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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
13 March 2008 (13.03.2008)

PCT

(10) International Publication Number
WO 2008/030935 A2

(51) International Patent Classification:
A61B 17/80 (2006.01) *A61B 17/70* (2006.01)

(21) International Application Number:
PCT/US2007/077726

(22) International Filing Date:
6 September 2007 (06.09.2007)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
11/470,810 7 September 2006 (07.09.2006) US

(71) Applicant *(for all designated States except US)*: **WARSAW ORTHOPEDIC, INC.** [US/US]; 2500 Silveus Crossing, Warsaw, Indiana 46581 (US).

(72) Inventors; and
(75) Inventors/Applicants *(for US only)*: **ANDERSON, Kent M.** [US/US]; 1310 Bocage Cove, Number 201, Memphis, Tennessee 38103 (US). **STOKLUND, Ole** [US/US]; 3360 Golden Chance Cove, Germantown, t 38138 (US).

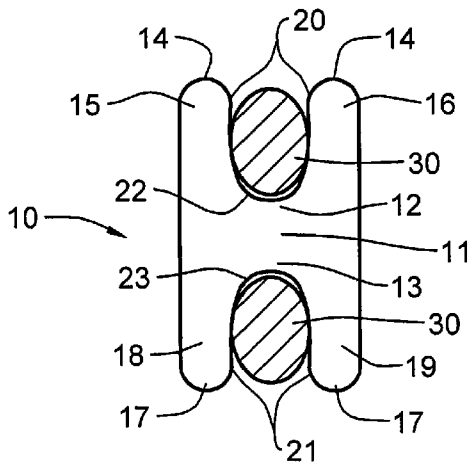
(74) Agents: **HAINES, Warren, M.** et al.; 710 Medtronic Parkway MS LC340, Minneapolis, Minnesota 55432 (US).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, MT, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— *without international search report and to be republished upon receipt of that report*

(54) **Title:** INTERCOSTAL SPACER DEVICE AND METHOD FOR USE IN CORRECTING A SPINAL DEFORMITY



(57) **Abstract:** An intercostal spacer device for placement between two adjacent ribs, includes a spacer member and at least one pair of arms that extend from a first end of the spacer member and at least one pair of arms that extend from a second end of the spacer member. The intercostal spacer device may also include a flexible, fillable container for containing an injectable material that is compressible following implantation. The container is impermeable to the material it will be filled with. A structural mesh, for example, made of PET fabric and interwoven shape-memory alloy wire, provides structure for and containment of the container, as well as shape control of the intercostal spacer device. The material can be injected into the container through a conduit. The intercostal spacer device is sized and configured to allow for placement into the intercostal space to produce force for correcting a spinal deformity.

WO 2008/030935 A2

INTERCOSTAL SPACER DEVICE AND METHOD FOR USE IN CORRECTING A SPINAL DEFORMITY

Technical Field

The present invention relates generally to orthopaedic implants used for the correction of spinal deformities, and more specifically, but not exclusively, concerns apparatuses placed within the intercostal space of two ribs to allow for deformity correction or healing of the spinal column.

Background of the Invention

To secure and treat spinal deformities, including scoliosis, it is a generally accepted practice to place implants adjacent to or into the vertebrae to produce loads for correcting an abnormal curvature of the spine and to maintain appropriate vertebral support for the healing of the implanted bone fusion material.

Typical spinal implant systems are implanted through a posterior approach to the spinal column and utilize a rod as the support and stabilizing element connected to a series of two or more bone fasteners that have been inserted into two or more vertebrae. The connections between these components are then secured, thereby fixing a supporting construct to multiple levels in the spinal column.

Summary of the Invention

Advancement of the state of orthopaedic implants and the treatment of pediatric and adolescent scoliosis is believed to be desirable. The present invention satisfies the need for improvements to the surgical treatment by providing a more mechanically efficient intercostal spacer device for implantation into multiple intercostal spaces of a patient's rib cage. The intercostal spacer device is a one piece construct fabricated from a biocompatible material. Alternatively, the intercostal spacer device may be a multiple piece construct that includes a flexible container that is fillable in situ to a desired amount, with a structure for at least part of the container providing shape control of the intercostal spacer device. An optional conduit coupled to the container allows for filling of the container, for example, by injecting a material into the container.

The present invention provides in one aspect, an intercostal spacer device. The intercostal spacer device includes a spacer member that has a superior end and an inferior end. Extending from both the superior end and inferior end are at least one pair of arms with a channel defined between each pair of arms. The spacer member is sized and configured to enable placement of the spacer member within an intercostal space, with each channel being sized to receive a rib allowing the intercostal spacer device to resist dislodgement from the ribs and produce a force for correcting a spinal deformity.

The present invention provides in another aspect, an intercostal spacer device that includes a flexible container for receiving an injectable material that is compressible following implantation between two adjacent ribs, wherein the flexible container is substantially impermeable to the injectable material. The intercostal spacer device further includes a conduit coupled to the flexible container for accepting the injectable material, and a structure for at least part of the flexible container when containing the material, wherein the structure has a shape to fit between two adjacent ribs.
Another aspect of the present invention provides a method of controlling at least part of the shape of the intercostal spacer device. The intercostal spacer device has a flexible container for containing an injectable material that is compressible following implantation, wherein the container is substantially impermeable to the injectable material. The intercostal spacer device further includes a structure for at least part of the flexible container. The method provides for creating the structure with at least one material for controlling at least part of the shape of the intercostal spacer device following implantation into the intercostal space.

The present invention provides in yet another aspect, an intercostal spacer system. The intercostal spacer system includes a plurality of intercostal spacer devices, with each of the intercostal spacer devices having a spacer member that has a superior end and an inferior end. Extending from both the superior end and inferior end are at least one pair of arms with a channel being defined between each pair of arms. The spacer member is sized and configured to enable placement of the member within an intercostal space, with each channel being sized to receive a rib, allowing the intercostal spacer device to resist dislodgement from the ribs when implanted. Following implantation, the plurality

of intercostal spacer devices cooperate to dynamically produce a force for correcting a spinal deformity within a patient.

The present invention provides another aspect, a method of correcting a spinal deformity. The method includes the step of providing at least one intercostal spacer device, the intercostal spacer device includes a spacer member having first and second ends with at least one pair of arms extending from each of the first and second ends. The spacer member, the first pair of arms extending from the first end and the second pair of arms extending from the second end of the at least one intercostal spacer are sized for placement between a first rib and an adjacent second rib of a patient. The method further includes the positioning of the at least one intercostal spacer device into the intercostal space between the two adjacent ribs of the patient with the first rib disposed between the first pair of arms and the adjacent second rib disposed between the second pair of arms and thus securing the intercostal spacer device within the intercostal space and producing a force to correct the spinal deformity of the patient.

Another aspect of the present invention provides a method of correcting a spinal deformity. The method includes providing an intercostal spacer device, the intercostal spacer devices includes a flexible container for containing an injectable material that is compressible following implantation, wherein the flexible container is substantially impermeable to the injectable material. The intercostal spacer device further includes a conduit coupled to the flexible container for accepting the injectable material, and a structure for at least part of the flexible container when containing the material, wherein the structure has a shape of the intercostal spacer device that is sized and configured to fit between adjacent ribs in a patient. The method further includes implanting the intercostal spacer device between two adjacent ribs. The injectable material is then injected into the flexible container through the conduit such that the shape of the structure is achieved, thus producing a force to correct the spinal deformity of the patient.

Further, additional features and advantages are realized through the techniques of the present invention. Other embodiments and aspects of the invention are described in detail herein and are considered a part of the claimed invention.

