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(12) **United States Patent**
Suddaby

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(45) **Date of Patent: Jul. 18, 2023**

(54) **STAND-ALONE EXPANDABLE INTERBODY SPINAL FUSION DEVICE WITH INTEGRATED FIXATION MECHANISM**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 225 days.

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(22) Filed: **Sep. 24, 2020**

(65) **Prior Publication Data**

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Related U.S. Application Data

(63) Continuation-in-part of application No. 15/416,270, filed on Jan. 26, 2017, now Pat. No. 11,207,192.

(51) **Int. Cl.**
A61F 2/44 (2006.01)
A61F 2/30 (2006.01)

(52) **U.S. Cl.**
CPC ***A61F 2/447*** (2013.01); ***A61F 2/4405*** (2013.01); *A61F 2002/3085* (2013.01); *A61F 2002/30525* (2013.01); *A61F 2002/30579* (2013.01)

(58) **Field of Classification Search**
CPC A61F 2/4455; A61F 2/446; A61F 2/4465; A61F 2/447; A61F 2/4405
See application file for complete search history.

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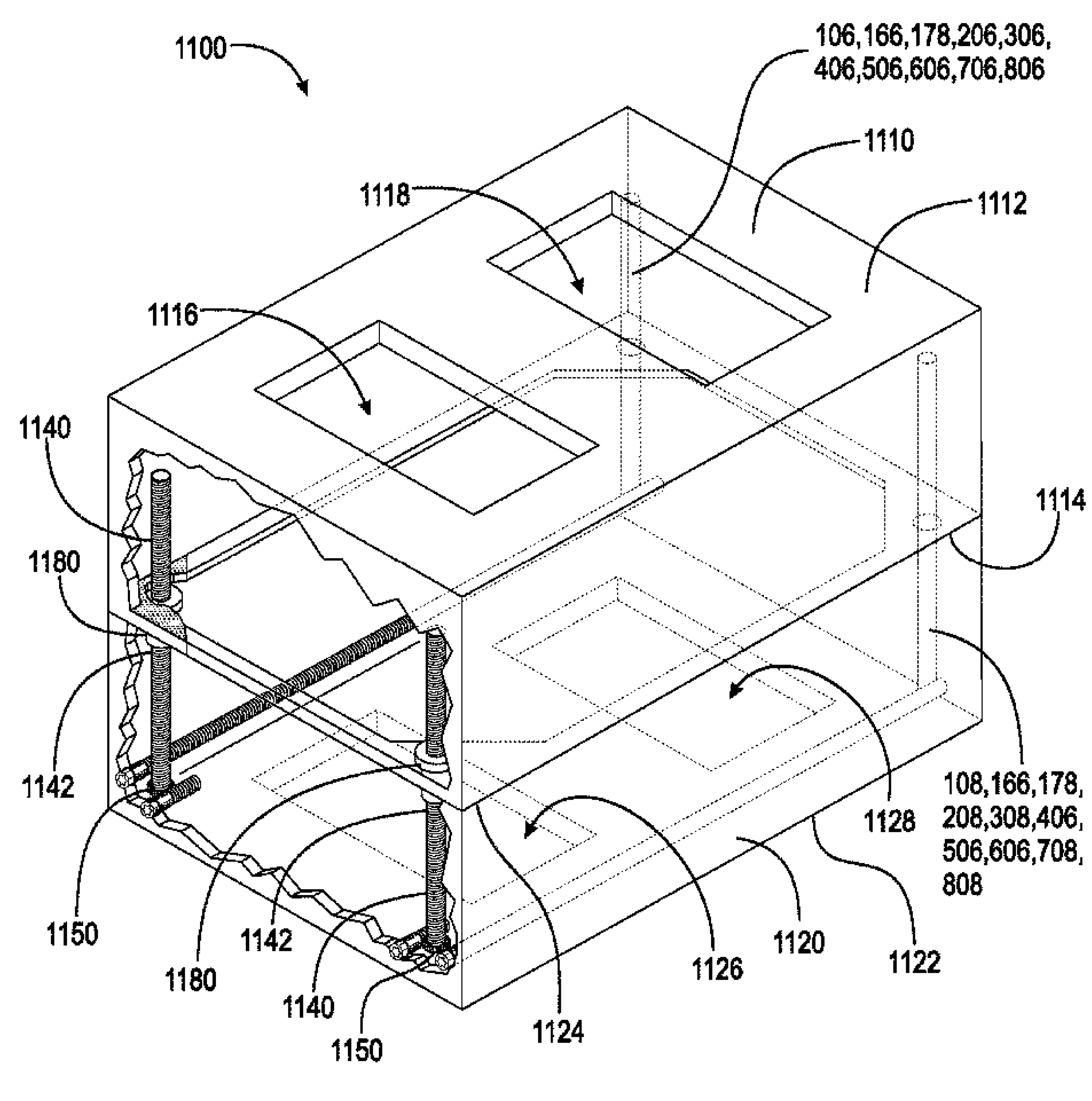
(57) **ABSTRACT**

A stand-alone expandable interbody spinal fusion device, including a superior component, an inferior component, and an expansion mechanism operatively arranged to displace the superior component relative to the inferior component, the expansion mechanism including a threaded rod including a first end engaged with the superior component and a second end engaged with the inferior component, wherein when the threaded rod is rotated in a first circumferential direction, the superior component is displaced in a first direction relative to the inferior component.

20 Claims, 42 Drawing Sheets



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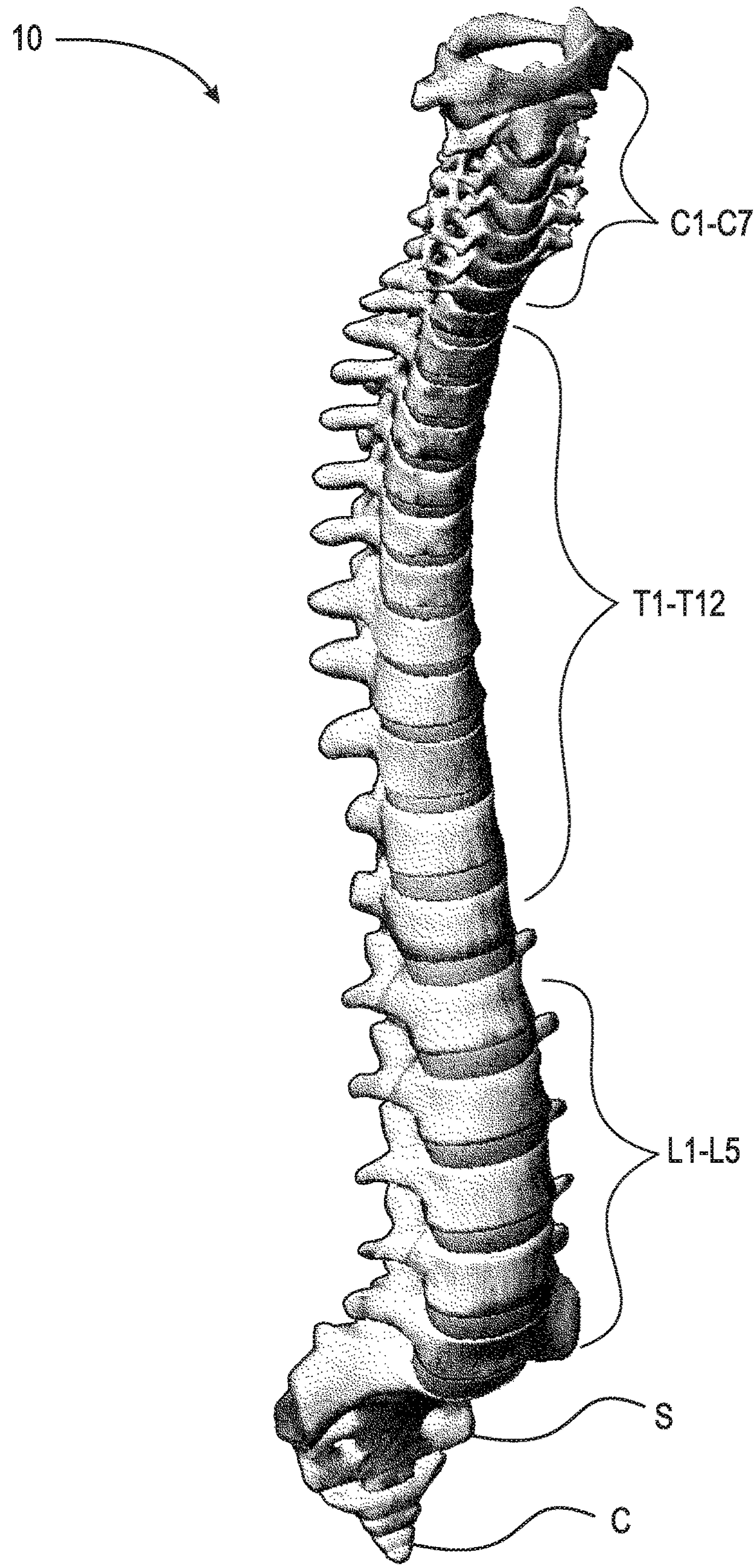

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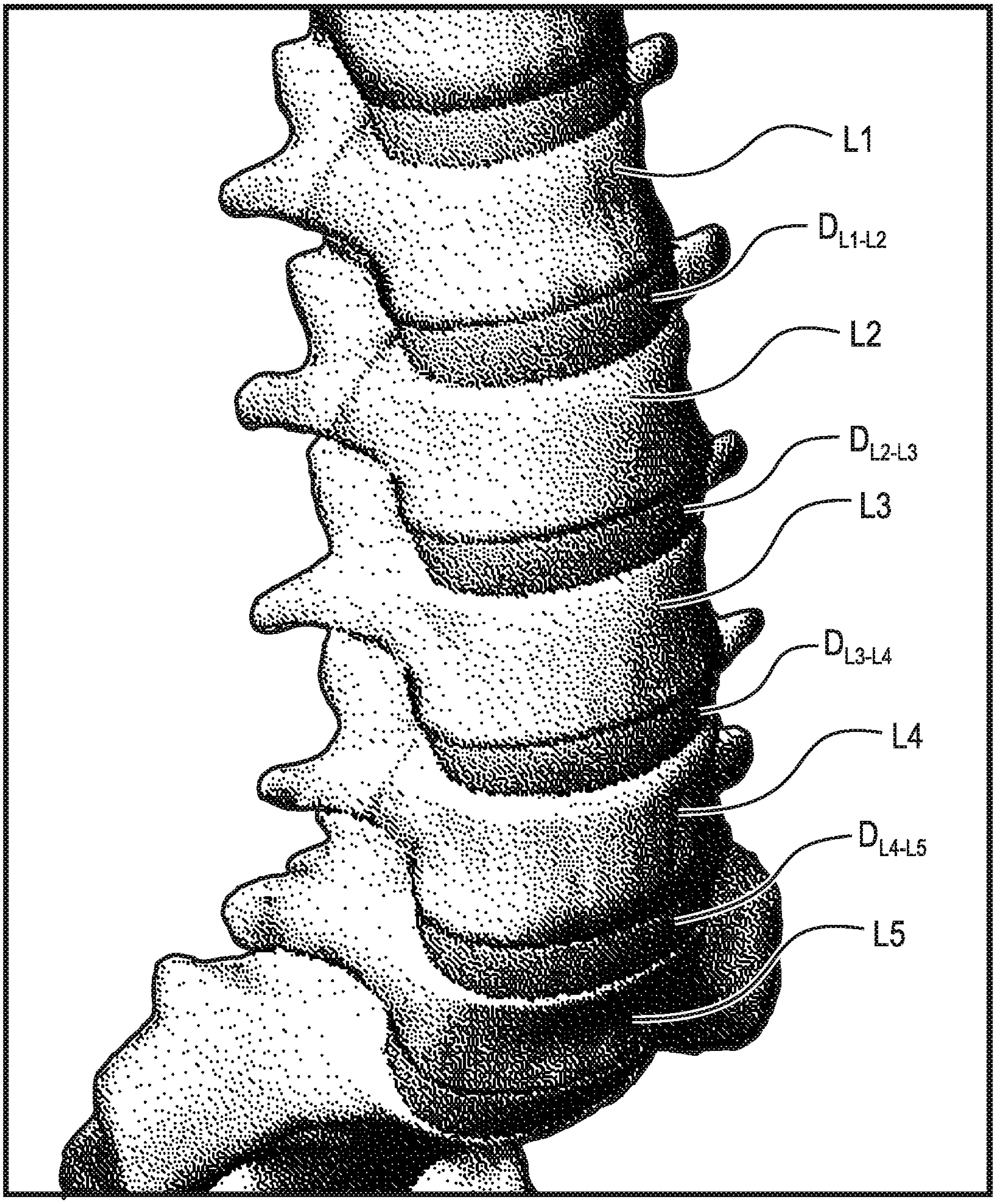

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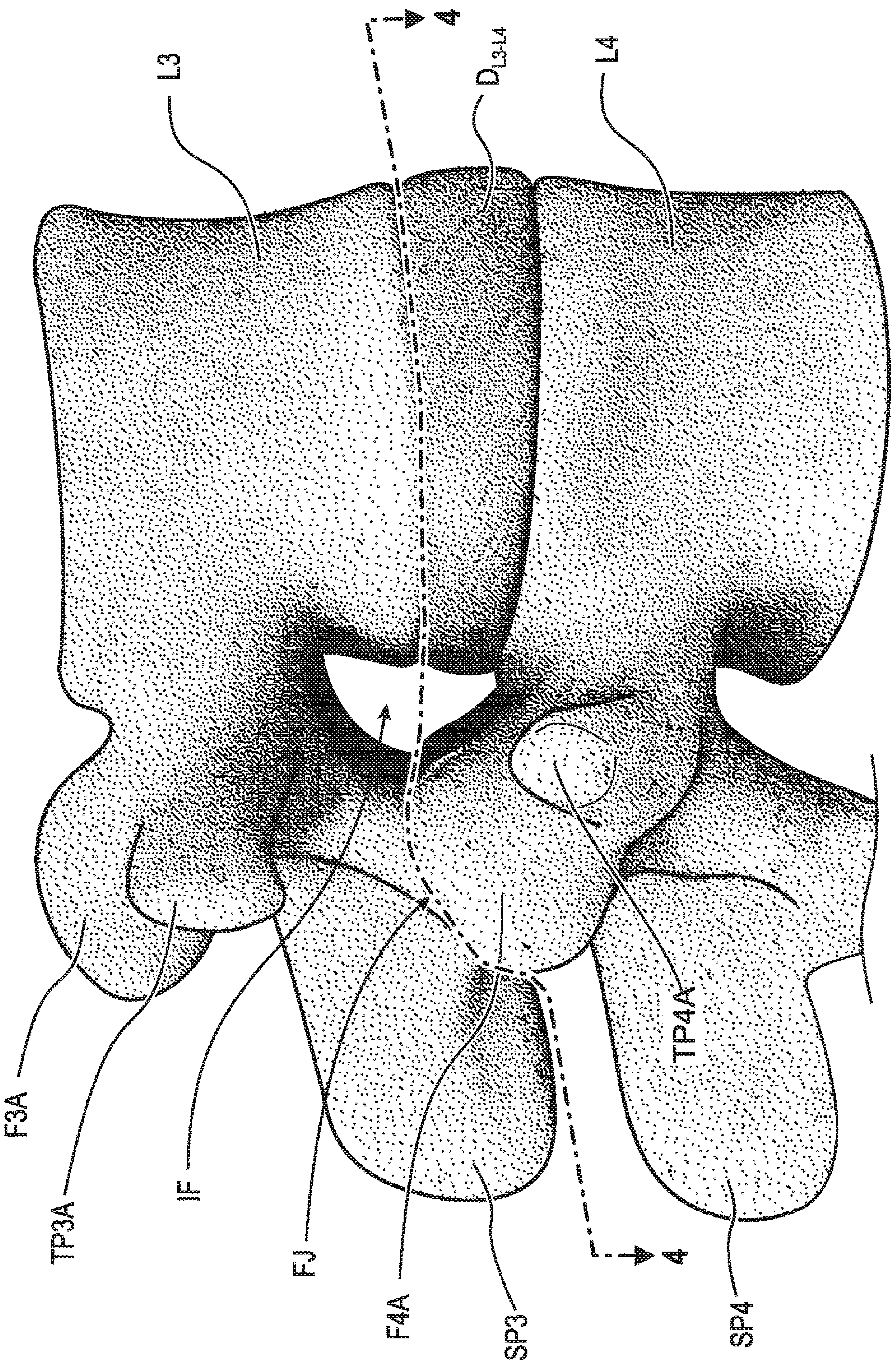

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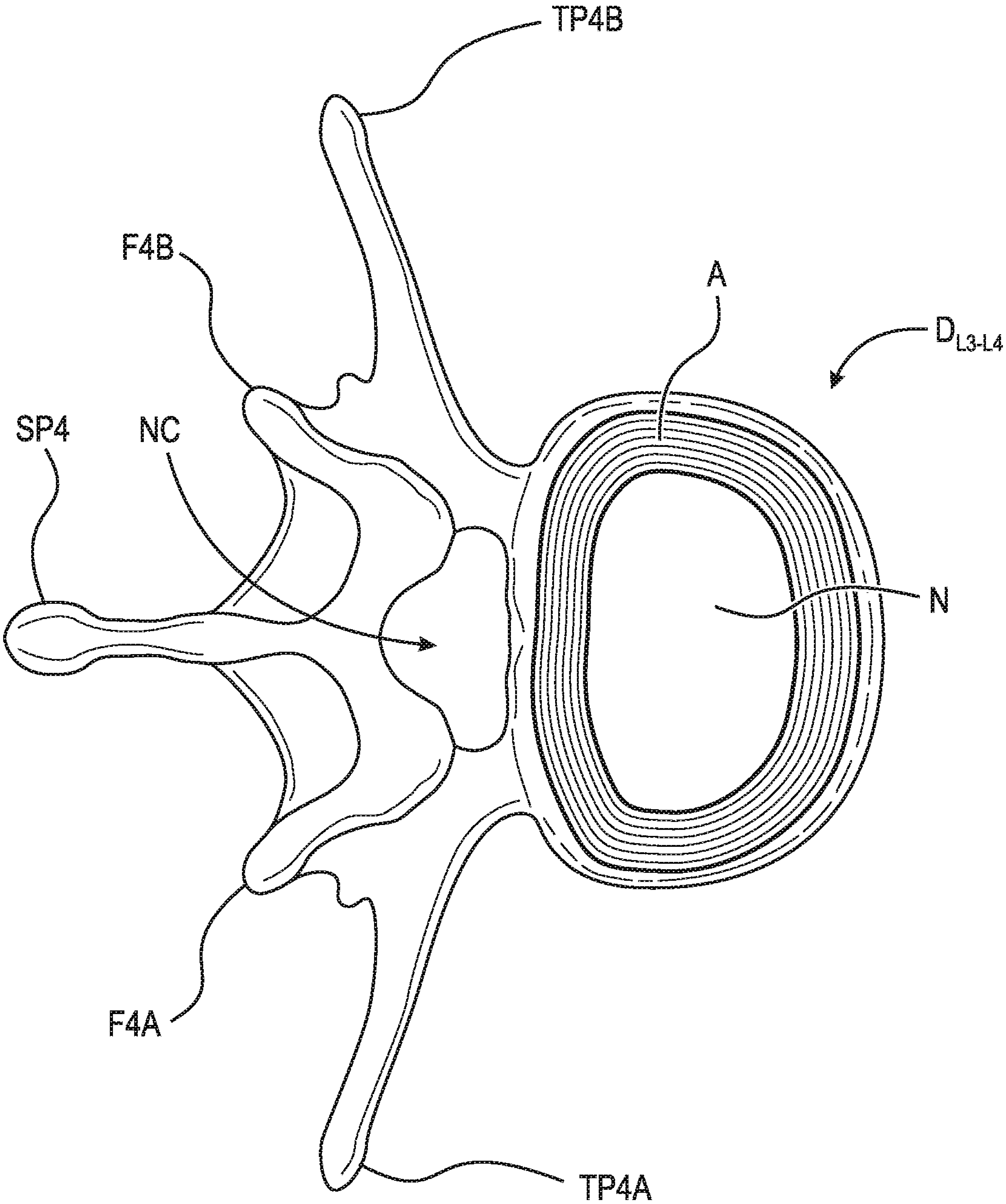

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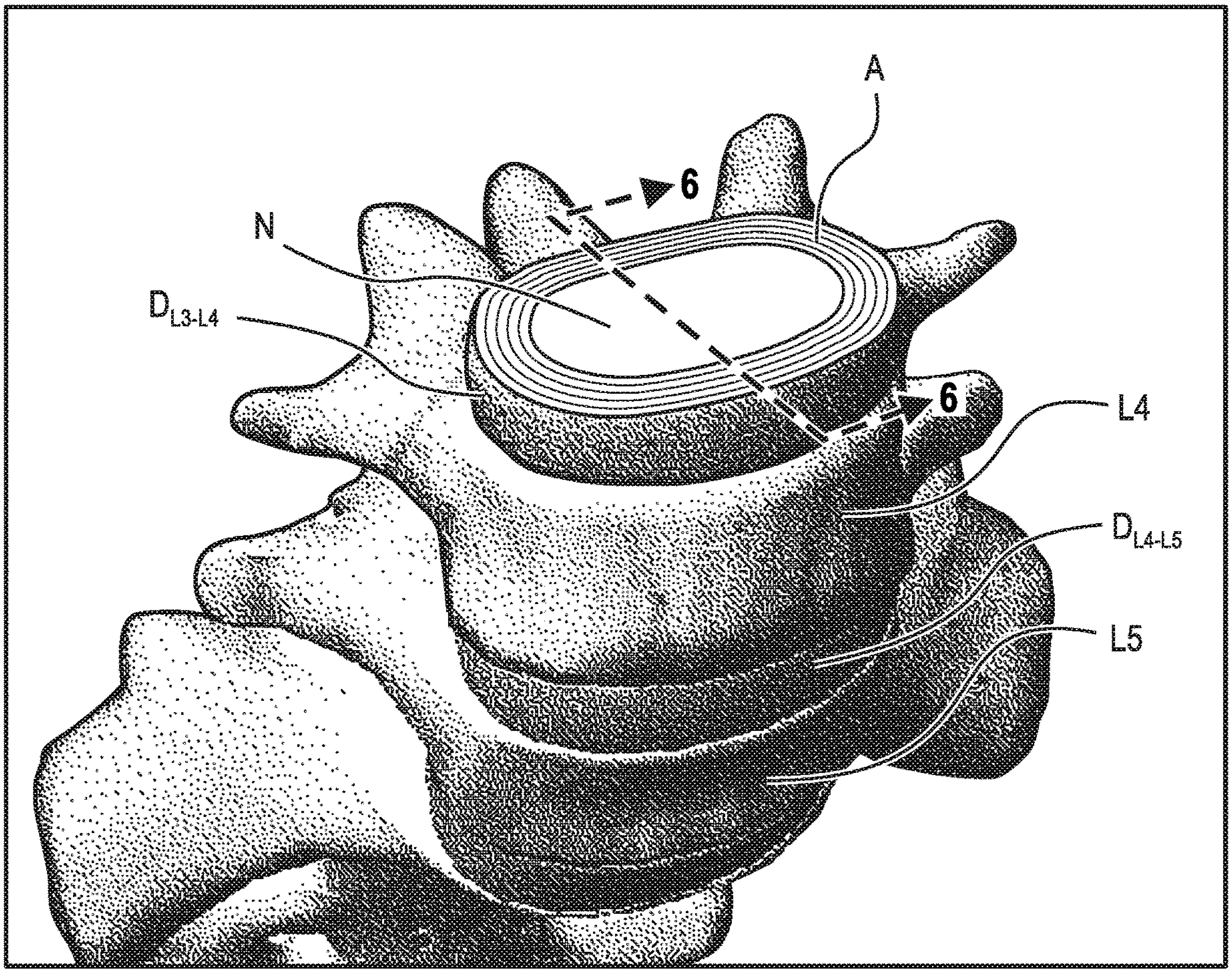

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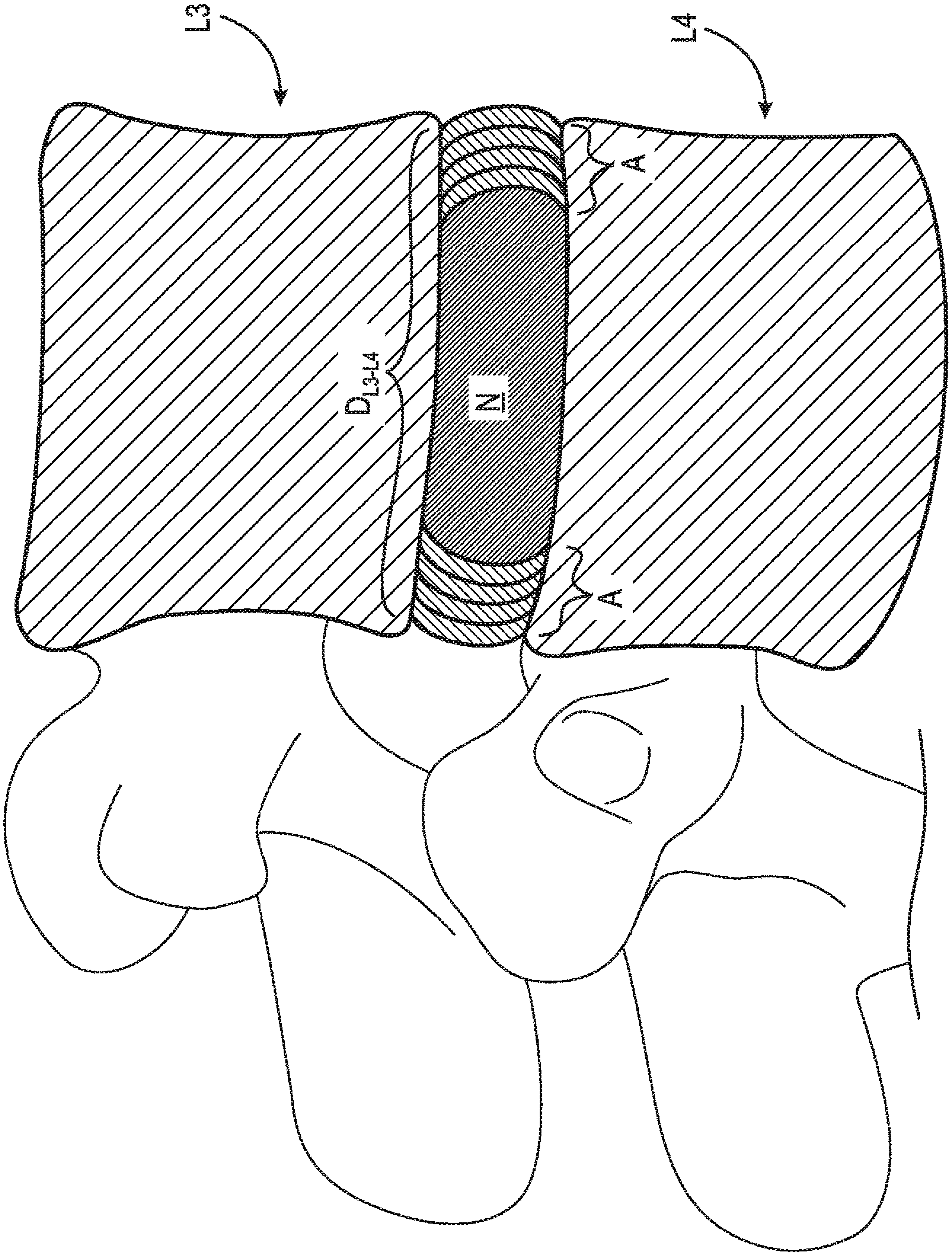

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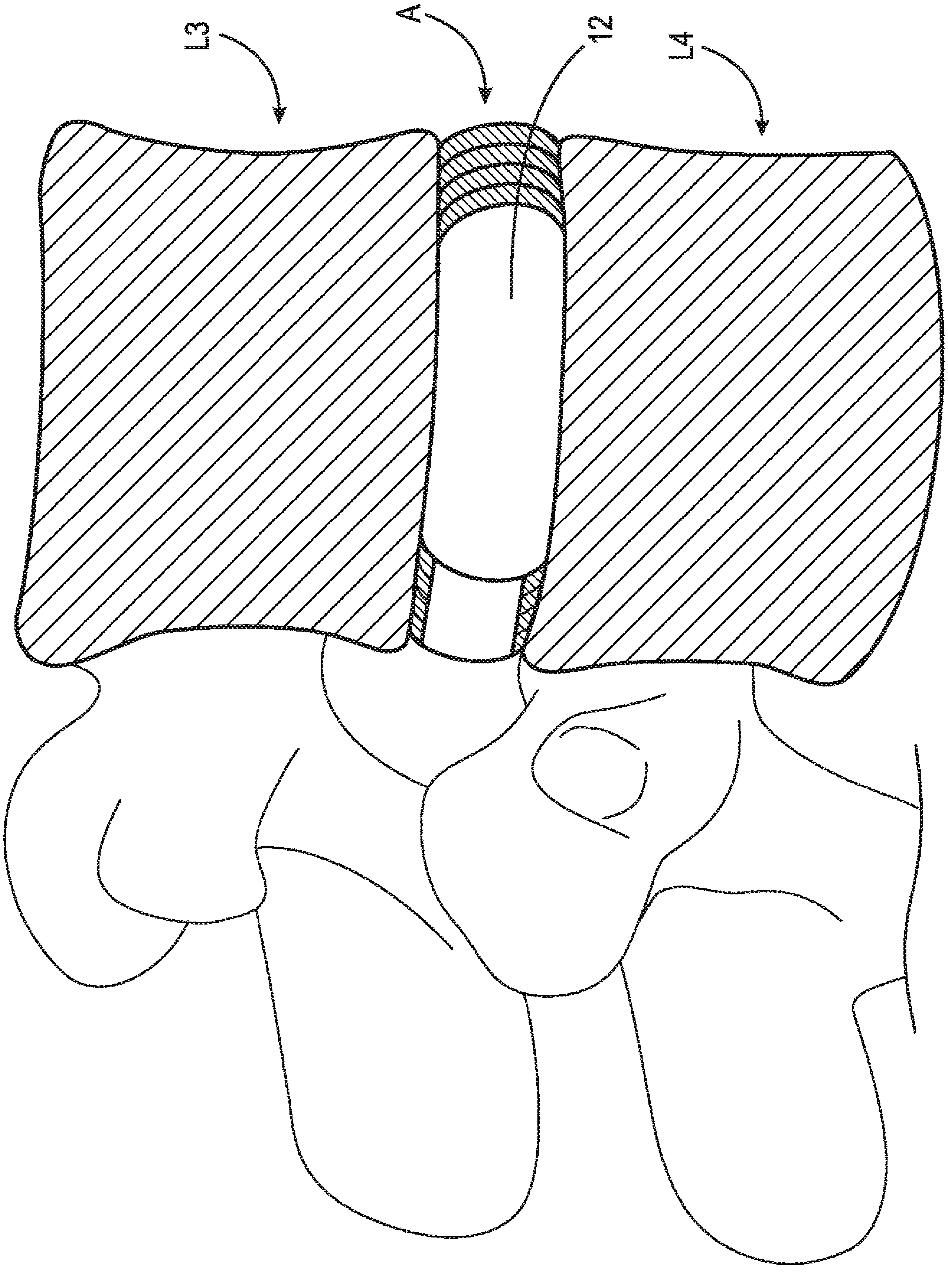

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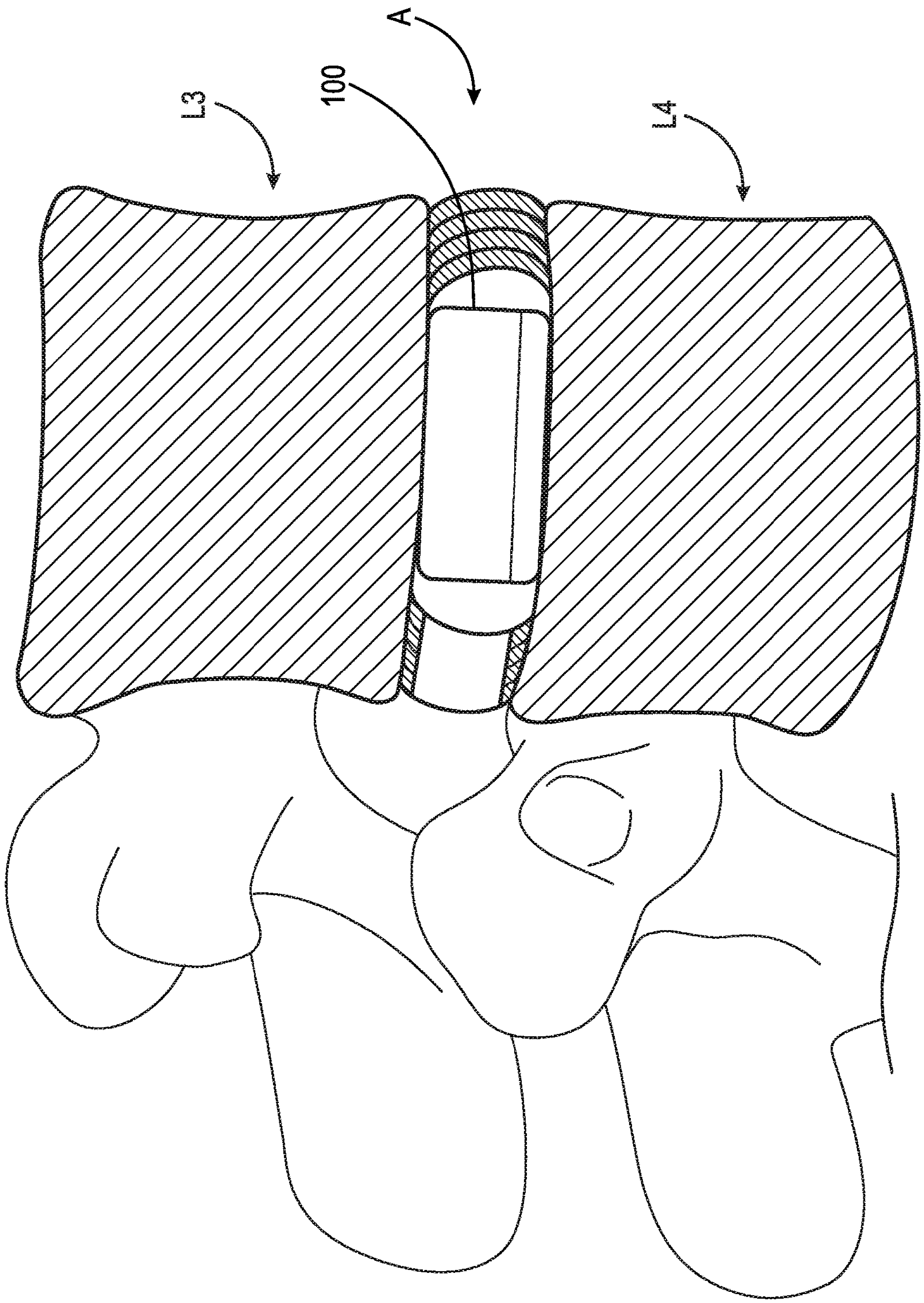

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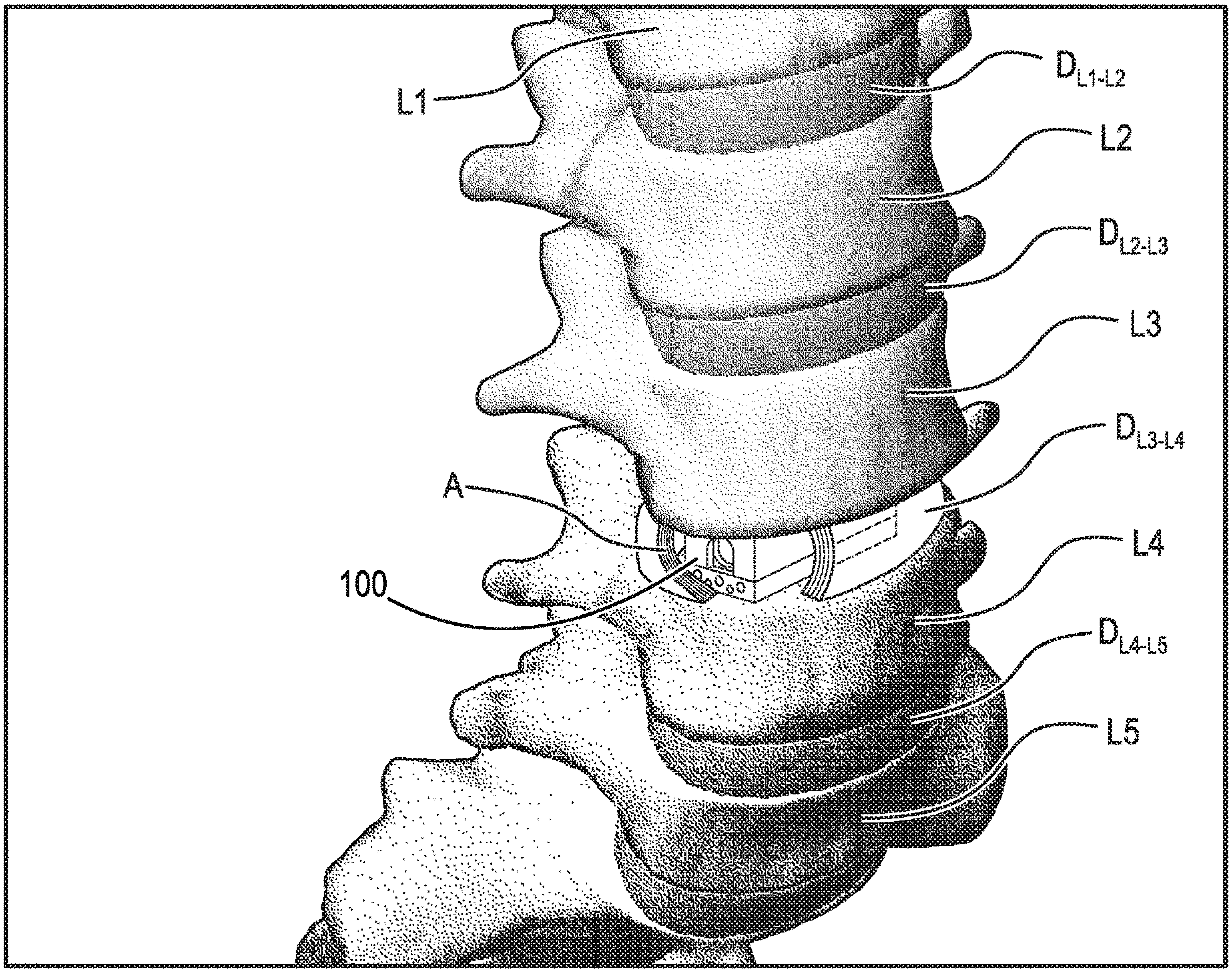

