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(71) Applicant: **WRIGHT MEDICAL TECHNOLOGY, INC.** [US/US]; 1023 Cherry Road, Memphis, TN 38117 (US).

(72) Inventor: **MCCORMICK, Daniel, F.**; 6853 Wytham Drive, Memphis, TN 38119 (US).

(74) Agents: **APICELLI, Samuel, W.** et al.; Duane Morris LLP, 30 South 17th Street, Philadelphia, PA 19103 (US).

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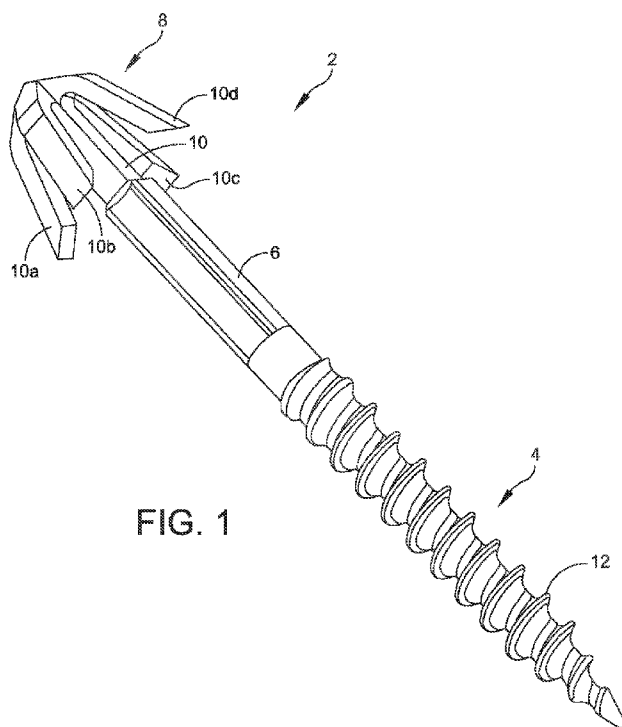


FIG. 1

(57) Abstract: A bone implant comprising an elongate body having a first end and a second end coupled by a shaft is disclosed. The first portion is configured to couple to a first bone. The second portion comprises a first expandable section comprising at least one expandable feature. The first expandable section is configured to be received within a reverse countersink in a second bone in a collapsed state and to expand within the reverse countersink. The expandable feature couples to a bearing surface of the reverse countersink. A surgical tool comprising a shaft and at least one expandable cutting edge is disclosed. The shaft is sized and configured to be received within a canal formed in a bone. The expandable cutting edge is formed integrally with the shaft. The expandable cutting edge is configured to expand from a collapsed position to an expanded position for forming a reverse countersink.

HAMMERTOES IMPLANT AND INSTRUMENT

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 hammertoe implants.

BACKGROUND

[0002] A hammertoe, or contracted toe, is a deformity of the proximal inter-phalangeal joint of the second, third, or fourth toe causing the toe to be permanently bent and giving the toe a semblance of a hammer. Initially, hammertoes are flexible and may be corrected with simple measures but, if left untreated, hammertoes may require surgical intervention for correction. Persons with hammertoe may also have corns or calluses on the top of the middle joint of the toe or on the tip of the toe and may feel pain in their toes or feet while having difficulty finding comfortable shoes.

[0003] One method of treatment may include correction by surgery if other non-invasive treatment options fail. Conventional surgery usually involves inserting screws, wires or other similar implants in toes to straighten them. Traditional surgical methods generally include the use of Kirschner wires (K-wires). K-wires require pins protruding through the end of respective toes due to their temporary nature. As a result, K-wires often lead to pin tract infections, loss of fixation, and other conditions. Additional disadvantages of K-wires include migration and breakage of the K-wires thus resulting in multiple surgeries. Due to the various disadvantages of using K-wires, however, compression screws are being employed as an implant alternative.

[0004] Screw implants may provide a more permanent solution than K-wires as such implants do not need removal and have no protruding ends. Further, with the use of screw implants, a patient may wear normal footwear shortly after the respective surgery. There are generally two types of known screw implants: single-unit implants, which possess a completely threaded body and do not provide a flexibility to the respective toe in its movement, and articulated or two-unit implants, which typically have one unit that is anchored into the proximal phalanx, a second unit that is anchored into the distal phalanx, and a fitting by which the two units are coupled. Either or both of the two units may be threaded or have other anchoring structures such as barbs or splaying arms.

[0005] Among other disadvantages, both kinds of known implants result in an undesirable pistoning effect, i.e., part or all of the implant will toggle or move within the bone as the patient's toe moves. Pistoning decreases the stability of the implant and lessens the compression across the joint. Moving parts, such as fittings, hinges, expansion pieces, and the like also decrease the stability, lifespan, and compression force of the implant. Accordingly, there remains a need for durable hammertoe implants which are not only stable but provide adequate compression across a joint with minimal pistoning. There also remains a need for an implant which can provide these advantages, while being easily inserted with minimal damage to the surrounding tissue.

SUMMARY

[0006] The present subject matter relates to a type of bone implant useful in the correction of hammertoe and similar maladies, as well as methods of inserting the implant into bones to effectuate that correction. The bone implant has a number of different embodiments, each of which correspond to different nuances in their respective methods of insertion. All of the hammertoe implant embodiments have an elongate shaft having a first end and a second end coupled by a shaft. The first end is configured to couple to a first bone. The second end comprises an expandable section comprising at least one expandable feature. The expandable feature is configured to be received within a reverse countersink in a second bone in a collapsed state. The first expandable section expands within the reverse countersink such that the at least one expandable feature couples to a bearing surface of the reverse countersink.

[0007] In some embodiments, a surgical tool is disclosed. The surgical tool comprises a shaft sized and configured to be received within a canal formed in a bone. At least one expandable cutting edge is formed integrally with the shaft. The expandable cutting edge is configured to expand from a collapsed position for insertion into the canal to an expanded position for forming a reverse countersink in the canal.

[0008] In some embodiments a method for correcting a hammertoe is disclosed. The method comprises the steps of forming a first canal in a first bone and forming a second canal in a second bone. A second step of the method comprises inserting a surgical instrument into the second canal. The surgical instrument comprises a shaft, a head located at a first end of the shaft, and an expandable cutting edge formed integrally with the shaft. The expandable cutting

edge is deployable from a collapsed position to a deployed position to forming a reverse countersink in the canal. In a third step, the surgical instrument is rotated to form the reverse countersink in the second canal of the second bone.

BRIEF DESCRIPTION OF THE DRAWINGS

[0009] 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:

[0010] FIG. 1 illustrates one embodiment of a hammertoe implant comprising an expandable section and a threaded section.

[0011] FIG. 2 is a side-view of the hammertoe implant of FIG. 1 having the expandable section in a collapsed state.

[0012] FIG. 3 is a side-view of the hammertoe implant of FIG. 1 having the expandable section in an expanded state.

[0013] FIG. 4. illustrates one embodiment of a cutting instrument having a deployable cutting section for forming a reverse countersink in a bone.

[0014] FIG. 5 illustrates the cutting instrument of FIG. 4 having the deployable cutting section in a deployed position.

[0015] FIG. 6 illustrates one embodiment of the cutting instrument of FIG. 4 inserted into a canal formed in a bone.

[0016] FIG. 7 illustrates one embodiment of the hammertoe implant of FIG. 1 engaging a bone section in a collapsed state.

[0017] FIG. 8 illustrates one embodiment of the hammertoe implant of FIG. 1 inserted into a reverse countersink.

[0018] FIG. 9 illustrates an expanded view of a conical countersink having the hammertoe implant of FIG. 1 inserted therein.

[0019] FIG. 10 illustrates one embodiment of a hammertoe implant comprising an expandable section having a first arm and a second arm.

[0020] FIG. 11 illustrates one embodiment of a hammertoe implant comprising a cylindrical shaft section.

[0021] FIG. 12 illustrates one embodiment of a hammertoe implant having a first expandable section and a second expandable section.

[0022] FIG. 13 is a perspective view of the hammertoe implant of FIG. 12 in a collapsed state.

[0023] FIG. 14 is a perspective view of the hammertoe implant of FIG. 12 in an expanded state.

[0024] FIG. 15 illustrates one embodiment of a hammertoe implant having a first expandable section, a second expandable section, and a cylindrical shaft.

[0025] FIG. 16 is a perspective view of the hammertoe implant of FIG. 15 in an expanded state.

[0026] FIG. 17 illustrates the hammertoe implant of FIG. 15 inserted into a first bone and a second bone.

[0027] FIG. 18 illustrates one embodiment of a combination sleeve and driver configured to insert the hammertoe implant of FIG. 1.

[0028] FIG. 19 illustrates one embodiment of a combination sleeve and driver configured to insert the hammertoe implant of FIG. 1.

[0029] FIG. 20 illustrates a method of treating a hammertoe using a hammertoe implant.

DETAILED DESCRIPTION

[0030] 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,” “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.

[0031] The present disclosure generally provides a hammertoe implant and instrument for joining a first bone and a second bone, such as, for example, a proximal phalanx and a middle phalanx. The hammertoe implant generally comprises a first end and a second end coupled by a shaft. The first end is configured to couple to the first bone. The second end comprises an expandable section. The expandable section is configured to couple the implant to the second bone. The expandable section expands into a reverse countersink formed in the second bone. The countersink is formed by an instrument generally comprising a shaft having an expandable cutting member formed integrally therein. The expandable cutting member is deployable from a collapsed position to an expanded position configured to form the reverse countersink in the bone.

[0032] FIG. 1 illustrates one embodiment of a hammertoe implant 2 comprising a first end 4 and a second end 8 coupled by a shaft 6. The first end 4 is configured to anchor the hammertoe implant 2 to a first bone. For example, in some embodiments, the first end 4 comprises a threaded section 12 configured to be received within a canal formed in a first bone. The threaded section 12 may be configured to be inserted into a pre-drilled and/or pre-tapped canal and/or may comprise a self-drilling and/or self-tapping thread. The threaded section 12 may comprise a predetermined length configured to be fully implanted into the first bone. In some embodiments, the first end 4 comprises other suitable mechanisms for coupling the hammertoe implant 2 to the first bone.

[0033] The second end 8 comprises an expandable section 10. The expandable section 10 comprises one or more expandable features. For example, in some embodiments, the expandable section 10 comprises a plurality of expandable arms 10a-10d. In other embodiments, the expandable section 10 may comprise, for example, one or more expandable cones, sleeves, threads, or any other suitable expandable feature. The expandable section 10 is configured to transition from a collapsed position to an expanded position. The expandable arms 10a-10d may be arranged in any suitable configuration. For example, the expandable section 10 comprises four expandable arms 10a-10d arranged in a plus-sign configuration having a separation angle between each of the expandable arms 10a-10d of ninety degrees. It will be recognized that other configurations, including fewer or additional expandable arms and/or different angles of separation, are within the scope of the claims.

[0034] The first end 4 and the second end 8 are coupled by a shaft 6. The shaft 6 may comprise any suitable cross-section, such as, for example, a cylinder, square, triangle, and/or other suitable cross-section. The shaft 6 comprises a predetermine length. The predetermined length of the shaft 6 may be configured to provide a predetermined spacing between the first bone and the second bone when the hammertoe implant 2 is inserted. In some embodiments, the shaft 6 comprises a predetermined length such that there is substantially no space between the first bone and the second bone after insertion of the hammertoe implant 2.

