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(71) Applicant (for all designated States except US): **SPINE WAVE, INC.** [US/US]; Three Enterprise Drive, Suite 210, Shelton, CT 06484 (US).

(72) Inventors; and

(75) Inventors/Applicants (for US only): **MCLEAN, Scott** [US/US]; 42 Southridge Drive, Waterbury, CT 06708 (US). **SEYER, Steven** [US/US]; 17 Mulberry Lane, Shelton, CT 06484 (US).

(74) Agents: **ABBRUZZESE, Salvatore, J.** et al.; Hoffmann & Baron, LLP, 6900 Jericho Turnpike, Syosset, NY 11791 (US).

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[Continued on next page]

(54) Title: SCREW DRIVER FOR A MULTIAXIAL BONE SCREW

(57) Abstract: A screwdriver for driving multi-axial bone screws into vertebra includes an elongate shaft defining a driving tip engaging the head of the bone screw for joint rotational movement. The screw driver also includes an outer sleeve within which the inner shaft rotates freely. The outer retention sleeve releasably attaches to the yoke of the bone screw. Rotation of the inner shaft enables rotation of the bone screw threaded shank while the outer sleeve and yoke remain fixed. In another configuration, instead of the outer retention sleeve the screwdriver comprises a screw engagement member affixed to the shaft for joint rotational movement therewith, the screw engagement member comprising a stop sized to seat within a slot of the bone screw yoke. A releasable retention member is provided on the engagement member for releasably attaching the screwdriver to the bone screw.

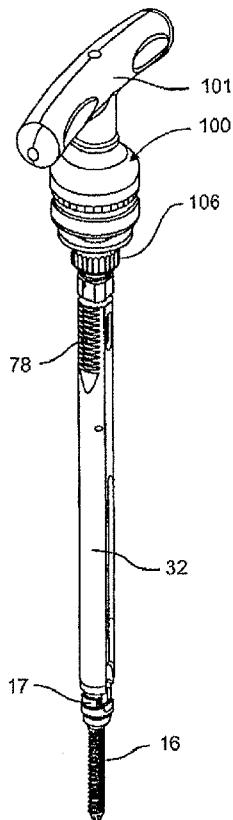


FIG. 3



CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

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UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

- with international search report (Art. 21(3))
- with information concerning one or more priority claims considered void (Rule 26bis.2(d))

SCREW DRIVER FOR A MULTIAXIAL BONE SCREW

CROSS-REFERENCE TO RELATED APPLICATIONS

5 This application claims priority to U.S. Patent Application No. 13/118,868, filed May 31, 2011, which is a continuation-in-part application of Application No. 12/818,979, filed June 18, 2010, now pending, which is herein incorporated by reference in its entirety.

BACKGROUND

10 The present disclosure contemplates instrumentation and procedures for achieving spinal fixation and more particularly to a screw driver for driving a bone screw into a vertebra of a patient.

15 A typical spinal fixation system **10** as shown in **FIG. 1** spans between successive vertebrae **V** of the spine. An elongated member, such as rod **12**, extends along the length of the spine and provides an anchor point for connecting each vertebra to the rod. The rod is typically contoured to approximate the normal curvature of the spine for the particular instrumented spinal segments, which may include lordosis or kyphosis. Anchor devices **15** are provided for connecting the vertebral segments to the elongated member. These anchor devices may include hooks, bolts, screws or other means for engaging a vertebra. For the purposes of the present discussion, the anchor device **15** is a bone screw assembly, such as 20 the screw assembly shown in **FIG. 2**.

25 The bone engaging fastener or screw assembly **15** includes a shank **16** that carries threads configured to engage vertebral bone. For instance, the fastener is a multi-axial pedicle screw with a shank that is threaded for engagement within the pedicle of the vertebra. The screw assembly further includes a head **16a** by which the screw, and ultimately the vertebra, is fastened to the spinal rod **12**. In particular, the head **16a** supports a yoke **17** that is generally U-shaped to receive the spinal rod therethrough, as depicted in **FIG. 2**. The rod **12** may be supported in part by a collar **18** mounted over the head **16a** of the bone screw. A

cap **19** may carry a set screw **20** that locks the rod within the yoke **17** and thus fastens the rod **12** to the bone screw or the set screw **20** may be threadably attached directly to the yoke **17**.