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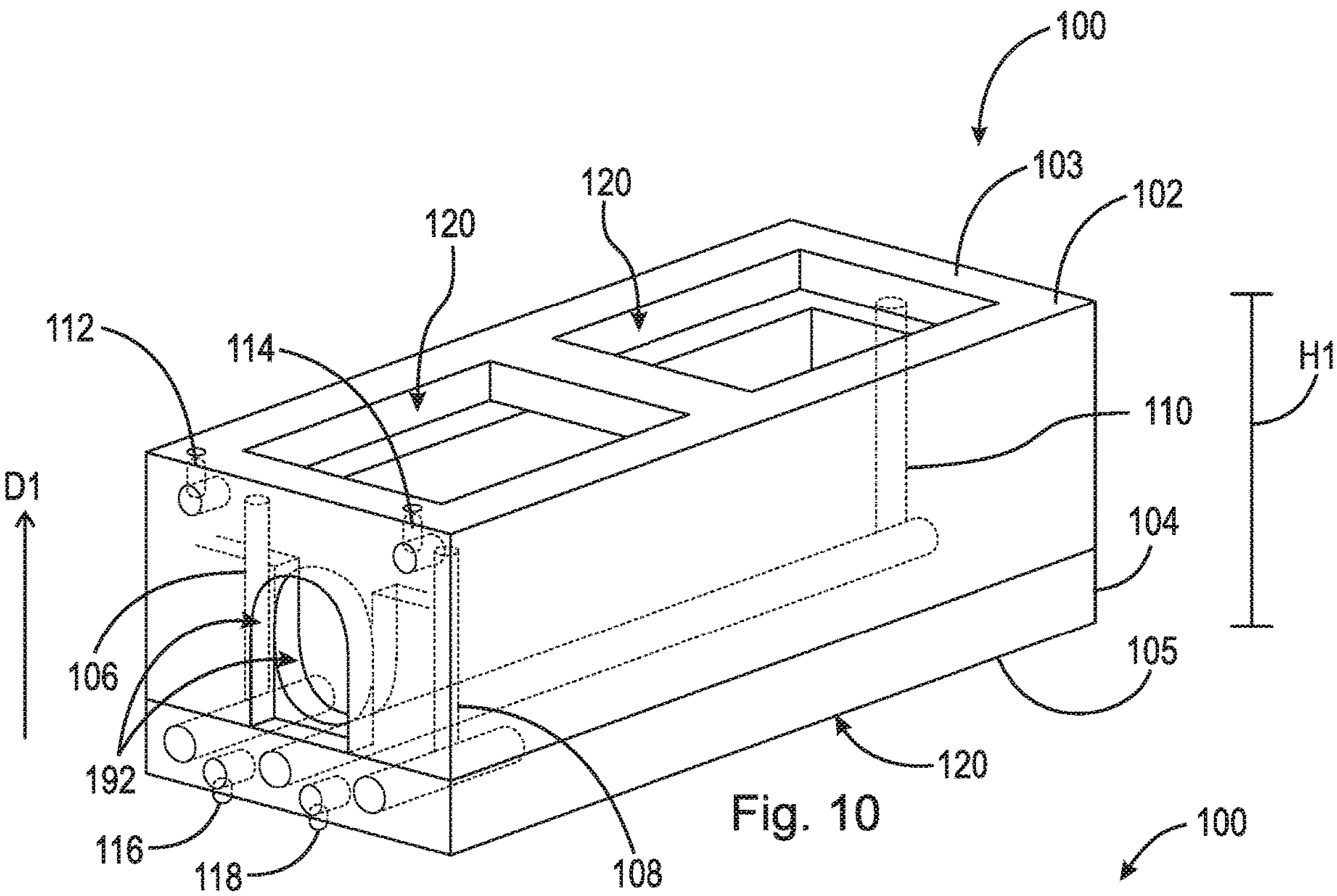

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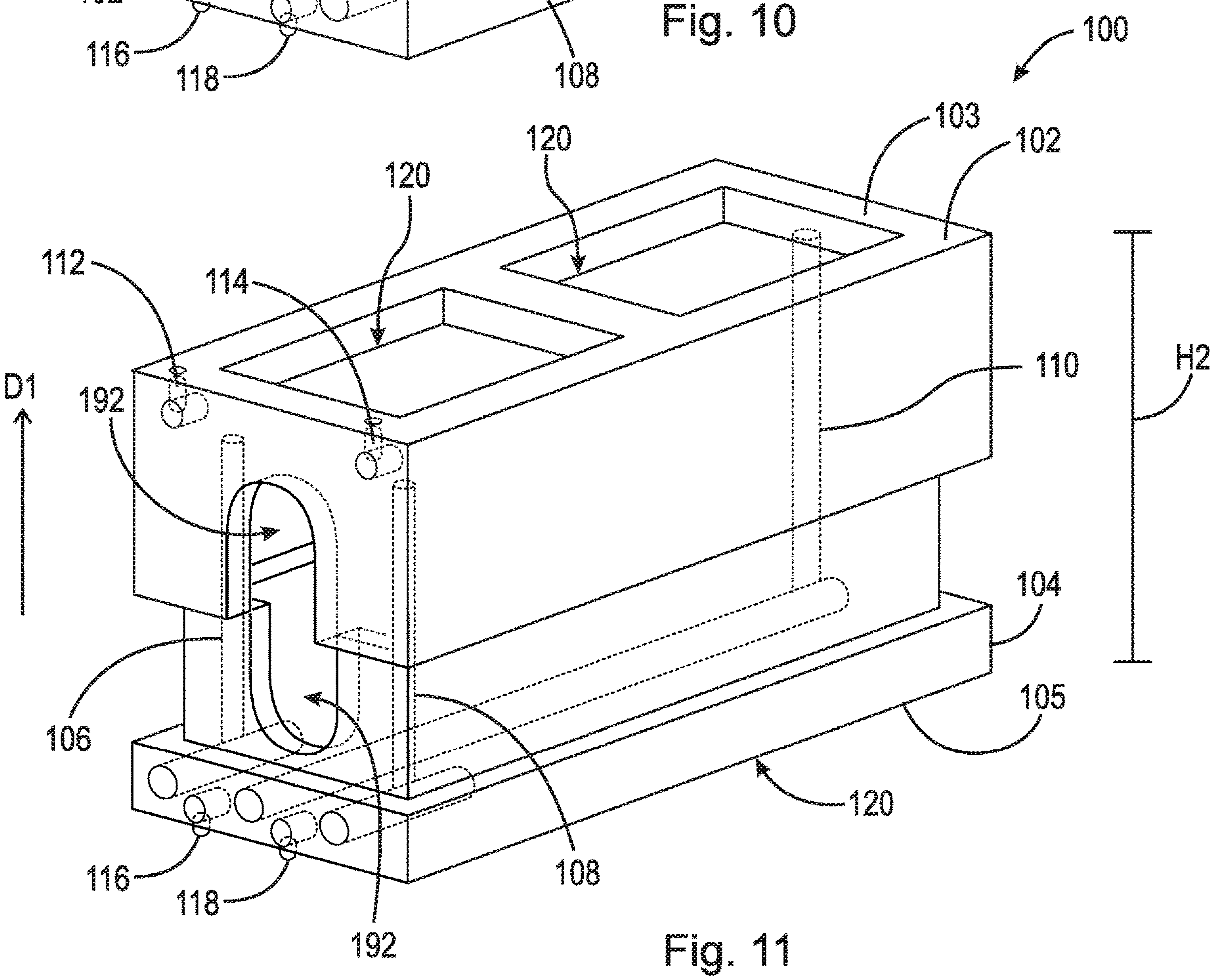

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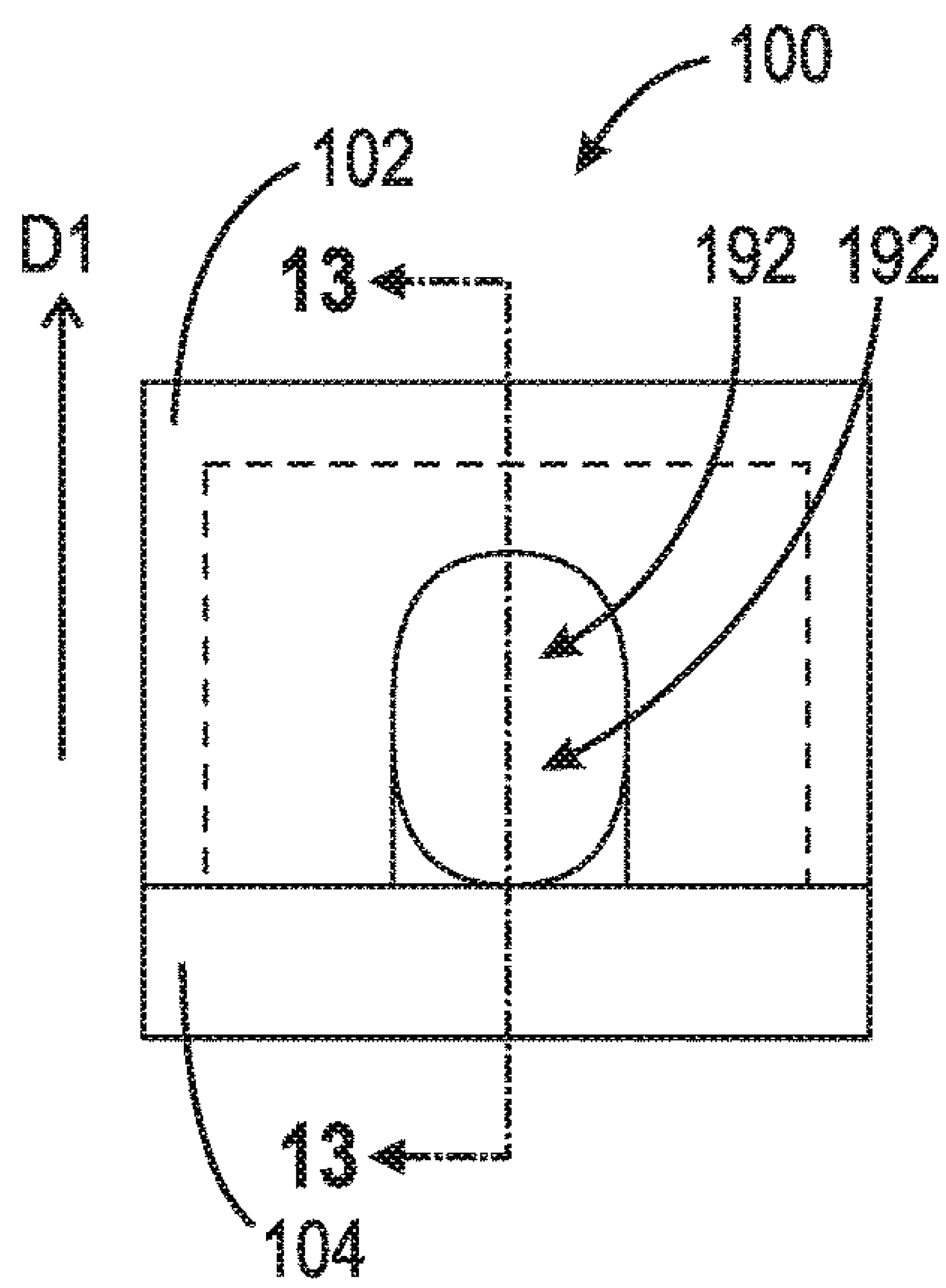

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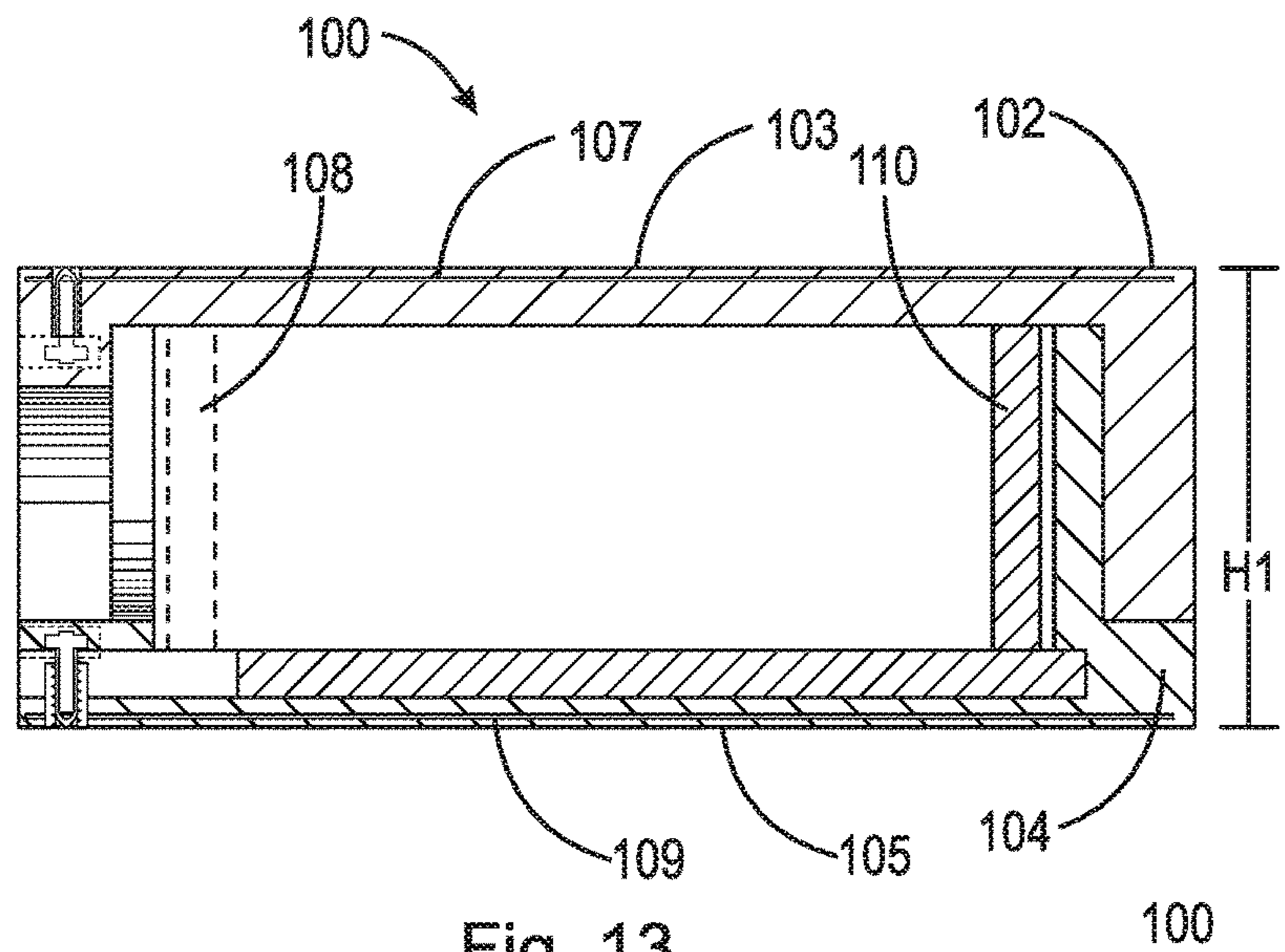

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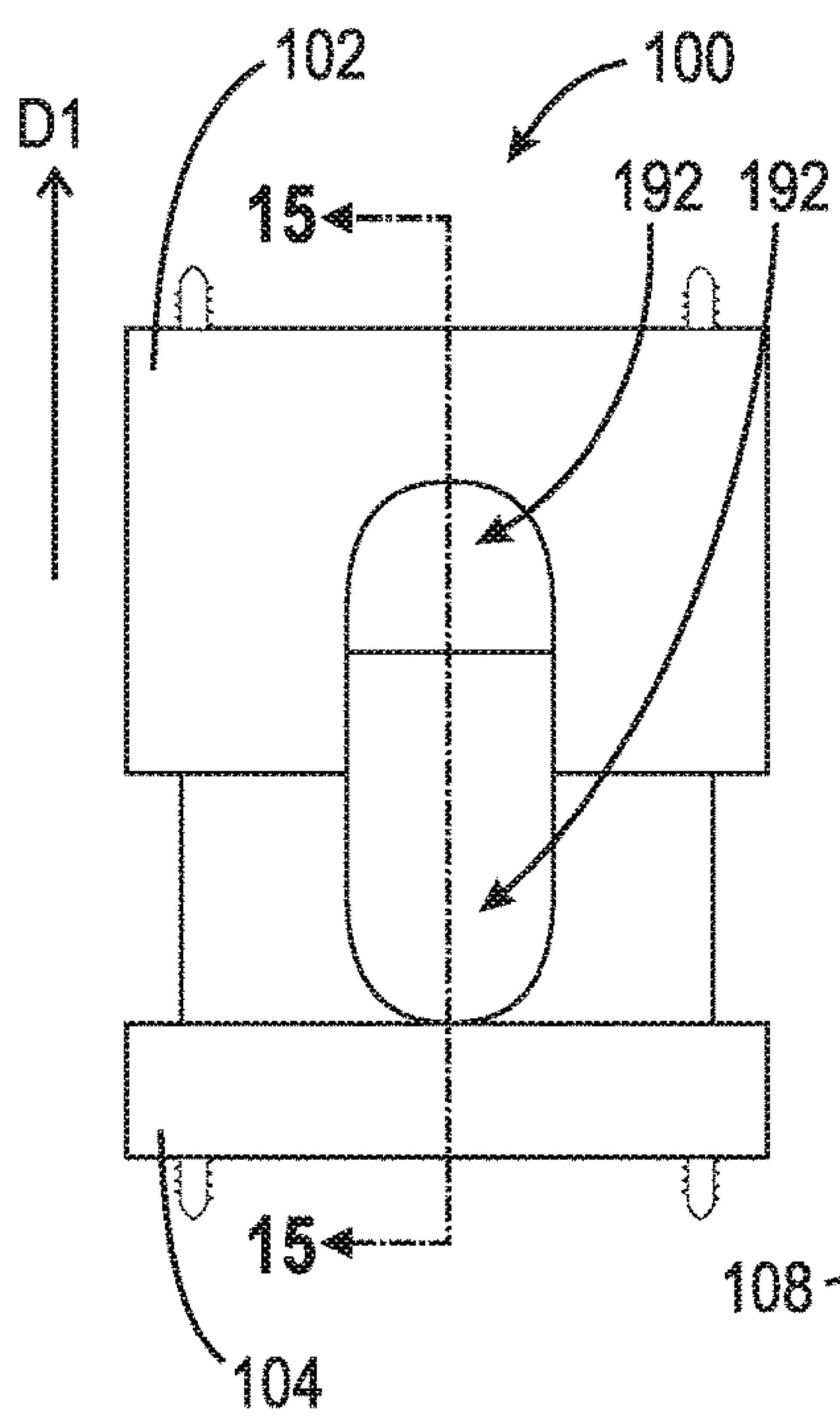

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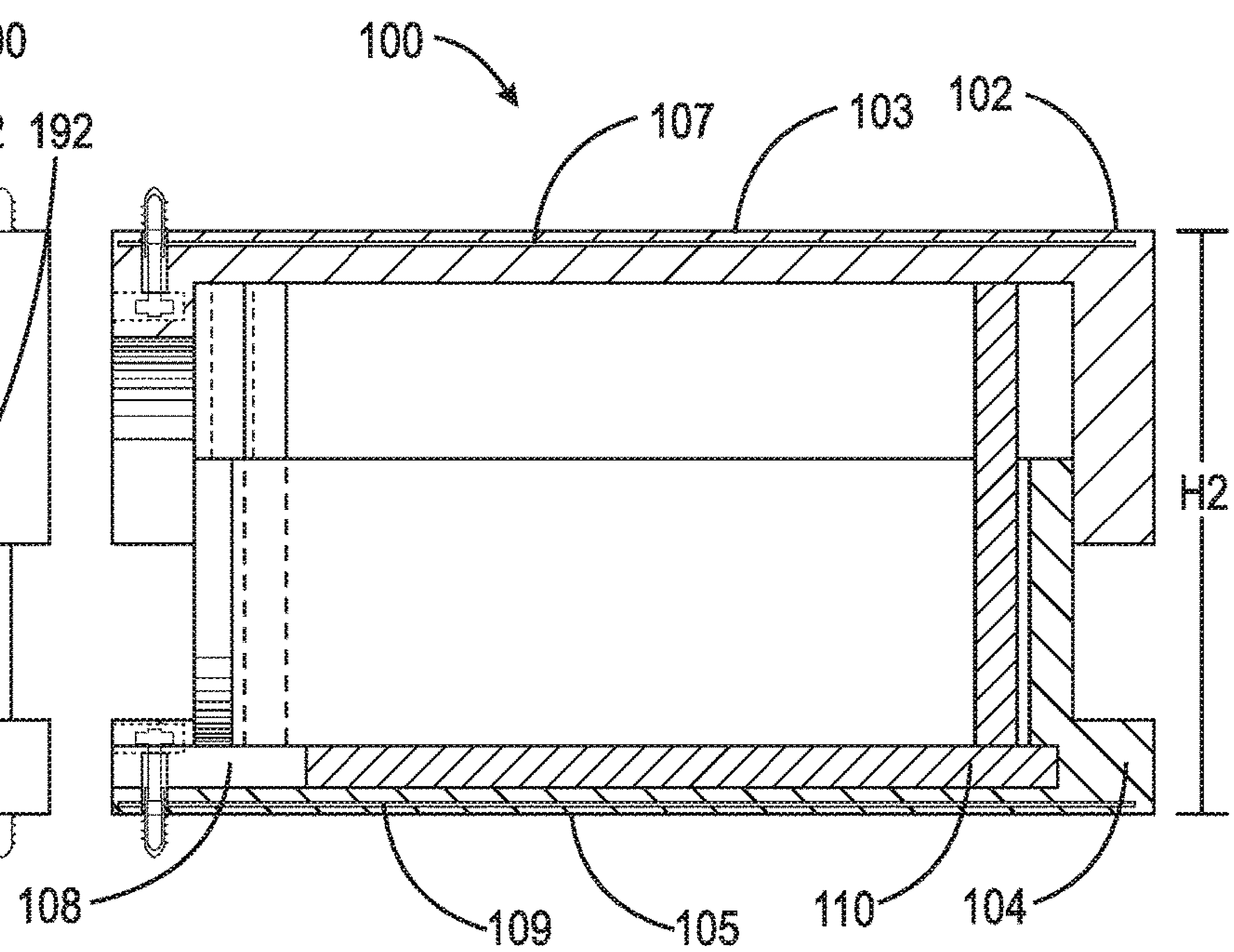

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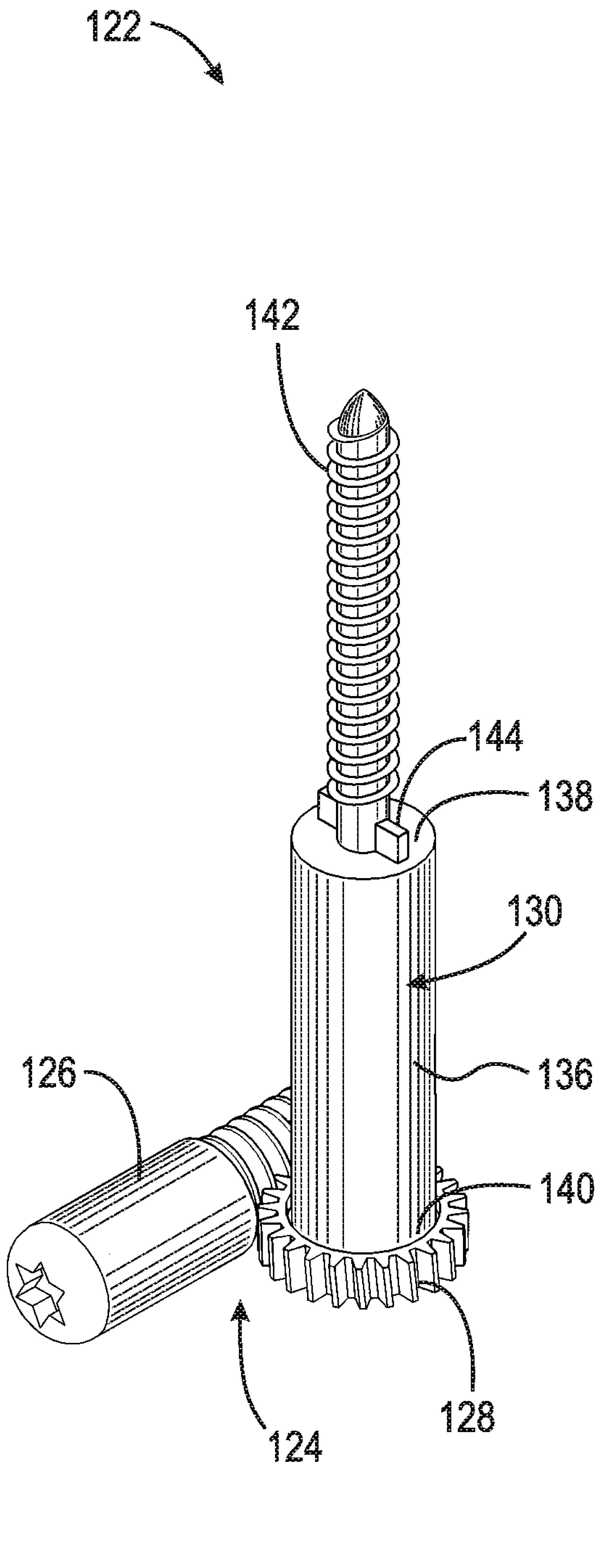
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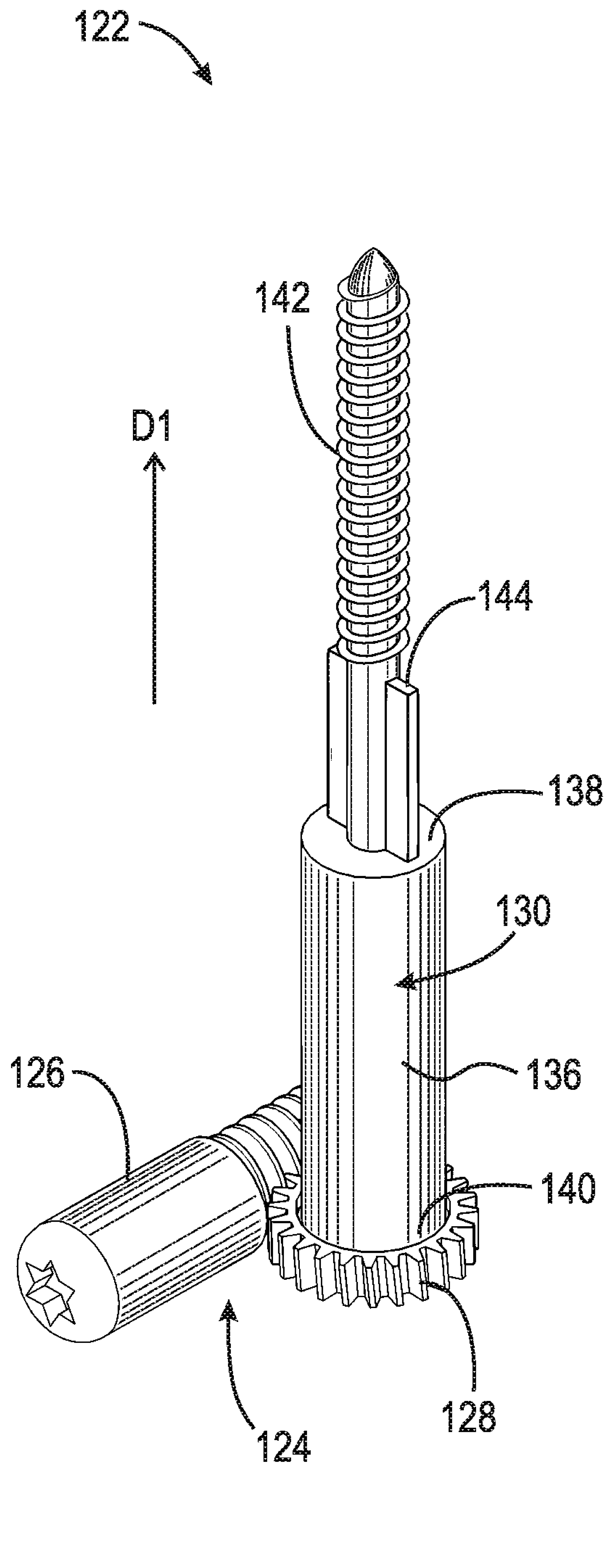
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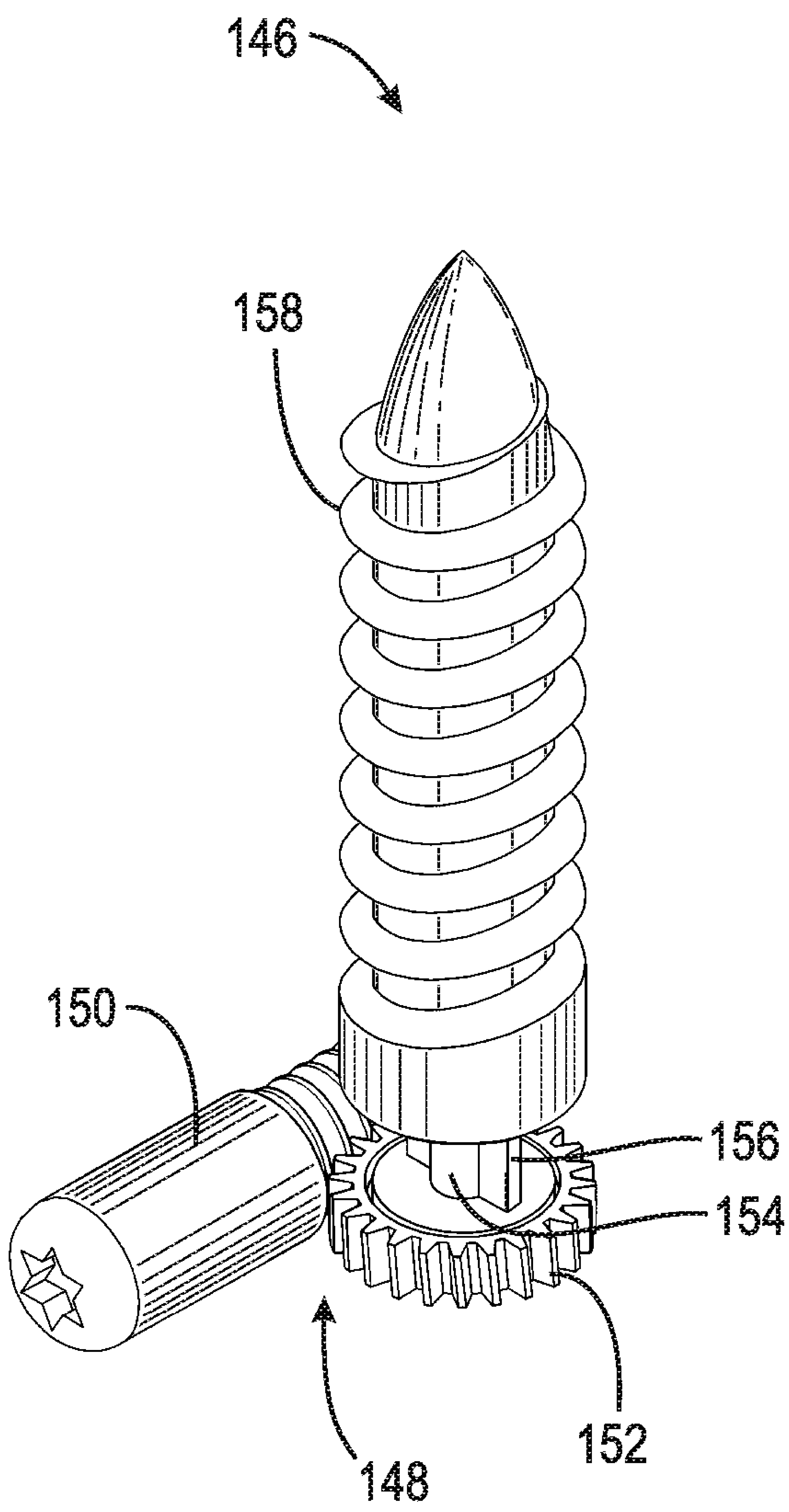

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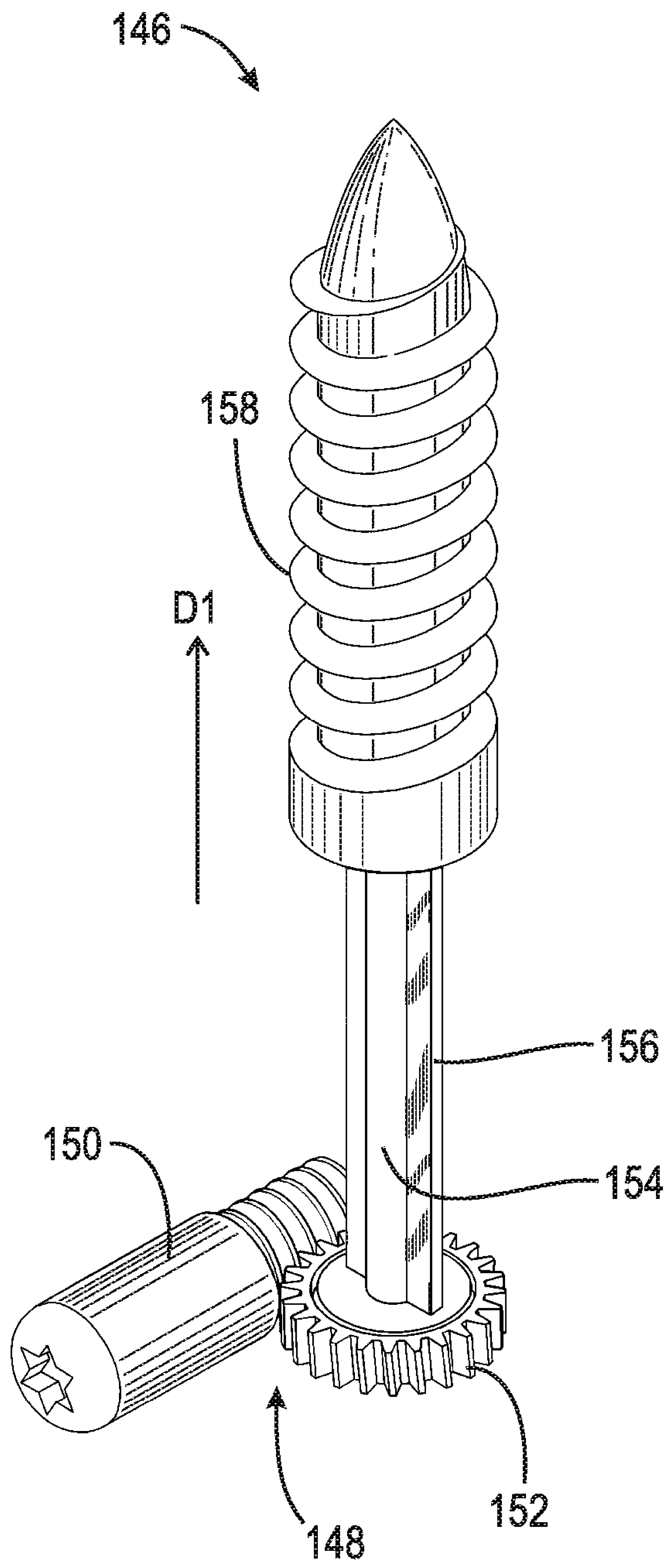

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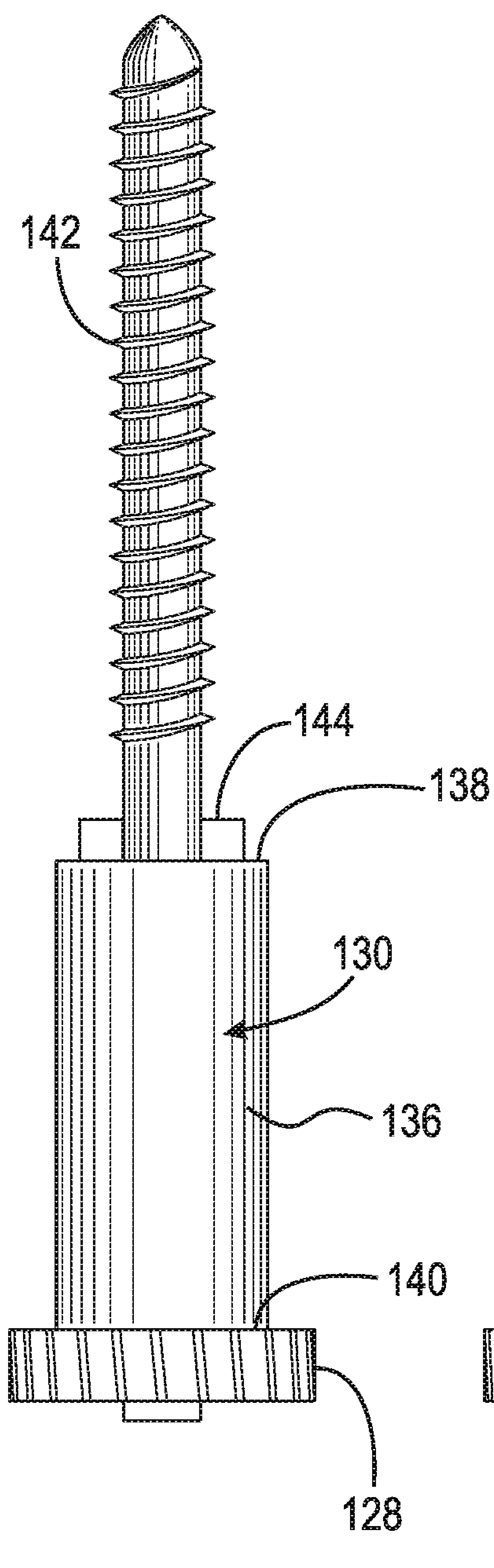

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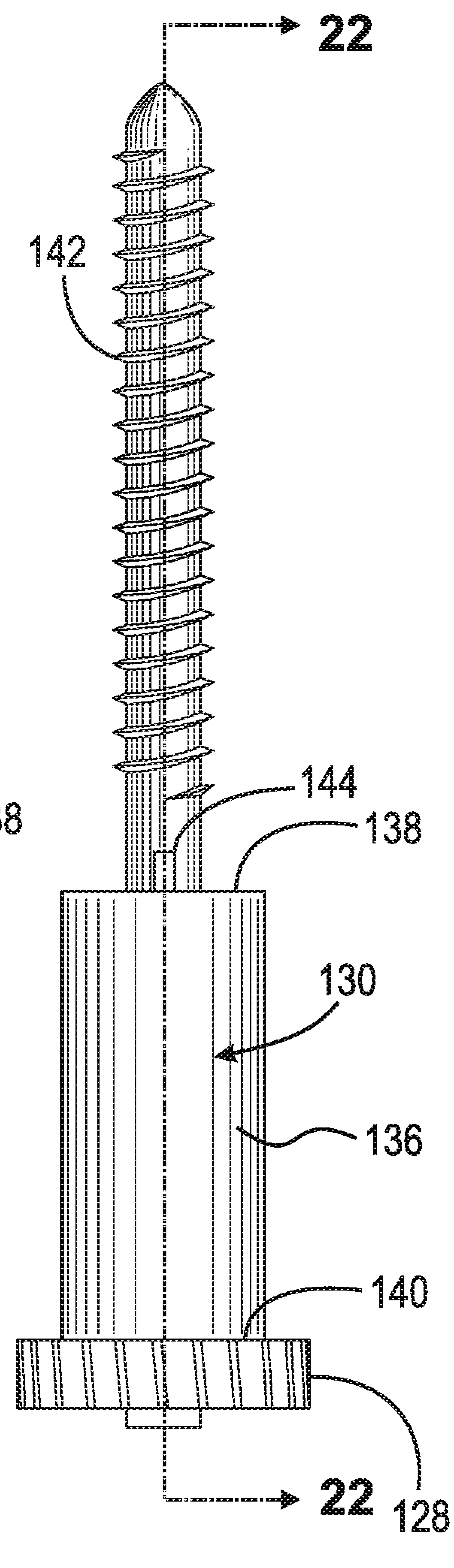

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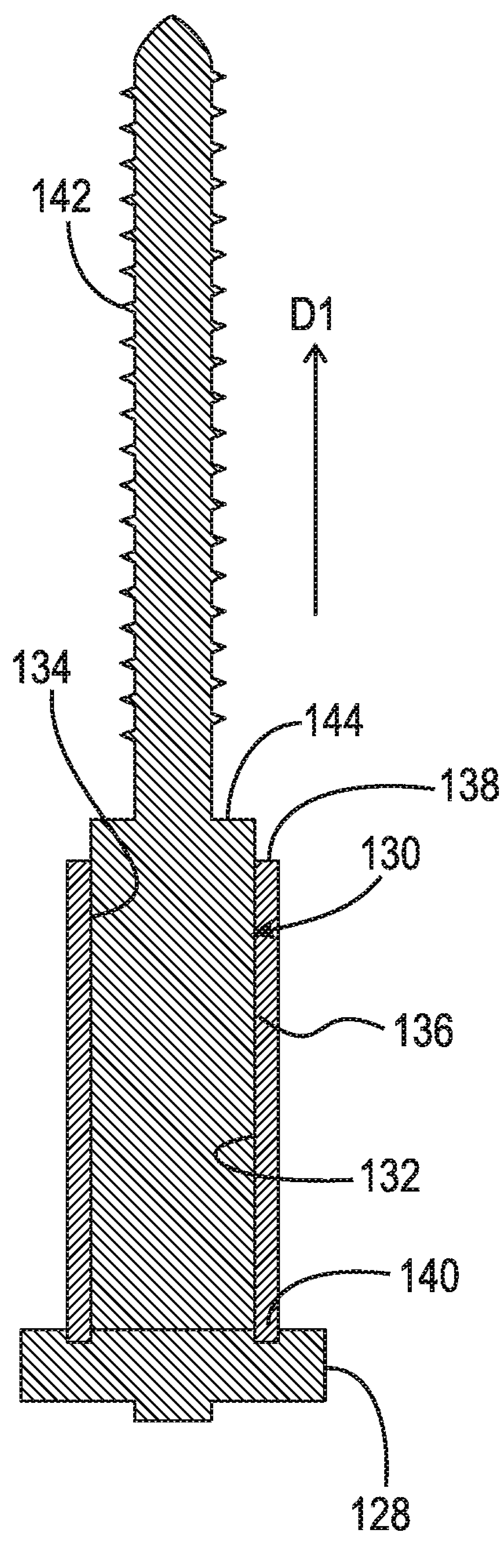