[0035] The hammertoe implant 2 is configured to couple the first bone to the second bone. In some embodiments, the threaded section 12 is inserted into the first bone by rotating the threaded section 12 into contact with the predrilled canal formed in the first bone. The expandable section 10 is received within a cavity in the second bone. The cavity in the second bone comprises a reverse countersink. The expandable arms 10a-10d are configured to couple to a bearing surface of the reverse countersink and maintain the hammertoe implant 2 in the second bone. In some embodiments, the hammertoe implant 2 is configured to join a middle phalanx and a proximal phalanx.

[0036] The hammertoe implant 2 may comprise any suitable material or combination of materials. For example, in some embodiments, the hammertoe implant 2 may comprise Nitinol (in either the super-elastic or shape memory state), a Titanium alloy, stainless steel, an equivalent bio-material, and/or any combination thereof. In some embodiments, one or more sections of the hammertoe implant 2, such as the expandable section 10, comprises a first material, for example Nitinol, and a second section of the hammertoe implant 2, such as the threaded section 12, comprises a second material, for example, stainless steel.

[0037] FIG. 2 illustrates a side-view of the hammertoe implant 2 of FIG. 1 having the expandable section 10 in a collapsed state. In the collapsed state, the expandable arms 10a-10d are compressed to a first diameter. When the expandable arms 10a-10d are collapsed, the expandable end 10 is sized and configured to be inserted through a canal formed in the second bone. The canal may comprise an internal diameter substantially equal to the first diameter of the expandable section 10. In some embodiments, a sleeve (see FIG. 18) is disposed over the expandable end 10 to maintain the expandable arms 10a-10d in a collapsed state prior to insertion of the expandable section 10 in the second bone. The expandable arms 10a-10d may be maintained in a collapsed state, for example, during insertion of the first end 4 into the first bone.

[0038] FIG. 3 illustrates a side-view of the hammertoe implant 2 of FIG. 1 having the expandable section 10 in an expanded, or deployed, state. In the deployed state, the expandable arms 10a-10d are allowed to flare, or expand, out to a second diameter. The second diameter is greater than the diameter of the canal in the second bone. The expandable arms 10a-10d may be biased to an expanded position. In some embodiments, the second diameter is greater than or equal to a diameter of a reverse countersink formed in the second bone. In the expanded state, the expandable arms 10a-10d interface with a bearing surface of the reverse countersink.

[0039] In some embodiments, the reverse countersink in the second bone is formed by an instrument prior to insertion of the hammertoe implant 2 into the second bone. FIGS. 4 and 5 illustrate one embodiment of an instrument 50 configured to form a reverse countersink in the second bone. The instrument 50 comprises an instrument tip 52 coupled to a shaft 54. The shaft 54 has a cutting edge 56 formed integrally therewith. The cutting edge 56 is deployable from a collapsed state (as shown in FIG. 4) to a deployed state (as shown in FIG. 5). The cutting edge 56 may comprise any suitable deployment mechanism such as, for example, a mechanical deployment mechanism, a hinged deployment mechanism, and/or any other suitable deployment mechanism. The shaft 54 comprises a cavity 58 configured to receive the cutting edge 56 such that the cutting edge 56 is flush with the shaft 54 in a collapsed position. In some embodiments, one or more additional cutting edges 56 may be formed integrally with the shaft 54 and deployed simultaneously. In some embodiments, the diameter of the shaft 54 of the instrument 50 is substantially equal to the diameter of the expandable section 10 of the hammertoe implant 2 in a collapsed position. The cutting edge 56 is configured to form a reverse countersink having a diameter that is substantially equal to or less than a diameter of the expandable section 10 of the hammertoe implant 2 in a deployed position. The reverse countersink provides a bearing surface for the expandable section 10 of the hammertoe implant 2.

[0040] FIG. 6 illustrates one embodiment of a second bone 62 having the cutting instrument of FIG. 4 inserted therein. The instrument 50 is inserted into a canal 65 formed in the second bone 62 to a first predetermined depth. The instrument tip 52 and the shaft 54 position the cutting edge 56 at a second predetermined depth in the second bone 62. The cutting edge 56 is deployed from a collapsed position (shown in FIG. 4) suitable for insertion through the canal to a deployed position (shown in FIG. 5). The instrument 50 is rotated about a central axis, causing the cutting edge 56 to form a reverse countersink 66 in the second bone 62. The cutting edge 56

may transition from a partially deployed position to a fully deployed position as bone is removed by the cutting edge 56 during rotation of the instrument 50. Although the cutting edge 56 is configured to form a conical reverse countersink 66, it will be appreciated that the cutting edge 56 may be configured to form any suitable cavity, such as, for example, a conical, square, or cylindrical countersink. After forming the reverse countersink 66, the cutting edge 56 is transitioned from the deployed position to the collapsed position and the instrument 50 is removed from the canal 65.

[0041] FIG. 7 illustrates the hammertoe implant 2 anchored to the first bone 60 and partially inserted into the second bone 62. The first end 4 of the hammertoe implant 2 is coupled to the first bone 60 by the threaded section 12. The threaded section 12 is inserted into a canal 68 formed in the first bone 60. The canal 68 may be predrilled in the first bone 60 by, for example, a drill, k-wire, and/or other suitable device and/or may be formed by the hammertoe implant 2 during insertion of the threaded section 12. The threaded section 12 extends within the first bone 60 to a predetermined depth. In some embodiments, the threaded section 12 may extend substantially the entire width of the first bone 60. In some embodiments, the threaded section 12 is inserted to a depth such that a portion of the shaft 6 is located within the canal 68. The expandable section 10 is maintained in a collapsed position during insertion of the first end 4 into the first bone 60. The expandable section 10 may be maintained in the collapsed position by, for example, a sleeve (see FIG. 18) disposed over the expandable section 10.

[0042] After coupling the hammertoe implant 2 to the first bone 60, the second end 8 of the hammertoe implant 2 is inserted into the second bone 62. The expandable section 10 is inserted into a canal 65 formed in the second bone 62. The canal 65 applies a force to the expandable section 10 that maintains the expandable arms 10a-10d in a collapsed position during insertion and allows the expandable section 10 to traverse the canal 65. A gap exists between the first bone 60 and the second bone 62 as the hammertoe implant 2 has not been fully inserted into the bone 62.

[0043] A first length, 'A', illustrates the distance of travel of the expandable end 10 from the initial position illustrated in FIG. 7 bearing surface of the reverse countersink. A second length, 'B', illustrates the corresponding gap between the first bone 60 and the second bone 62. Having a distance 'A' substantially equal to the length 'B' ensures the joint fully closes when the implant 2 is inserted.

[0044] FIG. 8 illustrates the hammertoe implant 2 fully inserted into the second bone 62. The first bone 60 and the second bone 62 are aligned and the joint therebetween is closed, forcing the expandable section 10 into the reverse countersink 66 formed in the second bone 62. As shown in FIG. 8, the expandable arms 10a-10d expand to a deployed position when inserted fully into the reverse countersink 66. The expandable arms 10a-10d have a deployed diameter sufficient to expand beyond the canal 65 and to engage with a bearing surface of the reverse countersink 66. The reverse countersink 66 is sized such that the expandable section 10 fits within the reverse countersink with minimal or no additional space to maintain the hammertoe implant 2 in a fixed position. In some embodiments, the expandable arms 10a-10d comprise an expanded diameter equal to the diameter of the reverse countersink 66. In some embodiments, the expandable arms 10a-10d are biased to a diameter greater than the diameter of the reverse countersink 66, allowing the expandable arms 10a-10d to contact the inner walls of the reverse countersink 66.

[0045] FIG. 9 illustrates an isolated view of the expandable section 10 inserted into the reverse countersink 66. As shown, the expandable arms 10a-10d expand to a diameter that is substantially equal to the diameter of the reverse countersink 66. In some embodiments, the expandable arms 10a-10d are biased to a diameter greater than the diameter of the cavity 66 to ensure the expandable arms 10a-10d expand to the full diameter of the countersink 66. The reverse countersink 66 is sized and configured to receive the expandable section 10 with minimal extra space to prevent movement of the hammertoe implant 2 after installation. Although the reverse countersink 66 is shown as a conical cavity, the reverse countersink 66 may comprise any suitable shape corresponding to the shape of the expandable section 10 in an expanded configuration.

[0046] With reference to FIGS. 6-9 and 20, a method 600 for coupling a first bone 60 and a second bone 62 is discussed. In a first step 602, a canal 68 is formed in the first bone 60. The canal 68 is sized and configured to receive a first end 4 of an hammertoe implant 2. In a second step 604, a canal 65 is formed in the second bone 62. The canal 65 in the second bone 62 is sized and configured to receive an instrument 50 therein. The instrument 50 is configured to form a reverse countersink 66 in the second bone 62. The canal 68 in the first bone 60 and/or the canal 65 in the second bone 62 may be formed using, for example, a k-wire, a drill and/or any

other suitable device. In some embodiments, the first bone 60 comprises a proximal phalanx, the second bone 62 comprises a middle phalanx.

[0047] In a third step 606, the instrument 50 is inserted into the canal 65 formed in the second bone 62. The instrument 50 comprises an instrument tip 52 and a shaft 54. The instrument 50 is inserted to a first predetermined depth in the canal 65. In some embodiments, the instrument 50 is inserted until the instrument tip 52 contacts a closed end of the canal. In other embodiments, the instrument tip 52 is inserted to a first predetermined depth indicated on the instrument 52. A deployable cutting edge 56 is coupled to the shaft 54. The instrument tip 52 and the shaft 54 are configured to locate the cutting edge 56 at a second predetermined depth within the canal 65. In a fourth step 608, the cutting edge 56 is deployed and the instrument 50 is rotated about a central axis to form a reverse countersink 66 within the second bone during a fourth step 608. After forming the reverse countersink 66, the cutting edge 56 is collapsed against the shaft 54 and, in a fifth step 610, the instrument 50 is removed from the canal 65.

[0048] In a sixth step 612, a sleeve (see FIG. 18) is placed over an expandable section 10 of a hammertoe implant 2. The sleeve is configured to compress the expandable section 10 and to provide a handle for rotating the hammertoe implant 2. In some embodiments, the sixth step 612 is omitted. In a seventh step 614, the first end 4 of the hammertoe implant 2 is inserted into the canal 68 formed in the first bone 60. The hammertoe implant 2 may be inserted by, for example, rotatably interfacing the threaded section 12 with the canal 68. The hammertoe implant 2 is inserted to a predetermined depth in the first bone 60. The predetermined depth may correspond to a length of the threaded section 12. In some embodiments, the threaded section 12 is configured to extend substantially through the entire width of the first bone 60. In some embodiments, a portion of the shaft 6 is inserted into the canal 68.

[0049] After the first end 4 is inserted into the first bone 60, the second end 4 of the hammertoe implant 2 is inserted into the second bone 62 during an eighth step 616. If a sleeve was disposed over the expandable section 10 to maintain the expandable arms 10a-10d in a collapsed position, the sleeve is removed prior to insertion of the second end 4 into the second bone. In some embodiments, the expandable arms 10a-10d are biased to an expanded position.

