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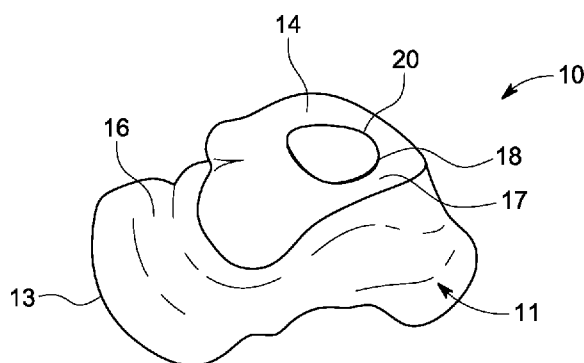


FIG. 1A

(57) Abstract: A talar implant having at least one body section, at least one mesh section and at least one solid section extending down from the body section. The solid section having at least one point end. Further disclosed is a kit for inserting a talar implant including at least one tibial guide, at least one talar guide and at least one impactor for inserting the talar implant into a patient's talus. In addition, a method for implanting a talus implant is disclosed. The method may include identifying a damaged area on a talus, projecting a missing damaged area on a contralateral joint and printing an implant based upon a mirror image of a portion of the contralateral joint. The method may include applying at least one guide, removing at least a portion of a damaged region of the talus, inserting the talar implant and setting the talar implant in the talus.

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IMPLANT FOR FOCAL TALUS DEFECTS AND METHOD

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This application claims priority benefit under 35 U.S.C. §119(e) of U.S. provisional application No. 63/068,425, filed August 21, 2020, which is incorporated herein by reference in its entirety.

TECHNICAL FIELD

[0002] The present invention relates generally to general, podiatric, and orthopaedic surgery related to the repair of focal defects in a bone. More specifically, but not exclusively, the present invention relates to focal defects in a talus of an ankle joint.

BACKGROUND OF THE INVENTION

[0003] At least one embodiment of the invention relates to an implant used to repair a focal talus defect and a method for inserting this implant into a focal talus defect. The talus bone is positioned in the lower part of an ankle joint. It can bear the weight of an individual as the weight of the individual is transmitted from the person's leg to their foot. Portions or all of a talus bone can become compromised by disease or injury. Therefore, there is a need for an implant for a talus bone, in particular there is a need for a focal talus or talar implant and a method for efficiently implanting this implant into a patient's talus.

SUMMARY

[0004] At least one embodiment discloses a talar implant having at least one body section, at least one mesh section and at least one solid section extending down from the body section, with the solid section having at least one point or spike.

[0005] In at least one embodiment there is a kit for inserting a talar implant including at least one tibial guide, at least one talar guide and at least one impactor for inserting the talar implant into a patient's talus.

[0006] In addition, there is also a method for implanting a talus implant that may include identifying a damaged boney area, projecting a missing damaged area on a contralateral joint and then printing an implant based upon a mirror image of a normal portion of the contralateral joint. The method may also include using at least one guide,

removing at least a portion of a damaged region of the talus and then inserting the talar implant and setting the talar implant.

BRIEF DESCRIPTION OF THE DRAWINGS

[0007] The accompanying drawings, which are incorporated in and constitute a part of the specification, illustrate embodiments of the invention and together with the detailed description herein, serve to explain the principles of the invention. It is emphasized that, in accordance with the standard practice in the industry, various features are not drawn to scale. In fact, the dimensions of the various features may be arbitrarily increased or reduced for clarity of discussion. The drawings are only for purposes of illustrating preferred embodiments and are not to be construed as limiting the invention.

FIG. 1A is a top perspective view of an implant implanted into a talus, in accordance with an aspect of the present invention;

FIG. 1B is a top view of the implant of FIG. 1 implanted into the talus, in accordance with an aspect of the present invention;

FIG. 2A is a side perspective view of the implant of FIG. 1 positioned above the talus prior to implantation, in accordance with an aspect of the present invention;

FIG. 2B is a side view of the implant of FIG. 1, in accordance with an aspect of the present invention;

FIG. 2C is a top view of the implant of FIG. 1, in accordance with an aspect of the present invention;

FIG. 2D is a top perspective view of the implant of FIG. 1, in accordance with an aspect of the present invention;

FIG. 3 is a medial view of the ankle joint with the talus implant of FIG. 1 implanted into the talus bone, in accordance with an aspect of the present invention;

FIG. 4A is a side perspective view of an impactor instrument for implanting an focal talar implant, in accordance with an aspect of the present invention;

FIG. 4B is another side perspective view of the impactor instrument of FIG. 4A, in accordance with an aspect of the present invention;

FIG. 4C is a side perspective view of the impactor instrument of FIG. 4A, in accordance with an aspect of the present invention;

FIG. 4D is a side view of the impactor instrument of FIG. 4A, in accordance with an aspect of the present invention;

FIG. 4E is another side view of the impactor instrument of FIG. 4A, in accordance with an aspect of the present invention;

FIG. 4F is a perspective view of the impactor instrument of FIG. 4A, in accordance with an aspect of the present invention;

FIG. 5A is a side view of a reamer, in accordance with an aspect of the present invention;

FIG. 5B is a side perspective view of the reamer of FIG. 5A, in accordance with an aspect of the present invention;

FIG. 5C is a side view of the reamer of FIG. 5A, in accordance with an aspect of the present invention;

FIG. 5D is a front perspective view of the reamer of FIG. 5A, in accordance with an aspect of the present invention;

FIG. 5E is an end side view of the reamer of FIG. 5A, in accordance with an aspect of the present invention;

FIG. 6A is a perspective view of a custom tibial guide, in accordance with an aspect of the present invention;

FIG. 6B is a side perspective view of the custom tibial guide of FIG. 6A, in accordance with an aspect of the present invention;

FIG. 6C is a perspective top view of the custom tibial guide of FIG. 6A, in accordance with an aspect of the present invention;

FIG. 6D is a top view of the custom tibial guide of FIG. 6A, in accordance with an aspect of the present invention;

FIG. 7A is a side view of a custom talar guide, in accordance with an aspect of the present invention;

FIG. 7B is a bottom side of the custom talar guide of FIG. 7A, in accordance with an aspect of the present invention;

FIG. 7C is a top perspective view of the custom talar guide of FIG. 7A, in accordance with an aspect of the present invention;

FIG. 7D is a side view of the custom talar guide of FIG. 7A, in accordance with an aspect of the present invention;

FIG. 8A is a perspective view of a custom reamer, in accordance with an aspect of the present invention;

FIG. 8B is a top view of the custom reamer of FIG. 8A, in accordance with an aspect of the present invention;

FIG. 9A is a perspective view an ankle joint showing a step for inserting an implant in a talus, in accordance with an aspect of the present invention;

FIG. 9B is a perspective view an ankle joint showing another step for inserting an implant in a talus, in accordance with an aspect of the present invention;

FIG. 9C is a side view of an ankle joint showing another step for inserting an implant in a talus, in accordance with an aspect of the present invention;

FIG. 9D is an anterior view of an ankle joint showing another step for inserting an implant in a talus, in accordance with an aspect of the present invention;

FIG. 9E is side view of an ankle joint showing another step for inserting an implant in a talus, in accordance with an aspect of the present invention;

FIG. 9F is a side view oof an ankle joint showing another step for inserting an implant in a talus, in accordance with an aspect of the present invention; and

FIG. 10 is a flow chart for the method of fabricating and implanting the implant in the talus.

DETAILED DESCRIPTION FOR CARRYING OUT THE INVENTION

[0008] Generally stated, disclosed herein are guides, implants, devices, instruments, systems, and assemblies for achieving bone fusion. Further, methods for using the guides, implants, devices, instruments, systems, and assemblies to repair bone defects are discussed.

[0009] In this detailed description and the following claims, the words proximal, distal, anterior or plantar, posterior or dorsal, medial, lateral, superior and inferior are defined by their standard usage for indicating a particular part or portion of a bone or implant according to the relative disposition of the natural bone or directional terms of reference. For example, “proximal” means the portion of a device or implant nearest the torso, while “distal” indicates the portion of the device or implant farthest from the torso. As for directional terms, “anterior” is a direction towards the front side of the body, “posterior” means a direction towards the back side of the body, “medial” means towards the midline of the body, “lateral” is a direction

towards the sides or away from the midline of the body, “superior” means a direction above and “inferior” means a direction below another object or structure. Further, specifically in regards to the foot, the term “dorsal” refers to the top of the foot and the term “plantar” refers the bottom of the foot.

