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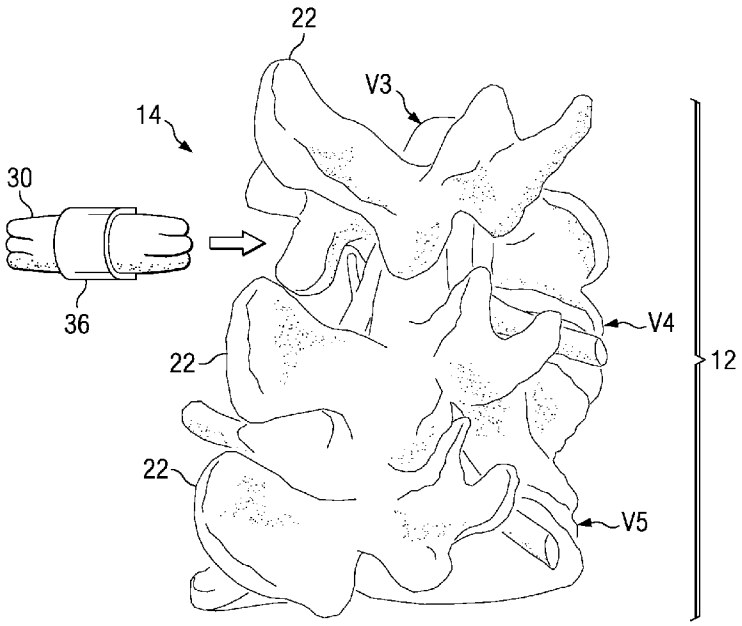
(54) **Title:** APPARATUS FOR INSERTION BETWEEN ANATOMICAL STRUCTURES AND A PROCEDURE UTILIZING SAME



(57) **Abstract:** A surgical procedure and apparatus according to which force is applied to a member to compress the member, and the member is retained in its compressed state while it is inserted between two anatomical structures. The member is then allowed to move from its compressed state towards its original state and into engagement with the structures.

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— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

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APPARATUS FOR INSERTION BETWEEN ANATOMICAL STRUCTURES AND A PROCEDURE UTILIZING SAME

Background

The present invention relates to an apparatus for insertion between anatomical structures and a procedure utilizing same and, more particularly, to such an apparatus that includes a member that is compressed before it is inserted and expands after it is inserted.

It is often desirable to insert a device between anatomical structures for several reasons. For example, it can be inserted in a manner so that it engages the structures and serves as an implant for stabilizing the structures and absorbing shock. Alternately, a device can be temporarily inserted between the structures and function to distract the structures to permit another device, such as a prosthesis, to be implanted between the structures. According to another example, a device can be inserted between the structures to distract the structures to permit another surgical procedure to be performed in the space formed by the distraction, after which the device is released and removed.

Although devices have been designed for one or more of the above uses they are not without problems. For example, it is often difficult to insert the device without requiring excessive invasion of the anatomy, damage to the adjacent anatomical structures, or over-distraction. Embodiments of the present invention improve upon these techniques and various embodiments of the invention may possess one or more of the above features and advantages, or provide one or more solutions to the above problems existing in the prior art.

Brief Description of the Drawings

Fig. 1 is a side elevational view of an adult human vertebral column.

Fig. 2 is a posterior elevational view of the column of Fig. 1.

Fig. 3 is an elevational view of one of the vertebrae of the column of Figs. 1 and 2.

Fig. 4A-4C are elevational views depicting apparatus for inserting in the column of Figs. 1-3.

Fig. 5A-5C are enlarged, partial, isometric views of a portion of the column of Figs. 1 and 2, including the lower three vertebrae of the column, and depicting a procedure for inserting the apparatus of Figs. 4A–4C between two adjacent vertebrae.

Fig. 6A-6D are elevational views depicting apparatus according to an alternate embodiment for inserting in the column of Figs. 1-3.

Fig. 7A-7C are enlarged, partial, isometric views of a portion of the column of Figs. 1 and 2, including the lower three vertebrae of the column, and depicting a procedure for inserting the apparatus of Figs. 6A–6D between two adjacent vertebrae.

Detailed Description

With reference to Figs. 1 and 2, the reference numeral 10 refers, in general, to the lower portion of a human vertebral column 10. The column 10 includes a lumbar region 12, a sacrum 14, and a coccyx 16. The flexible, soft portion of the vertebral column 10, which includes the thoracic region and the cervical region, is not shown.

The lumbar region 12 includes five vertebrae V1, V2, V3, V4 and V5 separated by intervertebral discs D1, D2, D3, and D4, with the disc D1 extending between the vertebrae V1 and V2, the disc D2 extending between the vertebrae V2 and V3, the disc D3 extending between the vertebrae V3 and V4, and the disc D4 extending between the vertebrae V4 and V5.

The sacrum 14 includes five fused vertebrae, one of which is a superior vertebrae V6 separated from the vertebrae V5 by a disc D5. The other four fused vertebrae of the sacrum 14 are referred to collectively as V7. A disc D6 separates the sacrum 14 from the coccyx 16, which includes four fused vertebrae (not referenced).

