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(54) **TENSION BAND**

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(57) **ABSTRACT**

Various embodiments of a vertebral tension band assembly and associated connection structure are provided. The tension band assemblies may be attached to vertebral bodies to, for example, connect one vertebrae to another, retain the band in approximately a preferred position by application of tension to the band during insertion and/or limit, impede, inhibit, reduce or interfere with the separation from one vertebra to another and may further block, impede, interfere with, inhibit, reduce or present an obstacle to dislodgement of a spinal implant from between the vertebrae to which it is attached. Flexible band portions of the assemblies may be treated and/or configured to promote bony integration between the band and the associated vertebrae, limit tissue adhesion to the band, and/or to elute a therapeutic substance from the installed band to the surgical site.

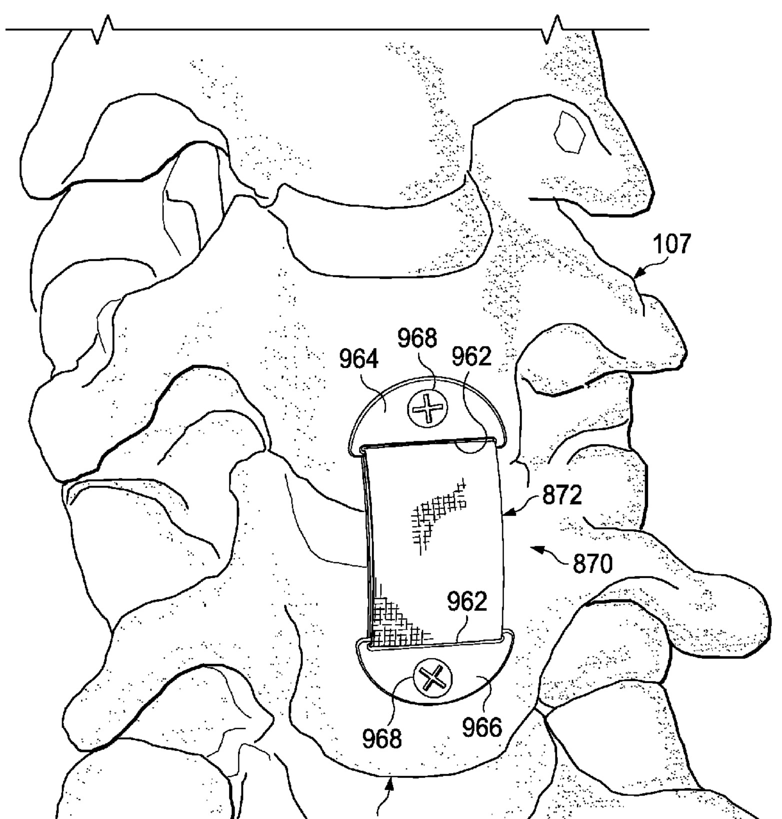

Fig. 1

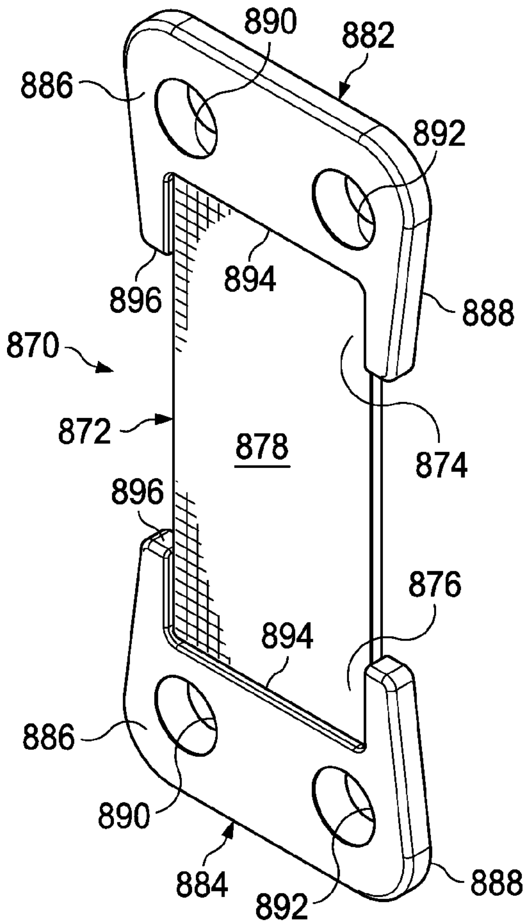
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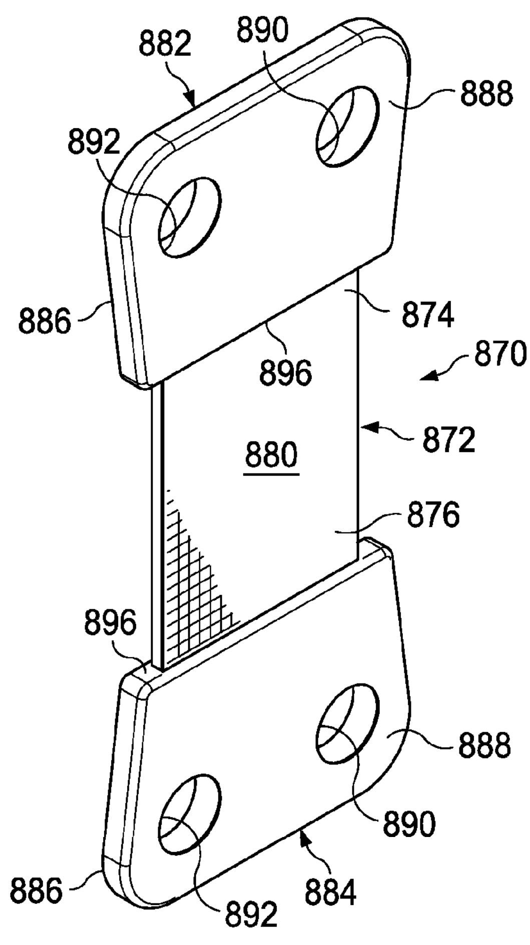
Fig. 2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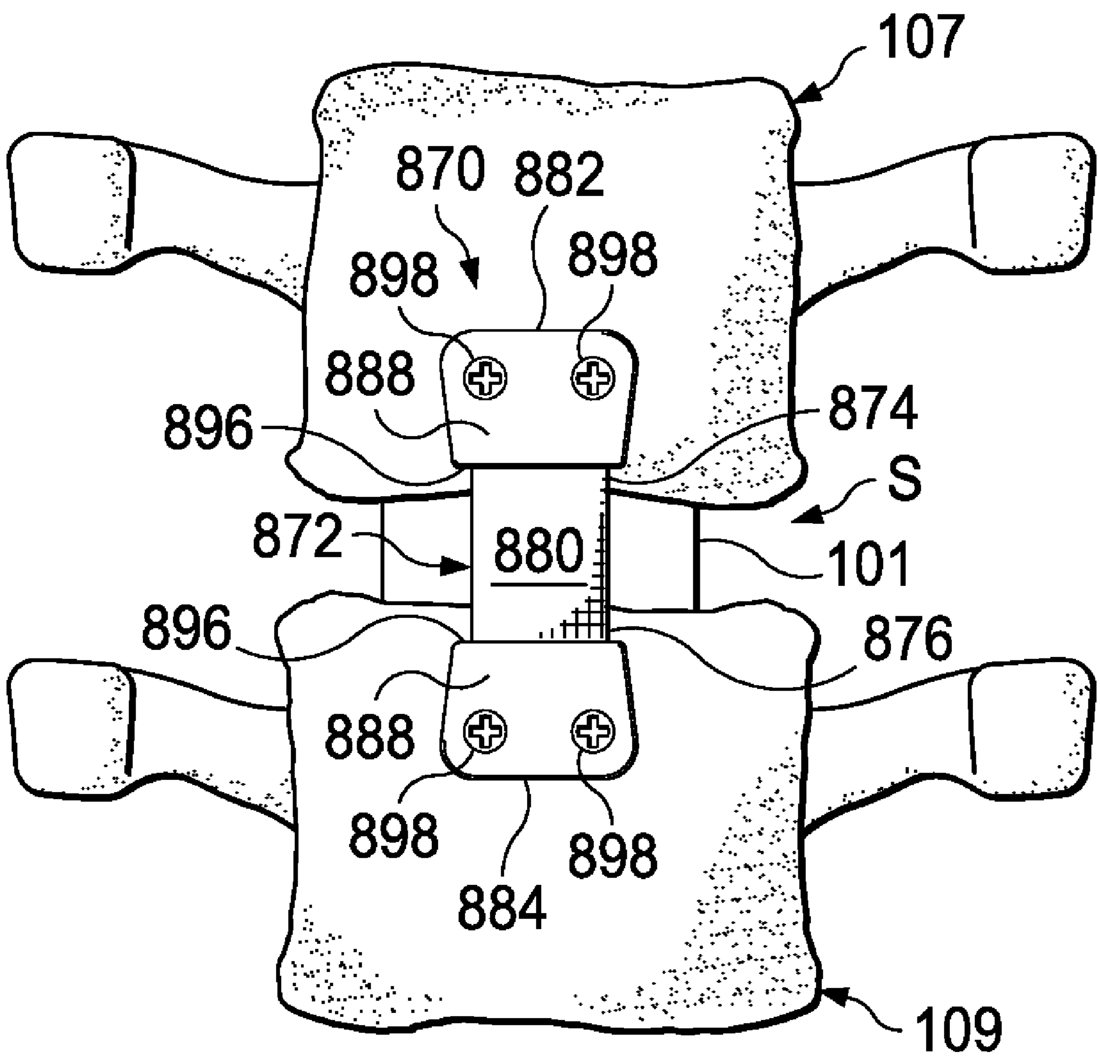
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Fig. 2A

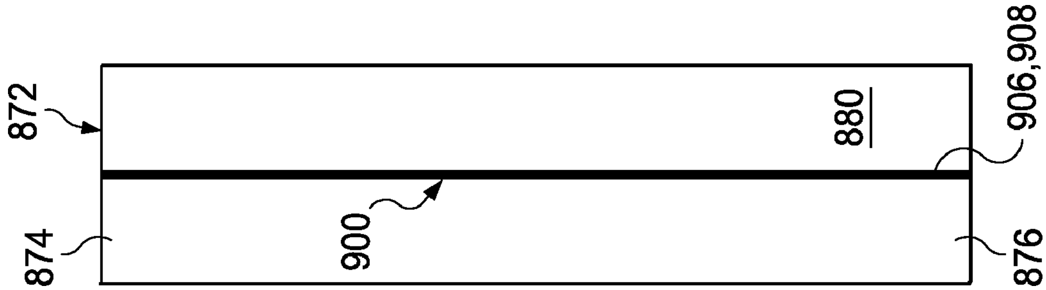

Fig. 4B

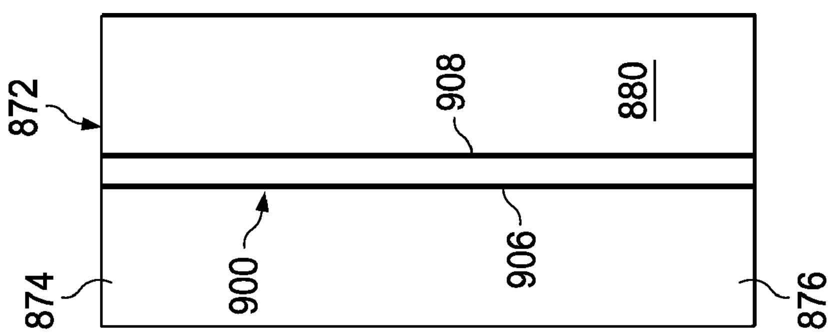

Fig. 4A

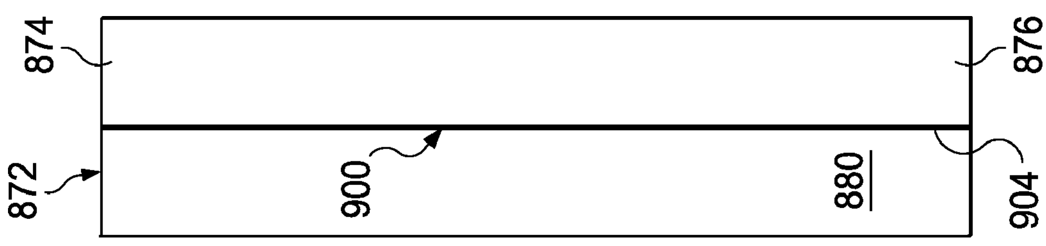

Fig. 3B

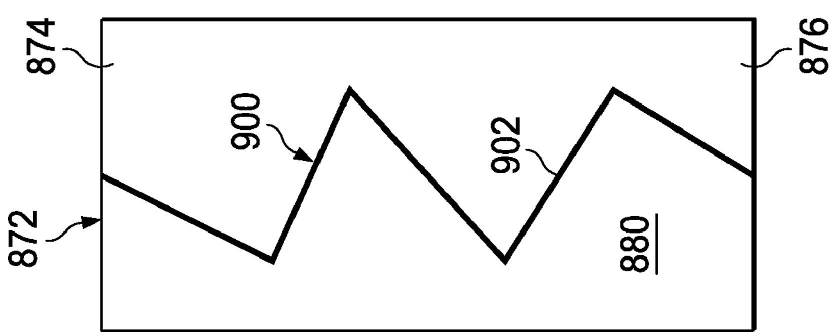

Fig. 3A

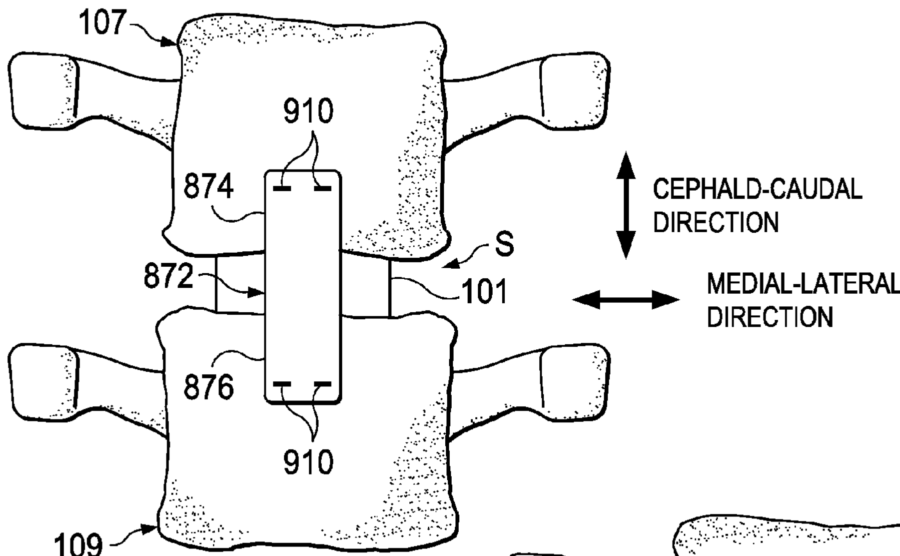

Fig. 5A

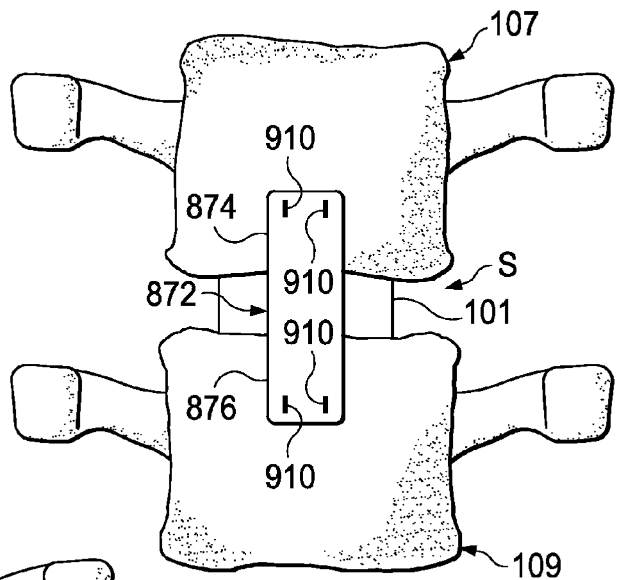

Fig. 5B

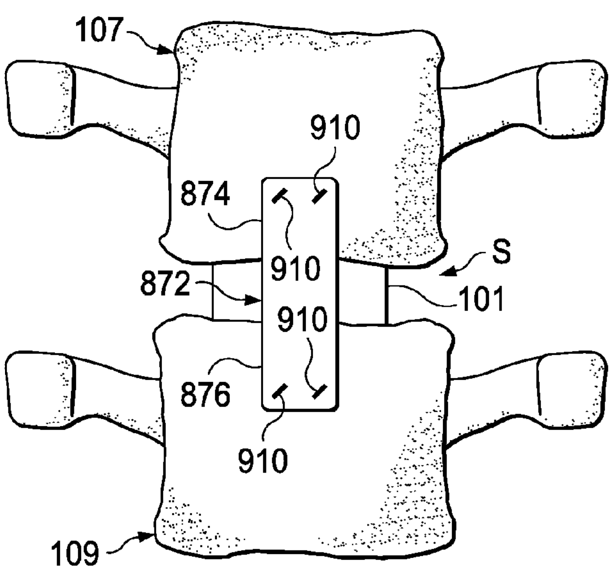

Fig. 5C

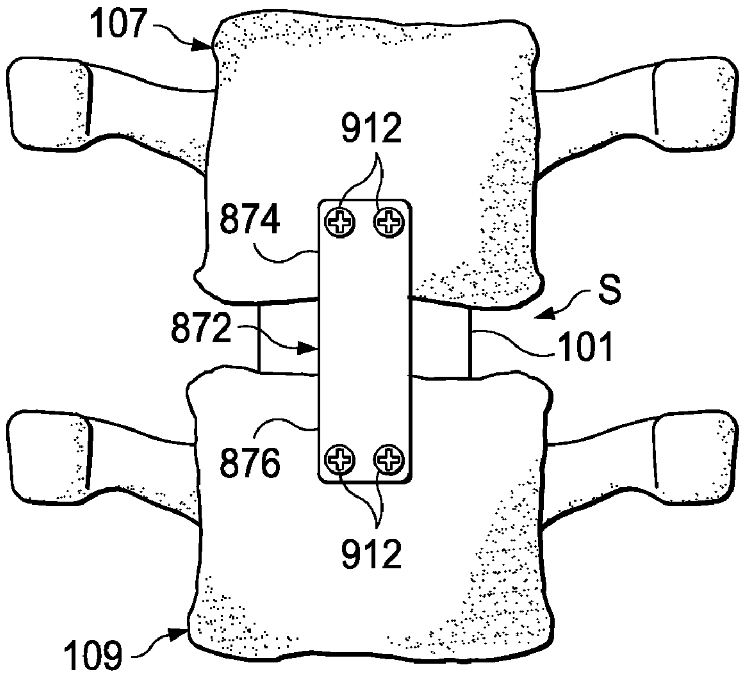
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Fig. 5D