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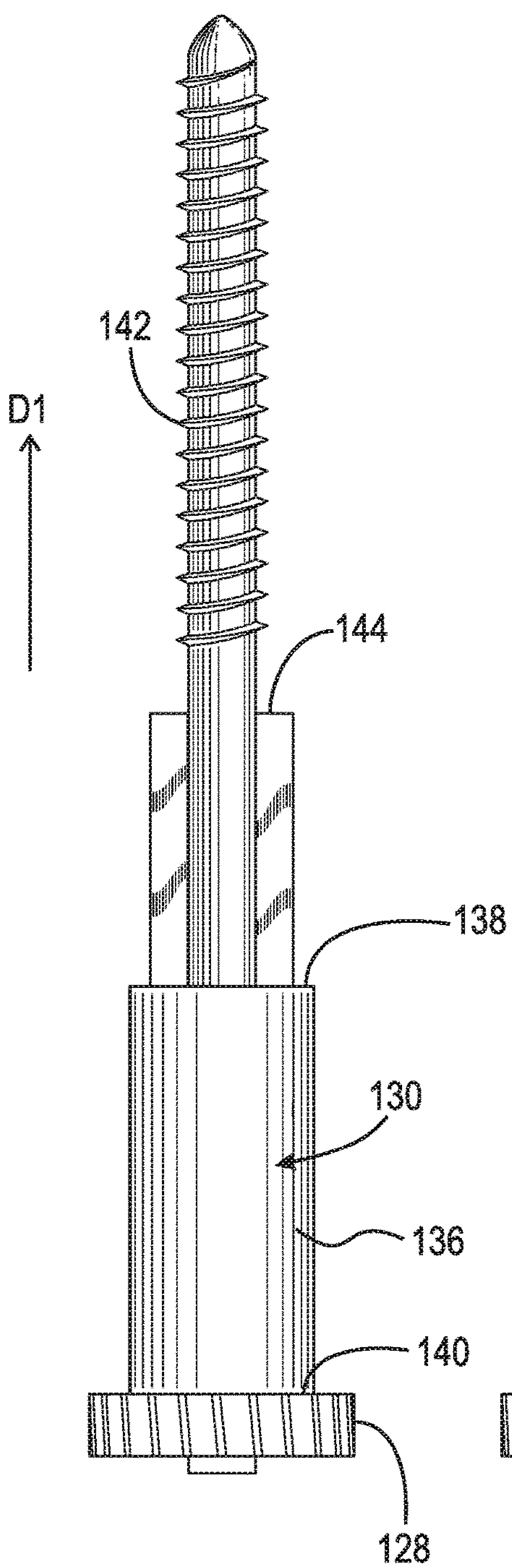

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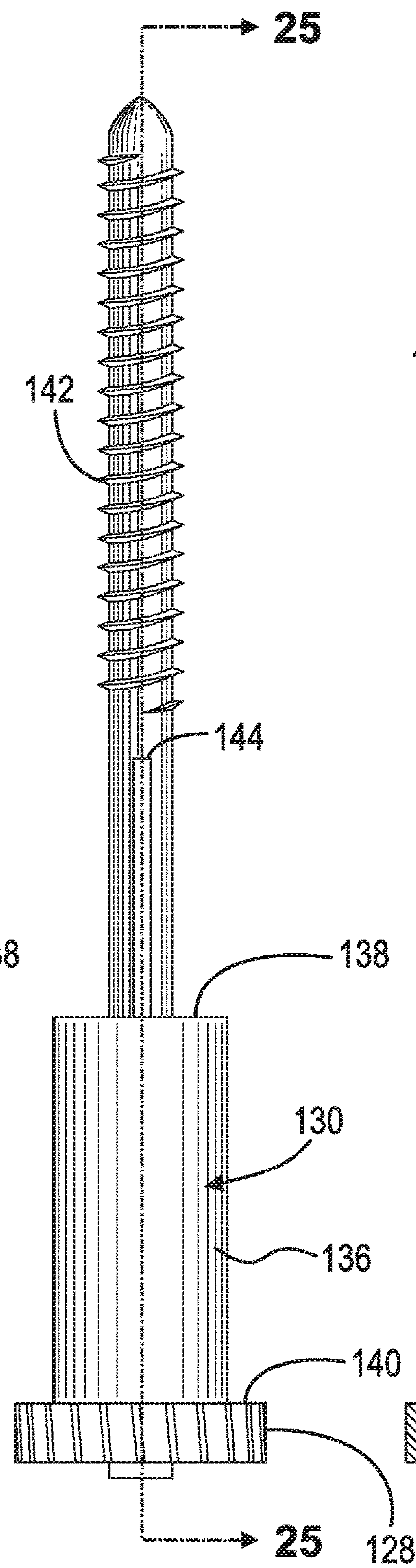

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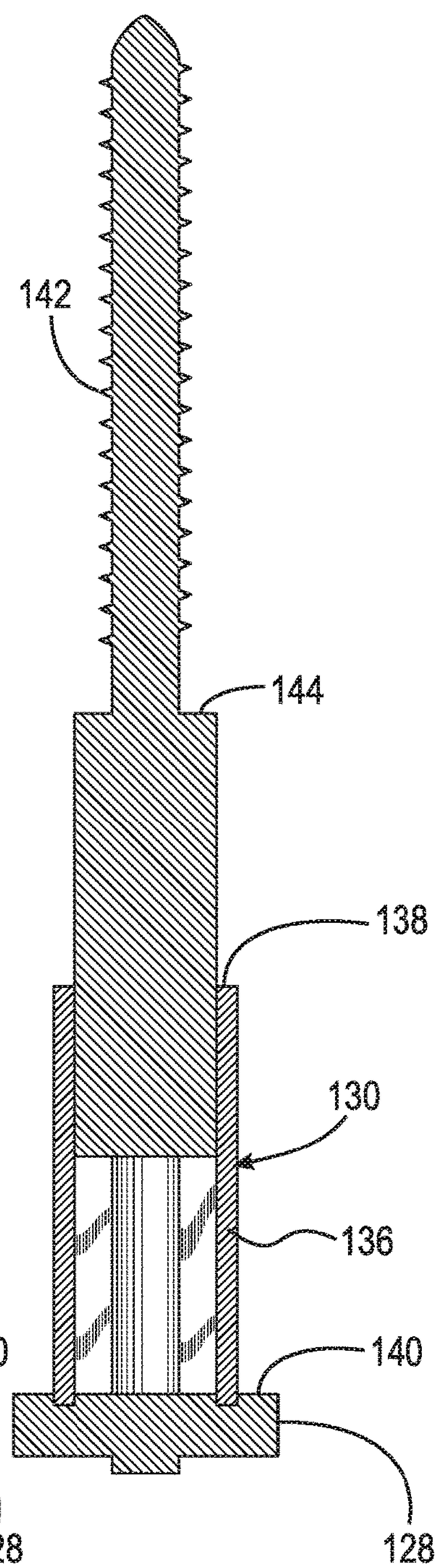

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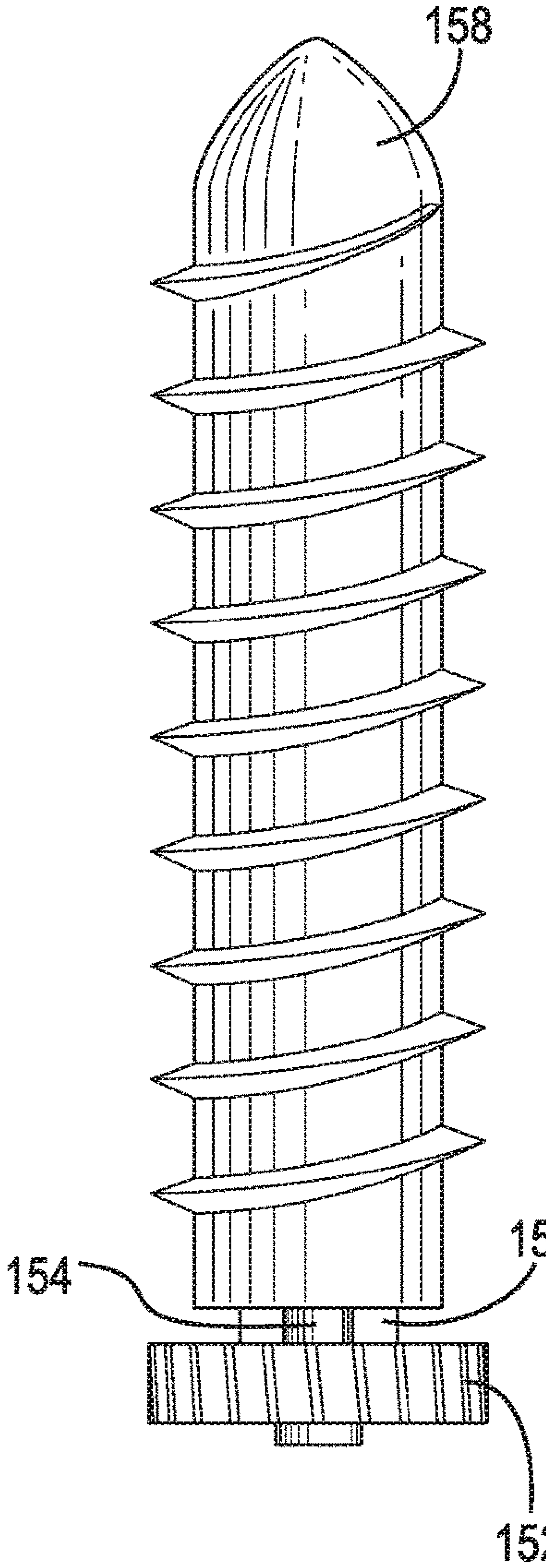

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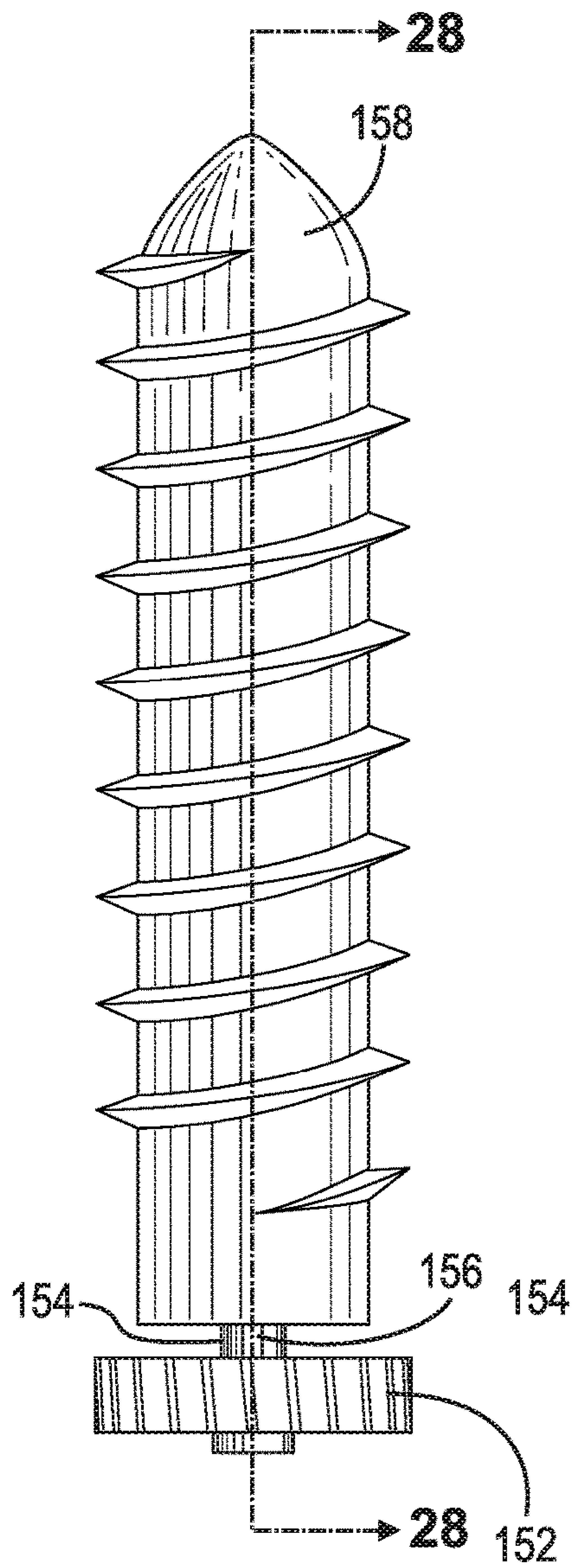

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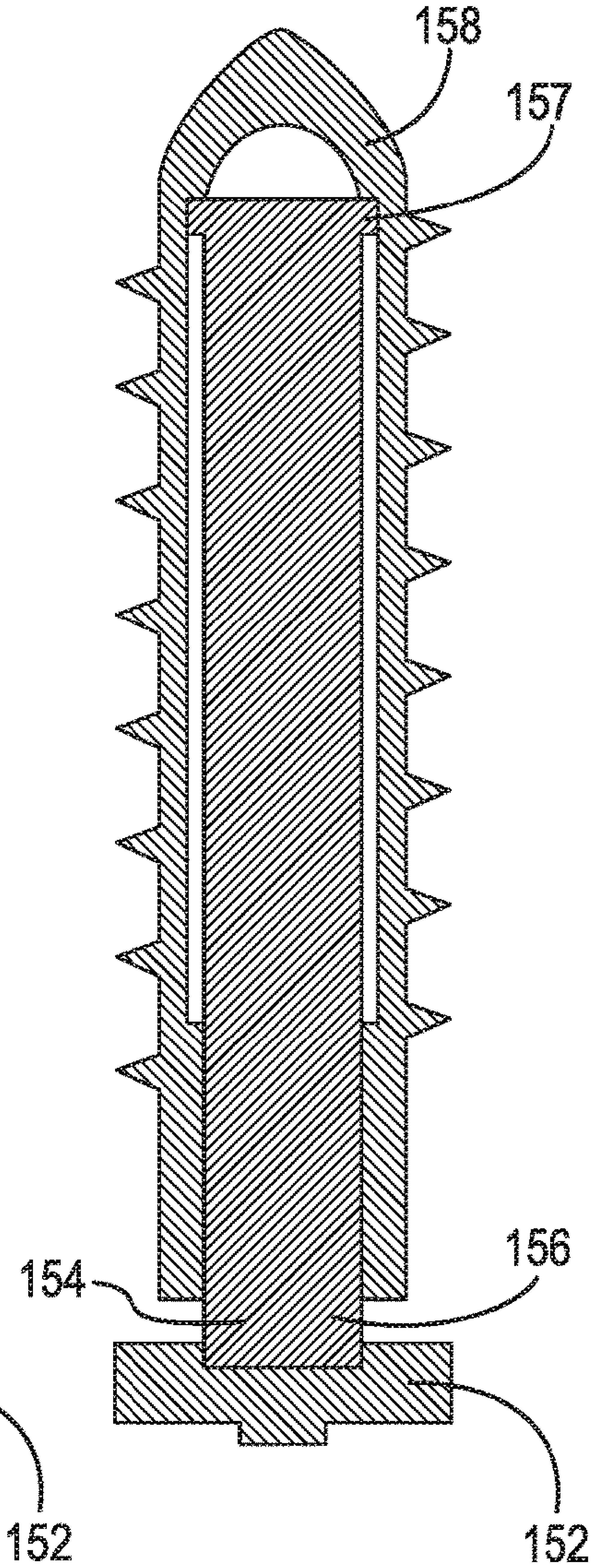

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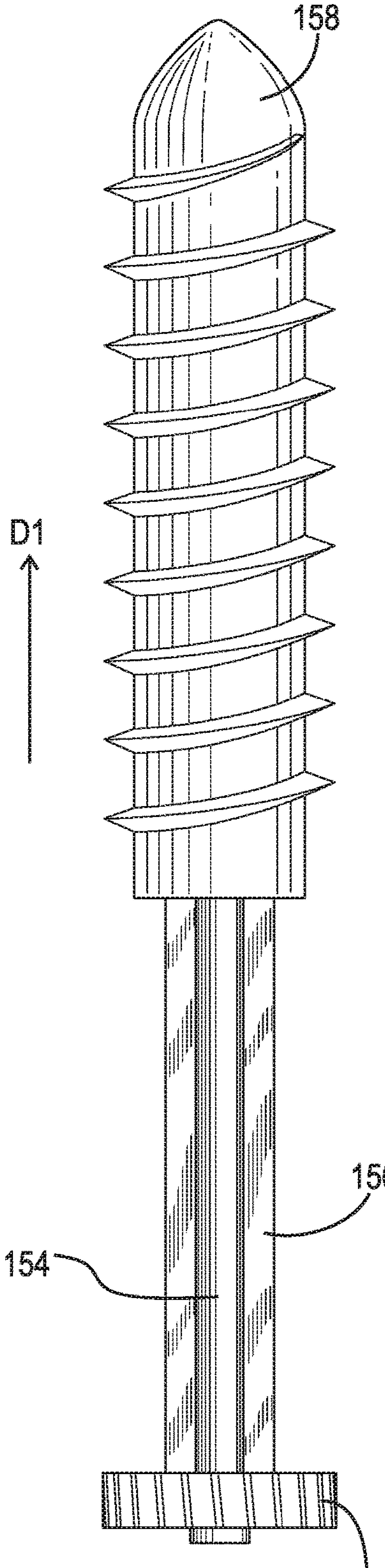

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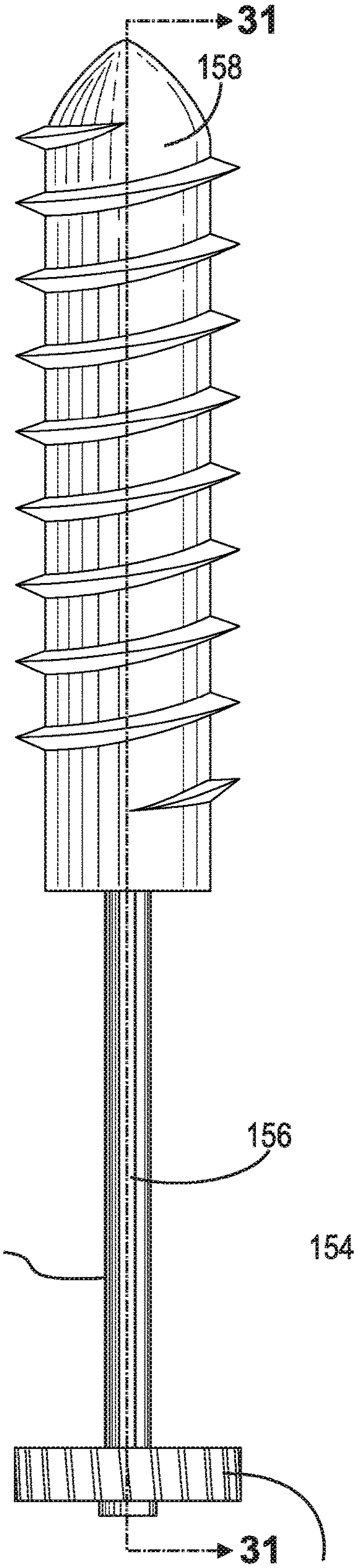

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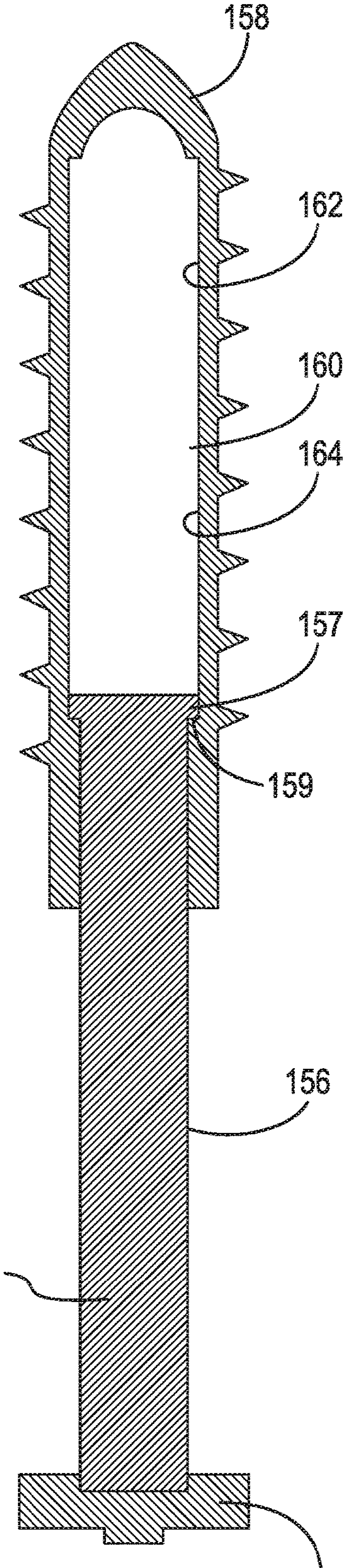

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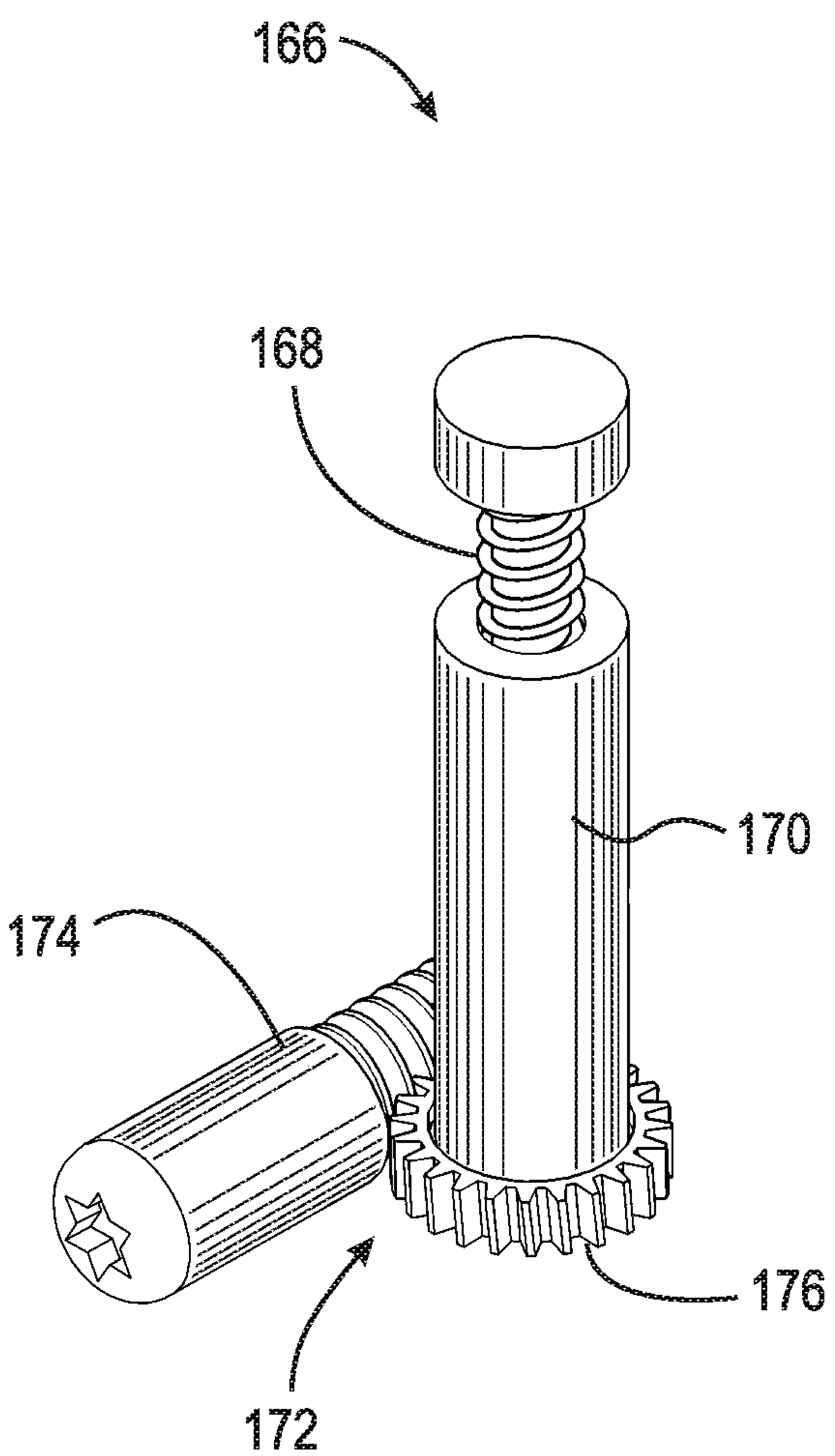

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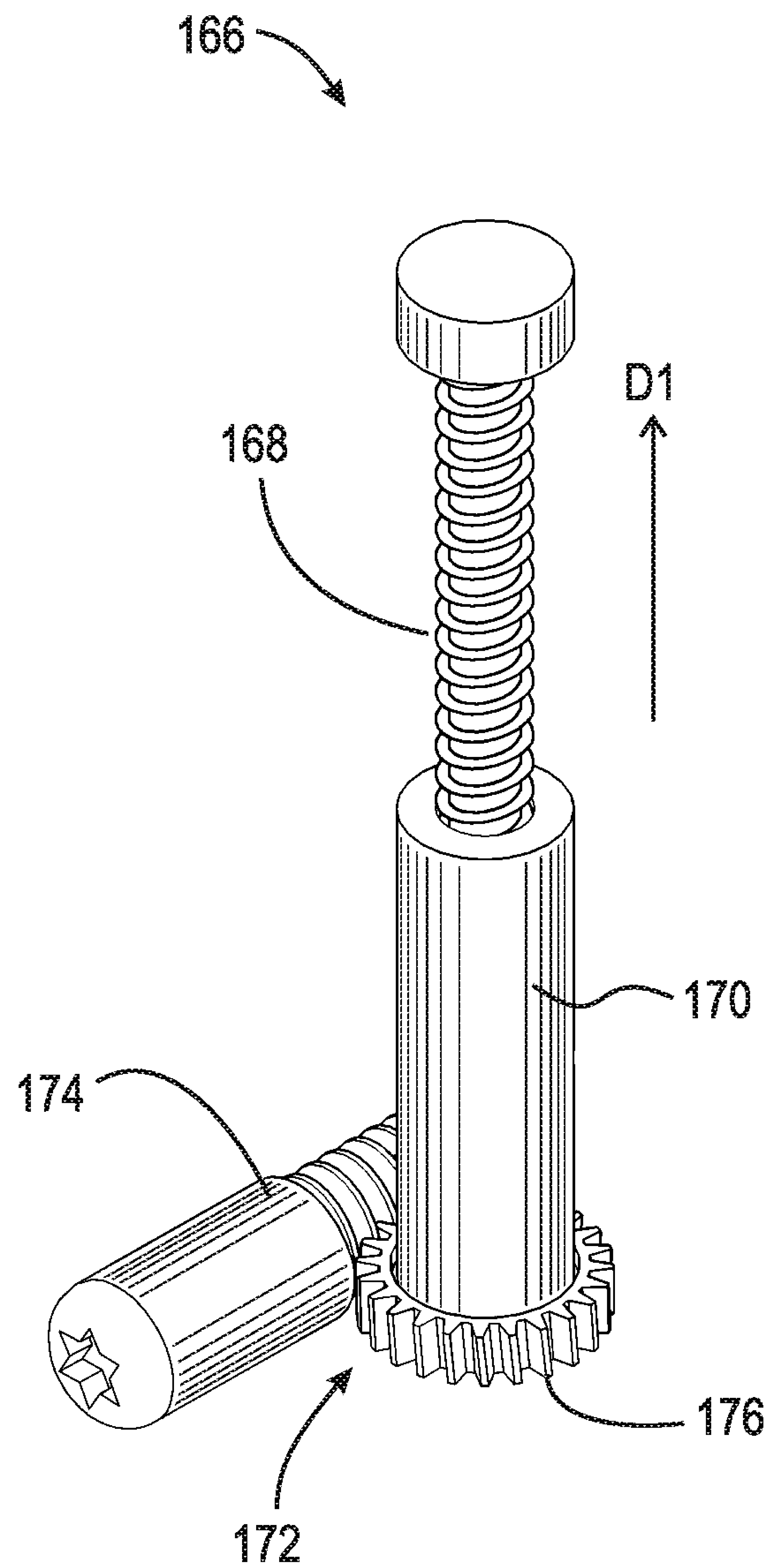

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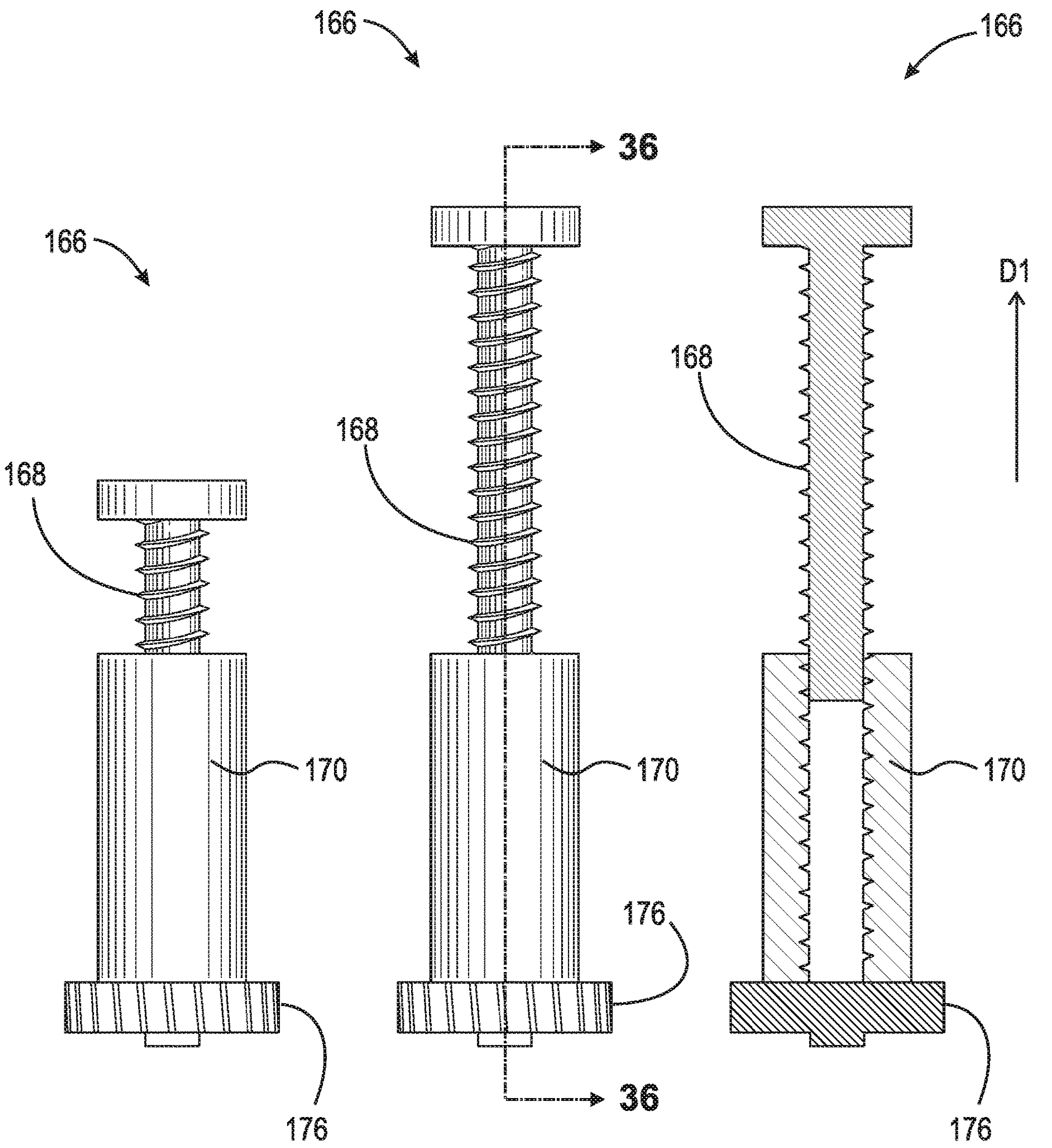

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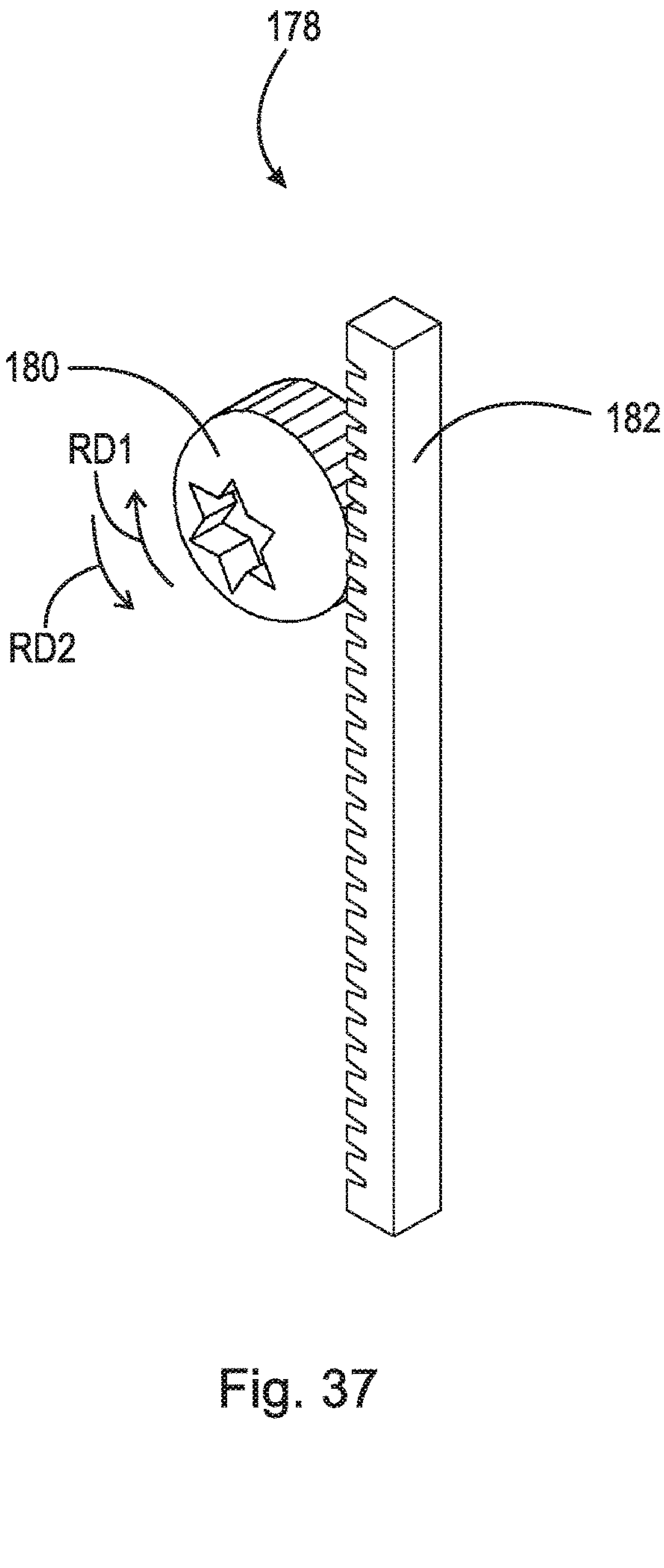

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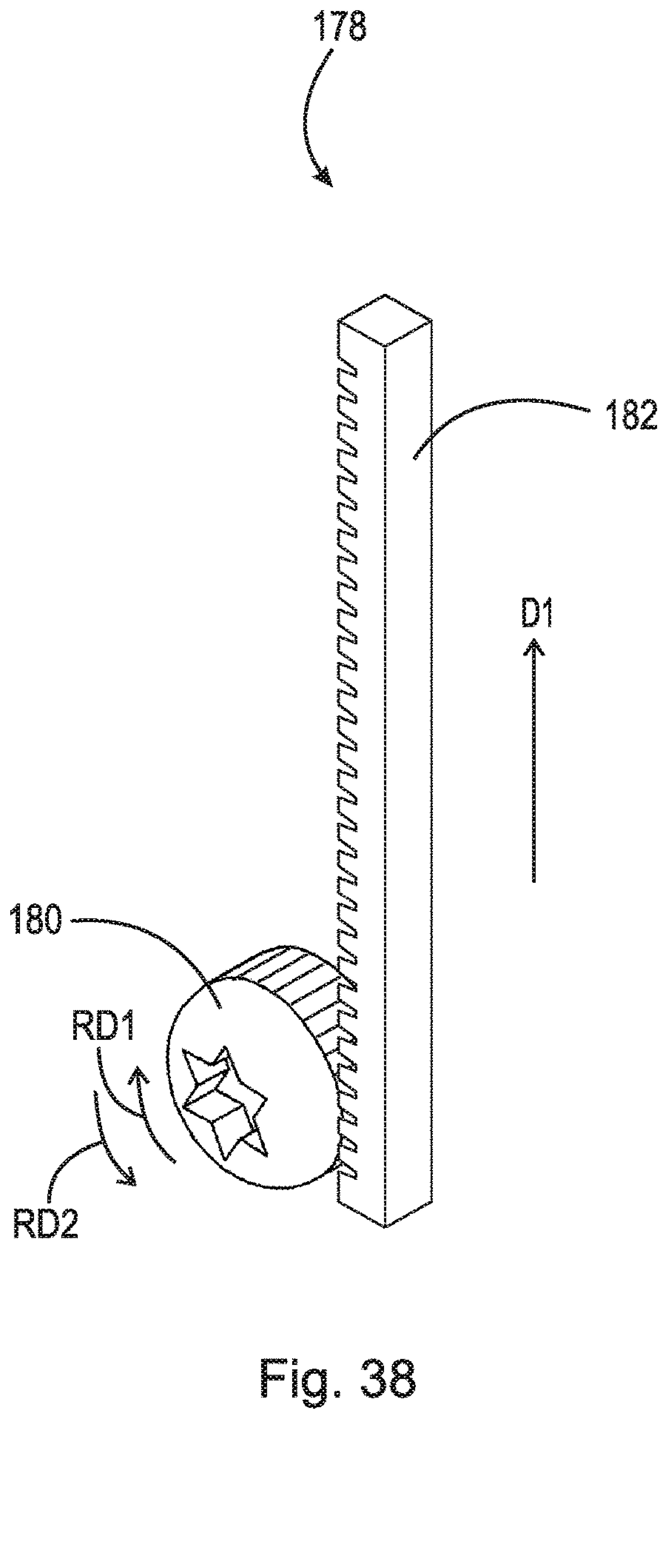