One embodiment of a bone screw assembly **15** is disclosed in co-pending, commonly assigned U.S. Application No. 11/762,898 (the ‘898 Application), entitled “Multi-Axial Fixation Assembly”, filed on June 14, 2007 and published as No. 2008/0119858, the disclosure of which is incorporated herein by reference in its entirety. For the purposes of the present disclosure, the bone screw **15** may be constructed as disclosed in the ‘898 Application, although it is understood that other multi-axial bone screw configurations may be implanted using the instruments and procedures disclosed herein. In the multi-axial bone screw assembly **15** the yoke **17** is articulately attached to the threaded bone screw **16**, and more specifically to the head **16a** of the bone screw, so that the yoke **17** can adopt a range of spherical angles relative to the bone screw. Thus, the yoke can articulate relative to the bone screw fastened in the vertebra so that the slot **42** can be aligned to receive the connecting rod **25**.

While in the past spinal fixation systems using screws of the ‘898 Application have been implanted in open procedures involving relatively large incisions through the patient’s tissue with significant muscle retraction, more recent procedures have been developed to introduce spinal fixation systems in a minimally invasive or percutaneous manner. With multi-axial pedicle screws being primarily used in these systems there is a need to provide instruments for the surgeons to properly and readily insert such screws into the vertebrae of the spine for suitably receiving and supporting spinal connecting rods.

SUMMARY

The present invention is directed to a screwdriver for driving a multi-axial bone screw into a vertebra of the spine.

In accordance with one arrangement, a bone screw includes an elongate shaft having a threaded screw portion at the distal end and a screw head at the proximal end. A yoke is articulately attached to the screw head, the yoke having a slot therethrough for receiving a connecting rod and having an opening communicating with the screw head. The screwdriver comprises an elongate inner shaft having a distal end and a proximal end, the inner shaft defining a driving tip at the distal end configured to engage the screw head for rotation

thereof. An outer retention sleeve disposed about the inner shaft has a distal end and a proximal end, the inner shaft being freely rotatable within the outer retention sleeve. The distal end of the outer retention sleeve is configured to releasably engage the yoke for joint rotational movement therewith.

5 In accordance with another arrangement, the screwdriver comprises a screw engagement member affixed to the shaft for joint rotational movement therewith, the screw engagement member comprising a stop sized to seat within the slot of the bone screw yoke and configured to rotate the yoke upon rotation of the shaft. A releasable retention member is included on the screw engagement member for releasable attachment to the yoke. The
10 releasable retention member may be releasably attached to an inner surface of the bone screw yoke or the outer surface.

DESCRIPTION OF THE FIGURES

FIG. 1 is a representation of a portion of a patient's spine instrumented with a multi-level fixation system.

15 **FIG. 2** is a perspective view of a bone engaging fastener in the form of a multi-axial pedicle screw suitable for use with a procedure disclosed herein.

FIG. 3 is a perspective view of the bone screw and screw extension assembly with a screw driver mounted thereon.

20 **FIG. 4** is a cross-sectional view of the bone screw, screw extension assembly and screw driver shown in **FIG. 3**

FIG. 5 is an exploded perspective view of the bone screw of **FIG. 4** and a screw driver in accordance with another procedure disclosed herein.

FIG. 6 is an enlarged exploded perspective view of the engagement portions of the bone screw and screw driver of **FIG. 5**.

25 **FIG. 7** is a cross-sectional view of the bone screw and screw driver of **FIG. 5** with the screw driver engaged with the bone screw.

FIG. 8 is an exploded perspective view of a bone screw and a screw driver in accordance with a further procedure disclosed herein.

FIG. 9 is an enlarged exploded perspective view of the engagement portions of the bone screw and screw driver of **FIG. 8**.

DETAILED DESCRIPTION

For the purposes of promoting an understanding of the principles of the invention, reference will now be made to the embodiments illustrated in the drawings and described in the following written specification. It is understood that no limitation to the scope of the invention is thereby intended. It is further understood that the present invention includes any alterations and modifications to the illustrated embodiments and includes further applications of the principles of the invention as would normally occur to one skilled in the art to which this invention pertains.

By reference also to **FIGS. 3-4**, a screw driver **100** is shown in assembled engagement with the multi-axial bone screw **15**. In this first procedure, the pedicle screw **15** with the attached screwdriver **100** is adapted for use particularly in the percutaneous procedures described in the co-pending, commonly assigned '979 Application referenced hereinabove. In the '979 Application screw extension assemblies **32** are described as being releasably attached to bone screws for use in percutaneous placement of spinal connecting rods between two or more pedicle screws to form a spinal fixation construct. In such procedure a single incision is described as being made for the insertion of each pedicle screw **15**, the pedicle screw **15** with attached extension assembly **32** being inserted through each respective incision. A connecting rod is percutaneously connected to the pedicle screws through slots in the screw extension assemblies by a separate rod introducer as further described in the '979 Application. The screw extension assembly **32** is also configured to accept tools for access to the bone screw assembly and insertion of the bone screw. For instance, the bore **58** of the inner sleeve **57** of screw extensions **32** is sized to receive the screw driver **100** as shown in **FIGS. 3-4**. The screw driver **100** includes at the proximal end a handle **101** connected to a shaft **102** to permit manual rotation of the shaft. The shaft **102** includes at the distal end a tip defining an engagement end **103** that is configured to engage a drive tool recess **22** in the base of the bone screw head **16a**. The engagement end and drive tool recess can be configured in a conventional manner, such as with a hex or Torx feature. The shaft **102** is sized so that the engagement end **103** can be received within the recess **22** while the handle **101** is accessible at the proximal end of the screw extension assembly **32**.