With reference to Fig. 3, the vertebrae V5 includes two laminae 20a and 20b extending to either side (as viewed in Fig. 2) of a spinous process 22 that extends posteriorly from the juncture of the two laminae. Two transverse processes 24a and 24b extend laterally from the laminae 20a and 20b, respectively; two articular processes 26a and 26b extend superiorly from the laminae 20a and 20b respectively; and two articular processes 28a and 28b extend inferiorly from the laminae 20a and 20b, respectively. The inferior articular processes 28a and 28b rest in the superior articular process of the vertebra V2 to form a facet joint. Since the vertebrae V1-V4 are similar to the vertebrae V5, and since the vertebrae V6 and V7 are not involved in the present invention, they will not be described in detail.

It will be assumed that, for one or more of the reasons set forth above, the vertebrae V3 and V4 are not being adequately supported by the disc D4, and that it is therefore necessary to provide supplemental support and stabilization of these vertebrae. To this end, and referring to Figs. 4A-4C, a device 30 according to an embodiment of the invention is implanted between the respective spinous processes 22 of the vertebrae V3 and V4.

The device 30 is generally rectangular in shape with two notches, or saddles, 30a and 30b formed at each end. The device 30 is fabricated from a soft flexible material that has a predetermined shape and elastic properties that will permit it to return towards its original state after it has been compressed. Examples of this type of material are polyurethane, rubber, RTV silicone, two-part silicone, silicone, two-part urethane PA, hydrogels, collagen matrix, bone matrix, ceramic granules suspended in an aqueous fluid, morsalized fascia, silk elastin, polymer proteins, proteins, protein hydrogel, and thermopolymer. Also, the device can be fabricated from a fabric and dipped in silicone thereby providing a memory, or preset shape, of the device to guide it during expansion.

Before the device 30 is implanted it undergoes a series of steps. Initially a compressive force, or load, is applied to the side walls of the device in a direction perpendicular to the axis of the device as shown by the arrows in Fig. 4B. This load can be applied by any mechanical device such as a vice, or the like, having two plates 34a and 34b that engage the respective side walls of the device 30. Equal and opposite forces are applied to the plates 34a and 34b in one plane in the directions of the arrows in any known manner, and the amount of the forces are regulated so that the device is compressed to a shape generally shown in Fig. 4C.

The plates 34a and 34b are released and a retaining ring 36 is immediately placed over the compressed device at a location approximately between its ends. The ring 36 thus prevents the device 30 from returning back to its original shape shown in Fig. 4A.

The apparatus consisting of the device 30, in its compressed shape, and the retaining ring 36 extending around the device, is inserted between the respective spinous processes 22 of the vertebrae V3 and V4 in the direction shown in Fig. 5A. Then the ring 36 is removed from the compressed device 30 and the memory characteristic of the material of the device, as discussed above, causes the device to start expanding in a

manner towards its original shape. Fig. 5B depicts an intermediate stage of the expansion of the device 30 as it expands from the fully compressed position of Fig. 5A to its fully expanded position as shown in Fig. 5C. In the last position, the device 30 engages the spinous processes 22 of the vertebrae V3 and V4, respectively, with enough force to firmly secure the device between the processes and stabilize the vertebrae. It is understood that, in moving from the position of Figs. 5B to 5C, the device 30 can engage and move at least one of the processes 22 slightly if it is desired to establish a predetermined spatial relationship between the processes.

In addition to stabilizing the vertebrae V3 and V4, the relatively flexible, soft material of the device 30 readily conforms to the processes and provides excellent shock absorption and deformability, resulting in an improved fit.

Referring to Figs. 6A - 6C, the reference numeral 40 refers to, in general, an implantable device according to another embodiment of the present invention. As in the previous embodiment, the device can be implanted between two spinous processes, such as the processes 22 associated with the vertebrae V3 and V4 as depicted in Figs. 5A-5C.

The device 40 comprises a hollow body member 42, generally rectangular in shape, and having two notches, or saddles, 42a and 42b, formed at each end. The body member 42 is fabricated from a soft flexible material that will deform, or compress, under load conditions to be described.

One end of a tube 44 registers with an opening in the body member 42, and the other end of the tube is adapted to be connected to a source of fluid (not shown) so that the fluid can be introduced into the interior of the body member. Examples of the type of fluid that can be used are air, water, and a curable polymer. The quantity of fluid introduced into the interior of the body member 42 is controlled so that the body member will expand in a manner to be described.

A sack, or sheath, 46 extends over the body member 42 and is sized so as to fit relatively tight in the axial direction, that is, the width of the sheath is only slightly greater that the length of the body member. The sheath 46 has two open ends so that the body member 42 can be inserted into and removed from, the sheath through either end. Preferably the sheath 46 is fabricated from a type of material that is heat shrinkable, that

is, it will shrink when subjected to sufficient heat. Since this type of material is conventional it will not be described in detail.

After the body member 42 is inserted in the sheath 46, heat is applied to the sheath in any conventional manner. As a result, the sheath 46 shrinks to the position shown in Fig. 6B and compresses the body member 42 in a manner that considerably reduces its axial length. The device 40 is then inserted between the respective spinous processes 22 of the vertebrae V3 and V4 in the direction shown in Fig. 7A, while the sheath retains the body member 42 in its compressed state.

The sheath 46 is then removed from the body member 42 by pulling on one end of the sheath, as shown in Figs. 6C and 7B. Fluid is then introduced into body member 42, via the tube 44, and the body member starts expanding until it reaches its fully expanded position as shown in Figs. 6D and 7C. The fluid flow is terminated when the body member 42 engages the respective spinous processes 22 of the vertebrae V3 and V4 with enough force to stabilize the vertebrae. It is understood that, in moving from the position of Fig. 7B to Fig. 7C, the body member 42 can engage and move at least one of the processes 22 slightly if it is desired to establish a predetermined spatial relationship between the processes.

