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IMPLANTS AND METHODS FOR INTER-SPINOUS PROCESS DYNAMIC STABILIZATION OF A SPINAL MOTION SEGMENT

BACKGROUND

Implants can be positioned between adjacent spinous processes to provide resistance to vertebral movement as a result of extension of the spinal column. These implants can provide a shock absorber or bumper that dynamically limits spinal extension. The implants can be secured to the adjacent spinous processes with looped cables or straps that extend completely about the spinous processes and implant to maintain positioning of the implant between the spinous processes while also limiting spinal flexion. However, in addition to controlling the range of motion between adjacent spinal motion segments, it has been discovered that more positive patient outcomes also rely on changing the manner in which the adjacent spinal motion segments move relative to each other. Thus, there remains a need for an implant which can both control motion and alter the manner in which the spinal motion segments move.

SUMMARY

There is provided spinal implants, implant assemblies and methods that provide stabilization of a spinal motion segment through the posterior vertebral elements.

According to one aspect, a spinal implant includes a spacer member which extends along a longitudinal axis between opposite upper and lower ends. The upper and lower ends are structured to receive a respective one of the adjacent upper and lower spinous processes of a spinal motion segment. The spacer member includes a body including at least a first and a second section. Each of the first and second sections includes a flexibility characteristic that is different from the other.

According to another aspect, a spinal implant includes a spacer sized and shaped to extend between adjacent upper and lower spinous processes of a spinal motion segment. The spacer member includes a body with an exterior wall extending between opposite upper and lower ends. In an implantation orientation between the upper and lower spinous processes, the exterior wall includes an anterior surface opposite a posterior surface. The

body further includes at least a first section having a first flexibility characteristic quality and a second section having a second flexibility characteristic that differs from the first flexibility characteristic. In one form, the first and second sections are configured to modify the manner of movement of the spinal motion segment when implanted between spinous processes of the adjacent vertebrae.

According to a further aspect, a method for stabilizing a spinal motion segment comprises: providing a spacer member including an upper end structured to contact an inferior surface of the upper spinous process and a lower end structured to contact a superior surface of the lower spinous process and a body including at least flexibly distinctive first and second sections, with the first section being less flexible than the second section; and positioning the spacer member between the adjacent upper and lower spinous processes of the spinal motion segment with the first section oriented anteriorly.

These and other aspects will be discussed further below.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is an elevation view of a posterior portion of a spinal column motion segment with a spinal implant in the form of a spacer member engaged therewith.

FIG. 2 is a lateral view of the spinal column motion segment of FIG. 1.

FIGS. 3A-3G are sectional views taken along view line 3-3 of FIG. 1 of various alternative embodiment spacer members.

FIG. 4 is a sectional view of the spacer member of FIGS. 1 and 2 taken along view line 4-4 in FIG. 2.

FIG. 4A is a sectional view of an alternative embodiment spacer member taken along a view plane corresponding to line 4-4 in FIG. 2.

FIG. 4B is a sectional view of an alternative embodiment spacer member taken along a view plane corresponding to line 4-4 in FIG. 2.

FIG. 5 is a perspective view of an alternative embodiment spacer member.

FIG. 6 is a sectional view taken along view line 6-6 in FIG. 5.

FIG. 7 is a perspective view in partial section of another embodiment spacer member.

FIG. 8 is an elevation view of the posterior portion of the spinal column motion segment of FIG. 1 with a spacer member assembly including a tethering system engaged therewith.

FIG. 9 is a lateral view of the spinal column motion segment and spacer member assembly of FIG. 8.

FIGS. 10A-10C are sectional views taken along view line 10-10 in FIG. 8 of various alternative embodiment spacer members.

DESCRIPTION OF THE ILLUSTRATED EMBODIMENTS

For the purposes of promoting an understanding of the principles of the invention, reference will now be made to the embodiments illustrated in the drawings and specific language will be used to describe the same. It will nevertheless be understood that no limitation of the scope of the invention is thereby intended. Any such alterations and further modifications in the illustrated devices, and such further applications of the principles of the invention as illustrated herein are contemplated as would normally occur to one skilled in the art to which the invention relates.

Implants are positionable between adjacent spinous processes of a spinal motion segment to dynamically stabilize and limit spinal extension and/or flexion while altering the manner of movement between adjacent vertebral bodies which in one form includes repositioning the center of rotation for one or both of flexion and extension movement at the spinal motion segment. The implant includes a spacer member that forms a composite structure received between the spinous processes. The implant includes at least a first section and a second section with a flexibility characteristic that differs from that of the first section. In one form, the configuration of the first and second sections provides an asymmetry of flexibility between anterior and posterior sides of the implant that provides preferential deformation and influences the repositioning of the centers of rotation for flexion and extension at the spinal motion segment. In another form, the spacer member may be employed alone or with other implants, such as rods, plates, tethers, interbody fusion devices, interbody spacers, artificial discs, annulus repair system, or staples, for example.

In a further form, one or more engaging members in the form of a tether couples the implant to one or more posterior vertebral elements or implants. The engaging members can be engaged to the spacer member, or extend through the spacer member. The engaging members can be engaged to the posterior elements in a configuration that at least partially limits spinal flexion. Alternatively or additionally, the engaging members can be engaged to the posterior elements in a manner that prevents or resists the spacer member from being displaced from its implantation location between the spinous processes. In yet another form, the engaging members may increase the rigidity of one or more of the first and second sections.

In Figs. 1 and 2 there is shown a spinal column segment 10 including an upper vertebra V_U , a lower vertebra V_L and a spinal disc 13 therebetween along a central axis 11 of the spinal column. The vertebrae V_U , V_L and disc 13 comprise a spinal motion segment, it being understood that a spinal motion segment may include multiple vertebral levels in one more of the lumbar, thoracic, and cervical regions of the spine. Upper vertebra V_U includes an upper spinous process SP_1 while the lower vertebra V_L includes a lower spinous process SP_2 , with the spinous processes SP_1 , SP_2 defining a space S therebetween. The spinous processes SP_1 and SP_2 comprise posterior elements of the vertebrae V_U , V_L of the spinal motion segment along with the transverse processes 15, 16, 17, and 18, laminae 19a, 19b, facets, pedicles and other posterior structures of each vertebrae V_U , V_L .

A spinal implant 30 in the form of a spacer member 31 is positioned in the space S and extends between and engages with the spinous processes SP_1 , SP_2 to provide stabilization and modification of the spinal motion segment. Spacer member 31 includes a body 32 which in its implanted orientation has a first lateral side 34 and a second lateral side 36, with the lateral sides 34, 36 extending between a superior end 38 and an inferior end 40. As best seen in FIG. 2, for example, the body also includes an anterior side 42 opposite a posterior side 44. It should be appreciated that the transition between each of the anterior and posterior sides 42, 44, lateral sides 34, 36, and superior and inferior ends 38, 40 may be rounded or beveled in order to decrease the profile of the body 32 and minimize intrusion and potential trauma to adjacent neural tissue and surrounding spinal anatomy.

