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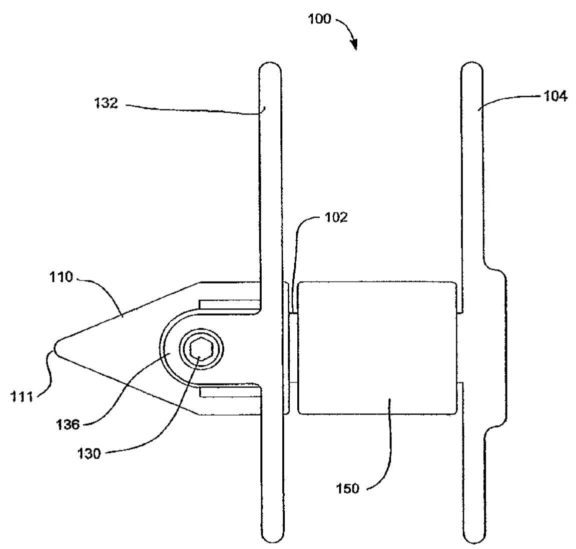
(54) **Title:** BIORESORBABLE INTERSPINOUS PROCESS IMPLANT FOR USE WITH INTERVERTEBRAL DISK REMEDIATION OR REPLACEMENT IMPLANTS AND PROCEDURES



(57) **Abstract:** A device for implantation between interspinous processes made of bioresorbable materials is described. The implant has a spacer that can be placed between adjacent spinous processes to limit the movement of the vertebrae. Once inserted between interspinous processes, the implant acts to limit extension (backward bending) of the spine without inhibiting the flexion (forward bending) of the spinal column. The device is used as an adjunct to repair or regeneration of an intervertebral disk.

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BIORESORBABLE INTERSPINOUS PROCESS IMPLANT FOR USE WITH INTERVERTEBRAL DISK REMEDIATION OR REPLACEMENT IMPLANTS AND PROCEDURES

CLAIM OF PRIORITY

U.S. Provisional Patent Application No. 60/526,353 entitled BIORESORBABLE INTERSPINOUS PROCESS IMPLANT FOR USE WITH INTERVERTEBRAL DISK REMEDIATION OR REPLACEMENT IMPLANTS AND PROCEDURES, by James F. Zucherman *et al.*, filed December 2, 2003 (Attorney Docket No. KLYCD-01082US1);

U.S. Patent Application No. 10/995,626 entitled BIORESORBABLE INTERSPINOUS PROCESS IMPLANT FOR USE WITH INTERVERTEBRAL DISK REMEDIATION OR REPLACEMENT IMPLANTS AND PROCEDURES, by James F. Zucherman *et al.*, filed November 23, 2004 (Attorney Docket No. KLYCD-01082US3);

U.S. Provisional Patent Application No. 60/526,215 entitled METHOD FOR REMEDIATION OF INTERVERTEBRAL DISKS, by James F. Zucherman *et al.*, filed December 2, 2003 (Attorney Docket No. KLYCD-01082US0);

U.S. Patent Application No. 10/996,996 entitled METHOD FOR REMEDIATION OF INTERVERTEBRAL DISKS, by James F. Zucherman *et al*, filed November 23, 2004 (Attorney Docket No. KLYCD-01082US2).

BACKGROUND

This field of art of this disclosure is an interspinous process implant.

The spinal column is a biomechanical structure composed primarily of ligaments, muscles, vertebrae and intervertebral disks. The biomechanical functions of the spine include: (1) support of the body, which involves the transfer of the weight and the bending movements of the head, trunk and arms to the pelvis and legs, (2) complex physiological motion between these parts, and (3) protection of the spinal cord and the nerve roots.

As the present society ages, it is anticipated that there will be an increase in adverse spinal conditions which are characteristic of older people. By way of example, with aging comes an increase in spinal stenosis (including, but not limited to, central canal and lateral stenosis), and facet anthropathy. Spinal stenosis typically results from the thickening of the bones that make up the spinal column and is characterized by a reduction in the available space for the passage of blood vessels and nerves. Pain associated with such stenosis can be relieved by medication and/or surgery.

In addition, to spinal stenosis, and facet anthropathy, the incidence of damage to the intervertebral disks due to injury or degeneration is also common. The primary purpose of the intervertebral disk is as a shock absorber. The disk is constructed of an inner gel-like structure, the nucleus pulposus (the nucleus), and an outer rigid structure comprised of collagen fibers, the annulus fibrosus (the annulus). At birth, the disk is 80% water, and then gradually diminishes, becoming stiff. With age, disks may degenerate, and bulge, thin, herniate, or ossify. Additionally, damage to disks may occur as a result spinal cord trauma or injury.

Given an increasing need, there is increasing attention currently focused on devices and methods for remediation of conditions of the spine. Remediation includes replacement or repair, or both of an affected part or parts of the spine, as will be discussed in more detail subsequently. Regarding the evolution of remediation of damage to intervertebral disks, rigid fixation procedures resulting in fusion are still the most commonly performed, though trends suggest a move away from such procedures. Currently, areas evolving to address the shortcomings of fusion for remediation of disk damage include technologies and procedures that preserve or repair the annulus, that replace or repair the nucleus, and that utilize technology advancement on devices for total disk replacement. The trend away from fusion is driven by both issues concerning the quality of life for those suffering from damaged intervertebral disks, as well as responsible health care management. These issues drive the desire for procedures that are minimally invasive, can be tolerated by patients of all ages, especially seniors, and can be performed preferably on an out patient basis.

Accordingly, there is a need in the art for innovation in technologies and methods that advance the art in the area of minimally invasive intervertebral disk remediation, thereby enhancing the quality of life for those suffering from the condition, as well as responding to the current needs of health care management.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGS. 1A-1F. **FIG. 1A** is a front plan view of an embodiment of an assembled the disclosed device; **FIG. 1B** is a left side view of what is shown in **FIG. 1A**, and **FIG. 1C** is a front plan view of **FIG. 1A** including a distraction guide, spacer, a central body and a first wing; **FIG. 1D** is a left side view of the second wing of **FIG. 1A**; **FIG. 1E** is a front plan view of the second wing of **FIG. 1A**; **FIG. 1F** is an end view of the spacer of **FIG. 1A**.

FIGS. 2 is a front plan view of a second embodiment of the disclosed device, including an end piece, a spacer, and a distraction guide.

FIG. 3 is a front plan view of a third embodiment of the disclosed device, which is an implant system including an insertion tool comprised of a distraction guide, a central body, a stop and a handle, with a spacer around the central body.

FIG. 4A and **4B** depict the use of the embodiment of **FIG. 1A** for distraction between vertebrae.

FIG. 5 depicts a further embodiment of the apparatus of the invention based on the embodiment in **FIG. 2**.

FIG. 6 depicts a further embodiment of the appratus of the invention based on the embodiment in **FIG. 1C.**

FIG. 7 depicts a further embodiment of the apparatus of the invention based on the embodiment in **FIG. 1A**.

FIG. 8 depicts an embodiment of the method of the present invention.

DETAILED DESCRIPTION

What is disclosed herein is a device that limits spinal extension without limiting spinal flexion. More specifically, the embodiments of the device disclosed herein act to limit extension (backward bending) of the spine without inhibiting the flexion (forward bending) of the spinal column.

The disclosed device is made in part or entirely from bioresorbable materials. The device is used to distract the spinous processes of adjacent vertebrae in order to increase the volume of the spinal canal, and concomitantly relieve intervertebral load. In this regard, the bioresorbable device may be used in procedures where temporary increase in spinal canal volume and relief of intervertebral load is indicated for remediation of an adverse spinal cord condition. Such distraction as a part of surgical remediation of spinal disorders may be performed either before or after the remediation procedure is performed. Remediation includes replacement or repair, or both of an affected part or parts of the spine. For example, remediation of the intervertebral disk may include either disk replacement or disk repair, as well as repair of one part of the disk; the annulus for example, and replacement of another; the nucleus for example. One feature of a bioresorbable device is that it does not require an additional surgery for removal after temporary use.

A bioresorbable material is a material that is broken down by natural processes, and removed thereby. Classes of materials that are useful as bioresorbable materials include polymers, ceramics, and glasses. Polymers of interest include polyesters, polyether esters, polycarbonates, polysaccharides, polyanhydrides, polyurethanes, and polyamide, including copolymers, composites, and blends thereof, as well as composites and blends with ceramics, glasses, and graphite, and the like. A copolymer is a polymer derived from more than one species of monomer. A polymer composite is a heterogeneous combination of two or more materials, wherein the constituents are not miscible, and therefore exhibit an interface between one another. A polymer blend is a macroscopically homogeneous mixture of two or more different species of polymer, the constituents of which are in principle separable by physical means. Fillers, which are solid extenders, may be added to a polymer, copolymer, polymer blend, or polymer composite. Fillers are added to modify properties, such as mechanical, optical, and thermal properties. For bioresorbable materials, it may be desirable to add a filler that would reinforce the material mechanically to enhance strength for certain uses, such as load bearing devices. Bioresorbable ceramics, glasses, and graphite are examples of classes of materials that are desirable for use as fillers to enhance polymer material strength. It may be desirable to add reinforcement elements to a bioresorbable polymer matrix that have the same chemical composition as the polymer matrix. In this instance, the material is referred to as self-reinforced ("SR").

Polyesters are a diverse class of polymers with a number of bioresorbable materials of interest. Poly ether esters are a closely related group, and due to the ester functionality, share many of the same properties of members of the polyester class. Since esters are a condensation polymer, they are easily degraded by hydrolytic processes. Moreover, the materials of interest are also biocompatible materials, meaning that they cause no untoward effect to the host; *e.g.*, excessive inflammation, thrombosis, and the like. Additionally, these bioresorbable polyesters are readily broken down *in vivo* and eventually excreted in a biocompatible fashion.

Polyesters meeting the criteria of biocompatible, bioresorbable materials include polymers made from monomers of hydroxy acids such as the α-hydroxylactic acid, α-hydroxyglycolidic acid, β-hydroxybutyric acid, γ-hydroxycaprolic acid, and δ-hydroxvaleric acid. Fumaric acid and hydroxyalkanes, such as propylene glycol, butylene glycol, etc., form copolymers that are also candidate bioresorbable polyesters. An example of a biodegradable poly ether ester is poly(dioxanone).

