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(71) Applicant: BEACON BIOMEDICAL, LLC [US/US];

967 Alternate A1a #1, Jupiter, FL 33477 (US).

(72) Inventors: TY, Dennis; 106 Lismore Lane, Jupiter, FL

33458 (US). MITCHELL, Dale; 967 N. Alternate A1a #1, Jupiter, FL 33477 (US).

(74) Agent: CAMPBELL, A., Keith et al.; McHALE &

SLAVIN, P.A., 2855 PGA Boulevard, Palm Beach Gardens, FL 33410 (US).

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(54) Title: FASTENING DEVICE FOR ACQUIRING BONE MARROW ASPIRATE

(57) Abstract: The invention involves a device and method for acquiring bone marrow aspirate. The system includes an elongated cannulated fastener having a threaded end for attachment to a bone. The threaded portion includes a directional aperture sized to allow marrow to be drawn into the cannula. The directional aperture also allows the user to direct the aperture in a desired direction within the bone for acquisition of the marrow. The distal end of the cannulated fastener includes a connector which may be in the form of a Luer lock to allow vacuum to be applied to the cannula for drawing the marrow into a syringe or the like.



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FASTENING DEVICE FOR ACQUIRING BONE MARROW ASPIRATE

FIELD OF INVENTION

The present invention generally relates to surgical procedures requiring bone graft; and more particularly, to
5 a surgical fastener and method for securing a surgical fixture and acquiring bone marrow aspirate.

BACKGROUND INFORMATION

In the U.S., bone grafts are most commonly used in spine fusion surgery and, more generally, in the fusion or
10 arthrodesis of any skeletal joint to bridge a gap between bone segments, and may also provide a three-dimensional scaffold on which the bone can grow.

In addition, bone graft may be used in trauma surgery for the treatment of fresh fractures and non-unions where
15 the bone has been shattered, or where the patient is at a very high risk of developing a non-union fracture.

Joint reconstruction and revision surgery is another area where a patient is likely to need a bone graft because a large void may result from the removal of the original
20 joint or implant.

There are different types of bone graft materials that may be used to assist a patient's body in bone regeneration. These bone graft materials are typically classified as either natural or synthetic materials.

25 Natural bone graft materials are classified in the following groups. Autograft is bone graft material that is obtained from the same individual that will receive the bone graft material. Allograft is bone graft material that is obtained from another human source, which typically is

from cadavers. Xenograft is bone graft material that is obtained from another species.

Bone grafts can also be categorized by their bone-forming properties as osteoconductive, osteoinductive or
5 osteogenic. Osteoconductivity is the ability of a material to provide an appropriate scaffold or matrix upon which new bone tissue can form. Osteoinductivity is the ability of a material to stimulate the patient's own system to form new bone. Osteogenic material generates new bone tissue itself.
10 Osteoblasts, which can be found in bone marrow and mesenchymal cells, are the only cells that can create new bone.

Autograft bone has historically been the standard of care because of its osteoconductive, osteoinductive and
15 osteogenic properties. At the time of surgery, bone is taken from a donor site in the patient, often the iliac crest bone, but others are used, and is then re-implanted back into the patient at the surgical site.

However, autograft is often not used because obtaining
20 the graft generally requires a second surgical procedure with associated risks and expenses. In addition, the autograft may also result in significant post-operative issues, most significantly pain.

Therefore, what is needed in the art is a device and
25 method of acquiring bone marrow aspirate that does not require a second surgical site. The device through which the bone marrow aspirate is acquired should provide additional function in the procedure, wherein acquiring the bone marrow aspirate is an additional feature provided by
30 the device. The device should be simple to operate and quickly assembled, requiring minimal tools. Moreover, the device should assemble and function in such a way as to not

distract or obstruct the surgeon from completing the surgery.

Thus, the present invention provides a device and method of acquiring bone marrow aspirate which overcomes
5 the disadvantages of prior art bone marrow acquiring systems. The fastener and bone marrow acquisition device of the present invention not only provides for relative ease of use, it also permits the securement of surgical fixtures without the need of additional fasteners. The
10 present invention also provides a tip suitable for boring pilot holes into bone, thereby eliminating or reducing the need for Jamshidi needles and Kirshner wires.

SUMMARY OF THE INVENTION

Briefly, the invention involves a device and method
15 for acquiring bone marrow aspirate. The system includes an elongated cannulated fastener having a threaded end for attachment to a bone. The threaded portion includes a directional aperture sized to allow marrow to be drawn into the cannula. The directional aperture also allows the user
20 to direct the aperture in a desired direction within the bone for acquisition of the marrow. The distal end of the cannulated fastener includes a connector which may be in the form of a Luer lock to allow vacuum to be applied to the cannula for drawing the marrow into a syringe or the
25 like.

Accordingly, it is an objective of the present invention to provide a cannulated fastener constructed to temporarily attach a surgical fixture to a bone while extending outside of the patient's anatomy.

30 It is a further objective of the present invention to provide a cannulated fastener constructed and arranged to

temporarily secure a surgical device to a bone, while allowing bone marrow to be acquired from the attachment site.

It is yet a further objective of the present invention
5 to provide a cannulated fastener that can be rotated to directionally acquire marrow.

It is another objective of the present invention to provide a cannulated fastener that includes an attachment on a distal end thereof to provide vacuum to the cannula.

10 Other objectives and advantages of this invention will become apparent from the following description taken in conjunction with the accompanying drawings wherein are set forth, by way of illustration and example, certain embodiments of this invention. The drawings constitute a
15 part of this specification, include exemplary embodiments of the present invention, and illustrate various objects and features thereof.

BRIEF DESCRIPTION OF THE FIGURES

Figure 1 is a side view of one embodiment of the
20 present invention;

Figure 2 is a section view of the embodiment shown in Fig. 1, taken along lines 2-2, illustrating the fastening cannula and the directional aperture;

Figure 3 is a partial top side view taken along lines
25 3-3 of Fig. 1, illustrating the directional aperture;

Figure 4 is a perspective view of the fastening cannula of the present invention;

Figure 5 is a section view taken along lines 5-5 of Fig. 4, illustrating the internal construction of the
30 fastening cannula;

Figure 6 is a perspective view, illustrating the fastening cannula securing a surgical fixture to a pelvis bone;

Figure 7 is a partial view taken along lines 7-7 of Fig. 6, illustrating the directional aperture within the bone;

Figure 8 is a perspective view, illustrating the connector on the distal end of the fastening cannula cooperating with a plate on a surgical drill fixture to secure the fixture in position;

Figure 9 is a partial perspective view, illustrating the directional aperture being utilized to draw in bone marrow;

Figure 10 is a perspective view, illustrating the fastening cannula securing the drill guide in place;

Figure 11 is a partial perspective view, illustrating the directional aperture being utilized to draw in bone marrow;

Figure 12 is a perspective view, illustrating one cannulated fastener securing the drill fixture, while a second cannulated fastener is utilized to provide pilot holes for drill bits while simultaneously providing additional bone marrow from locations where marrow is not typically removed; and

Figure 13 is a perspective view of the multiple cannulated fasteners of Fig 12.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

While the present invention is susceptible of embodiment in various forms, there is shown in the drawings and will hereinafter be described a presently preferred embodiment, with the understanding that the present

disclosure is to be considered an exemplification of the invention and is not intended to limit the invention to the specific embodiments illustrated.

