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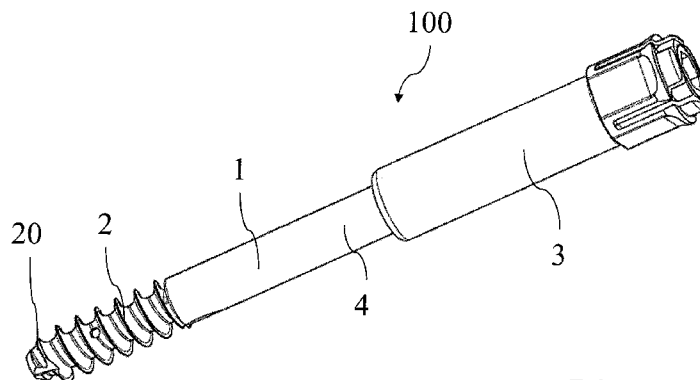
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- (54) **Title:** ENDOSSEOUS SCREW ASSEMBLY AND INTERNAL FIXATION SYSTEM COMPRISING SAID ENDOSSEOUS SCREW ASSEMBLY



**Fig. 1**

- (57) **Abstract:** An endosseous screw assembly (100) for an internal fixation system (SC; SP), whose connection to the rest of the system is unusually easy for the surgeon, comprising: a longitudinally extending rod (1) equipped with at least one threaded proximal portion (2); a connection sleeve (3), within which a portion of the rod (1) is slidably guided, said connection sleeve (3) being arranged to be inserted into a connection hole of an internal fixation member by snap-connecting within said connection hole up to reach a locking position; said rod (1) and said connection sleeve (3) comprising such mutual engagement means so as to form an axial constraint to the sliding of the rod (1) into the connection sleeve (3), so as to define, when the threaded proximal portion (2) advances into a bone site of the patient, a dragging of the connection sleeve (3) into the connection hole up to reach the locking position.

Title: Endosseous screw assembly and internal fixation system comprising said endosseous screw assembly

## DESCRIPTION

### Field of application

- 5 The present invention relates to the field of orthopedic surgery and it relates to an endosseous screw assembly, particularly of the type used in internal fixation systems comprising plates or nails.

The invention also relates to the internal fixation system comprising said endosseous screw assembly.

### 10 Prior art

Internal fixation systems, widely used in the orthopedic field, comprise different types of endosseous implants generally applied to stabilize the fractured bone site of a patient.

- 15 Internal fixation systems can comprise a bone plate, which is fixed in contact with an external surface of the fractured bone in order to ensure the alignment and fixation of two or more segments thereof. In order to allow the plate to be fixed, the system provides in these cases a plurality of endosseous screws crossing as many holes made on the element.

- 20 Internal fixation systems can also comprise an endomedullary nail, which is typically inserted into the medullary canal of the long bone of a patient. In this case too, one or more endosseous screws are generally provided, which transversely cross the cortical bone and interface the endomedullary nail in order to stabilize the system.

- 25 In both above-described implant types, a stable connection must be realized between the screw rod and the plate or nail body. This connection must be able to discharge on the plate/nail the torsional and bending stress applied to the screw rod, allowing in the meantime the controlled axial sliding of the rod itself in order to allow screwing and removal operations.

- 30 In order to meet said requirements, connection systems known in the art are generally quite elaborated and complex, thus defining a critical step –

both from the time point of view and from the point of view of the attention required by the surgeon – of the implantation of the fixation system.

By way of example, mention is made of the prior art patent applications US 2008/0119856 and WO 2013/075730. The suggested methods for  
5 inserting and connecting the screws to the endomedullary nail and/or plate provide the following use of a plurality of specific instruments, or a sequence of screwings on different components kept apart from each other. As a clear result, the screw insertion step in the prior art methods shown requires much attention and a quite long time to the surgeon  
10 charged of implanting the internal fixation system.

The technical problem underlying the present invention is therefore to provide an endosseous screw assembly and a related internal fixation system allowing both the operations of inserting and stabilizing the screw into the nail/plate, and the opposite operations in case of implant removal  
15 to be considerably simplified.

#### Summary of the invention

Said technical problem is solved by an endosseous screw assembly according to claim 1, as well as by an internal fixation system comprising said assembly, according to the text of claim 7.

20 Further features and advantages will become more apparent from the following detailed description of some preferred, but not exclusive, embodiments of the present invention, with reference to the attached figures, given by way of not-limiting example.

#### Brief description of the drawings

25 Figure 1 is a perspective view of an endosseous screw assembly according to the present invention, wherein a screw rod and a connection sleeve are arranged in a first relative position;

Figure 2 is a perspective view of the endosseous screw assembly of figure 1, wherein the rod and the connection sleeve are arranged in a second  
30 relative position;

Figure 3 is a perspective view of the sole rod belonging to the endosseous screw assembly of figure 1;

Figure 4 is a perspective view of a detail of the rod of figure 3;

Figure 5 is a front view of the rod of figure 3;

Figure 6 is a back view of the rod of figure 3;

5 Figure 7 is a perspective view of the sole connection sleeve belonging to the endosseous screw assembly of figure 1;

Figure 8 is a perspective view of a detail of the connection sleeve of figure 7;

Figure 9 is a back view of the connection sleeve of figure 7;

10 Figure 10 is a perspective view of a first embodiment of an internal fixation system according to the present invention;

Figure 11 is a perspective view of a detail of an endomedullary nail belonging to the internal fixation system of figure 10;

15 Figure 12 is a perspective view of a second embodiment of an internal fixation system according to the present invention, implanted on the bone site of a patient;

Figures 13-17 show following steps of a method for implanting the internal fixation system of figure 12;

Figure 18 is a perspective view of a bone plate belonging to the internal fixation system of figure 12;

20 Figure 19 shows a step of a method for removing the internal fixation system of figure 12;

Figure 20 shows a detail in section of an instrument used to remove an internal fixation system according to the present invention;

25 Figures 21-24 are perspective views of different instruments used to implant an internal fixation system according to the present invention;

Figure 25 shows a detail in partial section of an instrument used to remove an internal fixation system according to the present invention.

Detailed description

With reference to the attached figures, and particularly to figures 10 and 12, two internal fixation systems according to a first and second embodiment of the invention have been identified with references SC and SP.

- 5 In the first embodiment, shown in figure 10, the internal fixation system SC comprises an endomedullary nail 40, particularly a trochanteric nail, and two endosseous screw assemblies 100.

10 Endosseous screw assemblies 100 are inserted and locked on the trochanteric nail 40, along axes being parallel to each other and inclined compared to the nail axis, and arranged to anchor within the acetabular head of the patient.

In the second embodiment, shown in figure 12, the internal fixation system SP comprises a bone plate 40' fixed to the femoral surface of a patient by means of three endosseous screws 200 of the traditional type.

- 15 Moreover, the internal fixation system SP provides, in this case too, two endosseous screw assemblies 100 inserted and locked on the bone plate 40', along axes being parallel to each other and skew compared to those of other bone screws 200, and arranged to anchor within the acetabular head of the patient.

- 20 Both internal fixation systems SC, SP according to the present invention share a similar fixation system of the endosseous screw assemblies 100 to the internal fixation member, be it the endomedullary nail 40 or the bone plate 40'.

25 The endosseous screw assemblies 100 used in said two embodiments are in fact the same, and both internal fixation members 40; 40' provide a same connection hole to lock them.

30 Connection holes 41; 41', which can be seen in figure 11 for the endomedullary nail 40 and in figure 18 for the bone plate 40', are generally described hereafter. The description applies without distinction to the endomedullary nail and to the bone plate; it must be noted that, in the figure, the elements related to the bone plate have been identified with the same numeral reference as the endomedullary nail adding the first-

index.

Each connection hole 41; 41' has two following portions with a different diameter, which define between them a shoulder 43; 43'. The portion having the greater diameter is naturally turned towards the side of insertion of the endosseous screw assembly 100. On the internal surface thereof a groove 42; 42' is obtained, which extends circumferentially up to meet the outward outlet of the connection hole 41; 41'.

The endosseous screw assembly 100, globally illustrated in figures 1 and 2, comprises two elements being coupled but structurally distinct: a longitudinal rod 1 and a connection sleeve 3.

The rod 1 of the endosseous screw assembly 100, individually illustrated in figures 3-6, comprises a threaded proximal portion 2, a following cylindrical intermediate portion 4 and finally a distal portion 5, which is also cylindrical, but with a greater diameter.

In the embodiment here described, the whole rod 1 is cannulated, i.e. it has an axial passage connecting a distal opening 11 to a proximal opening 10. This solution allows a guide wire to be used to facilitate the insertion step of the endosseous screw assembly 100; moreover the axial passage can advantageously define an access way to inject in situ a bone substitute or other biological substances.

The threaded proximal portion 2 is arranged to penetrate into the bone site of the patient, and it is particularly equipped with a self-drill bit 20 that allows the screw to proceed into the bone. The bit 20 provides a plurality of circumferentially equidistant notches 21, three in the embodiment being presently illustrated, which facilitate the self-drilling and tapping step of the screw within the bone site. Moreover the proximal opening 10 of said axial passage opens in correspondence with the bit 20.

It must be noted that the external diameter of the thread of the proximal portion 2 is slightly greater than the diameter of the cylinder which forms the intermediate portion 4, so as to axially constrain the connection sleeve 3 sliding along the rest of the rod 1.

A radial notch 22 extending along the external surface of the intermediate

portion 4 is provided in correspondence with the thread interruption; said radial notch 22 increases the resistance to accidental unscrewing.

5 One or more radial holes 12, communicating with the above-mentioned axial passage, open on the external surface of the threaded proximal portion 2, particularly in correspondence with a thread bottom. These radial holes 12 allow the radial extrusion surface and the diffusion of a possible bone substitute to be increased.

10 The intermediate portion 4 and the distal portion 5 of the rod, as said above, are both cylindrical, but with a diameter increase in the distal part. It must be noted in particular how the diameter variation defines a shoulder serving as an axial clamp 6 for the connection sleeve 3 which slides above the rod 1, according to modes described hereafter.

The distal opening 11 of the axial passage opens in correspondence with the free end of the distal portion 5, as mentioned above.

15 That distal opening 11 provides a first cavity which defines a sunken housing 9, in the present example being hexagon-shaped, which allows an instrument to screw the rod 1 to be engaged.

20 Always within the distal opening, deeply compared to the sunken housing 9, an internal thread 15 is provided, which allows the possible attachment of an injection instrument or a plug or piston within the rod.

25 Moreover the internal thread 15 allows the rod 1 to be connected to a suitable cannulated screwdriver, equipped with an external-thread bar 610 axially constrained with the screwdriver itself, if the removal of the rod 1 is difficult. A detail of that screwdriver bit is shown in the attached figure 25: the external-thread bar 610 precedes the hexagonal head 620 defining an axial abutment, while the instrument body provides an internal cannula 630.

30 The connection sleeve 3, individually illustrated in figures 7-9, is slidingly associated to the intermediate 4 and distal 5 portions of the rod 1, as it can be inferred through the comparison of the relative position of the sleeve itself in figures 1 and 2.

The sliding of the connection sleeve 3 is axially constrained in both

directions: in the proximal direction by the external diameter of the thread; in the distal direction by the above-identified axial clamp 6.

It must be noted in particular how, in the present embodiment, the axial clamp 6 locks the connection sleeve 3 by abutting against an internal element of the connection sleeve 3 itself. By way of example, the internal abutting element can be realized by plastic deformation of the end part of the connection sleeve 3. Therefore, in the limit stop position identified in figure 1, the distal portion 5 of the rod 1 is completely inserted into the connection sleeve 3, and the distal ends of the sleeve and of the rod are arranged at level.

The connection sleeve 3 comprises a proximal cylindrical portion 13 and a distal collar 14.

While inserting the connection sleeve 3 into the respective internal fixation member 40; 40', the proximal cylindrical portion 13 is inserted in guided engagement into the smaller-diameter portion of the connection hole 41; 41', until the distal collar 14 abuts against the above-defined shoulder 43; 43' in a system locking position.

The distal collar 14 provides snap-connection means, described hereafter, arranged for stable engagement in the groove 42; 42' of the connection hole 41; 41' in said locking position.

The distal collar 14, with a prismatic or cylindrical shape, has an external diameter being substantially equal to the diameter of the greater-diameter portion of the connection hole 41; 41'. Tangential cuts are made in the body thickness, which define four brackets 8, joined to the connection sleeve 3 only in correspondence with the proximal end thereof. Since the sleeve is realized out of a flexible material, for example steel or titanium, the brackets 8 are able to bend, so that the free distal end thereof is able to elastically move in the substantially distal direction.

As many clutch claws 7 are defined in correspondence with the free end of the four brackets 8, which define in sequence a circular profile having a diameter substantially equal to the one of the bottom of the groove 42; 42'.

In the proximal direction, the clutch claws 7 are joined to the respective

brackets 8 through draft surfaces 7a.

Therefore, when the connection sleeve 3 is inserted into the connection hole 41; 41', a pressure is exerted on the respective draft surfaces 7a, which causes one or more clutch claws 7 to bend, until, once the locking position is reached, the clutch claws are then released within the groove 42; 42' making the two elements screw and plate or screw and nail integral with each other.

