 21 hat an seinem einen Ende eine axialsymmetrisch ausgerichtete erste Bohrung 22, deren Durchmesser größer als der des Gewindeabschnitts des Schafts 1 und kleiner als der des Kopfs 20 ist. Ferner weist das Aufnahmeteil 21 eine koaxiale zweite Bohrung 23 auf, die auf dem der ersten Bohrung 22 gegenüberliegenden Ende offen ist und deren Durchmesser so groß ist, daß das Schraubenelement durch das offene Ende mit seinem Gewindeabschnitt durch die erste Bohrung 22 hindurch und mit dem Kopf 20 bis zum Grund der zweiten Bohrung 23 führbar ist. Zwischen der ersten und der zweiten Bohrung ist ein kleiner koaxialer Abschnitt 24 vorgesehen, der unmittelbar an die erste Bohrung 22 angrenzt und zum offenen Ende hin sphärisch ausgebildet ist, wobei der Radius im wesentlichen gleich dem kugelsegmentförmigen Abschnitts des Kopfs 20 ist. Das Aufnahmeteil 21 weist ebenso wie das Aufnahmeteil 2 der ersten Ausführungsform eine zur Mitte des Teiles symmetrisch angeordnete U-förmige Ausnehmung 25 auf, deren Grund zur ersten Bohrung 22 hin gerichtet ist und durch die zwei freie Schenkel 26, 27 gebildet sind, deren freies Ende 28 den oberen Rand des Aufnahmeteils 21 bilden. In einem Bereich angrenzend an das freie Ende 28 weisen die Schenkel 26, 27 ein Innengewinde 29 auf.

[0013] Es ist ferner ein Druckelement 30 vorgesehen, das so ausgebildet ist, daß es an seiner dem Kopf 20 zugewandten Seite eine sphärische Ansenkung 31 aufweist, deren Radius im wesentlichen gleich dem Radius des kugelsegmentförmigen Abschnitts des Kopfes 20 ist. Der Außendurchmesser des Druckelements ist so gewählt, daß das Druckelement in dem Aufnahmeteil 21 eine Gleitbewegung durchführen kann, also zu dem Kopf 20 hin verschiebbar ist. Das Druckelement weist ferner eine koaxiale Bohrung 32 für den Zugriff auf eine Ausnehmung 33 in dem Schraubenkopf 20 zum Ineingriffbringen mit einem Eindrehwerkzeug auf.

[0014] Die Ausbildung des Verschlußelements 8 und der Innenschraube 15 ist wie bei der ersten Ausführungsform.

Im Betrieb wird das Schraubenelement nach Einsetzen in das Aufnahmeteil 21 in den Knochen eingeschraubt. Dann werden nacheinander das Druckelement 30 und der Stab 100 eingesetzt. In diesem Stadium ist der Schraubenkopf 20 noch verschwenkbar. Durch Einschrauben des Verschlußelements 8 und der Innenschraube 15 in derselben Weise wie bei der ersten Ausführungsform werden das Schraubenelement und das Aufnahmeteil 21 zueinander und damit auch der Stab 100 fixiert.

[0015] Die in Fig. 4 dargestellte dritte Ausführungsform zeigt ebenfalls eine Polyaxial-Knochenschraube. Der zweiten Ausführungsform entsprechende Teile sind mit denselben Bezugszeichen versehen. Die dritte Ausführungsform unterscheidet sich von der zweiten Ausführungsform im wesentlichen durch die Ausbildung des Druckelements 40.

[0016] Das Druckelement 40 dieser Ausführungsform ist im wesentlichen zylindrisch ausgebildet mit einem Außendurchmesser, der so gewählt ist, dass das Druckelement 40 in der zweiten Bohrung 23 des Aufnahmeteils 21' gleiten kann. An seinem einen Ende ist eine sich zu dem Ende hin erweiternde kugelsegmentförmige Ausnehmung 41 vorgesehen, deren Kugelradius so gewählt ist, dass er in einem in das Aufnahmeteil eingesetzten Zustand den Kopf 20 des Schraubenelements teilweise umfasst. Ein wesentlicher Unterschied zu dem Druckelement 30 der zweiten Ausführungsform besteht darin , daß das Druckelement40 der dritten Ausführungsform in Richtung des freien Endes 28 der Schenkel verlängert ist. Dazu weist es an seinem der kugelsegmentförmigen Ausnehmung 41 gegenüberliegenden Ende eine U-förmige Ausnehmung 42 auf, wobei die Abmessungen der U-förmigen Ausnehmungen des Druckelements so bemessen sind, dass in den dadurch gebildeten Kanal der Stab 100 eingelegt werden kann. Die in Richtung der Zylinderachse des Aufnahmeteils 21' gesehene Tiefe der U-förmigen Ausnehmung 42 ist größer als der Durchmesser des aufzunehmenden Stabs 100, so dass das Druckelement 40 mit seitlichen Schenkeln 43 über den eingelegten Stab 100 nach oben hervorsteht. Das Druk-

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kelement 40 weist ferner eine zentrale Bohrung 44 auf, die sich durch dieses hindurch erstreckt. Der Durchmesser der zentralen Bohrung 44 ist gerade so groß bemessen, dass ein Schraubwerkzeug zum Ineingriffbringen mit der in dem Kopf 20 vorgesehenen Ausnehmung 33 hindurchführbar ist.

[0017] Die Ausbildung des Verschlußelements 8 und der Innenschraube 15 ist wie bei der ersten und zweiten Ausführungsform.

[0018] Im Betrieb unterscheidet sich die in Fig. 4 gezeigte dritte Ausführungsform von der in Fig. 3 gezeigten zweiten Ausführungsform darin, daß über das Verschlußelement 8 zuerst der Kopf 20 in seiner Stellung blockiert wird, in dem das Verschlußelement 8 auf die verlängerten Schenkel 43 des Druckelements 40 drückt und damit auf den Kopf 20. Durch Festziehen der Innenschraube 15 wird dann der Stab 100 unabhängig von dem Kopf 20 fixiert. Die Verschließwirkung durch das Zusammenwirken von Verschlußelement 8 und Innenschraube 15 ist im übrigen wie bei der ersten und zweiten Ausführungsform.

[0019] Die in den Figuren 5 bis 7 gezeigten Ausführungsformen unterscheiden sich von der in Fig. 4 gezeigten dritten Ausführungsform durch die Art des Innengewindes 7 der Schenkel 26, 27 des Aufnahmeteils 21' und das entsprechende Außengewinde 9 des Verschlußelements 8. Das Innengewinde 10 des Verschlußelements 8 und das Außengewinde 16 der Innenschraube sind bei diesen Ausführungsformen jeweils als metrische Gewinde ausgebildet.

[0020] In der in Fig. 5 gezeigten Ausführungsform ist das Innengewinde 29 der Schenkel 26, 27 so ausgebildet, daß die dem freien Ende abgewandte Flanke 29a mit einer zur Mittenachse M des Aufnahmeteils senkrecht verlaufenden Ebene einen negativen Winkel α einschließt. Entsprechend schließt die in eingeschraubtem Zustand dem freien Ende abgewandte Flanke 9b des Außengewindes 9 des Verschlußelements 8 mit einer zur Schraubenachse S horizontal verlaufenden Ebene einen negativen Winkel ein. Die Maße von Innengewinde der Schenkel und Außengewinde des Verschlußelements sind derart, daß in unbelastetem Zustand zwischen den genannten Flanken 29a und 19b ein Zwischenraum ist.

[0021] Im Betrieb erfahren die Schenkel 26, 27 durch den negativen Flankenwinkel beim Festziehen des Verschlußelements 8 wobei, daß die Flanken 29a und 10b aufeinandergelangen eine radial nach innen gerichtete Kraftkomponente, so daß die Schenkel etwas zusammengezogen werden. Damit erfolgt eine zuverlässige Blockierung des Kopfes 20 über das Druckelement 40. Beim Einschrauben der Innenschraube spreizt sich das Verschlußelement 8 aufgrund der dann radial nach außen wirkenden Kraftkomponente und wirkt somit der Kraft, die die Schenkel zusammenzieht entgegen. Der Stab wird fixiert und gleichzeitig erfolgt ein gegeneinander Blockieren von Verschlußelelement 8 und Schenkel.

[0022] Die in Fig. 6 gezeigte Ausführungsform unterscheidet sich von der in Fig. 5 gezeigten Ausführungsform durch die Ausbildung der Gewinde 29, 9 als Sägengewinde mit einer horizontal zur Mittenachse M bzw. Schraubenachse S verlaufenden Lastflanke 29a bzw. 19b. Auch damit ist die erfindungsgemäße Funktion des Verschlußelements gegeben.

[0023] Die in Fig. 7 gezeigte Ausführungsform unterscheidet sich von der in Fig. 5 bzw. 6 gezeigten Ausführungsform dadurch, daß das Innengewinde 29 der Schenkel und das Außengewinde 9 des Verschlußelements als Flachgewinde ausgebildet sind. Dieses weist zwei horizontal zur Mittenachse M bzw. Schraubenachse S verlaufende Flanken 29a, 29b bzw. 9a, 9b auf. Der Gewindequerschnitt ist im wesentlichen rechteckig ausgebildet. Auch damit ist die erfindungsgemäße Funktion des Verschlußelements gegeben.

[0024] Auch bei den in Fig. 6 und 7 gezeigten Gewindeformen ist ein Flankenspiel derart vorgesehen, daß das Verblocken des Verschlußelements nach Einschrauben der Innenschraube möglich ist.

[0025] In der in Fig. 8 gezeigten Ausführungsform ist das Verschlußelement 80 mit einem ringförmigen Ansatz 81 an seinem stirnseitigen, die Einschnitte 13 aufweisenden Ende versehen. Der Schlitz 14 erstreckt sich in diesem Fall wie bei dem Verschlußelement 8 wenigstens durch den axialen Abschnitt, in dem das Außengewinde 9 vorgesehen ist, jedoch nicht durch den Ansatz 81. Der Schlitz 14 ist ferner in Umfangsrichtung so angeordnet, daß er sich in einen der Einschnitte 13 erstreckt.

[0026] Im Betrieb bildet der Ansatz 81 beim Einschrauben des Verschlußelements einen Anschlag, der die Kraft auf das Druckelement auf einen vorbestimmten Wert begrenzt.

[0027] Weitere Ausführungsformen der Erfindung ergeben sich durch das Vorsehen der Gewindearten gemäß den Ausführungsformen nach Fig. 5 bis 6 und/oder des Verschlußelements nach Fig. 8 bei einer Monoaxialschraube gemäß der ersten Ausführungsform nach Fig. 1 oder der Polyaxialschraube gemäß der zweiten Ausführungsform nach Fig. 3.

[0028] Anstelle der oben beschriebenen Ausführungen, bei denen der das Aufnahmeteil mit einer Knochenschraube verbunden ist, kann das Aufnahmeteil auch mit einem Haken verbunden sein, wie er in der Wirbelsäulenchirurgie zum Einhaken hinter Knochenvorsprüngen der Wirbelsäule verwendet wird.

[0029] In einer weiteren Abwandlung der polyaxialen Ausführungsformen ist anstelle des Gewindeschaftes 1 oder des Hakens eine Stange oder ein stabförmiges Element vorgesehen, das an beiden Enden einen kugelsegmentförmigen Kopf hat, der mit einem Aufnahmeteil der beschriebenen Art verbunden ist. Damit kann ein solches Element als Verbindungselement zwischen zwei Stäben 100 verwendet werden.

