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AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, 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, IR, IS, JP, KE, KG, 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, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, 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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(54) Title: FLEXIBLE SCREW AND METHODS FOR SYNDESISMOSIS REPAIR

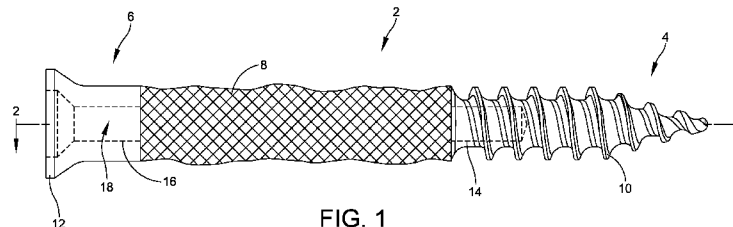


FIG. 1

(57) Abstract: A flexible screw comprising a first end and a second end coupled by a flexible mesh is disclosed. The first end comprises a threaded section. The second end comprises a head. The flexible mesh defines a hollow cylinder. A first driver engagement channel is defined by the head and extends from a proximal end of the head to the flexible mesh. A second driver engagement channel is defined by the threaded section and extends from the flexible mesh to a first depth within the threaded section. The first driver engagement channel and the second driver engagement channel are configured to receive a driver therein.

FLEXIBLE SCREW AND METHODS FOR SYNDESMOSIS REPAIR

FIELD OF THE INVENTION

[0001] This disclosure generally relates to systems and methods for orthopedic surgery. More particularly, this disclosure relates to systems and methods for syndesmosis repair.

BACKGROUND

[0002] Syndesmosis is a slightly moveable articulation where bony surfaces are coupled by an interosseous ligament. An example of a syndesmosis is the tibiofibular articulation syndesmosis between the tibia and the fibula. Syndesmosis may be torn as a result of bone fractures or other trauma.

[0003] Current syndesmosis repair systems and methods rely on rigid screws for coupling the tibia and the fibular and replacing the syndesmosis. The rigid screw inhibits normal movement and articulation of the bones, for example, the tibia and fibula, and further limits one or more corresponding joints. Current systems fail to provide the required flexibility to maintain the natural flexibility and lateral movement of the bones.

SUMMARY

[0004] The present subject matter relates to a flexible screw for syndesmotic repair, as well as methods of inserting the flexible screw into bones. The flexible screw has a number of different embodiments, each of which correspond to different nuances in their respective methods of insertion. All of the flexible screws disclosed herein comprise a first end and a second end coupled by a flexible mesh is disclosed. The first end comprises a threaded section. The second end comprises a head. The flexible mesh defines a hollow cylinder. A first driver engagement channel is defined by the head and extends from a proximal end of the head to the flexible mesh.

[0005] In some embodiments, a system comprising a flexible screw and a driver is disclosed. The flexible screw comprises a first end and a second end coupled by a flexible mesh is disclosed. The first end comprises a threaded section. The second end comprises a head. The flexible mesh defines a hollow cylinder. A first driver engagement channel is defined by the

head and extends from a proximal end of the head to the flexible mesh. The driver is sized and configured to be received within the first driver engagement channel.

[0006] In some embodiments, a method of syndesmotoc repair is disclosed. In a first step, a flexible screw is located proximal to a first bone. The flexible screw comprises a first end having a threaded section, a second end having a head, and a flexible mesh coupling the first end and the second end along a longitudinal axis. In a second step, a driver is inserted into a first driver engagement channel defined by the head of the flexible screw. In a third step, the flexible screw is rotated such that the flexible screw is driven through the first bone and into the second bone. The flexible screw is driven to a predetermined depth within the second bone.

BRIEF DESCRIPTION OF THE DRAWINGS

[0007] The features and advantages of the present invention will be more fully disclosed in, or rendered obvious by the following detailed description of the preferred embodiments, which are to be considered together with the accompanying drawings wherein like numbers refer to like parts and further wherein:

[0008] FIG. 1 illustrates one embodiment of a screw comprising a first end and a second end coupled by a flexible mid-section.

[0009] FIG. 2 illustrates a cross-sectional view of the screw of FIG. 1.

[0010] FIG. 3 illustrates one embodiment of a screw comprising a flexible mid-section and a driver configured to couple thereto.

[0011] FIG. 4 illustrates one embodiment of the screw of FIG. 3 having the driver inserted therein.

[0012] FIG. 5 illustrates a cross-sectional view of the screw of FIG. 4.

[0013] FIG. 6 illustrates one embodiment of a screw comprising a flexible mid-section coupling a first bone and a second bone.

[0014] FIG. 7 illustrates one embodiment of a method for syndesmosis repair using a flexible screw.

