(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
27 October 2022 (27.10.2022)

WIPO | PCT

(10) International Publication Number
WO 2022/226264 A1

(51) International Patent Classification:
A61F 2/44 (2006.01) *A61F 2/00* (2006.01)
A61B 17/70 (2006.01)

(21) International Application Number:
PCT/US2022/025880

(22) International Filing Date:
22 April 2022 (22.04.2022)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
63/178,308 22 April 2021 (22.04.2021) US

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(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DJ, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, IT, JM, JO, JP, KE, KG, KH, KN, KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU,

(54) Title: EXPANDABLE LAMINOPLASTY IMPLANT

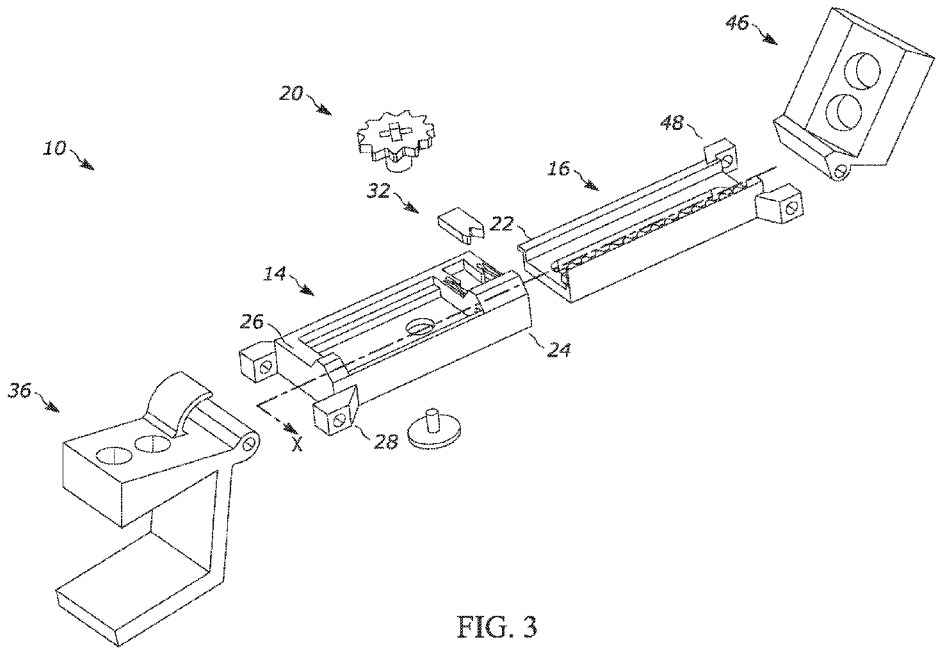


FIG. 3

(57) Abstract: An implantable laminoplasty device is provided that can be used in minimally invasive surgery. The device includes a main housing with an inner housing slidably receivable by an outer housing. A gear is disposed in the main housing and engageable with a gear rack of the inner housing to adjust the length of the main housing. The gear defines an aperture configured to accept a tool to translate rotational movement into linear motion. A lock is slidably disposed in the main housing sized and configured to fix the length of the main housing when the desired length is achieved by slidable translation of the inner housing in the outer housing. The device also includes a laminar shelf portion and a lateral mass connection portion defining bone screws and both being hingedly connected to the main housing.

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[Continued on next page]

RW, SA, SC, SD, SE, SG, SK, SL, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, WS, ZA, ZM, ZW.

(84) **Designated States** *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Published:

— *with international search report (Art. 21(3))*

EXPANDABLE LAMINOPLASTY IMPLANT

RELATED APPLICATIONS

[0001] This application claims priority to U.S. Provisional Patent Application Serial No. 63/178,308, filed April 22, 2021. The entirety of the '308 application is hereby incorporated by reference.

TECHNICAL FIELD

[0002] The present disclosure relates to a medical device implant for minimally invasive spinal laminoplasty surgery.

BACKGROUND

[0003] Laminoplasty is a surgical procedure in which spinal cord compression is relieved through opening of the spinal cord. This is accomplished by creating hinges in the vertebral lamina overlying the spinal cord using implants to keep the lamina in a permanent open position. In laminoplasty, the lamina is lifted but not removed, thus avoiding the complications associated with laminectomy where the lamina bone (and associated muscle/tendon/tissue attachments) is removed permanently. Laminoplasty was developed to improve the postoperative complexities associated with laminectomy such as kyphosis, instability, axial neck pain, and range of motion. Minimally invasive surgery (MIS) techniques that preserve paraspinal muscle structures can reduce these long-term complications. However, implants and tools needed for these approaches are not readily available or not available at all. With the rapid uptake of robotic spinal surgeries, MIS procedures are expected to become significantly more common requiring the development of suitable implants.

[0004] Currently, several types of implants are used in cervical laminoplasty with the majority having a fixed length, and a few with adjustable length. Drawback of these implants include special tools needed for each implant, adjustable implants only allowing discrete expansion as opposed to continuous expansion, inability to

control force exerted on the lamina thereby increasing risk of lamina fracture, screw loosening, and implant shapes that are not conducive for passing through MIS tubes.

[0005] Therefore, development of expandable implants that facilitate better bone fixation, can fit in MIS tubes used in minimally invasive techniques, and that use readily available surgical tools is needed.

SUMMARY

[0006] An implant is provided comprising a main housing comprising an outer housing and an inner housing slidably receivable by the outer housing. The inner housing includes a gear rack. A gear is disposed in the main housing and engageable with the gear rack of the inner housing to adjust the length of the main housing. The gear defining an aperture configured to accept a tool to translate rotational movement into linear motion. A lock is slidably disposed in the main housing sized and configured to fix the length of the main housing when the desired length is achieved by slidable translation of the inner housing in the outer housing. The implant includes a laminar shelf portion hingedly connected to a second end of the main housing, having a top portion, a side portion and a bottom portion sized and configured to be disposed against a lamina of a patient, the top portion defining bone screw holes extending therethrough. The implant also includes a lateral mass connection portion hingedly connected to a first end of the main housing, having a top side and a bottom side and a bone screw hole extending therethrough, the bottom side sized and configured to be disposed against a lateral mass of a vertebrae of the patient.

BRIEF DESCRIPTION OF THE DRAWINGS

[0007] FIG. 1 is perspective view of a medical device in a non-extended configuration according to an aspect of the present disclosure.

[0008] FIG. 2 is a perspective view of the medical device of FIG. 1 in an extended configuration.

[0009] FIG. 3 is an exploded view of the medical device of FIG. 1.

[0010] FIG. 4 is perspective view of a medical device in a non-extended configuration according to an aspect of the present disclosure.

[0011] FIG. 5 is a perspective view of a medical device in an extended configuration according to an aspect of the present disclosure.

[0012] FIG. 6 is a side view of a medical device in a non-extended configuration according to an aspect of the present invention.

[0013] FIG. 7 is a top view of the medical device of FIG. 7

[0014] FIG. 8 is a side view of the medical device of FIG. 6 in an extended configuration according to an aspect of the present disclosure.

[0015] FIG. 9 is a top view of the medical device of FIG. 8.

[0016] FIG. 10 is a schematic view depicting positioning of a medical device in a non-extended configuration according to an aspect of the present disclosure.

[0017] FIG. 10a is close-up partial view of the outer housing of the medical device of FIG. 10 in a non-extended configuration according to an aspect of the present disclosure.

[0018] FIG. 11 is a schematic view depicting positioning of the medical device of FIG. 10 in an extended configuration.

[0019] FIG. 11b is close-up partial view of the outer housing of the medical device of FIG. 11 in an extended configuration according to an aspect of the present disclosure.

[0020] FIG. 12 is a schematic view depicting positioning of a medical device in a non-extended configuration according to an aspect of the present disclosure.

[0021] FIG. 12a is close-up partial view of the outer housing of the medical device of FIG. 12 in a non-extended configuration according to an aspect of the present disclosure.

[0022] FIG. 13 is a schematic view depicting positioning of the medical device of FIG. 12 in an extended configuration.

