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(56) Related Art
US 2004/0267265
US 5171279
US 7335205
US 2004/0138662

20102010014 16 Mar 2010

SONIC SCREW

Abstract

A screw (10) for fixation of a fracture includes a hollow shaft, a first outer thread (12) and radial openings (17) at its distal end, and a second outer thread (14) and an inner engagement portion (18) at its proximal end. The second outer thread (14) is adapted to engage with a tissue protection sleeve (30). The inner engagement portion (18) is adapted to fit to a driving end (42) of a driving tool (40). By way of this, forces in axial or radial direction may be applied to the screw (10) by the sleeve (30), and forces in rotational direction may be applied by the driving tool (40).

Fig.3

2010201014 16 Mar 2010

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PATENTS ACT 1990

COMPLETE SPECIFICATION

FOR A STANDARD PATENT

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Invention Title:	Sonic screw

The following statement is a full description of this invention, including the best method of performing it known to me/us:

2010201014 16 Mar 2010

Sonic screw

BACKGROUND OF THE INVENTION

The invention relates in general to sonic fusion technology. It relates more particularly to a screw and a method for the fixation of fractures. The invention relates to a screw for augmenting within a fractured object, to a set including tools to implement the screw into the fractured object, as well as to the use of the mentioned set. The fractured object might be a bone or a wooden or plastic object like furniture.

Known from US patent 4, 653,489 is a system wherein a fixation cement is introduced through a screw into a portion of a bone afflicted by osteoporosis. Femoral neck fractures as well as distal femoral fractures can be fixated by means of this device.

The system in accordance with prior art comprises a screw having a flow cavity, i.e. an axial through bore through with bone cement can be introduced into the portion at the tip of the screw. The bone cement is advanced by a device which is releasably attached to the subsequent end of the screw. This device is similar to commercially available syringe, in comprising substantially a cylindrical barrel and a plunger. The barrel forms a cavity in which the plunger is moveable backwards and forwards.

20102010014 12 Jul 2011

In use of this prior art device, the fixation cement is filled into the barrel, after which the plunger is urged against the cement. By applying manual compression force, the fixation cement is jetted into the axial through bore of the screw. Due to the pressure, the fixation cement is adequately fluidized, so that it can pass through the proximal end of the screw into the bone, as a result of which the screw is augmented in the bone.

This system has the drawback that the manual pressure applied to the fixation cement varies, not only basically from application to application, but also during the application itself, so that the distribution of the fixation cement within the portion of the bone at the tip of the screw is neither reliable nor even.

A device for fixing bone fractures is shown in U.S. Patent Application Publication No. 2009/0018590 the disclosure of which is incorporated herein by reference. A device for applying ultrasonic energy to a screw is shown in U.S. Patent Application Publication No. 2009/0018471 the disclosure of which is incorporated herein by reference. As shown in FIG. 27 of U.S. Patent No. 7,335,205, use of ultrasonic energy and a polymer pin is known in fracture fixation. The disclosure of U.S. Patent No. 7,335,205 is incorporated herein by reference.

2010201014 09 Dec 2011

Object of the Invention

It is the object of the present invention to substantially overcome or ameliorate one or more of the disadvantages of the prior art.

Summary of the Invention

The present invention provides a screw for fixation of a fracture comprising

a shaft having a distal end, a proximal end, and a central axis,

a through bore extending along the central axis of the shaft,

a first outer thread located at the distal end,

a second outer thread, wherein an outer diameter of the second outer thread is greater than an outer diameter of the shaft,

a radially outwardly extending collar integrally formed on the shaft adjacent the proximal end of the shaft, the collar forming a smooth transition from the outer diameter of the shaft to the outer diameter of the second outer thread, and

an inner tool engagement portion at the proximal end.

Preferably, the inner tool engagement portion is formed to fit with a hexagonal or torx screw driver.

Preferably, a step in the inner diameter of the through bore is formed adjacent the distal end of the shaft, so that a polymer pin inserted into the through bore of the shaft can be supported by the step.

Preferably, the screw further comprises a radial opening at the distal end of the screw.

Preferably, a surface of the collar facing the distal end is part-spherical in shape.

The present invention also provides a system for installation of a screw comprising

a screw as described above,

a driving tool adapted to engage with the inner tool engagement portion of the screw, and

a hollow tissue protection sleeve adapted to engage with the second outer thread of the screw, and adapted to partially accommodate the driving tool.

Preferably, the system further comprises:

a polymer pin made of fluidicable material, adapted to be inserted into the axial through bore of the screw, and

2010201014 09 Dec 2011

an augmentation tool including a sonotrode for fluidizing the polymer material of the polymer pin, wherein the augmentation tool is adapted to be coupled with the proximal end of the tissue protection sleeve.

The present invention also provides a method of installation of a screw comprising the following steps:

coupling a tissue protection sleeve with an outer thread at a proximal end of the screw for fixation of a fracture, so that a junction between the screw and the tissue protection sleeve is smooth,

engaging with a driving end of a driving tool into an inner engagement portion at the proximal end of the screw, with at least a part of the driving tool extending through the tissue protection sleeve, and

installing the screw in an object.

Preferably, the method further comprises:

removing the driving tool,

inserting a polymer pin in the axial through bore of the screw,

positioning a sonotrode of an augmentation tool at the proximal end of the polymer pin,

fluidizing the material of the polymer pin,

pressing the fluidized material out of the screw to augment the screw in the object, and

removing the augmentation tool as well as the tissue protection sleeve.

Preferably, the method further comprises the step of rotating the screw and tissue protection sleeve about an axis transverse to the central axis after the screw is installed.

