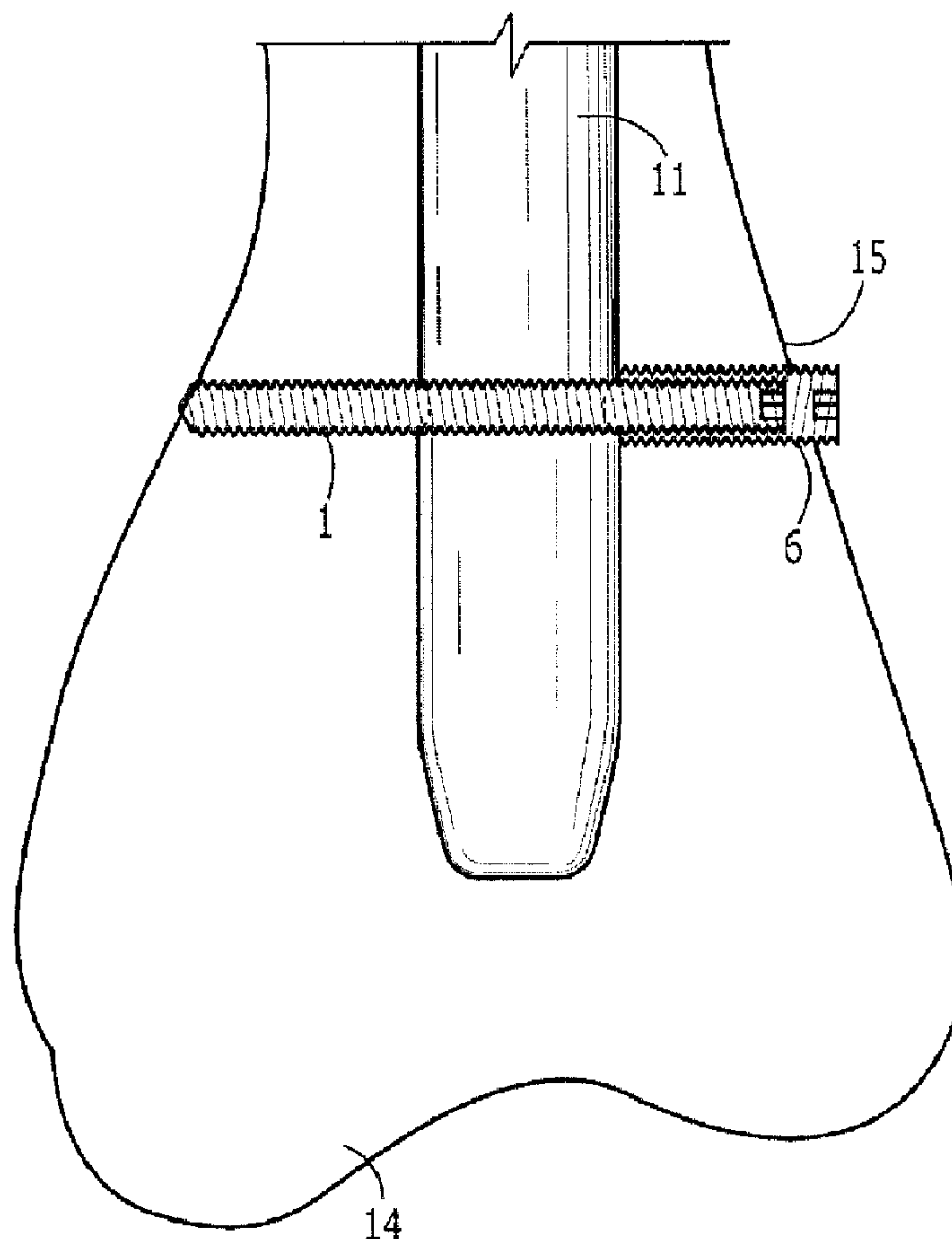




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(54) Title: INTRAMEDULLARY NAIL INCLUDING STABLE LOCKING BOLTS



(57) Abrégé/Abstract:

A device for securing an intramedullary implant (11) within a bone (14), comprises a bolt (1, 6) having a first portion extending proximally from a distal end of the bolt and a second portion extending proximally from a proximal end of the first portion to a

(57) **Abrégé(suite)/Abstract(continued):**

proximal end of the bolt. A length of the bolt is selected to substantially match a thickness of a portion of bone through which it is to be inserted and, a length, of the second portion being selected to substantially equal a distance from a point, on an outer surface of the bone through which the bolt is to be inserted into the bone to an outer surface of the implant so that, when the bolt, is fully inserted into the bone, the distal end of the second portion abuts an outer, surface of the implant.