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Patentansprüche

1. Verschlußeinrichtung zum Sichern eines stabförmigen Elements in einem mit einem Schaft (1) verbundenen Halteelement (2; 21; 21') zum Einsatz in der Wirbelsäulen- oder Unfallchirurgie, mit einem Verschlußelement (8; 80) mit einer im wesentlichen hohlzylindrischen Form mit einer Rotationsachse, einem Außengewinde (9) und einem Innengewinde (10)
gekennzeichnet durch einen sich in axialer Richtung **durch** das Verschlußelement (8) erstreckenden Schlitz (14).

2. Verschlußeinrichtung nach Anspruch 1, **gekennzeichnet durch** eine in das Verschlußelement (8; 80) einschraubbare Innenschraube (15).

3. Verschlußeinrichtung nach Anspruch 1 oder 2, **dadurch gekennzeichnet, daß** das Innengewinde (10) als metrisches Gewinde ausgebildet ist.

4. Verschlußeeinrichtung nach einem der Ansprüche 1 bis 3,
dadurch gekennzeichnet, daß das Außengewinde (9) als metrisches Gewinde oder als Gewinde mit horizontalem oder negativem Winkel der Lastflanke oder als Flachgewinde mit zwei horizontalen Flanken ausgebildet ist.

5. Element mit einem Schaft (1) und einem damit verbundenen Halteelement (2; 21; 21') zum Verbinden mit einem Stab (100), wobei das Halteelement (2; 21; 21') eine einen U-förmigen Querschnitt aufweisende Ausnehmung zur Aufnahme des Stabes mit zwei an einem Ende (6; 28) freien Schenkeln (4, 5; 26, 27) und einem Innengewinde (7; 29) an den freien Schenkeln aufweist und mit einem Verschlußelement (8; 80) mit einem Außengewinde (9) in wenigstens einem Abschnitt seiner Außenwand, wobei das Außengewinde (9) mit dem Innengewinde (7; 29) der Schenkel zusammenwirkt und wobei das Verschlußelement eine zentrale Bohrung aufweist,
dadurch gekennzeichnet, daß das Verschlußelement (8, 80) einen sich im wesentlichen in axialer Richtung durch seine Außenwand erstreckenden Schlitz (14) aufweist.

6. Element nach Anspruch 5, **dadurch gekennzeichnet, daß** das Verschlußelement (8, 80) ein Innengewinde (10) aufweist und eine Innenschraube (15) zum Einschrauben in das Verschlußelement vorgesehen ist.

7. Element nach Anspruch 5 oder 6, **dadurch gekennzeichnet, daß** das Innengewinde (10) des Verschlußelements (8; 80) und das damit zusammenwirkende Außengewinde (16) der Innenschraube (15) als metrische Gewinde ausgebildet sind.

8. Element nach einem der Ansprüche 5 bis 7, **dadurch gekennzeichnet, daß** das Innengewinde (7) der Schenkel (4, 5; 26, 27) als metrisches Gewinde ausgebildet sind.

9. Element nach einem der Ansprüche 5 bis 7, **dadurch gekennzeichnet, daß** das Innengewinde (7) der Schenkel (4, 5; 26,a b) als Gewinde mit einem negativen Flankenwinkel der Lastflanke ausgebildet ist.

10. Element nach einem der Ansprüche 5 bis 7, **dadurch gekennzeichnet, daß** das Innengewinde (7) der Schenkel (4, 5; 26, 27) als Sägengewinde mit einem im wesentlichen horizontalen Winkel der Lastflanke (29a) ausgebildet ist.

11. Element nach einem der Ansprüche 5 bis 7, **dadurch gekennzeichnet, daß** das Innengewinde (7) der Schenkel (4, 5; 26, 27) als Flachgewinde zwei horizontale Flanken (29a, 29b) ausgebildet ist.

12. Element nach einem der Ansprüche 5 bis 11, **dadurch gekennzeichnet, daß** das Außengewinde (9) des Verschlußelements (8, 80) mit einem zu dem Innengewinde (7; 29) der Schenkel (4, 5; 26, 27) passenden Gewindetyp ausgebildet ist.

13. Element nach einem der Ansprüche 5 bis 12, **dadurch gekennzeichnet, daß** das Verschlußelement (80) einen Anschlag (81) aufweist.

14. Element nach einem der Ansprüche 5 bis 13, **dadurch gekennzeichnet, daß** der Schaft (1) und das Halteelement (2) monoaxial verbunden sind.

15. Element nach einem der Ansprüche 5 bis 13, **dadurch gekennzeichnet, daß** der Schaft (1) und das Halteelement (21; 21') polyaxial verbunden sind.

16. Element nach Anspruch 15, **dadurch gekennzeichnet, daß** ein in dem Halteelement (21') vorgesehenes Druckelement (40) vorgesehen ist, auf welches das Verschlußelement (8, 80) zum Fixieren der Winkelstellung des Schafts (1) einwirkt.

17. Element nach Anspruch 16, **dadurch gekennzeichnet daß** die Winkelstellung des Schafts über das Verschlußelement (8, 80) und der Stab über die Innenschraube (15) fixierbar sind.

Claims

1. Fastener assembly for securing a rod-shaped element in a retaining element (2; 21; 21') connected

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to a shaft (1), for use in spinal surgery or accident and emergency surgery, with a fastener element (8; 80) of substantially hollow cylindrical shape with a rotation axis, an outer thread (9) and an inner thread (10), **characterized by** a slit (14) extending in the axial direction through the fastener element (8).

2. Fastener assembly according to Claim 1, **characterized by** an inner screw (15) that can be screwed into the fastener element (8; 80).

3. Fastener assembly according to Claim 1 or 2, **characterized in that** the inner thread (10) is designed as a metric thread.

4. Fastener assembly according to one of Claims 1 to 3, **characterized in that** the outer thread (9) is designed as a metric thread or as a thread with a horizontal or negative angle of the load-bearing flank or as a flat thread with two horizontal flanks.

5. Element with a shaft (1), and with a retaining element (2; 21; 21') which is connected to the latter and which serves for connection to a rod (100), the retaining element (2; 21; 21') having a recess with a U-shaped cross section for receiving the rod and with two free legs (4, 5; 26, 27) at one end (6; 28) and an inner thread (7; 29) on the free legs, and with a fastener element (8; 80) which has an inner thread (9) in at least one portion of its outer wall, the outer thread (9) cooperating with the inner thread (7; 29) of the legs, and the fastener element having a central bore, **characterized in that** the fastener element (8, 80) has a slit (14) extending substantially in an axial direction through its outer wall.

6. Element according to Claim 5, **characterized in that** the fastener element (8, 80) has an inner thread (10), and an inner screw (15) for screwing into the fastener element is provided.

7. Element according to Claim 5 or 6, **characterized in that** the inner thread (10) of the fastener element (8; 80) and the outer thread (16) of the inner screw (15) cooperating therewith are designed as metric threads.

8. Element according to one of Claims 5 to 7, **characterized in that** the inner thread (7) of the legs (4, 5; 26, 27) is designed as a metric thread.

9. Element according to one of Claims 5 to 7, **characterized in that** the inner thread (7) of the legs (4, 5; 26,a b) is designed as a thread with a negative flank angle of the load-bearing flank.

10. Element according to one of Claims 5 to 7, **characterized in that** the inner thread (7) of the legs (4, 5; 26, 27) is designed as a buttress thread with a substantially horizontal angle of the load-bearing flank (29a).

11. Element according to one of Claims 5 to 7, **characterized in that** the inner thread (7) of the legs (4, 5; 26, 27) is designed as a flat thread with two horizontal flanks (29a, 29b).

12. Element according to one of Claims 5 to 11, **characterized in that** the outer thread (9) of the fastener element (8, 80) is designed with a thread type corresponding to the inner thread (7; 29) of the legs (4, 5; 26, 27).

13. Element according to one of Claims 5 to 12, **characterized in that** the fastener element (80) has a limit stop (81).

14. Element according to one of Claims 5 to 13, **characterized in that** the shaft (1) and the retaining element (2) are connected monoaxially.

15. Element according to one of Claims 5 to 13, **characterized in that** the shaft (1) and the retaining element (21; 21') are connected multiaxially.

16. Element according to Claim 15, **characterized in that** a pressure element (40) provided in the retaining element (21') is provided, on which the fastener element (8, 80) acts in order to fix the angle position of the shaft (1).

17. Element according to Claim 16, **characterized in that** the angle position of the shaft can be fixed via the fastener element (8, 80), and the rod via the inner screw (15).

Revendications

1. Dispositif de fixation pour sécuriser un élément en forme de barre dans un élément de retenue (2 ; 21 ; 21') relié à une tige (1), pour utilisation dans la chirurgie de la colonne vertébrale ou des accidents, avec un élément de fixation (8 ; 80) ayant une forme sensiblement cylindrique creuse, avec un axe de rotation, un filetage extérieur (9) et un filetage intérieur (10),
caractérisé par une fente (14) s'étendant en direction axiale à travers l'élément de fixation.

2. Dispositif de fixation selon la revendication 1, **caractérisé par** une vis intérieure (15) susceptible d'être vissée dans l'élément de fixation (8 ; 80).

3. Dispositif de fixation selon la revendication 1 ou 2, **caractérisé en ce que** le filetage intérieur (10) est

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réalisé sous la forme de filetage métrique.

4. Dispositif de fixation selon l'une des revendications 1 à 3, **caractérisé en ce que** le filetage extérieur (9) est réalisé sous la forme de filetage métrique ou de filetage à angle horizontal ou négatif du flanc de charge, ou sous forme de filetage plat avec deux flancs horizontaux.

5. Elément avec une tige (1) et un élément de retenue (2 ; 21 ; 21') lui étant relié, pour assurer la liaison à une barre (100), l'élément de retenue (2 ; 21 ; 21') présentant un évidement à section transversale en forme de U pour recevoir la barre, avec deux branches (4, 5 ; 26, 27) libres, à une extrémité (6 ; 28), et un filetage intérieur (7 ; 29) sur les branches libres; et avec un élément de fixation (8 ; 80) ayant un filetage extérieur (9) en au moins un tronçon de sa paroi extérieure, le filetage extérieur (9) coopérant avec le filetage intérieur (7 ; 29) des branches, et l'élément de fixation présentant un perçage central, **caractérisé en ce que** l'élément de fixation (8, 80) présente une fente (14) s'étendant sensiblement en direction axiale à travers sa paroi extérieure.

6. Élément selon la revendication 5, **caractérisé en ce que** l'élément de fixation (8 ; 80) présente un filetage intérieur (10) et une vis intérieure (15), pour vissage dans l'élément de fixation.

7. Élément selon la revendication 5 ou 6, **caractérisé en ce que** le filetage intérieur (10) de l'élément de fixation (8 ; 80) et le filetage extérieur (16), coopérant avec lui, de la vis intérieure (15) sont réalisés sous forme de filetage métrique.

8. Élément selon l'une des revendications 5 à 7, **caractérisé en ce que** le filetage intérieur (7) des branches (4, 5 ; 26, 27) est réalisé sous la forme de filetage métrique.

9. Élément selon l'une des revendications 5 à 7, **caractérisé en ce que** le filetage intérieur (7) des branches (4, 5 ; 26, a b) est réalisé sous la forme de filetage, avec un angle de flanc négatif du flanc de charge.

10. Élément selon l'une des revendications 5 à 7, **caractérisé en ce que** le filetage intérieur (7) des branches (4, 5 ; 26, 27) est réalisé sous la forme de filetage en dents de scie, avec un angle sensiblement horizontal du flanc de charge (29a).

11. Élément selon l'une des revendications 5 à 7, **caractérisé en ce que** le filetage intérieur (7) des branches (4, 5 ; 26, 27) est réalisé sous forme de filetage plat à deux flancs horizontaux (29a, 29b).