2010201014 16 Mar 2010

The tissue protection sleeve is a kind of a lengthening piece, which may be suitable to facilitate the introduction of the screw into a bone, wherein muscles or other tissue surrounding the bone will complicate the attachment of an augmentation tool directly at the proximal end of the screw.

With two separate elements, i.e. the sleeve and the driver, each engaging directly at the proximal end of the screw, it is possible to apply forces with different direction precisely onto the screw, so that the screw may be positioned accurately at a appropriate site. With the driver, forces in circumferential direction may be applied to screw in (or out for explantation) the screw. With the sleeve, force in axial or radial direction may be applied to the screw. As another advantage, the screw may be held in place by the screw driver while the tissue protection sleeve is loosened and removed from the proximal end of the screw.

It will be understood that the combination of connections at the proximal end of the screw, i.e. the outer thread for a connection with a sleeve and the inner engagement portion for a connection with a driving tool, may also be suitable to manipulate a nail, a drive screw or another implant. Therefore, all aspects described with respect to a screw may also apply to a nail, a drive screw or other kind of implant.

According to a further embodiment, the set further comprises a polymer pin made of a fluidizable material, adapted to be inserted into the through bore of the screw, and an augmentation tool including a sonotrode for fluidizing the polymer material of the polymer pin, wherein the augmentation tool is adapted to be coupled with the proximal end of the screw or the proximal end of the tissue protection sleeve, wherein the sleeve may be located between the screw and the augmentation tool.

It is noted, that the material of the polymer pin may be bio-compatible, wherein a bio-compatible material may be a material which does not negatively interfere with human or animal tissue.

2010201014 16 Mar 2010

Examples of bio-compatible and also fluidizable materials may be specially adapted metal alloys such as titanium or specific plastics, e.g. PEEK (Polyetheretherketone), UHMWPE (Ultra high molecular weight polyethylene), PLA (Polylactic acid), PLLA (Poly-L-lactide), PLDLA (Poly(D,L-Lactid)), PDLLA (Poly-DL-lactide), PVDF (Polyvinylidene Difluoride).

Furthermore, it may be advantageous, that the material of the polymer pin is bio-absorbable. One possible bio-absorbable material comprises a copolymer comprising between 50% and 90% Poly-L-lactide and between 10% and 50% Poly-D, L-lactide. In particular, the bio-absorbable material may be a copolymer comprising 70 weight% Poly-L-lactide and 30 weigh% Poly-D, L-lactide. Preferably, the bio-absorbable material may be formed as an amorphous material.

It may be understood that in a set including a tissue protection sleeve, the length of the sonotrode of the augmentation tool as well as the length of the screw driving tool will be adapted to the lengthening.

In use, the tissue protection sleeve will be coupled with the proximal end of the screw, the driving end of the screw driver will be connected with the inner tool engagement portion at the proximal end of the screw, while the shaft of the screw driver is at least partially located inside the tissue protection sleeve. Now, the screw might be introduced or located in the object of interest, i.e. the screw may be screwed into the bone.

After positioning of the screw, the screw driver will be disconnected from the screw, the polymer pin will be inserted through the tissue protection sleeve into the through bore of the screw, and an augmentation tool may be coupled with the proximal end of the tissue protection sleeve, wherein the sonotrode of the augmentation tool is

2010201014 16 Mar 2010

located inside the tissue protection sleeve as well as inside the screw shaft, and is in contact with the polymer pin inside the screw. Subsequently, by applying ultrasound energy and/or force to the polymer material of the polymer pin, the polymer material will be fluidized or melted such that the material may flow out of the openings at the distal end of the screw into the cavities of the bone (or the wood).

The ultrasonic sonotrode may be adapted to generate ultrasonic vibrations at the tip with a frequency of between 10 and 50 kHz, preferably between 20 and 30 kHz, and a suitable vibration amplitude may be in the range between 1 and 100 µm, preferably between 5 and 30 µm. The vibrations can be generated preferably in a direction along the vibration shaft and/or in a direction perpendicular to the vibration shaft.

Additionally, a certain pressure should be applied by way of the sonotrode to the polymer pin. Firstly, the pressure will ensure that the vibrations will be transmitted reliably from the sonsotrode to the polymer pin. Secondly, the pressure will push the melted material of the pin out of the screw.

A description in more detail of the steps performed while using the set for installation of the screw according to the invention may be followed in conjunction with the detailed description of an exemplary embodiment below.

It has to be noted that embodiments of the invention are described with reference to different subject matters. In particular, some embodiments are described with reference to method type claims, whereas other embodiments are described with reference to apparatus type claims, however, a person skilled in the art will gather from the above and the following description that, unless, otherwise notified, in addition to any combination of features belonging to one type of subject matter, also any combination of features relating to different subject matters is considered to be disclosed with this application.

2010201014 16 Mar 2010

The aspects defined above and further aspects, features and advantages of the present invention can also be derived from the examples of the embodiments to be described hereinafter and are explained with reference to examples of embodiments to which the invention is not limited.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention will now be detailed by way of an exemplary embodiment with reference to the attached drawings.

Figs. 1 to 6 show subsequent steps illustrating the use of a set for installation of a screw according to the invention.

Fig. 7 illustrates a possible adjusting of fractured pieces relative to each other.

Fig. 8 is a side view as well as a section view of a screw according to the invention.

Fig. 9 is a side view as well as an enlarged section view of an assembled set for installation of a screw according to the invention.

Fig. 10 is a side as well as a section view of an assembled set for augmentation of a screw according to the invention.

