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(54) **INTEGRAL SPRING JUNCTION**

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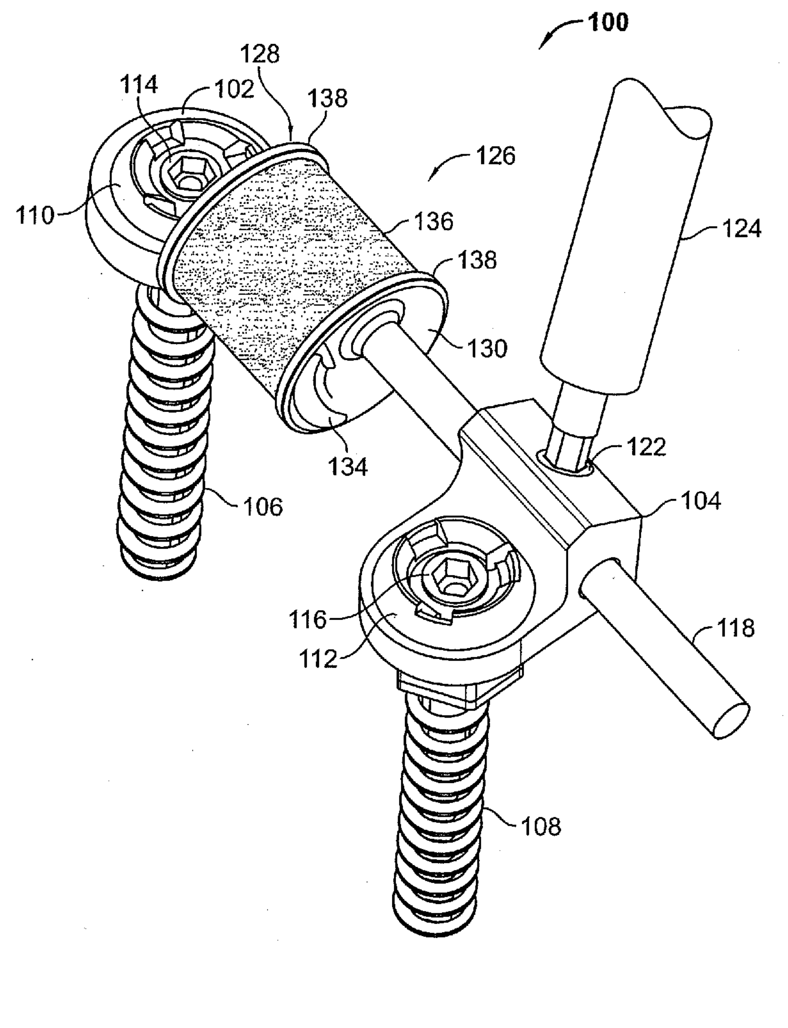
(57) **ABSTRACT**

Spinal stabilization devices, systems and methods are provided that include a spring junction wherein a structural member is mountable to a spine attachment fastener and a resilient element is affixed to the structural member along an attachment region of the resilient element. The attachment region is disposed physically separately with respect to an active region of the resilient element. The attachment region can include a weld region produced via an E-beam welding process involving temperatures of 1000° F. or greater, wherein a heat-affected zone adjacent the weld region is disposed physically separately with respect to the active region. The resilient element may be a coil spring including bend regions adjacent its outermost (i.e., last) coils wherein the material of the coil spring initially bends away from the last coil, then bends back toward the last coil before terminating near the last coil.



