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(54) **SHEATH ASSEMBLY FOR SPINAL STABILIZATION DEVICE**

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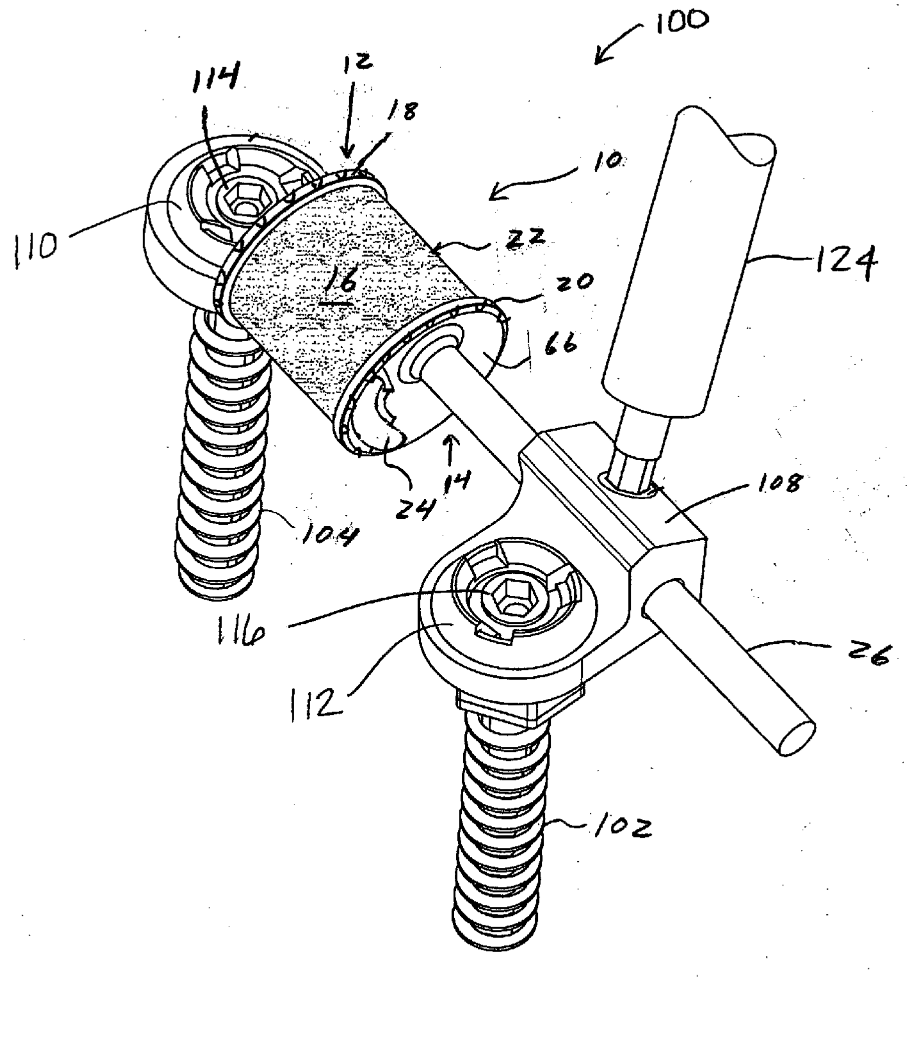
(52) **U.S. Cl.** **606/61**

(57) **ABSTRACT**

Systems, assemblies and methods for assembling a sheath member with respect to a spinal stabilization device are provided. The disclosed sheath assembly includes at least one connector ring mounted with respect to a sheath member. The connector ring defines an inner wall that shields the sheath member from elements positioned therewithin, e.g., spring members, and generally includes a plurality of radially-spaced notches. The connector ring receives the sheath member within an internal cavity and is secured thereto by crimping, compression or swaging. The sheath assembly may be mounted with respect to a spinal stabilization device by crimping, compressing or swaging the connector ring to an underlying structure, e.g., an end cap or associated flange. The internal cavity of the connector ring is generally defined by an inner face, an outer wall and an intermediate apex region. Methods for assembly are also disclosed.