[0023] FIG. 13b is close-up partial view of the outer housing of the medical device of FIG. 13 in an extended configuration according to an aspect of the present disclosure.

[0024] FIG. 14 is a perspective view of an inner housing of a medical device according to an aspect of the present disclosure.

[0025] FIG. 15 is a perspective view of an outer housing of a medical device according to an aspect of the present disclosure.

[0026] FIG. 16 is a perspective view of a gear of a medical device according to an aspect of the present disclosure.

[0027] FIG. 17 is a perspective view of a gear holder of a medical device according to an aspect of the present disclosure.

[0028] FIG. 18 is a perspective view of a lock of a medical device according to an aspect of the present disclosure.

[0029] FIG. 19 is a top view of an inner housing of a medical device according to an aspect of the present disclosure with a lock placed within a chamber of the inner housing according to an aspect of the present disclosure.

[0030] FIG. 20 is a top view of the inner housing of FIG. 18 with the lock in a locked position to constrain relative motion of the outer housing and the gear rack of the inner housing.

[0031] FIG. 21 is a close-up view of the chamber of the inner housing depicted in FIG. 18 and 19.

[0032] FIG. 22 is a perspective view of a laminar shelf portion of a medical device according to an aspect of the present disclosure.

[0033] FIG. 23 is a side view of the laminar shelf portion of FIG. 22.

[0034] FIG. 24 is a perspective view of a lateral mass connection portion of a medical device according to an aspect of the present disclosure.

[0035] FIG. 25 is a side view of the lateral mass connection portion of FIG. 24.

[0036] FIG. 26 is a perspective view of a lateral mass connection portion of a medical device according to an aspect of the present disclosure.

[0037] FIG. 27 is a side view of the lateral mass connection portion of FIG. 26.

DETAILED DESCRIPTION

[0038] As used herein with respect to a described element, the terms “a,” “an,” and “the” include at least one or more of the described elements including combinations thereof unless otherwise indicated. Further, the terms “or” and “and” refer to “and/or” and combinations thereof unless otherwise indicated. By

“substantially” is meant that the shape or configuration of the described element need not have the mathematically exact described shape or configuration of the described element but can have a shape or configuration that is recognizable by one skilled in the art as generally or approximately having the described shape or configuration of the described element. A “patient” as described herein includes a mammal, such as a human being. The term “top,” “bottom,” “upper,” “lower,” “above,” and “below,” “left” and “right” refer to the position or orientation of the components as depicted in the drawings. The terms "first," "second," etc. are used to distinguish one element from another and not used in a quantitative sense unless indicated otherwise. The term “plurality” includes two or more of the described components. In addition, when an element is referred to as being “on,” “attached” to, “connected” to, “coupled” with, “contacting,” in “communication” with, “extending” from etc., another element, it can be directly on, attached to, connected to, coupled with, contacting, in communication with, or extending from the other element or intervening elements may also be present. In contrast, when an element is referred to as being, for example, “directly on,” “directly attached” to, “directly connected” to, “directly coupled” with, “directly contacting,” in “direct communication” with, or “directly extending” from another element, there are no intervening elements present. An element that is disposed “adjacent” to another element may have portions that overlap or underlie the adjacent element. By "integral" or "integrated" is meant that the described components are fabricated as one piece or multiple pieces affixed during manufacturing and the described components are otherwise not separable using a normal amount of force without damaging the integrity (i.e., tearing) of either of the components. A normal amount of force is the amount of force a user would use to remove a component meant to be separated from another component without damaging either component. All devices described herein are for medical purposes and are therefore sterile.

[0039] The present disclosure relates to medical implants that can be used in a laminoplasty procedure. The implants can be deployed through MIS tubes, use existing tools in an operating room, facilitate controlled force application to lamina with minimal bending on the spine, provide adjustable attachment angles, provide continuous expandability and allow implementation of open door and double door

cervical laminoplasty with the same implant. With such adjustability and other features, an implant can address several of the challenges in laminoplasty. As the implant can be used in MIS, this can preserve muscle attachments and may reduce occurrence of post-operative complications such as axial neck pain, kyphosis, and C5 palsy.

[0040] In an aspect and with reference to FIGs. 1-3, an implant **10** is provided that can comprise a main housing **12** having a longitudinal axis **X** and that can comprise outer housing **14** and inner housing **16**, with inner housing **16** having a first end **22** received by a second end **24** of outer housing **14** and slidably extendable through outer housing **14** along longitudinal axis **X** until reaching an abutment wall **26** at second end **28** of outer housing **14** that prevents further longitudinal movement of inner housing **16** (inner housing **16** is shown in isolation in FIG. 14 and outer housing **24** is illustrated in isolation in FIG. 15). The outer housing effectively acts as the central part of the implant that connects all the components together. As shown in FIG. 14, inner housing **16** can include gear rack **18** which can slide through the outer housing. Gear **20** can be disposed in main housing **12** and can be engageable with gear rack **18** of inner housing **16** to adjust the length of main housing **12**. In particular, the relative movement of the gear rack with respect to the outer housing is controlled by the rotation of the gear. Middle long hole **66** serves as a rail for the gear. Upon rotation, the gear interacts with gear rack teeth **68** to move in a linear direction. Referring to FIG. 16, gear **20** defines an aperture **30** configured to accept a tool, such as a screwdriver for example, to translate rotational movement into linear motion. The implant can include a gear holder **60** illustrated in FIGs. 6, 8 and 17 that can extend through the inner and outer housings and engage a socket of the gear to maintain the gear in place. Lock **32** (illustrated in FIG. 1-3 and FIGs. 18-21) can be slidably disposed in a chamber **50** of the main housing, such as outer housing **14**, and can be sized and configured to fix the length of the main housing when the desired length is achieved by slidable translation of the inner housing in the outer housing. As such, the gear rack and the gear work in conjunction to control the length of the implant. With reference to FIGs. 19 and 20, lock **32** can be urged to the right, for example, until the lock (or a portion thereof) contacts springs(s) **54**, for

example, which can act as gear restraints to maintain the lock in place and prevent the lock from backing out of the chamber.

[0041] Laminar shelf portion **36** can be hingedly connected to a second end of the main housing, such as second end portion **28** of outer housing **14** so that the laminar shelf portion can rotate about the outer housing. Referring to FIG. 22, laminar shelf portion **36** can have top face **38**, side face **40** and bottom face **42** sized and configured to be disposed against a lamina of a patient (as described below). Bone screw holes **44a** and **44b** can extend through laminar shelf portion that can accept bone screws to attach the laminar shelf portion to the patient's lamina. Although only two bone screw holes are illustrated in the figures, the laminar shelf portion can include any number of suitable bone screw holes to fixate the laminar shelf portion to the lamina of a patient's vertebra(e). Referring to FIG. 6 and 8, the top and bottom faces of the laminar shelf portion can be tilted by approximately 15 degrees to increase the screw drill length. On the laminar shaft side , the shelf can be tilted around the longitudinal axis of the implant to provide optimal screw length inside the bone.

[0042] Lateral mass connection portion **46** can be hingedly connected to second end of the main housing such as second end **48** of inner housing **16** so that the lateral mass connection portion can rotate about the inner housing. Referring to FIG. 24, the lateral mass connection portion can have a top side **56** and a bottom side **52** and a bone screw hole **54** extending therethrough that can accept bone screws to attach the lateral mass connection portion to the patient's lateral mass. Although only two bone screw holes are illustrated in the figures, the lateral mass connection portion can include any number of suitable bone screw holes to fixate the lateral mass connection portion to the lateral mass of a patient's vertebra(e). Referring to FIG. 24 and 25, the lateral mass connection portion can have an approximately 30-degree tilt with a rotation axis perpendicular to the hinge axis $\mathbf{HA_1}$ of rotation to maximize screw length inside the superior articular facet. In this aspect, both the top side of the lateral mass connection portion and the screw holes are rotated approximately 30 degrees to provide sufficient contact between the implant and the bone. Referring to FIGs. 26 and 27, in certain aspects only the screw holes are rotated by 30 degrees to provide longer screw length.