The body 32 further includes a first concave portion 46 and a second concave portion 48 situated at respective superior and inferior ends 38, 40. Each of the concave portions 46,

48 is disposed between a pair of respective upright arms 50a, 50b and 52a, 52b. Concave portions 46, 48 are sized and shaped to engage with and receive respective inferior surface 12 of the upper spinous process SP_1 and superior surface 14 of the lower spinous process SP_2 . The arms 50a, 50b, 52a, and 52b extend beyond the respective concave portions 46, 48 to engage with the lateral sides of the spinous processes SP_1 , SP_2 . While concave portions 46, 48 are illustrated having a substantially arcuate shape, it should be appreciated that in one or more forms the concave portions 46, 48 may include an alternative configuration, such as a rectangular shape or may be structured to receive a greater portion of the spinous processes SP_1 , SP_2 to further resist dislodgement from space S.

As illustrated in Fig. 2, the upper vertebra V_U and lower vertebra V_L have a normal center of rotation COR_N (illustrated in phantom) for flexion and extension motion of the spinal motion segment when the spacer member 31 is not positioned in space S between the spinous processes SP_1 , SP_2 . While the normal center of rotation COR_N is located substantially in the center of the vertebral bodies VB_1 , VB_2 in Fig. 2, it should be appreciated that the position of the normal center of rotation COR_N may vary based on several factors, including the region of the spinal column, individual patient anatomy, disease state or the effects of concurrent procedures (such as spinal decompression), just to name a few. Also illustrated in Fig. 2 are the resultant positions for the center of rotation for flexion COR_F and the center of rotation for extension COR_E when one form of spacer member 31 according to the present application is inserted in space S between the spinous processes SP_1 , SP_2 . In this form, the center of rotation for flexion COR_F is repositioned anterior to the normal center of rotation COR_N while the center of rotation for extension COR_E is repositioned posterior to the normal center of rotation COR_N . Further details in regard to modifying the normal center of rotation COR_N will be set forth below.

Referring now to Fig. 3A there is shown a sectional view of one embodiment spacer member 31 along line 3-3 of Fig. 1. In this embodiment, the spacer member includes a first section 54 adjacent to anterior side 42 and a second section 56 positioned adjacent to posterior side 44 and abutting against first section 54, with each of the sections 54, 56 extending longitudinally between the spinous processes SP_1 , SP_2 . A portion of first section 54 is surrounded, at least along its superior and inferior sides, with second section 56. First and second sections 54, 56 form an overlapping arrangement in

the anterior-posterior directions that provides a transition in the stiffness profile where the stiffness decrease posteriorly. First section 54 includes a posterior portion 55 that extends part-way into second section 56 in the anterior to posterior direction.

In this and the other forms contemplated herein, the spacer member 31 is
5 fabricated from components that are flexible or exhibit at least some flexibility with the second section 56 being more flexible than the first section 54. Additionally, at least a portion of the spacer member 31 is resilient and/or elastic so it can assume various shapes during and after insertion and attachment. In one form, the flexibility of one or both of sections 54 and 56 is controlled by constructing the spacer member 31 with
10 longitudinal gradations. In another form, the flexibility of the sections 54, 56 is varied by using materials with different elasticity, flexibility, or rigidity qualities. In one form, it is contemplated that the materials for the first section 54 and the second section 56 are selected based upon their modulus of elasticity.

It should be appreciated that either of sections 54, 56 may comprise any
15 biocompatible material, material of synthetic or natural origin, and material of a resorbable or non-resorbable nature so long as the flexibility of the sections varies. For example, in one form of the present application, section 54 comprises PEEK while section 56 comprises silicone. It is also contemplated that other polymers such as ultra-high molecular weight polyethylene, polyaryletherketone, polyacetal, polysulfone, polyimide, polyester, polyvinyl
20 alcohol, polyacrylonitrile, polytetrafluorethylene, poly-paraphenylene, terephthalamide, cellulose, biocompatible rubber materials, and combinations thereof may be used. Suitable ceramic materials may include alumina, zirconia, polycrystalline diamond compact, pyrolitic carbon, and porous tantalum material. Suitable composite materials may include carbon-filled composites, hydroxyl-appetite-filled composites, and bioactive-glass-filled
25 composites. The spacer member 31 may also include autograft, allograft or xenograft material and tissue materials including soft tissues, connective tissues, demineralized bone matrix and combinations thereof. In an embodiment including a resorbable material, any one or more of polylactide, polyglycolide, tyrosine-derived polycarbonate, polyanhydride, polyorthoester, polyphosphazene, calcium phosphate, hydroxyapatite, bioactive glass,
30 collagen, albumin, fibrinogen and combinations thereof may be a suitable material. It

should be appreciated that the selection of material for one or both of sections 54, 56 will influence the positioning of the centers of rotation for flexion and extension COR_F , COR_E .

When spacer member 31 is inserted into the space S each of the spinous processes SP_1 , SP_2 bears against the first section 54 and the more flexible second section 56. Since the spinous processes bear against both sections 54 and 56, a preferential deformation of the spacer member 31 is formed by movement of the spinal motion segment and the centers of rotation for flexion and extension COR_F , COR_E are influenced. When the more rigid section 54 is disposed anterior to the second section 56 and the spinal motion segment undergoes extension, the center of rotation for extension COR_E is moved posterior to the normal center of rotation COR_N because the spinous processes SP_1 , SP_2 rotate about the more rigid section 54 and compress or deform the more flexible second section 56 as they move toward one another. As the spinal motion segment undergoes flexion movement, the spinous processes SP_1 , SP_2 again rotate about the more rigid section 54 until enough force is created to compress or deform section 54, thus repositioning the center of rotation for flexion COR_F anterior to the normal center of rotation COR_N . Moreover, when the more rigid section 54 is placed anterior to the second section 56, section 54 is provided with sufficient rigidity in one embodiment to maintain a distraction distance between the laminae 19a, 19b in order to avoid stenosis and associated neural complications.

Referring now generally to each of Figs. 3B-3G there is illustrated a sectional view of alternative embodiment spacer members 31b-31g. It should be understood that the configuration of each of the spacer members 31a-31g has been varied by adjusting the positioning of the first section 54 relative to the second section 56 in order to provide spacer members with alternative flexibility characteristics which may be used to alternatively vary or control movement of the spinal motion segment.

Referring to Fig. 3B, spacer member 31b further includes a third section 58 which comprises a material generally more flexible than the material of sections 54, 56. The material of section 58 is generally structured to conform to the respective adjacent spinous process SP_1 or SP_2 in order to provide enhanced reception and engagement and may comprise one or more of the materials suitable for sections 54 and 56. For example, in Figs. 3C and 3D the spacer members 31c and 31d will react much the same as spacer 31 during flexion and extension. In Fig. 3C, first section 54 and second section 56 are arranged

in side-by-side relation to one another in the anterior-posterior direction with no overlapping portions. In Fig. 3D, first section 54 includes a posterior extension 55 that is surrounded at least one its superior and inferior sides with second section 56, and extension 55 extends to the posterior side 44.

5 In Fig. 3E, the first section 54 is disposed both superiorly and inferiorly around the second section 56, such that the first section 54 creates an axial force which compresses the second section 56 during extension of the spinal motion segment. Moreover, in Fig. 3F the first section 54 of spacer member 31f is at least partially surrounded by the second section 56 such that the first section 54 will limit the flexibility of the second section 56 when a
10 force greater than the elastic or compressive limit of section 56 is applied thereto. In Fig. 3G, first section 54 is surrounded at least partially along its anterior and posterior sides with a more flexible second section 56. Spacer 31g will provide deformation of the second section 56 during both spinal extension and spinal flexion, while first section 54 provides resistance to deformation when the supported vertebrae are in their neutral position.