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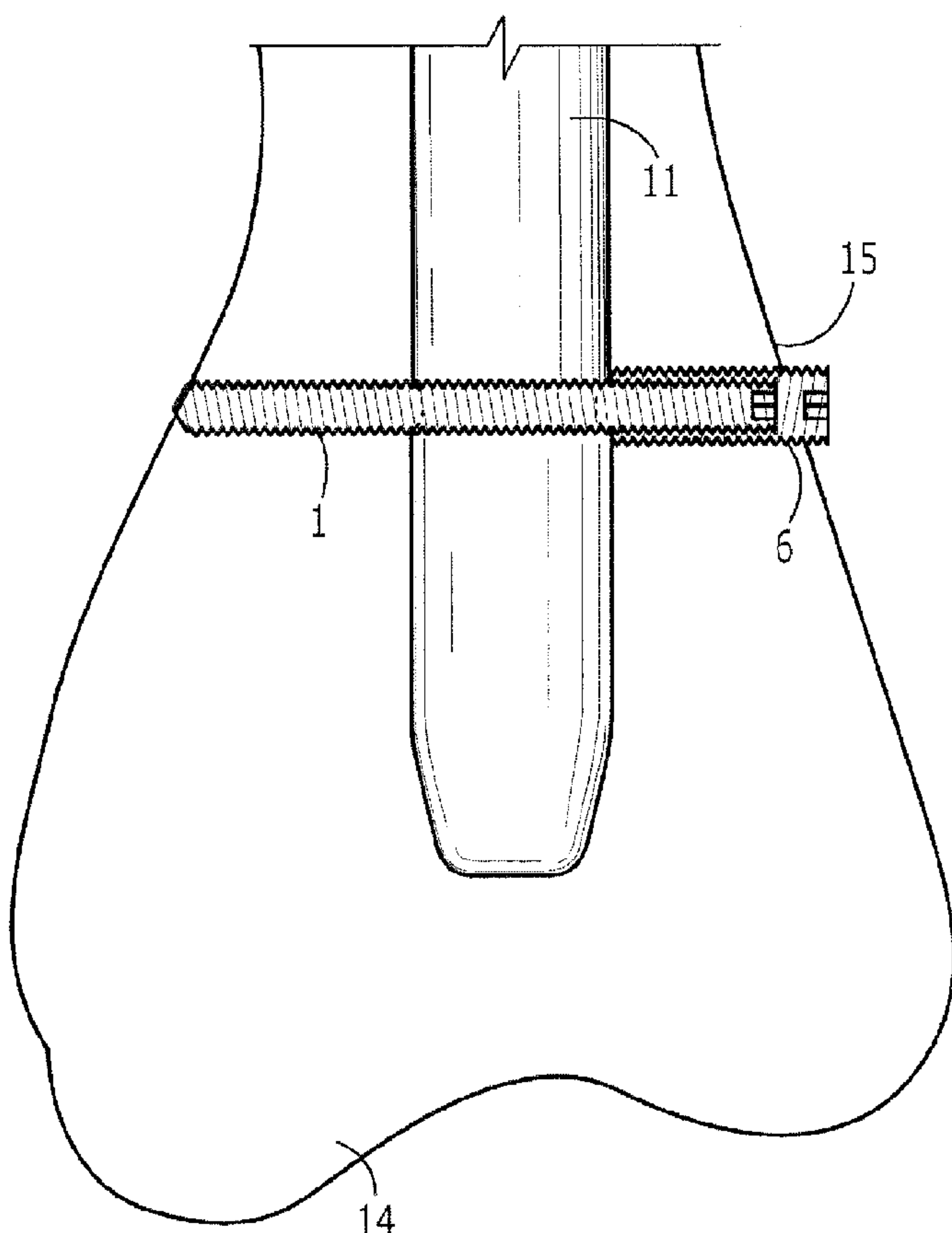
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(54) Title: INTRAMEDULLARY NAIL INCLUDING STABLE LOCKING BOLTS



(57) Abstract: A device for securing an intramedullary implant (11) within a bone (14), comprises a bolt (1, 6) having a first portion extending proximally from a distal end of the bolt and a second portion extending proximally from a proximal end of the first portion to a proximal end of the bolt. A length of the bolt is selected to substantially match a thickness of a portion of bone through which it is to be inserted and, a length, of the second portion being selected to substantially equal a distance from a point, on an outer surface of the bone through which the bolt is to be inserted into the bone to an outer surface of the implant so that, when the bolt, is fully inserted into the bone, the distal end of the second portion abuts an outer, surface of the implant.

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**INTRAMEDULLARY NAIL INCLUDING STABLE LOCKING BOLTS****Inventor:** Alberto Fernandez Dell'Oca**Field of the Invention**

[0001] The present invention relates to a device for use in osteosynthesis to treat fractures or to prophylactically treat potential fractures of long bones through the use of an intramedullary nail.