12. Élément selon l'une des revendications 5 à 11, **caractérisé en ce que** le filetage extérieur (9) de l'élément de fixation (8. 80) est réalisé avec un type de filetage s'ajustant au filetage intérieur (7 ; 29) des branches (4, 5 ; 26, 27).

13. Élément selon l'une des revendications 5 à 12, **caractérisé en ce que** l'élément de fixation (80) présente une butée (81).

14. Élément selon l'une des revendications 5 à 13, **caractérisé en ce que** la tige (1) et l'élément de retenue (2) sont reliés de façon monoaxiale.

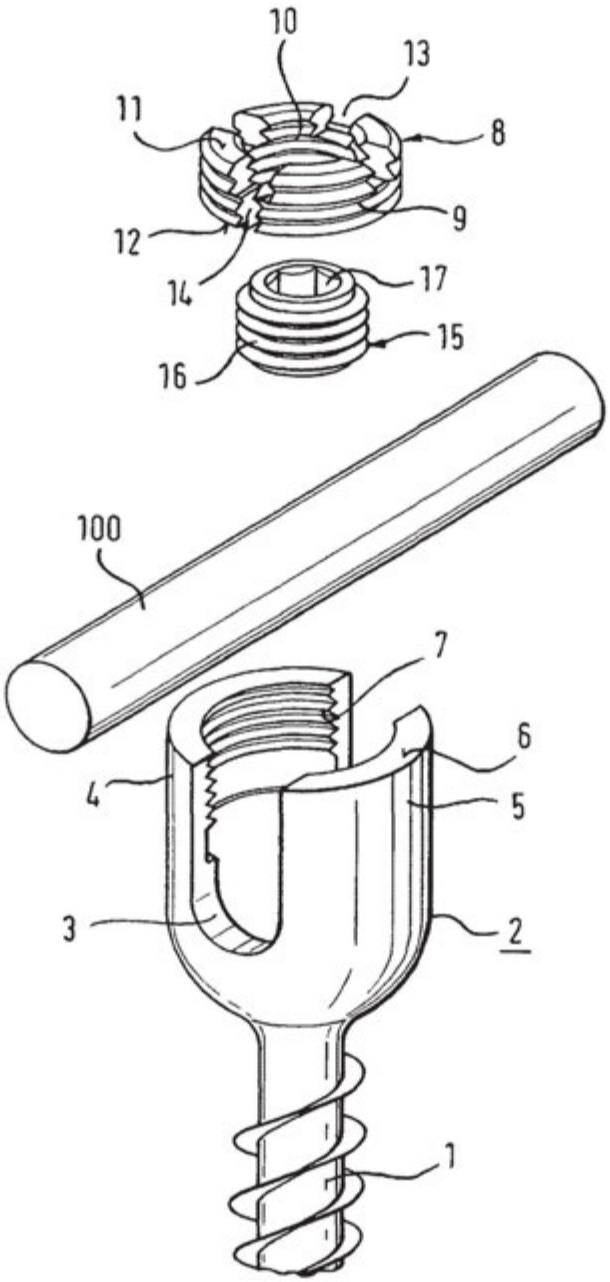
15. Élément selon l'une des revendications 5 à 13, **caractérisé en ce que** la tige (1) et l'élément de retenue (21 ; 21') sont reliés de façon polyaxiale.

16. Élément selon la revendication 15, **caractérisé en ce qu'**un élément de pressage (40) prévu dans l'élément de retenue (21') est prévu sur lequel l'élément de fixation (8, 80) agit pour la fixation de la position angulaire de la tige (1).

17. Élément selon la revendication 16, **caractérisé en ce que** la position angulaire de la tige est susceptible d'être fixée par l'intermédiaire de l'élément de fixation (8, 80). et la barre est susceptible d'être fixée par l'intermédiaire de la vis intérieure (15).

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FIG. 1



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FIG. 2a

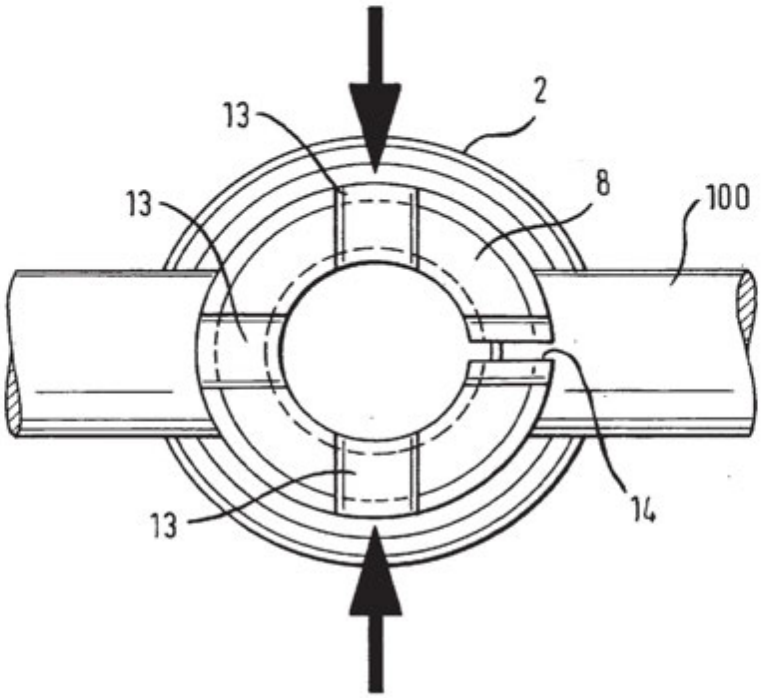
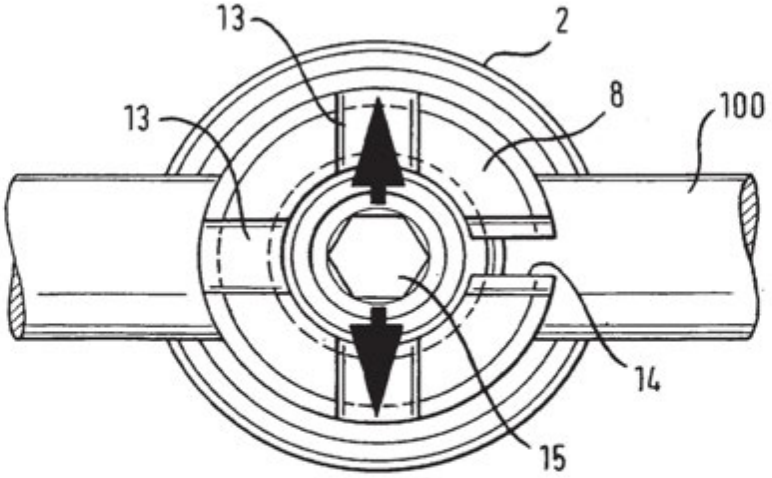


FIG. 2b



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FIG. 3

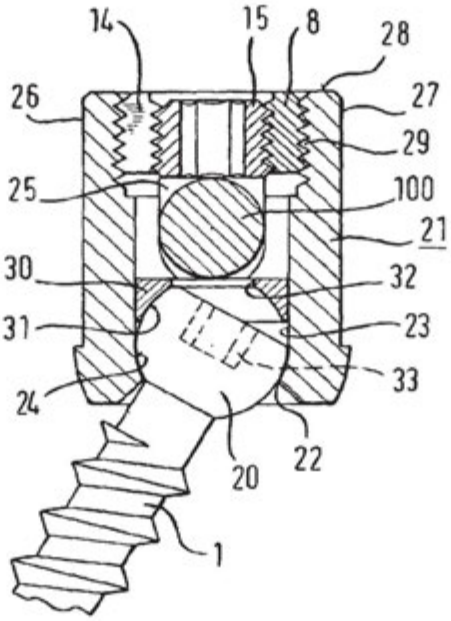
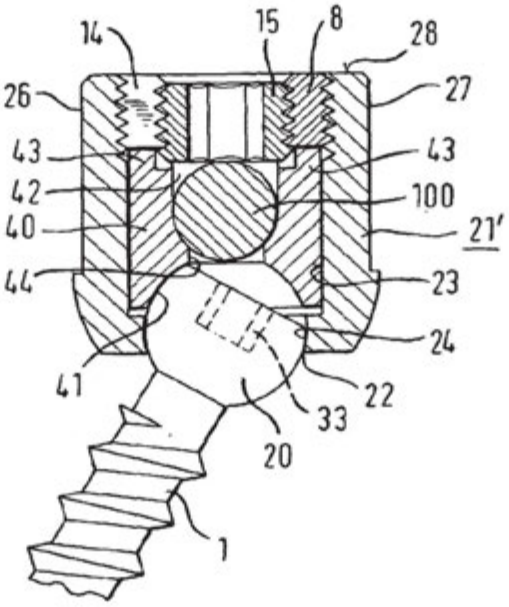


FIG. 4



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FIG. 5

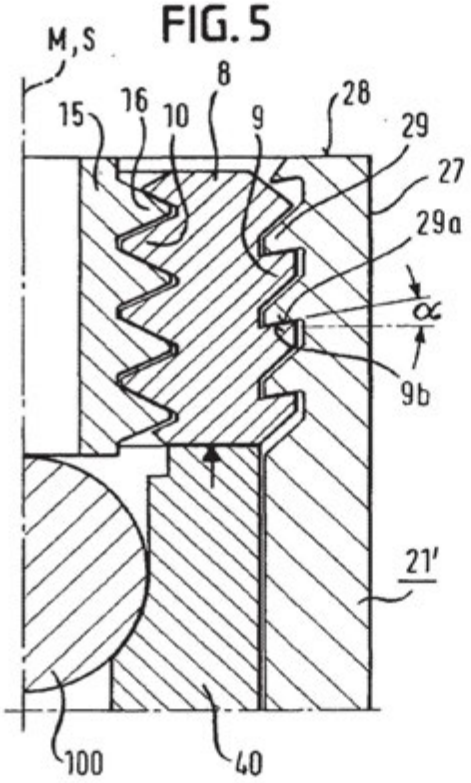


FIG. 6

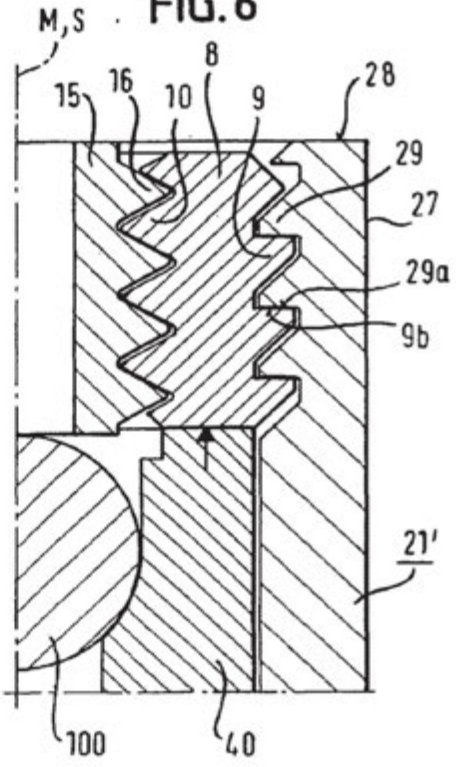
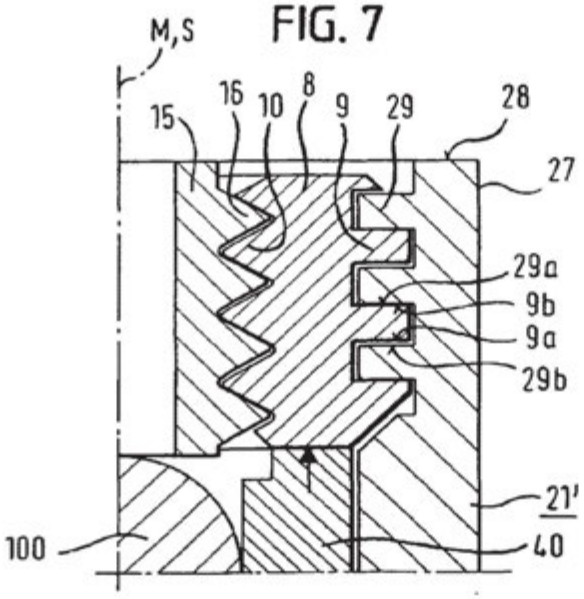
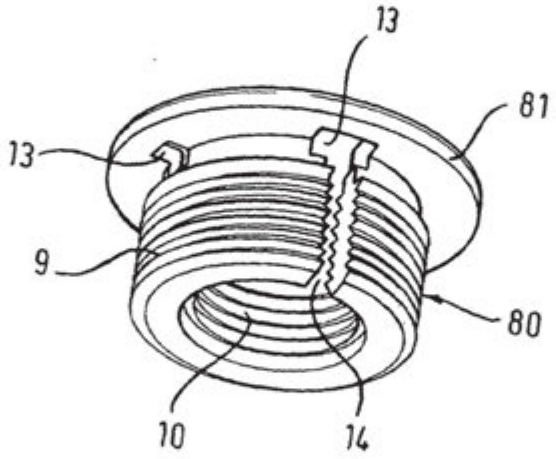