The device 40 is thus firmly secured in its implanted position shown in Fig. 7C. In addition to stabilizing the vertebrae V3 and V4, the relatively flexible, soft material of the body member 42 readily conforms to the respective processes 22 of the vertebrae and provides excellent shock absorption and deformability, resulting in an improved fit.

According to an alternate version of the embodiment of Figs. 6A-6C, the sheath 46 can be scored or perforated so that it does not have to be manually removed from the body member 42 after insertion between the spinous processes 22. Rather, the sheath 46 can be left on the body member 42 after the insertion of the device between the process 22. The scores or perforations will cause the sheath 46 to break apart during the introduction of the fluid into the interior of the body member 42 and allow the body member to expand into engagement with the processes 22 as described above.

In each of the foregoing embodiments, it is understood that the term “expand”, as used above is meant to cover the situation in which the body member 42 is allowed to move back towards its normal state when the sheath is removed after it was initially

contracted when put in the sheath 46; or the situation in which the body member is actually inflated in response to the introduction of the fluid; or both.

It is also understood that, in each of the above embodiments the devices 30 and 40 do not necessarily have to function as implants between two processes as described in the examples above, but rather can be used in other different procedures and in other different areas of the anatomy. For example, the devices 30 and 40 can be inserted between the two anatomical structures, such as the processes used in the above examples, and expanded to an extent that it engages and distracts, or moves, the structures in a direction away from each other, to permit another device, such as a prosthesis, to be implanted between the structures or in an area near the structures. According to another example, each device can be inserted between the structures and expanded to an extent that it engages and distracts the structures to permit another surgical procedure to be performed in the space formed by the distraction. In each of these examples, the device would be released and removed after the procedure is completed.

Variations

It is understood that variations may be made in the foregoing without departing from the invention and examples of some variations are as follows:

(1) The device 30 and the body member 42 can take shapes that are different from the examples disclosed above.

(2) The devices 30 and 40 can be inserted in other areas of the anatomy such as, for example, in an intervertebral disc space represented by the references D1-D5 in Fig. 1 or between the transverse processes 24a and 24b.

(3) The devices 30 and 40 can be inserted between two vertebrae following a corpectomy in which at least one vertebrae is removed.

(4) The members used to retain the device 30 and the body member 42 in their compressed condition can vary.

(5) The types of fluid introduced into the body member 42 can be vary.

(6) The expansion of the device 30 and the body member 42 can be such that they engage only one of the anatomical structures.

(7) In the embodiment of Figs. 6A-6C, the body member 42 can be compressed in the sheath 46 by techniques other than heat shrinking the sheath, such as, for example, stretching the sheath so that it changes from the shape shown in Fig. 6A to the shape shown in Fig. 6B.

(8) Any spatial references made above, such as "under", "over", "between", "upper", "lower", "top", "bottom", etc. are for the purpose of illustration only and do not limit the specific orientation or location of the structure described above.

The preceding specific embodiments are illustrative of the practice of the invention. It is to be understood, therefore, that other expedients known to those skilled in the art or disclosed herein, may be employed without departing from the invention or the scope of the appended claims, as detailed above. In the claims, means-plus-function clauses are intended to cover the structures described herein as performing the recited function and not only structural equivalents but also equivalent structures. Thus, although a nail and a screw may not be structural equivalents in that a nail employs a cylindrical surface to secure wooden parts together, whereas a screw employs a helical surface, in the environment of fastening wooden parts, a nail and a screw are equivalent structures.

Claims

What is claimed is:

1. A surgical apparatus comprising:

a compressible member fabricated from a material having a memory characteristic that will permit it to return towards its original state after it has been compressed;

means for applying force to the member to compress the member;

a retainer for maintaining the member in its compressed state and enabling the member to be inserted between two anatomical structures; and

the retainer being removable from the compressed member to allow the member to move from its compressed state towards its original state and into engagement with the structures.

2. The procedure of claim 1 wherein the material of the member is selected from a group consisting of polyurethane, rubber, RTV silicone, two-part silicone, silicone, two-part urethane PA, hydrogels, collagen matrix, bone matrix, ceramic granules suspended in an aqueous fluid, morsalized fascia, silk elastin, polymer proteins, proteins, protein hydrogel, and thermopolymer.

3. The procedure of claim 1 wherein the device is fabricated from a fabric that is covered with silicone to provide the device with a memory, or preset shape, to guide it during expansion.

4. The apparatus of claim 1 wherein the expandable member is of a generally rectangular shape having two saddles disposed at each end to receive the structures.

5. The procedure of claim 1 wherein the movement of the member causes distraction between the structures.

6. A surgical apparatus comprising:

an expandable member;

a sheath adapted to contain the member and adapted to be heated to compress the member so that the member can be inserted between two anatomical structures; and

means for introducing fluid into the member to expand the member into engagement with at least one of the structures.

7. The procedure of claim 6 wherein the sheath is manually removed from the member prior to the introduction of the fluid.

8. The apparatus of claim 6 wherein the member is of a generally rectangular shape having two saddles disposed at each end to receive the structures.