[0043] Referring to FIG. 4, implant **10A** can have surface features **58** (depicted by hash lines) that can enhance cell attachment and/or bone ingrowth. Such features can be included on the surfaces touching bone (such as the lateral mass connection portion and the laminar shelf portion). Non-limiting surface features include surface roughening, additive features, inclusion of biological agents in addition to other surface features. Referring to FIG. 5, the implant can also include a bone graft (attached to the bottom of the main housing for example) to increase the union of bone to the implant.

[0044] FIGs. 10-11 illustrate an exemplary implantation of implant 10 using bone screws. The implant length can be continuously adjusted from a closed length of approximately 12.5 mm, to a fully open length of approximately 25 mm providing an adjustment range 3 times that of current implants (*e.g.* 4mm). The expansion can be achieved via rotation of the gear, which allows a continuous and smooth expansion of the vertebral lamina as well as measurement of the expansion force using the torque applied to the gear. The control over the expansion force is beneficial because it can prevent the breakage of the vertebral bone at the gutter.

[0045] For open-door laminoplasty, before placing the implant, the vertebral lamina can be cut completely on one side, and partly on the other side, resulting in formation of a bony gutter, and creation of a hinge as shown in FIG. 10. Then the laminar shelf can be fixed to the lamina with bone screws. The shelf can be tilted approximately 15 degrees around the hinge axis of rotation to increase the screw length inside the lamina for better and stronger fixation. The free rotation around the hinge also provides a better and more natural connection to the lamina and avoids pre-stressing the connection. The implant can then be pushed downward to expand the vertebral lamina, and the lateral mass connection portion of the implant can be screwed to the lateral mass as shown in FIG. 11. In the case of an MIS surgery, at this step the gear and lock will be facing the MIS tube opening, allowing the surgeon to easily expand the vertebra by rotating the gear and then using the lock to fix the vertebral lamina in the open position. Similarly, double door laminoplasty can be performed using the implant via a MIS approach.

[0046] Referring to FIGs, 12 and 13, the implant can also include a hook **64** illustrated in FIGs. 6 and 8 that is coupled to the laminar shelf portion, for example,

to facilitate the usage of suture(s) **66** as an option instead of or in addition to screws, which can reduce possible screw misposition. The suture can be used instead of a screw for fixating the implant to the spinous process. One complexity for spine implants is the screw loosening due to the short penetration length of the screws in the vertebra. To address this issue, during implantation, there is a relative 15 degree angle between the lamina and the side portion of the laminar shelf portion shaft. This feature increases the screw penetration depth and transforms part of the shear stress at the threads into compressive stress hence helping with possible screw loosening.

[0047] Each of the disclosed aspects and embodiments of the present disclosure may be considered individually or in combination with other aspects, embodiments, and variations of the disclosure. Further, while certain features of embodiments and aspects of the present disclosure may be shown in only certain figures or otherwise described in the certain parts of the disclosure, such features can be incorporated into other embodiments and aspects shown in other figures or other parts of the disclosure. Along the same lines, certain features of embodiments and aspects of the present disclosure that are shown in certain figures or otherwise described in certain parts of the disclosure can be optional or deleted from such embodiments and aspects. Additionally, when describing a range, all points within that range are included in this disclosure. Further, unless otherwise specified, none of the steps of the methods of the present disclosure are confined to any particular order of performance. Furthermore, all references cited herein are incorporated by reference in their entirety.

What is claimed is:

1. An implant comprising:

a main housing comprising:

an outer housing;

an inner housing slidably receivable by the outer housing and comprising a gear rack;

a gear disposed in the main housing and engageable with the gear rack of the inner housing to adjust the length of the main housing, the gear defining an aperture configured to accept a tool to translate rotational movement into linear motion;

a lock slidably disposed in the main housing sized and configured to fix the length of the main housing when the desired length is achieved by slidable translation of the inner housing in the outer housing;

a laminar shelf portion hingedly connected to a second end of the main housing, having a top portion, a side portion and a bottom portion sized and configured to be disposed against a lamina of a patient, the top portion defining bone screw holes extending therethrough; and

a lateral mass connection portion hingedly connected to a first end of the main housing, having a top side and a bottom side and a bone screw hole extending therethrough, the bottom side sized and configured to be disposed against a lateral mass of a vertebrae of the patient.

2. The implant of claim 1, wherein the bone screw holes of the laminar shelf portion are angled approximately 15 degrees.

3. The implant of claim 1, wherein the lock is disposed in a chamber of the outer housing.

4. The implant of claim 3, further comprising springs located in the chamber that are sized and configured to engage the lock to maintain the lock in place and prevent the lock from backing out of the chamber.

5. The implant of claim 1, wherein the laminar shelf portion and the lateral mass connection portion include surface features to enhance cell attachment and bone ingrowth.

6. The implant of claim 1, wherein the implant further comprises a bone graft.

7. The implant of claim 1, wherein the laminar shelf portion is hingedly connected to the outer housing.

8. The implant of claim 1, wherein the lateral mass connection portion is hingedly connected to the inner housing.

9. The implant of claim 1, further comprising a hook extending from the laminar shelf portion or the main housing to receive a suture.