FIG. 7



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FIG. 8



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IN DER BESCHREIBUNG AUFGEFÜHRTE DOKUMENTE

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In der Beschreibung aufgeführte Patentdokumente

- WO 9501132 A **[0002] [0002]**
- US 6224598 B1 **[0002]**

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Espacenet

EP1570796A1 Bone fixing element and stabilising device comprising one such bone fixing element
Applicants: BIEDERMANN MOTECH GMBH [DE]
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IPC ***A61B17/70;*** *A61B17/86;* (IPC1-7): A61B17/70;

CPC **A61B17/7032 (EP);A61B17/7035 (EP);A61B17/7037 (EP);A61B17/7059 (EP);**A61B17/8605 (EP);

Application number: EP05004677A
Priority numbers: DE102004010382A 2004-03-03; US55000904P 2004-03-03
Publication date: 2005-09-07
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Priority date: 2004-03-03
Published as: **DE102004010382A1; DE102004010382B4;** EP1570796A1;**EP1570796B1; ES2286728T3; US2005216003A1; US7591839B2**
Abstract: Bone fixing element and stabilising device comprising one such bone fixing element
The device comprises a first element with a threaded shaft (1, 2, 3) and a first semispherical head segment (4) accommodated inside a second head segment (10) and held in place by an elastic element (20). The second head segment (10) is inserted into a spherical space underneath a pressure element (50) inside a cylindrical case (40). The unit is secured to a transversal rod (100) with a first wider screw (60) with an outer and an inner thread and a smaller screw (70) inserted into the threaded bore at the wider screw (60).

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(54) **Knochenverankerungselement und Stabilisierungseinrichtung mit einem solchen Knochenverankerungselement**

Bone fixing element and stabilising device comprising one such bone fixing element

Elément d'ancrage osseux et dispositif de stabilisation comprenant un tel élément d'ancrage osseux

(84) Benannte Vertragsstaaten:
CH DE ES FR GB IT LI

(30) Priorität: **03.03.2004 DE 102004010382**
03.03.2004 US 550009 P

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(56) Entgegenhaltungen:
EP-A- 1 273 269
WO-A-98/34554
US-A- 6 022 350

Anmerkung: Innerhalb von neun Monaten nach der Bekanntmachung des Hinweises auf die Erteilung des europäischen Patents kann jedermann beim Europäischen Patentamt gegen das erteilte europäische Patent Einspruch einlegen. Der Einspruch ist schriftlich einzureichen und zu begründen. Er gilt erst als eingelegt, wenn die Einspruchsgebühr entrichtet worden ist. (Art. 99(1) Europäisches Patentübereinkommen).

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Beschreibung

[0001] Die Erfindung betrifft ein Knochenverankerungselement zur Verankerung in einem Knochen oder einem Wirbel und eine Stabilisierungseinrichtung mit einem solchen Knochenverankerungselement.

[0002] Zur Fixierung von Knochenfrakturen oder zur Stabilisierung der Wirbelsäule sind Fixations- und Stabilisierungseinrichtungen bekannt, die aus wenigstens zwei im Knochen bzw. Wirbel verankerten und über eine Platte oder einen Stab verbundenen Knochenschrauben bestehen. Derartige starre Systeme erlauben keine Bewegung der relativ zueinander fixierten Knochenteile oder Wirbel.

[0003] Für bestimmte Indikationen ist jedoch eine dynamische Stabilisierung wünschenswert, bei der die zu stabilisierenden Knochenteile oder Wirbel eine kontrollierte begrenzte Bewegung zueinander ausführen können. Eine Realisierungsmöglichkeit für eine dynamische Stabilisierungseinrichtung besteht in der Verwendung eines beweglichen Elements anstelle eines die Knochenverankerungselemente verbindenden starren Stabes, wie es beispielsweise in der EP 0 669 109 B1 oder in der US 2003/0109880 A1 beschrieben ist.

[0004] Bei diesen bekannten Systemen kann häufiger das Problem auftreten, dass eine Übertragung der aus der Bewegung resultierenden Momente auf den im Knochen oder Wirbel verankerten Schaft der Verankerungselemente stattfindet, was aufgrund der dauernden zyklischen Teilbelastung des Knochenverankerungselements zur Lockerung des Schafts in dem umgebenden Knochenmaterial und damit zum Lösen der Verankerung führen kann.

[0005] Es besteht daher das Bedürfnis, die Bewegung der Knochen bzw. Wirbel von der Schaftverankerung weitgehend abzukoppeln, um der Forderung gerecht zu werden, dass das Implantat oft ein Leben lang sicher im Körper des Patienten verankert bleiben muss. Ferner soll aber bei einer Entkopplung der Bewegung der Knochen bzw. Wirbel von der Schaftverankerung trotzdem die Möglichkeit bestehen, das Verankerungselement relativ zu einem mehrere solcher Elemente verbindenden Stab oder zu einer solchen Platte optimal positionieren zu können, wie es z.B. von den herkömmlichen Polyaxialschrauben bekannt ist.

[0006] Die US 6,022,350 offenbart eine Knochenbefestigungsvorrichtung mit einem länglichen Verbindungsmittel, das eine durch eine Öffnung in dem Verbindungsmittel hindurch geführte Knochenbefestigungsschraube aufnimmt. In dem Boden des Verbindungsmittels ist eine Lagerungsfläche mit im Wesentlichen kreisförmigem Querschnitt vorgesehen und der Kopf der Schraube beinhaltet eine im Wesentlichen kugelförmige Oberfläche, die sich an der Lagerungsfläche abstützt. Bei einer Ausführungsform sind in der Öffnung in dem Verbindungsmittel ferner zwei O-Ringe aus z.B. Silikon vorgesehen.

[0007] Aus der US 5,474,555 ist ferner ein Knochenverankerungselement in Form einer Polyaxial-Knochenschraube mit einem Schraubenelement und einem Aufnahmeteil zur Verbindung mit einem Stab bekannt, bei der das im Knochen zu verankernde Schraubenelement mit dem Aufnahmeteil derart verbunden ist, daß Schwenkbewegungen zwischen dem Schraubenelement und dem Aufnahmeteil möglich sind. Die beschriebene Lösung erlaubt jedoch keine Stabilisierung der Knochenteile untereinander mit einer kontrollierten Teilbewegung.

[0008] Es ist Aufgabe der Erfindung ein Knochenverankerungselement und eine Stabilisierungseinrichtung für Knochen bzw. Wirbel mit einem solchen Knochenverankerungselement bereitzustellen, das bzw. die eine kontrollierte Teilbewegung der zu stabilisierenden Knochenteile oder Wirbel bei gleichzeitig hoher Sicherheit der Verankerung erlaubt und dabei optimal positionierbar ist.

[0009] Die Aufgabe wird gelöst durch ein Knochenverankerungselement zur Verankerung in einem Knochen oder in einem Wirbel nach Patentanspruch 1 und durch eine Stabilisierungseinrichtung mit einem solchen Knochenverankerungselement nach Patentanspruch 15.

[0010] Weiterbildungen der Erfindung sind in den Unteransprüchen angegeben.

[0011] Die Erfindung weist den Vorteil auf, daß das Knochenverankerungselement aufgrund seiner elastischen Verbindung von erstem und zweitem Kopfteil axiale Kräfte in Richtung seiner Schaftachse, Biegekräfte und Torsionskräfte aufnimmt. Damit wird eine durch die rücktreibende Kraft begrenzte Bewegung des Knochenteils oder Wirbels, in dem es verankert ist, erlaubt und die bei der Bewegung auf den Schaft wirkenden Momente werden reduziert, so dass ein Lösen der Verbindung durch dauernde zyklische Teilbelastung der Verankerung unterbleibt.

[0012] Die Erfindung weist weiterhin den Vorteil auf, dass eine gewünschte Ruhewinkelstellung zwischen dem Schaft und dem Aufnahmeteil wie bei einer herkömmlichen Polyaxialschraube justierbar ist.

[0013] Die elastischen Eigenschaften des Knochenverankerungselements können bei der Herstellung auf einfache Art durch Ändern der Dimensionen von erstem Kopfteil, zweitem Kopfteil und elastischem Druckelement und/oder des verwendeten Materials für das elastische Druckelement verwirklicht werden. Das Knochenverankerungselement ist mit den bekannten Verbindungselementen wie Platten und Stäben verwendbar. Somit kann eine dynamische Stabilisierungseinrichtung mit einer gewünschten Bewegungsbegrenzung durch Auswahl von Knochenverankerungselementen mit geeigneten elastischen Eigenschaften unter Verwendung von herkömmlichen Platten oder Stäben bereitgestellt werden.

[0014] Weitere Merkmale und Zweckmäßigkeiten der Erfindung ergeben sich aus der Beschreibung von Ausführungsbeispielen anhand der Figuren.

[0015] Von den Figuren zeigen:

Fig. 1 eine teilgeschnittene Darstellung eines

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Knochenverankerungselements nach einer ersten Ausführungsform;

Fig. 2 eine teilgeschnittene Explosionsdarstellung des Knochenverankerungselements der ersten Ausführungsform;

Fig. 3a bis 3c teilgeschnittene Darstellungen, die eine elastische Auslenkung des Knochenverankerungselements der ersten Ausführungsform aus der Ruhewinkelstellung schematisch darstellen.

Fig. 4 eine teilgeschnittene Darstellung eines Knochenverankerungselements nach einer zweiten Ausführungsform;

Fig. 5 eine teilgeschnittene Darstellung eines Knochenverankerungselements nach einer dritten Ausführungsform; und

Fig. 6 eine teilgeschnittene Darstellung eines Knochenverankerungselements nach einer vierten Ausführungsform.