[0010] Similarly, positions or directions may be used herein with reference to anatomical structures or surfaces. For example, as the current implants, devices, instrumentation and methods are described herein with reference to use with the bones of the foot, the bones of the foot, ankle and lower leg may be used to describe the surfaces, positions, directions or orientations of the implants, devices, instrumentation and methods. Further, the implants, devices, instrumentation and methods, and the aspects, components, features and the like thereof, disclosed herein are described with respect to one side of the body for brevity purposes. However, as the human body is relatively symmetrical or mirrored about a line of symmetry (midline), it is hereby expressly contemplated that the implants, devices, instrumentation and methods, and the aspects, components, features and the like thereof, described and/or illustrated herein may be changed, varied, modified, reconfigured or otherwise altered for use or association with another side of the body for a same or similar purpose without departing from the spirit and scope of the invention. For example, the implants, devices, instrumentation and methods, and the aspects, components, features and the like thereof, described herein with respect to the right foot may be mirrored so that they likewise function with the left foot. Further, the implants, devices, instrumentation and methods, and the aspects, components, features and the like thereof, disclosed herein are described with respect to the foot for brevity purposes, but it should be understood that the implants, devices, instrumentation and methods may be used with other bones of the body having similar structures.

[0011] Referring to the drawings, wherein like reference numerals are used to indicate like or analogous components throughout the several views, and with particular reference to FIG. 1A is a top side perspective view of the inventive implant 20 implanted into a talus.

[0012] FIG. 1B is a top view of the implant 20 implanted into the talus bone 11. For example, there is shown an implant body 20 implanted around an open rim of a talus bone 11. The talus bone includes a body 17, a neck 16 which leads to a head 13 and a process 14. This feature is shown in FIG. 1A as well.

[0013] FIG. 2A is a side perspective view of the implant 20 positioned above the talus, wherein the talus implant 20 includes a mesh region 22 having a patterned mesh that can be for example in the form of a honeycomb pattern of varying porosity or alternatively, of a standard or uniform porosity. A plurality of solid prongs such as prongs 26 and 28 (See FIG. 2B) extend out from implant 20 through the mesh and towards a spike end. The implant 20 is configured to be printed such as through 3D printing with the top surface 24 of implant 20 being further coated with a shiny or resilient coat 24 (See FIGS. 2C and 2D).

[0014] FIG. 3 is a side view of the ankle joint with the talus implant 20 implanted into the talus bone. For example, there is shown the talus 11 having the implant 20 positioned therein. A tibia bone 30 is positioned superior to the talus implant 20 and the talus bone 11. In addition, as shown, the neck of the talus 16 extends into a head 13 which then extends into contact with the navicular bone 19.

[0015] FIGS. 4A-4F show various views of an impactor instrument for implanting the implant 20. The impactor 50 is configured as a tool for inserting the implant 20 into the talus 11. For example, the impactor 50 includes a body section 52, a first end 54 and a second end 56 (See FIGS. 4B, 4D and 4F). The second end 56 is a cup shape (or concave bowl shape) configured to accept the head or surface of the implant 20. FIGS. 4C, 4E and 4F are 2-D wireframe depictions of the impactor 50 from various perspectives.

[0016] FIGS. 5A-5E show different views of a bone cutting reamer. For example, the reamer is configured to carve out a section of the talus 11 to facilitate the implantation of the implant 20. The reamer 60 includes a handle 62, having indents 63. The handle has a smooth or continuous section 64 that is proximate and extends to a cutting head 68. This handle extends to a head 68. The head 68 is configured to be a frusto-conical shape so that it can be extended into the talus 11 to create an opening that facilitate the implantation of the implant 20. The head also includes an open channel 66 which extends substantially longitudinally along the handle 62. This open channel 66 allows for the withdrawal of material or fluid from the talus 11 when it is being actuated.

[0017] FIG. 6A is a perspective view of a custom tibial cutting guide 70 for which the tibial guide 70 includes a body section 71 with wings 75 and 77 with an extension section 72 having holes 73.1 and 73.2. There is also a protrusion 76 having holes 78 and 79. In

addition, a slot 74 extends along the width of the tibial cutting guide through which a saw blade may be placed.

[0018] FIG. 6B is a side perspective view of the tibial cutting guide 70 and more clearly shows the body section 71 having the protrusion 76 with the holes 78 and 79 extending down in a cylindrical manner. In addition, FIG. 6B shows the wings 75 and 77. The cutting slot 74 is shown to extend from a first side shown in FIG. 6A to the second side shown in FIG. 6B (see also FIGS. 6C and 6D as well). The tibial cutting guide 70 is configured to be attached in close proximity to the tibia to allow a medical practitioner to slice or remove a portion of a patient's tibia through a knife or other cutting mechanism operating through the slot 74.

[0019] FIG. 7A is a side view of a custom talar cutting guide 80, which includes holes 82, 83 and 84 disposed in a U-shaped body 81. These holes 82, 83, and 84 extend in a cylindrical manner to form slots for receiving pins which are insertable into these holes and which are insertable into a corresponding talus implant.

[0020] FIG. 7B shows the bottom side for the talar cutting guide 80. The surface of the bottom side is configured to be placed on top of the talus 11 prior to a reaming step. Accordingly, the opposite facing top side of the talar cutting guide 80 which has holes 82, 83 and 84 which are configured to receive pins is shown in FIG. 7C. The body 81 of the talar cutting guide is shaped as a substantially U- shape or horseshoe shape having a first end 86 and a hole 84, a second end 85 having a hole 83 and a distal region 87 spaced opposite the ends 85 and 86. FIG. 7D is a side view of the custom talar cutting guide 80 which includes holes 82, 83 and 84. Hole 82 is positioned in the distal region 87 of the body 81.

[0021] FIG. 8A is a perspective view of a custom bone cutting reamer 90 which is positioned in talus 11 and configured to remove bone from a region of the talus 11 by using a head 99, and a shaft 92 which is integrally attached to the head 99. The head 99 has a plurality of teeth 98 as well as a central hole 96. The central hole 96 (See FIG. 8B) can be used to slide over a guide pin which can be set by the talus guide. (See FIG. 7B).

[0022] FIGS. 9A -9F show the method for preparing and implanting the talus implant 20 into a patient. FIG. 10 further shows as a flow chart the example steps for the fabrication and implantation method for the implant 20 into the talus 11. For example, the method

process may start at S1 during which the health care professional may identify the most damaged area of the talus 11. Once the damaged area is identified either through surgery or through an X-ray, MRI or CT scan, the extent of the damage of this region is assessed. The health care professional may expand the area that the implant 20 will replace beyond the damaged area by a pre-set amount. The method at S2 may include the health care professional projecting the missing or damaged area based upon a mirror view or image or projection of an undamaged contralateral talus. Next, at S3, the implant 20 may be printed, followed for example by S4, where the health care professional may remove damaged bone from the tibia by using a cutting instrument. This is shown at FIGS. 9A and 9B. It should be noted that S4 and S5 may be interchanged depending on the preference of the health care professional.

[0023] The health care professional may then apply the tibial guide 70 as shown in FIG. 9A and 9B S4, wherein the tibial guide can be inserted on to the tibia 30. Pins 110, 111, 112 and 113 are inserted into the respective holes 73.1 and 73.2 as well as holes 78 and 79. With the pins being inserted into these holes the tibial guide 70 is fixed to the tibia 30. The fixing of the tibial guide 70 allows for the extension of the slot 74 (See FIG. 6D) across the tibia 30 which allows for the cutting of the tibia S5 to expose the talus to the health care professional.

[0024] The method may include the application of the talar guide 80 by the health care professional S6 on to the talus 11 as shown in FIG. 9C. This is accomplished by placing the talar guide 80 having the surface 89 (See FIG. 7B) on the talus 11 and then inserting pins or rods such as pins 101, 103, and 105 through respective holes 82, 83, 84 (See FIG. 7C). The application of the talar guide 80 can be used to set a pin such as pin 105 which inserts through hole 82 on the talar guide 80 to fix the location of the guide 80 for the insertion of the reamer 60, 90 as listed at S7 of FIG. 10.

[0025] Next, as shown in FIGS. 9D and 9E and in FIG. 10, S8, the reamer 60, 90 is positioned to be inserted into the talus 11. Specifically, reamer 60 has a substantially frusto conical shaped head which closely approximates the implant 20, is inserted into the talus to remove the damaged bone and allow for the insertion of the implant 20. The reamer also includes the central hole 66, 96 which can be slid down on the pin 105 to then remove the damaged bone in a guided manner.