The screw driver tool **100** includes an outer retention sleeve **104** having an interior bore **104a** through which the shaft **102** extends. The shaft **102** and retention sleeve **104** are coupled to each other to allow free relative axial and rotational movement therebetween. The distal end **105** of the retention sleeve **104** is provided with exterior threads to match the

5 internal threads on the interior surfaces of yoke **17**. The retention sleeve **104** is connected to a knob **106** (FIG. 3) situated on or adjacent the proximal end of the screw extension assembly **32** that is configured to facilitate manual rotation of the retention sleeve to thread the distal end **105** into the yoke. A stop **108** is rotatably mounted on the shaft **102** and is configured to seat within the slot of the yoke **17** to support the shaft and retain the sleeve.

10 Upon threaded connection of the outer retention sleeve **104** to the yoke **17**, the retention sleeve **104** bears against the stop **108** and the stop bears against the yoke to provide joint rotational movement of the retention sleeve, stop and yoke. Prior to such threaded connection, the engagement end **103** of the inner shaft is guided into the drive tool recess **22** in the base of the bone screw head **16a**. The stop **108** may be sized to prevent threading of

15 the retention sleeve into the yoke unless and until the end **103** of the shaft is engaged within the tool recess of the bone screw. Once the tool **100** is properly seated, rotation of the handle **101** that is connected to the shaft **102** will rotate the bone screw shank **16**. With the screw extension assembly **32** and the retention sleeve **104** attached to the yoke for joint movement, and with the yoke **17** being able to freely articulate with respect to screw shank **16**, the screw

20 extension assembly **32** may be manually held while the handle **101** is rotated to drive the screw shank **16** into a pedicle of a vertebra.

The screw extension assembly thus provides an avenue for guiding the screw driver instrument **100** into engagement with the bone screw. Even if the screw extension assembly is articulated relative to the bone screw, a minor manipulation of the assembly will

25 automatically align the screw driver instrument with the drive tool recess. Once engaged the screw driver can be used to thread the bone screw **15** into the vertebra in a known manner and removed from the screw extension assembly. The shaft **102** of the screw driver **100** may be provided with a guide wire lumen **107** to allow introduction of the tool over a previously positioned guide wire.

30 In another procedure, a screw driver may be used for insertion of a multi-axial bone screw in a spinal surgery known as a mini-open procedure. In the mini-open procedure a

spinal fixation construct may be formed to connect to two or more pedicle screws with a spinal rod. A single incision may be formed over the pedicles by what is known in the art as a Wiltse-style approach and retracted sufficiently for the pedicle screws to be introduced through the incision on one side of the spine. Once the pedicle screws are placed, the spinal 5 rod may also be introduced through the same single incision. As shown in **FIGS. 5-7**, a multi-axial bone screw, such as the bone screw **15** used in the percutaneous procedure described hereinabove, may be used together with a screwdriver **200** in the mini-open procedure. Unlike the percutaneous procedure, no screw extension assemblies are typically used in the mini-open procedure.

10 The screw driver **200** includes at the proximal end a handle **201** connected to a shaft **202** to permit manual rotation of the shaft. The shaft **202** includes at the distal end a tip defining an engagement end **203** that is configured to engage the drive tool recess **22** in the base of the bone screw head **16a**. The engagement end and drive tool recess can be configured in a conventional manner similar to screw driver tip **103** to have a hex or Torx 15 feature. The shaft **202** is sized and of length so that the engagement end **203** can be received within the recess **22** while handle **201** is accessible at the proximal end outside the patient. The shaft **202** of the screwdriver **200** may be cannulated by providing a guide wire lumen **207** through the shaft **202** to allow introduction of the tool over a previously positioned guide wire which would also be used to guide the introduction of the cannulated bone screw **15**.