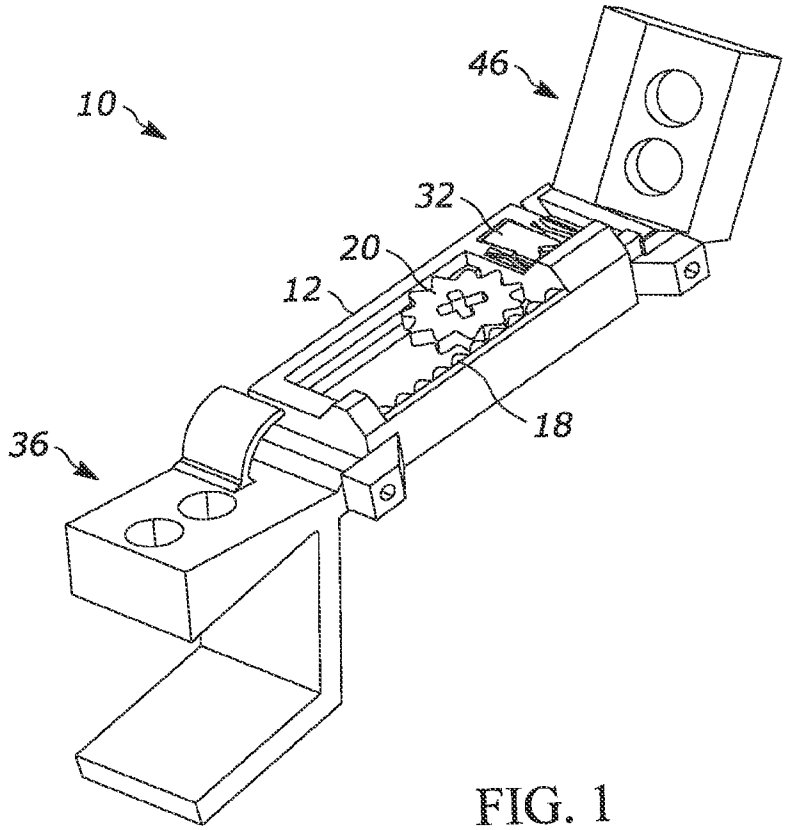


FIG. 1

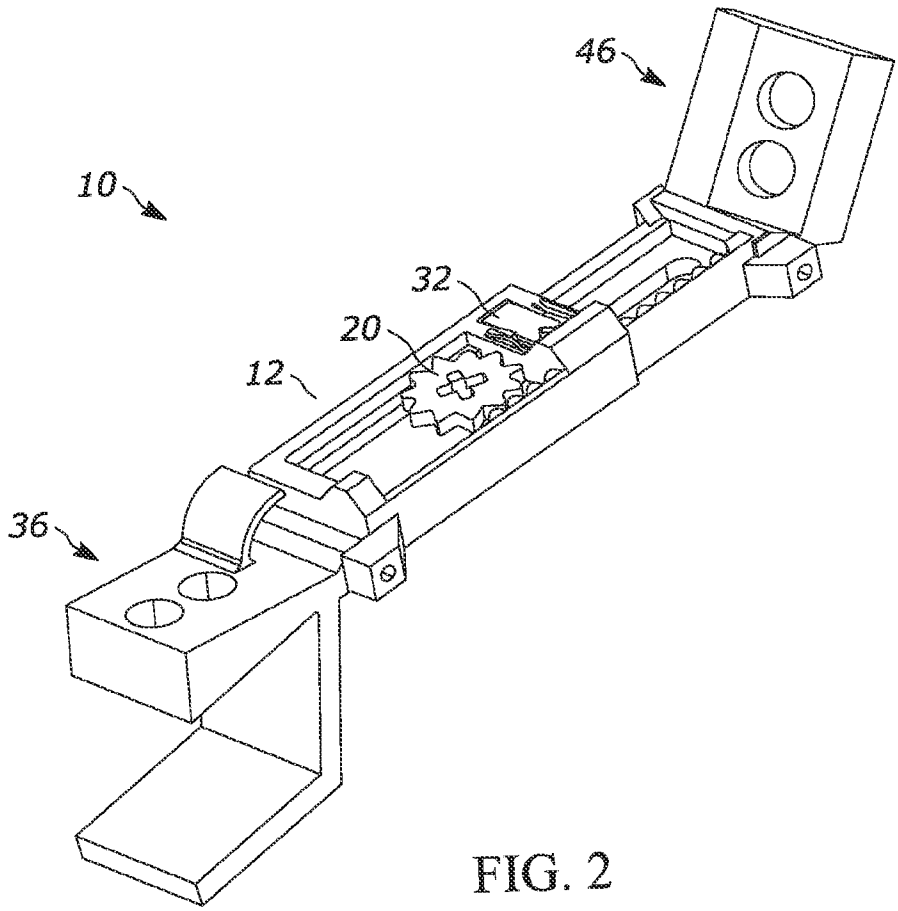


FIG. 2

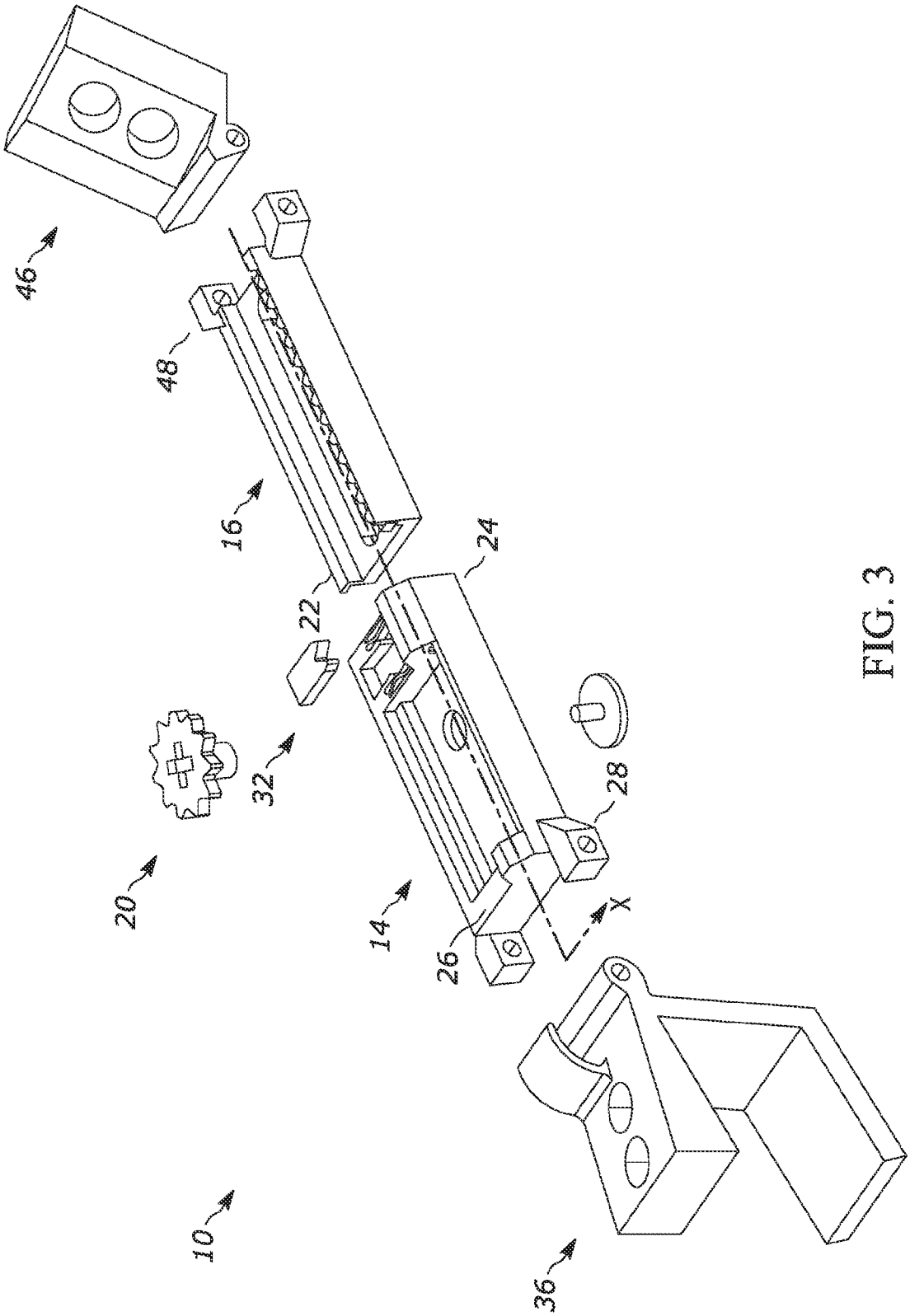


FIG. 3

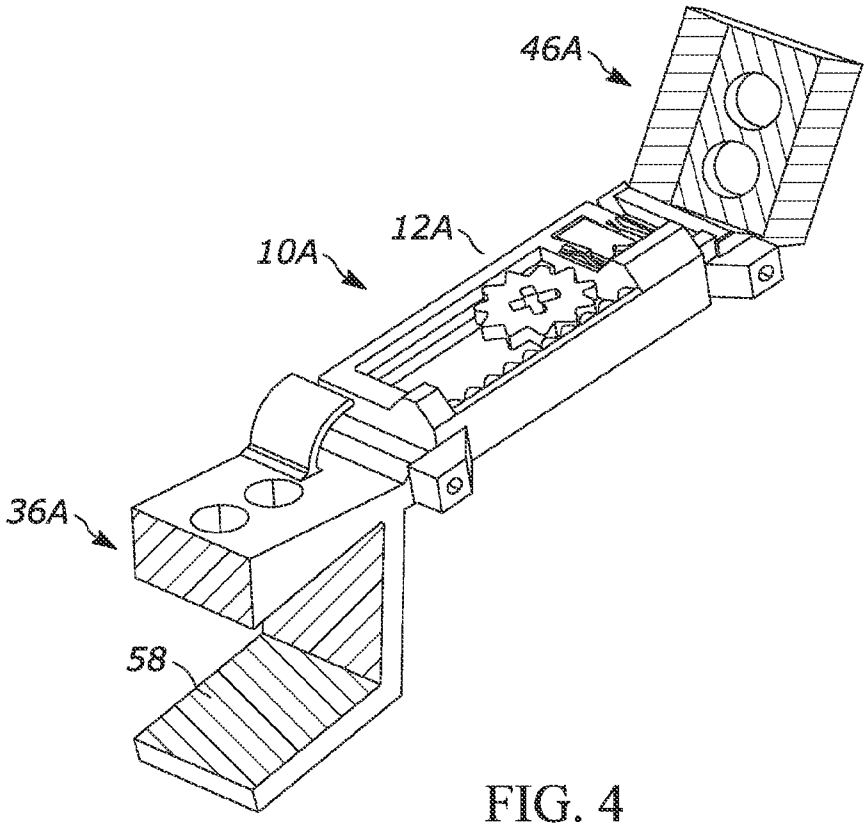


FIG. 4

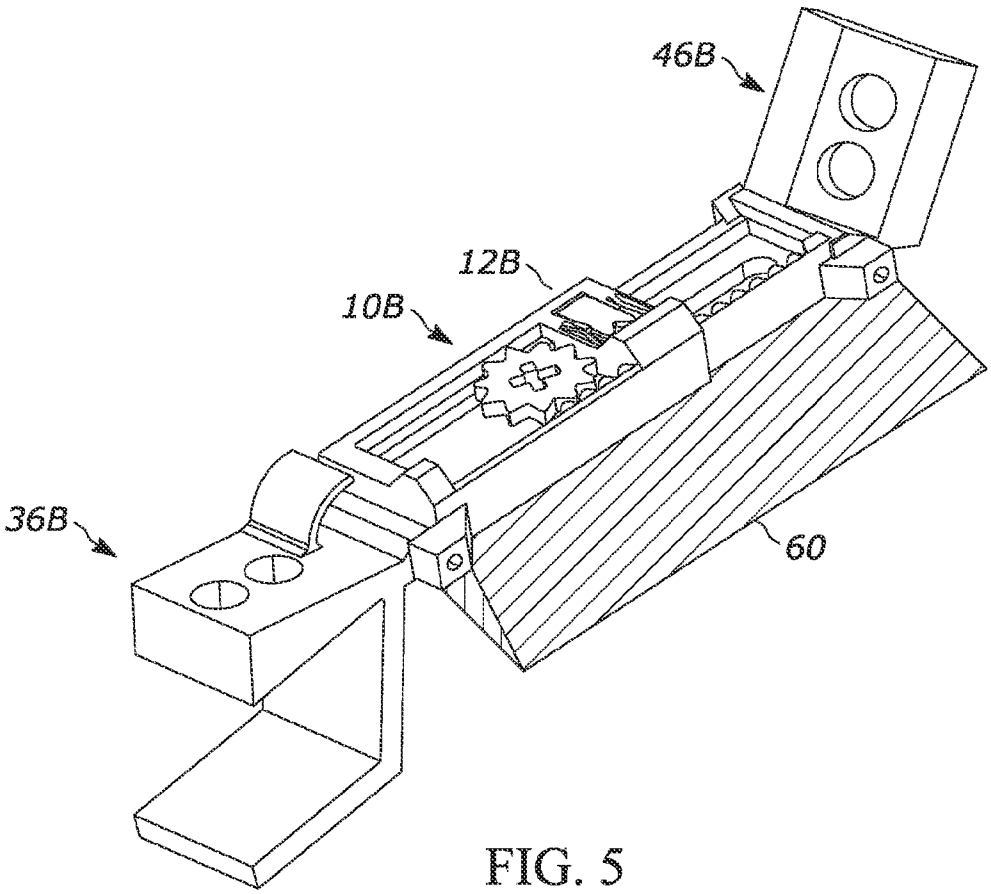


FIG. 5

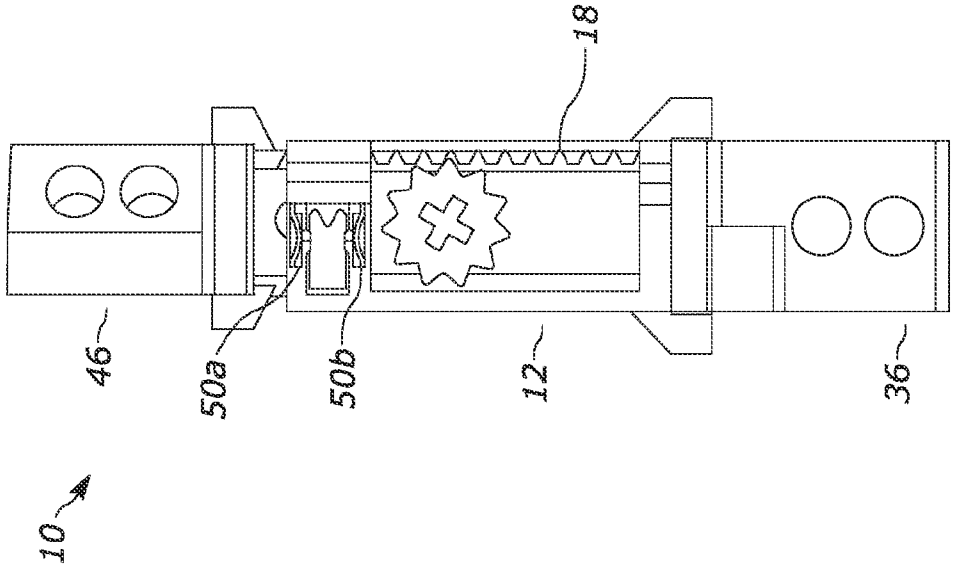


FIG. 7