Moreover it must be noted how, in correspondence with the free end thereof, the brackets 8 provide release tabs 7b projecting compared to the related clutch claw 7. The four release tabs 7b, which define in sequence a circular profile having a smaller diameter than the one of the clutch claws 7, allow, as it will appear in the following description, the connection sleeves 3 to be disengaged from the respective connection holes 41; 41'.

With reference to the attached figures 13-17, a method for implanting an internal fixation system SP according to the second one of the above-outlined embodiments is now described.

Nevertheless, a person skilled in the art will have no difficulty in adapting the operations described hereafter also to the implantation of an internal fixation system SC according to said first embodiment.

In a first step of the method, illustrated in figure 13, the bone plate 40' is inserted in position on the bone 1000 – in this case a femur – of a patient, by means of a suitable first surgical guide 300, individually illustrated in figure 21.

It must be noted that this operation requires a single incision by the surgeon.

In a second step of the method, illustrated in figure 14, the position of the bone plate 40' is stabilized by means of threaded wires 400, one of which is individually illustrated in figure 24.

Threaded wires 400 are inserted in peripheral slots of the plate 40' and have a function of stabilizing the element only temporarily.

In a third step of the method, illustrated in figure 15, the guide wire 550 is

inserted, which will serve to direct the bone screw assembly 100. The guide wire 550, which reaches in the present example the femur acetabular head, is inserted by means of a second surgical guide 500, individually illustrated in figure 23, which rests on the previously-  
5 positioned first surgical guide 300.

The second surgical guide 300 is then removed.

In a fourth step of the method, illustrated in figure 16, the endosseous screw assembly 100 is inserted in position by means of the previously-implanted guide wire 550.

10 In a fifth step of the method, illustrated in figure 17, the previously-inserted endosseous screw assembly 100 is correctly stabilized by using a screwdriver 600, individually illustrated in figure 22.

It must be noted that, in order to correctly guide the screwdriver 600, the second surgical guide 500 can be used again.

15 During the screwing step, the threaded portion of the rod 1 digs into the bone site of the patient defining a progressive advance of the rod itself. The rod 1 slides into the connection sleeve 3 up to reach the limit stop position defined by the axial clamp 6. Afterwards, the further rod advance drags the connection sleeve 3 therewith, which slides into the connection  
20 hole 41' up to reach the locking position in which the clutch claws 7 are snap-inserted into the groove 42', defining the stabilization of the whole system.

The above-mentioned operations are obviously repeated for the second bone screw assembly 100 to be implanted.

25 In order to remove a bone screw assembly 100 from the housing thereof, a radial pressure must be applied inwards on the above-defined release tabs 7b.

30 That operation can be performed by the release instrument 700, operatively illustrated in figure 19. The release instrument 700, with a tubular shape, provides a proximal mouth 701, internally equipped with a conical draft 702 which stands above the release tabs 7b bending the brackets 8 and thus disengaging the clutch claws 7 from the groove 42;

42'. The conformation of the mouth of the release instrument 700 can be appreciated in figure 20.

Moreover, the tubular body of the release instrument 700 can house said screwdriver 600, so that the surgeon is able to drive the rod 1 in rotation  
5 keeping the release tabs 7b lowered.

By unscrewing the rod 1, it is removed from its position dragging the connection sleeve 3 therewith, no more constrained to the internal fixation member 40, 40'.

The complete removal of the endosseous screw assembly is thus realized.

10 A main advantage of the invention derives from the fact that, as illustrated in the above-described surgical method, the stable connection of the endosseous screw assembly to the plate or to the endomedullary nail of the internal fixation system is obtained by using a simple screwdriver: the operations is thus extremely easy and rapid.

15 Similarly, the removal of the endosseous screw assembly requires the use of a simple two-stage instrument, one of which is still the screwdriver.

A further advantage of the invention derives from the high stability of the connection screw/plate or screw/nail obtained. The bending is in fact discharged by the connection of the connection sleeve with the body of the  
20 plate or of the nail, while the torsion is discharged by the simultaneous use of two coplanar screws.

Moreover, the great contact surface between the connection sleeve and the screw rod reduces the specific on-load contact pressure removing the risk of impingement present in other prior art devices.

25 Obviously, a person skilled in the art can bring several changes and alternatives to the above-described devices, in order to meet incidental and specific requirements, moreover all falling within the scope of protection of the invention as defined by the following claims.

## CLAIMS

1. An endosseous screw assembly (100) for an internal fixation system (SC; SP), comprising:

5 a rod (1) extending longitudinally and provided with at least one threaded proximal portion (2) to allow the anchorage to a bone site of a patient;

a connection sleeve (3), into which at least one portion of the rod (1) is slidingly guided in the axial direction, said connection sleeve (3) being arranged to be inserted into a connection hole (41; 41') of an internal fixation member (40; 40') by snap-connecting within said connection hole  
10 (41; 41') up to reach a locking position;

characterized in that said rod (1) and said connection sleeve (3) comprise mutual engagement means (6) suitable form an axial constraint to the sliding of the rod (1) into the connection sleeve (3), so as to define, when the threaded proximal portion (2) advances into the bone site of the  
15 patient, a dragging of the connection sleeve (3) into the connection hole (41; 41') up to reach the locking position.

2. An endosseous screw assembly (100) according to claim 1, wherein said mutual engagement means comprise an axial clamp (6) defined by a variation of the diameter of the rod (1), said axial clamp (6) being arranged  
20 to stop the connection sleeve (3) in a limit stop position compared to the rod (1).

3. An endosseous screw assembly (100) according to claim 2, wherein said axial clamp (6) cooperates in abutment with an internal conformation element of the connection sleeve (3), so that in the limit stop position the  
25 distal end of the rod (1) is contained in the connection sleeve (3).

4. An endosseous screw assembly (100) according to one of the previous claims, wherein said rod (1) provides, in correspondence with the distal end thereof: a sunken housing (9) to allow the connection with a screwing instrument; and an internal thread (15), which allows the  
30 possible connection of a syringe, a piston or a screw for the removal.

5. An endosseous screw assembly (100) according to one of the

previous claims, wherein said rod (1) is cannulated, i.e. it provides an axial passage connecting a distal opening (11) to a proximal opening (10) of the rod (1).

5 6. An endosseous screw assembly (100) according to claim 5, comprising moreover one or more radial holes (12) which put the axial passage in communication with the external surface of the threaded proximal portion (2).

10 7. An internal fixation system (SC; SP) comprising at least one endosseous screw assembly (1) according to one of the previous claims, said internal fixation system comprising moreover at least one internal fixation member (40; 40') equipped with at least one connection hole (41; 41') arranged to house the connection sleeve (3) of said endosseous screw assembly (1); snap-connection means (7, 42; 42') being arranged to ensure the stable connection of the connection sleeve (3) within the connection  
15 hole (41; 41').

8. An internal fixation system (SC; SP) according to claim 7, wherein said snap-connection means (7, 42; 42') comprise a clutch claw (7) and a groove (42; 42'), said clutch claw (7) being arranged to snap-connect within said groove (42; 42'), said clutch claw (7) and said groove (42; 42')  
20 being obtained on the connection sleeve (3) and on the connection hole (41; 41') respectively, or vice versa.

9. An internal fixation system (SC; SP) according to claim 8, wherein said clutch claw (7) is supported by a flexible bracket (8) tangentially oriented compared to the rod (1) or to the connection hole (41; 41'), so as  
25 to allow the clutch claw (7) to elastically move in the radial direction.

10. An internal fixation system (SC; SP) according to claim 9, wherein said clutch claw (7) has a slanting draft surface (7a) which joins the flexible bracket (8) to the tip of the clutch claw (7).

30 11. An internal fixation system according to one of claims 9 or 10, wherein said flexible bracket (8) has, in correspondence with the free end thereof, a release tab (7b) axially projecting compared to the clutch claw (7), said release tab (7b) being able to cooperate with a release instrument (700) to disengage the connection sleeve (3) from the connection hole (41;

41').

12. An internal fixation system according to one of claims 9-11, wherein the flexible bracket (8) and the related clutch claws (7) are a plurality, circumferentially arranged around an end portion of the connection sleeve (3); the groove (42; 42') being obtained on the connection hole (41; 41').

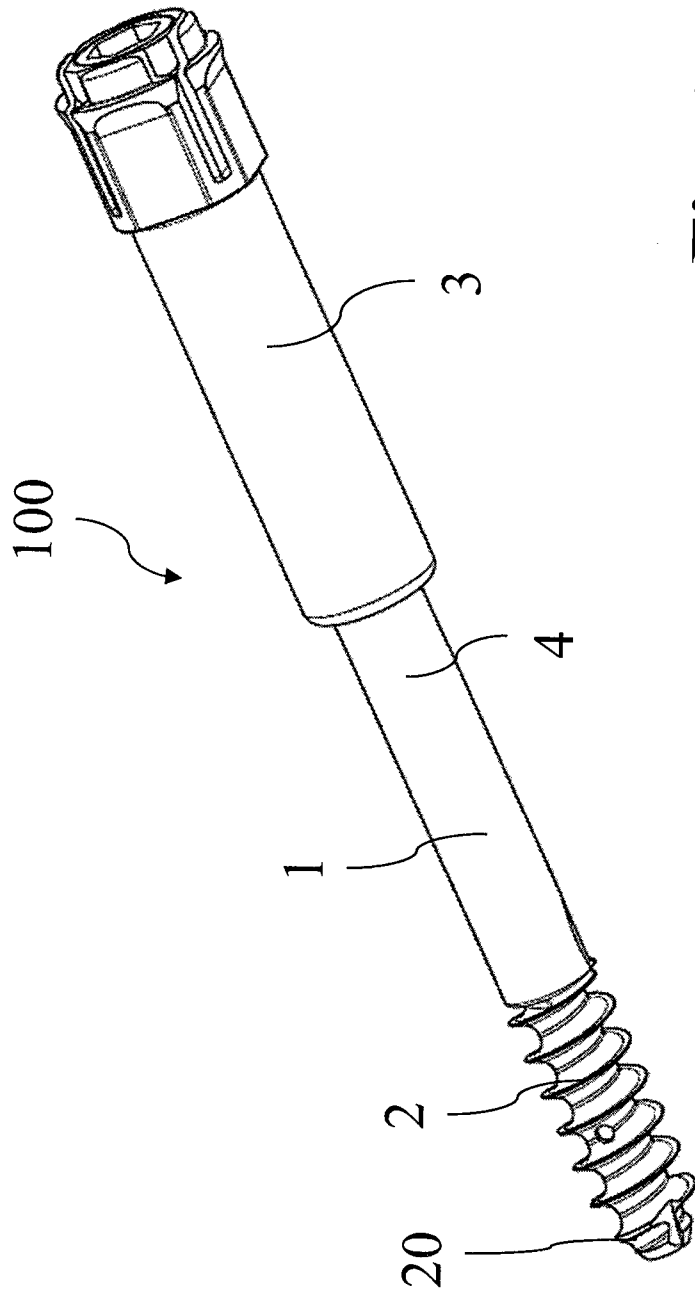
13. An internal fixation system according to one of claims 7-12, wherein said connection hole (41; 41') has following portions of different diameter, the connection sleeve (3) having externally a proximal cylindrical portion (13) and a distal collar (14); said proximal cylindrical portion (13) being slidingly guided into the smaller diameter portion of the connection hole (41; 41'), the snap-connection means (7, 42; 42') being arranged in correspondence with the greater diameter portion of the connection hole (41; 41') and of the distal collar (14) of the connection sleeve (3).

14. An internal fixation system according to claim 13, wherein the following portions of different diameter of the connection hole (41; 41') define a shoulder (43; 43'), said distal collar (14) abutting against said shoulder (43; 43') in the locking position of the connection sleeve (3).

