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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
61/634,361	02/28/2012		125	11,340		

CONFIRMATION NO. 4934

27456
LAW OFFICE OF JOHN C. MCMAHON
P.O. BOX 30069
KANSAS CITY, MO 64112

FILING RECEIPT



OC000000053104861

Date Mailed: 03/16/2012

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Applicant(s)

Roger P. Jackson, Prairie Village, KS;

Power of Attorney:

John McMahon--29415

If Required, Foreign Filing License Granted: 03/13/2012

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 61/634,361**

Projected Publication Date: None, application is not eligible for pre-grant publication

Non-Publication Request: No

Early Publication Request: No

**** SMALL ENTITY ****

Title

Multi-start closure for open implants

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PROVISIONAL APPLICATION FOR PATENT COVER SHEET – Page 1 of 2

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

Express Mail Label No. EM443537795US

INVENTOR(S)		
Given Name (first and middle [if any])	Family Name or Surname	Residence (City and either State or Foreign Country)
Roger P.	Jackson	Prairie Village, Kansas
Additional inventors are being named on the _____ separately numbered sheets attached hereto.		
TITLE OF THE INVENTION (500 characters max):		
MULTI-START CLOSURES FOR OPEN IMPLANTS		
Direct all correspondence to: CORRESPONDENCE ADDRESS		
☒ The address corresponding to Customer Number: 27456		
OR		
☒ Firm or Individual Name Law Office of John McMahon		
Address P.O. Box 30069		
City Kansas City	State Missouri	Zip 64112
Country United States of America	Telephone (816) 531-3470	Email john@mcmahonpatentlaw.com
ENCLOSED APPLICATION PARTS (check all that apply)		
☒ Application Data Sheet. See 37 CFR 1.76 ☐ CD(s), Number of CDs _____		
☒ Drawing(s) Number of Sheets <u>6</u> ☒ Other (specify) <u>Abstract</u>		
☒ Specification (e.g. description of the invention) Number of Pages <u>28</u>		
Fees Due: Filing Fee of \$250 (\$125 for small entity). If the specification and drawings exceed 100 sheets of paper, an application size fee is also due, which 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).		
METHOD OF PAYMENT OF THE FILING FEE AND APPLICATION SIZE FEE FOR THIS PROVISIONAL APPLICATION FOR PATENT		
☒ Applicant claims small entity status. See 37 CFR 1.27.		
☐ A check or money order made payable to the <i>Director of the United States Patent and Trademark Office</i> is enclosed to cover the filing fee and application size fee (if applicable).		125.00
☐ Payment by credit card. Form PTO-2038 is attached.		TOTAL FEE AMOUNT (\$)
☒ The Director is hereby authorized to charge the filing fee and application size fee (if applicable) or credit any overpayment to Deposit Account Number: <u>50-1253</u>		

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SIGNATURE _____

Date February 28, 2012

TYPED or PRINTED NAME John C. McMahon

REGISTRATION NO. 29,415
(if appropriate)

TELEPHONE (816) 531-3470

Docket Number: 11,340

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INVENTOR(S)		
Given Name (first and middle (if any))	Family Name or Surname	Residence (City and either State or Foreign Country)
Roger P.	Jackson	Prairie Village, Kansas
Additional inventors are being named on the _____ separately numbered sheets attached hereto.		
TITLE OF THE INVENTION (500 characters max):		
MULTI-START CLOSURES FOR OPEN IMPLANTS		
Direct all correspondence to: CORRESPONDENCE ADDRESS ☒ The address corresponding to Customer Number: 27456 OR ☒ Firm or Individual Name <u>Law Office of John McMahon</u> Address <u>P.O. Box 30069</u> City <u>Kansas City</u> State <u>Missouri</u> Zip <u>64112</u> Country <u>United States of America</u> Telephone <u>(816) 531-3470</u> Email <u>john@mcmahonpatentlaw.com</u>		
ENCLOSED APPLICATION PARTS (check all that apply)		
☒ Application Data Sheet. See 37 CFR 1.76 ☐ CD(s), Number of CDs _____ ☒ Drawing(s) Number of Sheets <u>6</u> ☒ Other (specify) <u>Abstract</u> ☒ Specification (e.g. description of the invention) Number of Pages <u>28</u>		
Fees Due: Filing Fee of \$250 (\$125 for small entity). If the specification and drawings exceed 100 sheets of paper, an application size fee is also due, which 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).		
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☒ Applicant claims small entity status. See 37 CFR 1.27. 125.00 ☐ A check or money order made payable to the <i>Director of the United States Patent and Trademark Office</i> is enclosed to cover the filing fee and application size fee (if applicable). ☐ Payment by credit card. Form PTO-2038 is attached. TOTAL FEE AMOUNT (\$) ☒ The Director is hereby authorized to charge the filing fee and application size fee (if applicable) or credit any overpayment to Deposit Account Number: <u>50-1253</u>		

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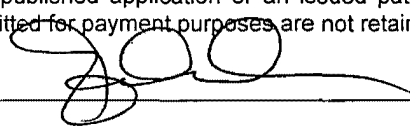
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SIGNATURE  Date February 28, 2012

TYPED or PRINTED NAME John C. McMahon REGISTRATION NO. 29,415
(if appropriate)

TELEPHONE (816) 531-3470 Docket Number: 11,340

APPLICATION DATA SHEET

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Citizenship: United States of America.