[0026] Once the damaged bone has been removed, at S9, the implant 20 can then be inserted with an impactor 50 to set the implant 20 into the talus. (See FIG. 9F and S9, 10 in FIG. 10). The impactor 50 has a concave face 56 that eliminates any damage to the domed surface of the implant 20. After the implant has been implanted, the procedure may be completed and the patient's incision may be closed.

[0027] The terminology used herein is for the purpose of describing particular embodiments only and is not intended to be limiting of the invention. As used herein, the singular forms "a", "an" and "the" are intended to include the plural forms as well, unless the context clearly indicates otherwise. It will be further understood that the terms "comprise" (and any form of comprise, such as "comprises" and "comprising"), "have" (and any form of have, such as "has", and "having"), "include" (and any form of include, such as "includes" and "including"), and "contain" (and any form of contain, such as "contains" and "containing") are open-ended linking verbs. As a result, a method or device that "comprises," "has," "includes," or "contains" one or more steps or elements possesses those one or more steps or elements, but is not limited to possessing only those one or more steps or elements. Likewise, a step of a method or an element of a device that "comprises," "has," "includes," or "contains" one or more features possesses those one or more features, but is not limited to possessing only those one or more features. Furthermore, a device or structure that is configured in a certain way is configured in at least that way, but may also be configured in ways that are not listed.

[0028] The invention has been described with reference to the preferred embodiments. It will be understood that the architectural and operational embodiments described herein are exemplary of a plurality of possible arrangements to provide the same general features, characteristics, and general system operation. Modifications and alterations will occur to others upon a reading and understanding of the preceding detailed description. It is intended that the invention be construed as including all such modifications and alterations.

CLAIMS

What is claimed is:

1. A talar implant comprising:
at least one body section;
at least one mesh section; and
at least one solid section extending down from the body section, the at least one solid section comprising at least one point.
2. The talar implant of claim 1, wherein the at least one body section is semi-spherical.
3. The talar implant of claim 2, wherein the at least one body section comprises at least one smooth continuous surface.
4. The talar implant of claim 1, wherein the at least one mesh section is configured as a honeycomb pattern comprising a plurality of cells.
5. The talar implant of claim 1, wherein the at least one mesh section has a variable porosity.
6. The talar implant of claim 1, wherein the at least one mesh section, the at least one body section and the at least one solid section are printed as one piece.
7. The talar implant of claim 1, wherein the at least one solid section comprises at least one spike element.
8. The talar implant of claim 1, wherein the at least one solid section comprises a plurality of spike elements extending out from the body section.

9. A kit for inserting a talar implant comprising:
 - at least one tibial guide;
 - at least one talar guide;
 - at least one impactor instrument for inserting the talar implant into a patient's talus.
10. The kit of claim 9, wherein the at least one tibial guide has at least one slot configured to accept a cutting tool to cut a tibia in a guided manner along the slot.
11. The kit of claim 9, wherein the at least one talar guide is substantially U-shaped and comprises a plurality of holes.
12. The kit of claim 9, wherein the impactor has a first end and a second end, wherein the first end is configured as a substantially concave surface.
13. A method for implanting a talus implant comprising:
 - identifying a damaged area;
 - projecting a missing damaged area on a contralateral joint;
 - printing an implant based upon a mirror image of a portion of the contralateral joint;
 - applying at least one cutting guide to a bone;
 - removing at least a portion of a damaged region of the talus;
 - inserting the talar implant into the talus; and
 - setting the talar implant within the talus.
14. The method of claim 13, wherein the method for setting the talar implant comprises using an impactor to set the talar implant.
15. The process of claim 13, wherein the at least one cutting guide comprises at least one of a tibial guide or a talar guide.

16. The method of claim 13, wherein the removing at least a portion of a damaged region of the talus comprises using at least one reamer for removing at least a portion of the talus that is either damaged or in a region of a damaged portion of the talus.
17. The method of claim 13, further comprising removing a portion of a tibia.
18. The method of claim 15, wherein the talar guide is configured to receive a pin, and wherein the method further comprises using a reamer guided by the pin on the talar guide to guide the reamer.
19. The method of claim 13, wherein the talar implant has at body, a mesh portion and a solid portion.
20. The method of claim 19, wherein the body of the talar implant has a polished surface, and wherein the mesh portion has variable porosity.