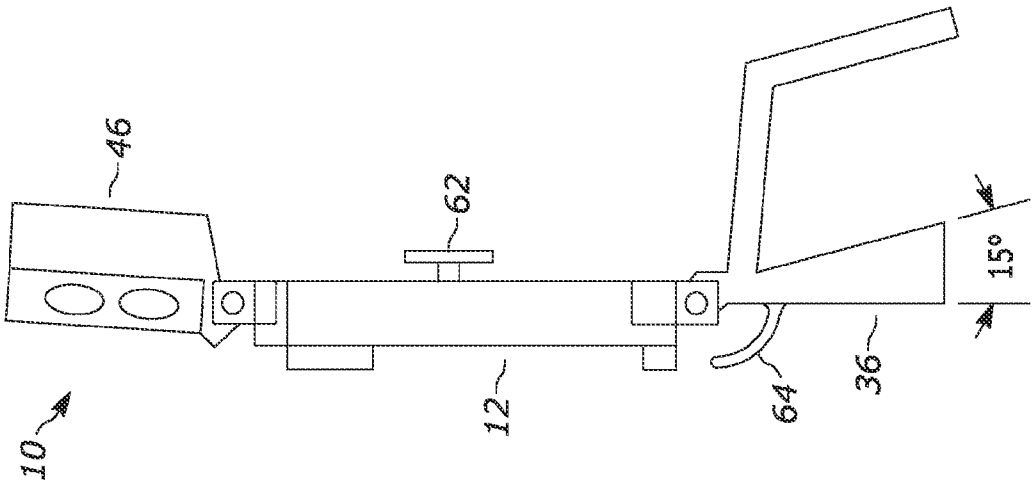


FIG. 6

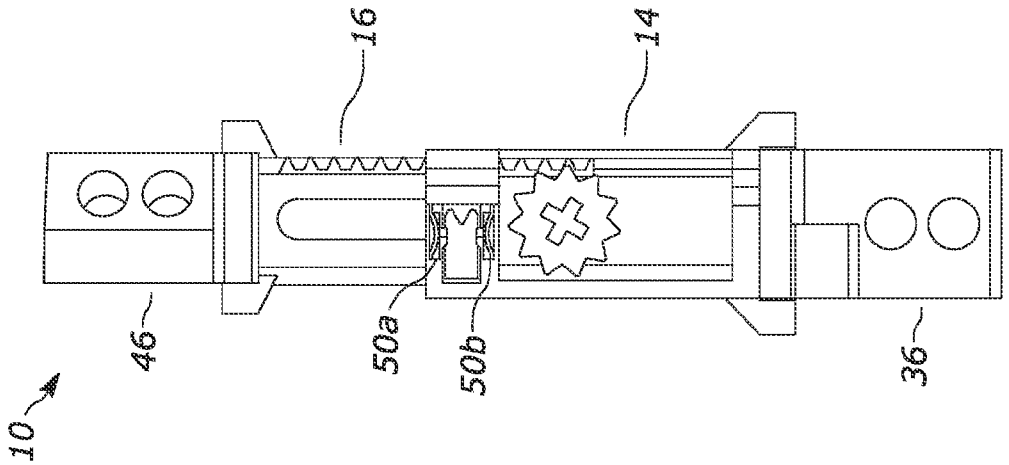


FIG. 9

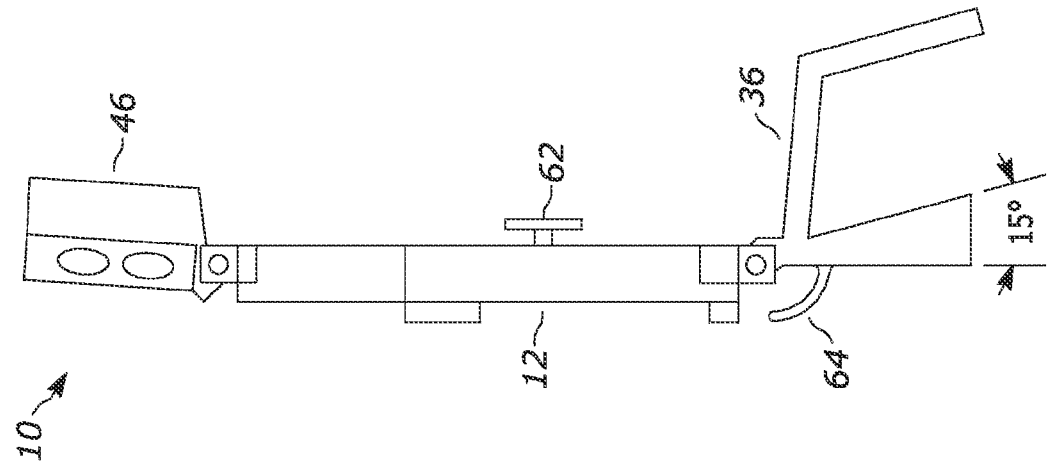


FIG. 8

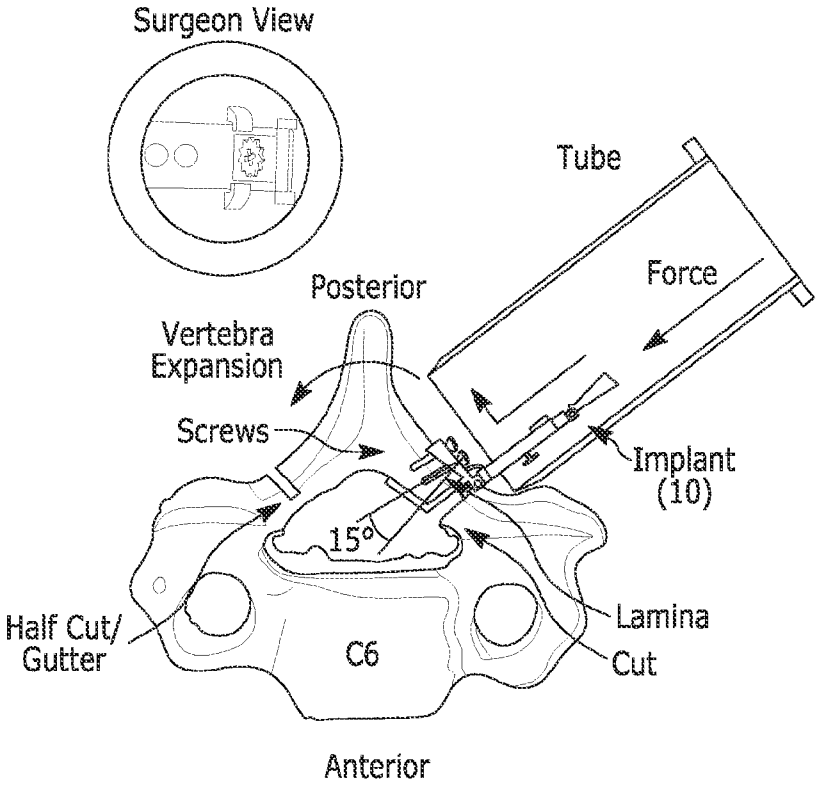

Surgeon View
Tube
Force
Posterior
Vertebra Expansion
Screws
Implant (10)
15°
Half Cut/ Gutter
C6
Lamina Cut