Referring generally to Figs. 1-13, a cannulated
5 fastener 100 and method of use for securing a surgical
fixture and withdrawing bone marrow from the bone puncture
is illustrated. The cannulated fastener includes a first
end 10 which includes a moil drill point 14, a tapered lead
16, threads 12, and a directional aperture 18. The second
10 or distal end 20 includes a connector 22, a shoulder 24 and
a spacer zone 26. The moil drill point 14 is polygonal in
shape, having a center point 28 and multiple sharp edges
30. The center point 28 allows the cannulated fastener to
be inserted through tissue and bone without a pilot hole.
15 The location of the center point 28 provides the user with
a positive location once the center point 28 contacts bone,
and resists walking of the point across the surface of the
bone, as is commonly seen with points, such as a trocar
point which positions the point to one side. The center
20 point 28 also allows the use of mallets and the like to
propel the point through the outer surface of the bone.
Still yet, the moil drill point 14 provides a closed first
end to the cannulated fastener 100. It should be noted
that split drill points, spade points and other points that
25 include a center point may be utilized without departing
from the scope of the invention. The tapered lead 16
extends between the moil drill point 14 and the threads 12.
In general, the tapered lead 16 is constructed and arranged
to expand the diameter of the hole created by the moil
30 drill point 14 and smooth or burnish the sidewalls, while
sizing the formed hole for compressive thread forming into
the bone. In this manner, threads are formed in the bone

without loose bone chips, which may cause various issues during or after the surgical procedure. Thus, the surface of the tapered lead 16 is smooth and free from cutting surfaces. The threads 12 may be single, double, triple or
5 more helix; the additional helix providing insertion into a bone with fewer rotations. The threads 12 are generally constructed to allow the cannulated fastener to be securely fastened to the bone. The threads 12 also allow the user to precisely rotate the directional aperture 18 for control
10 of the depth and direction from which the bone marrow is drawn from the bone. It should also be noted that while threads are the preferred embodiment, other holding surfaces may utilized without departing from the scope of the invention such holding surfaces may include, but should
15 not be limited to, knurling, annular rings, surface finish of the outer surface, coatings or the like may be utilized in place of or in conjunction with the threads to hold the cannulated fastener 100 suitably to the bone. The directional aperture 18 is positioned within the threaded
20 area 32. The directional aperture 18 is cut through the side of the cannulated fastener 100 to the cannula bore 34, which extends from behind the center point 28 to the distal end 20. The directional aperture 18 is preferably oval in shape, but may take any shape suitable for drawing marrow
25 or marrow aspirate from a bone. It should also be noted that a plurality of directional apertures may alternatively be utilized without departing from the scope of the invention. The cannula 36 extends through the threaded portion 32 to the distal end 20, terminating in a connector
30 22. The connector 22 may be welded, formed or overmolded to the cannula 36 to create an airtight connection therebetween. The connector 22 preferably includes a luer

lock 38, and may also include threads 40, illustrated herein as ACME threads. It should be noted that other thread forms suitable for securing the connector to a source of vacuum may be substituted for the ACME threads without departing from the scope of the invention. The connector 22 also includes a shoulder 24 arranged to be substantially perpendicular to the cannula 36. In this manner, the shoulder 24 can be utilized to contact an adjacently placed surface of a surgical fixture to retain the fixture's positioning. A spacer zone 26 is positioned between the shoulder 24 and the connector threads 40 to allow the vacuum source to be connected to the threads for marrow extraction, while the shoulder 24 is simultaneously utilized to retain a surgical fixture. Thus, the cannula 36 is preferably constructed from a suitable metal such as stainless steel, while the connector 22 is constructed from a suitable plastic or metal.

Referring to Figs. 6-13, the cannulated fastener 100 is illustrated as securing a surgical fixture 50 in position on a bone structure 52 for a surgical procedure. In this particular illustration, the bone structure 52 is a human pelvis bone 54. It should be noted that the present invention is suitable for use on all bones of mammals having suitable size for connection thereto without departing from the scope of the invention. As illustrated, the shoulder 24 cooperates with a surface 56 of the surgical fixture 50 to retain the positioning of the surgical fixture.

Figure 7 illustrates the position of the directional aperture 18 within the pelvis bone 54. Also illustrated is a tube 58 secured to the surgical fixture 50 to provide

additional alignment between the cannulated fastener 100 and the surgical fixture 50.

Figures 12 and 13 illustrate multiple cannulated fasteners 100 in use in a single procedure. As shown, a
5 first cannulated fastener 100 is used to secure the surgical fixture 50 in position, while a second cannulated fastener 102 is used to withdraw marrow through the surgical fixture 50 from an area that will be removed during the surgical procedure. In this manner, the present
10 device can harvest bone marrow from an area where the marrow is typically lost to the procedure, providing a significant advantage to the patient who can utilize the marrow to enhance bone growth in the same area. Thus, a cannulated fastener 100, 102 has been shown, and its method
15 of use explained, while several advantages of its use have been described.

CLAIMS

What is claimed is:

Claim 1. A cannulated fastener for surgical procedures comprising:

said cannulated fastener (100) including a first end (10), said first end (10) being closed including a drill point (14), said drill point (14) including a center point (28) positioned along a longitudinal centerline of said cannulated fastener (100), a tapered lead (16), said tapered lead (16) smooth and free from cutting surfaces extending between said drill point (14) and holding surface (11), and a directional aperture (18) extending through a sidewall of said cannulated fastener (100) to provide a fluid connection to a cannula bore (36) of said cannulated fastener (100);

a second end (20) including a connector (22) for connecting to a source of vacuum, whereby vacuum is applied to said cannula bore (36) and said directional aperture (18) for drawing bone marrow aspirate from a hole in a bone created by said cannulated fastener (100).

Claim 2. The cannulated fastener of Claim 1 wherein said holding surface (11) is helical threads (12).

Claim 3. The cannulated fastener of Claim 1 wherein said tapered lead (16) is constructed and arranged to expand and size the diameter of the hole created by said drill point (14) by smoothing or burnishing the sidewalls of said hole.

Claim 4. The cannulated fastener of Claim 1 wherein said threads (12) are constructed and arranged to form

conjugate threads in a bone by compression of bone material.

Claim 5. The cannulated fastener of Claim 4 wherein said threads (12) are at least double helix threads, each said additional helix providing insertion into a bone with fewer rotations of said cannulated fastener (100).

Claim 6. The cannulated fastener of Claim 4 wherein said cannulated fastener (100) includes an indicator aligned with said directional aperture (18), whereby said cannulated fastener (100) can be aligned with an area from which said bone marrow aspirate may be withdrawn through said cannulated fastener (100).

Claim 7. The cannulated fastener of Claim 1 wherein said cannulated fastener (100) includes a plurality of said directional apertures (18).

Claim 8. The cannulated fastener of Claim 1 wherein said connector (22) is constructed of plastic overmolded to said second end (20) of said cannulated fastener (100) to create an airtight connection therebetween.

Claim 9. The cannulated fastener of Claim 8 wherein said connector (22) includes a Luer lock connection (38) for connection to a source of vacuum.