1/18

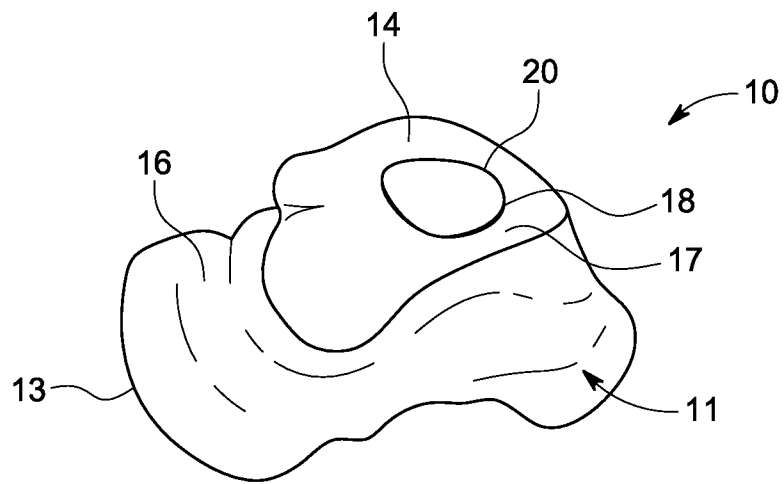


FIG. 1A

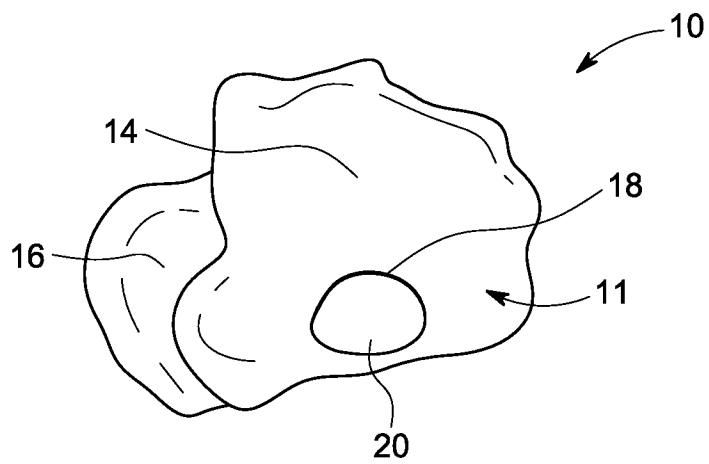


FIG. 1B

2/18

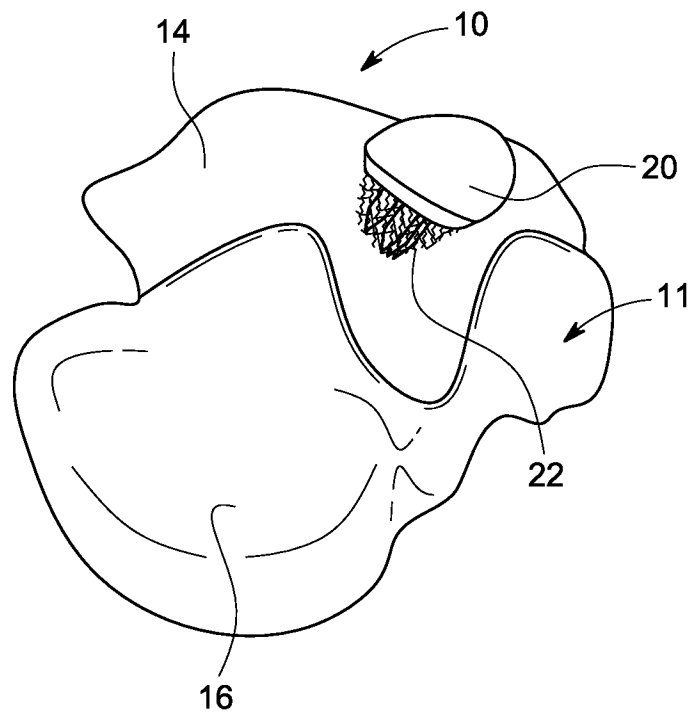


FIG. 2A

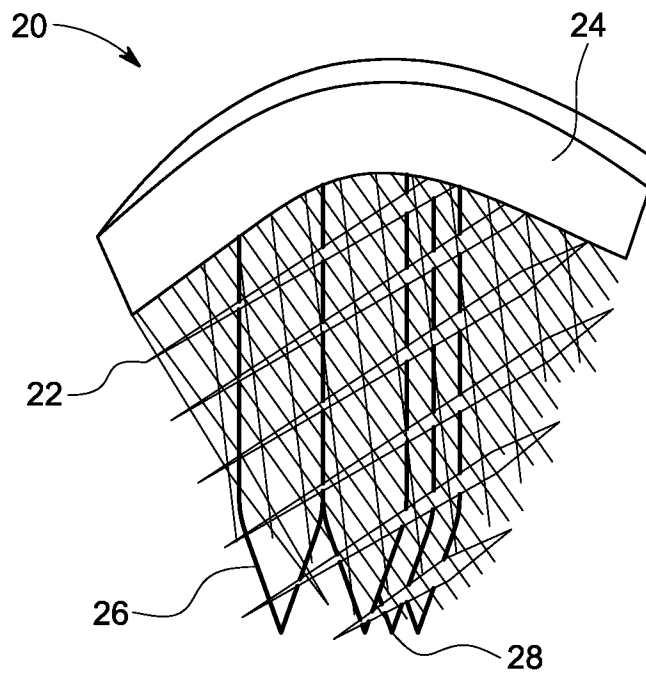


FIG. 2B

3/18

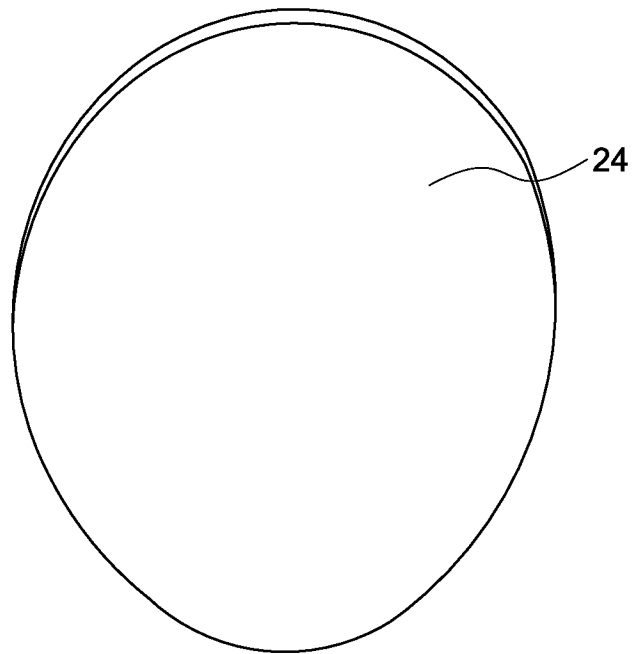


FIG. 2C

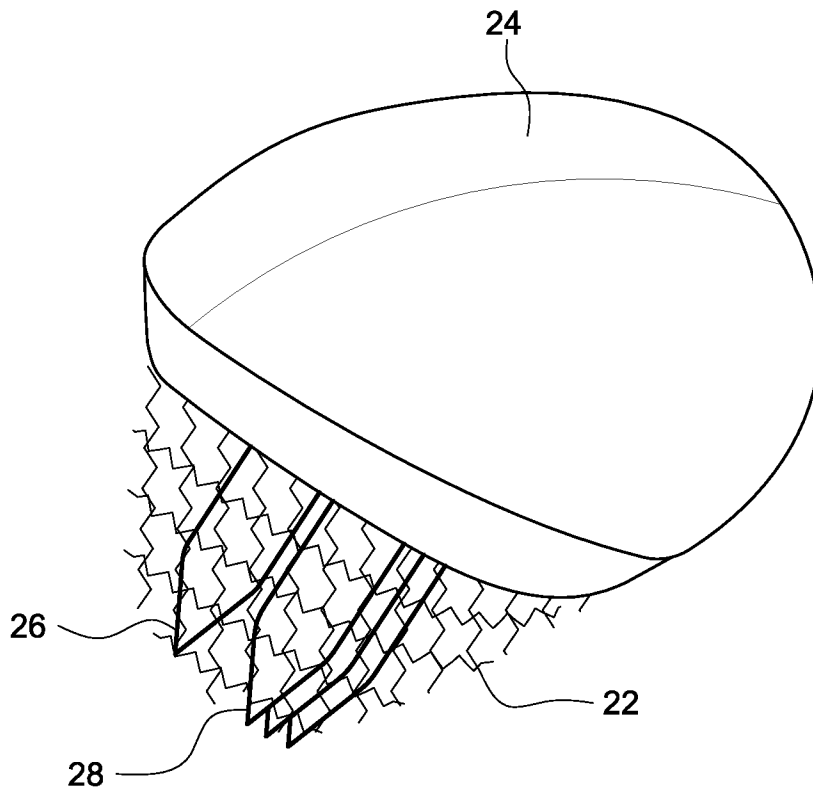


FIG. 2D

4/18

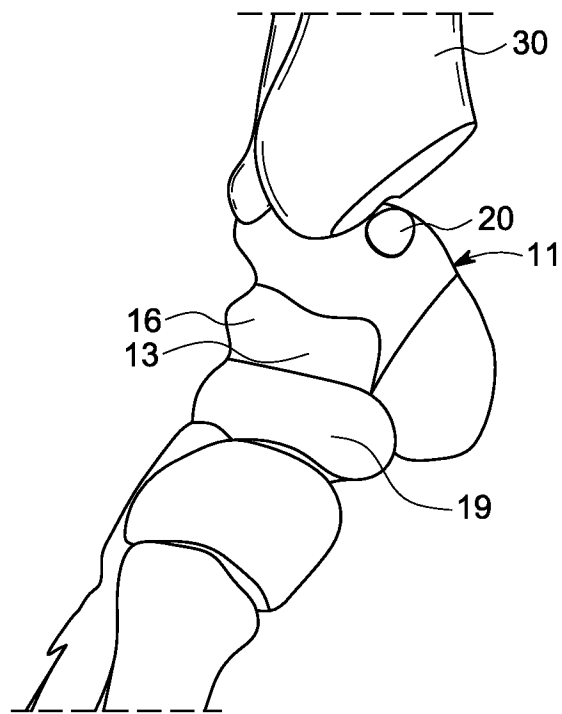


FIG. 3

5/18

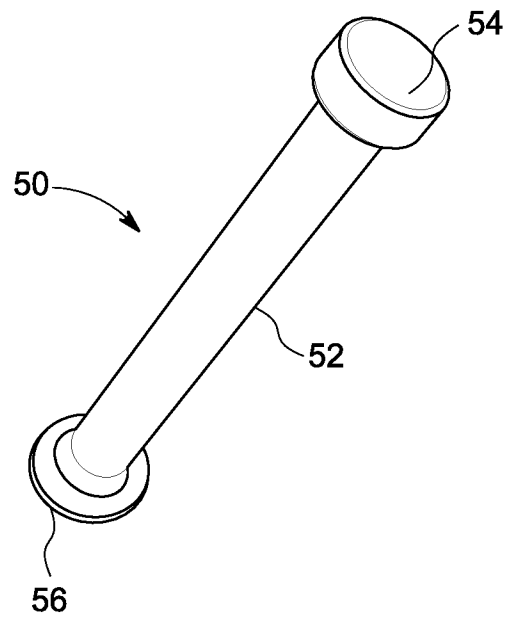


FIG. 4A

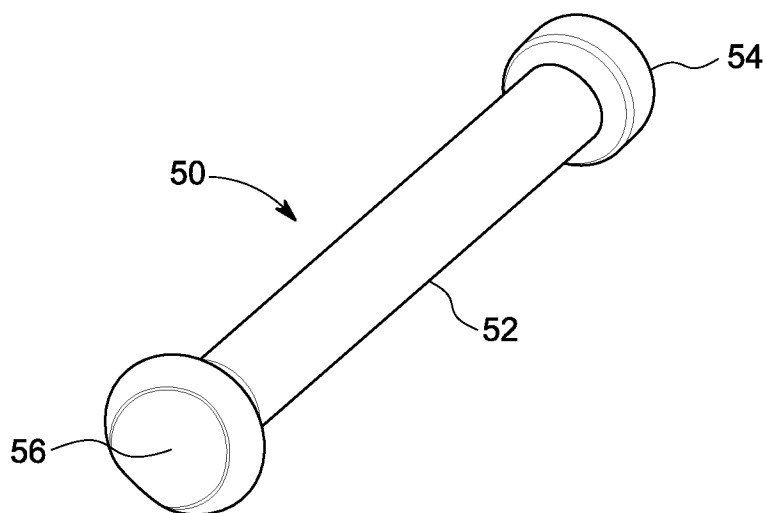


FIG. 4B

6/18

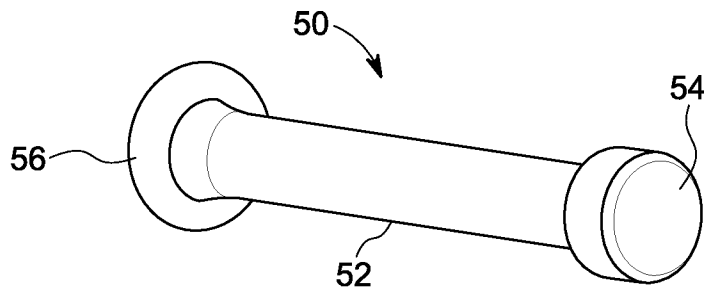


FIG. 4C

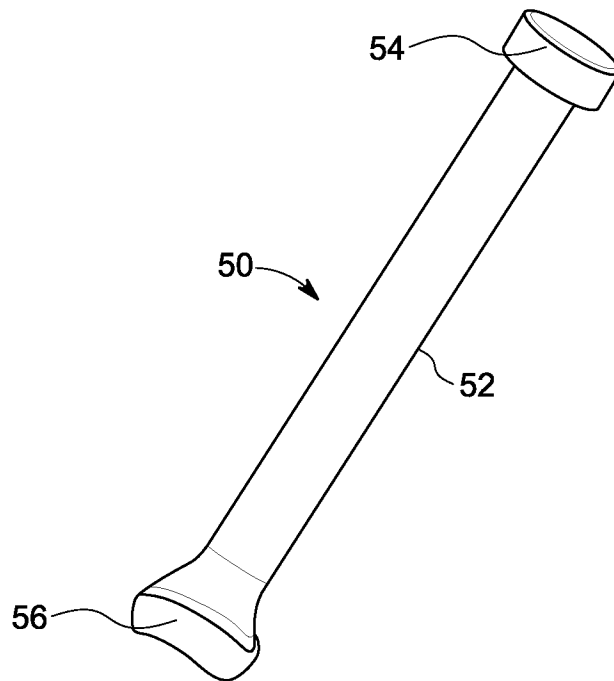


FIG. 4D

7/18

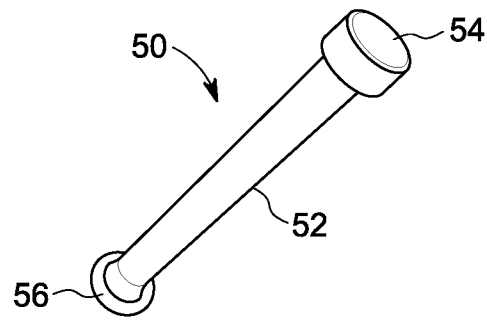


FIG. 4E

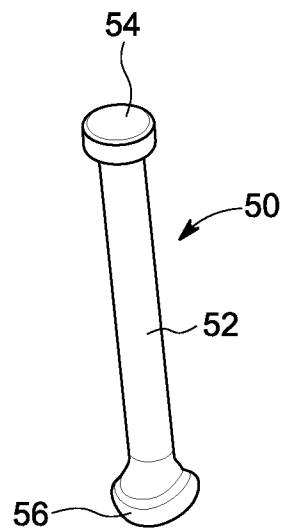


FIG. 4F

8/18

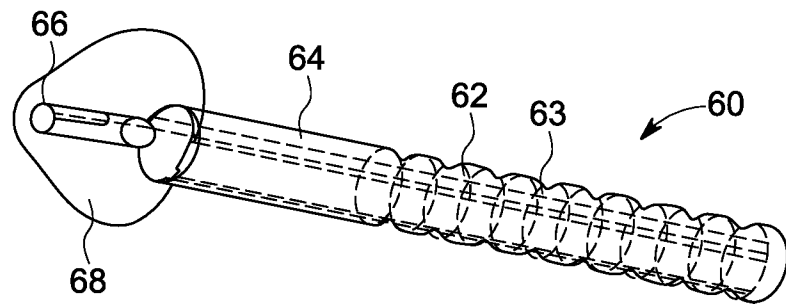


FIG. 5A

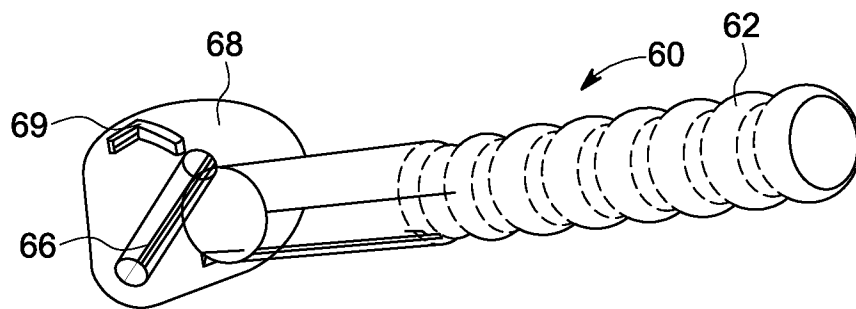


FIG. 5B

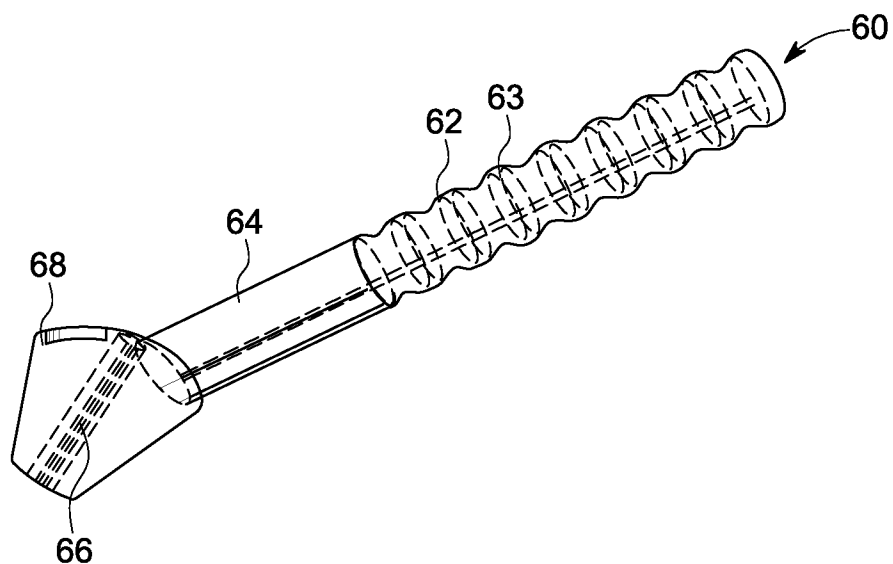


FIG. 5C

9/18

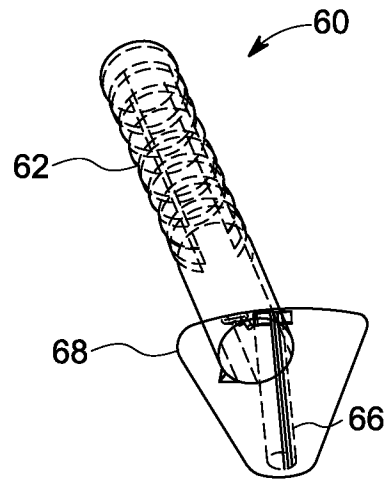


FIG. 5D

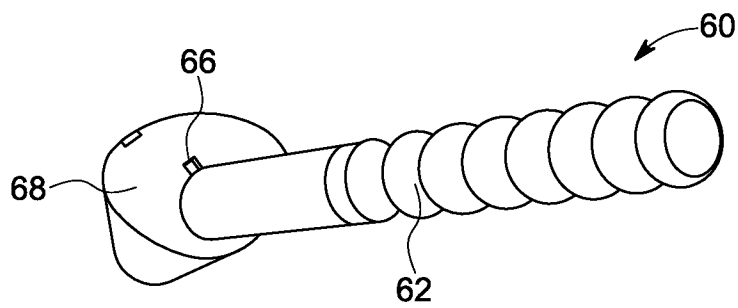


FIG. 5E

10/18

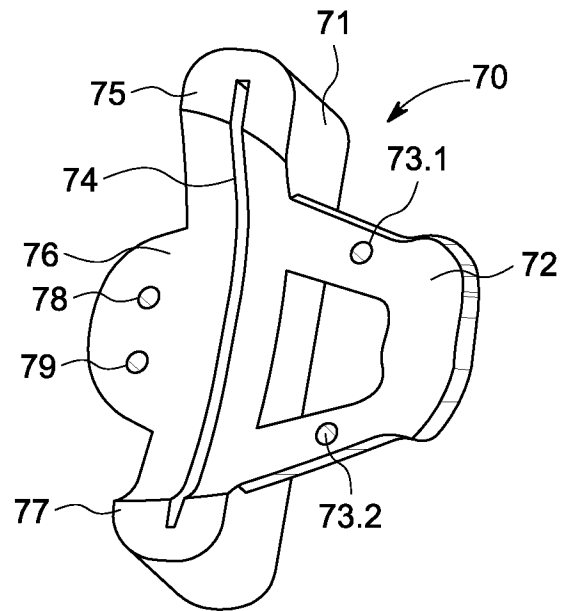


FIG. 6A

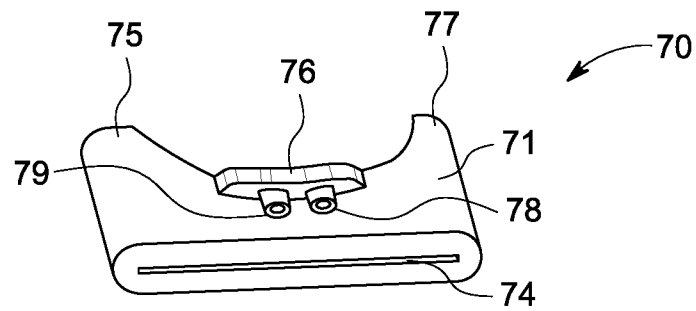


FIG. 6B

11/18

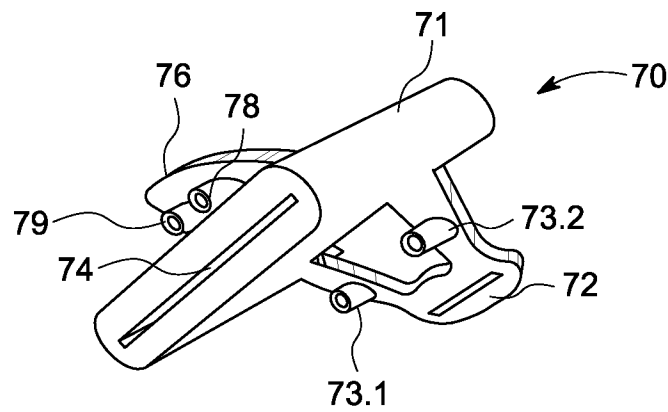


FIG. 6C

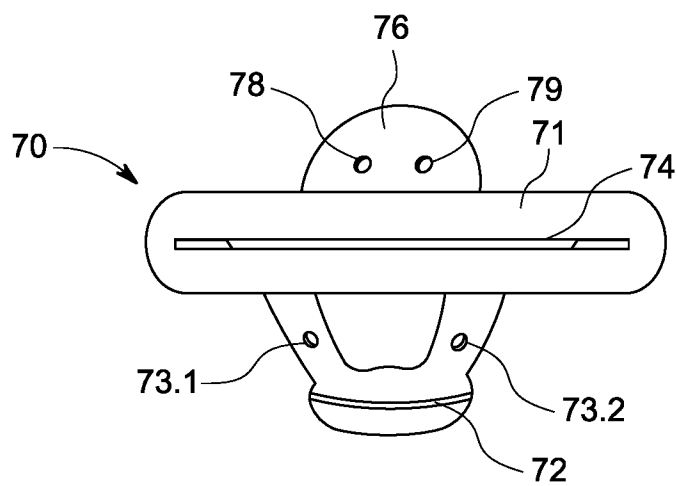


FIG. 6D

12/18

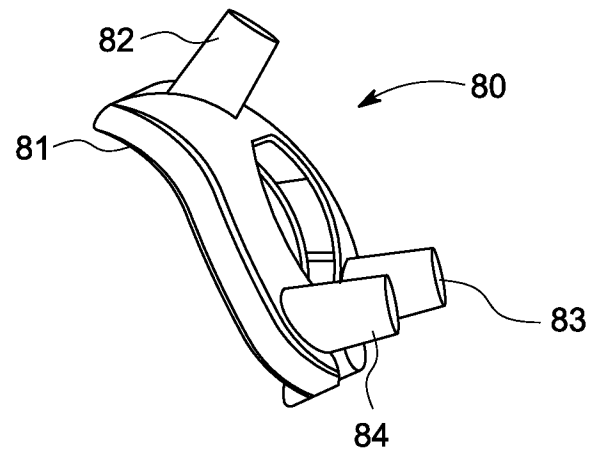