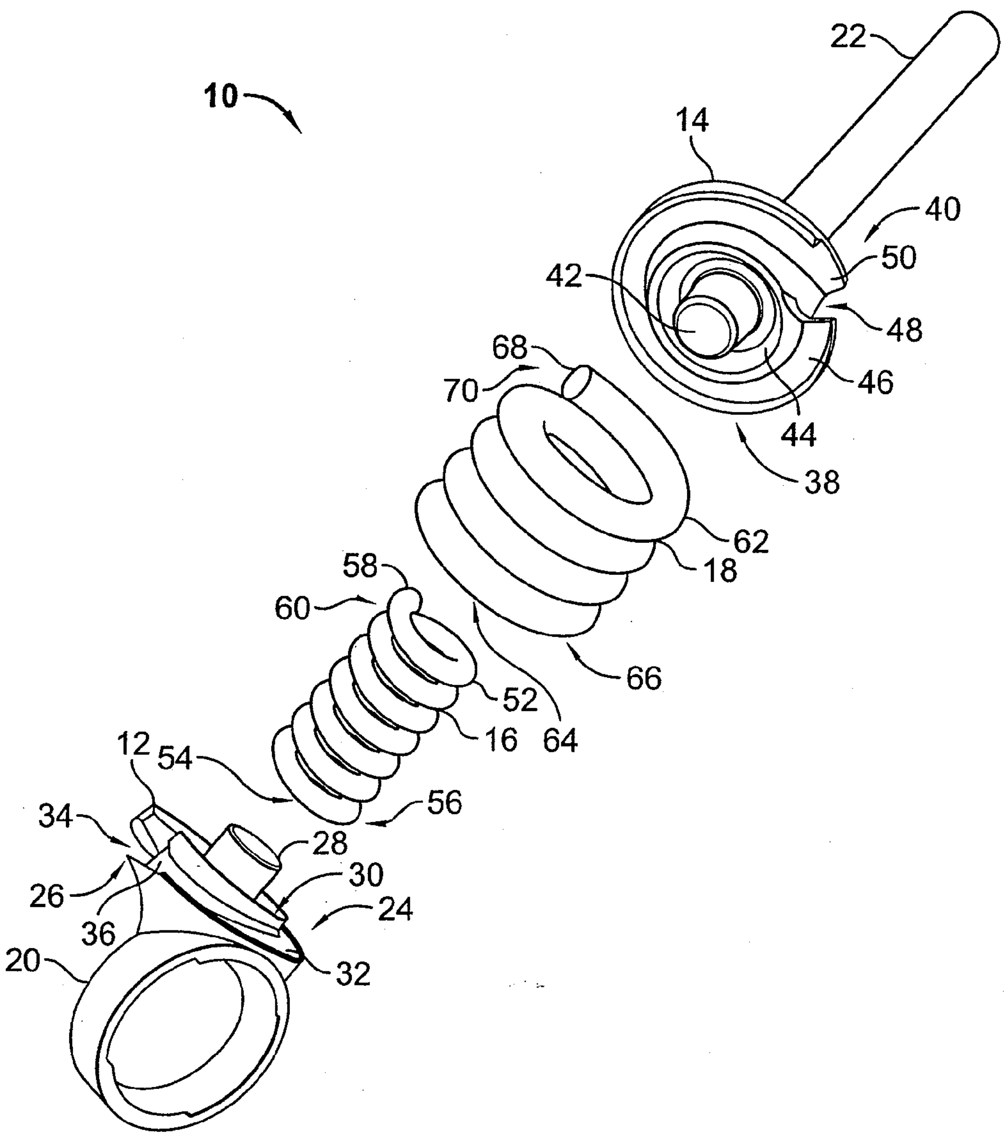

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FIG. 1

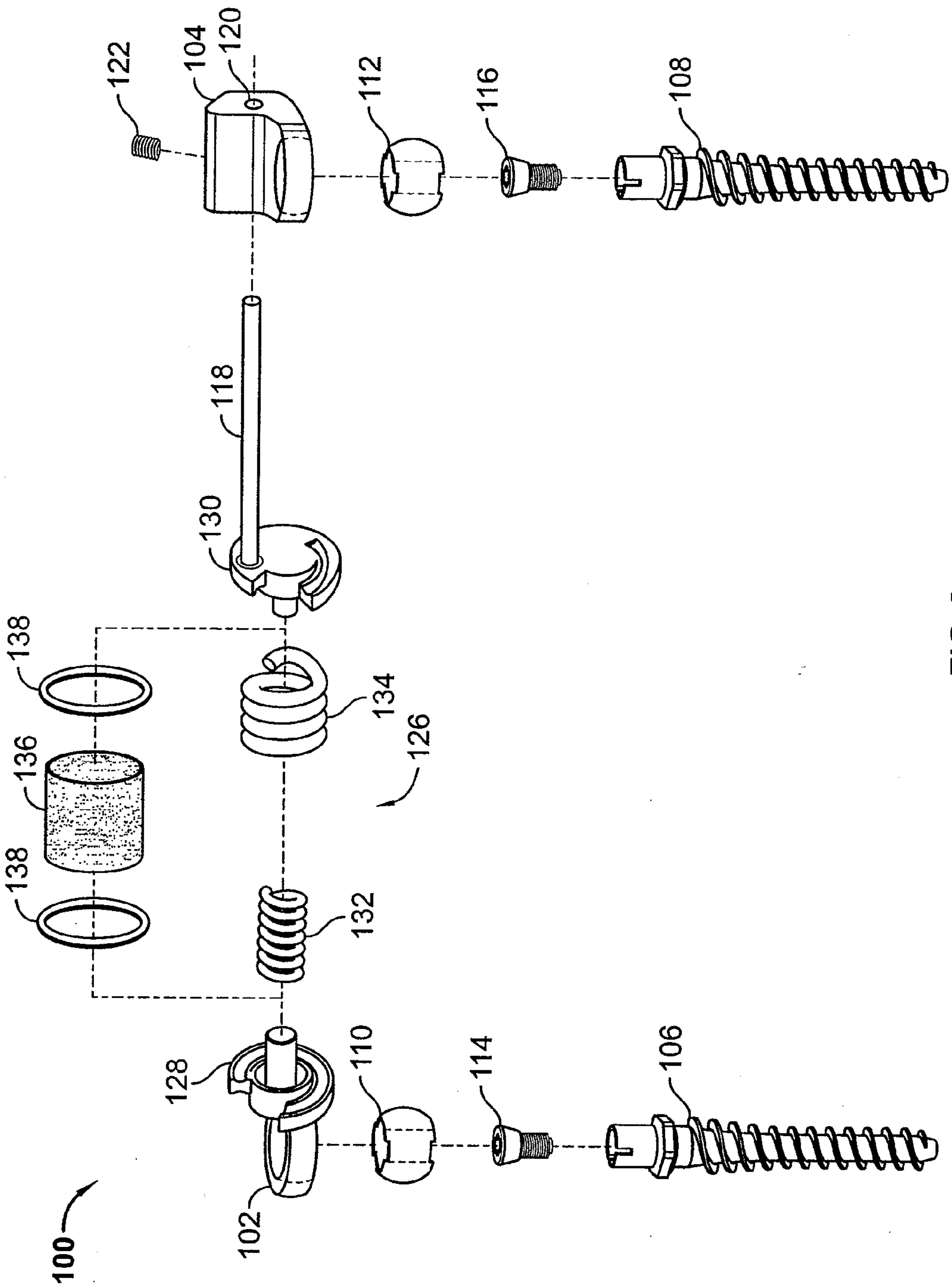

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FIG. 2

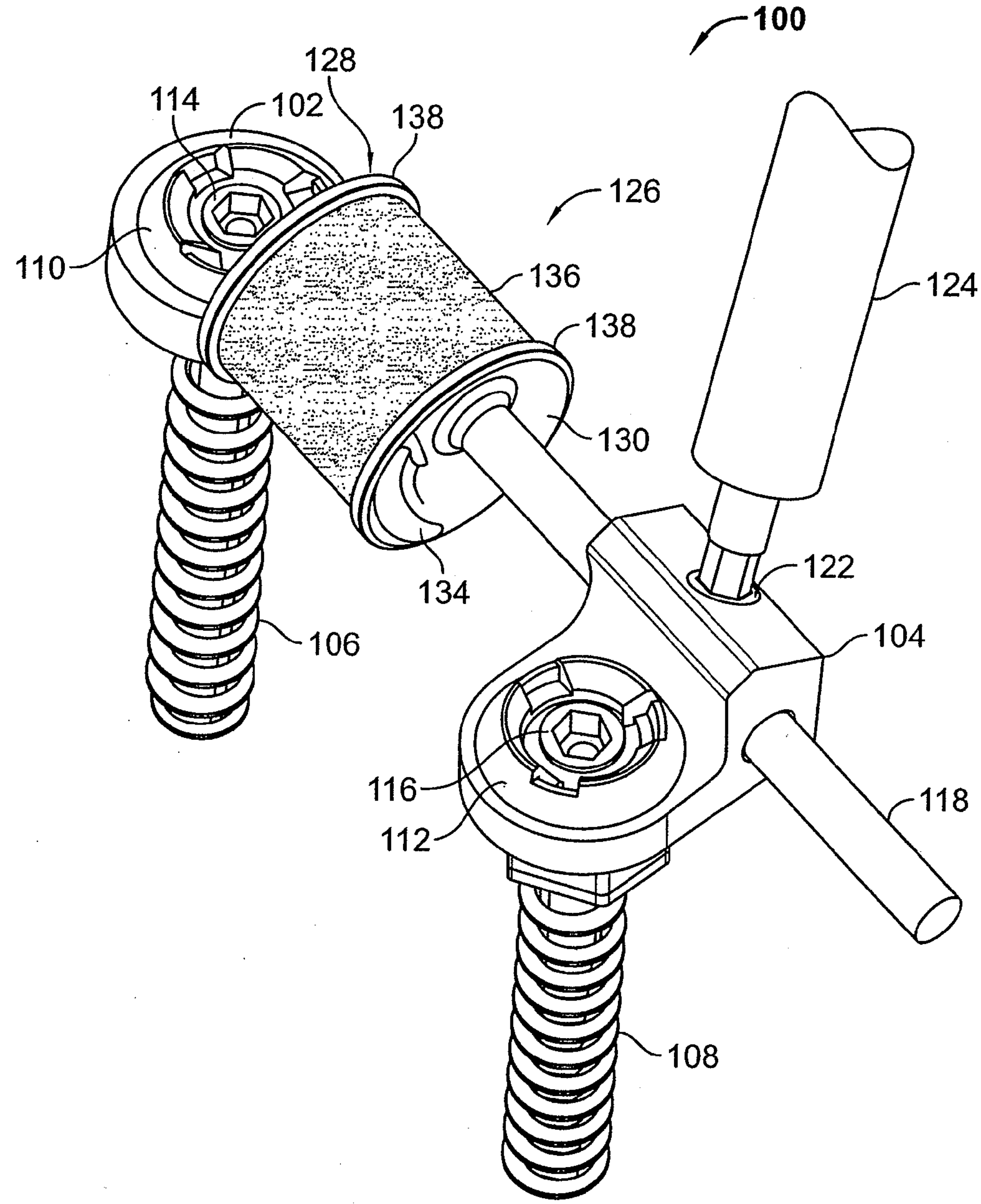
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FIG. 3

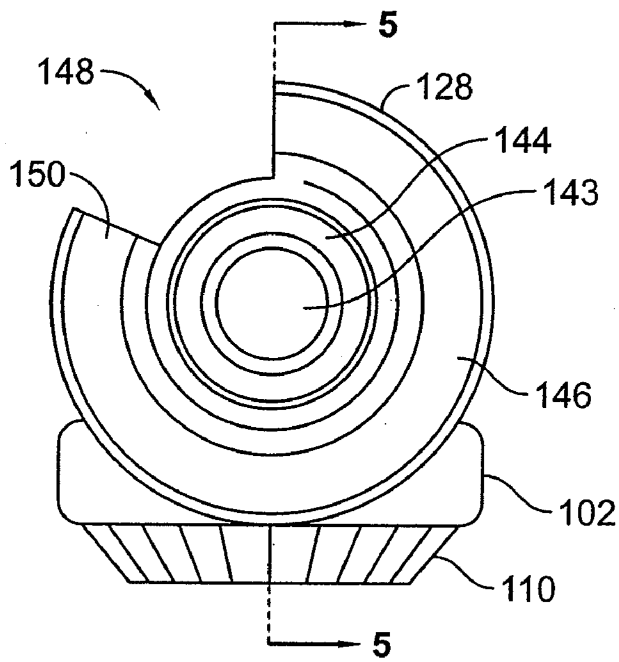

FIG. 4

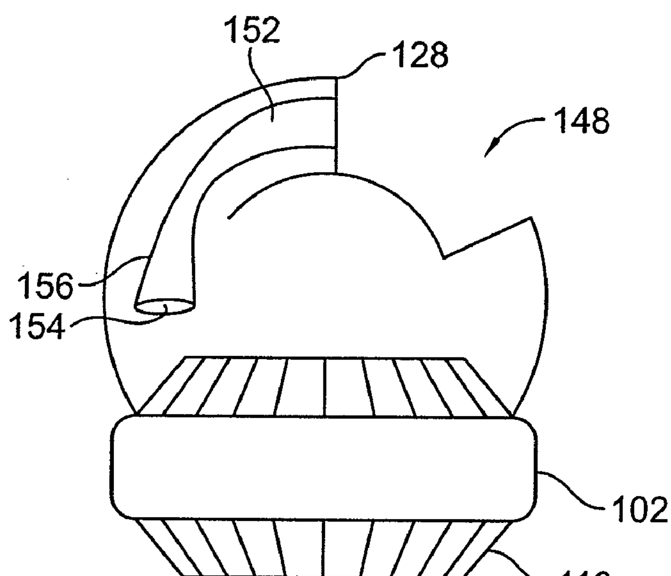

FIG. 5

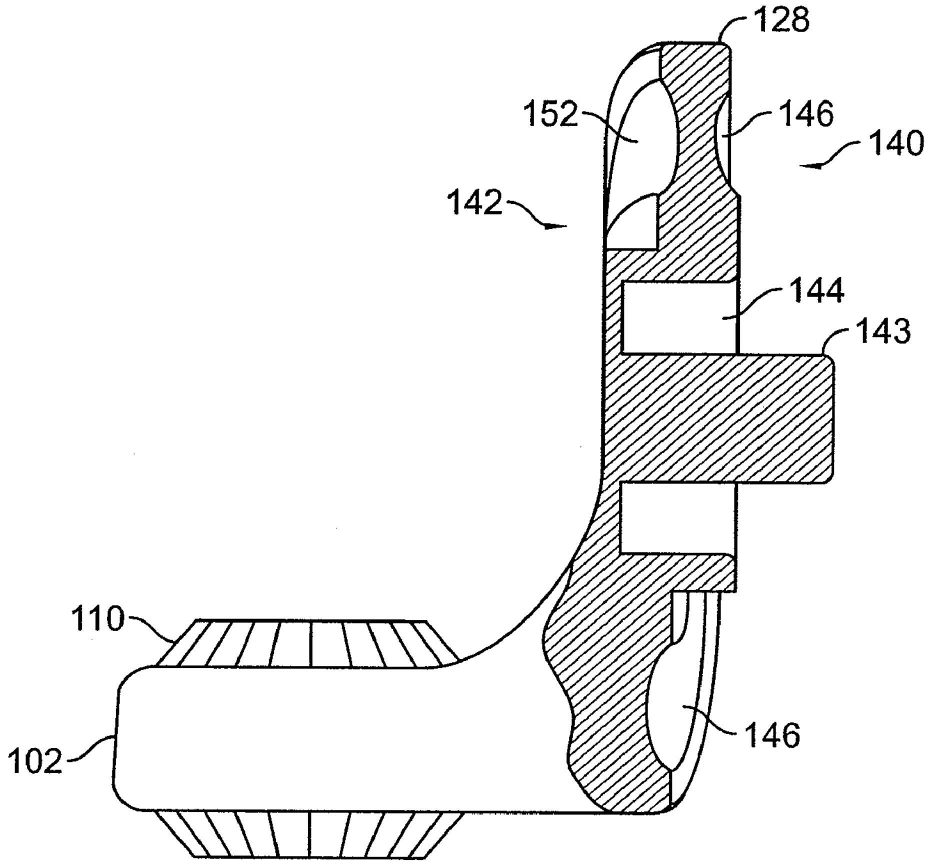
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FIG. 6

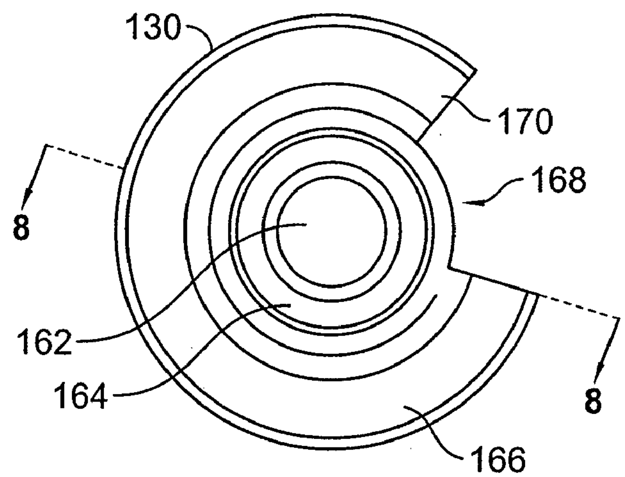
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FIG. 7

