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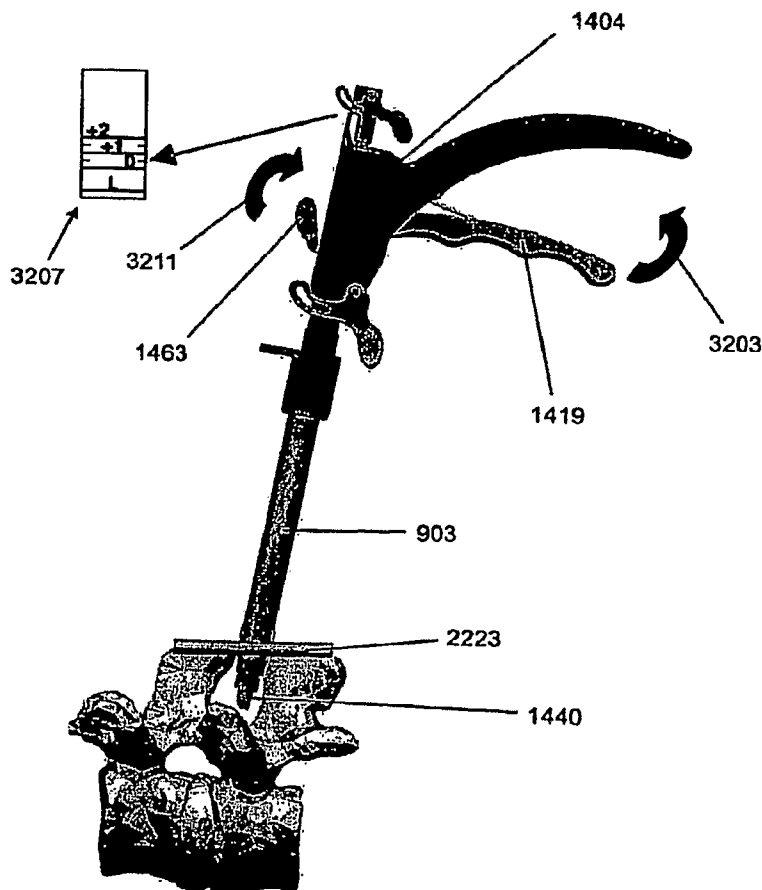
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(54) Title: MINIMALLY INVASIVE TOOLING FOR DELIVERY OF INTERSPINOUS SPACER



(57) Abstract: A plurality of individual tools is provided where each tool is uniquely configured to perform a step or a portion of a step in a novel procedure associated with the implantation of a stabilizing device (e.g., an interspinous spacer) for stabilizing at least one spinal motion segment. The tools are usable individually, or more preferably as a tooling system in which the tools are collectively employed to implant an interspinous spacer, generally in a minimally invasive manner. For example, each of the tools is arranged with coordinated markings and/or other features to ensure consistent depths of insertion, proper orientation of the tools with respect to each other or an anatomical feature of the patient, and precise delivery of the spacer to maintain safe positioning throughout the implantation procedure.



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MINIMALLY INVASIVE TOOLING FOR
DELIVERY OF INTERSPINOUS SPACER

STATEMENT OF RELATED APPLICATION

[0001] This application is a continuation-in-part of US Patent Application Serial Number 11/314,712, filed 12/20/05, entitled "Systems and Methods for Posterior Dynamic Stabilization of the Spine", which is incorporated herein by reference in its entirety.

TECHNICAL FIELD

[0002] The present invention is related to treatment of spinal disorders and pain and, more particularly, to minimally invasive tooling for delivery of an interspinous spacer device.

BACKGROUND

[0100] FIGs 1 and 2A illustrates a portion of the human spine having a superior vertebra 2 and an inferior vertebra 4, with an intervertebral disc 6 located in between the two vertebral bodies. The superior vertebra 2 has superior facet joints 8a and 8b, inferior facet joints 10a and 10b, and spinous process 18. Pedicles 3a and 3b interconnect the respective superior facet joints 8a, 8b to the vertebral body 2. Extending laterally from superior facet joints 8a, 8b are transverse processes 7a and 7b, respectively. Extending between each inferior facet joints 10a and 10b and the spinous process 18 are laminal zones 5a and 5b, respectively. Similarly, inferior vertebra 4 has superior facet joints 12a and 12b, superior pedicles 9a and 9b, transverse processes 11a and 11b, inferior facet joints 14a and 14b, laminal zones 15a and 15b, and spinous process 22.

[0101] The superior vertebra with its inferior facets, the inferior vertebra with its superior facet joints, the intervertebral disc, and seven spinal ligaments (not shown) extending between the superior and inferior vertebrae together comprise a spinal motion segment or functional spine unit. Each spinal motion segment enables motion along three orthogonal axes, both in rotation and in translation. The various spinal motions are illustrated in FIGs 2A-2C. In particular, FIG 2A illustrates flexion and extension motions

and axial loading, FIG 2B illustrates lateral bending motion and FIG 2C illustrates axial rotational motion. A normally functioning spinal motion segment provides physiological limits and stiffness in each rotational and translational direction to create a stable and strong column structure to support physiological loads.

[0102] Traumatic, inflammatory, metabolic, synovial, neoplastic and degenerative disorders of the spine can produce debilitating pain that can affect a spinal motion segment's ability to properly function. The specific location or source of spinal pain is most often an affected intervertebral disc or facet joint. Often, a disorder in one location or spinal component can lead to eventual deterioration or disorder, and ultimately, pain in the other.

[0103] Spine fusion (arthrodesis) is a procedure in which two or more adjacent vertebral bodies are fused together. It is one of the most common approaches to alleviating various types of spinal pain, particularly pain associated with one or more affected intervertebral discs. While spine fusion generally helps to eliminate certain types of pain, it has been shown to decrease function by limiting the range of motion for patients in flexion, extension, rotation and lateral bending. Furthermore, the fusion creates increased stresses on adjacent non-fused motion segments and accelerated degeneration of the motion segments. Additionally, pseudarthrosis (resulting from an incomplete or ineffective fusion) may not provide the expected pain-relief for the patient. Also, the device(s) used for fusion, whether artificial or biological, may migrate out of the fusion site creating significant new problems for the patient.

[0104] Various technologies and approaches have been developed to treat spinal pain without fusion in order to maintain or recreate the natural biomechanics of the spine. To this end, significant efforts are being made in the use of implantable artificial intervertebral discs. Artificial discs are intended to restore articulation between vertebral bodies so as to recreate the full range of motion normally allowed by the elastic properties of the natural disc. Unfortunately, the currently available artificial discs do not adequately address all of the mechanics of motion for the spinal column.

[0105] It has been found that the facet joints can also be a significant source of spinal disorders and debilitating pain. For example, a patient may suffer from arthritic facet joints, severe facet joint tropism, otherwise deformed facet joints, facet joint injuries, etc.

These disorders lead to spinal stenosis, degenerative spondylolithesis, and/or istlunic spondylotlisthesis, pinching the nerves that extend between the affected vertebrae.

[0106] Current interventions for the treatment of facet joint disorders have not been found to provide completely successful results. Facetectomy (removal of the facet joints) may provide some pain relief; but as the facet joints help to support axial, torsional, and shear loads that act on the spinal column in addition to providing a sliding articulation and mechanism for load transmission, their removal inhibits natural spinal function.

Laminectomy (removal of the lamina, including the spinal arch and the spinous process) may also provide pain relief associated with facet joint disorders; however, the spine is made less stable and subject to hypermobility. Problems with the facet joints can also complicate treatments associated with other portions of the spine. In fact, contraindications for disc replacement include arthritic facet joints, absent facet joints, severe facet joint tropism, or otherwise deformed facet joints due to the inability of the artificial disc (when used with compromised or missing facet joints) to properly restore the natural biomechanics of the spinal motion segment.

[0010] While various attempts have been made at facet joint replacement, they have been inadequate. This is due to the fact that prosthetic facet joints preserve existing bony structures and therefore do not address pathologies that affect facet joints themselves. Certain facet joint prostheses, such as those disclosed in U.S. Pat. No. 6,132,464, are intended to be supported on the lamina or the posterior arch. As the lamina is a very complex and highly variable anatomical structure, it is very difficult to design a prosthesis that provides reproducible positioning against the lamina to correctly locate the prosthetic facet joints. In addition, when facet joint replacement involves complete removal and replacement of the natural facet joint, as disclosed in U.S. Patent No. 6,579,319, the prosthesis is unlikely to endure the loads and cycling experienced by the vertebra. Thus, the facet joint replacement may be subject to long-term displacement. Furthermore, when facet joint disorders are accompanied by disease or trauma to other structures of a vertebra (such as the lamina, spinous process, and/or transverse processes) facet joint replacement is insufficient to treat the problem(s).

[0011] Most recently, surgical-based technologies, referred to as "dynamic posterior stabilization," have been developed to address spinal pain resulting from more than one disorder" when more than one structure of the spine have been compromised. An objective of such technologies is to provide the support of fusion-based implants while maximizing the natural biomechanics of the spine. Dynamic posterior stabilization systems typically fall into one of two general categories: posterior pedicle screw-based systems and interspinous spacers.

[0012] Examples of pedicle screw-based systems are disclosed in U.S. Patent Nos. 5,015,247, 5,484,437, 5,489,308, 5,609,636, 5,658,337, 5,741,253, 6,080,155, 6,096,038, 6,264,656 and 6,270,498. These types of systems involve the use of screws that are positioned in the vertebral body through the pedicle. Certain types of these pedicle screw-based systems may be used to augment compromised facet joints, while others require removal of the spinous process and/or the facet joints for implantation. One such system, the Zimmer Spine Dynesys® employs a cord which is extended between the pedicle screws and a fairly rigid spacer which is passed over the cord and positioned between the screws. While this system is able to provide load sharing and restoration of disc height, because it is so rigid, it does not effective in preserving the natural motion of the spinal segment into which it is implanted. Other pedicle screw-based systems employ articulating joints between the pedicle screws. Because these types of systems require the use of pedicle screws, implantation of the systems are often more invasive to implant than interspinous spacers.

[0013] Where the level of disability or pain to the affected spinal motion segments is not that severe or where the condition, such as an injury, is not chronic, the use of interspinous spacers are preferred over pedicle based systems as they require a less invasive implantation approach and less dissection of the surrounding tissue and ligaments. Examples of interspinous spacers are disclosed in U.S. Patent Nos. Re. 36,211, 5,645,599, 6,149,642, 6,500,178, 6,695,842, 6,716,245 and 6,761,720. The spacers, which are made of either a hard or compliant material, are placed in between adjacent spinous processes. The harder material spacers are fixed in place by means of the opposing force caused by distracting the affected spinal segment and/or by use of keels or screws that anchor into the spinous process. While slightly less invasive than the procedures required

for implanting a pedicle screw-based dynamic stabilization system, implantation of hard or solid interspinous spacers still requires dissection of muscle tissue and of the supraspinous and interspinous ligaments. Additionally, these tend to facilitate spinal motion that is less analogous to the natural spinal motion than do the more compliant and flexible interspinous spacers. Another advantage of the compliant/flexible interspinous spacers is the ability to deliver them somewhat less invasively than those that are not compliant or flexible; however, their compliancy makes them more susceptible to displacement or migration over time. To obviate this risk, many of these spacers employ straps or the like that are wrapped around the spinous processes of the vertebrae above and below the level where the spacer is implanted. Of course, this requires some additional tissue and ligament dissection superior and inferior to the implant site, i.e., at least within the adjacent interspinous spaces.

[0014] With the limitations of current spine stabilization technologies, there is clearly a need for an improved means and method for dynamic posterior stabilization of the spine that address the drawbacks of prior devices and associated delivery procedures and tooling. In particular, it would be highly beneficial to have a dynamic stabilization system that relies upon an implantation procedure using minimally invasive tooling. It would be additionally advantageous if the implantation procedure were reversible.

SUMMARY

[0015] A plurality of individual tools is provided where each tool is uniquely configured to perform a step or a portion of a step in a novel procedure associated with the implantation of a stabilizing device (e.g., an interspinous spacer) for stabilizing at least one spinal motion segment. The tools are usable individually, or more preferably as a tooling system in which the tools are collectively employed to implant an interspinous spacer, generally in a minimally invasive manner. For example, each of the tools is arranged with coordinated markings and/or other features to ensure consistent depths of insertion, proper orientation of the tools with respect to each other or an anatomical feature of the patient, and precise delivery of the spacer to maintain safe positioning throughout the implantation procedure.

DESCRIPTION OF THE DRAWINGS

[0016] The invention is best understood from the following detailed description when read in conjunction with the accompanying drawings. It is emphasized that, according to common practice, the various features of the drawings are not to scale. On the contrary, the dimensions of the various features are arbitrarily expanded or reduced for clarity. Included in the drawings are the following figures:

[0017] FIG 1 is a perspective view of a portion of the human spine having two vertebral segments;

[0018] FIGs 2A, 2B and 2C illustrate left side, dorsal and top views, respectively, of the spinal segments of FIG 1 undergoing various motions;

[0019] FIGs 3 and 3A are pictorial views of an illustrative target needle and inner puncher, respectively;

[0020] FIG 4 is a pictorial view of an illustrative K-wire;

[0021] FIG 4A is a detailed view of an circumferential notch forming a groove in an illustrative K-wire;

[0022] FIG 4B is a detailed view of a circumferential band in an illustrative K-wire;

[0023] FIG 5 is a pictorial view of an illustrative K-wire clamp;

[0024] FIG 5A is a pictorial view of an illustrative K-wire clamp arranged with optional sensor and alarm functions;

[0025] FIG 6 is a pictorial view of a first illustrative dilator;

[0026] FIG 6A is a detailed view of the distal end of the first illustrative dilator shown in FIG 6;

[0027] FIG 7 is a pictorial view of a second illustrative dilator;

[0028] FIG 7A is a detailed view of the distal end of the second illustrative dilator shown in FIG 7;

[0029] FIGs 8, 8A, 8B and 8C show various pictorial views of an illustrative mounting bracket in various alternative arrangements;

[0030] FIGs 8D – L show various pictorial views of an illustrative mounting tower;

[0031] FIGs 9, 9A and 9B are a side, and two perspective views, respectively, of an illustrative cannula;

[0032] FIG 10 is a pictorial view of an illustrative flexible stabilizing arm;

[0033] FIG 11 is a pictorial view of a first illustrative interspinous knife;

[0034] FIG 11A is a detailed view of the distal end of the interspinous knife shown in FIG 11;

[0035] FIG 11B is a detailed view of the proximal end of the interspinous knife shown in FIG 11;

[0036] FIG 11C is a pictorial view of a second illustrative interspinous knife;

[0037] FIG 11D is a detailed view of the distal end of the interspinous knife shown in FIG 11C as inserted through a cannula and into the interspinous space;

[0038] FIG 12 is a pictorial view of a core cutting portion of a first illustrative interspinous reamer;

[0039] FIG 12A is pictorial view of a hole cutting portion of the first illustrative interspinous reamer;

[0040] FIG 12B is a pictorial view of the hole cutting and core cutting portions of the first illustrative interspinous reamer in operative engagement for performing a hole cutting process;

[0041] FIG 12C is a pictorial view of the hole cutting and core cutting portions of the first illustrative interspinous reamer in operative engagement for performing a core cutting process;

[0042] FIG 12D is pictorial view of a second illustrative interspinous reamer;

[0043] FIG 12E is a detailed view of the distal end of the interspinous reamer shown in FIG 12D;

[0044] FIG 12F is a detailed view of the distal end of the interspinous reamer shown in FIG 12D as inserted through a cannula and into the interspinous space.

[0045] FIG 13 is a pictorial view of a first illustrative interspinous gauge;

[0046] FIG 13A is a detailed view of the distal end of an elongated tube in the interspinous gauge shown in FIG 13;

[0047] FIG 13B is a pictorial view of a second illustrative interspinous gauge;

[0048] FIG 13C is a detailed view of a sizing scale disposed in interspinous gauge shown in FIG 13B;

[0049] FIG 13D is a view of the distal end of the interspinous gauge shown in FIG 13B;

[0050] FIG 14 and 14A are pictorial views of a first illustrative insertion instrument;

[0051] FIG 14B is a detailed view of the distal tip of the insertion instrument shown in FIGs 14 and 14A;

[0052] FIG 14C is a detailed view of the distal tip of the insertion instrument shown in FIGs 14 and 14A in operative engagement with an interspinous spacer;

[0053] FIG 14D shows a visual scale disposed in the insertion instrument shown in FIGs 14 and 14A;

[0054] FIG 14E illustrates the deployment positions of an interspinous spacer indicated by the visual scale shown in FIG 14D;

[0055] FIG 14F is a pictorial view of a second illustrative insertion instrument;

[0056] FIG 14G is a detailed view of a load/deploy indicator disposed in the insertion instrument shown in FIG 14F;

[0057] FIG 15 is a pictorial view of an illustrative ligament splitter;

[0058] FIG 15A is a detailed view of the distal end of the ligament splitter shown in FIG 15;

[0059] FIGs 16, 17, 18, 19 and 20 are illustrations which show various anatomical locations having relevance to the present tooling and procedure for implanting an interspinous spacer;

[0060] FIGs 21 and 21A comprise a flowchart of an illustrative procedure for implanting an interspinous spacer using the tooling shown in FIGs 3 to 15;

[0061] FIG 22 is a pictorial view of the illustrative target needle of FIGs 3 and 3A as inserted through the supraspinous ligament;

[0062] FIG 22A is a detailed view of the distal end of the target needle showing its approximately centralized position between the superior and inferior spinous processes;

[0063] FIG 23 is a detailed view of the target needle as inserted to an appropriate depth;

[0064] FIG 23A is a detailed view of the illustrative K-wire of FIG 4 as inserted through the target needle;

[0065] FIG 23B is a detailed view of the alignment of the K-wire to the target needle;

[0066] FIG 24 is a pictorial view of an optional use of the illustrative K-wire clamp of FIG 5 during positioning of the K-wire;

[0067] FIG 25 is a pictorial view of the first illustrative dilator shown in FIG 6 as inserted through the supraspinous ligament;

[0068] FIG 25a is a detailed view of the first illustrative dilator as inserted through the supraspinous ligament to an appropriate depth;

[0069] FIG 26 is a pictorial view of the second illustrative dilator shown in FIG 7 as inserted through the supraspinous ligament;

[0070] FIG 26A is a detailed view of the second illustrative dilator as inserted through the supraspinous ligament to an appropriate depth;

[0071] FIG 26B is a detailed view of the alignment of the first dilator to the second dilator;

[0072] FIG 27 is a pictorial side view of the mounting bracket shown in FIGs 8, 8A, 8B and 8C as inserted over the second dilator;

[0073] FIG 27A is top view of the mounting bracket and dilator with respect to the mid-line of the spine;

[0074] FIG 27B is a pictorial view of an illustrative docking tower being loaded over the dilator;

[0075] FIG 27C is a side view of the docking tower and dilator showing a preferred trajectory with respect to the supraspinous ligament and spinous processes;

[0076] FIG 27D is a view of the docking tower and dilator with respect to the mid-line of the supraspinous ligament;

[0077] FIG 27E is a view of the docking tower in a deployed position;

[0078] FIG 27F is a detailed side view of the docking tower and dilator showing the positioning of the distal end of the dilator just past the anterior side of the supraspinous ligament;

[0079] FIG 28 is a pictorial side view of the cannula shown in FIGs 9, 9A and 9B as inserted through the mounting bracket and over the dilators;

[0080] FIG 28A is a detailed view of the distal end of the cannula showing the alignment of the end channels with the spinous processes;

[0081] FIG 28B is a detailed side view of the distal end of the cannula with respect to the distal end of the dilator, supraspinous ligament, and spinous processes;

[0082] FIG 28C is a pictorial view of the mounting bracket and cannula showing the

[0083] locking orientation of a rotating nut;

[0084] FIG 28D is a pictorial view of the mounting tower, cannula and dilator;

[0085] FIG 29 is a pictorial view of the interspinous knife shown in FIGs 11, 11A and 11B as inserted into the cannula;

[0086] FIG 29A is a detailed view of the initial cut pattern and the orientation of the interspinous knife with respect to the cannula;

[0087] FIG 29B is a detailed view of an optional cut pattern that is oriented 45 degrees from the initial cut through rotation of the interspinous knife with respect to the cannula;

[0088] FIG 30 is a pictorial view of the first illustrative interspinous gauge shown in FIGs 13 and 13A making a measurement of the interspinous space between the superior and inferior spinous processes;

[0089] FIGs 30A and 30B are pictorial views of the second illustrative interspinous gauge shown in FIGs 13B, 13C and 13D;

[0090] FIGs 31A – F are pictorial views of an interspinous spacer in a variety of positions;

[0091] FIG 31G is a pictorial view of the insertion instrument of FIGs 14, 14A, 14B, 14C, 14D showing operation of the handle which rotates a shaft in the elongated tube;

[0092] FIG 31H is a detailed view of the distal end of the elongated tube of the insertion instrument with rotatable shaft;

[0093] FIG 31I shows a visual scale disposed in the insertion instrument shown in FIGs 31G and 31H;

[0094] FIGs 31J and 31K are pictorial views of an illustrative interspinous spacer in operative engagement with the insertion instrument shown in FIGs 31G and 31H;

[0095] FIG 32 is a detailed view of a flat portion of the insertion instrument in alignment with a flat surface of the cannula that sets a depth indicator of “zero”;

[0096] FIG 32A is a pictorial view of the insertion instrument with loaded interspinous spacer as inserted through the cannula;

[0097] FIG 32B is a pictorial view of the insertion instrument of FIGs 14F and 14G in operative engagement with an interspinous spacer as placed into the interspinous space in an undeployed position;

[0098] FIG 32C is a pictorial view of the insertion instrument of FIGs 14F and 14G in operative engagement with an interspinous spacer as placed into the interspinous space in a deployed position;

[0099] FIG 33 is a pictorial view of an interspinous spacer as deployed; and FIG 34 is a pictorial representation of an image that shows the interspinous spacer as deployed.

DETAILED DESCRIPTION

[0100] Before the subject devices, systems and methods are described, it is to be understood that this invention is not limited to particular embodiments described, as such may, of course, vary. It is also to be understood that the terminology used herein is for the purpose of describing particular embodiments only, and is not intended to be limiting, since the scope of the present invention will be limited only by the appended claims.

[0101] Unless defined otherwise, all technical and scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which this invention belongs.

[0102] It must be noted that as used herein and in the appended claims, the singular forms “a”, “an”, and “the” include plural referents unless the context clearly dictates otherwise. Thus, for example, reference to “a spinous process” may include a plurality of such spinous processes and reference to “the marker” includes reference to one or more markers and equivalents thereof known to those skilled in the art, and so forth.

[0103] Where a range of values is provided, it is understood that each intervening value, to the tenth of the unit of the lower limit, unless the context clearly dictates otherwise, between the upper and lower limits of that range is also specifically disclosed. Each smaller range between any stated value or intervening value in a stated range and any other stated or intervening value in that stated range is encompassed within the invention. The upper and lower limits of these smaller ranges may independently be included or excluded in the range, and each range where either, neither or both limits are included in the smaller ranges is also encompassed within the invention, subject to any specifically excluded limit in the stated range. Where the stated range includes one or both of the limits, ranges excluding either or both of those included limits are also included in the invention.

[0104] All publications mentioned herein are incorporated herein by reference to disclose

and describe the methods and/or materials in connection with which the publications are cited. The publications discussed herein are provided solely for their disclosure prior to the filing date of the present application. Nothing herein is to be construed as an admission that the present invention is not entitled to antedate such publication by virtue of prior invention. Further, the dates of publication provided may be different from the actual publication dates which may need to be independently confirmed.

[0105] The present invention will now be described in greater detail by way of the following description of exemplary embodiments and variations of the devices and methods of the present invention. The invention generally includes a group of tools arranged for the percutaneous implantation of an interspinous spacer using an inventive method. A key feature of the interspinous spacer device is that it is expandable from a low profile configuration to a higher profile or operative configuration. This design allows the device, when in the low profile condition, to be delivered percutaneously through use of the tooling without requiring the removal of any portion of the spinal motion segment into which the device is implanted.

[0106] Each of the tools shown in the FIGs and described in the accompanying text are advantageously used as part of as a tooling system to perform the inventive method. That is, the tools are arranged to be used as a group – each tool in combination with others and/or sequentially as described in detail below. Accordingly, the tools generally are configured with coordinated markings and/or features to enable the tools to be used cooperatively and to ensure consistency of operation during the implantation procedure. For example, as noted above and without limiting the invention, each of the tools is arranged with coordinated markings and/or other features to ensure consistent depths of insertion, proper orientation of the tools with respect to each other or an anatomical feature of the patient, and precise delivery of the spacer to maintain safe positioning throughout the implantation procedure.

[0107] However, while use of the tools as a tooling system is preferable in some applications of the invention, it is emphasized that each tool may also be beneficially and advantageously utilized alone or in subset combination with other tools, but without using all of the tools in the tooling system. Thus while the utilization of the entire set of tools in the tooling system is often beneficial in many applications, it is not mandatory.

[0108] In addition, each of the tools shown in the FIGs and described in the accompanying text are advantageously utilized to perform the inventive percutaneous spacer implantation in a minimally invasive manner so as to minimize the affect of the procedure on the patient's tissues and, in particular, the supraspinous ligament. Utilization of such minimally invasive techniques can shorten the procedure's time and speed recovery by the patient. However, the application of the tools in a minimally invasive manner is not a requirement in order to realize many of the benefits provided by the tooling.

[0109] Referring now to FIGs 3 and 3A, pictorial views of an illustrative target needle 305 and inner puncher 312 are respectively provided. The target needle 305 and inner puncher 312, when assembled (e.g., locked) together, function to place a guidewire (e.g., a K-wire) through the patient's skin into an area which neighbors a vertebral segment of interest. Accordingly, target needle 305 and inner puncher 312 are configured to penetrate the supraspinous ligament and other tissue. Target needle 305 and inner puncher 312 are preferably disposable tools (i.e., arranged as single use instrumentalities in most applications of the invention).

[0110] Both the target needle 305 and inner puncher 312 are arranged with graspers on the proximal ends as indicated by reference numerals 318 and 321. Target needle 305 further includes wings 325 that are arranged to facilitate gripping of target needle 305 by an operator.

[0111] Target needle 305 includes a hollow needle portion 327 that is arranged to removably receive a needle portion 330 of the inner puncher 312, typically in a close-fitting manner. That is, the outside diameter of the needle portion 330 is sufficiently close in dimension to the inner diameter of the hollow needle portion 327 so that the inner puncher 312 is substantially radially fixedly positioned once needle portion 330 completes its slideable engagement with hollow needle portion 327. Both the hollow needle portion of target needle 305 and the needle portion 330 of inner puncher 312 are preferably composed of stainless steel for most applications of the invention and are thus configured to be visible using fluoroscopy to assist insertion to the desire depth. The inner diameter of target needle 305 is further selected to allow the removable insertion of a guidewire.

[0112] Target needle 305 and inner puncher 312, in this illustrative example, are further configured with a positive attachment comprising a threaded-type connection or, as shown in FIGs 3 and 3A, a rotatably engagable bayonet-type lock. In this arrangement, a pin 321 radially extends from a distal portion of the target needle 305. Pin 321 rotatably lockably engages with a mating slot 336 disposed in a lower portion of the grasper 321 when the inner puncher 312 is fully inserted through the needle portion 327 of target needle 305. When thus locked, the inner punch 312 is substantially fixedly radially and axially located within target needle 305. By anti-rotating the inner punch 312 with respect to the target needle 305, the inner punch 312 is unlocked so it can be removed from the target needle 305.

[0113] Inner puncher 312 includes a sharpened portion 335 at the distal end of the needle portion 330 as shown. The needle portion 330 of inner puncher 312 is configured (i.e., has sufficient length) so that the sharpened portion 335 is exposed when the inner puncher 312 is inserted into the hollow needle portion 327 of the target needle 305 and locked into position.

[0114] In an optional arrangement for the target needle 305, an energy delivery functionality is provided whereby an energy delivery unit (not shown) such as an RF (radio frequency) unit is operatively coupled to the distal end of the target needle 305 and/or inner puncher 312. Such energy delivery functionality may be utilized to assist with skin or other tissue penetration or blood coagulation, for example.

[0115] In another optional arrangement, target needle 305 and/or inner puncher 312 are arranged with one or more markers such as ultrasonic, magnetic, or other types of markers. Use of such markers may advantageously reduce or eliminate the need for fluoroscopic imaging in some applications of the invention.

[0116] FIG 4 is a pictorial view of an illustrative K-wire 402 that is arranged to be inserted through the target needle 305 (FIG 3) after the inner punch 312 (FIG 3) is unlocked and removed. K-wire 402 functions to allow one or more devices to be placed over it to a particular anatomical location. K-wire 402 includes a groove 406 which is also shown in the detailed view of FIG 4A. Groove 406 is arranged as a circumferential notch in most applications of the invention and provides for depth placement on a matched basis

among the one or more devices. Accordingly, groove 406 is spaced at a specific depth relative to the end of the target needle 305.

[0117] K-wire 402 is constructed from stainless steel in a similar manner to conventional guidewires. K-wire 402 may alternatively include other depth markings such as circumferential markers (not shown) or be arranged to be radiopaque (i.e., not allow X ray or other radiation to penetrate) or include radiopaque sections. K-wire 402 is preferably arranged as a disposable or single-use tool.

[0118] In an optional arrangement for K-wire 402, a circumferential band 412 is disposed along its length as shown in FIG 4B. Circumferential band 412 provides for depth placement in a similar manner as groove 406, and may also be utilized to perform as a mechanical stop to limit the advancement of the K-wire 402 through the target needle 305.

[0119] In another optional arrangement, K-wire 402 is arranged with one or more markers such as ultrasonic, magnetic markers or other marker types, for example, to avoid the need for fluoroscopy.

[0120] FIG 5 is a pictorial view of an illustrative K-wire clamp 505 that, when placed by an operator on a guidewire such as K-wire 402 (FIG 4) near the tissue entry site, functions to stabilize the guidewire. Such stabilization may be helpful to prevent further insertion of the guidewire beyond a desired depth and unwanted inadvertent movement of the guidewire.

[0121] K-wire clamp 505 is generally configured in a hinged clamp arrangement in most applications of the invention in which each clamp portion is biased with a spring (e.g., a torsional spring) to provide a desired level of clamping pressure on the guidewire. K-wire clamp 505 is preferably arranged as a disposable or single-use tool.

[0122] In an optional arrangement for K-wire clamp 505A, a slip sensor 510 and/or alarm transducer 517 are disposed along portions of the K-wire clamp 505 as shown in FIG 5A. If slippage (i.e., relative movement between the K-wire clamp 505 and the guidewire) beyond a predetermined threshold is detected by slip sensor 510, then a signal over signal path 522 triggers the alarm transducer 517 to transmit an alarm to an alarm receiving location or alarm monitor (not shown). In such optional arrangement, K-wire clamp 505A provides a positive indication such as a visual indicator (e.g., activation of a light source

such as a light emitting diode) or audible alarm (e.g., activation of a tone generator or buzzer) in the event that the K-wire clamp is inadvertently opened (either completely or partially) or the guidewire slips. Slip sensor 510 is alternatively arranged as a magnetic sensor or electrical/resistance-sensing sensor, for example.

[0123] Referring to FIGs 6, 6A, 7 and 7A, pictorial and detailed views of two illustrative dilators are shown. FIG 6 is a pictorial view of a first illustrative dilator 605 that is arranged with a through channel that slidably engages with a guidewire such as K-wire 402 (FIG 4) and is inserted through the supraspinous ligament. When used alone or in combination with the second illustrative dilator 705 shown in FIGs 7 and 7A, dilator 605 progressively (or sequentially) dilates tissue to thereby enable insertion of devices through the dilated opening.

[0124] Dilators 605 and 705 are preferably radiopaque and arranged as disposable, single use tools in most applications of the invention. Dilators 605 and 705 are typically constructed from stainless steel, titanium or similar materials. Dilator 605 includes a grip portion 607 at the proximal end, which in this illustrative example, is arranged as series of rings that alternate with recessed portions. Dilator 705 is arranged with a similar grip portion 707. A grip portion employing knurling or other material texturing may be alternatively utilized with either or both dilators 605 and 705 in some applications of the invention.

[0125] Dilator 605 includes a groove 611, for example a circumferential notch, that functions as a visible depth marker. Dilator 705 is similarly arranged with a groove 711. Dilators 605 and 705 may optionally include other markers such as ultrasonic, magnetic or other markers, for example, to avoid the need for fluoroscopy.

[0126] Dilator 605 is arranged, in this illustrative example, with a mid-line/orientation indicator such as a longitudinal groove 615 that is disposed substantially along the entire length of the dilator (i.e., from the proximal to distal end). Such mid-line/orientation indicator provides a visual marker that assists proper insertion of the dilator 605. Dilator 705 is also arranged with a longitudinal groove 715 in a similar manner.

[0127] Dilators 605 and 705 share similar construction and features but differ in size, notably inside and outside diameters (ID and OD, respectively). The respective diameters are selected such that dilator 605 and 705 are mateably and slidably engagable (i.e., in a

telescoping manner). In this illustrative example, the OD of dilator 605 is 5 mm and the OD of dilator 705 is 9.3 mm.

[0128] Dilator 605 includes a tapered portion 621 at its distal end in which a spinous process channel 626 is disposed. The spinous process channel 626 is configured to align and/or mateably engage with a spinous process to thereby maintain a desired mid-line position of the dilator 605. In addition, the spinous process channel may be utilized to distract tissue whereby a forward force is applied. A scalloped leading edge 630 is optionally disposed at the tapered portion 621 of dilator 605 which is arranged to facilitate insertion of the dilator through the tissue while minimizing tissue trauma.