20 The screw driver **200** includes adjacent the distal end of the shaft **202** and spaced proximally from tip **203** an engagement member **204**. Engagement member **204** is affixed to the shaft **202** for joint rotational movement therewith. Engagement member **204** includes at its distal end a stop **206** that is shaped and configured to seat within the slot **42** of the yoke **17**. The stop **206** is configured to rotate the yoke **17** upon rotation of the shaft **202** as the 25 engagement end **203** drives the threaded shank **16** into a pedicle of a vertebra.

The engagement member **204** includes a releasable retention member **208** for 30 releasable attachment to the yoke **17**. Releasable retention member **208** comprises a pair of flexible elements **208a** and **208b**. Flexible elements **208a** and **208b** are preferably cantilevered spring elements each having an outward projection **210a** and **210b**, respectively, at the free ends thereof. Flexible elements **208a** and **208b** are formed to provide an outward bias. The outward projections **210a** and **210b** are configured and shaped to releasably engage

undercuts 212 extending into the interior surfaces 44 of each of the upstanding apposed arms of the yoke 17 with the flexible elements 208a and 208b providing an outward bias against the yoke arms. In addition to the releasable retention member 208 releasably retaining the screw driver 200 attached to the bone screw 15, the flexible elements 208a and 208b may 5 provide an audible click upon attachment of the screw driver 200 to the bone screw 15 allowing the surgeon to known that proper attachment has been made.

Once engaged, the screw driver 200 can be used to thread the bone screw 15 into the vertebra in a known manner. With the engagement portion 204 affixed to the shaft 202, it can be seen that upon rotation of the shaft 202 by the handle 201, the screw 15 including its 10 threaded shank 16 and yoke 17 will be jointly rotated upon rotation of the shaft 202. Upon completion of threaded insertion of the bone screw 15, the screw driver 200 may then be removed. A manual force applied by the surgeon to the handle in the proximal direction is sufficient to overcome the bias of the flexible elements 208a and 208b and separate the screw driver 200 from the screw 15.

15 In a further procedure, a screw driver may be used for insertion of a multi-axial bone screw in an open spinal procedure. In an open procedure a spinal fixation construct may be formed to connect to two or more pedicle screws with a spinal rod in single or multi-level surgeries. The incision may be formed midline through the patient's tissue with significant muscle retraction to permit introduction of the pedicle screws and the rod to form a construct 20 on both sides of the spine through the one incision. As shown in FIGS. 8-9, a multi-axial bone screw 315 used may be used together with a screwdriver 300 in such an open procedure. Like the mini-open procedure, no screw extension assemblies are typically used in the open procedure.

25 In the open procedure the multi-axial bone 315 may be the screw described in the above-referenced co-pending, commonly assigned '898 Application. Such a screw 315 is substantially similar to bone screw 15 described herein except that the internal surfaces 344 of the upstanding opposed arms of yoke 317 are not provided with undercuts. Instead, the exterior surfaces of each arm of yoke 317 are respectively provided with an inwardly directed slot 312 located adjacent the upper end of each yoke arm as shown in FIG. 9. In addition, the 30 threaded shank 316 of the bone screw 315 is not cannulated unlike shank 16 of screw 15. The construction of the screw driver 300 is substantially the same as the screw driver 200

except that the flexible elements **308a** and **308b** of releasable retention member **308** are formed to provide an inward bias with projections **310a** and **310b** extending releasably into the slots **312** in the exterior surfaces of the yoke arms. As such, flexible elements **308a** and **308b** attach releasably to the outside of the yoke **317** and may provide an audible click upon 5 such attachment. Also, since the screw **315** is not canulated there is no internal lumen provide through the shaft **302** of screw driver **300**.

While the invention has been illustrated and described in detail in the drawings and foregoing description, the same should be considered as illustrative and not restrictive in character. For example, the screws **15** used in the mini-open procedure may, if desired, be 10 used in an open procedure and as such, the screw drivers associated therewith may likewise be so used. It is understood that only the preferred embodiments have been presented and that all changes, modifications and further applications that come within the spirit of the invention are desired to be protected.

What is claimed is:

1. A screw driver for driving a multi-axial bone screw into a vertebra of a spine, the bone screw including an elongate shaft having a threaded screw portion at the distal end and a screw head at the proximal end, and a yoke articulatingly attached to the screw head, 5 the yoke having a slot therethrough for receiving a connecting rod and including a lower surface, the yoke having an opening communicating with the screw head, said screw driver comprising:

an elongate inner shaft having a distal end and a proximal end, said inner shaft defining a driving tip at said distal end configured to engage the screw head for rotation 10 thereof; and

an outer retention sleeve disposed about said inner shaft and having a distal end and a proximal end, the inner shaft being freely rotatable within said outer retention sleeve and including said tip at the distal end thereof, the distal end of said outer retention sleeve configured to releasably engage the yoke for joint rotational movement therewith.