It is noted that the illustration in the drawings is only schematically and not to scale. In different figures, similar elements are provided with the same reference signs.

DETAILED DESCRIPTION OF AN EXEMPLARY EMBODIMENT

Figs. 1 to 6 are a schematic illustration showing different steps in the use of a set for installation of a screw according to the invention.

2010201014 16 Mar 2010

Fig. 1 shows a screw 10 including a first outer thread 12 and a second outer thread 14. A tissue protection sleeve 30 is shown with a small distance behind the second outer thread 14 of the screw 10. Furthermore, there is indicated by arrow A that the tissue protection sleeve may be screwed onto the second outer thread 14. Even though the arrow A indicates a right hand thread, a left hand thread may also suitable.

Consequently, the distal end 32 of the tissue protection sleeve 30 is provided with an inner thread corresponding to the outer thread 14 of the screw10. The arrow B indicates that a force transmission from the tissue protection sleeve to the screw is possible in axial direction.

With the tissue protection sleeve 30 connected with the screw, it may be possible to insert a shaft 41 of a screw driver 40 in the tissue protection sleeve 30 so as to bring the engagement portion 42 of the screw driver 40 into engagement with the inner engagement portion of the screw 10. Furthermore illustrated in Fig. 2 is the configuration of the screw 10 at the connection point with the tissue protection sleeve 30. The screw 10 includes a collar 13 near to the second outer thread at the proximal end of the shaft. The tissue protection sleeve 30 is slightly conical at the distal end 32 of the sleeve 30. Therefore, the junction between the screw 10 and the tissue protection sleeve 30 may be smooth, which will provide for less tissue irritation.

Fig. 3 shows that by means of the assembly consisting of the screw 10, the tissue protection sleeve 30 and the screw driver 40 it is possible to insert or implant the screw 10 into a bone at a fracture site. In this example, the screw is implanted into a femoral bone to fix a fracture of the femoral neck. Indicated by the arrows B and C is the possibility to simultaneously press in axial direction and rotate around the axis of the screw so as to easily drive the screw 10 into the bone.

2010201014 16 Mar 2010

In Fig. 4 there is shown a state in which the screw 10 is already inserted into the bone and the screw driver is removed from the screw 10 and out of the tissue protection sleeve 30. Now, as depicted in Fig. 4, a polymer pin 20 may be inserted into the screw 10 through the tissue protection sleeve 30. Furthermore, there is shown an augmentation tool 50 including a sonotrode 52 with a tip 53. The length of the sonotrode 52 is dimensioned so that when the polymer pin is inserted into the screw 10 the tip 53 of the sonotrode 52 will make contact with the proximal end 24 of the polymer pin 20 inside the screw 10 while the housing of the augmentation tool 50 is coupled with the proximal end 34 of the tissue protection sleeve 30.

The assembly of the screw 10, the tissue protection sleeve 30 and the augmentation tool 50 is also depicted in Fig. 5. Furthermore, in Fig. 5 the screw 10 is illustrated as a section view so that a polymer pin 20 as well as the sonotrode 52 is visible inside the screw 10. In an additional detailed view, there is shown the polymer pin 20 together with an insert 22 at the tip of the polymer pin, wherein the insert 22 provides for a support inside the screw 10, when, by means of the sonotrode 52 an ultrasonic vibration as well as an axial force is applied to the polymer pin. The ultrasonic vibration and the axial force are indicated by arrow D in Fig. 5.

To provide a appropriate support for the insert 22 at the distal end of the polymer pin 20 there is formed a step in the inner wall of the through bore of the screw near the distal end of the through bore.

It is noted that the counter force to the force applied in axial direction from the sonotrode to the polymer pin, will be a pull force affecting on the tissue protection sleeve and thus on the second outer thread of the screw and the connection between the sleeve and the housing of the augmentation tool.

By applying the energy and/or force to the polymer pin, the material of the polymer pin will melt or fluidize so that the melted polymer material will exit out of the tip

2010201014 16 Mar 2010

portion of the screw 10 through radial openings into the bone. Accordingly, Fig. 6 shows a situation in which the screw 10 is inserted into the bone, the tip of the screw 10 is augmented by the polymer material and the augmentation tool as well as the tissue protection sleeve is already removed from the proximal end of the screw.

Fig. 7 illustrates another possibility during the implantation of the screw, i.e. the fixation of a fracture of a femoral neck. After the screwing in of the screw into the bone, it may be possible especially in an osteoporotic bone to pivot the screw at the entrance into the bone in the corticalis so as to correctly position the joint head of the femur relative to the neck and shaft of the femur (for example from Position A to Position B). PoR in fig. 7 indicates the point of Rotation. Such a correction or movement is possible as long as the tissue protection sleeve is connected to the proximal end of the screw, since said sleeve may be gripped and a force for a pivot movement (indicated by arrow G) as well as a pull movement (indicated by arrow F) may be performed.

Fig. 8 is an illustration of a screw according to one embodiment of the invention. The illustration includes a side view, a section view and the proximal end of the screw as detail side view and detail section view.

As shown in fig. 8, a screw 10 according to the invention may comprise at its distal end an outer thread 12, radial openings 17 and a step 16 in the axial through bore. The outer thread 12 may be machined only in an end portion of the shank, wherein the thread may also cover the shank of the screw full length. Provided along the longitudinal centre line of the screw is a through bore composed of two bore portions. The proximal bore portion comprises a first diameter and the distal bore portion a second diameter, wherein the first diameter being larger than the second diameter. The proximal bore portion may form the main portion of the through bore. Just a small end portion of the shank of the screw in which portion the thread 12 is machined is formed by the distal bore portion. The transition from the proximal bore

2010201014 16 Mar 2010

portion to the distal bore portion is formed by a step 16 in the diameter. The step 16 in the diameter forms an annular ridge having substantially right-angled edges at the wall of the through bore within the screw. Each edge of the step 16 in the diameter may be machined flat or rounded or conical. However, the step may also provide for a closed distal end of the screw.