Erste Ausführungsform

[0016] Ein Knochenverankerungselement nach der in den Fig. 1 und 2 gezeigten ersten Ausführungsform ist als Polyaxial-Knochenschraube zum Verbinden mit einem Stab 100 ausgebildet. Die Polyaxial-Knochenschraube weist ein im Knochen zu verankerndes Schraubenelement 1 mit einem Schaft 2 mit einem Knochengewinde 3 und mit einem mit dem Schaft 2 in diesem Ausführungsbeispiel einstückig verbundenen ersten Kopfteil 4 auf. Desweiteren weist die Polyaxial-Knochenschraube ein hülsenförmiges zweites Kopfteil 10 zur Aufnahme des ersten Kopfteils 4 und ein Aufnahmeteil 40 zur Aufnahme des zweiten Kopfteiles 10, eines auf dieses einwirkenden zweiten Druckelements 50 und des Stabes 100, sowie eine erste und eine zweite Sicherungsschraube 60, 70 auf.

[0017] Das erste Kopfteil 4 des Schraubenelements 1 weist angrenzend an den Schaft 2 einen kugelsegmentförmigen Abschnitt 5 mit einem Durchmesser auf, der größer ist als der Schaftdurchmesser. Auf der dem Schaft 3 abgewandten Seite ist ein verbreiterter Rand 6 bzw. Kragen vorgesehen, wodurch eine kreisförmige Fläche 7 gebildet ist, die im Wesentlichen glatt ist und in der sich koaxial zur Schaftachse eine Ausnehmung 8 zum Eingreifen mit einem Schraubwerkzeug befindet. In Fig.1 ist eine sechskantförmige Ausnehmung 8 für einen Inbusschlüssel dargestellt.

[0018] Es ist jedoch auch eine andere Ausnehmung, wie z.B. ein Kreuzschlitz, zum Eingreifen mit einem Einschraubwerkzeug möglich.

[0019] Das hülsenförmige zweite Kopfteil 10 ist kugelsegmentförmig mit einer sphärischen Außenfläche 11 und zwei gegenüberliegenden ebenen Enden 12, 13 ausgebildet. Von dem einen Ende 12 erstreckt sich eine koaxiale erste Bohrung 15 mit einem Durchmesser, der größer ist als der Außendurchmesser des verbreiterten Rands 6 des Schraubenelementes 1. Angrenzend an die erste Bohrung 15 erstreckt sich eine koaxiale zweite Bohrung 16 deren Durchmesser angrenzend an das zweite Ende 13 kleiner ist als der Kugeldurchmesser des ersten Kopfteils 4 aber größer als der Durchmesser des Schafts 2, so daß dieser hindurchgeführt werden kann. Die zweite Bohrung 16 erweitert sich ferner ausgehend vom zweiten Ende 13 bis zur ersten Bohrung 15 hin sphärisch mit einem Kugelradius, der so bemessen ist, daß das zweite Kopfteil 4 daran anliegt. Angrenzend an die erste Bohrung 15 ist der Durchmesser der zweiten Bohrung kleiner als der Kugelradius des Kopfteils 4.

[0020] Das Schraubenelement 1 ist derart in das zweite Kopfteil 10 eingesetzt, dass der Schaft 2 durch das Ende 13 angrenzend an die Bohrung 16 hindurchgeführt ist und der kugelsegmentförmige Abschnitt 5 des ersten Kopfteils 4 in der zweiten Bohrung 16 des zweiten Kopfteils 10 gehalten ist.

[0021] Auf der von dem verbreiterten Rand 6 des ersten Kopfteils 4 gebildeten Fläche 7 ist ein elastisches erstes Druckelement 20 angeordnet, das bevorzugt aus einem Elastomer ausgebildet ist. Das erste Druckelement 20 weist die Form einer Scheibe mit kreisförmigem Querschnitt und einer vorbestimmten Dicke auf und besitzt eine koaxiale Bohrung 21, die ein Hindurchgreifen mit dem Schraubwerkzeug in die Ausnehmung 8 der von dem verbreiterten Rand 6 gebildeten Fläche 7 ermöglicht. Der Außendurchmesser des ersten Druckelements 20 ist so gewählt, dass es in die erste Bohrung 15 des zweiten Kopfteils 10 einführbar ist. Vorzugsweise ist zwischen Druckelement 20 und der Seitenwand der Bohrung ein Freiraum 22 vorgesehen, so dass das Druckelement bei elastischer Deformation ausweichen kann.

[0022] Auf der dem Rand 6 des ersten Kopfteils 4 abgewandten Seite des ersten Druckelements 20 ist eine starre Befestigungskappe 30 angeordnet. Die Befestigungskappe 30 weist die Form einer kreisförmigen Scheibe mit einer koaxialen Bohrung 31 auf, die ein Hindurchgreifen mit dem oben genannten Schraubwerkzeug ermöglicht.

[0023] Der Außendurchmesser der Befestigungskappe 30 entspricht in einem dem ersten Druckelement 20 zugewandten Abschnitt 32 dem Innendurchmesser der ersten Bohrung 15 in dem zweiten Kopfteil 10 bzw. ist um soviel kleiner, dass ein Einsetzen und Fixieren z.B. mit Presspassung in dem zweiten Kopfteil 10 ermöglicht ist.

[0024] In einem in eingesetztem Zustand dem ersten Druckelement 20 abgewandten Abschnitt 33 weist die Befestigungskappe 30 einen verbreiterten Außendurchmesser auf, der beim Einsetzen in das zweite Kopfteil 10 durch Zusammenwirken mit dem ersten Ende 12 des zweiten Kopfteils 10 einen Anschlag bildet. Die Außenfläche des Abschnitts 33 ist derart sphärisch ausgebildet,

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dass sie im eingesetzten Zustand der Befestigungskappe 30 eine Fortführung der sphärischen Außenfläche 11 des zweiten Kopfteils 10 bildet.

[0025] Die Dicke des ersten Druckelements 20 ist so gewählt, dass es, wenn die Befestigungskappe 30 in das zweite Kopfteil eingesetzt ist, unter Vorspannung gesetzt ist und Druck auf die von dem verbreiterten Rand 6 des ersten Kopfteils 4 gebildete Fläche 7 ausübt, so dass das erste Kopfteil 4 gegen die zweite Bohrung 16 des zweiten Kopfteils 10 gedrückt wird und das Schraubenelement 1 elastisch in dem zweiten Kopfteil 10 gehalten ist. Vorteilhafterweise ist die Lagerung des ersten Kopfteils 4 in der zweiten Bohrung 16 durch Einbringen einer speziellen Gleitbeschichtung, einer Gleitfolie oder eines Gleitringes im Hinblick auf minimale zwischen dem kugelsegmentförmigen Abschnitt 5 und der zweiten Bohrung 16 wirkende Reibungskräfte optimiert.

[0026] Das Aufnahmeteil 40 ist im Wesentlichen zylindrisch ausgebildet. Ausgehend von seinem ersten Ende 41 ist in dem Aufnahmeteil 40 eine koaxiale erste Bohrung 48 vorgesehen, deren Durchmesser größer ist, als der Außendurchmesser des zweiten Kopfteils 10. Angrenzend an das andere Ende 49 des Aufnahmeteils 40 ist eine koaxiale zweite Bohrung 47 vorgesehen, deren Durchmesser sich vom Durchmesser der ersten Bohrung 48 gegen das zweite Ende 49 hin sphärisch verjüngt. Dadurch ist das zweite Kopfteil 10 in dem Aufnahmeteil 40 gehalten und um einen vorbestimmten Winkelbereich schwenkbar.

[0027] Ausgehend von seinem einen ersten Ende 41 ist ferner eine Ausnehmung 42 mit einem U-förmigen Querschnitt vorgesehen, die gerade so groß bemessen ist, dass der Stab 100 einlegbar ist. Durch die U-förmige Ausnehmung 42 sind zwei freie Schenkel 44, 45 gebildet, die angrenzend an ihr freies Ende ein Innengewinde 46 aufweisen, welches mit einem entsprechenden Außengewinde 61 der zwischen die Schenkel 44, 45 einzuschraubenden ersten Sicherungsschraube 60 zusammenwirkt.

[0028] Auf der der zweiten Bohrung 47 abgewandten Seite befindet sich in dem Aufnahmeteil 40 ein auf das zweite Kopfteil 10 einwirkendes zweites Druckelement 50. Das zweite Druckelement 50 ist im Wesentlichen zylindersymmetrisch mit einem Außendurchmesser, der kleiner ist, als der Innendurchmesser der ersten Bohrung 48, dass das Druckelement in die erste Bohrung 48 einsetzbar ist. Die dem zweiten Kopfteil 10 zugewandte Stirnseite 51 des zweiten Druckelements 50 ist konkav sphärisch ausgebildet, wobei der Radius dem Radius der sphärischen Außenfläche 11 des zweiten Kopfteils 10 und der daran befestigten Befestigungskappe 30 entspricht. Auf der dem zweiten Kopfteil 10 abgewandten Seite weist das zweite Druckelement 50 eine Ausnehmung 52 mit U-förmigem Querschnitt auf, deren Grund 53 einen Radius aufweist, der etwas größer als der Radius des Stabes 100 ist und in die der Stab 100 eingreift.

[0029] Das zweite Druckelement 50 weist ferner eine koaxiale Bohrung zum Hindurchgreifen mit einem Schraubwerkzeug auf.

[0030] In Richtung der Zylinderachse des Aufnahmeteils 40 ist die Höhe des zweiten Druckelements 50 gerade so gewählt, dass durch Anziehen der ersten Sicherungsschraube 60 derart Druck auf das zweite Druckelement 50 ausgeübt werden kann, dass das zweite Kopfteil 10 in dem Aufnahmeteil 40 in einer zu dem Zeitpunkt des Anziehens der Sicherungsschraube 60 eingestellten Winkelstellung vorfixierbar ist, die nachfolgend als Ruhewinkelstellung bezeichnet ist.

[0031] Mit dieser Anordnung wird erreicht, dass das zweite Kopfteil 10 relativ zu dem Aufnahmeteil 40 ausgerichtet und anschlie-ßend in dieser Ausrichtung vorfixiert werden kann.

[0032] Die erste Sicherungsschraube 60 weist eine Bohrung 62 auf, die mit einem Innengewinde 63 versehen ist, das mit einem Außengewinde 71 der zweiten Sicherungsschraube 70 zusammenwirkt. Desweiteren weist die Sicherungsschraube 60 auf ihrer dem Druckelement 50 abgewandten Seite nicht dargestellte Ausnehmungen zum Eingreifen mit einem Schraubwerkzeug auf.

[0033] Die zweite Sicherungsschraube 70 weist an ihrer Oberseite eine Ausnehmung 72 zum Eingreifen mit einem Schraubwerkzeug auf. In Fig.1 ist eine sechskantförmige Ausnehmung 72 für einen Inbusschlüssel dargestellt. Es ist jedoch auch eine andere Ausnehmung, wie z.B. ein Kreuzschlitz, zum Eingreifen mit einem Einschraubwerkzeug möglich.

[0034] Durch Anziehen der zweiten Sicherungsschraube 70 wird der Stab 100 gegen den Grund 53 der Ausnehmung 52 gedrückt und damit Druck auf das zweite Druckelement 50 und damit auf das zweite Kopfteil 10 ausgeübt, um ein optimales Fixieren der Ruhewinkelstellung zu erzielen. Der Stab 100 wird dabei durch die zweite Sicherungsschraube 70 und den Grund 53 in der U-förmigen Ausnehmung 42 des Aufnahmeteils fixiert.