- 2) Correspondence Address:

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PO Box 30069
Kansas City, MO 64112

Patent Office Client No.: 27456

- 3) Title of Invention: MULTI-START CLOSURES FOR OPEN IMPLANTS
Suggested Classification: Class _____ Subclass _____
Technology Center _____
Total Number of Drawing Sheets 6
Docket No. 11,340
Type of Application: Provisional

- 4) Attorney: John C. McMahon
Address: PO Box 30069
Kansas City, MO 64112
Telephone: (816) 531-3470

Attorney Reg. No. 29,415

- 5) Domestic Priority:

NONE

- 6) Foreign Priority:

NONE

- 7) Assignee:

NONE

MULTI-START CLOSURES FOR OPEN IMPLANTS

Background of the Invention

[0001] 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.

[0002] 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.

[0003] Typical open-ended bone screws include a threaded shank with a head or receiver having 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.

[0004] 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 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

[0005] 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 dual- 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.

[0006] 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.

[0007] A multi-start closure of the invention is described herein with a polyaxial 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 structure of the helically wound multi-start closure of the invention. In an illustrated embodiment, the bone anchor assembly includes a

shank, a split or open retainer that engages and pivots with the shank, a compression insert and the receiver having the pair of opposed arms for receiving a rod or other longitudinal connecting member as well as the guide and advancement structure for mating with the multi-start closure.

[0008] 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.

[0009] 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

[0010] Fig. 1 is a perspective view of a multi-start closure according to the invention.

[0011] Fig. 2 is another perspective view of the multi-start closure of Fig. 1.

[0012] 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 Figs. 8 and 9, 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.

[0013] Fig. 4 is a reduced top plan view of the closure of Fig. 1.

[0014] Fig. 5 is a reduced bottom plan view of the closure of Fig. 1.

[0015] Fig. 6 is an enlarged front elevational view of the closure of Fig. 1 with portions broken away to show the detail thereof.

[0016] Fig. 7 is a reduced cross-sectional view taken along the line 7-7 of Fig. 6.

[0017] Fig. 8 is an exploded perspective view of a polyaxial bone screw assembly, with portions broken away to show the detail thereof, including a receiver, an open retainer and a compression insert and also shown with the closure top of Fig. 1 (in reduced view) and a longitudinal connecting member in the form of a hard rod.

[0018] Fig. 9 is an enlarged and partial front elevational view of the assembly of Fig. 8 shown assembled and with portions broken away to show the detail thereof.

[0019] Fig. 10 is a front elevational view of an alternative closure 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. 11 is another front elevational view of the alternative closure of Fig. 10 with portions broken away to show the detail thereof.

[0021] Fig. 12 is a front elevational view of an alternative square-thread closure 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. 13 is a front elevational view of an alternative reverse angle closure 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. 14 is a front elevational view of an alternative v-thread closure 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. 15 is a front elevational view of an alternative buttress-thread closure 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.

Detailed Description of the Invention

[0025] 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.

[0026] 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.

[0027] With reference to Figs. 1-9, and in particular to Figs. 8 and 9, 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 of the invention. The bone screw assembly 1 is described in detail in U.S. Provisional Patent Application No. 61/631,746 filed January 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 an explanation of the reference numbers indicated on Figs. 8 and 9. It is noted that multi-start

closures of the invention 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.

[0028] Briefly, the illustrated assembly 1 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 the 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. 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 into fixed frictional contact with the retainer 12, 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 receiver 10, retainer 12 and compression insert 14 are initially assembled and may be further assembled with the shank 4 either prior or subsequent to implantation of the shank body 6 into a vertebra. 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.

[0029] 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 in the '746 application that is incorporated by reference herein.

[0030] 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. Patent No. 6,726,689, also incorporated by

reference herein. Alternately, when the closure structure includes a different helical form, the structures 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.

[0031] 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. Patent 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 receiver 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 Figures 1-7, as well as acceptable alternative locking forms, are described in detail in Applicant's U.S. Patent 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.

[0032] 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.

[0033] 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 dual- 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. 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.

[0034] 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 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. 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. 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.

[0035] With specific reference to Figs. 3 and 9, 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. Also, for example, 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 also expands slightly upon locking, providing a full and

secure frictional locking engagement with the receiver at the surface 203.

[0036] 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.

[0037] With reference to Figs. 10 and 11, 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. 11. The inner drive 56' is used for disassembly or loosening of the closure 18' from the receiver 10, if needed.

[0038] With reference to Fig. 12, 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. 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.

[0039] With reference to Fig. 13, 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 described in detail in the '746 application incorporated by reference herein.

[0040] With reference to Fig. 14, 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.

[0041] With reference to Fig. 15, 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.

[0042] 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.