DETAILED DESCRIPTION

[0015] The description of the exemplary embodiments is intended to be read in connection with the accompanying drawings, which are to be considered part of the entire written

description. In the description, relative terms such as “lower,” “upper,” “horizontal,” “vertical,” “proximal,” “distal,” “above,” “below,” “up,” “down,” “top” and “bottom,” as well as derivatives thereof (e.g., “horizontally,” “downwardly,” “upwardly,” etc.) should be construed to refer to the orientation as then described or as shown in the drawing under discussion. These relative terms are for convenience of description and do not require that the apparatus be constructed or operated in a particular orientation. Terms concerning attachments, coupling and the like, such as “connected” and “interconnected,” refer to a relationship wherein structures are secured or attached to one another either directly or indirectly through intervening structures, as well as both movable or rigid attachments or relationships, unless expressly described otherwise.

[0016] The present disclosure generally provides a flexible screw for syndesmosis repair and/or stabilization. The flexible screw generally comprises a first end comprising a threaded section and a second end comprising a head coupled by a flexible mid-section. The mid-section comprises a metal mesh material configured to maintain a desired tensile strength while providing flexibility between a first bone and a second bone.

[0017] FIG. 1 illustrates one embodiment of a flexible screw 2 comprising a first end 4 and a second end 6 coupled by a flexible mid-section 8. The first end 4 comprises a threaded section 10. The threaded section 10 is configured to be inserted through a first bone and into a second bone to anchor the first bone to the second bone. The threaded section 10 may comprise threads suitable for cancellous and/or cortical bone anchoring. The threaded section 10 may define a distal driver channel 14. The distal driver channel 14 is configured to receive a driver therein. The distal driver channel 14 extends from a proximal end of the threaded section 10 distally to a predetermined depth in the threaded section 10. In some embodiments the threaded section 10 comprises a self-drilling and/or self-tapping thread. In other embodiments, the threaded section 10 is configured to engage a pre-drilled and/or pre-tapped hole. The threaded section 10 may comprise any suitable material, such as, for example, titanium.

[0018] The second end 6 comprises a metal head 12. The metal head 12 defines a proximal driver channel 16. The proximal driver channel comprises a longitudinal channel extending from a proximal opening 20 of the metal head 12 to the distal side of the metal head 12. The proximal driver channel 16 is configured to receive a driver therethrough. The proximal driver channel 16 may be configured to engage a second portion of a driver, such as, for example, a second portion

of a hex driver. The metal head 12 may comprise any suitable material to provide an interface to the driver, such as, for example, titanium.

[0019] The flexible mid-section 8 comprises a flexible metal mesh. The flexible mid-section 8 is configured to provide flexibility to the flexible screw 2 while maintaining a required tensile strength for coupling a first bone and a second bone. In some embodiments, the flexible mid-section 8 comprises a cylinder defining a hollow column extending longitudinally therethrough. The flexible metal mesh may comprise, for example, a titanium mesh.

[0020] In some embodiments, the proximal driver channel 16, flexible mid-section 8, and the distal driver channel 14 define a continuous driver channel 18. The driver channel 18 extends from a proximal opening 20 in the metal head 12, through the proximal driver channel 16 and the flexible mid-section 8, and into the distal driver channel 14. The driver channel 18 is configured to receive a driver therein. A driver inserted into the driver channel 18 engages the first end 4 and the second end 6 of the flexible screw 2 to prevent twisting the flexible metal mesh 8 during insertion of the flexible screw 2.

[0021] In some embodiments, the flexible screw 2 is configured to engage cancellous and/or cortical bone. The threaded section 10 may comprise any predetermined thread pattern to engage a bone and may comprise a self-drilling and/or a self-tapping thread. The threaded section 10 may comprise a length sufficient to engage a bone. For example, in some embodiments, the threaded section 10 comprises a threaded section having a length of 3.5-4.0mm. In some embodiments, the length of the threaded section 10 corresponds to a thickness of a bone anchored by the threaded section 10.

[0022] FIG. 2 illustrates a cross-sectional view of the flexible screw 2 of FIG. 1. As shown in FIG. 2, the channel 18 comprises a proximal driver channel 16 in the metal head 12 and the distal driver channel 14 in the threaded section 10. The proximal driver channel 16 and the distal driver channel 14 are coupled through the hollow interior of the flexible metal mesh 8. A proximal opening 20 comprising sloped sides is configured to receive a driver therein and direct the driver into the proximal driver channel 16. The proximal driver channel 16 aligns the driver with the distal driver channel 14 during insertion. The proximal driver channel 16 and the distal driver channel 14 comprise internal geometries configured to match the geometry of a driver inserted therein.

[0023] FIG. 3 illustrates one embodiment of a flexible screw 2 and a driver 22. The driver 22 comprises a driving section 24 and a shaft 26. The shaft 26 extends proximally to a handle 28. The driver 22 is sized and configured to be received within the proximal driver channel 16 and the distal driver channel 14. In some embodiments, the driving section 24 comprises a distal driving section and a proximal driving section coupled by a smooth shaft. In some embodiments, the driving section 24 comprises a continuous driving section having a length sufficient to extend from the proximal opening 20 of the metal head 12 into the distal driver channel 14.