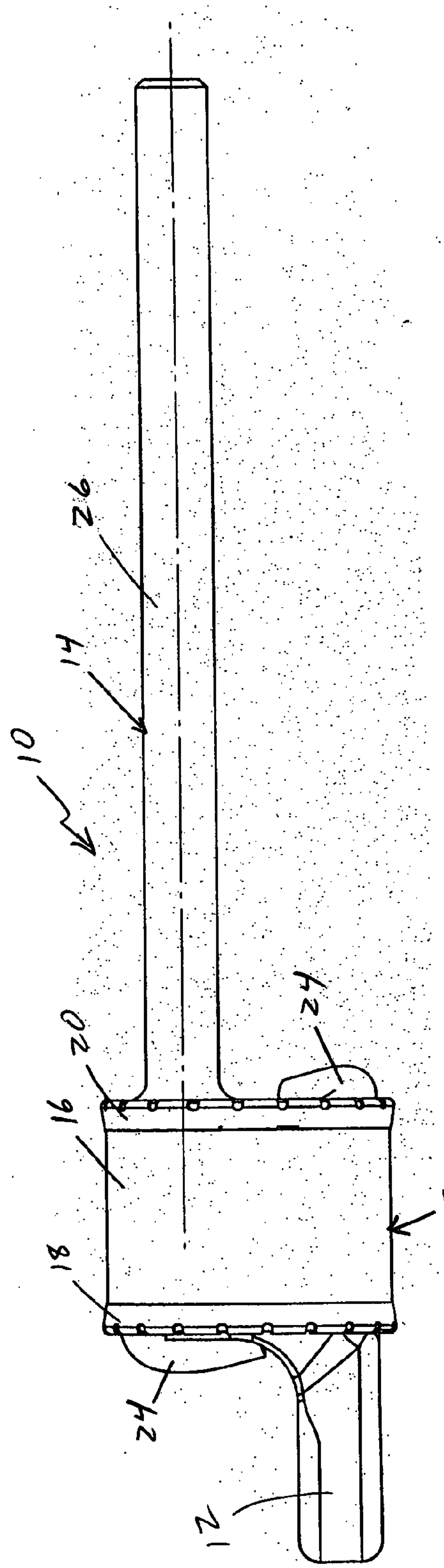


FIG. 1A

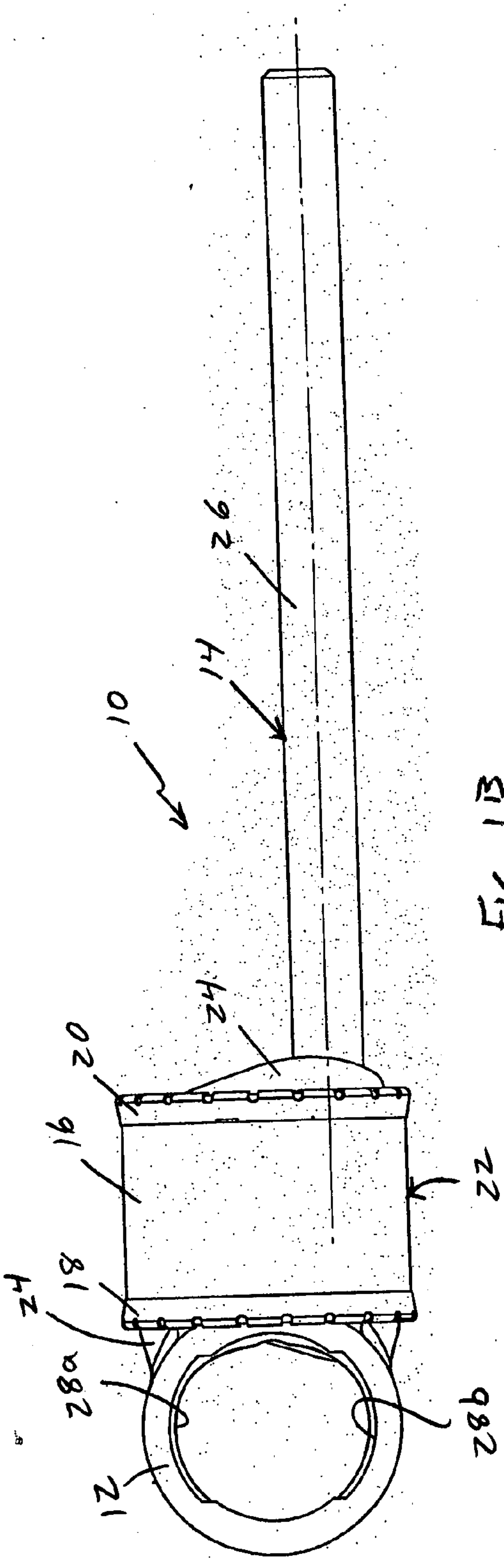


FIG. 1B

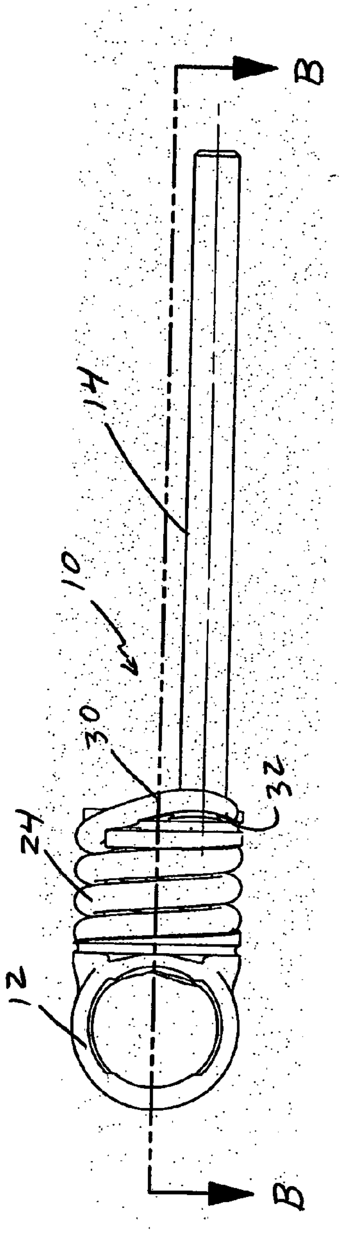


FIG. 2A

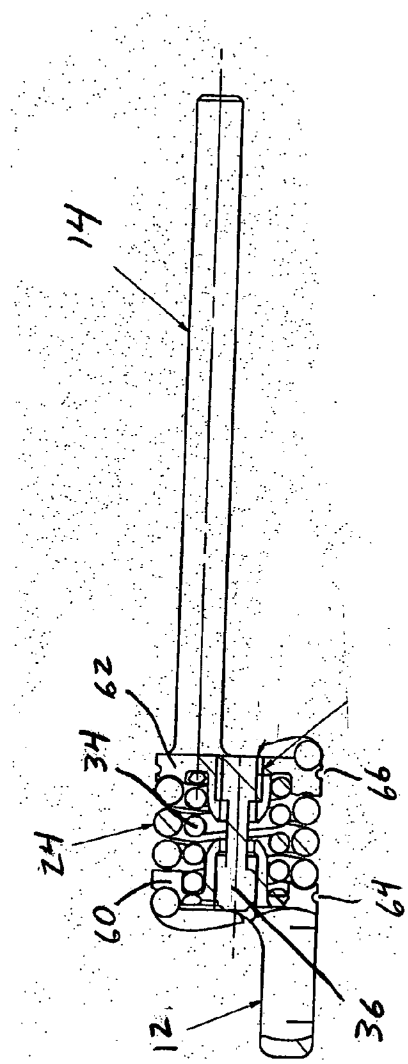


FIG. 2B

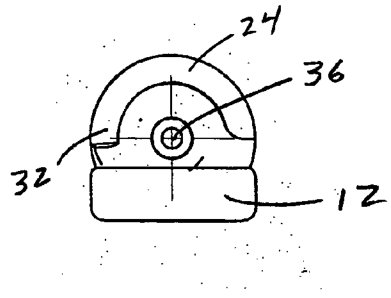


FIG. 2C

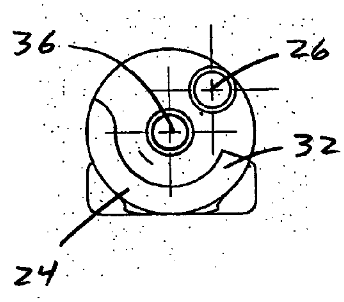


FIG. 2D

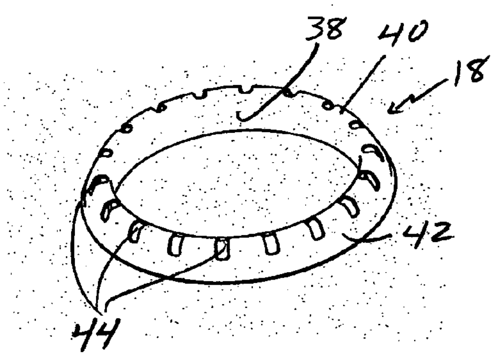


FIG. 3A

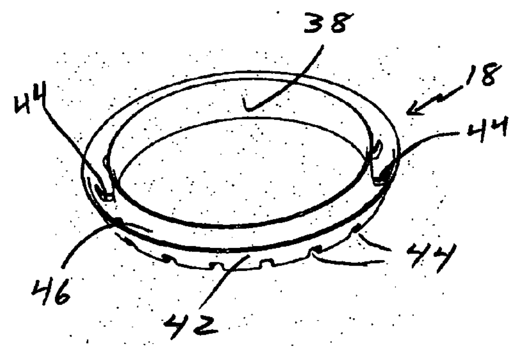


FIG. 3B

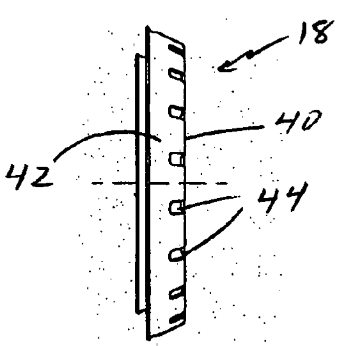


FIG. 3C

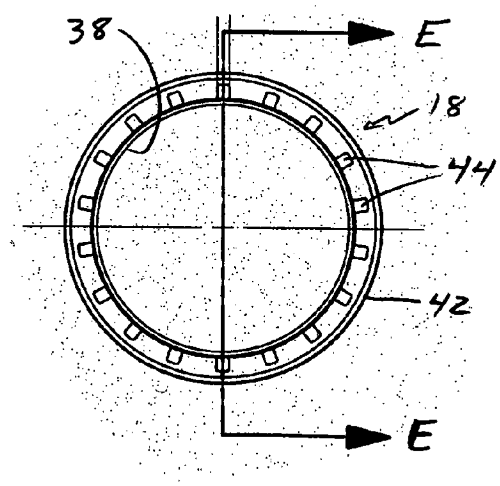


FIG. 3D

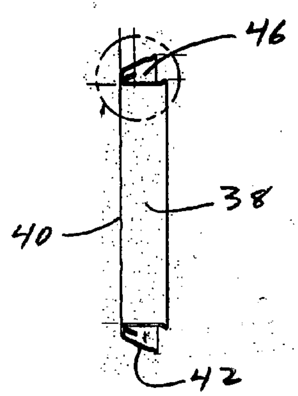


FIG. 3E

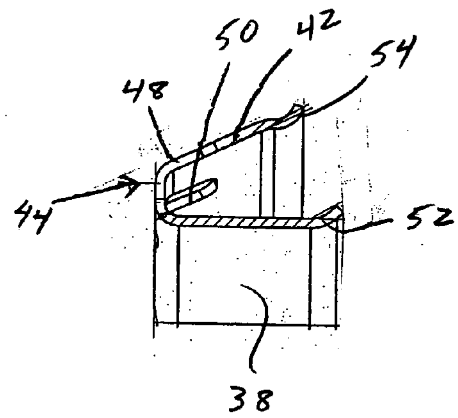


FIG. 4