C L A I M S

What is claimed and desired to be secured by Letters Patent is as follows:

1. In a medical implant having a substantially cylindrical closure member and a receiver member having first and second spaced arms forming an open channel, the closure member having an axis of rotation for closing the open channel, the improvement comprising:

a) at least first and second helically wound forms located on the closure member, the first form having a first start and the second form having a second start; and

b) at least a first discontinuous helically wound structure on the receiver first arm and at least a second discontinuous helically wound structure on the receiver second arm and wherein simultaneous mating of the first start with the arm first helically wound structure and the second start with the arm second helically wound structure occurs when the closure member is rotated between the first and second arms of the receiver member.

2. The improvement of claim 1 wherein the first and second helically wound forms are each a flange form that interlocks with the respective helically wound structures on the receiver.

3. The improvement of claim 1 wherein the first and second helically wound forms are v-threads.

4. The improvement of claim 1 wherein the first and second helically wound forms are square threads.

5. The improvement of claim 1 wherein the first and second helically wound forms are reverse angle threads.

6. The improvement of claim 1 wherein the first and second helically wound forms are buttress threads.

7. The improvement of claim 1 wherein the closure member has a break-off head.

8. A medical implant comprising:

a) a receiver having a body and a pair of upstanding spaced arms forming a channel for receiving a longitudinal connecting member, each arm having an inwardly facing surface with a first discontinuous helically wound guide and advancement structure located thereon;

b) a closure structure having a cylindrical body and a second helically wound guide and advancement structure having at least two starts.

9. The implant of claim 8 wherein the first and second helically wound guide and advancement structures are interlocking flange forms.

10. The improvement of claim 8 wherein the second helically wound guide and advancement structure includes at least two v-threads.

11. The improvement of claim 8 wherein the second helically wound guide and advancement structure includes at least two square threads.

12. The improvement of claim 8 wherein the second helically wound guide and advancement structure includes at least two reverse angle threads.

13. The improvement of claim 8 wherein the second helically wound guide and advancement structure includes at least two buttress threads.

14. The improvement of claim 8 wherein the closure structure has a break-off head.

15. In a medical implant, the improvement comprising:

a) an open receiver member with spaced arms having inwardly facing surfaces, each with a first helically wound guide and advancement form located thereon; and

b) a helically wound multi-start closure member having an axis of rotation, the closure member rotatably mounted on the receiver member at the spaced arm inwardly facing surfaces.

16. The improvement of claim 15 wherein the multi-start closure is a double-start closure.

17. The improvement of claim 15 wherein the multi-start closure includes at least two helically wound forms, each form being one of a flange form, a v-thread, a square thread, a reverse angle thread and a buttress thread, the form mating with the first helically wound guide and advancement form.

Abstract of the Disclosure

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.