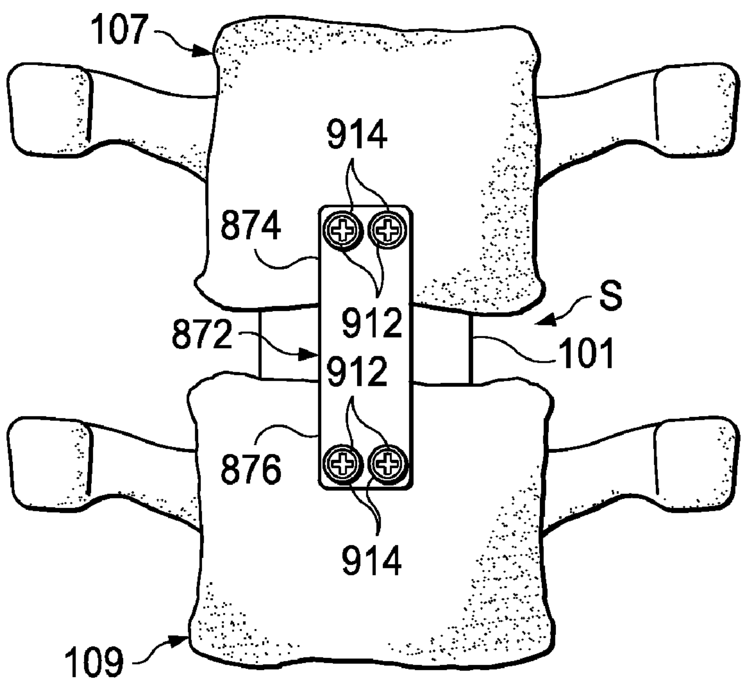
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Fig. 5E

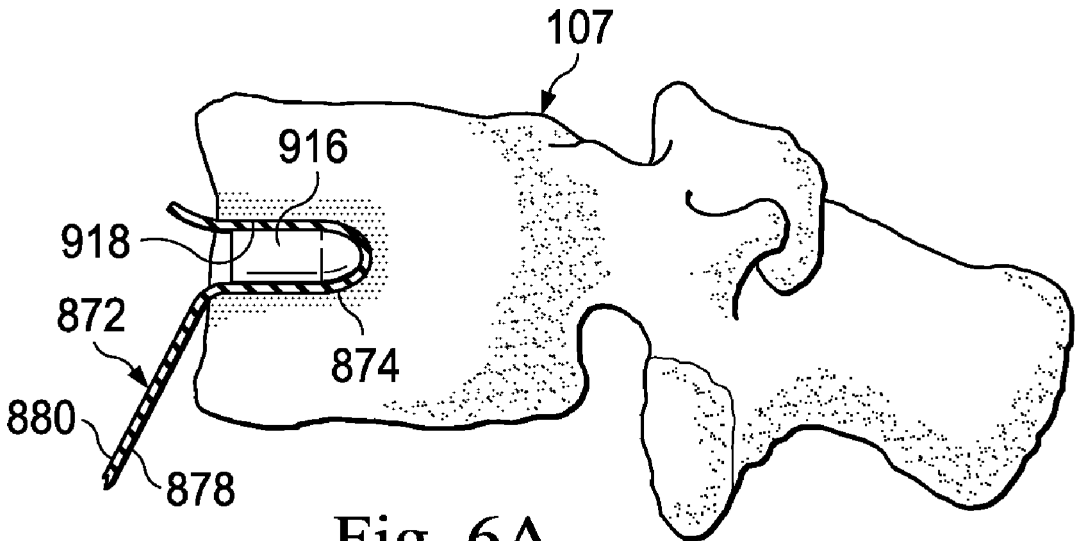

Fig. 6A

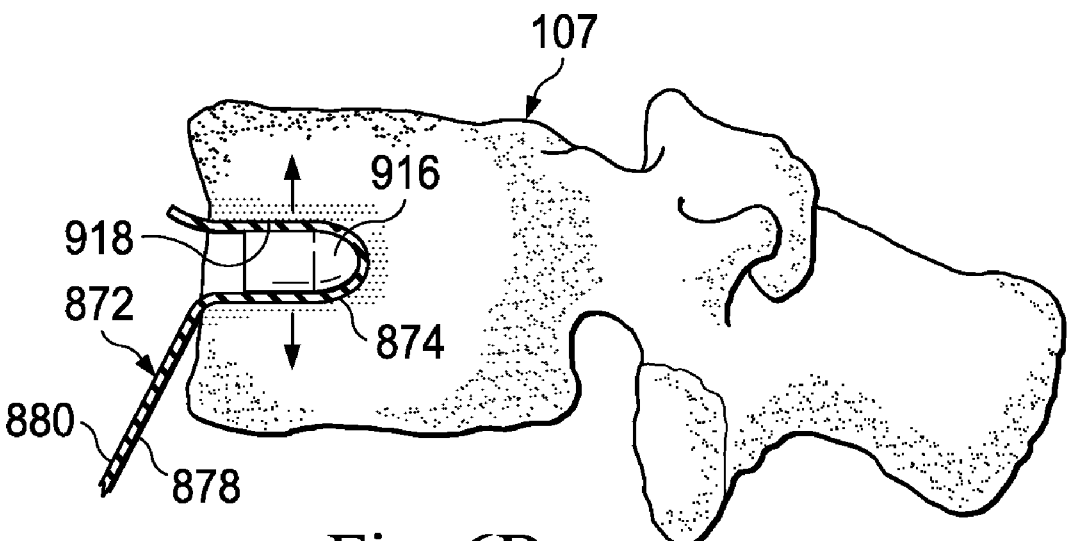

Fig. 6B

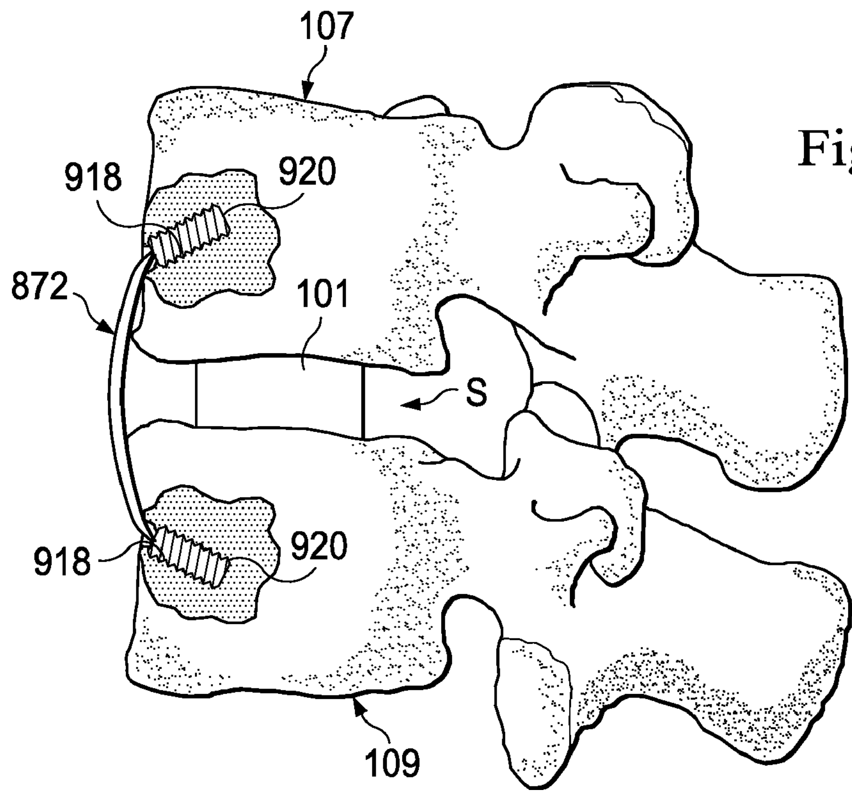
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Fig. 7

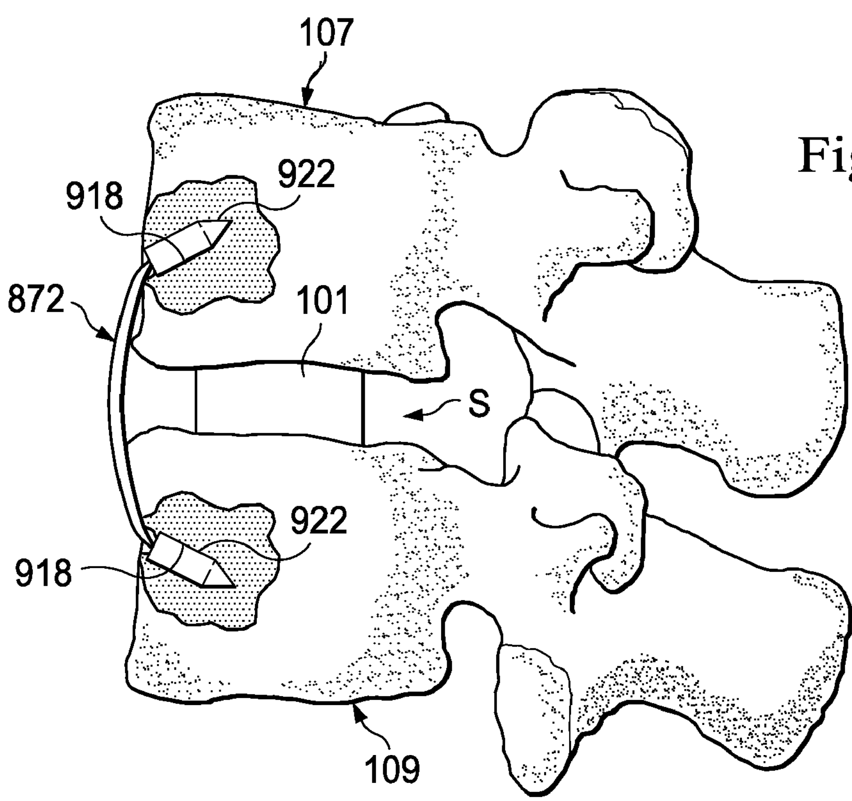
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Fig. 8

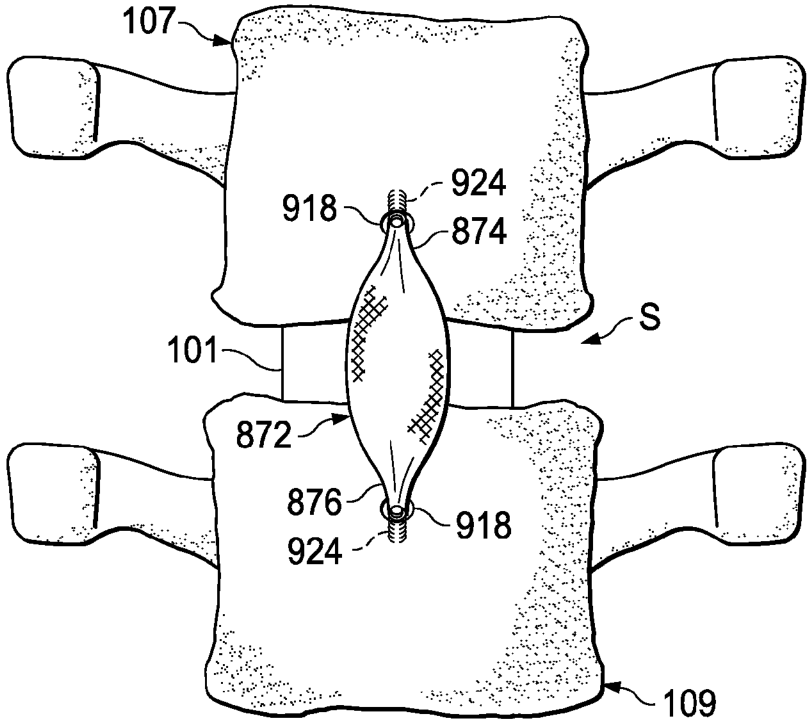
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Fig. 9

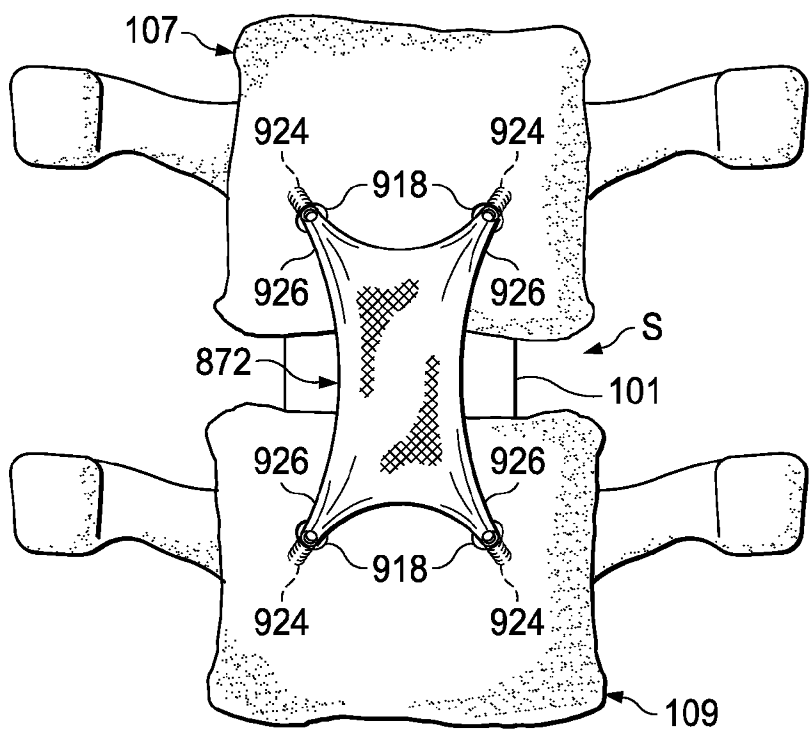
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Fig. 10

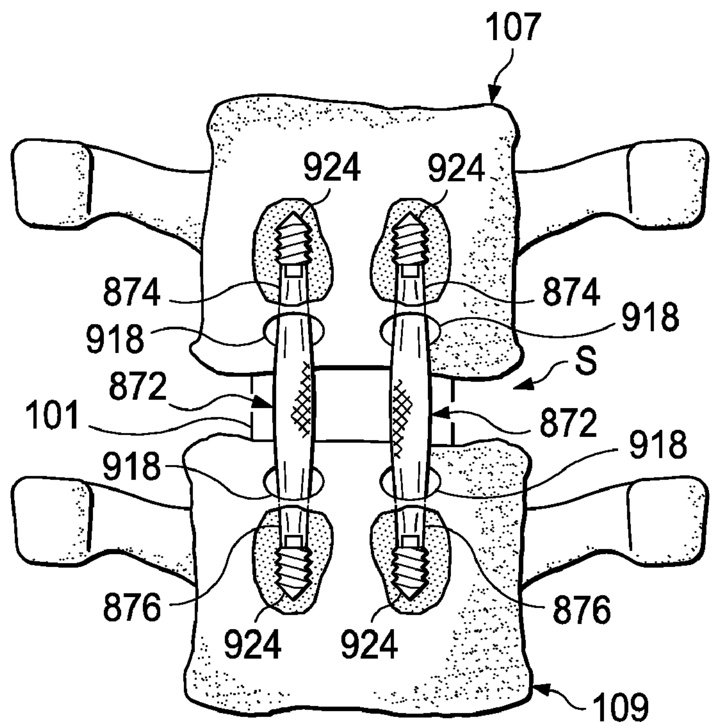
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Fig. 11