[0024] FIG. 4 illustrates the flexible screw 2 of FIG. 3 having the driver 22 inserted therein. The driving section 24 of the driver 22 comprises a length such that the driving section 24 extends from the proximal driver channel 16 to the distal driver channel 14. A handle 28 is coupled to the shaft 26 to allow an operator to rotate the driver 22 to drive the flexible screw 2 into a bone. By engaging both the metal head 12 and the threaded section 10 of the screw, the driver 22 prevents the flexible mid-section 8 from twisting during insertion.

[0025] FIG. 5 illustrates a cross-sectional view of the flexible screw 2 of FIG. 3 having the driver 22 inserted therein. The driver 22 is inserted through the proximal opening 20 in the metal head 12, through the proximal driver channel 22 in the metal head 12, the hollow middle of the flexible mesh 8, and into a distal driver channel 14 formed in the threaded section 10. The distal driver channel 14 extends at least partially into the first end 4. By engaging both the metal head 12 and the threaded section 10 simultaneously, the driver 22 rotates the metal head 12 and the threaded section 10 in unison, preventing twisting of the flexible mesh 8 during insertion of the flexible screw 2.

[0026] In some embodiments, the flexible screw 2 is configured for use in syndesmotic repair and fixation. FIG. 6 illustrates one embodiment of the flexible screw 2 coupling a first bone 52 and a second bone 54. The first bone 52 and the second bone 54 may be joined through the syndesmosis 56 between the first bone 52 and the second bone 54. The flexible screw 2 provides a required tensile strength for syndesmotic fixation while providing for the necessary proximal/distal motion of the first bone 52 and the second bone 54. In some embodiments, the first bone 52 comprises a tibia and the second bone 54 comprises a fibula. As shown in FIG. 6, the flexible screw 2 extends from a first, or proximal, side of a first bone 52, through the first bone and out of a second, or distal side, of the first bone 52, across a syndesmosis between the

first bone 52 and a second bone 54, and at least partially into a proximal side of the second bone 54. In some embodiments, the flexible mid-section 8 comprises a length sufficient to bridge the gap between the first bone 52 and the second bone 54. In some embodiments, the length of the flexible mid-section 8 corresponds to a lateral width of the syndesmosis between the first bone 52 and the second bone 54.

[0027] FIG. 7 is a flowchart illustrating one embodiment of a method 100 for performing syndesmotic repair between a first bone and a second bone. In some embodiments, in a first step 102, a pilot hole is formed in one of a first bone 52 and/or a second bone 54. The pilot hole may be formed by, for example, a k-wire, a drill, and/or any other suitable device. In a second step 104, a flexible screw 2 is aligned with the first bone 52. The flexible screw 2 comprise a first driver engagement channel 16 defined by a head 12 and a second driver engagement channel 14 defined by a threaded section 10. In a third step 106, a driver 22 is inserted into the first and second driver engagement sections 14, 16 of the flexible screw 2. The driver 22 engages a proximal channel 16 and a distal channel 14 formed in the flexible screw 2. In some embodiments, the flexible screw 2 comprises a self-drilling and/or self-tapping thread. In other embodiments, the pilot hole comprises a pre-drilled and/or pre-tapped hole.

[0028] In a fourth step 108, the driver 22 is rotated by a clinician to drive the flexible screw 2 through the first bone 52 and into the second bone 54. The flexible screw 2 is driven to a predetermined depth within the second bone 54. In some embodiments, the predetermined depth corresponds to a length of the threaded section 10. In some embodiments, a flexible section 8 of the flexible screw 2 comprises a length such that the flexible section 8 extends into partially into the first bone 52 and/or the second bone 54 when the flexible screw 2 is installed. In other embodiments, a solid section (not shown) may couple the flexible mesh 8 to the metal head 12 such that the flexible mesh 8 extends from a distal side of the second bone 54 to a proximal side of the first bone 52. The flexible screw 2 provides tensile strength sufficient to maintain the syndesmotic fixation between the first bone 52 and the second bone 54 while allowing natural movement of the first bone 52 and the second bone 54. The flexible screw 2 allows for the necessary proximal/distal motion of the first bone 52 and the second bone 54 while maintaining the proper later and medial gap. The method 100 further comprises a step 110 of removing the driver 22 from the flexible screw 2. The driver 22 is withdrawn proximally from the flexible

screw 2. Once the driver 22 is removed, the flexible section 8 is allowed to flex and/or move to allow natural movement of the first bone 52 and the second bone 54.

[0029] In some embodiments, a flexible screw is disclosed. The flexible screw comprises a first end and a second coupled by a flexible mesh. The first end comprises a threaded section. The second end comprises a head.

[0030] In some embodiments, the flexible mesh defines a hollow cylinder.

[0031] In some embodiments, the head defines a first driver engagement channel configured to receive a driver therein. The first driver engagement channel extends from a proximal end of the head to the flexible mesh.

