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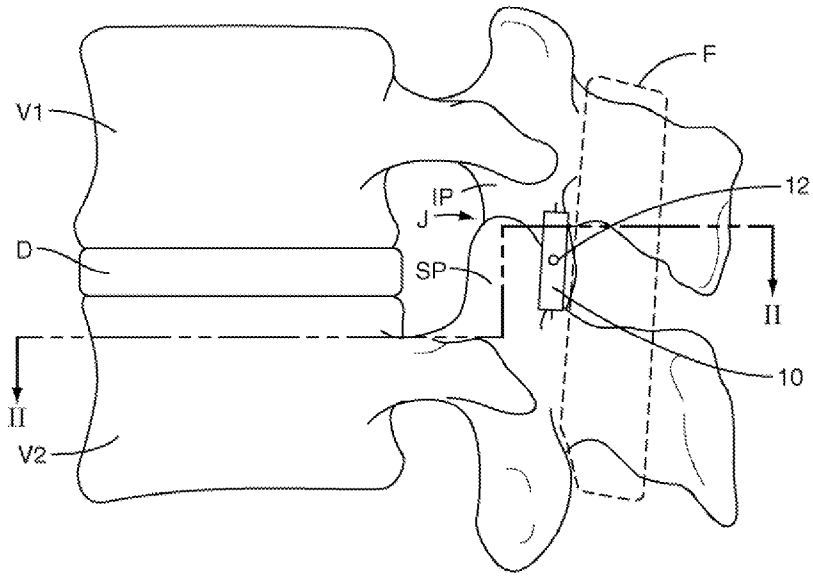
(54) **Title:** FACET FUSION IMPLANTS AND METHODS OF USE



(57) **Abstract:** ABSTRACT An implant is insertable onto a vertebral facet joint includes a body with an inner surface that mates with one or both articular processes of the facet joint. The inner surface may define an interior cavity that accepts at least a portion of an inferior articular process and a superior articular process forming the facet joint. The body may be constructed of a bone growth material that fuses with the articular processes. The implant may help retain bone growth promoting substance that is inserted between or on articulating surfaces of the facet joint. A receiving portion of an exterior surface of one or both articular process may be prepared to stimulate bone growth. The implant may be placed onto the receiving portion to cover an exterior junction between or on the articulating surfaces of the facet joint. The implant may be secured to one or both of the articular processes.

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FACET FUSION IMPLANTS AND METHODS OF USE

Background

The human spine serves many functions. The vertebral members of the spinal column protect the spinal cord. The spinal column also supports other portions of the human body. Furthermore, moveable facet joints and resilient discs disposed between the vertebral members permit motion between individual vertebral members. Each vertebrae includes an anterior body and a posterior arch. The posterior arch includes two pedicles and two laminae that join together to form the spinous process. A transverse process is laterally positioned at the transition from the pedicles to the laminae. Both the spinous process and transverse process provide for attachment of fibrous tissue, including muscle. Two inferior articular processes extend downward from the junction of the laminae and the transverse process. Further, two superior articular processes extend upward from the junction. The articular processes of adjacent vertebrae form the facet joints. The inferior articular process of one vertebra articulates with the superior articular process of the vertebra below. The facet joints are gliding joints because the articular surfaces glide over each other.

Vertebral implants are often used in the surgical treatment of spinal disorders such as degenerative disc disease, disc herniations, curvature abnormalities, and trauma. Many different types of treatments are used. In some cases, spinal fusion is indicated to inhibit relative motion between vertebral bodies. Spinal fusion often involves the removal of the vertebral disc and insertion of an interbody implant to create a fused junction between a pair of vertebral bodies. Furthermore, the facet joints may be fused to complete the fusion between vertebral pairs. Facet fusion often involves destruction of the facet by decorticating the opposing articulating surfaces and packing bone growth promoting substances such as grafts or synthetic materials into the space between the articular processes. The facet joints are generally small as compared to the intervertebral space. Consequently, limited amounts of bone-growth promoting substances may be inserted into the joint. Some of the bone-growth promoting substances tend to disperse post-operatively resulting in a less robust fusion. Furthermore, the overlying fibrous tissue may

further disperse the bone-growth promoting substances as a result of contact, friction, and/or the ingrowth of fibrous mass. These and other factors may result in pseudarthrosis or inadequate fusion.

Summary

Illustrative embodiments disclosed herein are directed to an implant that is insertable onto a vertebral facet joint. The implant includes a body with an inner bone-contact surface that is configured to fuse with the articular processes. The inner surface may define an interior cavity that is configured to accept at least a portion of an inferior articular process and a superior articular process forming the facet joint. The inner surface may include curved and/or planar portions. The body may be constructed of a bone growth material that fuses with the articular processes. The implant body may be constructed from manufactured materials that include bone growth promoting materials and/or bone ingrowth promoting features.

The implant may be used in conjunction with bone growth promoting materials that are packed into the facet joint. The implant may help retain the bone growth promoting substance between the articulating surfaces of the facet joint. The implant may also protect the bone growth promoting substance from adjacent muscle compression and fibrous tissue invasion and may improve bone fusion rate and size of the fusion mass. A receiving portion of an exterior surface of one or both articular process may be prepared to stimulate bone growth. The implant may be placed onto the receiving portion to cover an exterior junction between the articulating surfaces of the facet joint. The implant may be secured to one or both of the articular processes. For example, the implant may be staked, pinned, screwed, or adhered to the exterior of one or both articular processes.

Brief Description of the Drawings

Figure 1 is a lateral view of a facet implant according to one embodiment shown relative to vertebral bodies;

Figure 2 is a section view according to the section lines in Figure 1;

Figure 3 is a detail view of a facet joint showing one embodiment of a facet implant;

Figure 4 is a perspective view of a facet implant according to one embodiment;

Figure 5 is a detail view of a facet joint showing the preparation of a receiving area about the exterior of the articular processes according to one embodiment;

Figure 6 is a detail view of a facet joint showing one embodiment of a facet implant;

Figure 7 is a detail view of a facet joint showing one embodiment of a facet implant;

Figure 8 is a perspective view of a facet implant according to one embodiment;

Figure 9 is a detail view of a facet joint showing the preparation of a receiving area about the exterior of the articular processes according to one embodiment;

Figure 10 is a detail view of a facet joint showing one embodiment of a facet implant;

Figure 11 is a perspective view of a facet implant according to one embodiment;

Figure 12 is a detail view of a facet joint showing the preparation of a receiving area about the exterior of the articular processes according to one embodiment;

Figure 13 is a detail view of a facet joint showing one embodiment of a facet implant;

Figure 14 is a perspective view of a facet implant according to one embodiment;

Figure 15 is a detail view of a facet joint showing the preparation of a receiving area about the exterior of the articular processes according to one embodiment;

Figure 16 is a detail view of a facet joint showing one embodiment of a facet implant;

Figure 17 is a perspective view of a facet implant according to one embodiment;

Figure 18 is a perspective view of a facet implant according to one embodiment;

Figure 19 is a detail view of a facet joint showing the preparation of a receiving area about the exterior of the articular processes according to one embodiment;

Figure 20 is a detail view of a facet joint showing one embodiment of a facet implant; and

Figure 21 is a detail view of a facet joint showing one embodiment of a facet implant.