15 In the embodiments discussed above, the arrangement of the first and second sections can be reversed so that the first section 54 is more flexible than the second section 56. Still other embodiments contemplate more than first and second sections to provide additional gradations in the flexibility of the implant. In still other embodiments, it is contemplated that one of the first and second sections may be removable from the spacer member and
20 replaced with an alternative replacement section in order to alter the flexibility characteristics of the spacer member. For example, in the embodiment illustrated in Fig. 3A, second section 56 may be removable from the spacer member 31. A plurality of replacement sections having flexibility characteristics different from the first section 54 and the second section 56 may be provided to replace the second section 56. It should be
25 appreciated that both the second section 56 and the replacement sections may be engaged with the spacer member 31 and the first section 54 through any standard manner, including a friction fit, pinning, tacking, stapling, screwing and/or any combination thereof, just to name a few possibilities. In this form, the stabilization of the spinal motion segment may be monitored subsequent to positioning the spacer member 31 between the spinous processes
30 SP₁, SP₂ to determine if alterations to the stabilization are desired. For example, it may be desired to adjust the positioning of one or both of the centers of rotation for flexion and

extension COR_F , COR_E . When an alteration to the stabilization of the spinal motion segment is desired, the removable section may be replaced with one of the replacement sections having different flexibility characteristics. For example, in one non-limiting form, when it is desired to reposition the center of rotation for extension COR_E in an anterior direction, the flexibility of the selected replacement section may be less than that of the second section 56 but greater than that of the first section 54. It should be appreciated that the stabilization of the spinal motion segment may be continually monitored and that the removable one of the first and second sections may be replaced with one of the replacement sections until the desired stabilization is achieved. The procedure of removing the removable section and replacing it with the alternative section may be performed through any standard surgical procedure. However, in one form, in order to minimize surgical complexity and trauma to the patient, it is contemplated that the procedure is performed percutaneously through a minimally invasive procedure.

Referring now to Figs. 4A and 4B, wherein like numerals refer to like features previously described, there is shown a sectional view of respective spacer members 31 and 31b along line 4-4 of Fig. 2. In Fig. 4A, the portion of the body 32 of spacer member 31 which forms arms 50a, 50b, 52a, and 52b engages with the upper and lower spinous processes SP_1 , SP_2 . In one form, this portion of the body 32 may be flexible enough to at least partially conform to the spinous processes SP_1 , SP_2 . In an alternative embodiment such as spacer 31b, the third section 58 is disposed around the concave portions 46b, 48b to provide a surface that conforms to the spinous processes SP_1 , SP_2 regardless of the flexibility or rigidity of the rest of the body 32b.

An alternative embodiment spinal implant 70 in the form of spacer member 71 is illustrated in perspective view in Fig. 5. The spacer member 71 includes a substantially U-shaped body 73 including longitudinal members 75 and 76 and an arcuate portion 82 extending between the longitudinal members 75, 76 to form a concave area 84 extending between surfaces 78 and 80. In an implantation orientation the body 72 is structured for positioning in the space S between the upper and lower spinous processes SP_1 , SP_2 such that the concave area 84 faces in an anterior direction with the upright members 75, 76 abutting a posterior surface of the laminae 19a, 19b and the upper spinous process SP_1 engaging with surface 78 and the lower spinous process SP_2 engaging with surface 80. In one non-

illustrated embodiment, the body 72 may be structured so that the longitudinal members 75, 76 may be positioned between the adjacent laminae 19a, 19b to keep a distraction space between the laminae 19a, 19b while the surfaces 78, 80 engage with and support the adjacent spinous processes SP_1 , SP_2 . In one or more forms, the body 72 may include one or more features structured to resist anterior migration of the implant 70 into the spinal canal. In yet another non-illustrated form, it is contemplated that surfaces 78, 80 may include a recessed area for receiving and engaging the spinous process SP_1 , SP_2 .

Referring to Fig. 6, there is shown a section view of the spacer member 71 along view line 6-6 of Fig. 5. In this form, spacer member 71 includes a first section 86 disposed generally in the longitudinal members 75, 76 and a second section 88 disposed generally in the arcuate portion 82. As described above in regard to spacer member 31, the spacer member 71 can be fabricated from components that are flexible or exhibit at least some flexibility with the second section 88 being more flexible than the first section 86. In one form, the flexibility of the sections 86, 88 may be varied by using materials with different elastic, flexibility, or rigidity qualities. It is further contemplated that one or more of the materials comprising sections 86, 88 may be selected from the materials set forth herein above in regard to spacer member 31. In the implantation orientation of spacer member 71, the more rigid first section 86 is positioned anterior to the more flexible second section 88 and the centers of rotation for flexion and extension COR_F , COR_E will be repositioned relative to the normal center of rotation COR_N as described above in regard to spacer member 31. Moreover, with the more rigid section 86 disposed generally in longitudinal members 75, 76, the spacer member 71 will maintain a distraction distance between the laminae 19a, 19b to help avoid stenosis and associated neural complications. While alternative section views of spacer member 71 have not been provided, it is contemplated that the configuration and positioning of the first section 86 and the second section 88 may be modified in order to provide a spacer member 71 with various flexibility and stabilization features.

An additional alternative embodiment spinal implant 100 in the form of spacer member 101 is illustrated in perspective view in Fig. 7. Spacer member 101 is generally similar to spacer member 31 and includes a body 102 which in an implantation orientation extends between a superior end 104 and an inferior end 106. The body 102 also generally

includes lateral sides 108, 110 and anterior side 112 and posterior side 114. The concave portions 116, 118 are structured to engage with and receive the upper and lower spinous processes SP_1 , SP_2 as described herein. In the illustrated form, the body includes a first section 120 positioned anterior to a hollow chamber 122 with the chamber 122 being structured to receive one or more injectable materials. When the chamber 122 includes the injectable material, the body 102 includes a second section in addition to the first section 120. The injectable material may include gels, pastes, slurries, or liquids, just to name a few possibilities. In one form, the injectable material may be deliverable in a first state and cure to a second state after injection. However, regardless of the form, the injectable material will be more flexible than the first section 120 in order to provide an implant with flexibility and stabilization features similar to that of spacer member 31. In one non-illustrated form, the body 102 may include one or more injection ports to receive the injectable material from a delivery instrument. In yet another form, it is contemplated that the body 102 may include one or more chambers in addition to chamber 122. It should also be appreciated that the positioning of the one or more chambers 122 or first section 120 may be altered to provide spacer members with various flexibility and stabilization features. Moreover, it is contemplated that section 120 may be the more flexible section and that the more rigid material may be delivered to the one or more chambers 122.

In another form, it is contemplated that the injectable material may be removed from the chamber 122 subsequent to positioning of the spacer member 101 at an implantation location. In this form, a patient may be monitored to determine if changes to the stabilization of the spinal motion segment are necessary. For example, after the initial positioning of the spacer member 101, it may be determined that one or both of the centers of rotation for flexion and extension COR_F , COR_E needs to be adjusted. If an adjustment is necessary, the injectable material may be removed and replaced with an alternative injectable material having different flexibility characteristics in order to alter one or both of the centers of rotation for flexion and extension COR_F , COR_E as desired. It is further contemplated that the stabilization of the spinal motion segment may be continuously monitored and, if necessary, the injectable material may be varied until desired stabilization of the spinal motion segment is accomplished. The injectable material may be removed and introduced to the chamber 122 of the spacer member 101 through any known surgical

procedure. In one form however, the spacer member 101 is structured for access by a delivery instrument through a percutaneous surgical procedure in a minimally invasive manner in order to minimize surgical complexity and trauma to the patient.