[0032] In some embodiments, the threaded section defines a second driver engagement channel configured to receive the driver therein. The second driver engagement channel extends from the flexible mesh to a predetermined depth within the threaded section. The first driver engagement channel and the second drive engagement channel are coupled through the hollow cylinder of the flexible mesh.

[0033] In some embodiments, the head comprises titanium.

[0034] In some embodiments, the threaded section comprises a titanium thread.

[0035] In some embodiments, the threaded section comprises a 3.5-4.0mm thread.

[0036] In some embodiments, the flexible mesh comprises a titanium mesh.

[0037] In some embodiments, a system for bone fixation is disclosed. The system comprises a flexible screw and a driver. The flexible screw comprises a first end and a second end coupled by a flexible mesh. The first end comprises a threaded section. The second end comprises a head defining a first driver engagement channel. The flexible mesh extends along a longitudinal axis. The driver is sized and configured to be received within the first driver engagement channel.

[0038] In some embodiments, the flexible mesh defines a hollow cylinder.

[0039] In some embodiments, the threaded section defines a second driver engagement channel sized and configured to receive the driver therein. The first driver engagement channel extends from a proximal end of the head to the flexible mesh and the second driver engagement channel extends from the flexible mesh to a predetermined depth within the threaded section. The first driver engagement channel and the second driver engagement channel are axially aligned.

- [0040] In some embodiments, the head of the flexible screw comprises titanium.
- [0041] In some embodiments, the flexible mesh comprises a titanium mesh.
- [0042] In some embodiments, the threaded section comprises a titanium thread.
- [0043] In some embodiments, the threaded section comprises a 3.5-4.0mm thread.
- [0044] In some embodiments, the driver comprises a hex driver and the first and second engagement channels comprise complementary hex engagement channels.
- [0045] In some embodiments, a method of syndesmotoc fixation is disclosed. The method comprises locating a flexible screw proximal to a first bone, inserting a driver into a driver engagement channel in the flexible screw, and rotating the flexible screw to drive the flexible screw through the first bone and into a second. The flexible screw comprises a first end and a second end coupled by a flexible mesh. The first end comprises a threaded section. The second end comprises a head. The flexible mesh extends along a longitudinal axis. The first driver engagement channel is defined by the head.
- [0046] In some embodiments, the driver is inserted into a second driver engagement channel defined by the threaded section. The driver extends through the first driver engagement channel, the flexible mesh, and into the second driver engagement channel.
- [0047] In some embodiments, the first bone comprises a fibula and the second bone comprises a tibia.
- [0048] In some embodiments, the driver is removed from the first and second engagement channels after the flexible screw is driven into the second bone.
- [0049] Although the subject matter has been described in terms of exemplary embodiments, it is not limited thereto. Rather, the appended claims should be construed broadly, to include other variants and embodiments, which may be made by those skilled in the art.

CLAIMS

What is claimed is:

1. A screw, comprising:
 - a first end comprising a threaded section;
 - a second end comprising a head; and
 - a flexible mesh coupling the first end and the second end.
2. The screw of claim 1, wherein the flexible mesh defines a hollow cylinder.
3. The screw of claim 2, wherein the head defines a first driver engagement channel configured to receive a driver therein, wherein the first driver engagement channel extends from a proximal end of the head to the flexible mesh.
4. The screw of claim 3, wherein the threaded section defines a second driver engagement channel configured to receive the driver therein, wherein the second driver engagement channel extends from the flexible mesh to a predetermined depth within the threaded section.
5. The screw of claim 1, wherein the head comprises titanium.
6. The screw of claim 1, wherein the threaded section comprises a titanium thread.
7. The screw of claim 6, wherein the threaded section comprises a 3.5-4.0 mm thread.
8. The screw of claim 1, wherein the flexible mesh comprises a titanium mesh.
9. A system for bone fixation, comprising:
 - a flexible screw comprising:
 - a first end comprising a threaded section;
 - a second end comprising a head defining a first driver engagement channel;
 - a flexible metal coupling the first end and the second end on a longitudinal axis;and
 - a driver sized and configured to be received within the driver engagement channel.

10. The system for bone fixation of claim 9, wherein the flexible mesh comprises a hollow cylinder.

11. The system for bone fixation of claim 10, wherein the threaded section defines a second driver engagement channel sized and configured to receive the driver therein, wherein the first driver engagement channel extends from a proximal end of the head to the flexible mesh, wherein the second driver engagement channel extends from the flexible mesh to a predetermined depth within the threaded section, and wherein the first driver engagement channel and the second driver engagement channel are axially aligned.

12. The system of claim 11, wherein the head of the flexible screw comprises titanium.

13. The system of claim 11, wherein the flexible mesh comprises a titanium mesh.

14. The system of claim 11, wherein the threaded section comprises a titanium thread.

15. The system of claim 14, wherein the titanium thread comprises a 3.5-4.0 mm titanium thread.

16. The system of claim 11, wherein the driver comprises a hex driver and wherein the first driver engagement channel and the second driver engagement channel comprise hex engagement channels.