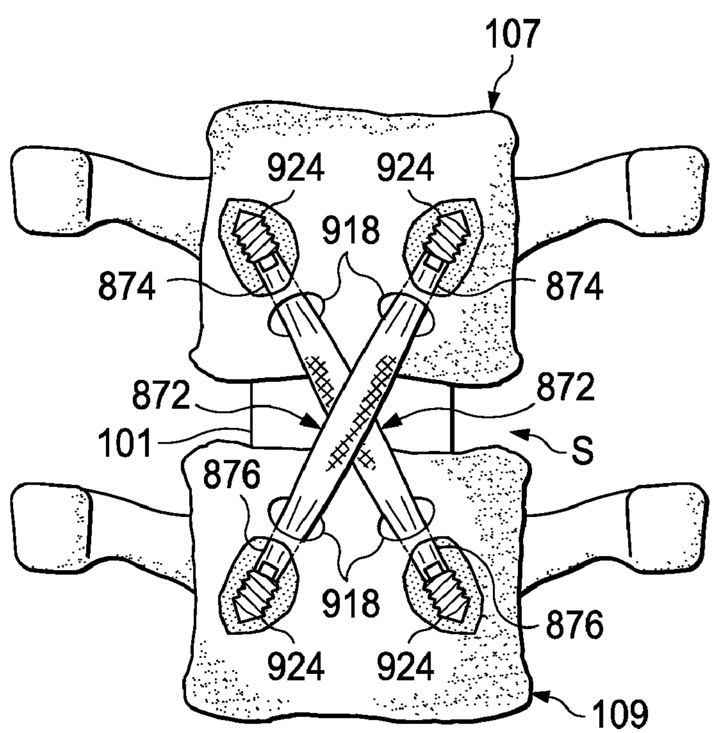
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Fig. 12

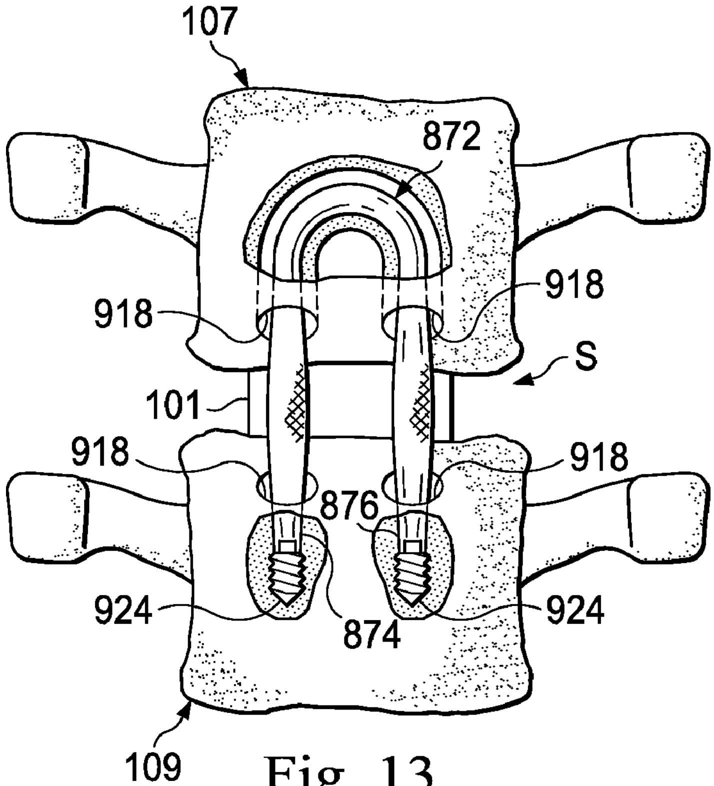
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Fig. 13

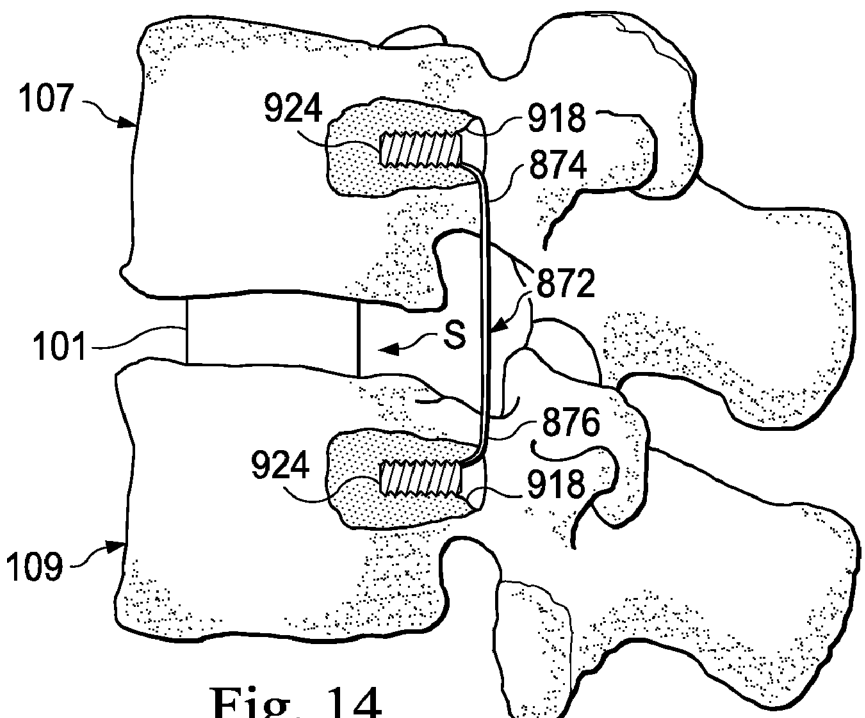
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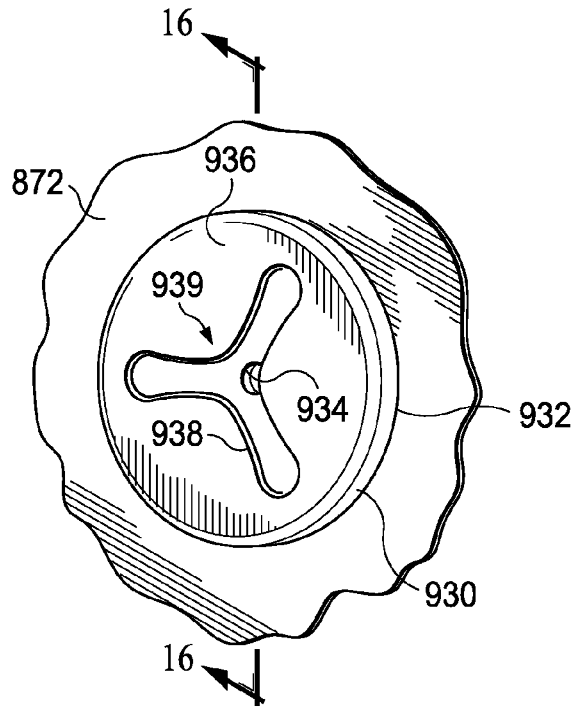
Fig. 14



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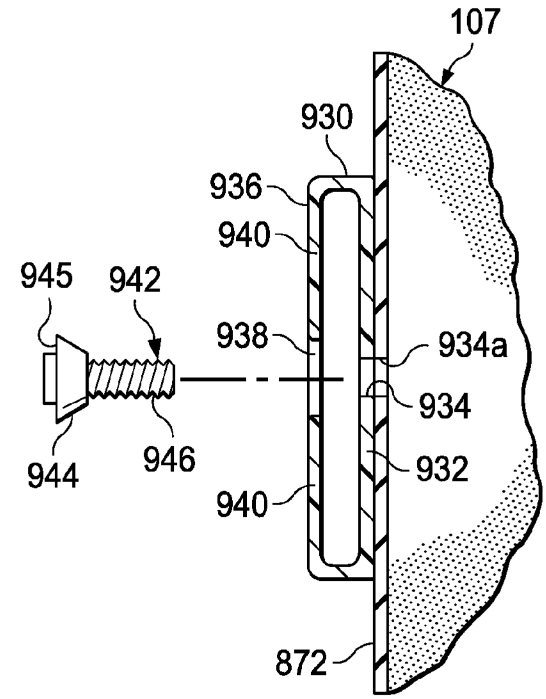
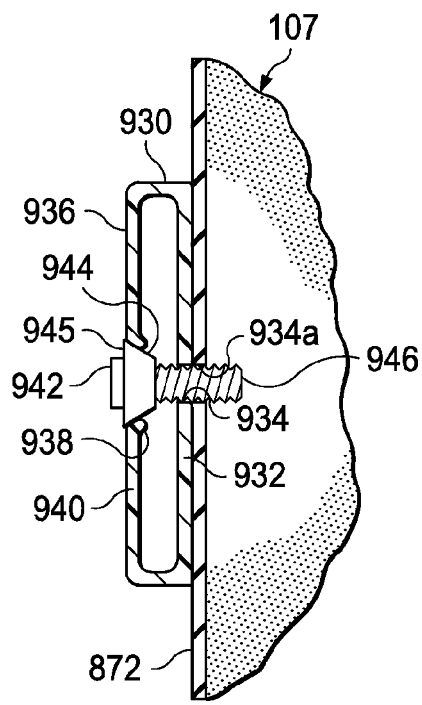


Fig. 16A



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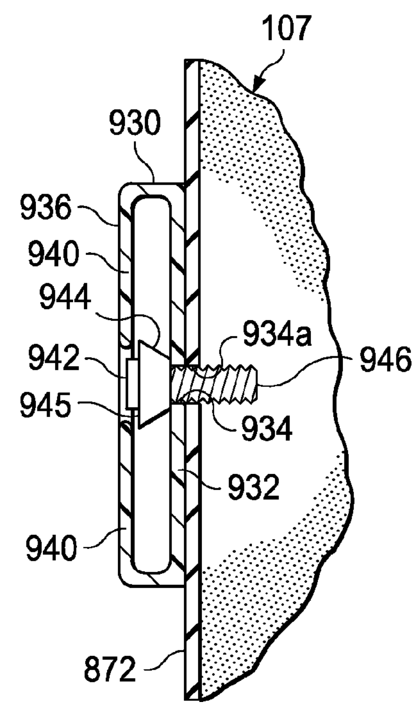

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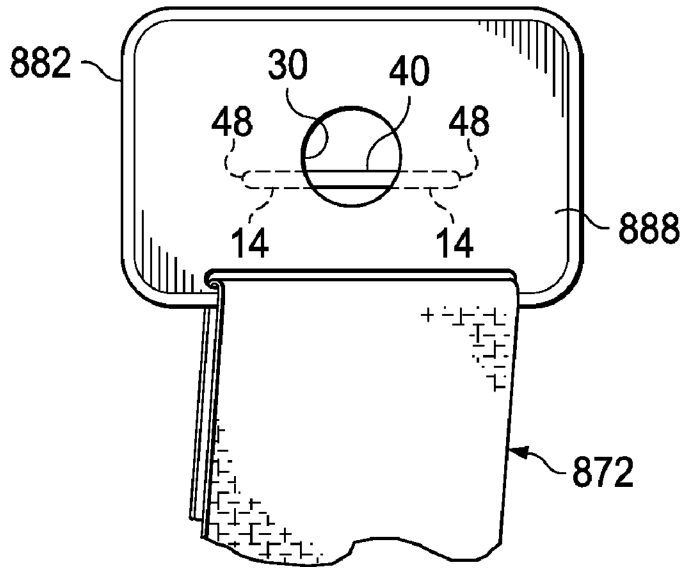
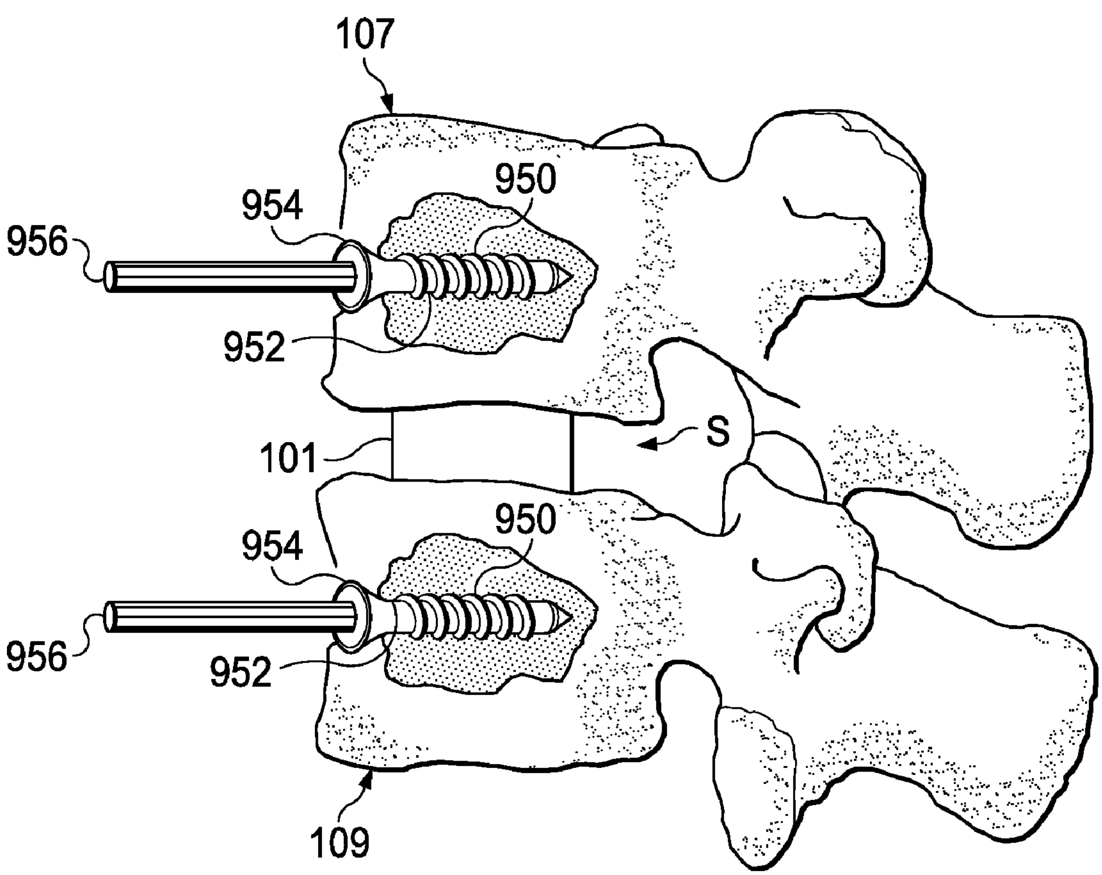


Fig. 16D



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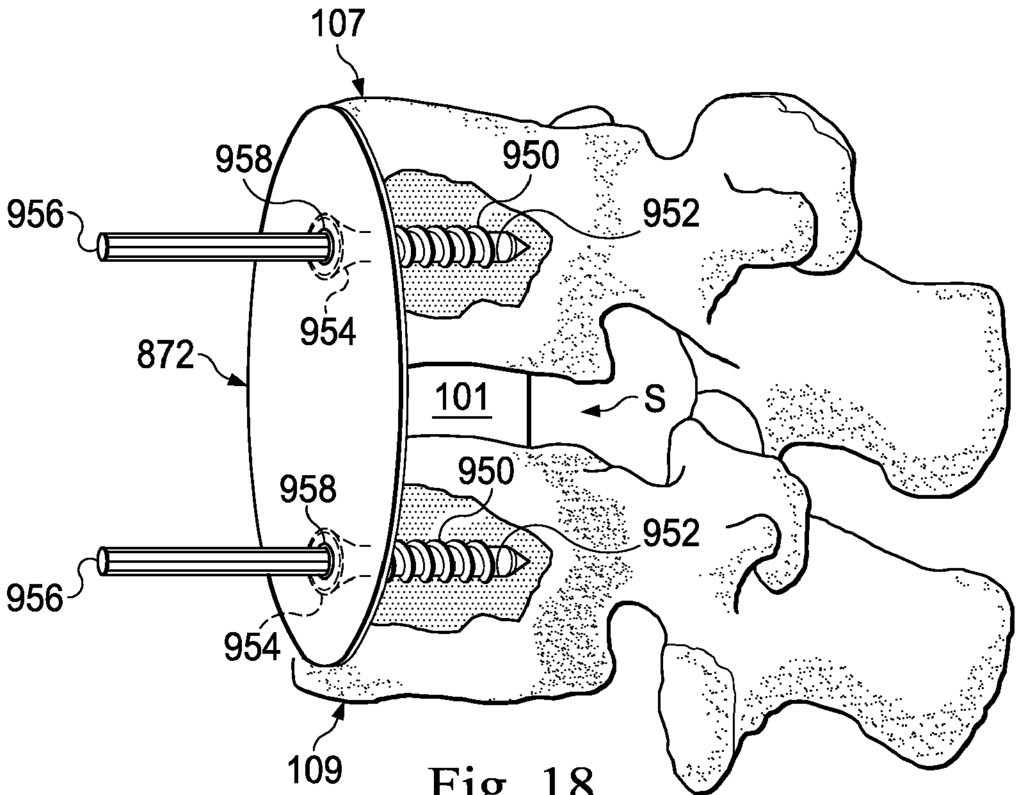
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Fig. 18