[0129] Dilator 705 also includes a tapered portion 721 and a spinous process channel 726 that are each configured in a similar manner as those corresponding features in dilator 605. A scalloped leading edge 730 is preferably included along the far distal end of dilator 705.

[0130] The tapered portions 621 and 721 of dilators 605 and 705, respectively, are preferably sized, when inserted, to end on the anterior side of the supraspinous ligament (which can be verified under fluoroscopy or other visualization means such as ultrasound). Such arrangement is intended to minimize damage to the supraspinous ligament since any trauma to underlying tissue is less consequential. Table 1 below provides illustrative key dimensions for dilators 605 and 705.

	Taper Length	Taper Angle	Spinous Process Channel Length	Channel Taper
Dilator 605	0.250 in.	27 degrees	0.225 in.	27 degrees
Dilator 705	0.570 in.	17 degrees	0.530 in.	15 degrees

Table 1

[0131] Dilators 605 and 705 are each optionally arranged to include an energy delivery functionality using an operatively coupled energy delivery unit (not shown) such as an RF (radio frequency) unit. In most applications, the energy is delivered through the tip of the dilator to assist with tissue penetration or coagulation.

[0132] In an alternative arrangement, a third dilator (not shown) is also utilized. Such third dilator is intermediately-sized between dilator 605 and dilator 705. Accordingly, the third dilator is configured with appropriate inside and outside diameter dimensions to be slidably engaged over the OD of dilator 605 and slidably inserted into the ID of dilator 705, typically in a close-fitting arrangement.

[0133] In a second alternative arrangement, a longitudinally oriented, relatively narrow opening such as a slit (not shown) is disposed substantially along the length of dilator 605 and/or dilator 705. Such a feature enables the dilator to be removed from the guidewire without requiring the retraction of the full length of the guidewire. For example, the dilator can be simply removed by passing the guidewire through the longitudinal opening to thereby clear an object or device at the proximal end of the guidewire.

[0134] FIGs 8, 8A, 8B and 8C show pictorial views of an illustrative mounting bracket 802 in various alternative arrangements. Mounting bracket 802 functions to create a stable working platform by holding an elongated device such as a cannula in a fixed position. Mounting bracket 802 is generally positioned over the dilator 705 (FIG 7) prior to the insertion of a cannula. Alternatively, mounting bracket 802 may be positioned after the insertion of the cannula.

[0135] Mounting bracket 802 is typically further attached to a stabilizing device (such as that shown in FIG 10) using a dual mounting slot arrangement 805 as shown in FIG 8, or a single mounting slot 807 in base 809. The alternative mounting slot arrangements enable such a stabilizing device to be attached to the superior or inferior ends of mounting bracket 802 (using slot arrangement 805) or laterally (i.e., left or right, using the mounting slot 807). The other end of the stabilizing device is typically fixedly attached to a table or other immobile object. In addition to slots, mounting through-holes are alternatively utilizable for some applications. In alternative arrangements, mounting bracket 802 is configured for attachment directly to the patient (instead of, for example, a

table-mounted stabilizing device) through use of adhesives or sutures for skin-mounting or via screws or other mechanical fasteners for bone-mounting.

[0136] Base 809 may be optionally arranged to include unique markings which, in this illustrative example, are arranged as dots 811. For example, radiopaque markings or conventional visible markings are usable to assist with alignment, depth control, or mating with other discrete devices or tools. Alternatively, the markings may be arranged using ultrasonic, magnetic or other marker-types, for example, to avoid the need for fluoroscopy.

[0137] Mounting bracket 802 thus facilitates the alignment of the cannula with the spine so that an operator may select a desired trajectory and orientation of the cannula into the tissue. That is, mounting bracket 802 with the associated stabilizing device provides positive control of axial, sagittal and coronal positioning of the interspinous spacer as implanted by the present procedure and tooling.

[0138] As shown in FIG 8A, mounting bracket 802A includes a single threaded nut 813 that is rotatably coupled to an externally threaded cylinder 815 having a cylindrically shaped passageway through which the tool is inserted. Cylinder 815 includes one or more longitudinally oriented slots 818 (FIG 8) that enable the walls of the cylinder 815 to move slightly radially inward to thereby provide a clamping force against the inserted tool when the nut 813 is tightened on the threads of the cylinder 815. The inner walls of the cylinder are optionally configured with projections or texturing to enhance the grip on the tool. Accordingly, nut 813 and cylinder 815 combine to form a receiving tube 820 that surrounds and clamps a portion of the tool's elongated element (which is generally a tubular element).

[0139] In FIG 8B, mounting bracket 802B includes an alternative dual nut design using a primary threaded nut 813B and a secondary locking threaded nut 814. Primary nut 813B is first tightened to fixedly clamp the tool's elongated element in the receiving tube 820. Secondary nut 814 is then tightened to thereby lock the primary nut 813B in place. Other locking-type arrangements are also usable in some applications. For example, a nylon or other plastic insert (not shown) is disposed around the inner threaded portion of nut 813 to provide anti-rotation capabilities. A clutch-type mechanism (not shown) that slips upon reaching a predetermined torque or engagement travel may also be incorporated into the

nut/cylinder arrangement. In addition, a positive locking arrangement such as push-to-turn or lift-to-turn (as commonly used in child-proof medicine containers) may be employed in the nut/cylinder mechanism in those applications where a positive lock and unlock feature is desirable.

[0140] Mounting bracket 802 is typically arranged, in most applications of the invention, with a semi-spherical projection 825 that is disposed on a bottom surface of the base 809 so that the spherical portion of the projection 825 projects substantially downward when mounting bracket 802 is oriented as shown in the FIGs 8A and 8B. Projection 825 functions to substantially fill the area between the base 809 and the patient's tissue to thereby assist with stabilization of the mounting bracket 802. The semi-spherical shape of projection 825 provides for such stabilization while simultaneously allowing rotation about three axes (i.e., yaw, pitch and roll) to facilitate setting of the trajectory of a coupled tool such as a cannula.

[0141] Base 809 of mounting bracket 802 is arranged in a stepped, or dual plane, configuration in the illustrative example shown in FIGs 8, 8A and 8B. Base 809 includes a planar portion 832 from which receiving tube 820 upwardly projects and a planar portion 835 in which the one or more mounting slots are disposed. Planar portions 832 and 835 are substantially parallel while being offset to thereby enable mounting bracket 802 to be aligned with the patient's body particularly when using a non-orthogonal tool trajectory. The combination of the dual plane configuration with use of the projection 825 is particularly advantageous in many applications of the invention to provide stability for the mounting bracket 802 over a range of tool trajectories.

[0142] An alternative configuration for the mounting bracket is shown in FIG 8C. There, mounting bracket 802C employs an angled base 809C that may provide additional flexibility for aligning mounting bracket 802C with the body in some applications of the invention.

[0143] Mounting bracket 802 is preferably radiopaque and arranged as a disposable, single use tool in most applications of the invention. Mounting bracket 802 is generally preferred to be of rigid construction to provide for stable orientation of the coupled tool. In most applications of the invention, base 809 is constructed of aluminum with the nut 813 and cylinder 815 being formed from radiopaque plastic such as polyphenylsulfone

thermoplastic (sold under the brand Radel® R). Markers 811, when arranged as radiopaque markers, are formed using stainless steel.

[0144] In an alternative arrangement, mounting bracket 802 is configured with more than one receiving tube 820 (i.e., more than one nut/cylinder combinations). The other receiving tubes (not shown) may fixedly clamp other tools, instruments or devices such as a laparoscopic camera or light. The other receiving tubes may be oriented with the same trajectory as receiving tube 820, or be oriented orthogonally or at some other trajectory with respect to receiving tube 820.

[0145] FIGs 8D and 8E show pictorial views of an illustrative mounting tower 850. Mounting tower 850 is used as an alternative to mounting bracket 802 and similarly functions to create a stable working platform by holding an elongated device such as a cannula in a fixed position. Mounting tower 850 is generally positioned over the dilator 705 (FIG 7) prior to the insertion of a cannula.

[0146] Mounting tower 850 is typically further attached to a stabilizing device (such as that shown in FIG 10) using a dual mounting slot arrangement 855 in a base 858 as shown in FIGs 8D and 8E, or alternatively using a single mounting slot or a plurality of mounting slots, i.e., three or more (not shown). The alternative mounting slot arrangements enable such a stabilizing device to be attached to the superior or inferior ends of mounting tower 850 (using slot arrangement 855) or laterally (i.e., left or right, using a mounting slot 855). The other end of the stabilizing device is typically fixedly attached to a table or other immobile object. In addition to slots, mounting through holes are alternatively utilizable for some applications. In alternative arrangements, mounting tower 850 is configured for attachment directly to the patient (instead of, for example, a table-mounted stabilizing device) through use of adhesives or sutures for skin-mounting or via screws or other mechanical fasteners for bone-mounting.

[0147] Mounting tower 850 includes a pointing arrow 861 (such as a Cephalad indicator) that, in this illustrative example, is integrally formed with and laterally extending from base 858.

[0148] Mounting tower 850 is arranged with two pairs of spinous process grippers indicated by reference numerals 864 and 866 in FIGs 8D and 8E. Each spinous process gripper pair comprises two longitudinally extending, opposing, pivotally-mounted legs.

Opposing gripping surfaces are disposed at the distal ends of the legs and are arranged with a plurality of laterally inwardly extending serrated edges 869 in FIG 8G. When the mounting tower 850 is in a fully deployed condition, spinous process grippers 864 are arranged to clamp to the superior spinous process and spinous process grippers 866 clamp to the inferior spinous process.

[0149] Mounting tower 850 further includes a superior depth post 870 and an inferior depth post 871 which project axially downward from the base 858. Superior depth post 870 is disposed substantially between the legs of spinous process gripper 864. Inferior depth post 871 is disposed substantially between the legs of spinous process gripper 866. Posts 870 and 871 function as depth stops. Thus, posts 870 and 871 are arranged to interface with the posterior side of the supraspinous ligament so as to thereby limit the travel of the mounting tower 850 and position the spinous process grippers 864 and 866 in an appropriate orientation with respect to the spinous processes. In this illustrative example, inferior depth post 871 is shorter than superior depth post 870 so as to provide some angular freedom of motion in the plane including the longitudinal axis of the supraspinous ligament.

[0150] Mounting tower 850 thus facilitates the alignment of the cannula and subsequently utilized tools or devices with the spine so that an operator may select a desired trajectory and orientation of the cannula into the tissue. That is, mounting tower 850 with the associated stabilizing device provides positive control of axial, sagittal and coronal positioning of the interspinous spacer as implanted by the present procedure and tooling.

[0151] Mounting tower 850 includes a rotatably-mounted lower cylindrically-shaped collar 872 that extends axially upwards from base 858. Collar 872 rotates about a spindle 873 having a receiving tube (i.e., lumen) therethrough. Collar 872 is operatively coupled using a linkage that is internally disposed in mounting tower 850 to the spinous process grippers 864 and 866. Collar 872 is biased against an internally disposed spring to hold the collar 872 against an internally disposed stop. The stop prevents rotation of the collar 872 until the collar 872 is pushed axially downward against the spring bias to thereby disengage from the stop and rotate freely.

[0152] Collar 872 includes surface features, for example knurling, to enhance the operator's grip on the collar 872 when being manipulated.

[0153] An internally disposed spring normally biases the spinous process grippers 864 and 866 outwardly as indicated by Position 1 in FIG 8H. The internal linkage is arranged so that rotation of the collar 872 causes movement of the spinous process grippers 864 and 866. In particular, clockwise rotation (when looking axially downward from the orientation of the mounting tower 850 shown in the figures) of collar 872 causes relative inward motion of spinous process grippers 864 with respect to spinous process grippers 866 as indicated by the arrows in FIG 8H until the spinous process grippers 864 and 866 reach Position 2. As shown, the direction of motion of the spinous process grippers 864 and 866 are in planes which are substantially parallel to the line 874 defined by the longitudinal axis of pointing arrow 861 (i.e., Cephalad indicator).

[0154] Clockwise rotation of collar 872 further causes relative outward motion of the opposing legs in each pair of the spinous process grippers 864 and 866 as indicated by the arrows in FIG 8I. As shown, the direction of motion of each of the opposing legs are in planes that are substantially perpendicular to the line 874 which is defined by the longitudinal axis of pointing arrow 861 (i.e., Cephalad indicator).

[0155] Typically, collar 872 is rotated clockwise to place the pairs of spinous process grippers 864 and 866 into a "ready" position prior to deployment. That is, the above-described inward motion of the spinous process grippers 864 and 866 reduces the size of the incision required to pass the spinous process grippers 864 and 866 into the operative position with respect to the spinous processes. In addition, the above-described outward motion of the legs in each pair of spinous process grippers 864 and 866 ensures that a sufficient distance "D," as indicated in FIG 8I, is obtained for the legs to pass over the entire width of the supraspinous ligament as is required to clamp to the spinous processes.

[0156] FIG 8J shows the position of the spinous process grippers 864 and 866 as placed in the ready position through clockwise rotation of collar 872 and positioned over the supraspinous ligament 875. Rotation of the collar 872 in a counterclockwise direction allows the spinous process grippers 864 and 866 to return to their normal outwardly-disposed position as shown in FIG 8K.

[0157] Mounting tower 850 further includes a rotatably-mounted upper cylindrically-shaped collar 880 as shown in FIGs 8D – G and FIG 8L that is axially disposed above collar 872. In this illustrative example, the upper collar 880 is arranged to have a slightly

larger diameter than lower collar 875 to thereby allow the upper collar 880 to be disposed in a partially overlapping annular manner with respect to the lower collar 875. Collar 880 is arranged in a similar manner as collar 872 with surface features, such as knurling, to enhance gripping by the operator.

[0158] Collar 880 is threadedly engaged with the spindle 873. Clockwise rotation of collar 880 thus causes the spindle 873 to move axially upwards with respect to the collar 880. An internally disposed linkage couples spindle 873 to the spinous process grippers 864 and 866 and is configured so that the axial upward motion of the spindle 873 causes the opposing legs in each spinous process gripper to move inwards and clamp the spinous processes, i.e., the superior spinous process 881 and inferior spinous process 882. Continued clockwise rotation of collar 880 by the operator functions to put sufficient clamping force "F," as shown in FIG 8L, on the spinous processes (collectively designated by reference numeral 884) by the spinous process grippers 864 and 866 to thereby hold the mounting tower 850 securely to the patient's spine.

[0159] In alternative arrangements, mounting tower 850 may be arranged with a single set of spinous process grippers or more than two pairs of spinous process grippers. In addition, while rotatably-configured actuation is often preferable, other mechanisms including levers and other linear-type actuators are also usable. Mounting tower arrangements using multiple receiving tubes are also contemplated as being desirable in some applications.

[0160] Mounting tower 850 is beneficially arranged, in most applications, as a reusable, or multiple-use tool. Mounting tower 850 is generally preferred to be of rigid construction to provide for stable orientation of the coupled tool. In most applications, mounting tower 850 utilizes metal construction.

[0161] Mounting tower 850 may be optionally arranged to include unique markings. For example, radiopaque markings or conventional visible markings are usable to assist with alignment, depth control, or mating with other discrete devices or tools. Alternatively, the markings may be arranged using ultrasonic, magnetic or other marker-types, for example, to avoid the need for fluoroscopy.

[0162] FIGs 9, 9A and 9B are side, and two perspective views, respectively, of an

illustrative cannula 903. Cannula 903 is arranged to be fixedly attached (i.e., clamped) in mounting bracket 802 (FIG 8) to ensure proper orientation of the cannula 903 and delivery of the interspinous spacer in a desired manner. An internal lumen 906 in cannula 903 allows implants such as the interspinous spacer to pass through and is further configured in diameter and length to mate with devices and the present tools. Such mating may be performed in a fixed arrangement using a clamp or other removably coupling device (not shown). Cannula 903 thereby provides alignment and depth control, for example, via mechanical surfaces, visual markers and other indicators as described below. Cannula 903 may also be used, in some applications of the invention, to distract (i.e., push forward) the spinous processes or tissue. It is noted that the ID of the cannula 903 will typically vary according to the size of the interspinous spacer being implanted.

[0163] Cannula 903 is preferably arranged as a disposable, single use tool in most applications of the invention. Cannula 903 is typically constructed from a metal elongated tube 909 and includes a pointing arrow 912 (such as a Cephalad indicator) at the proximal end that provides a reference orientation along the mid-line towards the head. Cannula 903 includes a tapered tip 915 at the distal end.

[0164] The proximal end further includes a counterbore 918 that extends partially, longitudinally inward (towards the distal end of cannula 903) and a flat 921 disposed on the inside wall of cannula 903 formed by the counterbore 918. Counterbore 918 and flat 921 are examples of mechanical surfaces disposed on or within cannula 903 that function to provide visual or mechanical alignment. For example, counterbore 918 and flat 921 provide alignment for devices or tools that are subsequently inserted into cannula 903 and/or provide a fixed insertion depth.

[0165] Tapered tip 915 includes one or more tapered spinous process channels 924 which are configured to align and/or mateably engage with a spinous process to thereby maintain a desired position of the cannula 903. In addition, the spinous process channels 924 may be utilized to distract tissue whereby a forward force is applied. A scalloped leading edge 930 is preferably disposed at the tapered tip 915 which is arranged to facilitate insertion of the cannula 903 through the tissue while minimizing tissue trauma. In particular, the scalloped leading edge 930 may help to part the supraspinous ligament,

for example, using a rotating motion of cannula 903. Table 2 below provides illustrative key dimensions for cannula 903.

	Taper Length	Taper Angle	Spinous Process Channel Length	Channel Taper
Cannula 903	0.100 in.	24 degrees	0.475 in.	6 degrees

Table 2

[0166] Tapered tip 915 may be optionally arranged with an energy delivery functionality using an operatively coupled energy delivery unit (not shown) such as an RF (radio frequency) unit. In most applications, the energy is delivered through the tapered tip 915 of cannula 903 to assist with tissue penetration or coagulation.

[0167] As an alternative to the pointing arrow 912 noted above, cannula 903 may include a longitudinal groove or marking that is disposed along the length, or a portion of the length of the elongated tube 909. In addition, cannula 903 is generally arranged to include unique markings, for example, radiopaque markings or conventional visible markings that are usable to assist with alignment, depth control, or mating with other discrete devices or tools. Alternatively, the markings may be arranged using ultrasonic, magnetic or other marker-types, for example, to avoid the need for fluoroscopy.

[0168] FIG 10 is a pictorial view of an illustrative flexible stabilizing arm 1012.

Stabilizing arm 1012 functions to stabilize one or more devices or tools with respect, for example, to the patient or operating table. Stabilizing arm 1012 further enables an operator to make adjustments to the position and trajectory of coupled devices or tools. The stabilizing arm 1012 is preferably arranged as a reusable, or multiple-use tool.

[0169] Stabilizing arm 1012 includes a first attachment element 1018 and a second attachment element 1021 as shown in FIG 10. A flexible (i.e., articulating) portion 1025 couples the first and second attachment elements 1018 and 1021, respectively. As shown in FIG 10, flexible portion 1025 comprises a plurality of individual ball and socket type elements that enable stabilizing arm 1012 to be manipulated by the operator into a variety of shapes and configurations that are maintained through friction between such elements.

While other types of stabilizing arms (e.g., those having fewer degrees of freedom of motion) are also usable in many applications of the invention, a flexible stabilizing arm such as that shown in FIG 10 is generally preferred.

[0170] First attachment element 1018 is arranged to be removably coupled to a tool or device holding device such as mounting bracket 802 (FIG 8). As shown in FIG 10, first attachment element 1018 comprises a threaded screw 1028 having a plurality of gripping ridges 1030 extending radially outward to facilitate threaded screw 1028 to be tightened by hand (i.e., without requiring the use of tools) into the screw receiving portion 1033 of first attachment element 1018. Screw shank 1036 is arranged to engage with a slot or through-hole in mounting bracket 802 to thereby fixedly and removably hold the mounting bracket 802 to the stabilizing arm 1012 when the screw 1028 is tightened.

[0171] Second attachment element 1021 is configured for removably or non-removably coupling to a fixture such as an operating table, bed or other fixed or relatively immobile object. For example, second attachment element 1021 is attached to an operating table using mechanical fasteners such as screws or bolts inserted through holes or slots (not shown) in second attachment element 1021. In an alternative arrangement, second attachment element 1021 is configured for attachment directly to the patient (instead of the operating table as provided in the example above) through use of adhesives or sutures for skin-mounting or via screws or other mechanical fasteners for bone-mounting.

[0172] In another alternative arrangement, a third attachment element (not shown) is utilized. The third attachment element is disposed between the first attachment element 1018 and second attachment element 1021. Or, the second attachment element 1021 may be disposed between the first attachment element 1018 and the third attachment element. Such a third attachment element advantageously enables, for example, two mounting brackets (such as mounting bracket 903 in FIG 9) to be presented on a single stabilizing arm.

[0173] FIG 11 is a pictorial view of a first illustrative interspinous knife 1102 which functions to cut through tissue to enable the percutaneous access associated with the subsequent implantation of an interspinous spacer. Interspinous knife 1102 provides a plunge cut-type action through the mechanical manipulation of a plunger 1107 by the operator in a pushing motion, typically by depressing the plunger 1107 with the thumb

while gripping the handle portions 1109 with the fingers. The plunge depth is both controlled and adjustable in this illustrative example as described below.

[0174] As shown in the detailed view of FIG 11A, the plunger includes an elongated inner tube 1110 which is rotatably located in the elongated outer tube 1115 of interspinous knife 1102 to thereby enable the operator to make rotations of the cutting blades 1117 disposed at the distal end of the inner tube 1110. As shown, blades 1117 are configured in an "X" pattern, but other blade counts (including a single blade) and patterns are usable depending on the specific requirements of an application of the invention.

[0175] Inner tube 1110 is arranged for slideable excursion through the outer tube 1115 to effectuate the plunge cutting action. In various alternative arrangements, plunger 1107 is biased against a spring force provided by a spring element (not shown) or is provided with a linear actuator such as a pneumatic actuator or spring loaded actuator. In another alternative arrangement, the plunge cut action is supplied with a mechanical advantage to increase cutting force. For example, a cam or lever type mechanism (not shown) may be utilized to increase the force applied by the blades 1117 by having the operator manipulate an actuating portion of the plunger through an increased distance.

[0176] A depth setting slide 1120 is disposed along a top surface of the handle portions 1109 of interspinous knife 1102 as shown in FIGs 11 and 11B. Depth setting slide 1120 is arranged to move laterally in a sliding motion from a first position as shown in FIG 11 to a second position as shown in FIG 11B. When the depth setting slide 1120 is in the first position, the plunge depth of the plunger 1107 is limited to nominally 15 mm. When in the depth setting slide 1120 is in the second position, the plunge depth of the plunger 1107 is limited to nominally 20 mm. It is emphasized that such plunge depth settings are illustrative and other plunge depths may be selected according to the specific requirements of an application of the invention.

[0177] Interspinous knife 1102 is preferably arranged as a disposable, single use tool in most applications of the invention. Blades 1117 are constructed from stainless steel in most applications of the invention. The remaining components of interspinous knife 1102 – including inner tube 1110, outer tube 1115, plunger 1107 and depth setting slide 1120 –

are generally formed from a polymeric material (i.e. plastic) such as a biocompatible plastic.

[0178] In the illustrative example shown in FIGs 11, 11A and 11B, the inner tube 1110 is arranged to be rotated in an indexed manner. That is, the magnitude of rotation angles and the number of rotated positions of the inner tube 1110 are constrained with respect to outer tube 1115. In other applications, an infinitely rotatable inner tube 1110 is utilizable. It may be particularly beneficial in some applications for an initial plunge cut to be performed followed by a second plunge cut after the blades 1117 are rotated at an angle of 45 degrees to the initial plunge cut.

[0179] Interspinous knife 1102 includes a widened shoulder feature 1121 that is configured to engage with the counterbore 918 and flat 921 in cannula 903 (FIG 9) when the interspinous knife 1102 is inserted through the lumen 906. Such engagement between the shoulder feature and counterbore/flat thereby locates and aligns the interspinous knife 1102 at the proper depth and orientation with respect to the cannula 903 and the spine.

[0180] Interspinous knife 1102 is typically arranged with radiopaque or conventional visible markings that are usable to assist with alignment, depth control, or mating with other discrete devices or tools. For example, such markings can be used to indicate the longitudinal position (i.e., plunge depth) or orientation (i.e., rotation angle) of the blades 1117. Alternatively, the markings may be arranged using ultrasonic, magnetic or other marker-types, for example, to avoid the need for fluoroscopy.

[0181] Interspinous knife 1102 may be optionally arranged with an energy delivery functionality using an operatively coupled energy delivery unit (not shown) such as an RF (radio frequency) unit. In most applications, the energy is delivered through the blades 1117 to assist with tissue penetration or coagulation.

[0182] FIG 11C is a pictorial view of a second illustrative interspinous knife 1130 which functions to cut through tissue to enable the percutaneous access associated with the subsequent implantation of an interspinous spacer. Interspinous knife 1130 is usable to supplement interspinous knife 1102 (FIG 11) or as an alternative to interspinous knife 1102.

[0183] Interspinous knife 1130 includes a semi-spherical depth stop 1135 that is

integrally disposed in a handle 1138. Depth stop 1135 is sized and arranged to interface with the counterbore 918 (FIG 9) in cannula 903 to thereby limit the cutting depth of interspinous knife 1130. Shaft 1141 is sized in length to place the cutting blade 1145 at a predetermined distance from the depth stop 1135. Shaft 1141 is sized so that cutting blade 1145 cuts to a nominal depth "D" of 15 mm, as indicated in FIG 11D, from the anterior side of the supraspinous ligament 875. Alternatively, shaft 1141 is sized so that cutting blade 1145 cuts to a nominal depth of 20 mm.

[0184] Operation of the interspinous knife 1130 includes articulation of interspinous knife 1130 in cannula 903. In addition to a plunge-type cut that is depth controlled by the depth stop 1135, interspinous tissue is also cut by levering the handle 1138 so that the interspinous knife pivotally rotates about the semi-spherically shaped depth stop as a fulcrum. The distal end of the interspinous knife thus sweeps through an arc so that the cutting blade 1145 is movable through a range of positions including that indicated by 1145' in FIG 11D.

[0185] Interspinous knife 1130 is preferably arranged as a disposable, single use tool in most applications of the invention. Cutting blade 1145 and shaft 1141 are constructed from stainless steel in most applications of the invention. The depth stop 1135 and handle 1138 of interspinous knife 1130 are generally formed from plastic such as a biocompatible plastic.

[0186] FIGs 12, 12A, 12B and 12C show various views and features of a first illustrative interspinous reamer 1201 and its constituent components. Interspinous reamer 1201 is an optionally utilized tool in the tooling set described herein and functions to create a channel through which an interspinous spacer is inserted by removing bone and other tissue when required. Interspinous reamer 1201 is configured to remove both tough tissues including bone, as well as soft tissues. Interspinous reamer 1201 enables percutaneous access in combination, for example, with the mounting bracket 802 (FIG 8) and cannula 903 (FIG 9).

[0187] Interspinous reamer 1201 is configured to perform a tissue removal with a fixed diameter to thereby minimize damage to non-targeted tissue. Such diameter is preferably selected according to the size of the interspinous spacer being utilized. Interspinous reamer 1201 is further configured for controlled depth of penetration as described below.

[0188] Interspinous reamer 1201 uses a two-piece construction comprising a core cutter 1208, as shown in FIG 12, and a hole cutter 1212, as shown in FIG 12A. Core cutter 1208 is inserted into hole cutter 1212 to thereby form the interspinous reamer 1201 as shown in FIGs 12B and 12C. FIG 12B shows the core cutter 1208 being fully inserted into hole cutter 1212, while FIG 12C shows the core cutter 1208 being partially inserted into the hole cutter 1212.

[0189] The interspinous reamer 1201 is generally operated in a two-step process. A hole cut is made into the target tissue using hole cutter 1212 which is followed by a core cut by the core cutter 1208 which evacuates the tissue from the tube of the hole cutter 1212.

[0190] Core cutter 1208 is comprised of a flat bottom drill bit having a sharpened tip 1215 and a forward serrated circumferential edge 1218. An evacuation port 1221 is disposed on the face of core cutter 1208. A spiral evacuation channel 1227 is disposed at the exit of the evacuation port 1221 for transporting removed tissue away from the working channel in the tissue when the interspinous reamer 1201 is coupled to a drill (such as a conventional bone drill, not shown) and rotated. Interspinous reamer 1201 is alternatively arranged to have an integrally incorporated drill or to be coupled to a drill in a conventional manner.

[0191] Hole cutter 1212 is arranged as an elongated tube having a sharpened distal end, for example, arranged as a forward serrated circumferential edge 1230, as shown in FIG 12A. A plurality of laterally disposed holes 1233 are arranged along the elongated tube of hole cutter 1212 to enable cleaning or evacuation of removed tissue into a cannula.

[0192] Core cutter 1208 and/or hole cutter 1212 are typically marked to allow for controlled penetration depth. Alternatively, core cutter 1208 and/or hole cutter 1212 can be constructed to include a mechanical lock or positive stop to physically limit or control penetration depth. For example, core cutter 1208 and/or hole cutter 1212 may include a lateral projection that positively engages with the counterbore 918 (FIG 9B) in cannula 903 (FIG 9) to function as a stop to limit penetration beyond a predetermined depth.

[0193] Interspinous reamer 1201 is typically arranged with radiopaque or conventional visible markings that are usable to assist with alignment, depth control, or mating with other discrete devices or tools. Alternatively, the markings may be arranged using

ultrasonic, magnetic or other marker-types, for example, to avoid the need for fluoroscopy.

[0194] Interspinous reamer 1201 may be optionally arranged with an energy delivery functionality using an operatively coupled energy delivery unit (not shown) such as an RF (radio frequency) unit. In most applications, the energy is delivered through the distal ends of core cutter 1208 and/or hole cutter 1212 to assist with tissue penetration or coagulation. In an alternative arrangement, interspinous reamer 1201 is configured as an over-the-wire tool using a centrally disposed lumen in the core cutter 1208.

[0195] In most applications, interspinous reamer 1201 is beneficially arranged as a reusable, or multiple-use tool.

[0196] FIG 12D is a pictorial view of a second illustrative interspinous reamer 1225. As with the first illustrative interspinous reamer 1201 shown in FIGs 12, 12A, 12B and 12C, interspinous reamer 1225 is an optionally utilized tool in the tooling set described herein and functions to create a channel through which an interspinous spacer is inserted by removing bone and other tissue when required. Interspinous reamer 1225 is configured to remove both tough tissues including bone, as well as soft tissues. Interspinous reamer 1225 is usable to supplement interspinous reamer 1201 (FIGs 12 and 12A – C) or as an alternative to the interspinous reamer 1201.

[0197] Interspinous reamer 1225 includes a substantially spherically-shaped handle 1228 that is disposed at the proximal end of an elongated shaft 1231. At the shaft's distal end, a substantially cylindrically-shaped cutting element 1235 is disposed. Cutting element 1235 includes a plurality of radially outwardly projecting teeth disposed around the cylinder's surface in multiple rows as shown in the detailed view of FIG 12E.

[0198] Interspinous reamer 1225 includes semi-disc-shaped depth stop 1238 that is disposed between the handle 1228 and the proximal end of the shaft 1231. Depth stop 1238 is sized and arranged to interface with the counterbore 918 (FIG 9) in cannula 903 to thereby limit the cutting depth of interspinous reamer 1225. Shaft 1231 is sized in length to place the cutting element 1235 at a predetermined distance from the depth stop 1238. Shaft 1231 is sized so that cutting element 1235 cuts to a nominal depth "D" of 15 mm, as indicated in FIG 12F, from the anterior side of the supraspinous ligament 875.

[0199] Interspinous reamer 1225 is typically arranged with radiopaque or conventional

visible markings that are usable to assist with alignment, depth control, or mating with other discrete devices or tools. Alternatively, the markings may be arranged using ultrasonic, magnetic or other marker-types, for example, to avoid the need for fluoroscopy.

[0200] Interspinous reamer 1225 may be optionally arranged with an energy delivery functionality using an operatively coupled energy delivery unit (not shown) such as an RF (radio frequency) unit. In most applications, the energy is delivered through the distal end of the cutting element 1235 to assist with tissue penetration or coagulation. In an alternative arrangement, interspinous reamer 1225 is configured with a centrally disposed lumen and utilized as an over-the-wire tool.

[0201] In most applications, interspinous reamer 1225 is beneficially arranged as a reusable, or multiple-use tool. Handle 1228 is generally preferred to be formed from a polymeric material (i.e., plastic) such as a biocompatible plastic. Shaft 1231, depth stop 1238 and cutting element 1235 are typically formed from stainless steel.

[0202] FIG 13 is a pictorial view of a first illustrative interspinous gauge 1306 which primarily functions to measure the distance between two adjacent spinous processes at an intended insertion point for the interspinous spacer. An operator manipulates control lever 1314 to deploy feelers 1317 from the distal end of an elongated barrel 1322 as shown in FIG 13A. A gauge (not shown) on the handle 1326 provides a visual indication of the separation distance between the feelers 1317.

[0203] In the illustrative example of FIG 13, a pair of feelers are shown in a deployed position. In other arrangements, other numbers of feelers are usable. In addition, in some applications it may be useful to employ an arrangement where only one feeler is movable while the others remain fixed in position.

[0204] The gauge may be selected, for example, from a mechanical type gauge using a needle or pointer on a scale, or an electronic type gauge with a numerical readout using an LCD (liquid crystal display) or LED (light emitting diode) array to indicate the distance between the feelers. In this latter case, the display typically is arranged to receive a signal from one or more sensors disposed on the feelers 1317. The sensor is generally selected from one of strain gauge, force-sensing resistor, potentiometer (e.g., linear potentiometer), magnetic sensor, rotational encoder (where the angle of rotation is

correlated to distance) or optical sensor (e.g., phototransistor). Alternatively, in addition to being transmitted to the gauge, the sensor signal may be transmitted to a separate or standalone read-out device or display.