Brief Description of the Drawings

The subject matter which is regarded as the invention is particularly pointed out and distinctly claimed in the claims at the conclusion of the specification. The foregoing and other objects, features and advantages of the invention are apparent from the following detailed description taken in conjunction with the accompanying drawings in which:

FIG. 1A is a side elevational view of one embodiment of an intercostal spacer device shown disposed between the cross-section of two adjacent ribs, in accordance with an aspect of the present invention;

FIG. 1B is a side elevational view of one embodiment of an intercostal spacer device with two single connectors shown disposed between the cross-section of two adjacent ribs, in accordance with an aspect of the present invention;

FIG. 1C is a side elevational view of one embodiment of an intercostal spacer device shown disposed between the cross-section of two adjacent ribs, with a single connector surrounding the entire intercostal spacer device, in accordance with an aspect of the present invention;

FIG. 1D is a side elevational view of one embodiment of an intercostal spacer device, shown disposed between the cross-section of two adjacent ribs, with a single connector utilizing an alternative securing configuration, in accordance with an aspect of the present invention;

FIG. 1E is a side elevational view of one embodiment of an intercostal spacer device shown disposed between the cross-section of two adjacent ribs, with two alternative single connectors inserted through two bore holes, in accordance with an aspect of the present invention;

FIG. 1F is a perspective view of the intercostal spacer device embodiment of FIG. 1E with the two alternative single connectors extracted from the two bore holes, in accordance with an aspect of the present invention;

FIG. 2 is a posterior elevational view of one embodiment of an intercostal spacer system implanted in the posterior aspect of the rib cage, in accordance with an aspect of the present invention;

FIG. 3 is a perspective view of one embodiment of an intercostal spacer device, in accordance with an aspect of the present invention;

FIG. 4A is a posterior elevational view of one embodiment of an intercostal spacer system shown disposed between three ribs, in accordance with an aspect of the present invention;

FIG. 4B is a cross-section side elevational view of the intercostal spacer device system of FIG. 4A taken along line 4B-4B shown disposed between the cross-section of four adjacent ribs, in accordance with an aspect of the present invention;

FIG. 4C is a posterior perspective view of one embodiment of an intercostal spacer system shown disposed between four adjacent ribs, in accordance with an aspect of the present invention;

FIG. 5 is a perspective view of one embodiment of an intercostal spacer device, in accordance with an aspect of the present invention;

FIG. 6 is a posterior elevational view of one embodiment of an intercostal spacer system implanted in the posterior aspect of the rib cage, in accordance with an aspect of the present invention;

FIG. 7 is a posterior elevational view of one embodiment of an intercostal spacer device system shown disposed between four adjacent ribs, in accordance with an aspect of the present invention;

FIG. 8 is a perspective partial cut-away view of one embodiment of an unfilled intercostal spacer device with the container in the structure, in accordance with an aspect of the present invention;

FIG. 9 is a posterior elevational view of one embodiment of an intercostal spacer device with an integrated container and structure, in accordance with an aspect of the present invention;

FIG. 10 is a cross-sectional elevational view of one embodiment of an intercostal spacer device with an external container, in accordance with an aspect of the present invention; and

FIG. 11 depicts another embodiment of an intercostal spacer device with an integrated container and structure, in accordance with another aspect of the present invention.

Best Mode for Carrying Out The Invention

As depicted in FIG.1A, the general arrangement of an intercostal spacer device 10, in accordance with an aspect of the present invention, includes a spacer member 11 comprising a superior end 12 and an inferior end 13 with a central axis (not shown) extending between superior end 12 and inferior end 13. Extending in an upward direction from superior end 12 is preferably one pair of arms 14 that may include an anterior arm 15 and a posterior arm 16. Further, extending in a downward direction from inferior end 13 is preferably one pair of arms 17 that may include an anterior arm 18 and a posterior arm 19. Each pair of arms 14, 17 are integral to spacer member 11 and are sized to resist dislodgement of intercostal spacer device 10 following placement within the intercostal space. Further, each pair of arms 14, 17 are centered about the central axis of spacer member 11 resulting in a roughly H-shaped overall structure. An upper channel 20 is typically defined by a seat 22, anterior arm 15 and posterior arm 16. Additionally, a lower channel 21 is defined by a seat 23, anterior arm 18 and posterior arm 19. Anterior arm 15 and posterior arm 16 are disposed relatively parallel to each other and project in an upward manner from seat 22. Anterior arm 18 and posterior arm 19 project in a downward manner from seat 23 and are substantially parallel to each other. Each pair of arms 14, 17, together with seats 22, 23 form U-shaped channels 20, 21 respectively, which are each appropriately sized to receive a rib 30. When in use in the rib cage, intercostal spacer device 10 is placed within an intercostal space. Preferably, intercostal spacer device 10 is maneuvered in a manner allowing two adjacent ribs 30 to be positioned within channels 20, 21, causing the anterior aspect of the two adjacent ribs 30 to contact anterior arms 15, 18 and the posterior aspect of the two adjacent ribs 30 to contact posterior arms 16, 19.

With reference to FIGS. 1B, 1C, 1D, 1E and 1F, intercostal spacer device 10 includes a spacer member 11 comprising a superior end 12 and an inferior end 13. Extending in an upward direction from superior end 12 is preferably one pair of arms 14 that may include an anterior arm 15 and a posterior arm 16. Further, extending in a downward direction from inferior end 13 is preferably one pair of arms 17 that may include an anterior arm 18 and a posterior arm 19. An upper channel 20 is typically defined by a seat 22, anterior arm 15 and posterior arm 16. Additionally, a lower channel 21 is defined by a seat 23, anterior arm 18 and posterior arm 19. Each pair of arms 14, 17 together with seats 22, 23 form U-shaped channels 20, 21 respectively, which are each appropriately sized to receive a rib 30. Typically, at least one through hole 24 is directed in the anterior to posterior direction and located within spacer member 11 in the intercostal spacer device 10. In one approach, connector 40 (see FIG. 1B) is inserted into hole 24 following the placement of intercostal spacer device 10 between adjacent ribs 30. As depicted in FIG. 1B, a first connector 40 may be inserted through passage or hole 24 that extends from an anterior surface 31 of spacer member 11 to a posterior surface 32 of spacer member and then wraps over the superior surface of rib 30 which is positioned within upper channel 20. A second connector 40 may be inserted through a second passage or hole 24 that extends from anterior surface 31 of spacer member 11 to posterior surface 32 of spacer member 11 and then wraps over the inferior surface of a second adjacent rib 30 which is positioned within lower channel 21. The ends of connectors 40 may be secured using crimps, knots, ties or other suitable fasteners. It is understood to those skilled in the art that other securement techniques and configurations are contemplated and will depend on the type of connector 40 used within intercostal spacer device 10.

As shown in FIG. 1C, an alternative method of securing intercostal spacer device 10 within the intercostal space may include extending at least one connector 40 around the circumference of the exterior surface of intercostal spacer device 10 and the two adjacent ribs 30. The ends of connector 40 may be then be secured using crimps, knots, ties or other suitable fasteners, although it is understood to those skilled in the art that other securement techniques and configurations are contemplated and will depend on

the type of connector 40 used in securing intercostal spacer device 10 within the intercostal space.

As seen in FIG. 1D, another alternative method of securing intercostal spacer device 10 within the intercostal space is contemplated. FIG. 1D depicts the use of at least one connector 40 typically utilizing a figure-8 configuration. A single or multiple connector 40 may be inserted through an angled passage or hole 25 that extends from anterior surface 31 of spacer member 11 to posterior surface 32 of spacer member 11 and then looped over the superior surface of rib 30 which is positioned within upper channel 20. Connector 40 is further passed through a second angled passage or hole 25 that extends from anterior surface 31 of spacer member 11 to posterior surface 32 of spacer member allowing connector 40 to also loop over the inferior surface of a second adjacent rib 30 which is positioned within lower channel 21. The two ends of connector 40 may be secured using crimps, knots, ties or other suitable fastener. It is understood to those skilled in the art that other securement techniques and configurations are contemplated and will depend on the type of connector 40 used within intercostal spacer device 10. Connector 40 may be in the form of a wire, cable, tether, belt, band, cord or other suitable structure for securement within the intercostal space and may be fabricated from a material selected from the group consisting of carbon fiber composite polymers, bio-compatible metals, resorbable polymers, bio-inert polymeric materials, and any combinations of these materials.