FIG. 7A

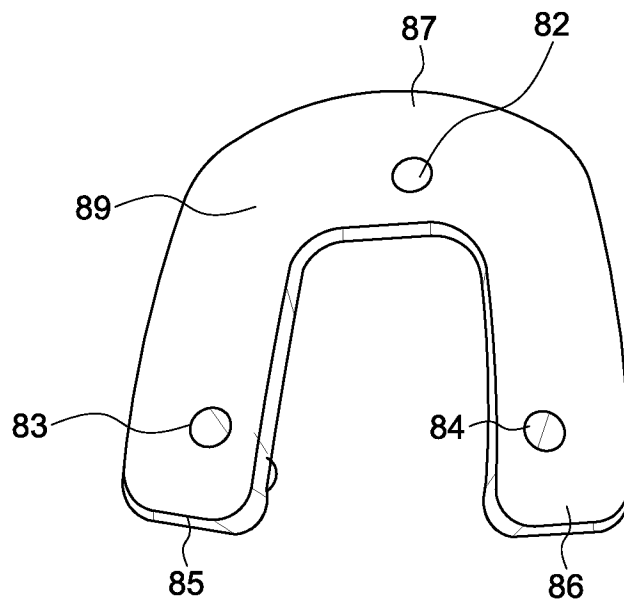


FIG. 7B

13/18

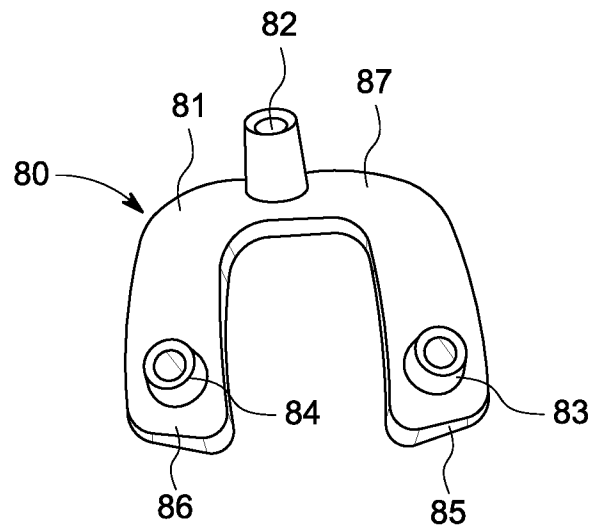


FIG. 7C

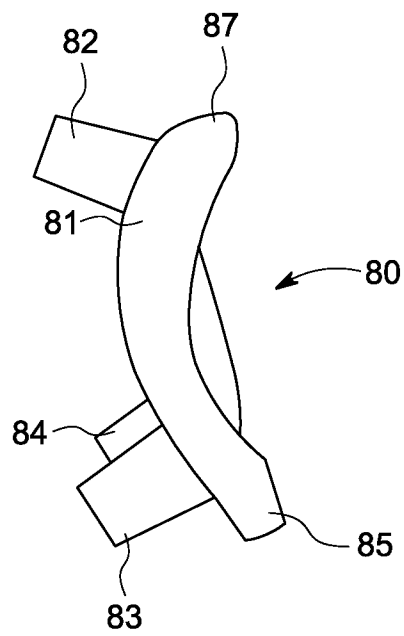


FIG. 7D

14/18

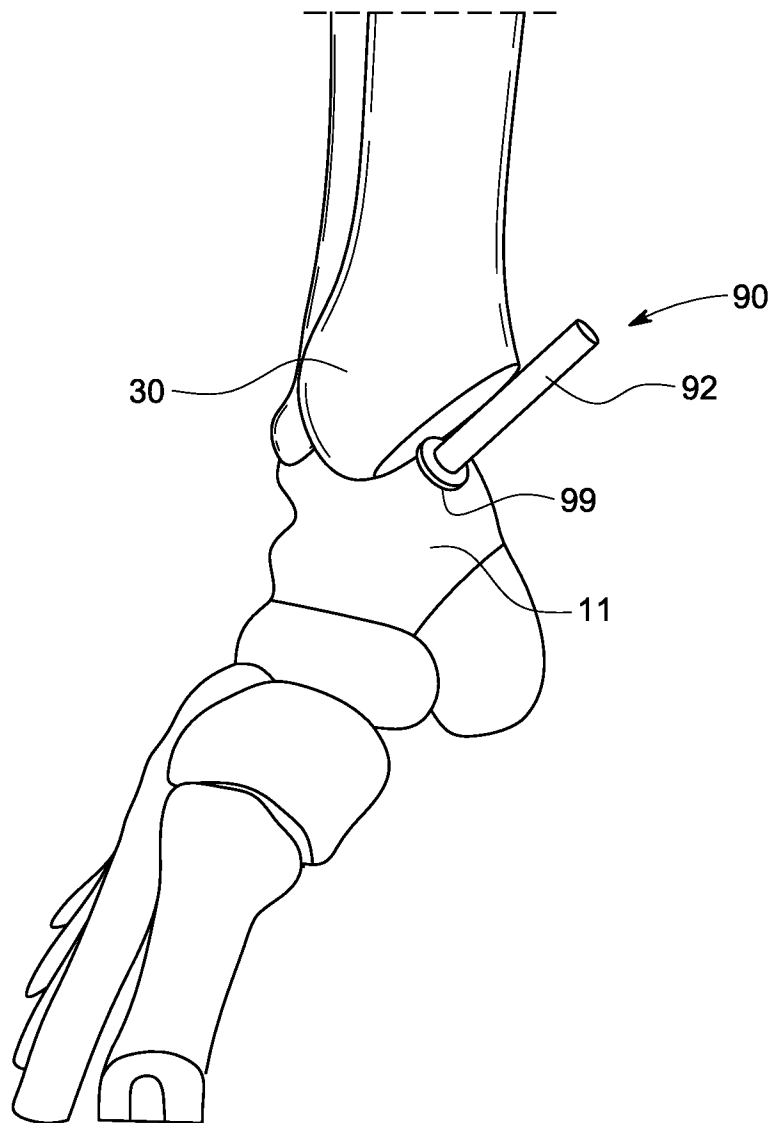


FIG. 8A

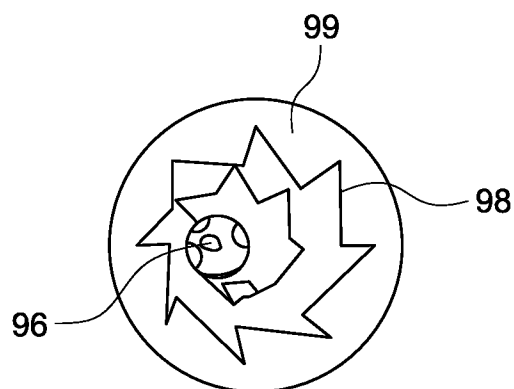


FIG. 8B

15/18

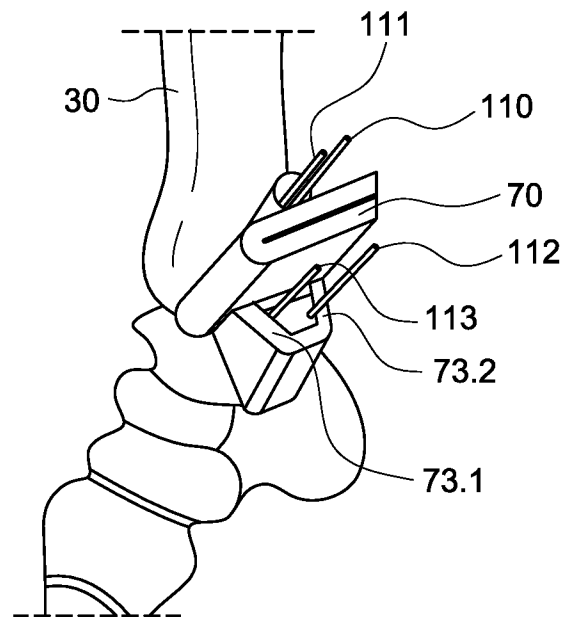


FIG. 9A

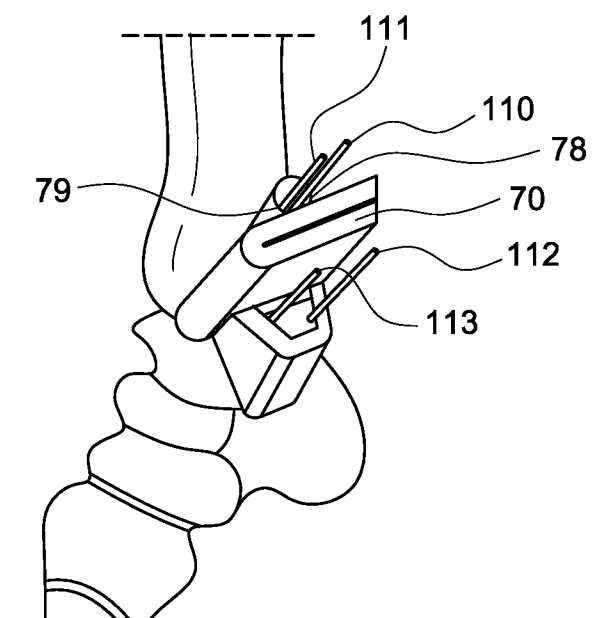


FIG. 9B

16/18

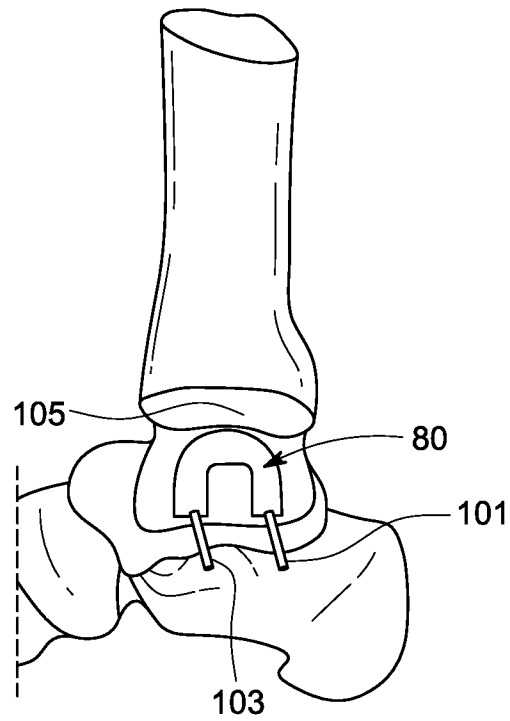


FIG. 9C

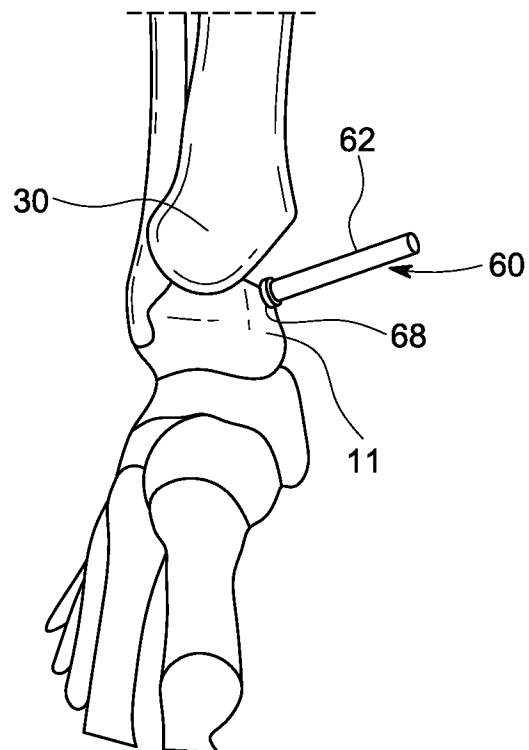


FIG. 9D

17/18

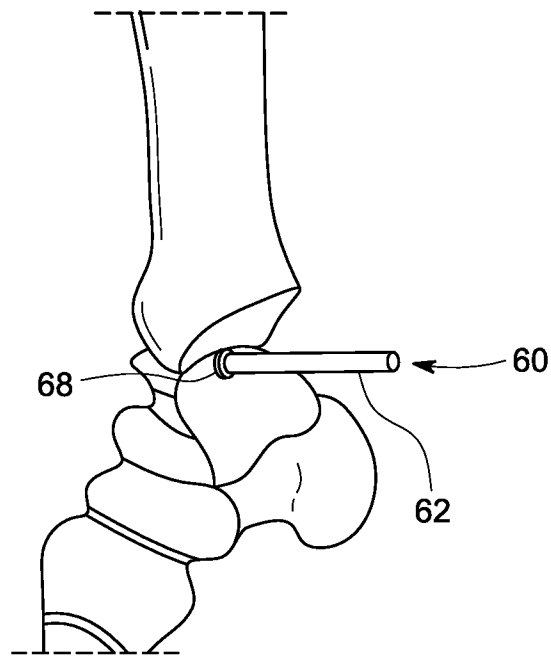


FIG. 9E

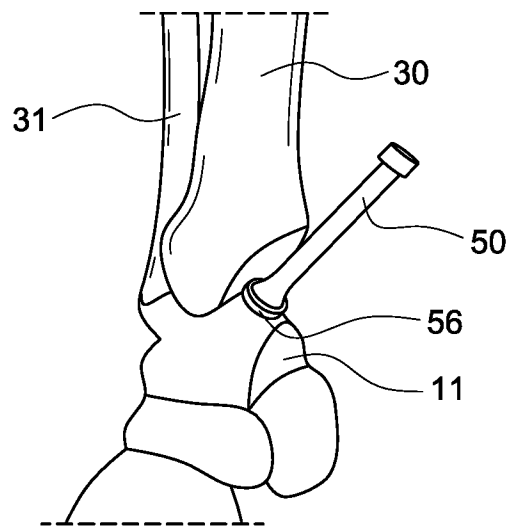


FIG. 9F

18/18

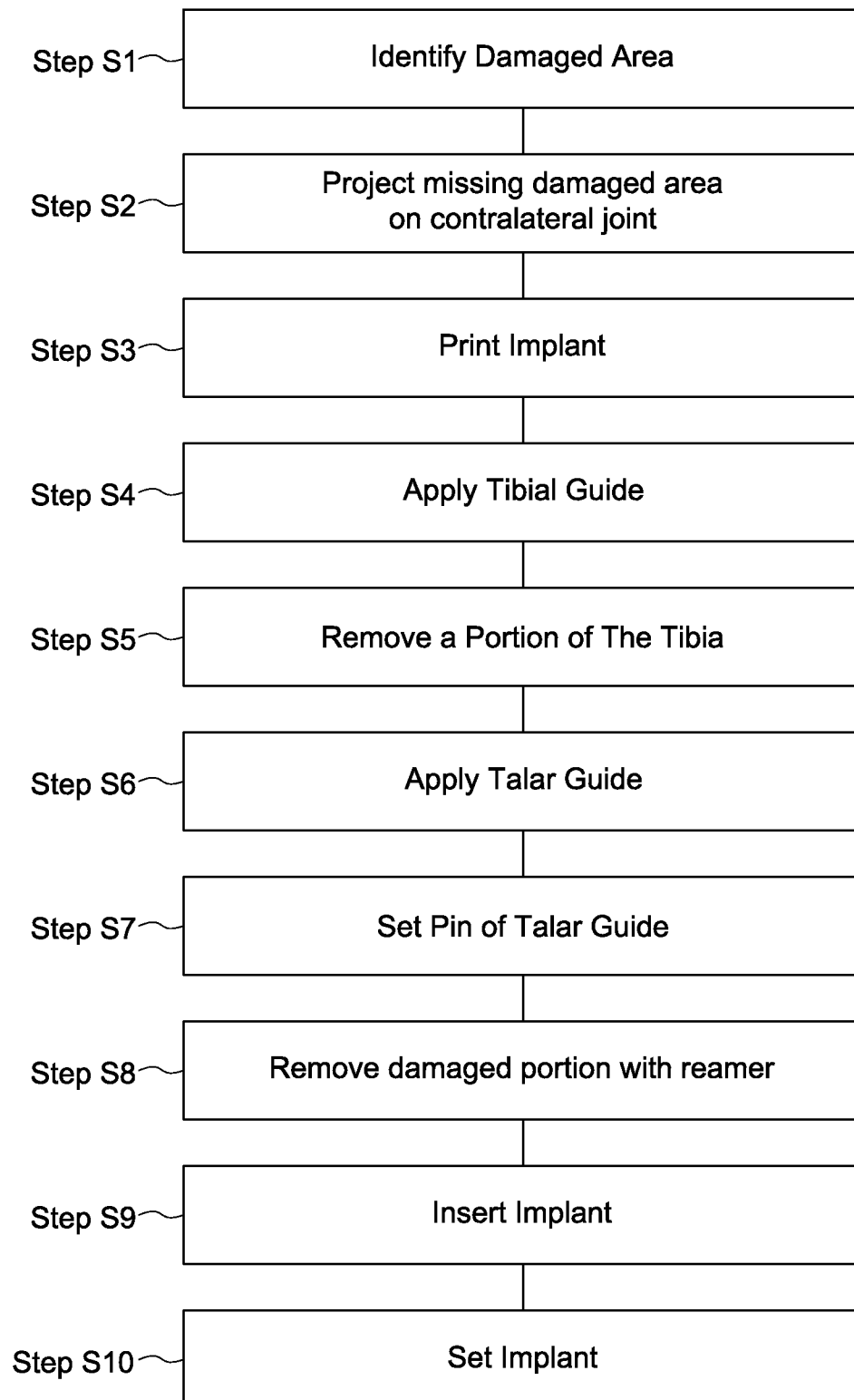


FIG. 10

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2021/047117

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61F 2/42; A61B 17/15; A61B 17/92; A61F 2/46 (2021.01)

CPC - A61F 2/4202; A61F 2002/2835; A61F 2002/30001; A61F 2002/30841; A61F 2002/30985; A61F 2002/4207 (2021.08)

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)

see Search History document

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

see Search History document

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