[0205] In typical applications, interspinous gauge 1306 is arranged with radiopaque or conventional visible markings that are usable to assist with alignment, depth control, or mating with other discrete devices or tools. Alternatively, the markings may be arranged using ultrasonic, magnetic or other marker-types, for example, to avoid the need for fluoroscopy. In another alternative arrangement, the markings include an indication of the interspinous spacer size or spacer catalog number to be used with the interspinous gauge 1306 (where interspinous spacer sizing is typically rounded, for example, to indicate an optimal or “best” size or catalog number). Instructions-for-use applicable to the interspinous gauge 1306 may also be included in the markings in such alternative arrangement.

[0206] Data provided to the operator on the gauge or via the markings is selected, for example, from one or more of position or orientation of the interspinous gauge 1306, deployment or distraction force being applied at the tool’s distal end (e.g., through feelers 1317), deployment depth or level of the interspinous gauge 1306, or position and orientation of the interspinous spacer.

[0207] Interspinous gauge 1306 is preferably arranged as a reusable, multi-use tool in most applications. Interspinous gauge 1306 further includes a widened shoulder feature 1330 that is configured to engage with the counterbore 918 and flat 921 in cannula 903 (FIG 9B) when the interspinous gauge 1306 is inserted through the lumen 906 of cannula 903. Such engagement between the shoulder feature and counterbore/flat thereby locates and aligns the interspinous gauge 1306 at the proper depth and orientation with respect to the cannula 903 and the spine.

[0208] Interspinous gauge 1306 is alternatively arranged to perform a variety of optional functions including:

- 1) Measure distraction force. Interspinous gauge 1306 includes force measuring components, such as sensors, that are disposed on the movable feelers 1317 in this alternative arrangement.

- 2) Distract spinous processes. In this alternative arrangement, the operator

manipulates control lever 1314 to deploy feelers 1317 to perform the distraction function. In an optional configuration, the control lever 1314 or other structures in the interspinous gauge 1306 are equipped with distraction force-limiting or distraction distance-limiting features.

3) Determine "Go" or "No Go" status for interspinous spacer implantation. In this alternative arrangement, there are several scenarios, for example, that interspinous gauge 1306 may be used to address: a) evaluation of poor bone quality result in bone deformation instead of distraction; b) identification and/or treatment (e.g., smooth and/or remove) osteophytes that neighbor the point of contact, c) determination of inadequate spinous process thickness for interspinous spacer implantation, and d) other anatomical abnormalities that may be incompatible with the interspinous spacer or the tooling and/or procedures used to implant it. The osteophytes are treatable using directed energy such as an RF energy source coupled to the feelers 1317, for example. Alternatively, mechanical abrasion may be applied through the feelers 1317. Feelers 1317 are generally provided with an abrasive surface and further configured to oscillate through operation of the control level 1314.

[0209] In some applications of the invention, interspinous gauge 1306 may also be arranged to include functionalities provided by the insertion instrument shown in FIG 14 and described in the accompanying text.

[0210] FIG 13B is a pictorial view of a second illustrative interspinous gauge 1350 that is alternatively used in place of the interspinous gauge 1306 shown in FIGs 13 and 13A. Interspinous gauge 1350 functions in a similar manner to the interspinous gauge 1306 in that it measures the distance between two adjacent spinous processes at an intended insertion point for the interspinous spacer.

[0211] An operator manipulates control lever 1355 by squeezing towards handle 1357 to deploy feelers 1361 from the distal end of the elongated barrel 1365. A gauge 1368, as shown in the detailed view of FIG 13C, provides a visual indication of the separation distance between the feelers 1361. FIG 13D shows the feelers 1361 in the deployed position in the interspinous space formed between the superior spinous process 881 and inferior spinous process 882.

[0212] Interspinous gauge 1350 includes a widened shoulder feature 1370 that is configured to engage with the counterbore 918 and flat 921 in cannula 903 (FIG 9) when the interspinous gauge 1350 is inserted through the lumen 906 of cannula 903. Such engagement between the shoulder feature and counterbore/flat thereby locates and aligns the interspinous gauge 1350 at the proper depth and orientation with respect to the cannula 903 and the spine.

[0213] Extending axially upward towards the handle 1357 from the widened shoulder 1370 is a marker area 1373 that is arranged to include one or more markers to assist with depth control of the interspinous gauge into the cannula 903. In typical applications, the markings are selected from radiopaque or conventional visible markings. Alternatively, the markings may be arranged using ultrasonic, magnetic or other marker-types, for example, to avoid the need for fluoroscopy.

[0214] Interspinous gauge 1350 is alternatively arranged to perform the optional functions discussed above in the description of interspinous gauge 1306. Interspinous gauge 1350 is preferably arranged as a reusable, multi-use tool in most applications.

[0215] FIG 14 and 14A are pictorial views of an illustrative insertion instrument 1404. Insertion instrument 1404 functions to engage with, insert and deploy an interspinous spacer. Illustrative examples of interspinous spacers that are compatible with the insertion instrument 1404 are described in applicant's co-pending U.S. patent application ser. no. 11/314,712, entitled "Systems and Methods for Posterior Dynamic Stabilization of the Spine" filed December 20, 2005, the disclosure of which is incorporated by reference herein. In the illustrative example shown in FIGs 14 and 14A, the depicted interspinous spacer uses a deployment mechanism which is activated by translation and/or rotation.

[0216] Insertion instrument 1404 uses the working channel that is preferably created by use of tools shown in FIGs 3 – 13 and described above including, for example, target needle 305, K-wire 402, dilators 605 and 705, mounting bracket 802, cannula 903, stabilizing arm 1012, interspinous knife 1102, optionally utilized interspinous reamer 1201, and interspinous gauge 1306. Insertion instrument 1404 is typically inserted through cannula 903 (FIG 9) in mounting bracket 802 which provides alignment and depth control and, in particular, precise control of the optimal axial, sagittal and coronal implant positioning.

[0217] Insertion instrument 1404 includes an elongated barrel 1410 that extends from a handle 1416 to which deployment lever 1419 is pivotally disposed. Deployment lever 1419 is operatively coupled to extend and/or rotate an inner shaft 1422 that is disposed within barrel 1410 and extends just beyond the distal end of barrel 1410. In this illustrative example, when the insertion instrument 1404 is engaged to an interspinous spacer, translation, and/or rotation of the inner shaft 1422 expands the movably extendable elements of the interspinous spacer to thereby place it into a deployed condition. Reversal of the translation or rotation places the interspinous spacer back into a collapsed, un-deployed condition through the use of retraction lever 1463.

[0218] The deployment lever is alternatively arranged as a T-handle 1475 that is disposed at the proximal end of insertion instrument 1404 and coupled to inner shaft 1422 as shown in FIG 14F. In this alternative arrangement, rotation of the T-handle 1475 expands the interspinous spacer to thereby deploy it. In this alternative example, the T-handle 1475 rotates in an indexed fashion through use of a laterally projecting pin 1481 from the T-handle axle that travels through a spiral track 1484 to thereby create several discrete positions corresponding to varying deployment positions for the interspinous spacer. These positions "L", "D", and "DE" are visually indicated on the insertion instrument 1404 corresponding to interspinous spacer states Load, Deployed, and Deployed Extended which are described below in the text accompanying FIGs 31A – F.

[0219] It is emphasized that other interspinous spacer types and designs (i.e., those that use other deployment mechanisms than that described above) are also usable with insertion instrument 1404. In addition, the interspinous spacer is optionally pre-attached (typically by the manufacturer) to the insertion instrument 1404.

[0220] In most applications, insertion instrument 1404 is beneficially arranged as a reusable, or multiple-use tool. In some applications of the invention, it may also be desirable to combine the functionalities provided by insertion instrument 1404 with those provided by interspinous gauge 1306 (FIG 13) into a single instrumentality or tool.

[0221] An outer clamping mechanism 1426 is also disposed at the distal end of barrel 1410 and extends outwardly. As shown in FIG 14B, outer clamping mechanism 1426 includes an extended tang 1428 and a non-extended tang 1430. Outer clamping mechanism 1426 is operatively coupled to a first operating lever 1435 as shown in FIG

14. Operation of the first operating lever 1435 causes the outer clamping mechanism 1426 to lock to interspinous spacer 1440 and, in particular, by the engagement of lateral ribs 1442 on the proximal end of interspinous spacer 1440 into corresponding slots 1450 in extended tang 1428 and non-extended tang 1430, as shown in FIG. 14C.

[0222] A second operating lever 1438 is operatively coupled to the distal end of inner shaft 1422 to which an inner clamping mechanism 1455 is disposed. Inner clamping mechanism 1455 is comprised of opposing jaws (not shown) that are arranged to grasp a mating projection 1458 extending normally rearward from the proximal end of the interspinous spacer 1440. Translation and/or rotation of mating projection 1458 operates the deployment mechanism of the interspinous spacer 1440. Operation of the second operating lever 1438 causes the inner clamping mechanism to lock to projection 1458 on interspinous spacer 1440.

[0223] First and second operating levers 1435 and 1438 are each arranged to include both locking and unlocking functionality through forward and reverse operation of the levers, respectively. Accordingly, insertion instrument 1404 is configured to both engage and disengage interspinous spacer 1440 through operation of the operating levers 1435 and 1438 by the operator. Insertion instrument 1404 is further preferably configured to re-engage with interspinous spacer 1440, for example, for further distraction if required or to remove the interspinous spacer.

[0224] In typical applications, insertion instrument 1404 includes a variety of markings, for example, to indicate various status conditions of the tool and the associated interspinous spacer 1440. In an alternative arrangement, the markings are selected as conventional visible markings or may be radiopaque. Insertion instrument 1404 may also be optionally arranged with one or more markers selected, for example, from ultrasonic, magnetic markers or other marker types to advantageously avoid the need for fluoroscopy.

[0225] A visual scale 1470 as shown in FIG. 14D is provided as one example of markings to indicate the amount of interspinous spacer deployment and/or the engagement condition (i.e., locked, unlocked, degree of lock etc.) of the interspinous spacer 1440 to the insertion instrument 1404. Visual scale 1470 thus provides quantitative feedback to

the operator including “Go” or No Go” deployment status. FIG 14E illustrates the deployment positions of the interspinous spacer 1440 indicated by the visual scale 1470.

[0226] A zero depth indicator is provided by a widened shoulder feature 1473 on insertion instrument 1404 that is configured to engage with the counterbore 918 and flat 921 in cannula 903 (FIG 9) when the insertion instrument 1404 is inserted through the lumen 906 of cannula 903. Such engagement between the shoulder feature and counterbore/flat thereby locates and aligns the insertion instrument 1404 at the proper depth and orientation with respect to the cannula 903 and the spine.

[0227] Insertion instrument 1404 may be optionally arranged with an energy delivery functionality using an operatively coupled energy delivery unit (not shown) such as an RF (radio frequency) unit. In most applications, the energy is delivered through the distal end of barrel 1426 (e.g., through clamping outer mechanism 1426, the distal end of inner shaft 1422, or inner clamping mechanism 1455) or via the coupled interspinous spacer 1440 to assist with tissue penetration or coagulation.

[0228] FIG 15 is a pictorial view of an illustrative ligament splitter 1505 that functions to split or part ligaments, such as the supraspinous ligament, or other tissues. Ligament splitter 1505 is intended for use in the beginning steps of interspinous spacer implantation or during subsequent steps, i.e., one or more times, as required. The ligament is typically separated with ligament splitter 1505 along ligamentous strands to minimize tearing, trauma, or other damage to the ligament. Such separation eases insertion of other devices, instrumentalities or tools (e.g., dilators 605 and 705 in FIGs 6 and 7, and cannula 903 in FIG 9). Separation is generally performed along a posterior, mid-line approach through the supraspinous ligament, although alternative approaches are also usable to thereby atraumatically part tissue.

[0229] Ligament splitter 1505 is beneficially arranged as a reusable, or multiple-use tool in most applications of the invention.

[0230] Ligament splitter 1505 is constructed from an elongated tube 1510 with an internally disposed lumen 1516 through which a guidewire such as K-wire 402 (FIG 4) is passed. The proximal end includes a handle 1508 that is typically formed from a polymeric material (i.e., plastic) such as a biocompatible plastic. The distal end of ligament splitter 1505, as shown in FIG 15A, includes cutting blades 1522, which in this

illustrative example, are arranged as a pair of blades. In alternative arrangements, other blade counts may be used as required by a particular application of the invention. Cuttings blades 1522 are illustratively arranged with forward cutting surfaces and side cutting surfaces.

[0231] The distal end of ligament splitter 1505 is generally tapered, and in one preferred arrangement, the taper length is nominally 0.550 inches with a nominal taper angle of 12 degrees.

[0232] The handle 1508 at the proximal end of ligament splitter 1505 is optionally utilized. Such handle may be used to assist with the insertion of ligament splitter 1505 in some applications. When thus equipped, the lumen 1516 is arranged to pass through the handle 1508. The optional handle is further arranged to include one or more markings to indicate an orientation of the handle and/or ligament splitter 1505. Such markings are typically visible markings, but may also be configured as radiopaque in some applications.

[0233] Ligament splitter 1505 may be optionally arranged with an energy delivery functionality using an operatively coupled energy delivery unit (not shown) such as an RF (radio frequency) unit. In most applications, the energy is delivered through the cutting blades 1522.

[0234] Ligament splitter 1505 is arranged, in most typical applications, to include a variety of markings, for example, to indicate orientation and/or depth of the ligament splitter 1505 when in use. In an alternative arrangement, the markings are selected as radiopaque markers to provide one or more depth markers to thereby assist with the splitting of the ligament. Ligament splitter 1505 may also be optionally arranged with one or more markers selected, for example, from ultrasonic, magnetic markers or other marker types to advantageously avoid the need for fluoroscopy.

[0235] In an alternative arrangement that may be particularly useful in some applications of the invention, two or more ligament splitters are utilized. Such ligament splitters share the above-described features and benefits of ligament splitter 1505, but are sized sequentially larger (i.e., in diameter and/or length).

[0236] Referring now to FIGs 16 – 20, several illustrations are presented which show

various anatomical locations having relevance to the present tooling and an inventive procedure for implanting an interspinous spacer such as interspinous spacer 1440 in FIG 14C.

[0237] The procedure is generally intended to be performed in an operating room with the use of fluoroscopy. However, in an alternative arrangement, ultrasound may be used instead of fluoroscopy to thereby allow the procedure to be performed in a doctor's or clinician's office.

[0238] FIG 16 provides an anteroposterior (AP) view of a lumbar spine 1604 and FIG 17 provides a side view. Shown are the supraspinous ligament 1607 (with ligamentous strands), superior spinous process 1608 and inferior spinous process 1610. The inset illustration – indicated by reference numeral 1620 – shows a dilated portion 1625 of supraspinous ligament 1607. FIG 17 also shows approach angle 1722 and zero point 1732.

[0239] A posterior mid-line approach (designated by reference numeral 1802) through the supraspinous ligament 1607, as illustrated in the AP view of FIG 18, is generally preferred. However, non-mid-line approaches are also usable. For example, an approach 1902 just lateral of the supraspinous ligament is shown in the AP view of FIG 19. A pure lateral approach 2002 is shown in the AP view of FIG 20. In such alternative non-mid-line approaches, the same tooling is often utilizable as with the mid-line approach. In some cases, however, similar tooling is utilized with modifications to make the tooling longer, if necessary. The interspinous spacer implantation is alternatively performed using percutaneous or minimally invasive surgical approaches, or using traditional open surgery.

[0240] The procedure for implantation of the interspinous spacer preferably includes the creation of a working channel through dilation of tissue (including ligaments) using the tooling system shown in FIGs 3 to 15 and described in the accompanying text including, for example, target needle 305, K-wire 402, dilators 605 and 705, mounting bracket 802, cannula 903, stabilizing arm 1012, interspinous knife 1102, optionally utilized interspinous reamer 1201, and ligament splitter 1505. The procedure overall is relatively rapid and enables a shortened recovery period. Advantageously, the procedure is completely reversible at each step.

[0241] The interspinous spacer 1440 is preferably deployed into an un-distracted working space 1704 (FIG 17) adjacent to the anterior wall 1708 of supraspinous ligament 1607. However, interspinous spacer 1440 is alternatively deployed in a pre-distracted, or partially distracted space.

[0242] FIGs 21 and 21A show a flowchart of an illustrative procedure for implanting an interspinous spacer using the tooling shown in FIGs 3 to 15. The description of the flowchart that follows makes reference to a number of illustrations shown in FIGs 22 to 33 below. The illustrative procedure starts at block 2104.

[0243] Blocks 2107 and 2112 include Step 1 in the illustrative procedure. As indicated in block 2107, the target needle 305 (FIG 3) is inserted through the supraspinous ligament 2223 (FIG 22) to an appropriate point beyond its anterior side as confirmed through the use of fluoroscopy. As indicated in block 2112, the inner puncher 321 (FIG 3) is then removed. The result is illustrated in FIG 22 where the target needle 305 is shown inserted to an appropriate depth past the zero point 2205 (which is defined as the anterior side of the supraspinous ligament 2223). FIG 22 also shows that the inner puncher 321 is removed from the target needle 305.

[0244] Block 2115 in FIG 21 includes Step 2 in the illustrative procedure in which the K-wire 402 (FIG 4) is inserted through the hollow needle portion 327 of target needle 305. FIG 23 shows the hollow needle portion 327 in cross section and the K-wire 402 inserted therethrough to zero point 2205. As shown in FIGs 23A and 23B, K-wire 402 is inserted to an appropriate depth by aligning the groove 406 to the top of the wing 325. Alternatively, the appropriate depth may be determined using fluoroscopy.

[0245] As indicated by block 2120 in FIG 21, the target needle 305 is next removed, leaving the K-wire 402 in place.

[0246] Block 2126 in FIG 21 shows an optional Step 3A in the illustrative procedure. K-wire clamp 505 (FIG 5) is optionally utilized to prevent inadvertent advancement of K-wire 402 while an operator determines the proper orientation of other devices that are installed over the K-wire 402. Once such determination is completed, K-wire clamp 505 is typically removed.

[0247] FIG 24 shows K-wire clamp 505 being utilized on K-wire 402 to hold it at the zero point 2025 in supraspinous ligament 2223 (FIG 22).

[0248] Block 2129 in FIG 21 shows an optional Step 3B in the illustrative procedure where the ligament splitter 1505 (FIG 15) is inserted over the K-wire 402 (FIG 4). Ligament splitter 1505 is optionally utilized to split supraspinous ligament 2223 (FIG 22) and/or other tissue (e.g., non-ligament tissue when utilizing a lateral approach). Typically, the blades 1522 of ligament splitter 1505 are aligned with the superior and inferior spinous processes 1608 and 1610 (FIG 16) to thereby be parallel with the ligamentous strands of the supraspinous ligament 2223 (FIG 22). A minimal amount of axial force is then imparted through ligament splitter 1505 to thereby part (i.e., split) the supraspinous ligament 2223. Subsequent tools in the tooling system of the present invention may then be placed through such parted tissue.

[0249] In alternative arrangements, ligament splitter 1505 is utilized in non-posterior mid-line approaches such as those encountered with lateral procedures and open surgeries (i.e., non-minimally-invasive surgeries). In addition, it is noted that ligament splitter 1505 may be beneficially used repeatedly, as required, in subsequent steps in the illustrative procedure described herein, or used solely in procedural steps that occur after the initial penetration of the supraspinous ligament.

[0250] Block 2133 in FIG 21 indicates Step 4 in the illustrative procedure in which dilation of tissue is started. Here, the first illustrative dilator 605 (FIG 6) is passed over the K-wire 402 to an appropriate depth which is, typically, determined using fluoroscopy so that the tapered end portion 621 of dilator 605 is located just past the anterior side of the supraspinous ligament 2223 (FIG 22). In some applications of the invention, it may be helpful for the operator to rotate or rock the dilator 605 using a back and forth motion as it is being inserted through the tissue. Markers, such as circumferential groove 611 and longitudinal groove 615, described above, generally provide alignment and/or proper depth control of dilator 605. In addition, the spinous process channel 626 on dilator 605, which is also described above, helps to maintain a desired mid-line positioning of dilator 605 with respect to the supraspinous ligament 2223.

[0251] In alternative arrangements, dilator 605 is usable to distract the spinous processes (e.g., spinous processes 1608 and 1610 in FIG 16). Either the spinous process channel 626 or tapered end portion 621 may be used in such cases.

[0252] FIG 25 shows dilator 605 placed over K-wire 402 and inserted through the

supraspinous ligament 2223 at the zero point 2025. FIG 25A is an enlarged view which shows the tapered end portion 621 of dilator 605 located just past the anterior side of the supraspinous ligament 2223.

[0253] After the insertion of the first dilator to start the tissue dilation in Step 4 of the illustrative procedure, the K-wire is removed. This is indicated by block 2136 in FIG 21.

[0254] Block 2138 in FIG 21 indicates Step 5 in the illustrative procedure in which dilation of tissue is continued. Here, the second illustrative dilator 705 (FIG 7) is inserted over the first illustrative dilator 605 to an appropriate depth so that the tapered end portion 721 of dilator 705 is located just past the anterior side of the supraspinous ligament 2223 (FIG 22). The appropriate depth is determined using fluoroscopy, or alternatively, by aligning the proximal end of dilator 705 with the groove 611 in dilator 605. In some applications of the invention, it may be helpful for the operator to rotate or rock the dilator 705 using a back and forth motion as it is being inserted through the tissue. Markers, such as circumferential groove 711 and longitudinal groove 715, described above, generally provide alignment and/or proper depth control of dilator 705. In addition, the spinous process channel 726 on dilator 705, which is also described above, helps to maintain a desired mid-line positioning of dilator 705 with respect to the supraspinous ligament 2223.

[0255] In alternative arrangements, a third dilator (not shown) may be utilized. Such third dilator may be arranged to be: a) smaller in diameter than dilator 605; b) intermediately-sized between dilator 605 and dilator 705; or c) larger in diameter than dilator 705. Use of such a third dilator is optional in most applications, but may be helpful to minimize tissue trauma.

[0256] FIG 26 shows dilator 705 placed over dilator 605 and inserted through the supraspinous ligament 2223 at the zero point 2025. FIG 26A is an enlarged view which shows the tapered end portion 721 of dilator 705 located just past the anterior side of the supraspinous ligament 2223. FIG 26B shows the alignment of circumferential notch 611 with the top of the proximal end of dilator 705 as a means of assuring proper depth control of dilator 705 with respect to dilator 605, zero point 2025, and supraspinous ligament 2223.

[0257] After dilator 705 is positioned over dilator 605 to the appropriate depth, as

described above, dilator 605 is removed. Such removal is indicated by block 2140 in FIG 21A.

[0258] Block 2143 in FIG 21A indicates an optional Step 6 in the illustrative procedure in which the mounting bracket 802 (FIG 8) is placed over the second illustrative dilator 705 (FIG 7). Mounting bracket 802 is preferably oriented in-line with the spine along the mid-line of the supraspinous ligament. Such alignment may be achieved using fluoroscopy and/or using the visual and/or radiopaque markings described above in the text accompanying FIG 8.

[0259] In alternative arrangements where a lateral approach to the supraspinous ligament is taken, the mounting bracket 802 is positioned with respect to the spine to enable such lateral approach.

[0260] FIG 27 shows mounting bracket 802 placed over dilator 705. FIG 27A shows the orientation of the mounting bracket 802 with respect to the mid-line 2707 of supraspinous ligament 2223.

[0261] Block 2143 in FIG 21A further indicates an alternative optional approach in the illustrative procedure in which the mounting tower 850 (FIG 8D) is used instead of the mounting bracket 802. Here, the mounting tower 850 is typically placed over the first illustrative dilator 605 (FIG 6) after being placed into the "ready" position through manipulation of the lower collar 872 in a clockwise rotation as described above. The operator may wish to grasp the base 858 as necessary to provide a counter-torque when rotating the collar 872, if necessary.

[0262] The pointing arrow 861 of mounting tower 850 is oriented superiorly and lowered over the proximal end of the dilator 605 while maintaining the existing trajectory "T" effectuated by the dilator 605 as shown in FIG 27B and mid-line orientation as shown in FIG 27D. Preferably, dilator 605 is not further advanced into the interspinous space as the mounting tower 850 is positioned.

[0263] Once the distal tips of the spinous process grippers 864 and 866 are inserted through the incision, the operator begins to de-rotate the collar 872 in a counterclockwise direction to allow the distal tips to be inserted through the fascia just lateral of the supraspinous ligament 2223. Mounting tower 850 is lowered until the superior depth post

870 contacts the supraspinous ligament 2223. The operator should recheck that the mid-line orientation and trajectory are satisfactorily maintained.

[0264] Collar 872 is then fully de-rotated to enable the spinous process grippers 864 and 866 to fully extend, as shown in FIG 27E. The upper collar 880 is then rotated clockwise to tighten the spinous process grippers 864 and 866 and clamp the superior spinous process 1608 and inferior spinous process 1610, respectively. The operator should verify that the mounting tower 850 is firmly clamped to the spinous processes. If adjustment is required, collar 880 is de-rotated counterclockwise and then subsequently retightened.

[0265] The second illustrative dilator 705 (FIG 7) is then placed over the first illustrative dilator 605 and through the center lumen of the mounting tower 850. The second illustrative dilator 705 is inserted over the first illustrative dilator 605 to an appropriate depth so that the tapered end portion 721 of dilator 705 is located just past the anterior side of the supraspinous ligament 2223 as shown in FIG 27F. The appropriate depth is determined using fluoroscopy, or alternatively, by aligning the proximal end of dilator 705 with the groove 611 in dilator 605. In some applications of the invention, it may be helpful for the operator to rotate or rock the dilator 705 using a back and forth motion as it is being inserted through the tissue. Markers, such as circumferential groove 711 and longitudinal groove 715, described above, generally provide alignment and/or proper depth control of dilator 705. In addition, the spinous process channel 726 on dilator 705, which is also described above, helps to maintain a desired mid-line positioning of dilator 705 with respect to the supraspinous ligament 2223.

[0266] Block 2146 in FIG 21A indicates Step 7 in the illustrative procedure in which a working channel is created by the insertion of cannula 903 (FIG 9) over the second dilator 705 (FIG 7) and, if utilized, through mounting bracket 802 (FIG 8). The operator may rotate and/or rock cannula 903 during insertion in some applications of the invention. In some alternative applications, the second dilator 705 may be used to distract the spinous processes using its tapered end portion 721.

[0267] Pointing arrow 912 (FIG 9) of cannula 903 is aligned by the operator with the cephalad and mid-line of the supraspinous ligament. The markers 811 disposed in mounting bracket 802 are also used to align the mounting bracket 802 with the mid-line of the supraspinous ligament. The cannula 903 is advanced to an appropriate position

where the spinous processes channels 924 at its distal end is aligned and/or touching (i.e., mating) with adjacent spinous processes. In some applications, the appropriate depth is achieved by having the operator align the top of proximal end of the cannula 903 with the circumferential groove 711 in the dilator 705.

[0268] Once the cannula 903 is positioned, the operator locks the mounting bracket 802 to the cannula 903 by turning the nut 813 (FIG 8). Second dilator 705 is removed as indicated in block 2149 in FIG 21A and mounting bracket 802 is then fixedly attached to a stabilizing device such as stabilizing arm 1012 (FIG 10).

[0269] FIG 28 shows the operative relationship between the cannula 903, mounting bracket 802 and second dilator 705 where the top of the proximal end of cannula 903 is aligned with the groove 711 in dilator 705. FIG 28A is an enlarged view showing the cannula 903 inserted through the supraspinous ligament 2223 prior to the removal of dilator 705. FIG 28B is an enlarged view showing a desired alignment of the spinous process channels 924 with the superior spinous process 1608 and inferior spinous processes 1610. FIG 28C shows a desired alignment of the markers 811 in mounting bracket 802 and pointing arrow 912 of cannula 903 with the mid-line 2707 of the supraspinous ligament 2223. FIG 28C also shows the operative relationship between the mounting bracket 802 and cannula 903 whereby the nut 813 is rotated (as indicated by the reference arrow 2806) in order to clamp cannula 903 in a releasable fashion. Note that in FIG 28C, a stabilizing device, such as stabilizing arm 1012 (FIG 10) may be used but is not shown.

[0270] In cases where the mounting tower 850 (FIG 8D) is utilized instead of the mounting bracket 802, the first illustrative dilator 605 is removed from the mounting tower 850. The cannula 903 (FIG 9) is inserted over the second illustrative dilator 705 and through the center lumen of the mounting tower 850 as shown in FIG 28D. The operator ensures the correct orientation of cannula 903 by aligning the cannula's pointing arrow 912 with pointing arrow 861 of the mounting tower 850. The cannula 903 is advanced to an appropriate position where the spinous processes channels 924 at its distal end is aligned and/or touching (i.e., mating) with adjacent spinous processes. In some applications, the appropriate depth is achieved by having the operator align the top of the proximal end of the cannula 903 with the circumferential groove 711 in the dilator 705.

[0271] Block 2155 in FIG 21A shows Step 8 in the illustrative procedure in which the interspinous knife 1102 (FIG 11) is inserted into the cannula 903. In most applications, the interspinous knife 1102 is inserted just to the distal end of cannula 903 by lowering the interspinous knife 1102 until its shoulder feature 1121 (FIG 11) bottoms out on the counterbore 918 (FIG 9B) of cannula 903. Alternatively, the interspinous knife 1102 is inserted to a depth in cannula 903 that is determined using other depth indicators (including for example, visual markers), or to some fixed depth, or as indicated through use of fluoroscopy.

[0272] Once inserted into cannula 903 to the desire depth, interspinous knife 1102 is generally operated to perform one, or in some applications more than one, plunge cut. A typical plunge cut depth is 15 mm, although interspinous knife 1102 may be arranged as shown in FIGs 11 and 11B to be adjustable so that other plunge cut depths are achievable, for example, 20 mm in typical alternative arrangements. In alternative arrangements, other set plunge cut depths may be accommodated by interspinous knife 1102, or an infinitely adjustable plunge cut depth may be utilized.

[0273] In some applications of the invention where a second plunge cut is utilized, interspinous knife 1102 is typically adjusted so that the cutting blades 1117 (FIG 11) are rotated to thereby enable the second plunge cut to be oriented at a different angle from the first plunge cut. With the interspinous knife 1102 shown in FIGs 11, 11A and 11B, such adjustment is effectuated by rotating the inner tube 1110 to some desired angle with respect to outer tube 1115. As noted above, such rotation may be arranged using constrained rotation angles in an indexed manner. Alternatively, interspinous knife 1102 may be rotated with respect to cannula 903 to implement a rotated second plunge cut. In alternative arrangements, interspinous knife 1102 may be configured to use a mechanically assisted plunge cut.

[0274] Upon completion of the desire plunge cuts, interspinous knife 1102 is removed from cannula 903.

[0275] FIG 29 shows the operative relationship between the interspinous knife 1102 and cannula 903 when the interspinous knife 1102 is oriented to the appropriate depth through supraspinous ligament 2223. FIG 29A shows the cutting pattern 2903 of the initial plunge cut. FIG 29B shows the cutting pattern 2905 of the second plunge cut that is implemented

through rotation of the interspinous knife 1102 with respect to the cannula 903. In the illustrative example shown in FIGs 29A and 29B, the first and second plunge cuts are rotated 45 degrees with respect to each other. As noted above, other rotation angles may be employed as may be desired for a particular application of the invention.

[0276] Step 8 in the illustrative procedure may alternatively use interspinous knife 1130 (FIG 11C) instead of interspinous knife 1102, or to supplement the cuts made by interspinous knife 1102.

[0277] Block 2158 in FIG 21 shows an optional Step 9 in the illustrative procedure in which interspinous reamer 1201 (FIG 12B) is used, as needed, to remove bone and/or other tissue in order to create a working space for an interspinous spacer. In typical applications where the interspinous reamer is used, the hole cutter 1212 (FIG 12A) is first inserted through the cannula 903 (FIG 9). Depth control may be maintained, for example, visually or using mechanical indicators or stops as the hole cutter 1212 cuts the tissue. Core cutter 1208 (FIG 12) is then inserted into the hole cutter 1212 so that the hole cut of the tissue is followed by core cut by the core cutter 1208 to evacuate the tissue from the tube of the hole cutter 1212. Depth control of core cutter 1208 is maintained visually or using mechanical indicators or stops, for example. Once the interspinous reamer 1201 completes the tissue cutting, it is removed from cannula 903.

[0278] In alternative arrangements, optional Step 9 in the illustrative procedure may use one or more interspinous reamers that are configured to have different diameters and/or different distal end geometries to accommodate a variety of tissue types.

[0279] Block 2161 in FIG 21 shows Step 10 in the illustrative procedure in which the interspinous gauge 1306 (FIG 13) is used to measure or size the appropriate interspinous spacer for a particular patient application by measuring the space between the spinous processes. The interspinous gauge 1306 is first inserted through the cannula 903 (FIG 9) where the depth and alignment of the insertion is typically determined through use of markers or via fluoroscopy. Alternatively, the widened shoulder feature 1330 (FIG 13) of interspinous gauge 1306 is configured to engage with the counterbore 918 and flat 921 (FIG 9) in cannula 903 when the interspinous gauge 1306 is inserted through the lumen 906 of cannula 903. Such engagement between the shoulder feature and counterbore/flat

may thereby locate and align the interspinous gauge 1306 at the proper depth and orientation with respect to the cannula 903 and the spine.