Another alternative method for securing intercostal spacer device 10 within the intercostal space is seen at FIGS. 1E and 1F. As shown, intercostal spacer device 10 includes a spacer member 11 comprising a superior end 12 and an inferior end 13. Extending in an upward direction from superior end 12 is preferably one pair of arms 14, including anterior arm 15 and posterior arm 16. Further, extending in a downward direction from inferior end 13 is preferably one pair of arms 17 that may include anterior arm 18 and posterior arm 19. As provided above, upper channel 20 is typically defined by seat 22, anterior arm 15 and posterior arm 16. Additionally, lower channel 21 is defined by seat 23, anterior arm 18 and posterior arm 19. Each pair of arms 14, 17 together with seats 22, 23 form U-shaped channels 20, 21 respectively, which are each appropriately sized to receive a rib 30. Preferably, at least one through hole 26 is directed in an anterior

to posterior direction and passes through anterior arms 15, 18 and posterior arms 16, 19 located within superior pair of arms 14 and inferior pair of arms 17, respectively. As seen in FIG. 1E, at least one hole 26 extends through superior pair of arms 14 and is substantially parallel to a second hole 26 extending through inferior pair of arms 17. In use, intercostal spacer device 10 is placed within an intercostal space and typically is maneuvered in a manner to allow two adjacent ribs 30 to be positioned within upper and lower channels 20, 21, causing the anterior aspect of two adjacent ribs 30 to contact anterior arms 15, 18 and the posterior aspect of two adjacent ribs 30 to contact posterior arms 16, 19. Following final placement of intercostal spacer device 10, a connector 41 (see FIG. 1F) is inserted into hole 26 following the placement of intercostal spacer device 10 between adjacent ribs 30. As depicted in FIG. 1E, one connector 41 may be inserted through hole 26 that is located in the most upper portion of superior pair of arms 14 and span upper channel 20 and across the superior margin of rib 30. Preferably, a second connector 41 is inserted through a second hole 26 located in the most downward portion of inferior set of arms 17 and span lower channel 21 and across the inferior margin of rib 30. The ends of the two connectors 41 may be secured using crimps, caps, nuts, rivets, or other suitable fastener device. It is understood to those skilled in the art that other securement techniques and configurations are contemplated and will depend on the type of connector 41 used within intercostal spacer device 10. Connector 41 may be in the form of a bolt, screw, lock pin, rivet, staple, press-fit pin or other suitable structure for securement within the intercostal space and may be fabricated from a material selected from the group consisting of carbon fiber composite polymers, bio-compatible metals, resorbable polymers, bio-inert polymeric materials, and any combinations of these materials.

FIG. 2 depicts an intercostal spacer system that includes a plurality of intercostal spacer devices 10 placed within the rib cage to correct a spinal deformity of a patient. Multiple intercostal spacer devices 10 are inserted into the intercostal spaces of several adjacent ribs 30 at corresponding deformed spinal levels. Adjacent intercostal spacer devices 10 are preferably implanted in an offset manner relative to each other, resulting in an overall generally staggered arrangement. As described previously, each of the plurality of intercostal spacer devices 10 may be secured within the intercostal space

with at least one connector 40, 41 (not shown). Alternatively, at least one connector 40 may link or couple each of the plurality of intercostal spacer devices 10 to each other (not shown). Typically, the number of intercostal spacer devices 10 implanted may be dependent upon the severity of the spinal deformity and the affected levels of the spinal column. By way of example only, in FIG. 2, three intercostal spacer devices 10 are placed on the concave side of a medial-lateral deformity that spans four levels of the spinal column.

FIG. 3 depicts an alternative embodiment of an intercostal spacer device 100. Intercostal spacer device 100 includes a spacer member 110 comprising of a superior end 112 and an inferior end 113 with a central axis (not shown) extending between superior end 112 and inferior end 113. Extending in an upward direction from superior end 112 is preferably two pair of arms 114, with each pair of arms including an anterior arm 115 and a posterior arm 116. Further, extending from inferior end 113 in a downward direction is preferably one pair of arms 117 that may include an anterior arm 118 and a posterior arm 119. Each pair of arms 114, 117 are integral to spacer member 110 usually with one of the two superior pair of arms 114 being offset laterally relative to the central axis and the second of the two superior pair of arms 114 being offset medially relative to the central axis. The inferior pair of arms 117 are preferably centered about the central axis resulting in a roughly Y-shaped overall structure defining intercostal spacer device 100. For each of superior pair of arms 114, an upper channel 120 is typically defined by a seat 122, anterior arm 115 and posterior arm 116. Additionally, for inferior pair of arms 117, a lower channel 121 is defined by a seat 123, anterior arm 118 and posterior arm 119. For both superior pair of arms 114, anterior arm 115 and posterior arm 116 are disposed relatively parallel to each other and project in a generally upward manner from seat 122. For inferior pair of arms 117, anterior arm 118 and posterior arm 119 project in a generally downward manner from seat 123 and are substantially parallel to each other. Each pair of arms 114, 117, together with seats 122, 123 form U-shaped channels 120, 121 respectively, which are each appropriately sized to receive a rib 30 and allow intercostal spacer device 100 to resist dislodgement following implantation within the rib cage.

Although not shown, it is contemplated that either connector 40, 41 may be utilized with intercostal spacer device 100 to secure intercostal spacer device 100 within

an intercostal space. As described above, it is contemplated that connector 40 may pass through anterior to posterior directed, single or multiple, straight or angled holes or passages (not shown) within spacer member 110, thereby allowing connector 40 to wrap or loop around or over both superior pair of arms 114 and inferior pair of arms 117 allowing for securement of intercostal spacer device 100 within the intercostal space in the same or similar manner as described above for intercostal spacer device 10. Further, as discussed above, it is understood that connector 41 may be inserted through anterior to posterior directed, single or multiple straight holes or passages (not shown) within both superior pair of arms 114 and inferior pair of arms 117. The holes located in both superior pair of arms 114 being substantially parallel to the hole or passage located in inferior pair of arms 117. When in use, connector 41 preferably will be inserted through the holes that are located in the upper most portion of both superior pair of arms 114 and span each upper channel 120 and across the superior margin of rib 30. Additionally, a second connector 41 may be inserted through a hole or passage located in the downward most portion of inferior set of arms 117 and span lower channel 121 crossing over the inferior margin of rib 30.

As shown in FIGS. 4A, 4B and 4C, when used in the rib cage, intercostal spacer device 100 is typically placed within an intercostal space. Preferably, intercostal spacer device 100 is maneuvered in a manner allowing two adjacent ribs 30 to be positioned within two upper channels 120 and lower channel 121, causing the anterior aspect of two adjacent ribs 30 to contact anterior arms 115, 118 and the posterior aspect of two adjacent ribs 30 to contact posterior arms 116, 119.

FIGS. 4A and 4B further depict an alternative embodiment of an intercostal spacer system that includes a plurality of intercostal spacer devices 100 in use within the rib cage to correct a spinal deformity of a patient. Multiple intercostal spacer devices 100 are inserted into the intercostal spaces of adjacent ribs 30 at corresponding affected spinal levels. Adjacent intercostal spacer devices 100 are preferably implanted in close association relative to each other, resulting in an overall generally linear arrangement of the system as shown in FIG. 4A. Preferably, when implanted, the shape and size of intercostal spacer device 100 allows for inferior pair of arms 117 of an upper placed intercostal spacer device 100 to be positioned proximate or within the space defined

between the two superior pair of arms 114 of an adjacent lower placed intercostal spacer device 100. As described previously, each of the plurality of intercostal spacer devices 100 may be secured within the intercostal space with at least one connector 40, 41 (not shown). Alternatively, at least one connector 40 may link or couple each of the plurality of intercostal spacer devices 100 to each other (not shown). Typically, the number of intercostal spacer devices 100 implanted is dependent upon the severity of the spinal deformity and the affected levels of the spinal column. By way of example only, in FIG. 4C, three intercostal spacer devices 100 are shown to be used to correct a spinal deformity that spans four levels of the spinal column.

FIG. 5 depicts still another alternative embodiment of an intercostal spacer device 200. Intercostal spacer device 200 includes a spacer member 210 comprising a superior end 212 and an inferior end 213 with a central axis (not shown) extending between superior end 212 and inferior end 213. Extending in an upward direction from superior end 212 is preferably one pair of arms 214 including an anterior arm 215 and a posterior arm 216. Further, extending in a downward direction from inferior end 213 is preferably one pair of arms 217 that may include an anterior arm 218 and a posterior arm 219. Each pair of arms 214, 217 are integral to spacer member 210 usually with superior pair of arms 214 being offset laterally relative to the central axis and inferior pair of arms 217 being preferably offset medially relative to the central axis. It is contemplated, that an alternative configuration of intercostal spacer device 200 may include each pair of arms 214, 217 to be opposite as described previously, in that superior pair of arms 214 being offset medially relative to the central axis and inferior pair of arms 217 being offset laterally relative to the central axis. An upper channel 220 is typically defined by a seat 222, anterior arm 215 and posterior arm 216. Additionally, for inferior pair of arms 217, a lower channel 221 is defined by a seat 223, anterior arm 218 and posterior arm 219. Anterior arm 215 and posterior arm 216 are disposed relatively parallel to each other and project in a generally upward direction from seat 222. Inferior pair of arms 217, anterior arm 218 and posterior arm 219 project in a generally downward direction from seat 223 and are substantially parallel to each other. Each pair of arms 214, 217, together with seats 222, 223 form U-shaped channels 220, 221 respectively, which are each appropriately sized to receive a rib 30.