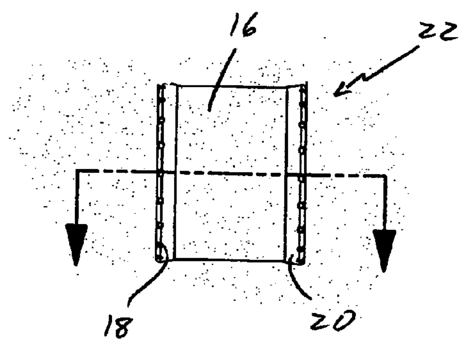


FIG. 5A

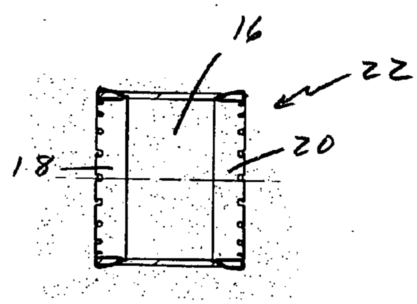


FIG. 5B

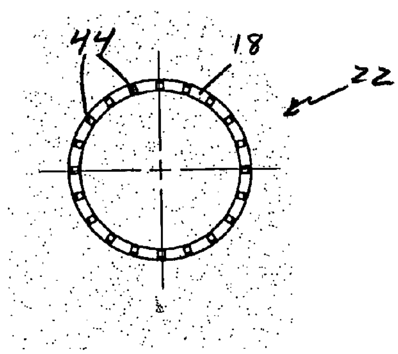


FIG. 5C

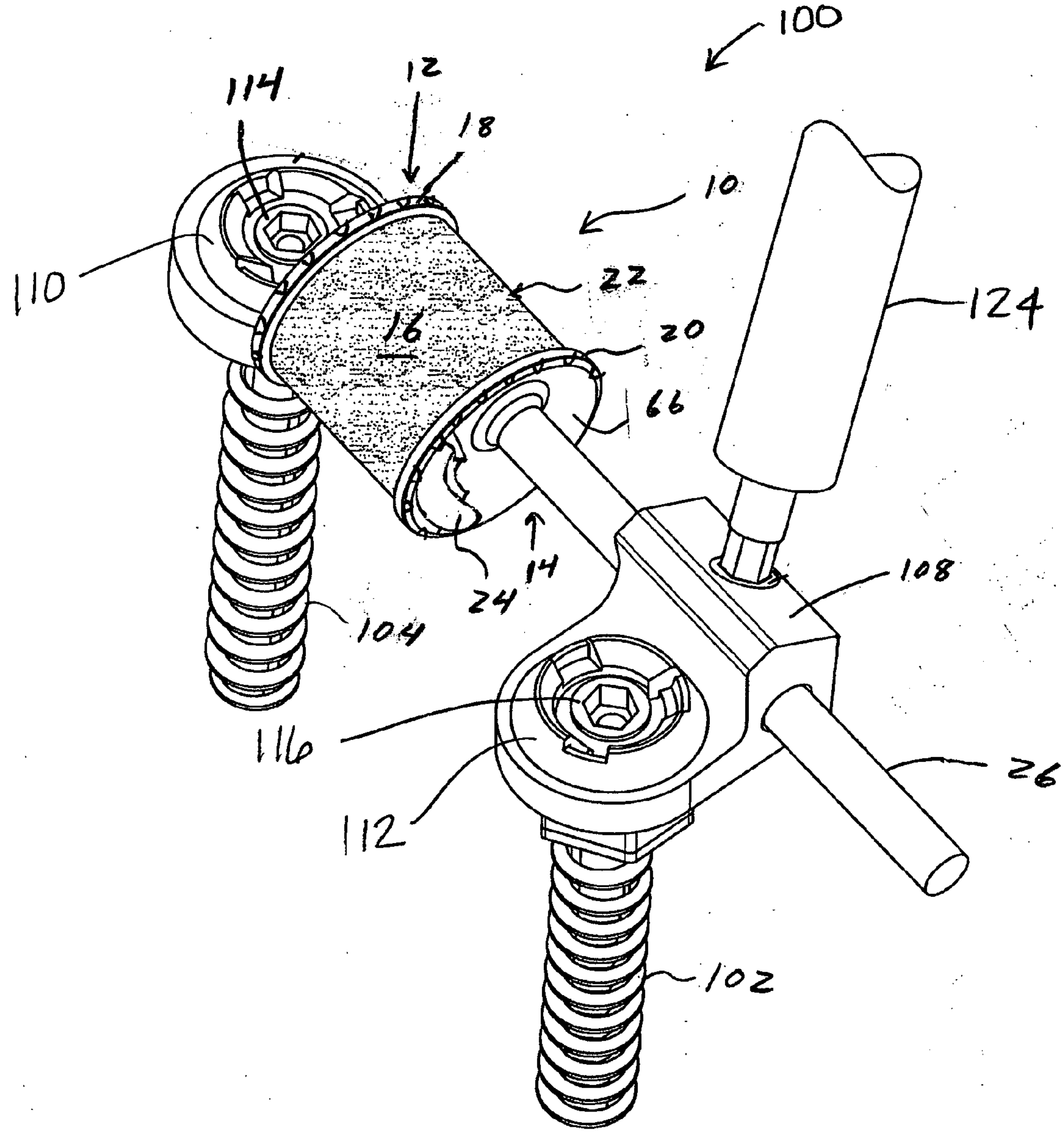


FIG. 6

SHEATH ASSEMBLY FOR SPINAL STABILIZATION DEVICE

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] The present application is a continuation-in-part of a co-pending, commonly assigned U.S. patent application entitled "Surgical Implant Devices and Systems Including a Sheath Member," which was filed on Dec. 31, 2004 and assigned Ser. No. 11/027,073. The entire contents of the foregoing patent application are incorporated herein by reference.