[0280] The operator then manipulates the control lever 1314 (FIG 13) to radially extend the feelers 1317 to touch adjacent spinous processes. The operator reads the distance between the distal ends of the feelers on a gauge or other visual readout on the interspinous gauge 1306.

[0281] FIG 30 shows the interspinous gauge 1306 with deployed feelers 1317 in operative relationship with the superior and inferior spinous processes 1608 and 1610. The distance indicated by reference numeral 3006 is provided to the operator on a gauge that is typically affixed to interspinous gauge 1306 to assist in selecting the appropriately sized interspinous spacer. Note that the cannula 903 is not shown for the sake of clarity in the illustration.

[0282] In alternative arrangements, Step 10 in the illustrative procedure may include using the interspinous gauge 1306 to distract the spinous processes. Once the spinous processes are distracted, the interspinous gauge 1306 may be used as a measuring instrument as described above. The interspinous gauge 1306 may further be configured and used to measure the force applied to the spinous processes during distraction.

[0283] Interspinous gauge 1306 may be further utilized during Step 10 in the illustrative procedure to provide "Go" and/or "No Go" information as described above in the text accompanying FIGs 13 and 13A. Such information may be helpful in shortening the procedure and avoiding wasting product (e.g., interspinous spacer) and disposable tooling when it is determined that a No Go condition exists.

[0284] Step 10 in the illustrative procedure may be alternatively performed using interspinous gauge 1350 (FIG 13B), as shown in FIGs 30A and 30B. In this alternative process step, interspinous gauge 1350 is shown inserted through cannula 903 (FIG 9) as held in the alternatively utilized mounting tower 850 (FIG 8D) rather than the mounting bracket 802 (FIG 8). The operator firmly actuates trigger 1355 until resistance is detected at the distal feelers 1361. As the supraspinous ligament may relax over time, the interspinous space measurement is preferably taken over a two to four minute time interval. A readout of the distance between adjacent spinous processes is provided on the gauge 1368. The insertion depth is read from the markings disposed on the marker area

1373 with respect to the top of the cannula 903. In some applications, an accurate measurement is achieved after some degree of distraction of the spinous processes is performed.

[0285] Steps 11 and 12 in the illustrative procedure are described below with reference to FIGs 31A – F which show the interspinous spacer 1440 (FIG 14) in various positions. Interspinous spacer 1440 comprises a body 3102, actuator 1458, and cam lobes which are pivotally mounted to the body 3102. A superior cam lobe 3105 is arranged to interface with the superior spinous process when the interspinous spacer 1440 is deployed. An inferior cam lobe 3110 interfaces with the inferior spinous process when the interspinous spacer 1440 is deployed.

[0286] FIGs 31A and 31B show the interspinous spacer 1440 in the Undeployed position in which the superior cam lobe 3105 and inferior cam lobe 3110 are in a non-extended (i.e., collapsed) position and the actuator 1458 is in a fully extended position with respect to the body 3102. FIGs 31C and 31D show the interspinous spacer 1440 in the Deployed position in which the superior cam lobe 3105 and inferior cam lobe 3110 are rotated about their pivots to extend laterally outward from the body 3102. When in the deployed position, the actuator 1458 is partially translated into body 3102. FIGs 31E and 31F show the interspinous spacer in the Extended position in which the superior cam lobe 3105 and inferior cam lobe 3110 are further extended laterally from the body 3102. When in the extended position, actuator 1458 is fully translated into body 3102.

[0287] Referring again to FIG 21A, block 2167 shows Step 11 in the illustrative procedure in which an undeployed interspinous spacer is loaded on the insertion instrument 1404 (FIG 14). Referring to FIGs 31G – K, the operator first ensures that the inner shaft 1422 (FIG 31H) of insertion instrument 1404 is fully retracted by appropriate manipulation of deployment lever 1419 (FIG 31G) so that the deployment scale 1470 (FIG 31I) indicates “L” for load. The operator then confirms the proper orientation of the interspinous spacer 1440 (FIG 31J) with respect to the insertion instrument 1404 by aligning the extended tang 1428 (FIG 14B) to the spacer 1440. Actuation of the second operating lever 1438 (FIG 31G) locks the inner clamping mechanism 1455 at the distal end of the inner shaft 1422 to the actuator 1458 of the interspinous spacer 1440 as shown in FIGs 31H, 31J, and 31K. Next, actuation of the first operating lever 1435 (FIG 31G)

locks the outer clamping mechanism 1426 to the lateral ribs on the proximal end of interspinous spacer 1440. In an alternative arrangement of the invention, it may be desirable to utilize only a single (e.g., the inner) clamping mechanism to lock the interspinous spacer 1440 to the insertion instrument 1404. Once loaded onto insertion instrument 1404, interspinous spacer 1440 is ready to be implanted.

[0288] Block 2172 in FIG 21 shows Step 12 in the illustrative process in which the interspinous spacer 1440 (FIG 14) is deployed. The insertion instrument 1404 (FIG 14), with the interspinous spacer 1440 loaded as described above, is inserted into cannula 903 (FIG 9). The insertion instrument 1404 is then advanced by the operator to a desired depth using, for example, depth markings under fluoroscopy. Alternatively by bottoming the widened shoulder feature 1473 (FIG 14) against the counterbore 918 and flat 921 (FIG 9) in cannula 903, insertion instrument 1404 may be located at both an appropriate “zero” depth with a desired orientation, for example, with respect to the mid-line of the supraspinous ligament. Such zero depth alignment is shown in FIG 32.

[0289] Referring to FIG 32A, the operator actuates deployment lever 1419 on insertion instrument 1404 as indicated by arrow 3203 until the deployment scale 3207 reaches “D” to thereby deploy the interspinous spacer 1440. The operator then confirms that the interspinous spacer 1440 is properly deployed in its expanded and locked position, and extends deployment as necessary.

[0290] The above described steps advantageously implant the interspinous spacer 1440 very precisely. Such precision prevents interspinous spacer migration, minimizes local fractures, and minimizes intrusion upon the dural canal by maintaining the interspinous spacer 1440 with the interspinous space (i.e., a “safe zone”).

[0291] Optionally, the operator may reverse the extension of interspinous spacer 1440 by using retraction lever 1463.

[0292] Block 2176 in FIG 21 shows Step 13 in the illustrative procedure in which the deployed interspinous spacer 1440 (FIG 14) is extended to the proper height by the operator by actuating the deployment lever 1419 on insertion instrument 1404 to thereby rotate the inner shaft 1422 (FIGs 14, 14B and 14C) and expand the interspinous spacer 1440. Such height is verified using various alternatives including, for example, visible, radiopaque, ultrasonic or magnetic markers. Upon the extension of spacer 1440 to the

proper height, insertion instrument 1404, cannula 903 (FIG 9) and mounting bracket 802 (FIG 8) are removed. The illustrative procedure ends at block 2183 in FIG 21A.

[0293] FIG 32B is a pictorial view of the alternatively utilized insertion instrument 1404 with an attached, loaded interspinous spacer 1440 in the Undeployed position. Insertion instrument 1404 is shown with cannula 903 in the alternatively utilized mounting tower 850. FIG 32C is a pictorial view of the interspinous spacer in the Deployed position.

[0294] FIG 33 is a pictorial view of the interspinous spacer 1440 in the deployed condition after the insertion instrument is withdrawn. FIG 34 is a fluoroscopic image of the interspinous spacer 1440 (FIG 14) in the deployed condition.

[0295] The preceding merely illustrates the principles of the Invention. It will be appreciated that those skilled in the art will be able to devise various arrangements which, although not explicitly described or shown herein, embody the principles of the invention and are included within its spirit and scope. Furthermore, all examples and conditional language recited herein are principally intended to aid the reader in understanding the principles of the invention and the concepts contributed by the inventors to furthering the art, and are to be construed as being without limitation to such specifically recited examples and conditions. Moreover, all statements herein reciting principles, aspects, and embodiments of the invention as well as specific examples thereof, are intended to encompass both structural and functional equivalents thereof. Additionally, it is intended that such equivalents include both currently known equivalents and equivalents developed in the future, i.e., any elements developed that perform the same function, regardless of structure. The scope of the present invention, therefore, is not intended to be limited to the exemplary embodiments shown and described herein. Rather, the scope and spirit of the present invention is embodied by the appended claims.

WHAT IS CLAIMED IS:

1. A system of tools for performing a procedure on a patient's spine, the system comprising:
 - a guidewire comprising a flexible filament configured to be placed through skin of the patient to a location proximate the patient's spine;
 - a cannula comprising a rigid elongated tube with a proximal end, a distal end, and a lumen therethrough;
 - a stabilizing device comprising a first attachment element and a second attachment element; and
 - a mounting bracket comprising a receiving tube and an attachment port, said receiving tube configured to attach to the cannula and the attachment port configured to attach to the first attachment element of the stabilizing device,wherein the mounting bracket is configured to allow an operator to orient the cannula relative to the stabilizing device.
2. The system of claim 1 wherein the guidewire is a K-wire.
3. The system of claim 1 wherein the guidewire further comprises a visualization marker along at least a portion of its length.
4. The system of claim 3 wherein the visualization marker is selected from the group consisting of visible markers, radiopaque markers, ultrasonic markers, magnetic markers, or combinations thereof.
5. The system of claim 3 wherein the visualization marker is a circumferential or partial circumferential groove.
6. The system of claim 3 wherein the visualization marker is a circumferential band.

7. The system of claim 6 wherein the band extends radially out from the outside diameter of the guidewire and the band is configured to limit travel of a device placed over said guidewire.
8. The system of claim 1 further comprising a device configured to be placed over the guidewire.
9. The system of claim 8 wherein a portion of the device is configured to align with the visualization marker.
10. The system of claim 1 wherein the cannula further comprises a visual alignment element.
11. The system of claim 10 wherein the visual alignment element is configured to allow an operator to control the orientation of a device inserted into the cannula.
12. The system of claim 10 wherein the visual alignment element is configured to allow an operator to control the depth of insertion of a device inserted into the cannula.
13. The system of claim 10 wherein the visual alignment element is a radiopaque marker.
14. The system of claim 10 wherein the visual alignment element is configured to allow an operator to position the cannula relative to a portion of the patient's anatomy.
15. The system of claim 14 wherein said portion of the patient's anatomy includes the supraspinous ligament.
16. The system of claim 10 wherein the visual alignment element is for rotational orientation of the cannula.

17. The system of claim 10 wherein the visual alignment element comprises an arrow shaped geometry located proximate to the proximal end of the cannula.
18. The system of claim 10 wherein the visual alignment element comprises a longitudinal marker disposed along the elongated tube of the cannula.
19. The system of claim 10 wherein the visual alignment element is selected from the group consisting of a visible marker such as a slot, a radiopaque marker, an ultrasonic marker, a magnetic marker, or combinations thereof.
20. The system of claim 10 wherein the visual alignment element is for depth control of insertion of the cannula.
21. The system of claim 1 wherein the cannula further comprises a mechanical alignment element configured to mate with a device inserted into the cannula.
22. The system of claim 21 wherein the mechanical alignment element is configured to allow only one or more specific orientations of a device inserted into the cannula.
23. The system of claim 21 wherein the mechanical alignment element is configured to limit insertion travel of a device inserted into said cannula.
24. The system of claim 21 wherein the mechanical alignment element comprises a flat segment of the lumen of the cannula.
25. The system of claim 21 wherein the mechanical alignment element comprises an eccentric portion of the lumen of the cannula.
26. The system of claim 1 wherein the proximal end of the cannula includes a grip for an operator of the system.

27. The system of claim 26 wherein the grip comprises one or more recessed rings.
28. The system of claim 26 wherein the grip comprises a knurled end.
29. The system of claim 26 wherein the grip comprises a textured surface.
30. The system of claim 1 wherein the distal end of the cannula includes at least one concave segment configured to align with a portion of a spinous process of the patient.
31. The system of claim 30 wherein the distal end of the cannula comprises at least two of the concave segments.
32. The system of claim 31 wherein the at least two concave segments are approximately 180 degrees apart.
33. The system of claim 30 wherein the at least one concave segment is configured to transmit a force to distract two spinous processes.
34. The system of claim 1 wherein the distal end of the cannula is sharpened.
35. The system of claim 34 wherein the distal end is sharpened to a geometry selected from the group consisting of scalloped portions, serrated portions, or combinations thereof.
36. The system of claim 34 wherein the sharpened distal end is configured to separate filamentous strands of the supraspinous ligament.

37. The system of claim 34 wherein the sharpened distal end is configured to separate filamentous strands of the supraspinous ligament when an operator oscillates the cannula in partial rotations in a clockwise and counterclockwise direction.
38. The system of claim 1 wherein the distal end of the cannula is tapered.
39. The system of claim 38 wherein the taper length is configured to terminate on the anterior side of the supraspinous ligament when the cannula is inserted into the patient's body.
40. The system of claim 39 wherein the taper length is approximately 0.10 inches.
41. The system of claim 39 wherein the taper angle is approximately 24 degrees.
42. The system of claim 1 wherein the distal end of the cannula further comprises an energy delivery assembly.
43. The system of claim 42 wherein the energy delivery assembly is configured to cut tissue and/or coagulate blood.
44. The system of claim 42 wherein the energy delivery assembly is configured to delivery radiofrequency energy.
45. The system of claim 1 wherein the cannula further includes a longitudinal slit disposed substantially from the proximal end to the distal end, wherein the slit is configured to allow a guidewire to laterally pass through the elongated tube of the cannula.
46. The system of claim 1 wherein the cannula further includes a clamp to allow an operator to fixedly secure a device inserted into the cannula.

47. The system of claim 1 wherein the mounting bracket is configured to allow axial, sagittal and/or coronal positioning of the cannula relative to the patient's spine.
48. The system of claim 1 wherein the mounting bracket further comprises at least one visualization marker configured to position the mounting bracket in a manner selected from the group consisting of alignment with patient or specific portion of patient anatomy, alignment or mating with a separate device, depth of insertion of a separate device, or combinations thereof.
49. The system of claim 48 wherein the visualization marker is selected from the group consisting of visible markers, radiopaque markers, ultrasonic markers, magnetic markers, and combinations thereof.
50. The system of claim 1 wherein the mounting bracket includes a cross-sectional profile configured to mate with the patient's skin during a spine procedure.
51. The system of claim 50 wherein the profile is multi-planar.
52. The system of claim 50 wherein the receiving tube is on a first plane and the attachment port is on the second plane.
53. The system of claim 1 wherein the mounting bracket further includes a spherical projection on its bottom surface, the projection configured to allow rotation of the receiving tube relative to the patient's body while maintaining contact with the patient's skin.
54. The system of claim 53 wherein the projection is a partial spherical projection.
55. The system of claim 1 wherein the receiving tube is configured for rotational attachment to the cannula.

56. The system of claim 1 wherein the receiving tube comprises a threaded cylinder and rotatable nut engaged thereon, wherein rotation of the nut causes the threaded cylinder to decrease in diameter.

57. The system of claim 56 wherein the rotatable nut includes one or more projections, the one or more projections configured to improve operator grip of the nut during rotation.

58. The system of claim 56 wherein the rotatable nut includes an outer portion and an inner threaded portion, the inner portion constructed of a softer material than the outer portion.

59. The system of claim 56 further including a second nut configured to engage the threaded cylinder.

60. The system of claim 59 wherein the second nut is configured to rotatably contact the first nut to prevent reverse rotation of the first nut.

61. The system of claim 56 wherein the rotatable nut is configured to not exceed a pre-determined maximum compressive or torsional force during rotation.

62. The system of claim 56 wherein the rotatable nut is configured to require an applied axial force to rotatably engage the threaded cylinder.

63. The system of claim 1 wherein the attachment portion of the mounting bracket is configured to be rotatably attached to the stabilizing device.

64. The system of claim 1 wherein the attachment port of the mounting bracket is selected from the group consisting of a slot, a hole such as a threaded hole, a projection such as a threaded rod, or combinations thereof.

65. The system of claim 1 wherein the stabilizing device attaches to an end of the mounting bracket located at a superior or inferior position related to the patient's anatomy.
66. The system of claim 1 wherein the stabilizing device attaches to a side of the mounting bracket
67. The system of claim 1 wherein the mounting bracket device further includes a second attachment element configured to attach to an additional device.
68. The system of claim 67 wherein the additional device is an additional cannula.
69. The system of claim 67 wherein the additional device is a camera device or camera holding device.
70. The system of claim 67 wherein the second attachment element attaches to an additional device at a trajectory fixed in relation to the cannula when the cannula is attached to the mounting bracket.
71. The system of claim 1 wherein the stabilizing device includes a flexible portion between the first and second attachment elements.
72. The system of claim 1 wherein the stabilizing device is a snake arm device.
73. The system of claim 1 wherein the second attachment element is mounted to a location selected from the group consisting of an operating room table, a patient bed, a portion of the patient's body, or combinations thereof.
74. The system of claim 73 wherein the second attachment element is mounted to the patient's body without penetrating the patient's skin.

75. The system of claim 73 wherein the second attachment element is mounted to the patient's body with penetration of the patient's skin.

76. The system of claim 1 wherein the stabilizing device further includes a third attachment element, the third attachment element being configured for attachment to an additional device.

77. The system of claim 76 wherein the second attachment element is located between the first attachment element and the third attachment element.

78. The system of claim 1 further comprising a target needle, the target needle comprising a hollow needle comprising a proximal end, a distal end, and a lumen therethrough, the needle configured to penetrate the supraspinous ligament, and an inner core slidably received by the hollow needle.

79. The system of claim 78 wherein the inner core of the target needle is removably locked to the hollow needle.

80. The system of claim 78 wherein the target needle further comprises a visualization marker.

81. The system of claim 80 wherein the visualization marker is selected from the group consisting of a visible marker, a radiopaque marker, an ultrasonic marker, a magnetic marker, or combinations thereof.

82. The system of claim 1 further including a guidewire clamp, the guidewire clamp being configured to attach to the guidewire and limit advancement of the guidewire into the patient's body.

83. The system of claim 82 wherein the guidewire clamp further includes an alarm assembly, the alarm assembly configured to notify the operator of relative motion between the guidewire and the guidewire clamp.

84. The system of claim 1 further including at least one dilator, the at least one dilator comprising an elongated tube with a proximal end, a distal end, and a lumen therethrough, the lumen configured to allow placement of the at least one dilator over the guidewire, and the distal end including a taper configured to dilate tissue.

85. The system of claim 84 wherein the at least one dilator has a diameter of approximately 9.3 mm substantially along a majority of its length.

86. The system of claim 84 wherein the distal end of the at least one dilator includes at least one concave segment configured to align with a portion of a spinous process of the patient.

87. The system of claim 84 wherein the distal end of the at least one dilator comprises at least two of said concave segments.

88. The system of claim 87 wherein the at least two concave segments are approximately 180 degrees apart.

89. The system of claim 86 wherein the at least one concave segment is configured to transmit a force to distract two spinous processes.

90. The system of claim 84 wherein the distal end of the at least one dilator is sharpened.

91. The system of claim 90 wherein the distal end is sharpened to a geometry selected from the group consisting of scalloped portions, serrated portions, or combinations thereof.

92. The system of claim 90 wherein said sharpened distal end is configured to separate filamentous strands of the supraspinous ligament.
93. The system of claim 90 wherein said sharpened distal end is configured to separate filamentous strands of the supraspinous ligament when an operator oscillates the cannula in partial rotations in a clockwise and counterclockwise direction.
94. The system of claim 84 wherein the at least one dilator further comprises an energy delivery assembly located proximate to the distal end.
95. The system of claim 94 wherein the energy delivery assembly is configured to cut tissue and/or coagulate blood.
96. The system of claim 94 wherein the energy delivery assembly is configured to deliver radiofrequency energy.
97. The system of claim 84 wherein the proximal end of the at least one dilator includes an operator grip portion.
98. The system of claim 97 wherein the operator grip portion comprises at least one recessed ring.
99. The system of claim 97 wherein the operator grip portion comprises a knurled end.
100. The system of claim 97 wherein the operator grip portion comprises a textured surface.
101. The system of claim 84 wherein the at least one dilator further comprises a visualization marker.

102. The system of claim 101 wherein the visualization marker is selected from the group consisting of a visible marker, a radiopaque marker; an ultrasonic marker, a magnetic marker, or combinations thereof.

103. The system of claim 101 wherein the visualization marker is a depth marker.

104. The system of claim 101 wherein the visualization marker is an orientation marker.

105. The system of claim 104 wherein the orientation marker comprises a longitudinal groove along the elongated tube of the at least one dilator.

106. The system of claim 84 wherein the at least one dilator further comprises a longitudinal slit substantially disposed from the proximal end to the distal end, said slit configured to allow a guidewire to laterally pass through the elongated tube of said cannula.

107. The system of claim 84 further comprising a second dilator.

108. The system of claim 107 wherein the second dilator comprises an elongated tube with a different diameter than the first dilator's elongated tube diameter.

109. The system of claim 107 wherein the second dilator has a diameter of approximately 5.0 mm substantially along a majority of its length.

110. The system of claim 107 further comprising a third dilator.

111. The system of claim 110 wherein the third dilator comprises an elongated tube with a different diameter than both the first dilator's elongated tube diameter and the second dilator's elongated tube diameter.

112. The system of claim 1 further comprising an interspinous knife, said interspinous knife comprising an elongated outer tube with a proximal end and a distal end, an inner tube with a proximal end and a distal end, the inner tube slidably received by the elongated outer tube and the distal end of the inner tube including a cutting element.

113. The system of claim 112 wherein the inner tube is spring loaded.

114. The system of claim 112 wherein the cutting element includes at least one blade.

115. The system of claim 112 wherein the cutting element includes two blades substantially arranged in an X pattern.

116. The system of claim 112 wherein the cutting element includes an energy delivery assembly.

117. The system of claim 116 wherein the energy delivery assembly is configured to cut tissue and/or coagulate blood.

118. The system of claim 116 wherein the energy delivery assembly is configured to delivery radiofrequency energy.

119. The system of claim 112 wherein the interspinous knife further includes a depth control element configured to allow an operator to select two or more depths of cutting.

120. The system of claim 119 wherein at least one depth of cutting is approximately 15mm and another at least one depth of cutting is approximately 20mm.

121. The system of claim 112 wherein the interspinous knife includes a multi-position slide arranged so that adjustment of the slide by an operator determines the depth of cutting.

122. The system of claim 112 wherein the interspinous knife includes an indexing element, the indexing element providing multiple fixed positions of the cutting element relative to the outer tube.

123. The system of claim 122 wherein the indexing element provides at least two positions of the cutting element and a first position is at an orientation approximately 45 degrees relative to a second position orientation.

124. The system of claim 112 wherein the interspinous knife further includes a lumen configured to allow over-the-wire delivery.

125. The system of claim 112 wherein the interspinous knife further includes a linear actuator configured to advance the inner tube.

126. The system of claim 125 wherein the linear actuator is selected from the group consisting of pneumatic actuators, hydraulic actuators, spring assisted actuators, solenoids; shape memory alloy actuators, or combinations thereof.

127. The system of claim 112 wherein the interspinous knife further includes a mechanical advantage assembly operatively attached to the inner tube.

128. The system of claim 127 wherein the mechanical advantage assembly includes one or more of a lever or a cam.

129. The system of claim 112 wherein the interspinous knife further includes a surface configured to make contact with a counterbore of the cannula.

130. The system of claim 112 wherein the interspinous knife further includes a visualization marker.

131. The system of claim 130 wherein the visualization marker is configured to indicate plunge position of the cutting element.

132. The system of claim 130 wherein the visualization marker is configured to indicate a rotational position of the cutting element.

133. The system of claim 130 wherein the visualization marker is selected from the group consisting of a visible marker, a radiopaque marker, an ultrasonic marker, a magnetic marker, or combinations thereof.

134. The system of claim 1 further comprising an interspinous reamer, the interspinous reamer comprising an elongated tube with a proximal end and a distal end, the distal end comprising an axial cutting element configured to cut tissue of the patient, and a flat-end drill, the drill configured to remove tissue from the elongated tube.

135. The system of claim 134 wherein the elongated tube of the interspinous reamer includes at least one side hole.

136. The system of claim 134 wherein the flat-end drill of the interspinous reamer includes a lumen therethrough that is configured to allow over-the-wire insertion.

137. The system of claim 134 wherein the interspinous reamer further includes a rotational assembly configured to rotate the elongated tube and/or the flat-end drill.

138. The system of claim 134 wherein the interspinous reamer further includes a depth limiting element configured to mate with the cannula to limit insertion of the elongated tube and/or the flat end drill.

139. The system of claim 138 wherein the depth limiting element is a radial projection on the elongated tube.
140. The system of claim 133 wherein the interspinous reamer further comprises a visualization marker.
141. The system of claim 140 wherein the visualization marker is selected from the group consisting of a visible marker, a radiopaque marker, an ultrasonic marker, a magnetic marker, or combinations thereof.
142. The system of claim 134 wherein the interspinous reamer further comprises an energy delivery assembly.
143. The system of claim 142 wherein the energy delivery assembly is configured to cut tissue and/or coagulate blood.
144. The system of claim 1 further including an interspinous gauge, the interspinous gauge comprising an elongated barrel with a proximal end and a distal end, and a handle attached to the proximal end of the elongated barrel wherein the interspinous gauge is configured to measure the distance between a first spinous process and a second spinous process of the patient.
145. The system of claim 144 wherein the first spinous process and the second spinous process are adjacent.
146. The system of claim 144 wherein the handle includes at least one control.
147. The system of claim 144 wherein the interspinous gauge includes at least one control that is configured to allow an operator to initiate the distance measurement.

148. The system of claim 144 wherein the interspinous gauge includes a first moveable lever disposed proximate to the distal end of the barrel, and the at least one control is configured to operatively move the lever.

149. The system of claim 148 wherein the interspinous gauge includes a second moveable lever disposed proximate to the distal end of the barrel, and the at least one control is further configured to operatively move the second lever.

150. The system of claim 147 wherein the at least one control is configured to allow an operator to apply a distraction force between a first spinous process and a second spinous process.

151. The system of claim 147 wherein the at least one control is configured to allow an operator to treat an osteophyte.

152. The system of claim 144 wherein the barrel of the interspinous gauge is configured to be inserted through the mounting bracket.

153. The system of claim 144 wherein the barrel of the interspinous gauge is configured to be inserted through the cannula.

154. The system of claim 142 wherein the barrel of the interspinous gauge includes a mechanical feature configured to mate with a mechanical feature of the cannula.

155. The system of claim 154 wherein said mechanical feature of the barrel is a flat surface that mates with a flat surface mechanical feature of the cannula.

156. The system of claim 144 wherein the interspinous gauge includes a gauge assembly configured to provide information to the operator related to the measured distance.

157. The system of claim 156 wherein the gauge assembly comprises a mechanical assembly.

158. The system of claim 156 wherein the gauge assembly comprises an electronic assembly.

159. The system of claim 158 wherein the electronic assembly includes a sensor, the sensor providing a measured distance information signal.

160. The system of claim 159 wherein the sensor is selected from the group consisting of a strain gauge, a force sensing resistor, a rotary encoder such as an optical rotary encoder, a potentiometer such as a linear potentiometer, a magnetic sensor, an optical sensor such as a phototransistor, or combinations thereof.

161. The system of claim 159 wherein the interspinous gauge further includes an expandable assembly disposed proximate to the distal end of the elongated barrel and configured for expansion between two spinous processes, wherein the sensor provides a signal indicating a state of expansion of the expandable assembly.

162. The system of claim 161 wherein the expandable assembly includes a first component which moves relative to a second component, and the sensor is a magnetic sensor configured to provide a signal indicative of the relative position between the first component and the second component.

163. The system of claim 161 wherein the expandable assembly includes a first component rotatably attached to a second component, and the sensor is a rotary encoder configured to provide a signal indicative of the angular orientation between the first component and the second component.

164. The system of claim 144 wherein the interspinous gauge further includes at least two sensors providing a measured distance information signal.

165. The system of claim 144 wherein the interspinous gauge further includes a force measurement assembly configured to provide information to an operator, the information correlating to a magnitude of force required to distract two spinous processes a fixed distance.

166. The system of claim 165 wherein the provided force information includes acceptability of the measured force.

167. The system of claim 165 wherein the force measurement assembly includes a sensor.

168. The system of claim 167 wherein the sensor is selected from the group consisting of a strain gauge, a force sensing resistor, a rotary encoder such as an optical rotary encoder, a potentiometer such as a linear potentiometer, a magnetic sensor, an optical sensor such as a phototransistor, or combinations thereof.

169. The system of claim 144 wherein the interspinous gauge further includes a spinous process thickness measurement assembly configured to provide information to an operator, the information correlating to a thickness of one or more spinous processes of the patient.

170. The system of claim 169 wherein the provided thickness information includes acceptability of the measured force.

171. The system of claim 169 wherein the thickness measurement assembly includes a sensor.

172. The system of claim 170 wherein the sensor is selected from the group consisting of a strain gauge, a force sensing resistor, a rotary encoder such as an optical

rotary encoder, a potentiometer such as a linear potentiometer, a magnetic sensor, an optical sensor such as a phototransistor, or combinations thereof.

173. The system of claim 144 wherein the interspinous gauge further comprises an osteophyte treatment assembly configured to remove, smooth and/or otherwise treat an osteophyte.

174. The system of claim 173 wherein the osteophyte treatment assembly comprises a mechanical assembly including an abrasive surface configured to be operatively moved in a back and forth motion to treat an osteophyte.

175. The system of claim 173 wherein the osteophyte treatment assembly comprises an energy delivery assembly configured to deliver energy to treat an osteophyte.

176. The system of claim 144 wherein the interspinous gauge further includes a spinous process distraction assembly.

177. The system of claim 176 wherein the interspinous gauge further includes a control for operatively engaging the distraction assembly.

178. The system of claim 176 wherein the distraction assembly is configured to not substantially exceed a pre-determined distraction force.

179. The system of claim 176 wherein the distraction assembly is configured to not substantially exceed a pre-determined distraction distance.

180. The system of claim 144 wherein the interspinous gauge further includes an implant insertion assembly configured to allow an operator to implant, expand, and release from an interspinous spacer device.

181. The system of claim 180 wherein the implant insertion assembly is further configured to unexpand and expand an interspinous spacer device.

182. The system of claim 180 wherein the implant insertion assembly is further configured to re-engage with an implanted interspinous spacer device.

183. The system of claim 180 wherein the implant insertion assembly is further configured to re-engage with and change the expansion of an implanted interspinous spacer device.

184. The system of claim 144 wherein the interspinous gauge further includes an information marker.

185. The system of claim 184 wherein the information marker is selected from the group consisting of a visible marker, a radiopaque marker, an ultrasonic marker, a magnetic marker, or combinations thereof.

186. The system of claim 184 wherein the information marker provides information selected from the group consisting of position information, orientation information, interspinous spacer information such as position and orientation of the interspinous spacer, level of deployment information, deployment force information, distraction force information, or combinations thereof.

187. The system of claim 144 wherein the interspinous gauge further includes an interspinous spacer size indicator.

188. The system of claim 187 wherein the indicator provides interspinous spacer size information.

189. The system of claim 187 wherein the indicator performs a rounding function prior to providing the size information.

190. The system of claim 187 wherein the indicator provides interspinous spacer model information.

191. The system of claim 1 further comprising a ligament separating tool comprising an elongated tube with a proximal end, a distal end, and a lumen therebetween, and a ligament separating assembly disposed proximate to the distal end of the elongated tube.

192. The system of claim 191 wherein the ligament separating tool's ligament separating assembly includes at least one cutting blade.

193. The system of claim 191 wherein the ligament separating assembly includes one single-plane blade.

194. The system of claim 192 wherein the at least one cutting blade includes a forward cutting surface and a side cutting surface.

195. The system of claim 192 wherein the at least one cutting blade includes a forward cutting surface and two side cutting surfaces.

196. The system of claim 191 wherein the ligament separating assembly includes an energy delivery assembly.

197. The system of claim 196 wherein the energy delivery assembly is configured to cut tissue.

198. The system of claim 196 wherein the energy delivery assembly is configured to coagulate blood.

199. The system of claim 196 wherein the energy delivery assembly is configured to deliver radiofrequency energy.
200. The system of claim 191 wherein the ligament separating tool further includes a handle disposed on the proximal end of the elongated tube.
201. The system of claim 200 wherein the handle is a T-handle.
202. The system of claim 200 wherein the handle includes a lumen therethrough in operative relation with the lumen of the elongated tube.
203. The system of claim 191 wherein the ligament separating tool further includes a visualization marker.
204. The system of claim 203 wherein the visualization marker is selected from the group consisting of a visible marker, a radiopaque marker, an ultrasonic marker, a magnetic marker, or combinations thereof.
205. The system of claim 203 wherein the visualization marker is a depth marker.
206. The system of claim 191 further including a second ligament separating tool comprising an elongated tube with a proximal end, a distal end, and a lumen therebetween, and a ligament separating assembly disposed proximate to the distal end of the elongated tube.
207. The system of claim 206 wherein the second ligament separating tool has a different geometry than the first ligament separating tool.
208. An insertion instrument for implanting an interspinous spacer in a patient, the insertion instrument comprising:

a barrel assembly with a proximal end and a distal end, the barrel assembly comprising an elongated outer tube, an inner shaft slidably received by the outer tube, and a handle assembly fixedly attached to the proximal end of the barrel assembly, wherein the barrel assembly is configured to engage with an interspinous spacer, insert the interspinous spacer into the body of the patient, expand the interspinous spacer, and disengage from the interspinous spacer.

209. The insertion instrument of claim 208 wherein the barrel assembly is further configured to unexpand and explant the interspinous spacer.

210. The insertion instrument of claim 208 wherein the barrel assembly is further configured to re-engage with the interspinous spacer.

211. The insertion instrument of claim 208 wherein the barrel assembly is further configured to re-engage with an implanted interspinous spacer device.