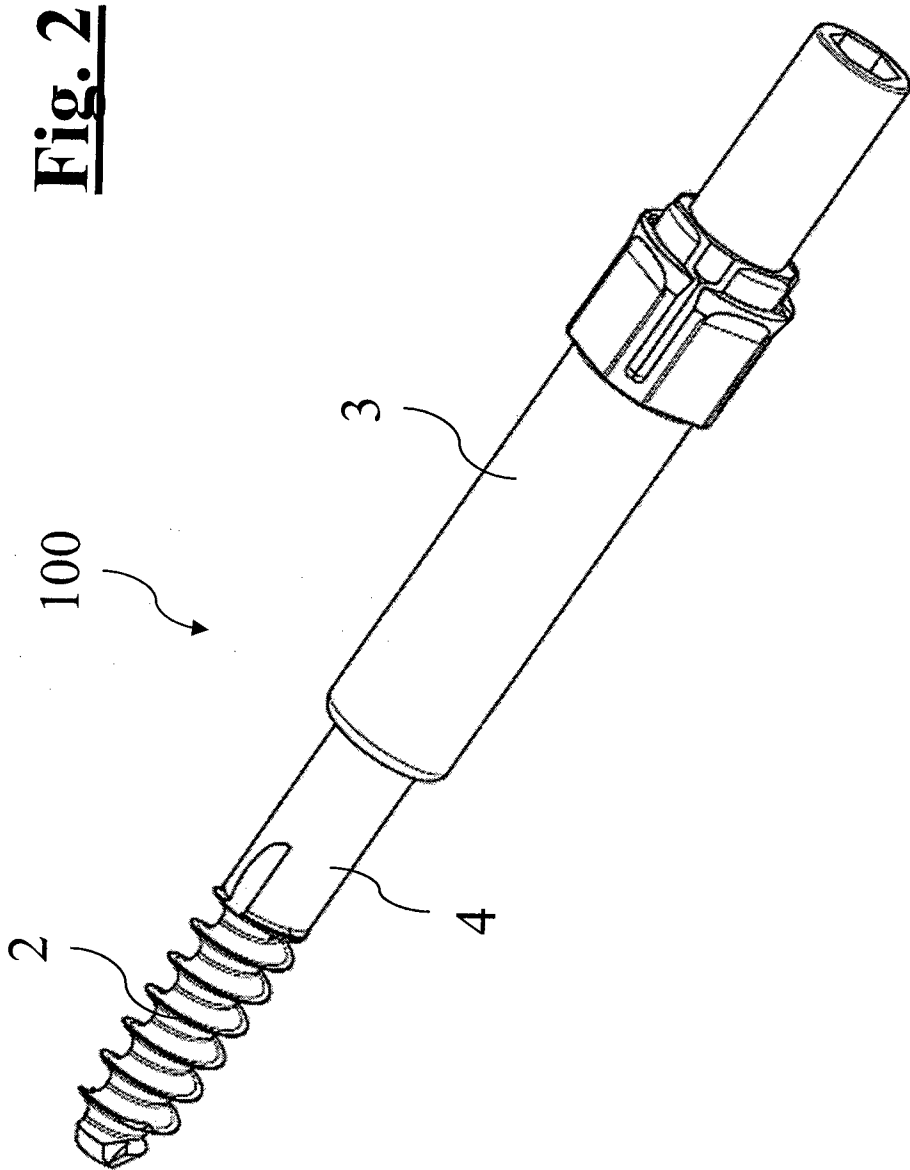
15. An internal fixation system (SC, SP) according to one of claims 7-14, comprising at least two endosseous screw assemblies (1) arranged to be fixed parallel to each other into two corresponding connection holes (41; 41') of the internal fixation member (40; 40').

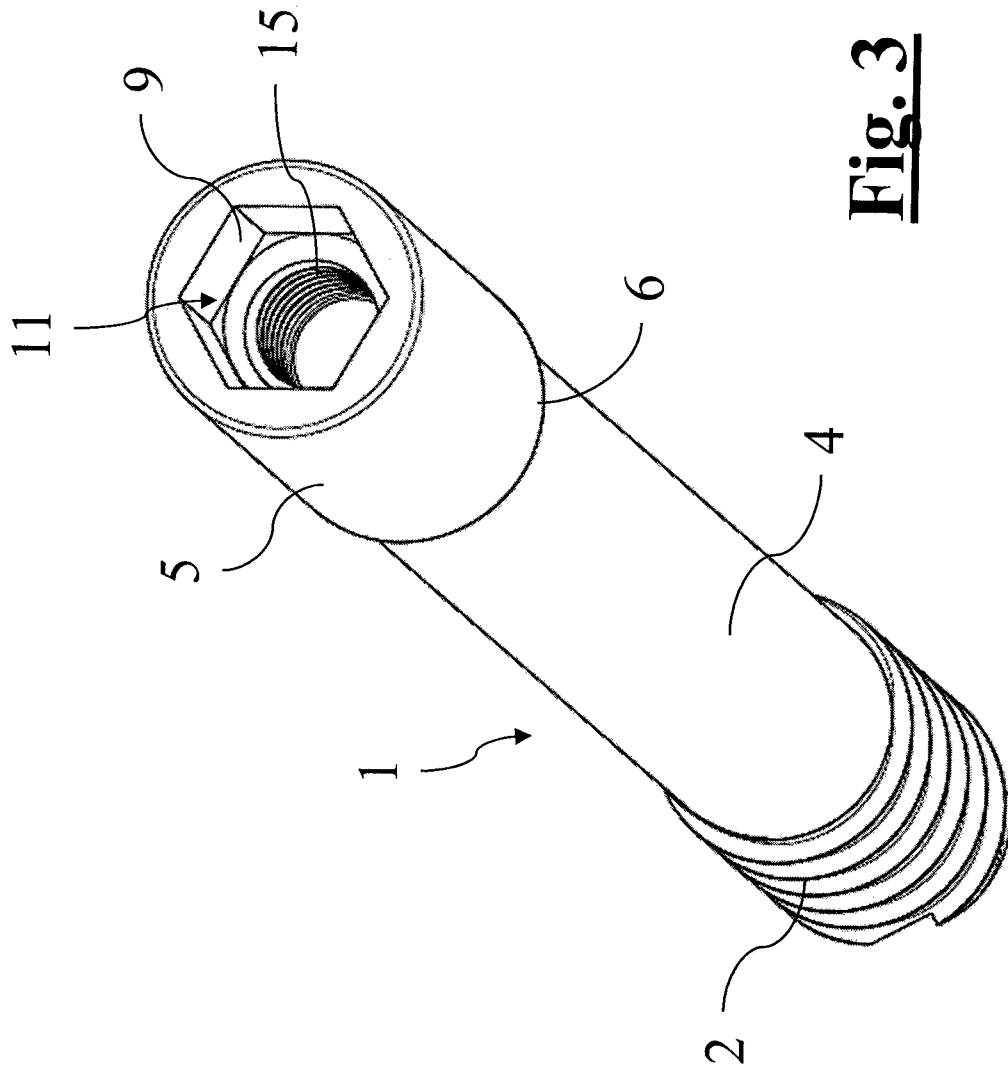
16. An internal fixation system (SC) according to one of claims 7-15, wherein said internal fixation member is an endomedullary nail (40) or a bone plate (40').

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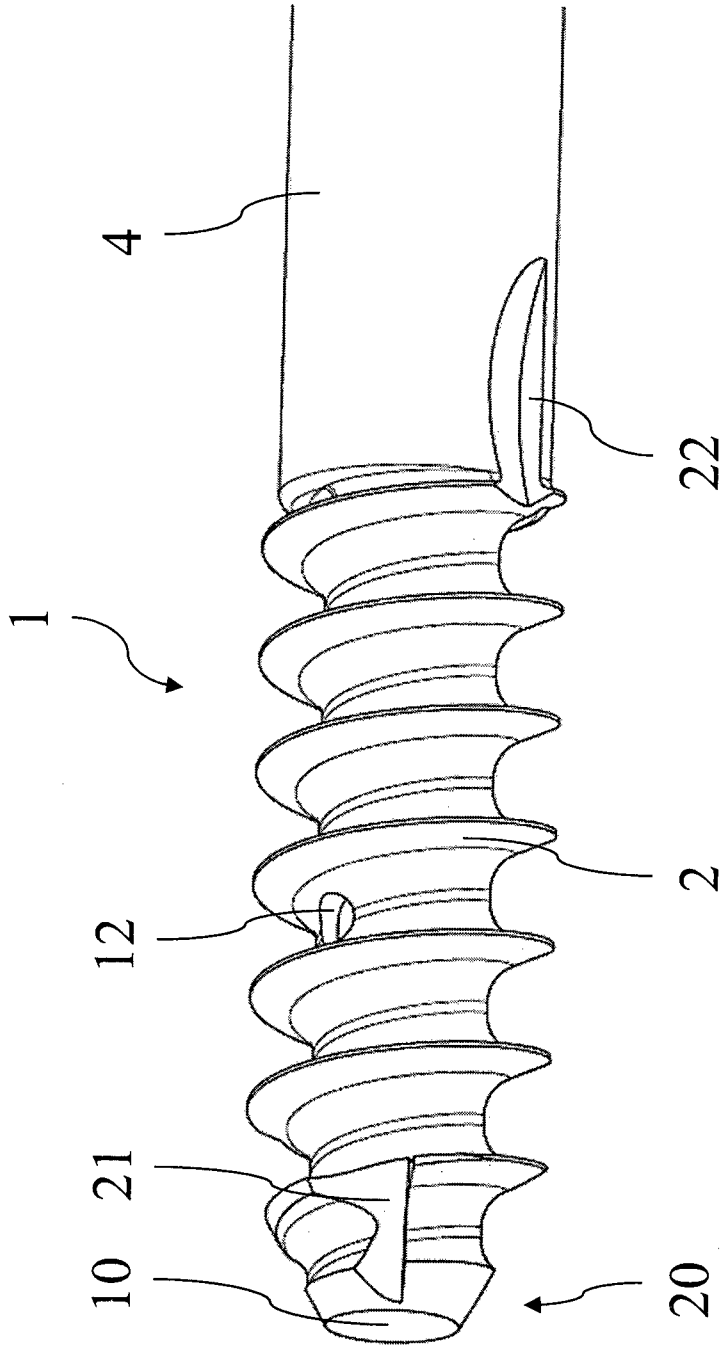


