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(54) INTERSPINOUS PROCESS DISTRACTION SYSTEM AND METHOD WITH POSITIONABLE WING AND METHOD

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**Related U.S. Application Data**

(63) Continuation of application No. 10/014,118, filed on Oct. 26, 2001, now Pat. No. 6,695,842, and which is a continuation-in-part of application No. 09/799,215, filed on Mar. 5, 2001, which is a continuation-in-part of application No. 09/473,173, filed on Dec. 28, 1999, now Pat. No. 6,235,030, which is a continuation of application No. 09/179,570, filed on Oct. 27, 1998, now Pat. No. 6,048,342.

(60) Provisional application No. 60/306,263, filed on Jul. 18, 2001.

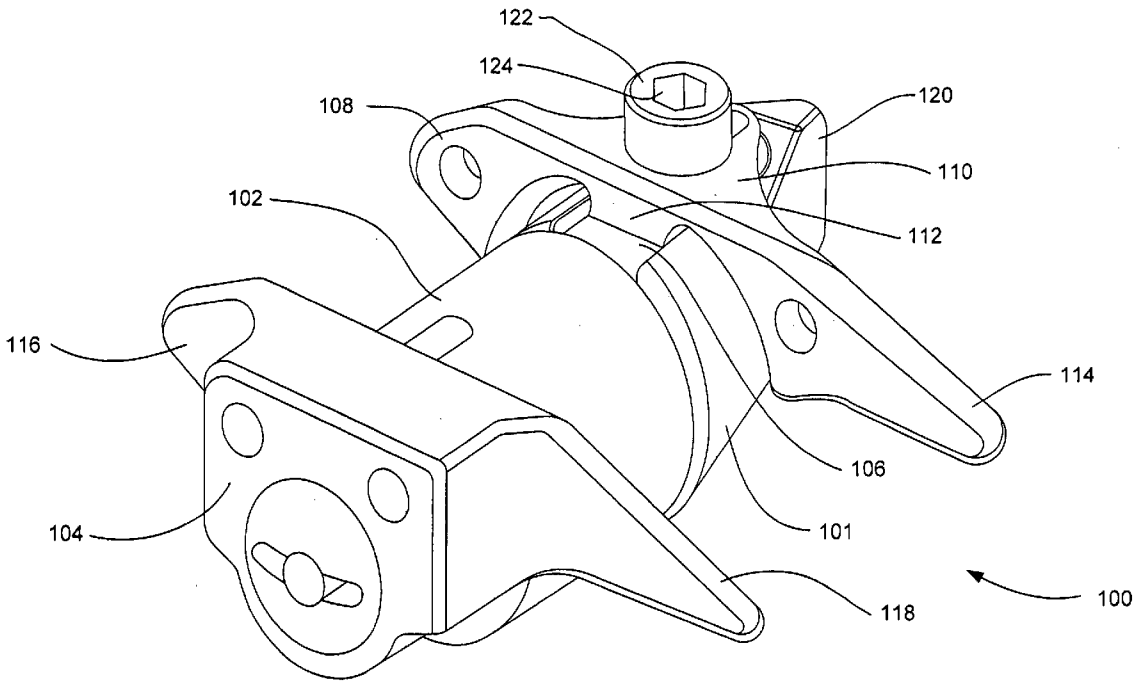
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(52) **U.S. Cl.** ..... **606/61**

(57) **ABSTRACT**

An implant that is implanted between adjacent spinous processes for the relief of pain associated with the spine. The device has a spacer to distract apart the adjacent spinous processes. To minimize trauma to the patient, the device has a tapered tissue expander to distract a previously created opening between the adjacent spinous processes. The device also has two wings. The position of one wing is adjustable to allow for ease of assembly in a patent.