Referring now to Figs. 8 and 9, there is shown an implant assembly 125 relative to the spinal motion segment of Figs. 1 and 2. Implant assembly 125 includes a spinal implant 130 in the form of a spacer member 131 positioned in the space S and extending between and engaging with the spinous processes SP_1 , SP_2 to provide stabilization and modification of the spinal motion segment. Spacer member 131 includes a body 132 which in its implanted orientation has a first lateral side 134 and a second lateral side 136, with the lateral sides 134, 136 extending between a superior end 138 and an inferior end 140. As best seen in Fig. 9, for example, the body also includes an anterior side 142 opposite a posterior side 144. It should be appreciated that the transition between each of the anterior and posterior sides 142, 144, lateral sides 134, 136, and superior and inferior ends 138, 140 may be rounded or beveled in order to decrease the profile of the body 132 and minimize intrusion and the potential for trauma to adjacent neural tissue and surrounding spinal anatomy.

The body 132 further includes a first concave portion 146 and a second concave portion 148 situated at respective superior and inferior ends 138, 140. Each of the concave portions 146, 148 is disposed between a pair of respective upright arms 150a, 150b and 152a, 152b. Concave portions 146, 148 are sized and shaped to engage with and receive respective inferior surface 12 of the upper spinous process SP_1 and superior surface 14 of the lower spinous process SP_2 . The arms 150a, 150b, 152a, and 152b extend beyond the respective concave portion 146 and concave portion 148 to engage with the lateral sides of the spinous processes SP_1 , SP_2 to prevent or resist dislodgement of the spacer member 131 from space S.

Spacer member 131 is similar to spacer member 31 discussed above but also includes an engaging member 160 extending therefrom to attach spacer member 131 to posterior vertebral elements or implants of the spinal motion segment. Spacer member 131 includes any arrangement for spacer member 31 discussed above in Figs. 1-3G. Spacer member 131 includes through-passages 162 extending between opposite sides thereof, which include the lateral sides 134, 136 of spacer member 131 in the illustrated embodiment. Passages 162

receive engaging member 160 therethrough. Engaging member 160 may comprise multiple engaging members, or a single engaging member looped through passages 162. Still other embodiments contemplate a single passage 162, or three or more passages 162, through which one or more engaging members 160 are positioned.

5 Referring to Fig. 10A there is illustrated a section view of spacer member 131 along view line 10-10 of Fig. 8. As indicated, spacer member 131 is similar to spacer member 31 and likewise includes a first section 154 and a more flexible second portion 156. Sections 154, 156 are also similar to sections 54, 56 described above in regard to spacer 31. However, the first section 154 includes passages 162 extending therethrough. When the
10 engaging member 160 is received in passages 162 and is engaged to posterior vertebral elements or other implants and an axial pulling force is exerted on the spacer member 131, the more rigid section 154 resists deformation of the spacer body. Moreover, alternative embodiment spacer members 131b and 131c are illustrated in section view in Figs. 10B and 10C. In Fig. 10B, the passages extend through the more rigid section 154 such that as an
15 axial pulling force is exerted on the spacer member 131b, the more rigid section 154 again resists deformation of the spacer member 131b. In Fig. 10C, the passages 162 extend through the more flexible second section 156 which is situated between superior and inferior portions of first section 154. In this form, the second section 156 is deformable in response to the axial pulling force until it is limited by the surrounding more rigid first
20 section 154. It should be appreciated that the engaging member 160 and the passages 162 may be alternatively configured relative to the first and second sections 154, 156 in accordance with the various embodiments set forth herein.

Engaging member 160 can be in the form of a tether, cord, wire, cable, suture, band, strap, belt, or other suitable structure for manipulation and securement to one or more
25 posterior vertebral elements. Engaging member 160 may be wrapped or positioned around posterior vertebral elements and then maintained in position with a crimp or other suitable fastener. Furthermore, engaging member 160 can be coupled to spacer member 131 in any suitable manner. In one embodiment, engaging member 160 is movably coupled to spacer member 131. Engaging member 160 can be integrally formed with spacer member 131, or
30 can be attached by a fastener, suture, anchor, cable, link, over-molding or other suitable connection. Spacer member 131 can be provided with ears, eyelets, recesses or other

suitable structure to facilitate engagement of engaging member 160 to spacer member 131. Engaging member 160 may be employed in spinal stabilization procedures where it is desired to limit spinal flexion by, for example, wrapping engaging member 160 about the superior surface of the upper spinous process and/or upper lamina and the inferior surface of the lower spinous process and/or the lower lamina. Engaging member may alternatively be employed as a retention mechanism to maintain spacer member 160 in position between the spinous processes.

With respect to the various embodiments described herein, the engaging member can be joined or fixed to the spacer member using various devices and/or techniques, or can be integrally formed with or form an extension of the spacer member. The spacer member can be joined or attached to the engaging member by, for example, sewing the engaging member to the spacer member, thermal welding or bonding, adhesive bonding, three dimensional weaving or braiding, screws, staples, pins, tacks or rivet fixation. Furthermore, the engaging member can be secured to the spacer member either before or after the spacing member is placed between the spinous processes. The engaging member can be engaged to other engaging members of other implant assemblies or to other implants engaged to the spinal column in the surgical procedure.

The engaging members described herein can be made from any one or combinations of biocompatible material, including synthetic or natural autograft, allograft or xenograft tissues, and can be resorbable or non-resorbable nature. Examples of tissue materials include hard tissues, connective tissues, demineralized bone matrix and combinations thereof. Further examples of resorbable materials are polylactide, polyglycolide, tyrosine-derived polycarbonate, polyanhydride, polyorthoester, polyphosphazene, calcium phosphate, hydroxyapatite, bioactive glass, and combinations thereof. Further examples of non-resorbable materials are carbon-reinforced polymer composites, shape-memory alloys, titanium, titanium alloys, cobalt chrome alloys, stainless steel, and combinations thereof.

While not illustrated, it should be appreciated that one or more of the spacers contemplated herein may include one or more additional sections with one more additional elasticity, flexibility, or rigidity qualities. Moreover, in another non-illustrated form, it is contemplated that upon implantation the spacer member may not include one of the first or second sections. In this form, a plurality of coupleable members sized and shaped like the

first or second section may be provided with differing flexibility characteristics so that a surgeon may select which to include at the implant site during a surgical procedure. It should be appreciated that the coupleable members may engage with the spacer members through any one or more of a press fit engagement, a mechanical connection, fusion, or adhesion, just to name a few possibilities. It should also be appreciated that in one or more forms the spacer members may be integrally formed or may include one or more portions coupled together.