15

2 The screw driver of claim 1, in which the slot of said yoke is defined by a pair of upstanding opposed arms having interior threaded surfaces, wherein said distal end of said outer retention sleeve is threaded exteriorly to engage the interior threaded surfaces of the yoke when said screw driver tip is engaged to the head of said bone screw.

20

3. A screw driver for driving a multi-axial bone screw into a vertebra of a spine, the bone screw including an elongate shaft having a threaded screw portion at the distal end and a screw head at the proximal end, and a yoke articulatingly attached to the screw head, the yoke having a slot therethrough for receiving a connecting rod and including a lower 25 surface, the yoke having an opening communicating with the screw head, said screw driver comprising:

an elongate shaft having a distal end and a proximal end, said shaft defining a driving tip at said distal end configured to engage the screw head for rotation thereof; and

30 a screw engagement member affixed to said shaft for joint rotational movement therewith, said screw engagement member comprising a stop sized to seat within the slot of

said yoke and configured to rotate said yoke upon rotation of said shaft, and a releasable retention member for releasable attachment to said yoke.

4. The screwdriver of claim 3, in which the slot of said yoke is defined by a pair 5 of upstanding opposed arms having interior surfaces and exterior surfaces respectively and wherein said releasable retention member comprises a pair of flexible elements releasably attachable to said respective pair of arms.

5. The screwdriver of claim 4, wherein each of said opposed arms of said yoke 10 comprises an undercut extending respectively into an interior surface thereof and wherein each of said flexible elements is configured to provide an outward bias and having a projection for releasably extending into said respective interior undercuts in said arms.

6. The screwdriver of claim 4, wherein each of said opposed arms of said yoke 15 comprises a slot extending respectively into an exterior surface thereof and wherein each of said flexible elements is configured to provide an inward bias and having a projection for releasably extending into said respective exterior slots in said arms.

7. The screwdriver of claim 3, further including a handle fixed to said shaft at 20 said distal end thereof, said shaft being of length such that said distal end with said handle extends outside a patient as said bone screw is driven into a vertebra of the spine.

8. The screwdriver of claim 3, further comprising a guide wire lumen extending through said shaft to allow introduction of the shaft over a previously positioned guide wire.