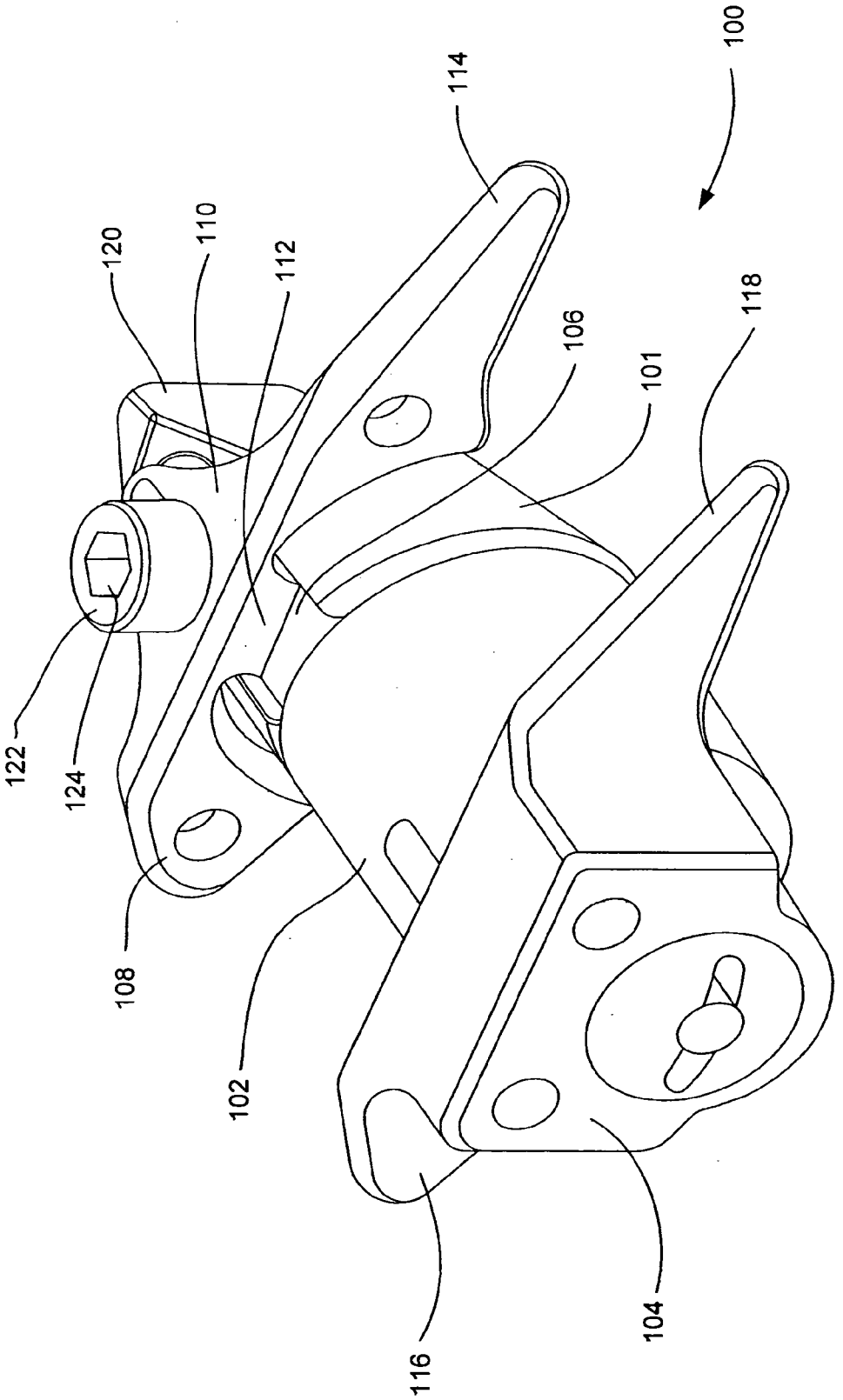



FIG. - 1

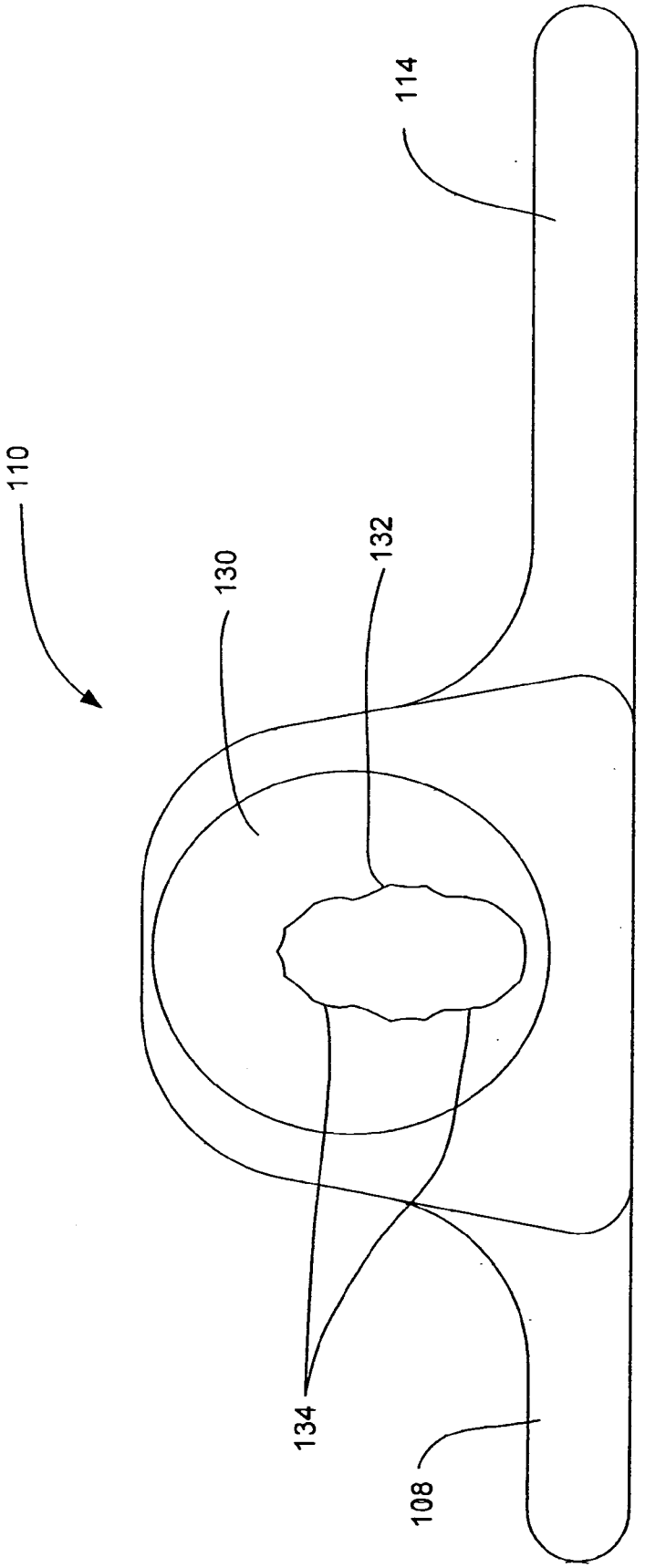



FIG. - 2

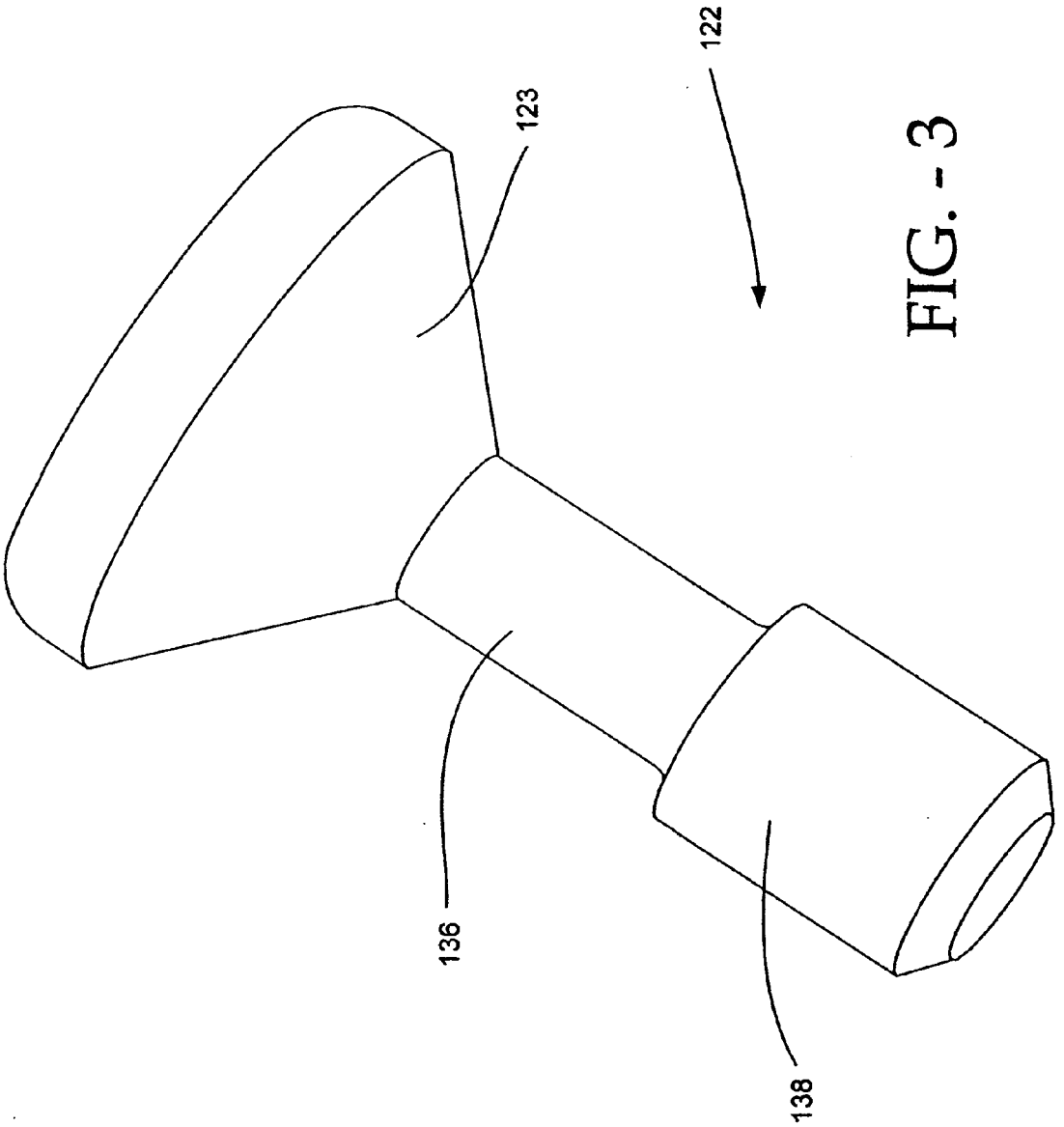



FIG. - 3

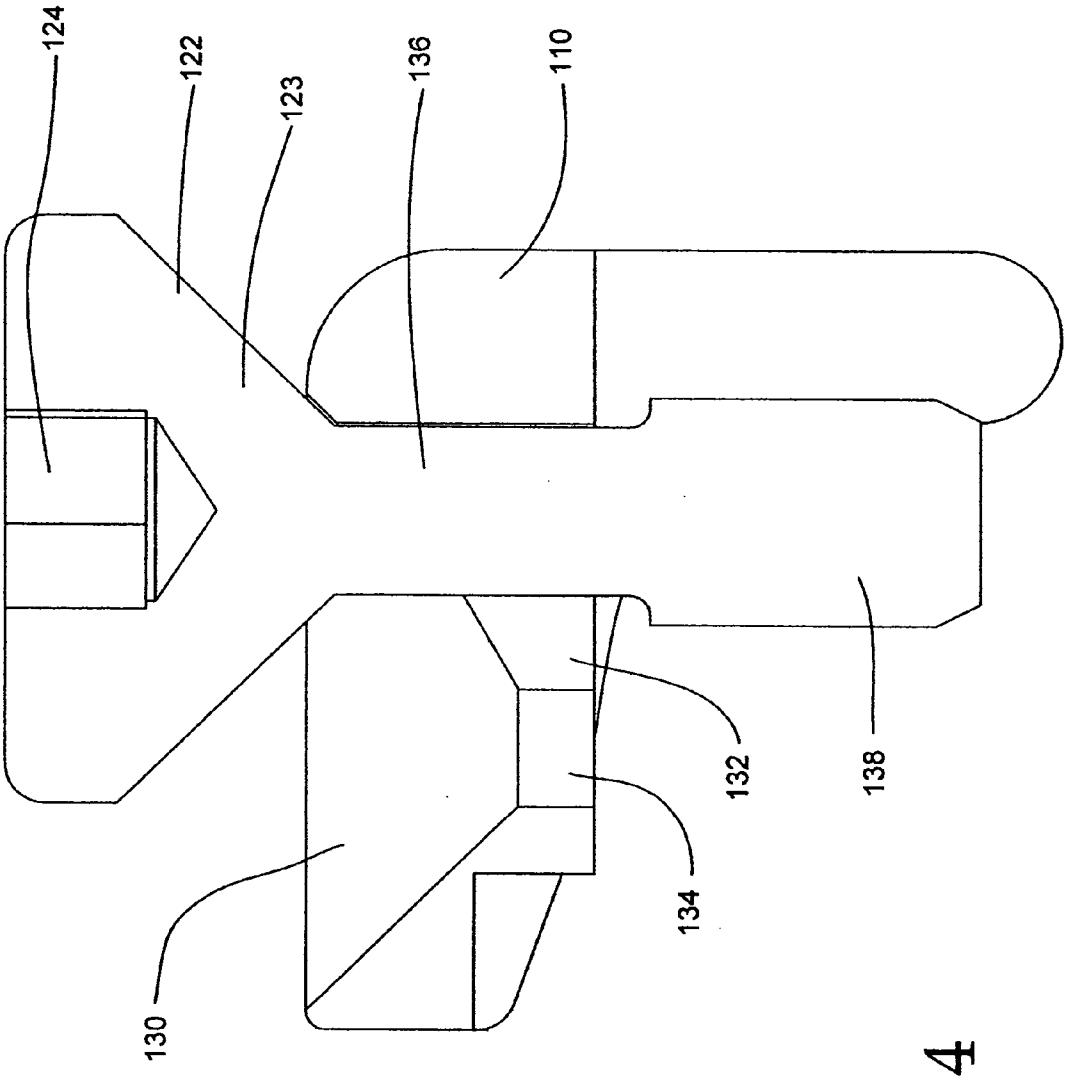



FIG. - 4

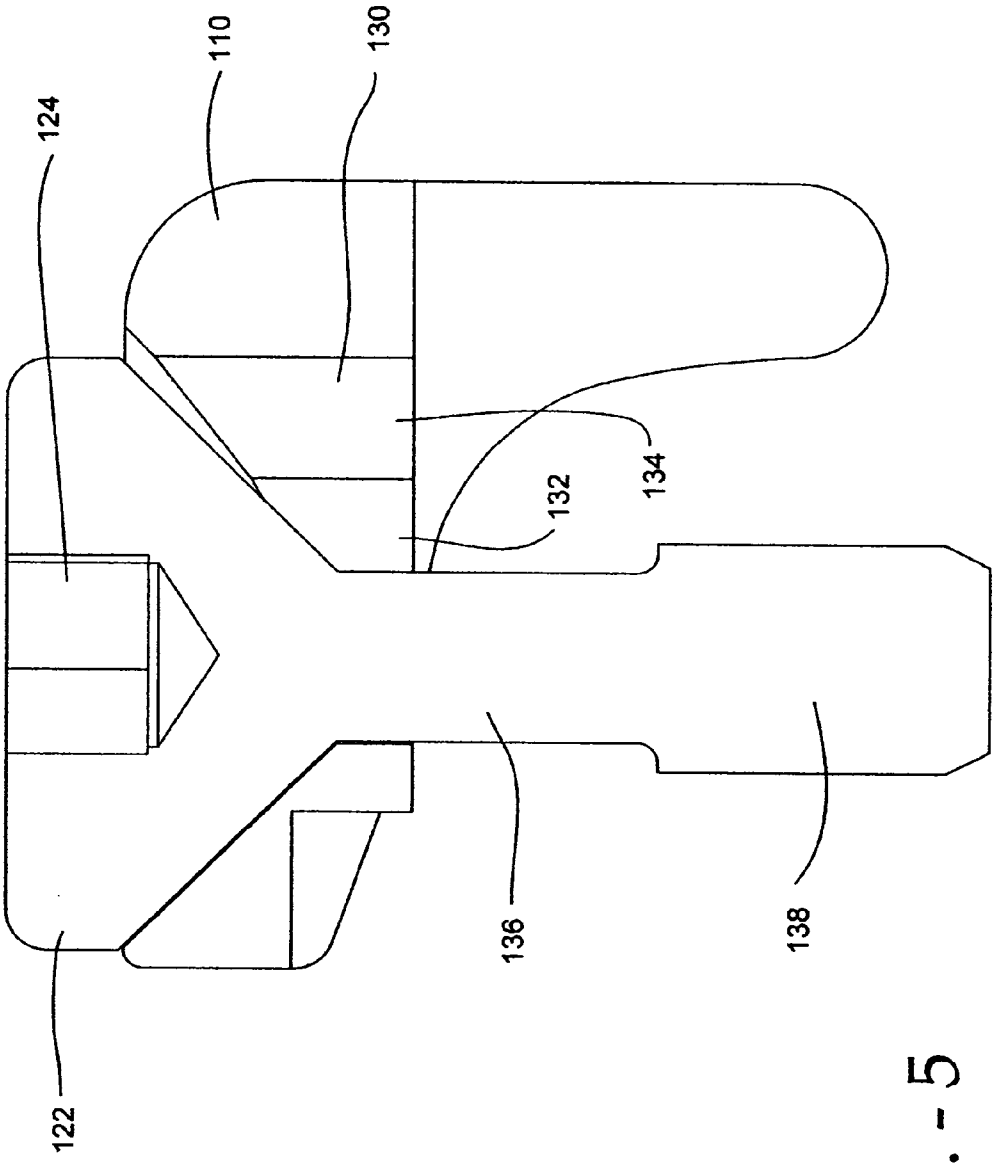



FIG. - 5

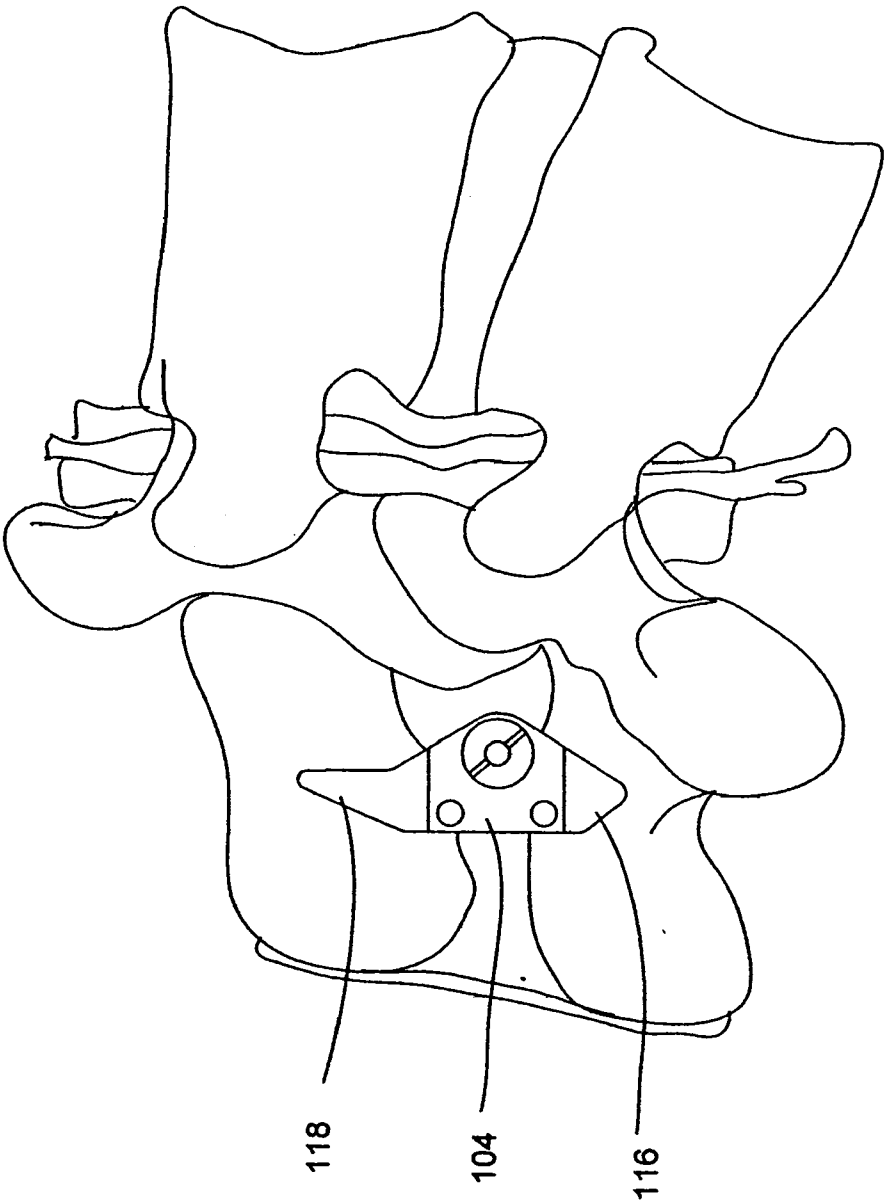



FIG. - 6

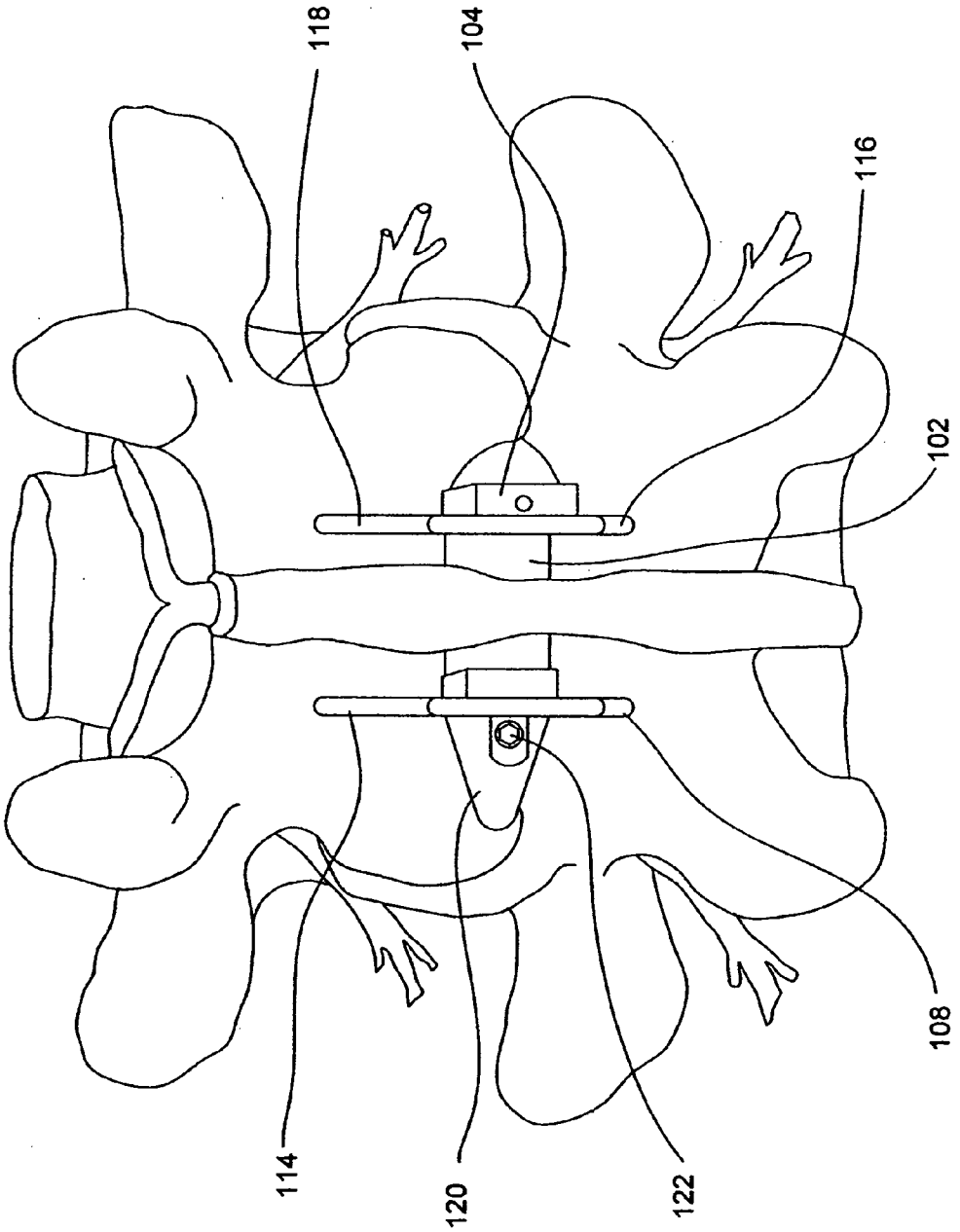



FIG. - 7

# INTERSPINOUS PROCESS DISTRACTION SYSTEM AND METHOD WITH POSITIONABLE WING AND METHOD

## CROSS REFERENCE TO RELATED APPLICATION

[0001] This application is a continuation of, and claims priority to, U.S. patent application Ser. No. 10/014,118, filed Oct. 26, 2001, which claims benefit to U.S. Provisional Application No. 60/306,263, filed Jul. 18, 2001, and is a continuation-in-part of U.S. patent application Ser. No. 09/799,215, filed Mar. 5, 2001, which is a continuation-in-part of U.S. patent application Ser. No. 09/473,173, filed Dec. 28, 1999, now U.S. Pat. No. 6,235,030, which is a continuation of U.S. patent application Ser. No. 09/179,570, filed Oct. 27, 1998, now U.S. Pat. No. 6,048,342, which is a