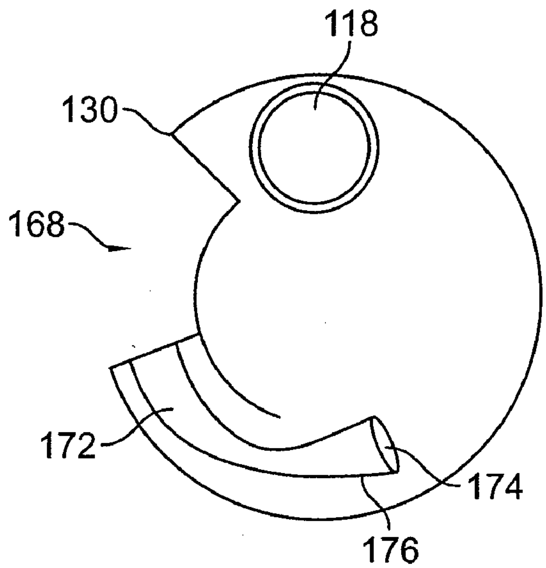

FIG. 8

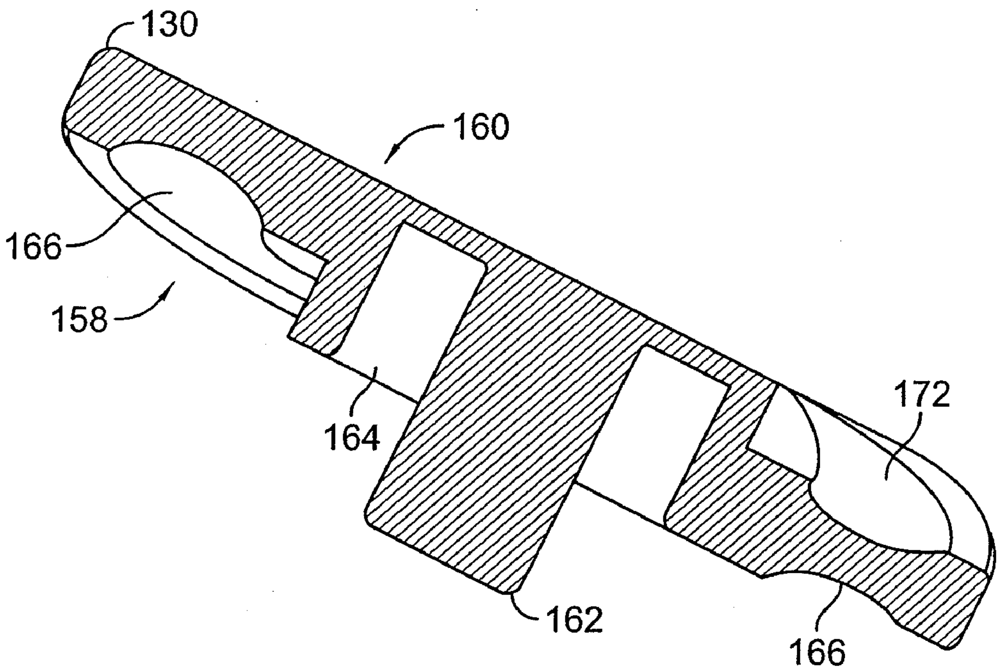

FIG. 9

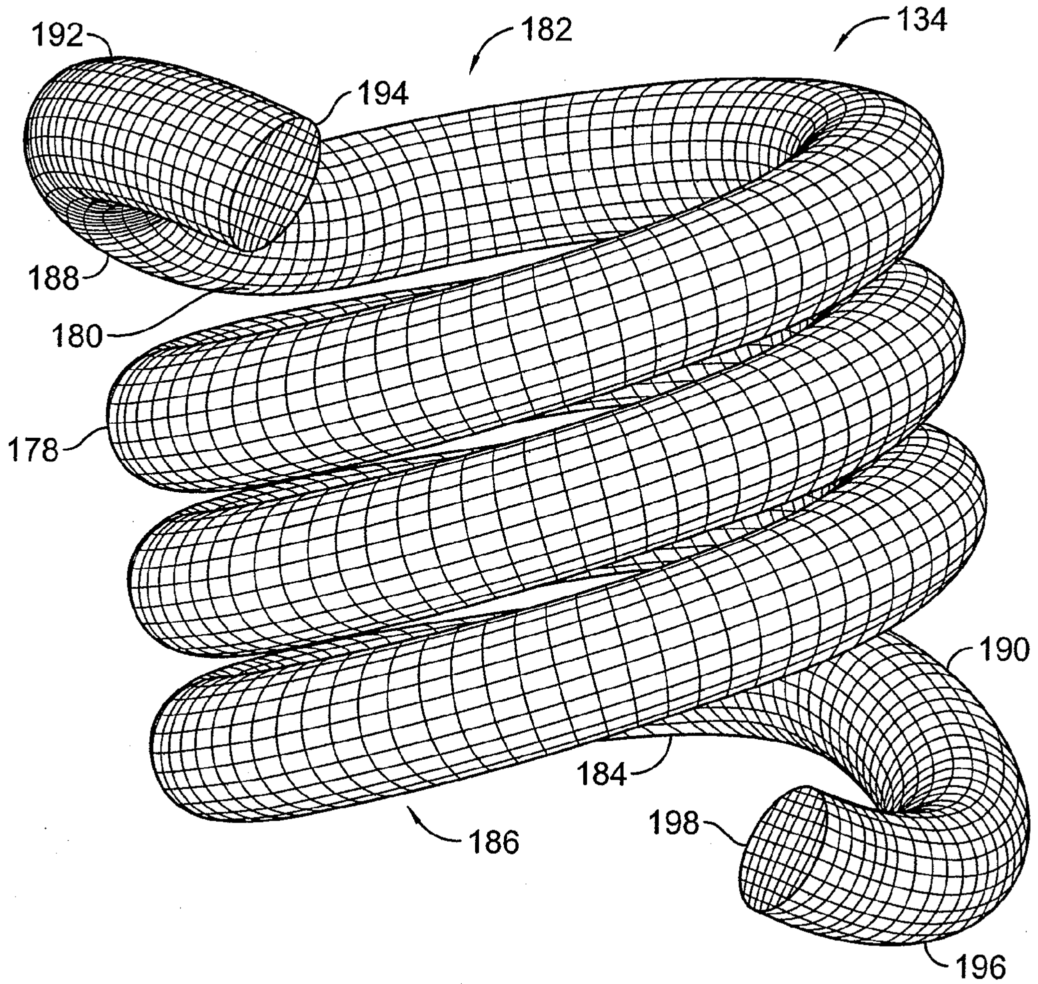

FIG. 10

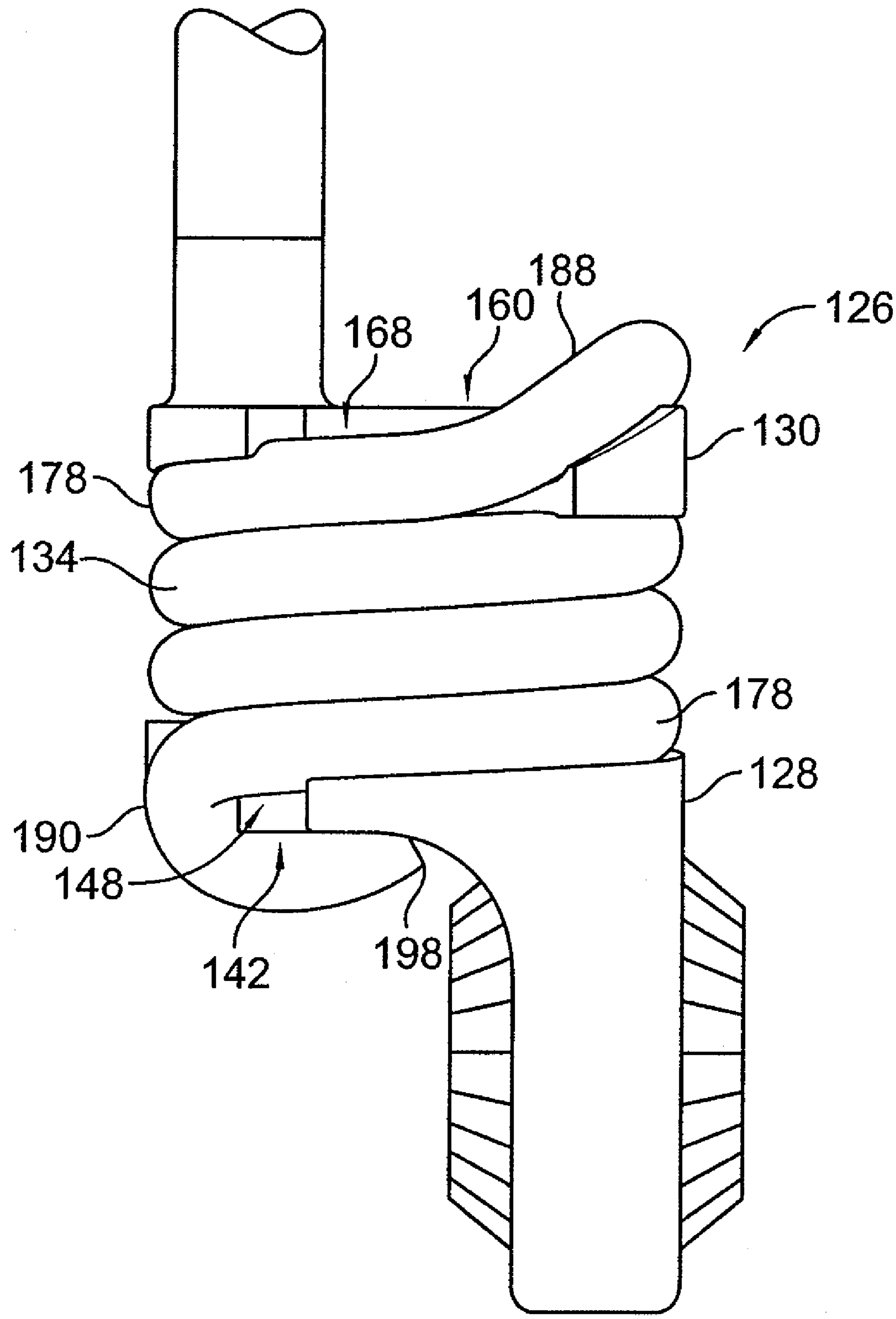

FIG. 11

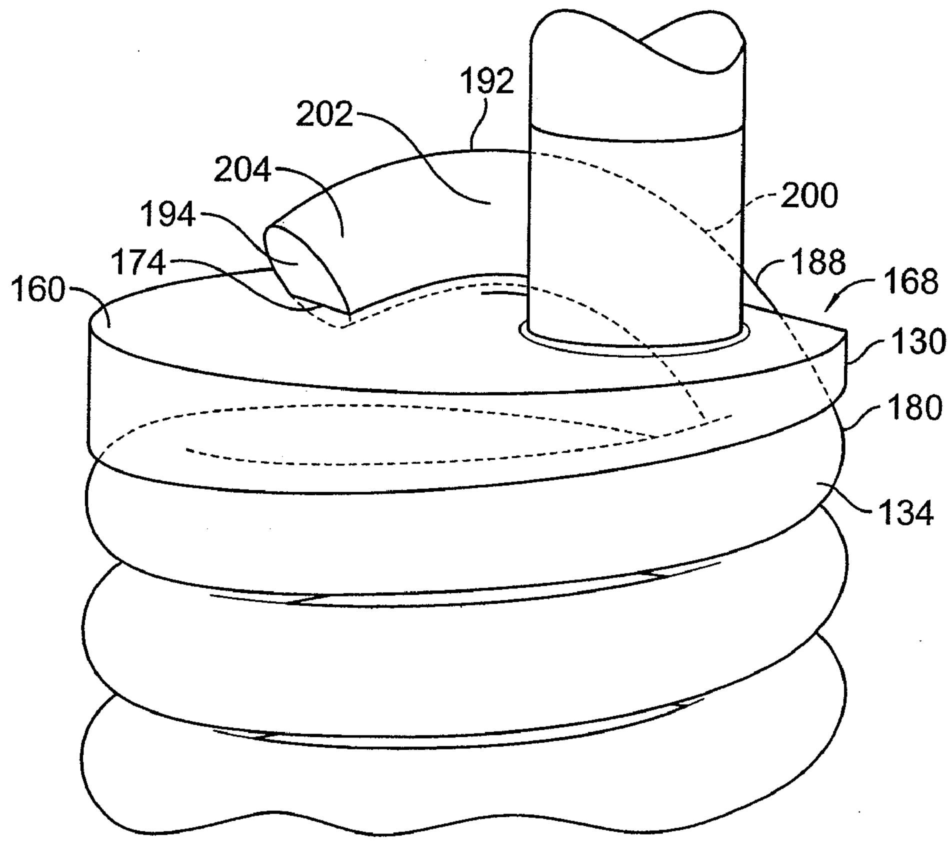
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FIG. 12

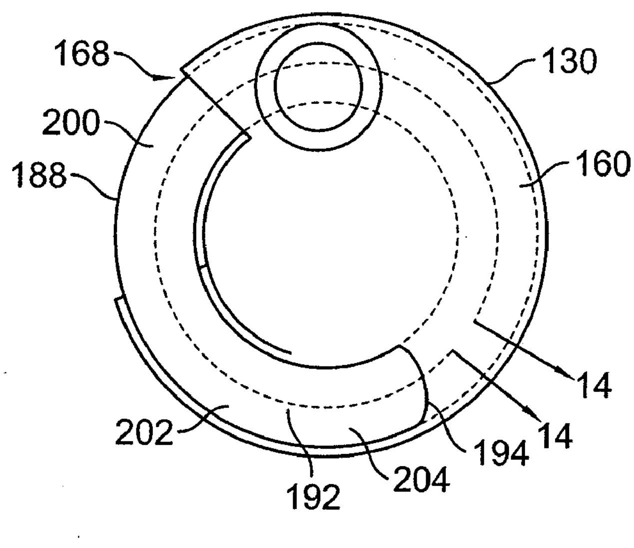
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FIG. 13

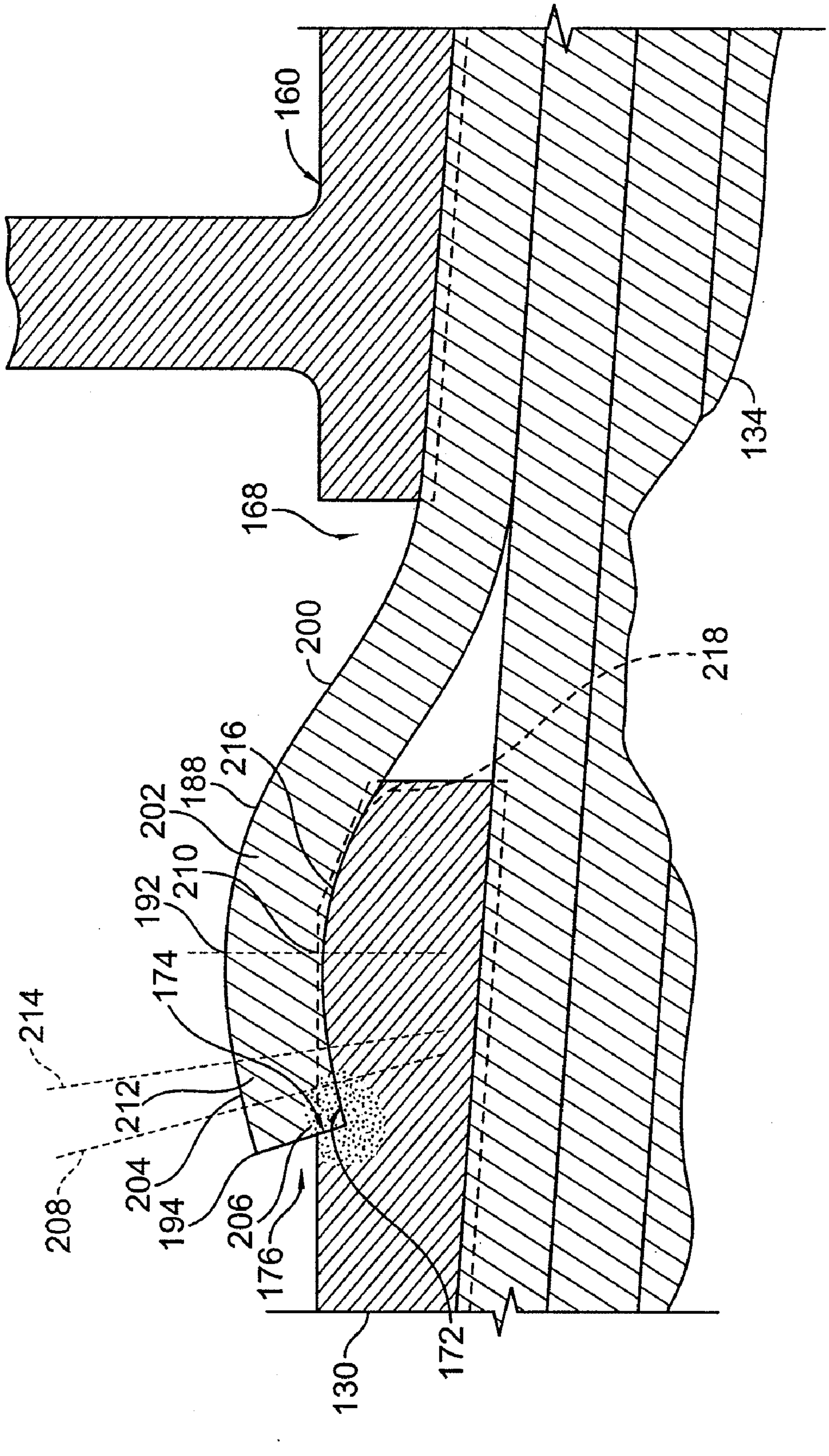
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FIG. 14