Anterior

FIG. 10

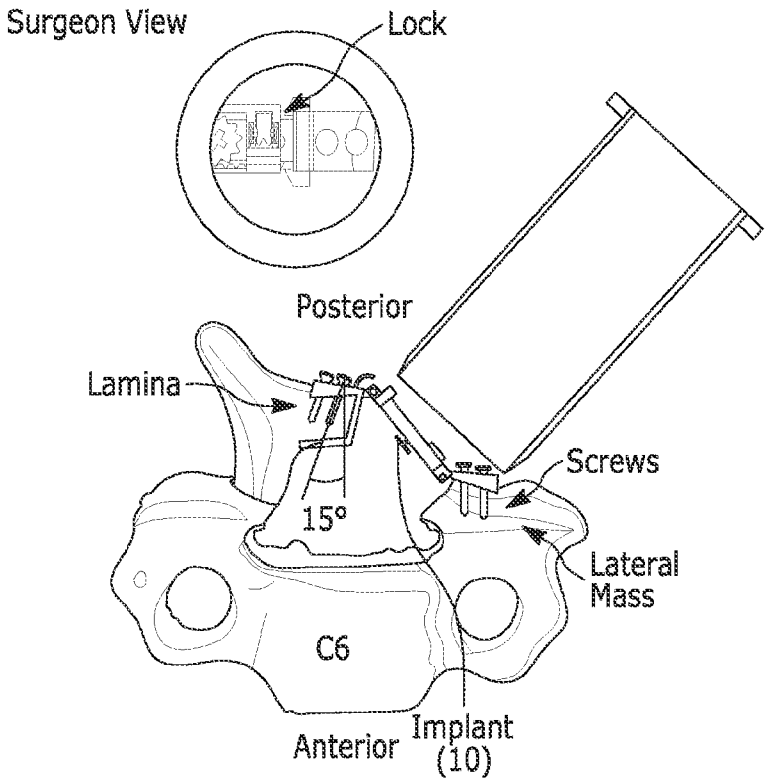

Surgeon View
Lock
Posterior
Lamina
Screws
15°
Lateral Mass
C6
Anterior
Implant (10)

FIG. 11

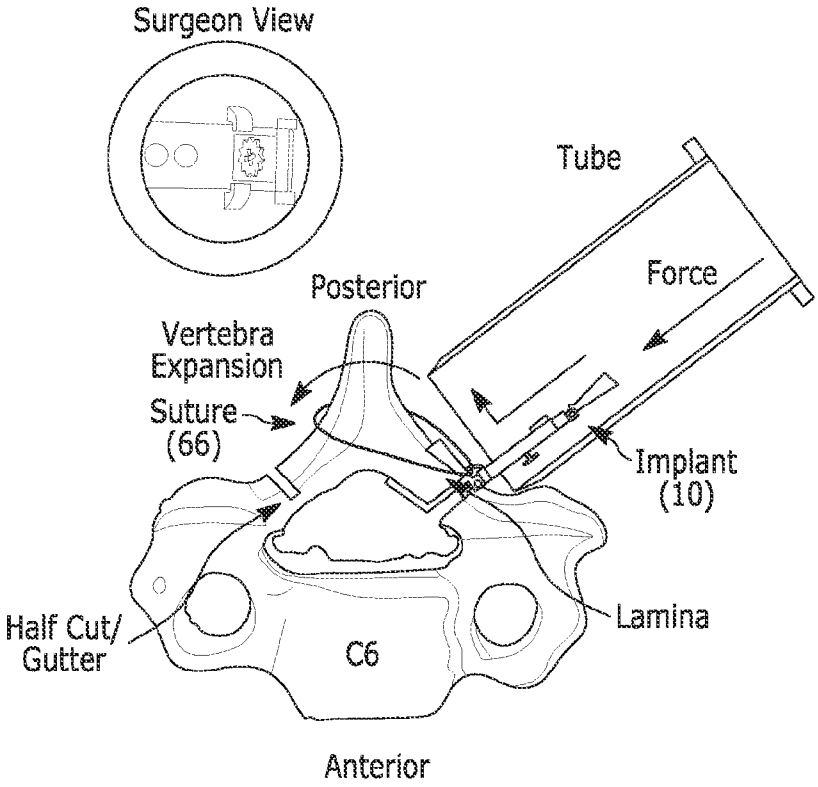

Surgeon View
Tube
Force
Posterior
Vertebra Expansion
Suture (66)
Implant (10)
Half Cut/ Gutter
C6
Lamina
Anterior