17. A method of syndesmotic fixation, comprising:

locating a flexible screw proximal to a first bone, the flexible screw comprising a first end having a threaded section, a second end having a head, and a flexible mesh coupling the first end and the second end along a longitudinal axis;

inserting a driver into a first driver engagement channel defined by the head of the flexible screw; and

rotating the flexible screw such that the flexible screw is driven through the first bone and into the second bone, wherein the flexible screw is driven to a predetermined depth within the second bone.

18. The method of claim 17, further comprising inserting the driver into a second driver engagement channel defined by the threaded section of the flexible screw, wherein the driver

extends through the first driver engagement channel, the flexible mesh, and into the second driver engagement channel.

19. The method of claim 18, wherein the first bone comprises a fibula and the second bone comprises a tibia.

20. The method of claim 18, further comprising removing the driver from the first and second driver engagement channels.

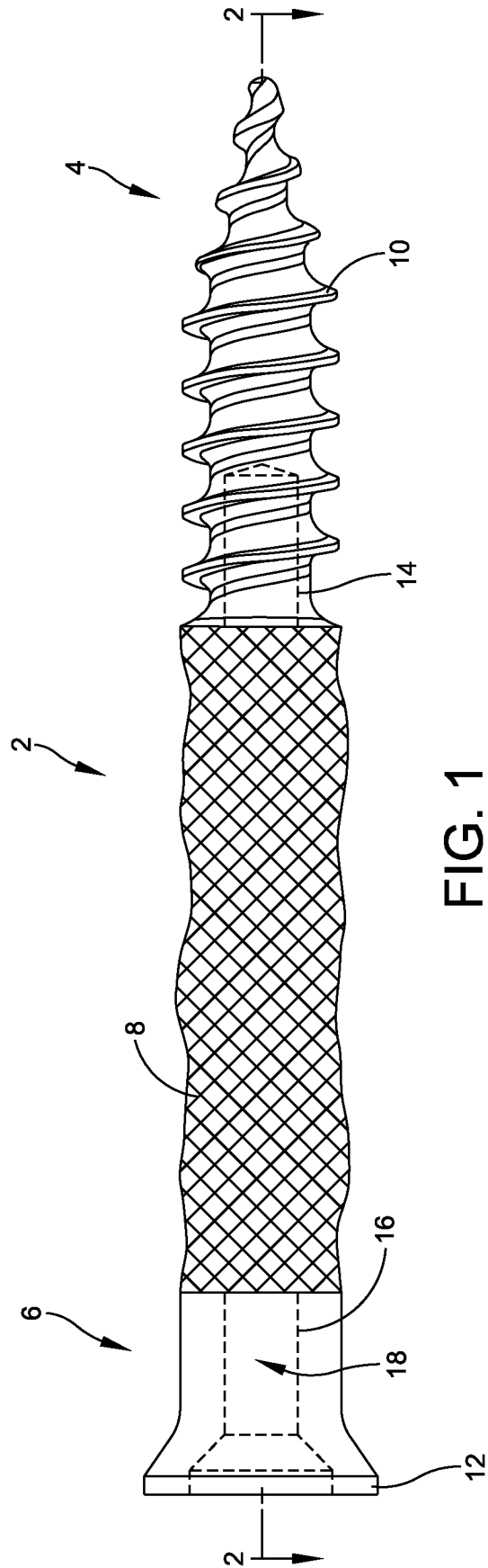


FIG. 1

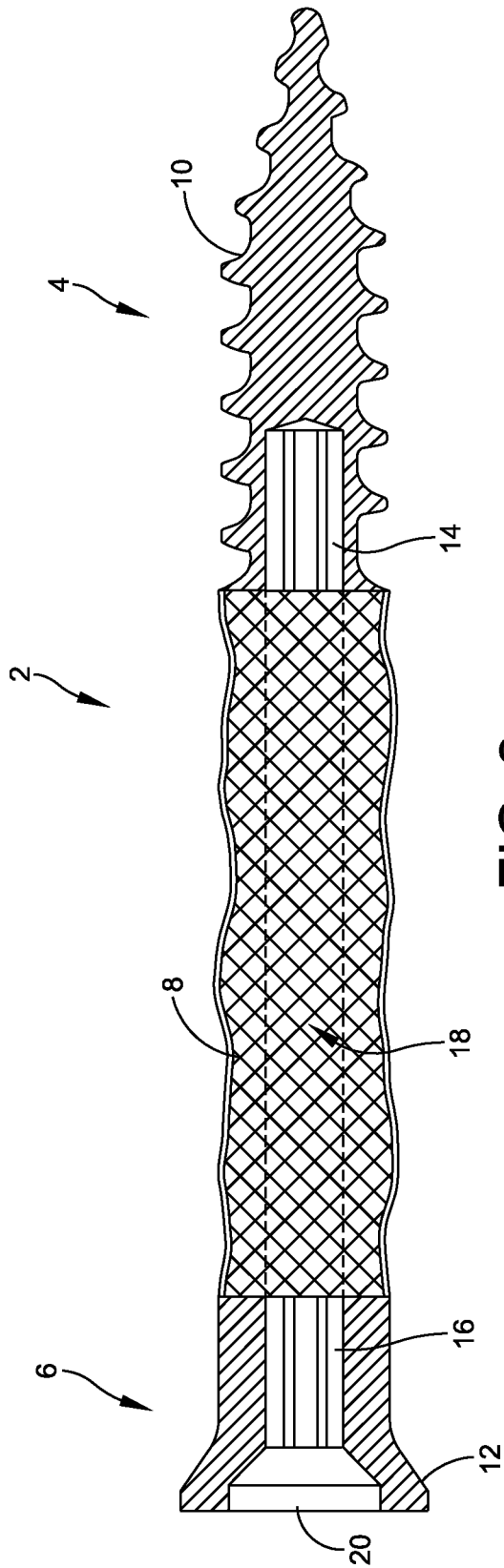
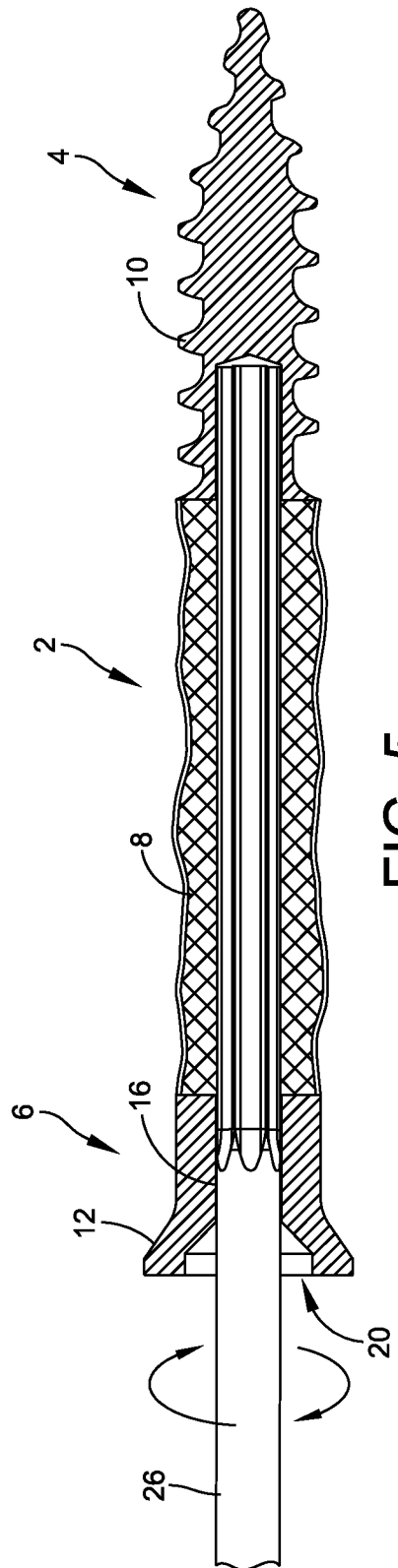
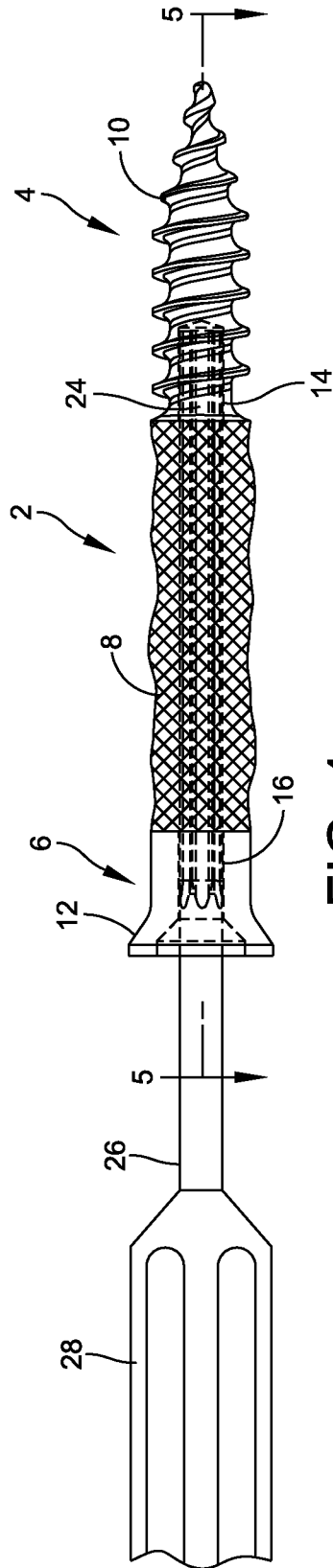
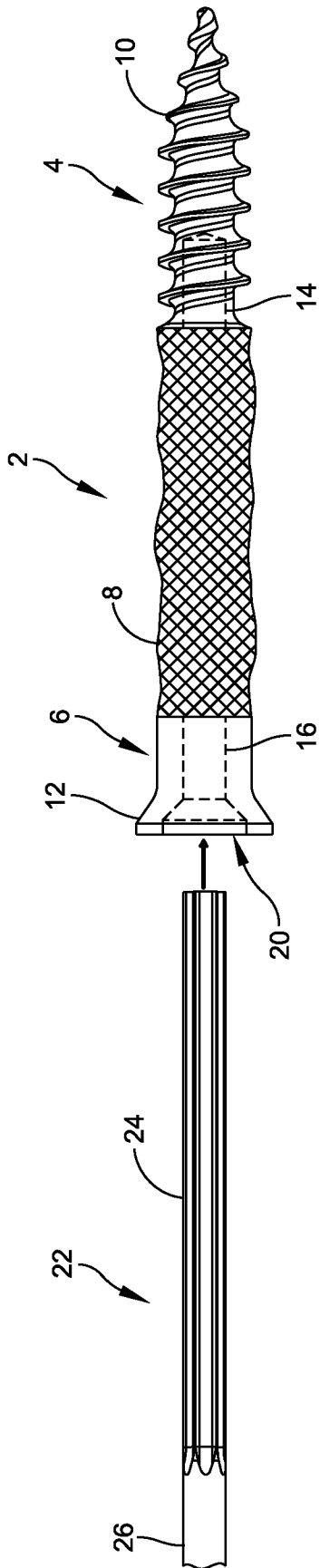