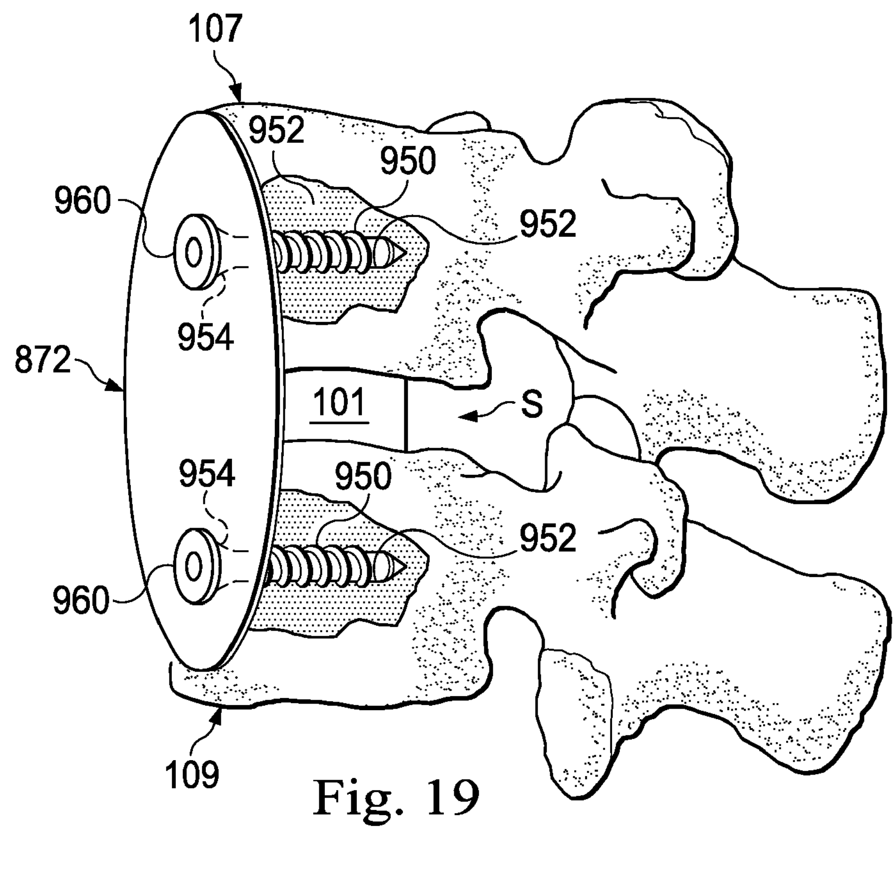
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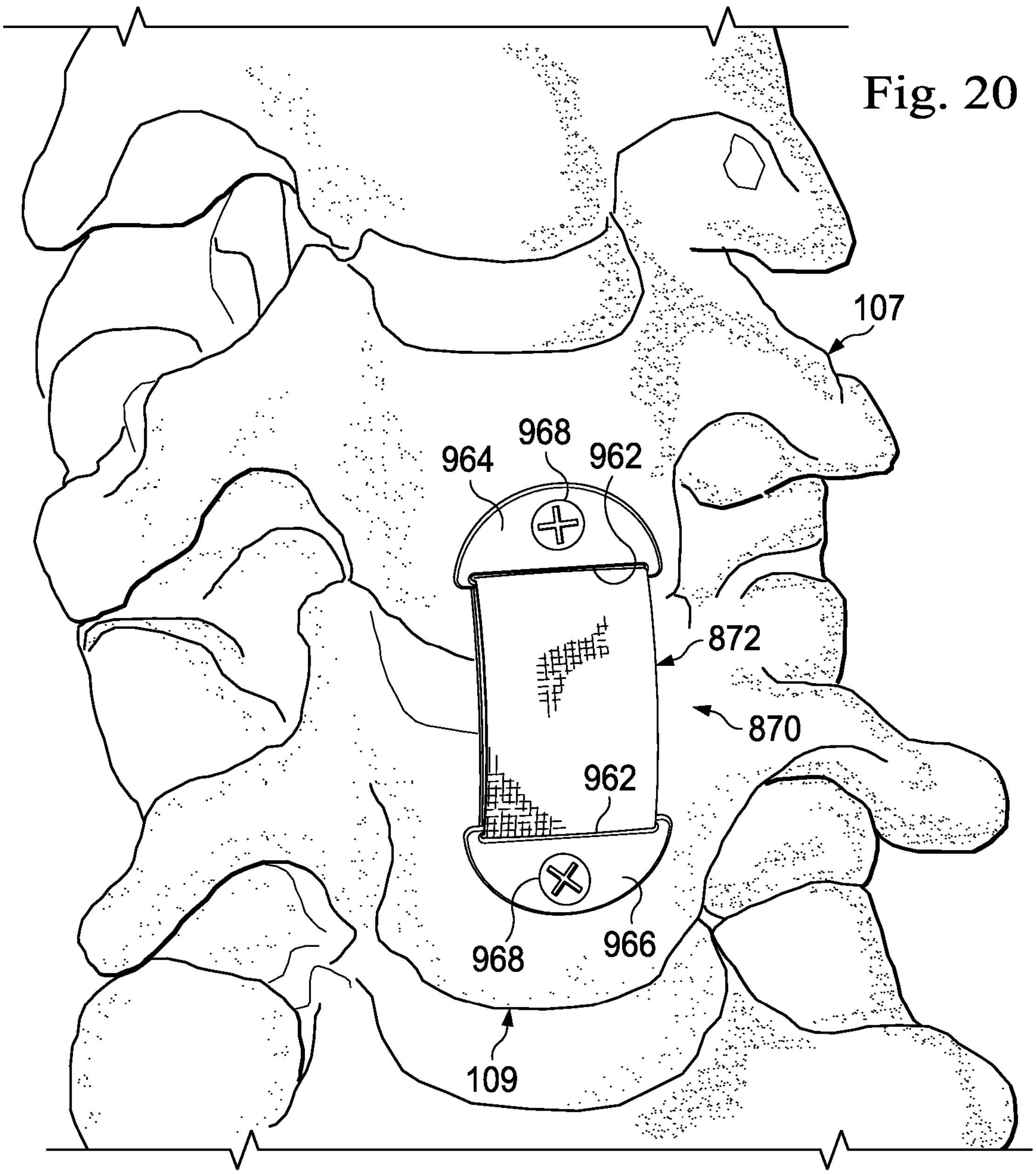
Fig. 19



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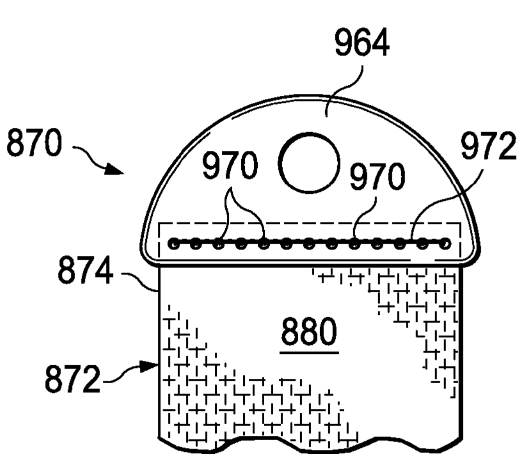
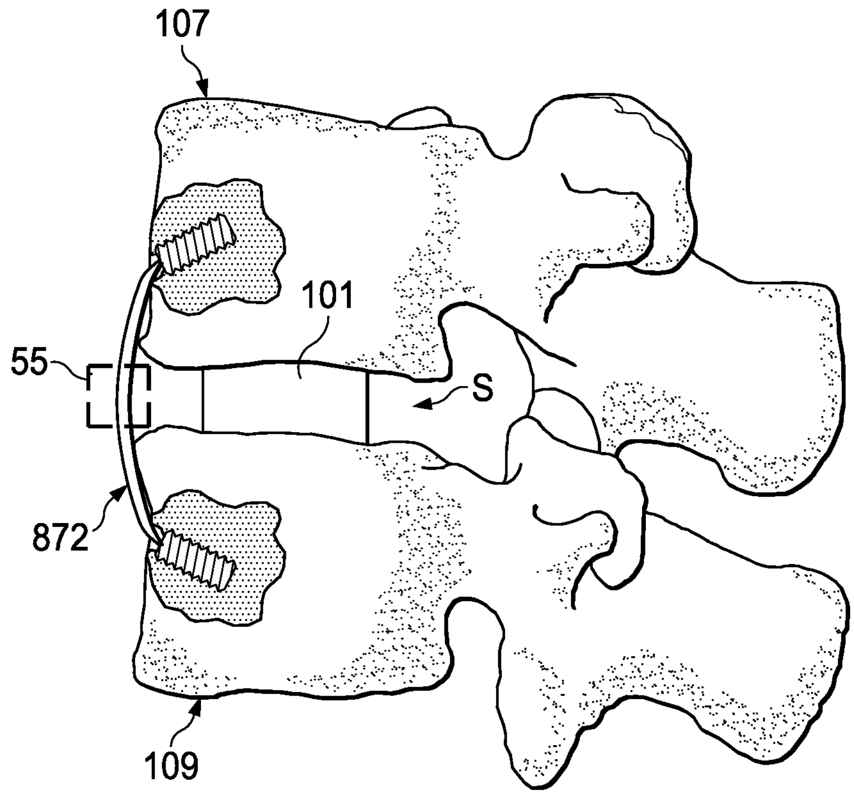


Fig. 20A



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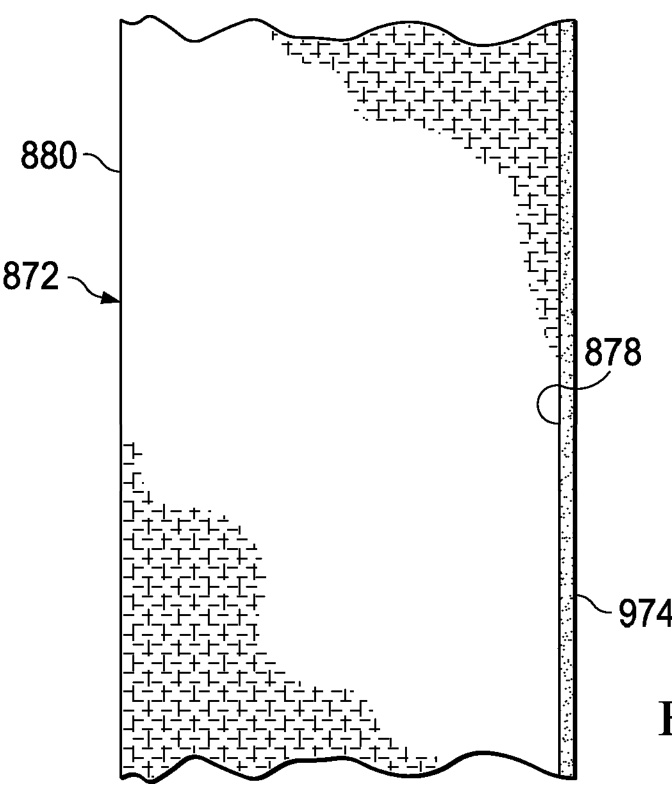

Fig. 22

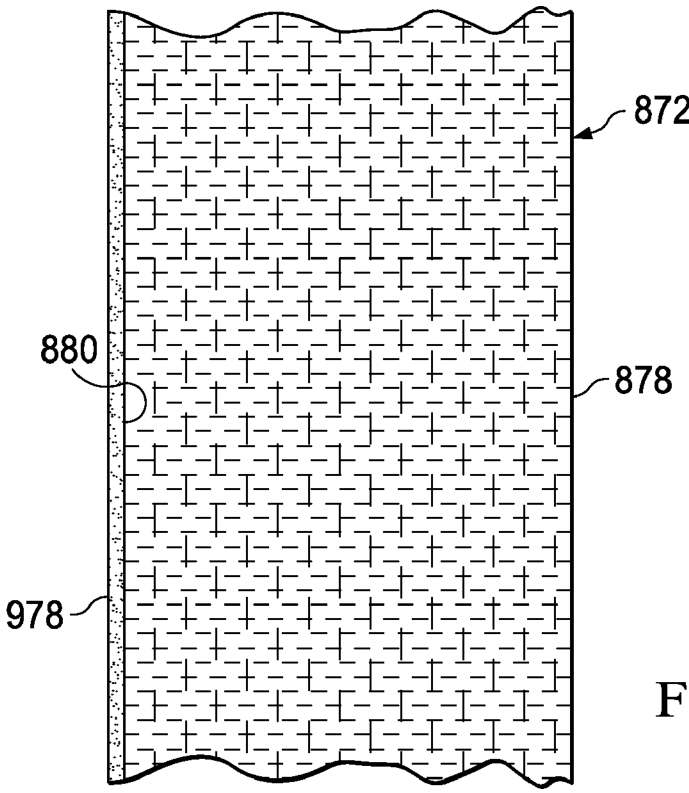

Fig. 22A

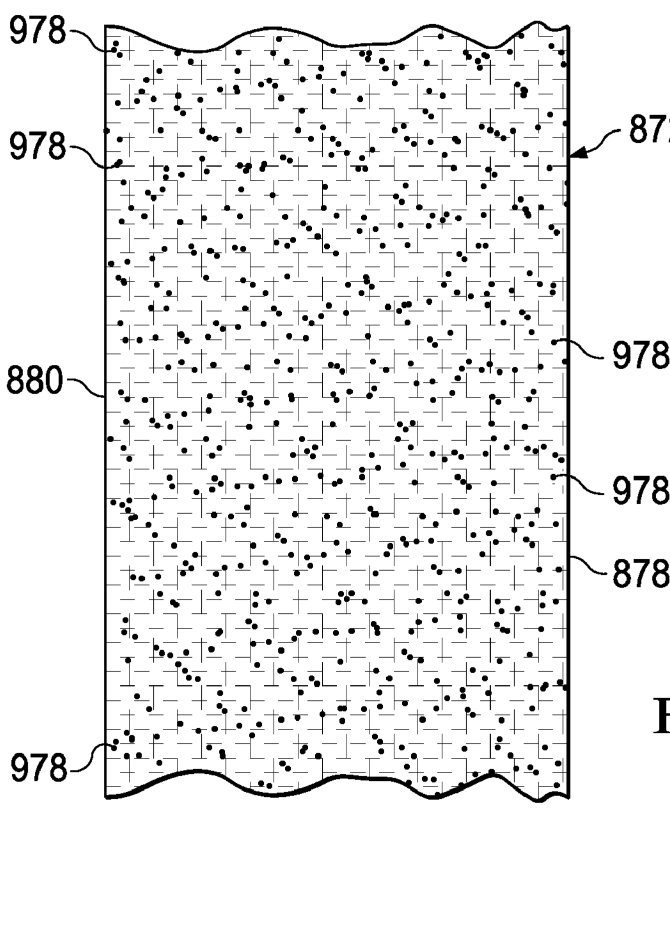

Fig. 22B

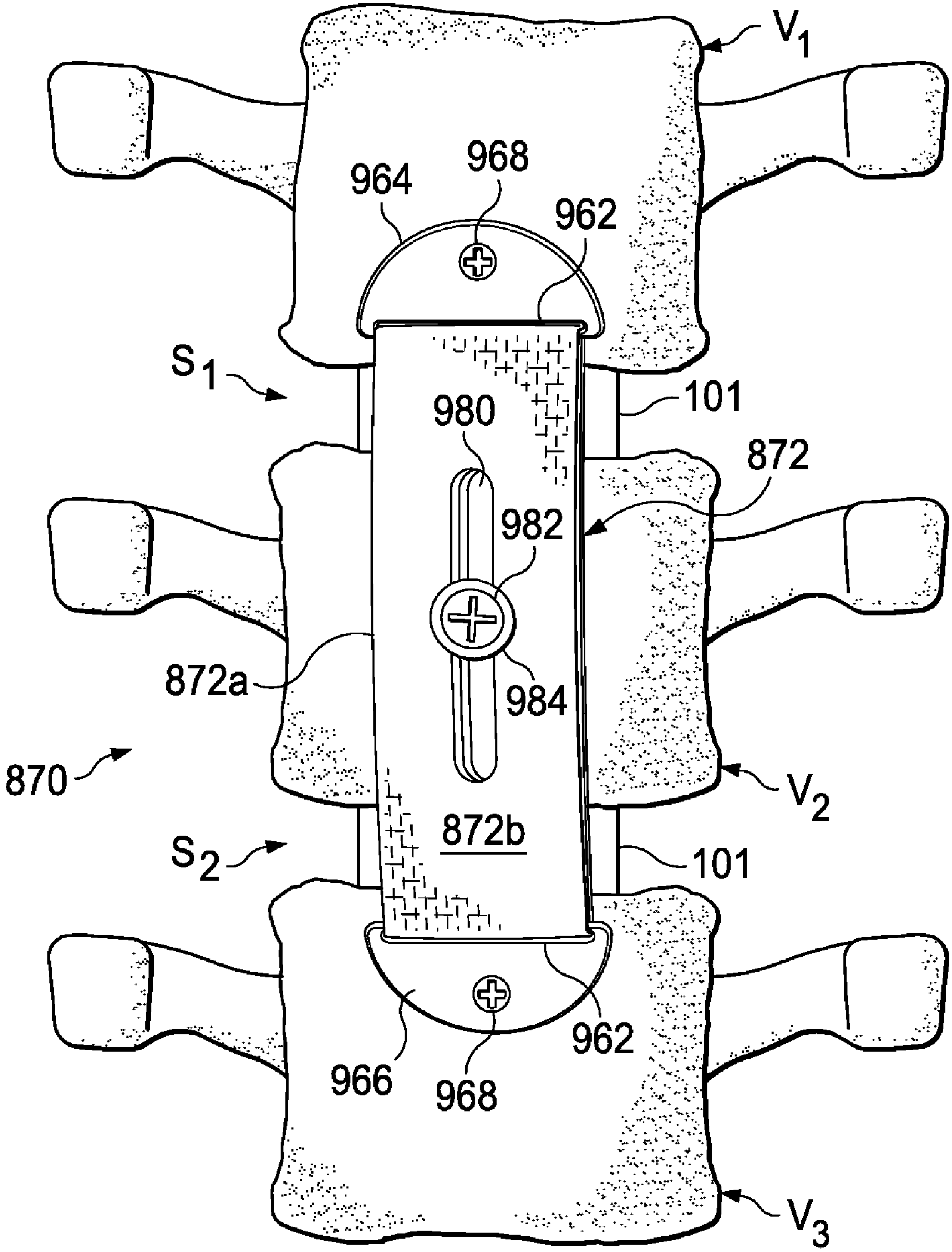
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Fig. 23