[0050] The expandable section 10 is inserted into the canal 65 formed in the second bone 62. The canal 65 exerts a force on the expandable arms 10a-10d and forces the expandable arms 10a-10d into a collapsed position. In the collapsed position, the expandable section 10 is sized and

configured to fit through the canal 65. For example, in some embodiments, the expandable arms 10a-10d have a diameter in a collapsed position equal to or less than an internal diameter of the canal 65. The expandable section 10 is inserted through the canal 65 to the reverse countersink 66 formed in the second bone 62. In a ninth step 618, the expandable arms 10a-10d assume an expanded configuration, as shown in FIGS. 8-9. The expandable arms 10a-10d interface with a bearing surface of the reverse countersink 66 formed in the second bone 62. In some embodiments, the reverse countersink 66 and the expandable section 10 of the hammertoe implant 2 are sized and configured to prevent movement of the hammertoe implant 2 after insertion of the expandable head 10 into the reverse countersink 66.

[0051] FIGS. 10-16 illustrate additional embodiments of implants for joining a first bone 60 and a second bone 62. FIGS. 10 and 11 illustrate one embodiment of an implant 102 comprising an expandable section 110 having a first expandable arm 110a and a second expandable arm 110b. In other aspects, the implant 102 is similar to the hammertoe implant 2 described in conjunction with FIGS. 1-9. The implant 102 is configured to couple a first bone 60 and a second bone 62, for example, a proximal phalanx and a middle phalanx. FIG. 10 illustrates one embodiment of an implant 102 having a square shaft 106a. FIG. 11 illustrates one embodiment of an implant 102 having a cylindrical shaft 106b. Those skilled in the art will recognize that the shaft 106 may comprise any suitable cross-sectional shape.

[0052] FIGS. 12-16 illustrate embodiments of hammertoe implants 202, 302 comprising a first expandable section 204a, 304a and a second expandable section 204b, 304b coupled by a shaft 206, 306. FIGS. 12-14 illustrate one embodiment of an implant 202 having a first expandable section 204a and a second expandable section 204b coupled by a square shaft 206. Each of the first and second expandable sections 204a, 204b comprise a plurality of expandable arms 210a-210d, 214a-214d. The expandable arms 210a-210d, 214a-214d are illustrated in a collapsed position in FIGS. 12 and 13. FIG. 14 illustrates the expandable arms 210a-210d, 214a-214d in an expanded position. The expandable sections 204a, 204b are similar to the expandable section 10 discussed with respect to FIGS. 1-9. FIGS. 15 and 16 illustrate one embodiment of an implant 302 comprising a first expandable section 304a and a second expandable section 304b coupled by a cylindrical shaft 306. Each of the expandable sections 304a, 304b comprise a plurality of expandable arms 310a-310d, 314a-314d.

[0053] The implants 202, 302 are configured to join a first bone to a second bone, such as, for example, a middle phalanx to a proximal phalanx. FIG. 17 illustrates one embodiment of the implant 302 coupling a first bone 360 and a second bone 364. Canals 365a, 365b comprising reverse countersinks 366a, 366b are formed in each of the first bone 360 and the second bone 362. The reverse countersinks 366a, 366b may be formed by, for example, the instrument 50 described in conjunction with FIGS. 4-6. The first end 304a of the implant 302 is inserted into the canal 365a of the first bone 360 in a collapsed state. In some embodiments, the canal 365a exerts a force on the expandable arms 310a-310d, maintaining the expandable arms 310a-310d in a collapsed position sized and configured to slideably transition through the canal 365a. When the expandable section 304a reaches the reverse countersink 366a, the expandable arms 310a-310d expand and engage a bearing surface of the reverse countersink 366a to maintain the implant 302 in the first bone 360.

[0054] The second expandable section 304b of the implant 302 is inserted into the canal 365b formed in the second bone 362. The canal 365b comprises a reverse countersink 366b. The second end 304b of the implant 302 is inserted into the canal 365b of the second bone 362 in a collapsed state. In some embodiments, the canal 365b forces the expandable arms 314a-314d into a collapsed state during insertion of the implant 302 to allow the second end 304b to traverse the canal 365b. When the second expandable section 304b reaches the reverse countersink 366b, the expandable arms 314a-314d expand to a deployed position and engage a bearing surface of the reverse countersink 366b. The first bone 360 and the second bone 362 are aligned and maintained by the implant 302.

[0055] With reference to FIGS. 12-17 and 21, a method 650 for coupling a first bone 60 and a second bone 62 is discussed. In a first step 652, a canal 68 is formed in the first bone 60. In a second step 654, a canal 65 is formed in the second bone 62. The canals 65 and 68 are sized and configured to receive an instrument 50 therein. The instrument 50 is configured to form a reverse countersink 66 in each of the first bone 60 and the second bone 62. The canal 68 in the first bone 60 and/or the canal 65 in the second bone 62 may be formed using, for example, a k-wire, a drill and/or any other suitable device. In some embodiments, the first bone 60 comprises a proximal phalanx, the second bone 62 comprises a middle phalanx.

[0056] In a third step 656, the instrument 50 is inserted into the canal 65 formed in the second bone 62. The instrument 50 comprises an instrument tip 52 and a shaft 54. The

instrument 50 is inserted to a first predetermined depth in the canal 65. In some embodiments, the instrument 50 is inserted until the instrument tip 52 contacts a closed end of the canal. In other embodiments, the instrument tip 52 is inserted to a first predetermined depth indicated on the instrument 52. A deployable cutting edge 56 is coupled to the shaft 54. The instrument tip 52 and the shaft 54 are configured to locate the cutting edge 56 at a second predetermined depth within the canal 65. In a fourth step 658, the cutting edge 56 is deployed and the instrument 50 is rotated about a central axis to form a reverse countersink 66 within the second bone during a fourth step 608. After forming the reverse countersink 66, the cutting edge 56 is collapsed against the shaft 54 and, in a fifth step 660, the instrument 50 is removed from the canal 65. In a sixth step 662, the instrument is inserted into the canal 68 formed in the first bone 60, the deployable cutting edge 56 is deployed, and a reverse countersink is formed in the first bone 60. The deployable cutting edge 56 is collapsed against the shaft 54 after forming the reverse countersink in the first bone and the instrument 50 is removed from the first bone 60.

[0057] In a seventh step 664, a sleeve (see FIG. 18) is placed over the second expandable section 214 of a hammertoe implant 202. The sleeve is configured to compress the second expandable section 214 and to provide a handle for gripping the hammertoe implant 2. In some embodiments, the sixth step 612 is omitted. In an eighth step 666, the first expandable end 210 of the hammertoe implant 2 is inserted into the canal 68 formed in the first bone 60. The canal 68 exerts a force on the expandable arms 210a-210d and forces the expandable arms 210a-210d into a collapsed position. In the collapsed position, the expandable section 210 is sized and configured to fit through the canal 68. For example, in some embodiments, the expandable arms 210a-210d have a diameter in a collapsed position equal to or less than an internal diameter of the canal 68. The expandable section 210 is inserted through the canal 68 to the reverse countersink formed in the first bone 60. In a ninth step 668, the expandable arms 210a-210d assume an expanded configuration. The expandable arms 210a-210d interface with a bearing surface of the reverse countersink formed in the first bone 60. In some embodiments, the reverse countersink and the expandable section 210 of the hammertoe implant 202 are sized and configured to prevent movement of the hammertoe implant 202 after insertion of the expandable head 210 into the reverse countersink.

[0058] After the first expandable section 210 is inserted into the first bone 60, the second expandable section 214 of the hammertoe implant 202 is inserted into the second bone 62 during

a tenth step 670. If a sleeve was disposed over the expandable section 214 to maintain the expandable arms 214a-214d in a collapsed position, the sleeve is removed prior to insertion. In some embodiments, the expandable arms 214a-214d are biased to an expanded position.

[0059] The second expandable section 214 is inserted into the canal 65 formed in the second bone 62. The canal 65 exerts a force on the expandable arms 214a-214d and forces the expandable arms 214a-214d into a collapsed position. In the collapsed position, the second expandable section 214 is sized and configured to fit through the canal 65. For example, in some embodiments, the expandable arms 214a-214d have a diameter in a collapsed position equal to or less than an internal diameter of the canal 65. The second expandable section 214 is inserted through the canal 65 to the reverse countersink 66 formed in the second bone 62. In an eleventh step 672, the expandable arms 214a-214d assume an expanded configuration. The expandable arms 214a-214d interface with a bearing surface of the reverse countersink 66 formed in the second bone 62. In some embodiments, the reverse countersink 66 and the second expandable section 214 of the hammertoe implant 202 are sized and configured to prevent movement of the hammertoe implant 202 after insertion of the second expandable section 214 into the reverse countersink 66.

[0060] FIG. 18 illustrates one embodiment of a combination sleeve and driver configured to insert one or more embodiments of the hammertoe implant. For example, in some embodiments, the combination sleeve and driver 400 is configured for use with the hammertoe implants 2, 102, 202, 302 illustrated in FIGS. 1-17. The combination sleeve and driver 400 comprises a longitudinal sleeve 402 defining a channel 404 configured to receive an expandable section 10 of an implant 2. The expandable features 10a-10d of the expandable section 10 are compressed against the implant 2 by the channel 404 and maintained in a collapsed position. The combination sleeve and driver 400 comprises a driver head 406. The driver head 406 may comprise a quick connect feature 408 configured to attach the combination sleeve and driver 400 to a handle to drive the implant 2. The quick connect feature 408 and the handle may be configured to provide translation, rotation, and/or any other suitable movement to couple the first end 4 to the first bone. In some embodiments, the internal mating features of the channel 404 provide rotational control such that the implant 2 can be driver proximally or backed out distally. For example, in one embodiment, the expandable features 10a-10d and the channel 404 operate as an inverted Phillips head interface. FIG. 19 illustrates an alternative embodiment of a

combination sleeve and driver 500. In the embodiment of FIG. 19, the channel 504 comprises a wider opening and rounded edges to accommodate the expandable features 10a-10d of the expandable side 10.

[0061] In some embodiments, a bone implant is disclosed. The bone implant comprises a first end configured to couple to a first bone, a second end defining a first expandable section comprising at least one expandable feature, and an elongate shaft extending longitudinally between the first end and the second end. The first expandable section is sized and configured to be received within a reverse countersink formed in a second bone in a collapsed state. The first expandable section expands within the reverse countersink such that the at least one expandable feature couples to a bearing surface of the reverse countersink.

[0062] In some embodiments, the first expandable section comprises a plurality of expandable arms.

[0063] In some embodiments, the expandable section comprises four expandable arms.

[0064] In some embodiments, the first end comprises a threaded section.

[0065] In some embodiments, the threaded section comprises a length sufficient to extend through a thickness of the first bone.

[0066] In some embodiments, the first end defines a second expandable section comprising at least one expandable feature. The second expandable section is configured to be received within a reverse countersink formed in the first bone in a collapsed state. The second expandable section expands within the reverse countersink such that the at least one expandable feature couples to a bearing surface of the reverse countersink.

[0067] In some embodiments, the second expandable section comprises a plurality of expandable arms.