Claim 10. The cannulated fastener of Claim 8 wherein said connector (22) includes a shoulder (24) arranged to be substantially perpendicular to said cannula bore (36), said shoulder (24) constructed and arranged to contact an

adjacently placed surface of a surgical fixture (50) to retain said fixture's positioning with respect to a bone.

Claim 11. The cannulated fastener of Claim 10 including a spacer zone (26) positioned between said shoulder (24) and a source of vacuum to allow said vacuum source to be connected to said Luer lock connection (38) for said bone marrow aspirate extraction, while said shoulder (24) is simultaneously utilized to retain a surgical fixture (50).

Claim 12. The cannulated fastener of Claim 10, wherein said cannula (36) is constructed from stainless steel.

Claim 13. The cannulated fastener of Claim 1 wherein said drill point (14) is a moil drill point (14) said moil drill point (14) polygonal in shape, having a center point (28) and multiple sharp edges (30).

Claim 14. The cannulated fastener of Claim 9, wherein said Luer lock connection (38) also includes threads (40).

Claim 15. The cannulated fastener of Claim 1 wherein said drill point (14) is a split drill point.

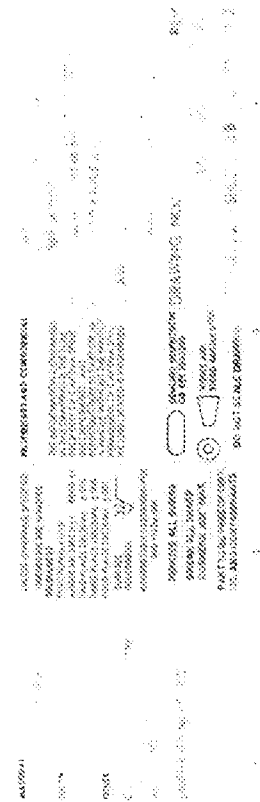
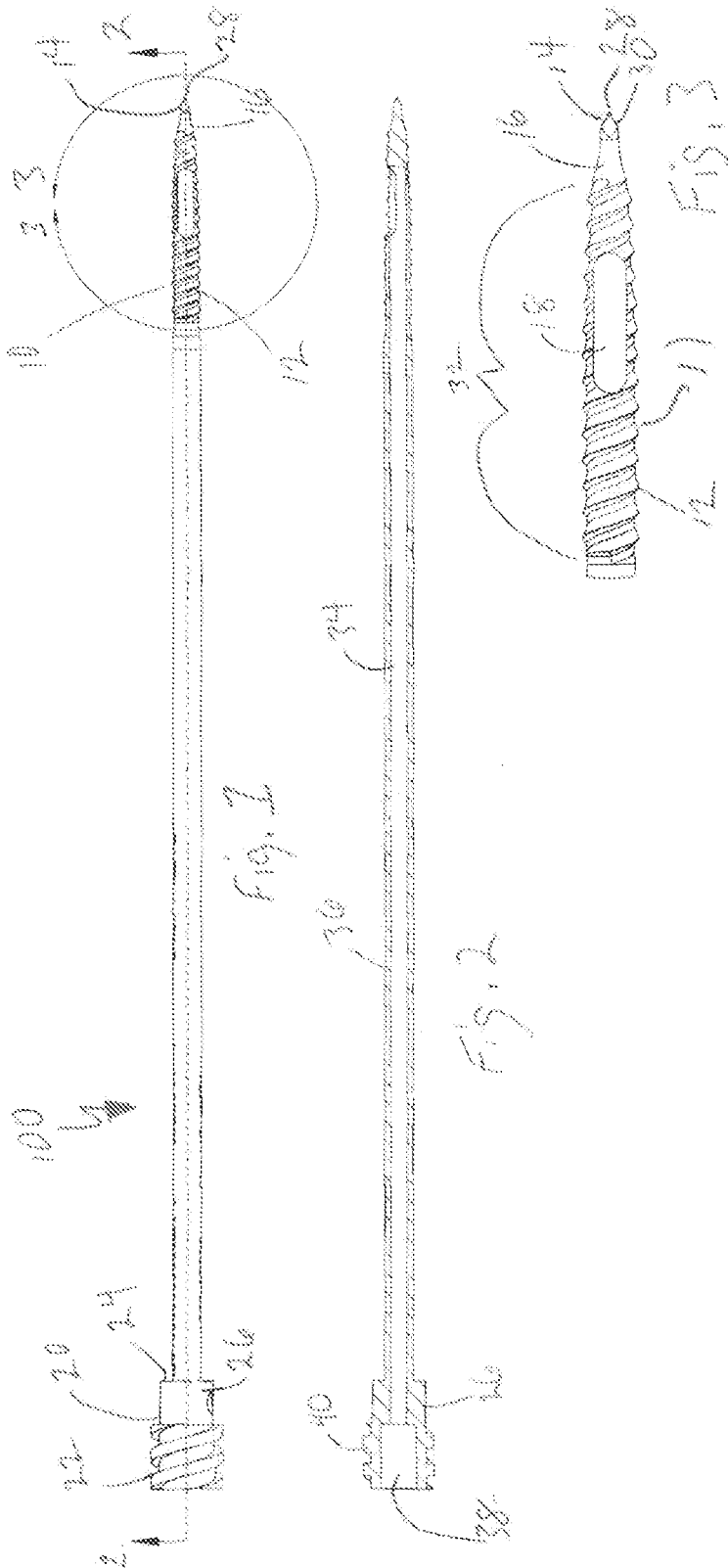
Claim 16. The cannulated fastener of Claim 1 wherein said drill point (14) is a spade drill point.

Claim 17. The cannulated fastener of Claim 1 wherein said holding surface (11) includes knurling.

Claim 18. The cannulated fastener of Claim 1 wherein said holding surface (11) includes annular rings.

Claim 19. The cannulated fastener of Claim 1 wherein said holding surface (11) includes a rougher surface finish than the remainder of said cannula.

Claim 20. The cannulated fastener of Claim 1 wherein said holding surface (11) includes a coating to create said surface finish.