[0035] Im Betrieb wird das Schraubenelement 1 zuerst mit dem Schaft 2 durch die Bohrungen 15, 16 in dem zweiten Kopfteil 10 hindurchgeführt, sodass das erste Kopfteil 4 in der zweiten Bohrung 16 gehalten wird. Anschließend wird das erste Druckelement 20 in das zweite Kopfteil 10 eingeführt und durch Einsetzen der Befestigungskappe 30 in das zweite Kopfteil 10 gegen die Fläche 7 des ersten Kopfteils 4 gedrückt und in diesem vorgespannten Zustand über die eingesetzte Befestigungskappe 30 gehalten. Dann wird das aus Schraube 1 und zweitem Kopfteil 10 gebildete Element in das Aufnahmeteil 40 eingebracht und anschließend das zweite Druckelement 50 in das Aufnahmeteil 40 eingesetzt. Dann wird das Schraubenelement 1 durch Hindurchgreifen durch die koaxialen Bohrungen des zweiten Druckelements 50, der Befestigungskappe 30 und des ersten Druckelements 20 und Eingreifen in die Ausnehmung 8 des Schraubenelements mit einem Schraubendreher in den Knochen oder Wirbel eingeschraubt. Anschließend wird der Stab eingelegt, wobei die Stellung des Aufnahmeteils 40 relativ zu dem zweiten Kopfteil 10 justiert wird.

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Diese Stellung, die die gewünschte Ruhewinkelstellung ist, wird durch die erste Sicherungsschraube 60, die auf das zweite Druckelement 50 drückt, vorfixiert.

[0036] Bei dem Vorfixieren der Ruhewinkelstellung wird die Befestigungskappe 30 durch Zusammenwirken ihrer sphärischen Außenfläche mit der sphärischen Ausnehmung der Stirnseite 51 des zweiten Druckelements 50 gegen das erste Druckelement 20 gedrückt und somit gegen Lösen gesichert.

[0037] Der Stab 100 wird anschließend durch Einschrauben der zweiten Sicherungsschraube 70 gegen den Grund 53 gedrückt und dadurch fixiert. Gleichzeitig wird durch das Anziehen der zweiten Sicherungsschraube 70 über den Stab 100 auf das zweite Druckelement 50 und damit auf das zweite Kopfteil 10 Druck ausgeübt, sodass damit eine zusätzliche Fixierung der Ruhewinkelstellung erzielt wird.

[0038] Das Vorsehen der beiden Sicherungsschrauben 60, 70 führt dazu, dass das zweite Kopfteil 10 und der Stab 100 unabhängig voneinander fixierbar sind.

[0039] In den Fig. 3a bis 3c ist schematisch die Auslenkbarkeit des Schraubenelementes 1 relativ zu dem zweiten Kopfteil 10 dargestellt. In Fig. 3a ist eine voreingestellte Ruhewinkelstellung gezeigt, die Fig. 3b und 3c zeigen jeweils eine Auslenkung aus dieser Ruhewinkelstellung in unterschiedliche Richtungen, wobei der Pfeil die Auslenkungsrichtung bezeichnet.

[0040] Wie in Fig. 3a gezeigt ist, weist das erste Druckelement 20 in der Ruhewinkelstellung eine gleichmäßige Dicke auf. In Fig. 3b ist schematisch dargestellt, dass ein Auslenken des Schraubenelements dazu führt, dass eine Seite 22 des Druckelements komprimiert wird, wohingegen die gegenüberliegende Seite 23 entspannt wird. Das Verformen des elastischen ersten Druckelementes 20 führt zum Aufbau internen Spannungen in diesem, die eine der Auslenkung entgegenwirkende rücktreibende Kraft ausüben, sodass das Schraubenelement 1 in die Ruhewinkelstellung zurückgedrängt wird.

[0041] Die Größe der rücktreibenden Kraft kann dabei zum Einen durch die Dicke des ersten Druckelements 20 beeinflusst werden, die die Vorspannung des ersten Druckelements 20 im eingebauten Zustand bestimmt. Desweiteren kann die Größe der rücktreibenden Kraft auch durch die Materialwahl für das erste Druckelement 20, wobei unterschiedlichste Elastizitäten und Kompressibilitäten möglich sind, und durch die genaue Formgebung des ersten Druckelements 20 eingestellt werden, so dass eine gewünschte Steifigkeit des Knochenverankerungselements gegenüber axialen Kräften, Biegekräften und Torsionskräften erzielt werden kann.

[0042] Bei der Auslenkung aus der Ruhewinkelstellung begrenzt das Verhältnis des Durchmessers des Rands 6 des Schraubenelementes 1 zu dem Durchmesser der ersten Bohrung 15 in dem zweiten Kopfteil 10 die Auslenkbarkeit. Durch unterschiedliche Größenverhältnisse zwischen dem Durchmesser des Randes 6 und dem Innendurchmesser der Bohrung 15 kann somit die Auslenkbarkeit variiert werden. Z.B. können durch Wahl von Schrauben 1 mit unterschiedlich breiten Rändern 6, die in ein zweites Kopfteil mit vorgegebenen Innendurchmesser der Bohrung 15 einsetzbar sind, somit Verankerungselemente mit unterschiedlicher Auslenkbarkeit bereitgestellt werden.

[0043] Ein besonderer Vorteil dieser Ausbildung eines Knochenverankerungselements ist die Entkopplung der elastischen Auslenkung des Schraubenelements 1 von der Einstellmöglichkeit der Ruhewinkelstellung, was durch die Kombination von erstem Kopfteil 4, zweitem Kopfteil 10 und Aufnahmeteil 40 erreicht wird.

[0044] Eine erfindungsgemäße Stabilisierungseinrichtung umfasst wenigstens ein Knochenverankerungselement wie oben beschrieben in Kombination mit einem Stab und ein zweites Knochenverankerungselement, das bevorzugt ebenfalls wie oben beschrieben ausgebildet ist.

[0045] Bei einer Bewegung des Knochens bzw. Wirbels aus der zu stabilisierenden Ruhelage heraus wird über das elastische erste Druckelement 20 eine rücktreibende Kraft auf den Knochen bzw. Wirbel ausgeübt, die ihn wieder in die Ruhelage bringt und somit die Bewegung limitiert. Dadurch wird ein über die Bewegung des Knochens oder des Wirbels auf den Schraubenschaft wirkendes Biegemoment abgefangen und es kommt nicht zu einer Lockerung der Knochenverankerung.

Zweite Ausführungsform

[0046] Bei einem Knochenverankerungselement der zweiten Ausführungsform, die in Fig. 4 dargestellt ist, ist das Knochenverankerungselement derart ausgebildet, dass nicht das Befestigen eines Stabes, sondern einer Platte vorgesehen ist. Bei dieser Ausführungsform entspricht der Aufbau von erstem Schraubenelement 1, erstem Druckelement 20, Befestigungskappe 30 und zweitem Kopfteil 10 dem Aufbau der ersten Ausführungsform, weshalb für diese Komponenten dieselben Bezugszeichen verwendet werden und eine erneute Beschreibung unterbleibt.

[0047] Der wesentliche Unterschied der zweiten Ausführungsform gegenüber der ersten Ausführungsform besteht darin, dass das Aufnahmeteil durch die zu befestigende Platte 200 gebildet wird.

[0048] Die Platte 200 weist eine erste Bohrung 248 auf, die von einer ersten Seite der Platte in die Platte hineinreicht und deren Durchmesser größer ist, als der Außendurchmesser des zweiten Kopfteils 10. Die erste Bohrung 248 weist in dem der ersten Seite der Platte zugewandten Bereich desweiteren ein Innengewinde 246 auf. Angrenzend an die andere Seite 249 der Platte ist koaxial zur ersten Bohrung 248 und verbunden mit dieser eine zweite Bohrung 247 vorgesehen, deren Durchmesser sich vom Durchmesser der ersten Bohrung 248 gegen die zweite Seite 249 hin sphärisch verjüngt. Dadurch ist das zweite Kopfteil 10 in der Platte 200 gehalten und um einen vorbestimmten Winkelbereich schwenkbar, wie bei der ersten Ausführungsform.

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[0049] Auf der der zweiten Bohrung 247 abgewandten Seite befindet sich in der ersten Bohrung 248 ein auf das zweite Kopfteil 10 einwirkendes zweites Druckelement 250. Das zweite Druckelement 250 ist im Wesentlichen zylindersymmetrisch mit einem Außendurchmesser, der kleiner ist, als der Innendurchmesser der ersten Bohrung 248, sodass das Druckelement in die erste Bohrung 248 einsetzbar ist. Die dem zweiten Kopfteil 10 zugewandte Stirnseite 251 des zweiten Druckelements 250 ist konkav sphärisch ausgebildet, wobei der Radius dem Radius der sphärischen Außenfläche 11 des zweiten Kopfteils 10 und der daran befestigten Befestigungskappe 30 entspricht. Das zweite Druckelement 250 weist ferner eine koaxiale Bohrung zum Hindurchgreifen mit einem Schraubwerkzeug auf.

[0050] In Richtung der Bohrung in der Platte ist die Höhe des zweiten Druckelements 250 gerade so gewählt, dass durch Anziehen einer Sicherungsschraube 260, die in das Innengewinde 246 der Bohrung 248 einschraubbar ist, derart Druck auf das zweite Druckelement 250 ausgeübt werden kann, dass das zweite Kopfteil 10 in der Platte in einer zu dem Zeitpunkt des Anziehens der Sicherungsschraube 260 eingestellten Winkelstellung fixierbar ist, die nachfolgend als Ruhewinkelstellung bezeichnet ist, und die Platte dabei gleichzeitig mit dem Schraubenelement 1 verbunden wird.

[0051] Mit dieser Anordnung wird erreicht, dass das zweite Kopfteil 10 relativ zu der Platte 200 ausgerichtet und anschließend in dieser Ausrichtung vorfixiert werden kann.

[0052] Die Sicherungsschraube 260 weist eine koaxiale Bohrung 262 zum Eingreifen mit einem Schraubwerkzeug auf. In Fig. 4 ist eine sechskantförmige Bohrung 262 für einen Inbusschlüssel dargestellt. Es ist jedoch auch eine andere Formgebung zum Eingreifen mit einem Einschraubwerkzeug möglich.

[0053] Die koaxiale Bohrung 262 weist einen solchen Querschnitt auf, dass ein Hindurchgreifen mit dem Schraubwerkzeug, für das die Ausnehmung 8 des ersten Kopfteils vorgesehen ist, ermöglicht ist.

[0054] Diese Ausführungsform weist den besonderen Vorteil auf, dass der gesamte Aufbau vormontiert werden kann. Im Betrieb ist zuerst nur die Sicherungsschraube 260 nicht angezogen. Das Schraubenelement kann in dem vormontierten Zustand in den Knochen oder Wirbel eingeschraubt werden, indem mit dem Schraubwerkzeug durch die konzentrischen Bohrungen in dem ersten Druckelement 20, der Befestigungskappe 30, des zweiten Druckelements 250 und der Sicherungsschraube 260 in die Ausnehmung 8 des Schraubenelements 1 eingegriffen wird. Anschließend kann die Winkelstellung der Platte 200 zum Schaft 2 eingestellt werden und durch Anziehen der Sicherungsschraube 260 Druck auf das zweite Druckelement 250 und damit auf das zweite Kopfteil 10 ausgeübt werden, um ein Fixieren der Ruhewinkelstellung zu erzielen.

[0055] Dritte Ausführungsform

[0056] Bei einem Knochenverankerungselement der dritten Ausführungsform, das in Fig. 5 dargestellt ist, unterscheidet sich das Knochenverankerungselement nur dadurch von der zweiten Ausführungsform, dass das zweite Druckelement und die Sicherungsschraube einstückig in Form einer Sicherungsschraube 280 ausgebildet sind.

[0057] Bei dieser Ausführungsform entspricht der Aufbau von erstem Schraubenelement 1, erstem Druckelement 20, Befestigungskappe 30, zweitem Kopfteil 10 und Platte 200 dem Aufbau der zweiten Ausführungsform, weshalb für diese Komponenten dieselben Bezugszeichen verwendet werden und eine erneute Beschreibung unterbleibt.