continuation-in-part of U.S. patent application Ser. No. 09/474,037, filed Dec. 28, 1999, now U.S. Pat. No. 6,190,387, which is a continuation of U.S. patent application Ser. No. 09/175,645, filed Oct. 20, 1998, now U.S. Pat. No. 6,068,630, which is a continuation-in-part of U.S. patent application Ser. No. 09/200,266, filed Nov. 25, 1998, now U.S. Pat. No. 6,183,471, which is a continuation of U.S. patent application Ser. No. 09/139,333, filed Aug. 25, 1998, now U.S. Pat. No. 5,876,404, which is a continuation of U.S. patent application Ser. No. 08/958,281, filed Oct. 27, 1997, now U.S. Pat. No. 5,860,977. All of the above applications and patents are incorporated herein by reference in their entireties.

## FIELD OF THE INVENTION

[0002] The present invention is directed to an interspinous process implant system and method which can, for example, distract apart and maintain said distraction of adjacent spinous process.

## BACKGROUND OF THE INVENTION

[0003] 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 only, with aging comes increases in spinal stenosis (including, but not limited to, central canal and lateral stenosis), the thickening of the bones which make up the spinal column and facet arthropathy. Spinal stenosis 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. Of course, it is desirable to eliminate the need for major surgery for all individuals and in particular for the elderly.

[0004] Accordingly, there needs to be developed procedures and implants for alleviating these and other spinal conditions, which procedures and implants are minimally invasive, can be tolerated by the elderly and can be performed preferably on an outpatient basis.

## SUMMARY OF THE INVENTION

[0005] The present invention is directed to providing a minimally invasive apparatus and method for alleviating discomfort associated with the spinal column.

[0006] The present invention provides for apparatus and method for relieving pain by relieving the pressure and restrictions on the aforementioned blood vessels and nerves. Such alleviation of pressure is accomplished in the present invention through the use of an implant and method which distract the spinous process of adjacent vertebra