Although not shown, as discussed above, it is contemplated that either connector 40, 41 may be utilized with intercostal spacer device 200 to secure intercostal spacer device 200 within an intercostal space. As described previously, it is contemplated that connector 40 may be positioned through anterior to posterior directed, single or multiple, straight or angled holes (not shown) within spacer member 210, thereby allowing connector 40 to wrap or loop around or over superior pair of arms 214 and inferior pair of arms 217 allowing for securement of intercostal spacer device 200 within the intercostal space in the same or similar manner as described for intercostal spacer device 10. Further, as discussed above, it is understood that connector 41 may be inserted through anterior to posterior directed, single or multiple straight holes or passages (not shown) within superior pair of arms 214 and inferior pair of arms 217. The hole or passage located in superior pair of arms 214 being substantially parallel to the hole located in inferior pair of arms 217. When in use, connector 41 preferably will be inserted through the hole or passage that is located in the upper most portion of superior pair of arms 214 and span upper channel 220 and across the superior margin of rib 30. Additionally, a second connector 41 may be inserted through a hole or passage located in the downward most portion of inferior set of arms 217 and span lower channel 221 and across the inferior margin of rib 30.

As shown in FIGS. 6 and 7, when used in the rib cage, intercostal spacer device 200 is placed within an intercostal space. Preferably, intercostal spacer device 200 is maneuvered in a manner allowing two adjacent ribs 30 to be positioned within each of the upper channel 220 and lower channel 221, causing the anterior aspect of two adjacent ribs 30 to contact anterior arms 215, 218 and the posterior aspect of two adjacent ribs 30 to contact posterior arms 216, 219. Upper channel 220 and lower channel 221 are sized and configured to provide resistance to any in vivo forces that may dislodge intercostal spacer device 200 from its position within the intercostal space.

FIGS. 6 and 7 further depict an alternative embodiment of an intercostal spacer system which includes a plurality of intercostal spacer devices 200 in use within the rib cage to correct a spinal deformity of a patient. Multiple intercostal spacer devices 200 are inserted into the intercostal spaces of adjacent ribs 30 at corresponding affected spinal levels. Adjacent intercostal spacer devices 200 are preferably implanted in close

approximation relative to each other, resulting in an overall generally linear arrangement of the system. Preferably, when implanted, the shape and size of intercostal spacer device 200 allows for inferior pair of arms 217 of an upper intercostal spacer device 200 to either contact or be proximate to spacer member 210 of the adjacent and lower intercostal spacer device 200. Additionally, when implanted, typically, superior pair of arms 214 of lower intercostal spacer device 200 will contact or be in close approximation to spacer member 210 of adjacent upper intercostal spacer device 200. As shown in FIG. 7, following implantation, rib 30 may be simultaneously located within lower channel 221 of a superior placed intercostal spacer device 200 and upper channel 220 of an inferior placed intercostal spacer device 200. As described previously, each of the plurality of intercostal spacer devices 200 may be secured within the intercostal space with at least one connector 40, 41 (not shown). Alternatively, at least one connector 40 may link or couple each of the plurality of intercostal spacer devices 200 to each other (not shown). Usually, the number of intercostal spacer devices 200 implanted is dependent upon the severity of the spinal deformity and the affected levels of the spinal column. By way of example only, in FIG. 6, three intercostal spacer devices 200 are used to correct a spinal deformity that spans four levels of the spinal column.

With respect to the various embodiments of the intercostal spacer device 10, 100, 200 described herein, the intercostal spacer device 10, 100, 200 can be fabricated from materials that are flexible or exhibit at least some flexibility. Additionally, the intercostal spacer device 10, 100, 200 may be fabricated from materials that are resilient and/or elastic, so it can assume various shapes during and after insertion and securement within the intercostal space.

The intercostal spacer device 10, 100, 200 can be made from any biocompatible material, material of synthetic or natural origin, and material of a resorbable or non-resorbable nature. Suitable examples of construct material include resorbable materials including polylactide, polyglycolide, tyrosine-derived polycarbonate, polyanhydride, polyorthoester, polyphosphazene, calcium phosphate, hydroxyapatite, bioactive glass, collagen, albumin, fibrinogen and combinations thereof; and non-resorbable materials including polyethylene, polyester, polyvinyl alcohol, polyacrylonitrile, polyamide, polytetrafluorethylene, poly-paraphenylene terephthalamide,

polyetheretherketone, poly urethane, and combinations thereof. Further non-resorbable materials may include carbon-reinforced polymer composites, shape-memory alloys, titanium, titanium alloys, cobalt chrome alloys, stainless steel, and combinations thereof. The intercostal spacer device 10, 100, 200 is preferably fabricated from material capable of resisting compressive motion (or loads) with a stiffness of about 10 to about 300 N/mm (newtons per millimeter).

The method for correcting a spinal deformity includes, providing at least one intercostal spacer device 10, intercostal spacer device 10 includes spacer member 11 comprising superior end 12 and inferior end 13 with a central axis (not shown) extending between superior end 12 and inferior end 13. Extending outward from superior end 12 is preferably at least one superior pair of arms 14 that may include anterior arm 15 and posterior arm 16. Further, extending outward from inferior end 13 is preferably one superior pair of arms 17 that may include anterior arm 18 and posterior arm 19. Each pair of arms 14, 17 are integral to spacer member 11. An upper channel 20 is typically defined by seat 22, anterior arm 15 and posterior arm 16. Additionally, a lower channel 21 is defined by seat 23, anterior arm 18 and posterior arm 19. Each pair of arms 14, 17, together with seats 22, 23 form U-shaped channels 20, 21 which are each appropriately sized to receive a rib 30. The method further includes preferably positioning intercostal spacer device 10 within the intercostal space between two adjacent ribs 30. Preferably, the intercostal spacer device 10 is maneuvered in a manner that typically results in the positioning of a first rib 30 into upper channel 20 between superior pair of arms 14 and a second rib 30 into lower channel 21 between inferior pair of arms 17. Placement of ribs 30 within upper and lower channels 20, 21 secures intercostal spacer device 10 within the patient's rib cage and produces a compressive or distraction force, depending on the spinal curvature geometry, for correcting a spinal deformity. It is further understood that the method may include inserting connectors 40, 41 into each of the intercostal spacer devices 10 following implantation into the intercostal space. Preferably, at least one connector 40 may be utilized with each individual intercostal spacer device 10 or alternatively, at least one connector 40 may link or couple the plurality of intercostal spacer devices to each other. It is contemplated herein that the steps of the method for connecting a spinal

deformity are analogous to those that may be used with intercostal spacer device 100 and intercostal spacer device 200 described herein.

FIGS. 8, 9, 10 and 11 show a further alternative embodiment of the intercostal spacer device 400 that can be formed in situ during a surgical procedure. Intercostal spacer device 400 includes the following basic aspects: a flexible container 402 and a structure 404 for at least part of flexible container 402 that controls at least part of the shape of intercostal spacer device 400. Flexible container 402 can be filled or injected through optional conduit 406 after placement. Further, structure 404 may be folded or otherwise reduced in size prior to use in some aspects. Together with an unfilled container 402, in some aspects, intercostal spacer device 400 can create a smaller footprint during implantation. Once filled, structure 404 provides support and containment for the flexible container 402, as well as providing shape control for at least part of intercostal spacer device 400.

FIG. 8 depicts a partially cut-away view of intercostal spacer device 400. As shown in FIG. 8, intercostal spacer device 400 comprises an unfilled flexible container 402 inside structure 404. Preferably, flexible container 402 is in an evacuated state during implantation and prior to being filled. Where a valve (e.g., a one-way valve) is coupled to flexible container 402, with flexible container 402 preferably being evacuated prior to or during the process of coupling the valve thereto. In this embodiment, structure 404 is outside flexible container 402. However, as will be described in more detail below, flexible container 402 can be outside structure 404, or flexible container 402 and structure 404 can be integrated. In addition, although structure 404 is shown to be roughly H-shaped to fit between adjacent ribs 30, structure 404 may have any shape necessary for the particular surgical application. For example, structure 404 could instead have a roughly cylindrical shape to replace an intervertebral disc. As another example, structure 404 could be spherically or elliptically shaped to replace part of the intervertebral disc, for example, the nucleus pulpous, leaving the rest of the disc intact. Further, although structure 404 is shown enveloping the flexible container 402, structure 404 could be for only a portion of flexible container 402, depending on the particular application. For example, it may be desired to prevent bulging of flexible container 402 only in a particular area. Coupled to flexible container 402 is optional conduit 406 for accepting a material

that is compressible following implantation. Structure 404 provides support for and containment of flexible container 402, when filled.