**Background of the Invention**

[0002] Intramedullary nails for use in the treatment of fractures of bone shafts have included holes close to ends of the nail on both sides of the fracture through which locking bolts were inserted substantially perpendicular to the nail to improve the rotational stability of the fracture and to avoid undesirable bone shortening at the fracture site. However, movement between the nail and locking bolts may cause difficulties especially where the bone is osteoporotic or where the fracture is close to an end of the bone.

**SUMMARY OF THE INVENTION**

[0003] The present invention is directed to a device for securing an intramedullary implant within a bone, comprising a bolt having a first portion extending proximally from a distal end of the bolt and a second portion extending proximally from a proximal end of the first portion to a proximal end of the bolt, wherein a length of the bolt is selected to substantially match a thickness of a portion of bone through which it is to be inserted. A length of the second portion is selected to substantially equal a distance from a point on an outer surface of the bone through which the bolt is to be inserted into the bone to an outer surface of the implant so that, when the bolt is fully inserted into the bone, the distal end of the second portion abuts an outer surface of the implant.

[0004] The present invention is further directed to an intramedullary osteosynthetic device for long bones fractures having improved bone holding power. In order to increase the bone holding

power of the locked nails, micro-movements between the nail and locking bolts is minimized by applying compression between the nail and the locking bolts. To achieve compression between the nail and locking bolts, a multi-diameter locking bolt is inserted through a threaded nail hole. In addition, if it is desired to reduce the number of different required bolts required in inventory, a two part locking bolt including a front male part and a rear female part may be applied. The male and female parts are preferably strongly locked together to form a unit that functions substantially as a single bolt.

#### Surgical technique.

[0005] After a nail or other implant has been inserted into the bone (e.g., within the medullary canal), a hole is drilled through the bone aligned with a level of a corresponding hole through the nail. A depth gauge is then used to determine a required total bolt length. The depth gauge is then used to determine a distance between the near bone cortex and the nail to determine the required length of an increased diameter portion of the bolt. Based on the total bolt length required and the required length of the increased diameter portion of the bolt, an appropriately dimensioned bolt is selected. For two part bolts, the required bolt length corresponds to the length of the male part as will be discussed in more detail below while the distance between the nail and the near bone cortex is used to select an appropriately sized female part. The appropriately sized single piece bolt is then inserted through the bone and the nail to lock the nail in the desired position and prevent undesired micro-movements thereof. For a two piece bolt, the selected male part is inserted into the selected female part and these parts are strongly fastened together to form a unit operating substantially as a single bolt -- i.e., to form a two diameter locking bolt. The two diameter locking bolt is inserted through the bone hole and through corresponding nail hole until the larger-diameter-rear-part of the two diameter locking bolt abuts the nail. The bolt is then strongly fastened to the nail to establish compression between the bolt and the nail forcing the combination of the two diameter locking bolt and the nail to operate as a single mechanical unit substantially eliminating micro-movements therebetween.

#### **Brief Description of the Drawings**

[0006] Fig. 1 shows a side view of a worm and threaded jacket according to the present

invention in a disassembled state;

Fig. 2 shows a side view of the threaded jacket inserted over the worm of Fig. 1;

Fig. 3 shows a cross-sectional view of the worm and threaded jacket of Fig. 1 in the disassembled state;

Fig. 4 shows a cross-sectional view of a threaded jacket inserted over the worm of Fig. 1;

Fig. 5 shows a perspective view of the worm and threaded jacket of Fig. 1;

Fig. 6 shows a side view of a distal end of an intramedullary nail for use in conjunction with the worm and threaded jacket of Fig. 1; and

Fig. 7 shows a cross-sectional view of a bone in which the nail of Fig. 6 and the worm and threaded jacket of Fig. 1 have been inserted.

### **Detailed Description**

[0007] The present invention, which may be further understood with reference to the following description and the appended drawing, relates to devices for treating fractures and, in particular, relates to internal fixation devices for treating fractures. It is noted that, although the exemplary embodiments of the present invention are described below with respect to the treatment of fractures of the femur, the description is not meant to limit the application of the invention to such fractures as the invention may be employed in the treatment of fractures of a number of bones including, for example, the femur, humerus, tibia, ulna, radius, ankle, etc.

[0008] To improve the performance of intramedullary nails in osteoporitic bones or in the case of a fracture adjacent to an end of a bone, embodiments of the present invention provide locking screws which substantially eliminate relative movement between an intramedullary nail and the locking screw and which, consequently, minimize relative motion between the intramedullary nail and the bone.