In a further embodiment, it is contemplated that stiffening members can be provided to enhance or increase the stiffness of spacer members 31, 71, 101, 131. For example, in one non-illustrated form, a stiffening member may be in the form of a band that extends about and contacts the perimeter of spacer members 31, 71, 101, 131. Moreover, more than one stiffening member can be provided about spacer members 31, 71, 101, 131 to allow the stiffness profile of the spacer members 31, 71, 101, 131 to be increased or decreased by adding or removing a stiffening member. Examples of suitable stiffening members include woven fabric tubing, woven and non-woven mesh, or braided or woven structures, sutures, tethers, cords, planar members, bands, wires, cables, or any other component capable of extending about the perimeter of the spacer member to increase stiffness thereof.

While the invention has been illustrated and described in detail in the drawings and foregoing description, the same is to be considered illustrative and not restrictive in character, it being understood that only selected embodiments have been shown and described and that all changes, equivalents, and modifications that come within the scope of the inventions described herein or defined by the following claims are desired to be protected. Any experiments, experimental examples, or experimental results provided herein are intended to be illustrative of the present invention and should not be construed to limit or restrict the invention scope. Further, any theory, mechanism of operation, proof, or finding stated herein is meant to further enhance understanding of the present invention and is not intended to limit the present invention in any way to such theory, mechanism of operation, proof, or finding. In reading the claims, words such as "a", "an", "at least on", and "at least a portion" are not intended to limit the claims to only one item unless specifically stated to the contrary. Further, when the language "at least a

portion" and/or "a portion" is used, the claims may include a portion and/or the entire item unless specifically stated to the contrary.

5 What is claimed is:

1. A spinal implant, comprising:

10 a spacer member extending along a longitudinal axis between opposite upper and lower ends, said upper and lower ends being structured to receive a respective adjacent one of upper and lower spinous processes of a spinal motion segment, said spacer member including a body with at least a first section and a second section structured for positioning between and in supporting engagement with the upper and lower spinous processes, said first and second sections including flexibility characteristics that differ from one another.

15 2. The implant of claim 1, wherein said first section includes a first material and said second section includes a second material, with said second material being more flexible than said first material.

20 3. The implant of claim 1, wherein said flexibility characteristic relates to a modulus of elasticity and wherein said second section has a smaller modulus of elasticity than said first section.

25 4. The implant of claim 3, wherein each of said upper and lower ends includes a concave portion sized and shaped to receive one of the respective upper and lower spinous processes, said concave portions being disposed between a pair arms extending from said upper and lower surfaces to engage with lateral surfaces of the spinous processes.

30 5. The implant of claim 4, wherein said spacer member includes a posterior surface and an anterior surface in an implantation orientation between the upper and lower spinous processes, said anterior and posterior surfaces extending between said upper and lower ends and wherein said first section is positioned adjacent said anterior surface and said second section is positioned adjacent said posterior surface.

5 6. The implant of claim 4, wherein said body further includes a third section disposed adjacent to said concave portions, said third section being structured to conform to the upper and lower spinous processes when the upper and lower spinous processes bear against said concave portions.

10 7. The implant of claim 1, wherein said first section of said body includes a first longitudinal member and a second longitudinal member and said second section includes a partially arcuate portion disposed between said first and second members such that said body is substantially U-shaped, said arcuate portion including first and second surfaces structured to receive a respective adjacent one of the upper and lower spinous processes and said first and second longitudinal members being structured to engage with upper and lower laminae of the spinal motion segment.

15 8. The implant of claim 7, wherein said characteristic relates to a modulus of elasticity and wherein said second section has a smaller modulus of elasticity than said first section.

20 9. The implant of claim 1, further comprising at least one tether engaged to said body and extending therefrom, said tether being engageable with one of the upper and lower spinous processes.

10. The implant of claim 9, wherein said at least one tether extends through said first section and wherein said first section is more rigid than said second section.

25 11. The implant of claim 10, wherein said first section includes at least one bore extending therethrough between opposite sides of said body transversely to a direction between said upper and lower ends, said at least one tether extending through said at least one bore.

30 12. The implant of claim 11, further comprising a second bore through said first section of said body adjacent to and paralleling said first bore.

13. The implant of claim 12, further comprising a second tether extending through said second bore, said second tether being engageable with the other of the upper and lower spinous processes.

14. The implant of claim 9, wherein said at least one tether extends through said second section of said body, said second section being less rigid than said first section and being at least partially surrounded by said first section.

15. A spinal implant, comprising:

a spacer sized and shaped to extend between adjacent upper and lower spinous processes of a spinal motion segment, said spacer member including a body with an exterior wall extending between opposite upper and lower ends, said exterior wall including a posterior surface and an anterior surface when in an implantation orientation between the upper and lower spinous processes and said body including at least a first section means having a first flexibility characteristic for movably supporting the upper and lower spinous processes when positioned therebetween and a second section means having a second flexibility characteristic for movably supporting the upper and lower spinous processes when positioned therebetween that differs from said first flexibility characteristic.

16. The implant of claim 15, wherein said second flexibility characteristic of said second section means is defined by a smaller modulus of elasticity than a modulus of elasticity of said first section means.

17. The implant of claim 15, wherein said first section means comprises a first material and said second section means comprises a second material, said second material being more flexible than said first material.

18. The implant of claim 15, wherein said first section means extends from said anterior surface toward said posterior surface and said second section means extends from said posterior surface toward said anterior surface.

19. The implant of claim 18, wherein said first section means includes a posterior extension that is at least partially surrounded by said second section means.

5 20. The implant of claim 18, wherein said first section means extends along upper and lower sides of said second section means.

21. The implant of claim 15, wherein said first section means extends substantially parallel to said anterior and posterior surfaces and said second section means extends along
10 anterior and posterior sides of said first section means.

22. The implant of claim 15, wherein said first section means and said second section means extend between extend between said anterior and posterior surfaces and said second section means extends along upper and lower sides of said first section.

15 23. The implant of claim 15, wherein said upper and lower surfaces include a concave portion structured to receive one of said respective upper and lower spinous processes.

24. The implant of claim 23, wherein said body further comprises a third section disposed adjacent said concave portions, said third section comprising a compressible material
20 structured to conform to the respective adjacent upper and lower spinous processes when the spinous processes bear against said concave portions.

25 25. The implant of claim 23, wherein each of said upper and lower surfaces includes a pair of arms extending therefrom to engage with lateral surfaces of one of said respective upper and lower spinous processes.

26. The implant of claim 15, wherein at least one of said first and second section means defines an internal chamber including an injectable material disposed therein, said injectable
30 material having a different modulus of elasticity than the other of the first and second section means.

27. The implant of claim 15, further comprising at least one tether engaged to said body and extending therefrom, said tether being engageable with one of the upper and lower spinous processes.

5

28. A method for stabilizing a spinal motion segment, comprising:

providing a spacer member including an upper end structured to contact an inferior surface of an upper spinous process and a lower end structured to contact a superior surface of a lower spinous process and a body including at least flexibly distinctive first and second sections forming an asymmetrical stiffness profile that varies between anterior and posterior sides of said body; and

10

positioning said spacer member between the upper and lower spinous processes of the spinal motion segment with said first section oriented anteriorly and said second section oriented posteriorly and with said first and second sections movably supporting the upper and lower spinous processes.

15

29. The method of claim 28, wherein said spacer member varies the center of rotation for flexion and extension of an upper vertebral body engaged to said upper spinous process relative to a lower vertebral body engaged to said lower spinous process.