[0058] Die Sicherungsschraube 280 weist einen ersten Abschnitt 281 auf, der mit einem Außengewinde 281 zum Einschrauben in das Innengewinde 246 der Bohrung 248 versehen ist. Angrenzend an den ersten Abschnitt 281 weist die Sicherungsschraube 280 auf der Seite, die der zweiten Bohrung 247 zugewandt ist, einen zweiten Abschnitt 282 auf. Der zweite Abschnitt 282 ist im Wesentlichen zylindersymmetrisch mit einem Außendurchmesser, der kleiner ist, als der Innendurchmesser der ersten Bohrung 248, sodass die Sicherungsschraube 280 in die erste Bohrung 248 einschraubbar ist.

[0059] Die dem zweiten Kopfteil 10 zugewandte Stirnseite 283 der Sicherungsschraube 280 ist konkav sphärisch ausgebildet, wobei der Radius dem Radius der sphärischen Außenfläche 11 des zweiten Kopfteils 10 und der daran befestigten Befestigungskappe 30 entspricht.

[0060] In Richtung der Bohrung in der Platte ist die Höhe der Sicherungsschraube 280 gerade so gewählt, dass durch Anziehen die Stirnfläche 283 derart Druck auf das zweite Kopfteil 10 ausübt, dass es in der Platte in einer zu dem Zeitpunkt des Anziehens der Sicherungsschraube 280 eingestellten Winkelstellung fixierbar ist, die nachfolgend als Ruhewinkelstellung bezeichnet ist. Die Platte 200 wird dabei gleichzeitig mit dem Schraubenelement 1 verbunden.

[0061] Mit dieser Anordnung wird erreicht, dass das zweite Kopfteil 10 relativ zu der Platte 200 ausgerichtet und anschließend in dieser Ausrichtung fixiert werden kann.

[0062] Die Sicherungsschraube 280 weist eine koaxiale Bohrung 285 auf, die ein Eingreifen mit einem Schraubwerkzeug ermöglicht. In Fig. 5 ist eine sechskantförmige Bohrung 285 für einen Inbusschlüssel dargestellt. Es ist jedoch auch eine andere Formgebung zum Eingreifen mit einem Einschraubwerkzeug möglich.

[0063] Die koaxiale Bohrung 285 weist einen solchen Querschnitt auf, dass ein Hindurchgreifen mit dem Schraubwerkzeug, für das die Ausnehmung 8 des ersten Kopfteils vorgesehen ist, ermöglicht ist.

[0064] Diese Ausführungsform weist den besonderen Vorteil auf, dass der gesamte Aufbau vormontiert werden kann. Im Betrieb ist zuerst nur die Sicherungsschraube 280 nicht angezogen. Das Schraubenelement kann in dem vormontierten Zustand in den Knochen oder Wirbel

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eingeschraubt werden, indem mit dem Schraubwerkzeug durch die konzentrischen Bohrungen in dem ersten Druckelement 20, der Befestigungskappe 30 und der Sicherungsschraube 280 in die Ausnehmung 8 des Schraubenelements 1 eingegriffen wird. Anschließend kann die Winkelstellung der Platte 200 zum Schaft 2 eingestellt und mit der Sicherungsschraube 280 fixiert werden.

Vierte Ausführungsform

[0065] Die in Fig. 6 dargestellte vierte Ausführungsform der vorliegenden Erfindung unterscheidet sich von der ersten bevorzugten Ausführung im Wesentlichen nur in der Ausbildung des ersten Kopfteiles und des elastischen ersten Druckelementes und gleiche oder ähnliche Elemente werden mit denselben Bezugszeichen bezeichnet.

[0066] Bei der vierten Ausführungsform schließt sich im Gegensatz zu der ersten Ausführungsform an den verbreiterten Rand 6 auf der dem Schaft 2 abgewandten Seite ein in dieser Ausführungsform mit dem ersten Kopfteil 4' einstückig verbundener zylinderförmiger Abschnitt 9 an, der als elastisches erstes Druckelement dient. Der zylinderförmige Abschnitt 9 erstreckt sich im Wesentlichen in Form eines Hohlzylinders koaxial zu der Achse des Schaftes 2 in Richtung des zweiten Druckelementes 50. In Richtung des zweiten Druckelements 50 weist der zylinderförmige Abschnitt 9 einen Bereich 9b mit einem verbreiterten Außendurchmesser auf, der in der ersten Bohrung 15 des zweiten Kopfteils 10 gehalten ist. Die dem zweiten Druckelement 50 zugewandte Stirnfläche des zylinderförmigen Abschnitts 9 ist derart sphärisch ausgebildet, dass sie im zusammengebauten Zustand des Knochenverankerungselementes eine Fortführung des der sphärischen Außenfläche 11 des zweiten Kopfteiles 10 bildet. Der Zylindermantel des zylinderförmigen Abschnittes 9 weist umlaufende Ausnehmungen 9a derart auf, dass der zylinderförmige Abschnitt 9 eine parallel zu der Schaftachse verlaufende Spiralfeder bildet.

[0067] Im Betrieb wird prinzipiell wie bei der ersten Ausführungsform verfahren und das zweite Kopfteil 10 durch den von dem zweiten Druckelement 50 ausgeübten Druck in dem Aufnahmeteil 40 in einer gewünschten Ruhewinkelstellung fixiert. In diesem Zustand ist wiederum, wie bei der ersten Ausführungsform eine Auslenkung des Schaftes 2 relativ zu dem zweiten Kopfteil 10 aus der Ruhewinkelstellung möglich. Bei der Auslenkung aus der Ruhewinkelstellung wird die Spiralfeder des zylinderförmigen Abschnitts 9 elastisch deformiert und es wirkt folglich auf das erste Kopfteil 4' eine in die Ruhewinkelstellung rücktreibende Kraft, wobei bei dieser Ausbildung in Form einer einstückig mit dem ersten Kopfteil 4 ausgebildeten Schraubenfeder eine Druck- und eine Zugseite zu der Rückstellung beitragen, da bei einer Auslenkung eine Seite komprimiert und die gegenüberliegende Seite gedehnt wird.

[0068] Durch die Spiralfeder des zylinderförmigen Abschnitts 9 können durch eine geeignete Wahl der Federkraft und der Vorspannung verschieden starke Rücktreibekräfte realisiert werden, was zu einer großen Variabilität des Knochenverankerungselementes führt.

[0069] Weiterhin ist auch eine Kombination der Merkmale der vierten Ausführungsführungsform mit denen der anderen Ausführungsformen möglich, insbesondere kann der beschriebene Aufbau auch in einer Platte wie bei der zweiten und dritten Ausführungsform Verwendung finden.

Weitere Ausführungsformen und Abwandlungen

[0070] Das erste Kopfteil 4 und die zweite Bohrung 16 in dem zweiten Kopfteil 10 müssen nicht kugelsegmentförmig bzw. hohlkugelsegmentförmig ausgebildet sein, sondern können eine andere Form aufweisen, solange die gewährleistet ist, daß das erste Kopfteil 4 in dem zweiten Kopfteil schwenkbar gehalten ist.

[0071] Ebenfalls müssen das zweite Kopfteil 10 und der das zweite Kopfteil haltende Bereich des Aufnahmeteils nicht kugelsegmentförmig bzw. hohlkugelsegmentförmig sein, sondern müssen ebenfalls eine Schwenkbarkeit des zweiten Kopfteils 10 in dem Aufnahmeteil und bei Fixierung in der gewünschten Ruhewinkelstellung eine ausreichende Haltekraft ermöglichen.

[0072] Das Halten der Befestigungskappe 30 in dem zweiten Kopfteil 10 kann auch durch ein auf dem Abschnitt 32 vorgesehenes Außengewinde realisiert sein, das mit einem Innengewinde der Bohrung 15 in einem an das erste Ende 12 angrenzenden Bereich zusammenwirkt.

[0073] Das erste Druckelement 20 muss nicht unbedingt aus einem Elastomer bestehen, sondern kann beispielsweise auch durch entsprechend angeordnete Federn realisiert werden, die die Rückstellkraft ausüben.

[0074] Es ist ebenfalls denkbar, zum Fixieren des Stabes 100 und zum Fixieren der Ruheposition nur eine Innenschraube zu verwenden, die über den Stab 100 Druck auf das zweite Druckelement 50 und damit auch auf das zweite Kopfteil 10 ausübt.

[0075] Der Schaft 2 und das erste Kopfteil 4 sind einstückig ausgebildet gezeigt, jedoch ist auch eine mehrstückige Ausbildung möglich, bei der zum Beispiel Schaft 2 und erstes Kopfteil 4 mittels einer Schraubverbindung, Passsitz oder ähnlichem verbunden sind.

[0076] Weitere Abwandlungen der vorher beschriebenen Ausführungsformen sind möglich. Insbesondere können Elemente einer Ausführungsform mit den Elementen einer anderen Ausführungsform kombiniert werden.

[0077] Es können zwei oder mehr erfindungsgemäße Knochenverankerungselemente in Kombination mit einem Stab oder mit einer Platte verwendet werden, ebenso können erfindungsgemäße Knochenverankerungselemente mit bekannten Knochenverankerungselementen, insbesondere mit Knochenschrauben oder Haken, kombiniert werden.

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[0078] Die Erfindung ist nicht auf die konkret beschriebenen Beispiele eines polyaxialen Knochenverankerungselements beschränkt. Es können auch andere Ausbildungen desselben, insbesondere der Aufnahmeteile und der Befestigungseinrichtungen möglich sein. Entscheidend ist, dass der Schaft elastisch aus einer Ruhewinkelstellung auslenkbar ist und dass die Einstellung der Ruhewinkelstellung von der elastischen Auslenkbarkeit entkoppelt ist.

[0079] Bei allen vorgenannten Ausführungsformen besteht ferner der Vorteil, daß die begrenzte Bewegungsmöglichkeit der Knochenteile bzw. Wirbel zu einer erhöhten zyklischen Teilbelastung führt, die das Knochenwachstum anregt. Gleichzeitig bleibt die Sicherheit der Verankerung im Knochen gewährleistet.

Patentansprüche

1. Knochenverankerungselement mit
einem Element (1) mit einem Schaft (2) zur Verankerung in einem Knochen oder einem Wirbel und mit einem mit dem Schaft (2) verbundenen ersten Kopfteil (4),
einem mit dem Element (1) verbindbaren zweiten Kopfteil (10), in dem das erste Kopfteil schwenkbar gehalten ist,
einem Aufnahmeteil (40, 200), in dem das zweite Kopfteil (10) aufgenommen ist, und
einer Fixiervorrichtung (60; 260; 280) zum Fixieren des zweiten Kopfteils (10) in dem Aufnahmeteil (40; 200)
dadurch gekennzeichnet, dass
das zweite Kopfteil (10) hülsenförmig zum Aufnehmen des ersten Kopfteils (4) ausgebildet und in dem Aufnahmeteil (40, 200) schwenkbar gehalten ist,
die Fixiervorrichtung das zweite Kopfteil (10) in dem Aufnahmeteil (40, 200) in einer Stellung fixiert, die eine Ruhewinkelstellung des Schaftes (2) relativ zu dem Aufnahmeteil bestimmt, und
das erste und das zweite Kopfteil derart miteinander elastisch verbunden sind, dass der Schaft (2) relativ zu dem zweiten Kopfteil (10) aus der Ruhewinkelstellung auslenkbar ist und dabei auf das erste Kopfteil (4) eine in die Ruhewinkelstellung rücktreibende Kraft wirkt.