BACKGROUND

[0002] 1. Technical Field

[0003] The present disclosure is directed to a system and method for assembling a sheath with respect to a spinal stabilization device. More particularly, the present disclosure is directed to a sheath subassembly that includes at least one connector ring mounted with respect to a sheath member, and methods for fabricating the sheath subassembly and subsequently mounting the sheath subassembly with respect to a spinal stabilization device.

[0004] 2. Background Art

[0005] Low back pain is one of the most expensive diseases afflicting industrialized societies. With the exception of the common cold, it accounts for more doctor visits than any other ailment. The spectrum of low back pain is wide, ranging from periods of intense disabling pain which resolve to varying degrees of chronic pain. The conservative treatments available for lower back pain include: cold packs, physical therapy, narcotics, steroids and chiropractic maneuvers. Once a patient has exhausted all conservative therapy, the surgical options generally range from micro discectomy, a relatively minor procedure to relieve pressure on the nerve root and spinal cord, to fusion, which takes away spinal motion at the level of pain.

[0006] Each year, over 200,000 patients undergo lumbar fusion surgery in the United States. While fusion is effective about seventy percent of the time, there are consequences even to these successful procedures, including a reduced range of motion and an increased load transfer to adjacent levels of the spine, which may accelerate degeneration at those levels. Further, a significant number of back-pain patients, estimated to exceed seven million in the U.S., simply endure chronic low-back pain, rather than risk procedures that may not be appropriate or effective in alleviating their symptoms.

[0007] Spinal stabilization devices have been developed to provide relief to individuals suffering from lower back pain. Spinal stabilization devices frequently extend from a first pedicle screw to a second pedicle screw, and may include one or more rigid rods to provide a stabilizing force to the treated spinal region. New treatment modalities, collectively called motion preservation devices, are currently being developed, such as nucleus, disc or facet replacements. Other motion preservation devices provide dynamic internal stabilization of the injured and/or degenerated spine, without removing any spinal tissues, e.g., the Dynesys stabilization system (Zimmer, Inc.; Warsaw, Ind.) and the Graf Ligament. A major goal of these devices/systems is stabilization of the spine to prevent pain while preserving near normal spinal function. The primary difference in the two types of motion preservation devices is that replacement devices are utilized with the goal of replacing degenerated anatomical structures which facilitate motion while dynamic internal stabilization devices are utilized with the goal of stabilizing and controlling abnormal spinal motion.

[0008] Over ten years ago a hypothesis of lower back pain was presented in which the spinal system was conceptualized as consisting of the spinal column (vertebrae, discs and ligaments), the muscles surrounding the spinal column, and a neuromuscular control unit which helps stabilize the spine during various activities of daily living. Panjabi M M. "The stabilizing system of the spine. Part I. Function, dysfunction, adaptation, and enhancement."*J Spinal Disord* 5 (4): 383-389, 1992a. A corollary of this hypothesis was that strong spinal muscles are needed when a spine is injured or degenerated. This was especially true while standing in neutral posture. Panjabi M M. "The stabilizing system of the spine. Part II. Neutral zone and instability hypothesis."*J Spinal Disord* 5 (4): 390-397, 1992b. In other words, a low-back patient needs to have sufficient well-coordinated muscle forces, strengthening and training the muscles where necessary, so they provide maximum protection while standing in neutral posture.

[0009] Dynamic stabilization (non-fusion) devices need certain functionality in order to assist the compromised (injured or degenerated with diminished mechanical integrity) spine of a back patient. Specifically, the devices must provide mechanical assistance to the compromised spine, especially in the neutral zone where it is needed most. The "neutral zone" refers to a region of low spinal stiffness or the toe-region of the Moment-Rotation curve of the spinal segment (see **FIG. 1**). Panjabi M M, Goel V K, Takata K. 1981 Volvo Award in Biomechanics. "Physiological Strains in Lumbar Spinal Ligaments, an in vitro Biomechanical Study."*Spine* 7 (3): 192-203, 1982. The neutral zone is commonly defined as the central part of the range of motion around the neutral posture where the soft tissues of the spine and the facet joints provide least resistance to spinal motion.

[0010] Experiments have shown that after an injury to the spinal column and/or degeneration of the spine, neutral zones, as well as ranges of motion, increase. However, the neutral zone increases to a greater extent than does the range of motion, when described as a percentage of the corresponding intact values. This implies that the neutral zone is a better measure of spinal injury and instability than the range of motion. Clinical studies have also found that the increase in range of motion does not correlate well with low back pain. Therefore, an unstable spine needs to be stabilized, especially in the neutral zone.

[0011] Dr. Panjabi discloses an advantageous dynamic spine stabilizer in U.S. Patent Publication No. 2004/0236329, the entire contents of which are incorporated herein by reference. The disclosed dynamic spine stabilizer generally includes a support assembly in the form of a first housing member and a second housing member that are telescopically connected. According to exemplary embodiments of the Panjabi disclosure, first and second springs are positioned between the housing members, and spring compression may be set by adjusting the relative distance between the first and second housing members. Although springs are employed in accordance with a preferred embodiment of the Panjabi disclosure, the use of other elastic members is also contemplated. A piston assembly links the first spring and the second spring to first and second ball joints associated with pedicle screws. The piston assembly generally includes a piston rod and retaining rods that cooperate with the first and second springs. The disclosed Panjabi devices/systems offer significantly enhanced spinal stabilization. See also U.S. Patent Publication No. 2005/0245930 to Timm and Panjabi, the entire contents of which are incorporated herein by reference.

[0012] In the noted Timm and Panjabi application to which the present application claims priority (U.S. Patent Publication No. 2005/0245930), a surgical implant is provided that includes first and second abutment surfaces between which are positioned a force imparting mechanism. A sheath is positioned between the first and second abutment surfaces, and surrounds the force imparting mechanism. The sheath is fabricated from a material that accommodates relative movement of the abutment members, while exhibiting substantially inert behavior relative to surrounding anatomical structures. The sheath is generally fabricated from expanded polytetrafluoroethylene, ultra-high molecular weight polyethylene, a copolymer of polycarbonate and a urethane, or a blend of a polycarbonate and a urethane. The force imparting member may include one or more springs, e.g., a pair of nested springs. The surgical implant may be a dynamic spine stabilizing member that is advantageously incorporated into a spine stabilization system to offer clinically efficacious results.

[0013] Despite efforts to date, a need remains for efficacious spinal stabilization devices that provide desired levels of stabilization and that exhibit clinically acceptable interaction with surrounding anatomical elements and structures. More particularly, a need remains for spinal stabilization devices that provide dynamic spinal stabilization while protecting against undesirable interaction between the dynamic force-imparting element(s) and the surrounding anatomy. Still further, a need remains for fabrication and/or assembly methods for manufacture of spinal stabilization devices, including particularly dynamic spinal stabilization devices, in a reliable and efficacious manner. These and other needs are satisfied by the disclosed spinal stabilization devices/systems and associated assembly methods.