[0009] Figs. 1 - 7 show an exemplary embodiment of a device of the present invention comprising an intramedullary nail 11 with a nail hole 13 that may be locked into position within a bone 14 with a two-diameter locking bolt inserted through the nail hole 13. As shown in Figs. 1 - 4, the two diameter locking bolt comprises a separate male part 1 and a female part 6 that may be coupled together to function substantially as a single locking bolt. As mentioned above,

the two-diameter locking bolt according to the invention may be integrally formed as a single piece which functions in a manner substantially identical to the two piece bolt described herein. The only practical distinction between such a one piece integrally formed two-diameter bolt and the described two-piece bolt is that a large variety of these bolts would need to be available to accommodate all the possible combinations of full bolt lengths and distance from the near bone cortex to the nail. Thus, although the description herein will focus on the two piece system those skilled in the art will understand that all of the aspects of the invention may just as well be implemented with a unitary construction. Fig. 1 shows a two diameter locking bolt according to the invention in a de-coupled state. Male part 1 is substantially cylindrical and extends from a proximal end 4 to a distal tip 3. The male part 1 has a thread 2 extending substantially helically along its entire length which preferably matches a corresponding thread formed on an internal surface of the nail hole 13 so that the male part 1 may be screwed thereinto. As would be understood by those skilled in the art, the tip 3 may be pointed or otherwise shaped to facilitate inserting the locking bolt into the nail hole 13. A tool receiving feature (e.g., hex recess 5) is formed at the proximal end 4 for use if the male part 1 is inserted first and then, after the male part 1 is in position, the female part 6 is inserted thereover to form the 2 diameter bolt in situ.

**[0010]** The female part 6 is also preferably substantially cylindrical with an outer, bone engaging thread 9 extending substantially helically along its entire length. A proximal end 7 of the female part 6 includes a feature for receiving a tool to be used to turn the female part 6 (e.g., hex recess 8). As would be understood by those skilled in the art, the female part 6 may be turned via this tool receiving feature to couple the female part 6 to the male part 1. A distal end 12 of the female part 6 includes an opening 21 to a lumen 16 including an internal thread 10 (shown in broken lines) which matches the thread 2 of the male part 1 so that the proximal end 4 may be screwed into the lumen 16 until the proximal end 4 abuts a proximal end 18 of the lumen 16. As would be understood by those skilled in the art, the diameter of the lumen 16 is preferably only slightly larger than the diameter of male part 1 so that the male part back 4 of male part 1 may be inserted into the lumen 16 of the female part 6 and the female part 6 may be screwed over the male part 1. As indicated above, the female part 6 may be screwed on male part 1 using a hex key or other tool with a hexagonal bit that fits in the hex recess 7 to drive the female part 6 while male part 1 is held in place, or by simply twisting male part 1 and/or female part 6. It will be understood by those skilled in the art that any type of recess (e.g., slotted, cross-point) may be used instead of the male hex recess 5 and the female hex recess 8 to drive

either of the male and female parts 1, 6, respectively.

[0011] Fig. 2 shows the male part 1 and the female part 6 in an assembled state forming a substantially rigidly bound two-diameter bolt. As shown in broken lines, the female part 6 is coupled to the male part 1 to create a two diameter locking bolt with an annular shoulder 19 formed by the projection of the distal end 12 of the female part 6 radially outward from the portion of the male part 1 adjacent thereto. The female part 6 is preferably shorter than the male part 1 so that a distal portion 20 of the male part 1 projects distally beyond the end 12 of the female part 6 when the male part 1 and the female part 6 are fully screwed onto one another. Those skilled in the art will understand that male parts 1 of varying length are preferably provided so that a user may select a male part 1 whose length is substantially equal to a thickness of the bone at the location of the screw hole 13 less a slight clearance for the portion of the female part 6 extending proximally beyond the proximal end 18 of the lumen 16. Then, when a female part 6 is selected having a length substantially corresponding to a distance between the near cortex 15 of the bone 14 and the close side of the nail 11, the female part 6 will screw over the male part 1 until the proximal end 7 of the female part 6 is substantially flush with the outer surface of the bone 14.

[0012] Fig. 3 shows a cross-sectional view as well as a top view of both the male part 1 and the female part 6 in the unassembled state. The top view shows the hex recess 5 at the proximal end 4 of the male part 1 and the hex recess 8 at the proximal end 7 of the female part 6 while the cross section of the female part 6 shows the inner thread 10 of the lumen 16. The diameter of the lumen 16 is shown in broken lines on the top view of female part 6. Fig. 4 shows a cross sectional view of the male part 1 and the female part 6 coupled to one another with the male thread 2 engaging the thread 10 of the lumen 16 with minimal clearance therebetween when the male part 1 and the female part 6 are coupled to one another to minimize or eliminate relative movement between these parts. The pitch of the threading of male part 1 and the female part 6 are also shown in Fig. 5.