Detailed Description

The various embodiments disclosed herein relate to an implant in which a graft plate or cap is disposed over the exterior of a facet joint to promote fusion of the facet in spinal fusion surgery. Figure 1 illustrates one embodiment of an implant 10 installed in this manner. Specifically, Figure 1 shows a lateral view of two vertebrae V1, V2 and an intervertebral disc D disposed therebetween. During fusion surgery, some or all of the disc D is removed and may be replaced with an implant or graft that ultimately fuses to the vertebrae V1, V2. In addition, a surgeon may elect to fuse the facet joints J that are formed between the inferior articular process IP of the superior vertebra V1 and the superior articular process SP of the inferior vertebra V2. To that end, the implant 10 may be attached to the articular processes IP, SP as illustrated and disclosed herein. In one or more embodiments, the implant 10 may be pinned or screwed to the articular processes IP, SP using a fastener 12. The fastener 12 may be implemented using a pin, a nail, a screw, a staple, a wedge, or other feature that secures the implant 10 to the facet joint J until fusion occurs. Other embodiments disclosed herein may be implemented without a fastener 12. In one or more embodiments, the implant 10 is disposed over the exterior of the facet joint J in a manner that physically separates the facet joint J from fibrous tissue (e.g., muscle and ligaments) that is depicted generally by the dashed lines and the letter F in Figure 1. Further, the exemplary implant 10 serves as a cap that covers the posterior junction between the inferior articular process IP of the superior vertebra V1 and the superior articular process SP of the inferior vertebra V2. The implant 10 and fastener 12 may be constructed of biocompatible materials, including metals, such as titanium or stainless steel, non-metals, such as PEEK or UHMWPE. The implant 10 and fastener 12 may be constructed of a graft material, which is interpreted herein to include implants constructed from natural or synthetic bone materials including, but not limited to autograft, allograft, xenograft, or calcium phosphate. In embodiments where the implant 10 is constructed from synthetic or manufactured materials, the implant 10 may be coated or textured to improve the likelihood of bony ingrowth into the implant. Similarly, the implant may be impregnated, packed, or filled with bone growth promoting substances such as Bone Morphogenetic Protein (BMP), demineralized bone matrix (DBM), allograft, autograft, xenograft, or other osteoinductive growth factors. For example, the implant 10 may have a porous structure with open portions of the implant 10 packed with the bone growth

promoting substance. In certain implementations, the implant 10 may osseointegrate or become part of the fusion mass at the facet joint J to increase the size and stability of the fusion mass. In one embodiment, the fastener 12 may be constructed from a bioabsorbable material that begins to dissolve after the implant 10 has begun to fuse to the facet joint J.

The section view shown in Figure 2 is depicted according to the section line labeled II-II in Figure 1. The exemplary implant 10 illustrated in Figure 1 is also presented in Figure 2. As described above, this embodiment of the implant 10 is disposed so that it covers the posterior side of the facet joint J and forms a barrier between joint J and the fibrous tissue F that covers the facet joint J. In other embodiments, the implant 10 may cover other portions of the facet joint, including lateral or anterior junctions between the inferior articular process IP of the superior vertebra V1 and the superior articular process SP of the inferior vertebra V2. Notably, Figure 2 includes a "DETAIL" callout that identifies the view illustrated in various other Figures. The detail views provide a magnified representation of the facet joint and various embodiments of the implant.

Figure 3 shows a detail view of the same embodiment of the implant 10 depicted in Figures 1 and 2. Figure 3 further illustrates bone growth promoting material 100 that is packed between the articular processes IP, SP that form the facet joint J. These bone growth promoting materials 100 are often used in an attempt to fuse the facet joint J and stabilize a motion segment of the spine. The fusion process may involve some destruction of the facet, including removing cartilage at the interface surfaces 26, 28, decorticating each interface surface 26, 28, and packing the bone growth promoting material 100 into the joint J in an attempt to promote new bone growth that will ultimately fuse the facet joint J. Some non-limiting examples of bone growth promoting substances that may be inserted into the facet joint J include Bone Morphogenetic Protein (BMP), demineralized bone matrix (DBM), allograft, autograft, xenograft, or other osteoinductive growth factors to facilitate fusion of the facet joint J.

An inner surface 14 of the implant 10 is positioned so that it contacts outer cortical surfaces 19, 20 of the inferior articular process IP and the superior articular process SP, respectively. In one embodiment, the implant 10 is generally curved to match the anatomy of the outer, cortical surfaces 19, 20. As such, the implant 10 may include an elongated,

curved shape as illustrated in the perspective view in Figure 4. Other shapes are possible as the various embodiments described below bear out.

The exemplary implant 10 covers the facet joint J by an amount that helps prevent the bone growth promoting substance 100 from evacuating the facet joint J. Further, the exemplary implant 10 may act as a barrier to prevent the migration of fibroblasts or other ingrowth of fibrous matter F (see Figures 1 and 2) that lies over or adjacent the facet joint J. The implant 10 may be secured as described above with a fastener 12 that extends through the implant 10, from the outer surface 16, and engages one or both of the articular processes IP, SP. In one embodiment, the implant 10 includes an aperture 18 through which the fastener 12 may pass. Additional apertures 18 may be included in the implant 10. The fastener 12 includes an enlarged head 22 and elongated body 24. The length of the illustrated body 24 is sufficient to engage both of the articular processes IP, SP. That is, the fastener 12 passes through the implant 10, through the superior articular process SP, across the interface surfaces 26, 28, and into the inferior articular process IP. In the embodiment shown, the aperture 18 is disposed in proximity to the superior articular process SP so that the fastener 12 initially engages the superior articular process SP of the inferior vertebra V2. In one embodiment, the aperture 18 is disposed so that the fastener 12 initially engages an inferior articular process IP of a superior vertebra V1. Certainly, the length of the elongated body 24 may be shortened so that it engages only one of the articular processes IP, SP that form the facet joint J.

The fastener 12 may require a pilot hole for attachment of the implant 10 over the facet joint J. Thus, in one implementation, the implant may be positioned as desired. Then, a pilot hole may be drilled into the articular processes IP and/or SP using the aperture 18 as a guide. Then, if necessary, the implant may be removed and bone growth promoting material 100 inserted into the facet joint J, between the interface surfaces 26, 28, and under the implant 10 as desired. The implant 10 is then secured to the articular processes IP, SP by inserting the fastener 12.

The illustrated embodiment of the implant 10 may be attached to the facet joint J without any preparation of the exterior surfaces 19, 20 of the articular processes IP, SP. In another embodiment, the exterior surfaces 19, 20 of the articular processes IP, SP are prepared for the implant 10. As used herein, the term "preparing" is intended to encompass such actions as abrading, ablating, roughening, or scouring such as with an

abrading tool (not shown). Alternatively, preparing the exterior surfaces 19, 20 may comprise contouring or decorticating, with bony material removed in preparation for receiving the implant 10. For example, Figure 5 shows a facet joint J as previously described with a dashed line 30 representing a region of the outer surfaces 19, 20 that are removed using conventionally known techniques. The dashed line 30 represents a receiving portion of the articular processes IP, SP that will receive the implant 10.

Figure 6 shows the previously described implant 10 inserted into the receiving portion 30 formerly occupied by the bony material that is removed according to Figure 5. As above, the implant 10 is retained with a fastener 12. Figure 7 shows an embodiment in which a similar implant 110 is inserted into a similar receiving portion 30 as in Figures 5 and 6. However, in this implementation, a fastener 12 is not used. The overlying fibrous tissue F may retain the implant 110 in the position shown. Further, the implant 110 may be adhered to the articular processes IP, SP with a biocompatible adhesive. Suitable adhesives may include protein derived, aldehyde based adhesive materials, albumin/glutaraldehyde materials, and cyanoacrylate-based materials.