**Fig. 1**

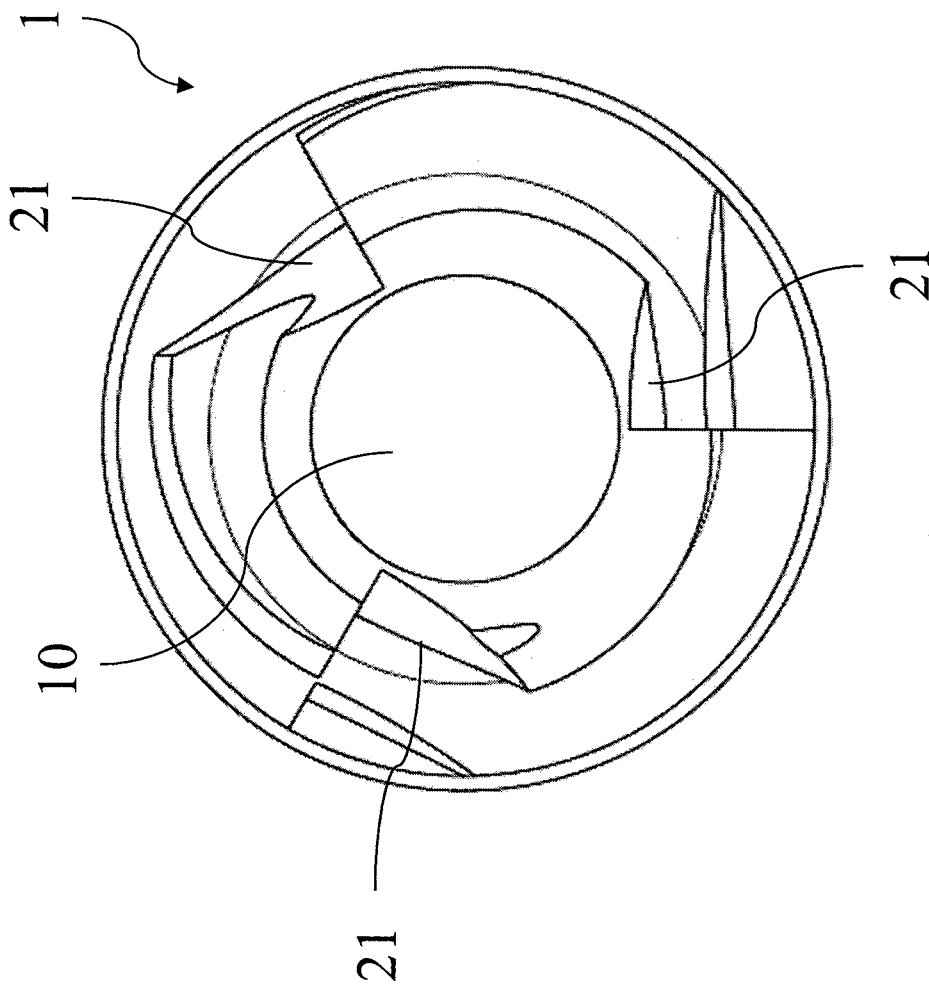




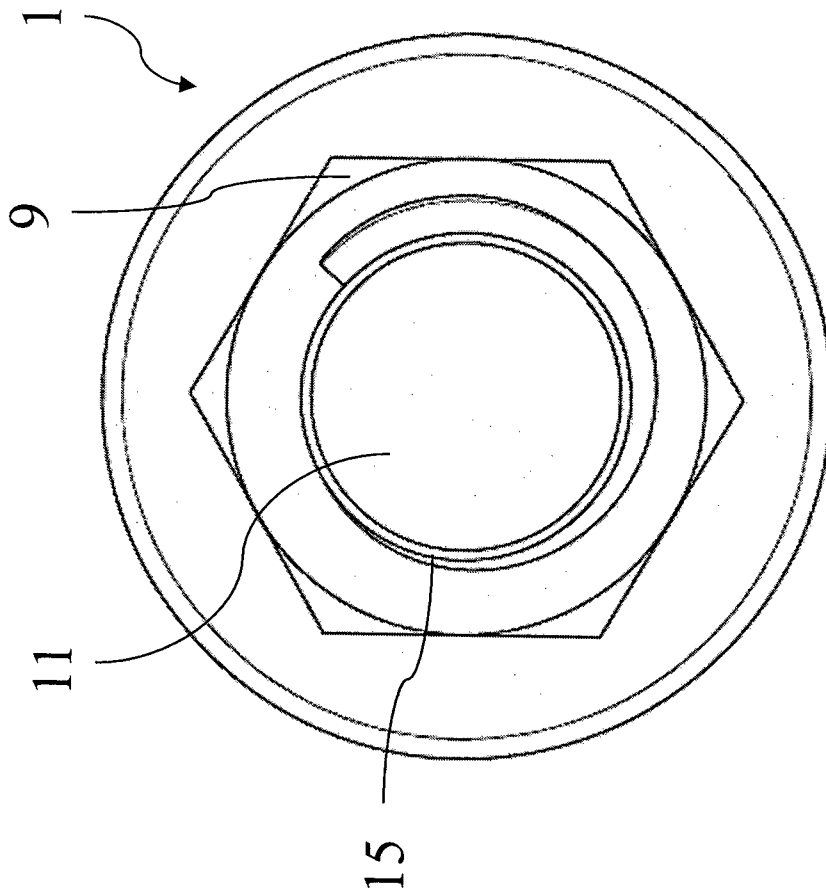
**Fig. 3**



**Fig. 4**

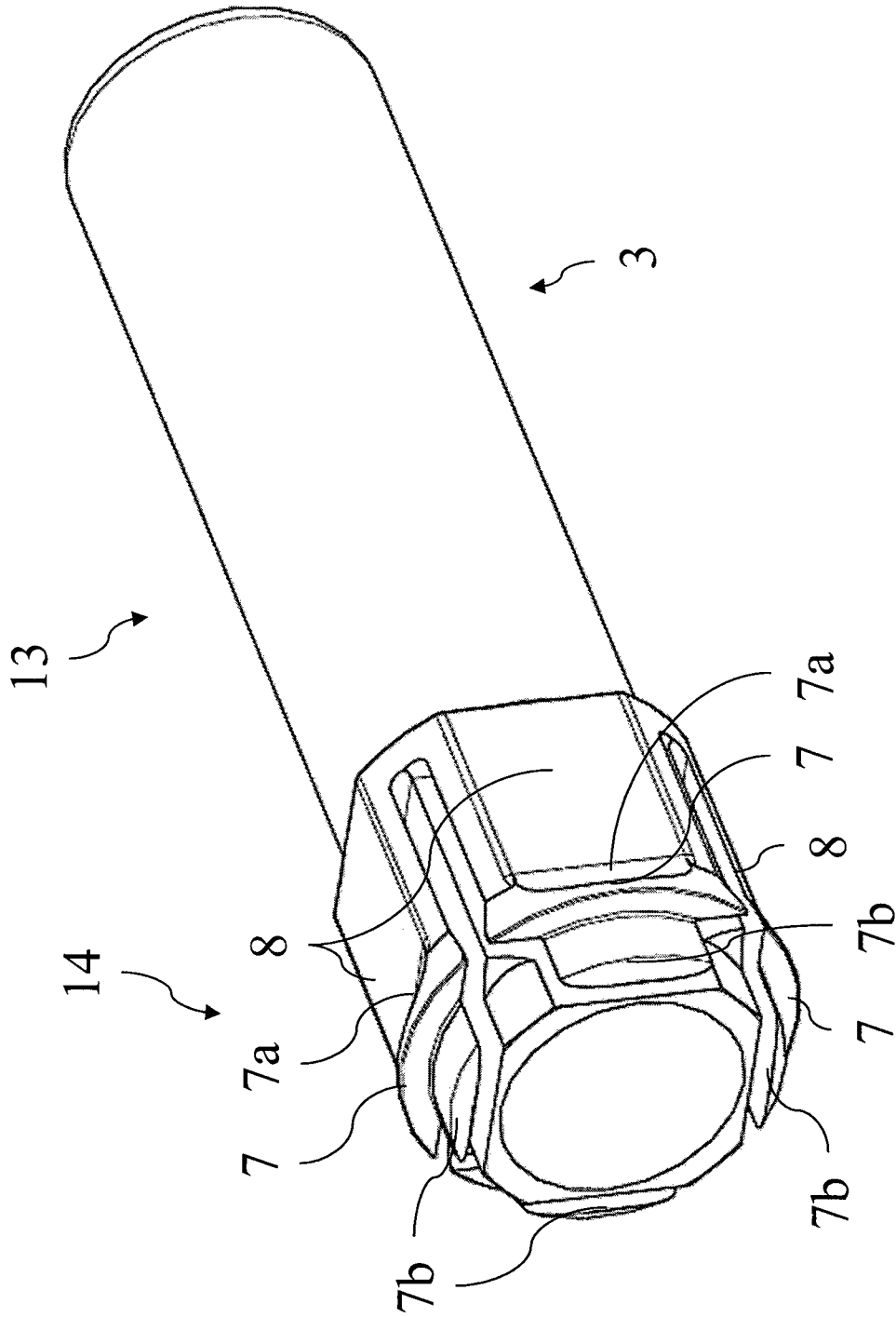


**Fig. 5**

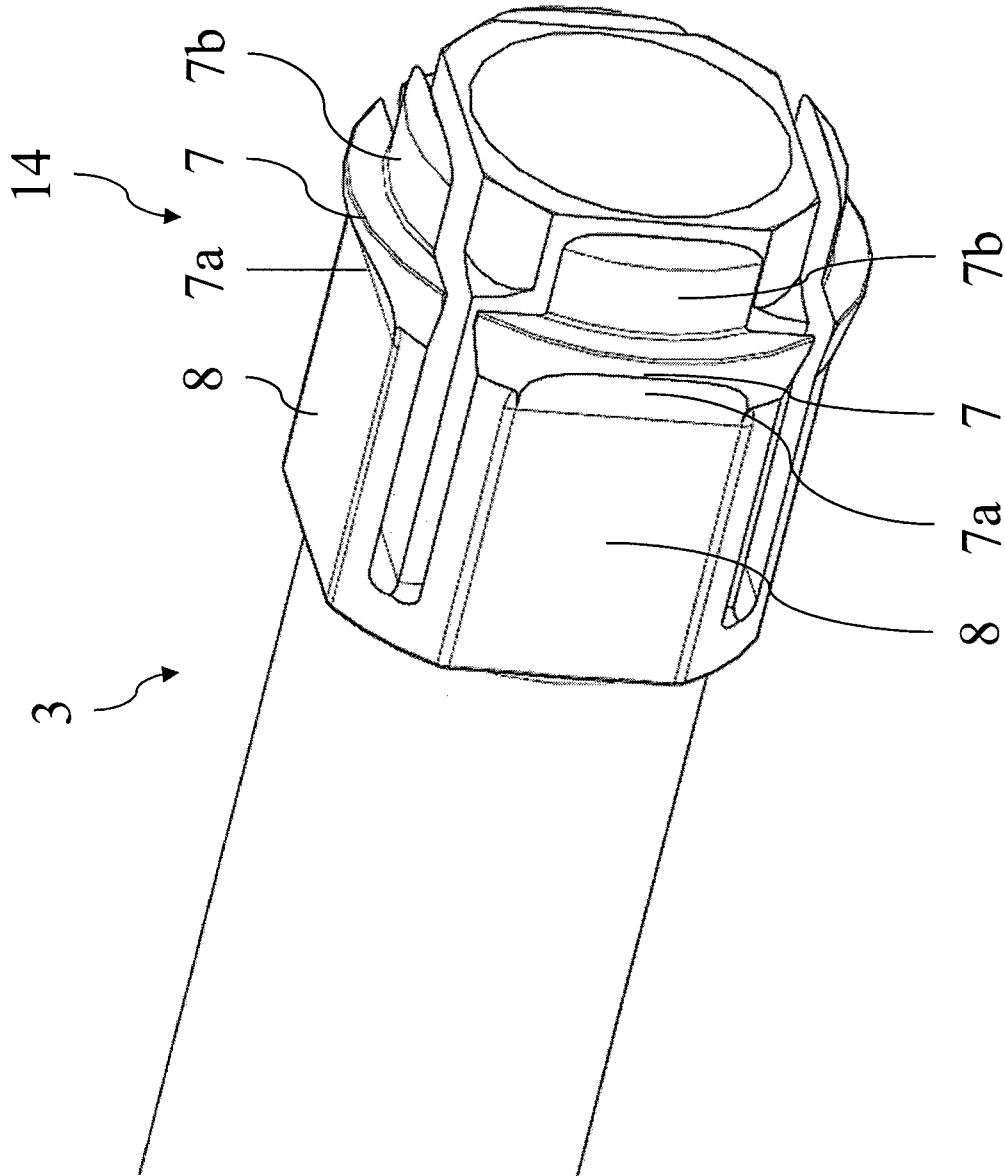


**Fig. 6**

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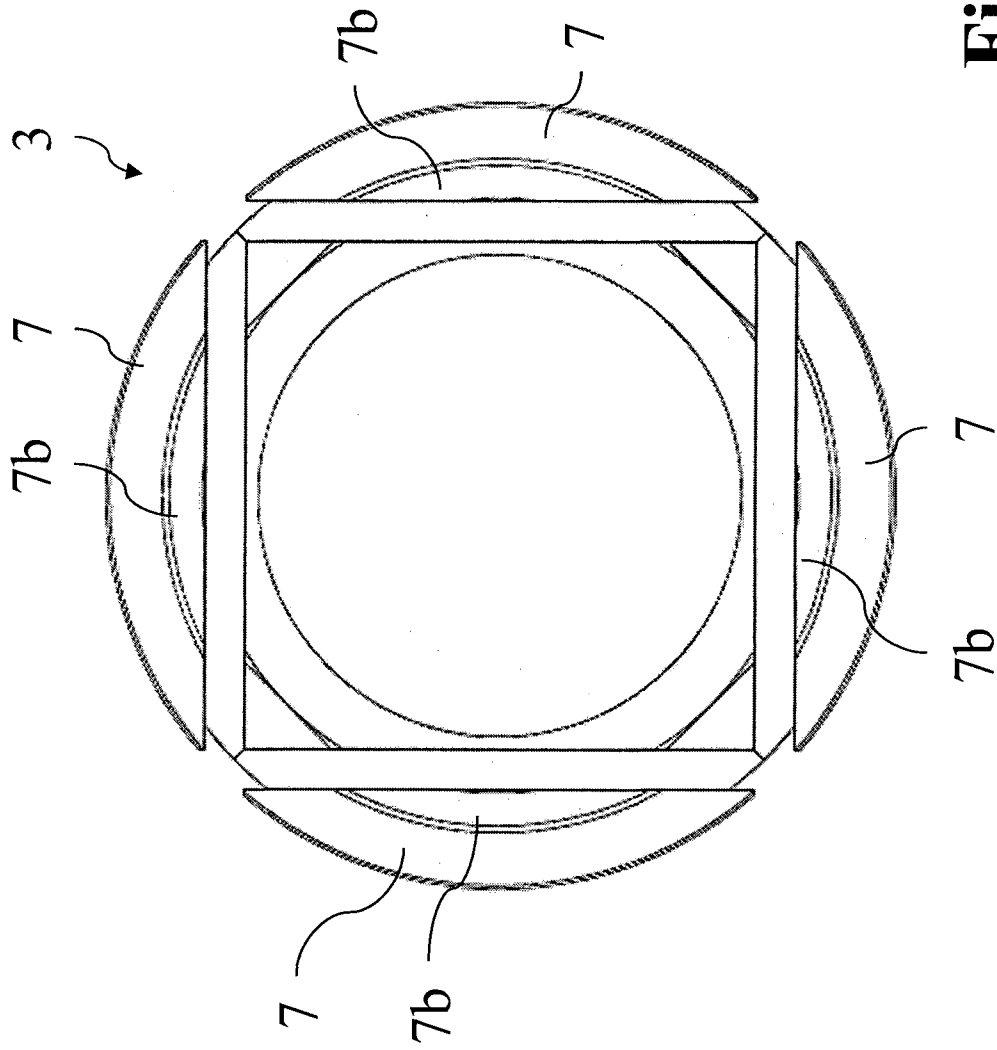