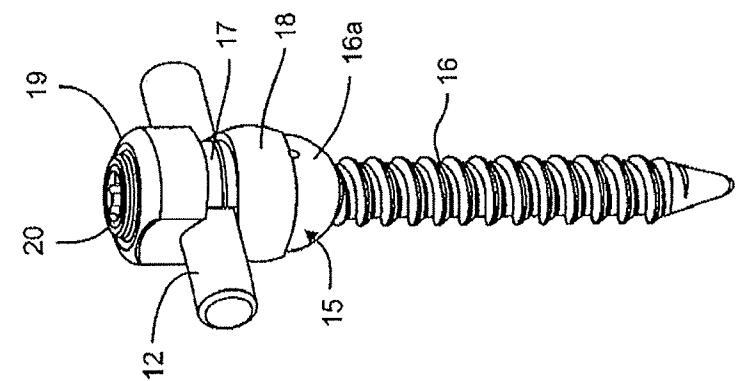


FIG. 2

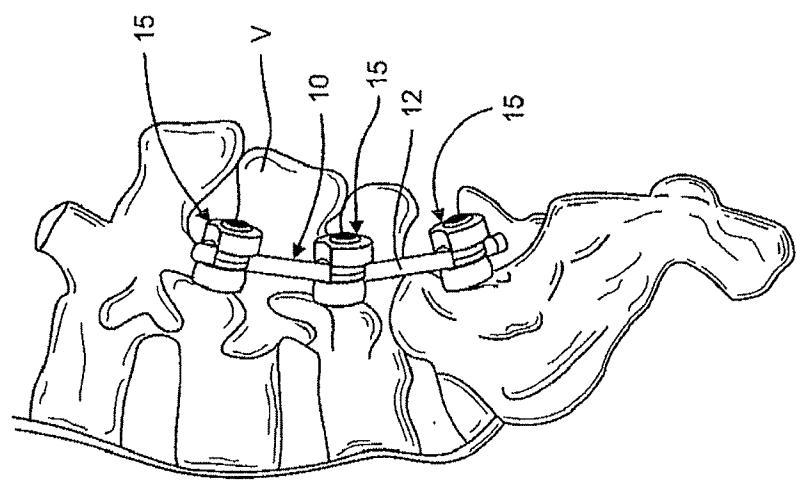


FIG. 1

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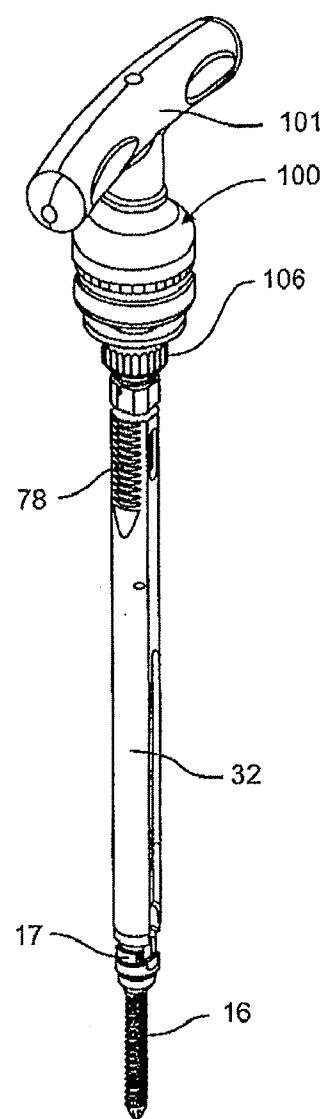


FIG. 3

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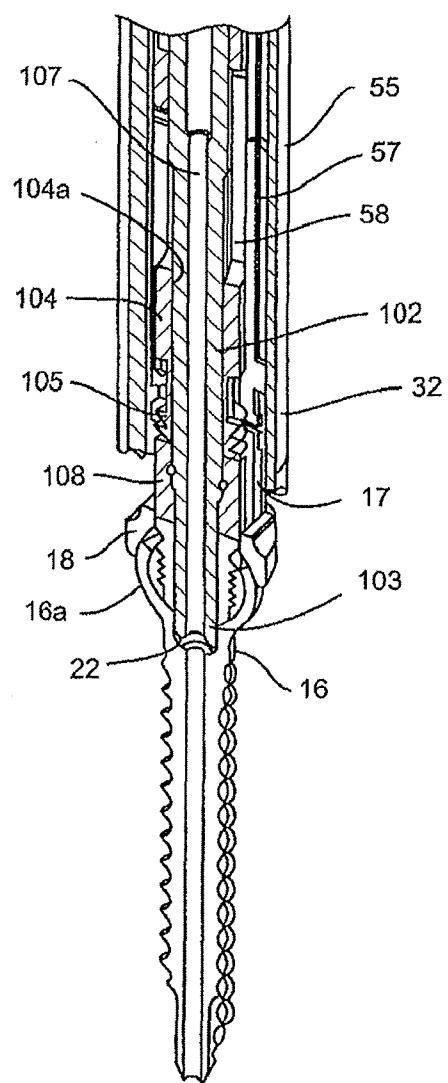