Flexible container 402 is flexible and substantially impermeable to the material it will be filled with. However, depending on the application, flexible container 402 may be permeable to other materials, for example, it may be air and/or water permeable. In the present example, flexible container 402 takes the form of a bag or balloon, but can take other forms, so long as flexible and substantially impermeable to the material it will be filled with. Thus, flexible container 402 must be substantially impermeable to the injectable material, for example, in a liquid state during filling and prior to curing. Examples of container materials include silicone, rubber, polyurethane, polyethylene terephthalate (PET), polyolefin, polycarbonate urethane, and silicone copolymers.

Conduit 406 accepts the injectable material being used to fill flexible container 402. Preferably, conduit 406 comprises a one-way valve, however, a two-way valve is also contemplated, as another example. Conduit 406 can comprise any material suitable for implanting, for example, various plastics. Also preferably, conduit 406 is constructed to be used with a delivery system for filling flexible container 402, such as, for example, a pressurized syringe-type delivery system. However, the delivery system itself forms no part of the present invention. It is contemplated that, conduit 406 may be optional. Other examples of how to fill flexible container 402 comprise the use of a self-sealing material for flexible container 402, or leaving an opening in flexible container 402 that is closed (e.g., sewn shut) intraoperatively after filling. Using a curable material to fill flexible container 402 may also serve to self-seal flexible container 402.

In use, flexible container 402 is filled with an injectable material that is compressible following implantation between two adjacent ribs of a patient. The compressibility characteristic ensures that the injected material exhibits viscoelastic behavior and that, along with structure 404, the intercostal spacer device 400 can accept compressive loads. Preferably, intercostal spacer device 400 may be capable of resisting compressive motion (or loads) with a stiffness of about 10 to about 300 N/mm (newtons per millimeter). The material is preferably injectable, and may be compressible immediately or after a time, for example, after curing. For purposes of the invention, the

compressibility characteristic is necessary during end use, i.e., after implantation. Materials that could be used include, for example, a plurality of beads (e.g., polymer beads) that in the aggregate are compressible, or materials that change state from exhibiting fluid properties to exhibiting properties of a solid or semi-solid. Examples of such state-changing materials include two-part curing polymers and adhesive, for example, platinum-catalyzed silicone, epoxy or polyurethane.

As noted above, structure 404 provides support for and containment of container 402 when filled, as well as at least partial shape control of intercostal spacer device 400. Structure 404 comprises, for example, a structural mesh comprising a plurality of fibers and/or wires 408. Within the structural mesh are shape-control fibers and/or wires 410. In one example, shape control is provided by wires of a shape-memory alloy (e.g., Nitinol). Shape-memory alloy wire(s) 410 can be coupled to the structural mesh (inside or outside), or weaved into the mesh (i.e., integrated). Coupling can be achieved, for example, by stitching, twisting, or closing the wire on itself. Alternatively, shape control can be provided by other wires or fibers that do not "give" in a particular direction, for example, metal or metal alloys (e.g., tantalum, titanium or steel, and non-metals, for example, carbon fiber, PET, polyethylene, polypropylene, etc.). The shape-memory alloy can be passive (e.g., elastic) or active (e.g., body-temperature activated). The use of metal, metal alloy or barium coated wires or fibers can also improve radiopacity for imaging. The remainder of structure 404 can take the form of, for example, a fabric jacket, as shown in FIG. 8. Although the shape-memory alloy wires 410 make up only a portion of the structural mesh of FIG. 8, it will be understood that there could be more such wires, up to and including comprising the entirety of the mesh. The fabric jacket in this example contains and helps protect flexible container 402 from bulging and damage from forces external to flexible container 402, while the shape-memory alloy provides shape control of intercostal spacer device 400 in a center region 412. The fibers of the jacket comprise, for example, PET fabric, polypropylene fabric, polyethylene fabric and/or steel, titanium or other metal wire. Depending on the application, structure 404 may be permeable to a desired degree. For example, if bone or tissue growth is desired to attach to structure 404, permeability to the tissue or bone of interest would be appropriate. As another example, permeability of structure 404 may be desired to allow the material used to fill flexible

container 402 to evacuate air or water, for example, from flexible container 402, in order to prevent bubbles from forming inside. Where a mesh is used, for example, the degree of permeability desired can be achieved by loosening or tightening the weave.

Although structure 404 is shown in a roughly H-shape in the example of FIG. 8, it will be understood that in practice, structure 404 can be made to be folded, unexpanded, or otherwise compacted. This is particularly true where, for example, structure 404 comprises a fabric or other easily folded material. A folded or unexpanded state facilitates implantation, allowing for a smaller surgical opening, and unfolding or expansion in situ upon filling of flexible container 402. Further, structure 404 can have a different final shape, depending on the shape-control material used. For example, the shape-memory wires in FIG. 8 may be in their inactive state, whereupon activation by body temperature causes contraction thereof, making the spacer of FIG. 8 "thinner" than shown in center region 412.

FIG. 9 depicts an outer view of another example of an intercostal spacer device 500 in accordance with an aspect of the present invention. A flexible container conduit 501 is shown pointing outward from an opening 503. As shown, the structure 502 delimits the final shape of intercostal spacer device 500. Structure 502 comprises a mesh 504 of shape-memory alloy wire, that is soaked through with a dispersion polymer 506 (e.g., silicone). The dispersion polymer (after curing) acts as the flexible container and is shown filled in FIG. 9. This is one example of the flexible container and structure 502 being integral. Although mesh 504 of FIG. 9 is described as being all shape-memory alloy wire, it will be understood that, like FIG. 8, the shape-memory alloy could only form a part of structure 502.

FIG. 10 is a cross-sectional view of another example of an intercostal spacer device 600 in accordance with the present invention. Intercostal spacer device 600 is similar to intercostal spacer device 500 of FIG. 9, except that instead of being soaked in a dispersion polymer, a structural mesh 602 of a shape-memory alloy wire is coated with a dispersion polymer (e.g., silicone) 604 or other curable liquid appropriate for the container material, creating an outer flexible container. The coating can be done in a conventional manner, for example, by dip molding on the outside of the mesh.

FIG. 11 depicts yet another example of an intercostal spacer device 800 with an integrated flexible container and structure, in accordance with another aspect of the present invention. The flexible container and structure in the example of FIG. 11 both comprise a single layer 802 of rubber that is thick enough for a given application to perform the functions of both the flexible container and structure (including shape control). Such a rubber shell would be able to return to its original shape when unconstrained. In addition, intercostal spacer device 800 preferably includes a conduit 804 (preferably, a one-way valve) for filling the internal space 806. The injectable material can be any of the filling materials described above, for example, silicone.

In an alternate aspect, the rubber shell 802 of FIG. 11 can be augmented with internal, external, or integrated features to further control shape. Examples of such features include thread, wires (e.g., metal, including shape-memory alloys), cables, tethers, rings or a mesh.

The method for correcting a spinal deformity utilizing an alternative embodiment of the intercostal spacer device includes, providing at least one intercostal spacer device 400, the intercostal device 400 includes a flexible container 402 used to contain an injectable material, with flexible container 402 being preferably impermeable to the injectable material, a conduit 406 coupled to flexible container 402 for receiving the injectable material and a structure 404, that controls at least part of flexible container 402 after injectable material is injected through conduit 406 and into flexible container 402. Structure 404 has a shape that is sized and configured for placement between two adjacent ribs of a patient. The method preferably provides for intercostal spacer device 400 to be implanted into the intercostal space between two adjacent ribs. The method would also typically include injecting the injectable material preferably through conduit 406 into flexible container 402, the injectable material being compressible following intercostal spacer device 400 implantation between two adjacent ribs. The compressibility characteristic ensures that the injectable material exhibits viscoelastic behavior and that, along with structure 404, the intercostal spacer device 400 can accept compressive loads and produce distraction forces for correcting a spinal deformity within a patient.

Although the preferred embodiments have been depicted and described in detail herein, it will be apparent to those skilled in the relevant art that various modifications, additions and substitutions can be made without departing from its essence and therefore these are to be considered to be within the scope of the following claims.

Claims

What is claimed is:

1. An intercostal spacer device for use in correcting a spinal deformity comprising:

a spacer member comprising a first end and a second end;

a first pair of arms extending from the first end of the spacer member and a second pair of arms extending from the second end of the spacer member; and

wherein the spacer member, first pair of arms and second pair of arms are sized and configured to allow for placement of the intercostal spacer device between two adjacent ribs of a patient to dynamically produce a force for correcting a spinal deformity of the patient.

2. The intercostal spacer device of claim 1, wherein the first pair of arms includes a first anterior arm and a first posterior arm, the first anterior arm and the first posterior arm being substantially parallel to each other and forming a first channel therebetween, and wherein the first channel is sized to receive a first rib of the two adjacent ribs, and wherein the second pair of arms includes a second anterior arm and a second posterior arm, with the second anterior arm and the second posterior arm extending substantially parallel to each other and forming a second channel therebetween, wherein the second channel is sized to receive a second rib of the two adjacent ribs of the patient.