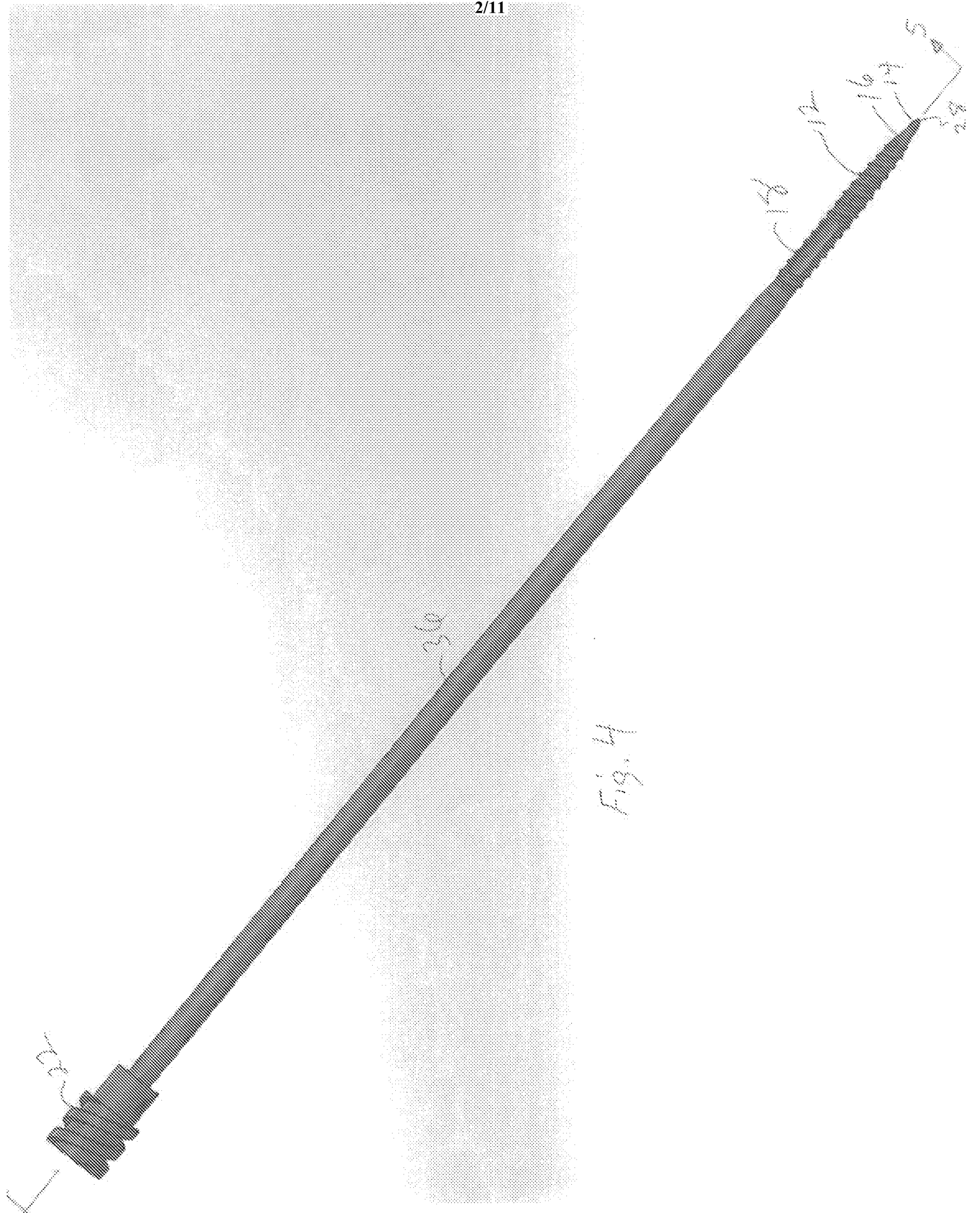


Fig. 4