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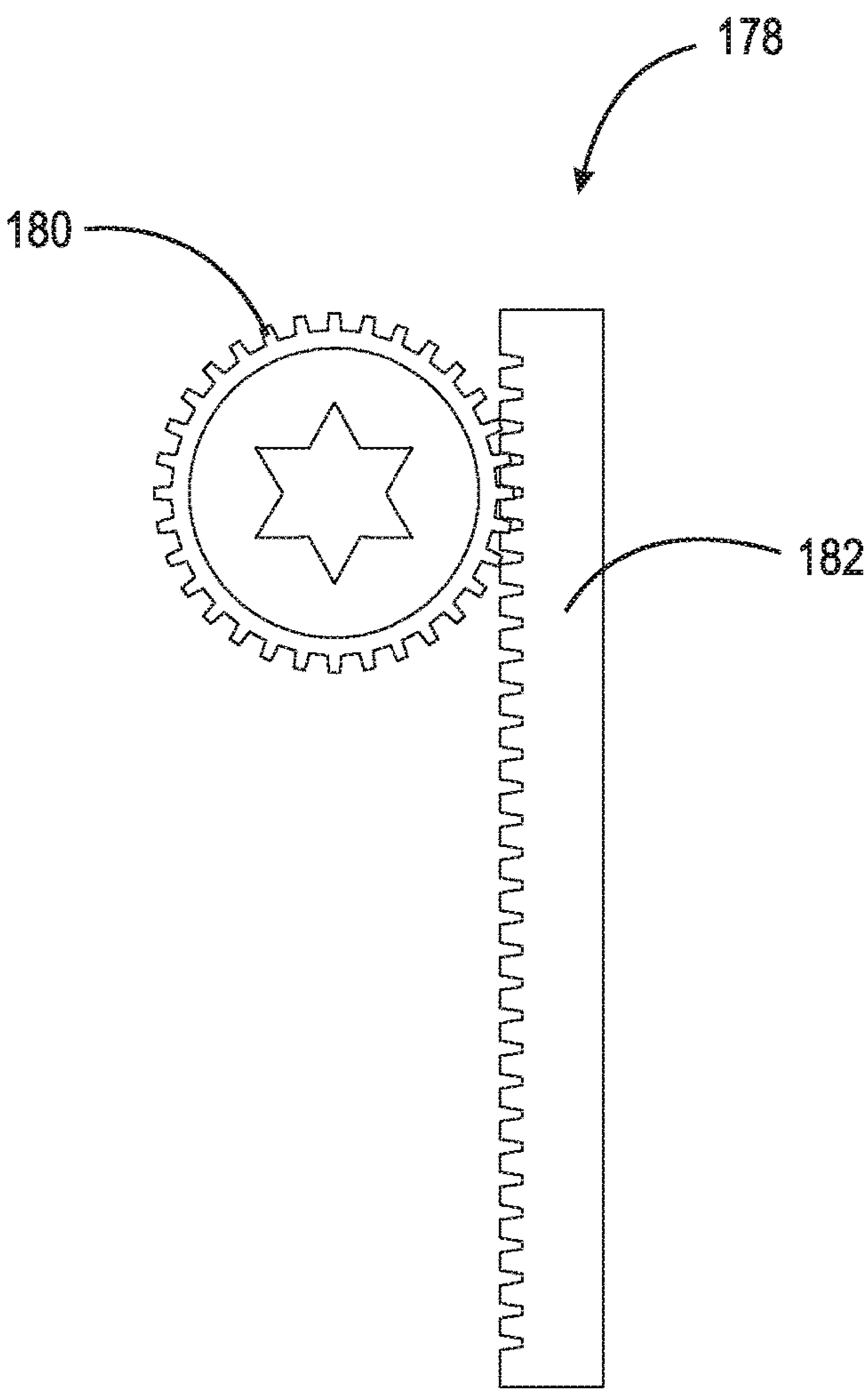

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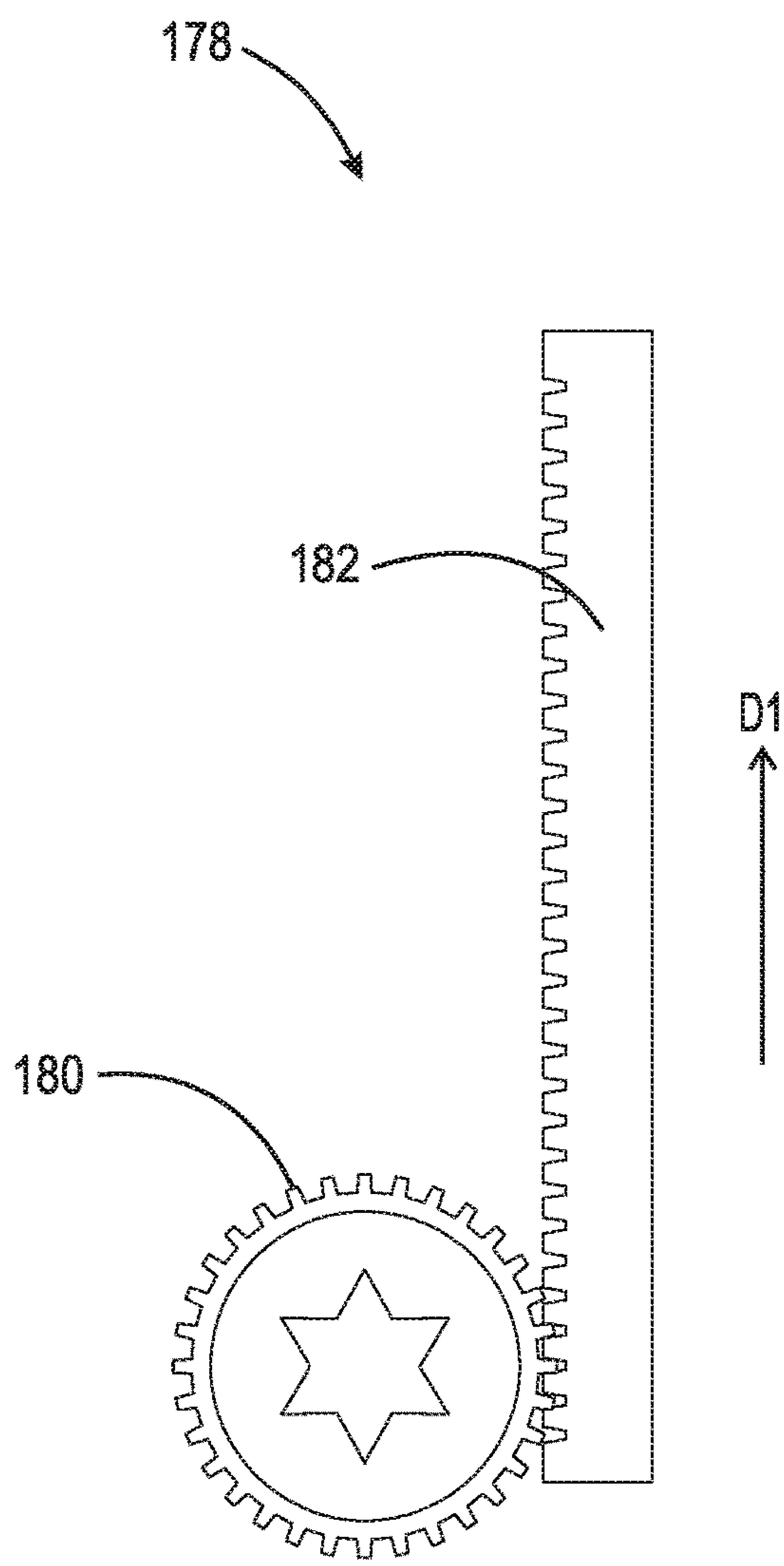

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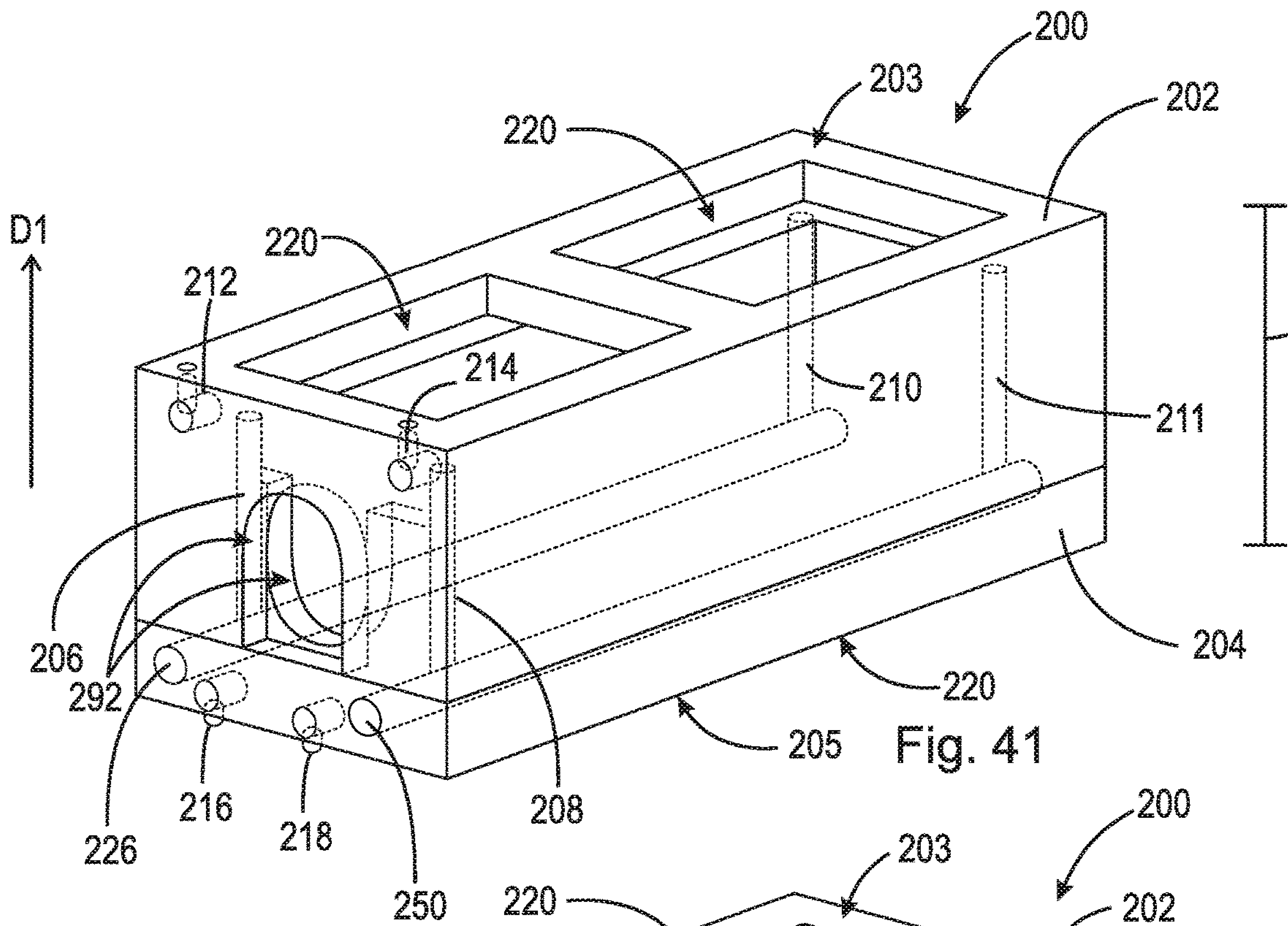
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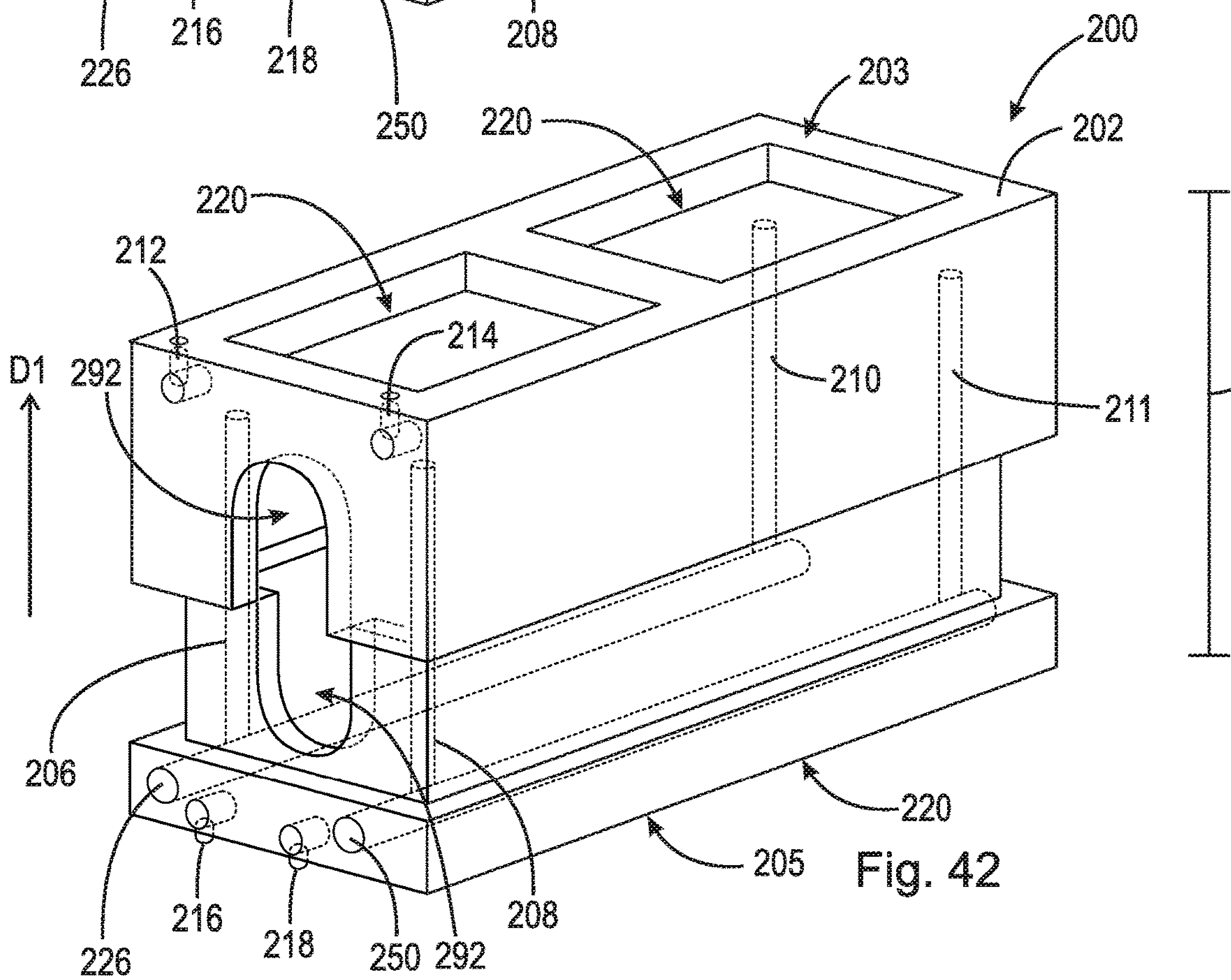
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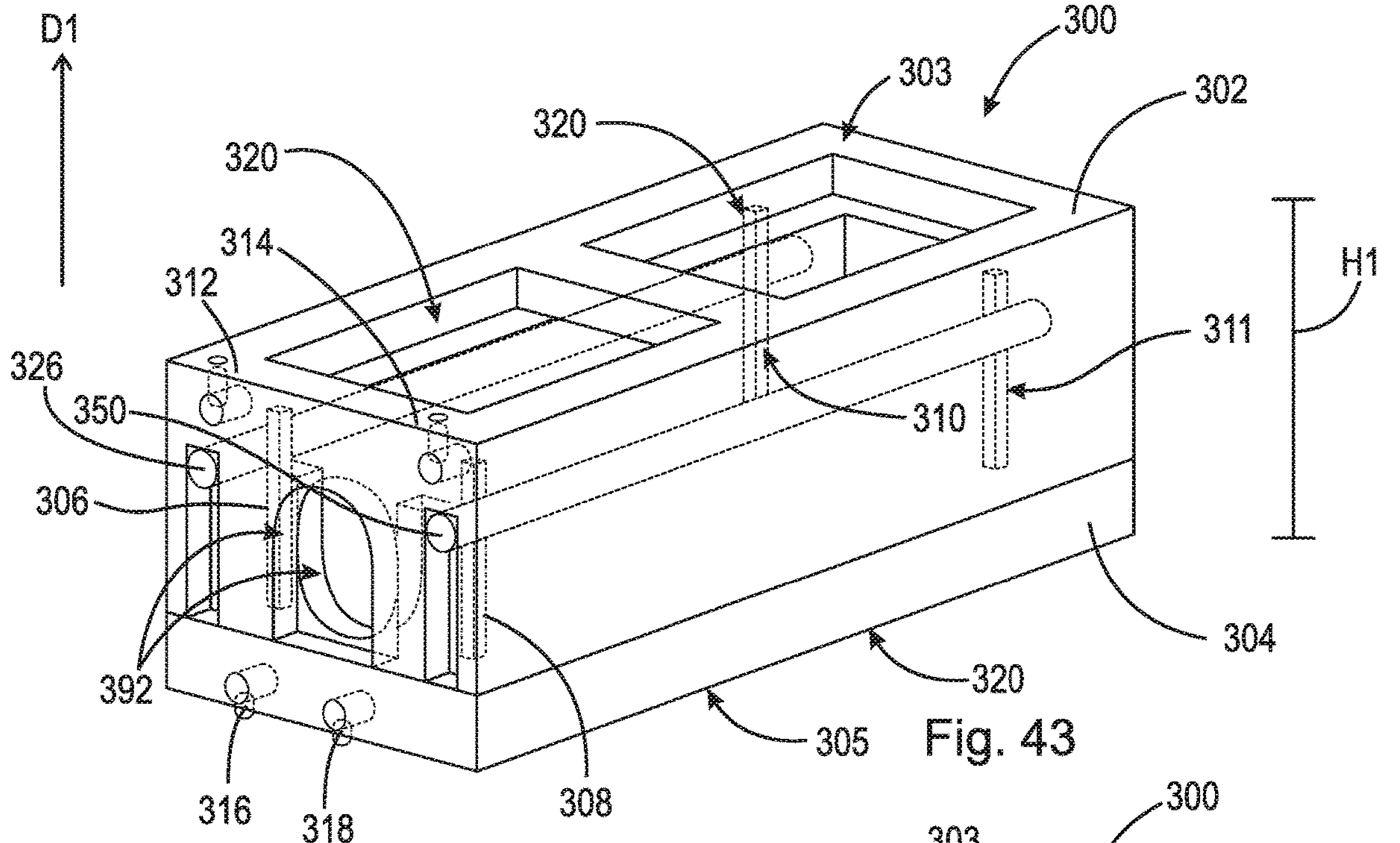
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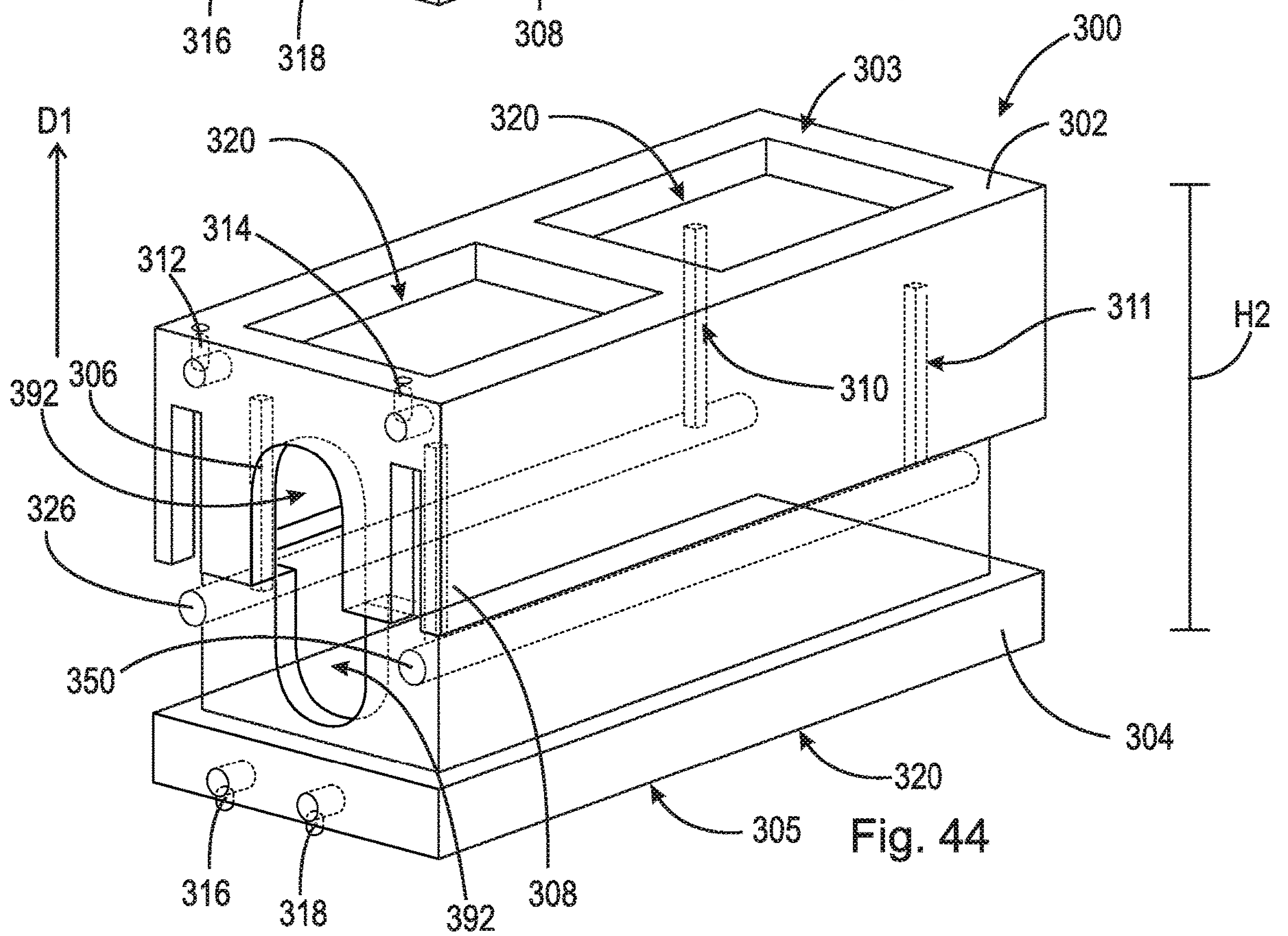
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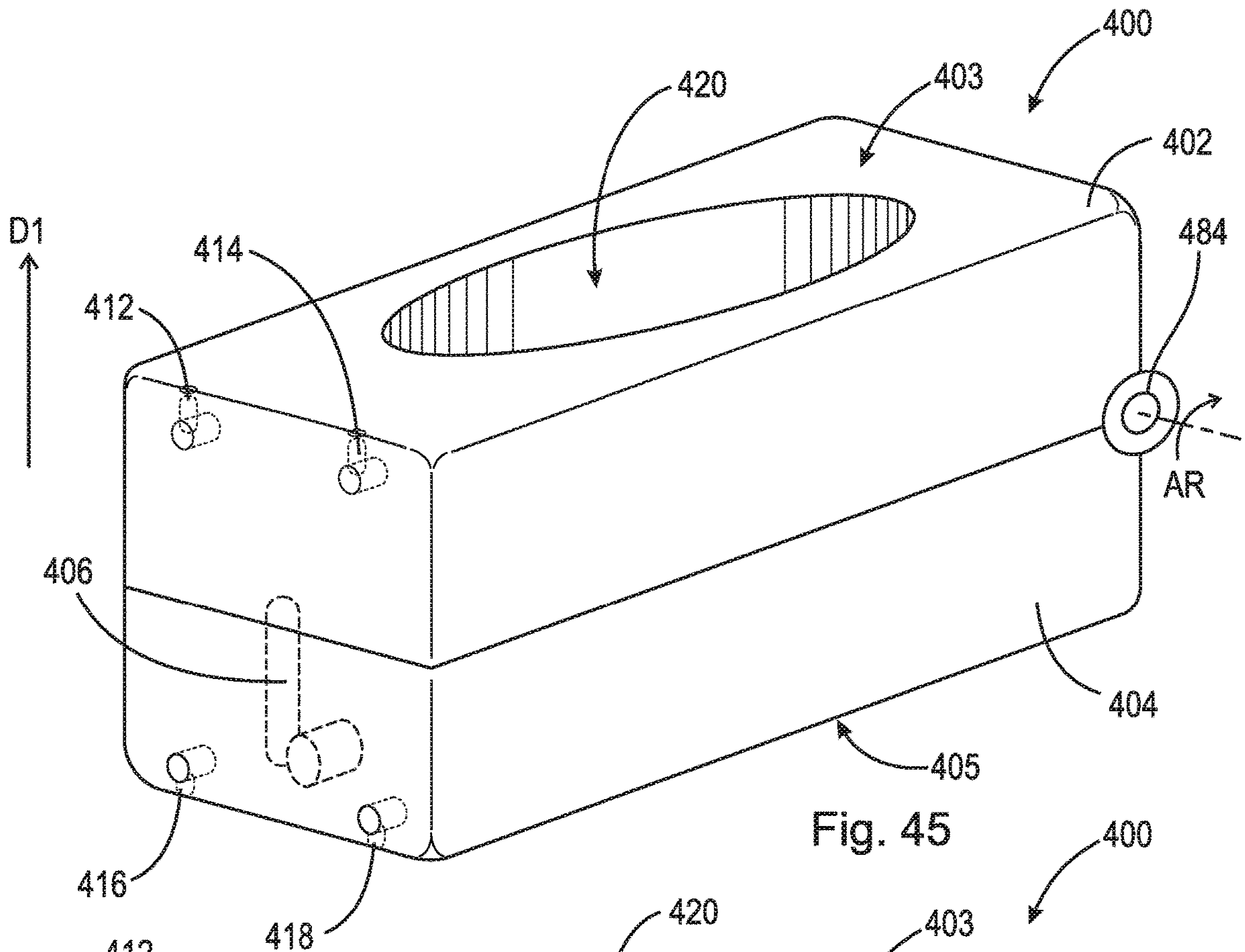
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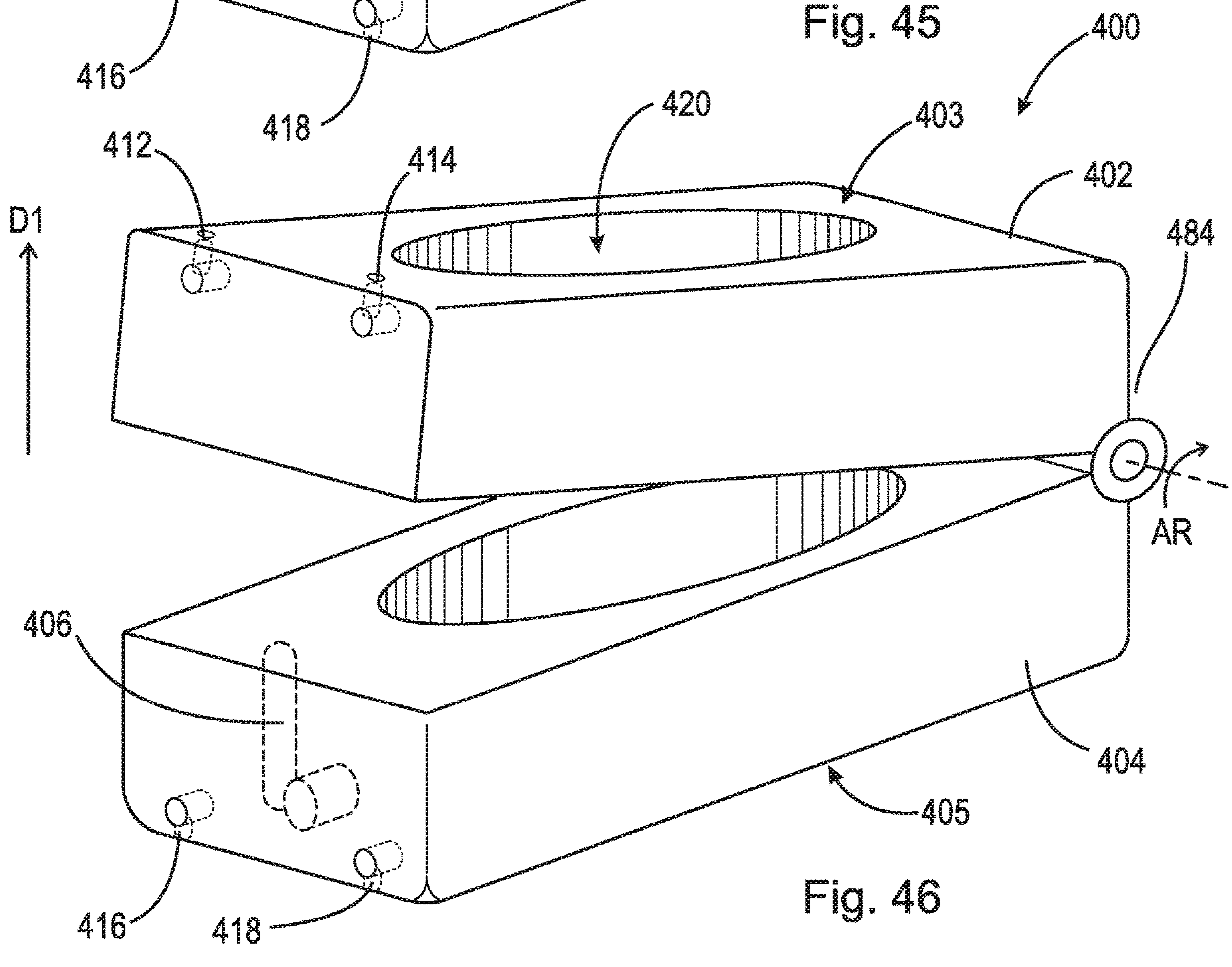
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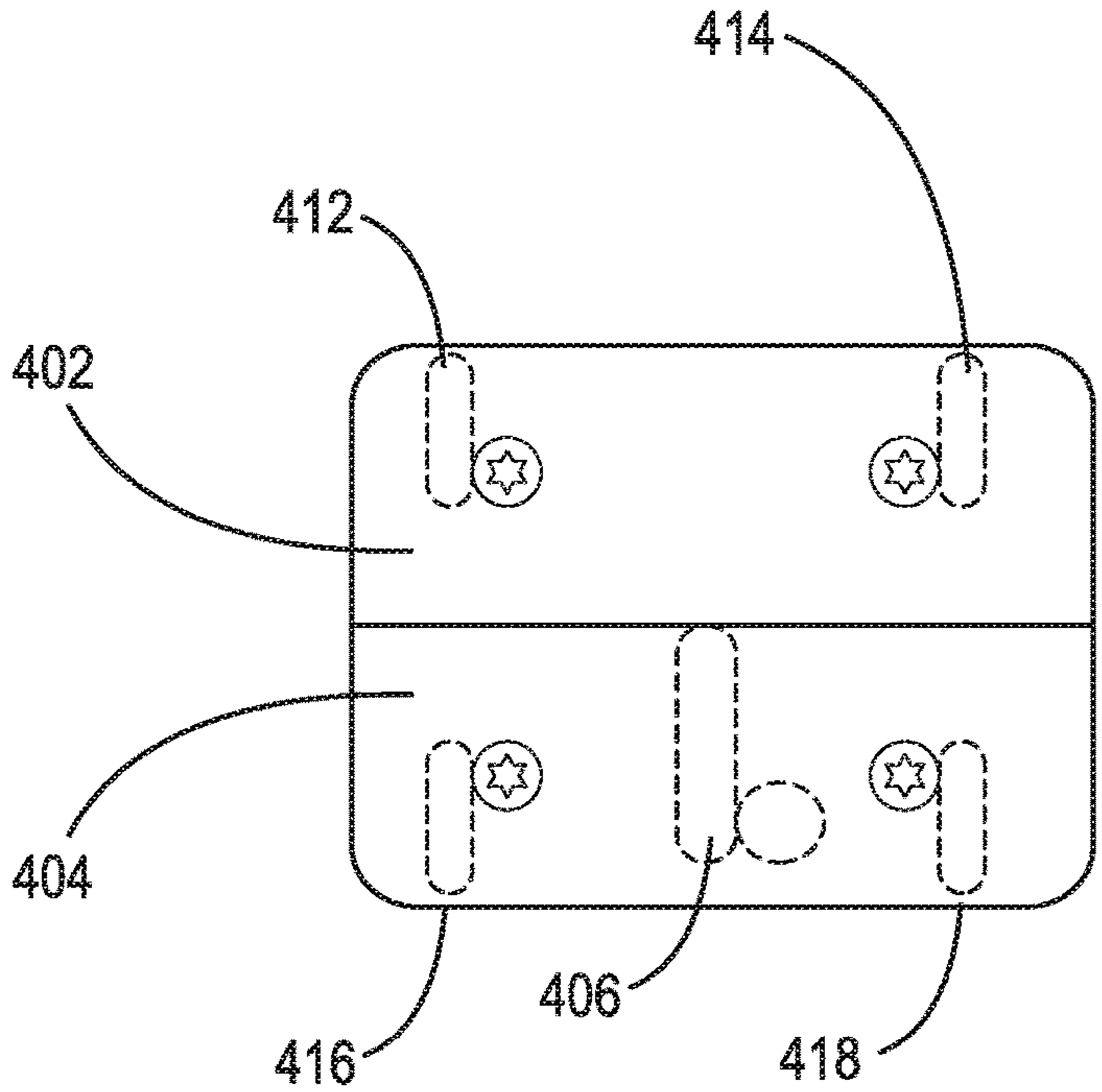
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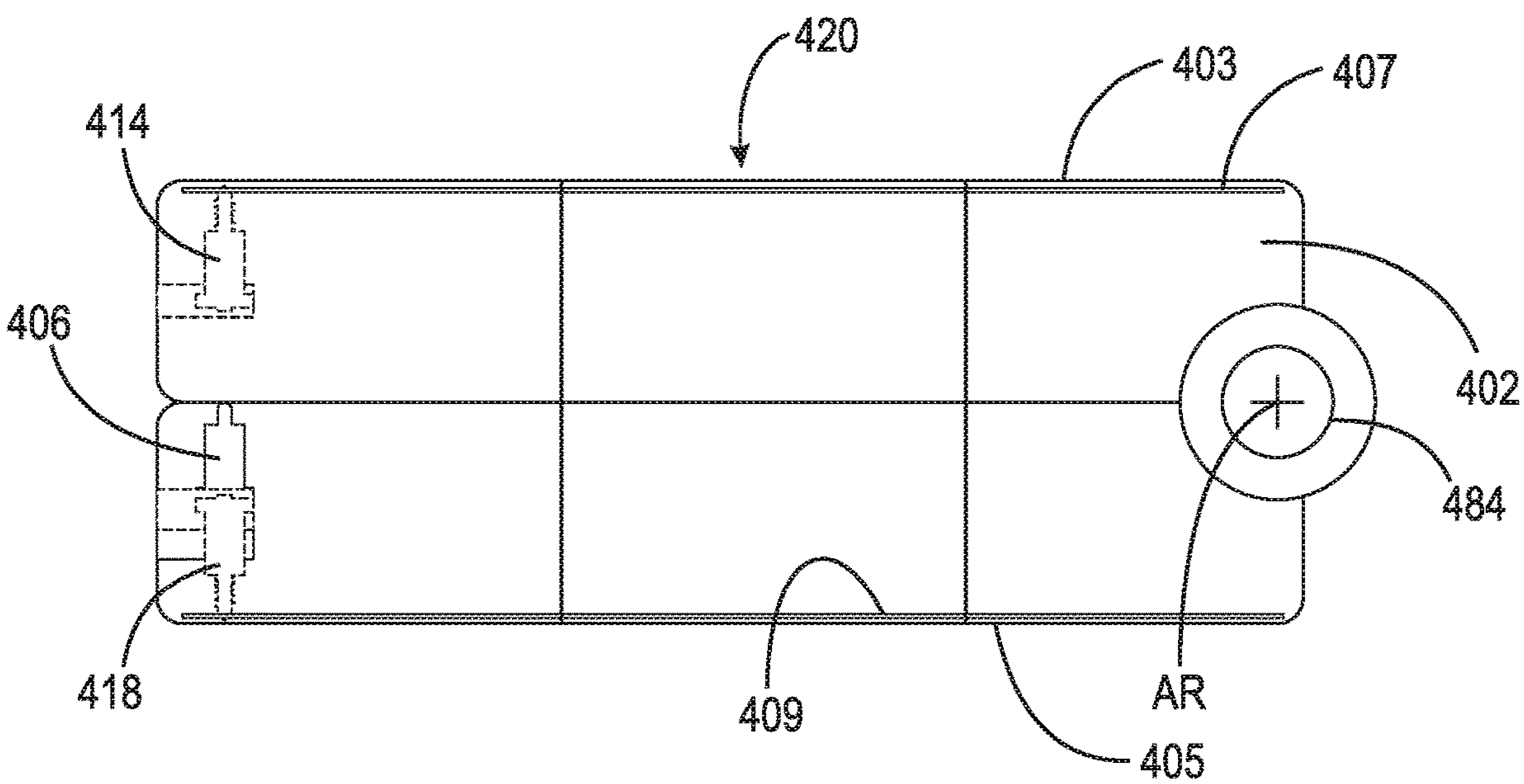
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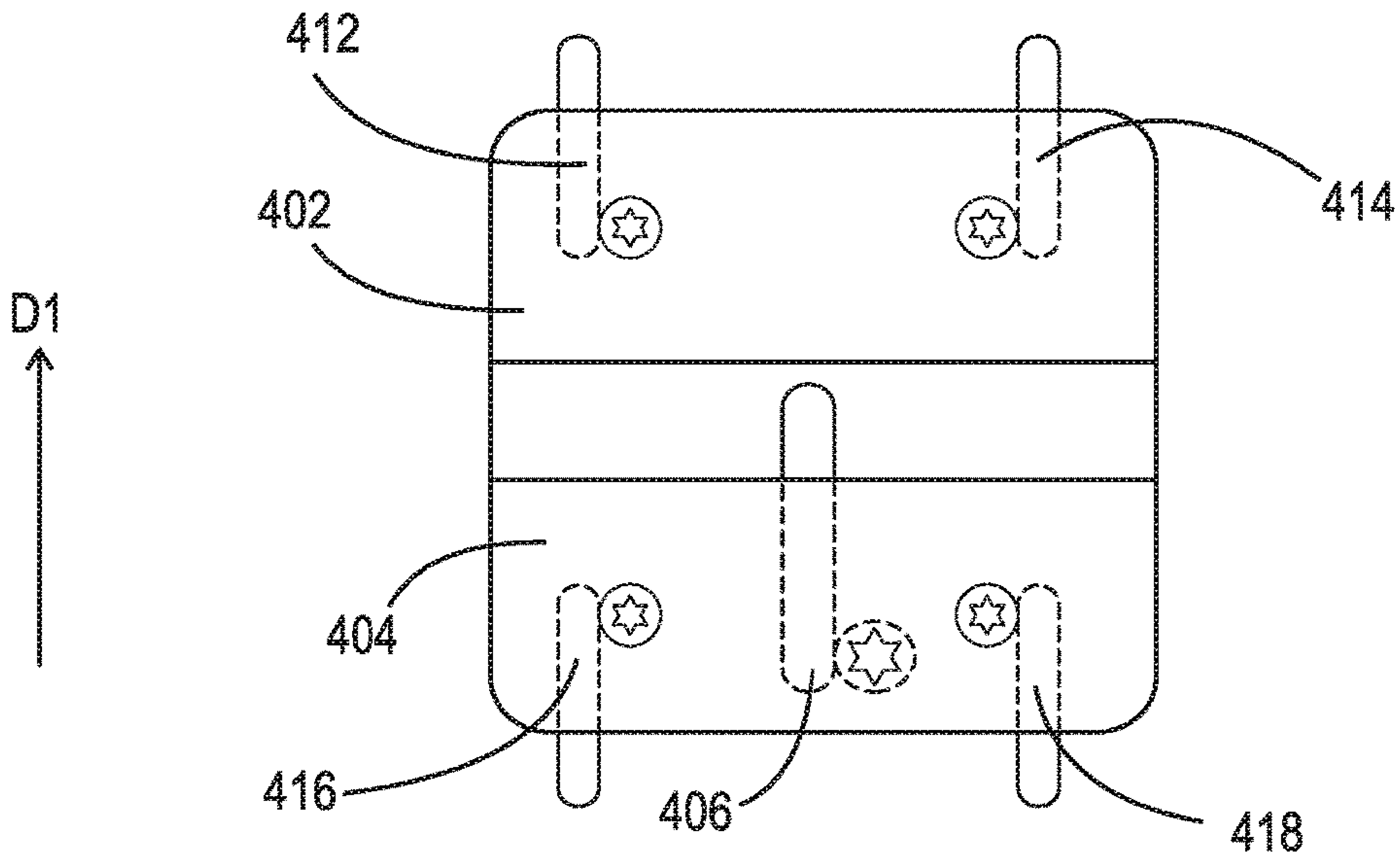