in order to alleviate the problems caused by spinal stenosis and facet arthropathy and the like as well as other spinal ailments. While the implant and method particularly address the needs of the elderly, the invention can be used with individuals of all ages and sizes where distraction of the spinous process would be beneficial.

[0007] In one aspect of the invention, an implant is provided for relieving pain comprising a device positioned between a first spinous process and a second spinous process. The device includes a spinal column extension stop and a spinal column flexion non-inhibitor.

[0008] In a further aspect of the invention, the implant includes a first unit having a body with a guide or tissue expander and a first wing, with the first wing located at first end of the body. The guide extends from a second end of the body located distally from the first wing. The implant further includes a sleeve or spacer provided over said body. The implant further includes a second wing and a device for securing the second wing to the first unit, wherein the sleeve or spacer is located between the first and second wings.

[0009] In yet still a further aspect of the invention, the implant includes a sleeve which is rotatable relative to the wings of the implant in order to be able to accommodate the anatomical structure of spinous processes.

[0010] In still another aspect of the invention, the implant includes a second wing that is movable toward the first wing after the second wing is assembled to the first unit in the patient. In this aspect a fastener can be operated to cause the second wing to move toward the first wing. Accordingly, the implant can be easily assembled in the patient without concern for the shape of the spinous processes and then the first and second wings can be drawn together so that these wings are positioned closer to the spinous processes.

[0011] In another aspect the second wing includes an alignment tab which is received in an alignment groove of the first unit in order to guide the second wing as it is urged toward the first wing.

[0012] In another aspect of the invention a ramp mechanism is used to urge the second wing toward the first wing.