FIG. 12

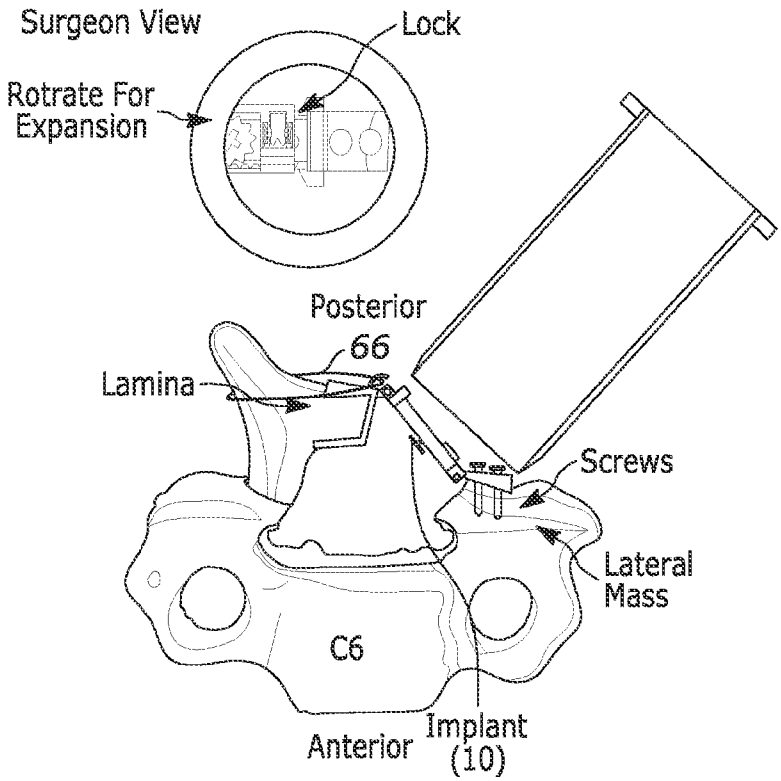

Surgeon View
Lock
Rotrate For Expansion
Posterior
66
Lamina
Screws
Lateral Mass
C6
Anterior
Implant (10)