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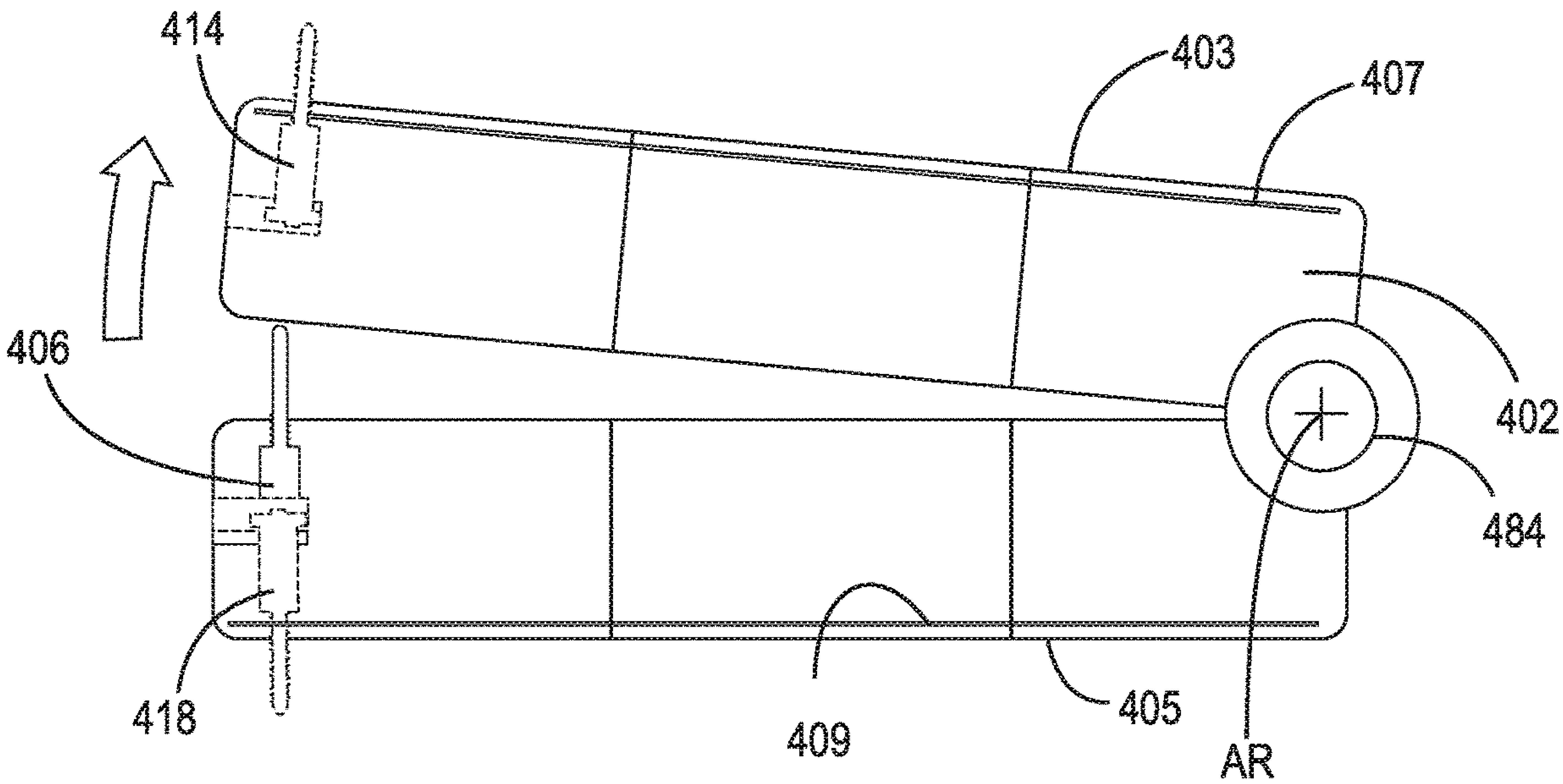
Fig. 49



414
403
407
406
402
484
418
409
405
AR

Fig. 50

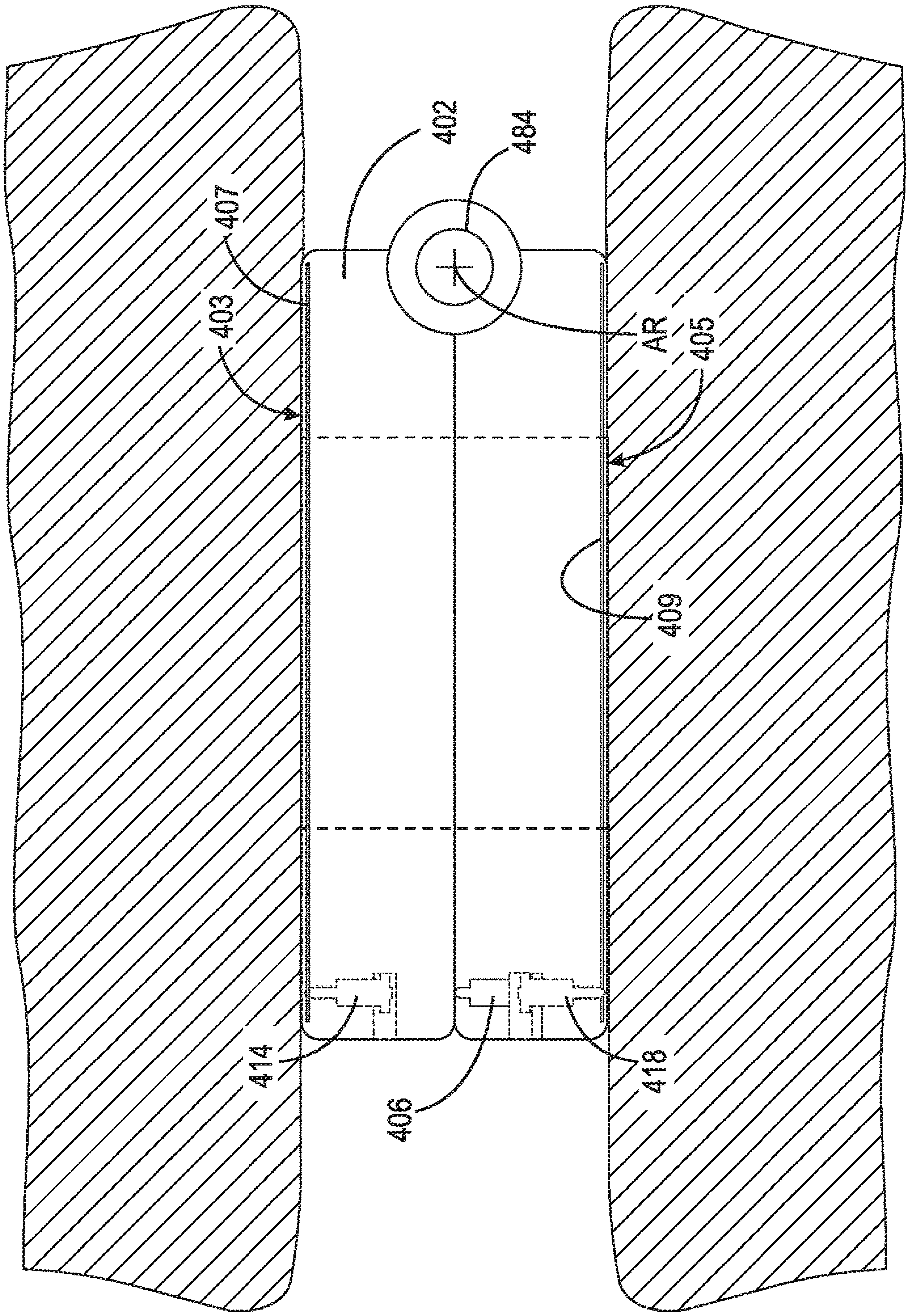


Fig. 51

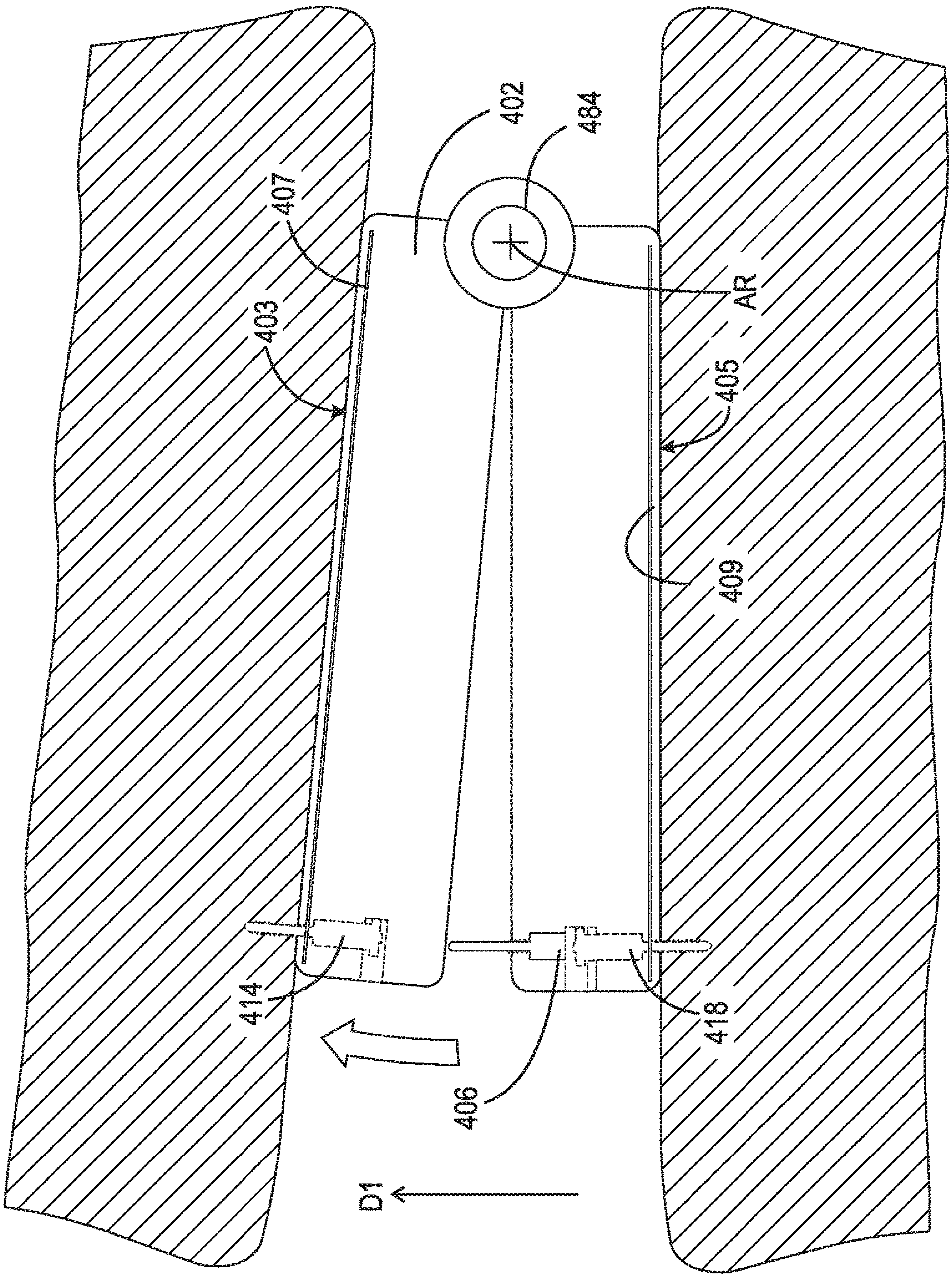


Fig. 52

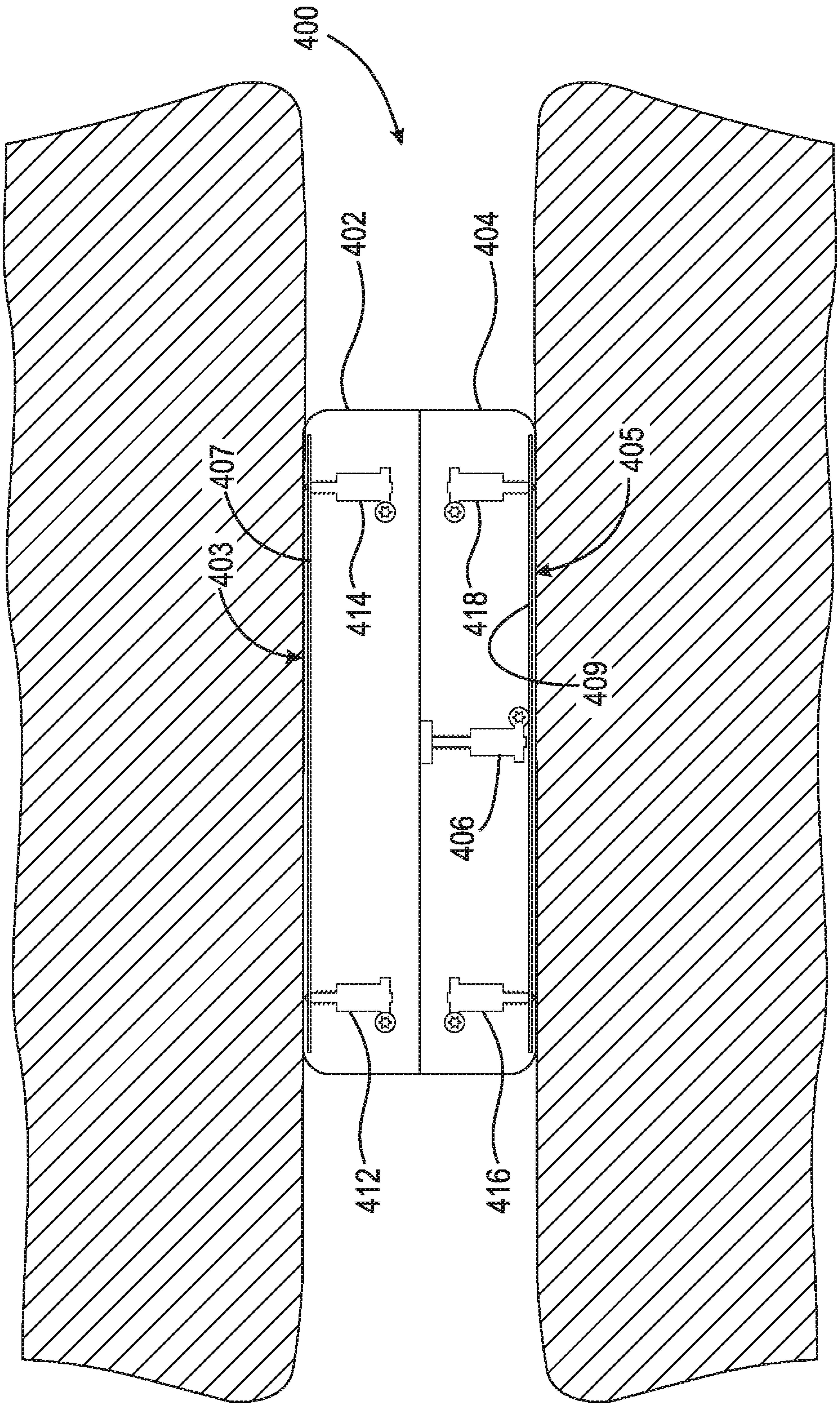


Fig. 53

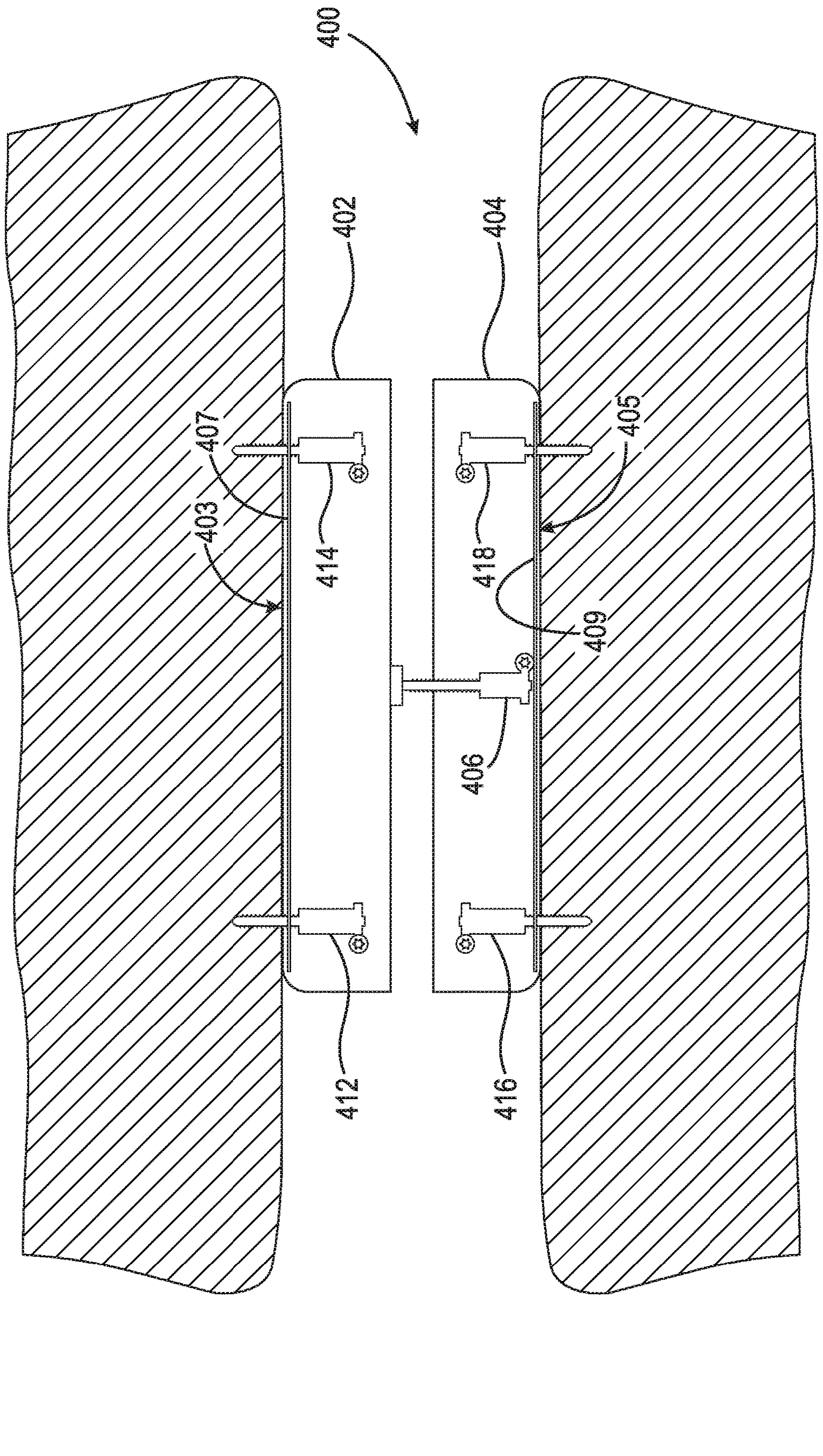


Fig. 54

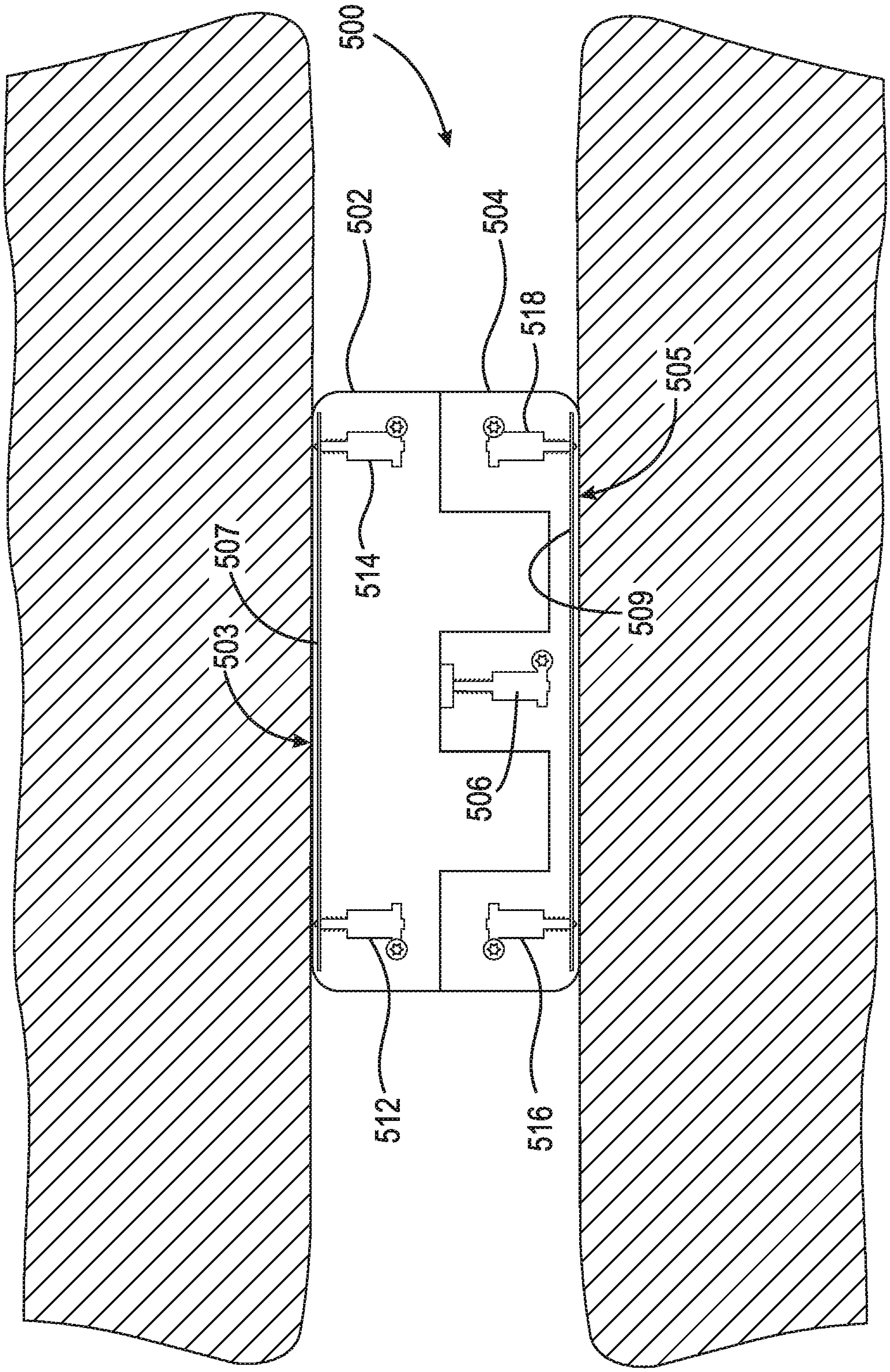


Fig. 55

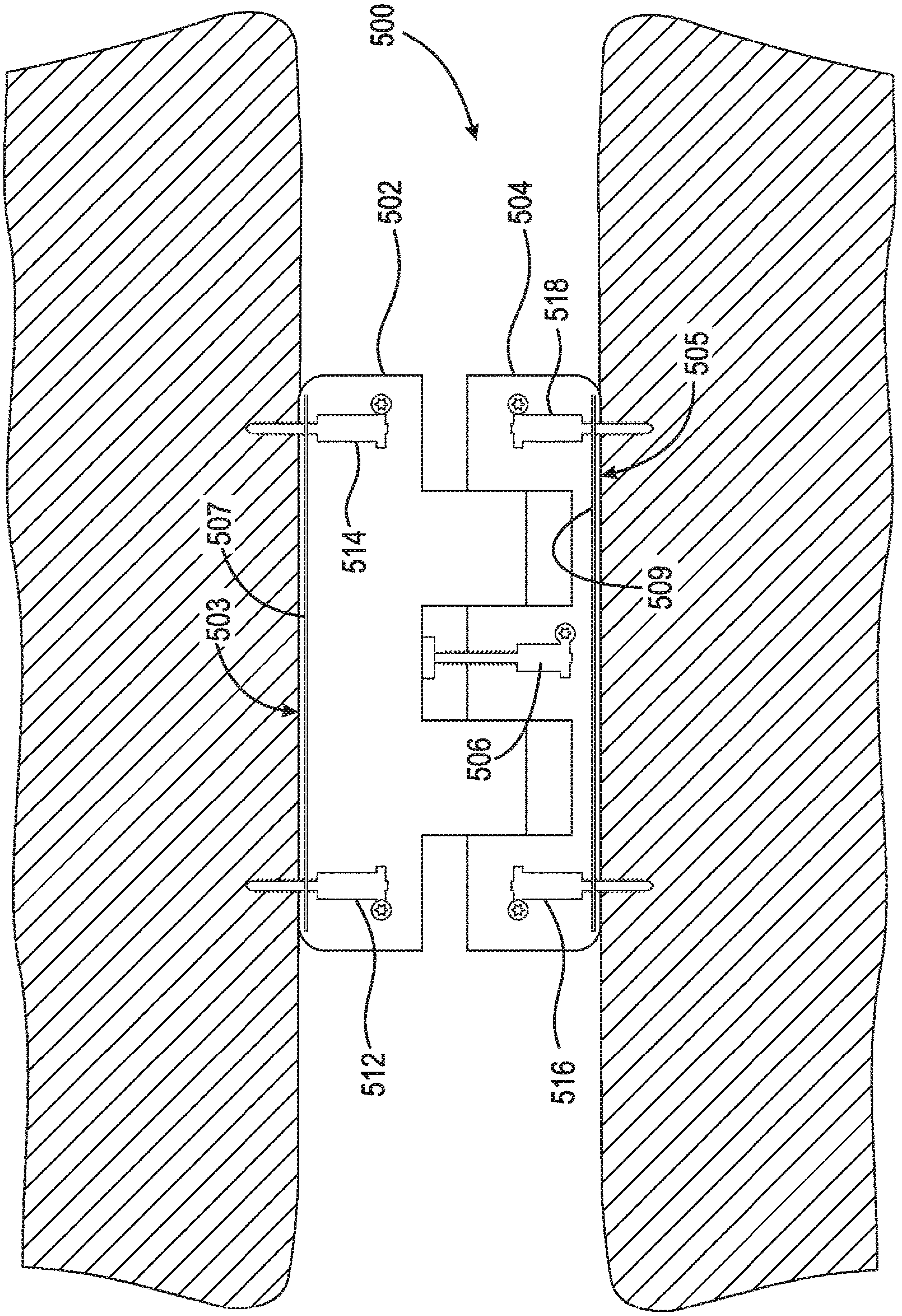


Fig. 56

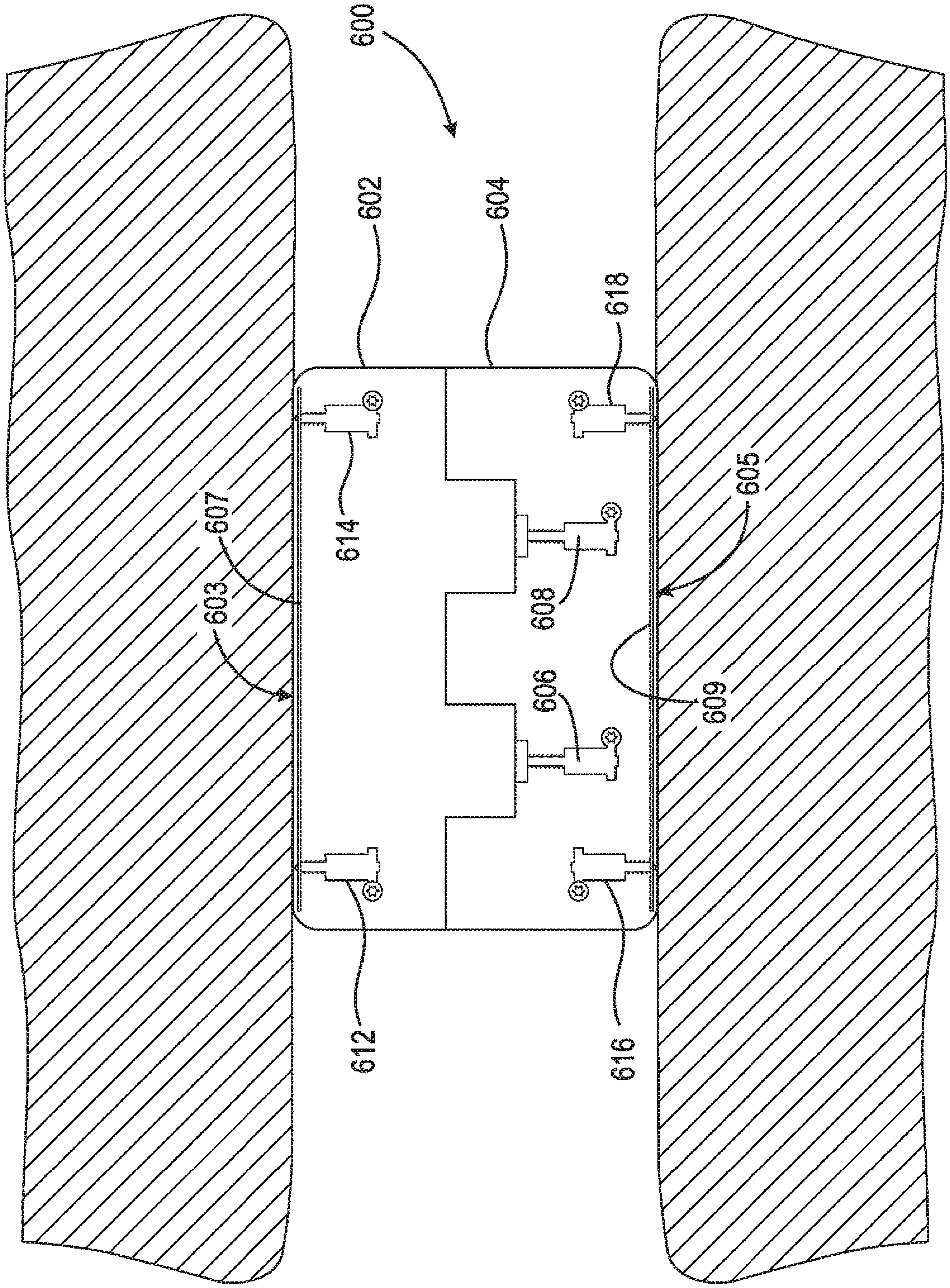


Fig. 57

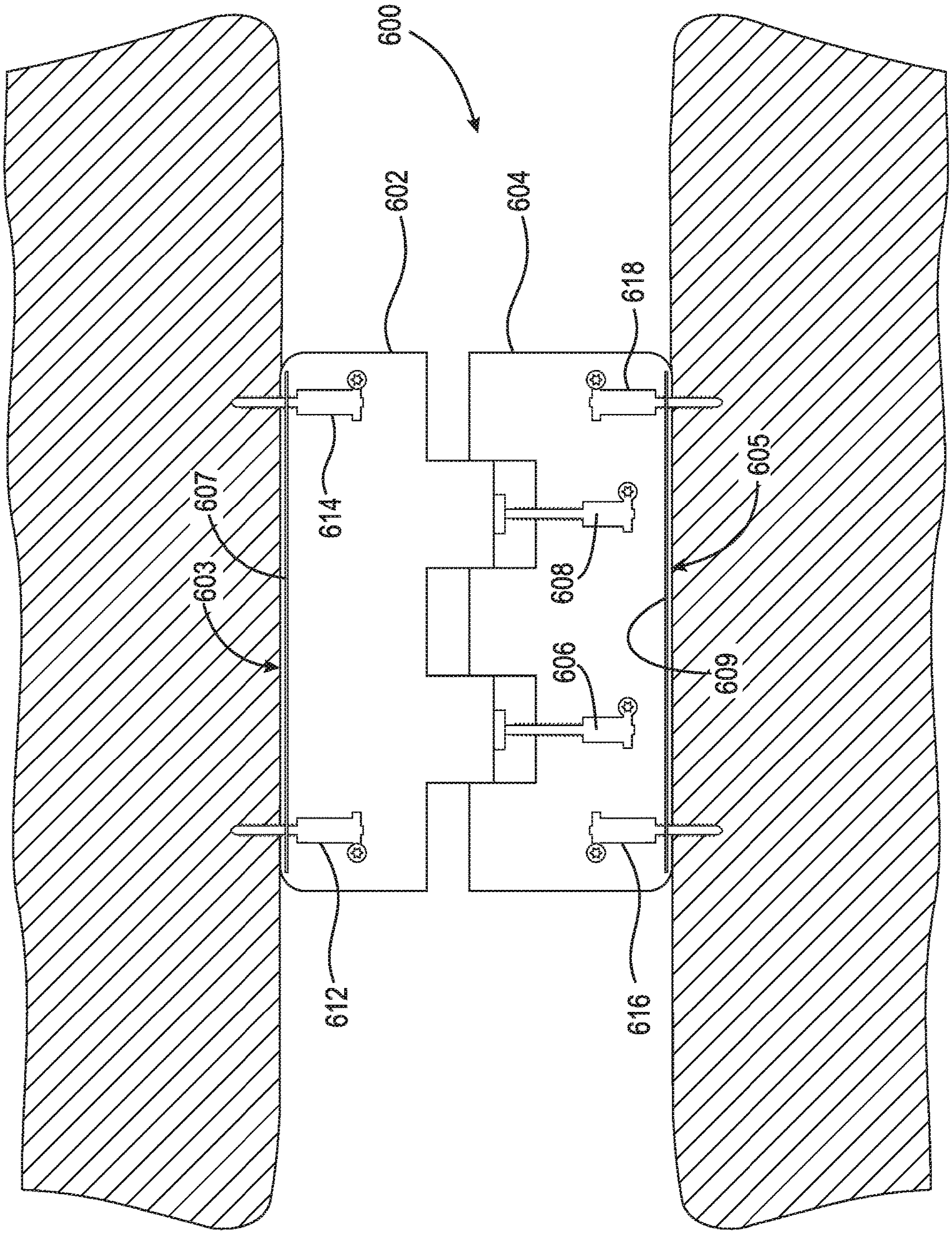


Fig. 58

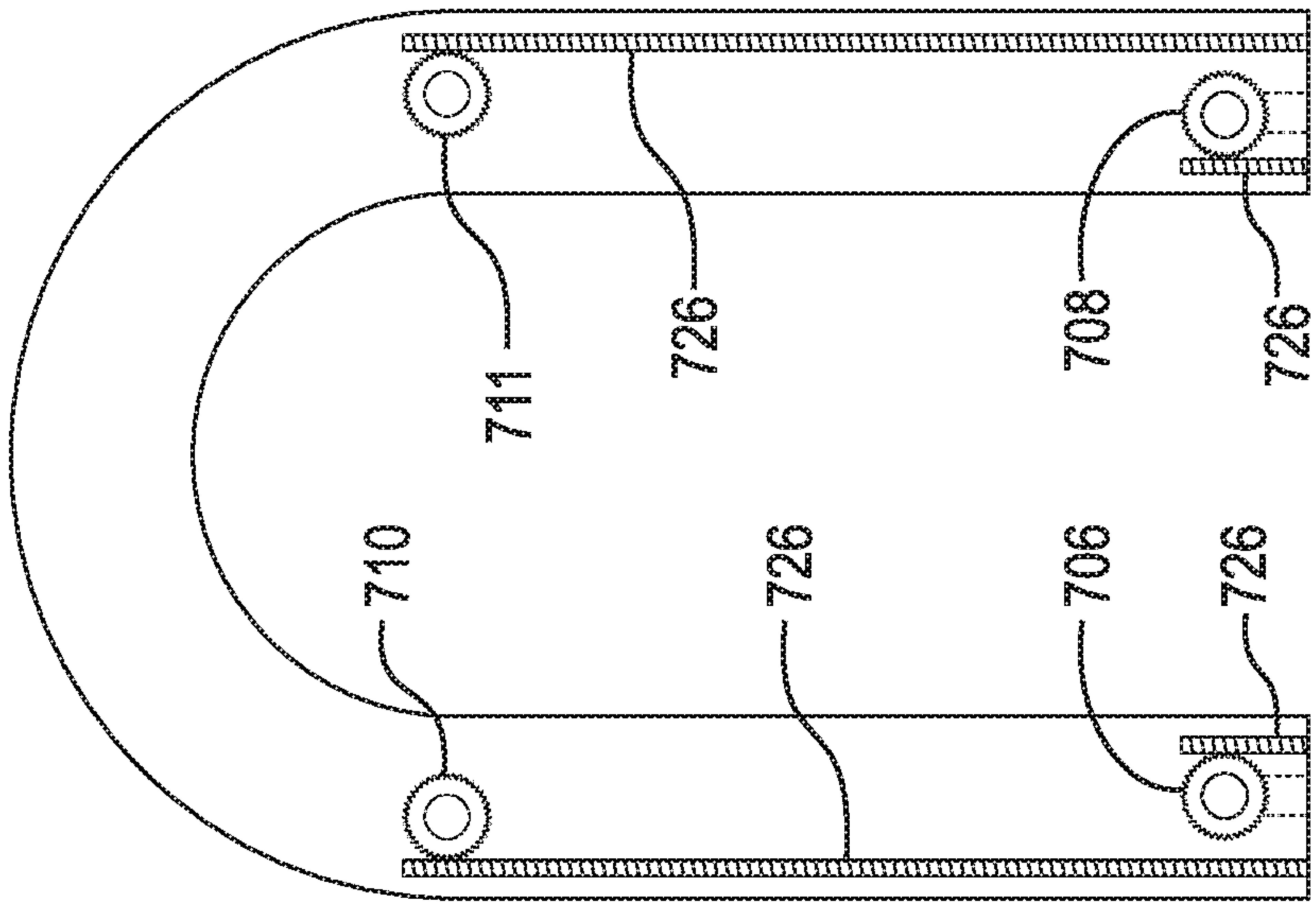
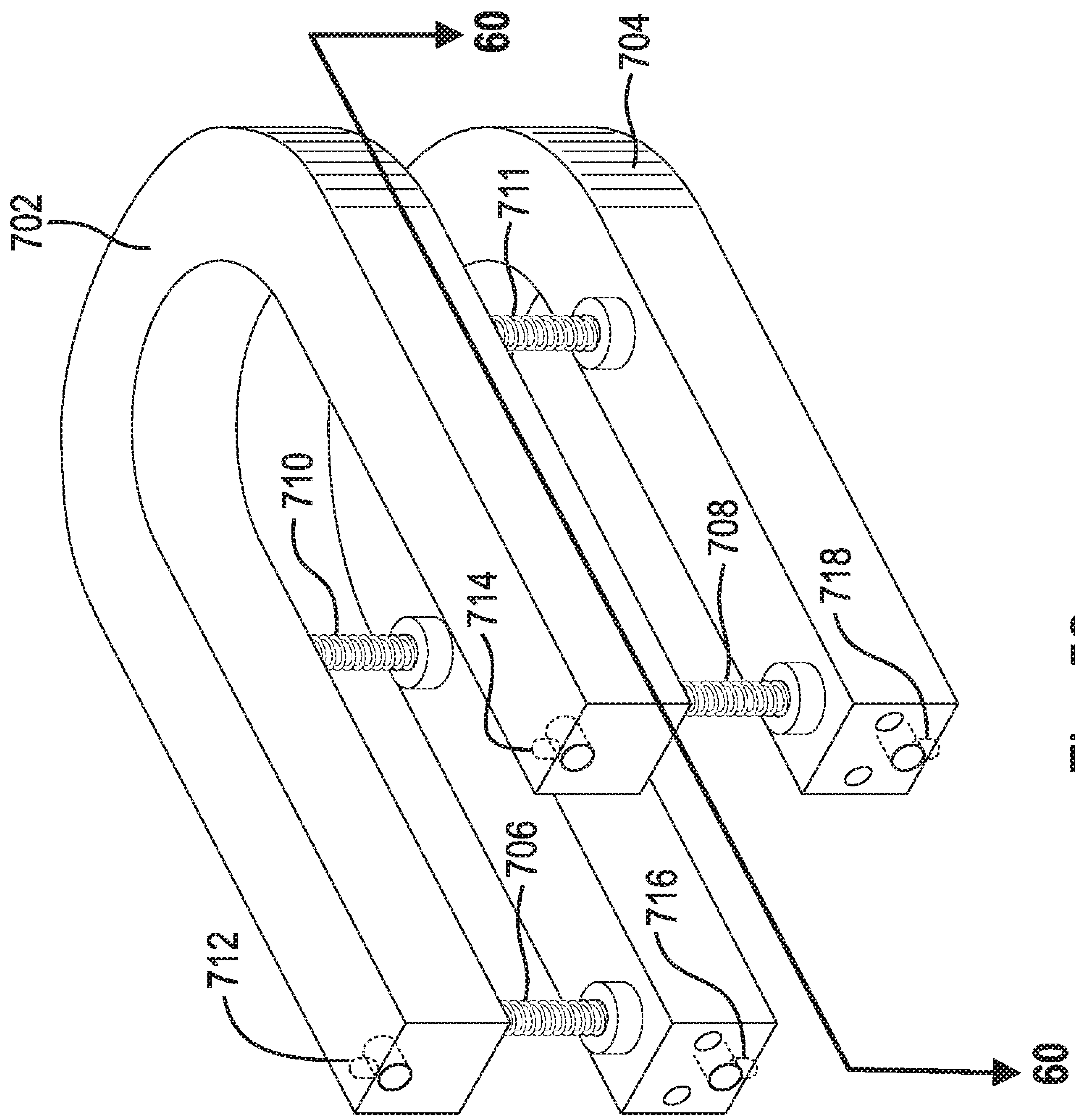