[0013] Figs. 6 and 7 show the nail 11 that is to be stabilized by a two-diameter locking bolt according to the present invention. As understood by those skilled in the art, a distal tip 12 of the nail 11 is inserted into a long bone 14 such as, for example, the femur through the medullary canal such that the entire length of the nail 11 is received within the bone 14 and provides

stability to a fracture (not shown). Once inserted, a hole is drilled through the bone 14 in alignment with the nail hole 13 so that a hole extends through one side of the bone cortex through the nail 11 (via hole 13) and through the opposite side of the bone cortex on the opposite side of the nail 11 to a position which may, for example, be adjacent to an outer surface of the bone 14. Using a depth gauge, a physician or other medical professional then determines the total length required for the two-diameter bolt to maximize the length of the two-diameter bolt engaging the bone 14 by measuring the distance from the hole in the bone cortex to the far end of the hole. This depth measurement is then used to select a male part 1 with a length which is approximately equal to the total length of the hole minus a thickness of the portion of the female part 6 extending proximally of the proximal end of the lumen 16 as described above. After selection of a male part 1 of the desired length, the depth gauge is used to measure the distance between the nail 13 and the opening into the hole in the near cortex of the bone 14. The user then selects a female part 6 of substantially this second length.

[0014] The selected male part 1 and female part 6 are then coupled to one another by inserting the proximal end 4 of the male part 1 into the lumen 16 of the female part 6 so that the thread 2 of the male part 1 engages the inner thread 10 and the two components are rotated relative to one another to securely fasten them together to form a single two-diameter locking bolt. The two-diameter locking bolt is then inserted through the bone hole and the corresponding nail hole 13 by rotating the two-diameter bolt via the hex recess 8 (e.g., using a hex key) until the shoulder 19 abuts the outer surface of the nail 11 surrounding the hole 13. As would be understood by those skilled in the art, at this point, the proximal end 7 of the female part 6 should be substantially flush with the outer surface of the bone 14. At this point, engagement between the nail 11 and the two-diameter locking bolt cause the bolt and the nail 11 to operate as substantially a single mechanical unit minimizing or eliminating micro-movements therebetween.