SUMMARY OF THE DISCLOSURE

[0014] Spinal stabilization systems and/or other surgical implants that include a cover and/or sheath structure are desirable in that they provide protection to inner force-imparting component(s), e.g., one or more springs, while exhibiting clinically acceptable interaction with surrounding anatomical fluids and/or structures. According to the present disclosure, a sheath member is provided for positioning with respect to a stabilization device, e.g., a spinal stabilization device. The sheath member is mounted with respect to at least one, and generally a pair of connector rings.

[0015] According to exemplary embodiments of the present disclosure, a sheath assembly is provided that includes a sheath member and at least one connector ring secured with respect to the sheath member. The connector ring generally defines a circumference and includes a plurality of radially-spaced notches positioned around such circumference. The sheath member is typically substantially cylindrical in geometry, and may be advantageously fabricated from expanded polytetrafluoroethylene (ePTFE), ultra-high molecular weight polyethylene, a copolymer of polycarbonate and a urethane, and a blend of a polycarbonate and a urethane.

[0016] Exemplary connector rings according to the present disclosure define a substantially V-shaped cross-section before being secured to the sheath member. The radially-spaced notches include an aperture region and a notch finger. Exemplary connecting rings also include an inner face, an apex region and an outer wall. The radially-spaced notches are generally formed in the apex region (in whole or in part). The inner face may define a deflected edge which, in preferred embodiments, is substantially parallel to the outer wall. The inner face advantageously spaces or shields the inner wall of the sheath member from dynamic member(s) that are positioned therewithin, thereby avoiding potentially undesirable wear or abrasion.

[0017] A pair of connector rings may be provided, with a first connector ring being secured to a first end of the sheath member and a second connector ring being secured to the second end of the sheath member. Generally, the connector ring defines an interior cavity and an end of the sheath member is positioned in the internal cavity prior to being secured thereto, e.g., by crimping, compression or swaging.

[0018] In further embodiments of the present disclosure, a spinal stabilization device is provided that includes first and second end caps in a spaced relation, at least one spring member positioned between the first and second end caps; and a sheath assembly mounted with respect to the first and second end caps and around the at least one spring member. The sheath assembly generally includes a sheath member and at least one connector ring secured with respect to the sheath member, the at least one connector ring defining a circumference and including a plurality of radially-spaced notches positioned around the circumference. As noted previously, the sheath member is typically fabricated from an inert material, e.g., expanded polytetrafluoroethylene (ePTFE), ultra-high molecular weight polyethylene, a copolymer of polycarbonate and a urethane, and a blend of a polycarbonate and a urethane. The sheath assembly may be advantageously secured with respect to the first and second end caps by crimping, compression or swaging.

[0019] The present disclosure further provides a method for assembling a sheath assembly that includes: (i) providing a sheath member; (ii) providing a first connector ring that includes an inner face, an apex region, an outer wall and a plurality of radially-spaced notches formed at least in part in the apex region, wherein the first connector ring defines an internal cavity; (iii) positioning an end of the sheath member within the internal cavity; and (iv) securing the sheath member with respect to the first connector ring by crimping, compression or swaging.

[0020] The disclosed method may further include the additional steps of (i) providing a second connector ring that includes an inner face, an apex region, an outer wall and a plurality of radially-spaced notches formed at least in part in the apex region, wherein the second connector ring defines a second internal cavity; (ii) positioning an opposite end of the sheath member within the second internal cavity; and (iii) securing the sheath member with respect to the second connector ring by crimping, compressing or swaging. The sheath member may be secured with respect to the spinal stabilization device by crimping, compressing or swaging of the first connector ring with respect to the first end cap, and crimping, compressing or swaging of the second connector ring with respect to the second end cap.

[0021] These and other structural, functional and operational benefits of the present disclosure will be apparent from the detailed description which follows, particularly when read in conjunction with the appended figures.

BRIEF DESCRIPTION OF THE FIGURES

[0022] To assist those of ordinary skill in the art in making and using the disclosed spinal stabilization devices, reference is made to the accompanying figures, wherein:

[0023] **FIG. 1A** is a side view of an exemplary spinal stabilization device according to the present disclosure;

[0024] **FIG. 1B** is a top view of the exemplary spinal stabilization device of **FIG. 1A**;

[0025] **FIG. 2A** is a top view of the exemplary spinal stabilization device of **FIGS. 1A and 1B** with the disclosed sheath assembly removed;

[0026] **FIG. 2B** is a cross-sectional view of the spinal stabilization device of **FIG. 2A** taken along line B-B;

[0027] **FIG. 2C** is an end view taken from the left end of the exemplary spinal stabilization device of **FIGS. 1A-1B** and 2A-2B;

[0028] **FIG. 2D** is an end view taken from the right end of the exemplary spinal stabilization device of **FIGS. 1A-1B** and 2A-2B;

[0029] **FIG. 3A** is a top plan view of an exemplary connector ring for use in assembling a sheath subassembly according to the present disclosure;

[0030] **FIG. 3B** is a bottom plan view of the exemplary connector ring of **FIG. 3A**;

[0031] **FIG. 3C** is a side view of the exemplary connector ring of FIGS. 3A and 3B:

[0032] **FIG. 3D** is an end view of the exemplary connector ring of **FIGS. 3A-3C**;

[0033] **FIG. 3E** is a sectional view of the exemplary connector ring of **FIGS. 3A-3D** taken along line E-E of **FIG. 3D**;

[0034] **FIG. 4** is a detail sectional view of a portion of the connector ring of **FIGS. 3A-3E**;

[0035] **FIG. 5A** is a side view of an exemplary sheath subassembly according to the present disclosure;

[0036] **FIG. 5B** is a sectional side view of the exemplary sheath subassembly of **FIG. 5A**, taken along line B-B, according to the present disclosure;

[0037] **FIG. 5C** is a front view of the exemplary sheath subassembly of **FIG. 5A**; and

[0038] **FIG. 6** is a side view of an exemplary stabilization device mounted with respect to a pair of pedicle screws according to the present disclosure.

DESCRIPTION OF EXEMPLARY EMBODIMENT(S)

[0039] The present disclosure provides advantageous spinal stabilization systems and methods for assembling, fabricating and/or manufacturing such spinal stabilization systems. More particularly, the present disclosure provides advantageous sheath subassemblies that are configured and dimensioned to be mounted with respect to a spinal stabilization system. In exemplary embodiments of the present disclosure, the disclosed sheath subassemblies may be mounted with respect to dynamic element(s), e.g., spring member(s), that are adapted to provide dynamic stabilization to a spinal region, thereby encasing or otherwise enclosing the dynamic element(s) and protecting against potentially undesirable anatomical interaction between such dynamic element(s) and the surrounding anatomical elements/structures. Still further, the present disclosure provides advantageous methods and/or techniques for fabricating a sheath subassembly for assembly as part of a spinal stabilization device, e.g., a dynamic spinal stabilization device.