9. The apparatus of claim 6 wherein the fluid is selected from a group consisting of air, water, and a curable polymer.

10. The apparatus of claim 6 wherein the expansion of the member causes distraction between the structures.

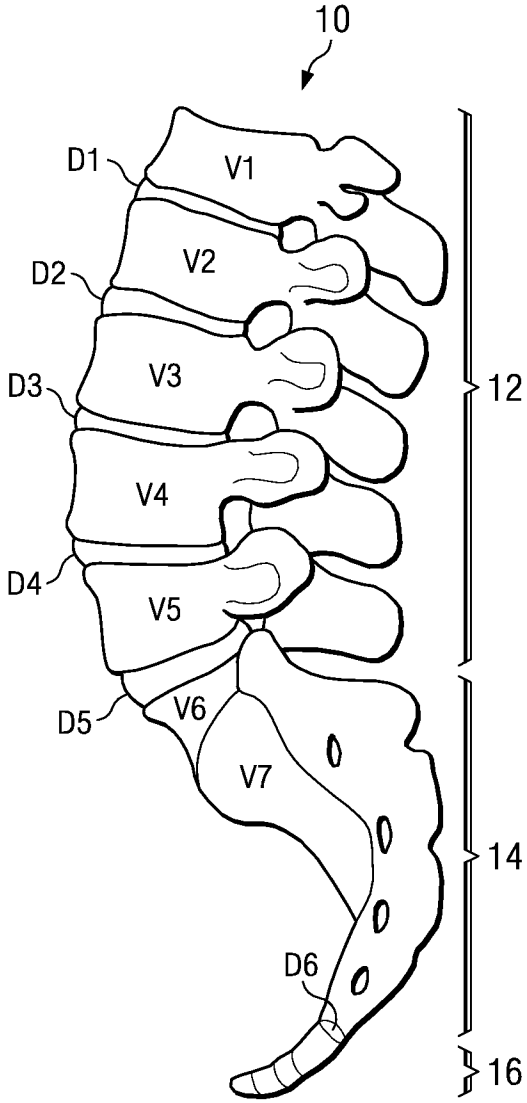
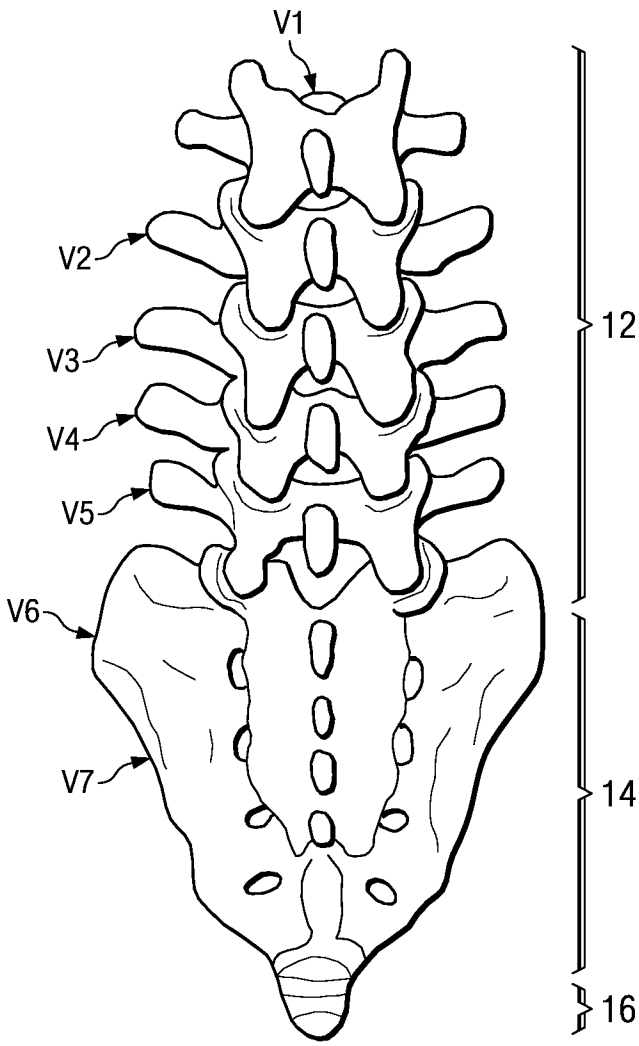

10
D1
V1
D2
V2
D3
V3
12
V4
D4
V5
D5
V6
V7
14
D6
16

Fig. 1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V6
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Fig. 2