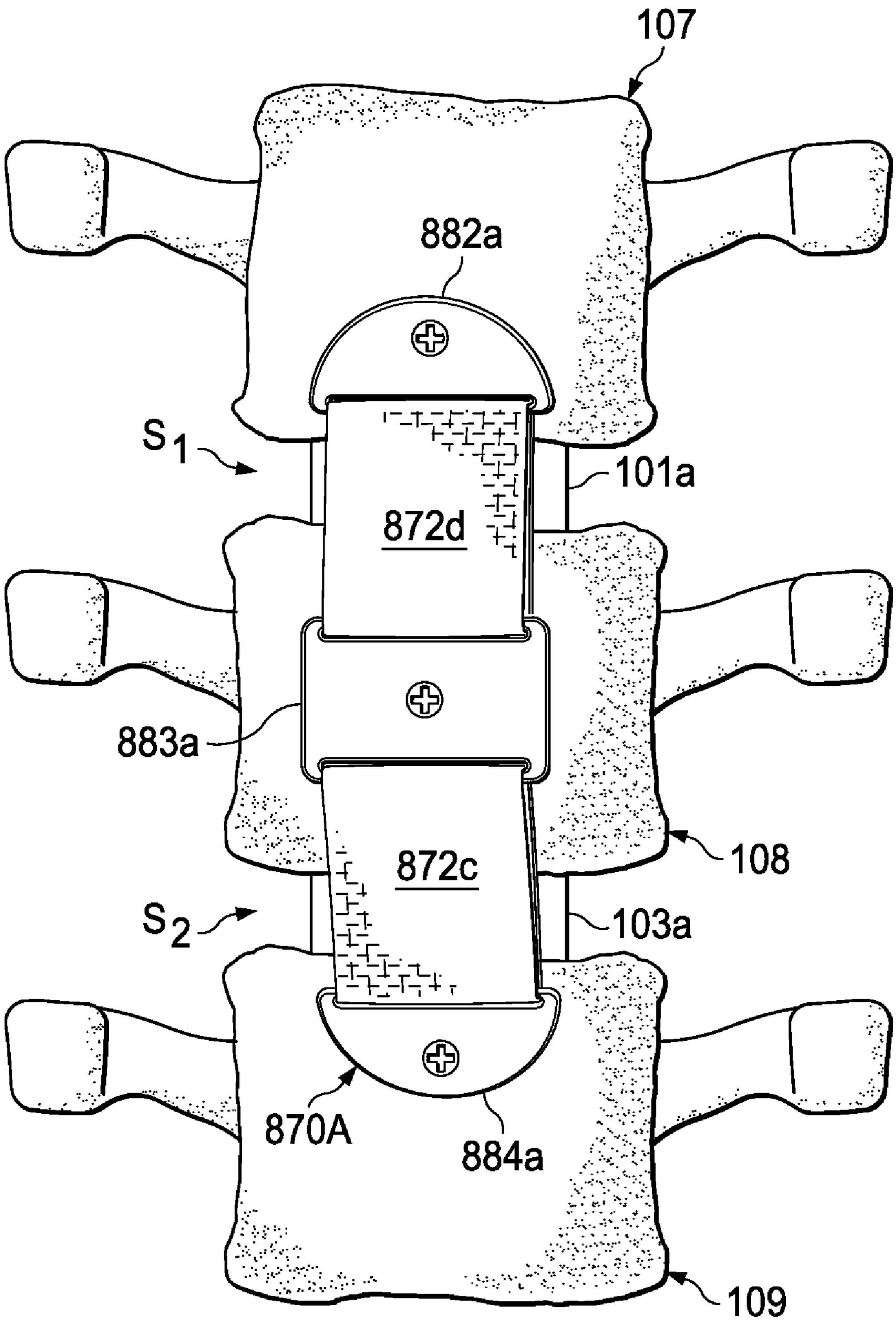

Fig. 24

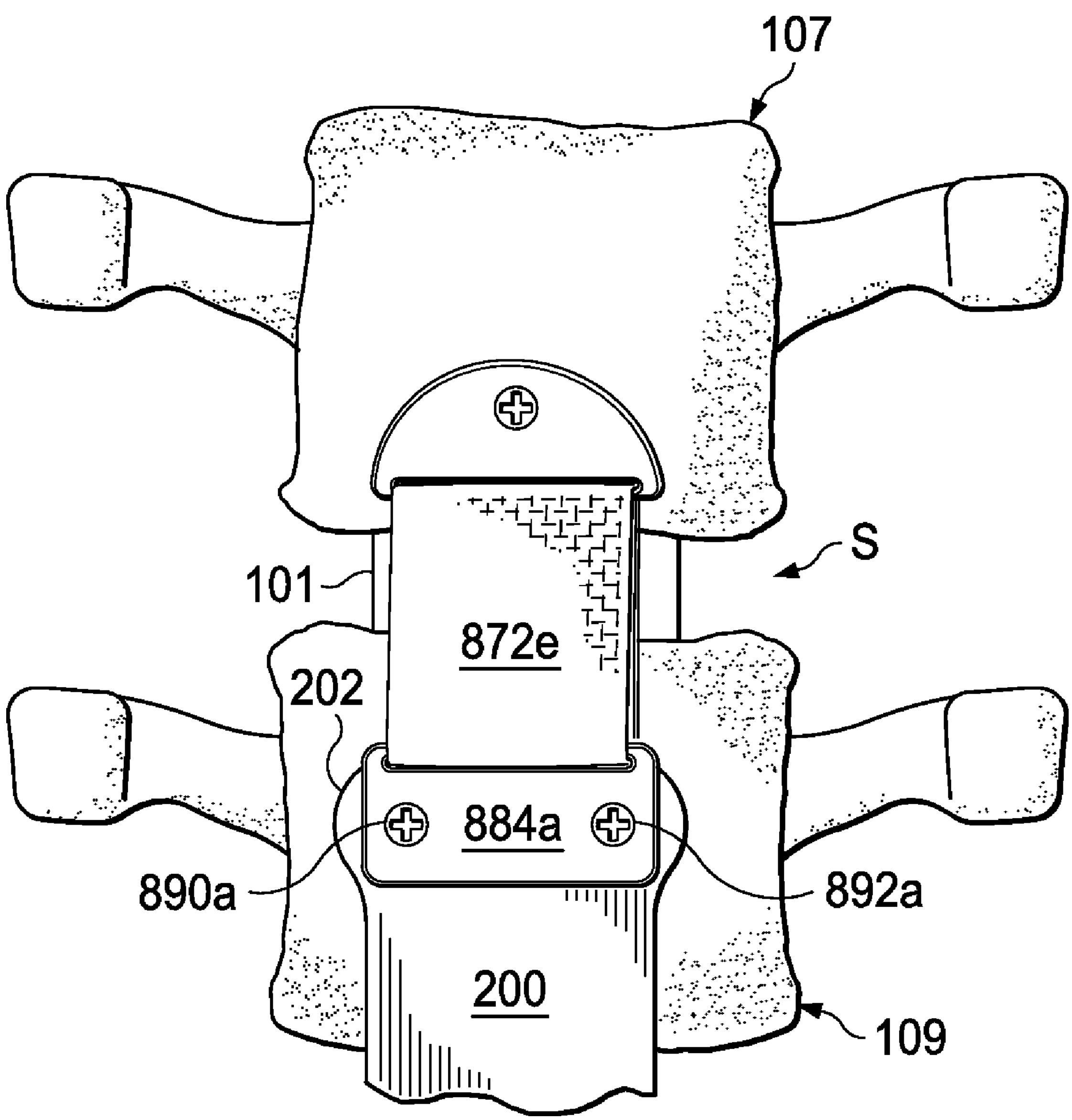

Fig. 25

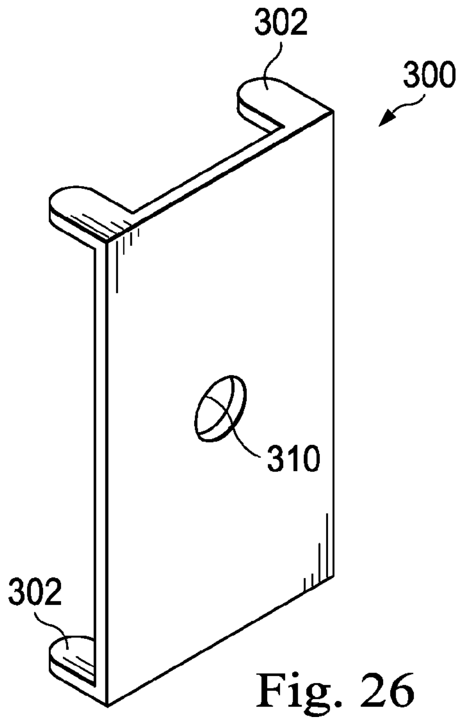

Fig. 26

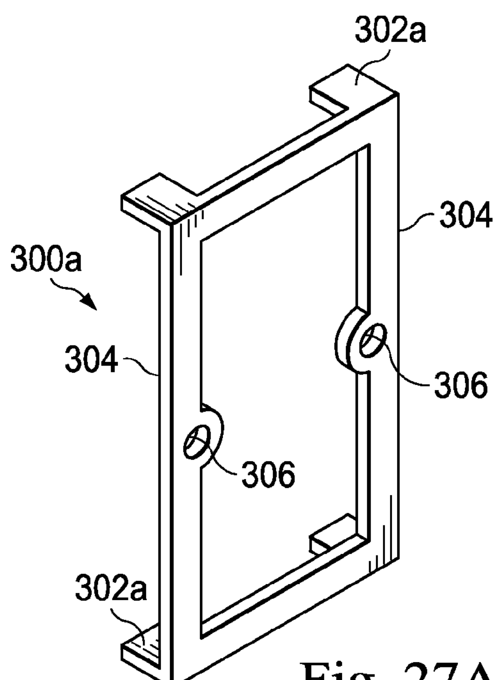

Fig. 27A

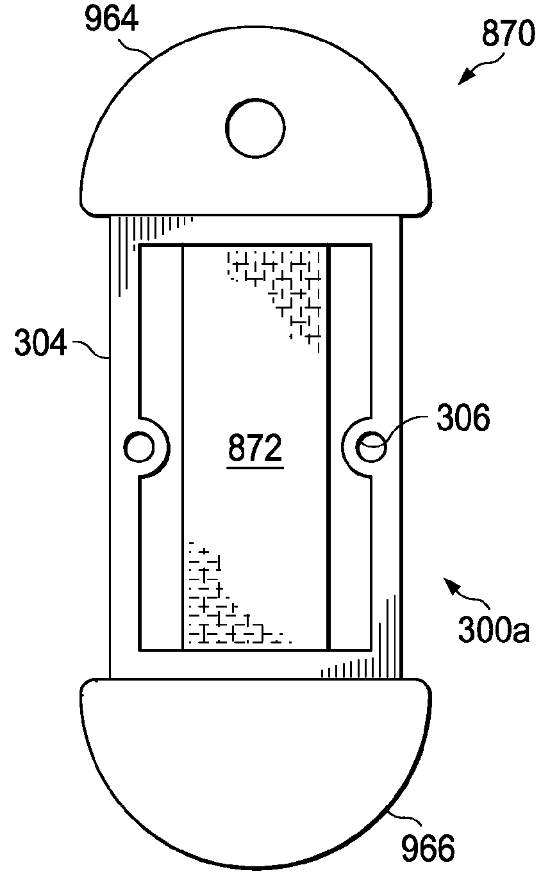

Fig. 27B

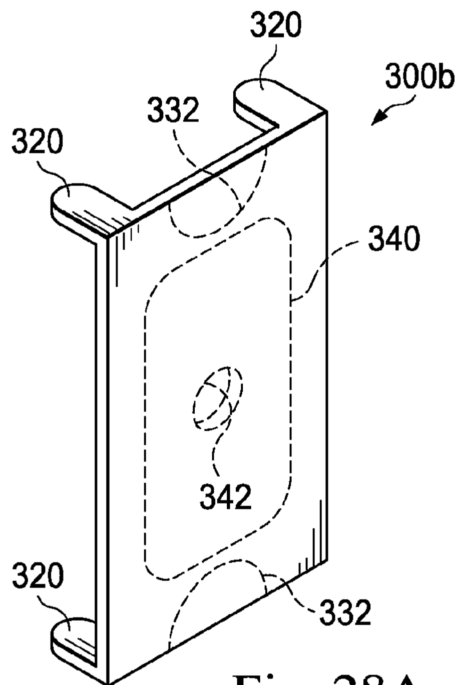

Fig. 28A

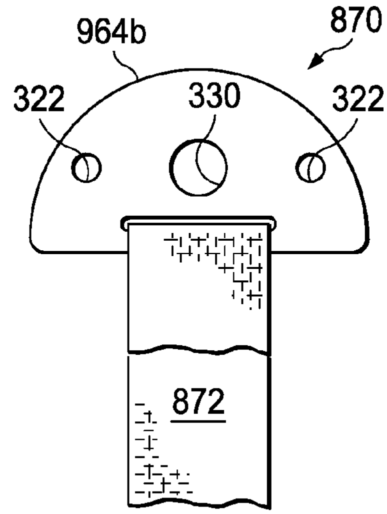

Fig. 28B

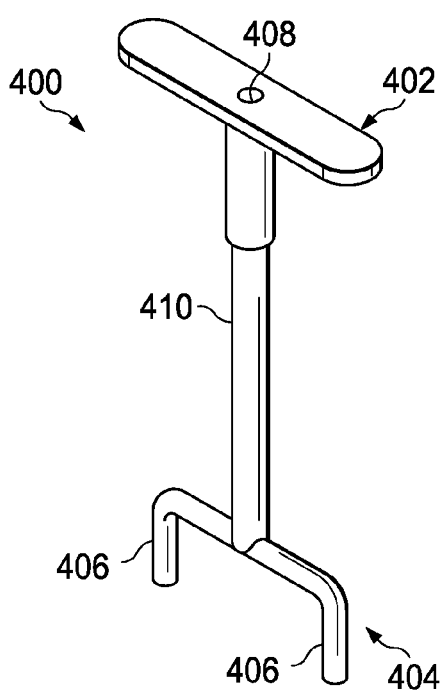

Fig. 29

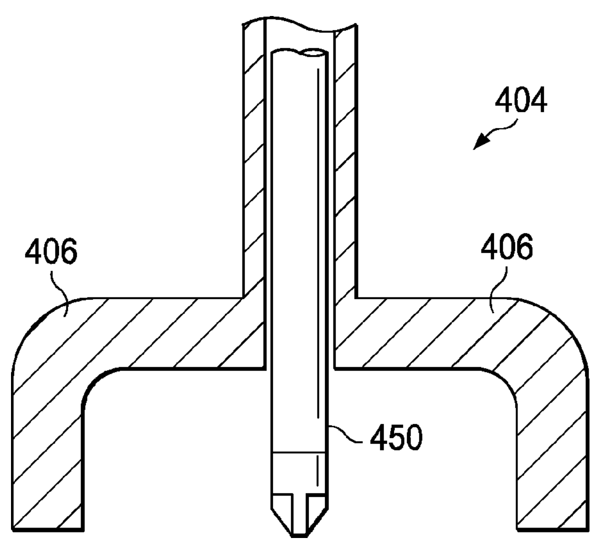

Fig. 29A

TENSION BAND

BACKGROUND OF THE INVENTION

[0001] The present invention generally relates, for example, to apparatus used to correctively link two or more vertebral bodies, and more particularly relates to tension band apparatus connectable to vertebral bodies.

[0002] Various flexible tension band assemblies have been previously proposed for attachment to vertebral bodies to limit the separation therebetween, and to outwardly block dislodgement of an implant disposed between the vertebral bodies. Several problems, limitations and disadvantages have commonly been associated with tension band assemblies of conventional design, including inaccuracies in achieving in-place tensioning thereof, lack of ease and reliability in the securement of the assemblies to the vertebral bodies, and the need to provide associated therapeutic and other treatment to the surgical site of the tension band installation. A need exists for alleviating these problems, limitations and advantages. It is to this need and others that various embodiments of the present invention are directed.

SUMMARY OF THE INVENTION

[0003] In carrying out principles of the present invention, in accordance with various representative embodiments thereof, vertebral linking assemblies, and associated connection structure, are, for example, provided for attachment to vertebral bodies in a manner that may either hold the assembly in a preferred position by the surgeon and/or affect, inhibit, contribute to or limit the separation of the vertebral bodies to which it is attached and/or cover, inhibit, or reduce the likelihood of subsidence and/or blocking dislodgement of a spinal implant from between the vertebrae. Representatively, the linking assemblies may, for example, include elastic, woven, knitted and/or braided fabric tension band embodiments, or combinations thereof, which may be operatively connectable to the vertebral bodies in a manner such that the band may, for example, exteriorly span at least one disc space between the vertebral bodies or span any two bone portions.

[0004] Various connection structures may be used to operatively secure the band to the vertebral bodies, and the band may be modified in several manners to increase its usefulness. For example, a visual and/or radiographic indicia may be placed on the band to provide the physician with a visual and/or radiographic assessment of the amount of tension present in the installed band as well as or alternatively, for example, providing information regarding the placement and/or orientation of the band. Additionally, the band may be configured and/or treated in a manner promoting bony integration between the band and the associated vertebrae, limit tissue adhesion to the band, and/or to elute a therapeutic substance from the installed band.