In addition, the screw 10 features openings or holes 17 radially configured through the wall of the screw. The openings 17 may be configured in differing directions, for example perpendicular to the longitudinal centre line of the screw and arranged in the end portion with the thread 12. Preferably the openings 17 are arranged in a region of the end portion which also features the proximal bore portion. According to one embodiment two openings 17 may be configured axially juxtaposed in the proximal bore portion and through the thread 12. Furthermore, four such pairs of openings may be evenly distributed about the circumference of the screw, in other words, circumferentially spaced by 90°. It is, however, just as possible that three, four, five or more openings may be provided circumferentially and it is not necessary that the holes circumferentially distributed are all at same level. It is, the openings might also be distributed circumferentially along the thread turn. Apart from this, transverse or longitudinal oblong holes, slots, or the like may be provided.

Furthermore the position of the step 16 in diameter together with the openings 17 in the wall can be positioned optionally along the longitudinal centre line and thus the siting of the augmentation can be determined in accordance with the particular application and the desired effect.

As also shown in fig. 8, the screw comprises at its proximal end a collar 13 forming a shoulder or transition from the outer diameter of the shaft to an outer diameter of a second outer thread 14. As mentioned above, the outer thread 14 is machined such that the outer edges of the thread line are rounded or at least not sharp. Since the proximal end of the screw i.e. the collar 13 and the outer thread 14 will remain

2010201014 16 Mar 2010

outside of a bone into which the screw is implanted, these elements should be formed such that an irritation or insurance of the tissue surrounding said end of the screw can be avoided. The length of the outer thread may be only a few millimetres, just enough to ensure a reliable connection between the screw and a tissue protection sleeve. Upon said connection forces in axial and/or in radial direction may be transmitted. Furthermore, the end projecting out of the bone should be as short as possible.

Further, the screw comprises an inner tool engagement portion 18 in its proximal end portion. The inner engagement portion 18 is provided for transmission of rotational forces. Furthermore, by holding the screw by means of a screw driver engaged in the inner engagement portion the tissue protection sleeve may be easily removed from the outer thread of the screw. The shape of the inner engagement portion may be a torx or hex fitting to a corresponding driving end of a screw driver. However, said shape may also be any suitable driving connection including slot, cross, customized or else. The only restriction is the fact that the axial through bore in the screw will provide for absence of material in the centre portion of the inner engagement portion.

In fig. 9, an assembly of a screw 10, a tissue protection sleeve 30 and a screw driver 40 is shown. Furthermore, the detail view Z shows the connection portion of the three mentioned elements in section. As depict, the shaft 41 of the screw driver 40 engages with its driving end 42 in the inner engagement portion of the screw, and the tissue protection sleeve 30 engages with its thread at its distal end in the outer thread 14 at the proximal end of the screw. In the enlarged view Z it can also be seen that the outer contour of the collar 13 of the screw 10 and the end portion of the sleeve 30 may be designed to have a smooth transition.

In fig. 10, an assembly of the screw 10, the tissue protection sleeve 30, a polymer pin 20 with an insert 22, and a sonotrode 52 of an augmentation tool like an ultrasound handpiece is shown. After removing the screw driver out of the sleeve, the polymer

20102010014 16 Mar 2010

pin 20 may be inserted into the hollow shaft of the screw 10, through the also hollow tissue protection sleeve 30. Proximally behind the polymer pin 20 is a sonotrode inserted through the sleeve 30 and into the through bore of the screw.

It should be noted that the polymer pin 20 may also be made of other materials such as for instance a thermoplastic material suitable for augmenting a screw, both resorptive and non-resorptive materials being useful. Further, it is to be noted that the technology described with respect to an implantation of a screw into a bone, is not just limited to the indications. In other words, all screw applications which can be supplied by cannulated screws can be potentially supplied by the set and screw in accordance with the invention. Advantageously, the material into which the screw will be screwed in, is a porous material. Furthermore, the material of the so called polymer pin may have adhesive properties, especially in case of an application in a non-medical field.

While the invention has been illustrated and described in detail in the drawings and foregoing description, such illustration and description are to be considered illustrative or exemplary and. not restrictive; the invention is not limited to the disclosed embodiments.

Other variations to the disclosed embodiments can be understood and effected by those skilled in the art in practicing the claimed invention, from a study of the drawings, the disclosure, and the appended claims. In the claims, the word "comprising" does not exclude other elements or steps, and the indefinite article "a" or "an" does not exclude a plurality. A single unit may fulfill the functions of several items recited in the claims. The mere fact that certain measures are recited in mutually different dependent claims does not indicate that a combination of these measured cannot be used to advantage. Any reference signs in the claims should not be construed as limiting the scope.

2010201014 09 Dec 2011

The claims defining the invention are as follows:

1. A screw for fixation of a fracture comprising

a shaft having a distal end, a proximal end, and a central axis,

a through bore extending along the central axis of the shaft,

a first outer thread located at the distal end,

a second outer thread, wherein an outer diameter of the second outer thread is greater than an outer diameter of the shaft,

a radially outwardly extending collar integrally formed on the shaft adjacent the proximal end of the shaft, the collar forming a smooth transition from the outer diameter of the shaft to the outer diameter of the second outer thread, and

an inner tool engagement portion at the proximal end.