**Fig. 7**



**Fig. 8**

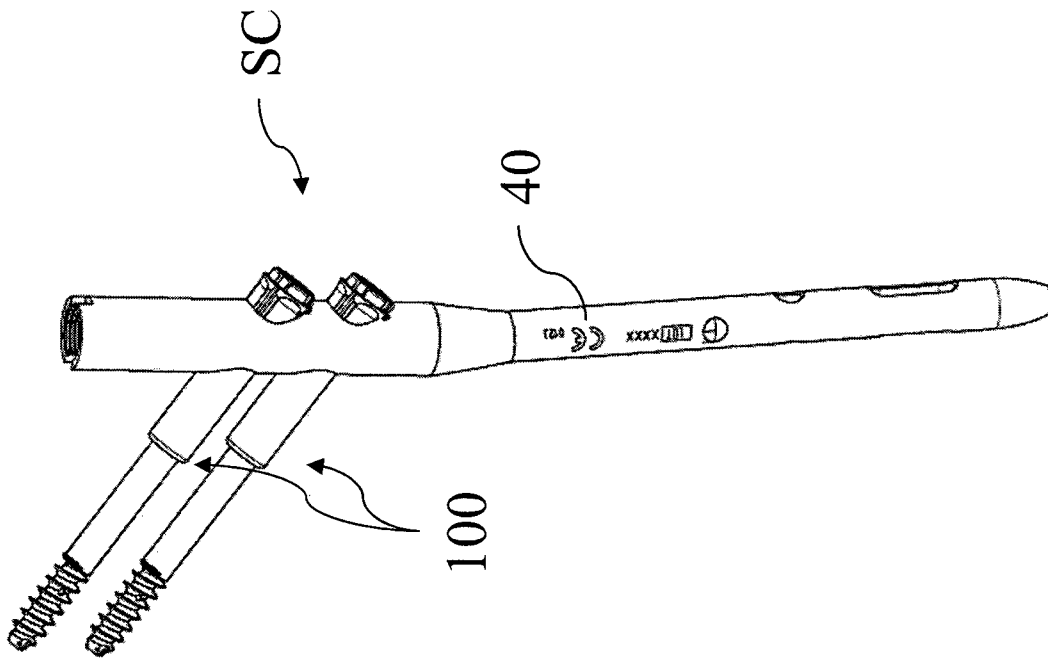
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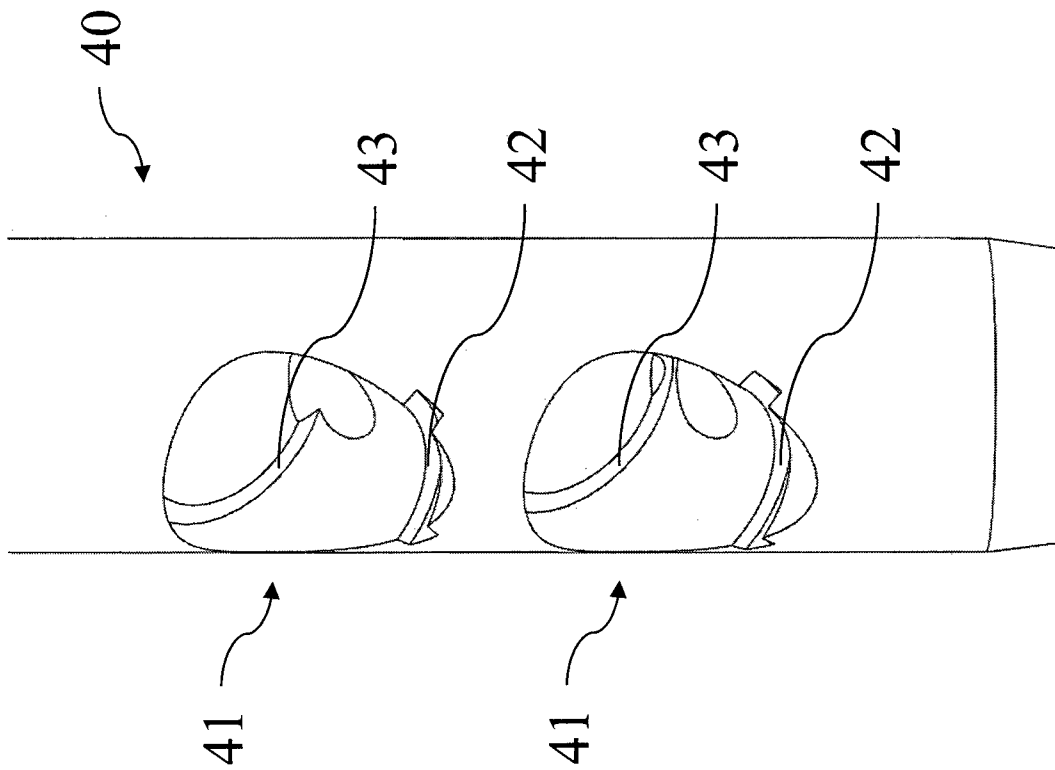
**Fig. 9**

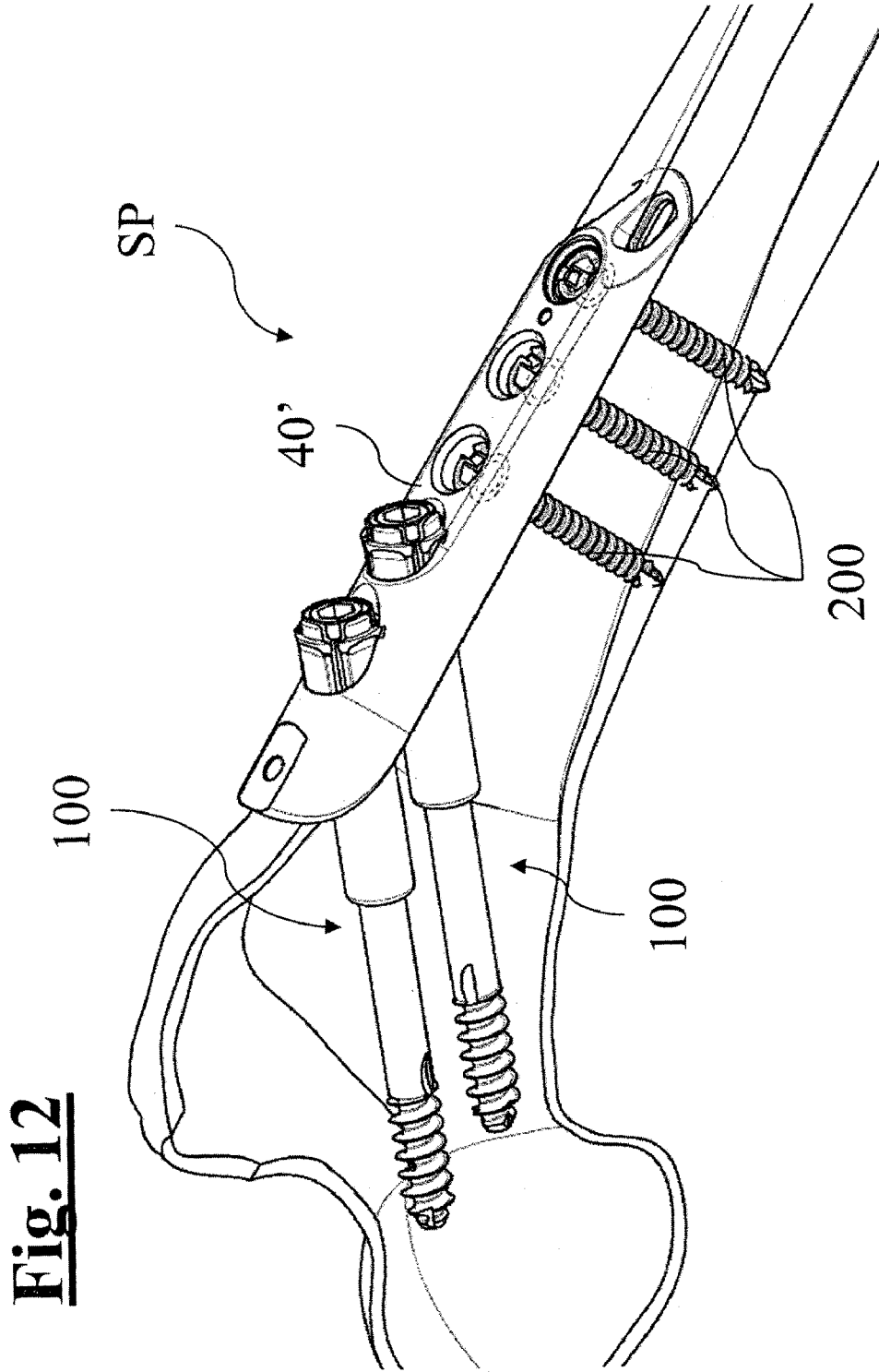
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**Fig. 10**