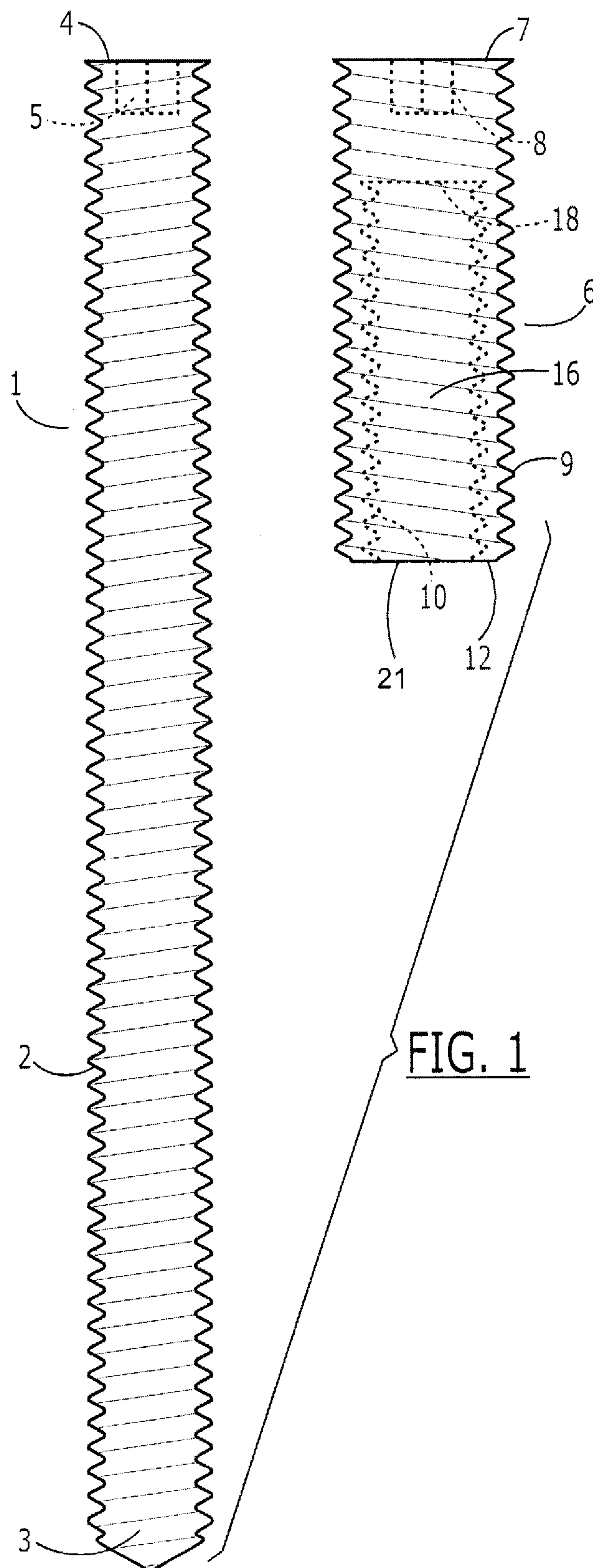
**What is claimed is:**

1. A device for securing an intramedullary implant within a bone, comprising a bolt having a first member extending proximally from a distal end of the bolt and a second member extending proximally from of the first member to a proximal end of the bolt, a length of the bolt being selected to substantially match a thickness of a portion of bone through which it is to be inserted and a length of the second member being selected to substantially equal a distance from a point on an outer surface of the bone through which the bolt is to be inserted into the bone to an outer surface of the implant so that, when the bolt is fully inserted into the bone, a distalmost end of the second member abuts an outer surface of the implant, wherein the second member directly threadably engages the first member.
2. The device of claim 1, wherein the first member is elongated and includes a first thread extending along an exterior thereof and the second member is elongated and includes a lumen extending therein from an opening in a distal end thereof, the lumen including a second thread extending along an inner wall thereof, the first and second threads and the diameters of the first and second members cooperating so that a proximal portion of the first member is threadably couplable within the lumen, a distal portion of the first member extending distally beyond a distal end of the second member.
3. The device of claim 1, wherein an outer diameter of the second member exceeds an outer diameter of the first member by a predetermined distance to form a shoulder at the distal end of the second member.
4. The device of claim 1, wherein an outer diameter of the first member substantially corresponds to an inner diameter of a hole in the implant through which the bolt is to be inserted.
5. The device of claim 1, wherein the first and second members are integrally formed to define a unitary two-diameter bolt.
6. A system device for treating a fracture comprising:

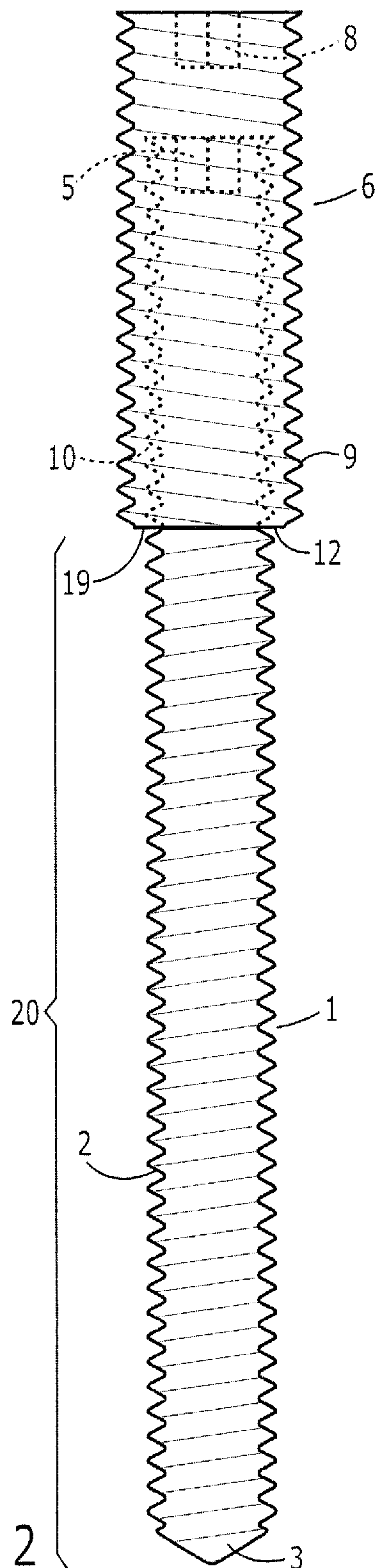
an implant sized and shaped for insertion into a medullary canal of a bone; and  
 a bolt having a first member extending proximally from a distal end of the bolt  
 and a second member extending proximally from the first member to a proximal end of  
 the bolt, a length of the bolt being selected to substantially match a thickness of a portion  
 of bone through which it is to be inserted and a length of the second member being  
 selected to substantially equal a distance from a point on an outer surface of the bone  
 through which the bolt is to be inserted into the bone to an outer surface of the implant so  
 that, when the bolt is fully inserted into the bone, a distalmost end of the second member  
 abuts an outer surface of the implant, wherein the second member directly threadably  
 engages the first member.