711
726
708
726
710
726
706
726

Fig. 60


702
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704
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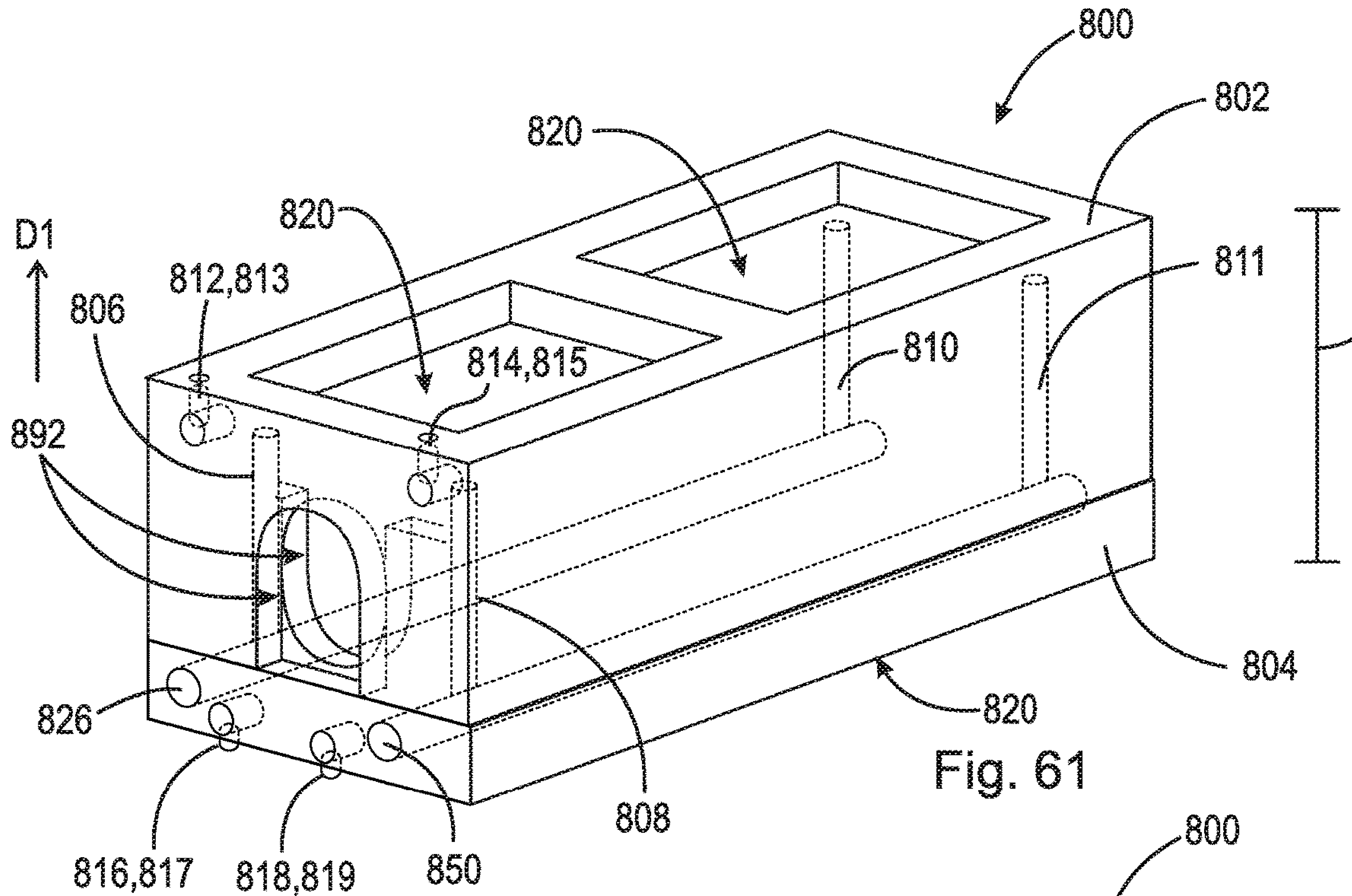
706
716
712
60

Fig. 59


800
802
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D1
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811
H1
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826
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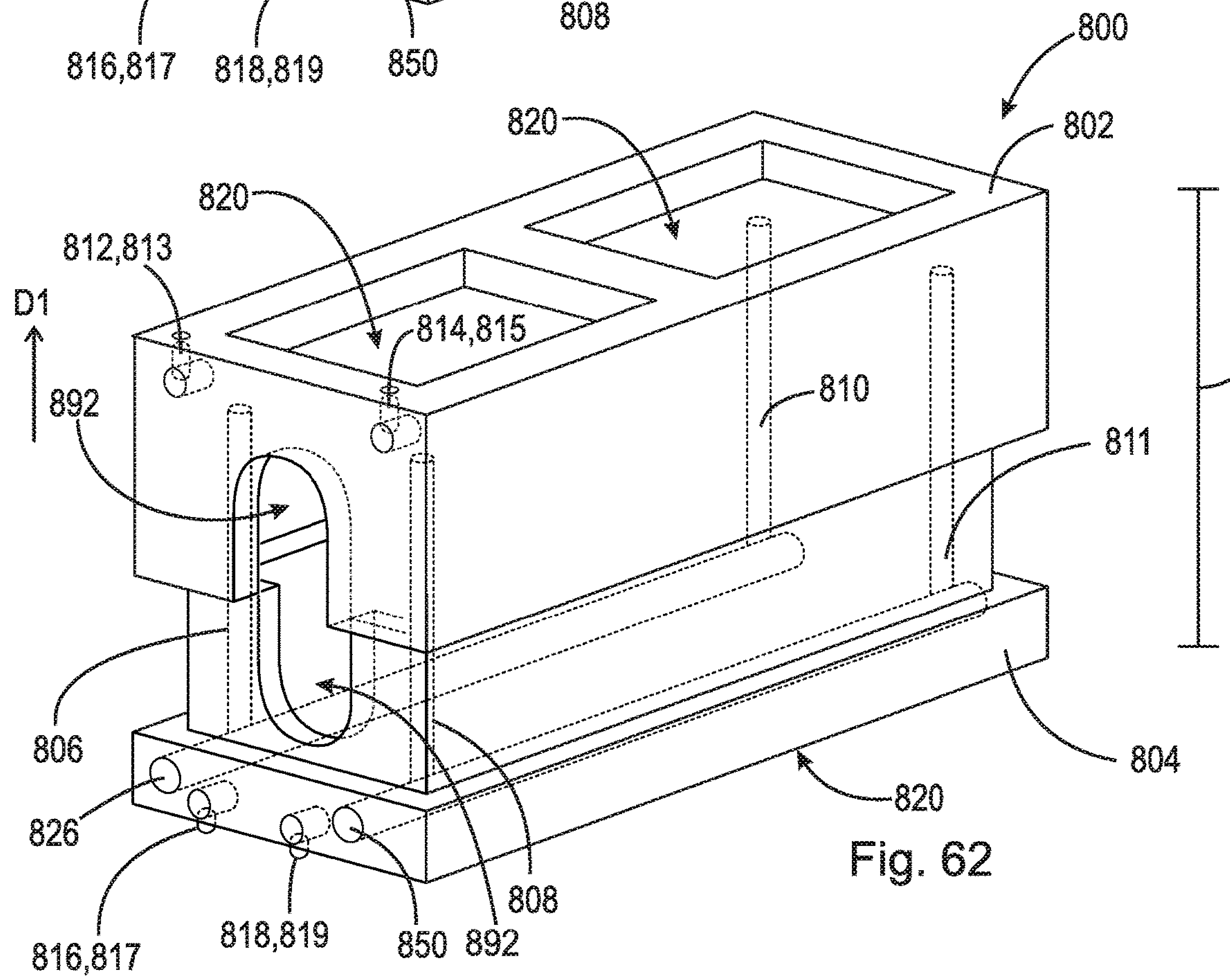
804
816,817
818,819
850
808

Fig. 61


800
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812,813
D1
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H2
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804
816,817
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850
892
808

Fig. 62

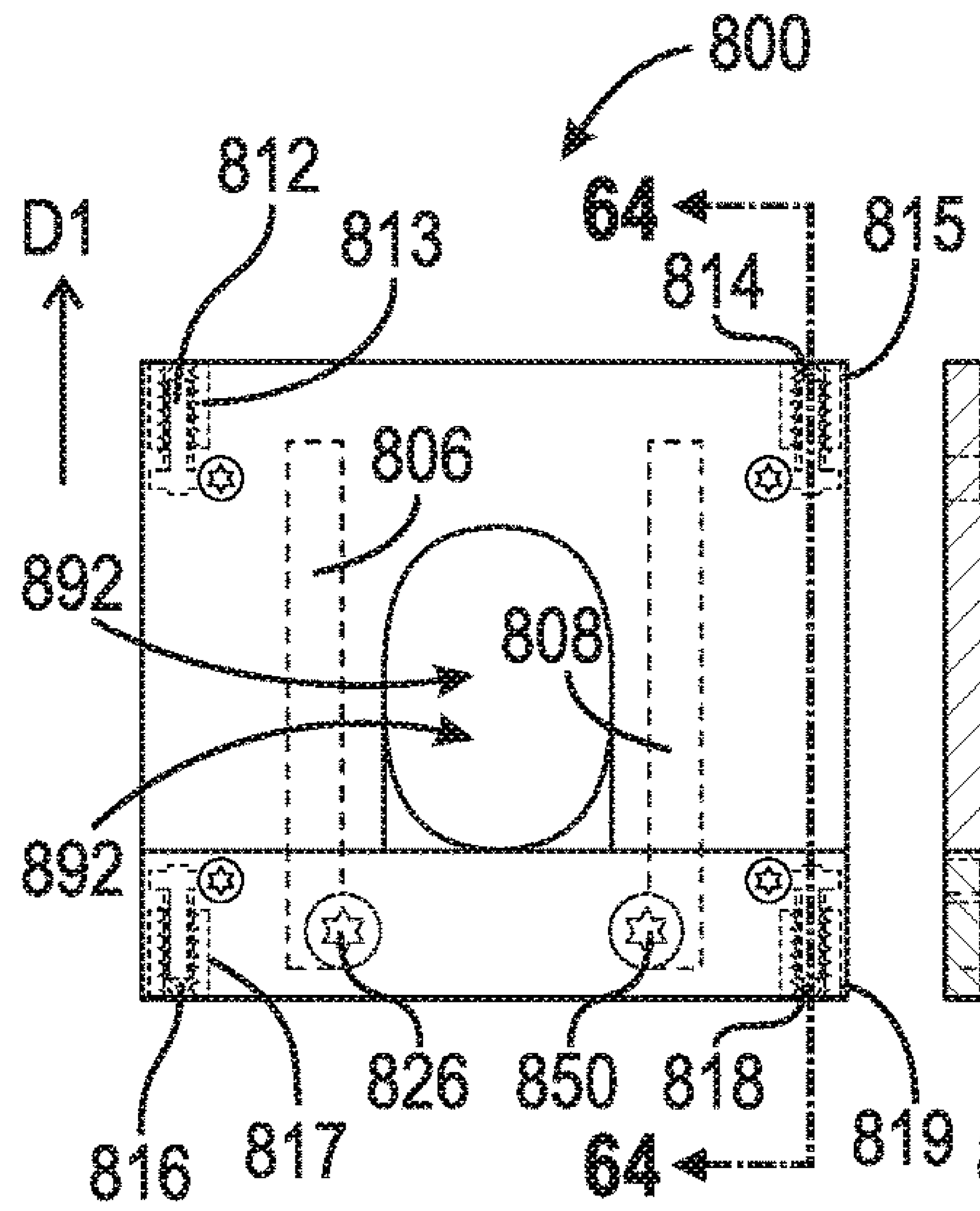


Fig. 63

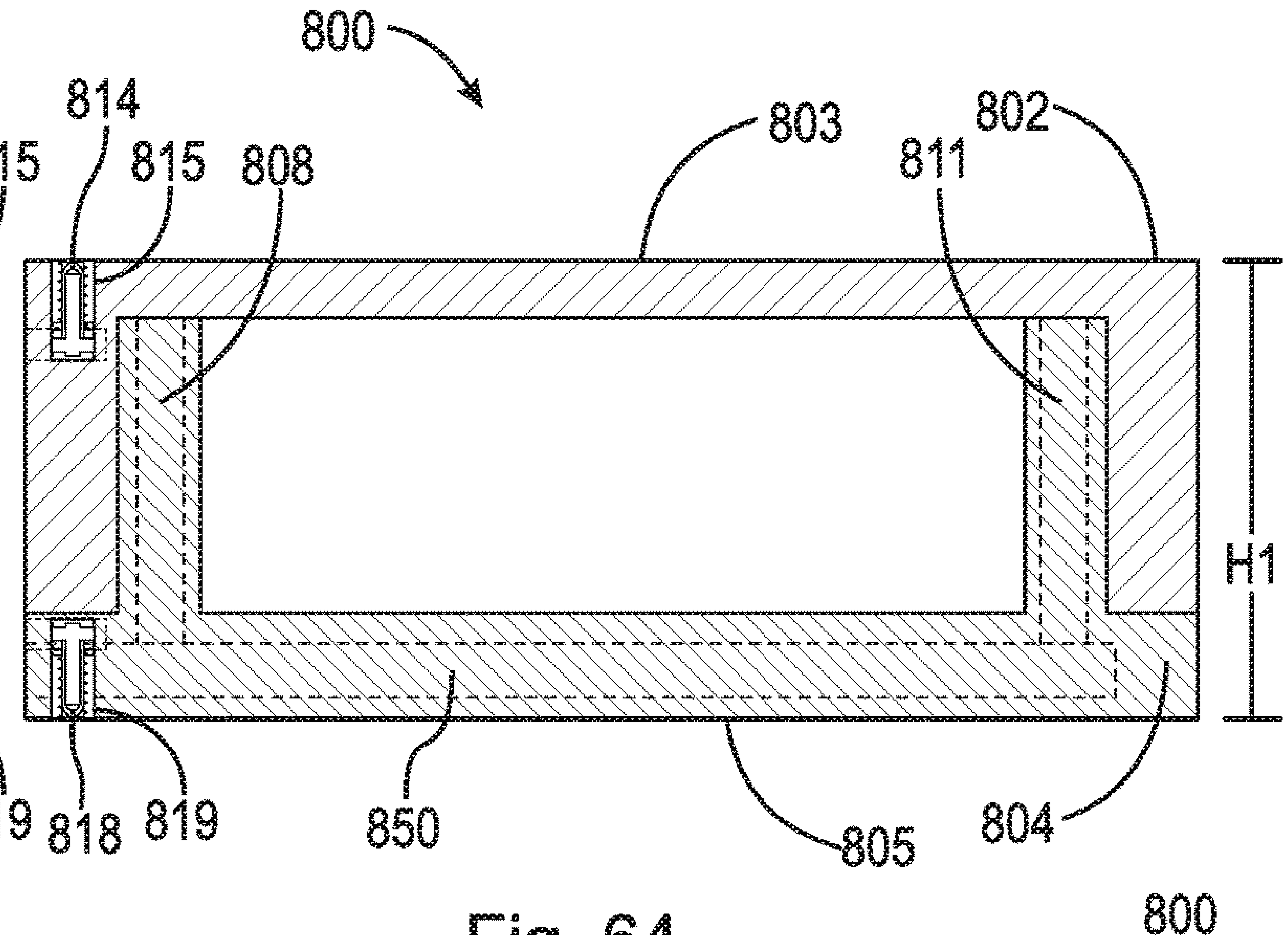


Fig. 64

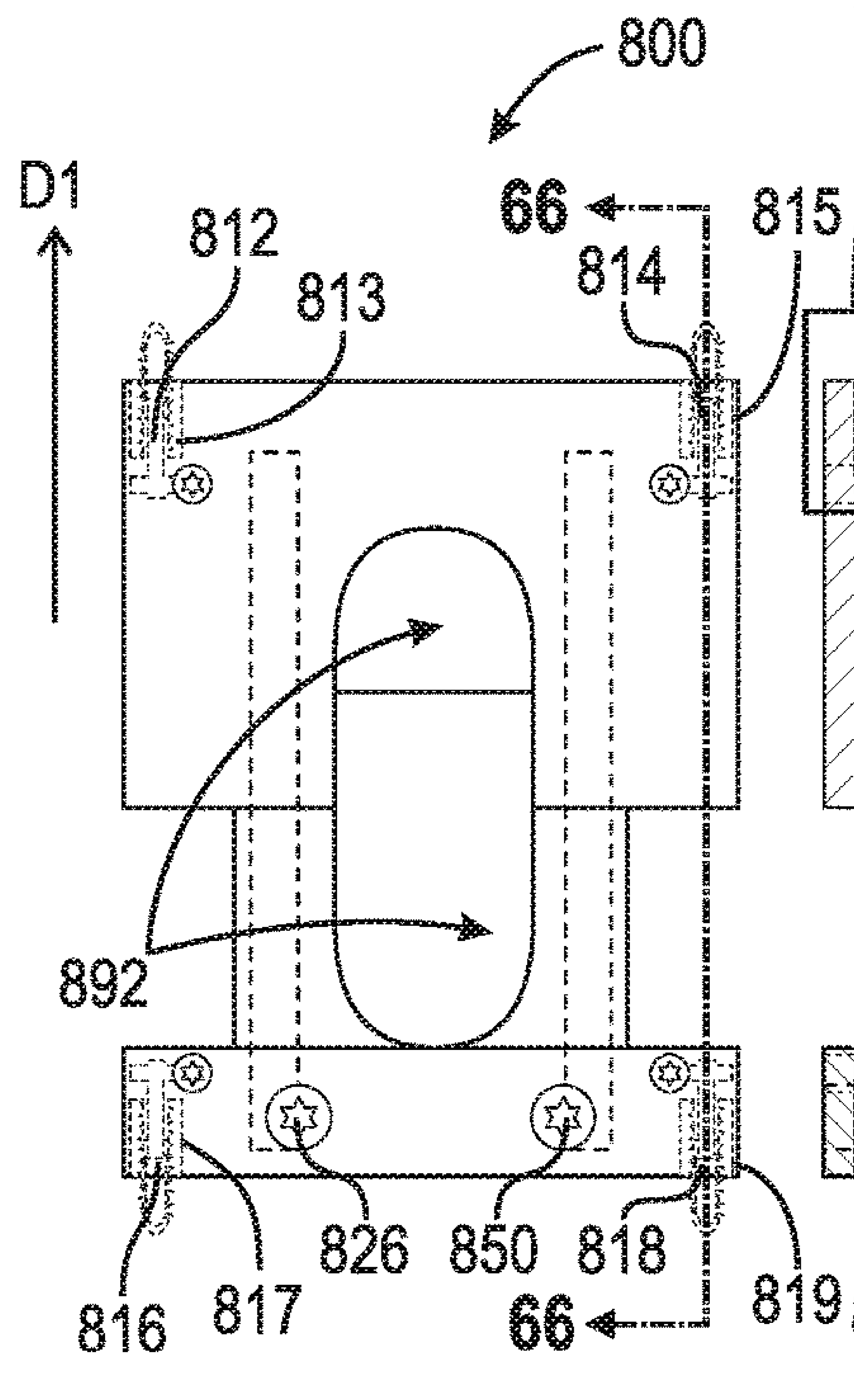


Fig. 65

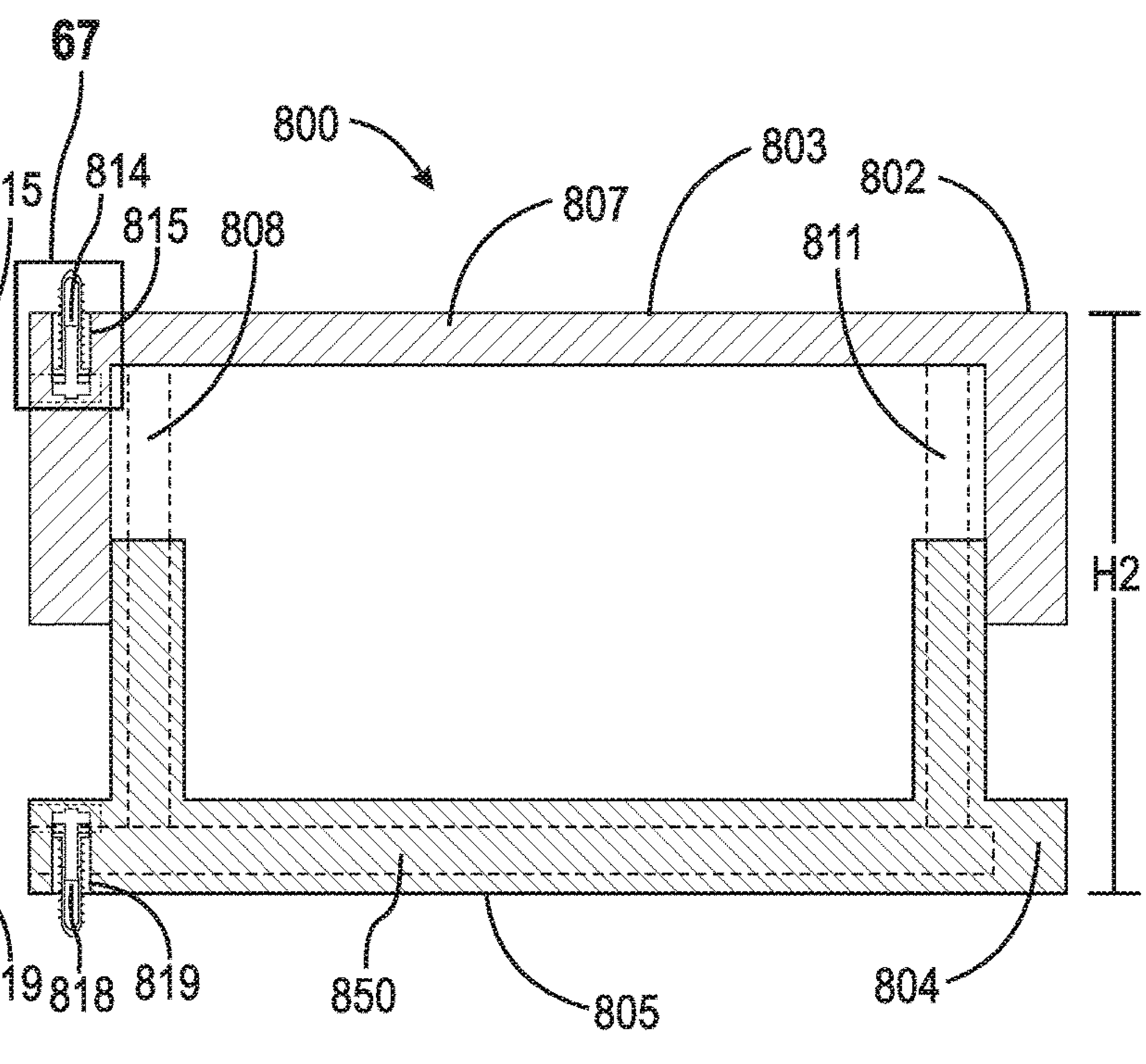


Fig. 66

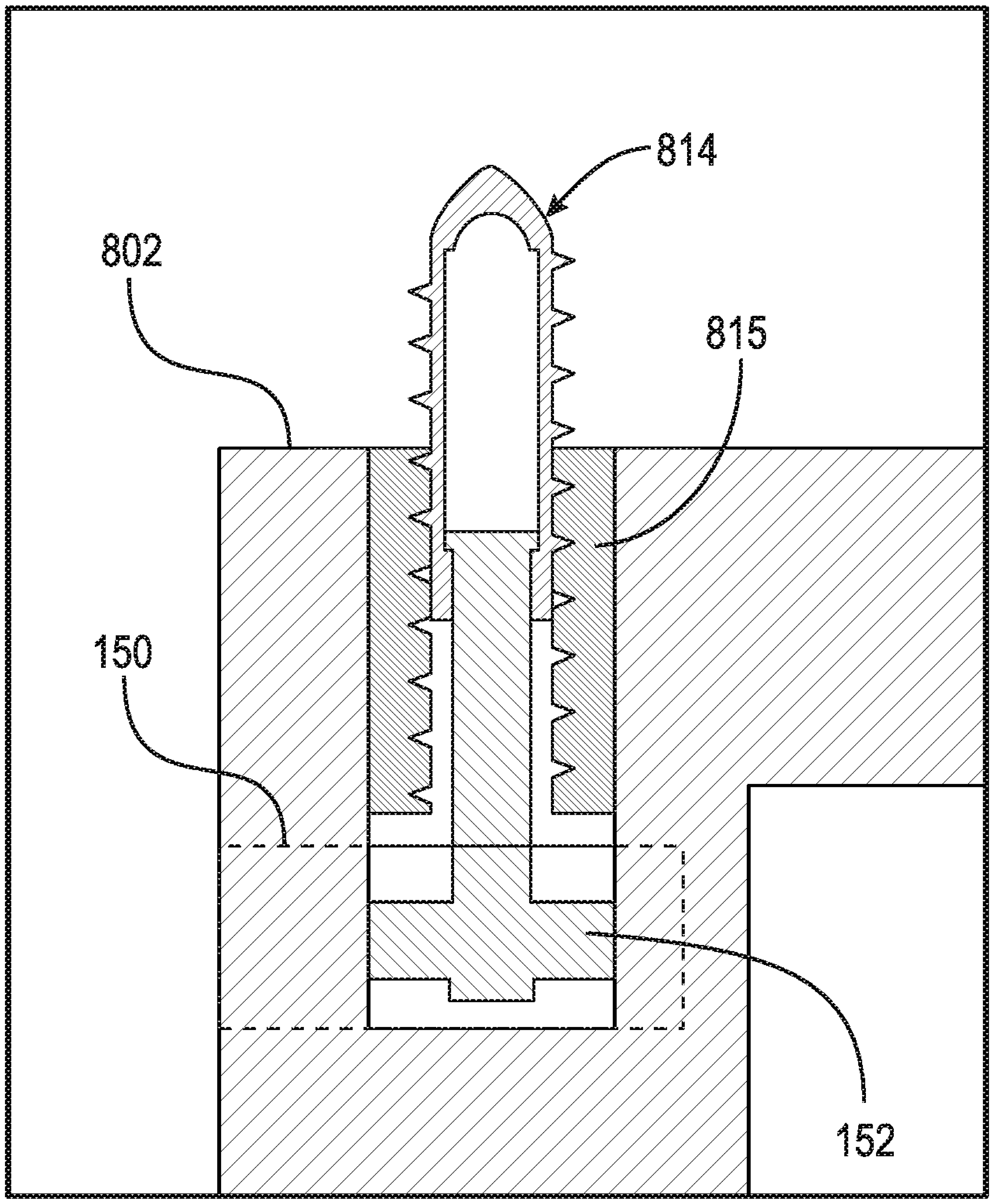


Fig. 67

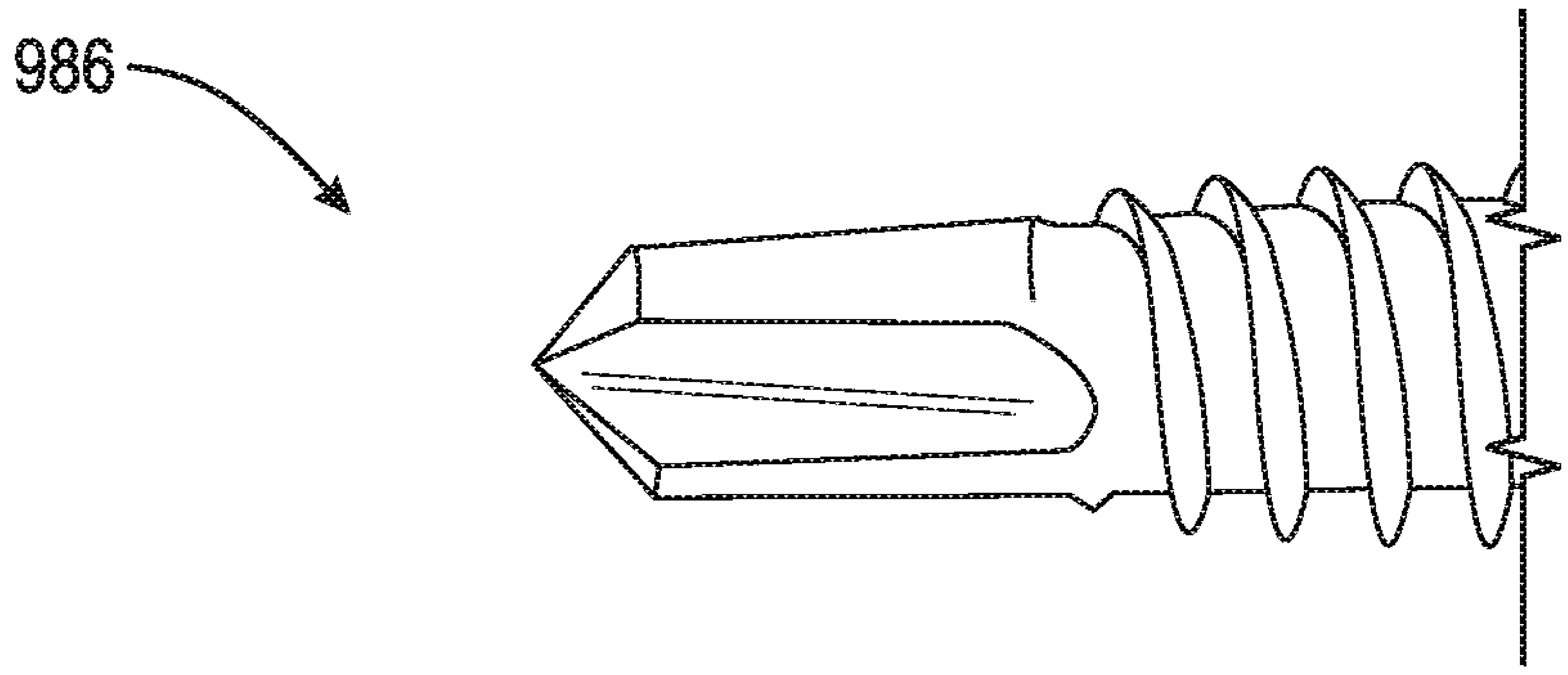


Fig. 68

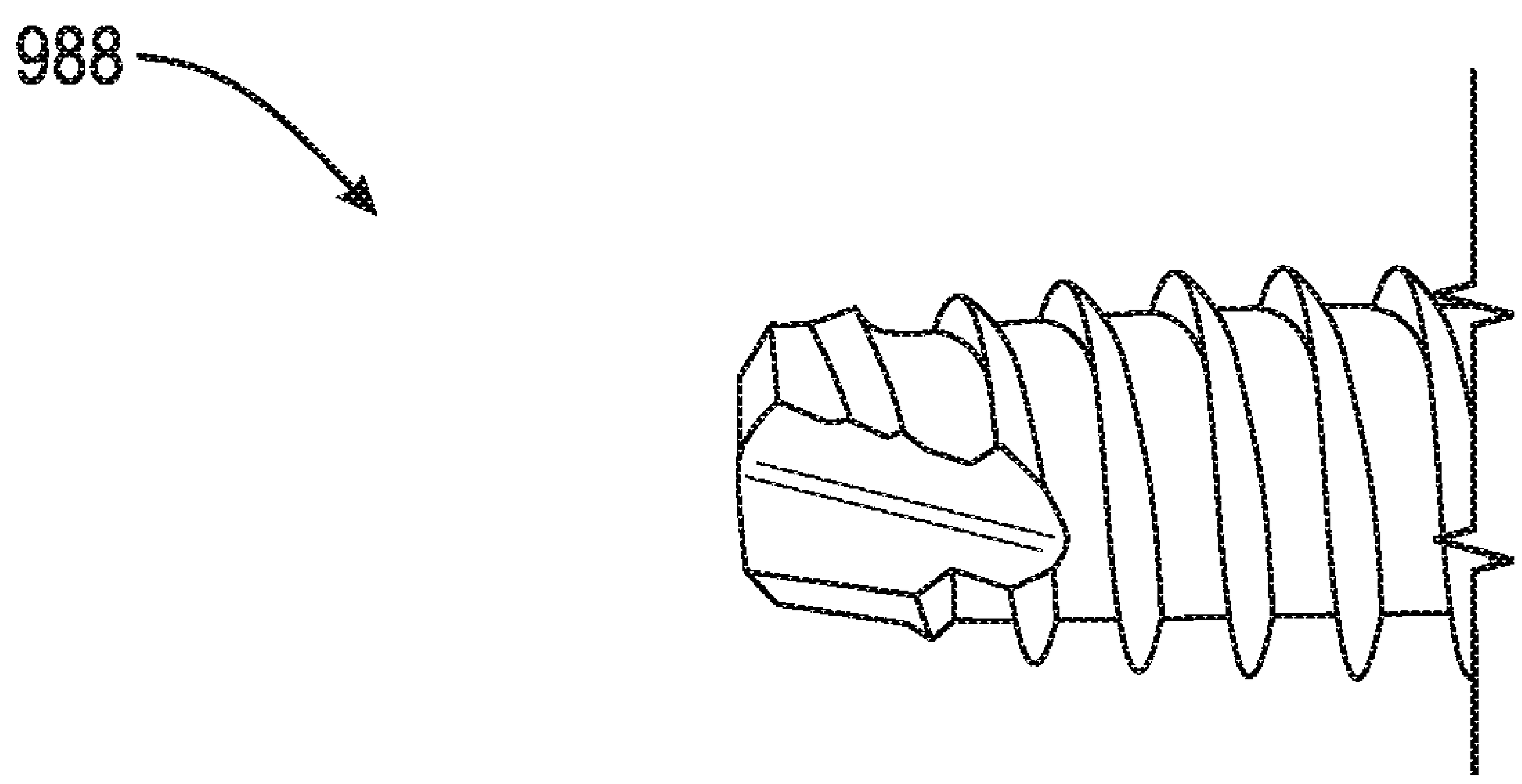


Fig. 69

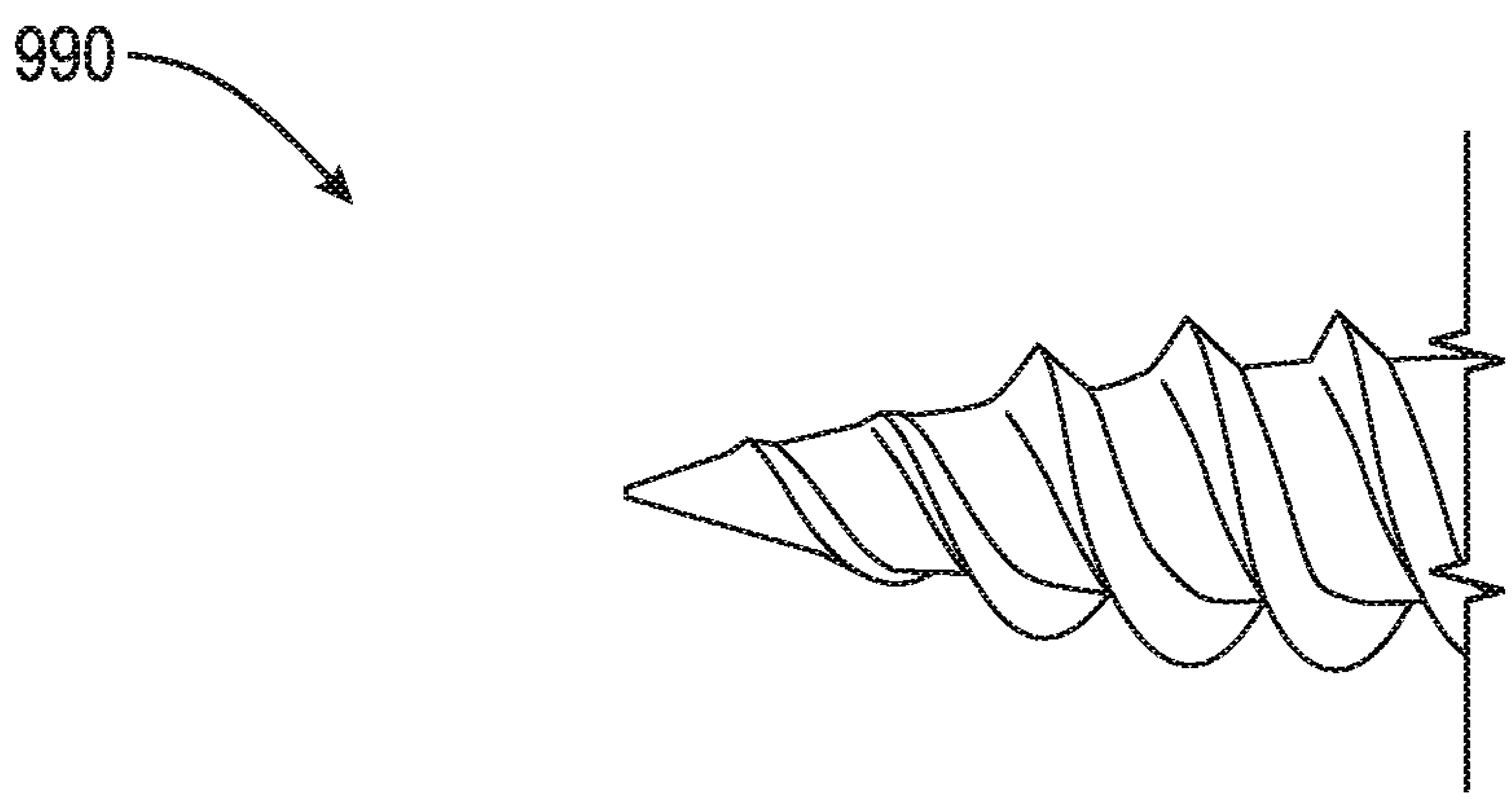


Fig. 70

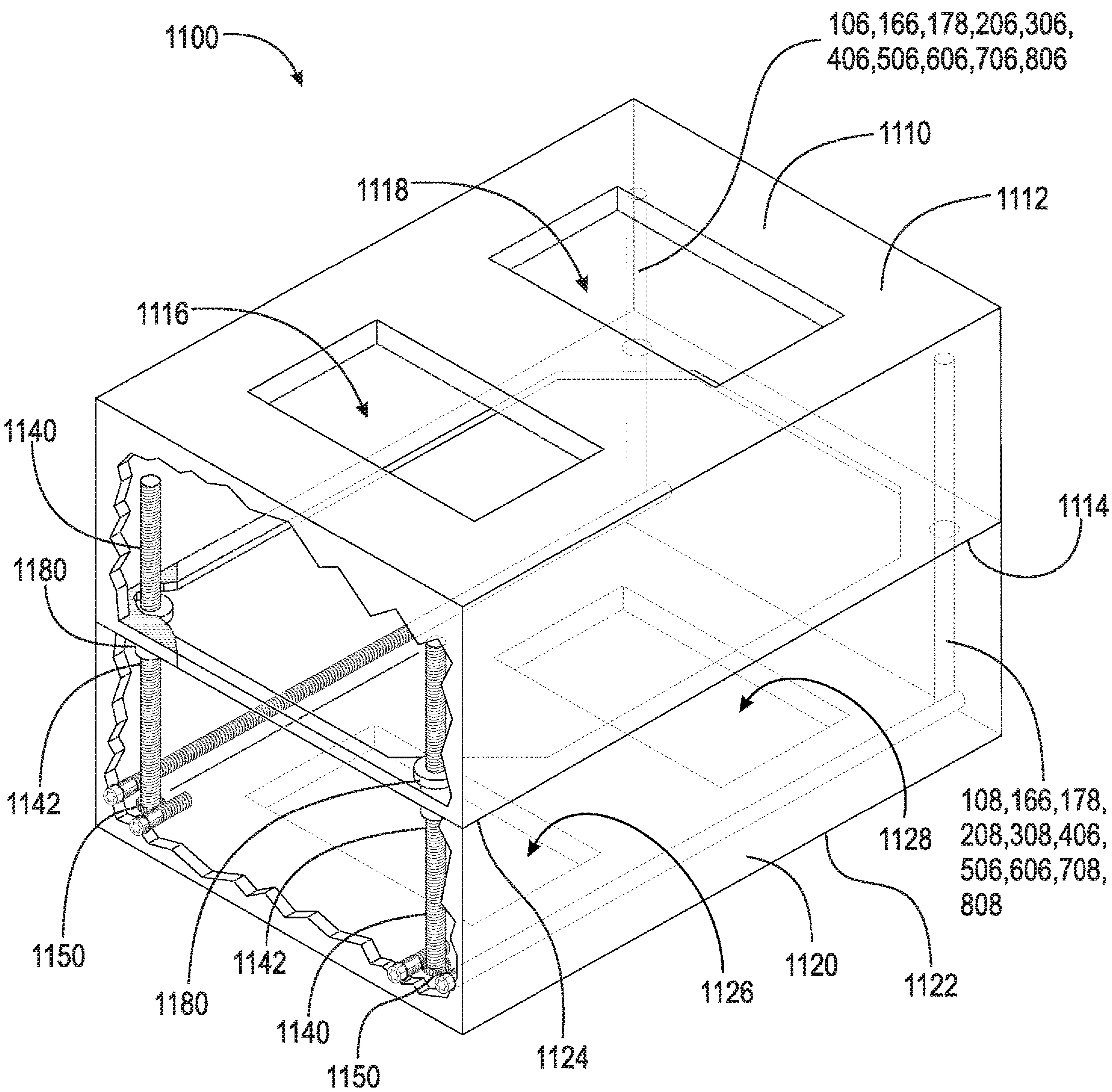
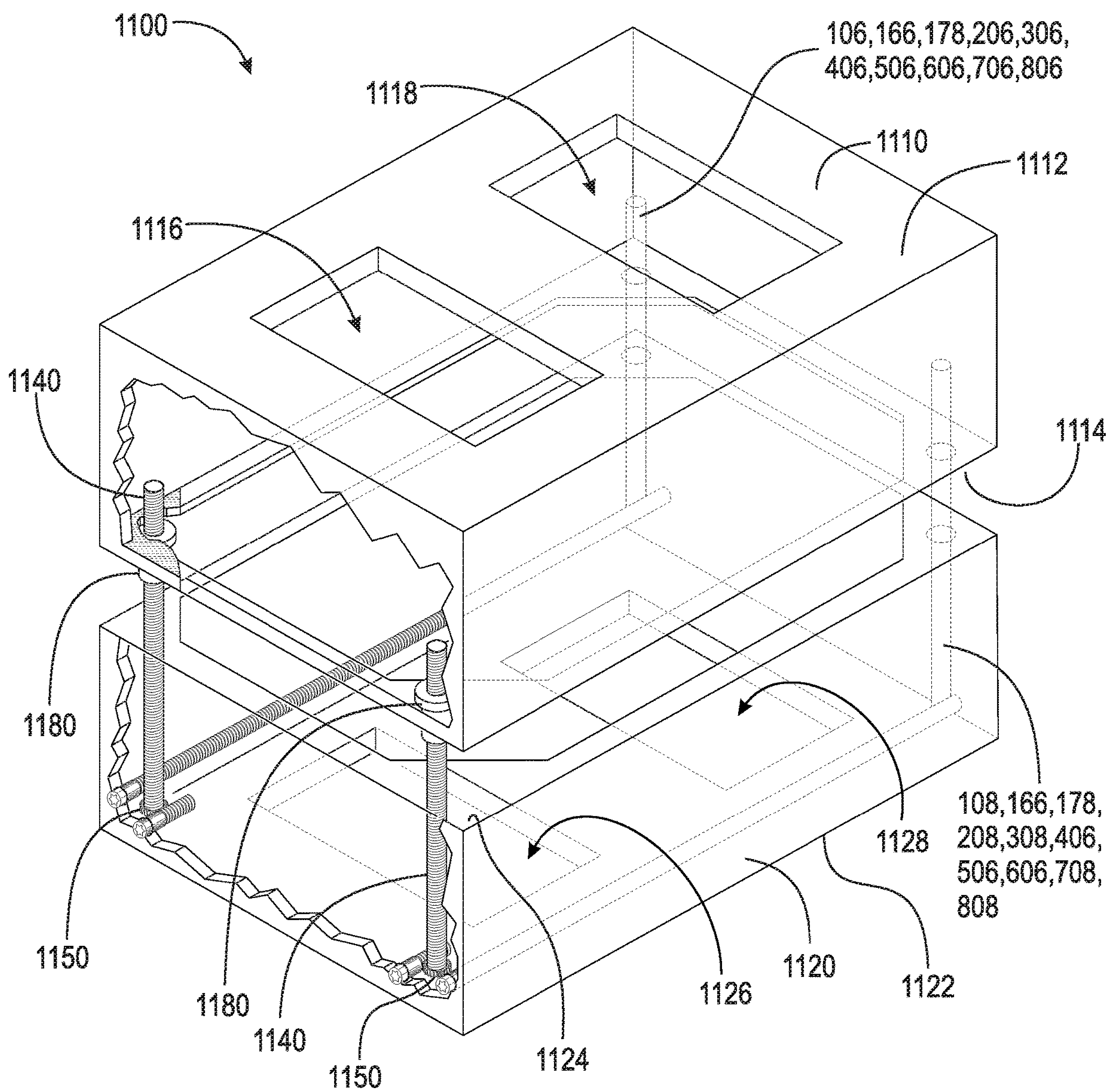