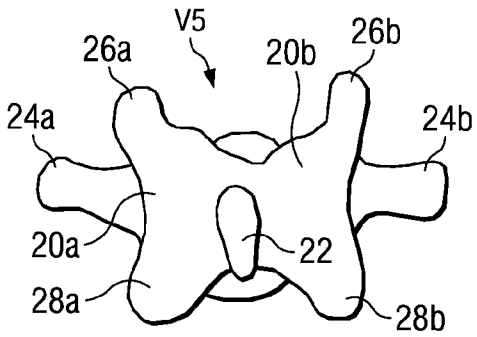

Fig. 3

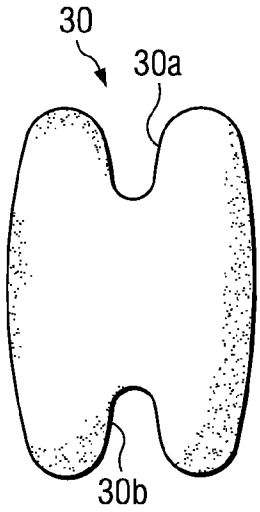

Fig. 4A

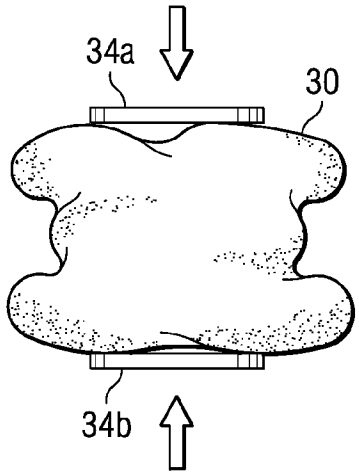

Fig. 4B

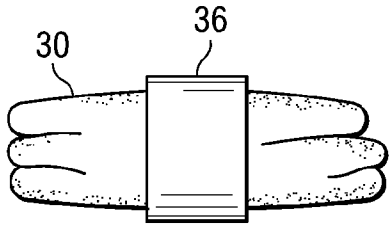

Fig. 4C

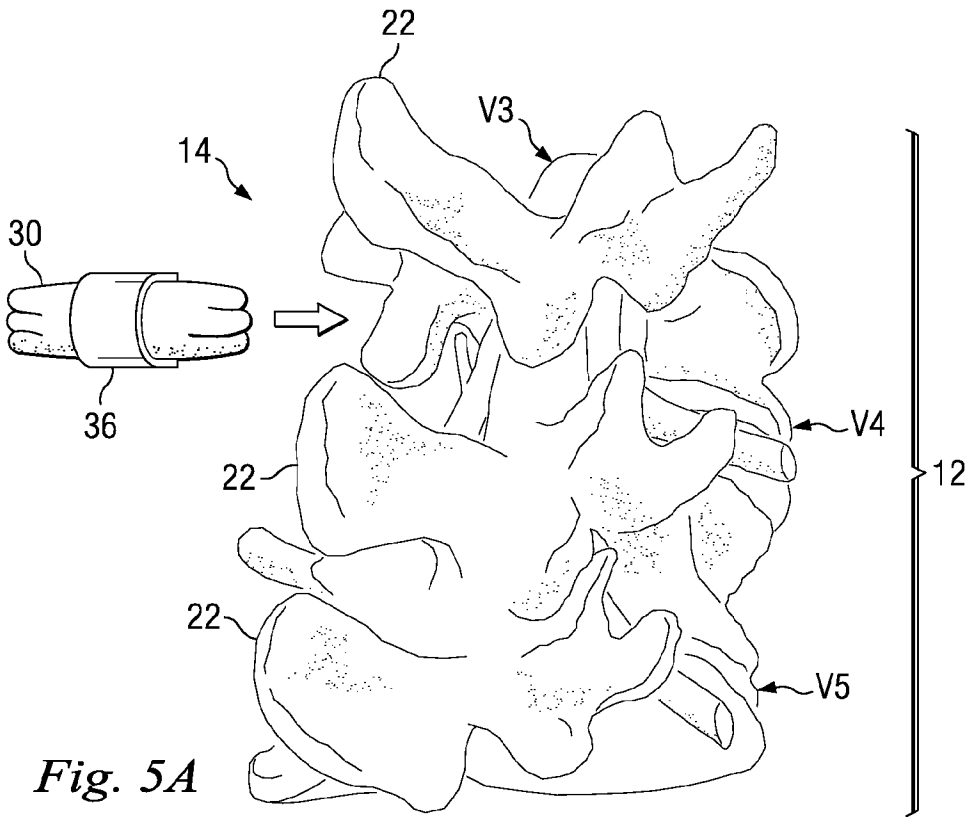

Fig. 5A

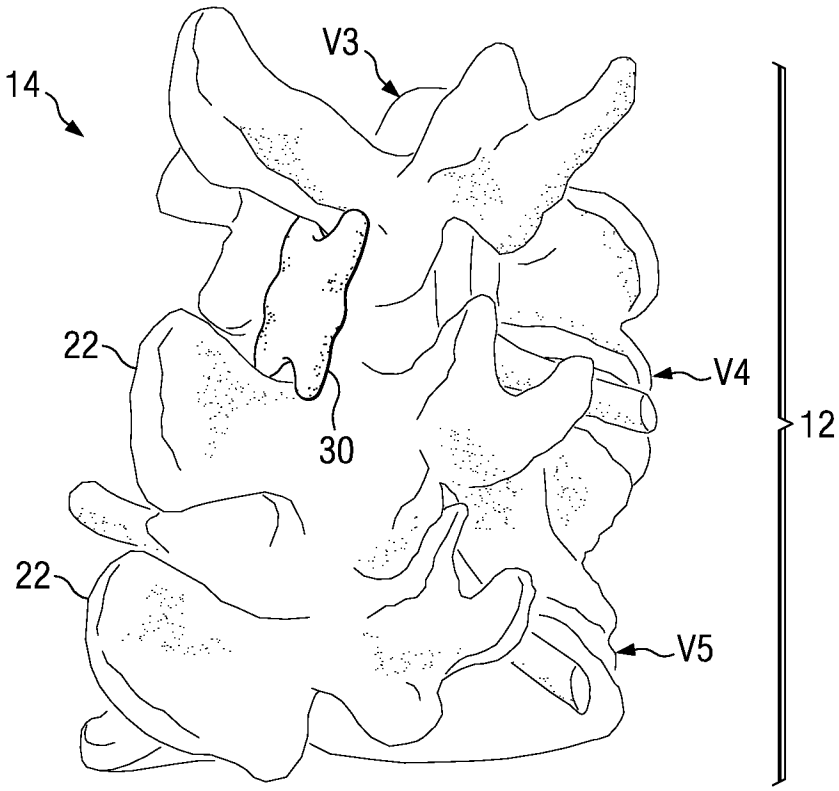

Fig. 5B

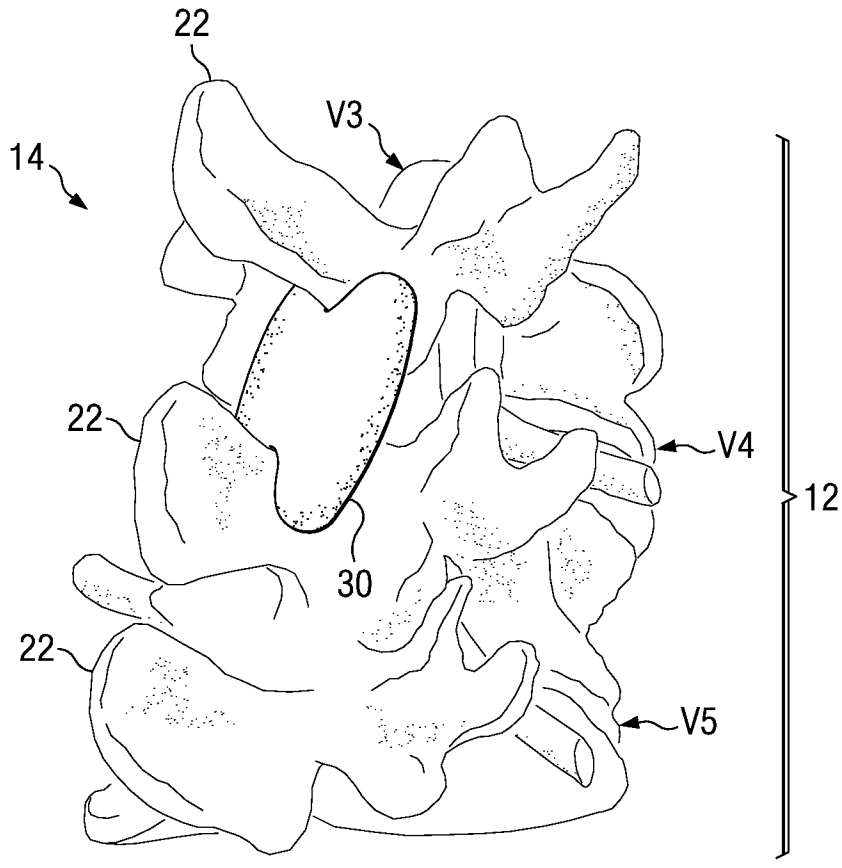

Fig. 5C

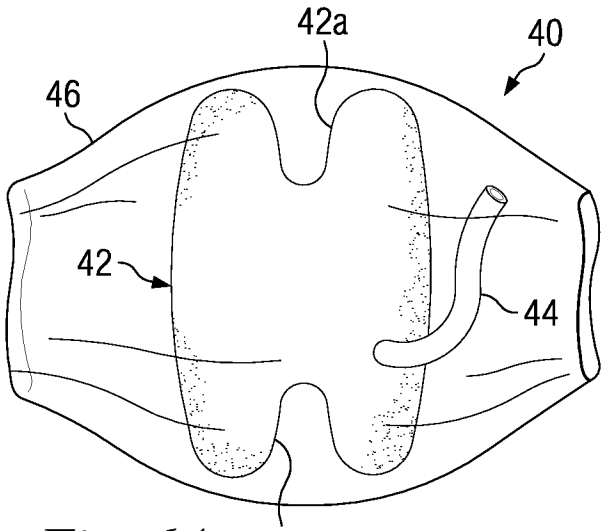

Fig. 6A