[0040] With initial reference to **FIGS. 1A and 1B**, an exemplary spinal stabilization device **10** is schematically depicted. Stabilization device **10** includes first end cap **12** and second end cap **14**. Sheath member **16** is positioned between first and second end caps **12**, **14**, and surrounds, inter alia, spring elements (described below). First and second connector rings **18**, **20** are secured with respect to sheath member **16** and, with sheath member, define a sheath assembly **22**. Outer spring member **24** is exposed at both ends of sheath assembly **22**. The design, operation and function of outer spring member **24** is described in greater detail below.

[0041] Second end cap **14** defines an elongated rod **26** that is generally of circular cross-section and that is adapted for mounting with respect to a pedicle screw (see, e.g., **FIG. 6**). First end cap **12** defines a substantially circular ring with opposed features **28***a*, **28***b* that facilitate interaction with cooperative structures/features on a pedicle screw mounting structure. For example, **FIG. 6** (described in greater detail below) illustrates an exemplary mounting arrangement for first end cap **12** with respect to a pedicle screw. The overall size and configuration of spinal stabilization device **10** is such that stabilization of a single spinal level is achieved. Multiple spinal stabilization devices may be advantageously employed to stabilize multiple levels, e.g., adjacent spinal levels.

[0042] Turning to **FIGS. 2A**, a further view of spinal stabilization device **10** is provided, with sheath assembly **22** removed. As shown therein, spinal stabilization device **10** includes an outer spring member **24** that is mounted with respect to first and second end caps **12**, **14**. An advantageous method for mounting outer spring member **24** with respect to end caps **12**, **14** is disclosed in a co-pending U.S. patent application entitled "Spring Junction and Assembly Methods for Spinal Device" (Ser. No. 11/196,102; filed Aug. 3, 2005), the contents of which are hereby incorporated by reference. Thus, in an exemplary assembly method according to the present disclosure, a spring junction is defined between outer spring member **24** and end caps **12**, **14**, and the spring junction includes a weld region **32**. With reference to **FIGS. 2A, 2C** and 2D, a heat-affected zone is defined at either end of outer spring member **24**, and is disposed adjacent weld region **32**. However, the heat-affected zone is physically separately disposed with respect to the active region of spring member **24**. Weld region **32** is subjected to a welding process, such as electron-beam welding, and accordingly may be exposed to welding temperatures of about 1000° F. or higher. Outer spring member **24** includes a bend region **30** disposed between weld region **32** and an adjacent coil of the spring member that extends along a helical path. Bend region **30** is generally sized and shaped so as to initially bend away from the spring member's helical path before bending back toward the helical path and terminating at or in weld region **32**. Of note, the disclosed spring junctions are typically formed at both ends of outer spring member **24**, thereby securing outer spring member **24** with respect to both end caps **12**, **14**.

[0043] With reference to **FIG. 2B**, a cross-sectional view of spinal stabilization device **10** taken along line B-B in **FIG. 2A** is provided. As shown in **FIG. 2B**, spinal stabilization device **10** includes a second, inner spring member **34** that is concentrically mounted within outer spring member **24**. An internal cable assembly **36** is concentrically positioned within both spring members **24**, **34**, and is fixedly mounted with respect to end caps **12**, **14**. The design, assembly and operation of an exemplary cable assembly **36** is described in a co-pending U.S. patent application entitled "Dynamic Spine Stabilization Device with Travel-Limiting Functionality" (Ser. No. 11/189,512; filed Jul. 26, 2005), the contents of which are hereby incorporated by reference. As described in the foregoing co-pending patent application, internal cable assembly **36** advantageously functions to define and/or impose a maximum distance by which end caps **12**, **14** may be separated, i.e., the relative travel therebetween.

[0044] Spring members **24**, **34** cooperate to provide advantageously dynamic spinal stabilization. Indeed, the advantageous performance of exemplary embodiments of the disclosed spinal stabilization device **10** is described in a co-pending U.S. patent application entitled "Dynamic Spine Stabilizer" (Ser. No. 11/132,538; filed May 19, 2005), the contents of which are hereby incorporated by reference. Through the cooperative action of spring members **24**, **34**, the resistance of spinal stabilization device **10** is applied to a spinal region such that greater mechanical assistance is provided while the spine is around its "neutral zone" and lesser mechanical assistance is provided while the spine bends beyond its neutral zone. In exemplary embodiments, the disclosed spinal stabilization device **10** delivers a predetermined level of resistance, while accommodating a predetermined travel distance (i.e., linear travel) between adjacent pedicles, e.g., a predetermined level of resistance in the range of about 150 lbs/inch to about 450 lbs/inch and a predetermined travel distance of about 1.5 mm to about 5 mm.

[0045] Turning to **FIGS. 3A-3D**, a series of views of an exemplary connector ring **18** according to the present disclosure are provided. Of note, connector rings **18**, **20** are generally identical and interchangeable. Thus, the description provided herein with respect to connector ring **18** applies with equal force to connector ring **20**. Connector ring **18** includes an inner cylindrical face **38**, a substantially circular apex region **40**, and an angularly oriented outer wall **42**. A plurality of radially-spaced notches **44** are formed in the apex region **40** of connector ring **18**. With reference to **FIG. 3B**, an internal cavity **46** is defined within connector ring **18** between cylindrical face **38** and outer wall **42**.

[0046] **FIGS. 3E and 4** provide more detailed views of exemplary connector ring **18**. With initial reference to **FIG. 3E**, a cross-section view of connector ring **18** taken along line E-E in **FIG. 3D** is provided. As shown therein, connector ring **18** is characterized by a substantially V-shaped cross-section with apex region **40** defining the apex thereof. Spaced notches **44** generally do not extend into inner face **38**, but are limited to the apex region **40** and, to a limited degree, downward extension to outer wall **42**. In the disclosed exemplary embodiment, eighteen (18) radially-spaced notches **44** are provided. However, the present disclosure is not limited to such exemplary notch count; indeed, more or less notches may be defined on connector ring **18**, without departing from the spirit or scope of the present disclosure. Indeed, it is contemplated that the number of radially-spaced notches may range, for example, from 12 to 30.

[0047] With reference to the detailed view of **FIG. 4**, which relates to the region shown within the dashed circle in **FIG. 3E**, additional structural details associated with an exemplary connector ring **18** according to the present disclosure are depicted. Notch **44** includes an aperture region **48** and a notch finger **50** which extends into internal cavity **46**. Notch finger **50** is typically defined by notching or lancing the apex region **40** to define aperture region **48** and flex notch finger **50** inwardly. Radially-spaced notches **44** may be individually formed using an appropriate fixture/tool. Alternatively, a plurality of radially-spaced notches **44** may be formed simultaneously, e.g., by fixturing connector ring **18** and simultaneously notching/lancing notches **44** around the circumference thereof According to preferred embodiments of the present disclosure, all radially-spaced notches **44** are simultaneously formed around the circumference of connector ring **18**.