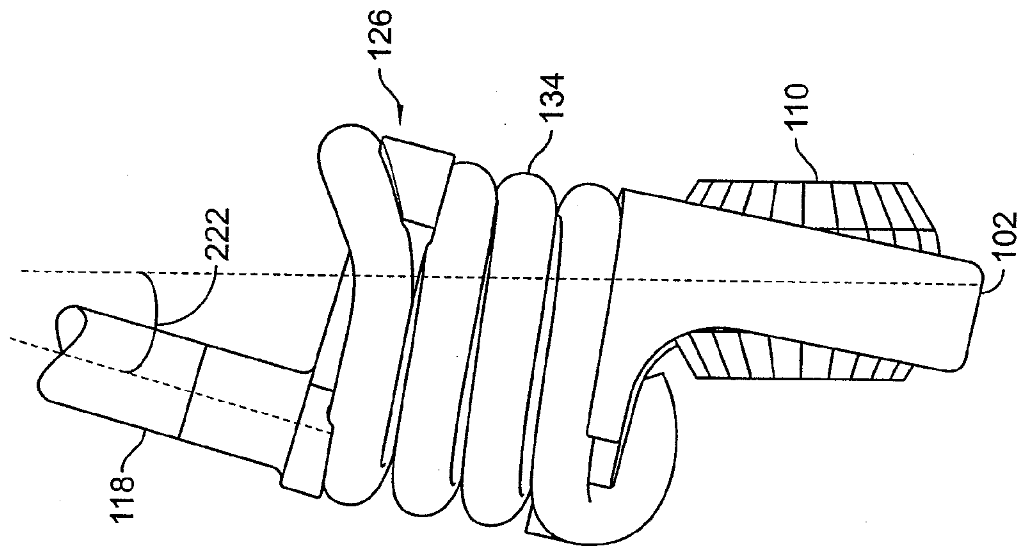

FIG. 16

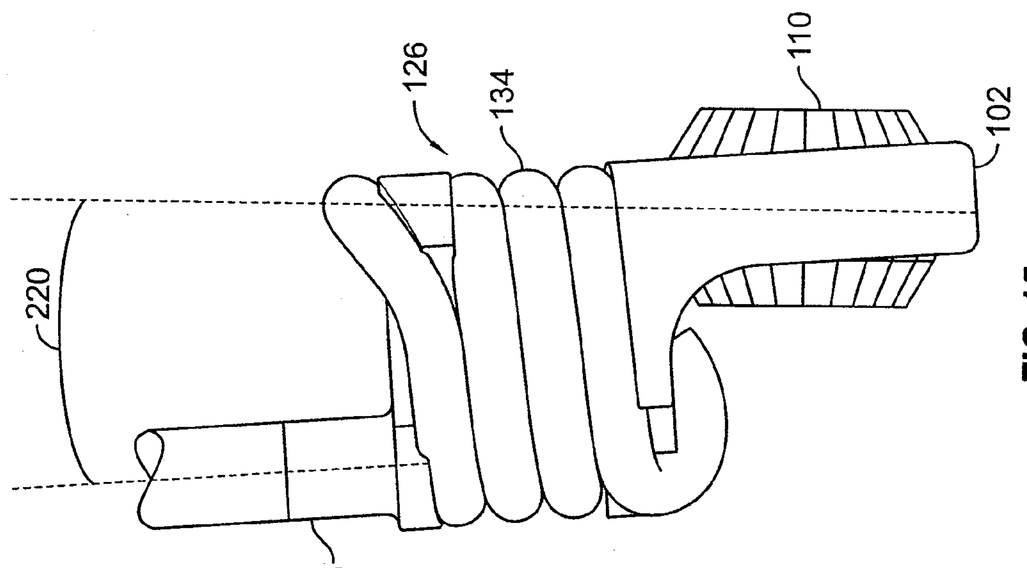

FIG. 15

INTEGRAL SPRING JUNCTION

CROSS-REFERENCE TO RELATED APPLICATION

[0001] The present application is a continuation application that claims priority benefit to a co-pending and commonly assigned non-provisional patent application entitled "Spring Junction and Assembly Methods for Spinal Device," which was filed on Aug. 3, 2005, and assigned Ser. No. 11/196,102.