[0068] In some embodiments, the first expandable section comprises a material selected from the group consisting of: Nitinol, titanium, alloy, and stainless steel.

[0069] In some embodiments, the first bone comprises a proximal phalanx and the second bone comprises a middle phalanx.

[0070] In some embodiments, the elongate shaft extends a predetermined length such that when the first end is fully inserted into the first bone and the second end is fully inserted into the second bone there is substantially no gap between the first and second bones.

[0071] In some embodiments, a surgical tool is disclosed. The surgical tool comprises a shaft sized and configured to be received within a canal formed in a bone and at least one expandable cutting edge formed integrally with the shaft. The expandable cutting edge comprises a collapsed position configured for insertion into the canal and an expanded position configured to form a reverse countersink in the canal. The expandable cutting edge is deployed to the expanded position after being inserted into the canal.

[0072] In some embodiments, the surgical tool comprises a conical head configured to contact an end of the canal and to space the expandable cutting edge a predetermined distance from the end of the canal.

[0073] In some embodiments, the at least one expandable cutting edge is deployed by mechanical deflection.

[0074] In some embodiments, the at least one expandable cutting edge comprises a hinge.

[0075] In some embodiments, the at least one expandable cutting edge is configured to form the reverse countersink when the shaft is rotated.

[0076] In some embodiments, a method for correcting hammertoe is disclosed. The method comprises the steps of forming a first canal in a first bone, forming a second canal in a second bone, inserting a surgical instrument into the second canal, and rotating the surgical tool to form a reverse countersink in the second canal of the second bone. The surgical instrument comprises a shaft, a head located at a first end of the shaft, and an expandable cutting edge formed integrally with the shaft and deployable from a collapsed position to an expanded position.

[0077] In some embodiments, the method further comprises inserting a first end of an implant into the first canal in the first bone.

[0078] In some embodiments, the method further comprises inserting a second end of an implant into the second canal in the second bone. The second end of the implant comprises an expandable section wherein the expandable section comprises at least one expandable feature. The expandable section is inserted through the second canal to the reverse countersink in a collapsed position. The at least one expandable feature expands within the reverse countersink such that the at least one expandable feature couples to a bearing surface of the reverse countersink.

[0079] In some embodiments, the canal exerts a force on the expandable section to maintain the expandable section in a collapsed state during insertion. The at least one expandable feature deploys when fully inserted into the reverse countersink.

[0080] In some embodiments, the first end of the implant comprises a threaded section. Inserting the first end of the implant comprises rotating the threaded section into engagement with the first canal.

[0081] In some embodiments, a method for correcting hammertoe is disclosed. The method comprises the steps of forming a first canal in a first bone, forming a second canal in a second bone, and inserting a surgical instrument into the first canal. The surgical instrument comprises a shaft, a head located at a first end of the shaft, and an expandable cutting edge formed integrally with the shaft and deployable from a collapsed position to an expanded position. The method further comprises rotating the surgical tool to form a reverse countersink in the first canal of the first bone, inserting the surgical instrument into the second canal, and rotating the surgical tool to form a reverse countersink in the second canal of the second bone.

[0082] In some embodiments, the method further comprises inserting a first end of an implant into the first canal in the first bone. The first end of the implant comprising a first expandable section having at least one expandable feature. The first expandable section is inserted through the first canal to the reverse countersink in a collapsed position. The at least one expandable feature expands within the reverse countersink such that the at least one expandable feature couples to a bearing surface of the reverse countersink.

[0083] In some embodiments, the first canal exerts a force on the first expandable section to maintain the first expandable section in a collapsed state during insertion. The at least one expandable feature deploys when fully inserted into the reverse countersink.

[0084] In some embodiments, the method further comprises inserting a second end of the implant into the second canal in the second bone. The second end of the implant comprises a second expandable section having at least one expandable feature. The second expandable section is inserted through the second canal to the reverse countersink in a collapsed position. The at least one expandable feature expands within the reverse countersink such that the at least one expandable feature couples to a bearing surface of the reverse countersink.

[0085] In some embodiments, the second canal exerts a force on the second expandable section to maintain the second expandable section in a collapsed state during insertion. The at least one expandable feature deploys when fully inserted into the reverse countersink.

[0086] 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 bone implant, comprising:
 - a first end configured to couple to a first bone;
 - a second end defining a first expandable section comprising at least one expandable feature, wherein the first expandable section is sized and configured to be received within a reverse countersink formed in a second bone in a collapsed state, and wherein the first expandable section expands within the reverse countersink such that the at least one expandable feature couples to a bearing surface of the reverse countersink; and
 - an elongate shaft extending longitudinally between the first end and the second end.
2. The bone implant of claim 1, wherein the first expandable section comprises a plurality of expandable arms.
3. The bone implant of claim 2, wherein the expandable section comprises four expandable arms.
4. The bone implant of claim 1, wherein the first end comprises a threaded section.
5. The bone implant of claim 4, wherein the threaded section comprises a length sufficient to extend through a thickness of the first bone.
6. The bone implant of claim 1, wherein the first end defines a second expandable section comprising at least one expandable feature, wherein the second expandable section is configured to be received within a reverse countersink formed in the first bone in a collapsed state, and wherein the second expandable section expands within the reverse countersink such that the at least one expandable feature couples to a bearing surface of the reverse countersink.
7. The bone implant of claim 6, wherein the second expandable section comprises a plurality of expandable arms.

8. The bone implant of claim 1, wherein the first expandable section comprises a material selected from the group consisting of: Nitinol, titanium, alloy, and stainless steel.
9. The bone implant of claim 1, wherein the first bone comprises a proximal phalanx and the second bone comprises a middle phalanx.
10. The bone implant of claim 1, wherein the elongate shaft extends a predetermined length such that when the first end is fully inserted into the first bone and the second end is fully inserted into the second bone there is substantially no gap between the first and second bones.
11. A surgical tool, comprising:
 - a shaft sized and configured to be received within a canal formed in a bone; and
 - at least one expandable cutting edge formed integrally with the shaft, wherein the expandable cutting edge comprises a collapsed position configured for insertion into the canal and an expanded position configured to form a reverse countersink in the canal, and wherein the expandable cutting edge is deployed to the expanded position after being inserted into the canal.
12. The surgical tool of claim 11, comprising a conical head configured to contact an end of the canal and to space the expandable cutting edge a predetermined distance from the end of the canal.
13. The surgical tool of claim 10, wherein the at least one expandable cutting edge is deployed by mechanical deflection.
14. The surgical tool of claim 10, wherein the at least one expandable cutting edge comprises a hinge.
15. The surgical tool of claim 10, wherein the at least one expandable cutting edge is configured to form the reverse countersink when the shaft is rotated.
16. A method for correcting hammertoe, comprising the steps of:
 - forming a first canal in a first bone;
 - forming a second canal in a second bone;
 - inserting a surgical instrument into the second canal, wherein the surgical instrument comprises a shaft, a head located at a first end of the shaft, and an expandable cutting edge

formed integrally with the shaft and deployable from a collapsed position to an expanded position; and

rotating the surgical tool to form a reverse countersink in the second canal of the second bone.

17. The method of claim 16, further comprising inserting a first end of an implant into the first canal in the first bone.

18. The method of claim 17, further comprising inserting an second end of an implant into the second canal in the second bone, the second end of the implant comprising an expandable section wherein the expandable section comprises at least one expandable feature, wherein the expandable section is inserted through the second canal to the reverse countersink in a collapsed position, and wherein the at least one expandable feature expands within the reverse countersink such that the at least one expandable feature couples to a bearing surface of the reverse countersink.

19. The method of claim 18, wherein the canal exerts a force on the expandable section to maintain the expandable section in a collapsed state during insertion, and wherein the at least one expandable feature deploys when fully inserted into the reverse countersink.

20. The method of claim 17, wherein the first end of the implant comprises a threaded section, and wherein inserting the first end of the implant comprises rotating the threaded section into engagement with the first canal.

21. A method for correcting hammertoe, comprising the steps of:

forming a first canal in a first bone;

forming a second canal in a second bone;

inserting a surgical instrument into the first canal, wherein the surgical instrument comprises a shaft, a head located at a first end of the shaft, and an expandable cutting edge formed integrally with the shaft and deployable from a collapsed position to an expanded position;

rotating the surgical tool to form a reverse countersink in the first canal of the first bone;

inserting the surgical instrument into the second canal; and

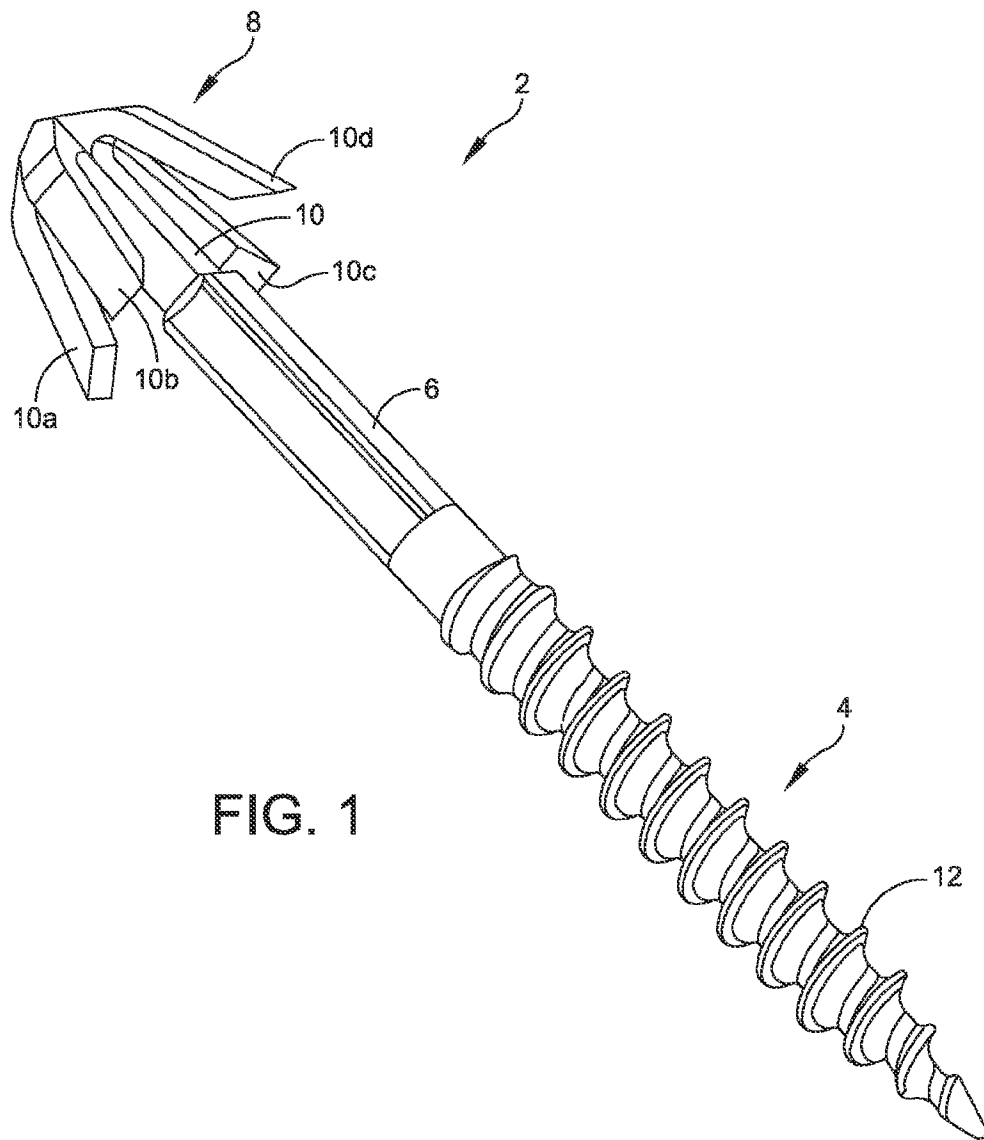
rotating the surgical tool to form a reverse countersink in the second canal of the second bone.