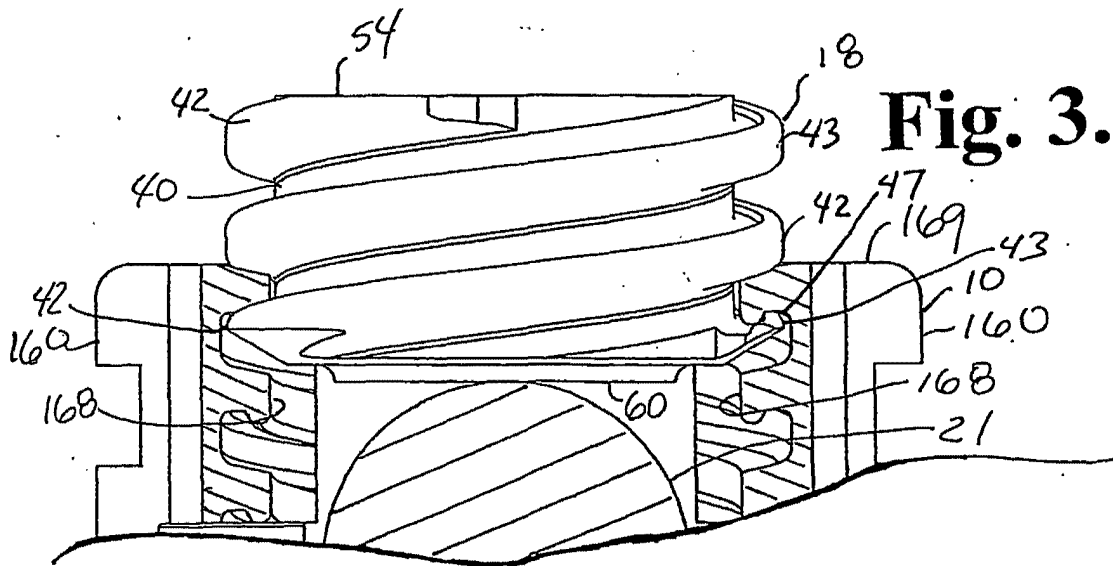
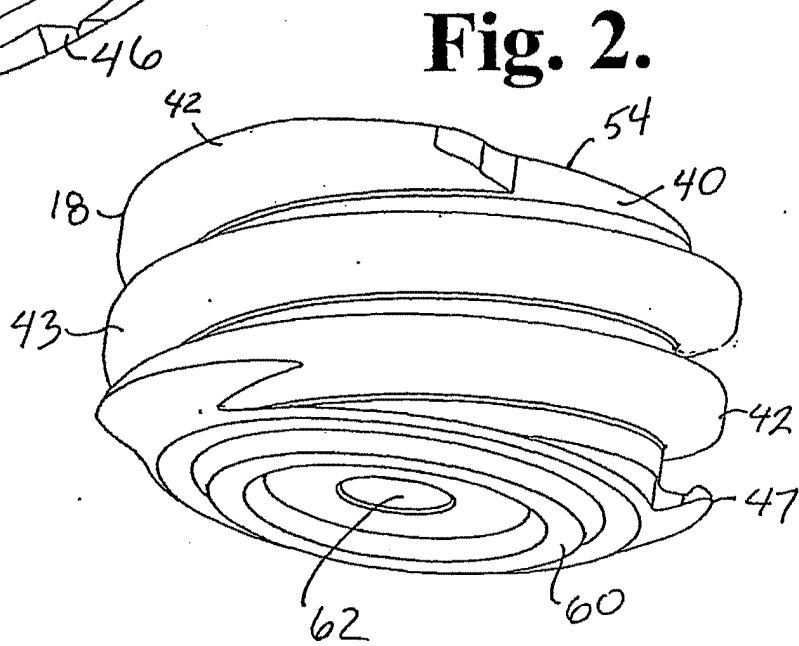
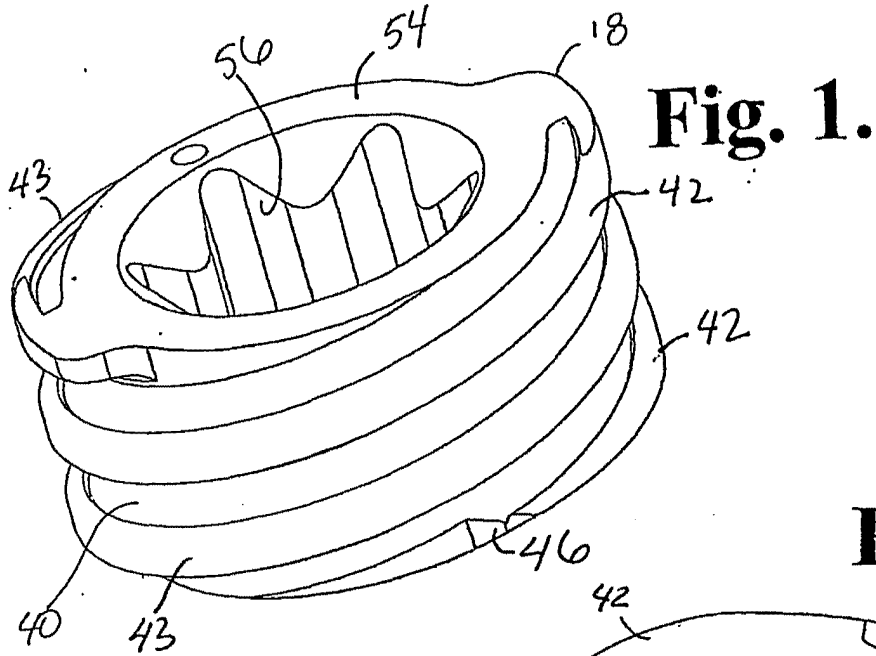


Fig. 4.

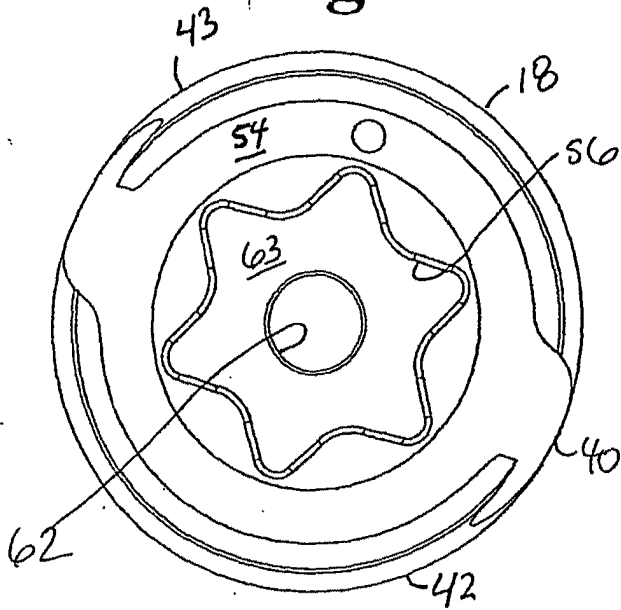


Fig. 5.