BACKGROUND

[0002] 1. Technical Field

[0003] The present disclosure relates to advantageous devices, systems and methods for spinal stabilization. More particularly, the present disclosure relates to devices, systems and methods for providing dynamic stabilization to the spine with systems/devices that include one or more enhanced spring junctions so as to provide clinically efficacious results.

[0004] 2. Background Art

[0005] 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.

[0006] New treatment modalities, collectively called motion preservation devices, are currently being developed to address these limitations. Some promising therapies are in the form of nucleus, disc or facet replacements. Other motion preservation devices provide dynamic internal stabilization of the injured and/or degenerated spine, e.g., the Dynesys stabilization system (Zimmer, Inc.; Warsaw, Ind.) and the Graf Ligament. A major goal of this concept is the stabilization of the spine to prevent pain while preserving near normal spinal function.

[0007] To provide dynamic internal spinal stabilization, motion preservation devices may advantageously include dynamic junctions that exhibit multiple degrees of freedom and commonly include active force-absorbing/force-generating structures. Such structures may include one or more resilient elements, e.g., torsion springs and/or coil springs, designed and deployed so as to contribute strength and flexibility to the overall device. While the flexibility afforded by such resilient elements is plainly critical to the effectiveness of the respective devices of which they faun a part, the elevated force levels associated with the use of such resilient elements can result in such resilient elements developing significant levels of internal stress. Depending on the magnitude and location thereof, internal stresses may pose the potential for stress-induced fatigue, material deformation and/or cracks. The FDA has promulgated rules (e.g., Title 21, Subchapter H, Part 888, Subpart D, Section 888.3070 regarding pedicle screw spinal systems) that, in relevant part, require manufacturers to demonstrate compliance with special controls, including but not limited to applicable mechanical testing standards geared toward high reliability and durability.

[0008] With the foregoing in mind, those skilled in the art will understand that a need exists for devices, systems and methods for motion-preserving spinal stabilization devices and systems having reliable, durable constructions. In addition, a need exists for manufacturing processes and/or techniques that may be used to reliably and efficiently produce motion-preserving spinal stabilization devices and systems. These and other needs are satisfied by the disclosed devices and systems that include advantageous spring junctions, as well as the associate methods for manufacture/assembly thereof.

SUMMARY OF THE PRESENT DISCLOSURE

[0009] According to the present disclosure, advantageous devices, systems and methods for spinal stabilization are provided. According to exemplary embodiments of the present disclosure, the disclosed devices, systems and methods include a spring junction that promotes reliable and efficacious spinal stabilization. The disclosed spring junction includes a structural member that is mounted or mountable with respect to a spine attachment fastener such as a pedicle screw, and a resilient element affixed to the structural member. The resilient element has an attachment region, along which the resilient element is affixed to the structural member, and an active region. The attachment region of the resilient element is physically separately disposed with respect to the active region thereof.

[0010] According to exemplary embodiments of the present disclosure, the spring junction includes a weld region. A heat-affected zone of the resilient element and associated with the weld region is disposed adjacent the weld region, but is physically separately disposed with respect to the active region of the resilient element. The active region of the resilient element is generally subjected to cyclical stress, e.g., during in situ use of the disclosed spinal stabilization device. In exemplary embodiments, the weld region is produced via a welding process, such as electron-beam welding, and accordingly may be subjected to welding temperatures of about 1000° F. or higher. In addition, in exemplary embodiments of the present disclosure, the resilient element takes the form of a spring, e.g., a coil spring or helical spring, which extends into the weld region and which is mounted with respect to the structural member to form the spring junction.

[0011] According to further exemplary embodiments of the present disclosure, the resilient element includes a bend region disposed between the weld region and an adjacent coil of the resilient element that extends along a helically-shaped path. The bend region is sized and shaped so as to initially bend away from the helically-shaped path before bending back toward the helically-shaped path and terminating at or in the weld region. In some such embodiments, the direction of the initial bend away from the helically-shaped path includes an axial component, but does not include a radial component. The bend region may further be sized and shaped so as to remain substantially peripherally aligned with such helically-shaped path when viewed in an axial direction with respect to the helically-shaped path. Of note, such spring junctions may be formed at opposite ends of the resilient element such that the resilient element/spring is mounted between spaced-apart structural members that are permitted to move relative to each other.

[0012] According to further exemplary embodiments of the present disclosure, a rod is mounted with respect to (or integrally formed with) the structural member. The rod may be advantageously adapted to mount with respect to an upwardly-extending structure associated with a pedicle screw. The rod/pedicle screw may be mounted with respect to each other such that relative movement of the rod relative to the pedicle screw is permitted in at least one plane.

[0013] In a still further embodiment, a method is disclosed for producing a spring junction in which a resilient element is welded to a structural member such that an active region of the resilient element is disposed physically separately with respect to the heat-affected zone associated with such welding. In some such embodiments, a further step is disclosed in which a resilient element is provided that defines an active region and a bend region, and wherein such welding results in the bend region being disposed between the active region and the heat-affected zone. Such a resilient element can include a coil extending along a helically-shaped path, and in which the bend region is configured so as to initially bend away from such helical path defined before bending back toward such helical path.

[0014] In a still further embodiment, a combination is provided that includes a structural member having a first end, a second end opposite the first end, an aperture between the first end and the second end, and a notch formed in the second end. The combination also includes a resilient element having a bend region at an end thereof, the bend region terminating at a termination. The resilient element is secured to the first end of the structural member such that the bend region extends through the aperture and the termination is lodged in the notch. In some such embodiments, the resilient element is further affixed to the structural member via a weld formed with respect to the termination and the structural member at the notch. In other such embodiments, the termination is configured and dimensioned so as to extend at least partially in the direction of the first end of the structural member, and the bend region is configured and dimensioned such that the termination can be threaded through the aperture, and thereby rotated toward and into the notch. In some such cases the structural member includes a helical groove formed in the first end and terminating adjacent the aperture, and the resilient element includes an active region adjacent the bend region and spaced apart from the termination, and the active region includes a coil threaded along the helical groove to an extent of the aperture.

[0015] The spring junction(s) of the present disclosure are typically employed as part of a spinal stabilization system that may advantageously include one or more of the following structural and/or functional attributes:

- **[0016]** Exemplary embodiments of the spring junction (and associated spring/structural member subassembly) are capable of undergoing at least approximately 10,000,000 cycles of combined extension/contraction and bending (e.g., during mechanical testing);
- **[0017]** Implementation of the disclosed spring junctions have no substantial effect on the footprint of the dynamic stabilization devices in which they are incorporated, e.g., the resilient elements (e.g., springs) of such spinal stabilization devices do not extend radially inwardly or outwardly to a greater extent than the dynamic stabilization devices that do not include the disclosed spring junctions, thereby preserving compatibility with existing components and/or proven or preferred geometries;
- **[0018]** An outwardly/upwardly, then inwardly/downwardly extending bend region at each end of the resilient element, combined with a notch on the external end of each spring cap plate provides a snap-fit system which positively locates the ends of the resilient element within their respective notches during pre-welding assembly, and presents a convenient face for purposes of electronic-beam welding without undue risk of annealing and/or other types of damage to the active region of the resilient element.

[0019] Advantageous spine stabilization devices, systems and methods may incorporate one or more of the foregoing structural and/or functional attributes. Thus, it is contemplated that a system, device and/or method may utilize only one of the advantageous structures/functions set forth above, a plurality of the advantageous structures/functions described herein, or all of the foregoing structures/functions, without departing from the spirit or scope of the present disclosure. Stated differently, each of the structures and functions described herein is believed to offer benefits, e.g., clinical advantages to clinicians and/or patients, whether used alone or in combination with others of the disclosed structures/functions.

[0020] Additional advantageous features and functions associated with the devices, systems and methods of the present disclosure will be apparent to persons skilled in the art from the detailed description which follows, particularly when read in conjunction with the figures appended hereto. Such additional features and functions, including the structural and mechanistic characteristics associated therewith, are expressly encompassed within the scope of the present invention.

BRIEF DESCRIPTION OF THE DRAWINGS

[0021] To assist those of ordinary skill in the art in making and using the disclosed devices, systems and methods for achieving enhanced reliability, dependability, and/or durability, e.g., in a dynamic spinal stabilization device, reference is made to the appended figures wherein:

[0022] FIG. **1** is a perspective exploded assembly view of a spinal stabilization device/system, according to the present disclosure;

[0023] FIG. **2** is an exploded assembly view of a spinal stabilization device/system, including pedicle screws and associated mounting structures, in accordance with an embodiment of the present disclosure;

[0024] FIG. **3** is an unexploded assembly view of the exemplary spinal stabilization device/system of FIG. **2**;

[0025] FIGS. **4**, **5** and **6** are interior end, exterior end, and cross-sectional views of a structural member associated with the exemplary spinal stabilization device/system of FIGS. **2-3**;

[0026] FIGS. **7**, **8** and **9** are interior end, exterior end, and cross sectional views of another structural member associated with exemplary spinal stabilization device/system of FIGS. **2-3**;

[0027] FIG. **10** is a side view of a resilient element that may be employed in forming one or more spring junctions according to the present disclosure;

[0028] FIG. **11** is a side assembly view of the exemplary spinal stabilization device/system of

[0029] FIGS. **2-3** illustrating assembly of the components of FIGS. **4-9**;

[0030] FIG. **12** is a perspective detail view of the interface between the structural member of FIGS. **7-9** and the resilient element of FIG. **10**;

[0031] FIG. **13** is a top view of the interface between the structural member of FIGS. **7-9** and the resilient element of FIG. **10**;

[0032] FIG. **14** is a sectional view of the interface between the structural member of FIGS. **7-9** and the resilient element of FIG. **10** taken along the line **14-14** of FIG. **13**; and

[0033] FIGS. **15** and **16** illustrate various exemplary types and ranges of motion associated with exemplary spinal stabilization devices/assemblies of the present disclosure.