[0048] With further reference to **FIG. 4**, inner face **38** defines a deflected edge **52** that extends toward internal cavity **46**. Deflected edge **52** typically extends around the circumference of inner face **38** and, according to preferred embodiments of the present disclosure, defines a surface that is substantially parallel to outer wall **42**. Deflected edge **52** is typically angled relative to inner face **38** at an angle of about 25°, although alternative angular orientations may be employed (including the omission of deflected edge **52**) without departing from the spirit or scope of the present disclosure. Similarly, outer wall **42** is typically angled relative to inner face **38** at an angle of about 25°, although alternative angular orientations may be employed according to the present disclosure. Indeed, outer wall **42** need not be planar, but may be radiused, in whole or in part. As shown in **FIG. 4**, an inward depression **54** may be formed along the edge of outer wall **42**, such inward depression **54** typically extending around the circumference of outer wall **42**. Deflected edge **52** and inward depression **54** advantageously function to capture and/or retain a sheath member during the assembly process, as described in greater detail. Alternative and/or additional techniques may be employed to facilitate such assembly processes, e.g., an adhesive and/or tacky material may be provided in internal cavity **46**.

[0049] Connector rings **18**, **20** are typically fabricated from a metal material, e.g., stainless steel or titanium. The dimensions associated with connector rings **18**, **20** will depend on the size and geometry of the spinal stabilization device with which they will be employed. However, in exemplary embodiments of the present disclosure, connector rings **18**, **20** define an inner diameter (i.e., the diameter of inner face **38**) of about 0.5 inches, although alternative geometries, e.g., diameters of about 0.4 to about 0.75 inches, are contemplated. The length of inner face **38** may range depending on the overall size and geometry of the spinal stabilization device, e.g., from about 0.075 to about 0.2 inches and, in exemplary embodiments of the present disclosure, the length of inner face is about 0.1 inch. The width and length of aperture regions **48** are typically selected so as not to risk the structural integrity of connector rings **18**, **20**, while simultaneously providing the advantageous mounting properties described below with reference to the assembly of sheath subassemblies. However, in exemplary embodiments of the present disclosure, the aperture regions **48** are approximately 0.025 inches in width and approximately 0.06 inches in length, although alternative dimensions, e.g., a width of between about 0.015 and 0.04 inches and a length of about 0.04 to about 0.125 inches, are contemplated.

[0050] Turning to **FIGS. 5A-5C**, an exemplary sheath assembly **22** according to the present disclosure is depicted. Sheath assembly **22** includes sheath member **16**, first connector ring **18** and second connector ring **20**. Sheath member **16** is substantially cylindrical in geometry and defines opposed, substantially circular edges. Sheath member **16** is fabricated from a material that accommodates relative movement of end caps **12**, **14**, while exhibiting substantially inert behavior relative to surrounding anatomical structures. The sheath member **16** is generally fabricated from expanded polytetrafluoroethylene, ultra-high molecular weight polyethylene, a copolymer of polycarbonate and a urethane, or a blend of a polycarbonate and a urethane. Additional disclosure with respect to exemplary sheath member design, function and operation for use according to the present disclosure is provided in a co-pending U.S. patent application entitled "Surgical Implant Devices and Systems Including a Sheath Member" (Ser. No. 11/027,073; filed Dec. 31, 2004), the contents of which are hereby incorporated by reference.

[0051] As most clearly depicted in **FIG. 5B**, the opposed edges of sheath member **16** are received within the internal cavities **46** defined by connector rings **18**, **20** and, once positioned therein, connector rings **18**, **20** are crimped, compressed or swaged so as to secure sheath member **16** relative to connector rings **18**, **20**, respectively. According to exemplary embodiments of the present disclosure, deflected edges **52** of the respective connector rings **18**, **20** assist in guiding sheath member **16** into the associated internal cavity and retaining the sheath member edges therein pending the crimping, compression or swaging operation. As noted above, alternative and/or additional steps may be taken to temporarily retain the positioning of sheath member **16** relative to connector rings **18**, **20**, e.g., an adhesive may be added to the edges of sheath member **16** and/or internal cavities **46** of connector rings **18**, **20**.

[0052] Of note, notches **44** advantageously facilitate the fabrication of sheath assembly **22** according to the present disclosure. More particularly, aperture regions **48** facilitate the compression of connector rings **18**, **20** into secure engagement with sheath member **16**. Indeed, aperture regions **48** permit the outer walls **42** of the respective connector rings **18**, **20** to assume a reduced diameter as the connector rings are crimped, compressed or swaged with respect to sheath member **16**, thereby avoiding any distortional effect (e.g., a "bottle cap effect" that may result in discontinuous crimping/swaging of the sheath member within the connector ring). The aperture regions **48** also provide regions that may be occupied by the sheath member **16** when the connector rings **18**, **20** are crimped, compressed or swaged relative thereto, and further provide an ability to visually confirm that the sheath member **16** is properly positioned within connector ring **18**, **20**. "Visual confirmation" may also be achieved through appropriate sensor equipment, e.g., in an automated fashion, as will be readily apparent to persons skilled in manufacturing techniques. A small portion of the sheath member **16** may protrude through one or more aperture regions **48**, depending on the compression force applied and/or the positioning of the sheath member within internal cavity **46**.

[0053] Once sheath assembly **22** is formed, the sheath member **16** and connector rings **16**, **18** may be advantageously handled as a unit, thereby enhancing inventory operations and further assembly steps. Thus, returning to **FIGS. 1A, 1B** and 2B, sheath assembly **22** may be mounted with respect to other components or subassemblies of a spinal stabilization device. In exemplary embodiments of the present disclosure, the sheath assembly **22** is positioned over or around spring members **24**, **34**, with connector rings **18**, **20** in a substantially concentric orientation with respect to flange portions **60**, **62** of end caps **12**, **14**, respectively. As shown in **FIG. 2B**, flange portions **60**, **62** may be provided with annular channels **64**, **66**, respectively. In assembling sheath assembly **22** to the subassembly shown in **FIGS. 2A and 2B**, the connector rings **18**, **20** are generally concentrically positioned with respect to the flange portions **60**, **62** (and preferably the annular channels **64**, **66** thereof), and the connector rings **16**, **18** are further crimped, compressed or swaged with respect thereto. Further deformation of connector rings **16**, **18** is accommodated by radially-spaced notches **44**, and the sheath assembly **22** is thereby fixedly mounted with respect to the underlying subassembly. According to exemplary embodiments of the present disclosure, sheath assembly **22** is mounted with respect to the underlying subassembly, e.g., the flange portions **60**, **62** of end caps **12**, **14**, such that there are substantially no gaps and substantially no rotation therebetween. Alignment operations of sheath member **16** relative to end caps **18**, **20**, and secure mounting therebetween, are substantially benefited by the pre-fabrication of sheath assembly **22**, as described herein.

[0054] With reference to **FIG. 6**, an exemplary system **100** including the disclosed spinal stabilization device **10** (which, in turn, includes sheath assembly **22**) and a pair of pedicle screws **102**, **104** is schematically depicted. Cooperation between the spinal stabilization device **10** and the pedicle screws **102**, **104** is facilitated by ball/spherical elements **110**, **112**, and set screws **114**, **116**. In the exemplary system of **FIG. 6**, the ball/spherical element **110** cooperates with the head of pedicle screw **104** such that a global/dynamic joint is formed therebetween. The set screw **114** is inserted into the head of the pedicle screw **106**, thereby securing the head of the pedicle screw **102** within the ball/spherical element **110**.