Frequently, the starting materials are condensation products of the free acids, producing cyclized structures used as the monomer starting materials. Poly(dioxanone) is formed from the cyclized monomer, p-dioxanone. For the lower molecular weight hydroxy acids, two molecules of hydroxy acid may be condensed to form a cyclized monomer. In the case of lactic acid, the corresponding cyclized condensation product of two lactic acid molecules is referred to commonly as a lactide. In the case of glycolic acid, the resultant molecule is referred to commonly as a glycolide. In this regard, whether one starts with lactic acid, or forms thereof, or with lactide, the resultant polymer is a homopolymer of lactic acid. Similarly, in the case of glycolic acid, or forms thereof, and glycolide, regardless of the starting monomer, the resultant polymer is a homopolymer of glycolidic acid. The higher molecular weight hydroxy acids can undergo an internal cyclization to form lactones that may be used as starting monomers, as can the uncyclized monomer forms. Examples of these include caproic acid, which forms εcaprolactone, and valeric acid, which forms δ-valerolactone. Again, whether the cyclized monomer, or the free acid monomer, or forms thereof are used as starting materials, homopolymers of the corresponding acids will result. In terms of the common nomenclature for designating these polymers, either form of the starting material may be used to refer to the polymer formed thereby. Hence, reference to polylactide is equivalent to polylactate, since both are homopolymers of lactic acid.

Stereoisomers of the lactic acid, and lactide exist. The properties of the copolymers formed from the stereoisomers of lactide may vary considerably. Interestingly, there is no linear relationship between properties of homopolymers, and their corresponding copolymers. In that regard, a 70:30 copolymer of poly-L-lactide with poly-D,L-lactide produces a material that has a degradation time of thirty-six months, while the degradation time of poly-D,L-lactide is about twelve months and that of poly-L-lactide is greater than twenty-four months. As another example, a 50:50 copolymer blend of glycolide with

D,L lactide produces a material that degrades in about two months, while the degradation of poly-D,L-lactide and polyglycolide is about twelve months.

Major suppliers of bulk biodegradable polyester materials include Boehringer Ingelheim, Purac, and Dow. Boehringer Ingelheim's extensive RESOMER® line includes a variety of medical grade poly(L-lactide), poly(D,L-lactide), poly(L-lactide-co-D,L-lactide), poly(L-lactide-co-glycolide), poly(L-lactide-co-ε-caprolactone), poly(L-lactide-co-trimethylene carbonate), and poly(dioxanone) resins for fabrication of the disclosed device. Similarly, Purac's PURASORB® line includes lactide and glycolide monomers, as well as polylactide, polyglycolide, and polylactide/glycolide copolymer resins. Dow's Tone™ products include high molecular weight polycaprolactone resins of high crystallinity. Metabolix Inc. is a supplier of a family of poly(hydroxybutryate-co-valerate) copolymer resins under the trade name Biopol.

Polycarbonates have strength properties desirable for biocompatible, bioresorbable load bearing implants. The copolymerization of lactide or glycolide with trimethylene carbonate produces poly(lactide-co-trimethylene carbonate) and poly(glycolide-co-trimethylene carbonate), respectively. These copolymers have been used to make a range of products from sutures to tacks and screws. Tyrosine derived polycarbonates such as poly(desaminotyrosyl-tyrosine ethyl carbonate) and poly(desaminotyrosyl-tyrosine hexyl carbonate) have also been used in orthopedic applications, such as bone pins and screws. As mentioned above, Boehringer Ingelheim is a bulk supplier of a poly(L-lactide-co-trimethylene carbonate) resin, RESOMER® LT 706. Additionally, Integra Life Sciences is a supplier of tyrosine polycarbonates.

Other examples of biocompatible, bioresorbable classes of polymers are polysaccharides and polyanhydrides. Polysaccharides are a diverse class and include glucans and glycosaminoglycans. Glucans are any homopolymer of glucose, and include celluloses, starches, and dextroses. Starch blends have properties desirable for load-bearing biocompatible, bioresorbable implants.

Blends exhibiting good strength characteristics include starch/cellulose acetate blends, starch/polycaprolactone blends, as well as starch blended with copolymers of ethylene and vinyl alcohol. Glucosaminoglycans includes hyaluronates, dermatan sulfates, chondroitin sulfates, heparins, keratans, chitins, and chitosans. The glucosaminoglycans are a ubiquitous class polysaccharides occurring naturally as structural materials, and show potential for as polymers and copolymers for biocompatible, bioresorbable implants. Polyanhydrides are formed by the condensation of diacid molecules. One example of a bioresorbable polyanhydride copolymer is the condensation of sebacic acid ("SA") with hexanedecandioic acid ("HAD") to form poly ("SA-co-HAD") anhydride.

It should be noted that there are two important phases of the process of bioresorption: time to complete loss of strength of the material, and time to complete resorption. There are several factors that affect the rate of degradation of bioresorbable materials, and hence both the time to complete loss of strength, and time to complete resorption. In general, reduction in strength follows the reduction in molecular weight of a polymeric material as it degrades. Factors that affect degradation of bioresorbable polymers include the crystalline nature of the starting material, the hydrophilic nature of the polymer backbone, whether or not the polymer has a reinforcing filler, the initial molecular weight of the polymer, the degree of porosity of the polymer material, the surface area to mass ratio of the device, and the degree of stress on the implanted device.

An example of how the crystalline vs. amorphous nature of the starting material impact degradation is illustrated in the comparing the properties of poly-L-lactide vs. poly-D,L-lactide. The time to complete loss of strength of poly-D,L-lactide is about 6 months, while that of poly-L-lactide is more than 12 months. Recalling from the above, poly-D,L-lactide degrades more rapidly (12 months) than poly-L-lactide (24 months). The racemic mixture of the stereoisomer produces significantly amorphous powders, which yield lower strength materials degrading more rapidly than polymers made from their highly crystalline counter part. Still another example of how the crystalline versus amorphous nature of a material affects degradation time comes from the previously given example of a 50:50 copolymer blend of glycolide with D,L lactide. This copolymer exhibits a highly amorphous state, and produces a material that degrades significantly faster (two months) than the degradation of poly-D,L-lactide and polyglycolide (twelve months).

Concerning the hydrophilic nature of the polymer backbone, an example of how this property impacts degradation is demonstrated through the comparison of the stability of poly-L-lactide against polyglycolide. Poly-L-lactide has an increased hydrophobic nature (decreased hydrophilic nature) compared with polyglycolide, due to the methyl group in the backbone structure, and is therefore less susceptible to hydrolysis. The time to complete loss of strength of poly-L-lactide is greater than twelve months, while that of polyglycolide is about two months. The comparative degradation times for poly-L-lactide and polyglycolide are twenty-four months versus about six to twelve months, respectively.

The impact of reinforcing filler on increasing material strength can be understood by comparing poly-L-lactide to SR poly-L-lactide properties. Time to complete loss of strength for poly-L-lactide is greater than twelve months, while for SR poly-L-lactide is about eighteen months, while the degradation times are about twenty-four months and seventy-two months, respectively. Other types of reinforcing fillers include ceramics, glasses, and graphite fibers. Ceramics including hydroxyapaptite and tricalcium phosphate, and blends thereof are commonly used reinforcing bioresorbable materials. Bioglasses are silicate glasses containing sodium, calcium, and phosphate as the main components. Ceramics, bioglasses, and bioglass/ceramic compositions have been used in numerous polymer and copolymer bioresorbable material blends to add strength to these materials. The bioresorption of the inorganic ceramic and glass materials follows as the dissolution of the ions, and bioresorption thereof.

In addition to the molecular properties influencing material properties that impact degradation, bulk properties of the material, such as the porosity of material, as well as properties of the device, such as the surface area to mass ratio, affect degradation time, as well. As previously mentioned, there are two phases to the degradation process: time to complete loss of strength and time to complete resorption. These two phases of degradation correlate to two distinct processes: (1) water penetration into the material, with initial degradation of polymer chains, referred to as the hydrolysis phase; and (2) degradation of material strength and fragmentation, and procession of enzymatic attack, phagocytosis, and metabolism. This phase is referred to as metabolism or bulk erosion. Increased porosity of a device and increased relative surface area to mass of a device will enhance the hydrolysis phase, and hence tend to hasten the overall degradation process.,

Regarding the impact of degradative processes on the site of the implant, as loss of strength proceeds, the implant will begin to fragment. Increased stress on the implant, and increased vascularization may increase the degradation time. Stress may have a role in decreasing structural integrity, and the increase in the rate of water absorption thereby, and hence affect the rate of bulk erosion. Once the polymer has fragmented into small pieces, *in vivo* processes, such as phagocytosis, and enzymatic activity speeding up the hydrolysis process may proceed to hasten in the bioresorption process. Such *in vivo* processes are enhanced by increased vascularization. The presence of the small particles, as well as a local drop in tissue pH in the case of ester hydrolysis due to increased levels of free acid, induces an inflammatory response in the tissue. When bioresorption is complete, the inflammatory response subsides. In that regard, it may be desirable, depending on the use of the device, to fabricate devices from polymers that take longer to complete loss of strength, and have slower rates of degradation.

By what is disclosed of molecular properties, bulk material properties, device design, and factors at the site of implantation, it is therefore possible to design devices from selected materials accordingly.

The following description is presented to enable any person skilled in the art to make and use the disclosed device. Various modifications to the embodiments described will be readily apparent to those skilled in the art, and the principles defined herein can be applied to other embodiments and applications without departing from the spirit and scope of the present disclosure as defined by the appended claims. Thus, the present disclosure is not intended to be limited to the embodiments shown, but is to be accorded the widest scope consistent with the principles and features disclosed herein.

An embodiment of an implant ***100*** of the disclosed device is depicted in **FIG. 1A**. This implant ***100*** includes a first wing ***104*** and a spacer ***150*** and a lead-in tissue expander or distraction guide ***110***. This embodiment further can include, as required, a second wing ***132***. As can be seen in **FIG. 1A**, a central body ***102*** extends from the first wing ***104*** and is the body that connects the first wing ***104*** to the tissue expander or distraction guide ***110***. Also, as can be seen in **FIG. 1A** and **1B**, the distraction guide ***110*** in this particular embodiment acts to distract the soft tissue and the spinous processes when the implant ***100*** is inserted between adjacent spinous processes. In this particular embodiment, the distraction guide ***110*** has an expanding cross-section from the distal end ***111*** to the area where the second wing ***132*** is secured to the distraction guide ***110***. In this embodiment the distraction guide ***110*** is wedge-shaped.