212. The insertion instrument of claim 208 wherein the barrel assembly is configured to be inserted through a cannula.

213. The insertion instrument of claim 212 wherein the barrel assembly includes a mechanical feature that mates with the cannula to determine depth of insertion and/or orientation of insertion.

214. The insertion instrument of claim 213 wherein the mechanical feature is a flat surface which mates with a flat surface of the cannula.

215. The insertion instrument of claim 213 wherein the barrel assembly distal end includes a spacer attachment mechanism.

216. The insertion instrument of claim 215 wherein the spacer attachment mechanism includes at least two prongs, the at least two prongs configured to be releasably engaged with an interspinous spacer device.
217. The insertion instrument of claim 216 wherein a first prong is longer than a second prong.
218. The insertion instrument of claim 215 wherein the at least two prongs engage with an outer surface of the interspinous spacer.
219. The insertion instrument of claim 215 wherein the spacer attachment mechanism includes a projection, the projection configured to releasably engage with an interspinous spacer device.
220. The insertion instrument of claim 219 wherein the projection comprises a threaded rod.
221. The insertion instrument of claim 219 wherein the projection engages with an actuator mechanism of the interspinous spacer device.
222. The insertion instrument of claim 215 wherein the spacer attachment mechanism further includes an attached interspinous spacer device.
223. The insertion instrument of claim 215 wherein the barrel assembly further comprises a second spacer attachment mechanism.
224. The insertion instrument of claim 208 wherein the handle further comprises a control operatively connected to the inner shaft and configured to translate and/or rotate the inner shaft.

225. The insertion instrument of claim 208 wherein the handle further includes a control, the control configured in a T-handle arrangement.
226. The insertion instrument of claim 208 wherein the handle further includes a control, said control configured in a trigger arrangement.
227. The insertion instrument of claim 208 wherein the handle further includes a control, the control configured to operatively expand and/or contract an interspinous spacer device.
228. The insertion instrument of claim 208 wherein the handle further includes a control, the control configured to engage and/or disengage the barrel assembly with an interspinous spacer device.
229. The insertion instrument of claim 208 wherein the handle further includes at least two controls, the at least two controls configured to collectively engage, re-engage, expand, contract and/or disengage the distal end of the barrel assembly with an interspinous spacer device.
230. The insertion instrument of claim 208 wherein the handle further includes a control, the control configured to operatively distract a first spinous process and a second spinous process.
231. The insertion instrument of claim 208 further comprising a deployment status indicator.
232. The insertion instrument of claim 231 wherein the deployment status indicator is a mechanical assembly.
233. The insertion instrument of claim 231 wherein the deployment status indicator is an electronic assembly.

234. The insertion instrument of claim 231 wherein the deployment status indicator provides quantitative deployment information.

235. The insertion instrument of claim 231 wherein the deployment status indicator provides a confirmation of successful expansion of an interspinous spacer device.

236. The insertion instrument of claim 208 further including an engagement status indicator.

237. The insertion instrument of claim 236 wherein the engagement status indicator is a mechanical assembly.

238. The insertion instrument of claim 236 wherein the engagement status indicator is an electronic assembly.

239. The insertion instrument of claim 236 wherein the engagement status indicator provides quantitative engagement information.

240. The insertion instrument of claim 236 wherein the engagement status indicator provides a confirmation of successful disengagement from an interspinous spacer device.

241. The insertion instrument of claim 236 wherein the engagement status indicator provides a confirmation of successful re-engagement with an interspinous spacer device.

242. The insertion instrument of claim 208 further comprising a visualization marker.

243. The insertion instrument of claim 242 wherein the visualization marker is selected from the group consisting of a visible marker, a radiopaque marker, an ultrasonic marker, a magnetic marker, or combinations thereof.

244. The insertion instrument of claim 243 wherein the visualization marker is configured to indicate the condition of engagement of the barrel assembly with an interspinous spacer device.

245. The insertion instrument of claim 243 wherein the visualization marker is configured to indicate the condition of deployment of an interspinous spacer device.

246. The insertion instrument of claim 208 further comprising an energy delivery assembly proximate to the distal end of the barrel assembly.

247. The insertion instrument of claim 246 wherein the energy delivery assembly is configured to cut tissue and/or coagulate blood.

248. The insertion instrument of claim 208 further comprising an interspinous spacer device.

249. The insertion instrument of claim 208 further including an interspinous gauge assembly, the interspinous gauge assembly configured to measure the distance between a first spinous process and a second spinous process of the patient.

250. The insertion instrument of claim 249 wherein the interspinous gauge assembly is a mechanical assembly.

251. The insertion instrument of claim 249 wherein the interspinous gauge assembly is an electronic assembly.

252. The insertion instrument of claim 249 wherein the interspinous gauge assembly includes a sensor which provides a signal correlating to the measured distance.

253. The insertion instrument of claim 252 wherein the sensor is selected from the group consisting of a strain gauge, a force sensing resistor, a rotary encoder such as an optical rotary encoder, a potentiometer such as a linear potentiometer, a magnetic sensor, an optical sensor such as a phototransistor, or combinations thereof.

254. The insertion instrument of claim 252 wherein the interspinous gauge assembly further includes an expandable assembly disposed proximate to the distal end of the elongated barrel and configured for expansion between two spinous processes, wherein the sensor provides a signal indicating the state of expansion of the expandable assembly.

255. The insertion instrument of claim 254 wherein the expandable assembly includes a first component which moves relative to a second component, and the sensor is a magnetic sensor configured to provide a signal indicative of the relative position between the first component and the second component.

256. The insertion instrument of claim 254 wherein the expandable assembly includes a first component rotatably attached to a second component, and the sensor is a rotary encoder configured to provide a signal indicative of the angular orientation between said first component and said second component.

257. The insertion instrument of claim 249 wherein the interspinous gauge assembly further comprises at least two sensors providing a measured distance information signal.

258. The insertion instrument of claim 249 wherein the handle further includes at least one control configured to operate the interspinous gauge assembly.

259. The insertion instrument of claim 208 further including a size indicator configured to provide interspinous spacer information.

260. The insertion instrument of claim 259 wherein the spacer information is spacer size information.
261. The insertion instrument of claim 260 wherein the size indicator includes a rounding function.
262. The insertion instrument of claim 259 wherein the spacer information is spacer model number information.
263. The insertion instrument of claim 208 further including a force measurement assembly configured to provide information to an operator, the information correlating to the magnitude of force required to distract two spinous processes a fixed distance.
264. The insertion instrument of claim 263 wherein the information includes acceptability of the measured force.
265. The insertion instrument of claim 263 wherein the force measurement assembly includes a sensor.
266. The insertion instrument of claim 265 wherein the sensor is selected from the group consisting of a strain gauge, a force sensing resistor, a rotary encoder such as an optical rotary encoder, a potentiometer such as a linear potentiometer, a magnetic sensor, an optical sensor such as a phototransistor, or combinations thereof.
267. The insertion instrument of claim 208 further including a spinous process thickness measurement assembly configured to provide information to an operator, the information correlating to a thickness of one or more spinous processes of the patient.
268. The tool of claim 267 wherein the provided thickness information includes acceptability of the measured force.

269. The insertion instrument of claim 267 wherein the thickness measurement assembly includes a sensor.
270. The insertion instrument of claim 269 wherein the sensor is selected from the group consisting of a strain gauge, a force sensing resistor, a rotary encoder such as an optical rotary encoder, a potentiometer such as a linear potentiometer, a magnetic sensor, an optical sensor such as a phototransistor, or combinations thereof.
271. The insertion instrument of claim 208 further including an osteophyte treatment assembly configured to remove, smooth and/or otherwise treat an osteophyte.
272. The insertion instrument of claim 271 wherein the osteophyte treatment assembly includes a mechanical assembly comprising an abrasive surface configured to be operatively moved in a back and forth motion to treat an osteophyte.
273. The insertion instrument of claim 271 wherein the osteophyte treatment assembly comprises an energy delivery assembly configured to deliver energy to treat an osteophyte.
274. The insertion instrument of claim 208 further including a spinous process distraction assembly.
275. The insertion instrument of claim 274 wherein the handle further comprises a control for operatively engaging the distraction assembly.
276. The insertion instrument of claim 274 wherein the distraction assembly is configured to not exceed a pre-determined distraction force.
277. The insertion instrument of claim 274 wherein the distraction assembly is configured to not exceed a pre-determined distraction distance.

278. A method for performing a procedure on a patient's spine, the method comprising the steps of:
- inserting a guidewire comprising a flexible filament through skin of the patient to a location proximate to the patient's spine;
 - inserting a cannula comprising a rigid elongated tube with a proximal end, a distal end, and a lumen therethrough proximate to the patient's supraspinous ligament;
 - placing a mounting bracket comprising a receiving tube and an attachment port over the cannula so that the cannula is received in the receiving tube;
 - attaching the attachment port to a stabilizing device; and
 - orienting the cannula relative to the stabilizing device.
279. The method of claim 278 in which the procedure is performed so that the cannula is inserted through the supraspinous ligament.
280. The method of claim 278 in which the procedure is performed so that the cannula is inserted into the patient laterally and proximate to the supraspinous ligament.
281. The method of claim 278 in which the procedure is performed so that the cannula is inserted into the patient laterally to the supraspinous ligament.
282. The method of claim 278 including a further step of delivering energy to the distal end of the cannula to thereby cut tissue and/or coagulate blood.
283. The method of claim 278 in which a portion of the mounting bracket is maintained in contact with the patient's skin.
284. The method of claim 283 in which the portion is a spherical projection or partial spherical projection.
285. The method of claim 278 including a further step of mounting an additional device to the mounting bracket.

286. The method of claim 285 in which the additional device includes an additional cannula, camera, or camera holding device.

287. The method of claim 278 including a further step of mounting the stabilizing device to a location selected from the group consisting of an operating room table, a patient bed; a portion of the patient's body, or combinations thereof.

288. The method of claim 287 including a further step of penetrating the supraspinous ligament using a target needle, the target needle comprising a hollow needle comprising a proximal end, a distal end, and a lumen therethrough and an inner core slidably received by the hollow needle.

289. The method of claim 288 including a further step of removing the inner core from the hollow needle after penetrating the supraspinous ligament.

290. The method of claim 278 including a further step of removably fixing a guidewire clamp to the guidewire to thereby limit advancement of the guidewire into the patient's body.

291. The method of 278 including a further step of inserting at least one dilator over the guidewire to thereby dilate the patient's tissue, the at least one dilator comprising an elongated tube with a proximal end, a distal end, and a lumen therethrough, the lumen configured to allow placement of the at least one dilator over the guidewire, and the distal end including a taper configured to dilate tissue.

292. The method of claim 291 in which the at least one dilator is used to separate filamentous strands of the supraspinous ligament.

293. The method of claim 278 including a further step of oscillating the cannula in partial rotations in clockwise and counterclockwise direction to separate filamentous strands of the supraspinous ligament.

294. The method of claim 291 in which energy is delivered to the distal end of the at least one dilator to thereby cut tissue and/or coagulate blood.

295. The method of claim 278 including a further step of making one or more plunge cuts using an interspinous knife, the interspinous knife comprising an elongated outer tube with a proximal end and a distal end, an inner tube with a proximal end and a distal end, the inner tube slidably received by the elongated outer tube and the distal end of the inner tube including a cutting element.

296. The method of claim 295 in which a first of the one or more plunge cuts comprises an "X" shaped cut that is oriented approximately 45 degrees from a second one of the one or more plunge cuts comprising an "X" shaped cut.

297. The method of claim 295 in which at least one depth of plunge cutting is approximately 15mm and another at least one depth of plunge cutting is approximately 20mm.

298. The method of claim 295 in which the interspinous knife is inserted into the cannula so that a surface feature of the interspinous knife comes in contact with a counterbore feature of the cannula to thereby provide a fixed orientation of the interspinous knife with respect to the cannula.

299. The method of claim 278 including a further step of using an interspinous reamer to remove tissue, the interspinous reamer comprising an elongated tube with a proximal end and a distal end, the distal end comprising an axial cutting element configured to cut tissue of the patient, and a flat end drill, the drill configured to remove the tissue from the elongated tube.

300. The method of claim 299 in which the interspinous reamer is inserted into the cannula until a depth-limiting element disposed in the interspinous reamer mates with the cannula to thereby limit insertion of the elongated tube and/or flat-end drill into the cannula.

301. The method of 299 including a further step of applying energy to the distal end of the interspinous reamer to thereby cut tissue and/or coagulate blood.

302. The method of 278 including a further step of measuring a distance between a first spinous process and a second spinous process of the patient using an interspinous gauge, the interspinous gauge comprising an elongated barrel with a proximal end and a distal end, and a handle attached to the proximal end of the elongated barrel.

303. The method of claim 278 including a further step of treating an osteophyte using an interspinous gauge, the interspinous gauge comprising an elongated barrel with a proximal end and a distal end, and a handle attached to the proximal end of the elongated barrel.

304. The method of claim 303 in which the treatment includes mechanically abrading the osteophyte using a back and forth motion.

305. The method of claim 303 in which the treatment includes delivering energy to the osteophyte.

306. The method of claim 278 including a further step of applying a distraction force between a first spinous process and a second spinous process using an interspinous gauge, the interspinous gauge comprising an elongated barrel with a proximal end and a distal end, and a handle attached to the proximal end of the elongated barrel.

307. The method of claim 278 including a further step of inserting an interspinous gauge through the cannula, the interspinous gauge comprising an elongated barrel with a proximal end and a distal end, and a handle attached to the proximal end of the elongated barrel.
308. The method of claim 307 in which the interspinous gauge is inserted into the cannula until a flat surface on the interspinous gauge mates with a counterbore of the cannula to thereby provide a fixed orientation of the interspinous gauge with respect to the cannula.
309. The method of claim 278 including a further step of measuring a magnitude of force required to distract two spinous processes a fixed distance using an interspinous gauge, the interspinous gauge comprising an elongated barrel with a proximal end and a distal end, and a handle attached to the proximal end of the elongated barrel.
310. The method of claim 278 including a further step of measuring a thickness of one or more spinous processes using an interspinous gauge, the interspinous gauge comprising an elongated barrel with a proximal end and a distal end, and a handle attached to the proximal end of the elongated barrel.
311. The method of claim 278 including a further step of implanting an interspinous spacer using a interspinous gauge, the interspinous gauge comprising an elongated barrel with a proximal end and a distal end, and a handle attached to the proximal end of the elongated barrel, and an implant insertion assembly that is configured to engage and re-engage with an interspinous spacer.
312. The method of claim 278 including a further step of separating the supraspinous ligament using a first ligament separating tool comprising an elongated tube with a proximal end, a distal end, and a lumen therebetween, and a ligament separating assembly disposed proximate to the distal end of the elongated tube.

313. The method of claim 312 including a further step of delivering energy to the distal end of the ligament separating tool to thereby cut tissue and/or coagulate blood.

314. The method of claim 312 including a further step of using a second ligament separating tool to separate the supraspinous ligament wherein the first and second ligament separating tools have different geometries.

315. A method of implanting an interspinous spacer in a patient, the method comprising the steps of:

operating an insertion instrument to thereby engage with an interspinous spacer, the insertion instrument comprising a barrel assembly with a proximal end and a distal end, the barrel assembly comprising an elongated outer tube, an inner shaft slidably received by the outer tube, and a handle assembly fixedly attached to the proximal end of the barrel assembly;

inserting the insertion instrument into a cannula that is located proximate to the patient's supraspinous ligament;

expanding the interspinous spacer by operation of the handle assembly; and
disengaging the insertion instrument from the interspinous spacer.

316. The method of claim 315 in which the barrel assembly is inserted into the cannula until a mechanical feature mates with the cannula to thereby set depth of insertion and/or orientation of the insertion instrument.

317. The method of claim 315 including a further step of reading a deployment status indicator to receive quantitative deployment information.

318. The method of claim 315 including a further step of delivering energy to the distal end of the barrel to thereby cut tissue, coagulate blood and/or treat osteophytes.

319. The method of claim 315 including a further step of measuring a distance between a first and a second spinous process using the insertion instrument configured with an interspinous gauge assembly.

320. The method of claim 315 including a further step of measuring a force required to distract two spinous processes a fixed distance using the insertion instrument configured with a force measurement assembly.

321. The method of claim 315 including a further step of measuring a thickness of one or more spinous processes using the insertion instrument configured with a thickness measurement assembly.

322. The method of claim 315 including a further step of treating an osteophyte using the insertion instrument configured with an osteophyte treatment assembly.

323. A system of tools for performing a procedure on a patient's spine, the system comprising:

- a guidewire comprising a flexible filament configured to be placed through skin of the patient to a location proximate to the patient's spine;

- a cannula comprising a rigid elongated tube with a proximal end, a distal end, and a lumen therethrough;

- a stabilizing device comprising a first attachment element and a second attachment element; and

- a mounting tower comprising a receiving tube, an attachment port, and at least one spinous process gripper, the receiving tube configured to attach to the cannula, the attachment port configured to attach to the first attachment element of the stabilizing device, and the at least one spinous process gripper configured to clamp to a spinous process, the spinous process being one of superior spinous process or inferior spinous process,

- wherein the mounting bracket is configured to allow an operator to orient the cannula relative to the stabilizing device.

324. The system of claim 323 in which the at least one spinous process gripper comprises a pair of spinous process grippers.
325. The system of claim 324 in which a first pair of the pair of spinous process grippers is arranged to clamp to the superior spinous process and a second pair of the pair of spinous process grippers is arranged to clamp to the inferior spinous process.
326. The system of claim 323 in which the at least one spinous process gripper comprises a pair of legs, a proximal end of at least one of the legs being pivotally mounted to the mounting tower and a distal end of at least one of the legs including a gripping feature for interfacing with a surface of the spinous process.
327. The system of claim 326 in which the at least one spinous process gripper is coupled via a linkage to a control interface.
328. The system of claim 327 in which the control interface includes a first control interface and a second control interface.
329. The system of claim 328 in which operation of the first control interface causes each leg in the pair of legs to pivot outward in a lateral direction with respect to the other leg.
330. The system of claim 329 in which operation of the first control interface further causes each spinous process gripper in the pair of spinous process grippers to pivot inward in an axial direction with respect to the other spinous process gripper.
331. The system of claim 330 in which the mounting bracket includes a Cephalad indicator oriented in the axial direction.

332. The system of claim 328 in which operation of the second control interface causes each leg in the pair of legs to pivot inward in a lateral direction with respect to the other leg to thereby impose a clamping force on the spinous process.

333. The system of claim 327 in which the control interface is rotatably disposed along a longitudinal axis of the mounting tower.

334. The system of claim 328 in which the first control interface and second control interface are co-axially disposed.

335. A method for performing a procedure on a patient's spine, the method comprising the steps of:

inserting a cannula through the skin of the patient to a location proximate to the patient's spine, the cannula comprising a rigid elongated tube with a proximal end, a distal end, and a lumen therethrough; and

delivering an interspinous spacer through the cannula using one or more tools from a tool set comprising a plurality of individual tools, the individual tools selected from one of interspinous knife, ligament separating tool, interspinous reamer and interspinous gauge, wherein

the interspinous knife comprises an elongated outer tube with a proximal end and a distal end, an inner tube with a proximal end and a distal end, the inner tube slidably received by the elongated outer tube and the distal end of the inner tube including a cutting element having two blades substantially arranged in an X pattern, the interspinous knife further including a depth control element configured to allow an operator to select from a plurality of pre-set cutting depths, and

the ligament separating tool comprises an elongated tube with a proximal end, a distal end, and a lumen therebetween, and a ligament separating assembly disposed proximate to the distal end of the elongated tube, and

the interspinous reamer comprises an elongated tube with a proximal end and a distal end, the distal end comprising an axial cutting element configured to cut

tissue of the patient, and a flat end drill, the drill configured to remove tissue from the elongated tube, and

the interspinous gauge comprises an elongated barrel with a proximal end and a distal end, and at least one control attached to the proximal end of the elongated barrel wherein the interspinous gauge is configured to measure the distance between a first spinous process and a second spinous process of the patient through operation of the at least one control.

336. The method of claim 335 in which the cannula has a lumen diameter that is less than approximately 20 millimeters .

337. The method of claim 335 in which the cannula has a lumen diameter that is less than approximately 15 millimeters.

338. The method of claim 335 in which the cannula has a lumen diameter that is in a range of approximately 8 to 10 millimeters.

339. The method of claim 335 in which the inserting is performed using a single insertion point that is substantially aligned with a midline of a supraspinous ligament.

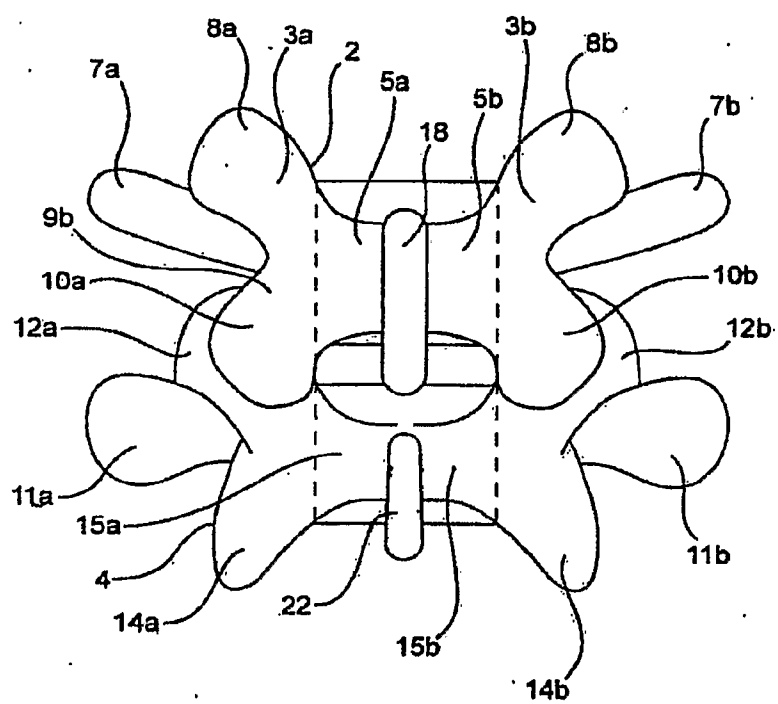
340. A method for using a combination of individual tools from a tooling set to create a working channel for implantation of an interspinous spacer, the method comprising the steps of:

selecting a combination of individual tools from the tooling set, the individual tools being configured to interoperate in a coordinated manner through the use of coordinated features to ensure commonality of operation selected from one of depth or orientation;

inserting the selected combination of individual tools, either one at a time, or simultaneously, through a lumen of a cannula that is positioned having a substantially fixed orientation with respect to a spine of a patient, the lumen having a diameter no greater than 20 millimeters.

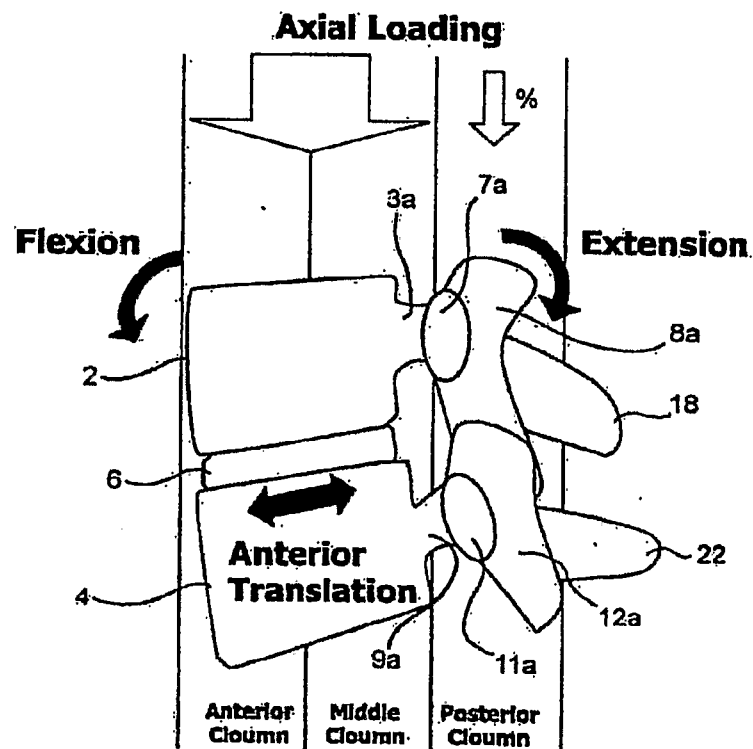
341. The method of claim 340 in which the tooling set includes at least an interspinous ligament separation tool for separating ligamentous tissue with minimal trauma.
342. The method of claim 340 in which the tooling set includes at least an interspinous gauge arranged for measuring space between adjacent spinous processes or for applying a distracting force to the spinous processes.
343. The method of claim 340 in which the tooling set includes at least an interspinous knife for enabling percutaneous access.
344. The method of claim 340 in which the tooling set includes at least an interspinous reamer for removing bone or tissue.
345. The method of claim 340 in which the cannula is placed through a mounting tower that is arranged with one or more spinous process grippers that grip one or more spinous processes to thereby assist with maintaining the cannula in a fixed orientation with respect to the one or more spinous processes.

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FIG. 1

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FIG. 2A



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FIG. 2B

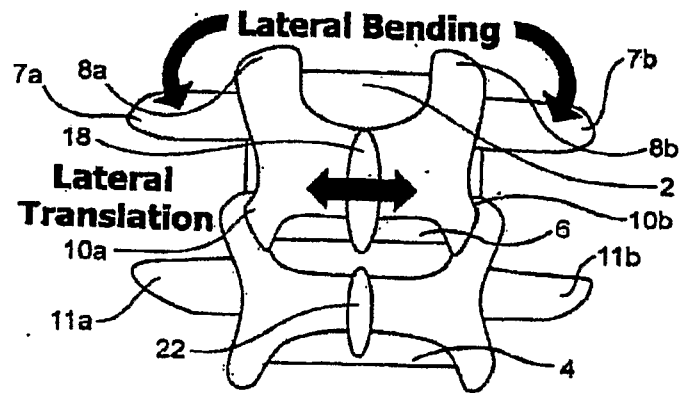
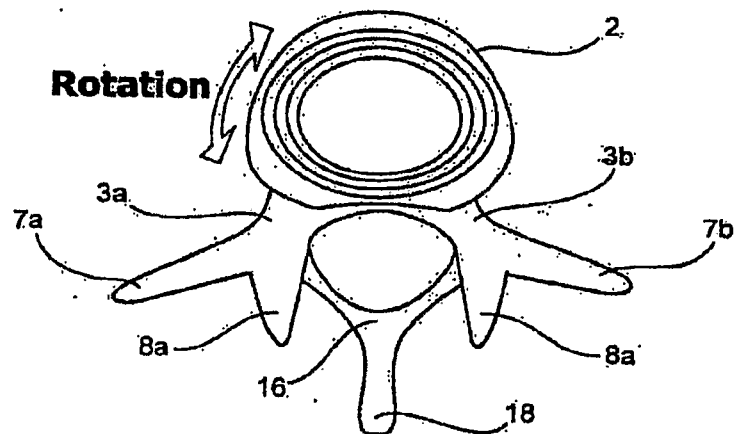


FIG. 2C



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FIG. 3

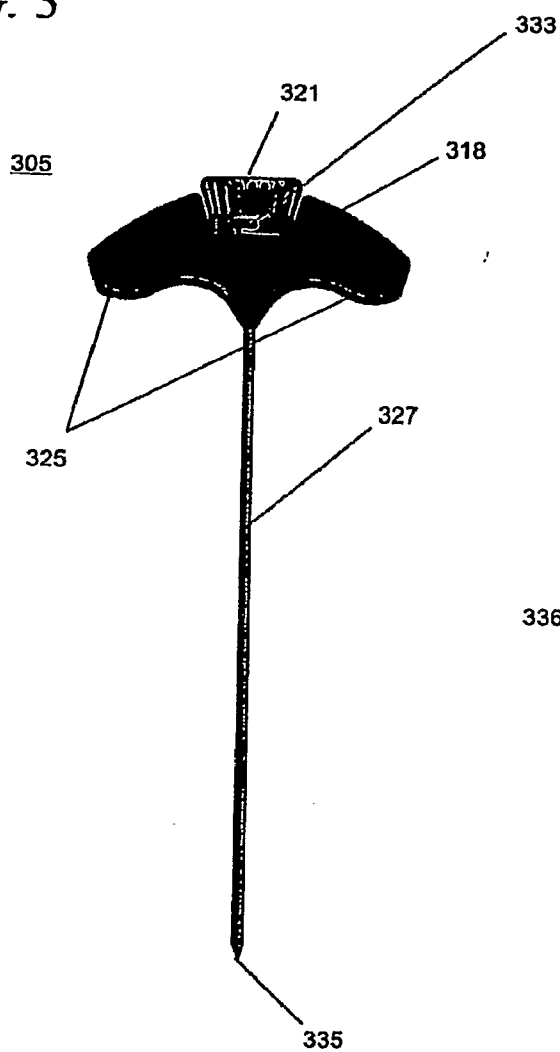
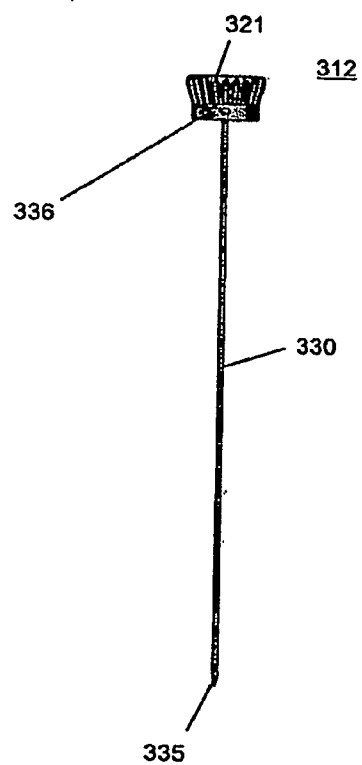
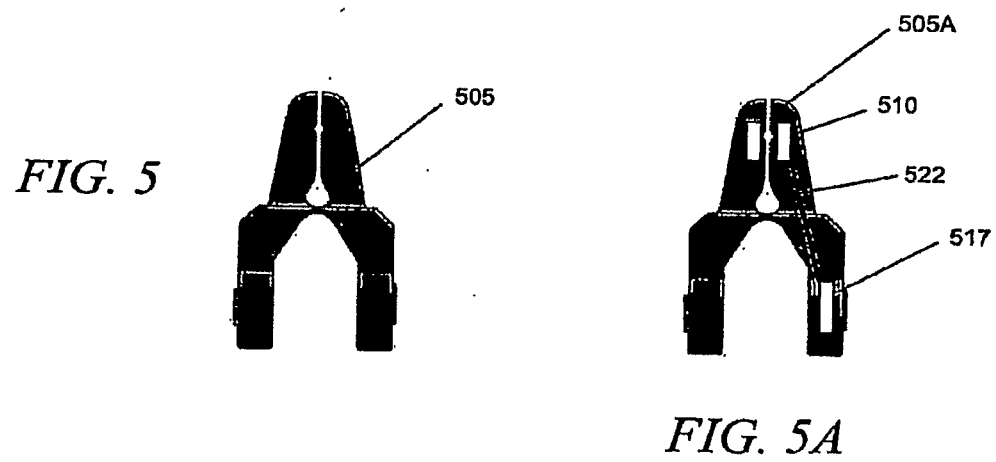
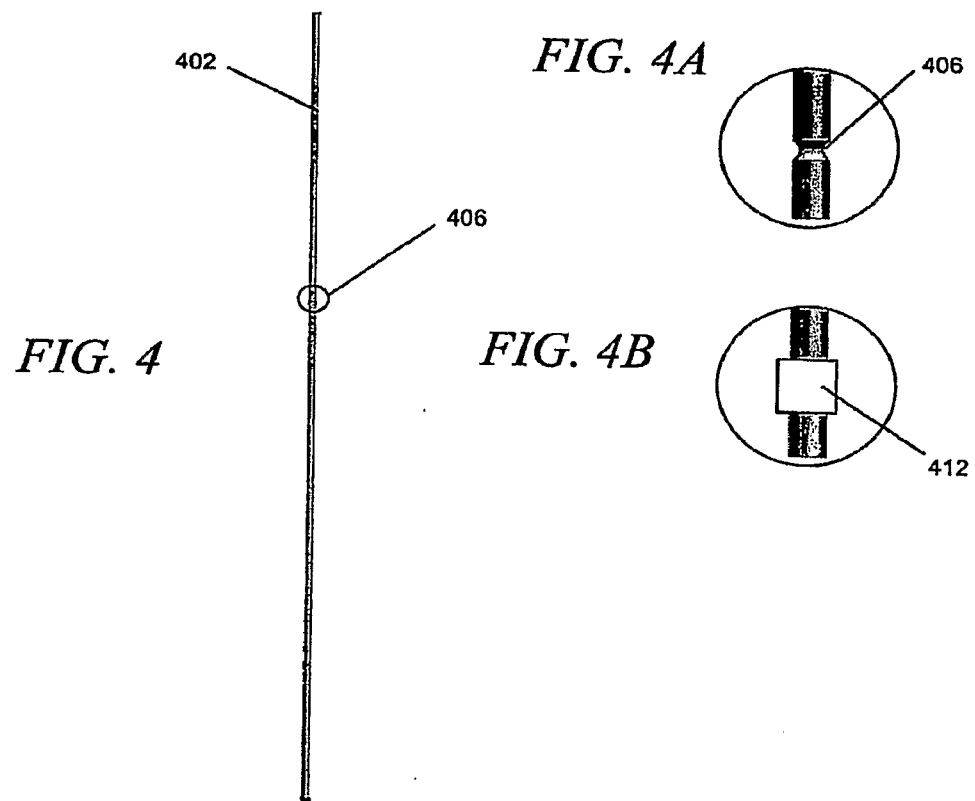