2. The screw according to claim 1, wherein the inner tool engagement portion is formed to fit with a hexagonal or torx screw driver.

3. The screw according to claim 1 or 2, wherein a step in the inner diameter of the through bore is formed adjacent the distal end of the shaft, so that a polymer pin inserted into the through bore of the shaft can be supported by the step.

4. The screw according to any one of claims 1 to 3, wherein the screw further comprises a radial opening at the distal end of the screw.

5. The screw according to any one of the claims 1 to 4, wherein a surface of the collar facing the distal end is part-spherical in shape.

6. A system for installation of a screw comprising

a screw according to any one of claims 1 to 5,

a driving tool adapted to engage with the inner tool engagement portion of the screw, and

a hollow tissue protection sleeve adapted to engage with the second outer thread of the screw, and adapted to partially accommodate the driving tool.

7. The system according to claim 6, further comprising

a polymer pin made of fluidicable material, adapted to be inserted into the axial through bore of the screw, and

an augmentation tool including a sonotrode for fluidizing the polymer material of the polymer pin, wherein the augmentation tool is adapted to be coupled with the proximal end of the tissue protection sleeve.

8. Method of installation of a screw according to claim 1, the method comprising the following steps

2010201014 09 Dec 2011

coupling a tissue protection sleeve with an outer thread at a proximal end of the screw for fixation of a fracture, so that a junction between the screw and the tissue protection sleeve is smooth,

engaging with a driving end of a driving tool into an inner engagement portion at the proximal end of the screw, with at least a part of the driving tool extending through the tissue protection sleeve, and

installing the screw in an object.

9. Method according to claim 8, comprising the further steps of

removing the driving tool,

inserting a polymer pin in the axial through bore of the screw,

positioning a sonotrode of an augmentation tool at the proximal end of the polymer pin,

fluidizing the material of the polymer pin,

pressing the fluidized material out of the screw to augment the screw in the object, and

removing the augmentation tool as well as the tissue protection sleeve.

10. The method according to claim 8, further comprising the step of rotating the screw and tissue protection sleeve about an axis transverse to the central axis after the screw is installed.

11. A screw for fixation of a fracture substantially as hereinbefore described with reference to any one of the embodiments of the screw as that embodiment is shown in the accompanying drawings.

12. A method of installation of a screw substantially as hereinbefore described with reference to the accompanying drawings.

13. A system for installation of a screw substantially as hereinbefore described with reference to any one of the embodiments of the system as that embodiment is shown in the accompanying drawings.