[0005] In accordance with one illustrative embodiment of the invention, a device is provided for linking first and second vertebral bodies having an implant therebetween. The device comprises a flexible member having first and second ends and being formed from a flexible and/or elastic material which may be stretched to place the flexible member in tension, the flexible member having a surface on which indicia is disposed that provides a physician with a visual and/or radiographic assessment of the degree of tension in the flexible member and/or orientation and/or location of the flexible member. Connector apparatus may be provided for securing the first and second ends of the flexible member to at least one of the first and second vertebral bodies in a manner causing the flexible member to remain generally in a desired location and/or to for example limit, inhibit, or otherwise affect separation of the first and second vertebral bodies and/or to inhibit, in part cover, or reduce the likelihood of or block dislodgement of the implant from between the vertebrae.

[0006] The flexible member may be configured, or a treatment may be added to at least a portion of the flexible member, to promote bony integration between the flexible member and the first and second vertebral bodies to which it is connected, or to reduce post-operative soft tissue adhesion to the flexible member. Further, the flexible member may be treated with a therapeutic substance, with the installed flexible member being operative and/or adapted to elute the therapeutic substance, over time, to the surgical site.

[0007] The connector apparatus may comprise, for example, first and second end caps, respectively secured to the first and second ends of the flexible member, having one or more openings formed therein through which one or more fastening members may be extended into the first and second vertebral bodies to operatively secure the device thereto. Alternatively, the connector apparatus may comprise one or more mechanical fasteners extendable through the flexible member into at least one of the first and second vertebral bodies. The flexible member may, alternatively, be glued, adhered, or otherwise stuck or affixed to one or more of the vertebral bodies and/or intervertebral implant(s). Additionally, tunnels may extend into at least one of the first and/or second vertebral bodies, with portions of the flexible member being disposed within the tunnel or tunnels, and the connector apparatus may comprise one or more fastening members, formed from shape memory material and/or having radially expandable structures, positionable in interference fits within the tunnels to bear against one or more of the flexible member portions and captively retain them in the tunnel or tunnels.

[0008] As a further alternative, the connector apparatus may comprise one or more connector structures, each being connectable to the first and/or second ends of the flexible member, for securing the first and/or second ends of the flexible member to at least one of the first and second vertebral bodies. Each of the connector structures may, for example, comprise (1) a hollow locking structure with a base wall having an opening therein and being securable to one of the first and/or second ends of the flexible member, and an outer wall spaced apart from and parallel to the base wall, the outer wall having an opening therein which opposes the base wall opening and is partially bounded by one or more resiliently deflectable lobe portions of the outer wall, and (2) a fastening member such as, for example, preferably a screw or otherwise a tack, staple, pin or other fastener, extendable sequentially through the outer wall opening, the base wall opening and the one of the first and/or second ends of the flexible member, and preferably threadable or otherwise insertable into one of the first and/or second vertebral bodies, the fastening member further having a transversely enlarged head portion configured to resiliently deflect the one or more lobe portions inwardly, as the fastening member passes through the interior of the hollow locking structure, and then permit the deflected lobe portion(s) to snap back to its undeflected position in which it may block or otherwise obstruct or inhibit at least in part outward passage of the head portion through the outer wall opening.

[0009] In accordance with another illustrative embodiment of the invention, a device is provided for linking first and second vertebral bodies having an implant therebetween, the device comprising a linking member having first and second ends, and a plurality of connector structures, connectable to the first and second ends of the linking member, for securing the first and second ends of the linking member to at least one of the first and second vertebral bodies.

[0010] Illustratively, each of the first and second ends of the linking member may have a mounting hole extending therethrough, and the plurality of connector structures comprises one or more of (1) first and/or second fastening members (such as, for example preferably a screw or alternatively a tack, staple, pin or other connector) each having a head portion through which an opening axially inwardly extends, the first and/or second fastening members being respectively threadable into the first and second vertebral bodies, (2) first and/or second elongated guide members, each configured to be respectively and removably inserted into the openings in the first and/or second fastening members, after the fastening members are threaded, inserted, attached, affixed and/or applied into or on their associated vertebral bodies, and to thereafter have longitudinal portions projecting outwardly from the first and second fastening members, the longitudinal portions of the guide members being movable away from or toward one another by exerting a separation or closing force thereon to increase or decrease the separation distance between the first and second vertebral bodies to facilitate the insertion therebetween of a supportive implant that substantially maintains the increased or decreased separation distance when the separation force is removed or applied from or by the outwardly projecting portions of the first and second elongated guide members, and thereby positions the outwardly projecting portions so that they can extend through the mounting holes of the linking member and permit the first and second linking member ends to be moved therealong into adjacency with the fastening member head portions, and (3) first and/or second locking members constructed and operative to respectively lock the first and/or second linking member ends to the head portions of the first and/or second fastening members before or after the first and second elongated guide members are respectively removed from the first and/or second fastening member openings.

[0011] In accordance with a further illustrative embodiment of the invention, multilevel apparatus may be provided for linking first and second vertebral bodies having a third vertebral body disposed therebetween, the apparatus comprising (1) a generally band-shaped flexible structure having first and second ends, and an elongated slot extending through a longitudinally intermediate portion of the flexible structure and longitudinally extending parallel to the length of the flexible structure, (2) first connection structure for respectively securing the first and second ends of the flexible structure to the first and second vertebral bodies, and (3) second connection structure, extendable through the slot through a selectively variable longitudinal portion thereof and securable to the third vertebral body, for securing a longitudinally intermediate portion of the flexible structure to the third vertebral body.

[0012] The flexible structure may be of a looped configuration, with a first connection structure comprising first and second end plates having slots therein through which the first and second end portions of the flexible structure respectively extend, openings through which fasteners such as, for example, screws, pins, staples, rivets, or other such devices may be extended and, for example, threaded, pressed, inserted or otherwise attached into or on the first and/or second vertebral bodies. A second connection structure may comprise a grommet configured to outwardly overlie the flexible structure at a portion of the slot, and a fastener extendable through the grommet and threadable or otherwise inserted, attached into or attached or applied onto the third vertebral body.

BRIEF DESCRIPTION OF THE DRAWINGS

[0013] FIGS. **1** and **2**, respectively, are inner and outer side perspective views of a tension band structure embodying principles of an embodiment of the present invention and representatively including a flexible tension band portion connected at its opposite ends to end cap members which, in turn, are connectable to vertebral bodies.

[0014] FIG. **2**A is a schematic anterior side elevational view of an embodiment of the tension band structure of FIGS. **1** and **2** operatively installed on and linking first and second vertebral bodies.

[0015] FIGS. **3**A-**4**B elevationally depict, in schematic form, two representative embodiments of a flexible tension band member having disposed thereon indicia providing a physician with a visual and/or radiographic assessment of the tension, location, and/or orientation of the band member.

[0016] FIGS. **5**A-**5**E schematically depict several representative embodiments of tension band members operatively spanning two adjacent vertebral bodies and secured thereto by a variety of simple mechanical fasteners extending directly through opposite ends of the band members into the vertebral bodies.

[0017] FIGS. **6**A-**14** cross-sectionally depict the attachment of representative embodiments of tension band members to vertebral bodies using various shape memory-capable and radial expansion-capable mechanical fasteners.

[0018] FIGS. **15**-**16**C schematically illustrate a technique for fastening various embodiments of a tension band member to a vertebral body utilizing an embodiment of a specially designed flexible petal fastener locking mechanisms, attached to the tension band member, and associated bone fasteners.

[0019] FIG. **16**D schematically illustrates a schematic view of an anti-rotation structure or locking mechanism that can be used with the present invention.

[0020] FIGS. **17**-**19** schematically illustrate an exemplary technique for fastening various embodiments of a tension band member, or other type of linking member, to two vertebral bodies, using an embodiment of a specially designed caspar pin-based anchoring system.

[0021] FIGS. **20** and **20**A illustrate two representative embodiments of specially designed end caps used to secure opposite ends of a tension band member to two vertebral bodies.

[0022] FIGS. **21**-**22**B schematically illustrate the use of various fabric-based tension band member embodiments in which the weave, knit or braid of the band member is adjusted, or a treatment is added to at least a portion of the band, to add useful effects to the operatively installed band member such as to promote bony growth between the band and the vertebrae, reduce tissue adhesion to the band, or to provide the elution over time of therapeutic substances from the installed band member.

[0023] FIG. **23** is an outer side perspective view of a slotted band embodiment of a tension band structure embodying principles of an embodiment of the present invention.

[0024] FIG. **24** shows a schematic view of another embodiment of a multilevel tension band assembly.

[0025] FIG. **25** schematically illustrates an "add on" band according to the present invention.

[0026] FIG. **26** shows an perspective schematic view of a holding device for use in cooperation with the band assembly according to the present invention.

[0027] FIG. **27**A shows an perspective schematic view of another embodiment of a holding device according to the present invention.

[0028] FIG. **27**B shows a front schematic view of holder of FIG. **27**A in cooperation with a band assembly according to the present invention.

[0029] FIG. **28**A shows an perspective schematic view of another embodiment of a holding device according to the present invention.

[0030] FIG. **28**B shows a cut-away schematic view of the embodiment of an end cap of an embodiment of a tension band assembly that works in cooperation with the holding device of FIG. **28**A.

[0031] FIG. **29** shows a schematic perspective view of a anti-rotation device according to the present invention.

[0032] FIG. **29**A shows a cut-away, enlarged cross-sectional schematic view of the distal end of the anti-rotation device of FIG. **29**.

DETAILED DESCRIPTION OF VARIOUS EXEMPLARY EMBODIMENTS OF THE PRESENT INVENTION

[0033] Turning first to FIGS. **1** and **2**, perspectively illustrated therein is a vertebral linking apparatus in the form of an assembly **870** which may be utilized, as subsequently described herein, to link two vertebral bodies (such as the upper and lower vertebrae **107**,**109** in FIG. **2**A) in a manner that may, for example (1) assist in holding the apparatus in a preferred location and/or orientation and/or affect, inhibit, contribute to or limit separation of the vertebral bodies, and (2) cover, inhibit or reduce the likelihood of subsidence of or enhance the potential blocking or hinder the dislodgment of a spinal implant (such as the illustrative implant **101** schematically depicted in FIG. **2**A) from between the vertebral bodies. Implant **101** may have a variety of different configurations and structures to suit the particular surgical procedure. For example, implant **101** may be a spacer such as a cage for stabilization or an artificial disc for preserving motion.

[0034] Vertebral linking assembly **870** comprises a flexible linking member, preferably in the form of a tension band **872** formed from an elastic, woven, knitted or braided or flexible material including but not limited to a cloth, polymer, metal, or tissue or combination thereof, and having first and second ends **874** and **876**. Tension band **872** may be formed from a wide variety of suitable materials, including natural or synthetic tissue biocompatible materials. Natural materials include autograft, allograft and xenograft tissues including but not limited to bone and ligaments. Synthetic materials include metallic materials and polymers. The metallic materials can be formed from shape memory alloy, including shape memory materials made from, for example, the nickel-titanium alloy known as Nitinol ("NiTi"). The shape memory materials may exhibit shape memory, but preferably exhibit superelastic behavior. Other metallic materials include titanium alloy, titanium, stainless steel, and cobalt chrome alloy. Suitable polymeric materials include, for example, polyethylene, polyester, polyvinyl, polyvinyl alcohol, polyacrylonitrile, polyamide, polytetrafluoroethylene, poly-paraphenylene, terephthalamide and combinations thereof. Some woven, knitted or braided materials may, for example, include nylon, Dacron®, and/or woven fibers or filaments of polyester, polyethelene, polypropylene, polyetheretherketone ("PEEK"), polytetrafluoroethylene ("PTFE"), woven PEEK, and/or Bionate® or Pursil® manufactured by DMS PTG, Inc. of Berkeley, Calif. Some elastic materials may, for example, include latex, rubber, silicone, polyurethane, silicone-polyurethane copolymers, and/or polyolefin rubbers. Other suitable materials may, for example, include Gore-Tex®, Kevlar®, Spectra, polyether, polycarbonate urethane, shape memory material with pseudo elastic or superelastic characteristics, metals, metal alloys, and polymers, braided polymers, materials made of bone, any bio-compatible material such as an elastomer, demineralized bone, or flexible composite material, ceramic materials, carbon fiber, other natural materials such as allograft, autograft and xenograft, polyacrilonitrile, glass fiber, collagen fiber, ceramic fiber, synthetic resorbable materials such as polyactide, polygycolide, polyorthoester, calcium phosphate, and/or glass, nonresorbable polyethylene, cellulose, materials that are potentially absorbable, and/or materials that are used in making artificial ligaments. In addition to woven, braided, or knitted structures, the band **872** also may be composed of non-woven structures such as non-woven mesh, or chained structures. Tension band **872** has an inner side **878** and an outer side **880**.

[0035] The assembly **870** further comprises first and second end cap connection members **882**, **884** each having inner and outer sides **886**, **888**, one or more connection holes **890**, **892** extending therethrough, and one or more rectangular notches **894** formed in the inner end cap sides **886** and extending inwardly from flat edge portions **896** of the end caps **882**, **884**. A single hole may be utilized in the end caps **882**, **884** to replace the illustrated dual holes **890**, **892** therein if desired. End caps **882**, **884** may be formed from a variety of alternative materials including, by way of non-limiting example, metal or a plastic material such as PEEK. Additional materials that the end caps **882**, **892** could be made of include metals, ceramics and other polymers, and could also include absorbables or adsorbables like Hydrosorb and natural materials like bone, and other tissue—natural or processed—PEK, Polyglycolic Acid, Hydroxyappetite (HA), or a stiffer fabric portion. If the end caps **882**, **884** are made of PEEK, they may be flexible and/or elastic to a certain degree. This will add to the flexibility of the overall tension band assembly.

[0036] The ends **874**, **876** of the tension band **872** may be disposed in the end cap notches **894** and may be secured to the end caps in a number of alternative manners including, by way of non-limiting example, clamping, looping the band material through slots in the end caps and then stitching or welding the band material to itself, welding the band to the end caps, suturing the band to the end caps, and gluing or otherwise adhesively securing the band to the end caps. Welding methods may include ultrasonic or regular heat welding, and other methods may include molding, pressurizing, and stapling.

[0037] FIG. **2**A schematically depicts an embodiment of a tension band assembly **872** operatively secured to the vertebral bodies **107**,**109** by respectively anchoring the end caps **882**, **884** to the vertebral bodies **107**,**109** using fasteners **898** (such as screws, tacks, pines or staples) extended through the end cap connection holes **890**, **892** (see FIGS. **1** and **2**) and threaded, inserted, pushed, advanced and/or affixed into the vertebral bodies **107**,**109**. In the installed assembly **870**, the band **872** is preferably in tension, thereby resiliently limiting, inhibiting, adjusting or affecting the separation of the vertebral bodies **107**,**109** from one another or merely connecting thereto and preferably retaining the band in approximately a preferred location and/or orientation, and externally spans the intervertebral space S between the vertebrae **107**,**109** to thereby block, inhibit, obstruct, or reduce the potential for dislodgement of or otherwise cover at least in part the implant **101** from between them. As illustrated in this embodiment, there may be no direct connection between the tension band assembly **870** and the implant **101**. Such direct connection could, however, be utilized if necessary or desirable. Examples of techniques for attaching an intervertebral implant/artificial disc to the band representatively include gluing, heating, and fastening by tack, screw, staple, etc. Additionally, a wrap around with a built-in snap fastener could be used to operatively connect the band to the implant. Alternatively, the implant may be integrally formed or manufactured with and/or as part of the band. Although the depicted tension band illustratively spans a single intervertebral space S, it will be readily appreciated by those of skill in this particular art that it could be easily modified to span a plurality of intervertebral spaces. For example, an extra end cap and length of tension band material could be joined to the illustrated assembly **870**, with the three end caps being secured to three vertebral bodies in a manner causing each of the two band lengths to externally span a different one of two intervertebral spaces. Alternatively, an embodiment with one, two or no end caps could be employed to span any particular space or combination of spaces attached by any of the described manners to various vertebra, bones, and/or implants. Other techniques for spanning a plurality of intervertebral spaces (for example, as shown in the subsequently discussed FIG. **23** herein) could also be utilized.

[0038] Turning now to FIGS. **3**A and **3**B, an alternate embodiment of a flexible tension band **872**, such as, for example, formed of a fabric and/or elastic material, may have formed on a side thereof (illustratively its outer side **880**) visual and/or radiographic tension, location and/or orientation indicia designed to provide a surgeon with a visual and/or radiographic assessment of the tension, location and/or orientation to which the band **872** is subjected after operative connection of the band to its associated vertebrae. For example, with the band **872** is its relaxed orientation as shown in FIG. **3**A, the indicia **900** may be configured to assume the indicated zig-zag line configuration extending along the length of the band **872**. However, when the band **872** is operatively tensioned in a longitudinal direction to a predetermined degree (as shown in FIG. **3**B), the zig-zag line **902** may be deformed to a straight line configuration **904**. The indicated indicia **900** may provide the surgeon with both a visual assessment (before the incision is closed) of the band tension, and a radiographic assessment (after the incision is closed) of the band tension, by simply forming the indicia from a suitable radio-opaque material of a color, contrast, density, or other image that contrasts with the color, contrast, density, or other image of the band **872**.