20

30. The method of claim 28, further comprising positioning each of the upper and lower spinous processes between arms at each of the upper and lower ends of the spacer member.

25

31. The method of claim 28, further comprising engaging the spacer member to posterior vertebral elements of the spinal motion segment with a tether.

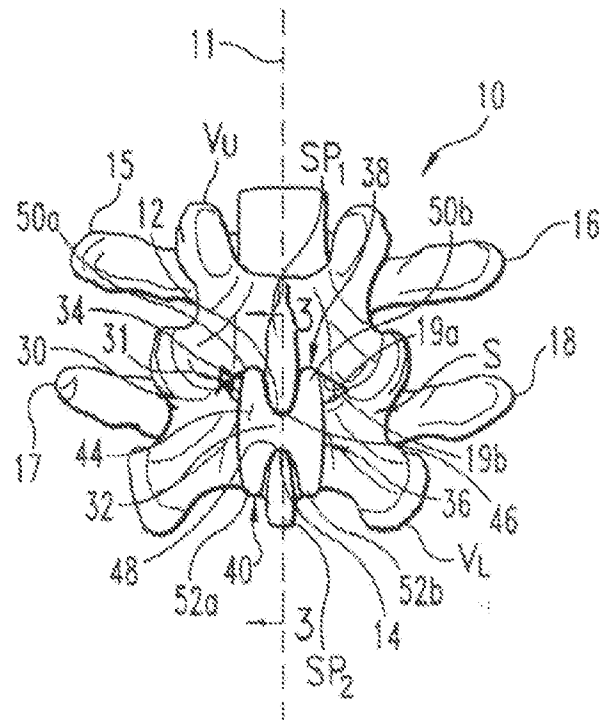


Fig. 1

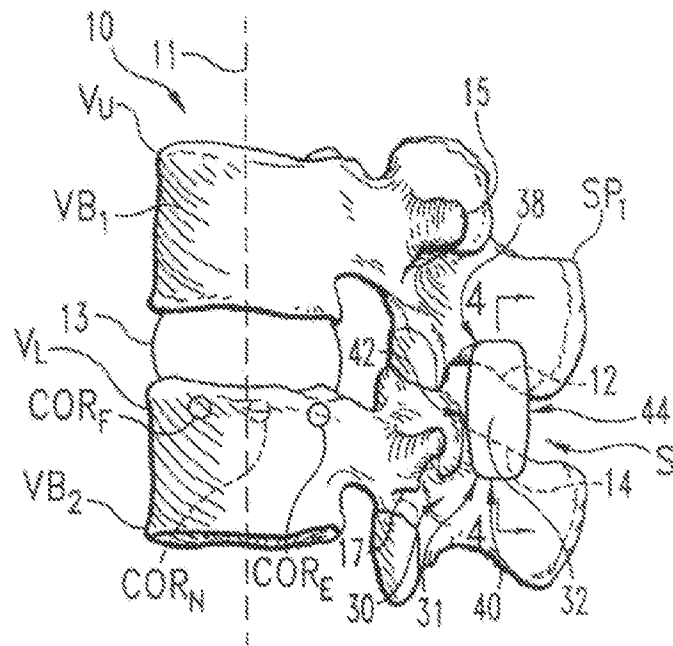
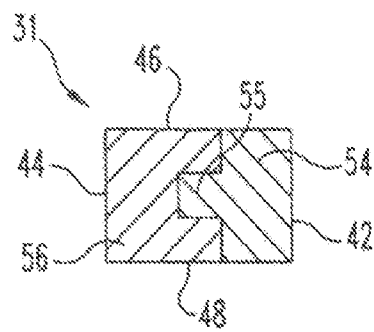
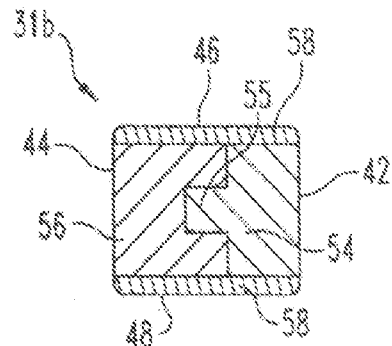
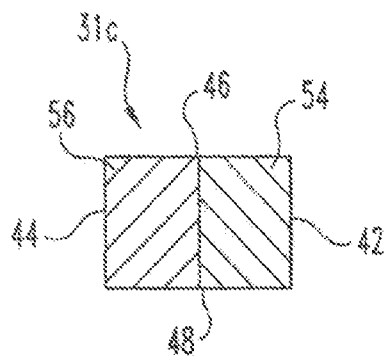
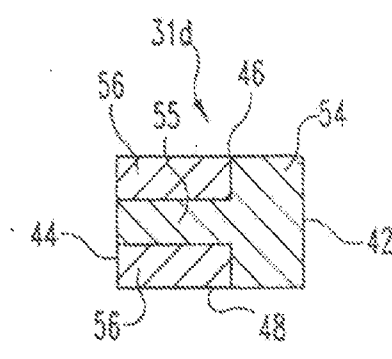
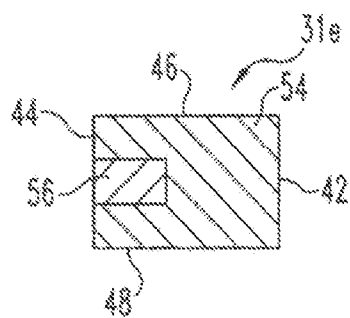
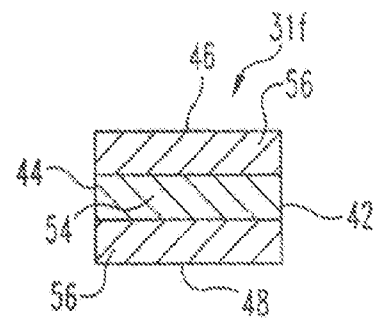
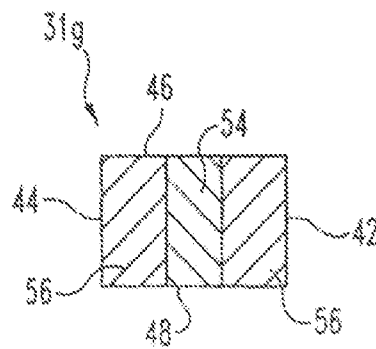