[0055] Turning to the opposite end of exemplary system **100**, attachment member **108** is configured to receive ball/spherical element **112**. The ball/spherical element **112** receives the head of pedicle screw **102**, such that a global/dynamic joint is formed therebetween. Set screw **116** is inserted into the head of the pedicle screw **102** , thereby securing the head of pedicle screw **102** within the ball/spherical element **112**. Rod **26** is configured to be inserted into the attachment member **108** which may include, for example, a transverse aperture to accommodate rod **26**, and a set screw is generally used to secure the rod at a desired position, e.g., using driver **124**.

[0056] Exemplary system **100** advantageously provides dynamic stabilization in clinical applications based on the dynamic properties of spinal stabilization device **10**. Moreover, sheath member **16** provides a protective casing to the spring elements positioned therewithin, while simultaneously accommodating relative movement between end caps **14**, **16**. The design and operation of spring connectors **18**, **20** facilitate efficient and reliable assembly, while also ensuring security of sheath member **16** relative to the underlying structures during in situ applications.

[0057] Although the present disclosure has been disclosed with reference to exemplary embodiments and implementations thereof, those skilled in the art will appreciate that the present disclosure is susceptible to various modifications, refinements and/or implementations without departing from the spirit or scope of the present invention. In fact, it is contemplated the disclosed sheath assembly may be employed in a variety of environments and clinical settings without departing from the spirit or scope of the present invention. Accordingly, while exemplary embodiments of the present disclosure have been shown and described, it will be understood that there is no intent to limit the invention by such disclosure, but rather, the present invention is intended to cover and encompass all modifications and alternate constructions falling within the spirit and scope hereof.

1. A sheath assembly comprising:

a. a sheath member;

b. at least one connector ring secured with respect to the sheath member, the at least one connector ring defining a circumference and including a plurality of radially-spaced notches positioned around the circumference.

2. A sheath assembly according to claim 1, wherein the sheath member is substantially cylindrical.

3. A sheath assembly according to claim 1, wherein the sheath member is fabricated from a material selected from the group consisting of expanded polytetrafluoroethylene, ultra-high molecular weight polyethylene, a copolymer of polycarbonate and a urethane, and a blend of a polycarbonate and a urethane.

4. A sheath assembly according to claim 1, wherein the at least one connector ring defines a substantially V-shaped cross-section before being secured to the sheath member.

5. A sheath assembly according to claim 1, wherein each of the plurality of radially-spaced notches includes an aperture region.

6. A sheath assembly according to claim 5, wherein each of the plurality of radially-spaced notches further includes a notch finger.

7. A sheath assembly according to claim 1, wherein the at least one connecting ring includes an inner face, an apex region and an outer wall, and wherein the plurality of radially-spaced notches are formed at least in part in the apex region.

8. A sheath assembly according to claim 7, wherein the inner face defines a deflected edge.

9. A sheath assembly according to claim 8, wherein the deflected edge is substantially parallel to the outer wall.

10. A sheath assembly according to claim 1, wherein the at least one connector ring includes a pair of connector rings, and wherein a first connector ring is secured to a first end of the sheath member and a second connector ring is secured to a second end of the sheath member.

11. A sheath assembly according to claim 1, wherein the at least one connector ring defines an interior cavity and a first end of the sheath member extends into the internal cavity.

12. A sheath assembly according to claim 1, wherein the at least one connector ring is secured with respect to the sheath member by crimping, compression or swaging.

13. A sheath assembly comprising:

a. a sheath member;

b. at least one connector ring secured with respect to the sheath member, the at least one connector ring including an inner cylindrical face, a substantially circular apex region and an angularly oriented outer wall,

wherein the at least one connector ring defines a substantially V-shaped cross-section that is configured and dimensioned to receive an end of the sheath member; and

wherein the inner cylindrical face is adapted to shield the end of the of the sheath member from one or more elements positioned therewithin.

14. A sheath assembly according to claim 13, wherein said at least one connector ring further comprises a plurality of radially-spaced notches.

15. A spinal stabilization device, comprising:

a. first and second end caps in spaced relation;

b. at least one spring member positioned between the first and second end caps; and

c. a sheath assembly mounted with respect to the first and second end caps and around the at least one spring member, the sheath assembly including a sheath member and at least one connector ring secured with respect to the sheath member, the at least one connector ring defining a circumference and including a plurality of radially-spaced notches positioned around the circumference.

16. A spinal stabilization system **15**, wherein the sheath member is fabricated from a material selected from the group consisting of expanded polytetrafluoroethylene, ultra-high molecular weight polyethylene, a copolymer of polycarbonate and a urethane, and a blend of a polycarbonate and a urethane.

17. A spinal stabilization system according to claim 15, wherein the at least one connector ring defines a substantially V-shaped cross-section before being secured to the sheath member.

18. A spinal stabilization system according to claim 15, wherein each of the plurality of radially-spaced notches includes an aperture region.

19. A spinal stabilization system according to claim 18, wherein each of the plurality of radially-spaced notches further includes a notch finger.

20. A spinal stabilization system according to claim 15, wherein the at least one connecting ring includes an inner face, an apex region and an outer wall, and wherein the plurality of radially-spaced notches are formed in the outer wall.

21. A spinal stabilization system according to claim 20, wherein the inner face defines a deflected edge.

22. A spinal stabilization system according to claim 21, wherein the deflected edge is substantially parallel to the outer wall.

23. A spinal stabilization system according to claim 15, wherein the at least one connector ring includes a pair of connector rings, and wherein a first connector ring is secured to a first end of the sheath member and a second connector ring is secured to a second end of the sheath member.

24. A spinal stabilization system according to claim 15, wherein the at least one connector ring defines an interior cavity and a first end of the sheath member extends into the internal cavity.

25. A spinal stabilization system according to claim 15, wherein the at least one connector ring is secured with respect to the sheath member by crimping, compression or swaging.

26. A spinal stabilization system according to claim 15, wherein the sheath assembly is secured with respect to the first and second end caps by crimping, compression or swaging.

27. A method for assembling a sheath assembly, comprising:

a. providing a sheath member;

b. providing a first connector ring that includes an inner face, an apex region, an outer wall and a plurality of radially-spaced notches formed at least in part in the apex region, wherein the first connector ring defines an internal cavity;

c. positioning an end of the sheath member within the internal cavity; and

d. securing the sheath member with respect to the first connector ring by crimping, compression or swaging.

28. A method according to claim 27, further comprising:

a. providing a second connector ring that includes an inner face, an apex region, an outer wall and a plurality of radially-spaced notches formed at least in part in the apex region, wherein the second connector ring defines a second internal cavity;

b. positioning an opposite end of the sheath member within the second internal cavity; and

c. securing the sheath member with respect to the second connector ring by crimping, compressing or swaging.

29. A method according to claim 28, further comprising securing the sheath member to first and second end caps of a spinal stabilization device.

30. A method according to claim 29, wherein the sheath member is secured with respect to the spinal stabilization device by crimping, compressing or swaging of the first connector ring with respect to the first end cap, and crimping, compressing or swaging of the second connector ring with respect to the second end cap.

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