Additionally, as can be seen in **FIG. 1A**, and **1F**, the spacer ***150*** is elliptical shaped in cross-section. The spacer ***150*** can have other shapes such as circular, oval, ovoid, football-shaped, and rectangular-shaped with rounded corners and other shapes, and be within the spirit and scope of what is disclosed.

In this embodiment, spacer ***150*** includes a bore ***152*** which extends the length of spacer ***150***. The spacer ***150*** is received over the central body ***102*** of the implant ***100*** and can rotate thereon about the central body ***102***. In these embodiments, the spacer ***150*** can have minor and major dimensions as follows:

MINOR DIMENSION (116A)	MAJOR DIMENSION (116 B)
6 mm	13.7 mm
8 mm	14.2 mm
10 mm	15.2 mm
12 mm	16.3 mm
14 mm	17.8 mm

The advantage of the use of the spacer ***150*** as depicted in the embodiment of **FIG. 1A** is that the spacer ***150*** can be rotated and repositioned with respect to the first wing ***104***, in order to more optimally position the implant ***100*** between spinous processes. It is to be understood that the cortical bone or the outer bone of the spinous processes is stronger at an anterior position adjacent to the vertebral bodies of the vertebra than at a posterior position distally located from the vertebral bodies. Also, biomechanically for load bearing, it is advantageous for the spacer ***150*** to be close to the vertebral bodies. In order to facilitate this and to accommodate the anatomical form of the bone structures, as the implant is inserted between the spinous processes and/or urged toward the vertebral bodies, the spacer ***150*** rotates relative to the wings, such as wing ***104***, so that the spacer ***150*** is optimally positioned between the spinous processes, and the wing ***104*** is optimally positioned relative to the spinous processes. Further, the broad upper and lower surfaces of the spacer ***150*** helps spread the load that the spinous processes place on the spacer ***150***.

As may be required for positioning the implant ***100*** between the spinous processes, implant ***100*** can also include a second wing ***132*** (**FIG. 1E**) which fits over the distraction guide ***110*** and is secured by a bolt ***130*** (**FIG. 1A**) placed through aperture ***134*** provided in a tongue ***136*** of second wing ***132*** (**FIG. 1E**). The bolt ***130*** is received and secured in the threaded bore ***112*** located in distraction guide ***110***. As implanted, the first wing ***104*** is located adjacent to first sides of the spinous processes and the second wing ***132*** is located adjacent to second sides of the same spinous processes.

In another embodiment, the spacer ***150*** has a cross-section with a major dimension and a minor dimension, wherein the major dimension is greater than the minor dimension and, for example, less than about two times the minor dimension.

Implant ***200*** is depicted in **FIG. 2**. This implant is similar to the implants ***100*** of **FIG. 1**, except that this implant does not have either first or second wings. Implant ***200*** includes a distraction guide ***210***, spacer ***220*** which surrounds a central body just as central body ***102*** of implant ***100*** in **FIG. 1**, and endpiece ***230***. The distraction guide ***210*** in this preferred embodiment is cone-shaped, and is located at one end of the central body (not shown). At the other end is an endpiece ***230***. Endpiece ***230*** is used to contain the other end of the spacer ***220*** relative to the central body. This embodiment is held together with a bolt (not shown).

FIG. 3 depicts an implant system ***300***. Implant system ***300*** includes an insertion tool ***310***. Insertion tool ***310*** includes a distraction guide ***320*** which in a preferred embodiment is substantially cone-shaped. Distraction guide ***320*** guides the insertion of the spacer ***330*** and the insertion tool ***360*** between adjacent spinous processes. The insertion tool ***310*** further includes a central body ***340***, a stop ***350***, and a handle ***360***. The distraction guide ***320*** at its base has dimensions which are slightly less than the internal dimensions of the spacer ***330*** so that the spacer can fit over the distraction guide ***320*** and rest against the stop ***350***. The tool ***310*** with the distraction guide ***320*** is used to separate tissues and ligaments and to urge the spacer ***330*** in the space between the spinous processes. Once positioned, the distraction guide insertion tool ***310*** can be removed leaving the spacer ***330*** in place.

For the implants ***200*** of **FIG. 2** and ***300*** of **FIG. 3**, such devices would be appropriate where the anatomy between the spinous processes was such that it would be undesirable to use either a first or second wing. However, these embodiment afford all the advantageous described hereinabove (**FIGS. 1A-1F**) with respect to the distraction guide and also with respect to the dynamics of the spacer.

Additionally, for the embodiments shown in **FIGS. 2** and **3**, the device may be secured in place via bioresorbable sutures or screws. The degradation times of sutures made from bioresorbable polymers are influenced by both the suture size and type of polymer. Suture products such as Maxon (Davis and Geck), a polyglyconate based suture material, and PDS (Ethicon), a polydioxanone based suture material, maintain tensile strength for four to six weeks, and may take up to six months to be resorbed completely. Depending on the material used, as detailed above, screws may have total time to resorption from six months to five years. Biologically Quite (Instrument Makar), a poly(D,L-lactide-co-glycolide) screw degrades in about six months, while Phusiline (Phusis), a poly(L-lactide-co-D,L lactide) copolymer degrades in about five years, and Bioscrew (Linvatec), a ploy(L-lactide) screw degrades in the range of two to three years.

In **FIGS. 4A, 4B**, what is shown is the view of the device ***100*** inserted between the spinous processes, so as to distract the two vertebrae ***410, 420***, thereby increasing the volume of the spinal canal, and concomitantly relieving the intervertebral load. The anterior direction is denoted "A," and the posterior direction is denoted "P."

The implants described also can be used with other elements that further stabilize the spine and the implant's ***100*** location in the spine as it functions to increase temporarily the volume of the spinal canal and to relieve the intervertebral load. For example, the implants ***100, 200, and 300*** can be used with a tether or suture which is fitted and secured around adjacent spinous processes. The tether or suture (these terms to be used interchangeably herein) can be made of biocompatible, bioresorbable material(s) described above and as such, the tether need not be explanted, sparing the patient from additional surgery.

A first use of a tether is depicted in **FIG. 5**. In this embodiment ***400***, an implant such as implant ***100*** or ***200*** can be positioned between a upper spinous process ***710*** and a lower spinous process ***720***, and a tether ***470*** can loop around the upper spinous process ***710*** and the lower spinous process ***720***. The tether ***470*** need not interact with the implant ***100, 200***, or ***300***; that is, there need not be a fastening mechanism to connect the implant ***100, 200***, or ***300*** with the tether ***470***. Instead, the ends of tether ***470*** can be fastened together in a loop by any suitable mechanism. Alternatively, the ends can be knotted or stitched to fasten them through the bores.

A further use of the tether is depicted in **FIG. 6**. In this embodiment ***500***, based upon implant ***100***, the tether ***570*** fastens to an upper bore ***505*** of the first wing ***504***, and loops around the upper spinous process ***710*** to be threaded through a bore ***515*** through the distraction guide ***510***. The tether ***570*** then continues to loop around by passing around the lower spinous process ***720*** and fastens to a lower bore ***507*** in the first wing ***504***. The tether ***570*** can be fastened at the upper bore ***505*** and lower bore ***507*** of the first wing ***504*** by an appropriate fastening means, such as a cuff made of biocompatible, bioresorbable material. Alternatively, the ends of the tether ***570*** fastened to the upper bore ***505*** and lower bore ***507*** can be knotted or tied off, or sewn with sutures.

As depicted in **FIG. 7**, a tether also can be used in conjunction with implant ***100*** where implant ***100*** has a second wing ***632***. The tether ***670*** need not pass through or connect with the second wing ***632***. Instead, the tether ***670*** fastens with an upper bore ***605*** in a first wing ***604*** and passes around an upper spinous process ***710*** and can then pass through a bore ***615*** in the distraction guide ***610***. The tether ***670*** then passes under the lower spinous process ***720*** and fastens with a lower bore ***607*** through the first wing ***604***. The tether ***670*** can be fastened at the upper bore ***605*** and lower bore ***607*** of the first wing ***604*** by an appropriate fastening means, such as a cuff made of biocompatible, bioresorbable material. Alternatively, the ends of the tether ***670*** fastened to the upper bore ***605*** and lower bore ***607*** can be knotted or tied off, or sewn with sutures.

One use contemplated for such devices is implantation in conjunction with intervertebral disk remediation, either implanting a disk replacement device or performing surgical repair on an intervertebral disk. Devices and methods suitable for disk replacement have been described in U.S. Patent Application No. 10/685,134, filed October 14, 2003, entitled "TOOLS FOR IMPLANTING AN ARTIFICIAL VERTEBRAL DISK AND METHOD," U.S. Patent Application No. 10/684,669, filed October 14, 2003, entitled "ARTIFICIAL VERTEBRAL DISK REPLACEMENT IMPLANT WITH TRANSLATING PIVOT POINT AND METHOD," U.S. Provisional Patent Application 60/526,724, filed December 2, 2003, entitled "ARTIFICIAL VERTEBRAL DISK REPLACEMENT IMPLANT WITH TRANSLATING PIVOT POINT AND LATERAL IMPLANT METHOD," U.S. Patent Application No. 10/684,668, filed October 14, 2003, entitled "ARTIFICIAL VERTEBRAL DISK REPLACEMENT IMPLANT WITH CROSSBAR SPACER AND METHOD," U.S. Provisional Application No. 60/517,973, filed November 6, 2003, entitled "ARTIFICIAL VERTEBRAL DISK REPLACEMENT IMPLANT WITH CROSSBAR SPACER AND LATERAL IMPLANT METHOD," U.S. Patent Application No. 10/685,011, filed October 14, 2003, entitled "ARTIFICIAL VERTEBRAL DISK REPLACEMENT IMPLANT WITH A SPACER AND METHOD," and U.S. Provisional Application No. 60/524,350, filed November 21, 2003, entitled "ARTIFICIAL

VERTEBRAL DISK REPLACEMENT IMPLANT WITH A SPACER AND LATERAL IMPLANT METHOD," and are incorporated herein by reference. In addition to the total disk replacement devices described in the aforementioned applications, polymer-filled implants based on a biomimetic approach to disk repair and replacement may be used for remediation. Devices and methods describing the use of such implants are found in U.S. Patent 6,416,766, issued July 9, 2002, entitled "BIOLOGICAL DISK REPLACEMENT BONE MORPHOGENIC PROTEIN (BMP) CARRIERS AND ANTI-ADHESION MATERIALS," and U.S. Patent Application No. 09/815,387, filed March 22, 2001, entitled "IMPLANTABLE PROSTHETIC OR TISSUE EXPANDING DEVICE," both incorporated herein by reference.