[0039] FIGS. **4**A and **4**B depict one of many possible alternatives to the shape of the indicia **900** shown in FIGS. **3**A and **3**B. With the band **872** in its relaxed orientation (FIG. **4**A) the modified indicia **900** may be shaped as two parallel, laterally spaced apart single straight lines **906** and **908**. When the band **872** is tensioned to a predetermined degree (as in FIG. **4**B), the lines **906**, **908** may laterally merge to form a single, thicker line **908**. As can be seen in FIGS. **3**B and **4**B, the indicia lines **904** and **906**,**908** therein each may provide the surgeon with a useful centerline marker which may be used to verify correct lateral centering alignment between the band and the patient's spine.

[0040] FIGS. **5**A-**14** illustrate various techniques for directly securing vertebral linking members, such as one or more of the previously described tension band members **872**, to first and second vertebral bodies, without using the previously described end cap members **882** and **884**, using a variety of simple mechanical fastening members extended through or forcibly contacting the vertebral linking members.

[0041] For example, as shown in FIGS. **5**A-**5**C, one or more staples **910** may be driven directly through the band ends **874**,**876** into the vertebral bodies **107**,**109** to operatively secure the tension band **872** to the vertebral bodies **107**,**109** in a manner such that the band **872** is, to some degree, held in a desired position and/or resiliently resists, inhibits and/or reduces further separation of the vertebral bodies from one another, and externally spans the intervertebral disc space S in a manner blocking at least in part, limiting, inhibiting or reducing the likelihood of dislodgement of the implant from space S and/or at least in part covers the implant or is in part attached to the implant. As illustrated, the lengths of the one or more staple bases may extend in a medial-lateral direction (FIG. **5**A), a cephald-caudal direction (FIG. **5**B), or in any direction between these two directions (FIG. **5**C). The staples **910** may be rigid, or their bases may be at least somewhat flexible, in order to control the degree of band retention forces provided by the installed staples.

[0042] As shown in FIG. **5**D, bone screws **912** may be extended directly through the opposite ends **854**, **876** of the tension band **872** and threaded into the vertebral bodies **107** and **109**, or, as shown in FIG. **5**E, the bone screws **912** may be extended through grommeted openings **914**, pre-formed in the band ends **874** and **876**, and threaded into the vertebral bodies **107**,**109**. The grommets **914** may be of a rigid material such as metal or plastic, or simply be stitched cloth hole reinforcing grommets. Alternatively, instead of grommets, the band may include formed, heated, cut, welded, reinforced, and/or otherwise created openings in the material for receiving a fastener or attaching compound or material of some shape or form.

[0043] Other techniques for utilizing mechanical fasteners to directly connect the tension band **872** (or other type of flexible vertebral linking member as the case may be) to vertebral bodies are shown in FIGS. **6**A-**14** and use what may be generally termed interference type fasteners—representatively either temperature-activated shape memory fasteners or radially expandable type mechanical fasteners.

[0044] Cross-sectionally illustrated in schematic form in FIGS. **6**A and **6**B is a shape-memory type interference pin **916** used to anchor an end **874** of a flexible vertebral linking member **870** (such as the previously described elastic tension band) to one of the vertebral bodies **107**. To achieve this anchoring, a tunnel **918** is first formed in the vertebral body **107**, and the linking member end **874** is suitably inserted into the tunnel **918**. Then, with the interference pin **916** at a temperature less than the patient's body temperature (and thus in a radially compressed configuration) the pin **916** is inserted into the tunnel **918**, so that the pin **916** is within the looped band end **844** (see FIG. **6**A), and allowed to warm up to the patient's body temperature, thereby radially jamming the looped band end **874** within the tunnel **918** as shown in FIG. **6**B.

[0045] FIGS. **7-14** depict various representative permutations of this interference fastener-based linking member-to-verterbra attachment technique. For example, in FIG. **7** opposite ends of a flexible vertebral linking member **872** are positioned within tunnels **918** formed within the vertebral bodies **107**,**109** and secured therein using threaded interference screws **920** of a shape-memory type, with the implant **101** between the vertebral bodies **107**,**109** being a fusion device implant. In FIG. **8**, fasteners **922** of the non-threaded shape memory type or mechanical fasteners with mechanical radial expansion capabilities such as, for example, gull anchors, are used to anchor the opposite ends of the linking member **872** in the vertebral tunnels **918**. Representatively, the implant **101** in this instance is an artificial disc. In FIG. **9** the flexible linking member **872** is generally band shaped, and has narrowed end portions **874**,**876** anchored in vertebral tunnels **918** by interference type fasteners **924**. In FIG. **10** the flexible linking member **872** is somewhat wider, and has corner end portions **926** thereof anchored in vertebral tunnels **918** by interference type fasteners **924** as previously described. FIGS. **11** and **12** respectively show parallel and crossed pairs of flexible vertebral linking members **876** secured to associated vertebral bodies using interference type fasteners **924**. FIG. **13** illustrates a flexible vertebral linking member **872** which is looped through a generally U-shaped tunnel **918** formed in the upper vertebral body **107**, and has its ends **874**,**876** secured within a pair of tunnels **918** in the lower vertebral body **109** by interference type fasteners **924**. FIG. **14** shows a flexible vertebral linking member **872** secured to a posterior side of vertebral bodies **107**,**109** using interference type fasteners **924**.

[0046] FIGS. **15-16**C illustrate a specially designed mechanical fastening structure for use in attaching the opposite ends **874**,**876** of the tension band **872** (or another type of vertebral linking member as the case may be) to the vertebral bodies **107**,**109**. In an exemplary form thereof, such structure includes a hollow, generally cylindrical locking body **930** having a circular base wall **932** with a central mounting hole **934** extending therethrough, and a spaced apart, facing circular outer wall **936** with a generally petal-shaped central opening **938** that overlies the mounting hole **934** and has a circumferentially spaced one or more inwardly projecting, resiliently deflectable lobe portions **939**. To ready the locking body **930** for use, its base wall **932** is suitable secured to the outer side of the flexible tension band **872**, as by a sonic welding or other securement process, so that the central mounting hole **934** overlies a corresponding mounting hole **934***a* formed in the tension band **872**.

[0047] The fastening structure may also comprise, for example, a bone screw **942** having a tapered head portion **944** on which an annular outer end ledge **945** is defined. To use the fastening structure to, for example, secure a tension band end to the vertebral body **107**, the tension band end is placed over the desired mounting location on the vertebral body **107** (see FIG. **16**A), and the threaded body portion **946** of the bone screw **942** is sequentially extended through the locking structure openings **938**, **934**, and the linking member opening **934**a, and then threaded into the vertebral body **107**.

[0048] As the tapered screw head **944** passes into the interior of the locking body **930**, it inwardly deflects the one or more lobes **940** (see FIG. **16**B), and then inwardly passes them, permitting them to snap back to their undeflected positions in which they overlie the annular screw head ledge **945**, thereby forming a barrier relative to this portion of the screw which blocks the screw **942** from backing out of the vertebral body **107**. It is to be understood, of course, that a plurality of fastening structures as just described can be used at each end of the linking member to be attached to the representatively illustrated vertebral bodies **107**,**109**.

[0049] A variety of anti-rotation structures may be utilized at the screw-cap interface, such as an elevated ramp or a flexible finger, to prevent loosening rotation of the installed screw **942** which could cause it to back out and lift the entire end cap off. This anti-rotation structure could also comprise one or more interfering structures on the cap and the screw head, plate, cap or a wire extending across at least a portion of the opening **938** and/or fastener or attachment compound or mechanism and functioning to retain the screw (or other fastener) head **944** in place.

[0050] Certain types of anti-rotation structures or anti-backing-out locking members are disclosed in copending U.S. application Ser. No. 11/863,969, which is hereby incorporated herein by reference in its entirety. FIG. **16**D shows a schematic view of an anti-rotation structure **40** that can be used with the present invention. Specifically, FIG. **16**D shows an embodiment of an end cap **882** with one connection hole **30** for attachment to a vertebra. The anti-rotation structure or locking member **40** may be press fit into guide holes **14**. Note that the size of the guide hole **14** may be slightly smaller than the locking member **40**. This sizing allows for the locking member **40** to be forced into the guide hole **14** and form a secure attachment. In addition, the ends **48** of the locking member **40** may protrude out of the guide holes **14** so long as the locking member **40** is securely attached to the end cap **882**. In the embodiment shown in FIG. **16**D, once the locking member **40** is placed within the guide holes **14**, the length of the locking member **40** prevents inadvertent removal of the locking member **40** and forms a secure attachment. Locking member **40** also may be attached to the end cap **882** by another arrangement of guide holes **40**, a single guide hole **40**, or for example, by a another fastener or adhesive.

[0051] Once the end cap **882** is positioned, a mechanical fastener such as a screw (not shown in FIG. **16**D) is inserted into the connection hole **30**. During insertion, the locking member **40** can yield in a direction away from a center of the connection hole **30** to allow for insertion of the mechanical fastener. After a head of the mechanical fastener passes beyond the locking member **40**, the resilient locking member **40** rebounds towards its original position, for example, as shown in FIG. **16**D. The locking member **40** extends over the head of the mechanical fastener, thus preventing the mechanical fastener from backing out of the bone and away from the end cap **882**. In one embodiment, the section of the locking member **40** that extends across the connection hole **30** is substantially straight prior to insertion of the mechanical fastener and after the fastener moves beyond the locking member **40**, whereas in another embodiment, the locking member **40** may have a curved shape to accommodate the geometries of the end cap **882** or other needs. The locking member **40** may be made of resilient material such as NiTi. An added benefit of utilizing such a locking member **40** is that it can be used as a visual aid, for example, to let the surgeon know that the screw is in far enough. When such a locking member **40** is made of NiTi or other radiopaque material, is also can be used as a visual aid for location of the band assembly **870**.

[0052] Other types of fasteners used to operatively connect a linking member between two vertebral bodies may include hybrid screws as illustrated and described in copending U.S. application Ser. No. 12/423,951, which is hereby incorporated herein by reference in its entirety. These screws are potentially hybrid screws that may, for example, include a sharp extended or elongated tip and that may, for example, be more easily tapped or tacked in and then may be screwed in place. Other types of fasteners could include pins, tacks, staples, or staples with hook ends or other features to keep the staple in the bone or enhance the retention of the fastener in the bone to which it is attached. These fasteners could be resorbable or absorbable and could be made of bone, tissue, plastic, hydrosorb, or a suitable metal material and may be coated with an adhesive, cement, rHBMP, or other material to assist and/or enhance retention of the fastener in or on the bone.

[0053] Shown in FIGS. **17-19** is a caspar pin-based system for operatively connecting a linking member between the two representatively illustrative vertebral bodies **107** and **109**. With initial reference to FIG. **17**, the system includes a pair of hollow bone screw members **950**, each having a passage **952** extending longitudinally inwardly through its head portion **954**. The system also includes a pair of elongated guide members **956**, representatively, for example, caspar posts. To ready the vertebral bodies **107,109** for operative insertion therebetween of the implant **101** (illustratively a bone graft implant), the screws **950** are threaded into the vertebral bodies **107** and **109** as shown in FIG. **17**, and the guide members **956** are removably inserted into the screw passages **952**. With the guide members **956** operatively inserted into the screw interiors, upper longitudinal portions of the guide members **956** extend upwardly beyond the screw heads **954**.

[0054] Next, a conventional ratcheting device (of the type used in caspar post procedures and not illustrated herein) may be used to transversely force the removable guide members **956** away from one another to thereby increase the separation distance between the vertebral bodies **107,109** to an extent permitting the implant **101** to operatively be inserted between the separated vertebral bodies **107,109**. The ratcheting device is then removed, with the inserted implant **101** now holding the vertebral bodies in their separated orientation shown in FIG. **17**.

[0055] Next, as shown in FIG. **18**, the upper ends of the guide members **956** are extended through end holes **958** in the vertebral linking member **872** which, in this exemplary embodiment of the present invention, is a rigid anterior cervical plate but could alternatively be a flexible linking member such as the flexible (which may, for example be elastic and/or woven fabric and/or tissue, metal or some combination thereof) tension band member previously described herein. The linking member **872** is then slid downwardly along the guide members **956** until the linking member's ends reach the screw heads **954**. Then, as depicted in FIG. **19**, the guide members **956** are pulled out of the hollow bone screws **950** (which are left in place in the vertebral bodies **107,109**). Finally, the linking member **872** is anchored in place by securing suitable locking caps **960** to the screw heads **954**. Alternatively, a mechanism may be provided which removes the guide members **956** and installs the locking caps **960** simultaneously. Examples of types of mechanisms which may be employed to perform variations of these techniques or steps such as, for example, inserting, guiding and/or removing or moving various elements and/or implants may be found in U.S. Pat. Nos. 7,008,422 and 6,235,028, each of which are hereby incorporated herein by reference in their entirety.

[0056] FIG. **20** illustrates an alternate embodiment of the previously described vertebral linking assembly **870** in which an embodiment of a tension band **872** is in a looped configuration, passing through slots **962** in end caps **964**, **966** securable to the representative vertebral bodies **107**, **109** using bone screws **968** (or other suitable fasteners or other attaching, adhering or connecting techniques and/or combination of elements) extending through mounting holes in the end caps **964**, **966** and threaded into the vertebral bodies **107,109**. Compared to passing discrete mechanical fasteners through the tension band **872**, the use of these slots greatly reduces undesirable stress concentrations on the tension band **872**. Another benefit of using the looped design and slots **962** of FIG. **20** is that it can approximately double the flexibility of the band **872** over the same distance, i.e., length. Advantageously, however, it is helpful for the overall effectiveness and implantation of such a design of the band assembly **870** if each slot **962** is approximately the same width or as close as possible as the width of the band **872**. Another technique for reducing such stress concentrations is shown in FIG. **20**A in which the end caps **964**, **966** (only end cap **964** being shown in FIG. **20**A) are each provided with a spaced series of stitch holes **970** therein through which a stitch line **972** may be extended into an underlying end (for example, end **874**) of the tension band **872**.

[0057] According to yet another aspect of an embodiment of the present invention, the exemplary woven, knitted or braided cloth or polymer and/or elastic and/or flexible tension band embodiment of the vertebral linking member **872** may be constructed and/or treated to provide the installed linking member with beneficial post-operative attributes.

[0058] For example, with initial reference to FIGS. **21** and **22**, the weave of a woven embodiment of band **872** could be adjusted (for example, to a more porous weave), or a treatment **974** could be added to the inner side **878** of the band **872**, to promote bony incorporation into the band from the vertebral bodies **107,109**. Examples of such surface treatment may include Hydroxyappetite ("HA") substances, allografts, biologics, etc. The treatment could potentially expedite healing and add stability to the construct. Additionally, as shown in FIG. **22**A, the weave of the band **872** could be adjusted, or a treatment **978** could be added to the outer side **880** of the band **872**, to reduce tissue adhesion to the outer side of the band. Such surface treatment or weave adjustment could include known adhesion prevention geometries, barriers, or biologic or non-biologic additives. This feature could potentially reduce the complications associated with soft tissue adhesions such as dyspahgia, vascular adhesions complicating lumbar revisions, etc. Treatments **974,978** could, for example, be rHBMP of various varieties, e.g., BMP2 or BMP 11 or 13—artificial ligaments and/or bone proteins and growth factors. Sponges, bladders, pockets, matrices, substrates, or other materials or capsules or compositions (such as a combination of calcium phosphate and Hyaluronic acid) could be incorporated into the weave to help hold, receive, and/or release the surface treatment. Steroidal treatments or anti-steroidals, antibiotics, pain relievers, medicament, anesthetic, muscle relaxants, tumor necrosis factors, anti-inflammatory, adhesion retardant and hypoallergy treatments may also be utilized.

[0059] Finally, as depicted in FIG. **22**B, the band **872** which may, for example, be made of a fabric, could be formed from a material adapted to be soaked in a therapeutic substance **978** and then allow for a controlled elution of the substance over time. For example, the eluted substance could be antibacterial, steroidal, anti-inflammatory, pain medication or an anti-scarring substance. The use of this therapeutic elution technique could potentially reduce the incidence of infection and tissue swelling. The slow release of a drug from the band material may be effected using a polymer, embedded capsule, or a wafer. Pockets or bladders can be affixed or sewn on the band material. Further, this drug-eluting technique may comprise both absorbing or adsorbing characteristics. Examples of drugs that may be utilized include Ancef, Vancomycen, and various pain medicines. One specific example is 40 mg. of Depromedrol.

[0060] U.S. Pat. No. 7,055,237, which is hereby incorporated herein by reference in its entirety, provides information on how drug eluting capabilities can be applied. For example, a coating (not shown) on the fabric band **872** can be used for a number of purposes, including, but not limited to, a diffusion barrier to control the elution rate of a therapeutic agent from the band **872**.

[0061] The band **872** may comprise one or more therapeutic agents dispersed within or encased by a polymeric coating (not shown), which are eluted from band **872** with controlled time delivery after installation of the band **872** within a body. As described, a therapeutic agent is capable of producing a beneficial effect against any number of adverse conditions, e.g., inflammation or pain. The elution rates of the therapeutic agents into the body and the tissue surrounding the band **872** are based on the constituency and thickness of how much coating is deposited or incorporated into the band **872**, the nature and concentration of the therapeutic agents, the thickness and composition of the particular agent, and other factors.

[0062] The coating used to help or control the elution of the agent can be a polymer including, but not limited to, urethane, polyester, epoxy, polycaprolactone (PCL), polymethylmethacrylate (PMMA), PEVA, PBMA, PHEMA, PEVAc, PVAc, Poly N-Vinyl pyrrolidone, Poly (ethylene-vinyl alcohol), combinations of the above, and the like. Suitable solvents that can be used to form a liquid coating include, but are not limited to, acetone, ethyl acetate, tetrahydrofuran (THF), chloroform, N-methylpyrrolidone (NMP), combinations of the above, and the like.