Fig. 2

**Fig. 3A****Fig. 3B****Fig. 3C****Fig. 3D****Fig. 3E****Fig. 3F****Fig. 3G**

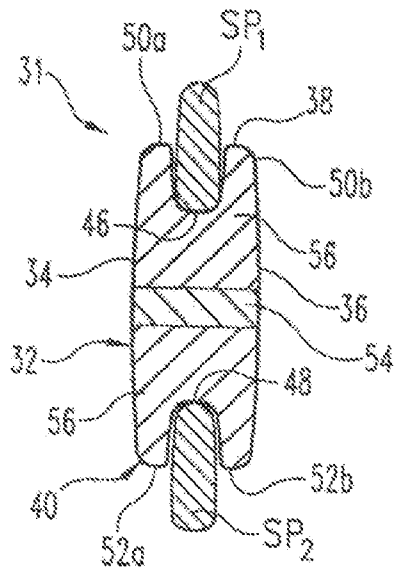


Fig. 4A

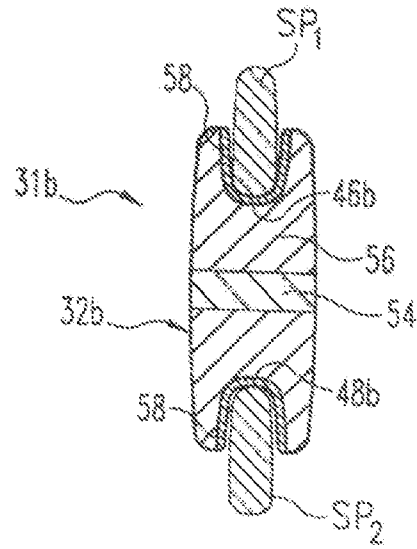


Fig. 4B

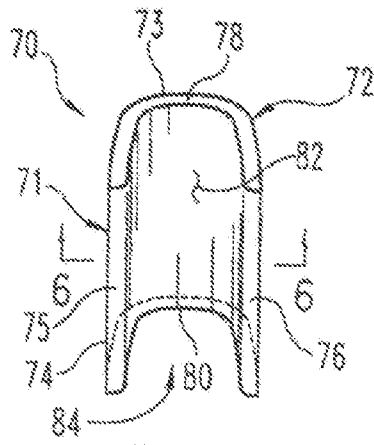


Fig. 5

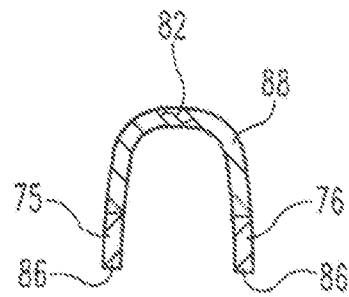


Fig. 6

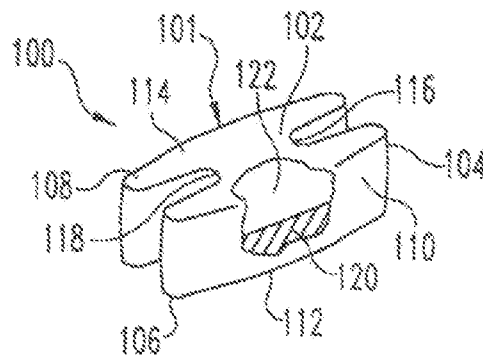
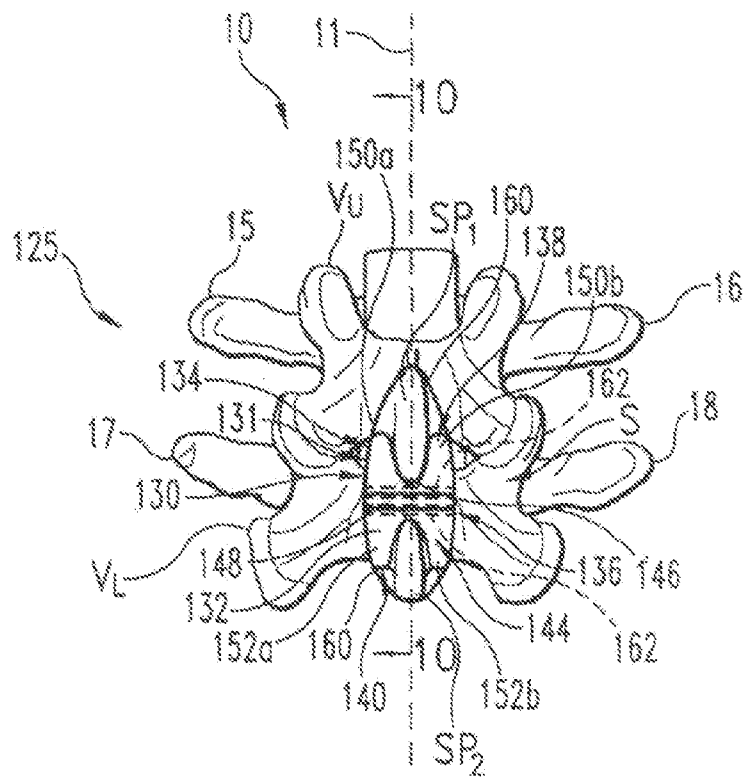
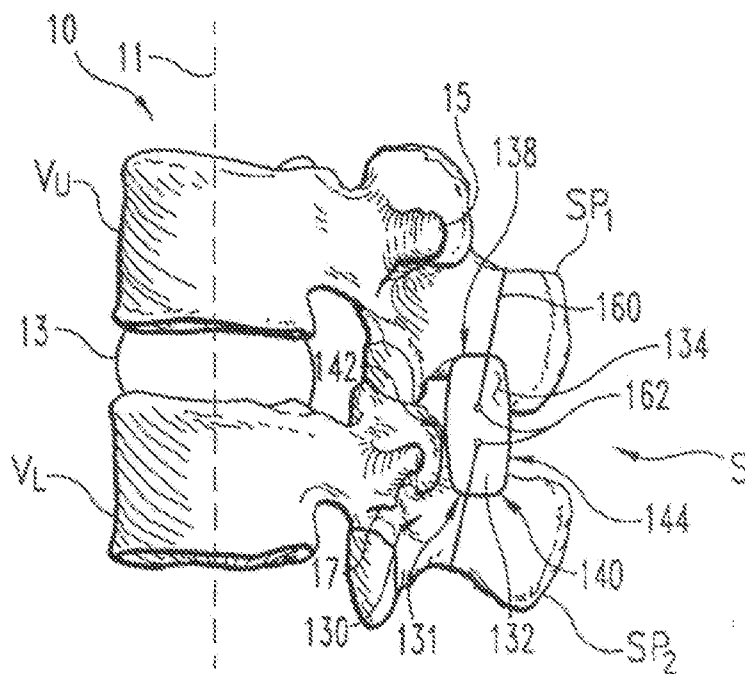