DESCRIPTION OF EXEMPLARY EMBODIMENTS

[0034] The present disclosure provides advantageous devices, systems and methods for improving the reliability, dependability and/or durability of spinal stabilization systems. More particularly, the present disclosure provides advantageous devices, systems and methods for mechanically mounting resilient elements (e.g., torsion springs and/or coil springs) to, and/or for coupling resilient elements between, structural members (e.g., plates, caps, flanges, rods, and/or bars) associated with dynamic spinal stabilization systems. The mounting and/or coupling methods/techniques of the present disclosure provide enhanced reliability, dependability and/or durability without significantly increasing material weight or volume requirements and without compromising the important functions of the dynamic spinal stabilization devices/systems of which they form a part.

[0035] The exemplary embodiments disclosed herein are illustrative of the advantageous spinal stabilization devices/systems and surgical implants of the present disclosure, and of methods/techniques for implementation thereof. It should be understood, however, that the disclosed embodiments are merely exemplary of the present invention, which may be embodied in various forms. Therefore, the details disclosed herein with reference to exemplary dynamic spinal stabilization systems and associated methods/techniques of assembly and use are not to be interpreted as limiting, but merely as the basis for teaching one skilled in the art how to make and use the advantageous dynamic spinal stabilization systems and alternative surgical implants of the present disclosure.

[0036] With reference to FIG. **1**, components of a dynamic stabilization element **10** disclosed in commonly assigned U.S. Non-Provisional patent application Ser. No. 11/027,270, filed Dec. 31, 2004 (hereinafter "the '270 Application"), are shown in an exploded view. The disclosure of the '270 Application is hereby incorporated herein by reference in its entirety. As shown in FIG. **1**, the dynamic stabilization element **10** includes two structural elements in the form of a spring cap **12** and a spring cap **14**, and two resilient elements in the form of an inner spring **16** and an outer spring **18**. The spring cap **12** is affixed to an attachment member **20** that is configured to be coupled to the head of a pedicle screw (not shown) via a dynamic joint (not shown). The spring cap **14** is affixed to a rod **22** that is configured to be attached to another attachment member (not shown) that is in turn coupled to the head of another pedicle screw (not shown) via another dynamic joint (not shown). The dynamic stabilization element **10** permits relative axial/longitudinal motion, as well as angular/rotational motion, of the rod **20** relative to the attachment member **20**, as part of a larger spinal stabilization system (shown only in relevant part).

[0037] The spring cap **12** includes an interior end **24**, an exterior end **26** opposite the interior end, a post **28** axially positioned on the interior end **24**, an annular channel **30** formed in the interior end **24** around the post **28**, a helically-shaped groove **32** formed in the interior end **24** around the annular channel **30**, and an aperture **34** passing through the spring cap **12** between the interior and exterior ends **24**, **26** thereof at an end **36** of the helically-shaped groove **32**. The spring cap **14** includes an interior end **38**, an exterior end **40** opposite the interior end **38**, a post **42** axially positioned on the interior end **38** around the post **42**, a helically-shaped groove **46** formed in the interior end **38** around the annular channel **44**, and an aperture **48** passing through the spring cap **14** between the interior and exterior ends **38**, **40** thereof at an end **50** of the helically-shaped groove **46**.

[0038] The inner spring **16** consists of coils **52** sharing a common diameter and arranged sequentially about a common axis between a coil termination **54** (obscured) at an end **56** of the inner spring **16** and a coil termination **58** at another end **60** thereof opposite the end **56**. The outer spring **18** consists of coils **62** sharing a common diameter and arranged sequentially about a common axis between a coil termination **64** (obscured) at an end **66** of the outer spring **18** and a coil termination **68** at another end **70** thereof opposite the end **66**.

[0039] In the assembled state of the dynamic stabilization element **10**, the inner spring **16** is positioned within the outer spring **18**. The coil **52** at the end **56** of the inner spring **16** is positioned on or around the post **28** of the spring cap **12**, and against the interior end **24** of the spring cap **12** so as to occupy (at least in part) the annular channel **30** formed therein. The coil **52** at the end **60** of the inner spring **16** is positioned on or around the post **42** of the spring cap **14** and against the interior end **38** of the spring cap **14** so as to occupy (at least in part) the annular channel **44** formed therein. In this way, the inner spring **16** is effectively captured between the spring cap **12** and the spring cap **14** and effectively floats relative to the opposing posts **28**, **42**. The coil **62** at the end **66** of the outer spring **18** is threaded into the interior end **24** of the spring cap **12** along the helically-shaped groove **32** at least until the coil termination **64** reaches the aperture **34** of the spring cap **12**. The outer spring **18** is fixed with respect to the spring cap **12**, e.g., by welding, and may be trimmed so as to be flush relative to an edge formed at the interface between the aperture **34** and the exterior end **26** of the spring cap **12**. The coil **62** at the end **70** of the outer spring **18** is threaded into the interior end **38** of the spring cap **14** along the helically-shaped groove **46** at least until the coil termination **68** reaches the aperture **48** of the spring cap **14**. The outer spring **18** is fixed with respect to the spring cap **14**, e.g., by welding, and may be trimmed so as to be flush relative to an edge formed at the interface between the aperture **48** and the exterior end **40** of the spring cap **14**.

[0040] As described in the '270 Application, the outer spring **18** is typically shorter than the inner spring **16**, such that as the spring cap **12** and the spring cap **14** are brought toward each other (i.e., to permit the outer spring **18** to be mounted on both), the inner spring **16** is placed in compression. The degree to which the inner spring **16** is compressed is generally dependent on the difference in length as between the inner and outer springs **16**, **18**. Thus, the preload compression of the inner spring **16** may be controlled and/or adjusted in part through selection of the relative lengths of the inner and outer springs **16**, **18**. In addition to the preload compression of the inner spring **16**, the mounting of the outer spring **18** with respect to the spring caps **12**, **14** includes placing the outer spring **18** in tension. The overall preload of the dynamic stabilization element **10** corresponds to equal and opposite forces experienced by and/or contained within the inner and outer springs **16**, **18**.

[0041] The inner spring **16** reaches its free length (i.e., non compressed state) at or about the point at which a patient's movement exceeds a "neutral zone" (as described more completely in the '270 Application). Beyond this point, the inner spring **16** is free floating (e.g., on the opposing posts **28**, **42**), while the outer spring **18**, already in tension, extends in length even further.

[0042] In the overall design of the disclosed spinal stabilization system, optimization of the attachment between the outer spring **18** and the spring cap **14** is desirable. In experimental studies associated with spinal stabilization devices of the type disclosed herein, it has been noted that direct welding of the outer spring **18** and the spring cap **14** may not provide an optimal means of attachment. While not intending to be bound by theory, it is believed that a "heat-affected" zone may be created in the coil **62** at the end **70** of the outer spring **18** as a result of the process of welding the outer spring **18** to the spring cap **14**. More particularly, such heat-affected zone is believed to arise as a result of an annealing effect brought about by the migration of excess heat arising from an electronic-beam welding process. In accordance with such electronic beam or E-beam welding processes, elevated temperatures in a range of approximately 1000° F. or higher are used to affix the outer spring **18** to the spring cap **14** by essentially melting such components together. The heat-affected zone so produced can be at least 0.005"-0.030" in axial length, and is located immediately adjacent the weld formed at the end **70** of the outer spring **18**, and along the active region of the outer spring **18**. (As used herein in reference to a spring or resilient element, the term "active region" or "active portion" refers to a region, portion, or part of the spring or resilient element which, during normal in-situ use and/or representative mechanical testing of the spring or resilient element, actively contributes to the characteristic stiffness of the spring or resilient element, and/or actively participates in the axial travel and/or lateral bending thereof.) The heat-affected zone can include a soft or weak point on the coil **62** at which a Rockwell hardness of the material of the outer spring **18**, ordinarily falling within a range of from approximately 46 to approximately 54, dips sharply; e.g., to a value in a range of from approximately 20 to approximately 24.

[0043] According to the present disclosure, geometric/structural modifications to the outer spring **18** and the spring cap **14** have been found to advantageously enhance the reliability and durability of dynamic stabilization element **10**. Exemplary embodiments of the advantageous geometric/structural modifications to the outer spring **18** and the spring cap **14** are described hereinbelow with reference to FIGS. **2-14**, as is a beneficial cooling/supercooling step involving the modified outer spring and the modified spring caps associated therewith. As a result of these geometric/structural modifications, and/or of the cooling/supercooling step, a durability standard of 10,000,000+failure-free cycles has been achieved with apparatus in which an outer spring has been welded to its associated spring caps to form a dynamic stabilization device as described herein.

[0044] According to exemplary embodiments of the present disclosure, the geometric/structural modifications include the creation of a substantial physical separation of the active portion of the outer spring from the heat-affected zone associated with the E-beam welding process, and/or from the actual site of the weld formed between the attached components. As a result of this separation, to the extent that any region of the outer spring becomes significantly annealed, and/or is brought to a significantly lowered Rockwell hardness value as a result of E-beam welding, the amount of cyclic stress to which that softened or annealed portion is exposed is substantially reduced and/or brought to such a low level that the respective junctions between the outer spring and its associated spring caps can exhibit very high levels of reliability/durability.

[0045] With reference to FIGS. **2** and **3**, a dynamic spinal stabilization system **100** is shown in accordance with an exemplary embodiment of the present disclosure. Referring to FIG. **2**, the spinal stabilization system **100** includes attachment members **102**, **104**, pedicle screws **106**, **108**, ball/spherical elements **110**, **112**, and set screws **114**, **116**. The attachment member **102** is configured to receive the ball/spherical element **110**. The ball/spherical element **110** then receives the head of the pedicle screw **106** such that a global/dynamic joint is formed between the attachment member **102** and the head of the pedicle screw **106** (see also FIG. **3**). The set screw **114** is then inserted into the head of the pedicle screw **106** (see also FIG. **3**), thereby securing the head of the pedicle screw **106** within the ball/spherical element **110**. The attachment member **104** is configured to receive the ball/spherical element **112**. The ball/spherical element **112** then receives the head of the pedicle screw **108** such that a global/dynamic joint is formed between the attachment member **104** and the head of the pedicle screw **108** (see also FIG. **3**). The set screw **116** is then inserted into the head of the pedicle screw **108** (see also FIG. **3**), thereby securing the head of the pedicle screw **108** within the ball/spherical element **112**.

[0046] The spinal stabilization system **100** also includes a rod **118**. The rod is configured to be inserted into the attachment member **104**, which includes a transverse aperture **120** to accommodate the rod **118**, and a set screw **122** to secure the rod **118** at a desired position within the transverse aperture **120** (see also FIG. **3**, in which a hex driver **124** is shown turning the set screw **122** against the rod **118**).