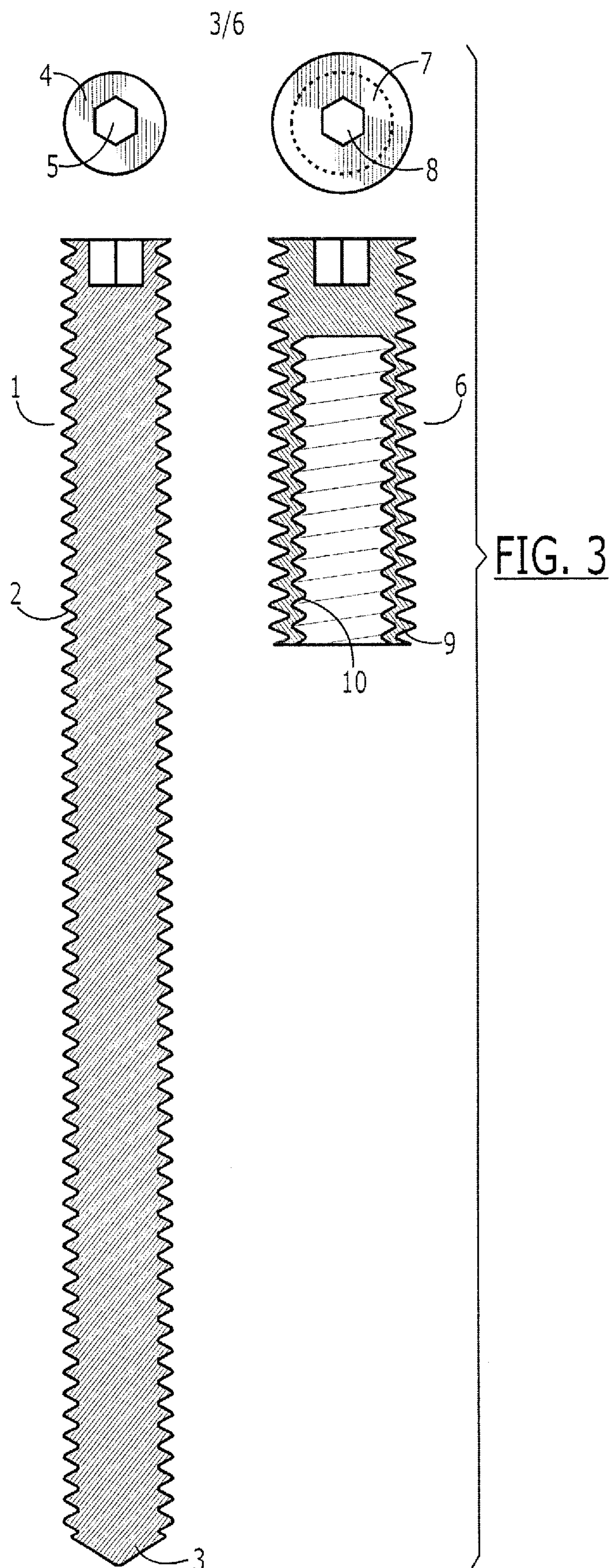
7. The system of claim 6, wherein the implant is an intramedullary nail.
8. The system of claim 6, wherein the first member is elongated and includes a first thread extending along an exterior thereof and the second member is elongated and includes a lumen extending therein from an opening in a distal end thereof, the lumen including a second thread extending along an inner wall thereof, the first and second threads and the diameters of the first and second members cooperating so that a proximal portion of the first member is threadably couplable within the lumen, a distal portion of the first member extending distally beyond a distal end of the second member.
9. The system of claim 6, wherein an outer diameter of the second member exceeds an outer diameter of the first member by a predetermined distance to form a shoulder at the distal end of the second member.
10. The system of claim 6, wherein an outer diameter of the first member substantially corresponds to an inner diameter of a hole in the implant through which the bolt is to be inserted.

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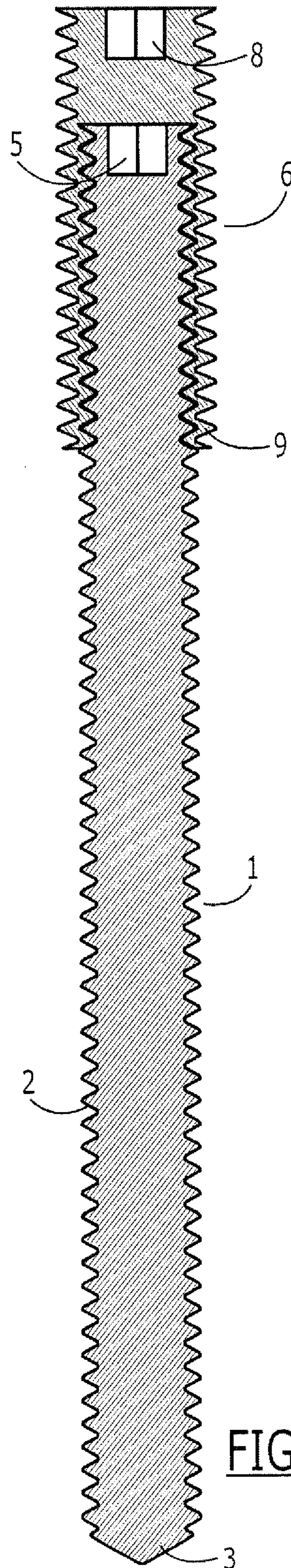
FIG. 1