FIG. 8 is a flowchart showing an embodiment of the method of the present invention. Regarding the disclosed devices used in conjunction with disk remediation implants and procedures like those described by the aforementioned incorporated references, load relief of the vertebral disks, either before or after a disk remediation procedure is done **820**, is indicated either to assist in the process of disk remediation, or to allow for effective recovery of the surgical procedure, or both. Moreover, the disclosed devices, made in part or completely from the biocompatible, bioresorbable materials described in this disclosure, require no additional surgical procedure for removal after recovery is complete.

The bioresorbable load relief/spinal distraction devices disclosed above can be inserted laterally. The implanting physician after accessing the intervertebral space **810** optionally can distract the spinous process before inserting the device **830, 840**. Alternatively, the tissue expander can be used to distract the spinous processes while inserting the device **830, 840**.

The spinous processes can be further stabilized by the use of a bioresorbable tether together with the resorbable distracting device adapted to accept the tether **855**, or with a bioresorbable device which does not have wings and need not be adapted to accept the tether **850**. If the device does not have a first or second wing, the tether is looped around the spinous processes and fastened, after the implant is positioned between the spinous processes **850**.

Certain of the bioresorbable devices are adapted to accept the tether so that the tether binds not only the spinous processes but also the implant, to maintain temporarily a minimum spacing between the spinous processes **855**. The adaptations include an upper bore and a lower bore on the first wing, and a bore through the distraction guide. During the implantation, the device is inserted between the spinous processes with one first of the tether attached to the upper bore of the first wing. A curved needle or other tool can then be used to lead the second end of the tether over an upper spinous process, through the bore in the tissue expander, under a lower spinous process, and through the lower bore of the first wing, to fasten the second end to the lower bore of the first wing. The tether is tightened to the desired degree to maintain a minimal distraction of the spinous processes and the ends of the tether are fastened **860**.

It is within the scope of the present invention to fasten the first end of the tether to the lower bore of the first wing, and to use a curved needle or other implement to lead the second end of the tether below the lower spinous process, through the bore in the tissue expander, over the upper spinous process, and through the upper bore on the first wing, to fasten the second end of the upper bore of the first wing.

Where the implant has a second wing, the same method is followed as for an implant with one wing, as the second wing need not engage the tether.

The foregoing description of embodiments of the present disclosure has been provided for the purposes of illustration and description. It is not intended to be exhaustive or to limit the disclosure to the precise forms disclosed. Many modifications and variations will be apparent to the practitioner skilled in the art. The embodiments were chosen and described in order to best explain the principles of this disclosure and its practical application, thereby enabling others skilled in the art to understand various embodiments and with various modifications that are suited to the particular use contemplated. It is intended that the scope of this disclosure be defined by the following claims and its equivalence.

WHAT IS CLAIMED

1. A device adapted to insert between the spinous processes, said device comprising a spacer made of a bioresorbable material.

2. The device of claim 1, wherein the bioresorbable material is selected from polyester, polysaccharide, polyanhydride, and polycarbonate, including copolymers, composites, and blends thereof.

3. The device of claim 2, wherein the polyester polymer is selected from polylactide, polyglycolide, poly-ε-caprolactone, poly-β-hydroxybutyrate, poly-δ-valerolactone, poly(dioxanone), and poly(ethylene terephthlate).

4. The device of claim 2, wherein the polysaccharide polymer is a selected from glucans and glucosaminoglycans.

5. The device of claim 2, wherein the polycarbonate polymer is selected from poly (desaminotyrosyl-tyrosine ethyl)carbonate, and poly(desaminotyrosyl-tyrosine hexyl)carbonate.

6. The device of claim 2, wherein the polyester copolymers are selected from poly(L-lactide-co-glycolide), poly(D,L-lactide-co-glycolide), poly(lactide-co-trimethylene carbonate), poly(D,L-lactide), poly(L-lactide-co-D,L-lactide), poly(lactide-co-tetramethylglycolide), poly(lactide-co-ε-caprolactone), poly(lactide-co-δ-valerolactone), poly(glycolide-co-trimethylene carbonate), poly(glycolide-co-ε-caprolactone), poly(glycolide-co-δ-valerolactone), poly(propylene fumarate), poly(propylene fumarate diacrylate), poly(hydroxybutyrate-co-hydroxyvalerate), and poly(ethylene terephthlate-co-dioxanone).

7. The device of claim 2, wherein the polymer further comprises a filler.

8. The device of claim 7, wherein the filler is selected from at least one of graphite, ceramic, and glass.

9. The device of claim 2, wherein the polymer is self-reinforced.

10. The device of claim 9, wherein the self-reinforced polymer is selected from polyesters and copolymers thereof.

11. The device of claim 1, further comprising;

an insertion tool having a distal end and a proximal end;

a distraction guide at the distal end if the insertion tool;

a handle at the proximal end of the insertion tool;

a central body proximal to the distraction guide; and

a stop between the central body and the distraction guide;

wherein the spacer fits over the distraction guide and is disposed between the stop and the distraction guide; and

the insertion tool removably guides the spacer between the spinous processes.

12. A device adapted to insert between spinous processes, with components comprising:

a central body with a distal end and a proximal end, said central body having a longitudinal axis;

a spacer associated with the central body, wherein said spacer is adapted to be placed between spinous processes;

a tissue expander extending from the distal end of the central body; and

wherein at least one of the components is made of a bioresorbable material.

13. The device as in claim 12 further comprising a tether made of a bioresorbable material, wherein the tether loops around adjacent spinous processes and the ends of the tether are fastened together.

14. The device of claim 12, further comprising;

a first wing located at the proximal end of the central body and a second wing located at the distal end of the central body, wherein the spacer is between the first wing and the second wing.

15. The device of claim 14, wherein all components are made of a bioresorbable material.

16. The device of claim 14, wherein the bioresorbable material is selected from polyester, polysaccharide, and polycarbonate, including copolymers, composites, and blends thereof.

17. The device of claim 16, wherein the polyester polymer is selected from polylactide, polyglycolide, poly-ε-caprolactone, poly-β-hydroxybutyrate, poly-δ-valerolactone, poly(dioxanone), and poly(ethylene terephthlate).

18. The device of claim 16, wherein the polysaccharide polymer is a selected from glucans and glucosaminoglycans.

19. The device of claim 16, wherein the polycarbonate polymer is selected from poly (desaminotyrosyl-tyrosine ethyl)carbonate, and poly(desaminotyrosyl-tyrosine hexyl)carbonate.

20. The device of claim 16, wherein the polyester copolymers are selected from poly(L-lactide-co-glycolide), poly(D,L-lactide-co-glycolide), poly(lactide-co-trimethylene carbonate), poly(D,L-lactide), poly(L-lactide-co-D,L-lactide), poly(lactide-co-tetramethylglycolide), poly(lactide-co-ε-caprolactone), poly(lactide-co-δ-valerolactone), poly(glycolide-co-trimethylene carbonate), poly(glycolide-co-ε-caprolactone), poly(glycolide-co-δ-valerolactone), poly(propylene fumarate), poly(propylene fumarate diacrylate), poly(hydroxybutyrate-co-hydroxyvalerate), and poly(ethylene terephthlate-co-dioxanone).

21. The device of claim 16, wherein the polymer further comprises a filler.

22. The device of claim 21, wherein the filler is selected from at least one of graphite, ceramic, and glass.

23. The device of claim 16, wherein the polymer is self-reinforced.

24. The device of claim 23, wherein the self-reinforced polymer is selected from polyesters and copolymers thereof.

25. A device adapted to insert between spinous processes, with components comprising:

a central body with a distal end and a proximal end, said central body having a longitudinal axis;

a spacer associated with the central body, wherein said spacer is adapted to be placed between spinous processes;

a stop located at the proximal end of the central body;

a tissue expander extending from the distal end of the central body; and

wherein at least one of the components is made of a bioresorbable material.

26. The device of claim 25, wherein the stop is a first wing.

27. The device of claim 26 further comprising a tether made of a bioresorbable material, wherein the tether loops around adjacent spinous processes and the ends of the tether are fastened together.

28. The device of claim 27 wherein the tether fastens to an upper bore on the first wing, passes over an upper spinous process, a bore in the tissue expander, and a lower spinous process, and fastens to a lower bore on the first wing.

29. The device of claim 25, further comprising a second wing located at the distal end of the central body, wherein the spacer is between the stop and the second wing.

30. The device of claim 29 further comprising a tether made of a bioresorbable material, wherein the tether loops around adjacent spinous processes and the ends of the tether are fastened together.

31. The device of claim 30 wherein the tether fastens to an upper bore on the first wing, passes over an upper spinous process, a bore in the tissue expander, and a lower spinous process, and fastens to a lower bore on the first wing.

32. The device of claim 29, wherein all components are made of a bioresorbable material.

33. The device of claim 30, wherein the bioresorbable material is selected from polyester, polysaccharide, and polycarbonate, including copolymers, composites, and blends thereof.

34. The device of claim 33, wherein the polyester polymer is selected from polylactide, polyglycolide, poly-ε-caprolactone, poly-β-hydroxybutyrate, poly-δ-valerolactone, poly(dioxanone), and poly(ethylene terephthlate).

35. The device of claim 33, wherein the polysaccharide polymer is a selected from glucans and glucosaminoglycans.

36. The device of claim 33, wherein the polycarbonate polymer is selected from poly (desaminotyrosyl-tyrosine ethyl)carbonate, and poly(desaminotyrosyl-tyrosine hexyl)carbonate.

37. The device of claim 33, wherein the polyester copolymers are selected from poly(L-lactide-co-glycolide), poly(D,L-lactide-co-glycolide), poly(lactide-co-trimethylene carbonate), poly(D,L-lactide), poly(L-lactide-co-D,L-lactide), poly(lactide-co-tetramethylglycolide), poly(lactide-co-ε-caprolactone), poly(lactide-co-δ-valerolactone), poly(glycolide-co-trimethylene carbonate), poly(glycolide-co-ε-caprolactone), poly(glycolide-co-δ-valerolactone), poly(propylene fumarate), poly(propylene fumarate diacrylate), poly(hydroxybutyrate-co-hydroxyvalerate), and poly(ethylene terephthlate-co-dioxanone).