Dated 8 December 2011

Stryker Trauma GmbH

Patent Attorneys for the Applicant/Nominated Person

SPRUSON & FERGUSON

2010201014 16 Mar 2010

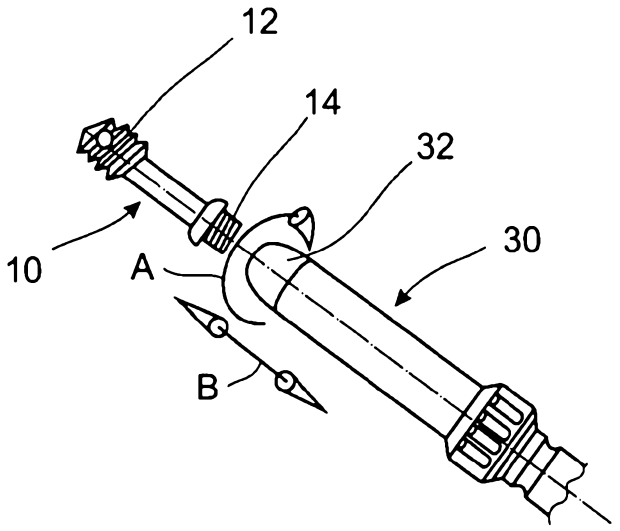

Fig. 1

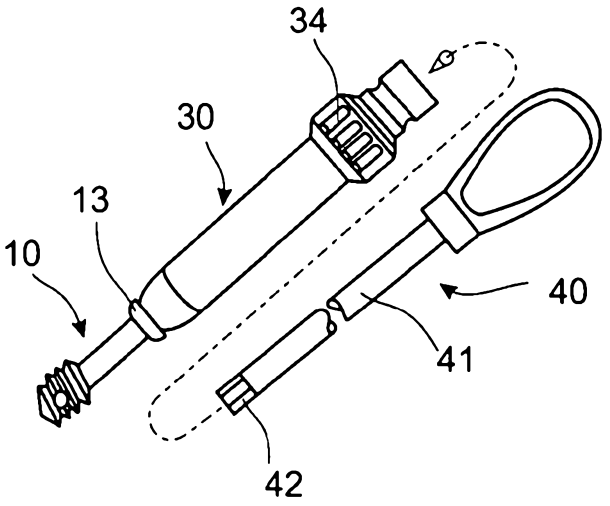

Fig. 2

2010201014 16 Mar 2010

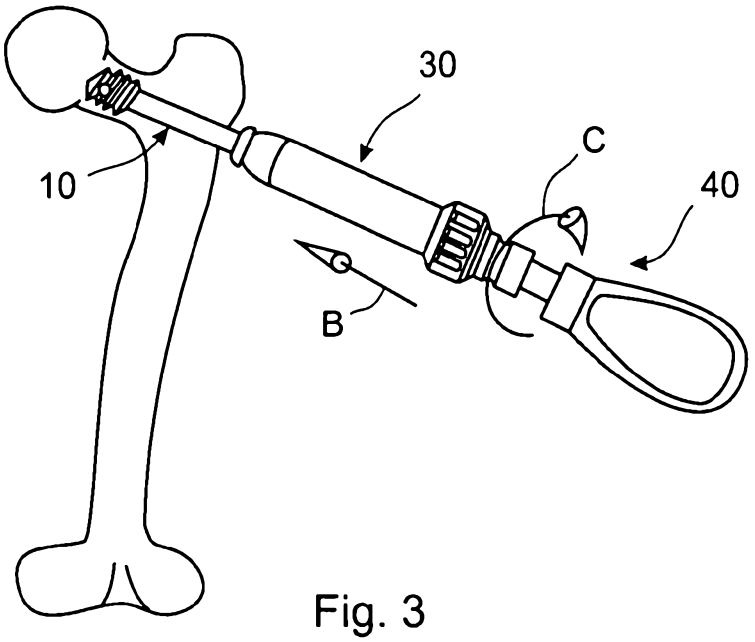

Fig. 3