The previously described implants 10, 110 included a substantially curved construction similar to that shown in Figure 4. In one embodiment shown in Figure 8, the implant 210 includes an inner surface 214 and outer surface 216 that are comprised of three substantially planar portions 214a, 214b, 214c oriented at angles relative to one another. In other embodiments, the implant 210 may include a single substantially planar portion or include two planar portions oriented at an angle with respect to each other. In other embodiments, the implant 210 may include four or more substantially planar portions oriented at angles with respect to one another. The angles between the planar portions 14a-c may be configured to substantially match the contour of the exterior surfaces 19, 20 of the facet joint J. The amount of bony material that is removed from the outer surfaces 19, 20 of the facet joint J may be minimized to the extent the implant 210 matches the contour of the exterior surfaces 19, 20. In other implementations, the implant 210 may be attached to a facet joint J where the exterior surfaces 19, 20 are not abraded or decorticated.

In implementations where the outer cortical surfaces 19, 20 of the facet joint J are decorticated in anticipation of receiving the implant 210, substantially planar faces may be formed in the articular processes IP, SP that substantially match the configuration of the

implant 210. For example, Figure 9 illustrates substantially planar cuts identified by the dashed line 32. Figure 10 illustrates the exemplary implant 210 inserted against the prepared articular processes IP, SP. In the illustrated embodiment, the implant 210 is secured to the inferior articular process IP with a threaded fastener 212. The threaded fastener 212 includes an enlarged head 222 and a threaded shank 224 that passes through the aperture 218 and into the inferior articular process IP. The threaded fastener 212 may include a drive feature (not shown) disposed in the head 222, such as a hex recess, slotted recess, cross recess, or other driving feature that permits insertion into the facet joint J. In other embodiments, the threaded fastener 212 may engage both articular processes IP, SP.

In yet other embodiments, multiple threaded fasteners 212 may be installed to secure the implant 210 to the articular processes IP, SP.

In an embodiment shown in Figure 11, the implant 310 includes a cover portion 312 and a wedge portion 314 joined together to form a substantially T-shaped implant 310. The cover portion 312 serves a similar purpose to embodiments described above. That is, the cover portion 312 covers the posterior junction between the inferior articular process IP of the superior vertebra V1 and the superior articular process SP of the inferior vertebra V2. Accordingly, the cover portion 312 may include a substantially planar configuration as shown in Figure 11 or include curved or partially curved configurations similar to previously described embodiments. In contrast with embodiments described above, this implant 310 includes a wedge portion 314 that is positionable within the facet joint J, between the interface surfaces 26, 28 of the articular processes IP, SP. Consequently, in addition to preparing the outer surfaces 19, 20 of the facet joint J to receive the implant 310, the fusion site may benefit from decorticating the interface surfaces 26, 28 as depicted by the dashed lines 36 in Figure 12. Once the facet joint J is prepared by removing cortical bone as shown in Figure 12, the implant 310 may be inserted as shown in Figure 13 and secured with a fastener 12.

In an embodiment shown in Figures 14, 15, and 16, the implant 410 includes an elongated stake 414 and an enlarged head 412. The stake portion 414 is similar to the retainer 12 used in other embodiments in that it includes a pointed insertion tip 420 that can be driven through one or both of the articular processes IP, SP. The head 412, being wider than the stake 414, limits the depth to which the stake 414 is inserted. In one implementation, the outer cortical surfaces 19, 20 of the articular processes IP, SP may be

prepared to receive the head 412. In one embodiment shown in Figure 15, only one of the articular processes SP is decorticated as indicated by dashed line 38 to receive the head 412. In other embodiments, neither or both articular processes IP, SP may be prepared by removing cortical bone.

The enlarged head 412 extends laterally from the stake 414 at a first end 416 and curves along an arcuate path towards a second end 418. The length and curvature of the head 412 may be configured so that the head covers the posterior junction between the inferior articular process IP and the superior articular process SP as shown in Figure 16. In other embodiments, the head 412 may be formed similar to the head 22 of the retainer 12 shown in other embodiments. That is, the head portion 412 may be configured with a substantially cylindrical or disc shape.

Figures 17 and 18 depict implant embodiments 510, 610, that are similar to one another in that lateral sides 514, 614 of the implants 510, 610 extend substantially perpendicular to a substantially planar top surface 512, 612. In each implant 510, 610, the top surface 512, 612 and lateral sides 514, 614 form an open bottom end that leads into an interior cavity 520, 620. In one embodiment, the intersection of the top surface 612 and side surface 614 may be rounded such that the implant 610 includes a substantially continuous outer surface forming a dome shaped structure. The facet joint J may be prepared to receive the implants 510, 610 by removing cortical bone from the exterior surfaces 19, 20 of the articular processes IP, SP as shown in Figure 19. The dashed line 40 illustrates an exemplary cutting path to accommodate the lateral sides 514, 614 of the implants 510, 610. Dashed line 42 represents a cut that reduces the height of the facet joint J and may be optional depending on the implementation. The cut may traverse a substantially cylindrical path or a square path depending on the shape of the side walls 514, 614 of the implant 510, 610. The prepared facet joint J is inserted into the interior cavity 520, 620 as shown in Figures 20 and 21.

Figure 17 shows that the implant 510 includes an aperture 516 in the top surface 512 through which bone growth promoting material 100 may be inserted. For example, Figure 20 shows the implant 510 inserted onto the facet joint J and the aperture 516 exposing the interface surfaces 26, 28 to permit packing of the bone growth promoting material 100 between the articular processes IP, SP. Notably, the top surface 512 of the implant 510 is disposed a distance H above the top surface of the articular processes IP,

SP, which may advantageously provide a buffer between the packed bone growth promoting material 100 and the overlying fibrous tissue. In Figure 17, this distance H is relative to an outer surface 19, 20 that is cut according to dashed line 42 in Figure 19. In other implementations, the height of the articular processes IP, SP may be retained by omitting the cut identified by dashed line 42 in Figure 19. In either case, the implant 510 can be configured to provide the buffer represented by dimension H.

Figure 17 also shows that the implant 510 includes two side surfaces 514. Thus, the implant 510 includes a generally inverted U-shaped structure. In other embodiments, the implant 510 may include three or four side surfaces 514 to form a box structure. The implant 510 also includes one or more apertures 518 that are sized to accept one of the aforementioned retainers 12, 212. Alternatively, the implant 510 may be attached to the facet joint J without a retainer 12, 212 as shown in Figure 20 and using one of the aforementioned adhering techniques.

Figure 18 also shows that the implant 610 includes one or more apertures 618 that are sized to accept a retainer 12, 212. Figure 21 illustrates that apertures 618 may be disposed opposite one another so that a retainer 12 can be driven through opposite sides of the side wall 614 and both articular processes IP, SP. Implant 510 may be secured to the facet joint J using a similar configuration.

Spatially relative terms such as "under", "below", "lower", "over", "upper", and the like, are used for ease of description to explain the positioning of one element relative to a second element. These terms are intended to encompass different orientations of the device in addition to different orientations than those depicted in the figures. Further, terms such as "first", "second", and the like, are also used to describe various elements, regions, sections, etc and are also not intended to be limiting. Like terms refer to like elements throughout the description.