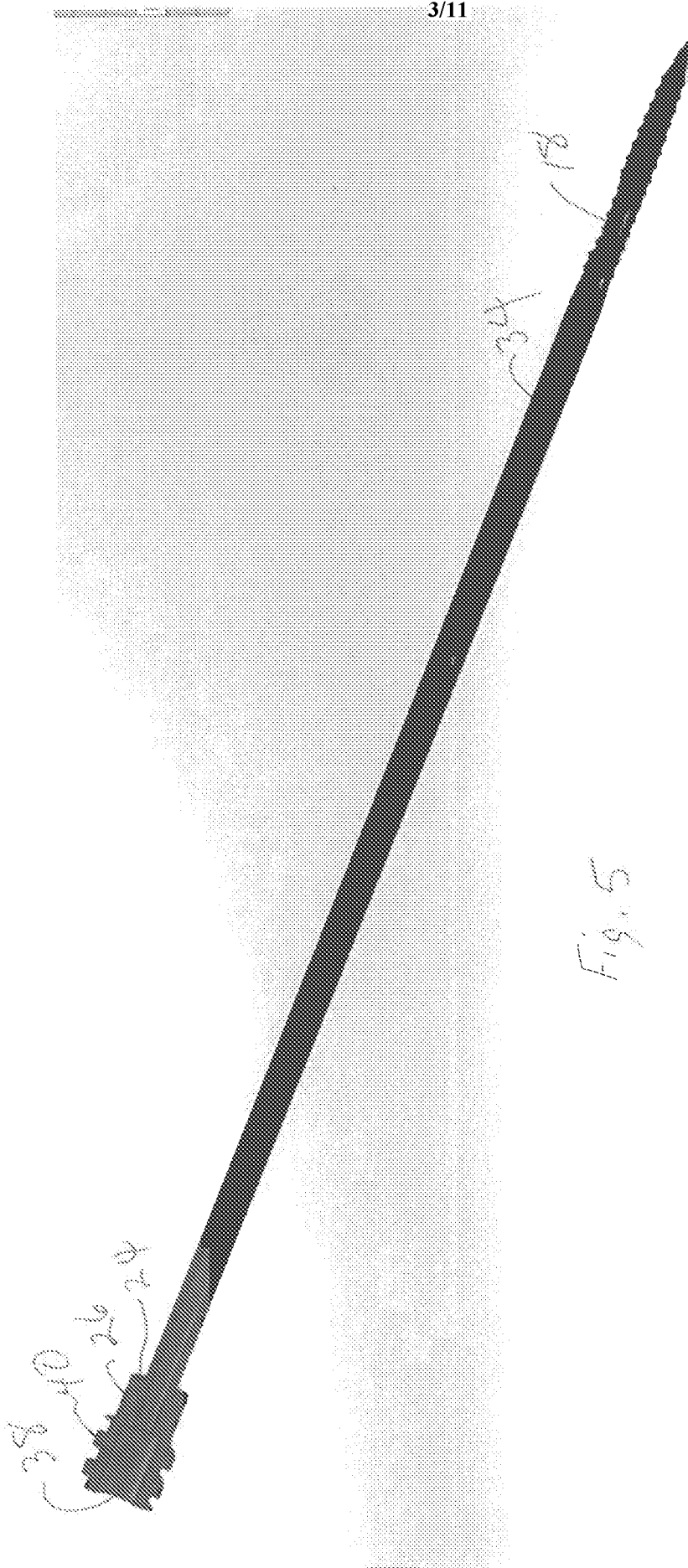
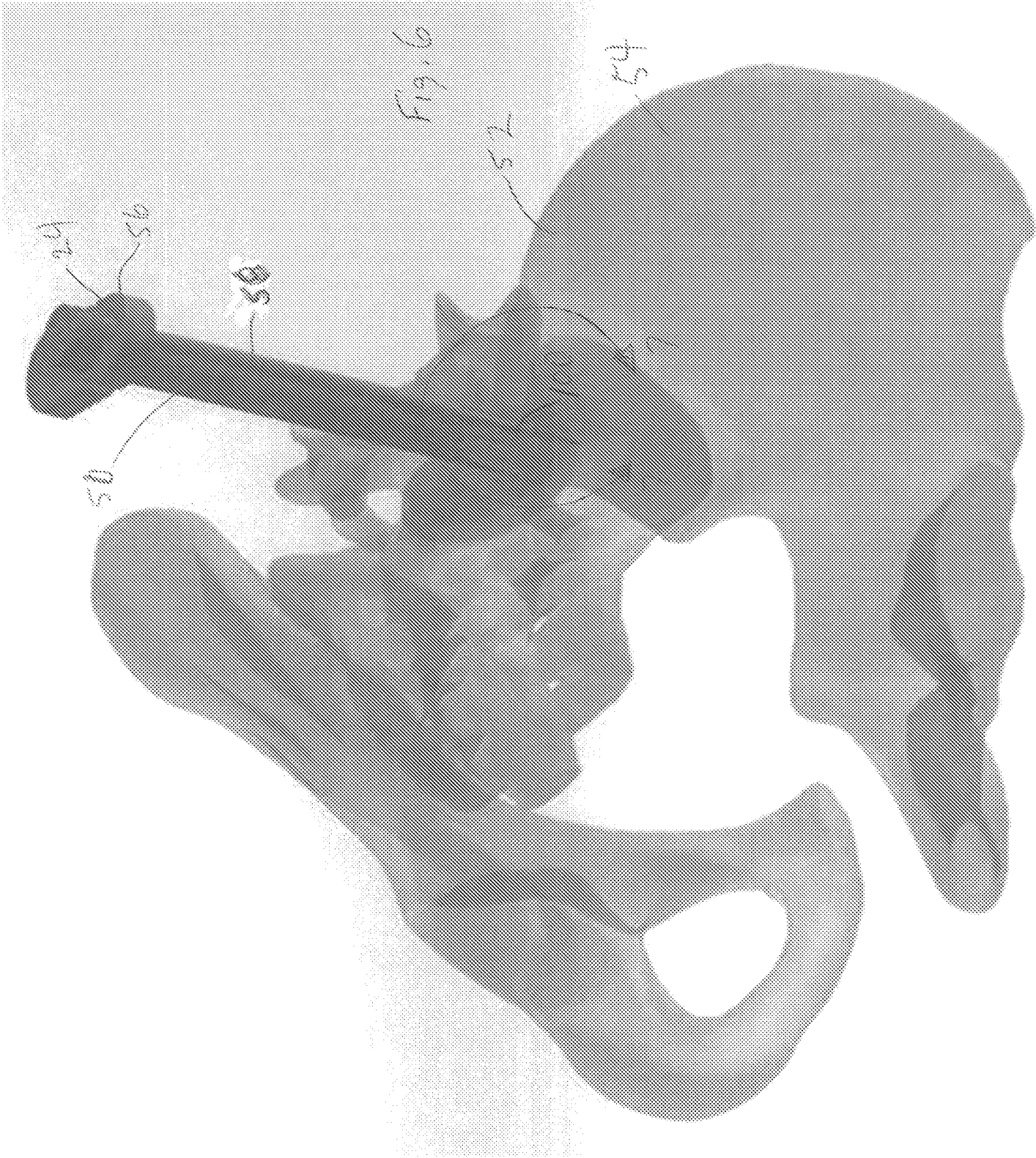