FIG. 13

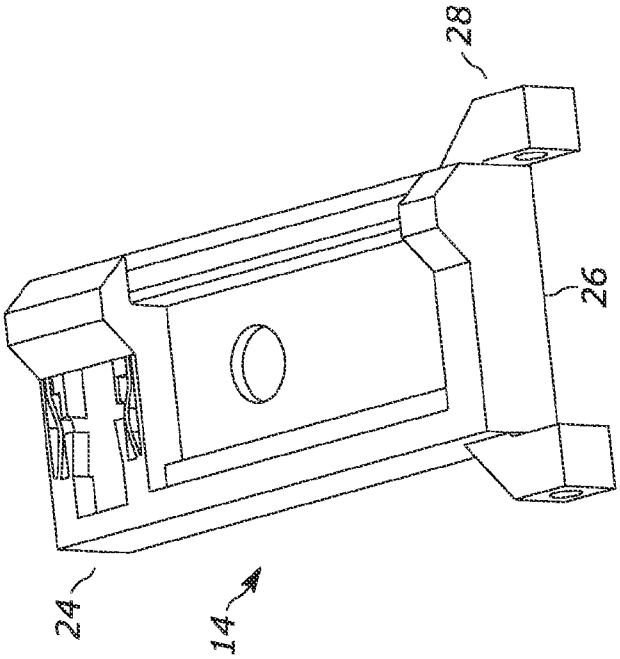


FIG. 15

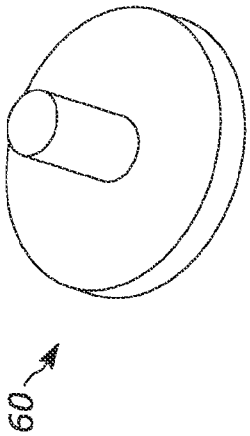


FIG. 17

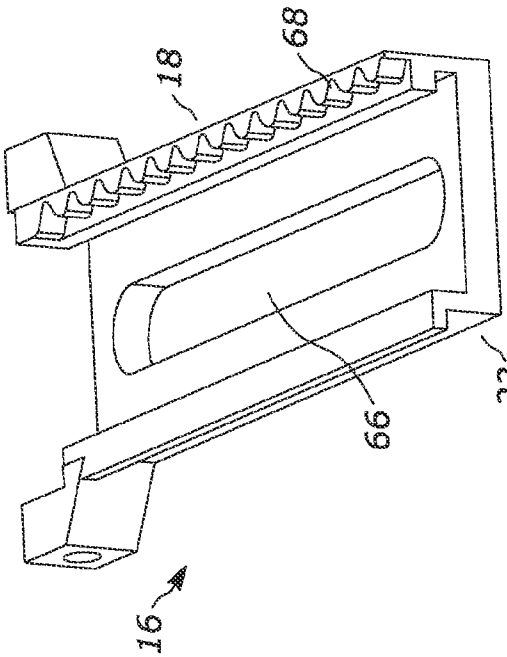


FIG. 14

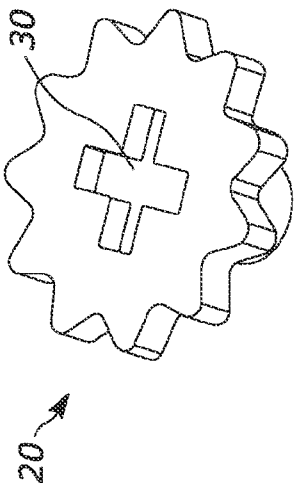


FIG. 16

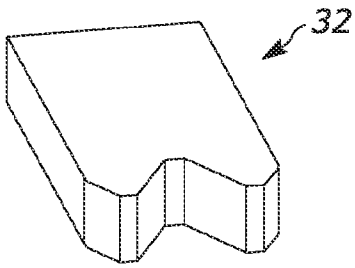


FIG. 18

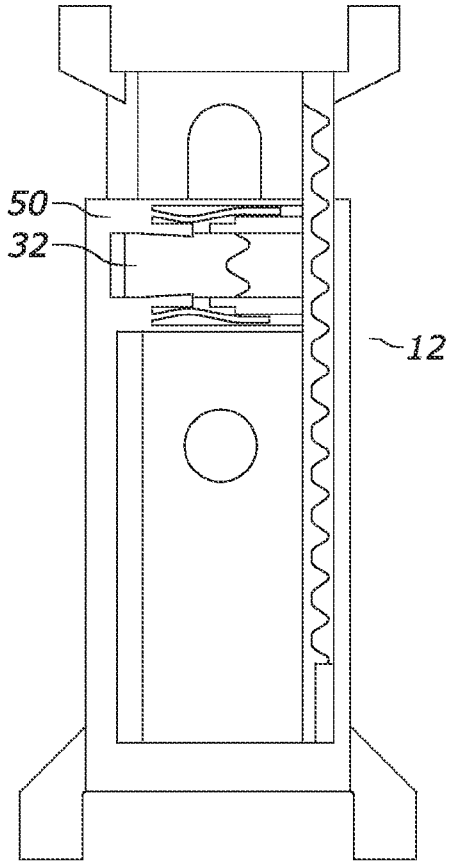


FIG. 19

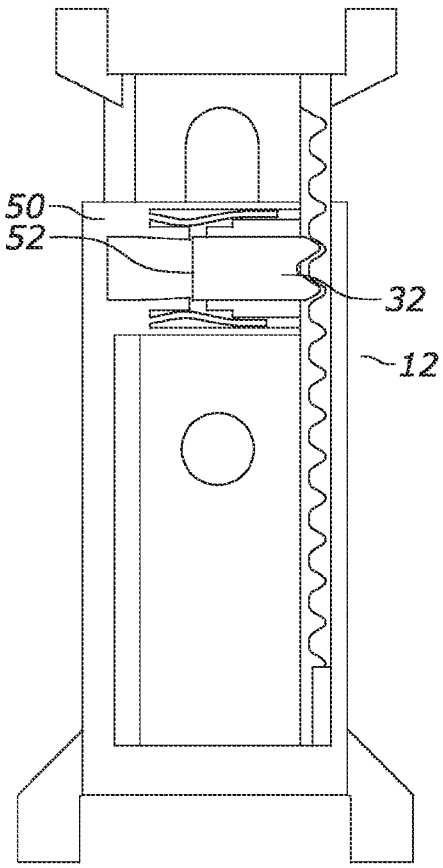


FIG. 20

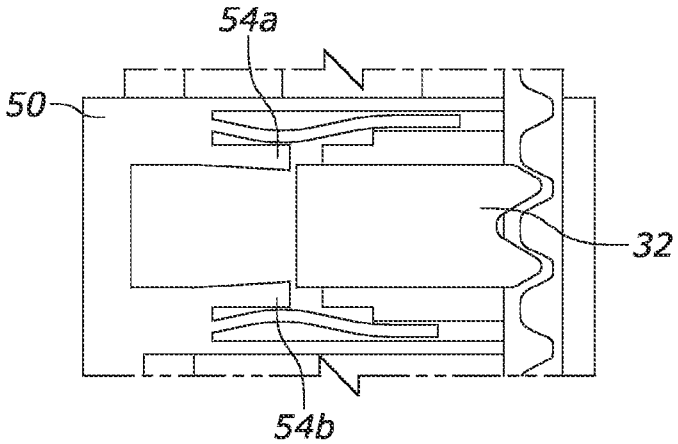


FIG. 21

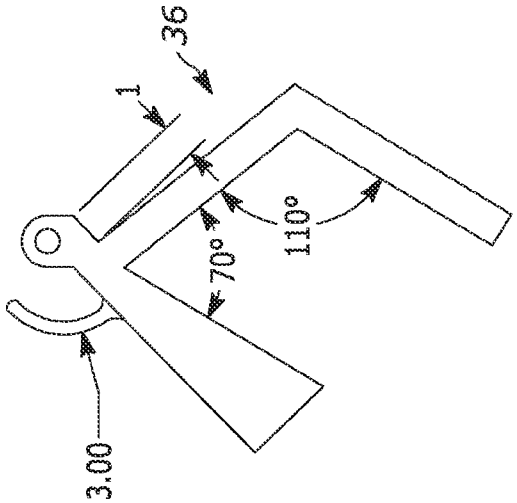


FIG. 23

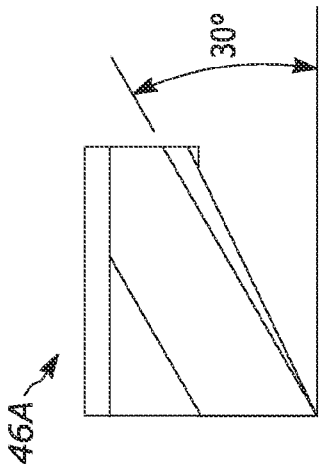


FIG. 25

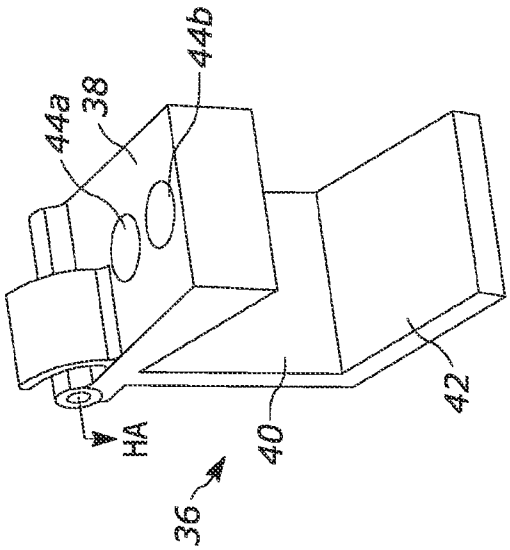


FIG. 22

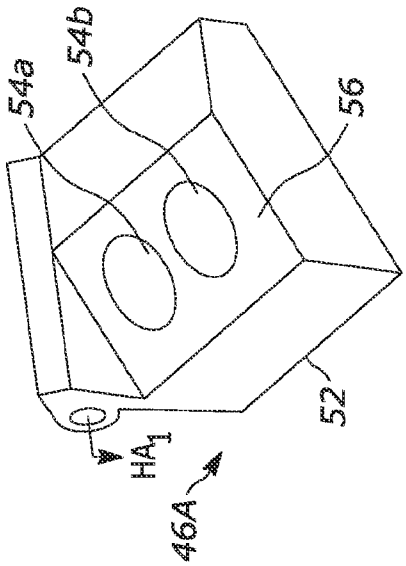


FIG. 24

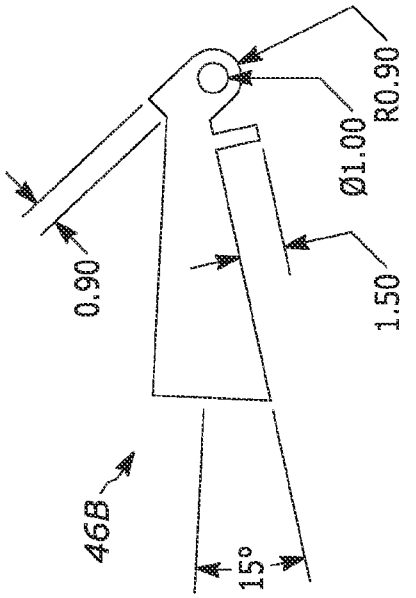


FIG. 27

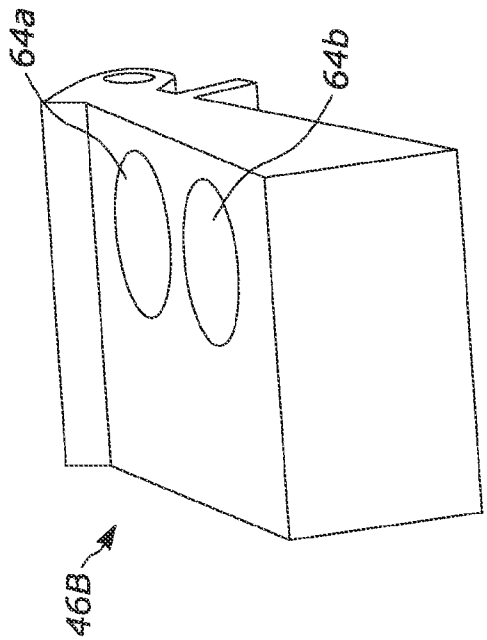


FIG. 26

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US22/25880

A. CLASSIFICATION OF SUBJECT MATTER

IPC - A61F 2/44; A61B 17/70; A61F 2/00 (2022.01)

CPC - A61B 17/7071; A61B 17/7062; A61F 2/44; A61B 17/00; A61B 17/1671; A61B 17/70; A61F 2/00

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 --- Y	US 2021/0059655 A1 (BOEHM, JR.) 04 March 2021; figures 1, 3; column 4, lines 50-65	1, 3-9 --- 2
Y --- A	US 5,653,708 A (HOWLAND ROBERT S) 05 August 1997; figures 7, 34A-34D; paragraphs [0015], [0020], [0077], [0089], [0094], [0106]-[0107], [0112], [0121], [0158], [0162]	2 --- 1, 3-9
A	US 2014/0200618 A1 (JCBD, LLC) 17 July 2014; entire document	1-9

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:
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"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	Date of mailing of the international search report
08 July 2022 (08.07.2022)	AUG 09 2022
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	Authorized officer Shane Thomas Telephone No. PCT Helpdesk: 571-272-4300