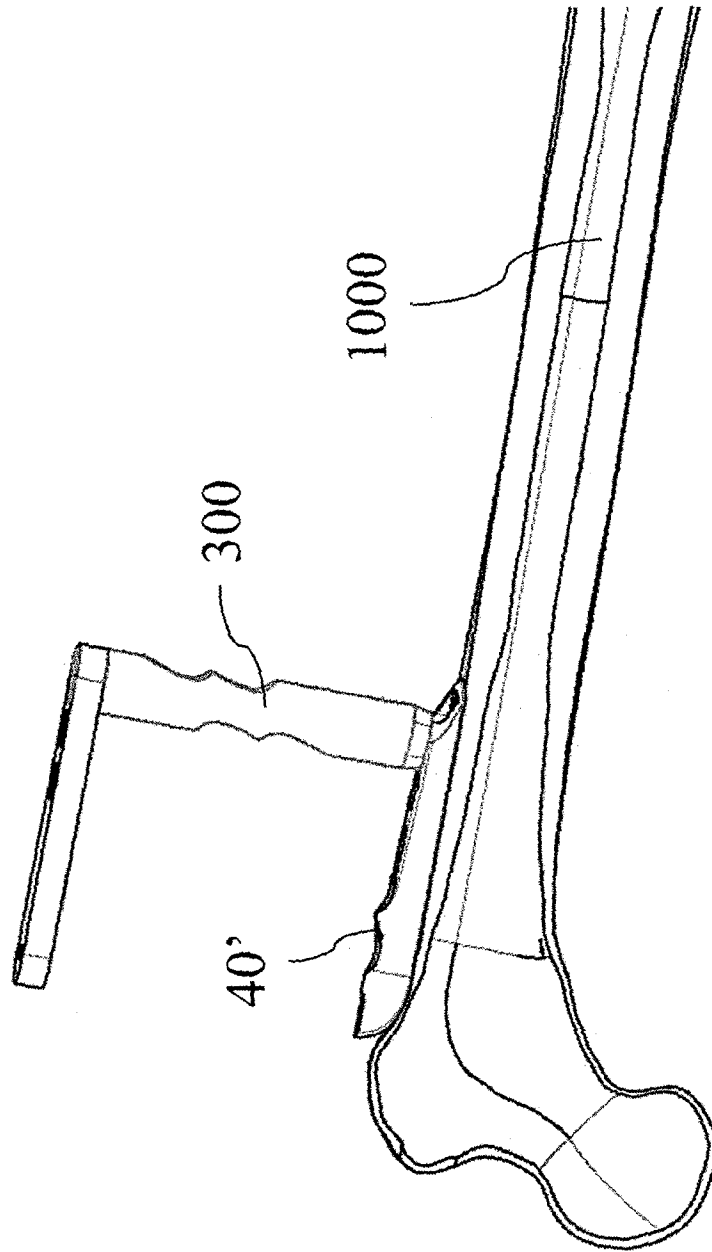


**Fig. 11**



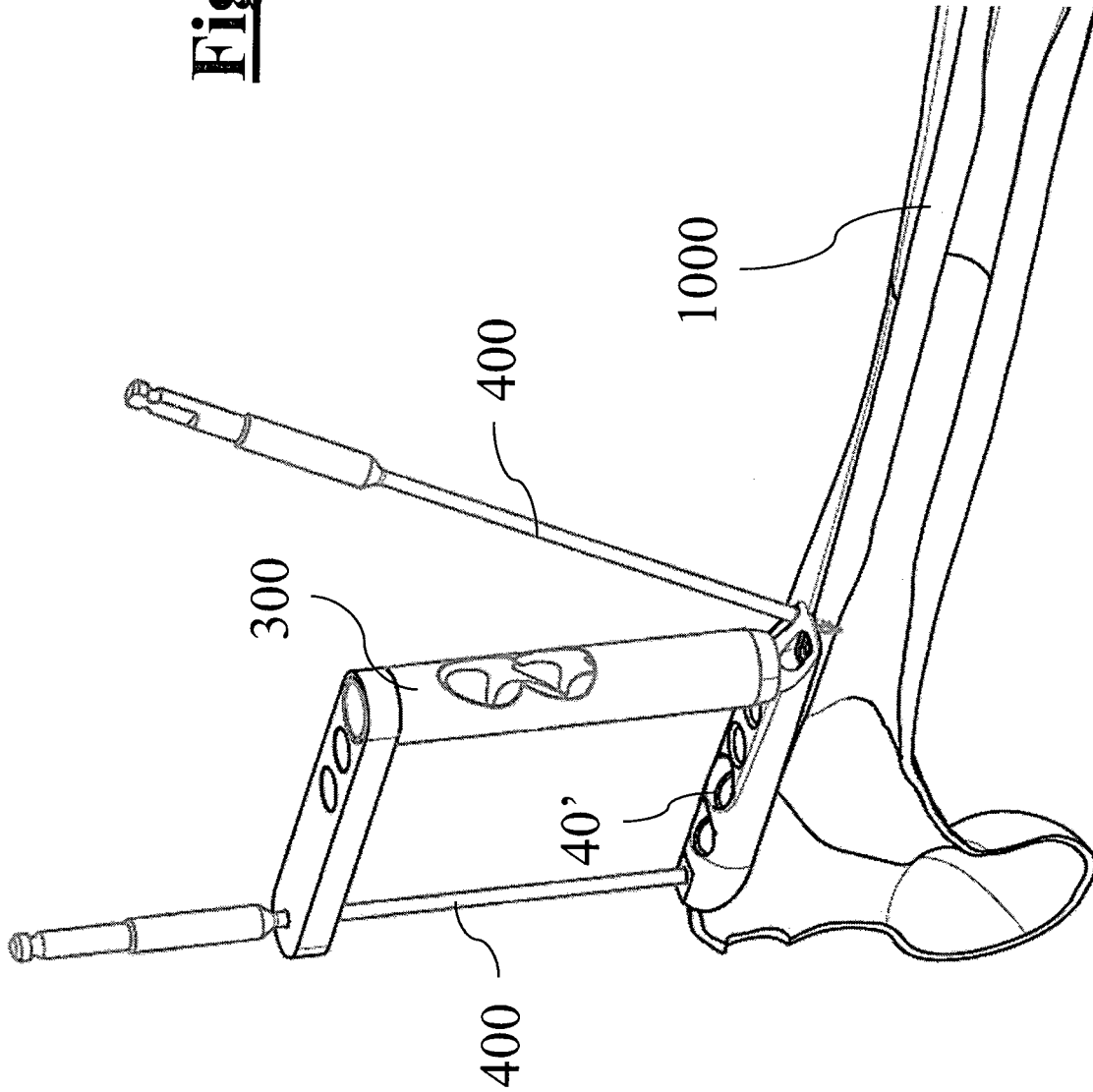


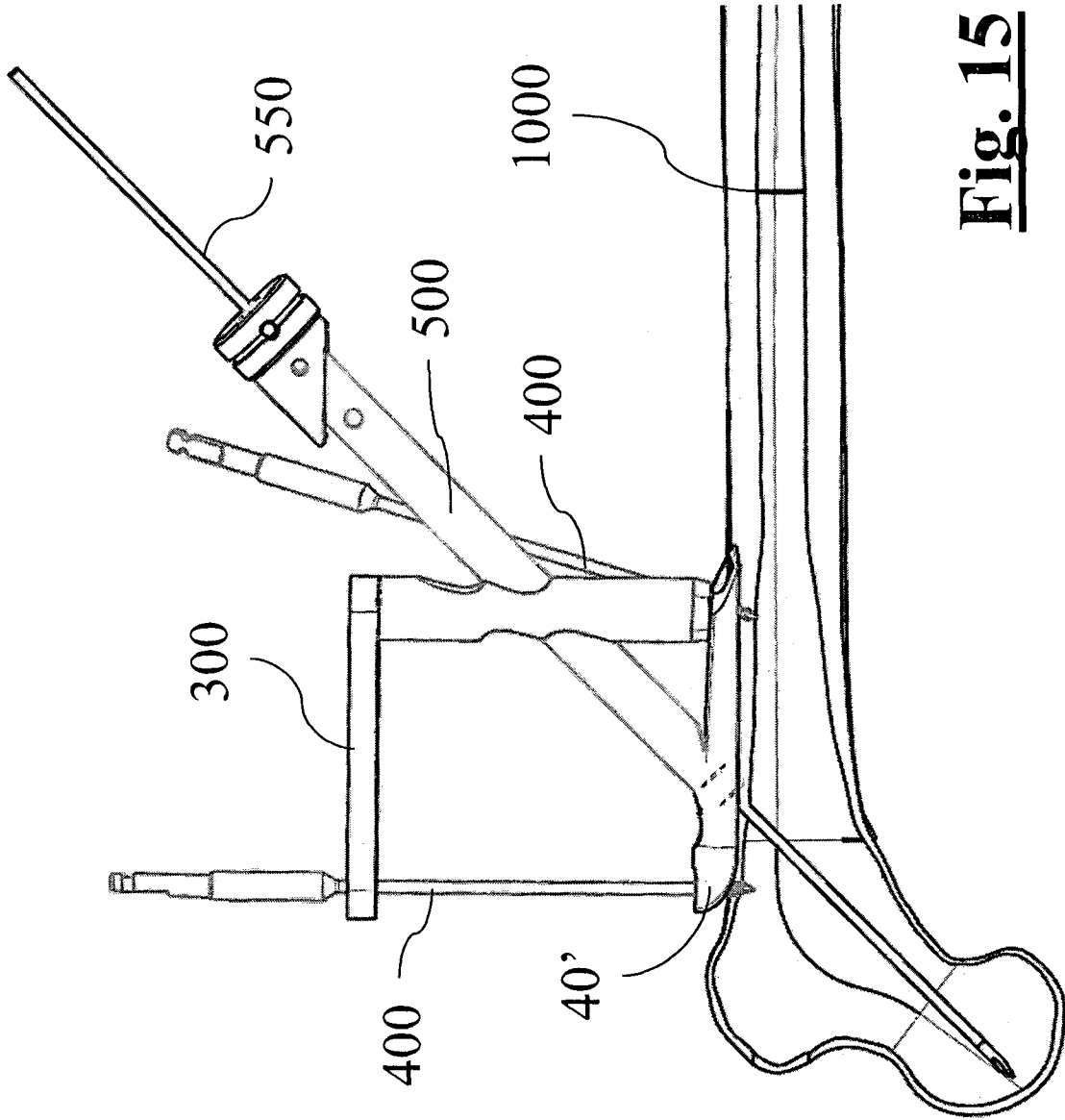
**Fig. 12**



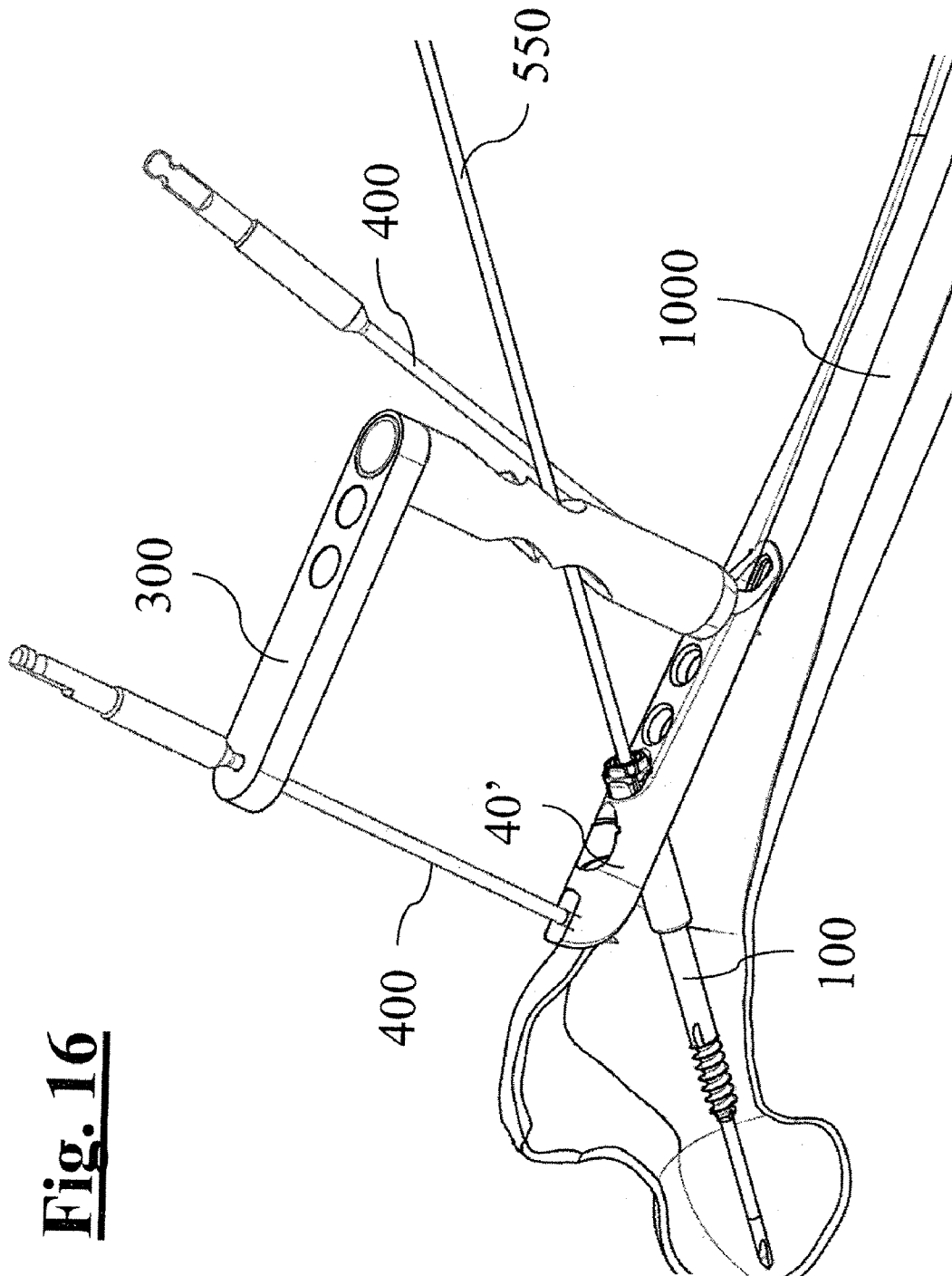
**Fig. 13**

**Fig. 14**

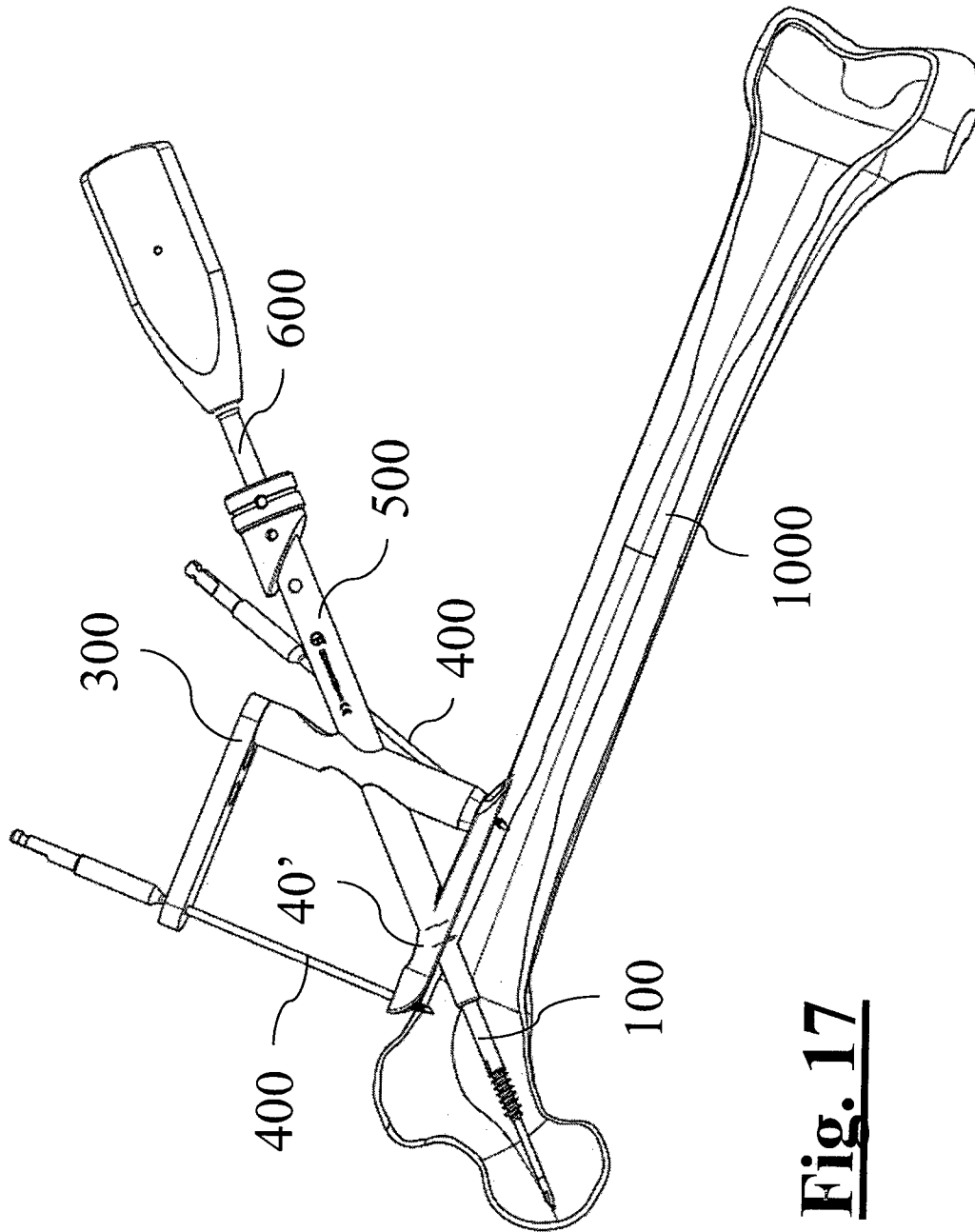




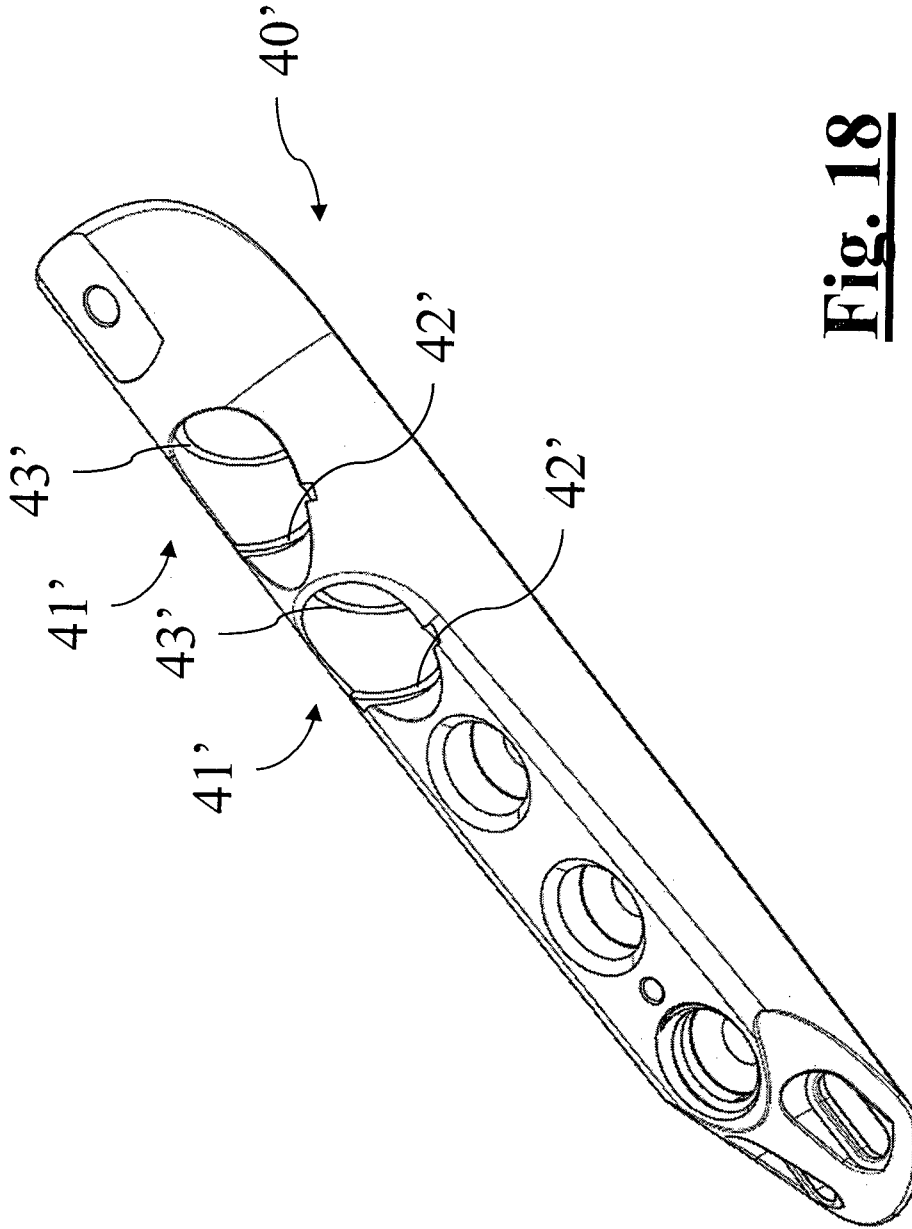