FIG. 3A



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FIG. 6

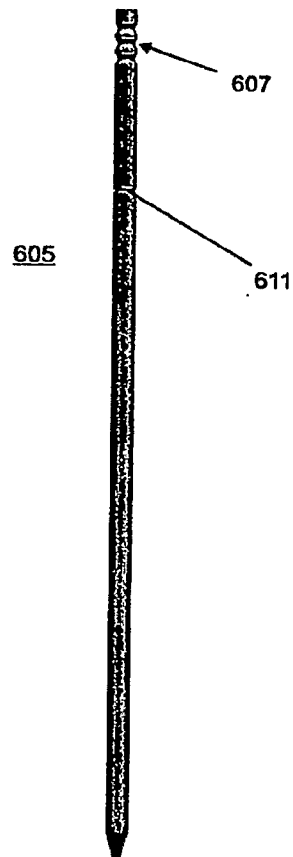


FIG. 7

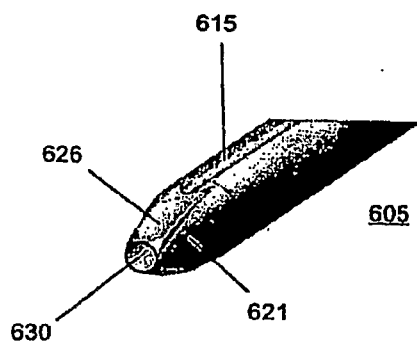
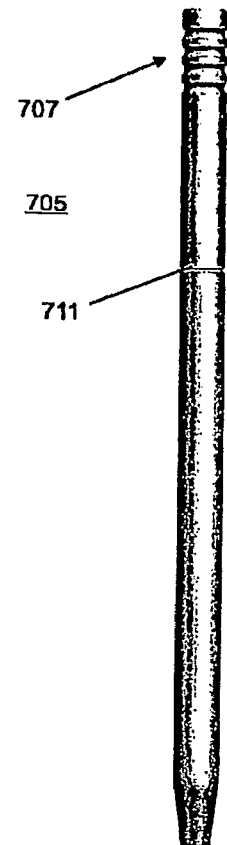


FIG. 6A

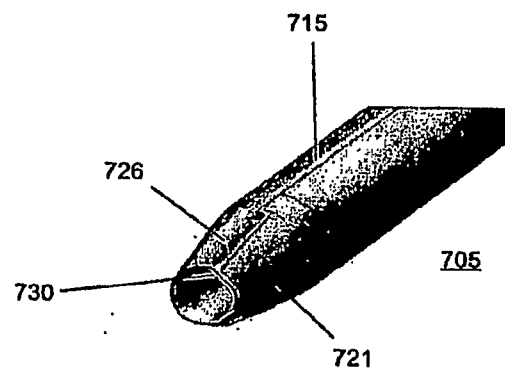


FIG. 7A

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FIG. 8

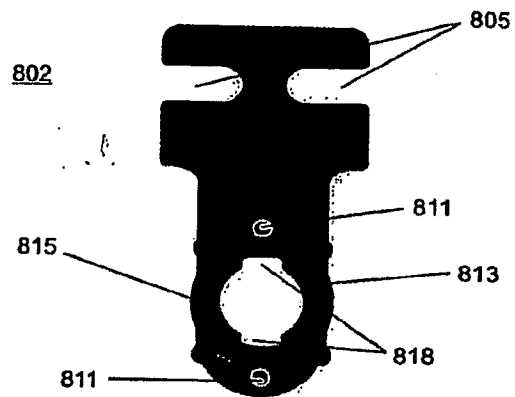


FIG. 8A

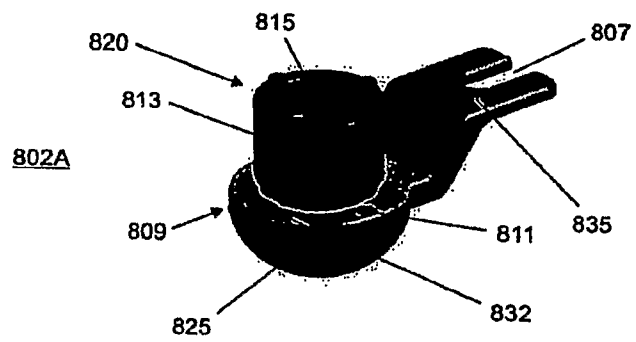


FIG. 8B

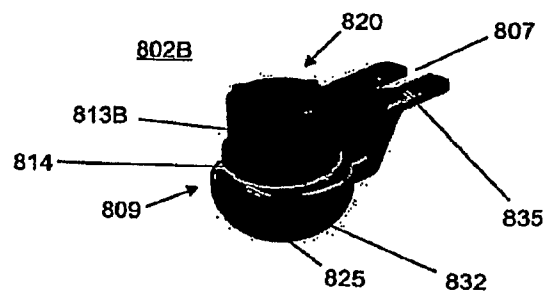
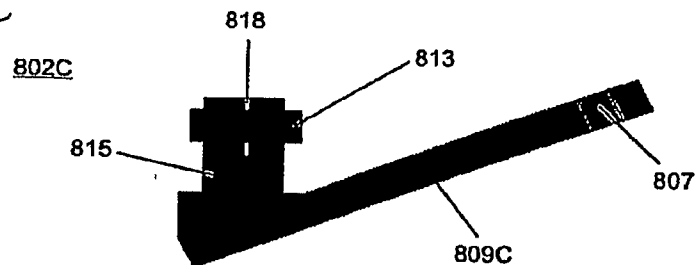


FIG. 8C



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FIG. 8D

850

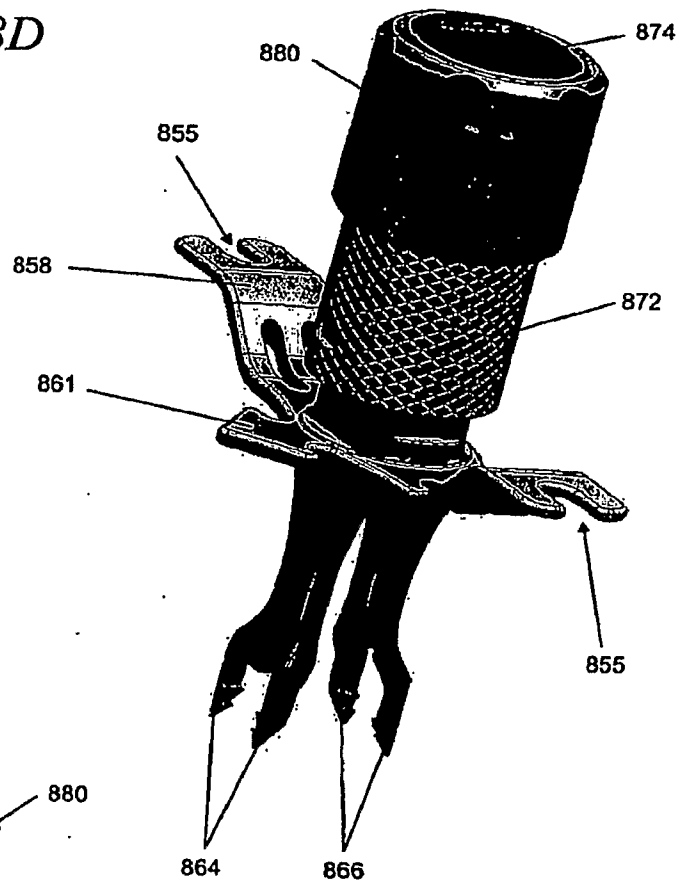
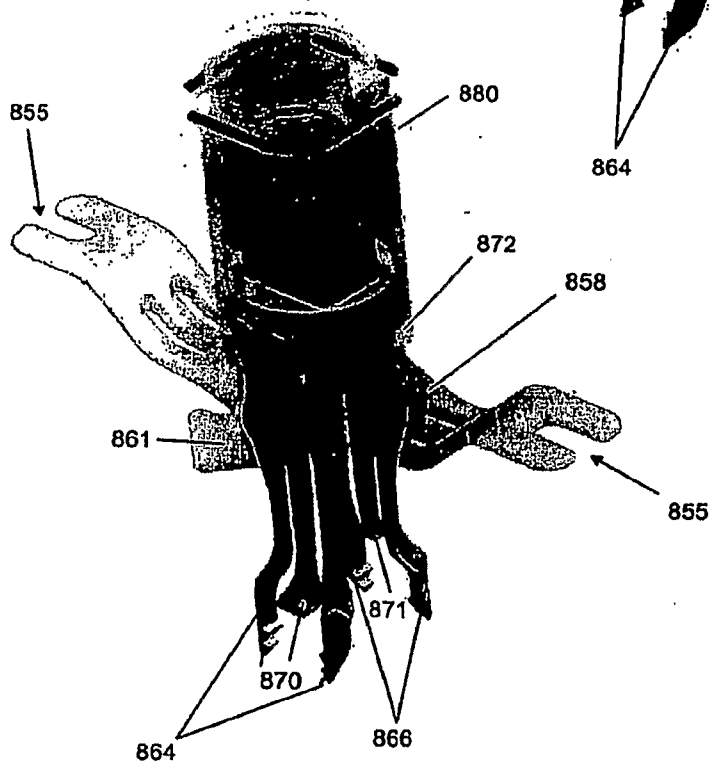


FIG. 8E

850



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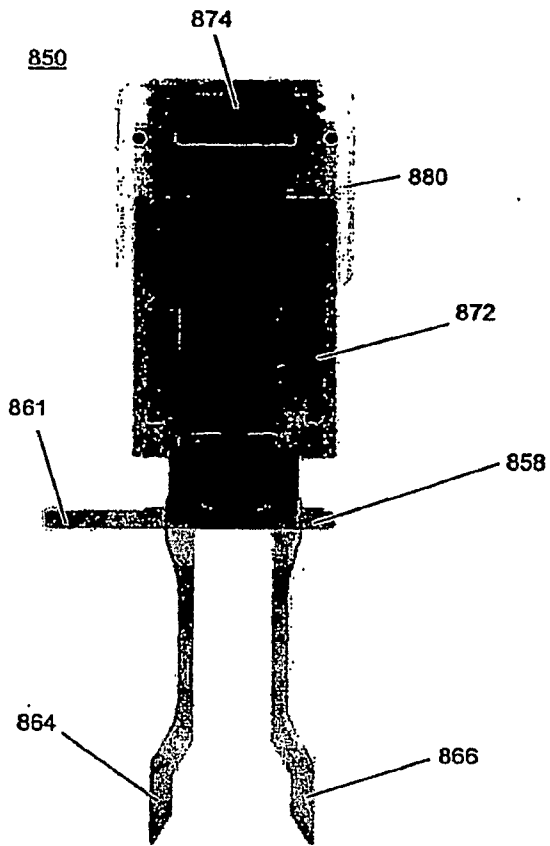


FIG. 8F

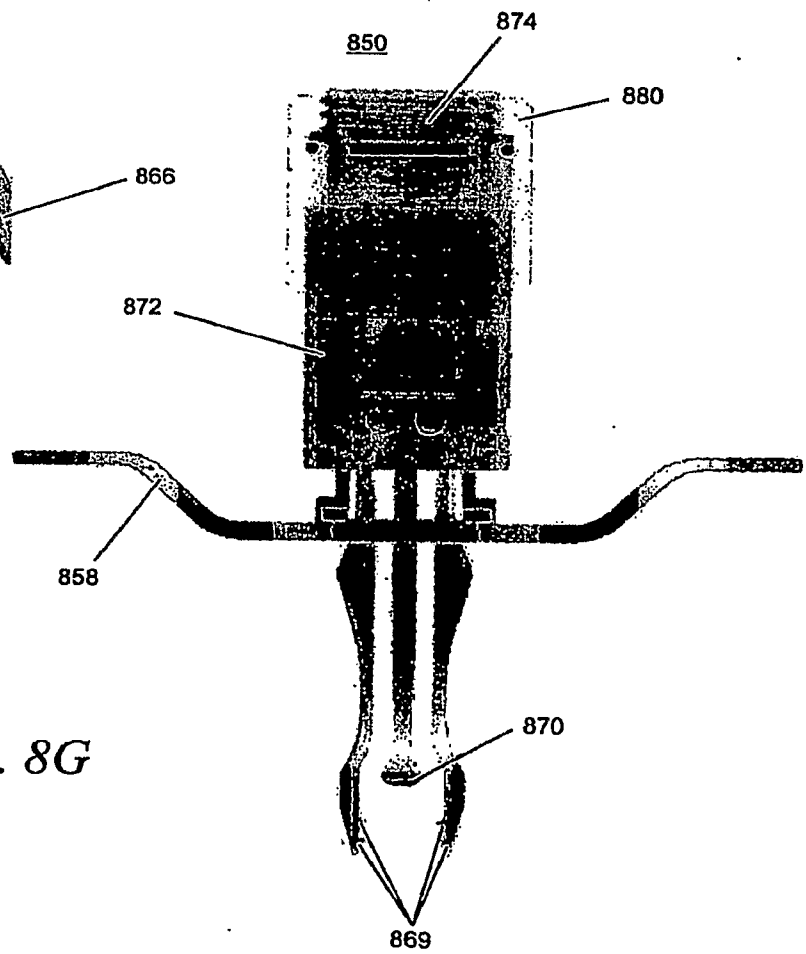


FIG. 8G

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FIG. 8H

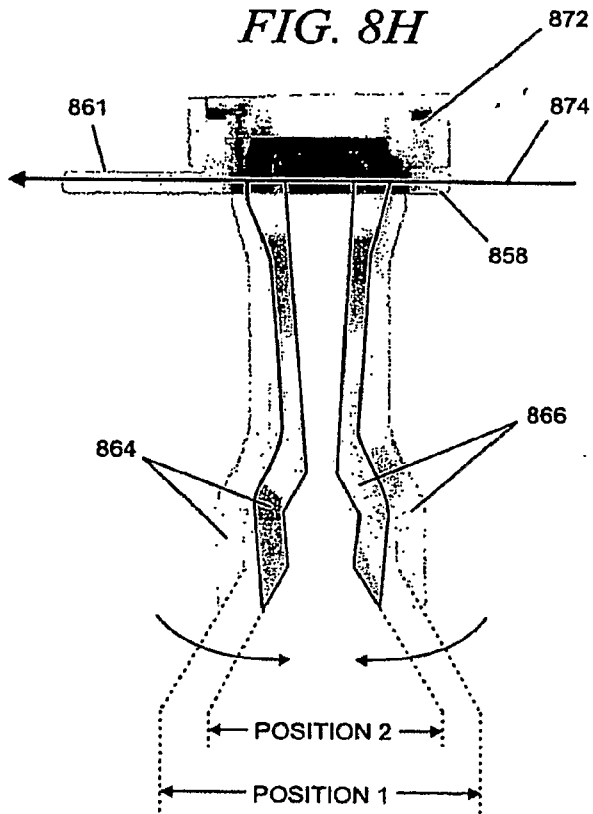
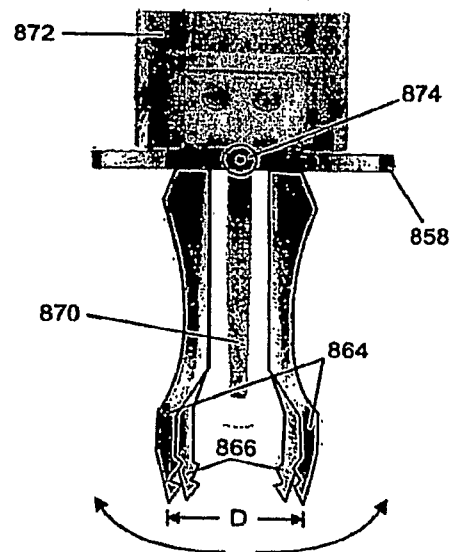


FIG. 8I



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FIG. 8J

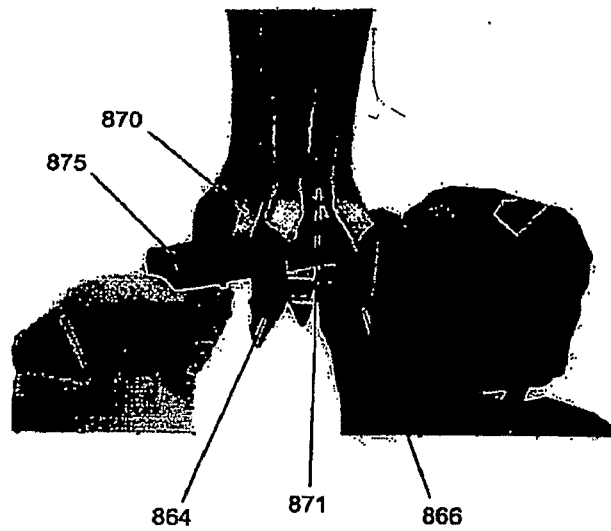
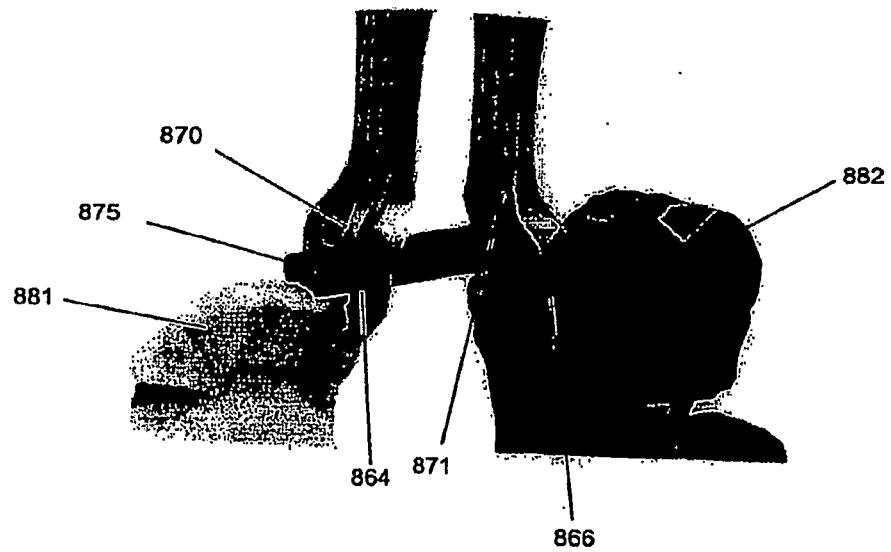
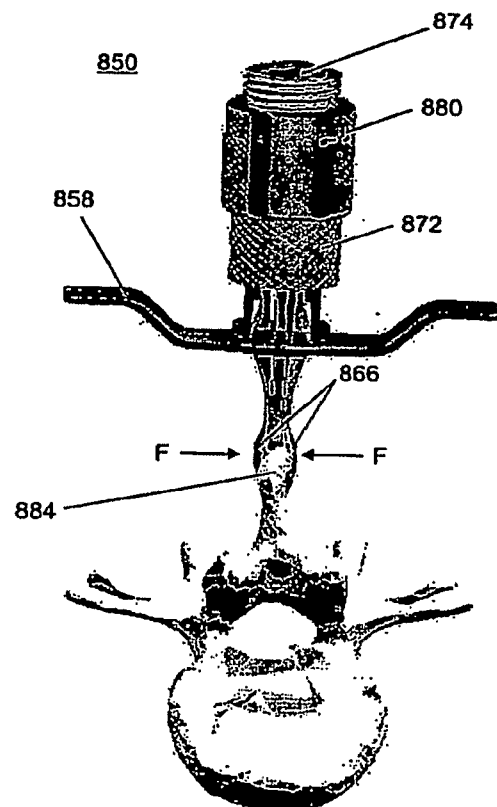


FIG. 8K



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FIG. 8L



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FIG. 9

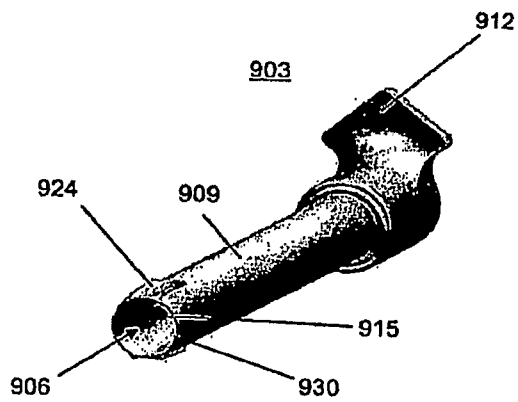
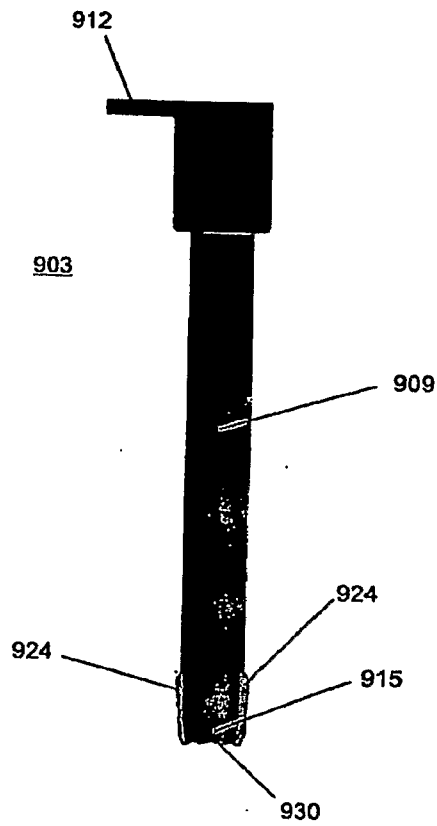


FIG. 9A

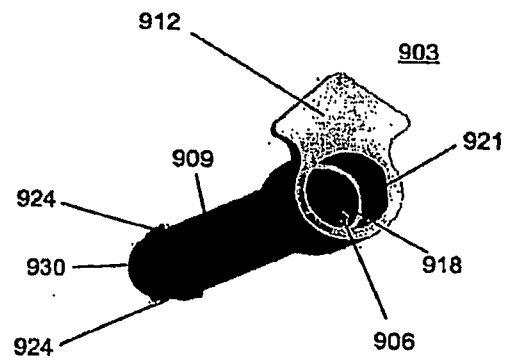
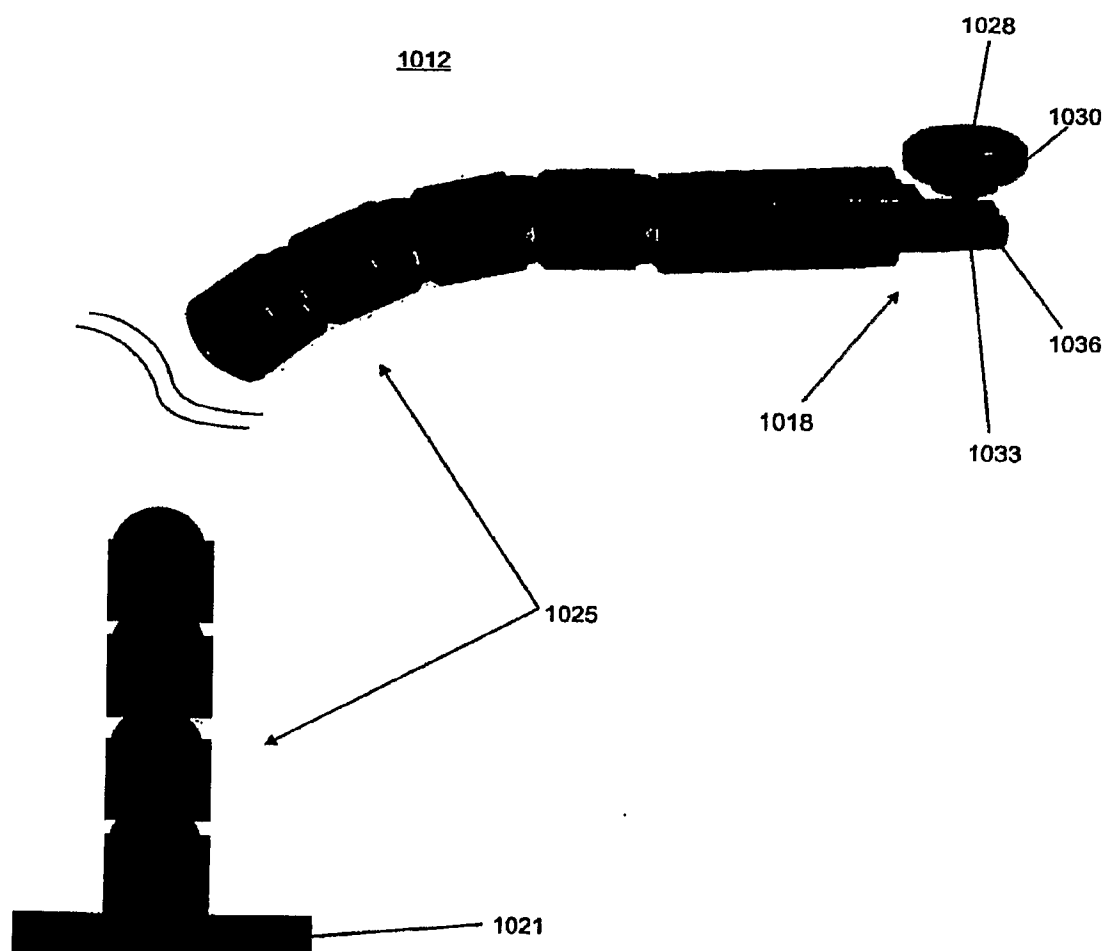


FIG. 9B

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FIG. 10



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FIG. 11

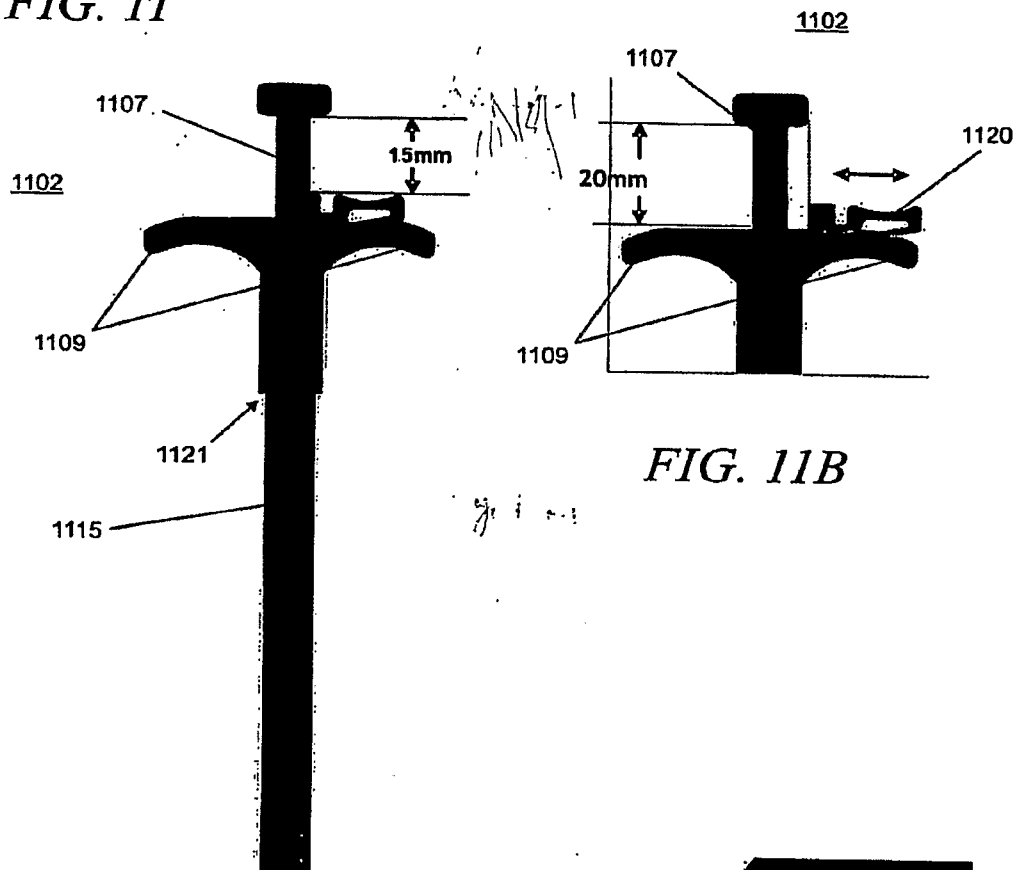


FIG. 11B

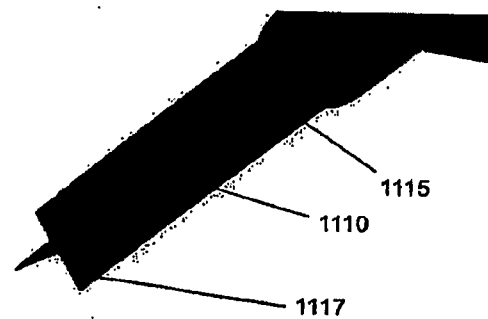


FIG. 11A

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FIG. 11C

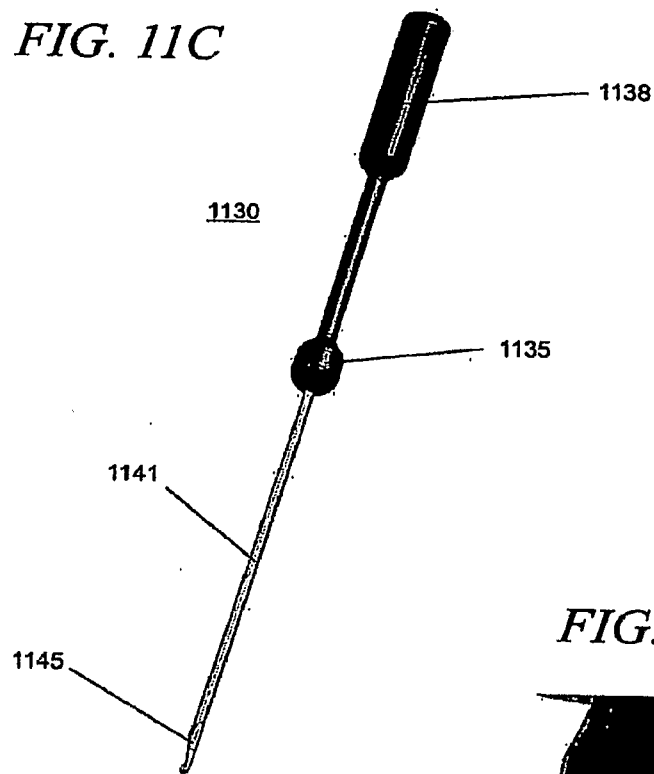
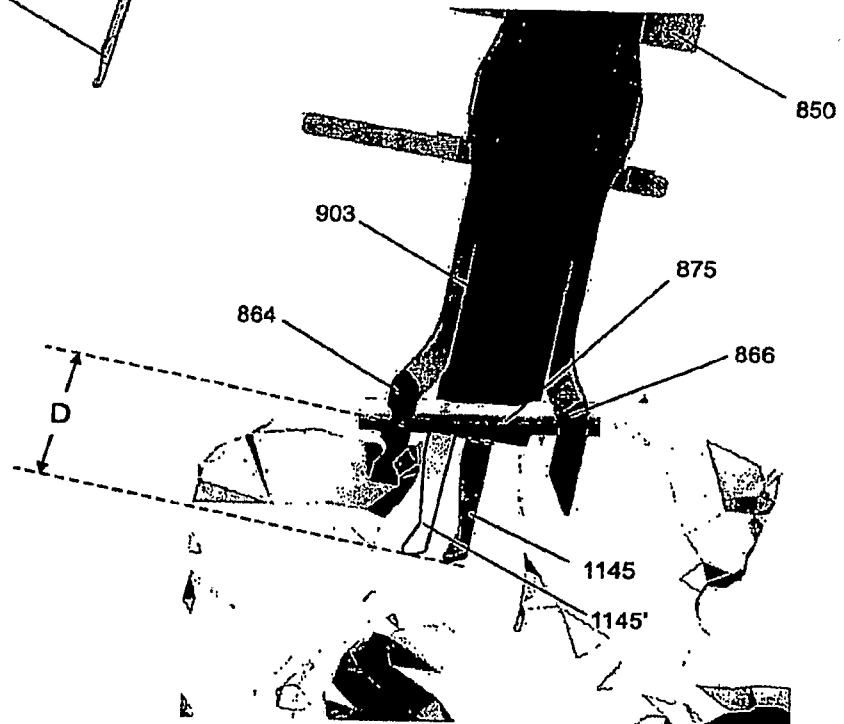


FIG. 11D



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FIG. 12

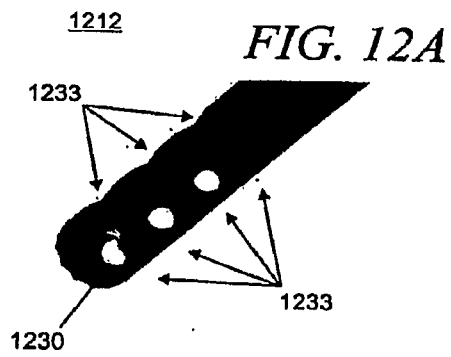
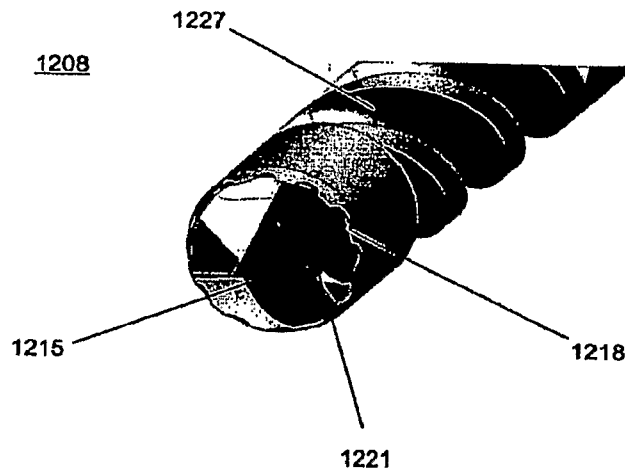