[0047] The spinal stabilization system **100** further includes a dynamic stabilization element **126** between the rod **118** and the attachment member **102**. The dynamic stabilization element **126** includes structural members **128**, **130**, an inner resilient element **132**, an outer resilient element **134**, a sheath member **136**, and two end clamps **138**. As shown in FIG. **3**, the inner resilient element **132** (obscured) and outer resilient element **134** (partially obscured) are positioned within the sheath member **136**, and an end clamp **138** secures the sheath member **136** to each of the structural members **128**, **130**. This prevents undesirable interaction or interference between the inner and outer resilient elements **132**, **134** and anatomical structures in situ. Referring again to FIG. **2**, the inner resilient element **132** is constructed and functions in manners substantially similar to those of the inner spring **16** described hereinabove with reference to the dynamic stabilization element **10**. The inner resilient element **132** is also deployed and employed in the dynamic stabilization element **126** in manners substantially similar to those in which the inner spring **16** is deployed and employed in the dynamic stabilization element **10** described hereinabove.

[0048] The following components of the dynamic stabilization element **126** will now be described in greater detail: the structural member **128** (with reference to FIGS. **4-6**), the structural member **130** (with reference to FIGS. **7-9**), and the outer resilient element **134** (with reference to FIG. **10**). Next, the manner in which the structural members **128**, **130** and the outer resilient element **134** are assembled will be discussed (with particular reference to FIGS. **11-14**). Then, the functions of the dynamic stabilization element **126** will be discussed, followed by a discussion of the characteristic advantages of the dynamic stabilization element **126**.

[0049] Referring now to FIGS. **4-6**, the structural member **128** is affixed to (e.g., is of unitary construction with) the attachment member **102** (the ball/spherical element **110** is also shown within the attachment member **102**) and takes the form of a plate having multiple features permitting the structural member **128** to function in the manner of an end cap or spring cap with respect to the inner and outer resilient elements **132**, **134** (FIG. **2**). The structural member **128** includes an interior end **140**, an exterior end **142** opposite the interior end **140**, a post **143** axially positioned on the interior end **140**, an annular channel **144** formed in the interior end **140** around the post **143**, a helically-shaped groove **146** formed in the interior end **140** around the annular channel **144**, an aperture **148** passing through the structural member **128** between the interior and exterior ends **140**, **142** thereof at an end **150** of the helically-shaped groove **146**, a short groove **152** formed in the exterior end **142** adjacent the aperture **148**, and a notch **154** formed in the exterior end **142** at an end **156** of the short groove **152**. The structure and function of the structural member **128** will be described in greater detail hereinafter.

[0050] Referring now to FIGS. **7-9**, the structural member **130** is affixed to (e.g., is of unitary construction with) the rod **118** (which is positioned off-axis or off-center with respect to the structural member **130**), and takes the form of a plate having multiple features permitting the structural member **130** to function in the manner of an end cap or spring cap with respect to the inner and outer resilient elements **132**, **134** (FIG. **2**). The structural member **130** includes an interior end **158**, an exterior end **160** opposite the interior end **158**, a post **162** axially positioned on the interior end **158**, an annular channel **164** formed in the interior end **158** around the post **162**, a helically-shaped groove **166** formed in the interior end **158** around the annular channel **164**, an aperture **168** passing through the structural member **130** between the interior and exterior ends **158**, **160** thereof at an end **170** of the helically-shaped groove **166**, a short groove **172** formed in the exterior end **160** adjacent the aperture **168**, and a notch **174** formed in the exterior end **160** at an end **176** of the short groove **172**. The structure and function of the structural member **130** will be described in greater detail hereinafter.

[0051] Referring now to FIG. **10**, the outer resilient element **134** consists of coils **178** sharing a common diameter and arranged sequentially about a common axis between a coil termination **180** at an end **182** of the outer resilient element **134** and a coil termination **184** at another end **186** thereof opposite the end **182**. Extending from the coil termination **180**, and substantially continuous therewith, is a bend region **188** of the outer resilient element **134**. Extending from the coil termination **184**, and substantially continuous therewith, is a bend region **190** of the outer resilient element **134**.

[0052] The bend regions **188**, **190** of the outer resilient element **134** extend peripherally from the respective coil terminations **180**, **184** along respective paths which, when viewed axially (see, e.g., FIG. **13**) from either end **182**, **186** of the outer resilient element **134**, are defined by respective single radii that extend from the common axis of the coils **178** of the outer resilient element **134** and that have extents approximately half that of the common diameter of the coils **178**. As a result, the bend regions **188**, **190** of the outer resilient element **134** remain within the same peripheral outline defined by the coils **178** of the outer resilient element **134**. When viewed from the side, however, as in FIG. **10**, the bend regions **188**, **190** of the outer resilient element **134** are seen to depart from the helical path defined by the coils **178**.

[0053] More particularly, the bend region **188**, when viewed from the side as in FIG. **10**, is seen to include a curve or bend in the path of extension of the bend region **188**, according to which the material of the outer resilient element **134**: (1) initially curves away from the adjacent coil **178** at the coil termination **180**; (2) reaches an apex **192** representing a point of maximum departure from the adjacent coil **178**; (3) curves therefrom back toward the adjacent coil **178**; and (4) terminates at a bend region termination **194** without fully returning to the helical path defined by the coils **178**. Also, the bend region **190**, when viewed from the side as in FIG. **10**, is seen to include a curve or bend in the path of extension of the bend region **190**, according to which the material of the outer resilient element **134**: (1) initially curves away from the adjacent coil **178** at the coil termination **184**; (2) reaches an apex **196** representing a point of maximum departure from the adjacent coil **178**; (3) curves therefrom back toward the adjacent coil **178**; and (4) terminates at a bend region termination **198** without fully returning to the helical path defined by the coils **178**. The structure and function of the outer resilient element **134** will be described in greater detail hereinafter.

[0054] In the assembled state of the dynamic stabilization element **126** shown in FIG. **11**, the inner resilient element **132** (obscured, see FIG. **2**) is positioned within the outer resilient element **134**, between the respective posts **143** (FIG. **4**), **162** (FIG. **7**), and within the respective annular channels **146** (FIG. **4**), **164** (FIG. **7**) of the structural elements **128**, **130**. The bend region **190** and the coil **178** at the end **186** (FIG. **10**) of the outer resilient element **134** are threaded into the interior end **140** (FIG. **6**) of the structural element **128** until the bend region **190** has substantially passed into or through the aperture **148** of the structural element **128** and the bend region termination **198** has been caused to drop or snap into place within the notch **154** (FIG. **5**) formed in the exterior end **142** of the structural element **128**. The bend region **188** and the coil **178** at the end **182** (FIG. **10**) of the outer resilient element **134** are threaded into the interior end **158** (FIG. **9**) of the structural element **130** until the bend region **188** has substantially passed into or through the aperture **168** of the structural element **130** and the bend region termination **194** (obscured, see FIG. **10**) has been caused to drop or snap into place within the notch **174** (FIG. **8**) formed in the exterior end **160** of the structural element **130**.

[0055] Referring now to FIG. **12**, the interface or spring junction between the outer resilient element **134** and the structural element **130** is shown in greater detail. As indicated above, the bend region **188** largely or completely extends into or through the aperture **168** formed in the structural element **130**, and the bend region termination **194** is lodged within the notch **174** formed in the exterior end **160** of the structural element **130**. More particularly, a portion **200** of the bend region **188** of the outer resilient element **134** near the coil termination **180** is lodged within the short groove **172** (FIG. **9**) formed in the exterior end **160** of the structural element **130**, a portion **202** of the bend region **188** associated with the apex **192** thereof is lodged within the short groove **172** and in longitudinal contact with the exterior end **160** of the structural element **130**, and a portion **204** of the bend region **188** associated with the bend region termination **194** is lodged within the short groove **172** to an extent of the notch **174**. The outer resilient element **134** is welded to the exterior end **160** of the structural element **130** in the vicinity of the notch **174**, e.g., via electronic-beam welding along an extent of the portion **204** of the bend region **188** that is lodged within the notch **174**. The outer resilient element **134** can be placed in a state of full compression in advance of such welding so as to ensure that after such welding, the portion **202** of the bend region **188** associated with the apex **192** thereof is biased in favor of continuous longitudinal contact with the exterior end **160** of the structural element **130** during normal in situ use of, and/or during representative mechanical testing of, the dynamic stabilization element **126**.

[0056] Though not shown in FIG. **12**, a portion (not separately shown) of the bend region **190** (FIG. **10**) near the coil termination **184** (FIG. **10**) is similarly lodged within the short groove **152** (FIG. **5**) formed in the exterior end **142** (FIG. **6**) of the structural element **128**, a portion (not separately shown) of the bend region **190** (FIG. **10**) associated with the apex **196** (FIG. **10**) thereof is lodged within the short groove **152** and in longitudinal contact with the exterior end **142** of the structural element **128**, and a portion (not separately shown) of the bend region **190** associated with the bend region termination **198** is lodged within the short groove **152** to an extent of the notch **154**. The outer resilient element **134** is welded to the exterior end **142** of the structural element **128** in the vicinity of the notch **154**, e.g., via electronic-beam welding along an extent of the portion (not separately shown) of the bend region **190** that is lodged within the notch **154** (FIG. **5**). The outer resilient element **134** can be placed in a state of full compression in advance of such welding for the same reasons and to achieve a similar biasing effect in the bend region **190** as is described above with reference to the bend region **188**.

[0057] A cooling/supercooling step may be advantageously undertaken in advance of welding such as is described immediately hereinabove. In accordance with such a step, the outer resilient element **134** and the structural members **128**, **130** are immersed in a bath of liquid nitrogen, and are withdrawn therefrom shortly before the resilient element **134** is welded to the structural elements **128**, **130**. Cooling/supercooling of the outer resilient element **134** and the structural members **128**, **130** functions to reduce the likelihood that high levels of heat will be experienced at a distance from the respective weld regions associated therewith. Accordingly, a given heat-affected zone associated with the migration of heat generated by electronic beam welding can be shrunken and/or reduced in extent, as can any soft or weak spot in such heat-affected zone associated with sharply reduced Rockwell hardness. This cooling/supercooling step was observed to increase resilient element durability during representative mechanical testing.