1100
106,166,178,206,306,
406,506,606,706,806
1110
1118
1112
1116
1140
1114
1180
1142
1128
108,166,178,
208,308,406,
506,606,708,
808
1150
1142
1180
1140
1150
1124
1126
1120
1122

Fig. 71A


1100
106,166,178,206,306,
406,506,606,706,806
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1110
1112
1116
1140
1114
1180
108,166,178,
208,308,406,
506,606,708,
808
1128
1150
1180
1140
1150
1126
1120
1122
1124

Fig. 71B

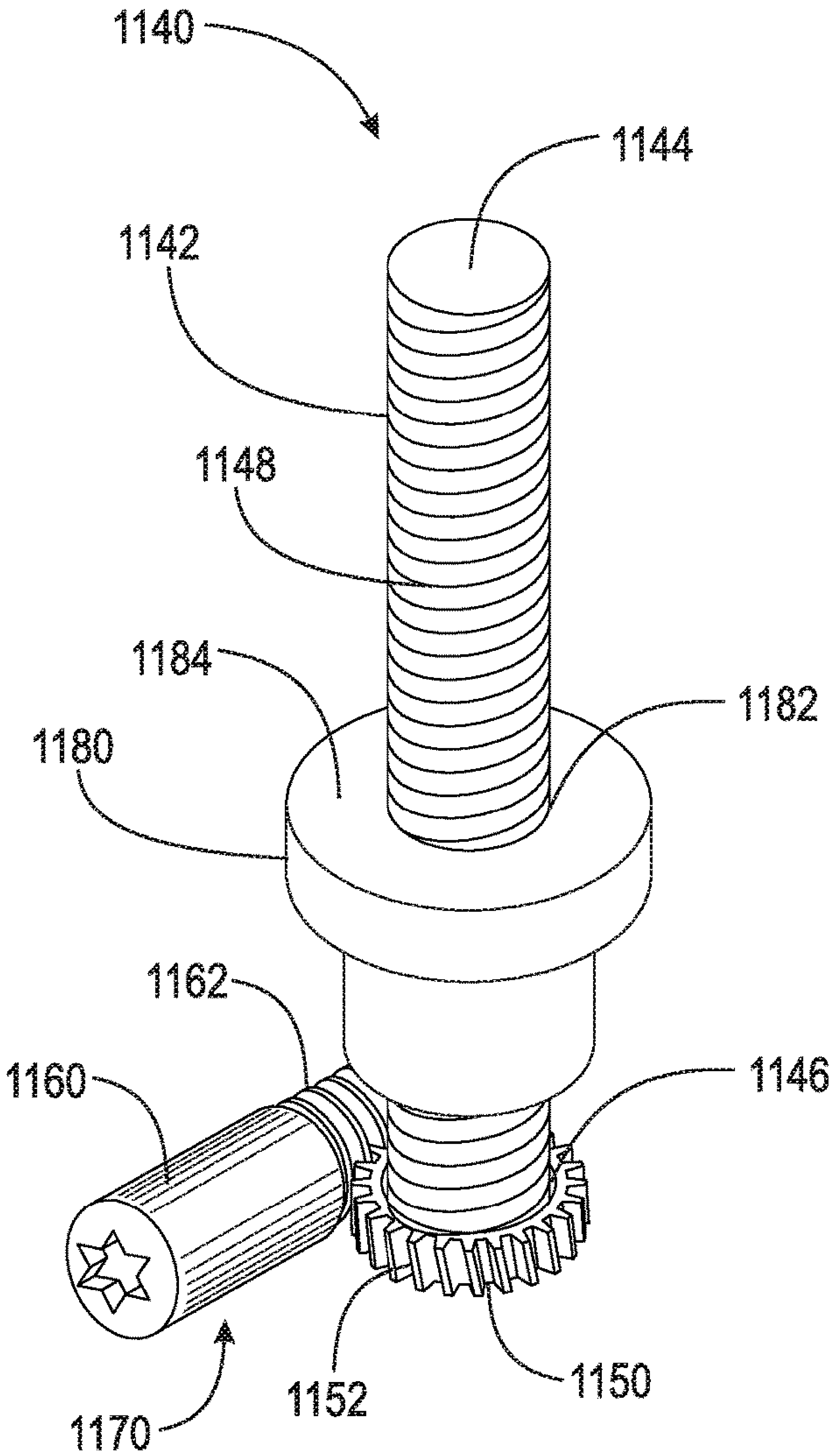

Fig. 72A

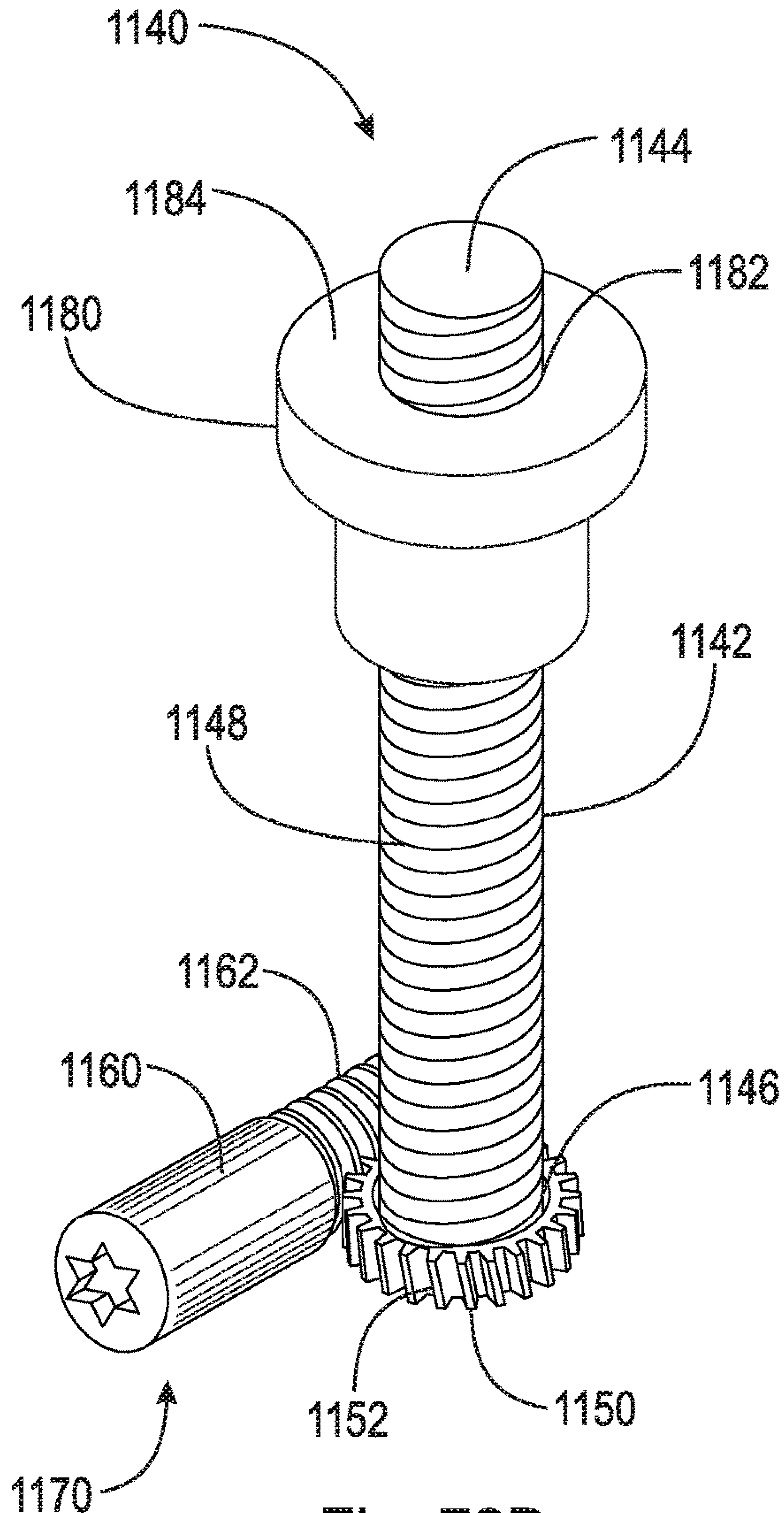

Fig. 72B

STAND-ALONE EXPANDABLE INTERBODY SPINAL FUSION DEVICE WITH INTEGRATED FIXATION MECHANISM

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is filed under 35 U.S.C. § 120 as a continuation-in-part of U.S. patent application Ser. No. 15/416,270, filed on Jan. 26, 2017, which reference is hereby incorporated by reference in its entirety.

FIELD

The invention relates to spinal surgery, more particularly to intervertebral prosthesis, and, even more specifically, to a stand-alone expandable interbody spinal fusion device with integrated fixation mechanism.

BACKGROUND

The spinal column, or backbone, is one of the most important parts of the body. It provides the main support, allowing us to stand upright, bend, and twist. As shown in FIG. **1**, thirty three (33) individual bones interlock with each other to form the spinal column. The vertebrae are numbered and divided into regions. The cervical vertebrae (C**1**-C**7**) form the neck, support the head and neck, and allow nodding and shaking of the head. The thoracic vertebrae (T**1**-T**12**) join with the ribs to form the rib cage. The five lumbar vertebrae (L**1**-L**5**) carry most of the weight of the upper body and provide a stable center of gravity when a person moves. Five vertebrae of the sacrum S and four of the coccyx C are fused. This comprises the back wall of the pelvis. Intervertebral discs are located between each of the mobile vertebra. Intervertebral discs comprise a thick outer layer with a crisscrossing fibrous structure annulus A that surrounds a soft gel-like center, the nucleus N. Discs function like shock-absorbing springs. The annulus pulls the vertebral bodies together against the elastic resistance of the gel-filled nucleus. When we bend, the nucleus acts like a ball bearing, allowing the vertebral bodies to roll over the incompressible gel. Each disc works in concert with two facet joints, forming a spinal motion segment. The biomechanical function of each pair of facet joints is to guide and limit the movement of the spinal motion segment. The surfaces of the joint are coated with cartilage that helps each joint move smoothly. Directly behind the discs, the ring-like vertebral bodies create a vertical tunnel called the spinal canal, or neuro canal. The spinal cord and spinal nerves pass through the spinal canal, which protects them from injury. The spinal cord is the major column of nerve tissue that is connected to the brain and serves as an information superhighway between the brain and the body. The nerves in the spinal cord branch off to form pairs of nerve roots that travel through the small openings between the vertebrae and the intervertebral foramens.

The repetitive forces which act on these intervertebral discs during repetitive day-to-day activities of bending, lifting and twisting cause them to break down or degenerate over time. Overt trauma, or covert trauma occurring in the course of repetitive activities disproportionately affect the more highly mobile areas of the spine. Disruption of a disc's internal architecture leads to bulging, herniation or protrusion of pieces of the disc and eventual disc space collapse. Resulting mechanical and chemical irritation of surrounding neural elements cause pain, attended by varying degrees of

disability. In addition, loss of disc space height relaxes tension on the longitudinal ligaments, thereby contributing to varying degrees of spinal instability such as spinal curvature.

Neural irritation and instability resulting from severe disc damage has been treated by removing the damaged disc and fusing adjacent vertebral elements. Removal of the disc relieves the mechanical and chemical irritation of neural elements, while osseous union solves the problem of instability. For example, in one surgical procedure, known as a discectomy (or diskectomy) with interbody fusion, the surgeon removes the nucleus of the disk and replaces it with an implant. As shown in FIG. **2**, it may be necessary, for example, for the surgeon to remove the nucleus of the disc between the L**3** and L**4** vertebrae. Disc $D_{L3\text{-}L4}$ is shown in an enlarged view in FIG. **3**. This figure also shows various anatomical structures of the spine, including facets F**3**A and F**4**A, facet joint FJ, spinous processes SP**3** and SP**4**, transverse processes TP**3**A and TP**4**A, and intervertebral foramen IF. FIG. **4** is a top view of the section of the spinal column shown in FIG. **3**, with the L**3** vertebra removed to expose annulus A and nucleus N of disc $D_{L3\text{-}L4}$. Neural canal NC is also shown. FIG. **5** is an anterior perspective view of the section of the spinal column shown in FIG. **4**. FIG. **6** is a partial cross-sectional view of the section of the spinal column shown in FIG. **5**, but with vertebra L**3** in place atop disc $D_{L3\text{-}L4}$.

While cancellous bone appears ideal to provide the biologic components necessary for osseous union to occur, it does not initially have the strength to resist the tremendous forces that may occur in the intervertebral disc space, nor does it have the capacity to adequately stabilize the spine until long term bony union occurs. For these reasons, many spinal surgeons have found that interbody fusion using bone alone has an unacceptably high rate of bone graft migration or even expulsion or nonunion due to structural failure of the bone or residual degrees of motion that retard or prohibit bony union.

Intervertebral prosthesis in various forms have therefore been used to provide immediate stability and to protect and preserve an environment that fosters growth of grafted bone such that a structurally significant bony fusion can occur.

Limitations of most present day intervertebral implants is their tendency to migrate after implantation, necessitating the use of supplemental fixation such as an anterior or lateral plating system or posterior pedicle screw or lateral mass fixation to prevent unexpected device dislodgement.

Other interbody devices have been designed with orifices through which screws, blades, or other metallic fixation devices are placed after device insertion to mitigate unwanted slippage of the device after implementation. In addition, these devices may require additional placement of hardware anteriorly or laterally at the time of surgery, or, require a second surgery so that hardware such as pedicle screws can be added posteriorly so that the device is held securely.

Thus, there is a long-felt need for a stand-alone expandable interbody spinal fusion device with integrated fixation mechanism that would obviate the need for supplemental fixation such that the device could be simply implanted between vertebral bodies and fixated using the insertion device such that it is easily inserted and could function in a stand-alone capacity.

SUMMARY

According to aspects illustrated herein, there is provided a stand-alone expandable interbody spinal fusion device, comprising a superior component, an inferior component, and an expansion mechanism operatively arranged to displace the superior component relative to the inferior component, the expansion mechanism including a threaded rod including a first end engaged with the superior component and a second end engaged with the inferior component, wherein when the threaded rod is rotated in a first circumferential direction, the superior component is displaced in a first direction relative to the inferior component.

In some embodiments, the expansion mechanism further comprises a gear rotatably connected to the inferior component, and the second end is fixedly secured to the gear. In some embodiments, the superior component comprises a threaded hole and the threaded rod is threadably engaged with the threaded hole. In some embodiments, the expansion mechanism further comprises a threaded collar threadably engaged with the threaded rod. In some embodiments, the threaded collar abuts against the superior component. In some embodiments, the expansion mechanism further comprises a worm rotatably connected to the inferior component and engaged with the gear. In some embodiments, the superior component comprises at least one aperture and the inferior component comprises at least one aperture. In some embodiments, when the threaded rod is rotated in a second circumferential direction, opposite the first circumferential direction, the superior component is displaced in a second direction relative to the inferior component.

According to aspects illustrated herein, there is provided a stand-alone expandable interbody spinal fusion device, comprising an inferior component including a first inward facing surface and a first outward facing surface, a superior component including a second inward facing surface and a second outward facing surface, and an expansion mechanism, including a gear rotatably connected to the inferior component, and a threaded rod including a first end engaged with the superior component and a second end fixedly secured to the gear, wherein when the threaded rod is rotated in a first circumferential direction, the superior component is displaced in a first direction relative to the inferior component.

In some embodiments, the superior component comprises a threaded hole and the threaded rod is threadably engaged with the threaded hole. In some embodiments, the expansion mechanism further comprises a threaded collar threadably engaged with the threaded rod. In some embodiments, the threaded collar abuts against the superior component. In some embodiments, the threaded collar is at least partially embedded in the superior component. In some embodiments, the expansion mechanism further comprises a worm rotatably connected to the inferior component and engaged with the gear. In some embodiments, the inferior component comprises at least one aperture extending from the first inner surface to the first outer surface and the superior component comprises at least one aperture extending from the second inner surface to the second outer surface. In some embodiments, when the threaded rod is rotated in a second circumferential direction, opposite the first circumferential direction, the superior component is displaced in a second direction relative to the inferior component.

According to aspects illustrated herein, there is provided a stand-alone expandable interbody spinal fusion device, comprising an inferior component including a first inward facing surface and a first outward facing surface, a superior component including a second inward facing surface and a second outward facing surface, and an expansion mechanism, including a gear rotatably connected to the inferior component, and a threaded rod including a first end threadably engaged with the superior component and a second end fixedly secured to the gear, wherein when the threaded rod is rotated the superior component is displaced relative to the inferior component.

In some embodiments, the threaded rod is threadably engaged with the superior component via a threaded collar, the threaded collar operatively arranged to abut against the second inward facing surface. In some embodiments, the expansion mechanism further comprises a worm engaged with the gear. In some embodiments, the superior component comprises a threaded hole extending from the second inward facing surface and the threaded rod is threadably engaged with the threaded hole.

According to aspects illustrated herein, there is provided a stand-alone expandable interbody spinal fusion device with an integrated fixation mechanism including a superior component, an inferior component, an expansion mechanism operatively arranged to displace the superior component in a first direction relative to the inferior component, and a first screw mechanism arranged within the superior component or inferior component.

According to aspects illustrated herein, there is provided a stand-alone expandable interbody spinal fusion device with integrated fixation mechanism including a body having a proximate end and a distal end, the body further includes a superior component, an inferior component, a first gear shaft operatively arranged to engage a first plurality of expansion mechanisms, where the first plurality of expansion mechanisms are operatively arranged to displace the superior component in a first direction relative to the inferior component, a first screw mechanism operatively arranged within the proximate end of the superior component, a second screw mechanism operatively arranged within the proximate end of the inferior component, and a first aperture operatively arranged on the superior or inferior components.

According to aspects illustrated herein, there is provided a stand-alone expandable interbody spinal fusion device with integrated fixation mechanism including a superior component, an inferior component, and a first screw mechanism arranged within the superior component or inferior component, where the superior component is operatively arranged to be displaced in a first direction relative to the inferior component.

These and other objects, features, and advantages of the present disclosure will become readily apparent upon a review of the following detailed description of the disclosure, in view of the drawings and appended claims.

BRIEF DESCRIPTION OF THE DRAWINGS

Various embodiments are disclosed, by way of example only, with reference to the accompanying schematic drawings in which corresponding reference symbols indicate corresponding parts, in which:

FIG. **1** is an anterior perspective view of spinal column **10**;

FIG. **2** is an anterior perspective view of the lumbar section of spinal column **10**;

FIG. **3** is a lateral perspective view of L**3**, L**4** vertebrae and disc D_{L3-L4} and related spinal anatomy;

FIG. **4** is a top view of a section of the spinal column, taken generally along line **4**-**4** in FIG. **3**;

FIG. **5** is an enlarged anterior perspective view of the spinal column shown in FIG. **2**, except with vertebra L**3** and all other structure above L**3** removed;

FIG. **6** is a partial cross-sectional view of the L**4** vertebra and D_{L3-L4} disc shown in FIG. **5**, including L**3** in cross-section;

FIG. **7** is a partial cross-sectional view of the L**4** vertebra and D_{L3-L4} disc shown in FIG. **5**, showing the removal of the disc nucleus post-discectomy;

FIG. **8** illustrates the introduction of the stand-alone expandable interbody spinal fusion device into the disc space in an unexpanded state;

FIG. **9** is an anterior perspective view of spinal column **10** including the stand-alone expandable interbody spinal fusion device in an unexpanded state;

FIG. **10** is a perspective view of a first embodiment of the stand-alone expandable interbody spinal fusion device, in an unexpanded state;

FIG. **11** is a perspective view of a first embodiment of the stand-alone expandable interbody spinal fusion device, in an expanded state;

FIG. **12** is a front view of a first embodiment of the stand-alone expandable interbody spinal fusion device, in an unexpanded state;

FIG. **13** is a cross-sectional view of a first embodiment of the stand-alone expandable interbody spinal fusion device, in an unexpanded state, taken generally along line **13-13** in FIG. **12**;

FIG. **14** is a front view of a first embodiment of the stand-alone expandable interbody spinal fusion device, in an expanded state;

FIG. **15** is a cross-sectional view of a first embodiment of the stand-alone expandable interbody spinal fusion device, in an expanded state, taken generally along line **15-15** in FIG. **14**;

FIG. **16** is a perspective view of a first embodiment of a self-piercing screw mechanism in an unexpanded state;

FIG. **17** is a perspective view of a first embodiment of a self-piercing screw mechanism in an expanded state;

FIG. **18** is a perspective view of a second embodiment of a self-piercing screw mechanism in an unexpanded state;

FIG. **19** is a perspective view of a second embodiment of a self-piercing screw mechanism in an expanded state;

FIG. **20** is a side view of a first embodiment of a self-piercing screw mechanism in an unexpanded state;

FIG. **21** is a side view of a first embodiment of a self-piercing screw mechanism in an unexpanded state;

FIG. **22** is a cross-sectional view of a first embodiment of a self-piercing screw mechanism is an unexpanded state, taken generally along line **22-22** in FIG. **21**;

FIG. **23** is a side view of a first embodiment of a self-piercing screw mechanism in an expanded state;

FIG. **24** is a side view of a first embodiment of a self-piercing screw mechanism in an expanded state;

FIG. **25** is a cross-sectional view of a first embodiment of a self-piercing screw mechanism is an expanded state, taken generally along line **25-25** in FIG. **24**;

FIG. **26** is a side view of a second embodiment of a self-piercing screw mechanism in an unexpanded state;

FIG. **27** is a side view of a second embodiment of a self-piercing screw mechanism in an unexpanded state;

FIG. **28** is a cross-sectional view of a second embodiment of a self-piercing screw mechanism is an unexpanded state, taken generally along line **28-28** in FIG. **27**;

FIG. **29** is a side view of a second embodiment of a self-piercing screw mechanism in an expanded state;

FIG. **30** is a side view of a second embodiment of a self-piercing screw mechanism in an expanded state;

FIG. **31** is a cross-sectional view of a second embodiment of a self-piercing screw mechanism is an expanded state, taken generally along line **31-31** in FIG. **30**;

FIG. **32** is a perspective view of a first embodiment of an expansion mechanism in an unexpanded state;

FIG. **33** is a perspective view of a first embodiment of an expansion mechanism in an expanded state;

FIG. **34** is a side view of a first embodiment of an expansion mechanism in an unexpanded state;

FIG. **35** is a side view of a first embodiment of an expansion mechanism in an expanded state;

FIG. **36** is a cross-sectional view of a first embodiment of an expansion mechanism in an expanded state taken generally along line **36-36** in FIG. **35**;

FIG. **37** is a perspective view of a second embodiment of an expansion mechanism in an unexpanded state;

FIG. **38** is a perspective view of a second embodiment of an expansion mechanism in an expanded state;

FIG. **39** is a side view of a second embodiment of an expansion mechanism in an unexpanded state;

FIG. **40** is a side view of a second embodiment of an expansion mechanism in an expanded state;

FIG. **41** is a perspective view of a second embodiment of the stand-alone expandable interbody spinal fusion device, in an unexpanded state;

FIG. **42** is a perspective view of a second embodiment of the stand-alone expandable interbody spinal fusion device, in an expanded state;

FIG. **43** is a perspective view of a third embodiment of the stand-alone expandable interbody spinal fusion device, in an unexpanded state;

FIG. **44** is a perspective view of a third embodiment of the stand-alone expandable interbody spinal fusion device, in an expanded state;

FIG. **45** is a perspective view of a fourth embodiment of the stand-alone expandable interbody spinal fusion device, in an unexpanded state;

FIG. **46** is a perspective view of a fourth embodiment of the stand-alone expandable interbody spinal fusion device, in an expanded state;

FIG. **47** is a front view of a fourth embodiment of the stand-alone expandable interbody spinal fusion device, in an unexpanded state;

FIG. **48** is a side view of a fourth embodiment of the stand-alone expandable interbody spinal fusion device, in an unexpanded state;

FIG. **49** is a front view of a fourth embodiment of the stand-alone expandable interbody spinal fusion device, in an expanded state;

FIG. **50** is a side view of a fourth embodiment of the stand-alone expandable interbody spinal fusion device, in an expanded state;

FIG. **51** is a partial cross-sectional view of a fourth embodiment of the stand-alone expandable interbody spinal fusion device, in an unexpanded state;

FIG. **52** is a partial cross-sectional view of a fourth embodiment of the stand-alone expandable interbody spinal fusion device, in an expanded state;

FIG. **53** is a partial cross-sectional front view of a fourth embodiment of the stand-alone expandable interbody spinal fusion device, in an unexpanded state;

FIG. **54** is a partial cross-sectional front view of a fourth embodiment of the stand-alone expandable interbody spinal fusion device, in an expanded state;

FIG. **55** is a partial cross-sectional front view of a fifth embodiment of the stand-alone expandable interbody spinal fusion device, in an unexpanded state;

FIG. **56** is a partial cross-sectional front view of a fifth embodiment of the stand-alone expandable interbody spinal fusion device, in an expanded state;

FIG. **57** is a partial cross-sectional front view of a sixth embodiment of the stand-alone expandable interbody spinal fusion device, in an unexpanded state;

FIG. **58** is a partial cross-sectional front view of a sixth embodiment of the stand-alone expandable interbody spinal fusion device, in an expanded state;

FIG. **59** is a perspective view of a seventh embodiment of the stand-alone expandable interbody spinal fusion device, in an expanded state;

FIG. **60** is a cross-sectional view of a seventh embodiment of the stand-alone expandable interbody spinal fusion device, in an expanded state taken along line **60-60** in FIG. **59**;

FIG. **61** is a perspective view of an eighth embodiment of the stand-alone expandable interbody spinal fusion device, in an unexpanded state;

FIG. **62** is a perspective view of an eighth embodiment of the stand-alone expandable interbody spinal fusion device, in an expanded state;

FIG. **63** is a front view of an eighth embodiment of the stand-alone expandable interbody spinal fusion device, in an unexpanded state;

FIG. **64** is a cross-sectional view of an eighth embodiment of the stand-alone expandable interbody spinal fusion device, in an unexpanded state taken generally along line **64-64** in FIG. **63**;

FIG. **65** is a front view of an eighth embodiment of the stand-alone expandable interbody spinal fusion device, in an expanded state;

FIG. **66** is a cross-sectional view of an eighth embodiment of the stand-alone expandable interbody spinal fusion device, in an expanded state taken generally alone line **66-66** in FIG. **65**;

FIG. **67** is an enlarged view of area **67** in FIG. **66**;

FIG. **68** is a side view of a self-drilling screw body tip;

FIG. **69** is a side view of a self-tapping screw body tip;

FIG. **70** is a side view of a self-piercing screw body tip;

FIG. **71**A is a perspective view of a stand-alone expandable interbody spinal fusion device, in an unexpanded state;

FIG. **71**B is a perspective view of the stand-alone expandable interbody spinal fusion device shown in FIG. **71**A, in an expanded state;

FIG. **72**A is a perspective view of the expansion mechanism in FIG. **71**A; and,

FIG. **72**B is a perspective view of the expansion mechanism in FIG. **71**B.

DETAILED DESCRIPTION

At the outset, it should be appreciated that like drawing numbers on different drawing views identify identical, or functionally similar, structural elements. It is to be understood that the claims are not limited to the disclosed aspects.

Furthermore, it is understood that this disclosure is not limited to the particular methodology, materials and modifications described and as such may, of course, vary. It is also understood that the terminology used herein is for the purpose of describing particular aspects only, and is not intended to limit the scope of the claims.

Unless defined otherwise, all technical and scientific terms used herein have the same meaning as commonly understood to one of ordinary skill in the art to which this disclosure pertains. It should be understood that any methods, devices or materials similar or equivalent to those described herein can be used in the practice or testing of the example embodiments. The assembly of the present disclosure could be driven by hydraulics, electronics, pneumatics, and/or springs.

It should be appreciated that the term "substantially" is synonymous with terms such as "nearly," "very nearly," "about," "approximately," "around," "bordering on," "close to," "essentially," "in the neighborhood of," "in the vicinity of," etc., and such terms may be used interchangeably as appearing in the specification and claims. It should be appreciated that the term "proximate" is synonymous with terms such as "nearby," "close," "adjacent," "neighboring," "immediate," "adjoining," etc., and such terms may be used interchangeably as appearing in the specification and claims. The term "approximately" is intended to mean values within ten percent of the specified value.

The term "Superior Component" as used in the present disclosure is intended to mean the component of the body of the implant located in the highest position relative to the other components in the first direction D**1**.

The term "Inferior Component" as used in the present disclosure is intended to mean the component of the body of the implant located in the lowest position relative to the other components in the first direction D**1**.

The term "screw body" as used in the present disclosure is intended to mean a sharp-pointed metal pin with a raised helical thread running around it (either left-handed or right-handed threads can be used) and can be used to join objects together by being rotated so that it pierces the surface of the material (e.g., wood, bone, or any other material less dense than the screw body material). The pitch of threading could be varied to allow for changes in bone density and the thread could be various threads known in the art such as V-thread, American, British, Square, Buttress, Knuckle, or any suitable threading that would engage with bone material. It should also be appreciated that, throughout this disclosure, a self-piercing screw is illustrated as a non-limiting example, and in the alternative a self-drilling, or a self-tapping screw could be used.

The term "gear shaft" as used in the present disclosure is intended to mean any gear currently understood in the art that has been elongated such that it is substantially cylindrical in shape.

The term "anchor layer" as used in the present disclosure is intended to mean a thin layer of material fixed within or on the superior and inferior components and creates a fixed point for a screw body to engage with and achieve the required leverage to engage the bone material of the adjacent vertebra. It should be appreciated that the anchor layer could be made out of ceramic, carbon fiber, high density plastic, polymer, or any suitable metal more dense than the metal of the screw body, such as titanium.

Adverting now to the Figures, and as described previously, FIGS. **1-6** depict various parts and sections of spinal anatomy. FIG. **7** illustrates a partial cross-sectional view of the L**3** and L**4** vertebra with disc D_{L3-L4} removed (post discectomy) able to receive stand-alone expandable interbody spinal fusion device **100**.

FIG. **8** illustrates a partial cross-sectional view of the L**3** and L**4** vertebra with stand-alone expandable interbody spinal fusion device **100** in place within disc space **12** in an unexpanded state.

FIG. **9** is an anterior perspective view of spinal column **10** including stand-alone expandable interbody spinal fusion device **100**.

FIG. **10** is a perspective view of stand-alone expandable interbody spinal fusion device **100**, in an unexpanded state.

Device **100** comprises superior component **102**, inferior component **104**, and expansion mechanisms **106**, **108**, and **110** arranged to displace superior component **102** in a first direction D1 relative to inferior component **104** giving device **100** an expanded height H_2 greater than unexpanded height H_1, and self-piercing screw mechanisms **112**, **114**, **116**, and **118**, arranged to engage the bone material of the surrounding vertebra (i.e., L3 and L4). Superior component **102** and inferior component **104** further comprise at least one first aperture **120** arranged to allow fusion between bone fusing material and the adjacent vertebra, and a second aperture **192** located on the front face of device **100** and arranged to allow the introduction of bone fusing material into device **100**. Second aperture **192** is illustrated as an arched slot as a non-limiting example, however, it should be appreciated that second aperture **192** could be any suitable aperture that would allow for the introduction of bone fusing material into device **100**. Superior component **102** has a first surface **103** and inferior component **104** has a first surface **105**. Embedded within the superior component, beneath surface **103**, or above surface **103** (not depicted in FIG. **10**), there is an anchor layer **107** (depicted in FIGS. **13** and **15**). Embedded within the inferior component, beneath surface **105**, or above surface **105** (not depicted in FIG. **10**), there is an anchor layer **109** (depicted in FIGS. **13** and **15**). Self-piercing screw mechanisms **112**, **114**, **116**, and **118** can comprise the embodiment of either self-piercing screw mechanism **122** (as described infra) or self-piercing screw mechanism **146** (as described infra). Expansion mechanisms **106**, **108**, and **110** can comprise the embodiment of either expansion mechanism **166** or **178** (as described infra).

FIG. **11** is a perspective view of stand-alone expandable interbody spinal fusion device **100**, in an expanded state. During surgery and after device **100** is implanted in disc space **12**, a surgeon can apply torque to expansion mechanisms **106**, **108**, and **110** via any device that imparts rotational force upon expansion mechanisms **106**, **108**, and **110** (e.g., a screw driver or impact driver). This rotational force causes expansion mechanisms **106**, **108**, and **110**, to displace superior component **102** in direction D1 relative to inferior component **104** giving device **100** an expanded height H_2, greater than H_1. It should be appreciated that expansion mechanisms **106**, **108**, and **110**, can be expanded to any height between unexpanded height H_1 and expanded height H_2.

FIG. **12** is a front view of stand-alone expandable interbody spinal fusion device **100**, in an unexpanded state having an unexpanded height H_1. FIG. **13** is a cross-sectional view of stand-alone expandable interbody spinal fusion device **100**, in an unexpanded state having an unexpanded height H_1. FIG. **14** is a front view stand-alone expandable interbody spinal fusion device **100**, in an expanded state having an expanded height H_2, greater than H_1. FIG. **15** is a cross-sectional view stand-alone expandable interbody spinal fusion device **100**, in an expanded state having an expanded height H_2, greater than H_1.

FIG. **16** is a perspective view of a self-piercing screw mechanism **122** in an unexpanded state. Self-piercing screw mechanism **122** comprises a worm drive **124** having a worm **126** and a gear **128**; a drive casing **130** having an inner radial surface **132** that has a keyed shaft **134** (not shown in this figure), an outer radial surface **136**, a first end **138**, and a second end **140**; and, self-piercing screw body **142** having tab **144**. The second end **140** is fixedly secured to gear **128**. During surgery and after device **100** is implanted in disc space **12**, a surgeon can apply torque to worm drive **124** via any device that imparts rotational force upon worm **126** (e.g., a screw driver or impact driver). Torque is transferred 90 degrees through worm drive **124**, via worm **126** and gear **128**. Rotation of gear **128** causes drive casing **130** to rotate. As drive casing **130** rotates, keyed shaft **134** engages tab **144** and imparts rotational force to self-piercing screw body **142**. It should be appreciated that worm drive **124** could be arranged to transfer torque in other arrangements, i.e., 180 degrees, 270 degrees, or any desirable angle required by the arrangement of worm **126** and gear **128**. It should further be appreciated that, although gear **128** is depicted in the figures as a spur gear, other suitable gears may be selected, i.e., a bevel gear, a hypoid gear, a spiral gear, or a face gear. Additionally, self-piercing screw body **142** may have more than one tab **144**.

FIG. **17** is a perspective view of self-piercing screw mechanism **122** in an expanded state. As discussed above, as drive casing **130** rotates, keyed shaft **134** engages tab **144** and imparts rotational force to self-piercing screw body **142**. Self-piercing screw body **142** rotates it engages with either anchor layer **107**, if self-piercing screw body **142** is embedded within superior component **102**; or, anchor layer **109**, if self-piercing screw body **142** is embedded within inferior component **104**. As self-piercing screw body **142** engages either anchor layer **107** or anchor layer **109**, the self-piercing screw body further engages the bone material of the adjacent vertebra (e.g., L3 or L4). As self-piercing screw body **142** engages bone material, tab **144** continues to transfer torque to the screw body and slides along keyed shaft **134**. When the screw body is at its maximum expansion, tab **144** abuts either anchor layer **107** or anchor layer **109** and can no longer screw deeper into the bone material of the adjacent vertebra.