38. The device of claim 33, wherein the polymer further comprises a filler.

39. The device of claim 38, wherein the filler is selected from at least one of graphite, ceramic, and glass.

40. The device of claim 33, wherein the polymer is self-reinforced.

41. The device of claim 40, wherein the self-reinforced polymer is selected from polyesters and copolymers thereof.

42. A device adapted to insert between spinous processes, with components comprising:

a central body with a distal end and a proximal end, said central body having a longitudinal axis;

a spacer associated with the central body, wherein said spacer is adapted to be placed between spinous processes;

a first wing located at the proximal end of the central body and a second wing located at the distal end of the central body, wherein the spacer is between the first wing and the second wing;

a tissue expander extending from the distal end of the central body; and

wherein at least one of the components is made of a bioresorbable material.

43. The device of claim 42 further comprising a tether made of a bioresorbable material, wherein the tether loops around adjacent spinous processes and threads through the device.

44. The device of claim 43 wherein the tether fastens to an upper bore on the first wing, passes over an upper spinous process, a bore in the tissue expander,

and a lower spinous process, and fastens to a lower bore on the first wing.

45. The device of claim 42 further comprising a second wing located at the distal end of the central body, wherein the tissue expander is between the first wing and the second wing.

46. The device of claim 45 further comprising a tether made of a bioresorbable material, wherein the tether loops around adjacent spinous processes and threads through the device.

47. The device of claim 46 wherein the tether fastens to an upper bore on the first wing, passes over an upper spinous process, a bore in the tissue expander, and a lower spinous process, and fastens to a lower bore on the first wing.

48. The device of claim 42, wherein all components are made of a bioresorbable material.

49. The device of claim 42, wherein the bioresorbable material is selected from polyester, polysaccharide, and polycarbonate, including copolymers, composites, and blends thereof.

50. The device of claim 42, wherein the polyester polymer is selected from polylactide, polyglycolide, poly-ε-caprolactone, poly-β-hydroxybutyrate, poly-δ-valerolactone, poly(dioxanone), and poly(ethylene terephthlate).

51. The device of claim 42, wherein the polysaccharide polymer is a selected from glucans and glucosaminoglycans.

52. The device of claim 49, wherein the polycarbonate polymer is selected

from poly (desaminotyrosyl-tyrosine ethyl)carbonate, and poly(desaminotyrosyl-tyrosine hexyl)carbonate.

53. The device of claim 49, wherein the polyester copolymers are selected from poly(L-lactide-co-glycolide), poly(D,L-lactide-co-glycolide), poly(lactide-co-trimethylene carbonate), poly(D,L-lactide), poly(L-lactide-co-D,L-lactide), poly(lactide-co-tetramethylglycolide), poly(lactide-co-ε-caprolactone), poly(lactide-co-δ-valerolactone), poly(glycolide-co-trimethylene carbonate), poly(glycolide-co-ε-caprolactone), poly(glycolide-co-δ-valerolactone), poly(propylene fumarate), poly(propylene fumarate diacrylate), poly(hydroxybutyrate-co-hydroxyvalerate), and poly(ethylene terephthlate-co-dioxanone).

54. The device of claim 49, wherein the polymer further comprises a filler.

55. The device of claim 54, wherein the filler is selected from at least one of graphite, ceramic, and glass.

56. The device of claim 49, wherein the polymer is self-reinforced.

57. The device of claim 56, wherein the self-reinforced polymer is selected from polyesters and copolymers thereof.

58. In a device used to limit extension of the spine without limiting flexion, the improvement of the device comprising the device is fabricated from a bioresorbable material.

59. The device of claim 58, wherein the bioresorbable material is selected from polyester, polysaccharide, and polycarbonate, including copolymers,

composites, and blends thereof.

60. The device of claim 59, wherein the polyester polymer is selected from polylactide, polyglycolide, poly-ε-caprolactone, poly-β-hydroxybutyrate, poly-δ-valerolactone, poly(dioxanone), and poly(ethylene terephthlate).

61. The device of claim 59, wherein the polysaccharide polymer is a selected from glucans and glucosaminoglycans.

62. The device of claim 59, wherein the polycarbonate polymer is selected from poly (desaminotyrosyl-tyrosine ethyl)carbonate, and poly(desaminotyrosyl-tyrosine hexyl)carbonate.

63. The device of claim 59, wherein the polyester copolymers are selected from poly(L-lactide-co-glycolide), poly(D,L-lactide-co-glycolide), poly(lactide-co-trimethylene carbonate), poly(D,L-lactide), poly(L-lactide-co-D,L-lactide), poly(lactide-co-tetramethylglycolide), poly(lactide-co-ε-caprolactone), poly(lactide-co-δ-valerolactone), poly(glycolide-co-trimethylene carbonate), poly(glycolide-co-ε-caprolactone), poly(glycolide-co-δ-valerolactone), poly(propylene fumarate), poly(propylene fumarate diacrylate), poly(hydroxybutyrate-co-hydroxyvalerate), and poly(ethylene terephthlate-co-dioxanone).

64. The device of claim 59, wherein the polymer further comprises a filler.

65. The device of claim 64, wherein the filler is selected from at least one of graphite, ceramic, and glass.

66. The device of claim 59, wherein the polymer is self-reinforced.

67. The device of claim 66, wherein the self-reinforced polymer is selected from polyesters and copolymers thereof.

68. A method for remediation of a damaged intervertebral disk, comprising the steps of:

accessing an intervertebral space;

restoring the damaged disk;

inserting a bioresorbable device between spinous processes of the spinal column; and

wherein the steps of restoring and inserting are done in any order.

69. The method of claim 68 further comprising the step of tethering the spinous processes with a bioresorbable tether.

70. The method of claim 69 wherein the tethering step further comprises threading the tether around the spinous processes and fastening the ends together.

71. The method of claim 68, where the step of inserting the device further comprises:

accessing adjacent first and second spinal processes of the vertebrae;

distracting the first and second spinous processes;

implanting the device between said spinous processes, said device comprising a spacer; and

where the distracting and implanting steps are done in any order or simultaneously.

72. The method of claim 71, wherein the step of implanting the spacer between the spinous processes further comprises;

assembling the spacer on an insertion tool with a distal end and proximal end, the tool comprising;

a distraction guide at the distal end of the insertion tool, a handle at the proximal end of the insertion tool, a central body proximal to the distraction guide, and a stop between the central body and the handle; and

wherein the spacer fits over the distraction guide and is disposed between the stop and the distraction guide;

separating tissues and ligaments with the distraction guide of the insertion tool;

urging the spacer into the space between the spinous processes;

removing the insertion tool, while leaving the spacer in place; and

where the distracting and implanting steps are done in any order or simultaneously.

73. The method of claim 68, where the step of inserting the device further comprises:

accessing adjacent first and second spinal processes of the vertebrae;

distracting the first and second spinous processes;

inserting a device between the spinous processes of the spinal column using the steps of:

a central body with a distal end and a proximal end, said central body having a longitudinal axis;

a spacer associated with the central body, wherein said spacer is adapted to be placed between spinous processes;

a tissue expander extending from the distal end of the body; and

where the distracting and inserting steps are done in any order or simultaneously.

74. The method of claim 68, where the step of inserting the device further comprises:

accessing adjacent first and second spinal processes of the vertebrae;

distracting the first and second spinous processes;

inserting a device between the spinous processes of the spinal column, the device comprising:

a central body with a distal end and a proximal end, said central body having a longitudinal axis;

a stop located at the proximal end of the central body;

a spacer associated with the central body, wherein said spacer is adapted to be placed between spinous processes;

a tissue expander extending from the distal end of the body; and

where the distracting and inserting steps are done in any order or simultaneously.

75. The method of claim 74, wherein the stop is a first wing.

76. The method of claim 75 further comprising tethering the spinous processes and the device wherein the device already is inserted between the spinous processes, and wherein the device has a bioresorbable tether anchored at a first end to the device.

77. The method of claim 76 wherein the tethering step further comprises

using a tool to guide a second end of the tether over an upper spinous process, through a bore through the tissue expander, under a lower spinous process, and through a lower bore in the first wing; and anchoring the second end of the tether to the lower bore in the first wing, the first end of the tether anchored to an upper bore in the first wing.

78. The method of claim 76 wherein the tethering step further comprises using a tool to guide a second end of the tether under a lower spinous process, through a bore through the tissue expander, over an upper spinous process, and through an upper bore in the first wing; and anchoring the second end of the tether to the upper bore in the first wing, the first end of the tether anchored to a lower bore in the first wing.

79. The method of claim 75, further comprising a second wing located at the distal end of the central body, wherein the spacer is between the stop and the second wing.

80. The method of claim 79 further comprising tethering the spinous processes and the device wherein the device already is inserted between the spinous processes, and wherein the device has a bioresorbable tether anchored at a first end to the device.

81. The method of claim 80 wherein the tethering step further comprises using a tool to guide a second end of the tether over an upper spinous process, through a bore through the tissue expander, under a lower spinous process, and through a lower bore in the first wing; and anchoring the second end of the tether to the lower bore in the first wing, the first end of the tether anchored to an upper bore in the first wing.

82. The method of claim 80 wherein the tethering step further comprises using a tool to guide a second end of the tether under a lower spinous process, through a bore through the tissue expander, over an upper spinous process, and through an upper bore in the first wing; and anchoring the second end of the tether to the upper bore in the first wing, the first end of the tether anchored to a lower bore in the first wing.

83. A method for remediation of a damaged intervertebral disk, comprising:

accessing the intervertebral space;

inserting a device between the spinous processes of the spinal column using the steps of:

accessing adjacent first and second spinal processes of the vertebrae;

distracting the first and second spinous processes;

implanting the device between the spinous processes; and

where the distracting and implanting steps are done in any order or simultaneously; and

replacing the intervertebral disk; and

wherein the steps of inserting and replacing are done in any order.

84. A method for remediation of a damaged intervertebral disk, comprising:

accessing the intervertebral space;

inserting a device between the spinous processes of the spinal column using the steps of:

accessing adjacent first and second spinal processes of the vertebrae;

distracting the first and second spinous processes;

implanting the device between the spinous processes; and where the distracting and implanting steps are done in any order or simultaneously; and

repairing the intervertebral disk; and

wherein the steps of inserting and repairing are done in any order.

85. In a method for remediation of an intervertebral disk, the improvement including the step of temporarily distracting spinous processes with the implantation of a bioresorbable spacer between the spinous processes.

86. In a method for remediation of an intervertebral disk, the improvement including the step of temporarily maintaining a minimum spacing between the spinous processes with the implantation of a bioresorbable spacer between the spinous processes.