[0058] Referring to FIGS. **13** and **14**, the above-described welding process produces a weld region **206** incorporating portions of the exterior end **160** of the structural element **130** at the end **176** of the short groove **172** in the vicinity of the notch **174**, as well as portions of the bend termination **194** of the bend region **188** of the outer resilient element **134**. The portion **204** of the bend region **188** is long enough, and the corresponding portion of the short groove **172** is long enough, such that weld region **206** terminates at a point **208** along the extent of the bend region **188** well short of the apex **192** thereof Accordingly, the weld region **206** also terminates well short of a corresponding apex **210** of the short groove **172** against which the portion **202** of the bend region **188** is biased. To the extent the portion **204** of the bend region **188** includes a heat-affected zone **212** associated with the process used to affix the outer resilient element **134** to the structural element **130**, such region **212** also terminates at a point **214** along the extent of the bend region **188** well short of the apex **192** thereof, as well as well short of the apex **210** of the short groove **172**. The portion **202** of the bend region **188** and the exterior end **160** of the structural member **130** are in intimate and continuous longitudinal contact along the short groove **172** at least from the apex **210** thereof and for an extent **216** extending toward the aperture **168**. Beyond the extent **216**, the short groove **172** tends to depart from intimate contact from the portion **200** of the bend region **188** for an extent **218** extending fully to the aperture **168**. The significance and functional benefits of such structure and/or such assembly arrangement between the bend region **188** of the outer resilient element **134** and the exterior end **160** of the structural element **130** will be explained more fully hereinafter.

[0059] Turning now to FIGS. **15** and **16**, in operation, the dynamic stabilization element **126** of the spinal stabilization system **100** (FIG. **2**) permits relative rotational motion, as well as relative translational motion, as between the rod **118** and the attachment member **102**, and/or as between the rod **118** and the ball/spherical element **110**, while providing enhanced spinal support for the patient, e.g., in the "neutral zone" described more fully in the '**270** Application. More particularly, the dynamic stabilization element **126** as a unit, and/or the outer resilient element **134** by itself, supports either and/or both of spinal extension and spinal flexion. Referring to FIG. **15**, the dynamic stabilization element **126** is shown as it would appear while supporting spinal extension, wherein an extent **220** of, for example, less than 5° of relative rotation as between the rod **118** and the ball/spherical element **110** is produced. Such spinal extension can also produce approximately one millimeter of travel in the resilient element **134** relative to the initial position thereof (i.e., wherein the resilient element **134** is preloaded in tension so as to be slightly extended), such that the resilient element **134** may now actually assume a fully compressed state. Referring to FIG. **16**, the dynamic stabilization element **126** is shown as it would appear while supporting spinal flexion, wherein an extent **222** of, for example, greater than 10° of relative rotation as between the rod **118** and the ball/spherical element **110** is produced. Such spinal flexion can produce approximately one and one-half millimeters of travel (i.e., additional extension) in the resilient element **134** relative to the initial position thereof.

[0060] Referring again to FIG. **14**, the outer resilient element **134** is shown in a state of full compression against the interior end **158** of the structural element **130**. As discussed above, when the outer resilient element **134** is in this condition, the bend region **188** of the outer resilient element **134** is biased toward contact with the exterior end **160** of the structural element **130**. To the extent the outer resilient element **134** is caused to expand from its fully compressed state, this bias is not relaxed. Rather, this bias is only reinforced by such torsional and/or bending forces as may tend to urge the portion **200** of the bend region **188** further through the aperture **168** in the direction of the interior end **158**. (For example, depending on the particular axial and/or lateral forces imposed upon the outer resilient element **134**, the portion **200** of the bend region **188** can tend to bend and/or twist close to/closer to the angled exterior surface associated with the extent **218** of the short groove **172**). At the same time, the portion **202** of the bend region **188** remains lodged in the short groove **172**, where it remains in intimate contact with the exterior end **160** of structural element **130**, and as such is not capable of being deflected any further in the direction of the interior end **158** by such axial and/or lateral forces. Accordingly, such axial and/or lateral forces are prevented from directly acting upon either of the weld region **206** or the heat-affected zone **212** of the outer resilient element **134**. More particularly, the consistent, continuous longitudinal contact between the portion **202** of the bend region **188** and the exterior end **160** of the structural element **130** along the short groove **172** thereof acts as a permanent 'fulcrum', beyond which the torsional and/or bending forces arising in the portion **200** of the bend region **188** are not necessarily transmitted as such to the weld region **206** or the heat-affected zone **212**, at least not in a form capable of producing fatigue-inducing stress in such region/zone. In other words, the active region of the outer resilient element **134** extends no further toward the weld region **206** or the heat-affected zone **212** than the apex **192** of the bend region **188**. Since such regions are physically separated from the apex **192** via corresponding structural features of the outer resilient element **134** and the structural member **130**, and/or via the manner in which the same are affixed to each other, such forces as are applied to the weld region **206** and the heat-affected zone **212** during in situ use or representative mechanical testing will have been channeled into a cantilevered arrangement. In accordance with such cantilevered arrangement, a fulcrum (e.g., the extent **216** within the short groove **172**) provides the weld region **206** with significant mechanical advantage by which to resist such forces without experiencing undue internal stress.

[0061] The dynamic stabilization element **126** associated with the spinal stabilization system **100** described hereinabove with regard to FIGS. **2-14** provides numerous advantages in comparison to other spinal stabilization systems associated therewith. Referring again to FIGS. **11** and **14**, and while not necessarily intending to be bound by theory, improved reliability and durability is achieved with the disclosed dynamic stabilization element based at least in part on the fact that the heat-affected zone associated with the process of joining the outer resilient element **134** to the structural elements **128**, **130** via welding is physically separated from the active region of the outer resilient element **134**, and is therefore isolated from the cyclical stress associated with repeated extension/contraction and/or bending during normal use and/or representative mechanical testing. More particularly, the portion **202** of the bend region **188** of the outer resilient element **134** fully separates the portion **202** of the outer resilient element **134** from the portion **204** thereof at which the outer resilient element **134** is welded to the structural member **130**. In like measure, and in a similar fashion, the welded and threaded connection between the outer resilient element **134** and the structural member **128** provides similar advantages. Typically, due to the particular structures and assembly methods described above, the heat-affected zone in exemplary embodiments of the present disclosure is observed to extend axially approximately 005"-0.030" from the weld region along the material of the outer resilient element **134**, and the active region of the outer resilient element **134** extends no farther in the direction of the welded interfaces than the respective apexes **192**, **196** of the bend regions **188**, **190**. Since the bend regions **188**, **190** are each approximately 0.150 inches in length, the increased reliability/durability found in the dynamic stabilization element of the present disclosure has been shown to be at least partially due to the fact that the active region of the outer resilient element **134** is substantially completely shielded from any material degradation that may result from the assembly step, e.g., via electronic-beam welding. In other words, to the extent the use of E-beam welding reduces the Rockwell hardness of a portion or portions of the outer resilient element **134**, such portion or portions are substantially completely shielded from fatigue-producing levels of cyclic stress.

[0062] The dynamic stabilization element **126** associated with the spinal stabilization system **100** described hereinabove with regard to FIGS. **2-14** can be the subject of numerous modifications and variations while still exhibiting the above-discussed advantages over other dynamic junctions for spinal stabilization systems. For example, the rod **118** can be repositioned to an axial position with respect to the structural member **130**. The bend region termination **194** can be affixed to the structural member **130** by other welding processes than E-beam welding, and/or by one or more non-welding means of attachment, such as by clamping or the use of mechanical fasteners appropriate for use in conjunction with small gage springs, by an adhesive-based process, or via the use of a single mold to form the two components together as a single piece. To the extent such attachment schemes result in respective attachment regions along which the bend region termination **194** is affixed to the structural member, such attachment regions are similarly disposed physically separately relative to the respective active region of the outer resilient element **134***s* (whether or not heat-affected zones are present), and are thereby similarly shielded from the types and levels of cyclical stress known to produce fatigue failure. The outer resilient element **134** need not necessarily be configured in the manner of a coil spring, but may instead take the form of one or more other types of resilient elements, such as a leaf spring, a torsion spring or bar, etc. Additionally, the outer resilient element **134** may be employed in a dynamic junction that does not also include the inner resilient element **132**. Many other variations and/or modifications are possible.

[0063] 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 connection structure 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 spinal stabilization element, comprising:

(a) a spring cap;

(b) an attachment member that is structurally associated with the spring cap, said attachment member being substantially transversely oriented relative to the spring cap and adapted to be mounted with respect to a first pedicle screw; and

(c) a resilient element that includes a bend termination at an end thereof, wherein said bend termination of said resilient element and said spring cap are integrally formed.

2. The spinal stabilization element according to claim **1**, wherein said resilient element defines a central axis and wherein said attachment member is offset from said central axis.

3. The spinal stabilization element according to claim **1**, wherein said spring cap defines an interior end and an exterior end, and wherein said resilient element is flush relative to the exterior end of the spring cap.

4. The spinal stabilization element according to claim **1**, wherein said resilient element is selected from the group consisting of a coil spring, a leaf spring, a torsion spring and a torsion bar.

5. The spinal stabilization element according to claim **1**, wherein said resilient element defines a second end opposite said bend termination and a central axis, and wherein said bend termination and said second end of said resilient element are spaced from one another along said axis.

6. The spinal stabilization element according to claim **5**, wherein said resilient element is compressible and extendable along said axis.

7. In combination:

(a) a first element including:

(i) a first spring cap;

(ii) an attachment member that is structurally associated with the first spring cap, said attachment member being substantially transversely oriented relative to the first spring cap and adapted to be mounted with respect to a pedicle screw; and

(iii) a resilient element that includes a bend termination at an end thereof, wherein said bend termination of said resilient element and said first spring cap are integrally formed; and

(b) a second element including a second spring cap in spaced relation relative to the bend termination of said resilient element and configured to be mounted with respect to a second pedicle screw.

8. The combination according to claim **7**, wherein said resilient element defines a central axis and wherein said attachment member of said first spring cap is offset from said central axis.

9. The combination according to claim **7**, wherein said resilient element defines a second end and said second end of said resilient element is operatively coupled to said second spring cap.

10. The combination according to claim **7**, wherein said resilient element defines an axis, said first and second ends of said resilient element are spaced from one another along said axis, and said resilient element is compressible and extendable along said axis.

11. The combination according to claim **7**, wherein said resilient element is selected from the group consisting of a coil spring, a leaf spring, a torsion spring and a torsion bar.

12. A spinal stabilization system comprising:

(a) first and second pedicle screw;

(b) a first element including:

(i) a first spring cap;

(ii) an attachment member that is structurally associated with the first spring cap, said attachment member being substantially transversely oriented relative to the first spring cap and adapted to be mounted with respect to a pedicle screw; and

(iii) a resilient element that includes a bend termination at an end thereof, wherein said bend termination of said resilient element and said first spring cap are integrally formed; and

(c) a second element including a second spring cap in spaced relation relative to the bend termination of said resilient element and configured to be mounted with respect to a second pedicle screw.

13. The spinal stabilization system according to claim **12**, wherein said resilient element is selected from the group consisting of a coil spring, a leaf spring, a torsion spring and a torsion bar.

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