**Fig. 15**



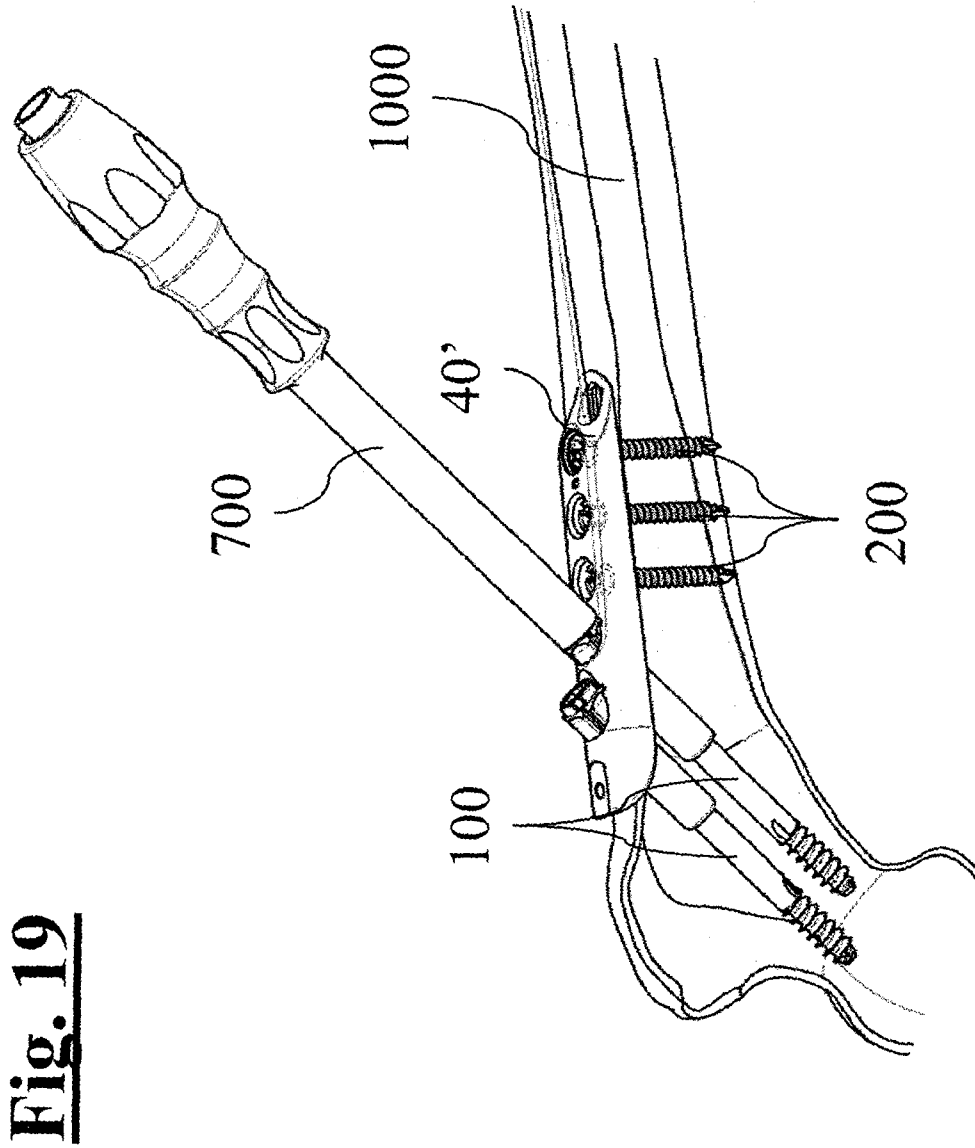
**Fig. 16**



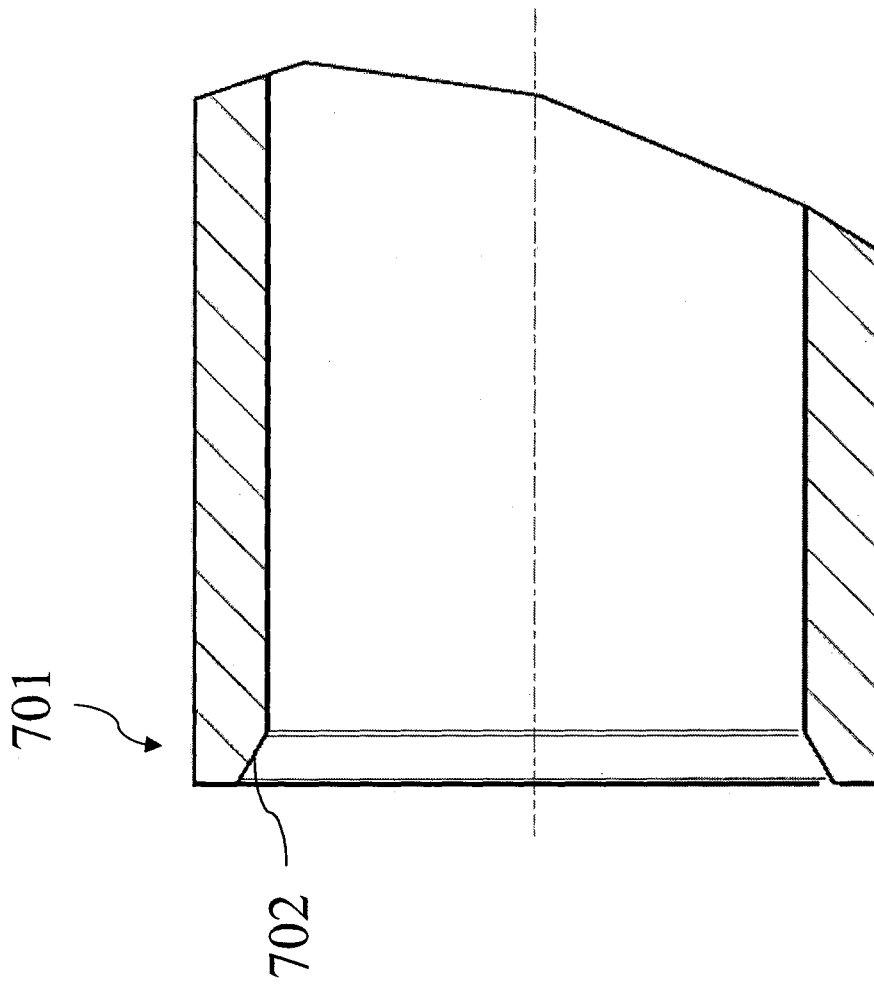
**Fig. 17**



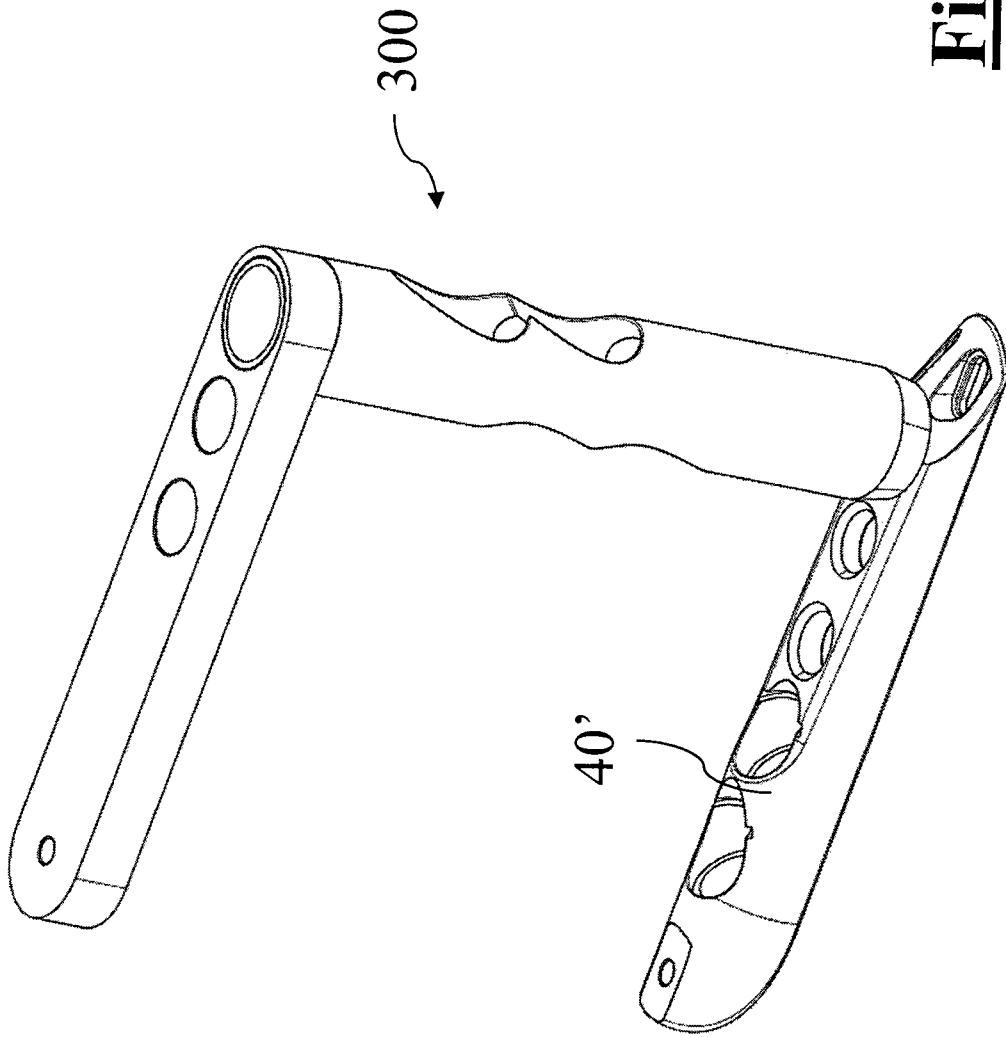
**Fig. 18**



**Fig. 19**

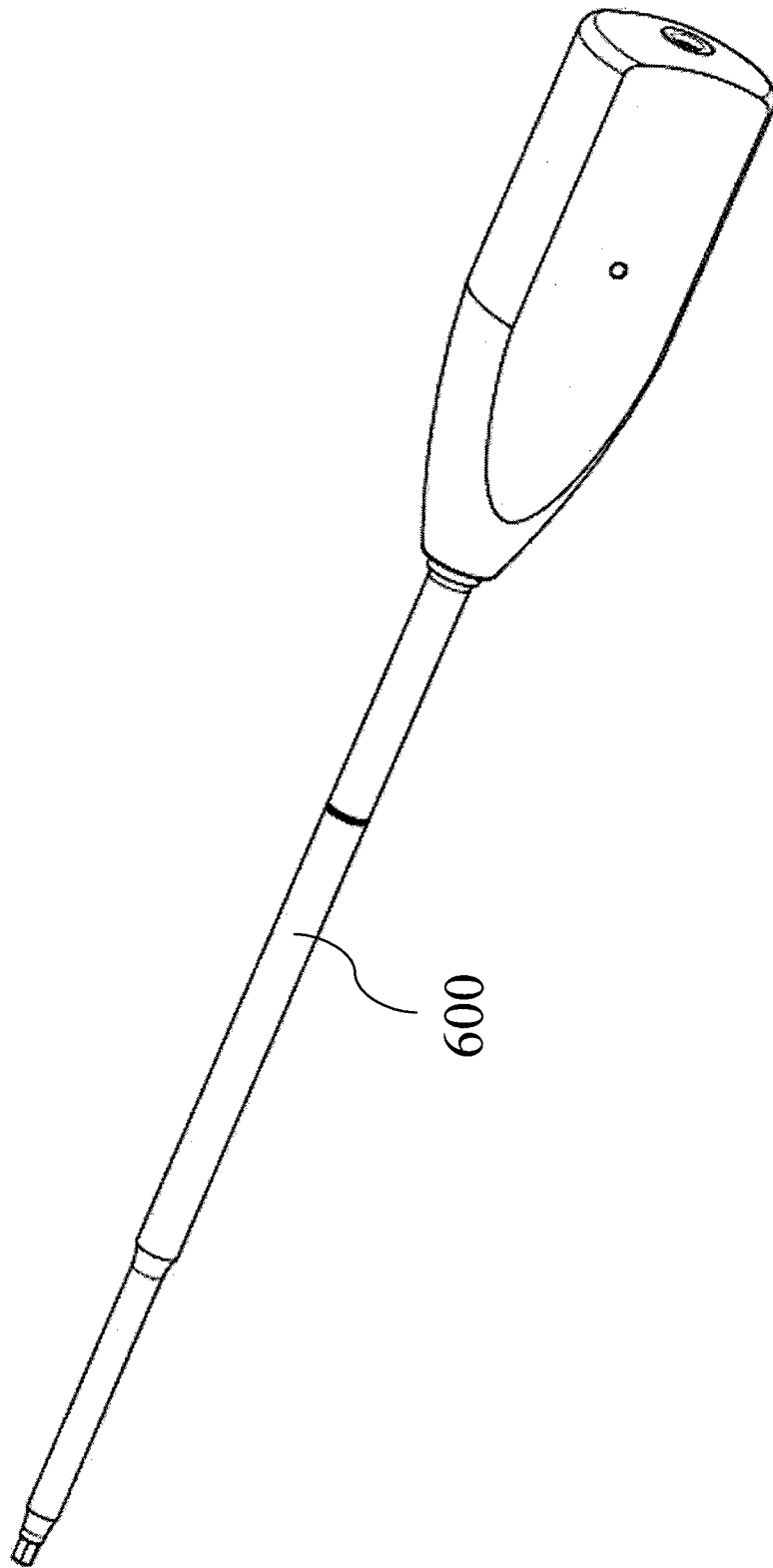


**Fig. 20**



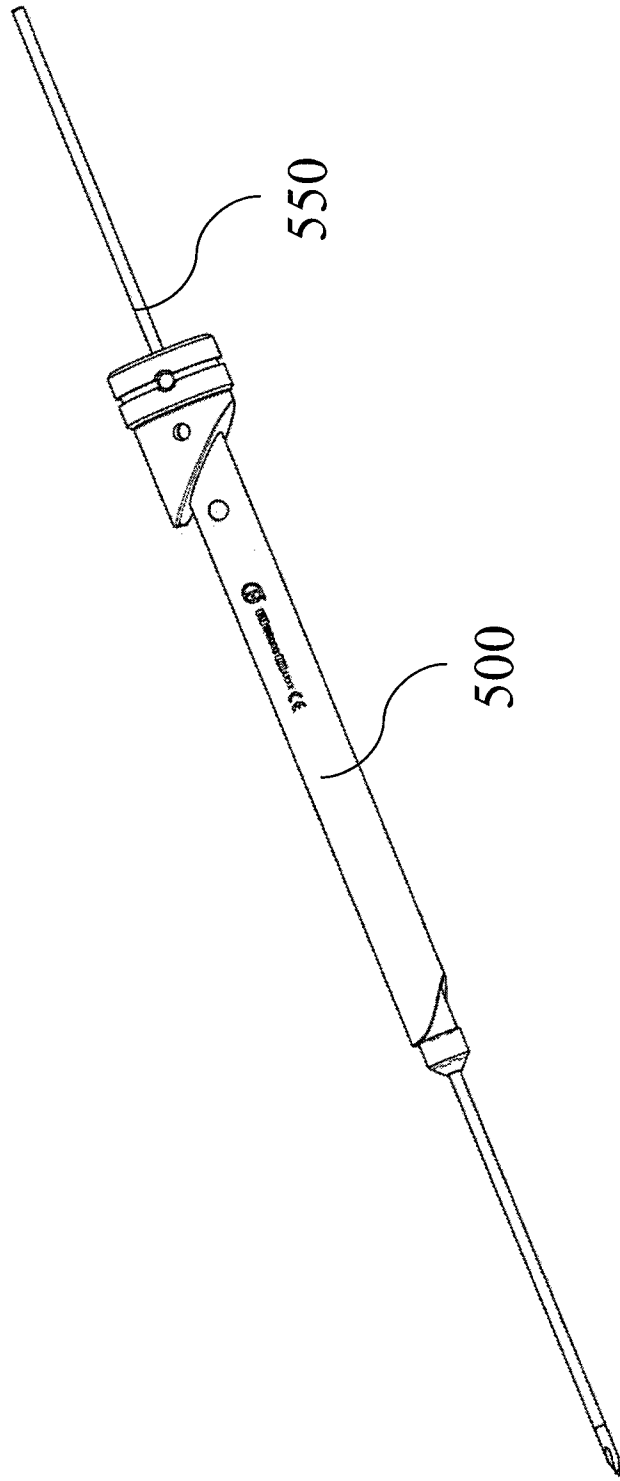