22. The method of claim 21, further comprising inserting a first end of an implant into the first canal in the first bone, the first end of the implant comprising a first expandable section having at least one expandable feature, wherein the first expandable section is inserted through the first canal to the reverse countersink in a collapsed position, and wherein the at least one expandable feature expands within the reverse countersink such that the at least one expandable feature couples to a bearing surface of the reverse countersink.

23. The method of claim 22, wherein the first canal exerts a force on the first expandable section to maintain the first expandable section in a collapsed state during insertion, and wherein the at least one expandable feature deploys when fully inserted into the reverse countersink.

24. The method of claim 22, further comprising inserting a second end of the implant into the second canal in the second bone, the second end of the implant comprising a second expandable section having at least one expandable feature, wherein the second expandable section is inserted through the second canal to the reverse countersink in a collapsed position, and wherein the at least one expandable feature expands within the reverse countersink such that the at least one expandable feature couples to a bearing surface of the reverse countersink.

25. The method of claim 24, wherein the second canal exerts a force on the second expandable section to maintain the second expandable section in a collapsed state during insertion, and wherein the at least one expandable feature deploys when fully inserted into the reverse countersink.



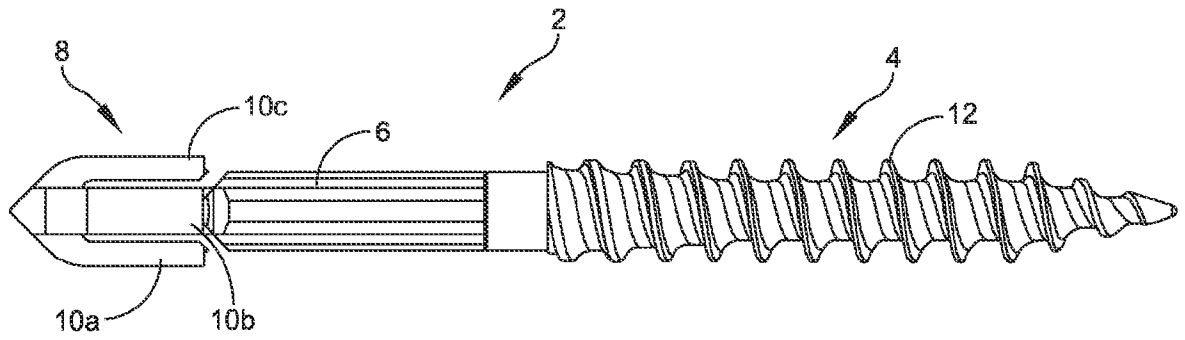


FIG. 2

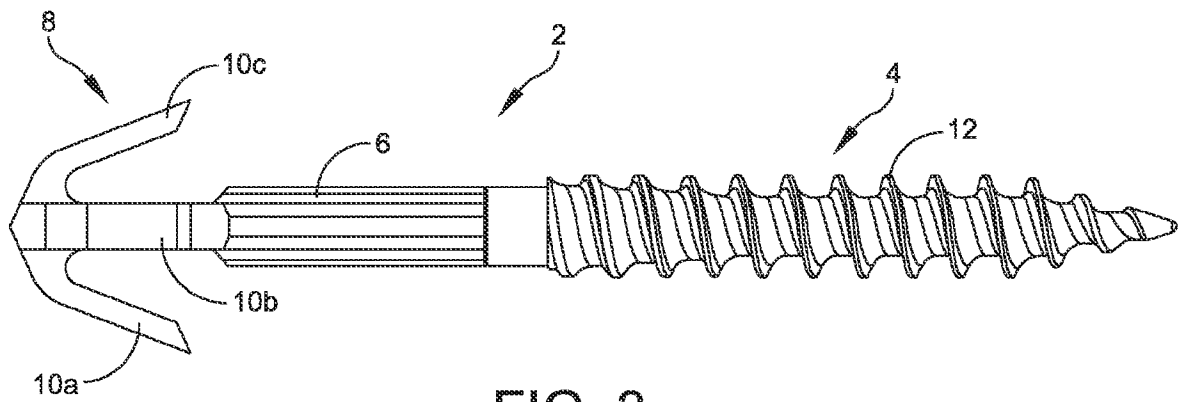


FIG. 3

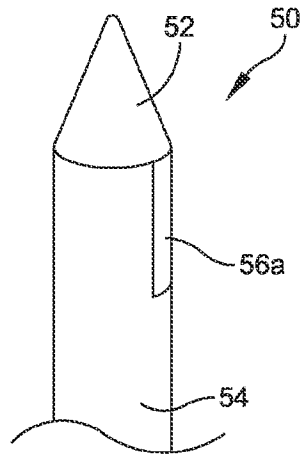


FIG. 4

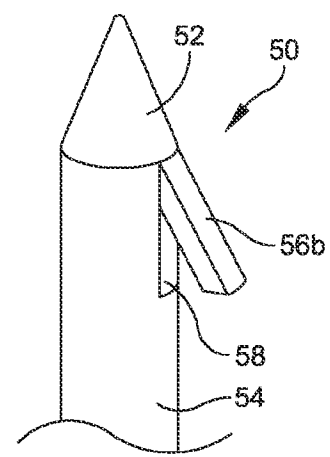


FIG. 5

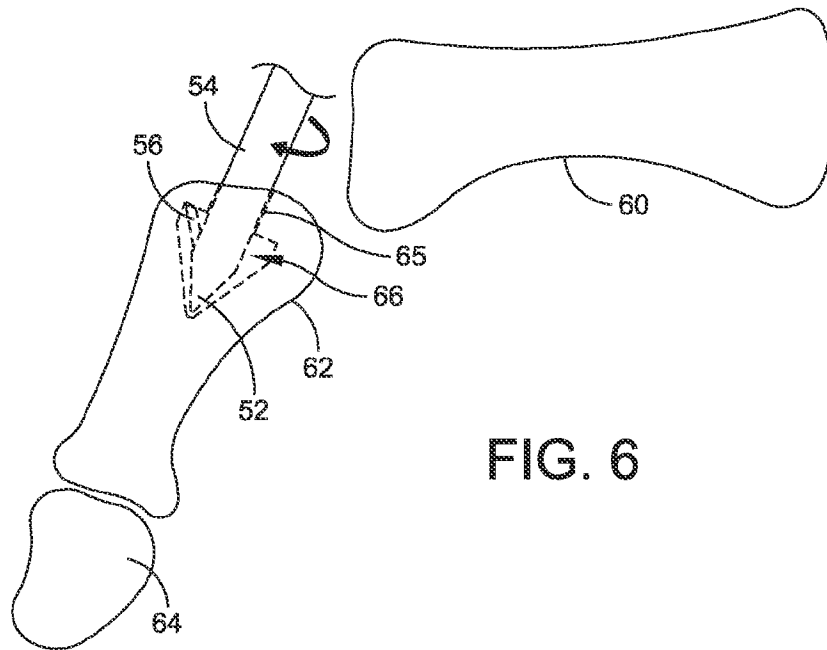


FIG. 6

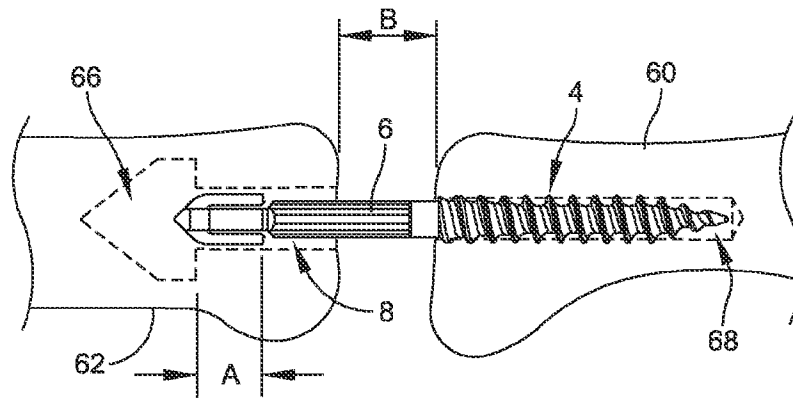


FIG. 7A

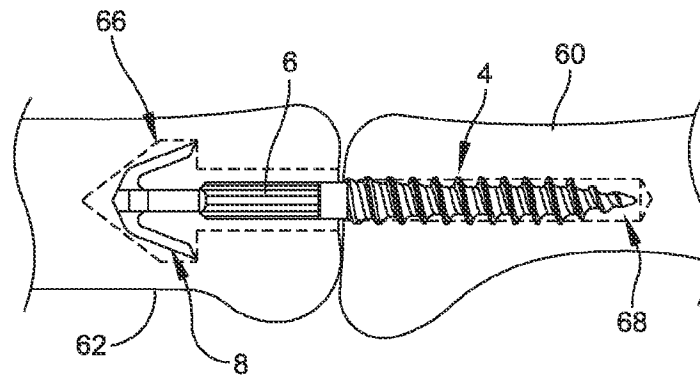


FIG. 7B

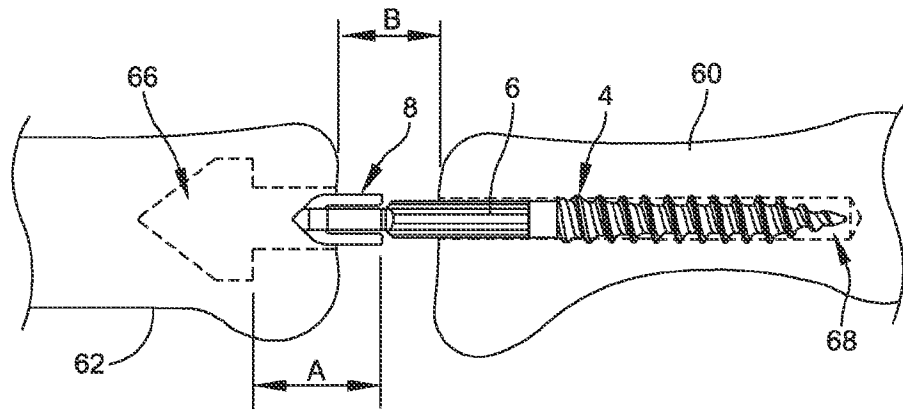


FIG. 8A

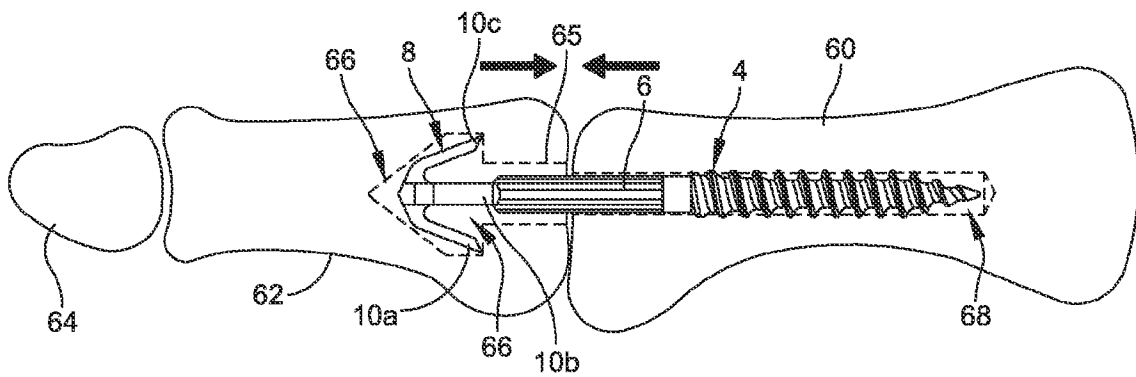


FIG. 8B

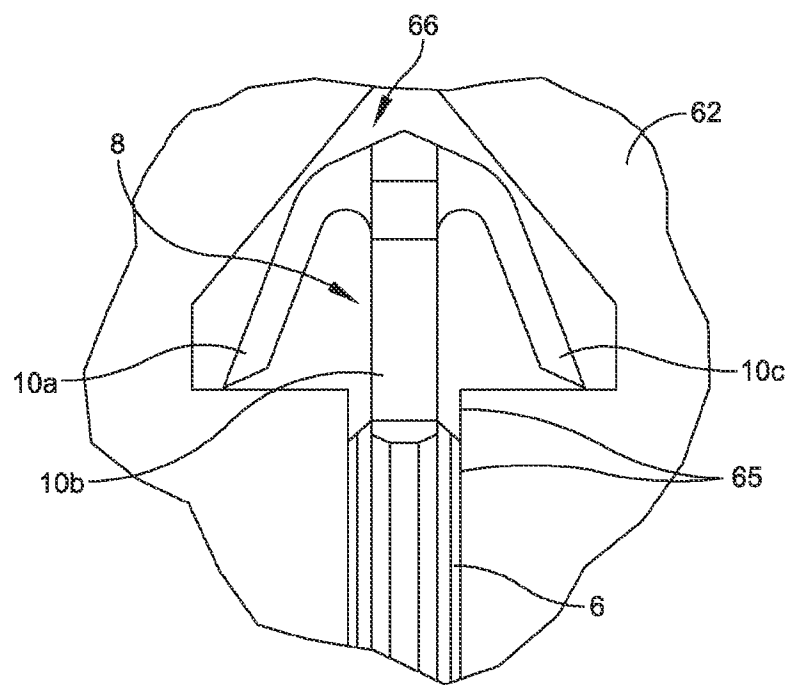
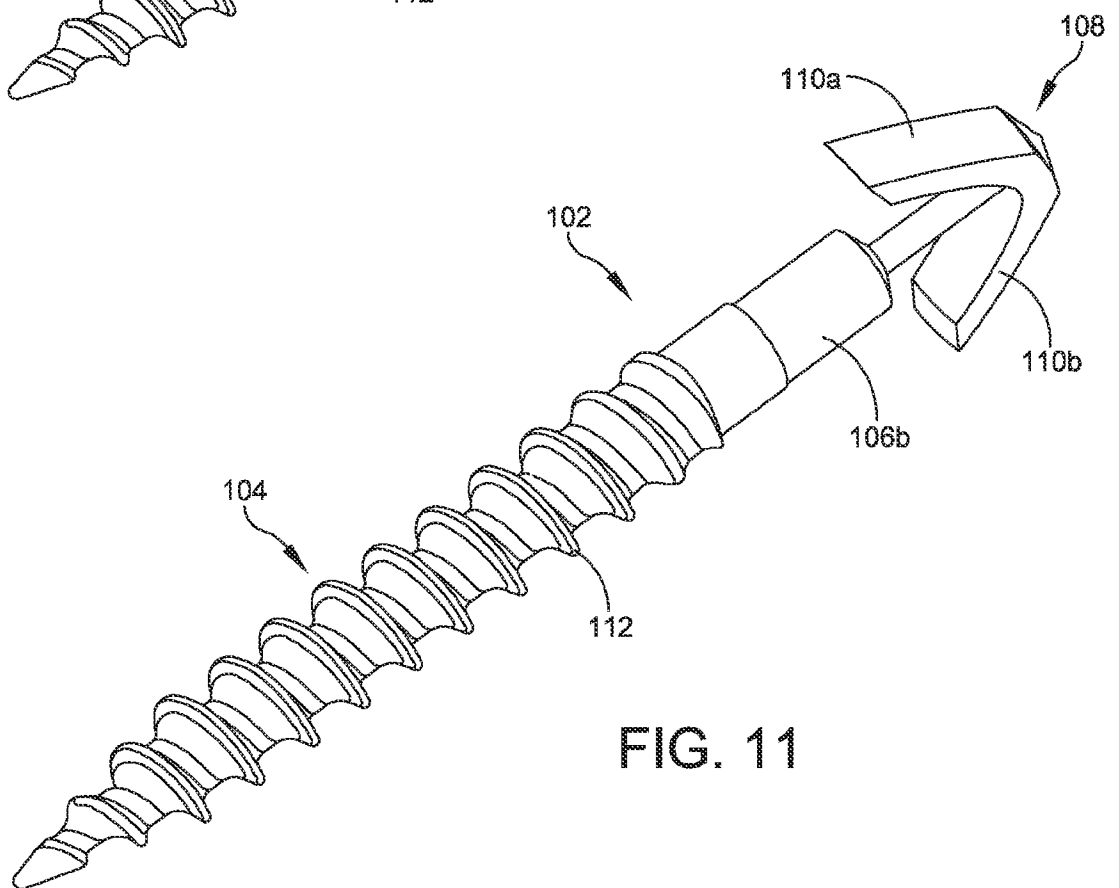
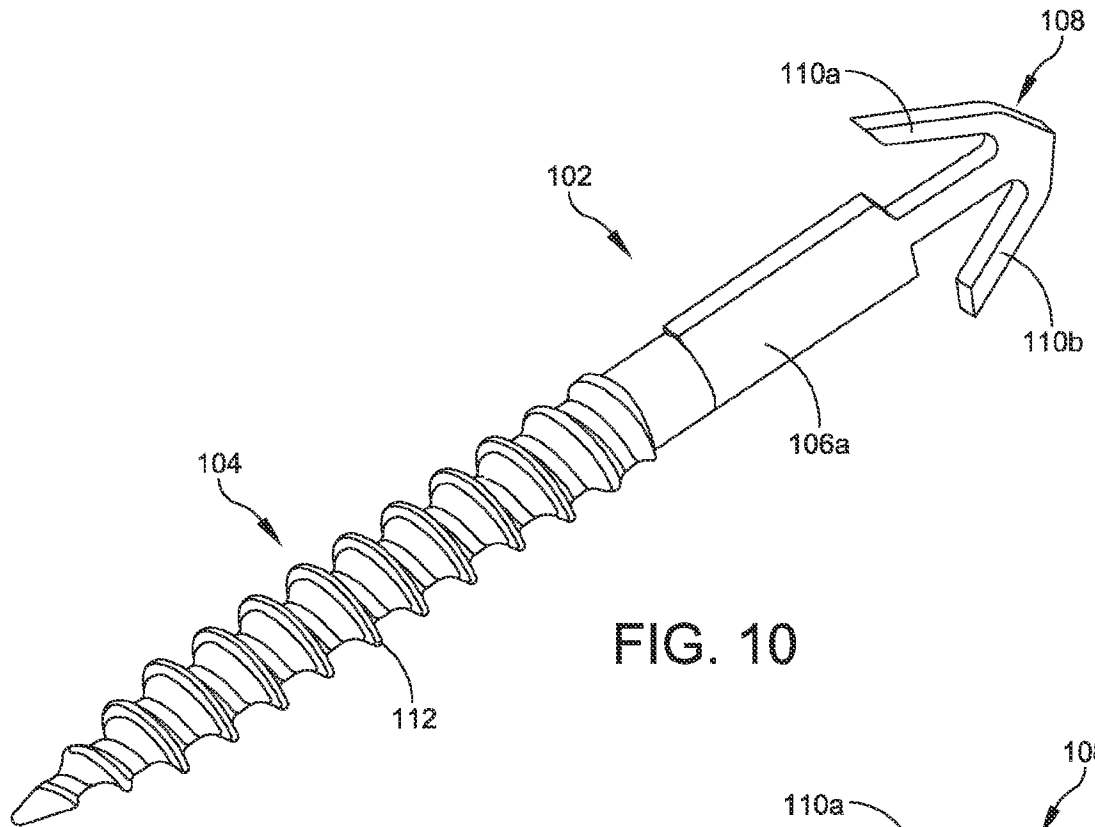