Fig. 5





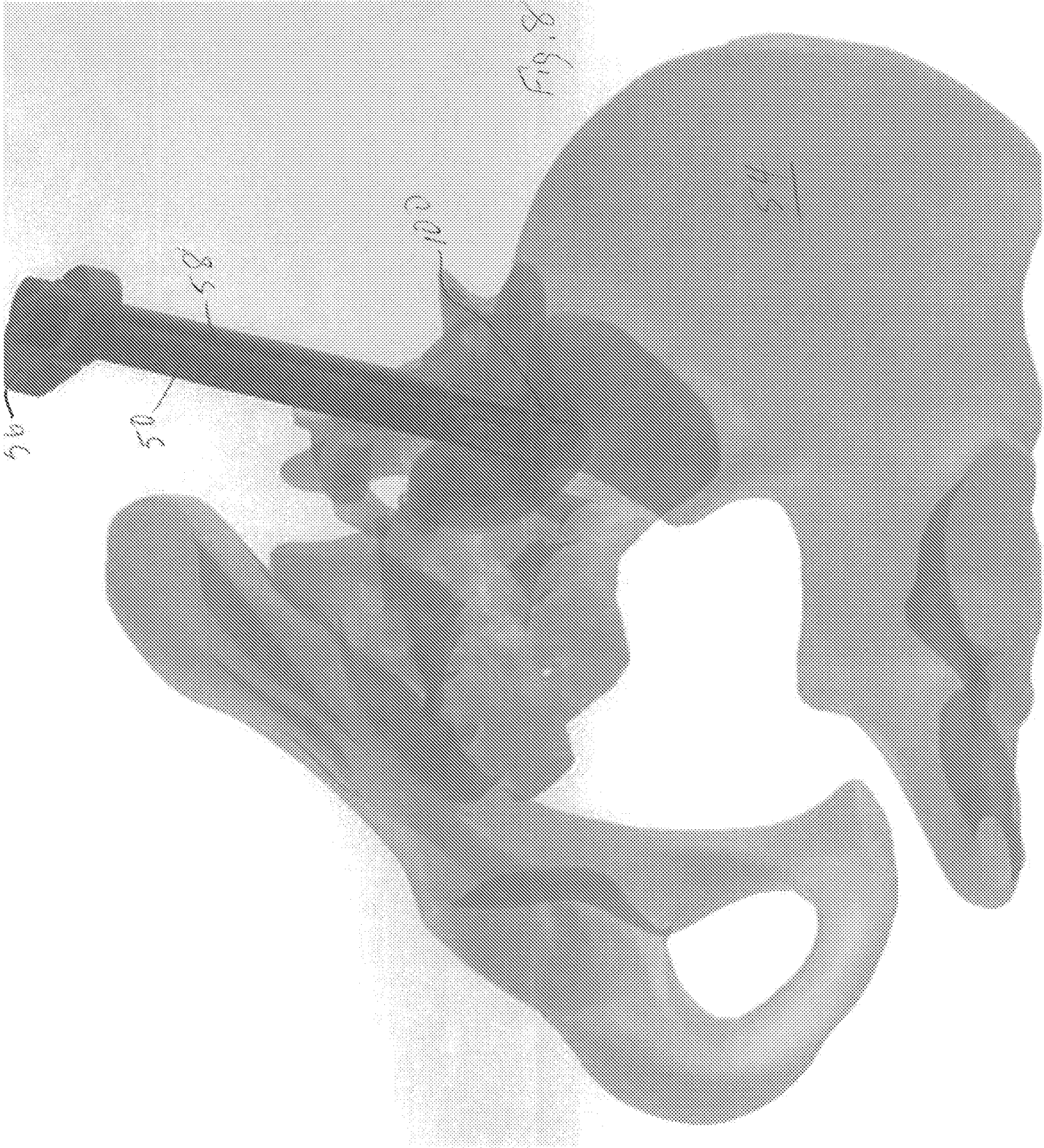
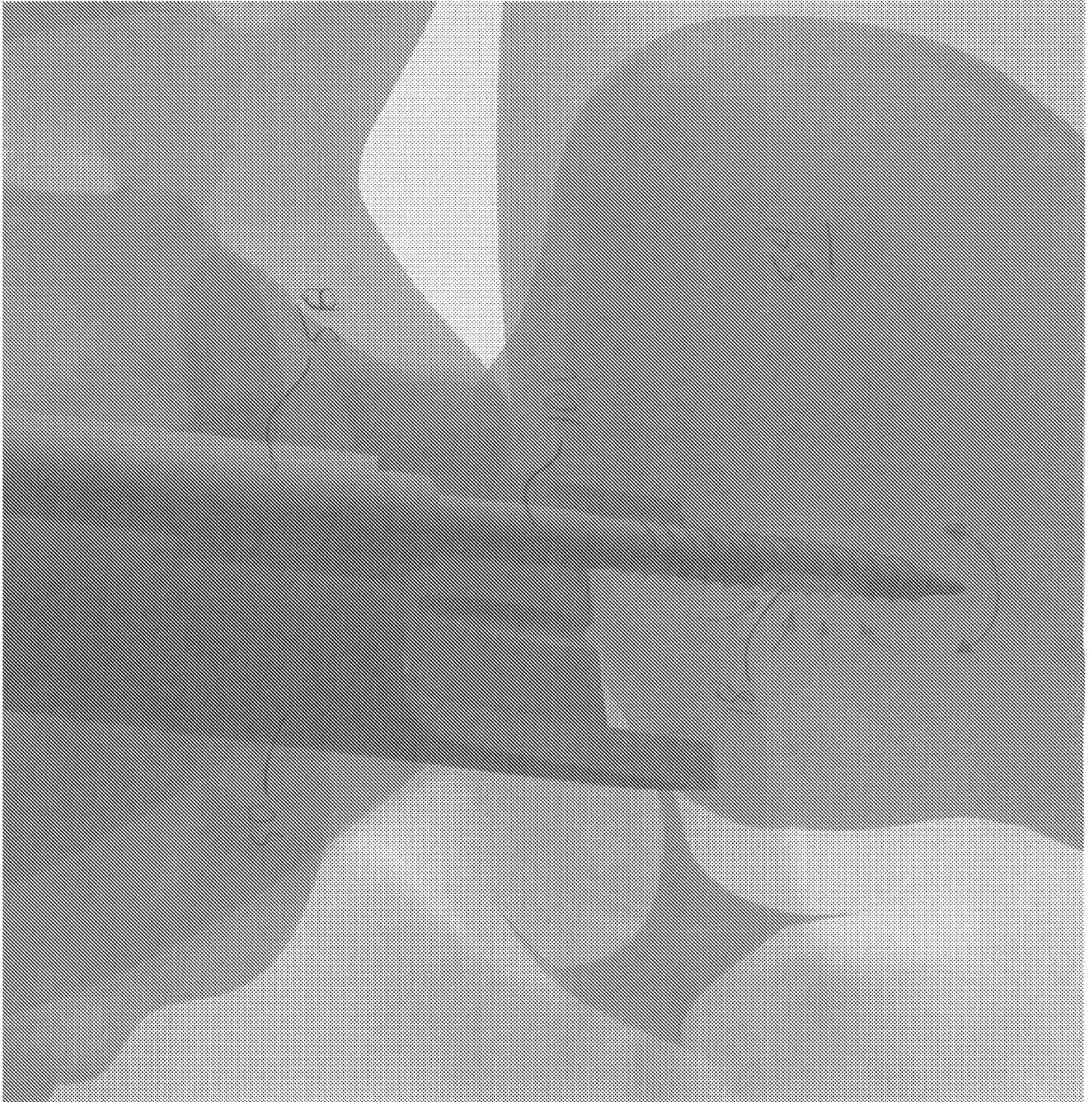