FIG. 4

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FIG. 5

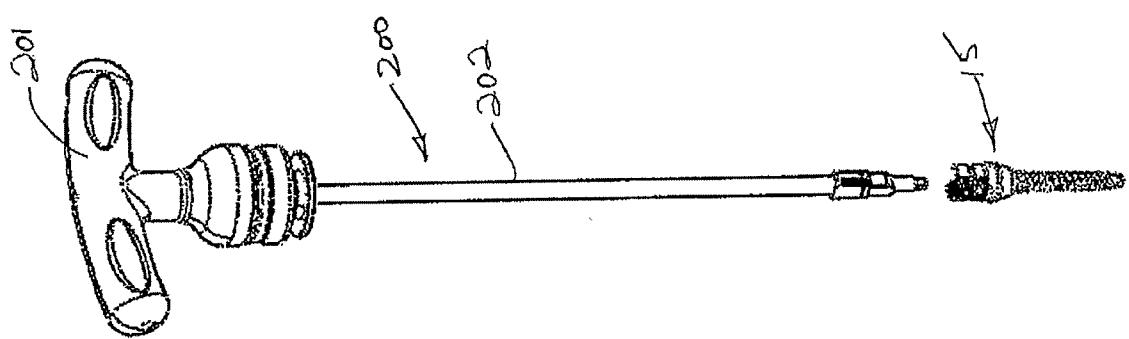


FIG. 6

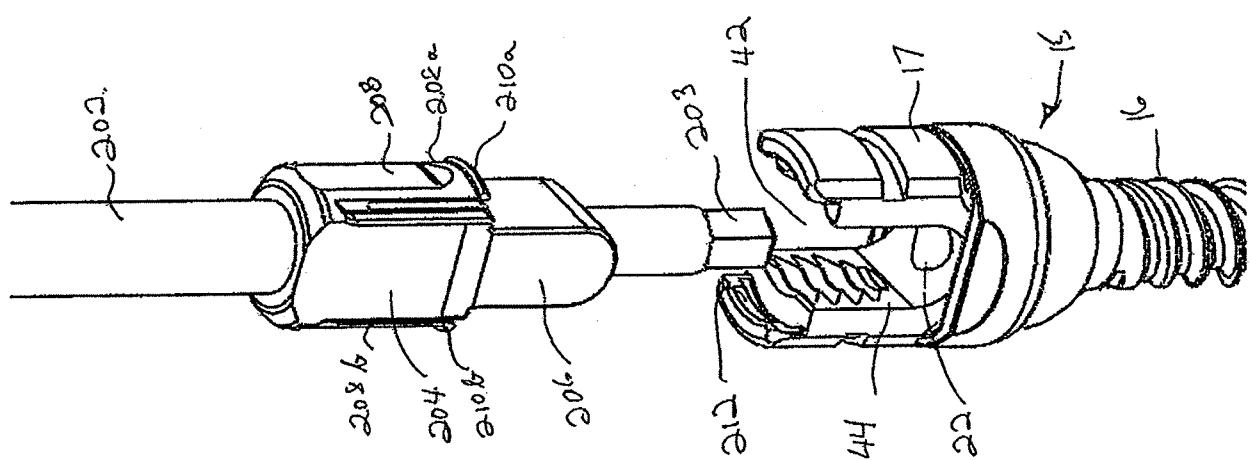
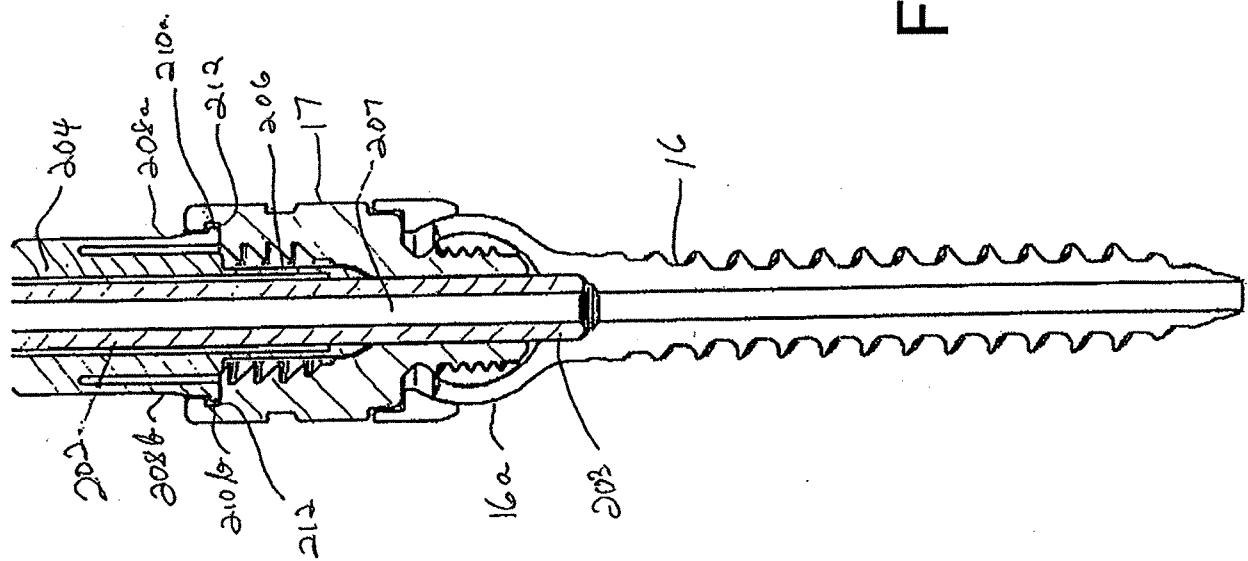