As used herein, the terms "having", "containing", "including", "comprising" and the like are open ended terms that indicate the presence of stated elements or features, but do not preclude additional elements or features. The articles "a", "an" and "the" are intended to include the plural as well as the singular, unless the context clearly indicates otherwise.

The present invention may be carried out in other specific ways than those herein set forth without departing from the scope and essential characteristics of the invention. For

instance, while only one of the two facet joints are depicted in the various detailed views provided according to the "DETAIL" callout in Figure 2, a similar configuration may exist at the facet joint located on the opposite lateral side of the spine. The descriptions disclosed herein are not intended to be limited to facet joints on a single side of the spine. Those skilled in the art will comprehend the symmetry and applicability of the various embodiments disclosed herein. The present embodiments are, therefore, to be considered in all respects as illustrative and not restrictive, and all changes coming within the meaning and equivalency range of the appended claims are intended to be embraced therein.

Claims

What is claimed is:

1. An implant for insertion onto a facet joint in a patient comprising:
a body including an inner bone-contact surface and an outer surface,
the bone-contact surface shaped to cover an exterior junction formed by articular processes of the facet joint, and
the body constructed of a graft material selected from a group consisting of autograft, allograft, and xenograft to fuse the processes together.

2. The implant of claim 1 wherein the inner bone-contact surface is curved to match a contour of an exterior of the articular processes of the facet joint.

3. The implant of claim 1 wherein the inner bone-contact surface is planar.

4. An implant for insertion onto a facet joint in a patient comprising:
a body including an outer surface and an inner surface defining an interior cavity,
the body shaped to accept at least a portion of an inferior articular process and a superior articular process forming the facet joint,
the body constructed of a graft material selected from a group consisting of autograft, allograft, and xenograft to fuse with the inferior articular process and the superior articular process.

5. The implant of claim 4 further comprising an aperture extending from the inner surface to the outer surface and sized to allow a bone fastener to pass.

6. The implant of claim 4 wherein the body is substantially dome shaped.

7. The implant of claim 4 wherein the interior cavity is rectangular.

8. The implant of claim 4 wherein the interior cavity is cylindrical.

9. An implant for insertion onto a facet joint in a patient comprising:
a body including an outer surface and an inner surface defining an interior cavity,
the body shaped to accept at least an exterior portion of a facet joint,
the body constructed of a graft material to fuse with the inferior articular process and the superior articular process.

10. The implant of claim 9 wherein the graft material is selected from a group consisting of autograft, allograft, and xenograft.