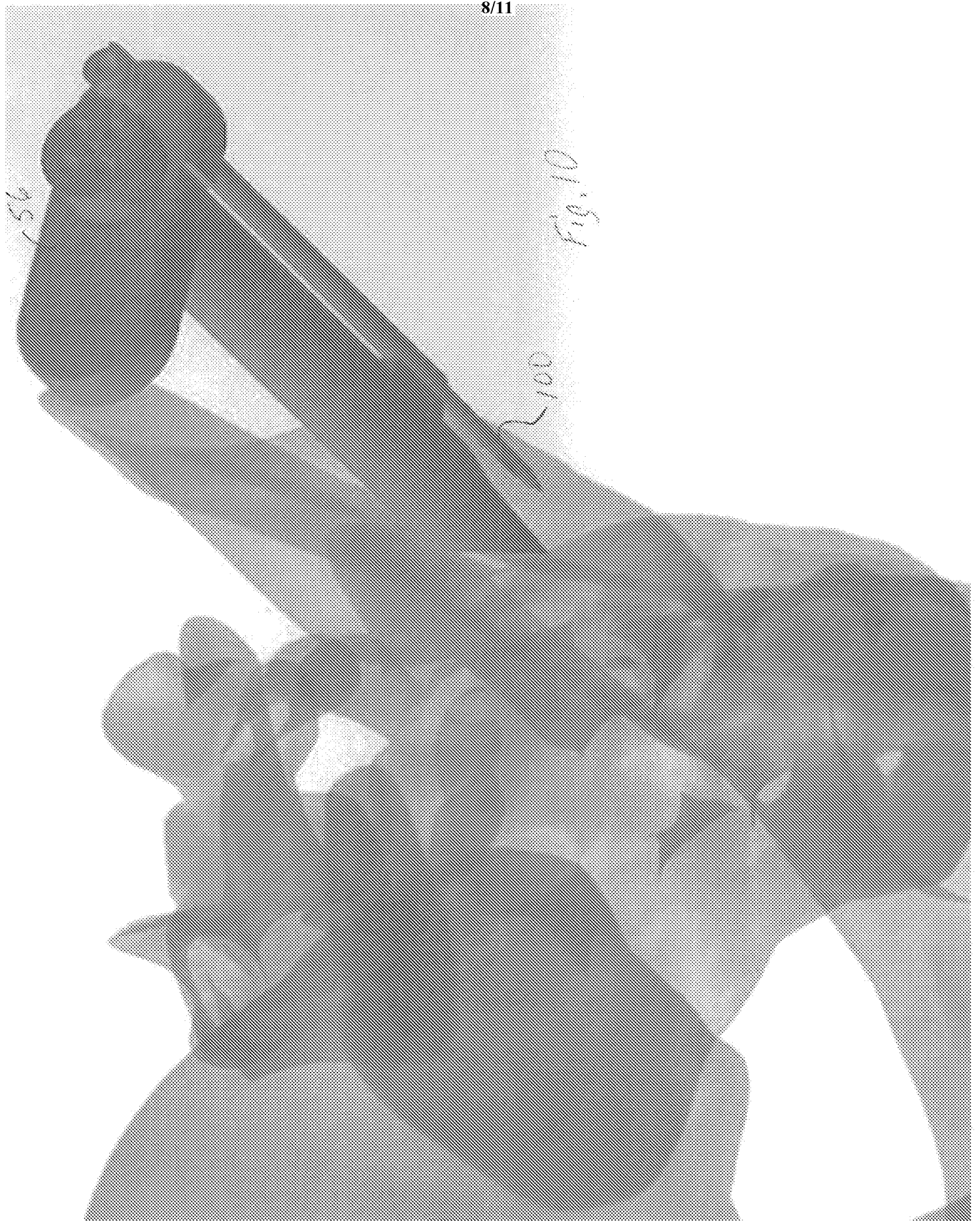
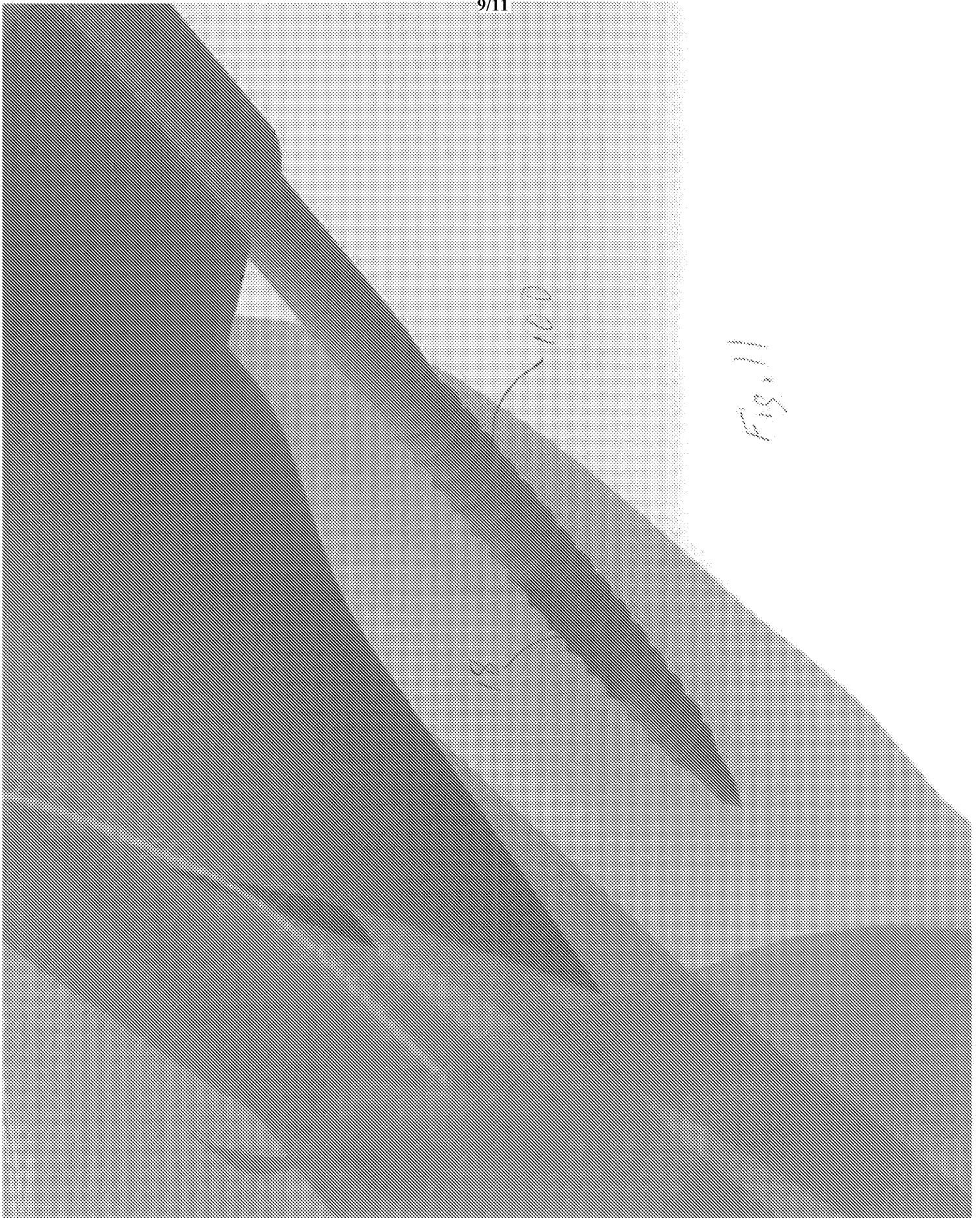