3. The intercostal spacer device of claim 1, further comprising at least one connector, wherein the at least one connector is configured to secure the intercostal spacer device between the first and second ribs of the patient.

4. The intercostal spacer device of claim 3, wherein the spacer member includes at least one bore extending therethrough between an anteriorly oriented

side and a posteriorly oriented side of the spacer member when positioned between the first and second ribs and the at least one connector extends through the at least one bore when employed to couple the intercostal spacer device to the first and second ribs.

5. An intercostal spacer device for use in correcting a spinal deformity comprising:

a flexible container for containing an injectable material, the flexible container being substantially impermeable to the injectable material and being compressible following implantation between two adjacent ribs of a patient;

a conduit coupled to the flexible container for injecting the injectable material into the flexible container;

a structure for at least part of the flexible container; and

wherein the structure controls at least part of a shape of the intercostal spacer device, and wherein the structure is sized and configured for placement of the intercostal spacer device between two adjacent ribs of a patient to produce a force for correcting a spinal deformity of the patient.

6. The intercostal spacer device of claim 4, wherein the conduit comprises a one-way valve.

7. The intercostal spacer device of claim 4, wherein the injectable material comprises at least one of a curable polymer and an adhesive.

8. The intercostal spacer device of claim 4, wherein the structure is at least partially permeable.

9. An intercostal spacer system, the intercostal spacer system comprising:
a plurality of intercostal spacer devices, the plurality of intercostal spacers including:

a first intercostal spacer device comprising a spacer member including a first end and a second end, and a first pair of arms extending from the first end and a second pair of arms extending from the second end, wherein the spacer member, first pair of arms and second pair of arms of the first intercostal spacer device are sized and configured for placement between a first rib and an adjacent second rib of a patient;

a second intercostal spacer device, comprising a spacer member including a first end and a second end, and a first pair of arms extending from the first end and a second pair of arms extending from the second end, wherein the spacer member, first pair of arms and second pair of arms of the second intercostal spacer device are sized and configured for placement between adjacent second rib and a third rib of the patient; and

wherein the first intercostal spacer and the second intercostal spacer cooperate to dynamically produce a force for correcting a spinal

10. The intercostal spacer system of claim 9, wherein the intercostal spacer system further comprising at least one connector, wherein the at least one connector is configured to couple each of the plurality of intercostal spacer devices together.

disposed within the first pair of arms extending in a direction substantially parallel to a direction of the at least one bore disposed within the second pair of arms, wherein the at least one connector is multiple connectors, and wherein a first connector of the multiple connectors extends through the at least one bore in the first pair of arms and a second connector of the multiple connectors extends a structure for at least part of the flexible container, the structure has a shape of the intercostal spacer device, with the intercostal spacer device being sized and configured for placement between two adjacent ribs of a patient;

implanting the intercostal spacer device between the two adjacent ribs of the patient; and

injecting the injectable material into the flexible container through the conduit so that the shape of the structure is achieved, thereby producing a force for correcting a spinal deformity of the patient.