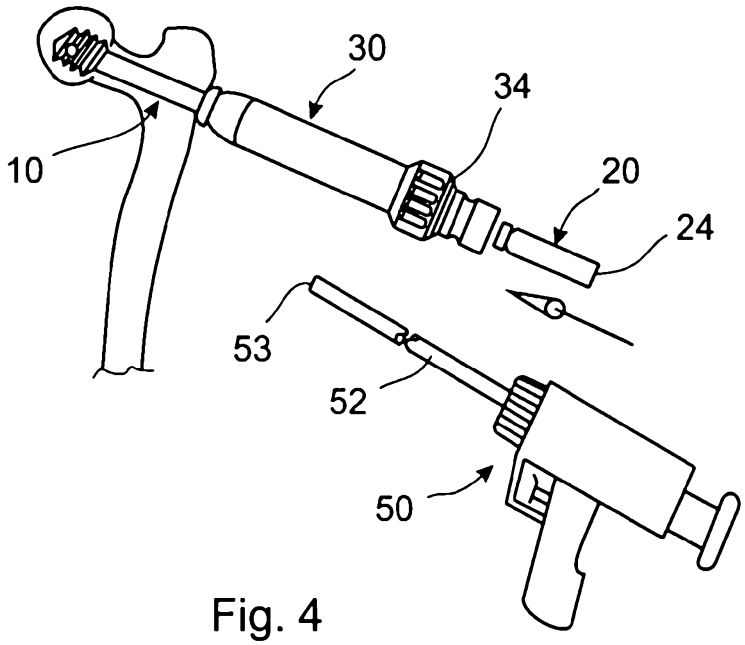

Fig. 4

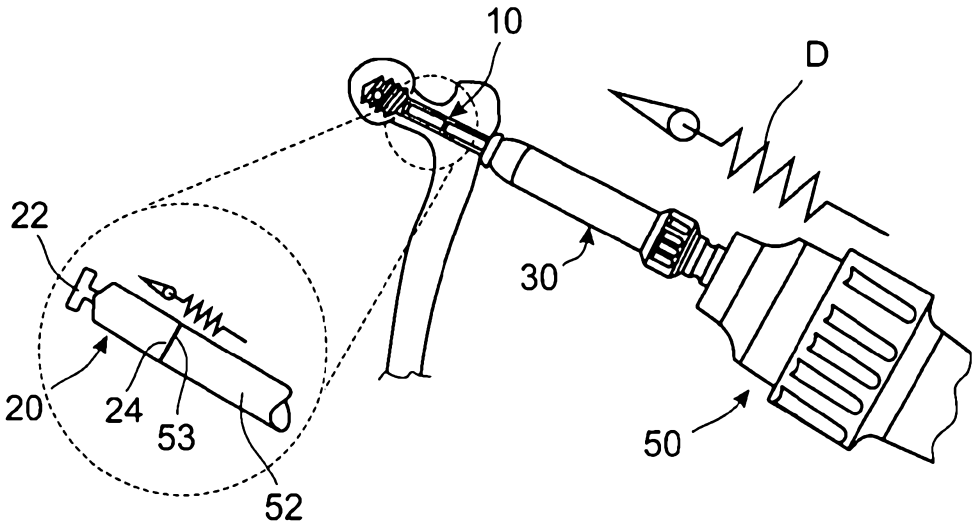

Fig. 5

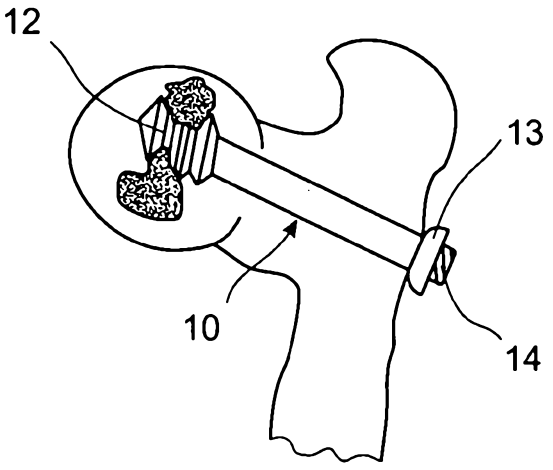

Fig. 6

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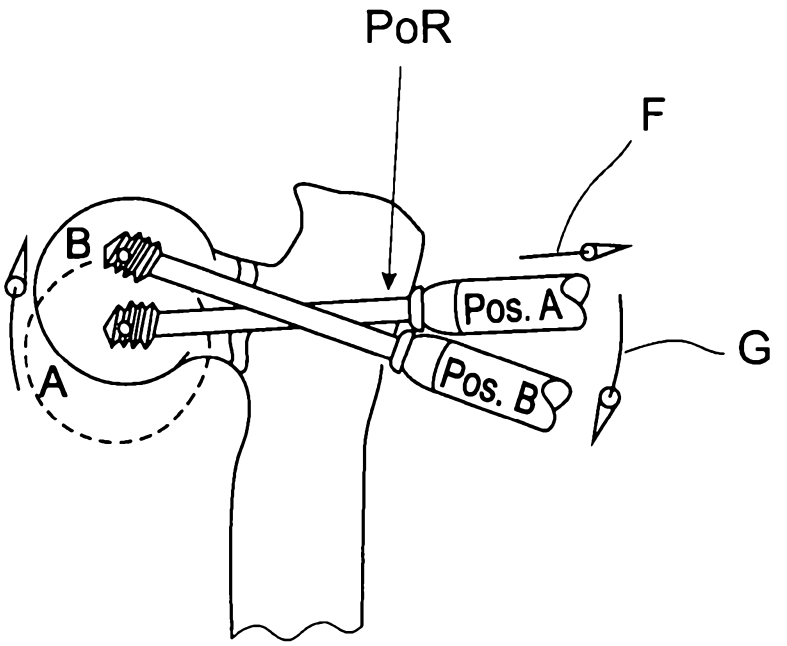


Fig. 7

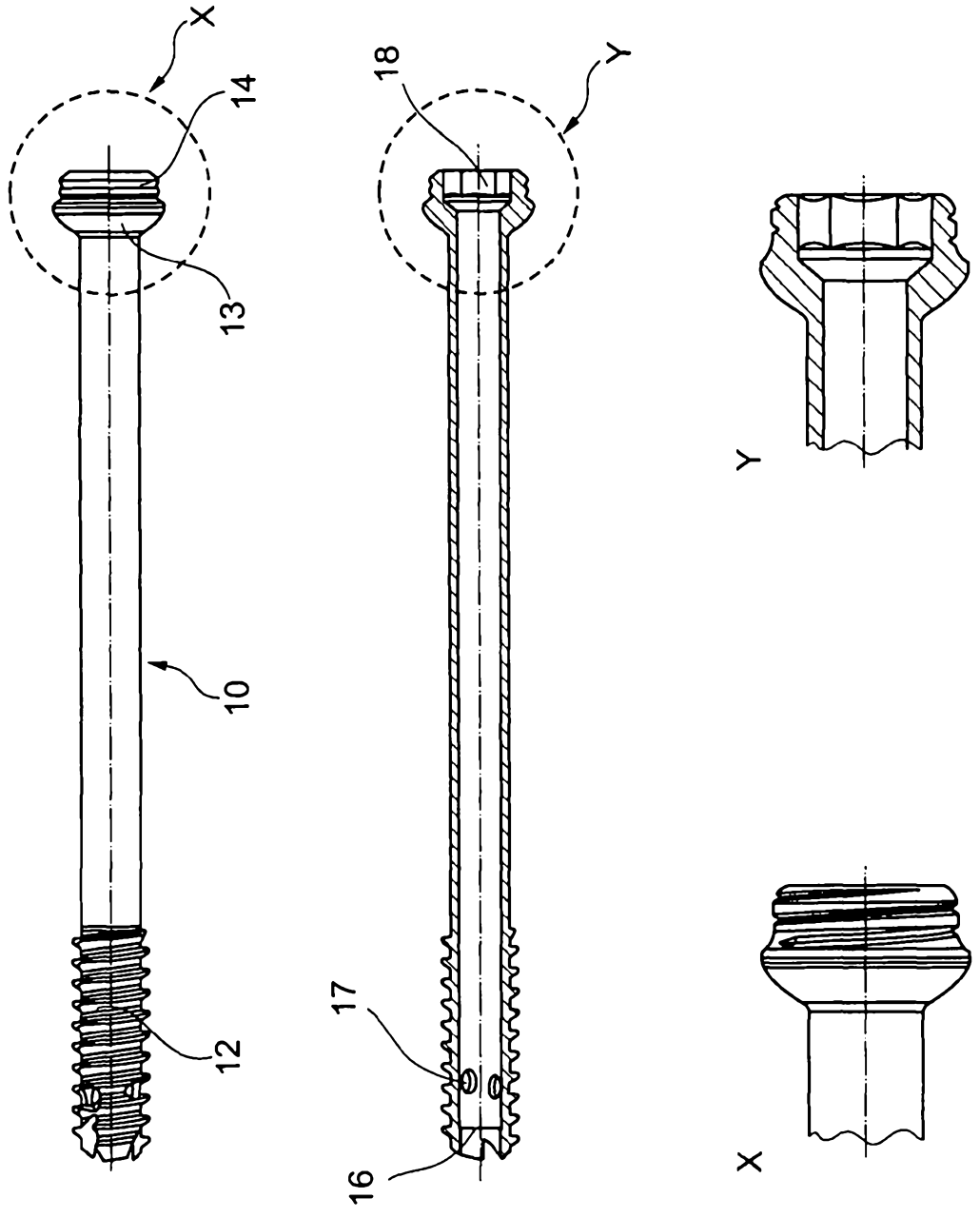
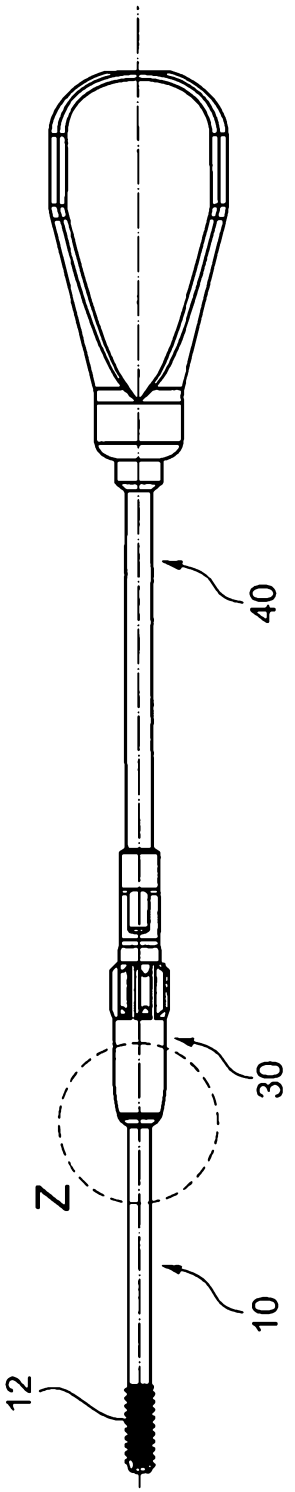