FIG. 2



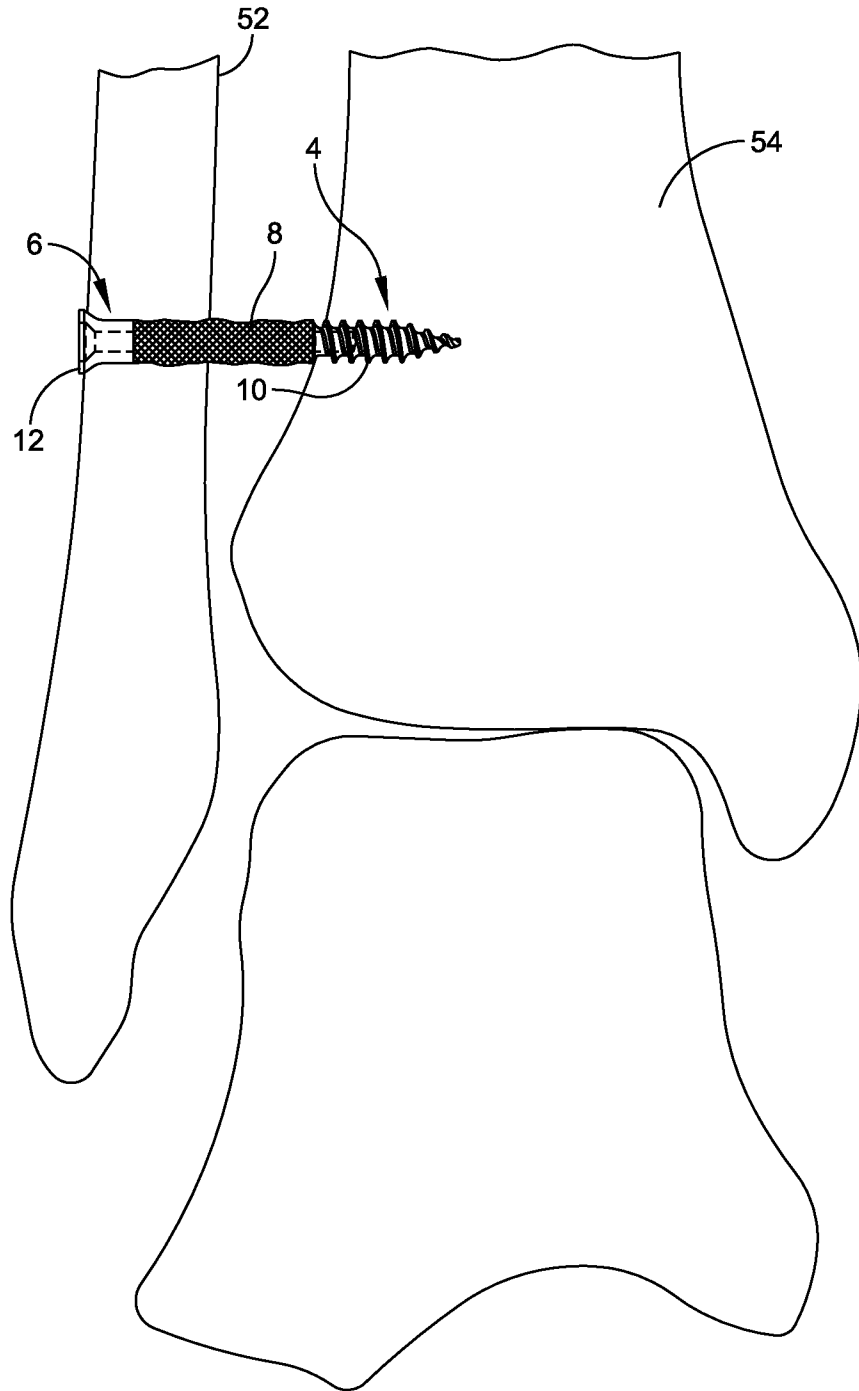


FIG. 6

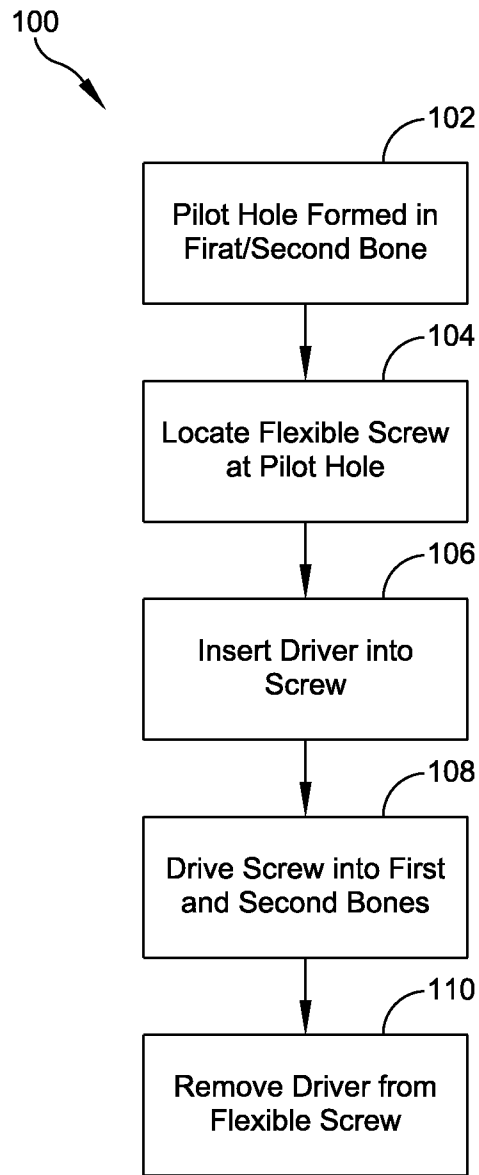


FIG. 7

A. CLASSIFICATION OF SUBJECT MATTER**A61B 17/86(2006.01)i, A61B 17/11(2006.01)i, A61B 17/88(2006.01)i, A61L 27/06(2006.01)i, A61B 17/04(2006.01)i**

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61B 17/86; F16B 15/99; F16B 19/00; A61B 17/84; A61B 17/04; A61B 17/11; A61B 17/88; A61L 27/06

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Korean utility models and applications for utility models

Japanese utility models and applications for utility models

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

eKOMPASS(KIPO internal) & Keywords: screw, threaded portion, head, flexible mesh, driver engagement channel, driver

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 7625395 B2 (MUCKTER, HELMUT) 1 December 2009 See column 5, lines 30-62; claims 1-5; and figures 6a-7.	1-16
A	US 2011-0144703 A1 (KRAUSE et al.) 16 June 2011 See paragraphs [0072], [0073], [0075], [0076], [0086]; and figures 3-6, 15.	1-16
A	US 5061137 A (GOURD, JAMES T.) 29 October 1991 See column 4, lines 12-38; and figures 1, 2.	1-16
A	US 2009-0062868 A1 (CASUTT, SIMON) 5 March 2009 See paragraphs [0121]-[0128]; and figures 8-10.	1-16
A	US 6908275 B2 (NELSON et al.) 21 June 2005 See column 4, line 38-column 7, line 17; and figures 1-4.	1-16



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

07 May 2015 (07.05.2015)

Date of mailing of the international search report

08 May 2015 (08.05.2015)

Name and mailing address of the ISA/KR

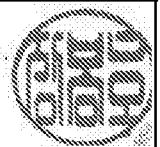
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Korean Intellectual Property Office
189 Cheongsu-ro, Seo-gu, Daejeon Metropolitan City, 302-701,
Republic of Korea

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2014/050560

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

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

1. Claims Nos.: 17-20
because they relate to subject matter not required to be searched by this Authority, namely:
Claims 17-20 pertain to methods for treatment of the human body by surgery and thus relate to a subject-matter which this International Searching Authority is not required, under PCT Article 17(2)(a)(i) and PCT Rule 39.1(iv), to search.
2. Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

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

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

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

Remark on Protest

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

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/US2014/050560

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 7625395 B2	01/12/2009	AU 2002-48881 A1	02/01/2003
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