11. The implant of claim 9 wherein the graft material is at least partially constructed of calcium phosphate.

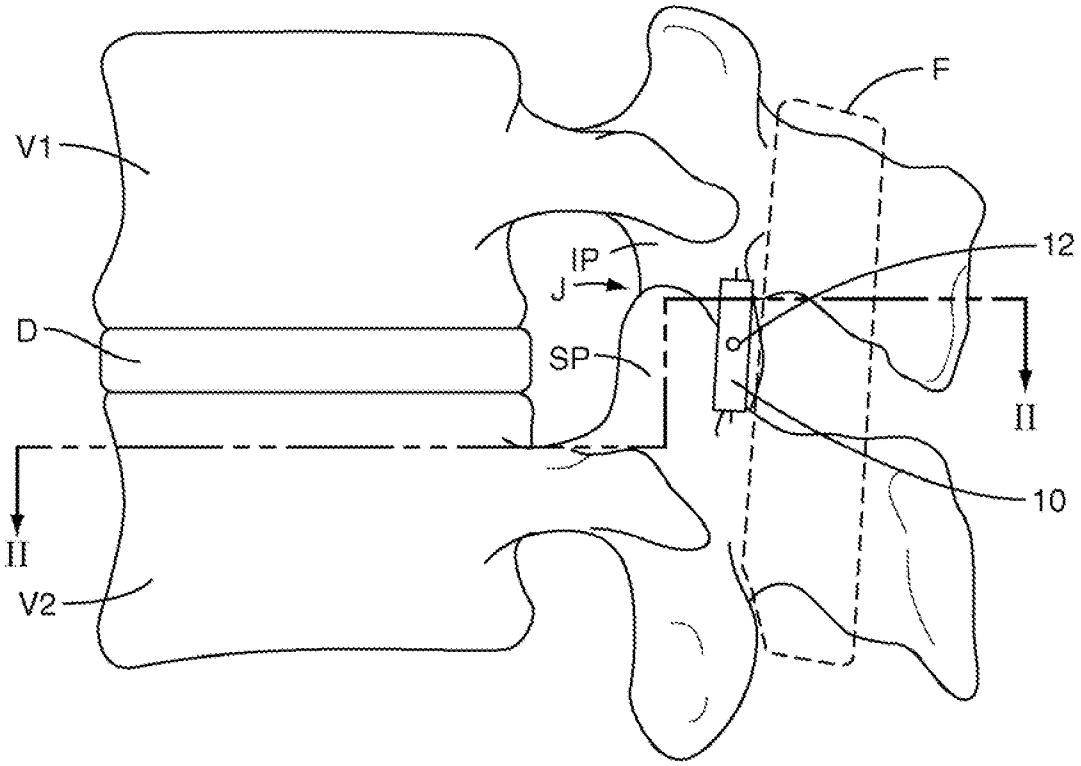


FIG. 1

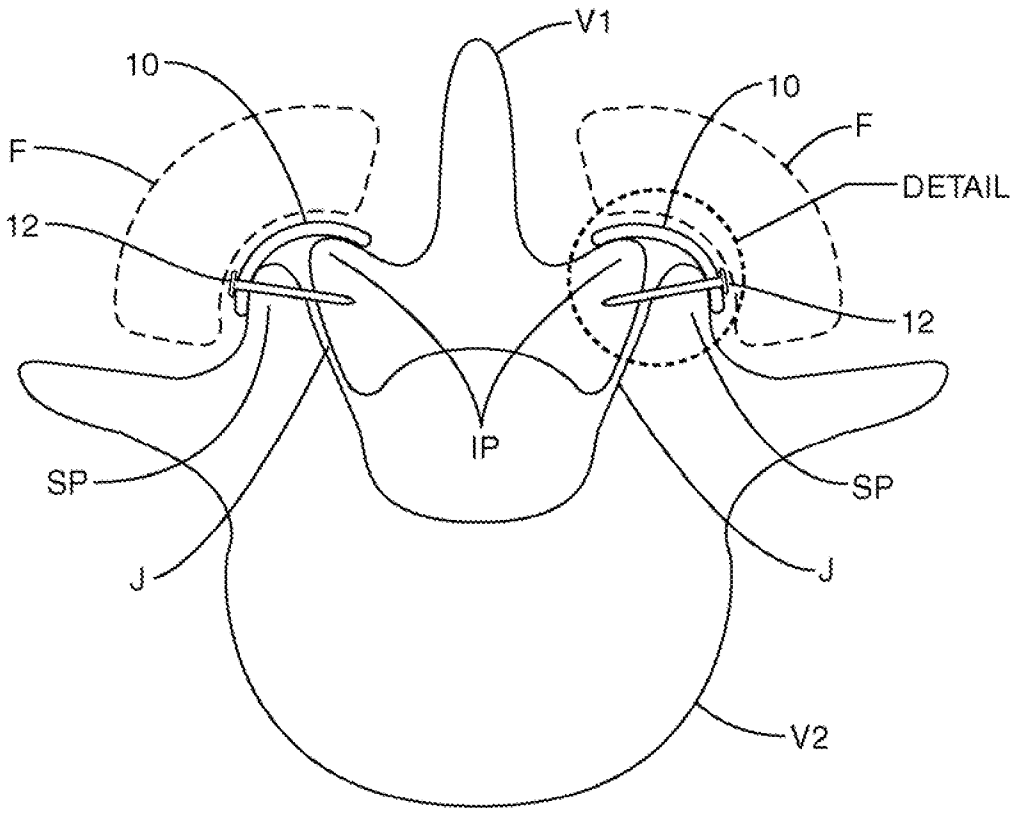


FIG. 2

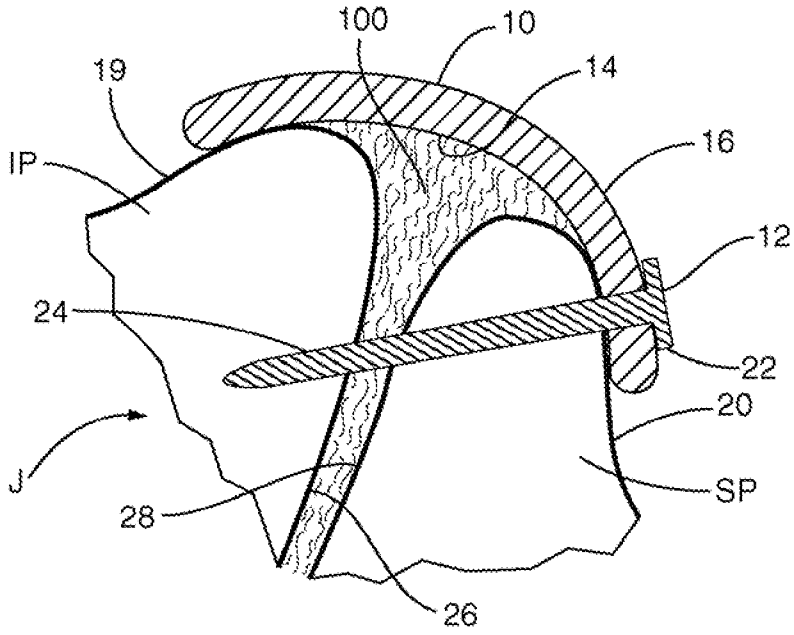


FIG. 3

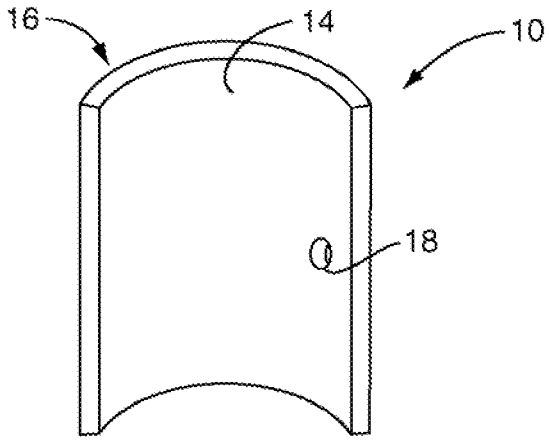


FIG. 4

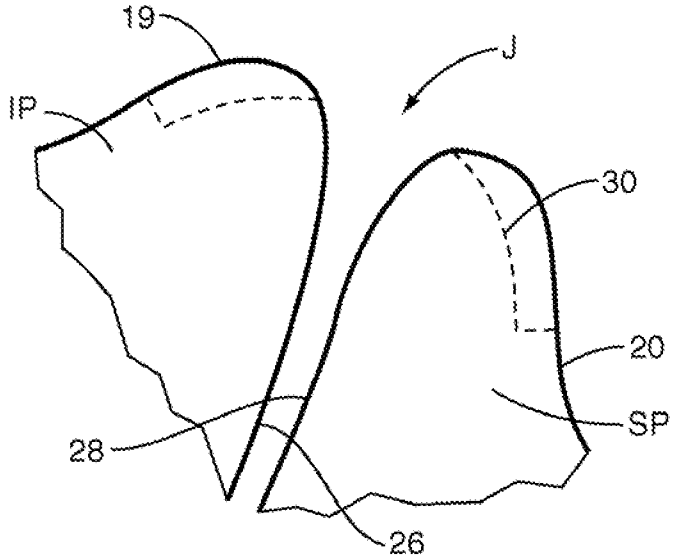
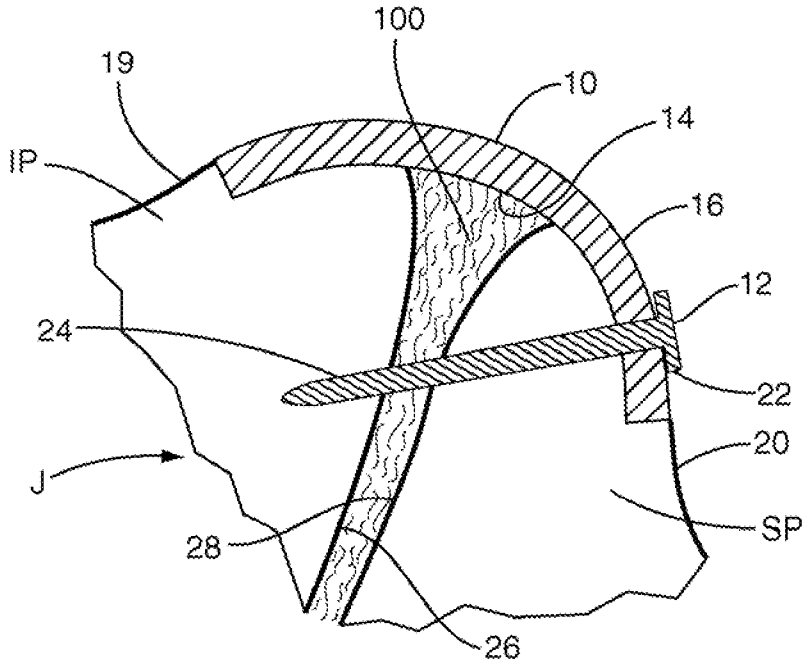


FIG. 5


100
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IP
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FIG. 6

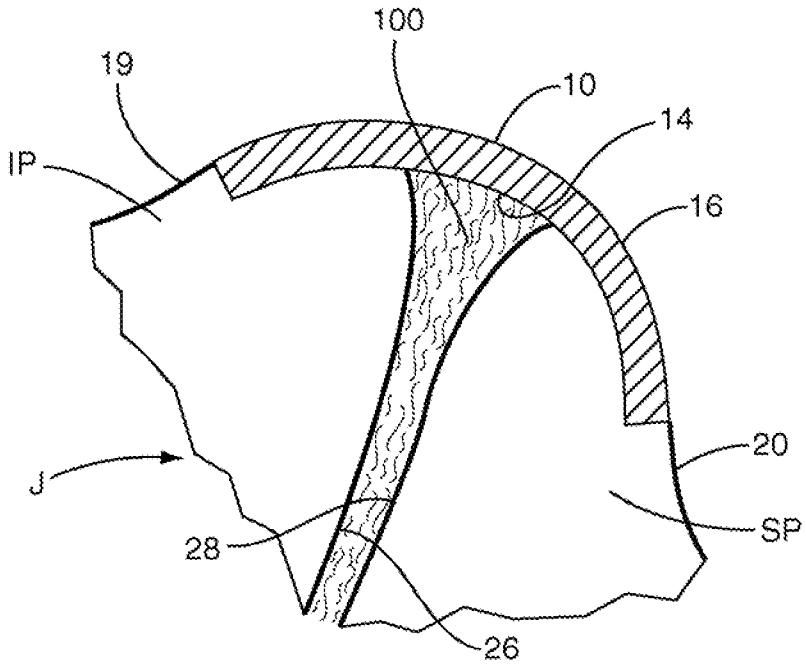
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FIG. 7