87. The method of claim 83 wherein the inserting step includes inserting a bioresorbable device.

88. The method of claim 84 wherein the inserting step includes inserting a bioresorbable device.

89. A method for remediation of a damaged intervertebral disk, comprising the steps of:

accessing an intervertebral space;

restoring the damaged disk;

inserting a device between spinous processes of the spinal column; and

wherein the steps of restoring and inserting are done in any order.

90. The method as in claim 89 further comprising the step of tethering the spinous processes with a bioresorbable suture after the inserting step.

91. The method as in claim 89 further comprising the step of tethering the spinous processes and the device with a bioresorbable suture after the inserting step.

92. In a method for remediation of an intervertebral disk, the improvement including the step of temporarily distracting spinous processes with the implantation of a spacer between the spinous processes.

93. In a method for remediation of an intervertebral disk, the improvement including the step of temporarily maintaining a minimum spacing between the spinous processes with the implantation of a spacer between the spinous processes.

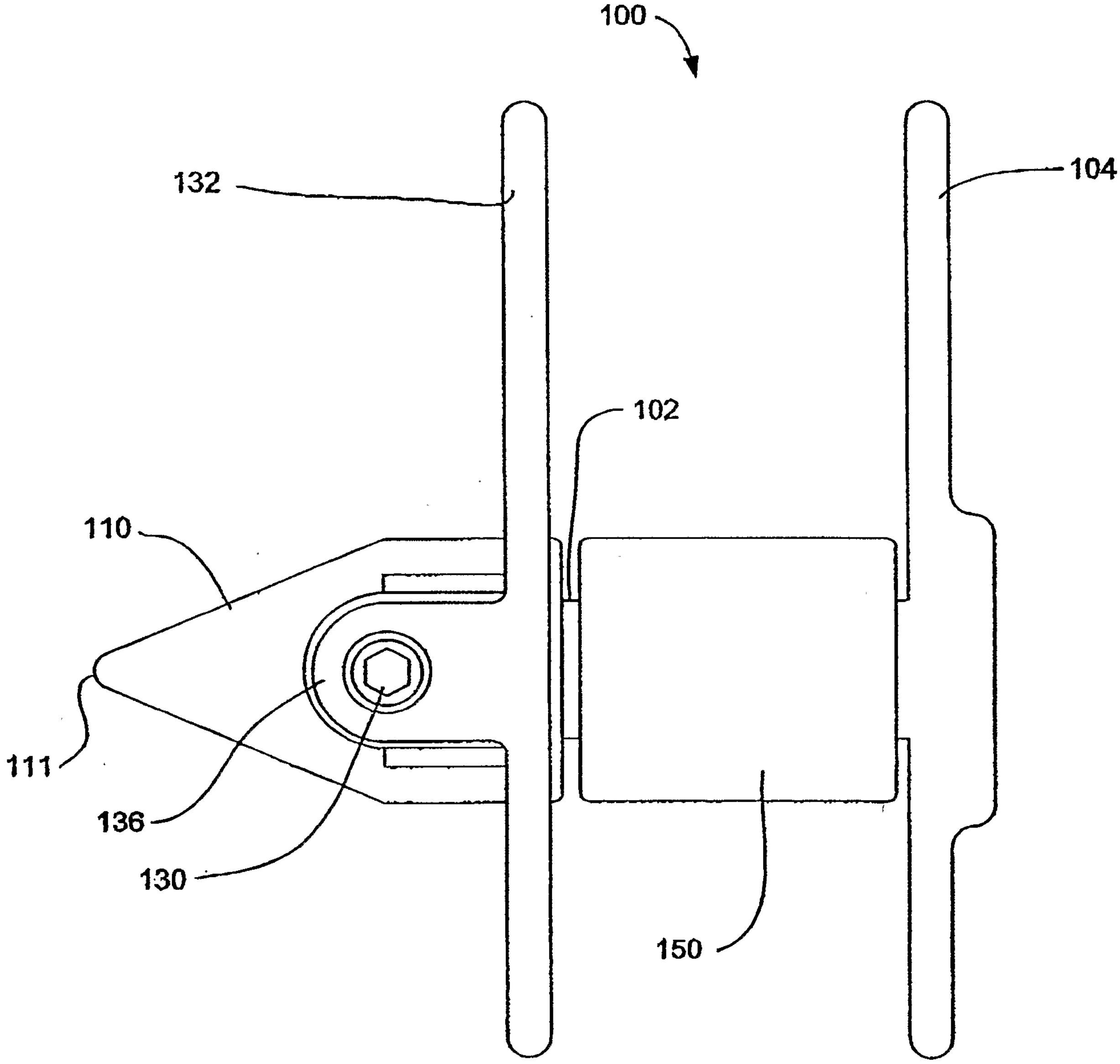

FIG. - 1A

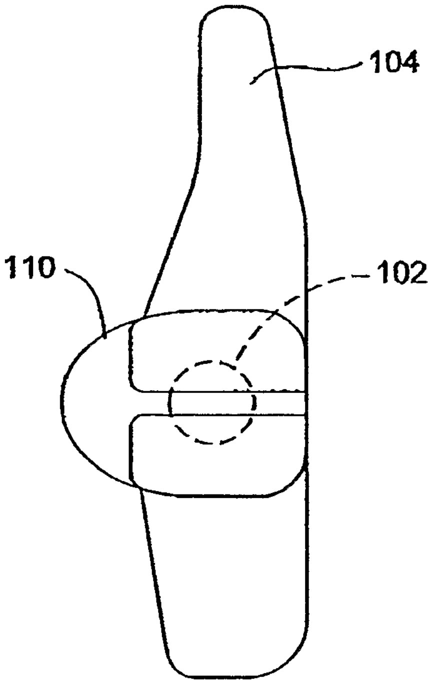

FIG. - 1B

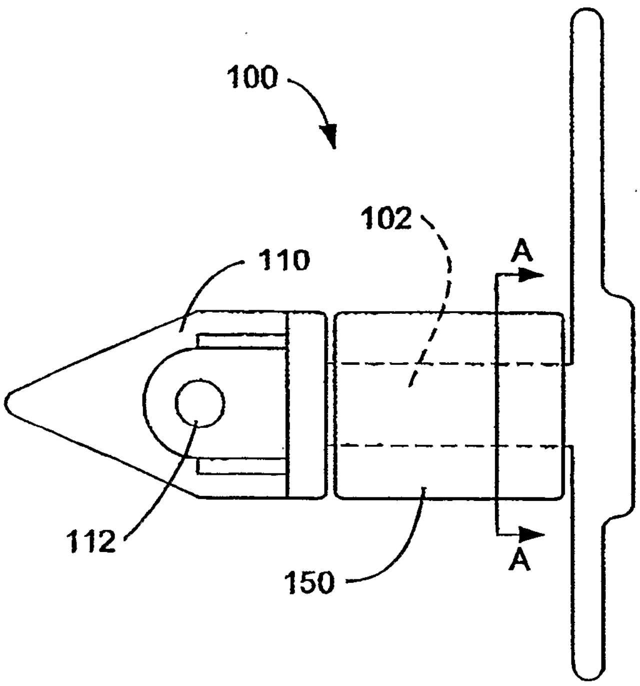

FIG. - 1C

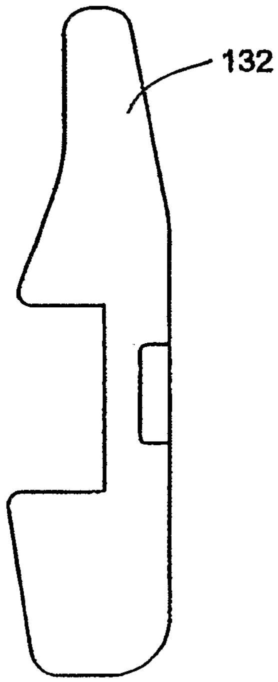

FIG. - 1D

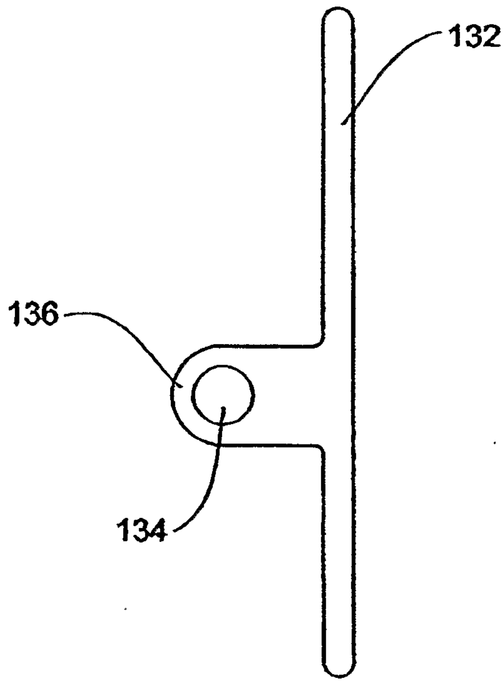

FIG. - 1E

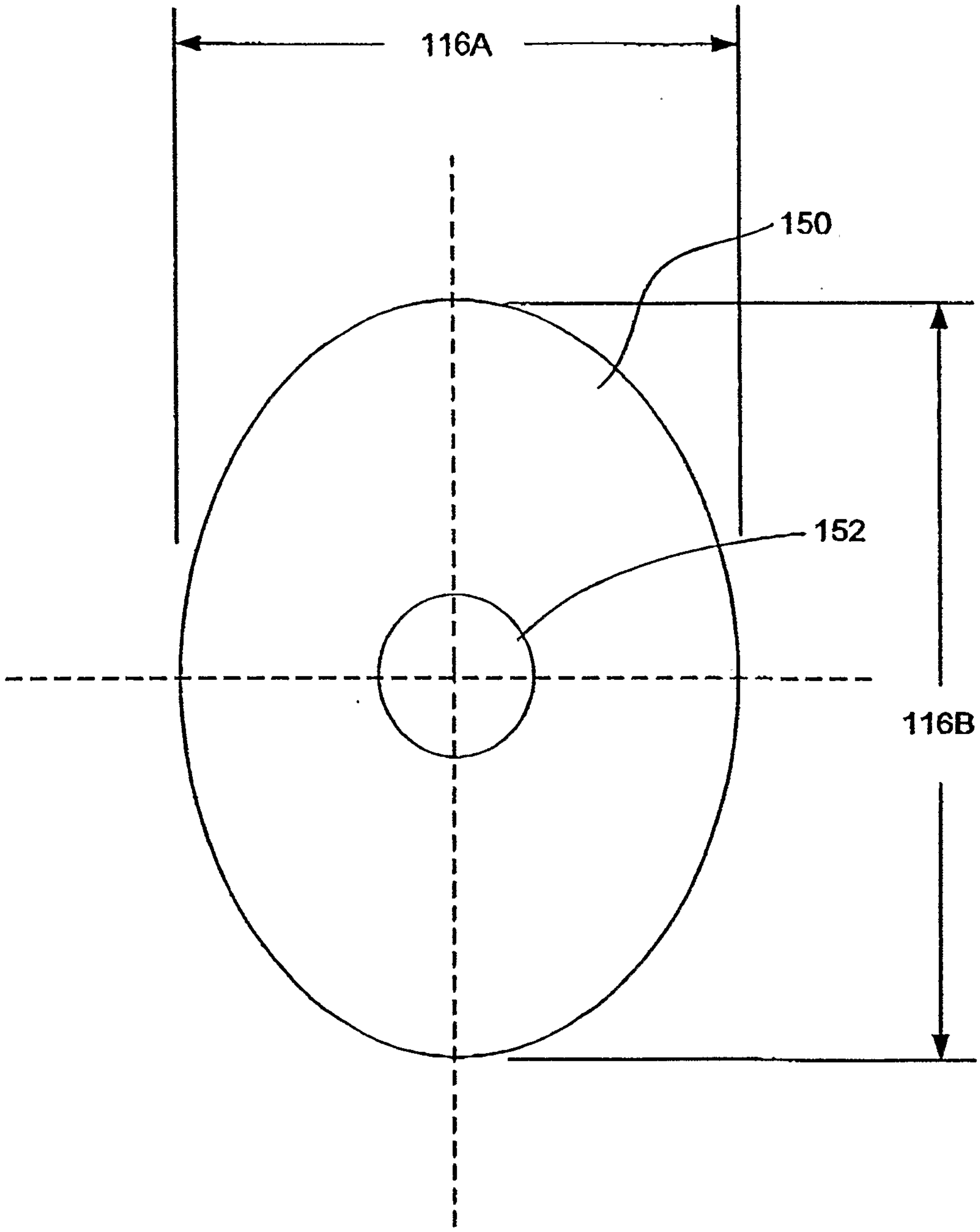

FIG. - 1F

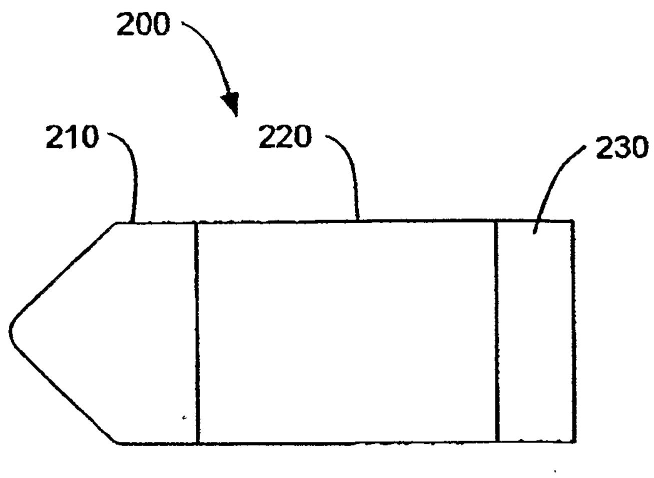

FIG. - 2