[0013] Other implants and methods within the spirit and scope of the invention can be used to release pain associated with the spine and/or increase the volume of the spinal canal thereby alleviating restrictions on vessels and nerves associated therewith and associated pain.

## BRIEF DESCRIPTION OF THE DRAWINGS

[0014] **FIG. 1** is a perspective view of an embodiment of the present invention;

[0015] **FIG. 2** is a top view of an embodiment of the adjustable wing of the present invention;

[0016] **FIG. 3** is a perspective view of an embodiment of the fastener used in the present invention;

[0017] **FIG. 4** is cut-away view illustrating the interaction between the fastener and the adjustable wing with the adjustable wing is in a first position;

[0018] **FIG. 5** is a cut-away view illustrating the fastener engaging the adjustable wing with the adjustable wing in a second position;

[0019] **FIG. 6** is a side view illustrating an embodiment of the present invention as implanted between adjacent spinous processes; and

[0020] **FIG. 7** is a front view of an embodiment of the present invention as implanted between adjacent spinous processes.

## DETAILED DESCRIPTION OF THE INVENTION

[0021] Referring to **FIG. 1**, the implant device **100** has a main body **101**. The main body **101** includes a spacer **102**, a first wing **104**, a tapered front end, lead-in guide or tissue expander **120** and an alignment track **106**. The main body **101** is inserted between adjacent spinous processes. Preferably, the main body **101** remains safely and permanently in place without attachment to the bone or ligaments. All of the components of the implant device **100** are made of biologically acceptable material such as, but are not limited to, high strength titanium alloy or stainless steel. Preferably the first wing **104** is laser welded to the main body **101**.

[0022] The tip of the tissue expander **120** has the smallest diameter, allowing the tip to be inserted into a small initial dilated opening. The diameter and/or cross-sectional areas of the tissue expander **120** then gradually increases until it is substantially similar to the diameter of the main body **101** and spacer **102**. The tapered front end **120** makes it easier for a physician to urge the implant device **100** between adjacent spinous processes. When urging the main body **101** between adjacent spinous processes, the front end **120** distracts the adjacent spinous processes to the diameter of the spacer **102**. As shown in **FIG. 1**, the tissue expander **120** is a pyramid shape. In another embodiment the tissue expander preferably has an angle of twenty-five degrees that allows it to clear the facet. This reduces the length of the front end **120**. One will appreciate that the shape of the tissue expander **120** can be other shapes such as, but not limited to, cone shaped, or any other shape with a small lead-in cross-section expanding into a larger cross-section. These types of shapes gradually distract the spinous processes to a sufficient distance so that the spacer **102** can conveniently fit between the spinous processes.

[0023] The spacer **102** can be made of stainless steel, titanium, a super-elastic material or silicone or other biologically acceptable material. The material can be rigid or resilient as desired. As shown in **FIG. 1**, the spacer **102** is an elliptically shaped cylinder. One will appreciate that the spacer can consist of other shapes such as, but not limited to, egg-shaped, round-shaped or saddle-shaped. For example, the spacer **102** can be saddle-shaped along the surface which engages the spinous processes so that the high edges and the lower central portions can more fully accommodate the shape of the spinous processes. Preferably, the spacer **102** can swivel, allowing the spacer **102** to self-align relative to the uneven surface of the spinous process. This ensures that compressive loads are distributed equally on the surface of the bone. By way of example only, the spacer **102** can have diameters of six millimeters, eight millimeters, ten millimeters, twelve millimeters and fourteen millimeters. These diameters refer to the height by which the spacer distracts and maintains apart the spinous process. Thus for an elliptical spacer the above selected height would represent the small diameter measurement from the center of the ellipse. The largest diameter would be transverse to the alignment, of the spinous process, one above the other. Smaller and larger diameters are within the scope of the invention.

[0024] The shape of the spacer **102** and for that matter the shape of the entire implant is such that for purposes of insertion between the spinous processes, the spinous processes do not need to be altered or cut away in any manner in order to accommodate the implant **100**. Additionally, the associated ligaments do not need to be cut away and there would be very little or no damage to the other adjacent or surrounding tissues other than piercing through and separating, or dilating an opening in a ligament.

[0025] The first wing **104** has a lower portion **116** and an upper portion **118**. The upper portion **118** is designed to preferably accommodate, in this particular embodiment, the anatomical form or contour of the L4 (for an L4-L5 placement) or L5 (for an L5-S1 placement) vertebra. It is to be understood that the same shape or variations of this shape can be used to accommodate other vertebra. The lower portion **116** is also rounded to accommodate, in a preferred embodiment, the vertebra. The lower portion **116** and upper portion **118** of the first wing **104** will act as a stop mechanism when the implant device **100** is inserted between adjacent spinous processes. The implant device **100** cannot be inserted beyond the surfaces of the first wing **104**. Additionally, once the implant device **100** is inserted, the first wing **104** can prevent side-to-side, or posterior to anterior movement of the implant device **100**.

[0026] The implant device **100** also has an adjustable wing **110**. The adjustable wing **110** has a lower portion **108** and an upper portion **114**. Similar to the first wing **104**, the adjustable wing **110** is designed to accommodate the anatomical form or contour of the vertebra.

[0027] The adjustable wing **110** is secured to the main body **101** with a fastener **122** provided through tapered cavity **130**. The adjustable wing **110** also has an alignment tab **112**. When the adjustable wing **110** is initially placed on the main body **101**, the alignment tab **112** engages the alignment track **106**. The alignment tab **112** slides within the alignment track **106** and helps to maintain the adjustable wing **110** substantially parallel with the first wing **104** in this preferred embodiment. When the main body **101** is inserted into the patient and the adjustable wing **110** has been attached, the adjustable wing **110** also can prevent side-to-side, or posterior to anterior movement.