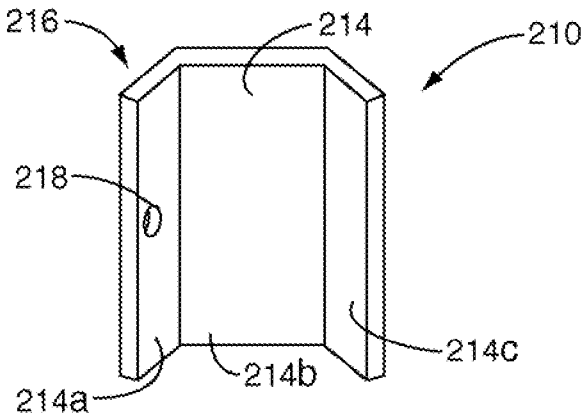

FIG. 8

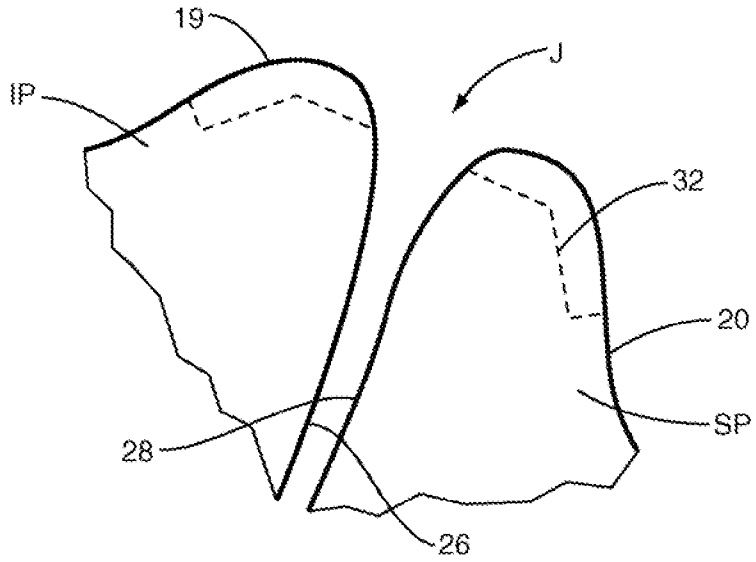

FIG. 9

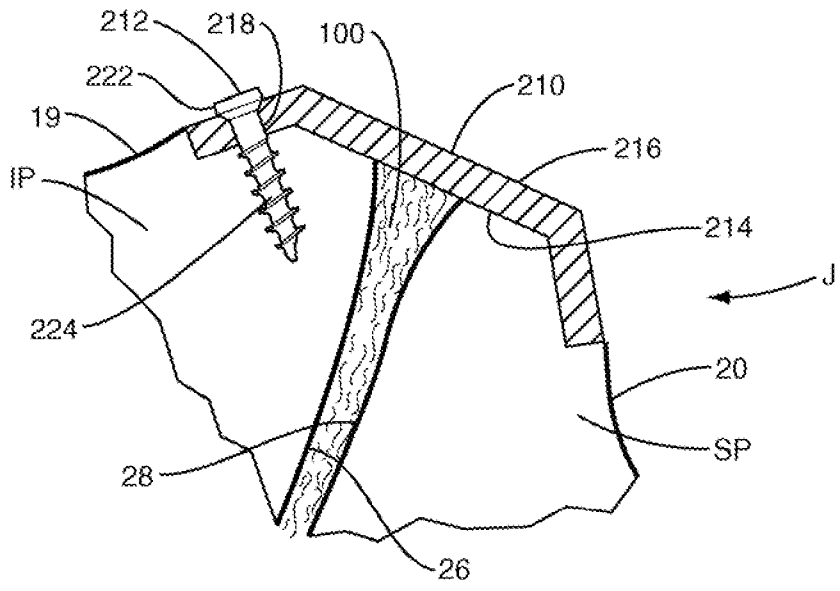

FIG. 10

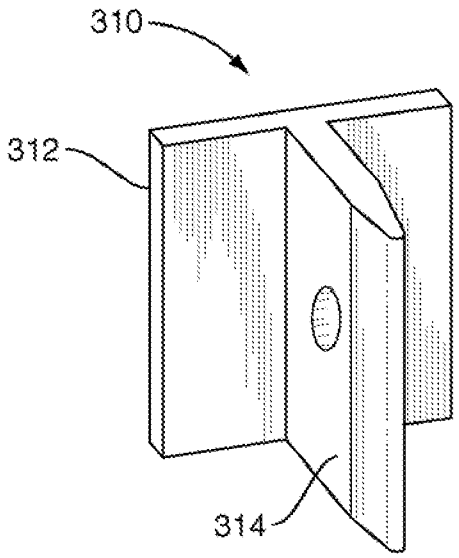

FIG. 11

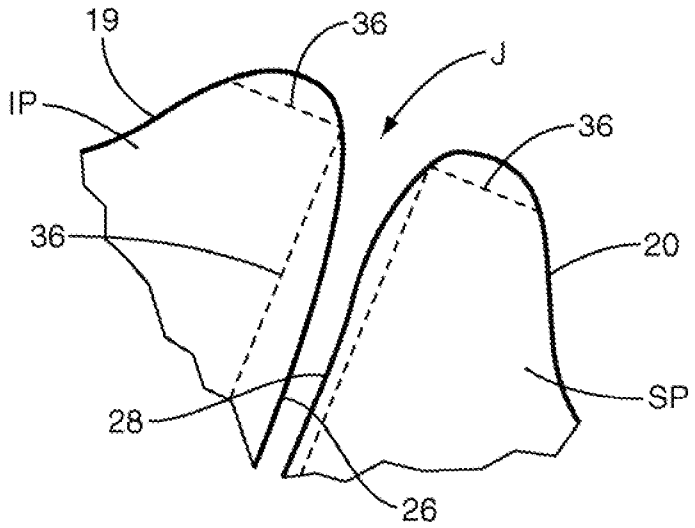

FIG. 12

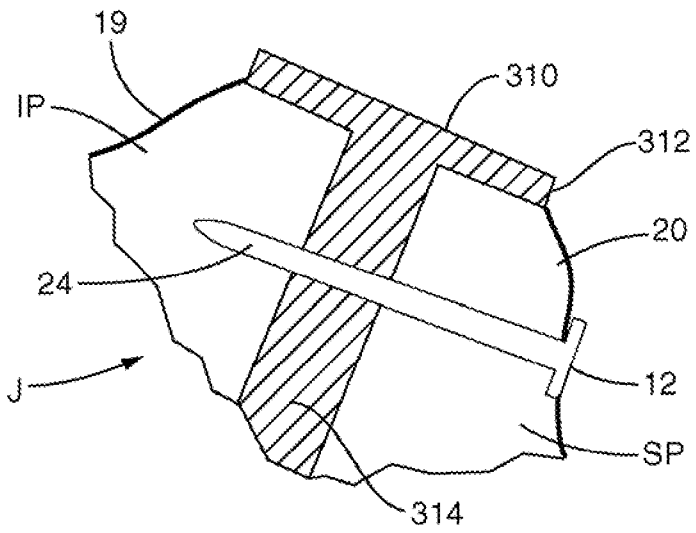

FIG. 13

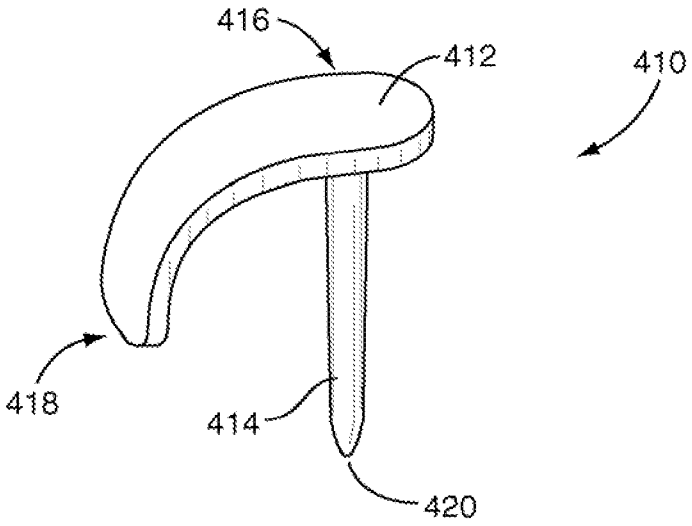

FIG. 14

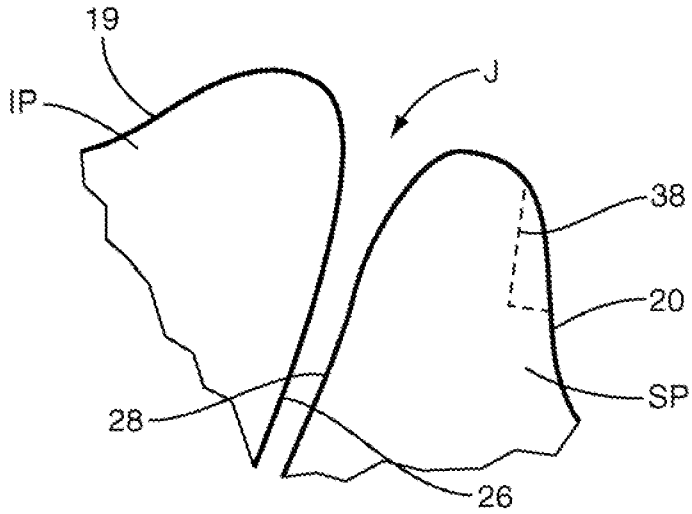

FIG. 15

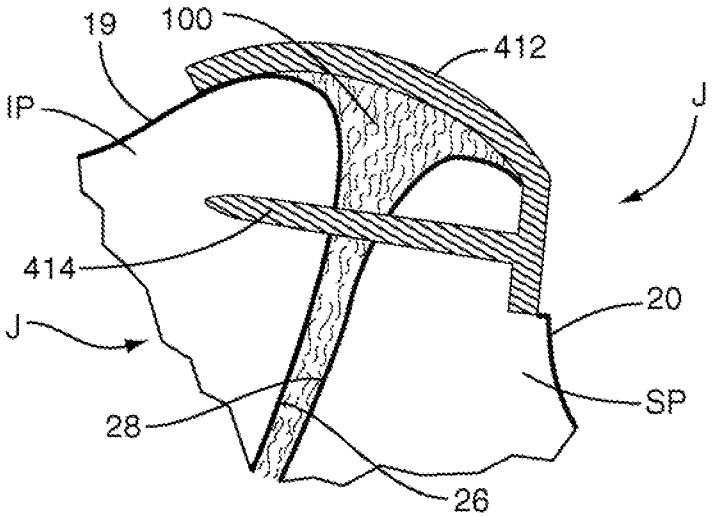

FIG. 16

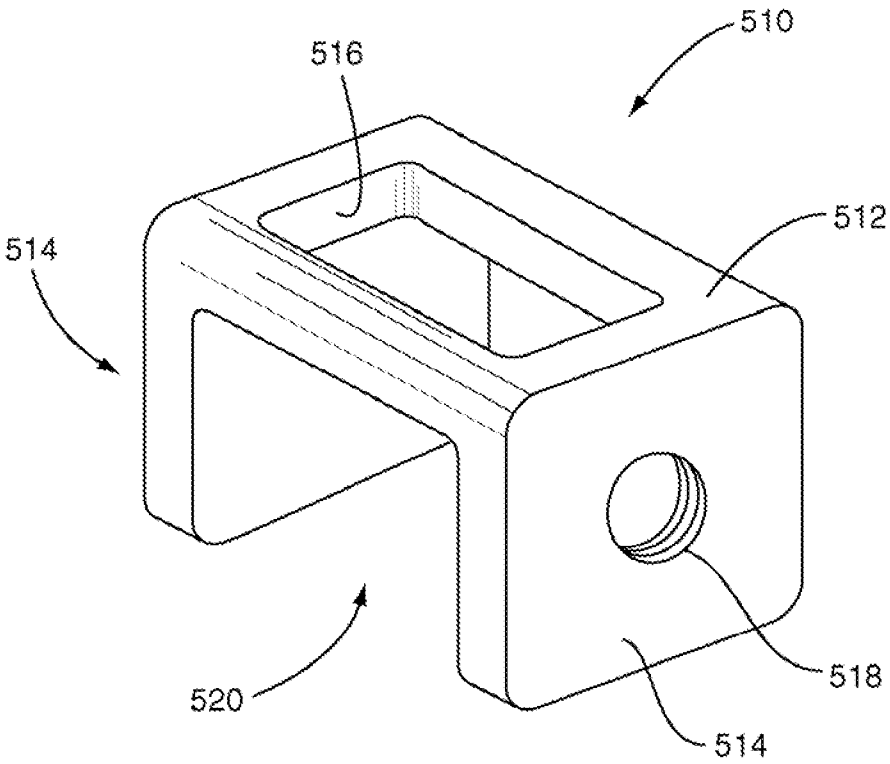

FIG. 17

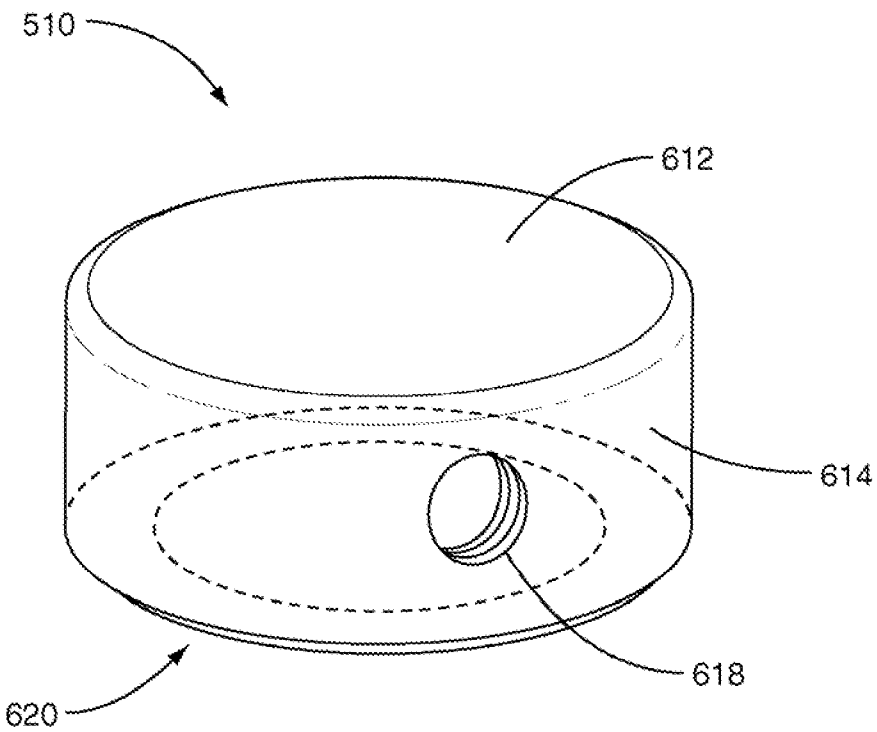

FIG. 18

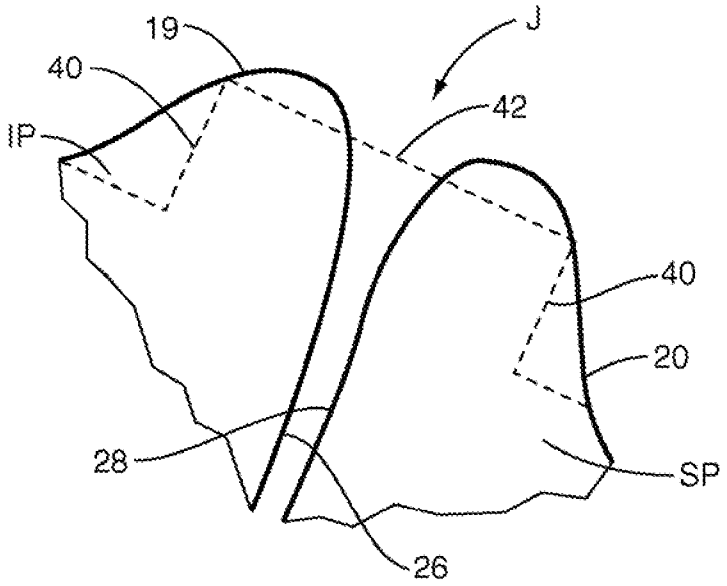
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FIG. 19

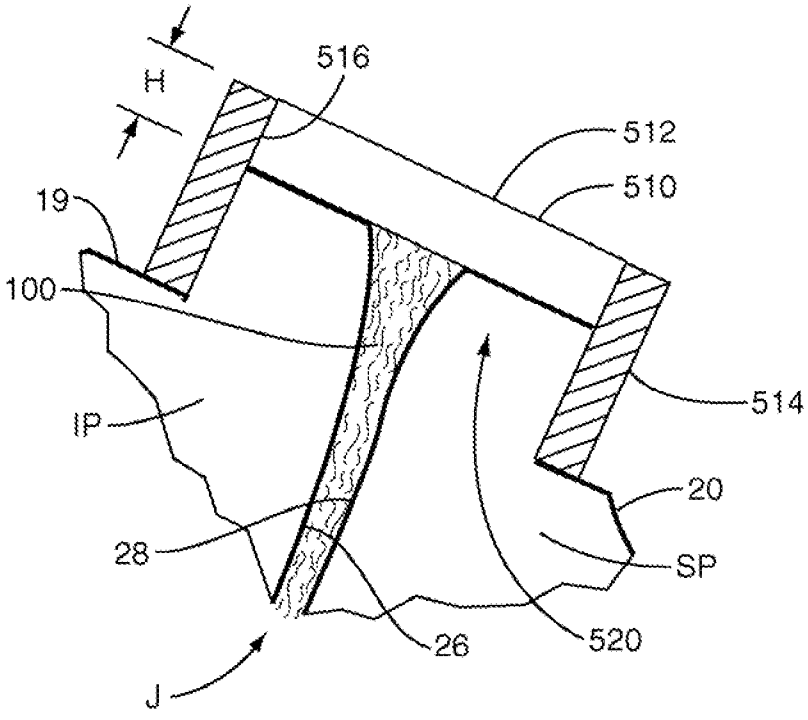