FIG. 9



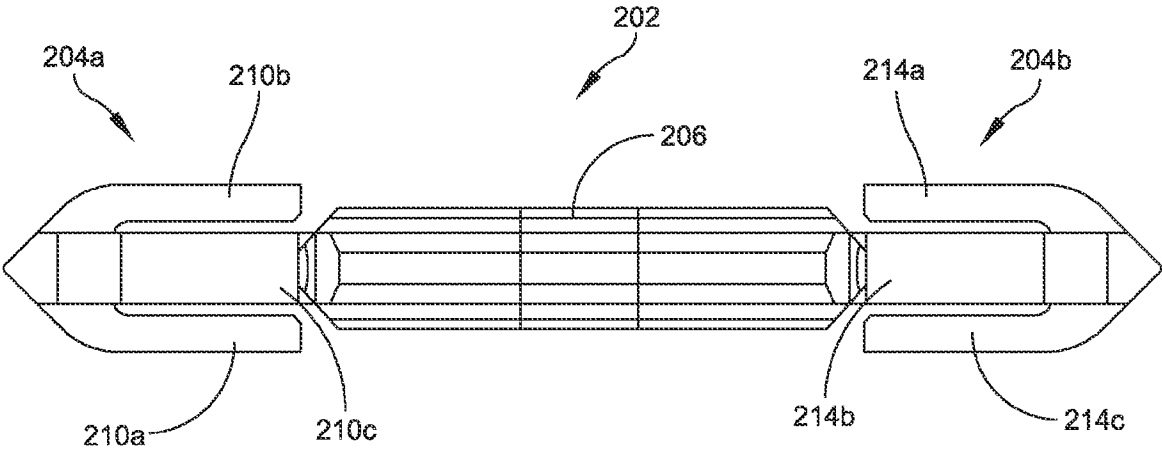
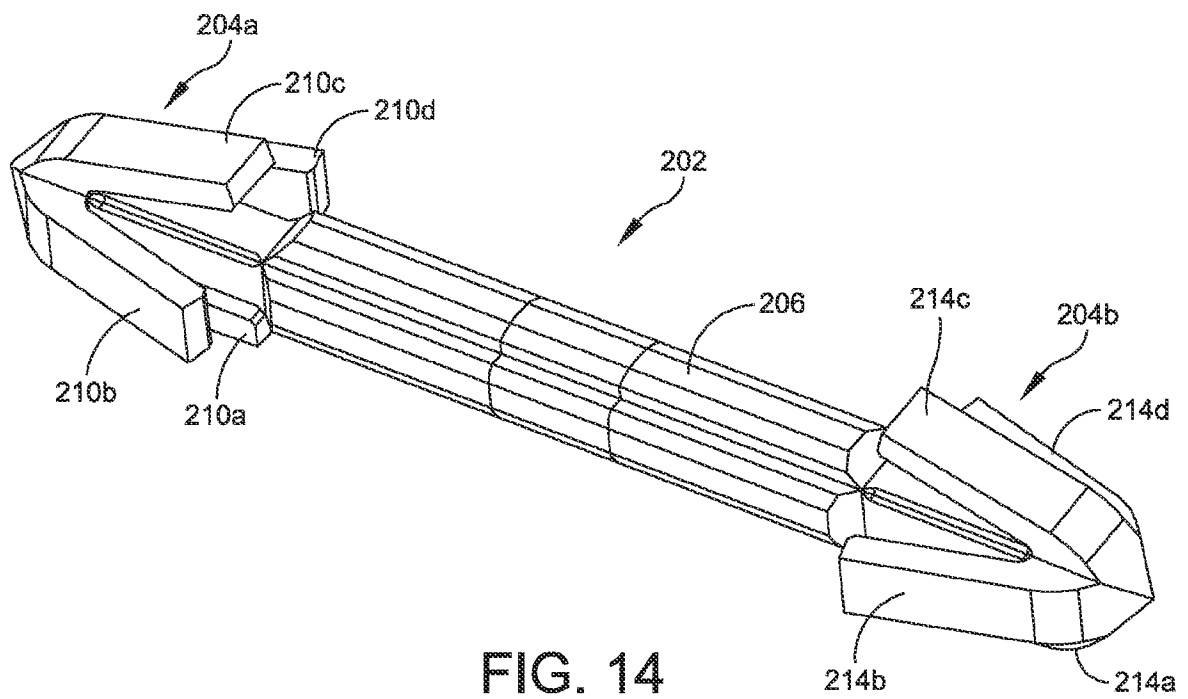
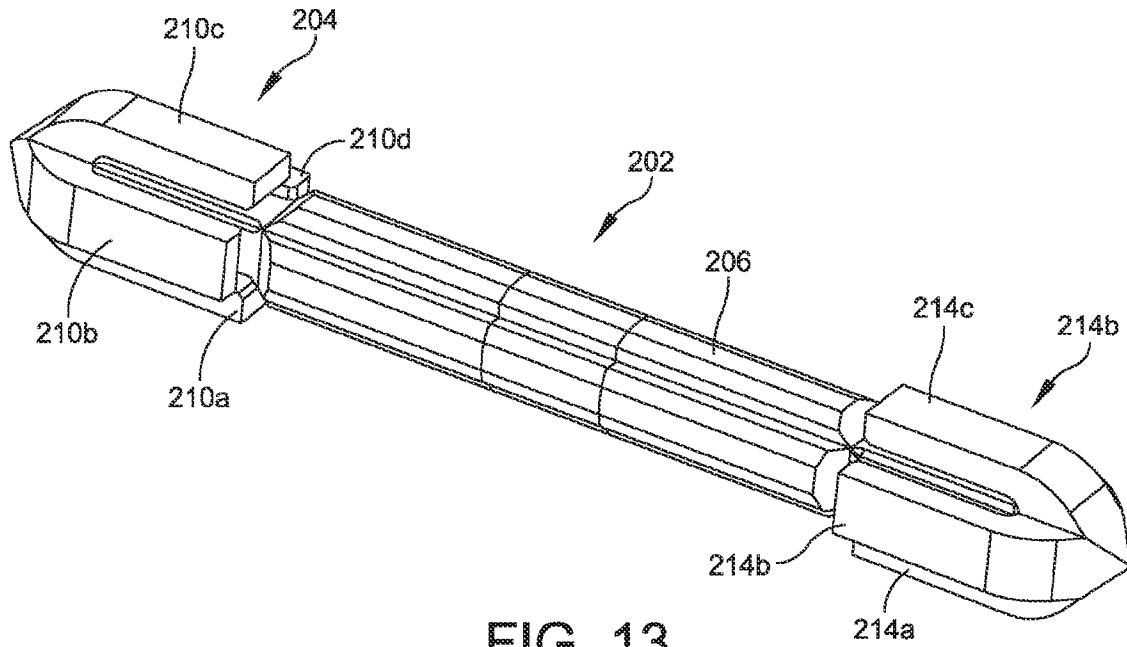