[0063] A coating and the above examples are merely exemplary, and it should be recognized that coating configurations other than a basic coating, such as multiple coating layers, are possible. In addition, the coating may cover a portion of the band **872** or the whole band **872**.

[0064] The different coatings can be made of the same material or different materials, and can contain the same therapeutic agents or different therapeutic agents. Coatings can be applied as a liquid polymer/solvent matrix. A liquid coating can be applied to the band **872** by pad printing, inkjet printing, rolling, painting, spraying, micro-spraying, dipping, wiping, electrostatic deposition, vapor deposition, epitaxial growth, combinations thereof, and other methods as will be appreciated by those skilled in the art.

[0065] Initial tensioning of a band member may be achieved using a suitable instrument which may attach to the end caps and could, for example, stretch the band member to a certain or desired tension. Such instrument could include, for example, a reverse pliers (to enable squeezing a handle to expand the ends that might attach to or grip the ends of the band) or combination pliers, retractor, and /or distractor or, for example include an instrument with moving tubes or guide rods such as disclosed in U.S. Pat. No. 7,008,422. The band member may also be tensioned by hand, with the surgeon tacking one end into place and then longitudinally stretching the band member to achieve proper tension before securing its other end to the patient. The band member may illustratively be 14 mm wide to achieve graft containment, and have a suitable length to accommodate patient anatomy. The material of the band member may illustratively be a polyester knit which stretches to that the original band member length increases 30% at 30 Newtons, and reaches failure at about 127 lbs. (approximately 58 Newtons) or at 78% stretch, i.e., when it has increased in length 78%.

[0066] FIG. **23** illustrates an embodiment of a "multilevel" previously described vertebral linking assembly **870** in which the tension band **872** is in a looped configuration, passing through slots **962** in end caps **964**, **966** securable to the representative vertebral bodies V_1 and V_3, between which vertebral body V_2 is disposed, using bone screws **968** extending through mounting holes in the end caps **964**,**966** and threaded into the vertebral bodies V_1 and V_3. As can be seen, the tension band **872**, which may be represented by an elastically deformable fabric construction, longitudinally spans the vertebral body V_2, as well as spanning a plurality of intervertebral spaces, namely the intervertebral space S_1 disposed between the vertebral bodies V_1 and V_2, and the intervertebral space S_2 disposed between the vertebral bodies V_2 and V_3. Although the band **872** is illustratively depicted as having a looped configuration, it could alternatively be of a non-looped, single layer construction. Additionally, it could be connected to the end caps **964**,**966** by a variety of different manners previously described herein.

[0067] The illustratively looped tension band **872** may have opposing inner and outer side layers **872***a* and **872***b* through vertically intermediate portions of which aligned vertically extending slots **962** are formed, such slots combinatively defining a vertically elongated slot **980** extending through the tension band **872**. A vertically intermediate portion of the tension band **872** may be secured to the vertebral body V_2 by means of a bone screw **982** threaded into the vertebral body V_2 or by other fasteners such as a tack, pin, staple, or other attaching structures such as a suture, preformed seal, adhesive, mold, or other connection feature or combination of features. Bone screw **982** extends through a grommet **984** that overlies the outer band layer **872***b*, thereby clamping a vertically intermediate portion of the band **872** to the vertebral body V_2. The presence of the slot **980** facilitates the attachment of the band **872** to the three vertebral bodies by permitting the bone screw **982** and the associated grommet **984** to be easily shifted in a vertical direction relative to the band (already secured at its opposite ends to the vertebral bodies V_1 and V_2), before being secured to the vertebral body V_2, thereby compensating for differences in the heights of the intervertebral spaces S_1 and S_2.

[0068] For multiple, consecutive levels of vertebrae as described in FIG. **23**, other embodiments may not need the slot **980**. For example, one may connect multiple tension bands **872** in series, or end to end, to cover more than one level of vertebrae. A schematic view of an example of such embodiment is provided in FIG. **24**, where a multilevel tension band assembly **870**A, which here covers two levels, spanning vertebrae **107**, **108** and **109**, comprises three end caps **882**A, **883**A, **884**A and two bands **872**C, **872**D. Also, the tension band assembly **870**A shown in FIG. **24** contains implants **101**A and **103**A. The looped version of band **872** may still be utilized in the embodiment of FIG. **24**, e.g., with looped bands **872**C, **872**D.

[0069] In addition to that described above, patients that have a single or multiple level plate for fixation of vertebrae, for example, can have a tension band **872**E added to one end of the existing plate. FIG. **25** schematically illustrates such an embodiment. One benefit of this, as opposed to removing the existing plate **200** and "starting from scratch" is, for example, the ability to address a problem in the spine, inferior or superior to the existing plate on an adjacent level. On such an "add-on" band **872**E, another beneficial feature is that an end **202** of the existing plate **200** and the end cap **884**A of the bands **872**E align so that, for example, the same screw(s) or faster(s) may be used to affix both respective ends of the existing plate **200** and the band **872**E by using holes **890**A and **892**A. Further, instead of a plate **200**, the band assembly **870** of the present invention may be used on a level of vertebrae adjacent an artificial disc or other motion-preserving device (not shown). Similar to that shown in FIG. **25**, in such an embodiment, the holes **890**A and **892**A of band **872**E may align with affixation holes of the adjacent artificial disc or they may not.

[0070] Another benefit of the present invention is that the when placed on an anterior section of vertebral endplates, band **872** allows for a surgeon to stabilize that anterior portion of spine and subsequently, perform some work on the posterior side at or near the same section of vertebrae just stabilized. The flexibility of the band **872** will, for example, allow for a surgeon to work posteriorly with some degree of flexibility, while knowing that there is some degree of stabilization on the anterior side. Also, the band **872** allows a surgeon to turn a patient over, i.e., from the patient being on their backside (while working anteriorly) onto the patient's stomach with greater confidence than if the anterior portion was not stabilized prior to such a maneuver.

[0071] FIG. **26** shows a perspective schematic view of a holding device **300** for holding and inserting the band assembly **870** into position in the body, while FIG. **27**A shows another perspective schematic view of another embodiment of such a device **300**A. One way that the device **300** can be used is that after a band **872** is stretched to its desired tension, the top and bottom faces **302** of the holder **300** are positioned against the interior surfaces of the end caps **964**, **966** of the band assembly **870**, as shown in a front schematic view of FIG. **27**B with respect to holder **300**A. Holder **300**A is used in the same manner, but also has distinct sides **304**. After holder **300**A is in position on a pre-tensioned band assembly **870** and attached or implanted in the proper location on the spine, for example, the sides **304** can be moved toward each other. This movement of the sides **304** toward each other will slightly reduce the length of the holder **300**A, thereby releasing it from the tension band assembly **870** by removing the tension caused by the holder **300**A itself. In the embodiment of **300**A, holes **306** are provided on the sides **304** to facilitate the desired movement of the sides **304** toward each other, for example, with an instrument or instruments that can be inserted into holes **306**. These holes **306** also will help with the act of holding and inserting of the band assembly **870**.

[0072] Note that if a holder similar to holder **300** is used, hole **310** can be used to align the band assembly **870** with a spacer or graft over which the band **872** will be placed, e.g., if the spacer already has a corresponding hole in its center. For this purpose, hole **310** may alternatively be a relatively large hole or window for better visualization. In this way, the holder **300** can be used as an aid for proper placement of the assembly **870**. Also, hole **310** also can help with the act of holding and inserting of the band assembly **870** with the aid of an appropriate instrument.

[0073] FIG. **28**A shows an perspective schematic view of another embodiment of a holding device **300**B, while FIG. **28**B shows a cut-away schematic view of the embodiment of an end cap **964**B of an embodiment of a tension band assembly **870** that works in cooperation with holder **300**B. Holder **300**B is used for the same purpose and similar manner as holder **300**, but instead of the top and bottom faces **302** abutting the interior surfaces of the end caps **964**, **966**, holder **300**B has four legs or posts **320** that cooperate with two holes **322** in each of the corresponding end caps of the band assembly **870**. After the desired tension is achieved on band **872**, posts **320** are positioned in each of holes **322** (two of which are shown in end cap **964**B of FIG. **28**B) to hold the band **872** in position. As with holder **300**, holder **300**B may have a window **340** or hole **342** in the plate that can be used as a visual indicator, e.g., used to align the band assembly **870** with a spacer or graft over which the band **872** will be placed, e.g., if the spacer already has a corresponding hole in its center. Further, holder **300**B may have cut-outs **332** to provide ample space for a screw or fastener to be placed in connection hole **330** for attachment to a vertebra.

[0074] With respect to holders **300** and **300**B, respectively, holes **310** and **342** may alternatively be replaced with a central post extending in the same direction as posts **320**. In this way, the central post **310** or **342** may be used as an aid for proper placement of the assembly **870** by, e.g., using it to align with a spacer or graft over which the band **872** will be placed, e.g., if the spacer already has a corresponding hole in its center. Such an embodiment will advantageously have a corresponding hole in the band **872** at the location of the post **310** or **342**. In addition, such a hole in the band **872** can be used to affix the band to the spacer or graft. Such a combination of a band **872** with a spacer or graft can be pre-assembled.

[0075] With the embodiments of holders **300**, **300**A, **300**B, a band **872** of a band assembly **870** can be pre-tensioned and held in place with one of the holders at the latter stages of manufacturing so that the combination can be provided to a surgeon already pre-tensioned with the holder **300**, **300**A, **300**B. Also, the holder **300**, **300**A, **300**B can be color-coded to correspond to various sizes or tensions of bands **872** or band assemblies **870**. Suitable materials for the holders **300**, **300**A, **300**B can include, but not limited to, various metals, various polymers, and specific materials such as Celcon® and Delrin®.

[0076] When affixing an end cap **964**, **882**, **884** of the present invention in place on a vertebra or other location with, e.g., a screw, one challenge is preventing the end cap **964**, **882**, **884** from rotating. It is desirable to keep the end cap **964**, **882**, **884** in place so that the band **872** is in proper alignment and placement. One way to prevent this is by utilizing small protrusions such as spikes, teeth or pins on the underside of the end cap **964**, **882**, **884** so that it grabs into the surface of the vertebra. In addition to such anti-rotation devices, a guide may be used to hold the end cap **964**, **882**, **884** in place while inserting a screw through the end cap **964**, **882**, **884**. FIG. **29** shows a schematic perspective view of an anti-rotation device **400** that can be used to address the problem of a rotating end cap **964**, **882**, **884** or assembly **870**. As shown in FIG. **29**, the anti-rotation device **400** comprises a proximal end **402**, a hollow shaft **410** and a distal end **404** that has two feet **406** that extend away from the proximal end **402**. FIG. **29**A shows a cut-away, enlarged cross-sectional schematic view of the distal end of the anti-rotation device **400**. In use, the proximal end **402** is designed to be hand-held by a user and the feet **406** are designed to cooperate with and be placed inside, e.g., holes **322** in an end cap **964**B. When this occurs, the end cap **964** B is held in place by the user, and a screw driver **450** or other instrument for securing a fastener is inserted through a hole **408** in the anti-rotation device **400**, thereby securing the end cap **964**B to the vertebra in its desired position. The holes **322** may be in vertical alignment with connection hole **330**, or may be offset, as shown, by example, in FIG. **28**B. If offset, then the corresponding feet **406** on anti-rotation device **400** should be offset by the same amount, so that the feet **406**, holes **322** and connection hole **330** all cooperate for proper functioning of the anti-rotation device **400**.

[0077] All references cited herein are indicative of the level of skill in the art and are hereby incorporated by reference in their entirety.

[0078] The foregoing detailed description is to be clearly understood as being given by way of illustration and example only, the spirit and scope of the present invention being determined solely by the appended claims. For example, the band **872** or band assembly of the present invention in cooperation with anterior faces of vertebrae can alternatively be attached to other surfaces of vertebrae, e.g., lateral faces or lamina, or other parts of the body or spine, such as, e.g., facets, pedicles, pars, transverse processes or spinous processes. Note also while the present invention may be used in both any portion of the spine, including cervical and lumbar areas, when used in the lumbar region it may be advantageous to utilize a band **872** with greater stiffness than that utilized in the cervical section.

What is claimed is:

1. A device for linking first and second vertebral bodies having an implant therebetween, comprising:

a flexible member having first and second ends and being formed from a flexible material, said flexible member having a surface on which indicia is disposed for a visual and/or radiographic assessment of the tension in the flexible member; and

connector apparatus for securing the first and second ends of the flexible member to at least one of the first and second vertebral bodies.

2. The device of claim **1** wherein:

said flexible member is shaped in a loop.

3. The device of claim **2** wherein:

the surface on which indicia is disposed is a side surface of the tension member.

4. The device of claim **1** wherein:

said flexible member comprises a woven, knitted or braided fabric material.

5. The device of claim **1** wherein:

said flexible member comprises a treatment on at least a portion of the flexible member, said treatment adapted to promote bony integration between the flexible member and the first and second vertebral bodies to which it is connected.

6. The device of claim **1** wherein:

said flexible member comprises a treatment on at least a portion of the flexible member, said treatment adapted to reduce post-operative soft tissue adhesion to the flexible member.

7. The device of claim **1** wherein:

said flexible member comprises a therapeutic substance, and said flexible member further adapted to elute the therapeutic substance, over time, to a surgical site.

8. The device of claim **1** wherein the connector apparatus comprises:

first and second end caps, respectively secured to the first and second ends of the flexible member, said end caps comprising at least one opening formed therein through which fastening members may be extended to operatively secure the device to the first and second vertebral bodies.

9. The device of claim **1** wherein the connector apparatus comprises:

a plurality of mechanical fasteners extendable through the flexible member into at least one of the first and second vertebral bodies.

10. The device of claim **9** wherein:

the plurality of mechanical fasteners are selected from the group consisting of staples, screws, pins, tacks, expandable members and fasteners formed from a shape memory material.

11. The device of claim **1** wherein:

tunnels extend into at least one of the first and second vertebral bodies,

portions of the flexible member are positionable in the tunnels, and

the connector apparatus comprises a plurality of fastening members, formed from shape memory material or having radially expandable structures, positionable within the tunnels to bear against the flexible member portions and captively retain them in the tunnels.

12. The device of claim **1** wherein the connector apparatus comprises:

a plurality of connector structures, connectable to the first and second ends of the flexible member, for securing the first and second ends of the flexible member to at least one of the first and second vertebral to provide an obstacle at least in part to the dislodgement of the implant from between them, and adapted to apply tension to the vertebral bodies, each of the connector structures comprising:

a hollow locking structure with a base wall having an opening therein and being securable to one of the first and second ends of the flexible member, and an outer wall spaced apart from and parallel to the base wall, the outer wall having an opening therein which opposes the base wall opening and is partially bounded by one or more resiliently deflectable lobe portions of the outer wall, and

a screw member extendable sequentially through the outer wall opening, the base wall opening and the one of the first and second ends of the flexible member, and threadable into one of the first and second vertebral bodies, the screw member further having a transversely enlarged head portion configured to resiliently deflect the one or more lobe portions, as the screw member passes through the interior of the hollow locking structure, and then permit the one or more deflected lobe portions to snap back to their undeflected positions in which they block outward passage of the head portion through the outer wall opening.

13. A device for linking first and second vertebral bodies having an implant therebetween, comprising:

a linking member having first and second ends; and

a plurality of connector structures, each connectable to one of the first and second ends of the linking member, for securing the first and second ends of the linking member to at least one of the first and second vertebral bodies and adapted to provide an obstacle to the dislodgement of the implant from between them, wherein:

each of the first and second ends of the linking member comprising a mounting hole extending therethrough, and

the plurality of connector structures comprise:

first and second screw members each having a head portion through which an opening extends axially inwardly, the first and second screw members being respectively threadable into the first and second vertebral bodies,

first and second elongated guide members, each configured to be respectively and removably inserted into the openings in the first and second screw members, after the screw members are threaded into their associated vertebral bodies, and to thereafter have longitudinal portions projecting outwardly from the first and second screw members, the longitudinal portions of the guide members being movable away from one another upon application of a separation force thereon to increase the separation distance between the first and second vertebral bodies, and configured such that outwardly projecting portions extend through the mounting holes of the linking member, and

first and second locking members constructed and operative to respectively lock the first and second linking member ends to the head portions of the first and second screw members after the first and second elongated guide members are respectively removed from the first and second screw member openings.

14. The device of claim **13** wherein:

the linking member is constructed from a flexible material.

15. The device of claim **14** wherein:

the linking member is an elastic tension band.

16. The device of claim **13** wherein:

the linking member is a rigid member.

17. Apparatus for linking first and second vertebral bodies having a third vertebral body disposed therebetween, comprising:

a flexible structure having first and second ends, and an elongated slot extending through a longitudinally intermediate portion of the flexible structure and longitudinally extending parallel to the length of the flexible structure;

first connection structure for respectively securing the first and second ends of the flexible structure to the first and second vertebral bodies; and

second connection structure, extendable through the slot through a selectively variable longitudinal portion thereof and securable to the third vertebral body.

18. The apparatus of claim **17** wherein:

said flexible structure comprises an elastic material.

19. The apparatus of claim **17** wherein:

said flexible structure comprises approximately a looped configuration, and the first connection structure comprises first and second end caps having slots therein through which the first and second end portions of the flexible structure respectively extend, and openings through which fasteners may be extended and positioned into the first and second vertebral bodies.

20. The apparatus of claim **17** wherein:

the second connection structure comprises a grommet configured to outwardly overlie the flexible structure at a portion of the slot, and a screw extendable through the grommet and threadable into the third vertebral body.

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