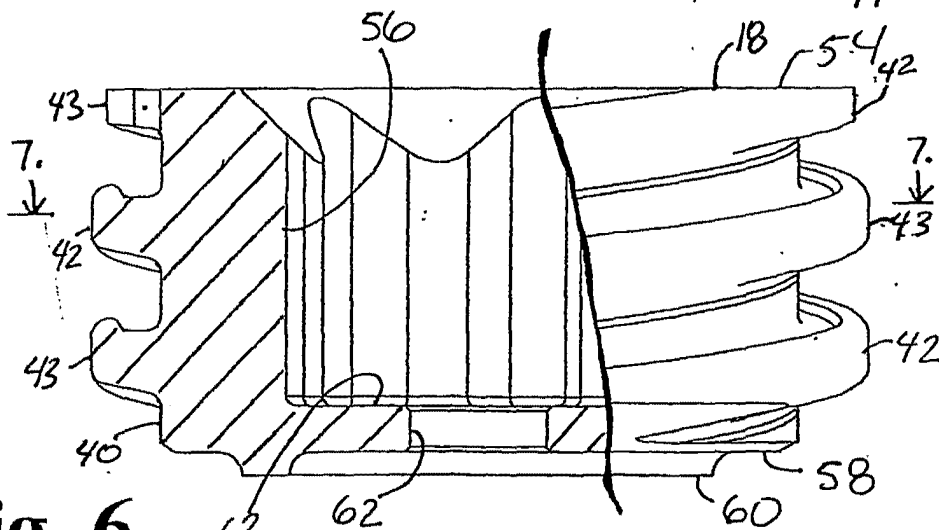
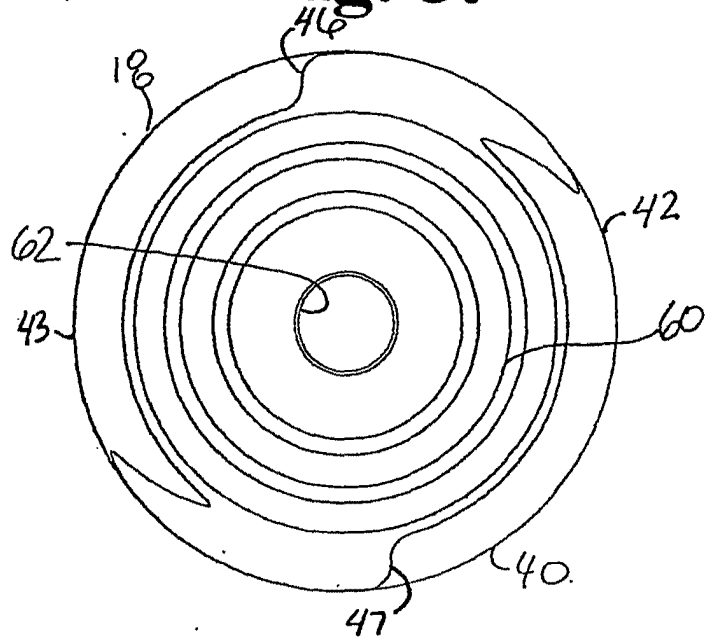


Fig. 6.

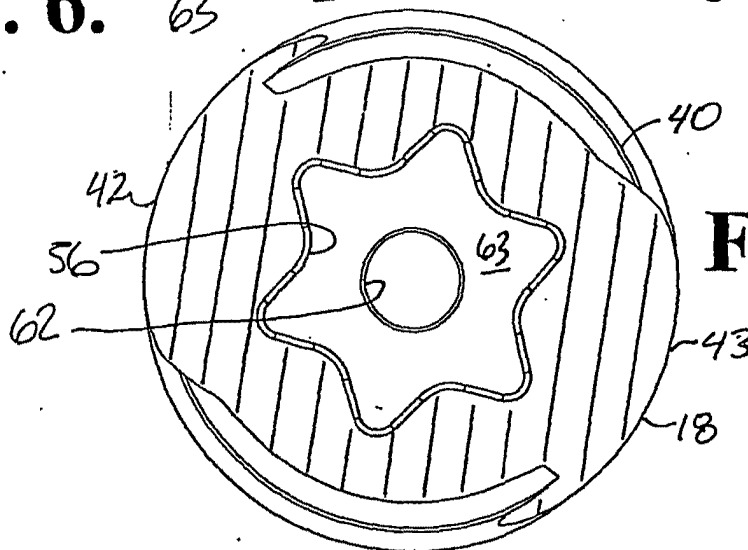


Fig. 7.

Fig. 8.

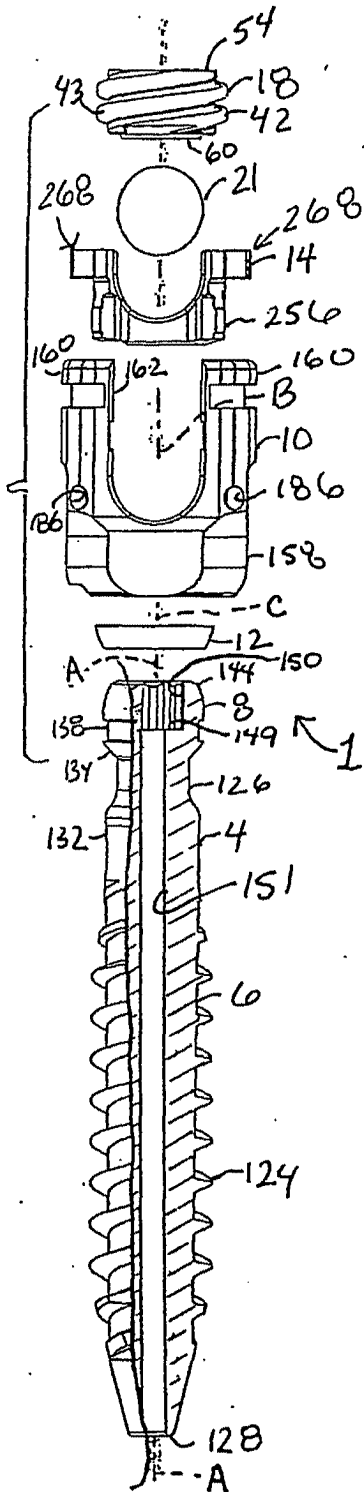


Fig. 9.