see Search History document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	CN 208989260 U (SOUTH CHINA UNIVERSITY OF TECHNOLOGY) 18 June 2019 (18.06.2019) see machine translation	1-5, 7, 8
X	CN 209316156 U (NANJING UNIVERSITY) 30 August 2019 (30.08.2019) see machine translation	1, 5-8
A	US 2020/0129311 A1 (MAKO SURGICAL CORP) 30 April 2020 (30.04.2020) entire document	1-8
A	US 10,016,811 B2 (NEAL) 10 July 2018 (10.07.2018) entire document	1-8
A	US 2016/0262903 A1 (WRIGHT MEDICAL TECHNOLOGY) 15 September 2016 (15.09.2016) entire document	1-8

☐ 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

"D" document cited by the applicant in the international application

"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

09 December 2021

Date of mailing of the international search report

DEC 28 2021

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Facsimile No. 571-273-8300

Authorized officer

Harry Kim

Telephone No. PCT Helpdesk: 571-272-4300

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2021/047117

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 extra sheet(s).

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 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.:

1-8

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2021/047117

Continued from Box No. III Observations where unity of invention is lacking

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I, claims 1-8, is drawn to a talar implant comprising: at least one body section; at least one mesh section.

Group II, claims 9-12, is drawn to a kit for inserting a talar implant comprising: at least one tibial guide; at least one talar guide.

Group III, claims 13-20, is drawn to a method for implanting a talus implant comprising: identifying a damaged area; projecting a missing damaged area on a contralateral joint.

The inventions listed as Groups I, II and III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The special technical feature of the Group I invention: at least one body section; at least one mesh section; and at least one solid section extending down from the body section, the at least one solid section comprising at least one point as claimed therein is not present in the invention of Groups II and III. The special technical feature of the Group II invention: at least one tibial guide; at least one talar guide; at least one impactor instrument for inserting the talar implant into a patient's talus as claimed therein is not present in the invention of Groups I or III. The special technical feature of the Group III invention: identifying a damaged area; projecting a missing damaged area on a contralateral joint; printing an implant based upon a mirror image of a portion of the contralateral joint; applying at least one cutting guide to a bone; removing at least a portion of a damaged region of the talus as claimed therein is not present in the invention of Groups I or II.

Groups I, II and III lack unity of invention because even though the inventions of these groups require the technical feature of inserting a talar implant into a patient's talus, this technical feature is not a special technical feature as it does not make a contribution over the prior art.

Specifically, US 2020/0129311 A1 to MAKO Surgical Corp. teaches inserting a talar implant into a patient's talus (The robotic system 10 may be employed to prepare the tibia Ti and talus Ta to receive the ankle implant system 100. In this case, the ankle implant system 100 comprises a tibial component 102, a talar component 104, and an insert 105, para. 0059).

Since none of the special technical features of the Group I, II or III inventions are found in more than one of the inventions, unity of invention is lacking.