[0028] Referring now to **FIG. 2**, the adjustable wing **110** includes the above mentioned tapered cavity **130**. The tapered cavity **130** has a middle portion **132**, two end portions **134** and a tapered wall **131**. The diameter of the middle portion **132** is larger than the diameter of either end portion **134**. The tapered wall **131** has a larger diameter at the top surface of the adjustable wing **110** than at the bottom surface. Accordingly a cone-like shape is formed. When the fastener **122** engages the main body **101** and is rotated, the fastener **122** travels into the main body **101** (see **FIG. 1**). As the fastener **122** travels into the main body **101**, the adjustable wing **110** will travel along the alignment track **106** towards the first wing **104**. The alignment tab **112** engages

the alignment track **106** and functions as a guide, keeping the adjustable wing **110** and the first wing **104** substantially parallel to each other.

[**0029**] The fastener **122** has a tapered head **123**, a middle section **136** and threaded bottom section **138** (see **FIG. 3**). The top end of the tapered head **123** was a diameter substantially similar to the diameter of the top surface of the tapered cavity **130**. The diameter of the tapered head **123** is reduced as the tapered head meets the middle section **136**. The slope of the tapered head **123** is similar to the slope of the tapered cavity **130** of the adjustable wing **110**. The middle section **136** has a diameter substantially similar to the end portions **134** of the adjustable wing **110**. The threaded bottom section **138** has a slightly larger diameter than the middle section **136** and is in one embodiment slightly smaller than the diameter of the middle portion **132** of the adjustable wing **110**.

[**0030**] As the diameter of the end portions **134** are smaller than the diameter of the bottom section **138**, the fastener **122** cannot initially be placed through the end portions **134** of the adjustable wing **110**. Accordingly, to fasten the adjustable wing **110** to the main body **101**, the threaded bottom section **138** of the fastener **122** is placed through the middle portion **132** of the adjustable wing **110** and into the main body **101**. With a turn of the fastener **122**, the threaded portion of the bottom section **138** will engage the main body **101**.

[**0031**] In another preferred embodiment the diameter of threaded bottom section **138** is larger than the diameter of the middle portion of the adjustable wing **110**. For this embodiment, the fasteners **122** is inserted into the cavity **130** by slicing the cavity **130** (**FIG. 2**) through the thinnest portion of the wall, spreading the wall open, inserting the middle section **136** in the cavity with the threaded bottom section **138** projection below the cavity **130**, and laser welding the wall closed. The slicing step preferably includes using a carbide slicing device.

[**0032**] When the adjustable wing **110** is in the position furthest from the position of the first wing **104**, the tapered head **123** of the fastener **122** is substantially out of, and not engaging, the tapered cavity **130** of the adjustable wing **110** (See **FIG. 4**). As the fastener **122** is rotated, the fastener **122** will continue to engage, and travel further into, the main body **101**. As the fastener **122** travels downwardly into the main body **101**, the tapered head **123** of the fastener **122** contacts the wall **131** of the tapered cavity **130**. The adjustable wing **110** can freely slide back and forth, limited by the end portions **134** of the tapered cavity **130**. When the tapered head **123** contacts the wall **131** of the tapered cavity **130**, the adjustable wing **110** moves towards the first wing **104** guided by the alignment tab **112** in the alignment track **106**. Therefore, the adjustable wing **110** remains substantially parallel to the first wing **104** in this preferred embodiment as the adjustable wing **110** moves toward the first wing **104** (see **FIG. 5**). It is to be understood that the tab **112** and the track **106** can be eliminated in another embodiment of the invention.

[**0033**] As shown in **FIG. 5**, the tapered head of **123** of the fastener **122** is mated in the tapered wall **131** of the adjustable wing **110**. Accordingly, with this ramp mechanism, the adjustable wing **110** is urged toward the spinous processes and the first wing **104** and is locked in position at its closest approach to the first wing **104**. This arrangement allows the surgeon to loosely assemble the implant in the patient and then urge the adjustable wing closer to the first wing, by rotating fastener **122** into body **110** making the implanting method more tolerant to the anatomy of the patient.

[**0034**] The structure of the spine is of course unique for every patient. Accordingly if the width of the spinous processes is excessive, the adjustable wing can be left in a position that is between that shown in **FIG. 4** and that shown in **FIG. 5**. The separation between the first wing **104** and the adjustable wing **110** can be incrementally adjusted by the number of turns of the fastener **122**.

[**0035**] **FIGS. 6 and 7** illustrate the position of the implant device **100** in a patient. As shown by **FIG. 6**, the lower portion **116** and upper portion **118** of the first wing **104** function to prevent side-to-side movement, toward and away from the vertebral body ensuring that the implant device **100** remains in place. Similarly, the adjustable wing **110** will also prevent excessive side-to-side movement. The wing also prevents motion in the direction of the main body into the space between the spinous processes.

[**0036**] The foregoing description of preferred embodiments of the present invention has been provided for the purposes of illustration and description. It is not intended to be exhaustive or to limit the invention to the precise forms disclosed. Obviously, 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 the invention and its practical application, thereby enabling others skilled in the art to understand the invention for various embodiments and with various modifications that are suited to the particular use contemplated. It is intended that the scope of the invention be defined by the following claims and their equivalence.

**1**. An implant for maintaining a space between adjacent anatomical structures, the implant comprising:

a spacer;

a wing; and

ramp device that positions the wing relative to the spacer.

**2**. An implant for maintaining a space between adjacent anatomical structures, the implant comprising:

a spacer;

a wing;

means for fastening the wing relative to the spacer; and

said fastening means including a ramp means for causing the wing to move relative to the spacer.

* * * * *