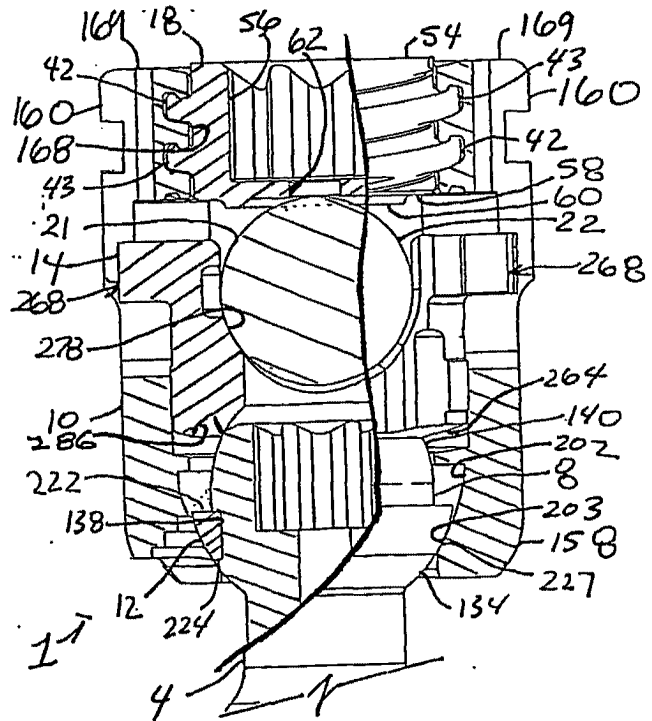


Fig. 10.

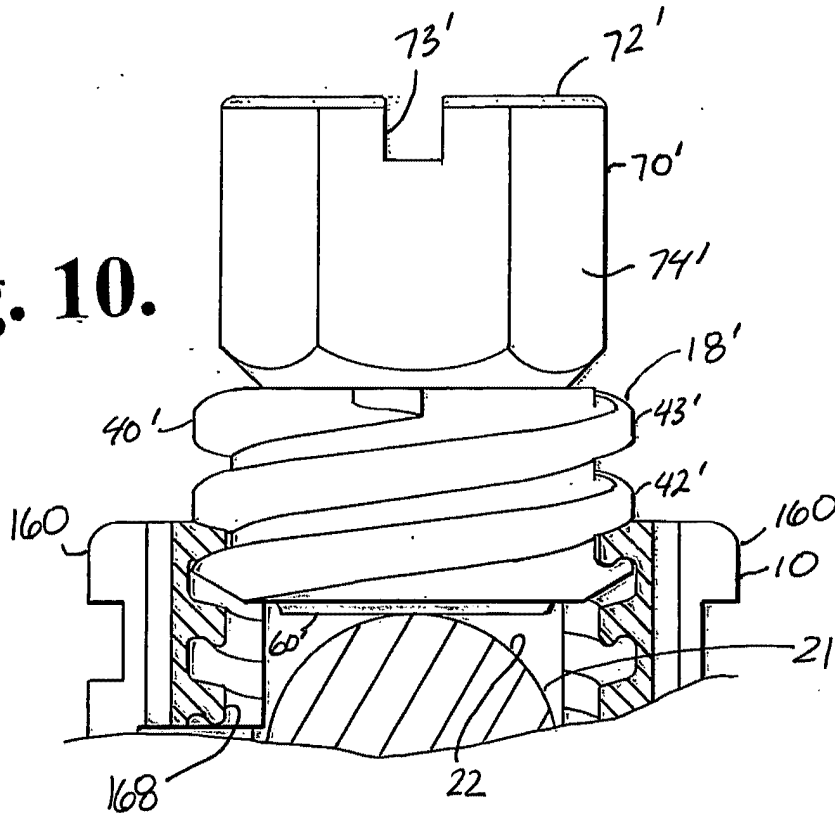
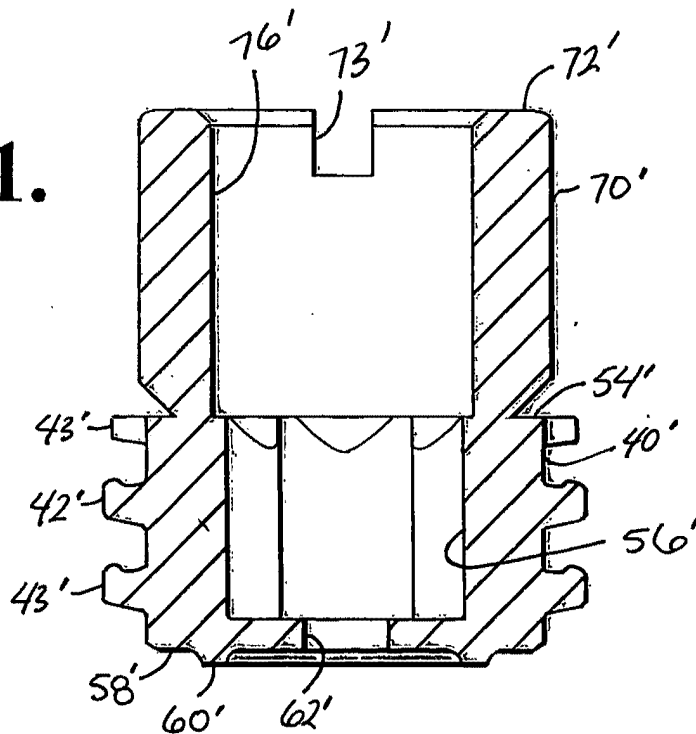