FIG. 7



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FIG. 8

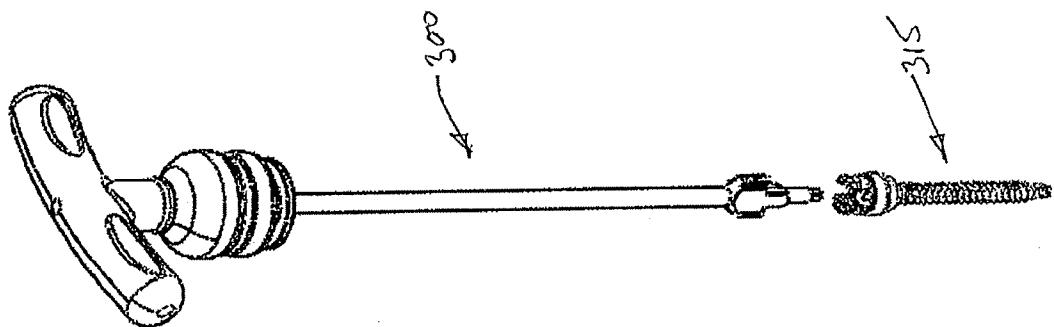
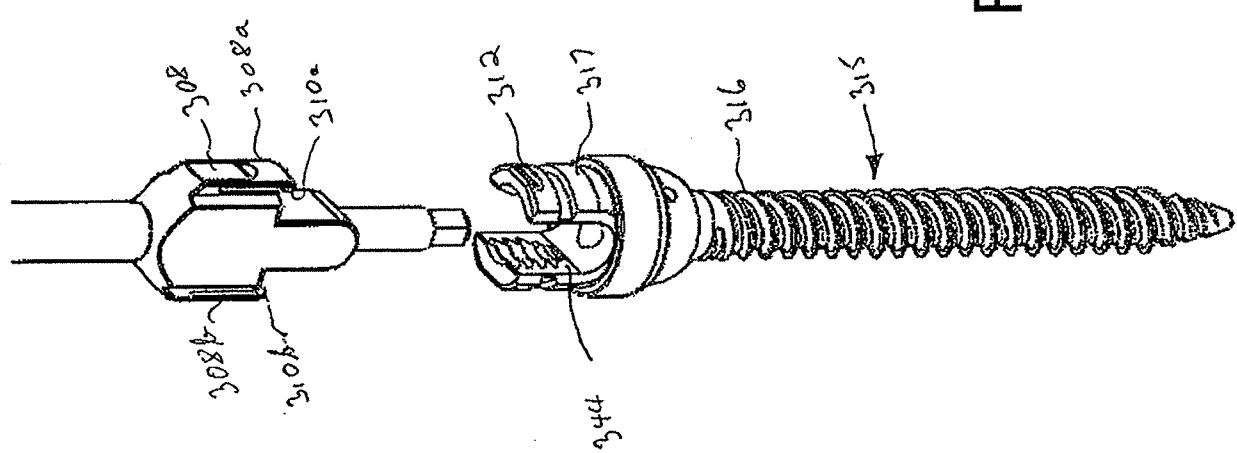


FIG. 9



INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 12/37916

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61B 17/88 (2012.01)

USPC - 606/104

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC(8) - A61B17/88 (2012.01)

USPC - 606/104

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
A61B17/00, 17/56, 17/58, 17/68, 17/70, 17/84, 17/86
606/1, 53, 60, 246, 264, 265, 266, 279, 300, 301, 305, 86, 86R

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
PubWest (PGPB, USPT, EPAB, JPAB); Google
Search Terms: Screw, vertebra, spine, pedicle, screwdriver, driver, polyaxial, axial, poly, bone, lumen, guidewire, channel, guide wire, outer, outside, external, sleeve, shaft, engage, lock, secure, attach, grasp, grab, thread, flexible, resilient, arms, tulip, yoke,

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2009/0264895 A1 (GASPERUT et al.) 22 October 2009 (22.10.2009) Entire document, especially Abstract, para[0001], para[0043], para[0049]- para[0054] and FIGS. 2, 3, 5-8.	1-2
X	US 2008/0221583 A1 (SHARIFI-MEHR et al.) 11 September 2008 (11.09.2008) Entire document, especially Abstract, para[0029]- para[0033], para[0036]- para[0038]	3-7
Y		—
Y	US 7,666,189 B2 (GERBER et al.) 23 February 2010 (23.02.2010) Abstract, col 2, In 24-39, col 8, In 65- col 9, In 25, col 11, In 22-34, col 22, In 55-67 and FIGS. 6A, 7F, 13B.	8
A	US 2006/0025773 A1 (YEVEMENENKO et al.) 02 February 2006 (02.02.2006) Entire document.	1-8
A	US 7,621,918 B2 (JACKSON) 24 November 2009 (24.11.2009) Entire document.	1-8

Further documents are listed in the continuation of Box C.

* Special categories of cited documents:

“A” document defining the general state of the art which is not considered to be of particular relevance
“E” earlier application or patent but published on or after the international filing date
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“Y” document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
“&” document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
08 August 2012 (08.08.2012)	23 AUG 2012
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774