FIG. 12

9/14



10/14

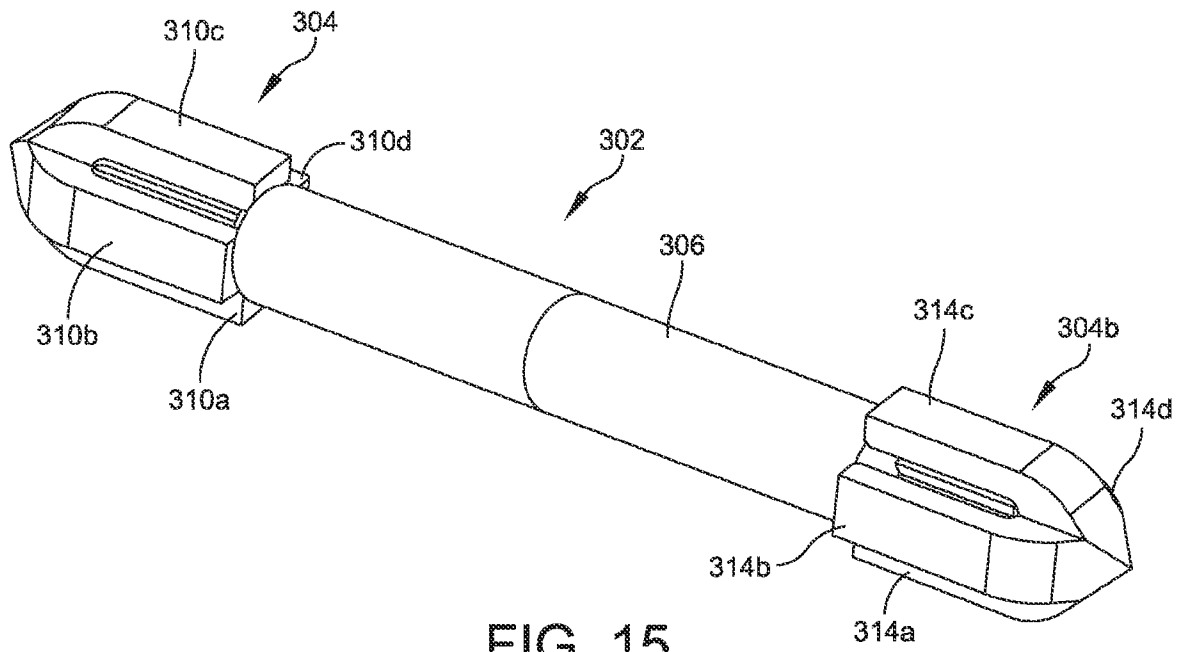


FIG. 15

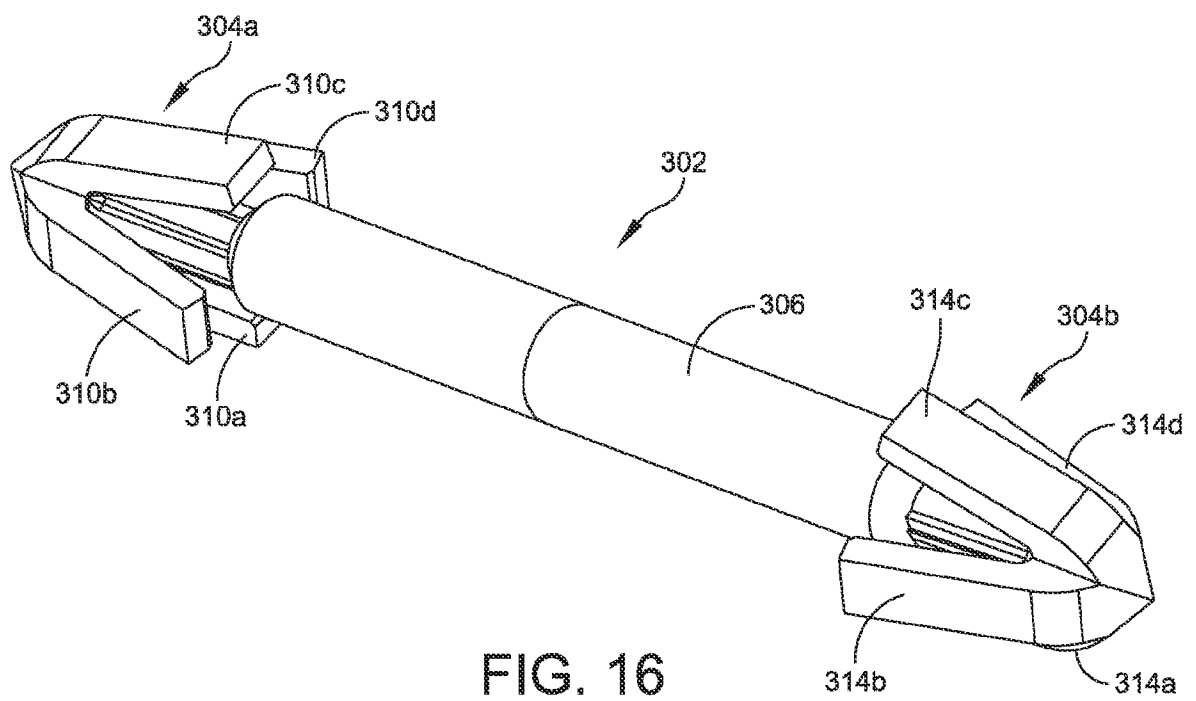


FIG. 16

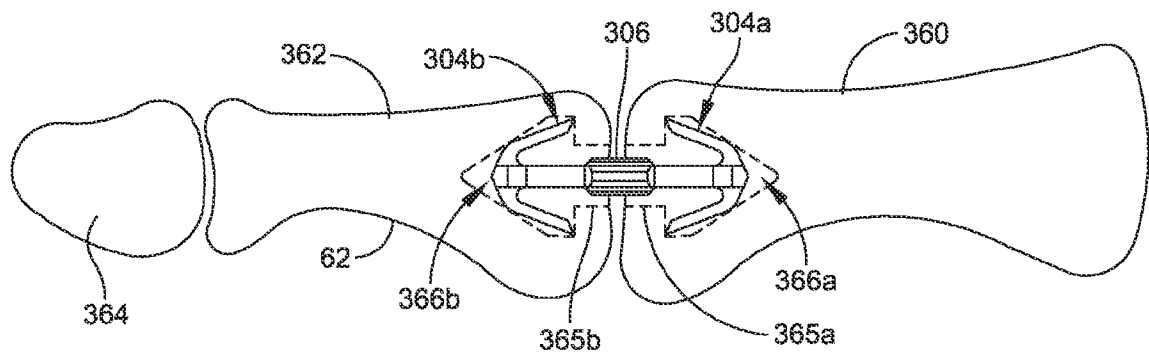
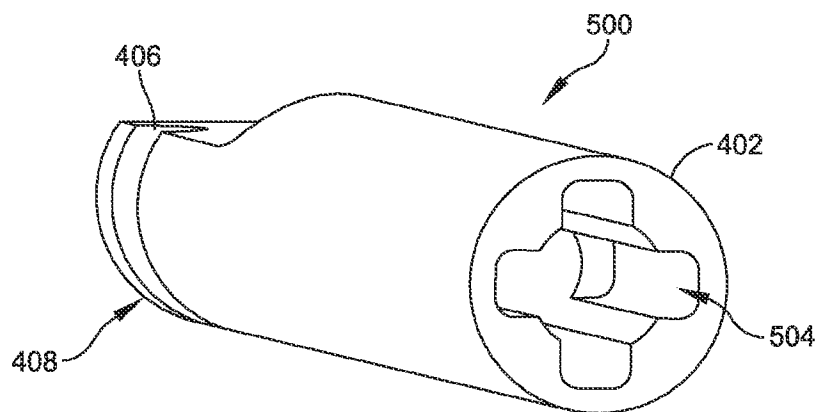
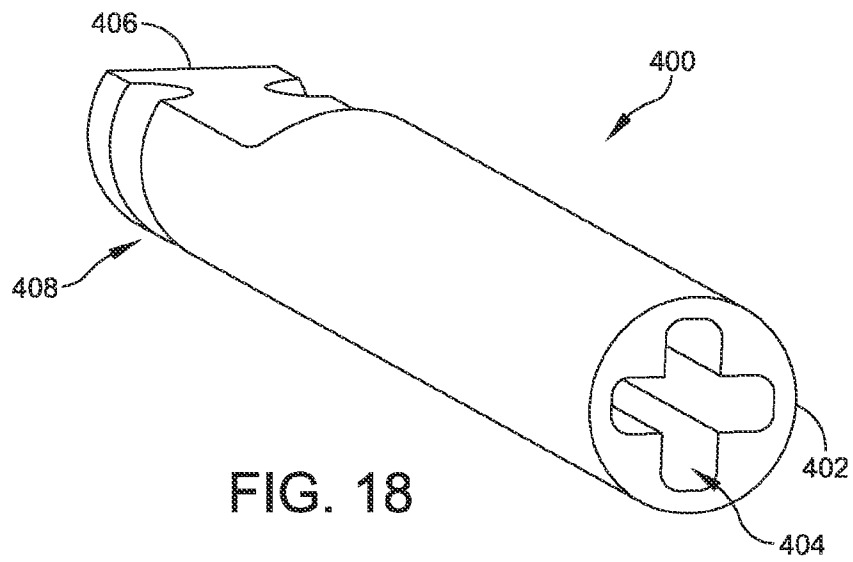


FIG. 17



13/14

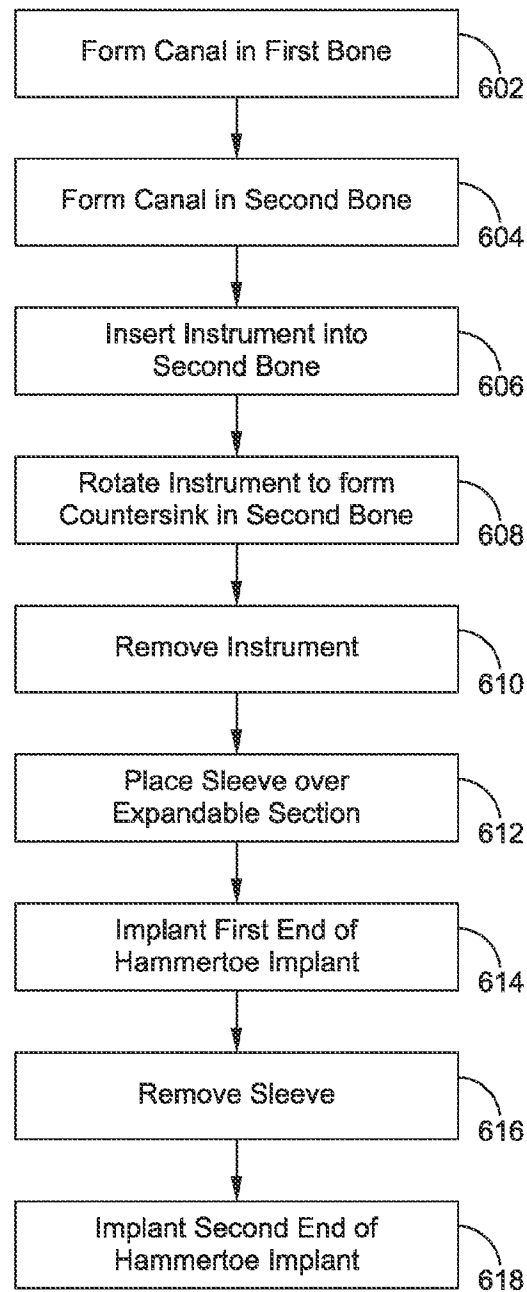


FIG. 20

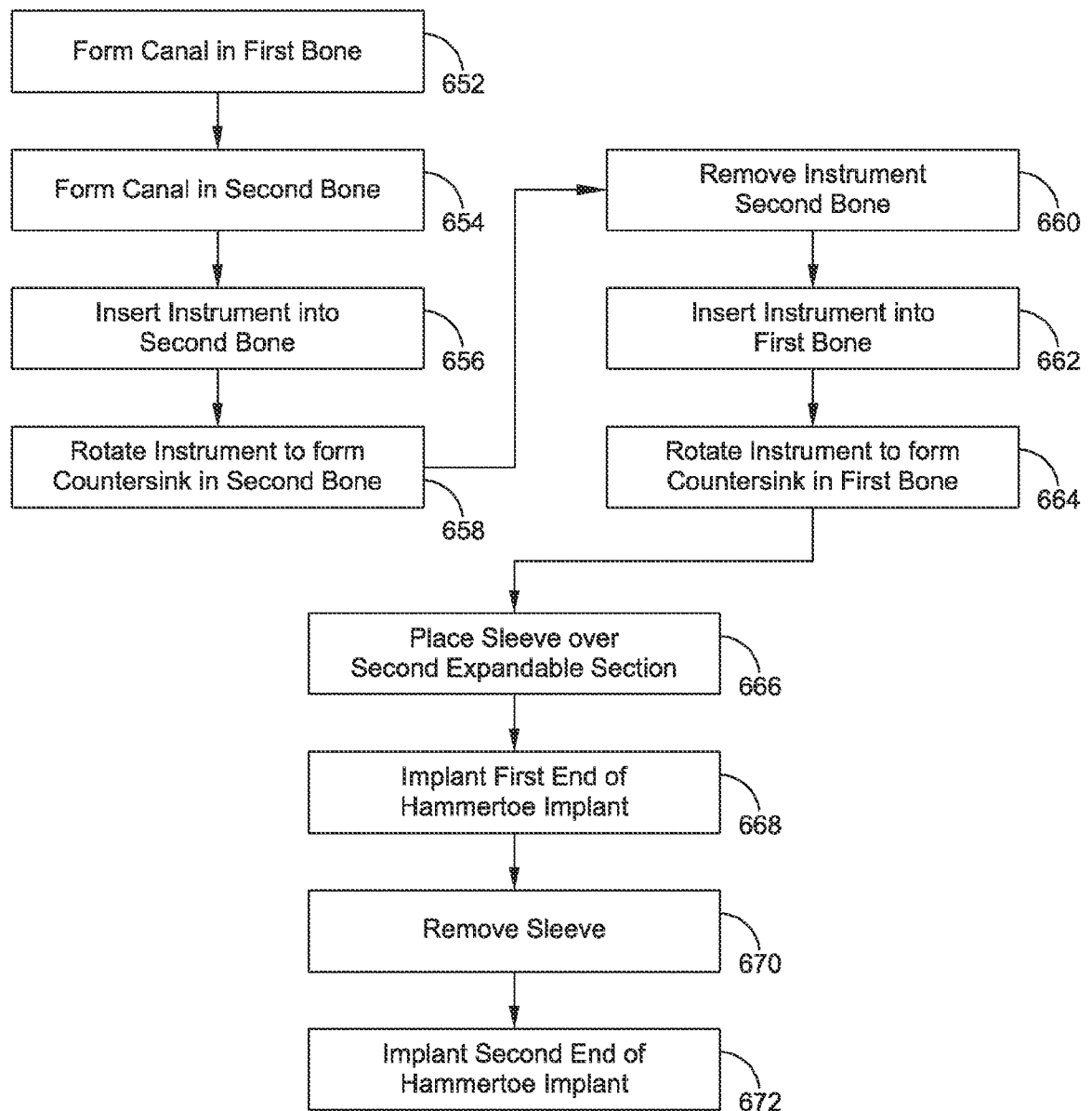


FIG. 21

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2014/056315**A. CLASSIFICATION OF SUBJECT MATTER****A61F 2/42(2006.01)i, A61B 17/86(2006.01)i, A61B 17/54(2006.01)i, A61B 17/16(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)

A61F 2/42; A61B 17/86; A61B 17/16; A61B 17/32; A61B 17/16; A61B 17/56; A61B 17/86; A61B 17/54

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: hammertoe, reverse countersink, tool, bone, screw, expandable, anchor, arm, cutting, edge, reamer, integrate

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2011-0301653 A1 (REED, W. and KOKA, D. V.) 08 December 2011 See paragraphs [0054]-[0082]; claims 1-11; figures 1A-23.	1-10
A		11-15
X	EP 2774556 A1 (ARTHREX, INC.) 10 September 2014 See abstract; paragraphs [0027]-[0042]; figures 1-8.	11-15
A		1-10
A	US 2005-0113836 A1 (LOZIER, A. J. et al.) 26 May 2005 See paragraphs [0033]-[0053]; claims 1-31; figures 1-7.	1-15
A	US 2011-0144644 A1 (PRANDI, B. et al.) 16 June 2011 See the whole document.	1-15
A	US 2012-0089197 A1 (ANDERSON, G. S.) 12 April 2012 See the whole document.	1-15



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

22 May 2015 (22.05.2015)

Date of mailing of the international search report

22 May 2015 (22.05.2015)

Name and mailing address of the ISA/KR


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

Facsimile No. ++82 42 472 7140

Authorized officer

Han, Inho

Telephone No. +82-42-481-3362



INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2014/056315

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.: 16-25
because they relate to subject matter not required to be searched by this Authority, namely:
Claims 16-25 pertain to a method 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/US2014/056315

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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US 2011-0144644 A1	16/06/2011	AU 2009-290724 A1 CA 2736587 A1 EP 2339977 A1 FR 2935601 A1 FR 2935601 B1 JP 05645826 B2 JP 2012-501773 A US 2013-0190761 A1 US 8414583 B2 WO 2010-029246 A1	18/03/2010 18/03/2010 06/07/2011 12/03/2010 01/10/2010 24/12/2014 26/01/2012 25/07/2013 09/04/2013 18/03/2010
US 2012-0089197 A1	12/04/2012	None	