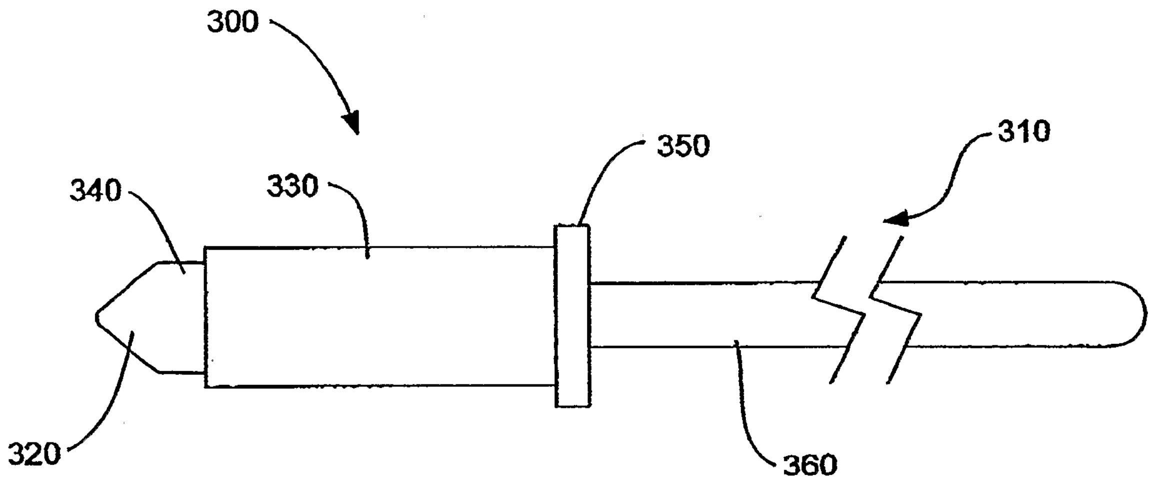

FIG. - 3

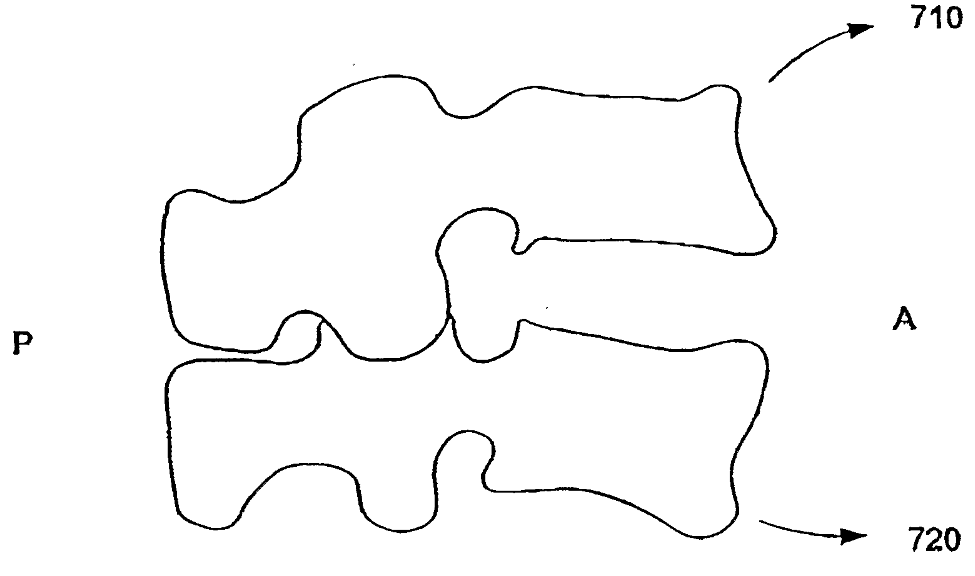

FIG. - 4A

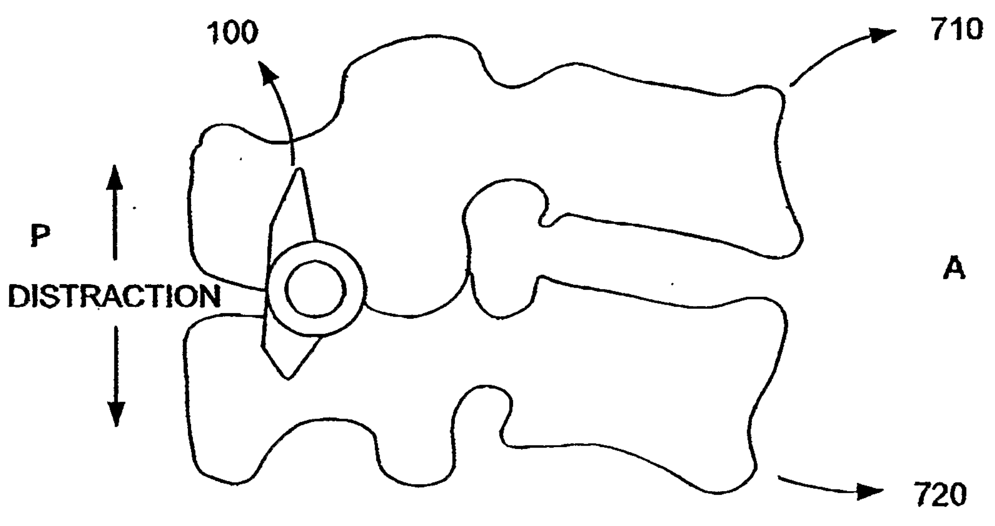

FIG. - 4B

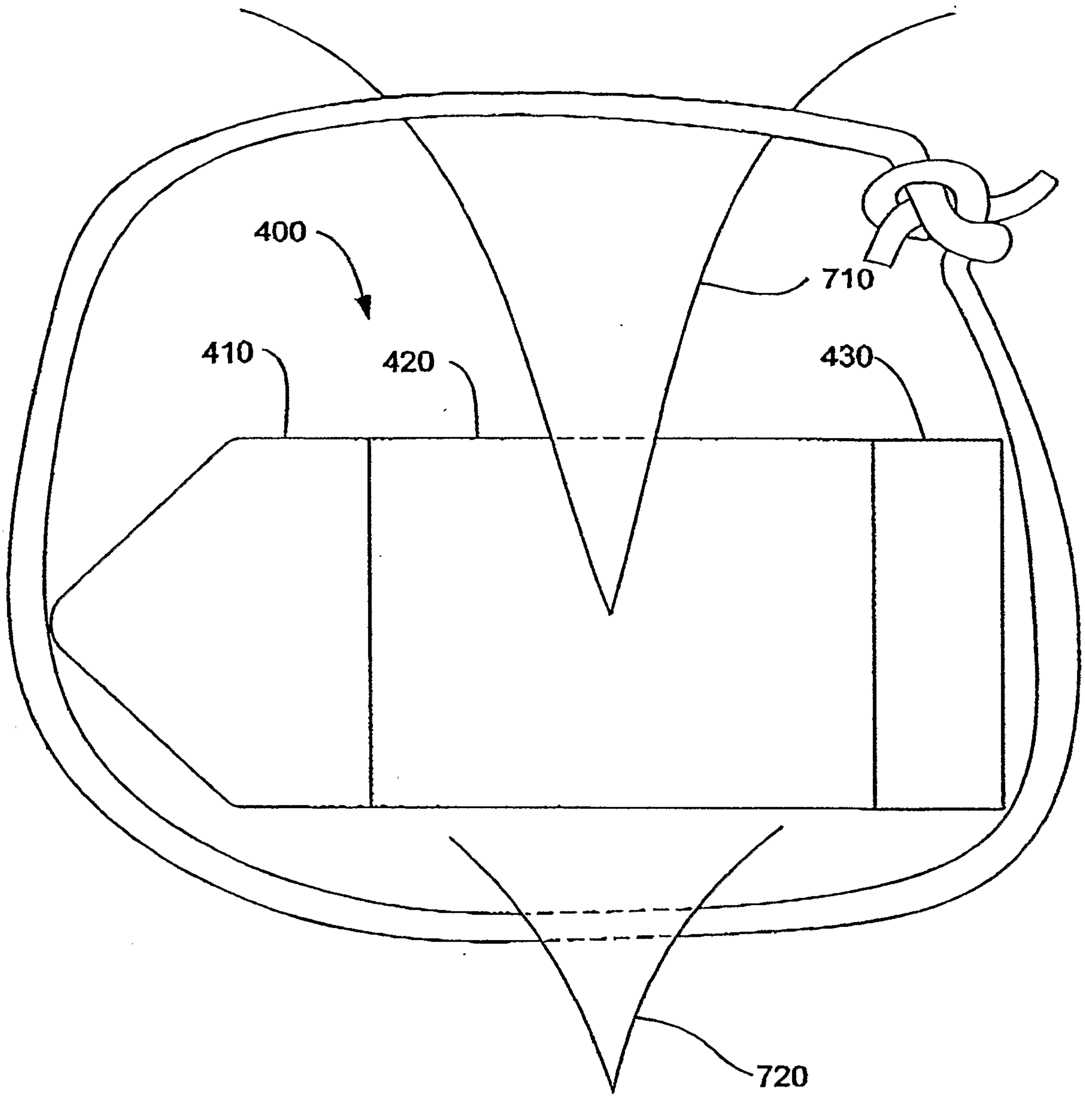

FIG. - 5

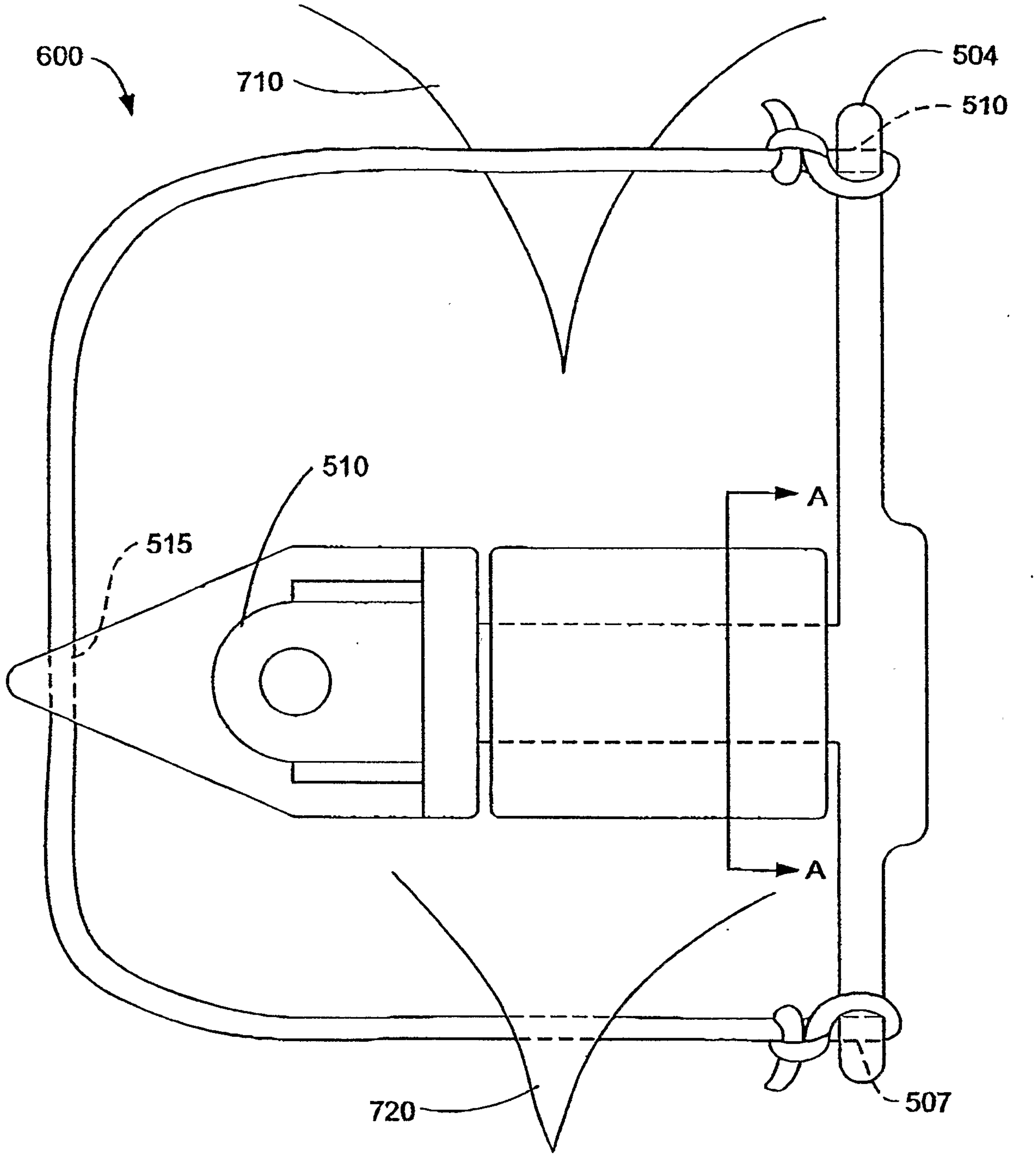

FIG. - 6

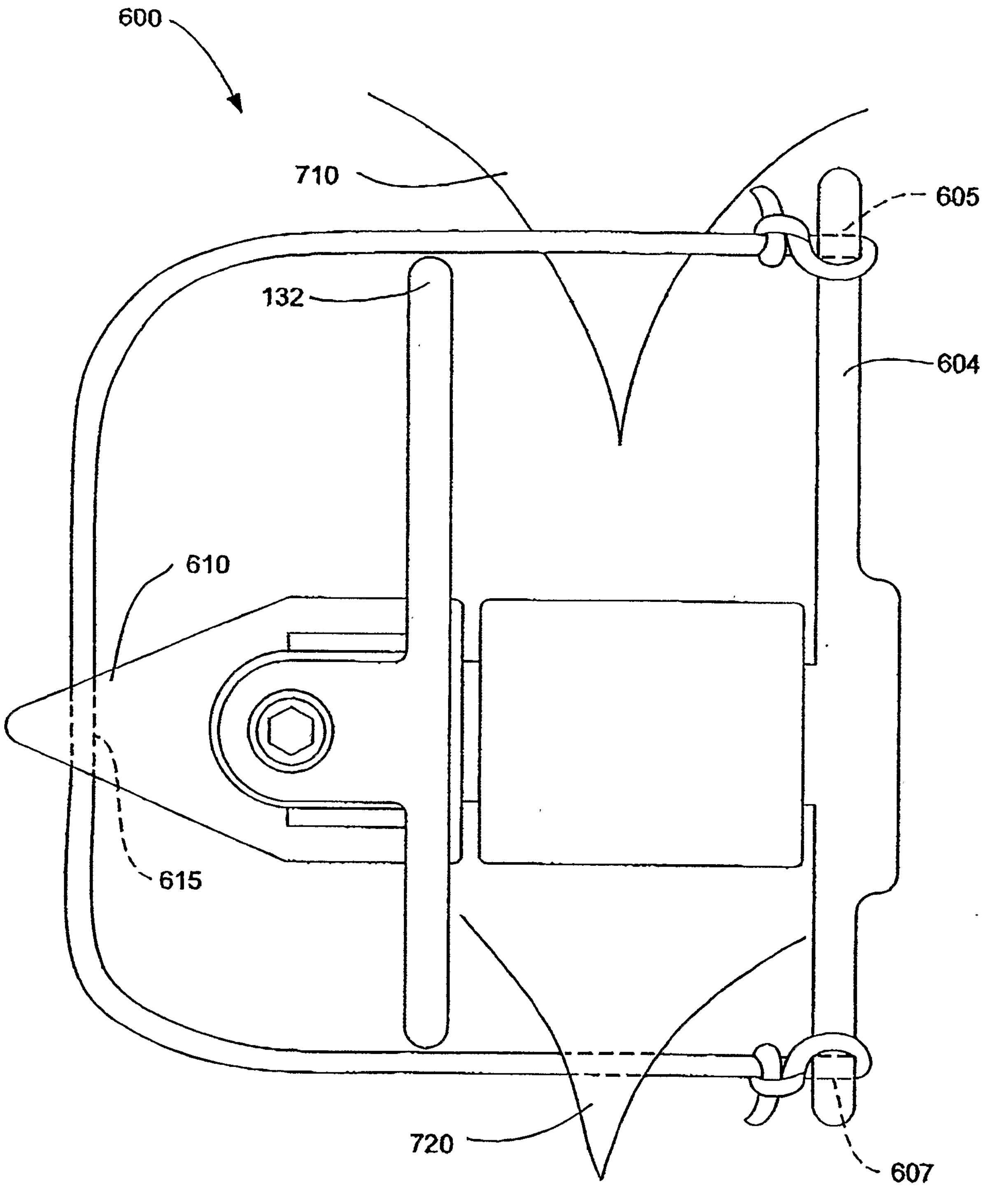

FIG. - 7

(800)

Accessing intervertebral space (810)

↓

Restoring damaged disk (820)

↓

One of implanting bioresorbable device and distracting adjacent spinous processes (830)

↓

The other of implanting bioresorbable device and distracting adjacent spinous processes (840)

↓

Tethering the spinous processes (850), or, tethering the spinous processes and bioresorbable device if said device has at least one of a first wing, and a first wing and a second wing (855)

↓

Fastening the ends of the tether (860)

Fig. 8