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FIG. 20

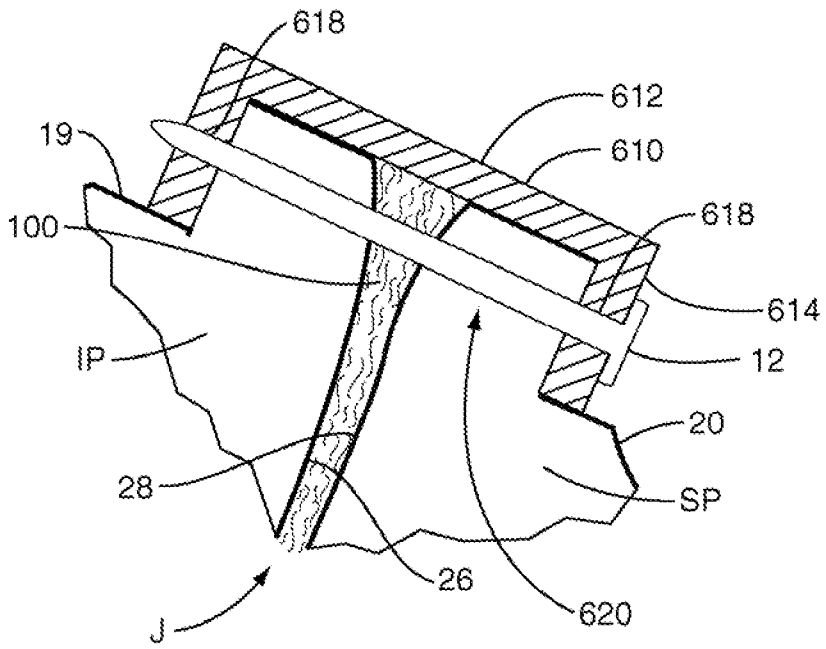

FIG. 21

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2007/066328

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/70

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

B. FIELDS SEARCHED

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

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

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, EMBASE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 2006/009855 A (CHEE U.H. & ALAMIN T.F.) 26 January 2006 (2006-01-26) paragraphs [0011], [0017], [0018], [0022], [0029], [0056], [0058]; claims 1,17-21,33,44; figure 9	1,4,9
A	DE 201 12 123 U (AESCULAP) 27 September 2001 (2001-09-27) page 10, line 4 - line 7 page 10, line 15 - line 16 figures 2,4,6,11,13	1,4,9

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents :

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"E" earlier document but published on or after the international filing date

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"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
22 August 2007	04/09/2007

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Nice, Philip

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2007/066328

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2006009855 A	26-01-2006	US 2006004367 A1	05-01-2006
DE 20112123 U	27-09-2001	NONE	