FIG. **18** is a perspective view of self-piercing screw mechanism **146** in an unexpanded state. Self-piercing screw mechanism **146** comprises a worm drive **148** having a worm **150** and a gear **152**. Gear **152** is fixedly secured to rod **154**. Rod **154** has a tab **156** and a flange **157** (not shown in FIG. **18**). Self-piercing screw mechanism **146** further comprises a self-piercing screw body **158** having a partial through bore **160** with an inner radial surface **162** that has a keyed shaft **164** (not depicted in FIG. **18**), arranged to slidingly engage tab **156**, and a retention shoulder **159** (not depicted in FIG. **18**). During surgery and after device **100** is implanted in disc space **12**, a surgeon can apply torque to worm drive **148** via any device that imparts rotational force upon worm **150** (e.g., a screw driver or impact driver). Torque is transferred 90 degrees through worm drive **148**, via worm **150** and gear **152**. Rotation of gear **152** causes rod **154** to rotate. As rod **154** rotates, tab **156** engages keyed shaft **164** within the partial through bore **160** of self-piercing screw body **158** and imparts rotational force to self-piercing screw body **158**. It should be appreciated that worm drive **148** could be arranged to transfer torque in other arrangements, i.e., 180 degrees, 270 degrees, or any desirable angle required by the arrangement of worm **150** and gear **152**. It should further be appreciated that although a gear **158** is depicted in the figures as a spur gear, other suitable gears may be selected, i.e., a bevel gear, a hypoid gear, a spiral gear, or a face gear.

FIG. **19** is a perspective view of self-piercing screw mechanism **146** in an expanded state. As discussed above, as rod **154** rotates, tab **156** engages keyed shaft **164** within the partial through bore **160** (depicted in FIG. **31**) of self-piercing screw body **158** and imparts rotational force to self-piercing screw body **158**. As self-piercing screw body **158** rotates it engages with either anchor layer **107**, if self-piercing screw body **158** is embedded within superior component **102**; or, anchor layer **109**, if self-piercing screw body **158** is embedded within inferior component **104**. As self-piercing screw body **158** engages either anchor layer **107** or anchor layer **109**, the self-piercing screw body is drawn deeper into, and further engages, the bone material of the adjacent vertebra (e.g., L**3** or L**4**). As self-piercing screw body **158** engages bone material, tab **156** continues to transfer torque to the screw body and slides along keyed shaft **164** with inner radial surface **162** of partial through bore **160**. When the screw body is at its maximum expansion flange **157** abuts retention shoulder **159** preventing the screw body from moving deeper into the bone material of the adjacent vertebra.

FIG. **20** is a side view self-piercing screw mechanism **122** in an unexpanded state. FIG. **21** is a side view of self-piercing screw mechanism **122** in an unexpanded state rotated 90 degrees. FIG. **22** is a cross-sectional view of self-piercing screw mechanism **122** in an unexpanded state, taken generally along line **22-22** in FIG. **21**.

FIG. **23** is a side view self-piercing screw mechanism **122** in an expanded state. FIG. **24** is a side view of self-piercing screw mechanism **122** in an expanded state rotated 90 degrees. FIG. **25** is a cross-sectional view of self-piercing screw mechanism **122** in an expanded state, taken generally along line **25-25** in FIG. **24**.

FIG. **26** is a side view self-piercing screw mechanism **146** in an unexpanded state. FIG. **27** is a side view of self-piercing screw mechanism **146** in an unexpanded state rotated 90 degrees. FIG. **28** is a cross-sectional view of self-piercing screw mechanism **146** in an unexpanded state, taken generally along line **28-28** in FIG. **27**.

FIG. **29** is a side view self-piercing screw mechanism **146** in an expanded state. FIG. **30** is a side view of self-piercing screw mechanism **146** in an expanded state rotated 90 degrees. FIG. **31** is a cross-sectional view of self-piercing screw mechanism **146** in an expanded state, taken generally along line **31-31** in FIG. **30**.

FIG. **32** is a perspective view of an expansion mechanism **166** in an unexpanded state. Expansion mechanism **166** comprises threaded rod **168**, threaded sleeve **170**, a worm drive **172** having a worm **174** and a gear **176**. A portion of threaded rod **168** can be embedded within superior component **102** such that it is rotationally fixed. It should be appreciated that although expansion mechanism **166** is depicted within inferior component **104**, expansion mechanism could be arranged within superior component **102**. During surgery and after device **100** is implanted in disc space **12**, a surgeon can apply torque to worm drive **172** via any device that imparts rotational force upon worm **174** (e.g., a screw driver or impact driver). Torque is transferred 90 degrees through worm drive **172**, via worm **174** and gear **176**. Rotation of gear **176** causes threaded sleeve **170** to rotate. As threaded sleeve **170** rotates, threaded rod remains rotationally locked due to the portion embedded within superior component **102**. As threaded sleeve **170** rotates, the threads of the rotationally locked threaded rod **168** ride upward along the threads within threaded sleeve **170**, this displaces threaded rod, and subsequently superior component **102** in direction D**1**. Threaded rod **168** includes a stopping feature to prevent threaded rod **168** from being ejected from threaded sleeve **170**. For example, the lower portion of threaded rod **168** could be threadless (shown in FIG. **36**), and therefore prevent threaded rod **168** from being ejected from threaded sleeve **170**. When threaded rod **168** reaches its maximum expansion, the unthreaded portion of rod **168** remains within threaded sleeve **170**, preventing threaded rod **168** from being pushed out of threaded sleeve **170**. Alternatively, the stopping feature could be a flange on the recessed portion of threaded rod **168** arranged to engage with a retention shoulder within threaded sleeve **170** in a fully expanded state (not shown in the Figures). It should be appreciated that worm drive **172** could be arranged to transfer torque in other arrangements, i.e., 180 degrees, 270 degrees, or any desirable angle required by the arrangement of worm **174** and gear **176**. It should further be appreciated that although a gear **176** is depicted in the figures as a spur gear, other suitable gears may be selected, i.e., a bevel gear, a hypoid gear, a spiral gear, or a face gear. FIG. **33** is a perspective view of an expansion mechanism **166** in an expanded state.

FIG. **34** is a side view of expansion mechanism **166** in an unexpanded state. FIG. **35** is a side view of expansion mechanism **166** rotated 90 degrees in an expanded state. FIG. **36** is a cross-sectional view of expansion mechanism **166**, taken generally along line **36-36** in FIG. **35**.

FIG. **37** is a perspective view of expansion mechanism **178** in an unexpanded state. Expansion mechanism **178** comprises a gear **180** and a toothed shaft **182**. Gear **180** and toothed shaft **182** are arranged within inferior component **104**; however, they could be arranged within superior component **102** (not shown). During surgery and after device **100** is implanted in disc space **12**, a surgeon can apply torque to gear **180** via any device that imparts rotational force (e.g., a screw driver or impact driver). Torque is transferred 90 degrees through gear **180** to toothed shaft **182**. When gear **180** is rotated in rotational direction RD**2** opposite RD**1**, superior component **102** is displace in direction D**1**. FIG. **38** is a perspective view of expansion mechanism **178** in an expanded state after rotation of gear **180** in direction RD**2**. It should be appreciated that although a gear **180** is depicted in the figures as a spur gear, other suitable gears may be selected, i.e., a bevel gear, a hypoid gear, a spiral gear, or a face gear. FIG. **39** is a side view of expansion mechanism **178** in an unexpanded state. FIG. **40** is a side view of expansion mechanism **178** is an expanded state.

FIG. **41** is a perspective view of stand-alone expandable interbody spinal fusion device **200** in an unexpanded state. Device **200** comprises superior component **202**, inferior component **204**, and expansion mechanisms **206**, **208**, **210**, and **211**, arranged to displace superior component **202** in a first direction D**1** relative to inferior component **204** giving device **200** an expanded height H_2 greater than unexpanded height H_1, self-piercing screw mechanisms **212**, **214**, **216**, and **218**, arranged to engage the bone material of the surrounding vertebra (i.e., L**3** and L**4**). Superior component **202** and inferior component **204** further comprise at least one first aperture **220** arranged to allow fusion between bone fusing material and the adjacent vertebra, and a second aperture **292** located on the front face of device **200** arranged to allow the introduction of bone fusing material into device **200**. Second aperture **292** is illustrated as an arched slot as a non-limiting example, however, it should be appreciated that second aperture **292** could be any suitable aperture that would allow for the introduction of bone fusing material into device **200**. Superior component **202** has a first surface **203** and inferior component **204** has a first surface **205**. Embedded within the superior component, beneath surface **203**, or above surface **203** (not depicted in FIG. **41**), there is an anchor layer **207**. Embedded within the inferior component, beneath surface **205**, or above surface **205** (not depicted in FIG. **41**), there is an anchor layer **209**. Self-piercing screw mechanisms **212**, **214**, **216**, and **218** can comprise the embodiment of either self-piercing screw mechanism **122** (as described supra) or self-piercing screw mechanism **146** (as described supra). Expansion mechanisms **206**, **208**, **210**, and **211** can comprise the embodiment of either expansion mechanism **166** or **178** (as described infra).

FIG. **42** is a perspective view of stand-alone expandable interbody spinal fusion device **200**, in an expanded state. During surgery and after device **200** is implanted into disc space **12**, a surgeon can apply torque to expansion mechanisms **206**, **208**, **210** and **211** via any device that imparts rotational force (e.g., a screw driver or impact driver). The rotational force causes expansion mechanisms **206**, **208**, **210** and **211** to displace superior component **202** in direction D**1** relative to inferior component **204**, giving device **200** an expanded height H_2 greater than H_1. This embodiment of the implant differs from stand-alone expandable interbody spinal fusion device **100**, as illustrated in FIGS. **10** and **11**, in that it has an additional expansion mechanism, and there are two gear shafts **226** and **250** in place of individual worms **126** or **150**. Gear shaft **226** is arranged to engage expansion mechanisms **206** and **210**, and gear shaft **250** is arranged to engage expansion mechanisms **208** and **211**. Although not shown in FIG. **41** or **42** it is possible to vary the thread ratio of each expansion mechanism allowing for an uneven expansion of superior component **202**.

FIG. **43** is a perspective view of stand-alone expandable interbody spinal fusion device **300** in an unexpanded state. Device **300** comprises superior component **302**, inferior component **304**, and expansion mechanisms **306**, **308**, **310**, and **311**, arranged to displace superior component **302** in a first direction D**1** relative to inferior component **304** giving device **300** an expanded height H_2 greater than unexpanded height H_1, self-piercing screw mechanisms **312**, **314**, **316**, and **318**, arranged to engage the bone material of the surrounding vertebra (i.e., L**3** and L**4**). Superior component **302** and inferior component **304** comprise at least one first aperture **320** arranged to allow fusion between bone fusing material and the adjacent vertebra, and a second aperture **392** located on the front face of device **300** and arranged to allow the introduction of bone fusing material into device **300**. Second aperture **392** is illustrated as an arched slot as a non-limiting example, however, it should be appreciated that second aperture **392** could be any suitable aperture that would allow for the introduction of bone fusing material into device **300**. Superior component **302** has a first surface **303** and inferior component **304** has a first surface **305**. Embedded within the superior component, beneath surface **303**, or above surface **303** (not depicted in FIG. **43**), there is an anchor layer **307**. Embedded within the inferior component, beneath surface **305**, or above surface **305** (not depicted in FIG. **43**), there is an anchor layer **309**. Self-piercing screw mechanisms **312**, **314**, **316**, and **318** can comprise the embodiment of either self-piercing screw mechanism **122** (as described supra) or self-piercing screw mechanism **146** (as described supra).

FIG. **44** is a perspective view of stand-alone expandable interbody spinal fusion device **300**, in an expanded state. Expansion mechanisms **306**, **308**, **310** and **311**, are fully extended giving device **300** an expanded height H_2, greater than H_1. This embodiment of the implant differs from stand-alone expandable interbody spinal fusion device **200**, as illustrated in FIGS. **41** and **42**, in that expansion mechanisms **306**, **308**, **310**, and **311**, comprise the embodiment of expansion mechanism **178** illustrated in FIGS. **37-40**. Additionally gear shaft **326** is arranged to engage expansion mechanisms **306** and **310**, and gear shaft **350** is arranged to engage expansion mechanisms **308** and **311**. Due to the gear shafts needing to start in a position closer to superior component **302**, as illustrated in previous embodiments, cutouts are shown on the proximate surface of superior component **302**, so that the gears of the expansion mechanisms can be accessed when device **300** is in an unexpanded state.

FIG. **45** is a perspective view of stand-alone expandable interbody spinal fusion device **400** in an unexpanded state. Device **400** comprises superior component **402**, inferior component **404**, expansion mechanism **406** arranged to displace superior component **402** in a first direction D**1** relative to inferior component **404**, self-piercing screw mechanisms **412**, **414**, **416**, and **418**, arranged to engage the bone material of the surrounding vertebra (i.e., L**3** and L**4**). Superior component **402** and inferior component **404** further comprise at least one first aperture **420** arranged to allow fusion between bone fusing material and the adjacent vertebra. Superior component **402** has a first surface **403** and inferior component **404** has a first surface **405**. Embedded within the superior component, beneath surface **403**, or above surface **403** (not depicted in FIG. **45**), there is an anchor layer **407**. Embedded within the inferior component, beneath surface **405**, or above surface **405** (not depicted in FIG. **45**), there is an anchor layer **409**. Although not illustrated in FIG. **45**, it should be appreciated that threaded inserts such as threaded inserts **813**, **815**, **817**, and **819** described infra, can be used in place of anchor layers **407** and **409** to provide sufficient leverage for the screw mechanisms to pierce the bone material of adjacent vertebra. Self-piercing screw mechanisms **412**, **414**, **416**, and **418** can comprise the embodiment of either self-piercing screw mechanism **122** (as described supra) or self-piercing screw mechanism **146** (as described supra). Device **400** further comprises hinge **484** fixedly secured to superior component **402** and inferior component **404** and arranged to rotatably displace the superior component about axis of rotation AR. Expansion mechanism **406** is preferably expansion mechanism **166** described supra.

FIG. **46** is a perspective view of stand-alone expandable interbody spinal fusion device **400** in an expanded state. As discussed above, expansion mechanism **406** is arranged to displace superior component in a first direction D**1**. In this embodiment expansion mechanism **406** is not partially embedded within superior component **402**. Instead, expansion mechanism **406** is illustrated with a rounded tip, such that during expansion the rounded tip can slide along the inner surface of the superior component. This allows expansion mechanism **406** to fully expand in direction D**1** without binding due to the angular displacement of superior component **402**.

FIG. **47** is a front view stand-alone expandable interbody spinal fusion device **400**, in an unexpanded state. FIG. **48** is a side view of stand-alone expandable interbody spinal fusion device **400**, in an unexpanded state. FIG. **49** is a front view stand-alone expandable interbody spinal fusion device **400**, in an expanded state. FIG. **50** is a side view of stand-alone expandable interbody spinal fusion device **400**, in an expanded state.

FIG. **51** is a partial cross-sectional view of stand-alone expandable interbody spinal fusion device **400**, in an unexpanded state. The self-piercing screw mechanisms **412**, **414**, **416**, and **418**, are engaged first to secure device **400** from shifting in disc space **12**. Once self-piercing screw mechanisms **412**, **414**, **416**, and **418** are engaged. Expansion mechanism **406** is utilized to displace superior component **402** in direction D**1** and expand device **400**.

FIG. **52** is a partial cross-sectional view of stand-alone expandable interbody spinal fusion device **400**, in an expanded state. FIG. **53** is a partial cross-sectional front view stand-alone expandable interbody spinal fusion device

400, in an unexpanded state. FIG. **54** is a partial cross-sectional front view of stand-alone expandable interbody spinal fusion device **400**, in an expanded state.

FIG. **55** is a partial cross-sectional front view of stand-alone expandable interbody spinal fusion device **500**, in an unexpanded state. Device **500** is comprised of the same elements as device **400**. Device **500** comprises superior component **502** and inferior component **504**, and expansion mechanism **506**. Superior component **502** and inferior component **504** further comprise at least one first aperture **520** (not shown in FIG. **55**) arranged to allow fusion between bone fusing material and the adjacent vertebra. Device **500** further comprises self-piercing screw mechanisms **512**, **514**, **516**, and **518**. Superior component **502** has a first surface **503** and inferior component **504** has a first surface **505**. Embedded within the superior component, beneath surface **503**, or above surface **503** (not depicted in FIG. **55**), there is an anchor layer **507**. Embedded within the inferior component, beneath surface **505**, or above surface **505** (not depicted in FIG. **55**), there is an anchor layer **509**. Although not illustrated in FIG. **55**, it should be appreciated that threaded inserts such as threaded inserts **813**, **815**, **817**, and **819** described infra, can be used in place of anchor layers **507** and **509** to provide sufficient leverage for the screw mechanisms to pierce the bone material of adjacent vertebra. Self-piercing screw mechanisms **512**, **514**, **516**, and **518** can comprise the embodiment of either self-piercing screw mechanism **122** (as described supra) or self-piercing screw mechanism **146** (as described supra). Device **500** further comprises hinge **584** (not shown in FIG. **55**) fixedly secured to superior component **502** and inferior component **504** and arranged to rotatably displace the superior component about axis of rotation AR. Device **500** differs from device **400** in that the superior component **502** and inferior component **504** each have a have a sinusoidal cross-section, inversely arranged with respect to each other such that in the unexpanded state, superior component **502** and inferior component **504** slidingly engage each other. FIG. **56** is a partial cross-sectional front view of stand-alone expandable interbody spinal fusion device **500**, in an expanded state.

FIG. **57** is a partial cross-sectional front view of stand-alone expandable interbody spinal fusion device **600**, in an unexpanded state. Device **600** differs from device **500** as illustrated in FIGS. **55** and **56**, in that it has two distinct expansion mechanisms **606**, and **608**, arranged to displace superior component **602** in direction D**1** relative to inferior component **604**. Superior component **602** and inferior component **604** further comprise at least one first aperture **620** (not shown in FIG. **57**) arranged to allow fusion between bone fusing material and the adjacent vertebra. Device **600** further comprises self-piercing screw mechanisms **612**, **614**, **616**, and **618**. Superior component **602** has a first surface **603** and inferior component **604** has a first surface **605**. Embedded within the superior component, beneath surface **603**, or above surface **603** (not depicted in FIG. **57**), there is an anchor layer **607**. Embedded within the inferior component, beneath surface **605**, or above surface **605** (not depicted in FIG. **57**), there is an anchor layer **609**. Although not illustrated in FIG. **57** it should be appreciated that threaded inserts such as threaded inserts **813**, **815**, **817**, and **819** described infra, can be used in place of anchor layers **607** and **609** to provide sufficient leverage for the screw mechanisms to pierce the bone material of adjacent vertebra. Self-piercing screw mechanisms **612**, **614**, **616**, and **618** can comprise the embodiment of either self-piercing screw mechanism **122** (as described supra) or self-piercing screw mechanism **146** (as described supra). FIG. **58** is a partial cross-sectional front view of stand-alone expandable interbody spinal fusion device **600**, in an expanded state.

FIG. **59** is a perspective view of a stand-alone expandable interbody spinal fusion device **700**, in an expanded state. Device **700** comprises expansion mechanisms **706**, **708**, **710** and **711** each having a worm **726** and arranged to displace superior component **702** in direction D**1** relative to inferior component **704**. Device **700** differs from previous embodiments in that the superior component **702** and inferior component **704** are formed in the shape of a horseshoe. Device **700** further comprises self-piercing screw mechanisms **712**, **714**, **716**, and **718**. Superior component **702** has a first surface **703** and inferior component **704** has a first surface **705**. Embedded within the superior component, beneath surface **703**, or above surface **704** (not depicted in FIG. **59**), there is an anchor layer **707** (not shown in FIG. **59**). Embedded within the inferior component, beneath surface **705**, or above surface **705** (not depicted in FIG. **59**), there is an anchor layer **709** (not shown in FIG. **59**). Although not illustrated in FIG. **59**, it should be appreciated that threaded inserts such as threaded inserts **813**, **815**, **817**, and **819** described infra, can be used in place of anchor layers **707** and **709** to provide sufficient leverage for the screw mechanisms to pierce the bone material of adjacent vertebra. Self-piercing screw mechanisms **712**, **714**, **716**, and **718** can comprise the embodiment of either self-piercing screw mechanism **122** (as described supra) or self-piercing screw mechanism **146** (as described supra). FIG. **60** is a cross-sectional view of stand-alone expandable interbody spinal fusion device **700**, in an expanded state taken along line **60-60** in FIG. **59**.

FIG. **61** is a perspective view of stand-alone expandable interbody spinal fusion device **800** in an unexpanded state. Device **800** comprises superior component **802**, inferior component **804**, expansion mechanisms **806**, **808**, **810**, and **811**, arranged to displace superior component **802** in a first direction D**1** relative to inferior component **804** giving device **800** an expanded height H_2 greater than unexpanded height H_1, self-piercing screw mechanisms **812**, **814**, **816**, and **818**, arranged to engage the bone material of the surrounding vertebra (i.e., L3 and L**4**). Superior component **802** has a first surface **803** and inferior component **804** has a first surface **805** (shown n FIGS. **64** and **66**). Superior component **802** and inferior component **804** further comprise at least one first aperture **820** arranged to allow fusion between bone fusing material and the adjacent vertebra, and a second aperture **892** located on the front face of device **800** and arranged to allow the introduction of bone fusing material into device **800**. Second aperture **892** is illustrated as an arched slot as a non-limiting example, however, it should be appreciated that second aperture **892** could be any suitable aperture that would allow for the introduction of bone fusing material into device **800**. Superior component **802** further comprises threaded inserts **813**, **815**, **817**, and **819**. Threaded inserts **813**, and **815** are fixedly secured within superior component **802**, and threaded inserts **817** and **819** are fixedly secured within inferior component **804**. Self-piercing screw mechanisms **812**, **814**, **816**, and **818** engage with the threads of the threaded inserts giving the self-piercing screw bodies the needed leverage to engage with the bone material of the adjacent vertebra. Threaded inserts **813**, **815**, **817**, and **819** can be made of titanium or other suitable material that is more dense than the metal used in the threading of the self-piercing screws. Self-piercing screw mechanisms **812**, **814**, **816**, and **818** can comprise the embodiment of either self-piercing screw mechanism **122** (as described supra) or self-piercing screw mechanism **146** (as described supra).

FIG. **62** is a perspective view of stand-alone expandable interbody spinal fusion device **800**, in an expanded state. During surgery and after device **800** is implanted into disc space **12**, a surgeon can apply torque to expansion mechanisms expansion mechanisms **806**, **808**, **810** and **811** via any device that imparts rotational force (e.g., a screw driver or impact driver). The rotational force causes expansion mechanisms **806**, **808**, **810** and **811** to displace superior component **802** in direction D**1** relative to inferior component **804** giving device **200** an expanded height H_2 greater than H_1. This embodiment of the implant differs from stand-alone expandable interbody spinal fusion device **200**, as illustrated in FIGS. **41** and **42**, in that instead of anchor layers **207** and **209**, each screw mechanism threads itself through threaded inserts **813**, **815**, **817**, and **819**. Although not shown in FIG. **61** or **62** it is possible to vary the thread ratio of each expansion mechanism allowing for an uneven expansion of superior component **802**.

FIG. **63** is a front view of stand-alone expandable interbody spinal fusion device **800**, in an unexpanded state having an unexpanded height H_1. FIG. **64** is a side view stand-alone expandable interbody spinal fusion device **800**, in an unexpanded state having an unexpanded height H_1. FIG. **64** illustrates the cross section along line **64-64** in FIG. **63**. FIG. **64** shows the cross section through self-piercing screw mechanism **814** fixedly secured within superior component **802**, and self-piercing screw mechanism **818** fixedly secured within inferior component **804**. Further, FIG. **64** illustrates the cross section of threaded inserts **815** operatively arranged to engage self-piercing screw mechanism **814**, and threaded insert **819** operatively arranged to engage self-piercing screw mechanism **818**.

FIG. **65** is a front view stand-alone expandable interbody spinal fusion device **800**, in an expanded state having an expanded height H_2, greater than H_1. FIG. **66** is a front view stand-alone expandable interbody spinal fusion device **800**, in an expanded state having an expanded height H_2, greater than H_1. As torque is transferred through self-piercing screw mechanisms **814** and **818**, the threads of the self-piercing screw mechanisms engage with the threads on the inner radial surface of threaded inserts **815** and **819**. This engagement provides the self-piercing screw bodies the necessary leverage to engage with the adjacent vertebra.

FIG. **67** is an expanded view of area **67** in FIG. **66**. FIG. **67** shows self-piercing screw mechanism **814** within superior component **802**, of stand-alone expandable interbody spinal fusion device **800**. Threaded insert **815** is shown fixedly secured within superior component **802**, and arranged to engage with the threads of self-piercing screw mechanism **814**. Threaded insert **815** acts as a leverage point for self-piercing screw mechanism **814**, providing the force necessary for self-piercing screw mechanism **814** to engage with adjacent vertebra.

FIG. **68** illustrates a non-limiting example of self-driving screw body tip **986** that can be used as the tip of the various screw mechanisms illustrated in this disclosure. FIG. **69** illustrates a non-limiting example of self-tapping screw body tip **988** that can be used as the tip of the various screw mechanisms illustrated in this disclosure. FIG. **70** illustrates a non-limiting example of self-piercing body tip **990** that can be used as the tip of the various screw mechanisms illustrated in this disclosure.

FIG. **71**A is a perspective view of stand-alone expandable interbody spinal fusion device **1100**, in an unexpanded state. FIG. **71**B is a perspective view of stand-alone expandable interbody spinal fusion device **1100**, in an expanded state. Stand-alone expandable interbody spinal fusion device **1100** comprises superior component **1110**, inferior component **1120**, and at least one expansion mechanism, for example, expansion mechanism **1140**, **106**, **108**, **166**, **178**, **206**, **208**, **306**, **308**, **406**, **506**, **606**, **706**, **708**, **806**, **808**. It should be appreciated that any of the expansion mechanisms disclosed in FIGS. **1-72**B may be used as the expansion mechanism of stand-alone expandable interbody spinal fusion device **1100**. Additionally, although not shown in FIGS. **71**A-B, stand-alone expandable interbody spinal fusion device **1100** may further comprise one or more screw mechanism. For example, any of the screw mechanisms disclosed in FIGS. **1-72**B may be used in stand-alone expandable interbody spinal fusion device **1100** to fixedly secure superior component **1110** and/or inferior component **1120** to an adjacent vertebra.

Superior component **1110** comprises outermost surface **1112** operatively arranged to engage a vertebra and innermost surface **1114**. Superior component **1110** further comprises at least one aperture, for example apertures **1116** and **1118**, which extends from innermost surface **1114** to outermost surface **1112**. In some embodiments, superior component **1110** further comprises holes extending from surface **1114** in which expansion mechanisms **1140** engage. In some embodiments, superior component **1110** further comprises holes that engage threaded rods **1142**, such holes having a counterbore that at least partially engages collar **1180** (i.e., collar **1180** is at least partially embedded in superior component **1110**). In some embodiments, and as previously described, superior component **1110** comprises at least one screw mechanism that is operatively arranged to protrude out through outer surface **1112** and engage an adjacent vertebra to fixedly secure stand-alone expandable interbody spinal fusion device **1100** to that vertebra.

Inferior component **1120** comprises outermost surface **1122** operatively arranged to engage a vertebra and innermost surface **1124**. Inferior component **1120** further comprises at least one aperture, for example apertures **1126** and **1128**, which extends from innermost surface **1124** to outermost surface **1122**. In some embodiments, inferior component **1120** further comprises holes extending from surface **1124** in which expansion mechanisms **1140** engage. In some embodiments, and as previously described, inferior component **1120** comprises at least one screw mechanism that is operatively arranged to protrude out through outer surface **1122** and engage an adjacent vertebra to fixedly secure stand-alone expandable interbody spinal fusion device **1100** to that vertebra.

In some embodiments, and as shown, stand-alone expandable interbody spinal fusion device **1100** comprises four expansion mechanisms **1140** arranged approximately at four corners of the implant. Each expansion mechanism **1140** comprises its own worm **1160**. Such embodiments enable the doctor to selectively expand stand-alone expandable interbody spinal fusion device **1100**. For example, stand-alone expandable interbody spinal fusion device **1100** may be expanded such that surface **1112** is non-parallel (or parallel) to surface **1122**. In some embodiments, one worm **1160** may engage two or more expansion mechanisms **1140**, for example, as shown in FIGS. **41-44**.

FIG. **72**A is a perspective view of expansion mechanism **1140** in an unexpanded state (i.e., stand-alone expandable interbody spinal fusion device **1100** is unexpanded as shown in FIG. **71**A). FIG. **72**B is a perspective view of expansion mechanism **1140** in an expanded state (i.e., stand-alone expandable interbody spinal fusion device **1100** is unexpanded as shown in FIG. **71**B). Expansion mechanism **1140** comprises threaded rod **1142**, gear **1150**, collar **1180**, and worm **1160**. Threaded rod **1142** comprises first end **1144**, second end **1146**, and threading **1148**. First end **1144** is arranged to engage superior component **1110**. Second end **1146** is fixedly secured to gear **1150**. Gear **1152** is arranged generally perpendicular to threaded rod **1142** and comprises teeth **1152**. Gear **1152** is rotatably connected to inferior component **1120**. Worm **1160** comprises threading **1162** that engages teeth **1152** such that, as worm **1160** is rotated in a first circumferential direction, gear **1150** rotates in a second circumferential direction. It should be appreciated that worm **1160** and gear **1150** together form worm drive **1170**. Worm **1160** is rotatably connected to inferior component **1120** and may be at least partially embedded therein. Collar **1180** is threadably engaged with threaded rod **1142**. Collar **1180** comprises threaded hole **1182** and surface **1184** engaged with superior component **1110**. In some embodiments, surface **1184** is engaged with surface **1114**. In some embodiments, collar **1180** is at least partially embedded in superior component **1110**. As gear **1150** and threaded rod **1142** rotate, collar **1180** (being non-rotatably engaged with superior component **1110**) is displaced axially up and down along threaded rod **1142** thereby expanding and contracting stand-alone expandable interbody spinal fusion device **1100**. Thus, by use of a tool (e.g., screw driver), a doctor can expand and contract stand-alone expandable interbody spinal fusion device **1100** by turning worm **1160**. Additionally, the use of multiple expansion mechanisms arranged at various locations within stand-alone expandable interbody spinal fusion device **1100** enables the doctor to expand stand-alone expandable interbody spinal fusion device **1100** at various heights (i.e., such that superior component **1110** is not necessarily parallel to inferior component **1120**).

It will be appreciated that various aspects of the disclosure above and other features and functions, or alternatives thereof, may be desirably combined into many other different systems or applications. Various presently unforeseen or unanticipated alternatives, modifications, variations, or improvements therein may be subsequently made by those skilled in the art which are also intended to be encompassed by the following claims.

LIST OF REFERENCE NUMERALS

10 Spinal column
C**1**-C**7** Cervical vertebrae
T**1**-T**9** Thoracic vertebrae
L**1**-L**5** Lumbar vertebrae
S Sacrum
C Coccyx
D**1** Direction
D_{L1-L2} Disc
D_{L2-L3} Disc
D_{L3-L4} Disc
D_{L4-L5} Disc
F Facet
FJ Facet joint
h_1 Collapsed height
h_2 Expanded height
SP Spinous process
TP Transverse process
IF Intervertebral foramen
A Annulus
AR Axis of rotation
N Nucleus
NC Neural canal
H_1 Unexpanded height
H_2 Expanded height
RD**1** Rotational direction **1**
RD**2** Rotational direction **2**
12 Disc space
100 Stand-alone expandable interbody spinal fusion device
102 Superior component
103 Superior component surface
104 Inferior component
105 Inferior component surface
106 First expansion mechanism
107 Anchor layer
108 Second expansion mechanism
109 Anchor layer
110 Third expansion mechanism
112 First self-piercing screw mechanism
114 Second self-piercing screw mechanism
116 Third self-piercing screw mechanism
118 Fourth self-piercing screw mechanism
120 First aperture
122 Self-piercing screw—first embodiment
124 Worm drive
126 Worm
128 Gear
130 Drive casing
132 Inner radial surface
134 Keyed shaft
136 Outer radial surface
138 First end
140 Second end
142 Self-piercing screw body
144 Tab
146 Self-piercing screw—second embodiment
148 Worm Drive
150 Worm
152 Gear
154 Rod
156 Tab
157 Flange
158 Self-piercing screw body
159 Retention shoulder
160 Partial through bore
162 Inner radial surface
164 Keyed shaft
166 Expansion mechanism—first embodiment
168 Threaded Rod
170 Threaded Sleeve
172 Worm Drive
174 Worm
176 Gear
178 Expansion mechanism—second embodiment
180 Gear
182 Toothed Shaft
192 Second aperture
200 Stand-alone expandable interbody spinal fusion device
202 Superior component
203 Superior component surface
204 Inferior component
205 Inferior component surface
206 First expansion mechanism
207 Anchor layer
208 Second expansion mechanism
209 Anchor layer
210 Third expansion mechanism
211 Fourth expansion mechanism
212 First self-piercing screw mechanism

214 Second self-piercing screw mechanism
216 Third self-piercing screw mechanism
218 Fourth self-piercing screw mechanism
220 First aperture
226 Gear shaft
250 Gear shaft
292 Second Aperture
300 Stand-alone expandable interbody spinal fusion device
302 Superior component
303 Superior component surface
304 Inferior component
305 Inferior component surface
306 First expansion mechanism
307 Anchor layer
308 Second expansion mechanism
309 Anchor layer
310 Third expansion mechanism
311 Fourth expansion mechanism
312 First self-piercing screw mechanism
314 Second self-piercing screw mechanism
316 Third self-piercing screw mechanism
318 Fourth self-piercing screw mechanism
320 First aperture
326 Gear shaft
350 Gear shaft
392 Second aperture
400 Stand-alone expandable interbody spinal fusion device
402 Superior component
403 Superior component surface
404 Inferior component
405 Inferior component surface
406 First expansion mechanism
407 Anchor layer
409 Anchor layer
412 First self-piercing screw mechanism
414 Second self-piercing screw mechanism
416 Third self-piercing screw mechanism
418 Fourth self-piercing screw mechanism
420 First aperture
484 Hinge
492 Second aperture
500 Stand-alone expandable interbody spinal fusion device
502 Superior component
503 Superior component surface
504 Inferior component
505 Inferior component surface
506 First expansion mechanism
507 Anchor layer
509 Anchor layer
512 First self-piercing screw mechanism
514 Second self-piercing screw mechanism
516 Third self-piercing screw mechanism
518 Fourth self-piercing screw mechanism
520 First aperture
584 Hinge
592 Second aperture
600 Stand-alone expandable interbody spinal fusion device
602 Superior component
603 Superior component surface
604 Inferior component
605 Inferior component surface
606 First expansion mechanism
607 Anchor layer
609 Anchor layer
612 First self-piercing screw mechanism
614 Second self-piercing screw mechanism
616 Third self-piercing screw mechanism

618 Fourth self-piercing screw mechanism
620 First aperture
684 Hinge
692 Second aperture
700 Stand-alone expandable interbody spinal fusion device
702 Superior component
703 Superior component surface
704 Inferior component
705 Inferior component surface
706 First expansion mechanism
708 Second expansion mechanism
710 Third expansion mechanism
711 Fourth expansion mechanism
712 First self-piercing screw mechanism
714 Second self-piercing screw mechanism
716 Third self-piercing screw mechanism
718 Fourth self-piercing screw mechanism
726 Gear shaft
800 Stand-alone expandable interbody spinal fusion device
802 Superior component
804 Inferior component
806 First expansion mechanism
808 Second expansion mechanism
810 Third expansion mechanism
811 Fourth expansion mechanism
812 First self-piercing screw mechanism
813 First threaded insert
814 Second self-piercing screw mechanism
815 Second threaded insert
816 Third self-piercing screw mechanism
817 Third threaded insert
818 Fourth self-piercing screw mechanism
819 Fourth threaded insert
820 First aperture
826 Gear shaft
850 Gear shaft
892 Second aperture
986 Self-drilling screw body tip
988 Self-tapping screw body tip
990 Self-piercing screw body tip
1100 Stand-alone expandable interbody spinal fusion device
1110 Superior component
1112 Surface
1114 Surface
1116 Aperture
1118 Aperture
1120 Inferior component
1122 Surface
1124 Surface
1126 Aperture
1128 Aperture
1140 Expansion mechanism
1142 Threaded rod
1144 End
1146 End
1148 Threading
1150 Gear
1152 Teeth
1160 Worm
1162 Threading
1170 Worm drive
1180 Collar
1182 Threaded hole
1184 Surface

What is claimed is:

1. A stand-alone expandable interbody spinal fusion device, comprising:

a superior component;

an inferior component; and,

an expansion mechanism operatively arranged to displace the superior component relative to the inferior component, the expansion mechanism including a threaded rod including a first end engaged with the superior component and a second end engaged with the inferior component;

wherein when the threaded rod is rotated in a first circumferential direction, the superior component is displaced in a first direction relative to the inferior component.

2. The stand-alone expandable interbody spinal fusion device as recited in claim **1**, wherein:

the expansion mechanism further comprises a gear rotatably connected to the inferior component; and,

the second end is fixedly secured to the gear.

3. The stand-alone expandable interbody spinal fusion device as recited in claim **2**, wherein the superior component comprises a threaded hole and the threaded rod is threadably engaged with the threaded hole.

4. The stand-alone expandable interbody spinal fusion device as recited in claim **2**, wherein the expansion mechanism further comprises a threaded collar threadably engaged with the threaded rod.

5. The stand-alone expandable interbody spinal fusion device as recited in claim **4**, wherein the threaded collar abuts against the superior component.

6. The stand-alone expandable interbody spinal fusion device as recited in claim **2**, wherein the expansion mechanism further comprises a worm rotatably connected to the inferior component and engaged with the gear.

7. The stand-alone expandable interbody spinal fusion device as recited in claim **1**, wherein the superior component comprises at least one aperture and the inferior component comprises at least one aperture.

8. The stand-alone expandable interbody spinal fusion device as recited in claim **1**, wherein when the threaded rod is rotated in a second circumferential direction, opposite the first circumferential direction, the superior component is displaced in a second direction relative to the inferior component.

9. A stand-alone expandable interbody spinal fusion device, comprising:

an inferior component including a first inward facing surface and a first outward facing surface;

a superior component including a second inward facing surface and a second outward facing surface; and,

an expansion mechanism, including:

a gear rotatably connected to the inferior component; and,

a threaded rod including a first end engaged with the superior component and a second end fixedly secured to the gear;

wherein when the threaded rod is rotated in a first circumferential direction, the superior component is displaced in a first direction relative to the inferior component.

10. The stand-alone expandable interbody spinal fusion device as recited in claim **9**, wherein the superior component comprises a threaded hole and the threaded rod is threadably engaged with the threaded hole.

11. The stand-alone expandable interbody spinal fusion device as recited in claim **9**, wherein the expansion mechanism further comprises a threaded collar threadably engaged with the threaded rod.

12. The stand-alone expandable interbody spinal fusion device as recited in claim **11**, wherein the threaded collar abuts against the superior component.

13. The stand-alone expandable interbody spinal fusion device as recited in claim **11**, wherein the threaded collar is at least partially embedded in the superior component.

14. The stand-alone expandable interbody spinal fusion device as recited in claim **9**, wherein the expansion mechanism further comprises a worm rotatably connected to the inferior component and engaged with the gear.

15. The stand-alone expandable interbody spinal fusion device as recited in claim **9**, wherein the inferior component comprises at least one aperture extending from the first inward facing surface to the first outward facing surface and the superior component comprises at least one aperture extending from the second inward facing surface to the second outward facing surface.

16. The stand-alone expandable interbody spinal fusion device as recited in claim **9**, wherein when the threaded rod is rotated in a second circumferential direction, opposite the first circumferential direction, the superior component is displaced in a second direction relative to the inferior component.

17. A stand-alone expandable interbody spinal fusion device, comprising:

an inferior component including a first inward facing surface and a first outward facing surface;

a superior component including a second inward facing surface and a second outward facing surface; and,

an expansion mechanism, including:

a gear rotatably connected to the inferior component; and,

a threaded rod including a first end threadably engaged with the superior component and a second end fixedly secured to the gear;

wherein when the threaded rod is rotated the superior component is displaced relative to the inferior component.

18. The stand-alone expandable interbody spinal fusion device as recited in claim **17**, wherein the threaded rod is threadably engaged with the superior component via a threaded collar, the threaded collar operatively arranged to abut against the second inward facing surface.

19. The stand-alone expandable interbody spinal fusion device as recited in claim **17**, wherein the expansion mechanism further comprises a worm engaged with the gear.

20. The stand-alone expandable interbody spinal fusion device as recited in claim **17**, wherein the superior component comprises a threaded hole extending from the second inward facing surface and the threaded rod is threadably engaged with the threaded hole.

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