Fig. 11.



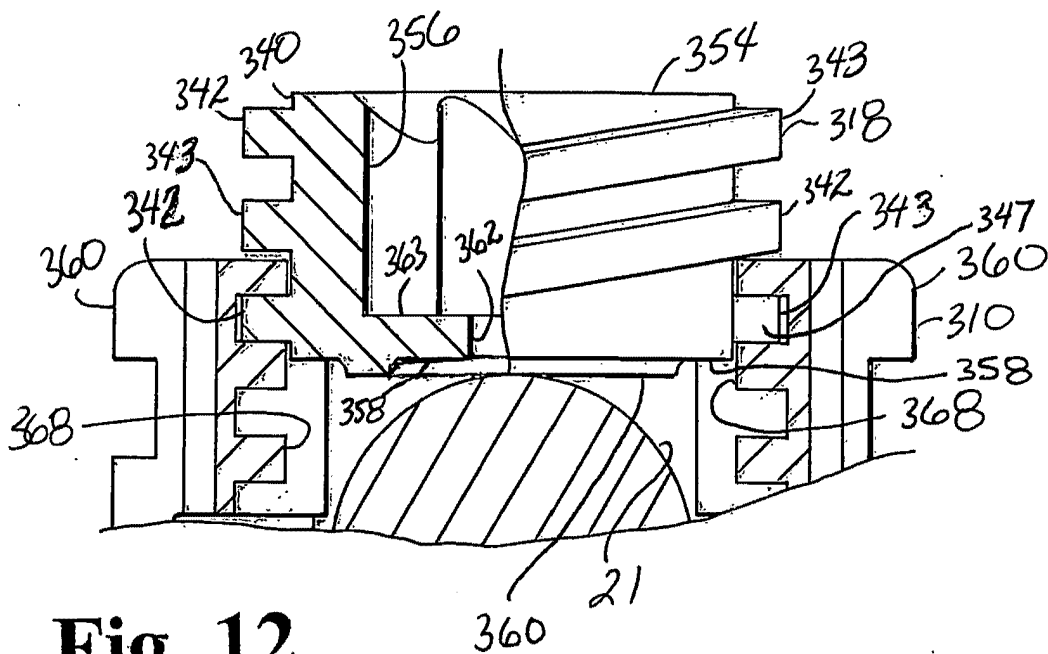


Fig. 12.

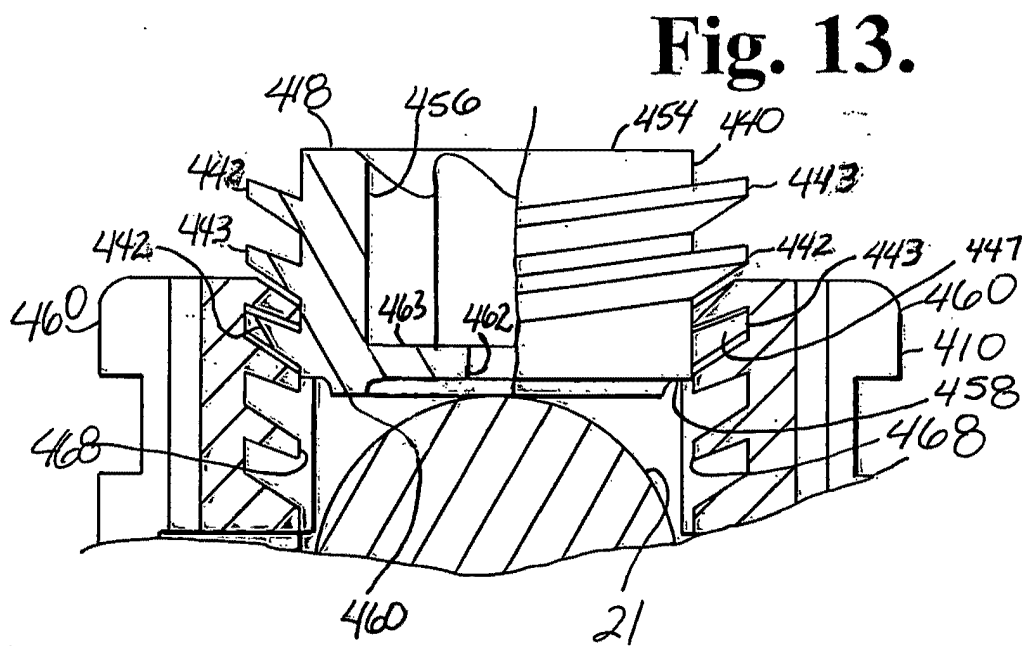


Fig. 13.