Fig. 8



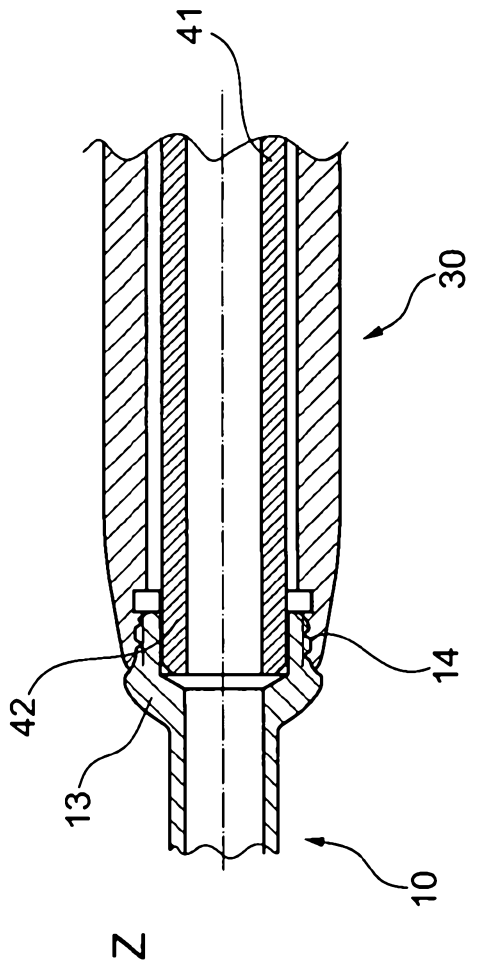


Fig. 9

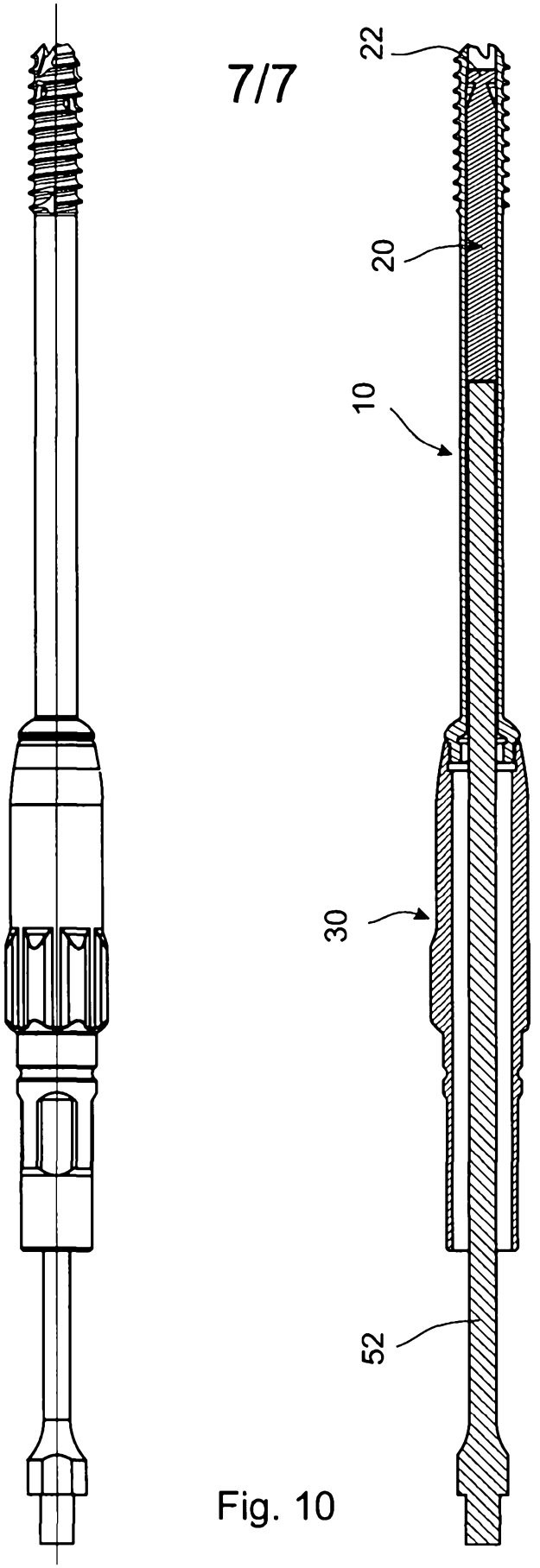


Fig. 10