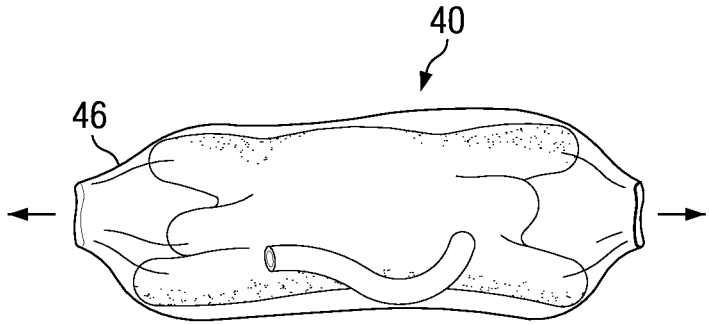

Fig. 6B

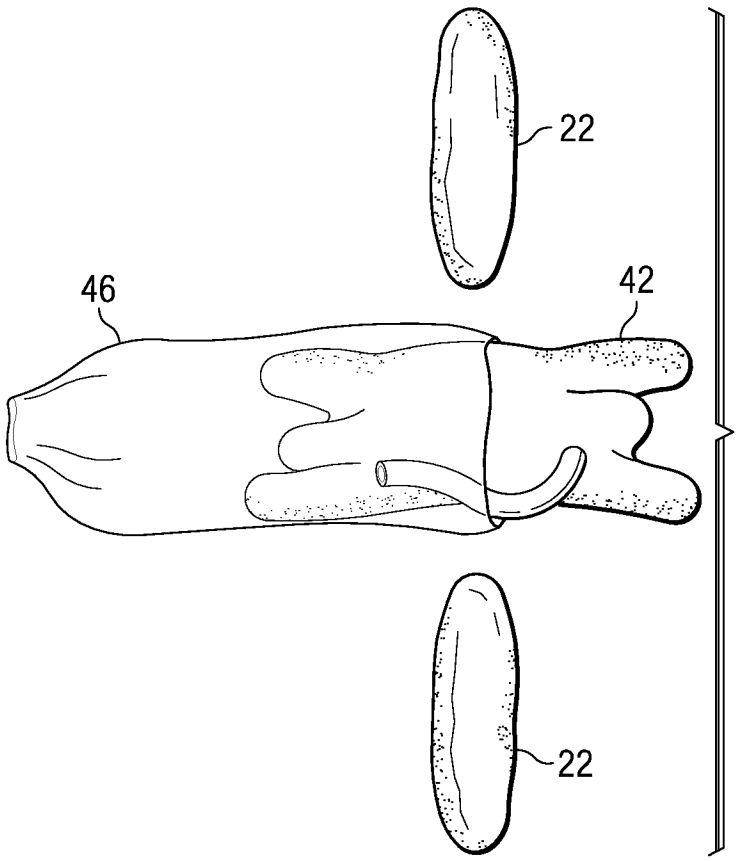

Fig. 6C

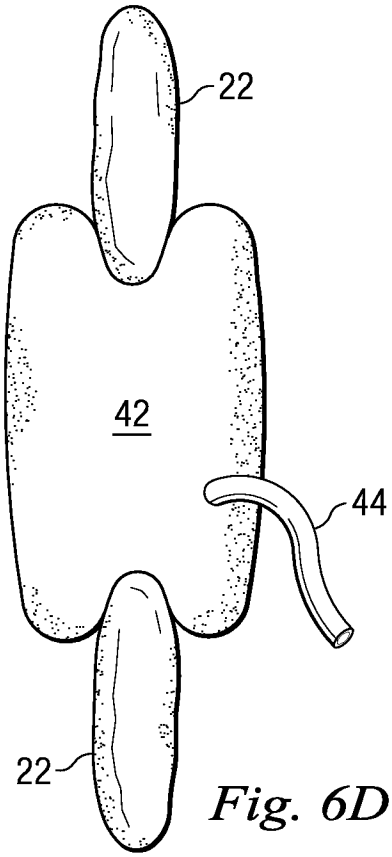

Fig. 6D

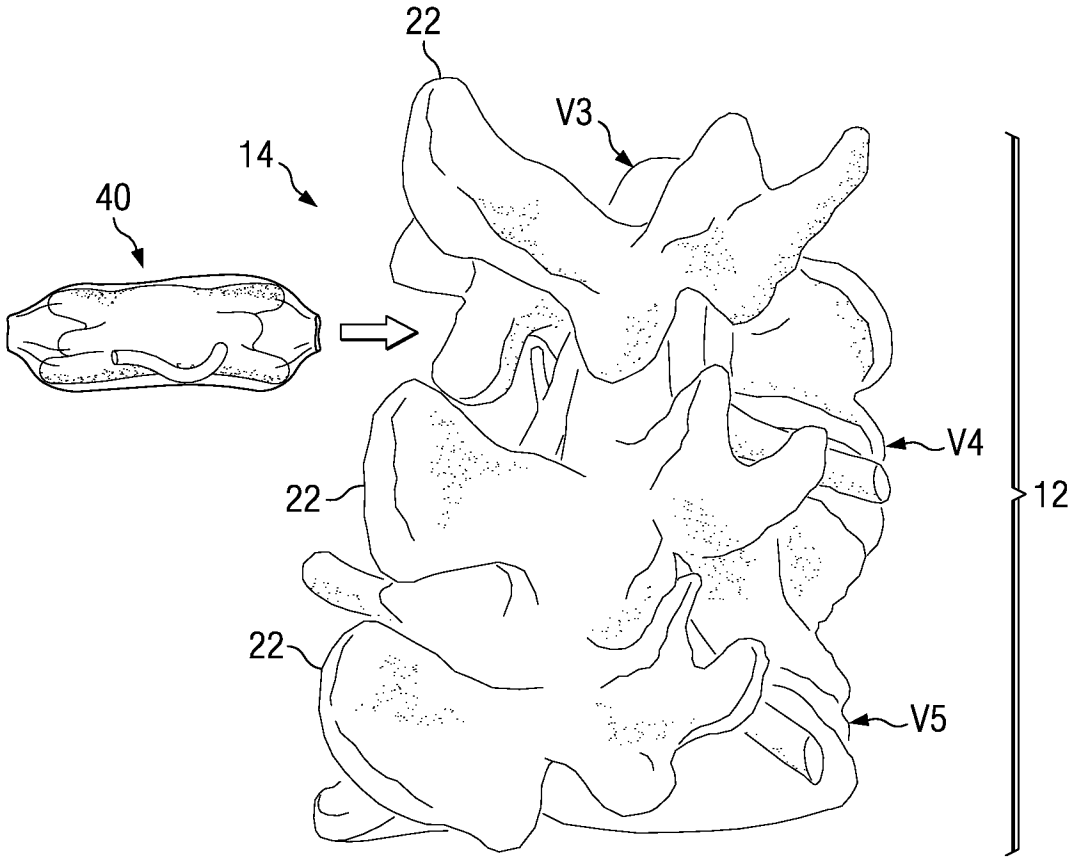

Fig. 7A

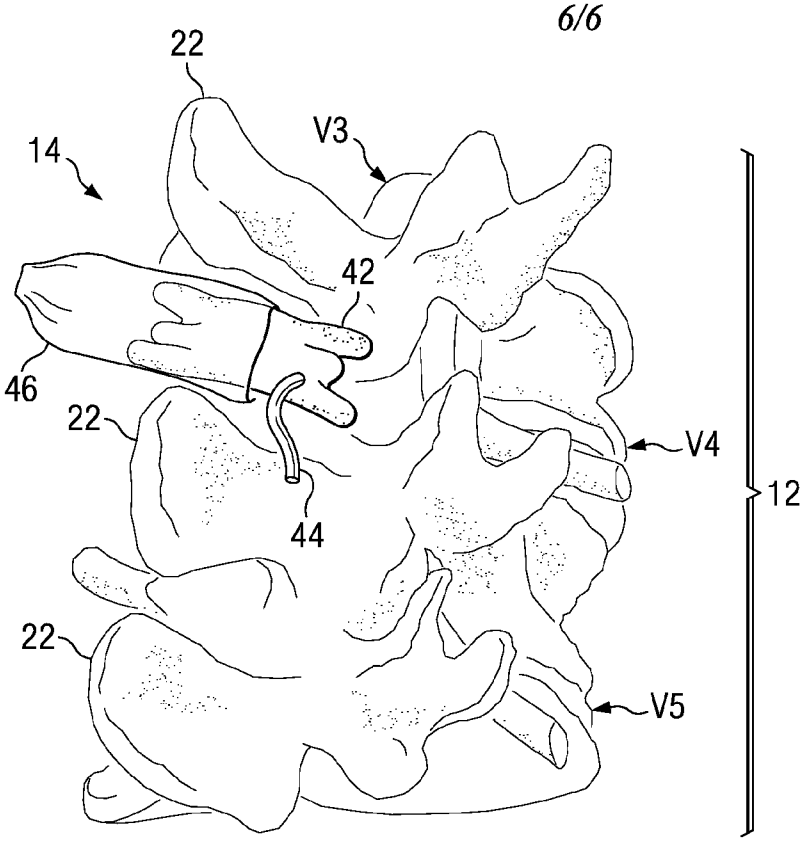

Fig. 7B

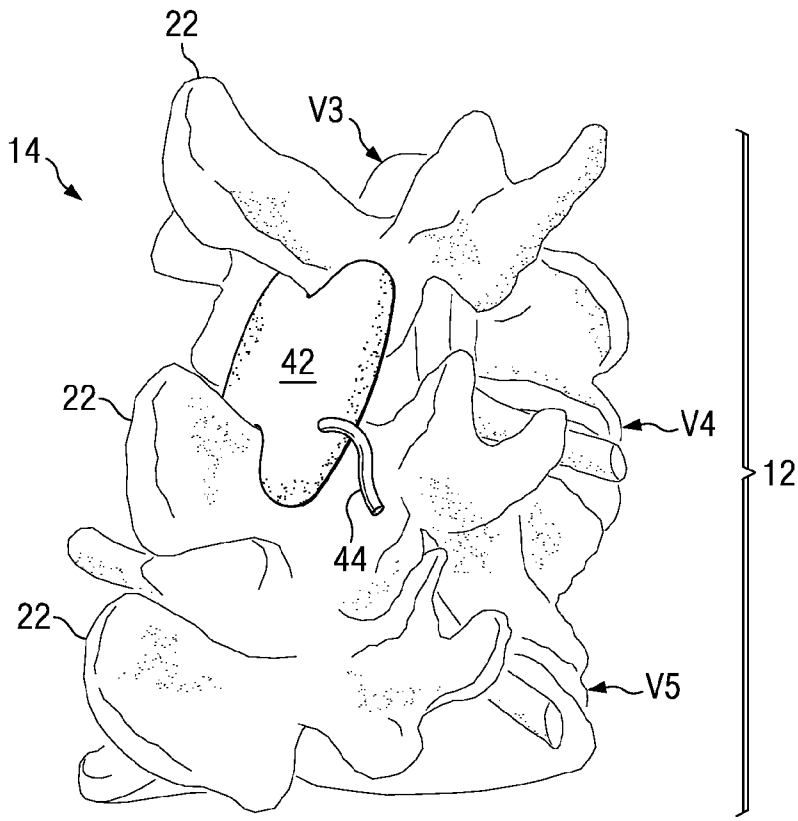

Fig. 7C

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2007/073604

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	FR 2 816 197 A (TAYLOR JEAN [FR]) 10 May 2002 (2002-05-10) page 7, line 8 - line 21; figure 1 page 8, line 19 - page 9, line 27; figures 5-9 page 10, line 21 - line 24; figures 10-14	1-5
X	US 2005/261768 A1 (TRIEU HAI H [US]) 24 November 2005 (2005-11-24) paragraph [0042]; figures 1A-1C paragraph [0044]; figures 2A-2E	1-5
X	US 2005/055031 A1 (LIM ROY [US]) 10 March 2005 (2005-03-10) paragraph [0067] - paragraph [0069]; figures 14-17	1-5

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[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
7 December 2007	17/12/2007

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INTERNATIONAL SEARCH REPORT

International application No
PCT/US2007/073604

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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