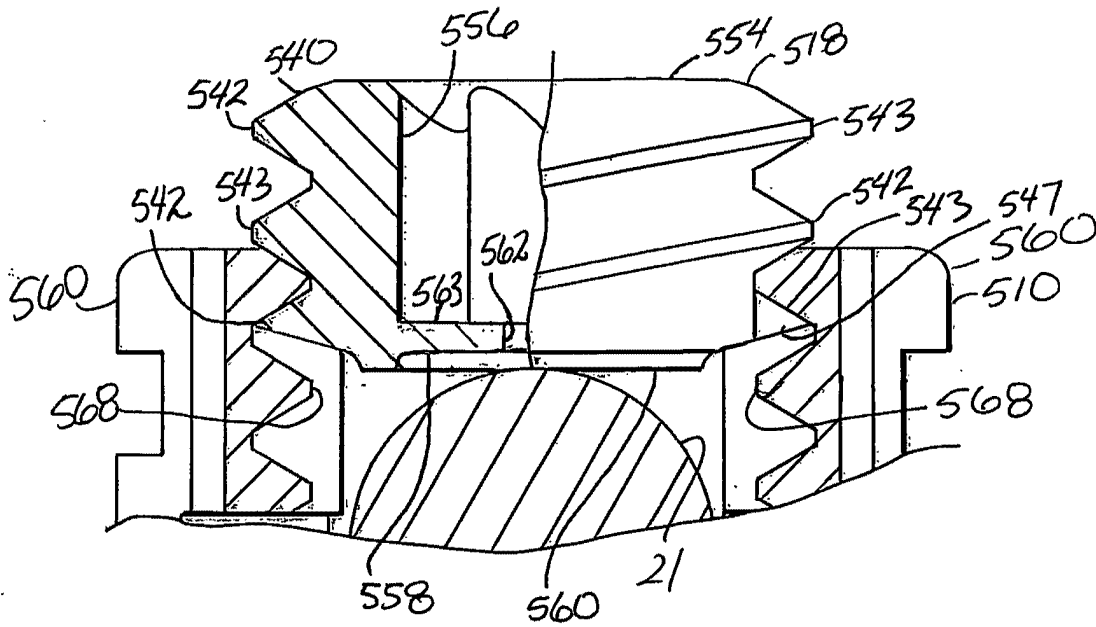


Fig. 14.

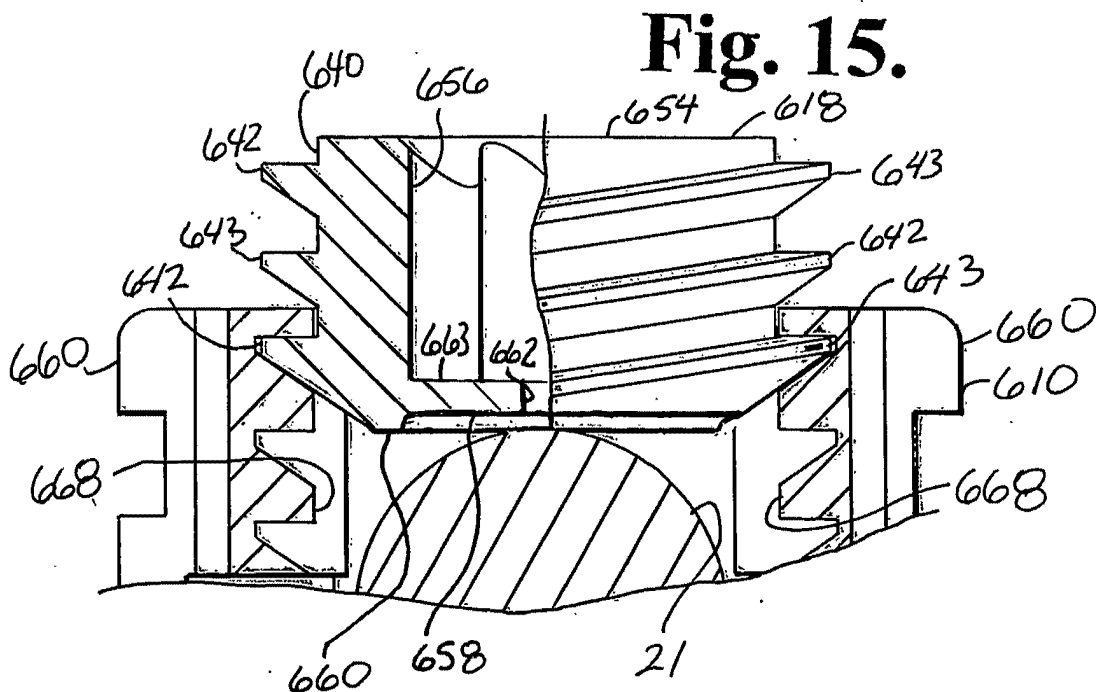


Fig. 15.

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