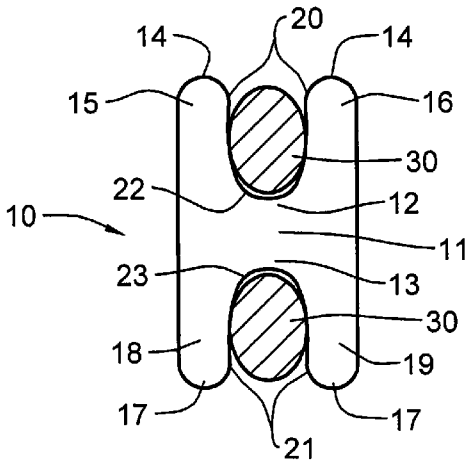


FIG. 1A

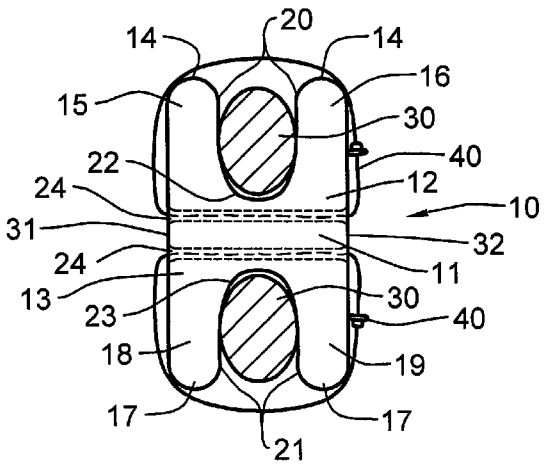


FIG. 1B

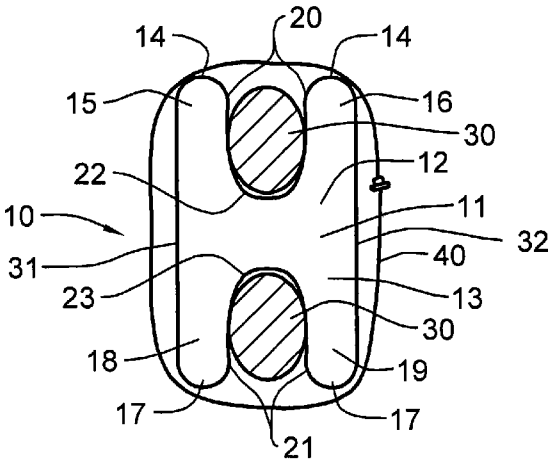


FIG. 1C

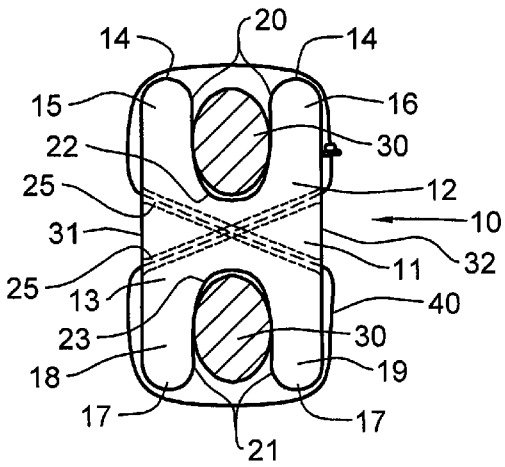


FIG. 1D

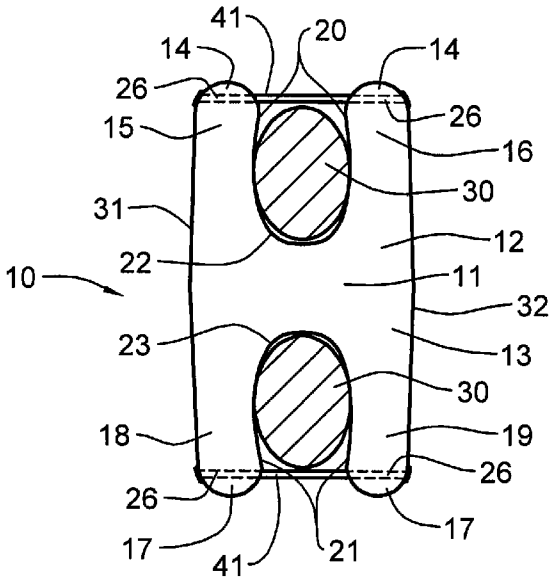


FIG. 1E

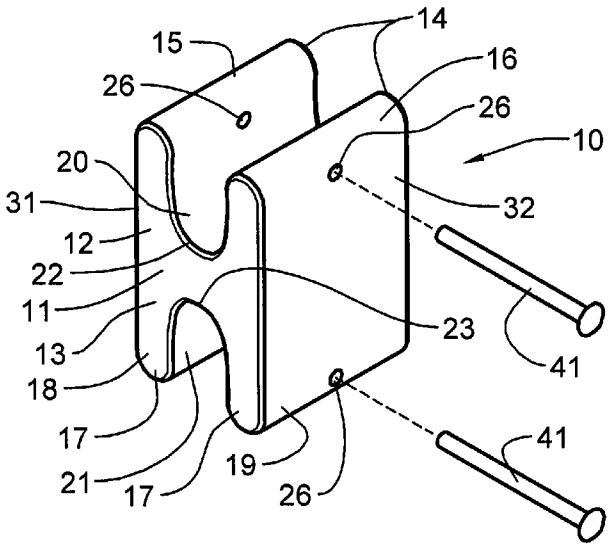


FIG. 1F

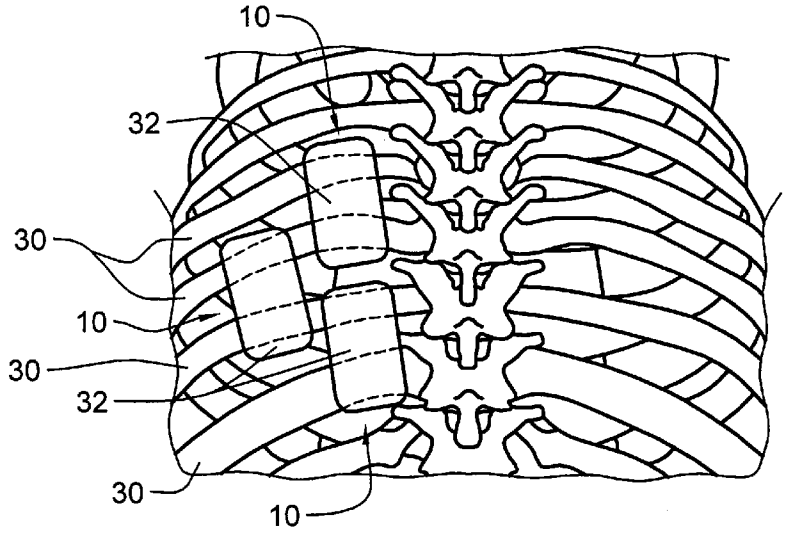


FIG. 2

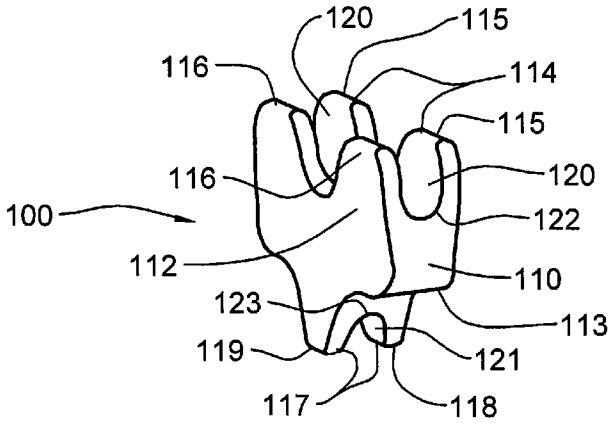

120
115
116
114
115
116
120
100
122
112
110
123
113
119
121
117
118

FIG. 3

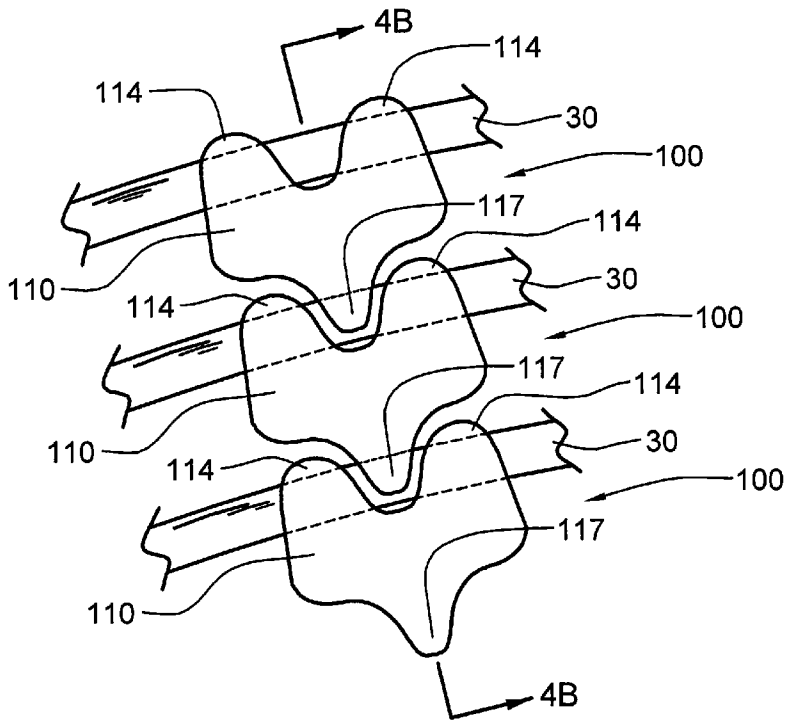

4B
114
114
30
100
117
114
110
30
114
100
117
114
110
30
114
100
117
110
4B

FIG. 4A

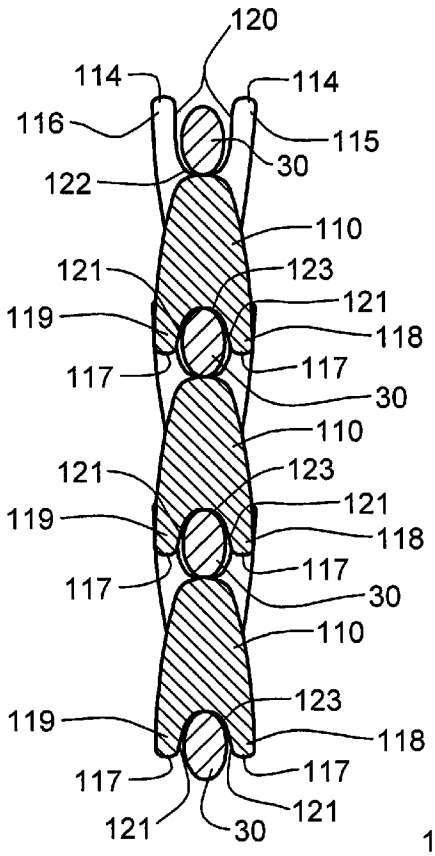

120
114
114
116
115
30
122
110
121
123
121
119
118
117
117
30
110
121
123
121
119
118
117
117
30
110
123
119
118
117
117
121
121
30

FIG. 4B

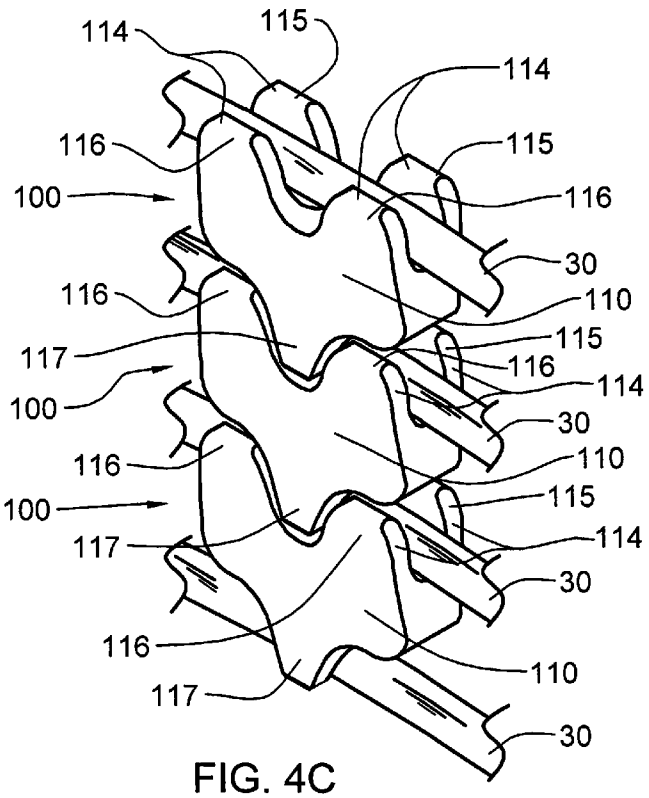

114
115
114
116
115
100
116
30
116
110
117
115
116
100
114
30
116
110
100
115
117
114
30
116
110
117
30