Fig. 9







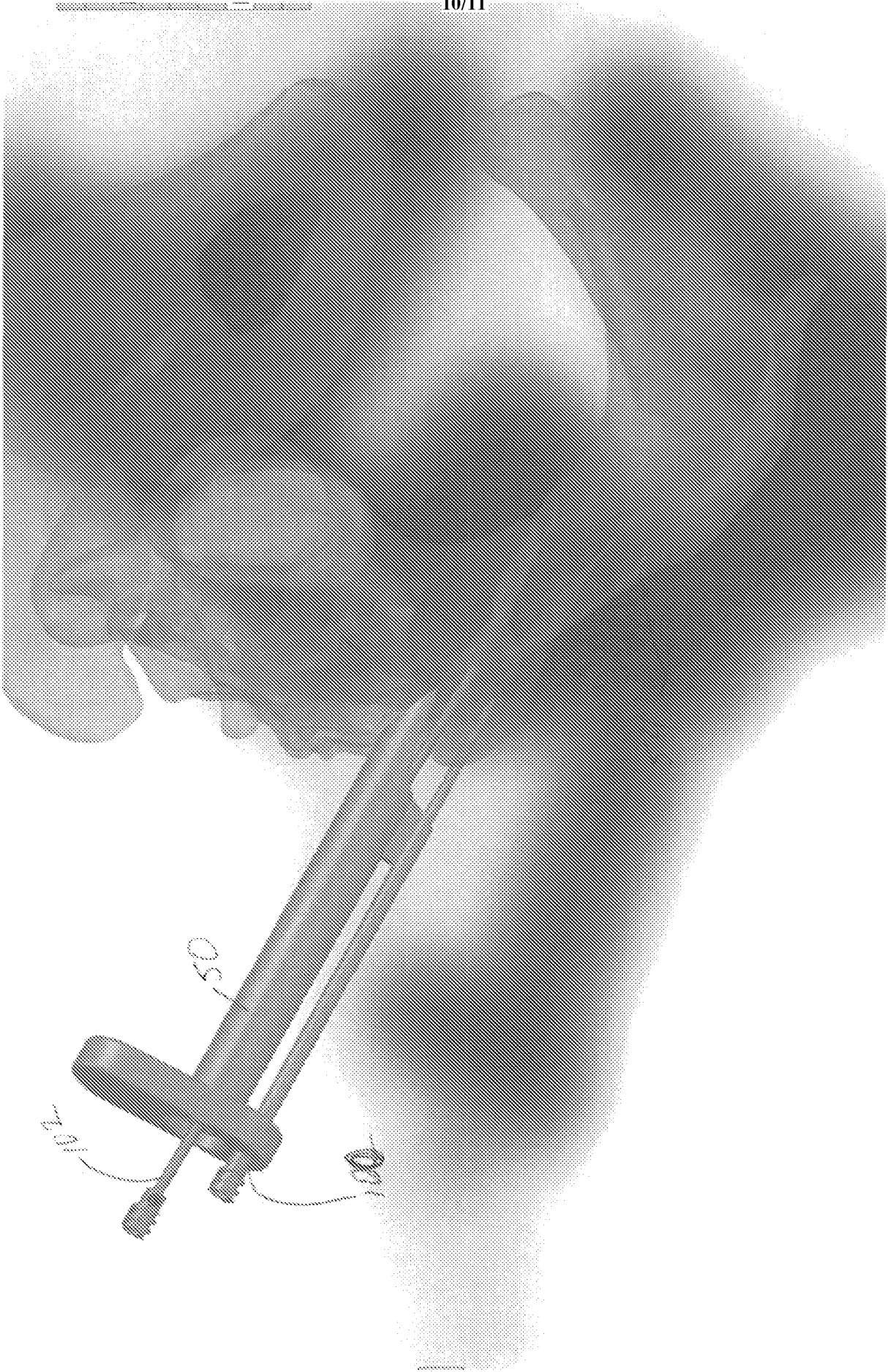


Fig. 12

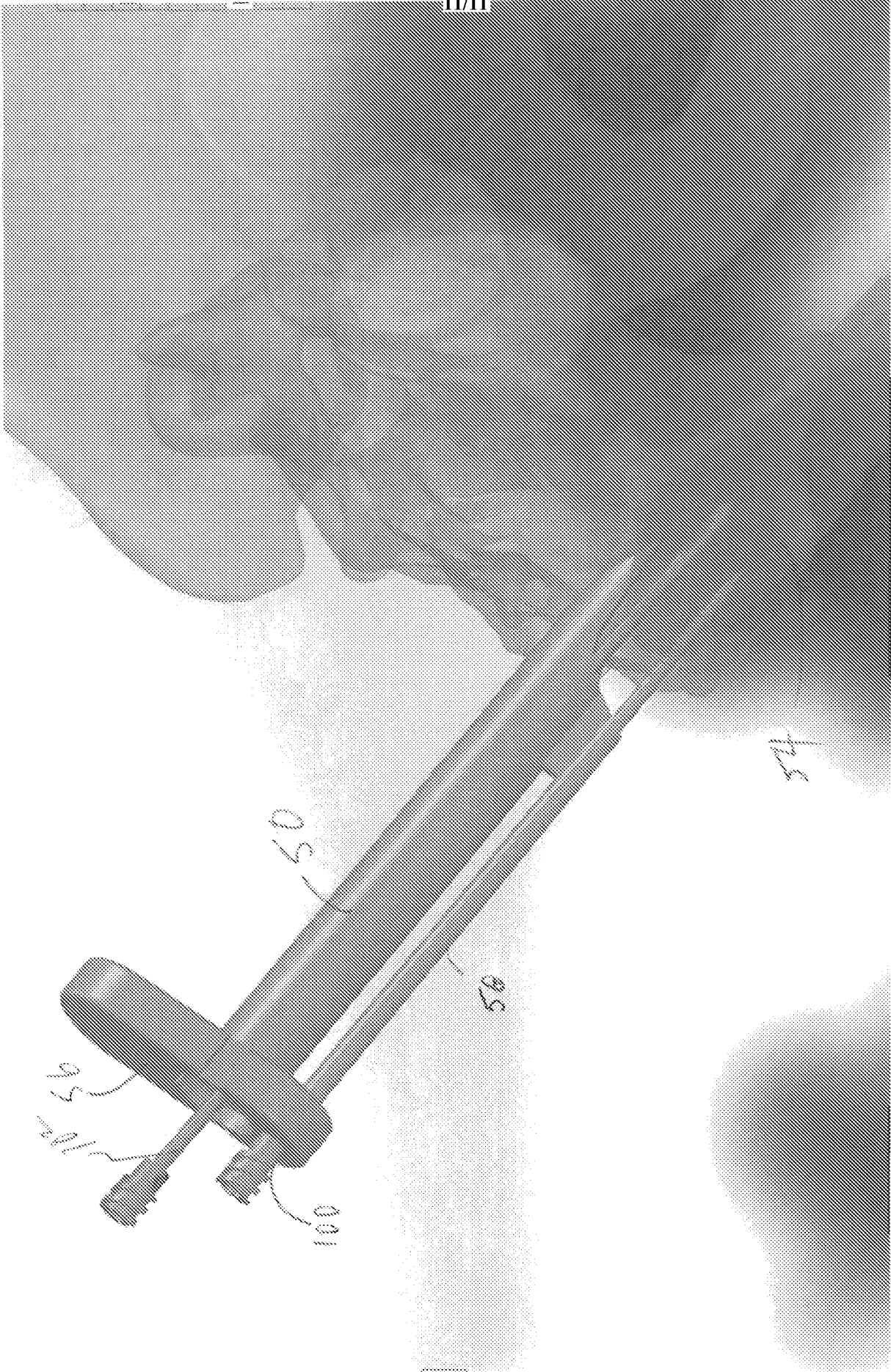


Fig. 13

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2020/020165

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/16 A61B17/86
ADD.

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B

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

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

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	US 5 098 435 A (STEDNITZ DENIS P [US] ET AL) 24 March 1992 (1992-03-24) figures 11-13 -----	1-4,7, 13,15,16 5
X	US 2014/066758 A1 (MARIK GREGORY [US] ET AL) 6 March 2014 (2014-03-06) figure 2 -----	1
X	US 2009/105775 A1 (MITCHELL DAVID [US] ET AL) 23 April 2009 (2009-04-23) paragraphs [0049], [0066]; figure 1 -----	1
X	US 2004/010236 A1 (MORAWSKI LINDA [US] ET AL) 15 January 2004 (2004-01-15) figure 6 ----- -/-	1



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

8 June 2020

Date of mailing of the international search report

11/08/2020

Name and mailing address of the ISA/

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040,
Fax: (+31-70) 340-3016

Authorized officer

Fernández Arillo, J

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2020/020165

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	CN 204 169 875 U (GAO HUI) 25 February 2015 (2015-02-25) figure 1 -----	1
X	WO 2011/054124 A1 (SPINWELDING AG [CH]; WENGER ANDREAS [CH]; MAYER JOERG [CH]) 12 May 2011 (2011-05-12) page 12; figures 17, 18 -----	1,4,5
Y	WO 2010/091368 A1 (SPINE VIEW INC [US]; TO JOHN T [US]) 12 August 2010 (2010-08-12) paragraph [0114]; figure 27 -----	5

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2020/020165

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.:
because they relate to subject matter not required to be searched by this Authority, namely:
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:

see additional sheet

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 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.:

1-5, 7, 13, 15, 16

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.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-5, 7, 13, 15, 16

The cannulated fastener of Claim 4, wherein the threads are double helix threads (claim 5), thereby solving the problem of needing fewer rotations to insert the cannulated fastener into the bone, thereby reducing the operation time.

2. claim: 6

The cannulated fastener of Claim 4, wherein the cannulated fastener includes an indicator aligned with the directional aperture, thereby solving the problem of more accurately aspirating in the target bone area.

3. claims: 8-12, 14

The cannulated fastener of Claim 1, wherein the connector is constructed of plastic overmolded to the second end of said cannulated fastener, thereby solving the problem of creating an airtight connection therebetween.

4. claims: 17-20

The cannulated fastener of Claim 1, wherein said holding surface includes knurling, annular rings, a rougher surface finish than the remainder of said cannula, or a coating, thereby solving the problem of providing alternative means of suitably holding the cannulated fastener to the bone.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2020/020165

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