FIG. 12B

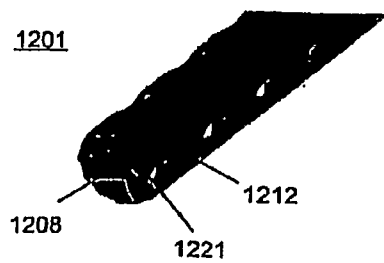
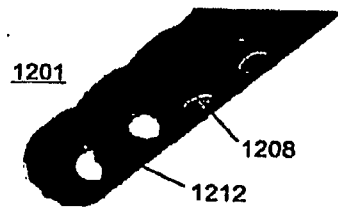


FIG. 12C



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FIG. 12D

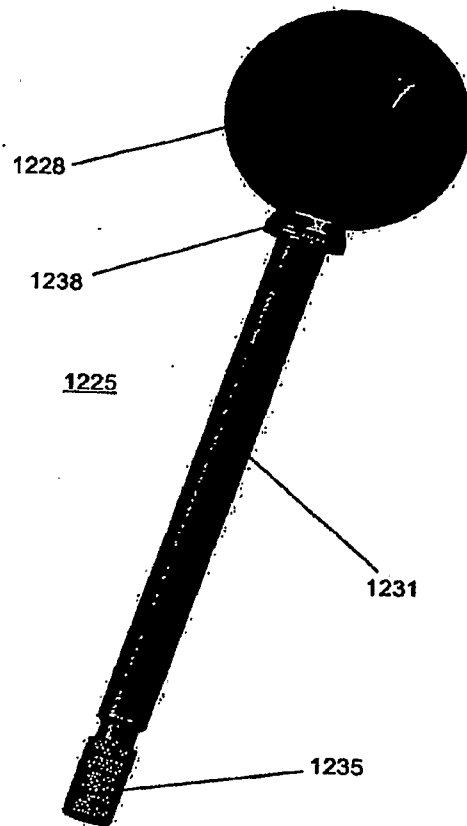


FIG. 12E

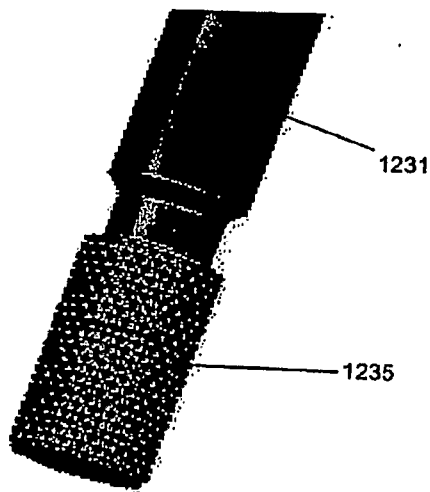


FIG. 12F

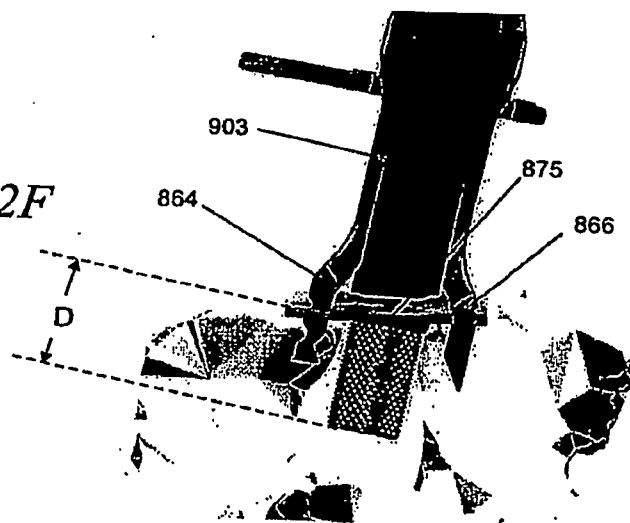


FIG. 13

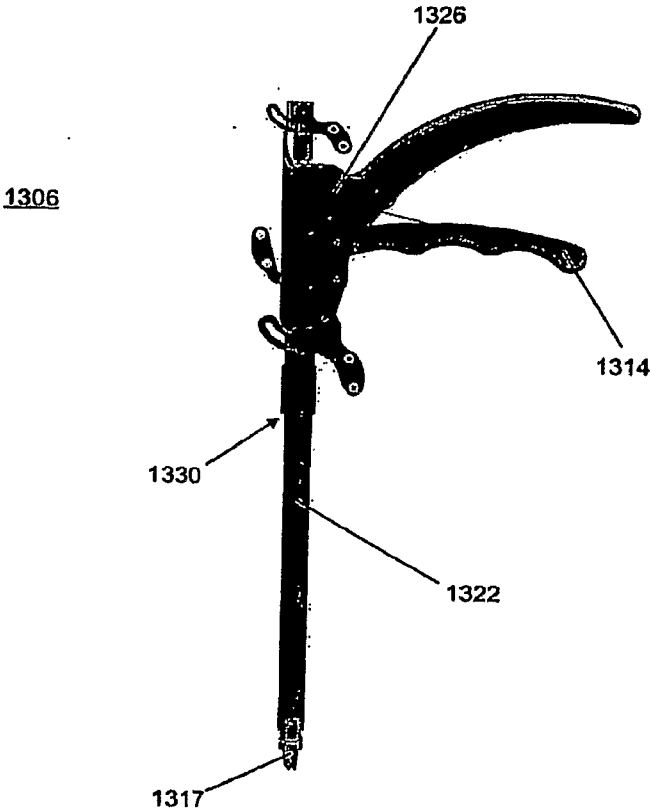
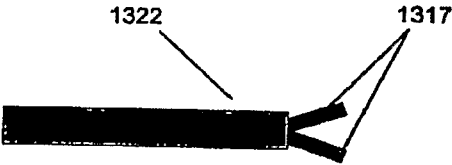
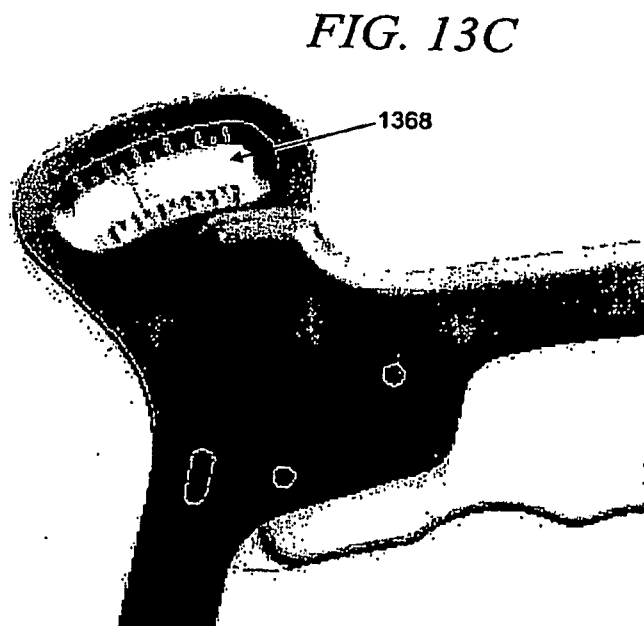
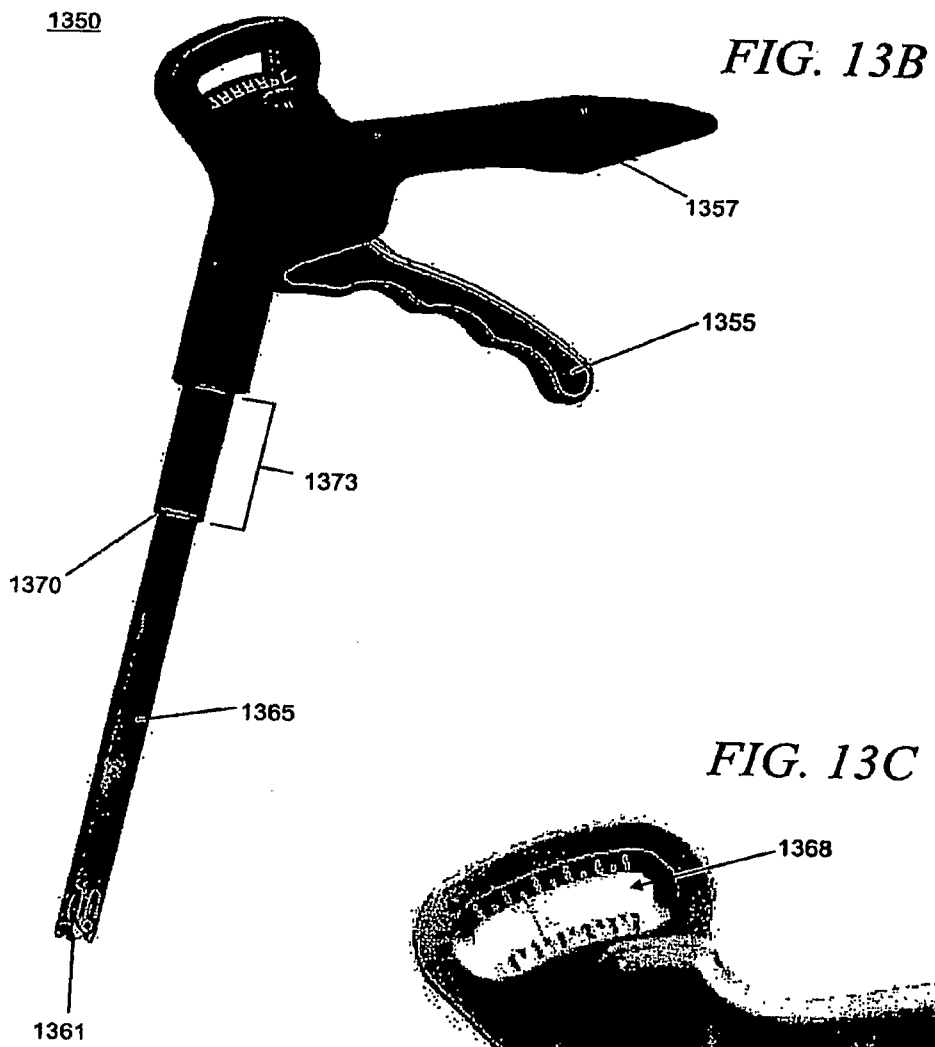


FIG. 13A

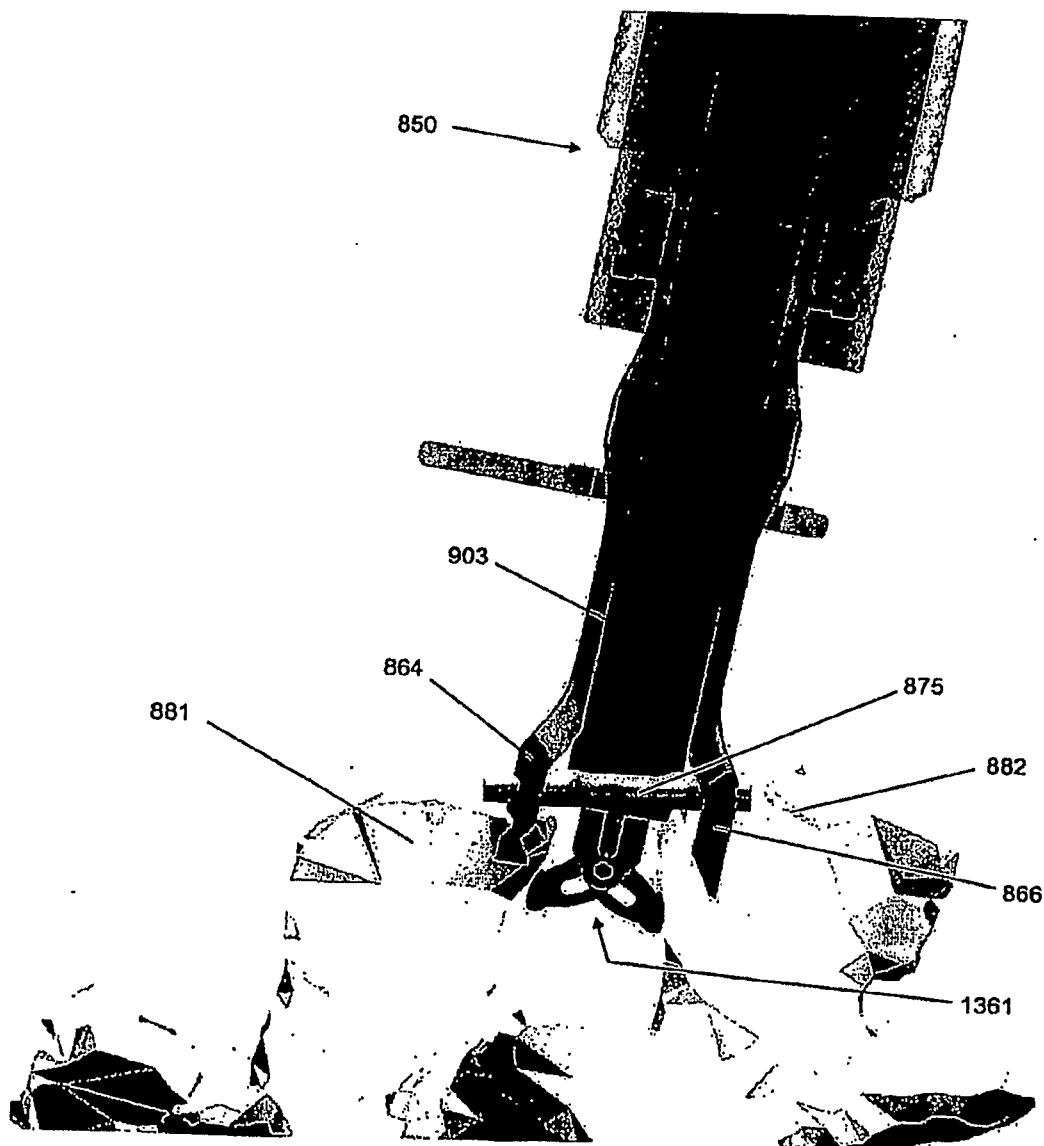


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FIG. 13D



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FIG. 14

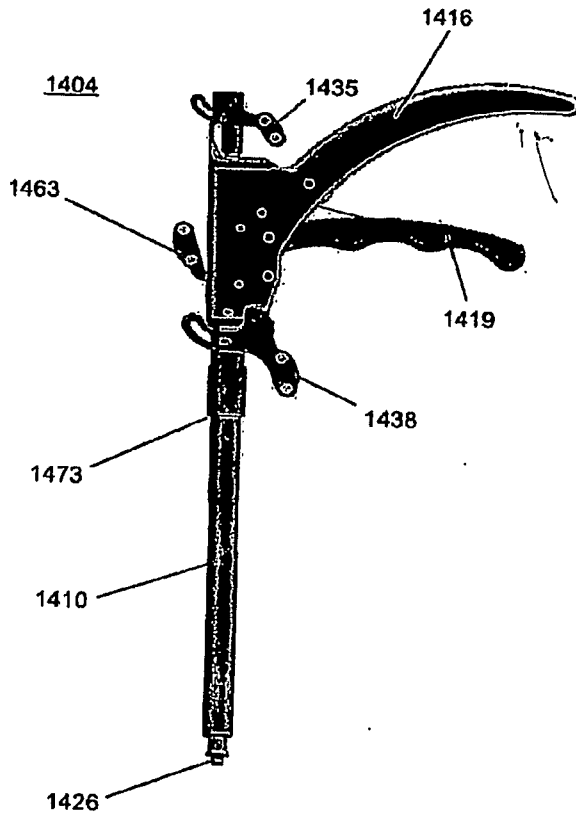


FIG. 14B

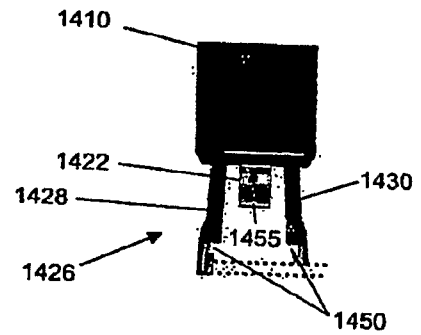


FIG. 14C

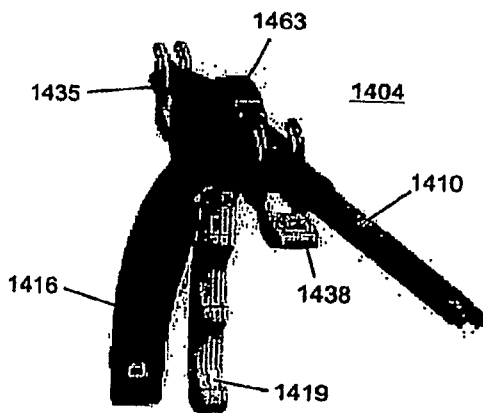
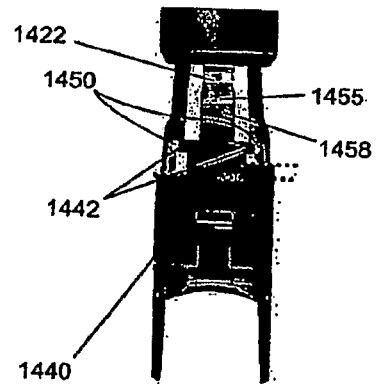


FIG. 14A



FIG. 14D

+2	= D+2mm
+1	= D+1mm
D	= DEPLOYED
L	= LOAD

FIG. 14E

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FIG. 14F

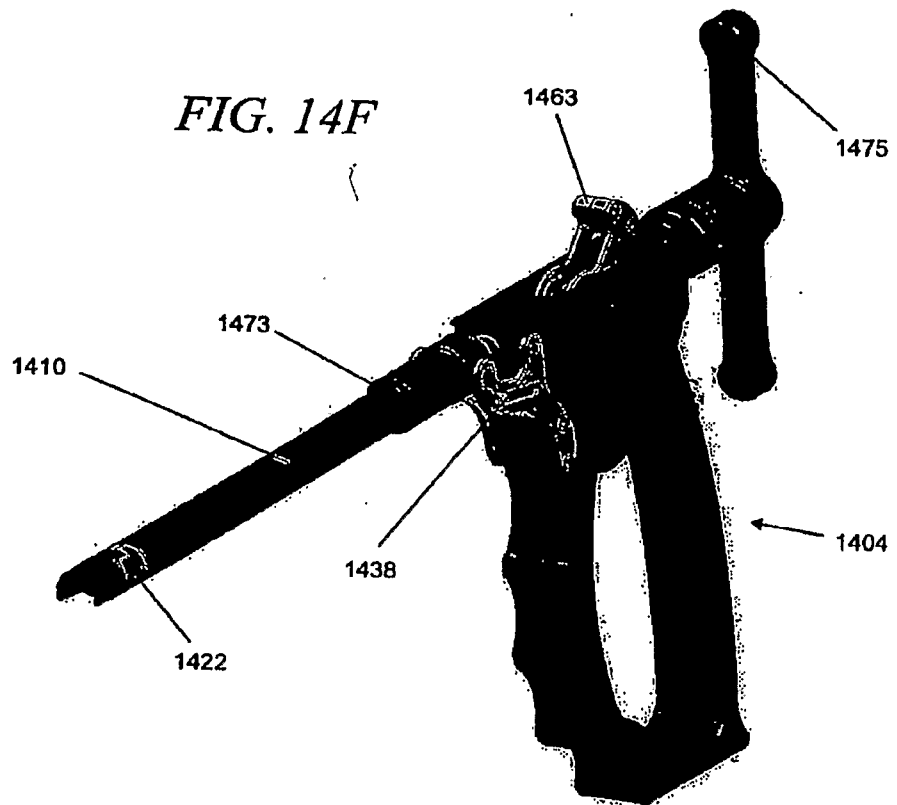
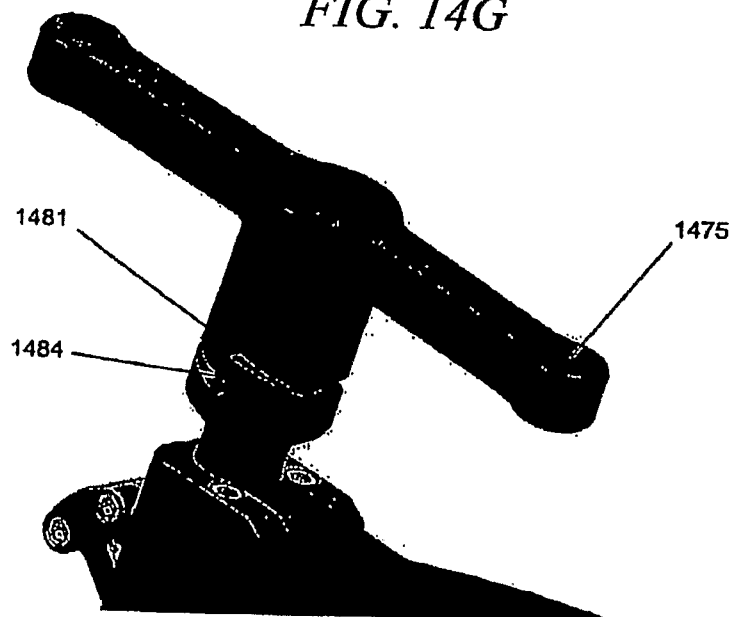


FIG. 14G



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FIG. 15

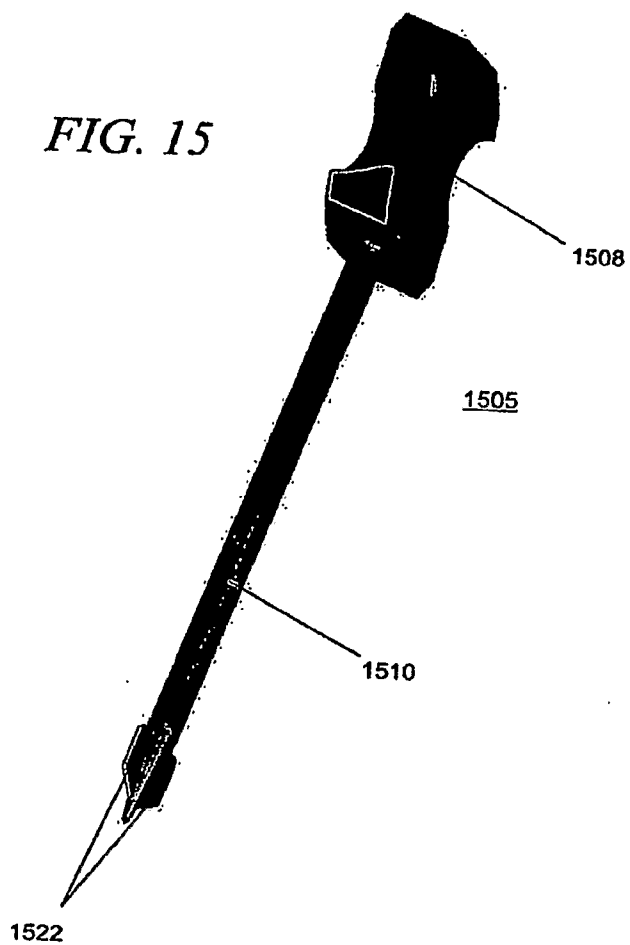
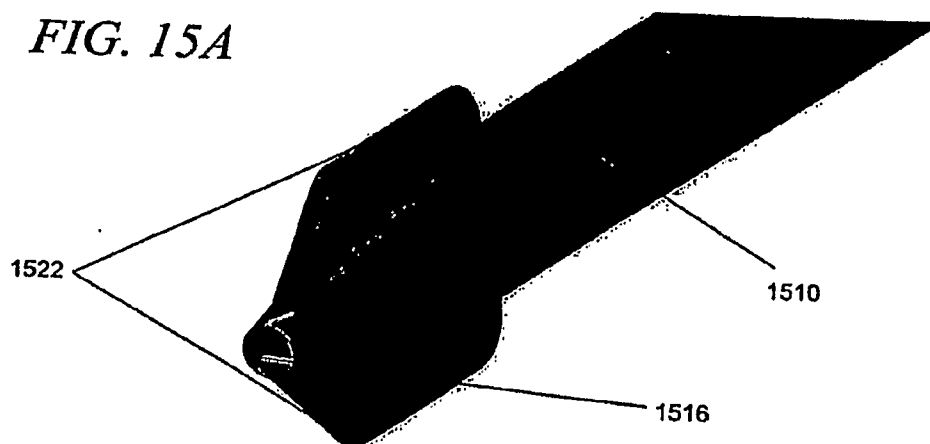


FIG. 15A



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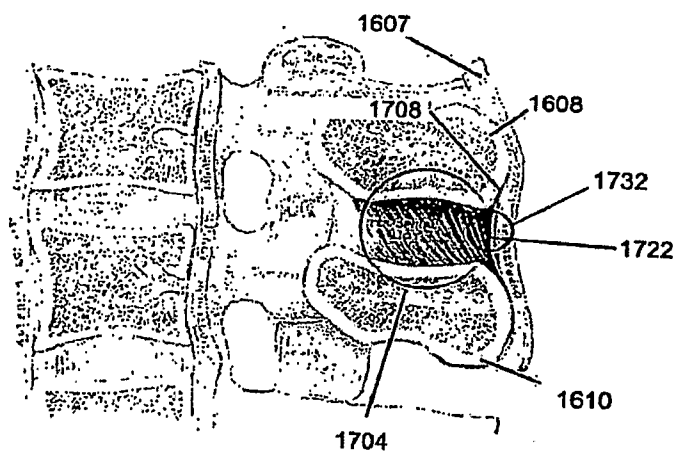
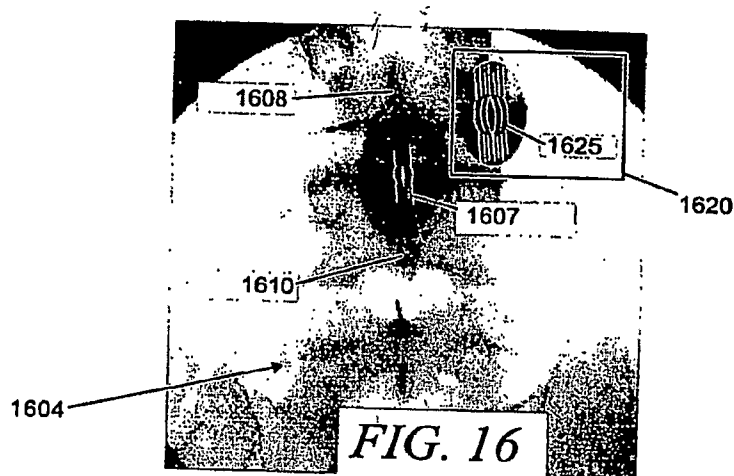
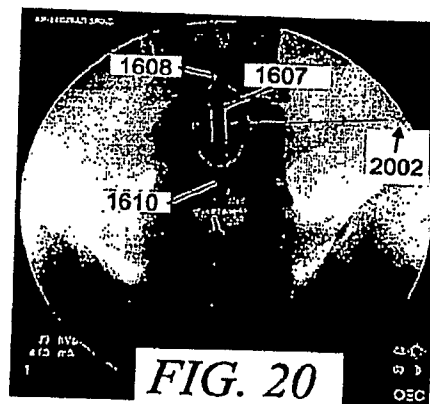
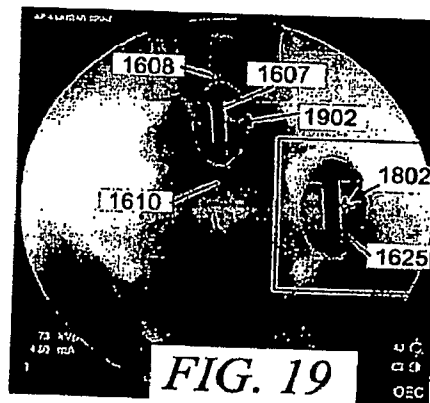
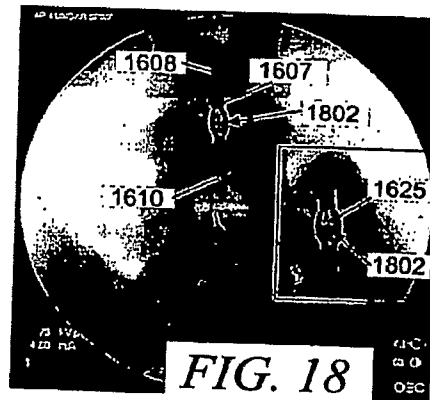


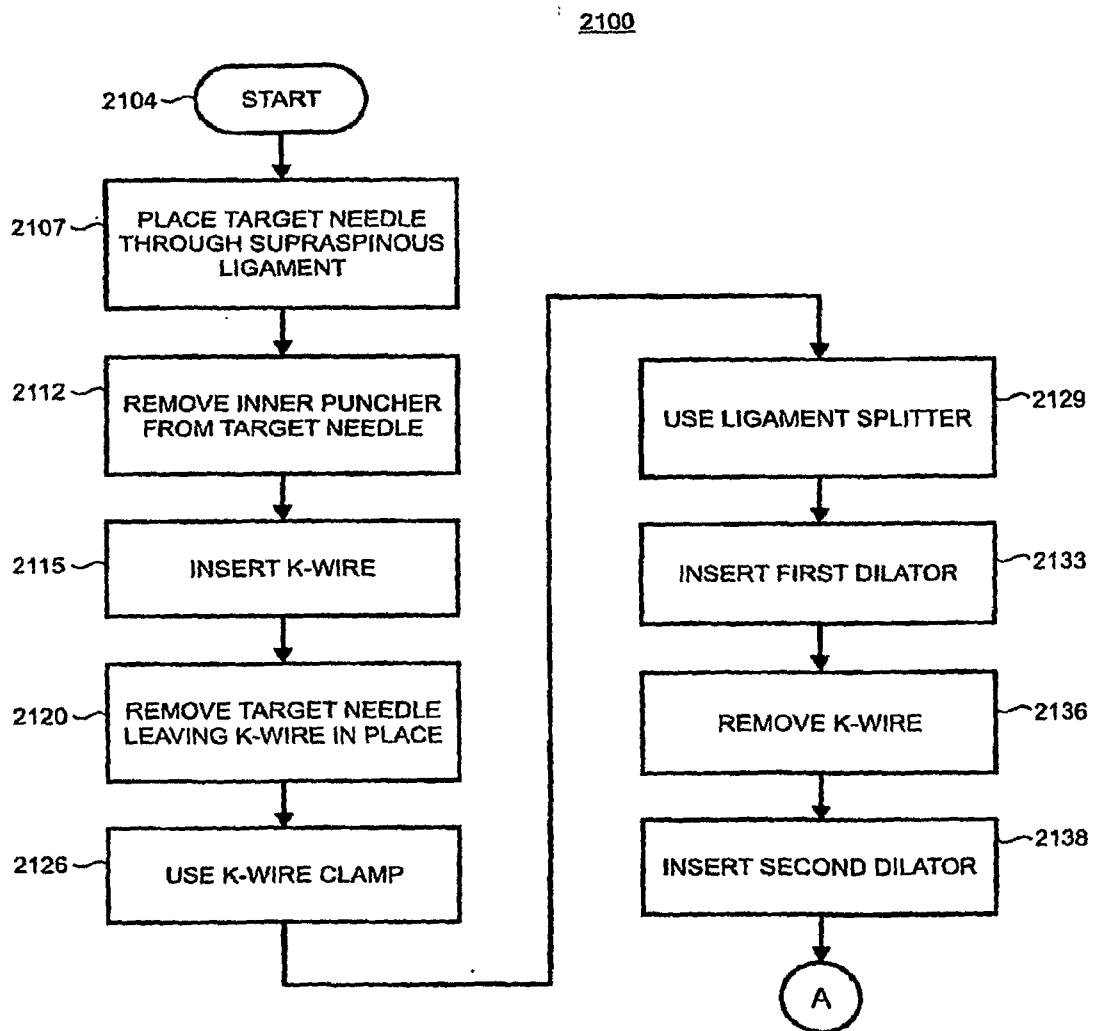
FIG. 17

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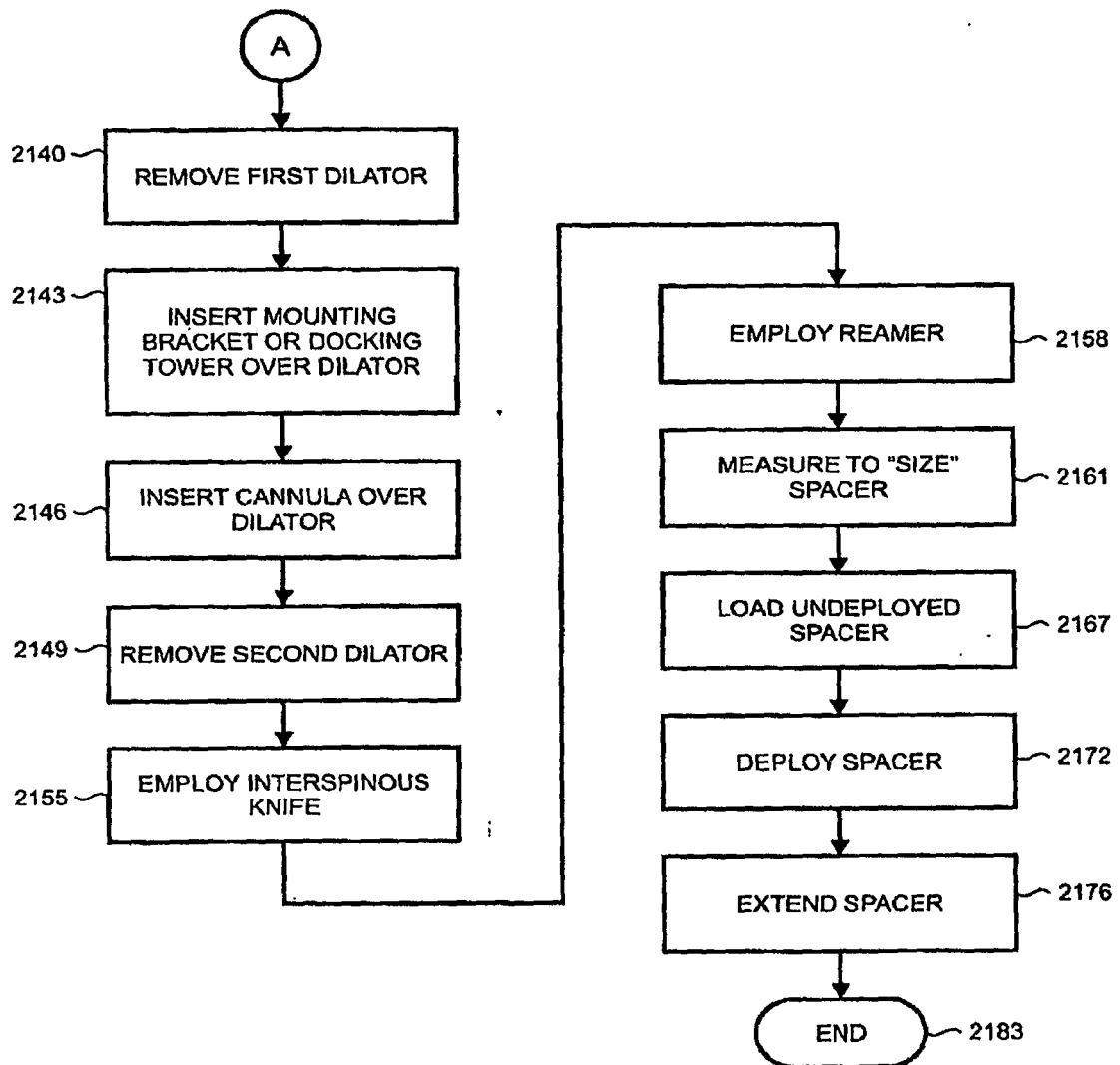
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FIG. 21