2. Knochenverankerungselement nach Anspruch 1, **dadurch gekennzeichnet, dass** die Auslenkung des Schaftes (2) aus der Ruhewinkelstellung von dem Fixieren der Ruhewinkelstellung entkoppelt ist.

3. Knochenverankerungselement nach Anspruch 1 oder 2, die derart ausgebildet ist, dass ein elastisches Druckelement (20, 9) vorgesehen ist, das auf das erste Kopfteil (4) einwirkt.

4. Knochenverankerungselement nach Anspruch 3, **dadurch gekennzeichnet, dass** das elastische Druckelement (20) aus einem Elastomer ausgebildet ist.

5. Knochenverankerungselement nach Anspruch 3, **dadurch gekennzeichnet, dass** das elastische Druckelement (9) einstückig mit dem ersten Kopfteil (4) ausgebildet ist.

6. Knochenverankerungselement nach einem der Ansprüche 1 bis 5, **dadurch gekennzeichnet, dass** das zweite Kopfteil (10) eine im Wesentlichen kugelsegmentförmige Außenfläche aufweist.

7. Knochenverankerungselement nach einem der Ansprüche 1 bis 6, **dadurch gekennzeichnet, dass** das erste Kopfteil (4) eine im Wesentlichen kugelsegmentförmige Form aufweist.

8. Knochenverankerungselement nach einem der Ansprüche 1 bis 7, **dadurch gekennzeichnet, dass** der Innendurchmesser des hülsenförmigen zweiten Kopfteils (10) in einem ersten Bereich (15) größer ist als der Durchmesser des ersten Kopfteils (4) und in einem zweiten Bereich (16) kleiner ist, so dass das erste Kopfteil (4) darin einführbar und schwenkbar gehalten ist.

9. Knochenverankerungselement nach einem der Ansprüche 1 bis 8, **dadurch gekennzeichnet, dass** das erste Kopfteil (4) an seiner dem Schaft (2) abgewandten Seite einen verbreiterten Rand (6) aufweist.

10. Knochenverankerungselement nach Anspruch 9, **dadurch gekennzeichnet, dass** der verbreiterte Rand (6) die Auslenkbarkeit des ersten Kopfteils (4) aus der Ruhewinkelstellung beschränkt.

11. Knochenverankerungselement nach einem der Ansprüche 3 bis 10, **dadurch gekennzeichnet, dass** das elastische Druckelement (20, 9) unter Vorspannung zwischen dem ersten Kopfteil (4) und einer das zweite Kopfteil (10) bedeckenden Kappe (30) befestigt ist.

12. Knochenverankerungselement nach einem der Ansprüche 1 bis 11, **dadurch gekennzeichnet, dass** ein zweites Druckelement (50; 250; 280) vorgesehen ist, das zum Fixieren der Ruhewinkelstellung auf das zweite Kopfteil einwirkt.

13. Knochenverankerungselement nach einem der Ansprüche 1 bis 12, **dadurch gekennzeichnet, dass** das Aufnahmeteil (40) im wesentlichen hohlzylinderförmig ausgebildet ist und an einem Ende einen Bereich (47) mit einem verjüngten Innendurchmesser zum Halten des zweiten Kopfteils (10) aufweist.

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14. Knochenverankerungselement nach einem der Ansprüche 1 bis 12, **dadurch gekennzeichnet, dass** das Aufnahmeteil als eine Platte (200) mit einer im wesentlichen hohlzylinderförmigen Bohrung (248; 247) ausgebildet ist und an einem Ende der Bohrung einen Bereich (247) mit einem verjüngten Innendurchmesser zum Halten des zweiten Kopfteils (10) aufweist.

15. Stabilisierungseinrichtung mit einem ersten Knochenverankerungselement und einem zweiten Knochenverankerungselement und einem diese verbindenden Stab (100) oder einer Platte (200), **dadurch gekennzeichnet, dass** wenigstens eines der Knochenverankerungselemente nach einem der Ansprüche 1 bis 14 ausgebildet ist.

Claims

1. Bone anchoring element with
an element (1) having a shaft (2) for anchoring in a bone or vertebra, and having a first head part (4) connected to the shaft (2),
a second head part (10) connectable to the element (1), in which the first head part is pivotably held,
a receiving part (40; 200) in which the second head part (10) is received, and
a fixation device (60; 260; 280) for fixing the second head part (10) in the receiving part (40; 200),
characterized in that
the second head part (10) is formed as sleeve-shaped for receiving the first head part (4) and is pivotably held in the receiving part (40, 200),
the fixing device fixes the second head part (10) in the receiving part (40, 200) in a position which determines a resting angular position of the shaft (2) relative to the receiving part, and
the first and second head parts are elastically connected to each other such that the shaft (2) is deflectable from the resting angular position relative to the second head part (10) and, in doing so, a force restoring to the resting angular position acts on the first head part (4).

2. Bone anchoring element according to Claim 1, **characterized in that** the deflection of the shaft (2) from the resting angular position is decoupled from the fixation of the resting angular position.

3. Bone anchoring element according to Claim 1 or 2, being formed such that an elastic pressure element (20, 9) acting on the first head part (4) is provided.

4. Bone anchoring element according to Claim 3, **characterized in that** the elastic pressure element (20) is made from an elastomer.

5. Bone anchoring element according to Claim 3, **characterized in that** the elastic pressure element (9) is formed in one piece with the first head part (4).

6. Bone anchoring element according to any one of Claims 1 to 5, **characterized in that** the second head part (10) comprises an outer surface essentially shaped as a segment of a sphere.

7. Bone anchoring element according to any one of Claims 1 to 6, **characterized in that** the first head part (4) essentially has a shape as a segment of a sphere.

8. Bone anchoring element according to any one of Claims 1 to 7, **characterized in that**, in a first region (15), the inner diameter of the sleeve-shaped second head part (10) is larger than the diameter of the first head part (4) and, in a second region (16), is smaller, such that the first head part (4) is insertable therein and pivotably held.

9. Bone anchoring element according to any one of Claims 1 to 8, **characterized in that** the first head part (4) comprises a widened edge (6) at its side facing away from the shaft (2).

10. Bone anchoring element according to Claim 9, **characterized in that** the widened edge (6) limits the capability of deflection of the first head part (4) from the resting angular position.

11. Bone anchoring element according to any one of Claims 3 to 10, **characterized in that** the elastic pressure element (20, 9) is attached under pre-load between the first head part (4) and a cap (30) covering the second head part (10).

12. Bone anchoring element according to any one of Claims 1 to 11, **characterized in that** a second pressure element (50; 250; 280) is provided which, for fixing the resting angular position, acts on the second head part.

13. Bone anchoring element according to any one of Claims 1 to 12, **characterized in that** the receiving part (40) is provided to be essentially hollow cylindrical in shape and, at one end, comprises a region (47) with a tapered inner diameter for holding the second head part (10).

14. Bone anchoring element according to any one of Claims 1 to 12, **characterized in that** the receiving part is provided as a plate (200) with an essentially hollow cylindrical bore (248; 247) and, at one end of the bore, comprises a region (247) with a tapered inner diameter for holding the second head part (10).

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15. Stabilization device with a first bone anchoring element and a second bone anchoring element and a rod (100) or a plate (200) connecting these, **characterized in that** at least one of the bone anchoring elements is provided according to any one of Claims 1 to 14.

Revendications

1. Élément d'ancrage osseux, comprenant :

   un élément (1) avec une tige (2), pour ancrage dans un os ou une vertèbre, et avec une première partie de tête (4) reliée à la tige (2),
   une deuxième partie de tête (10), susceptible d'être reliée à l'élément (1) et dans laquelle la première partie de tête est maintenue de façon à pouvoir pivoter,
   une partie de logement (40, 200) dans laquelle la deuxième partie de tête (10) est logée, et
   un dispositif de fixation (60; 260; 280) pour fixation de la deuxième partie de tête (10) dans la partie de logement (40 ; 200),

   caractérisé en ce que
   la deuxième partie de tête (10) est réalisée en forme de douille pour recevoir la première partie de tête (4) et est maintenue à pivotement dans la partie de logement (40 ; 200),
   le dispositif de fixation fixe la deuxième partie de tête (10) dans la partie de logement (40 ; 200), en une position déterminant une position angulaire de repos de la tige (2) par rapport à la partie de logement, et la première et la deuxième partie de tête étant reliées ensemble de façon élastique, de manière que la tige (2) puisse être déviée par rapport à la deuxième partie de tête (10) en partant d'une position angulaire de repos, et qu'une force, ramenant la première partie de tête (4) à la position angulaire de repos, agisse.

2. Élément d'ancrage osseux selon la revendication 1, **caractérisé en ce que** le débattement de la tige (2) depuis la position de repos, est désaccouplé de la fixation de la position angulaire de repos.

3. Élément d'ancrage osseux selon la revendication 1 ou 2, réalisé de manière qu'un élément de pressage (20, 9) élastique soit prévu, agissant sur la première partie de tête (4).

4. Élément d'ancrage osseux selon la revendication 3, **caractérisé en ce que** l'élément de pressage (20) élastique est réalisé en un élastomère.

5. Élément d'ancrage osseux selon la revendication 3, **caractérisé en ce que** l'élément de pressage (9) élastique est réalisé d'une seule pièce avec la première partie de tête (4).

6. Élément d'ancrage osseux selon l'une des revendications 1 à 5, **caractérisé en ce que** la deuxième partie de tête (10) présente une surface extérieure sensiblement en forme de segment de sphère.

7. Élément d'ancrage osseux selon l'une des revendications 1 à 6, **caractérisé en ce que** la première partie de tête (4) présente une forme sensiblement en forme de segment de sphère.

8. Élément d'ancrage osseux selon l'une des revendications 1 à 7, **caractérisé en ce que** le diamètre intérieur de la deuxième partie de tête (10) en forme de douille, dans une première zone (15), est plus grand que le diamètre de la première partie de tête (4) et, dans une deuxième zone (16), est plus petit, de manière que la première partie de tête (4) puisse y être introduite et y être maintenue à pivotement.

9. Élément d'ancrage osseux selon l'une des revendications 1 à 8, **caractérisé en ce que** la première partie de tête (4) présente sur sa face opposée à la tige (2) un bord (6) élargi.

10. Élément d'ancrage osseux selon la revendication 9, **caractérisé en ce que** le bord (6) élargi limite la possibilité de débattement de la première partie de tête (4) depuis la position angulaire de repos.

11. Élément d'ancrage osseux selon l'une des revendications 3 à 10, **caractérisé en ce que** l'élément de pressage (20, 9) élastique est fixé sous précontrainte entre la première partie de tête (4) et un capuchon (30) couvrant la deuxième partie de tête (10).

12. Élément d'ancrage osseux selon l'une des revendications 1 à 11, **caractérisé en ce qu'**un deuxième élément de pressage (50 ; 250 ; 280) est prévu, agissant pour fixer la position angulaire de repos sur la deuxième partie de tête.

13. Élément d'ancrage osseux selon l'une des revendications 1 à 12, **caractérisé en ce que** la partie de logement (40) est réalisée sensiblement avec une forme de cylindre creux, et présente à une extrémité une zone (47) ayant un diamètre intérieur effilé pour maintenir la deuxième partie de tête (10).

14. Élément d'ancrage osseux selon l'une des revendications 1 à 12, **caractérisé en ce que** la partie de logement est réalisée sous la forme d'une plaque (200) ayant un perçage (248 247) sensiblement en forme de cylindre creux, et présente sur une extrémité du perçage une zone (247) ayant un diamètre intérieur effilé, pour assure le maintien de la deuxième partie de tête (10).

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