Fig. 7

**Fig. 8****Fig. 9**

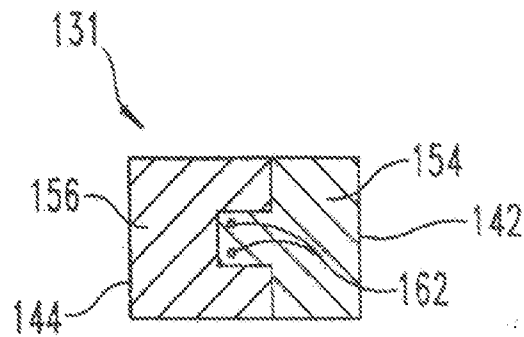


Fig. 10A

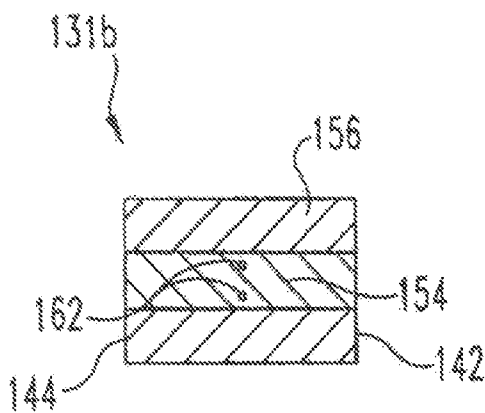


Fig. 10B

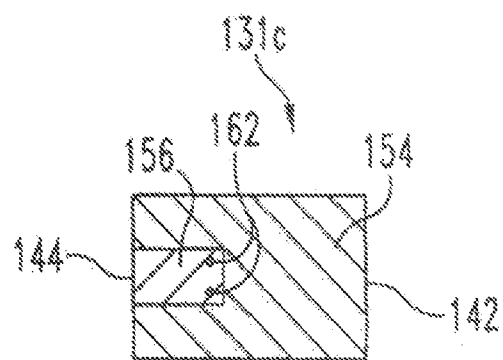


Fig. 10C

INTERNATIONAL SEARCH REPORT

International application No

PCT/US2009/034208

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2007/213829 A1 (LE COUEDIC REGIS [FR] ET AL) 13 September 2007 (2007-09-13) paragraph [0031]; figures 1,2	1-5, 9-13, 15-18, 20,22, 23,25,27
X	WO 2007/090009 A (WARSAW ORTHOPEDIC INC [US]; TRIEU HAI H [US]) 9 August 2007 (2007-08-09) paragraph [0069]; figure 24	1-6, 9-13, 15-18, 20, 22-25,27
X	US 2007/233084 A1 (BETZ RANDAL R [US] ET AL) 4 October 2007 (2007-10-04) paragraph [0081]; figures 13A,13B ----- -/--	1-6,15, 23-25

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

* Special categories of cited documents:

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- *&* document member of the same patent family

Date of the actual completion of the international search

8 April 2009

Date of mailing of the international search report

17/08/2009

Name and mailing address of the ISA/

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Authorized officer

Fernández Arillo, J

INTERNATIONAL SEARCH REPORT

International application No

PCT/US2009/034208

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	DE 20 2006 018978 U1 (AESCULAP AG & CO KG [DE]) 15 February 2007 (2007-02-15) paragraphs [0031], [0032], [0085]; figure 7 -----	1-6, 15, 23-25
X	US 2007/191838 A1 (BRUNEAU AURELIEN [US] ET AL) 16 August 2007 (2007-08-16) figure 9; compound 87 -----	1-6, 15, 23-25
X	WO 2007/090005 A (WARSAW ORTHOPEDIC INC [US]; ANDERSON KENT M [US]; BRUNEAU AURELIEN [US] 9 August 2007 (2007-08-09) figure 4 -----	1, 15
X	WO 2006/110767 A (SDGI HOLDINGS INC [US]; LIM ROY K [US]; SHERMAN MICHAEL C [US]) 19 October 2006 (2006-10-19) figure 12 -----	1, 15
X	WO 2005/044152 A (IMPLIANT LTD [IL]; ARNIN URI [IL]; TAUBER MICHAEL [IL]; SUDIN YURI [IL] 19 May 2005 (2005-05-19) figure 1C -----	1, 15
X	US 5 836 948 A (ZUCHERMAN JAMES F [US] ET AL) 17 November 1998 (1998-11-17) figure 67 -----	1, 15
X	WO 2007/127550 A (WARSAW ORTHOPEDIC INC [US]; BRUNEAU AURELIEN [US]; CARLS THOMAS A [US]) 8 November 2007 (2007-11-08) figure 12 -----	1, 15
X	US 2006/241757 A1 (ANDERSON KENT M [US]) 26 October 2006 (2006-10-26) figure 5 -----	1, 15

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2009/034208

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 28-31
because they relate to subject matter not required to be searched by this Authority, namely:
Pursuant to Rule 39.1(iv) PCT, the subject-matter of claims 28-31 has not been searched, since it is directed to a method for treatment of the human body by surgery (see, in particular, the step of "positioning said spacer member between the spinous processes" defined in claim 28).
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers allsearchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search reportcovers only those claims for which fees were paid, specifically claims Nos.:
4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

see additional sheet(s)

Remark on Protest

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

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

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

1. claims: 1-6, 9-13, 15-18, 20, 22-25 and 27

An implant according to either claim 4 or claim 23, further including a third section adjacent to the concave sections structured to conform to the spinous processes (claims 6 and 24), thereby solving the problem of providing enhanced reception and engagement of the implant with the spinous processes.

2. claims: 7, 8

An implant according to claim 1, wherein the first section includes two longitudinal members and the second section includes an arcuate portion between said longitudinal members so that the body is substantially U-shaped, thereby solving the problem of keeping a distraction space between the laminae to help avoid stenosis and associated neural complications.

3. claim: 14

An implant according to claim 9, wherein the tether extends through the second section of the body, said second section being less rigid than the first section and being at least partially surrounded by the first section, thereby solving the problem of improving the shock-absorption capability of the implant without increasing the pressure on the surface of the spinous processes (since a flexion force and the resulting tension force of the tether will be absorbed by the flexible second section at least partially rigidly encased within the rigid first section).

4. claim: 19

An implant according to claim 18, wherein the first section means includes a posterior extension partially surrounded by the second section means, thereby solving the problem of enhancing the fixation of said two section means to each other.

5. claim: 21

An implant according to claim 15, wherein the second section means extends along anterior and posterior sides of said first section means, thereby solving the problem of providing an implant having different flexibility in flexion than in extension.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

6. claim: 26

An implant according to claim 15, further comprising an injectable material, thereby solving the problem of allowing the stiffness of the implant to be changed during or after implantation.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2009/034208

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2007213829 A1	13-09-2007	AT 320761 T AU 7758301 A AU 2001277583 B2 DE 60118203 T2 EP 1299042 A2 ES 2260254 T3 FR 2811540 A1 WO 0203882 A2 JP 2004502490 T TW 592660 B US 2004106995 A1 ZA 200300158 A	15-04-2006 21-01-2002 08-12-2005 12-04-2007 09-04-2003 01-11-2006 18-01-2002 17-01-2002 29-01-2004 21-06-2004 03-06-2004 05-02-2004
WO 2007090009 A	09-08-2007	US 2007191837 A1	16-08-2007
US 2007233084 A1	04-10-2007	NONE	
DE 202006018978 U1	15-02-2007	NONE	
US 2007191838 A1	16-08-2007	NONE	
WO 2007090005 A	09-08-2007	US 2007191833 A1	16-08-2007
WO 2006110767 A	19-10-2006	US 2006241610 A1	26-10-2006
WO 2005044152 A	19-05-2005	AT 363250 T DE 602004006709 T2 EP 1578314 A1 ES 2287686 T3 US 2006149383 A1 US 2007213724 A1 US 2007191847 A1 US 2007191947 A1 US 2007191948 A1 US 2007191949 A1 US 2007203494 A1 US 2007191950 A1 US 2007288006 A1 US 2005102028 A1 US 2008009947 A1 US 2008004706 A1 US 2008009948 A1	15-06-2007 07-02-2008 28-09-2005 16-12-2007 06-07-2006 13-09-2007 16-08-2007 16-08-2007 16-08-2007 16-08-2007 30-08-2007 16-08-2007 13-12-2007 12-05-2005 10-01-2008 03-01-2008 10-01-2008
US 5836948 A	17-11-1998	DE 69738301 T2 US 6074390 A US 6090112 A US 2008172057 A1	18-09-2008 13-06-2000 18-07-2000 17-07-2008
WO 2007127550 A	08-11-2007	AU 2007243084 A1 EP 2020935 A2 US 2007270824 A1	08-11-2007 11-02-2009 22-11-2007
US 2006241757 A1	26-10-2006	NONE	