FIG. 4C

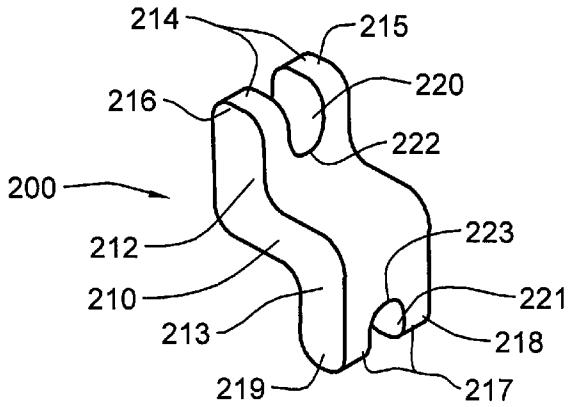

214
215
216
220
222
200
223
212
221
210
213
218
219
217

FIG. 5

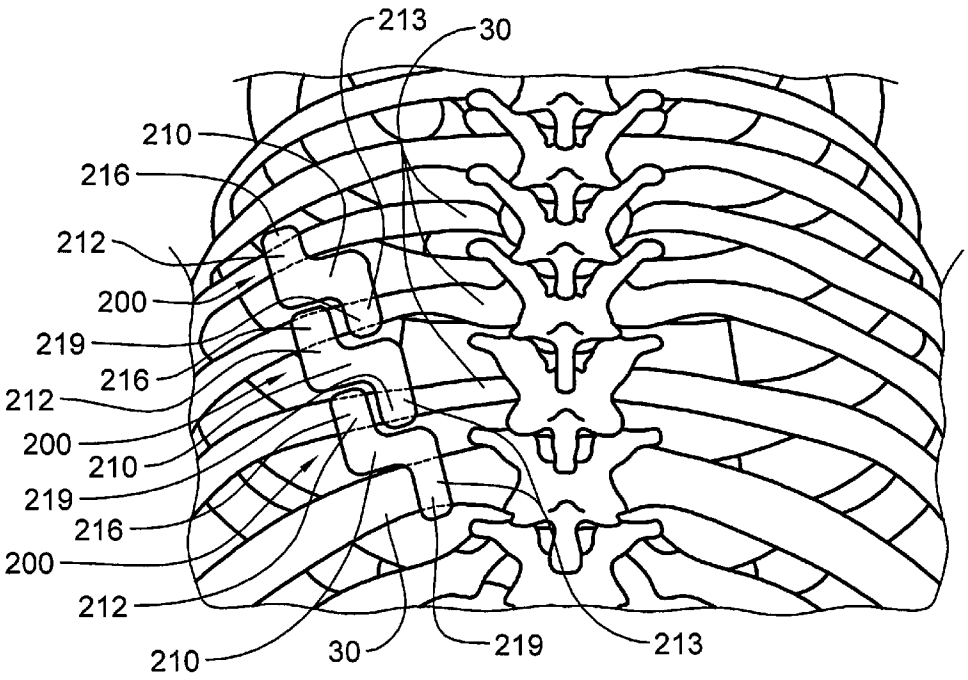

213
30
210
216
212
200
219
216
212
200
210
219
216
200
212
210
30
219
213

FIG. 6

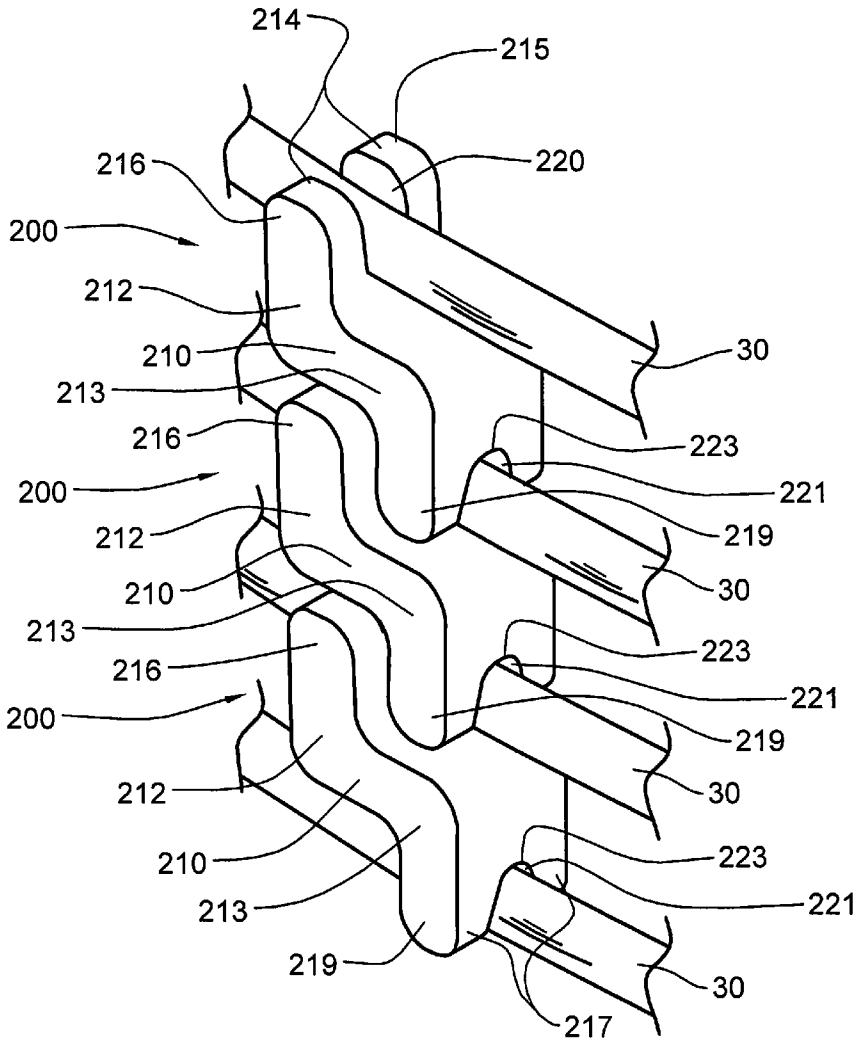

214
215
216
220
200
212
210
30
213
223
216
221
200
219
212
210
30
213
223
216
221
200
219
212
30
210
223
213
221
219
30
217

FIG. 7

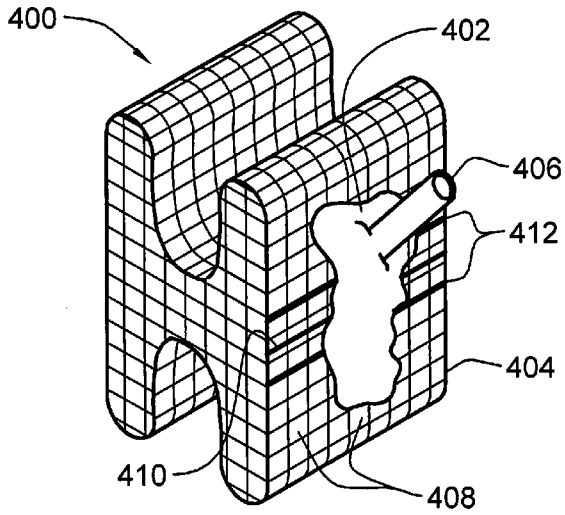


FIG. 8

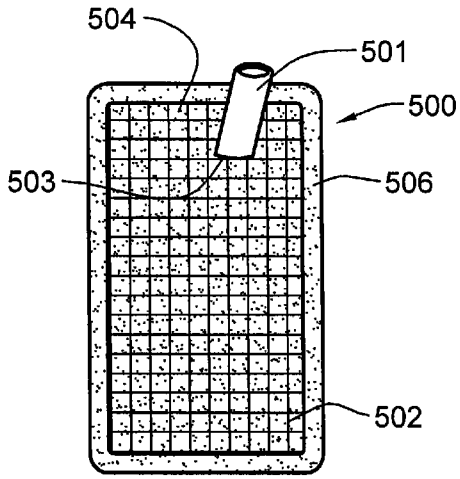


FIG. 9

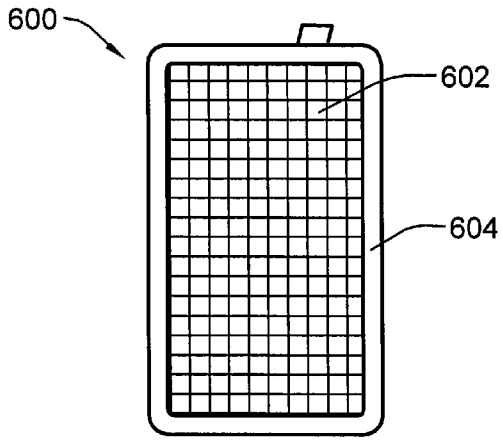


FIG. 10

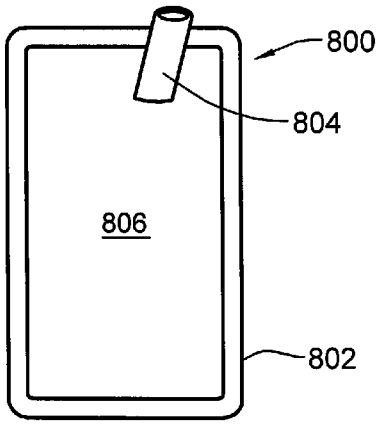


FIG. 11