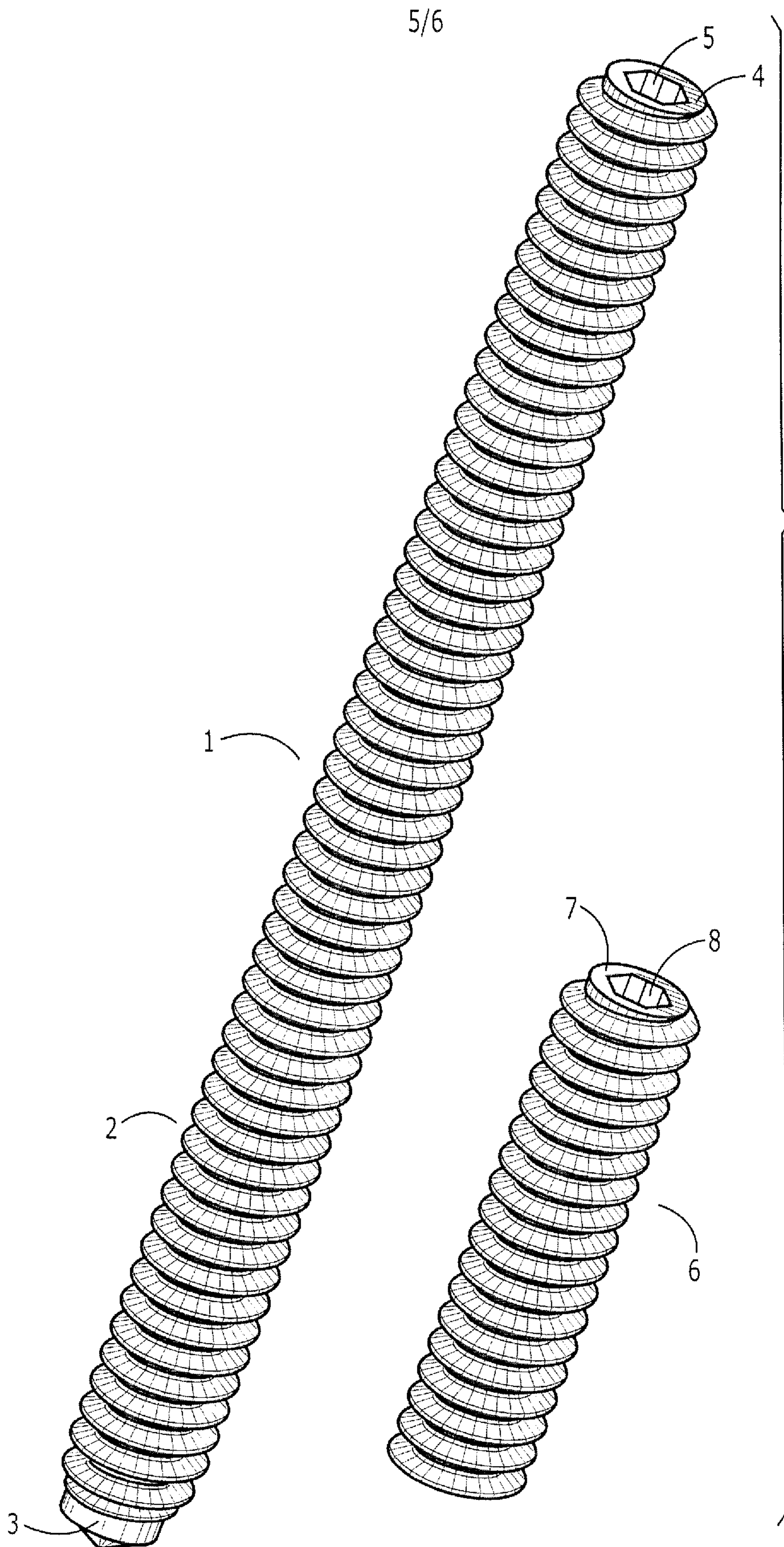
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4/6

FIG. 4



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