**Fig. 21**

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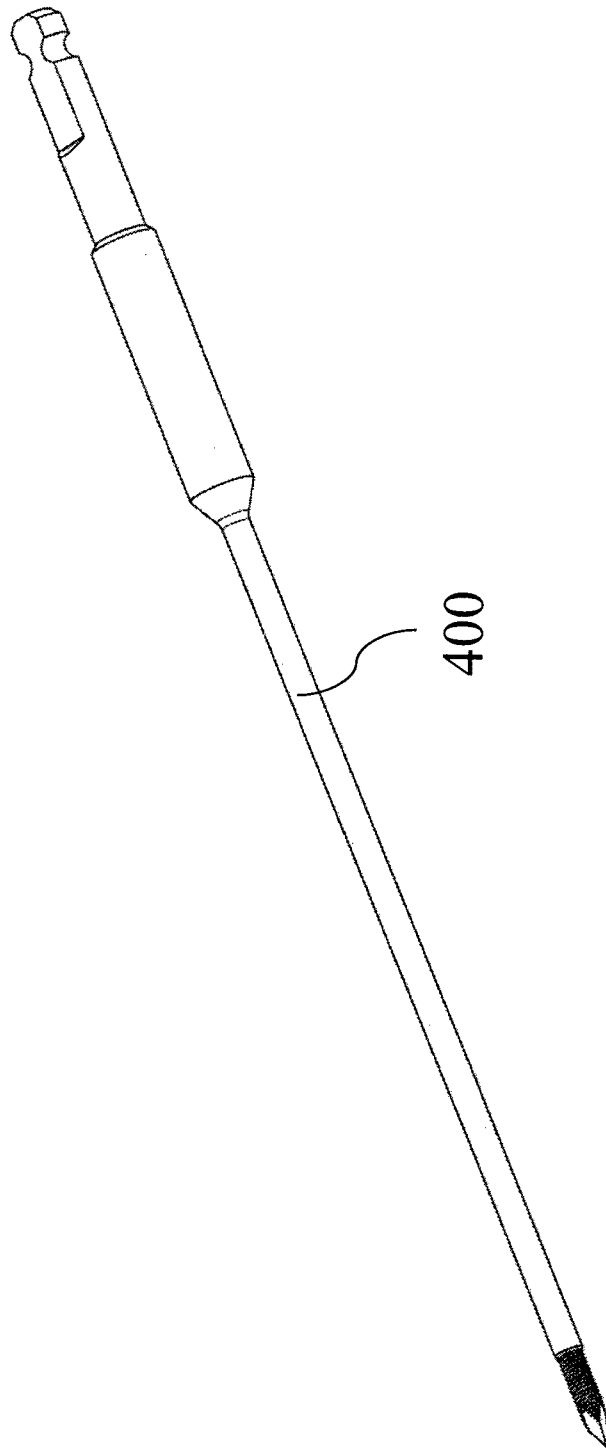
**Fig. 22**

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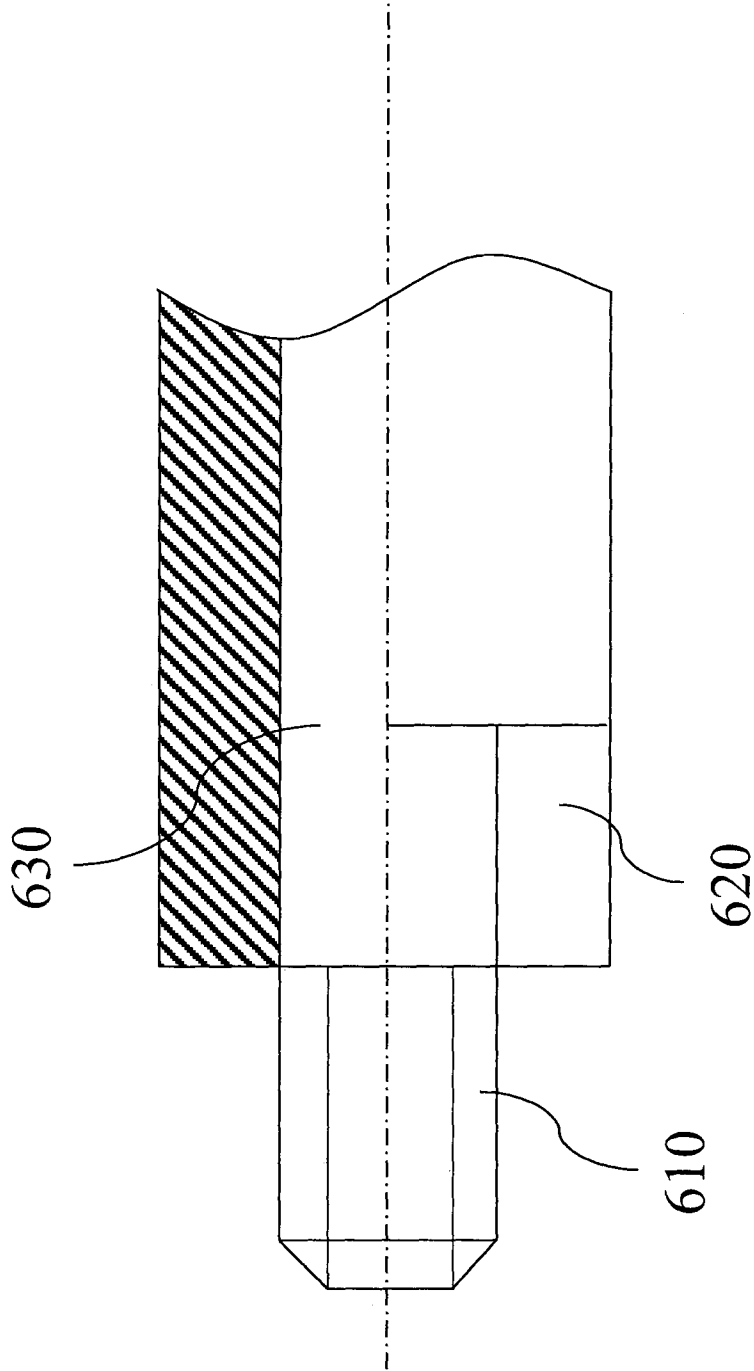


**Fig. 23**

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**Fig. 24**



**Fig. 25**