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FIG. 21A



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FIG. 22

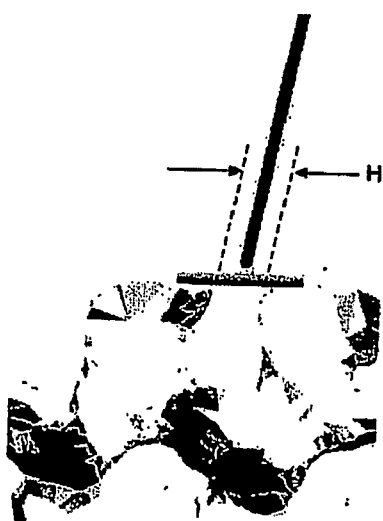
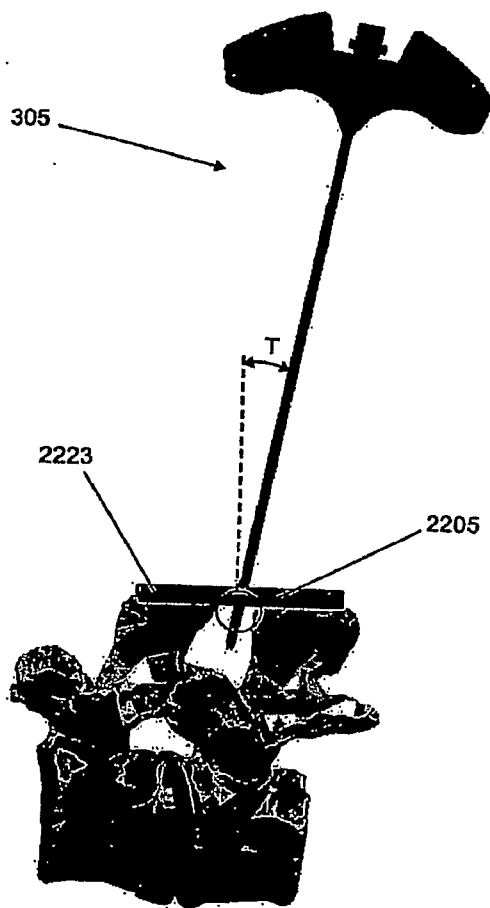


FIG. 22A

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FIG. 23

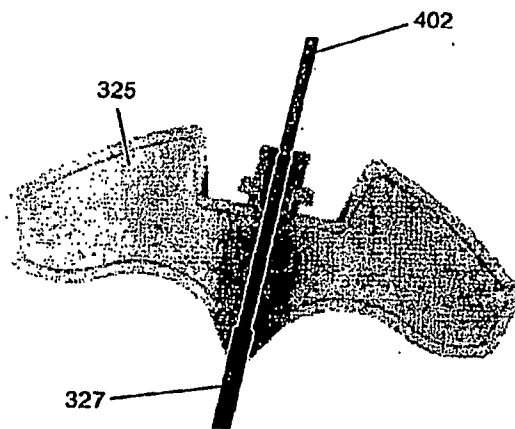
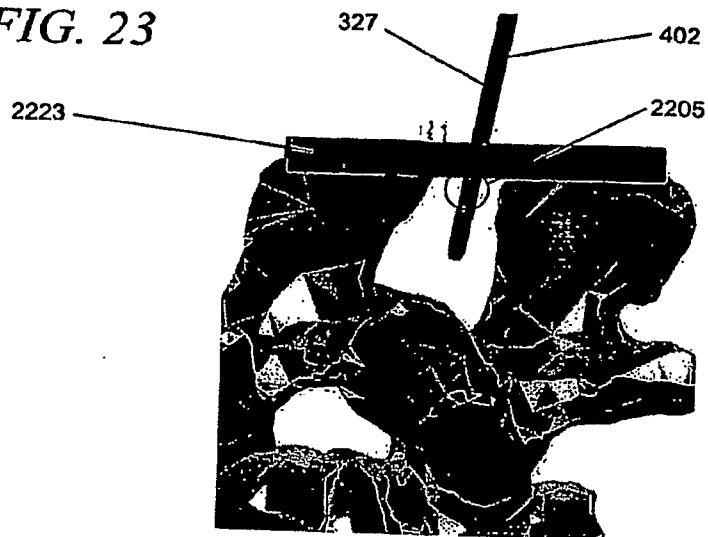


FIG. 23A

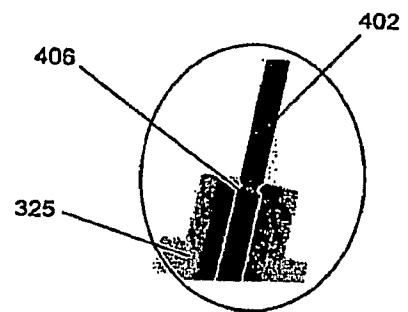
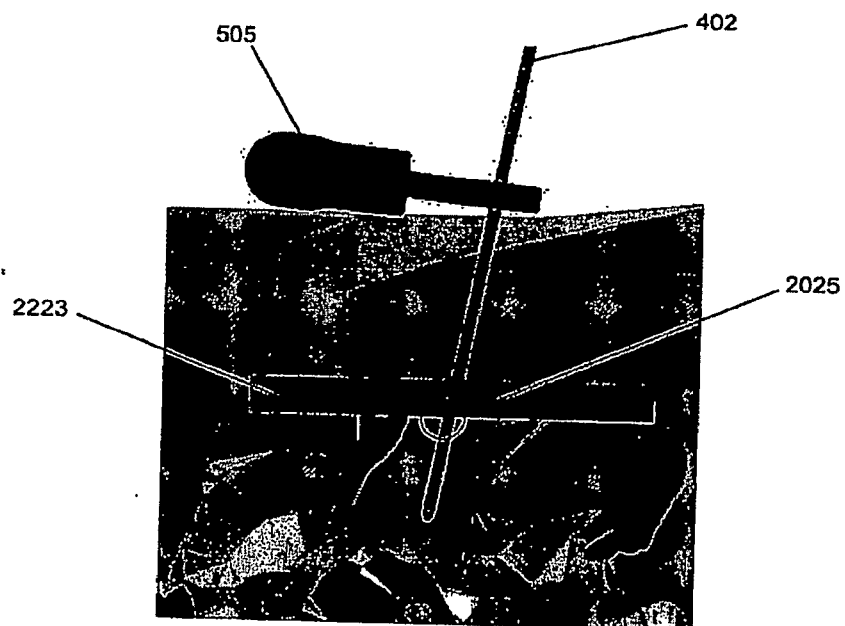


FIG. 23B

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FIG. 24



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FIG. 25

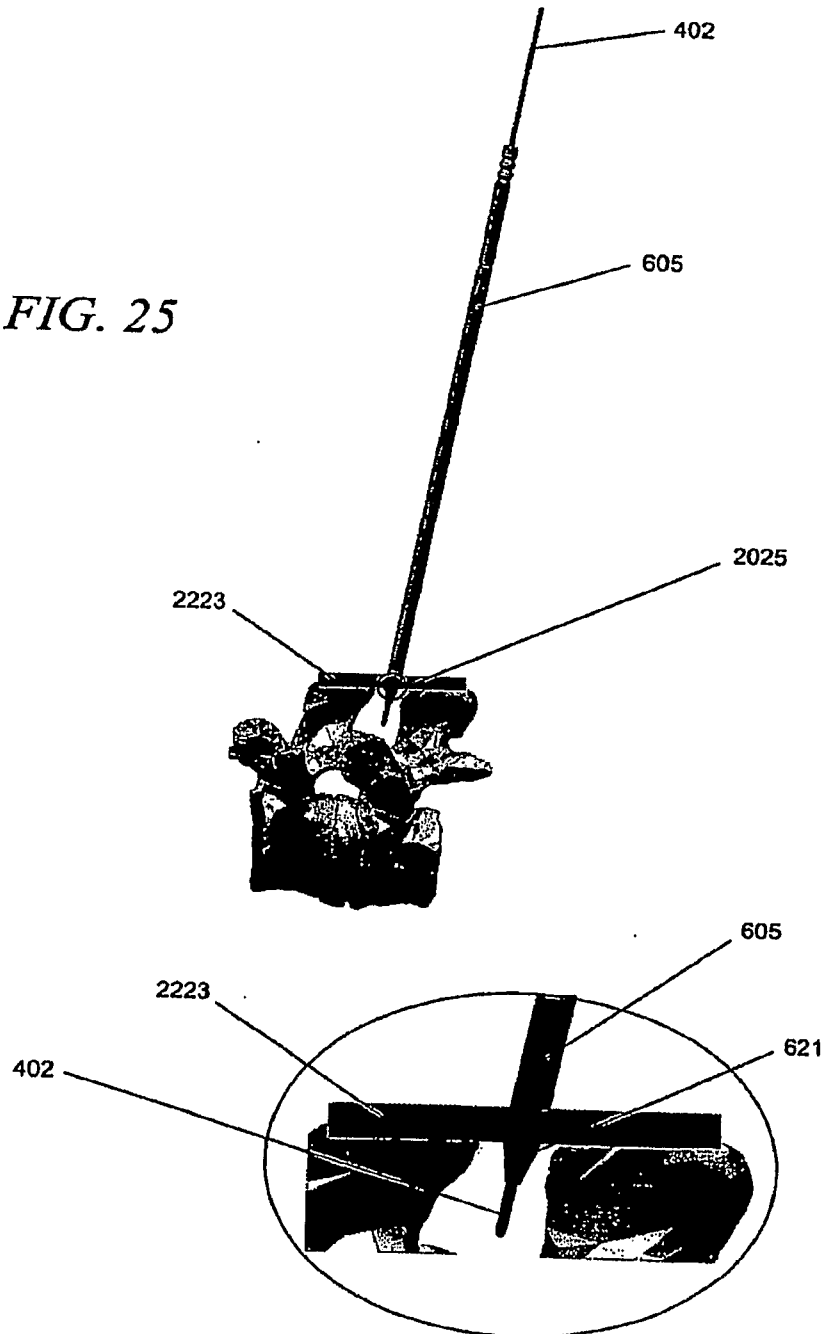
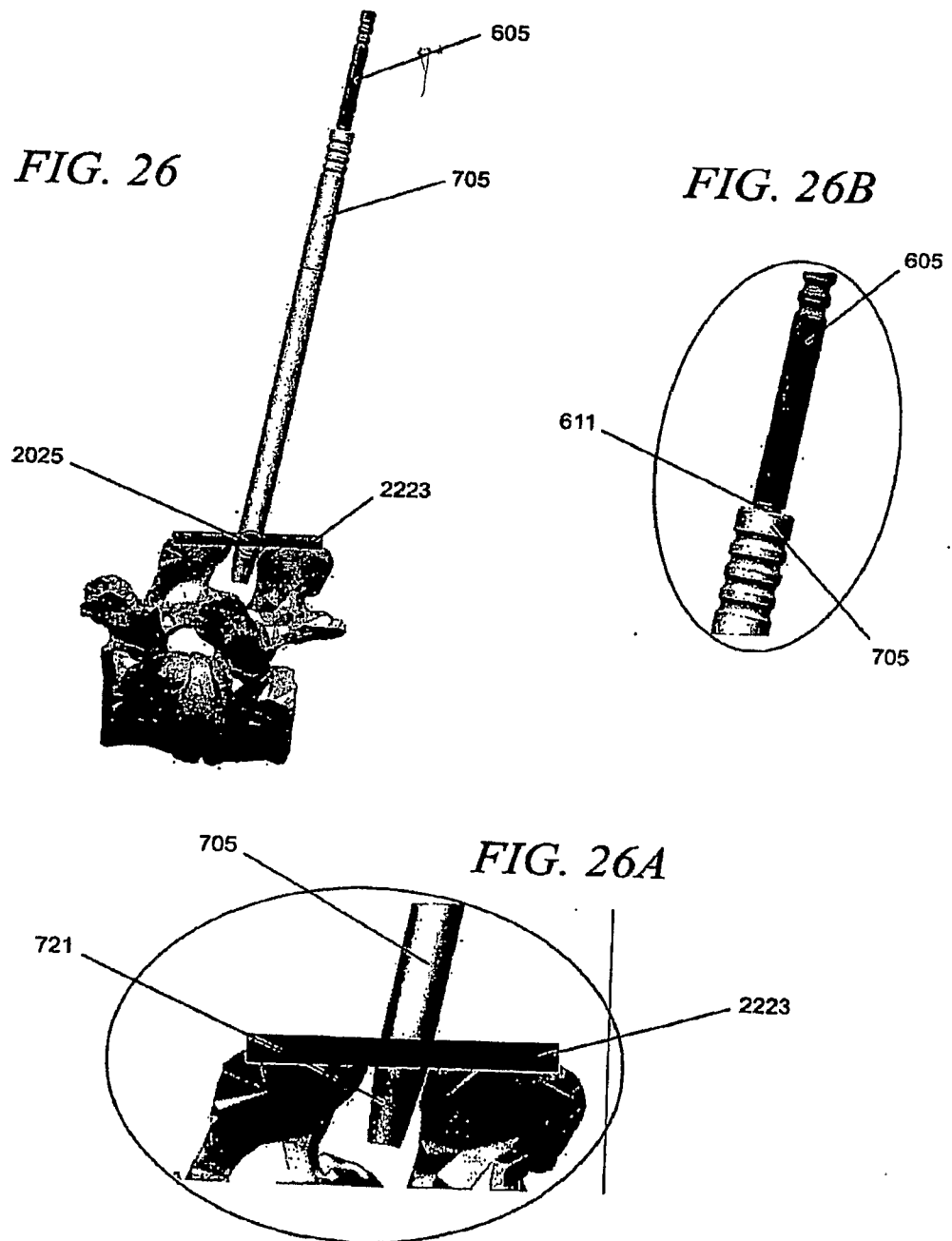


FIG. 25A

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FIG. 27

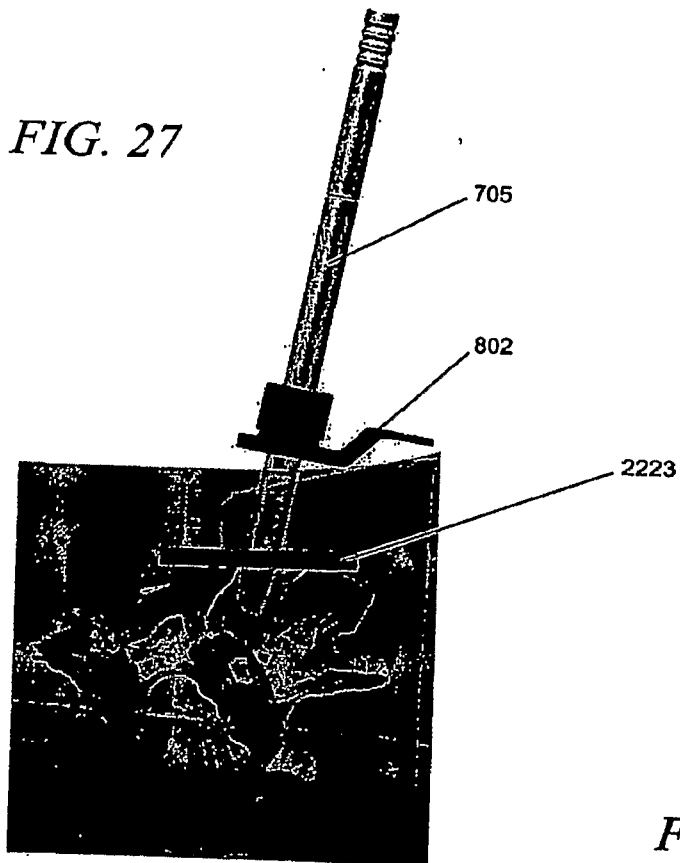
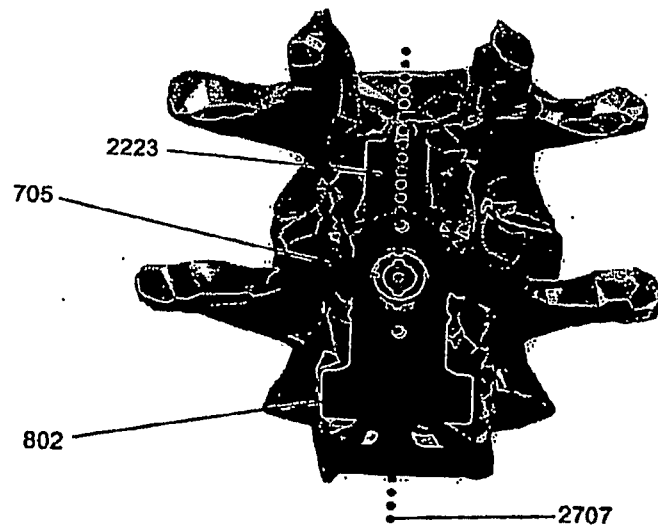
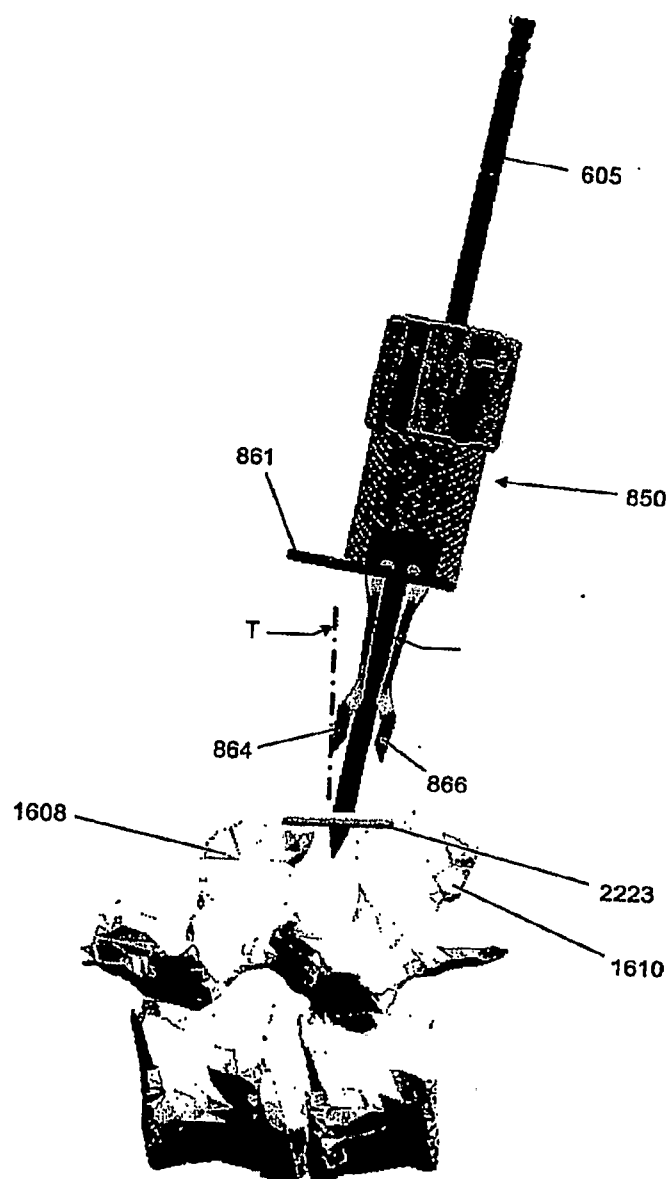


FIG. 27A



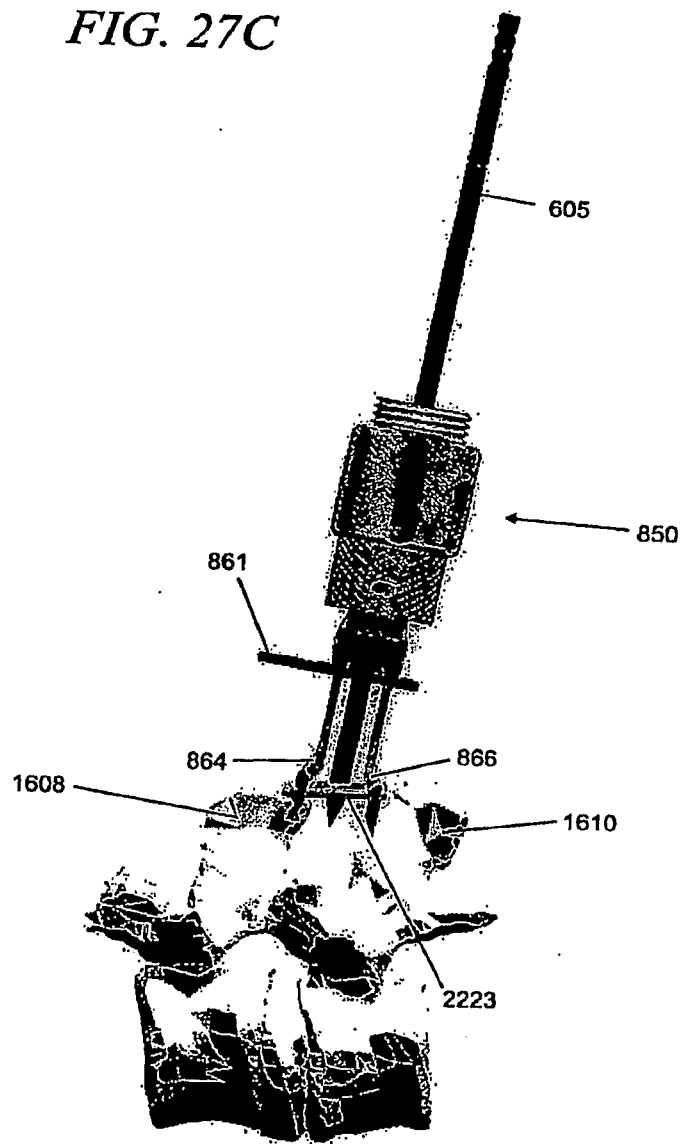
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FIG. 27B



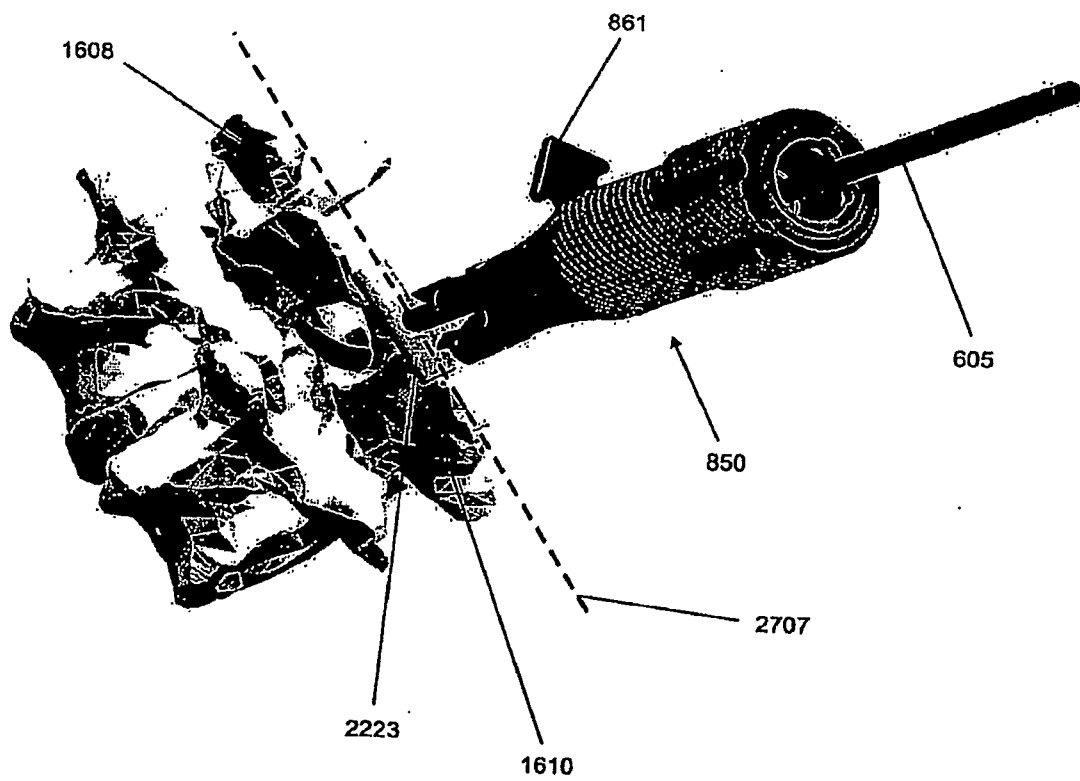
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FIG. 27C



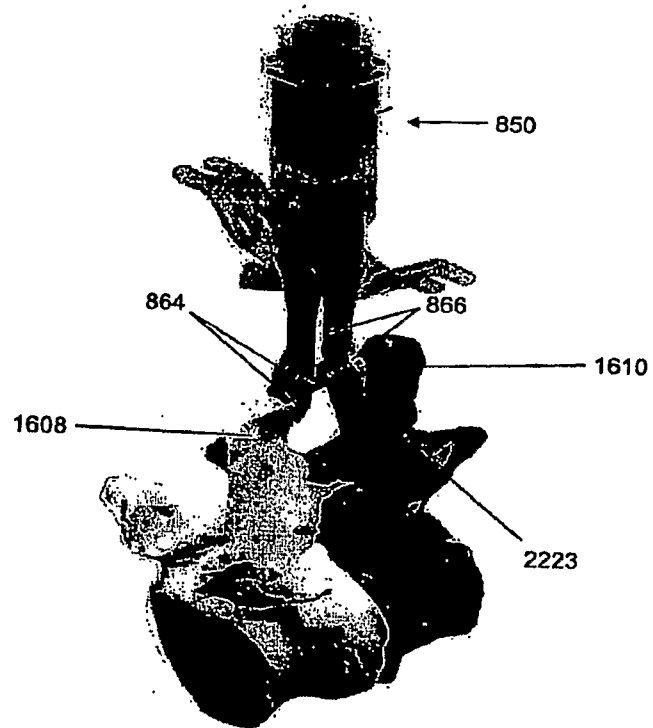
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FIG. 27D



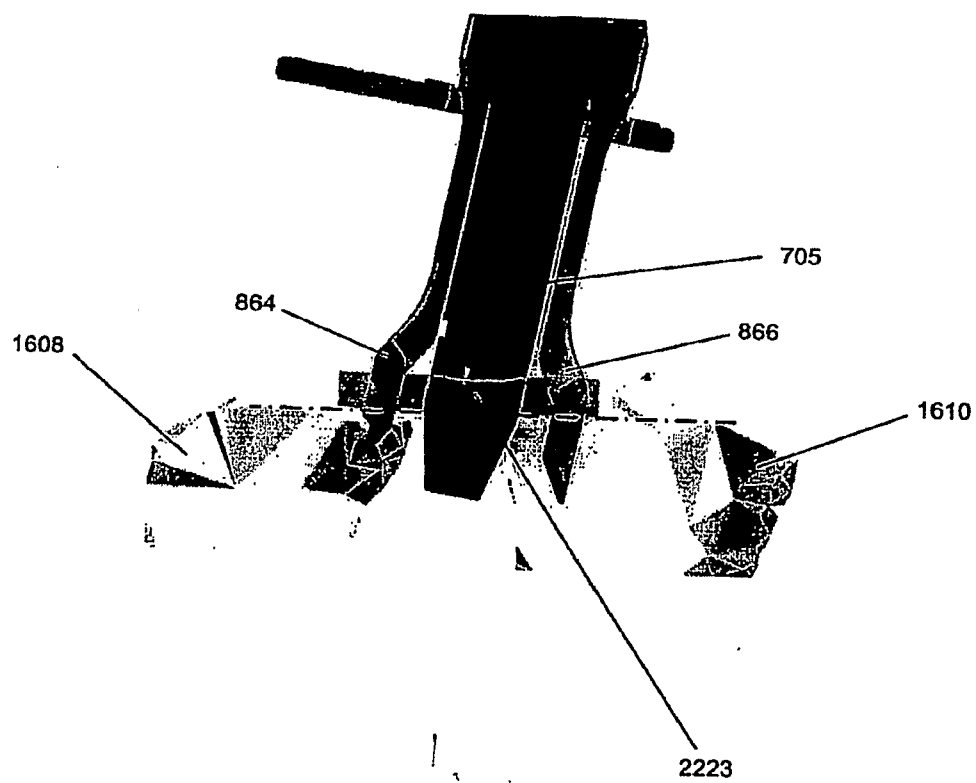
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FIG. 27E

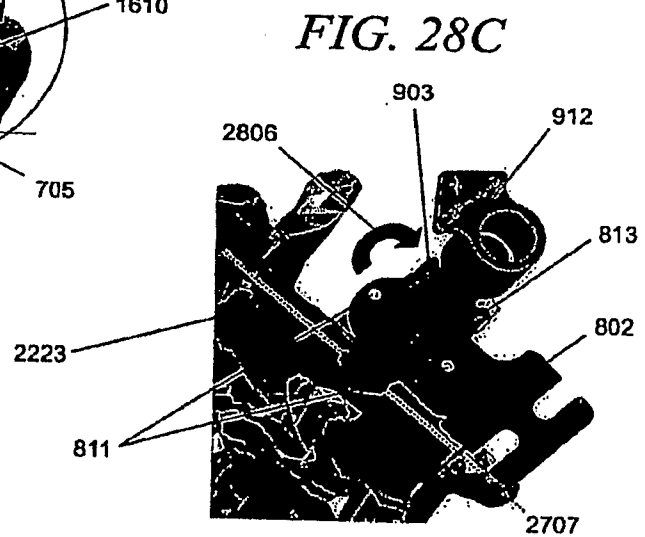
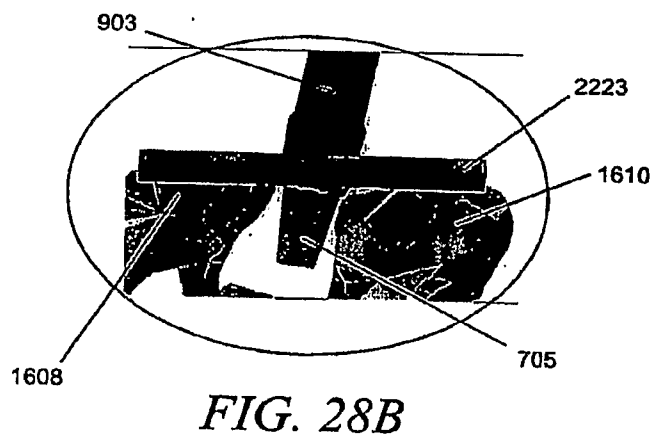
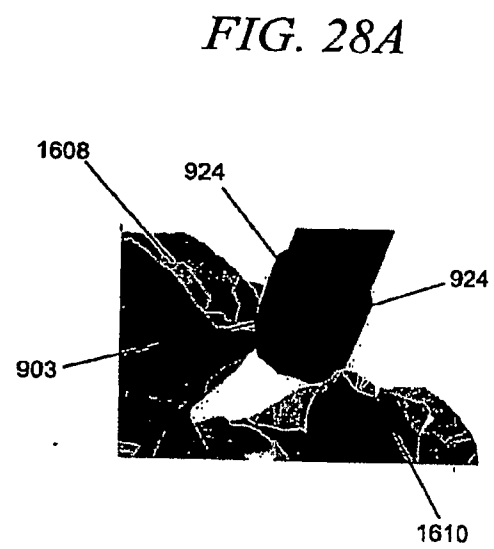
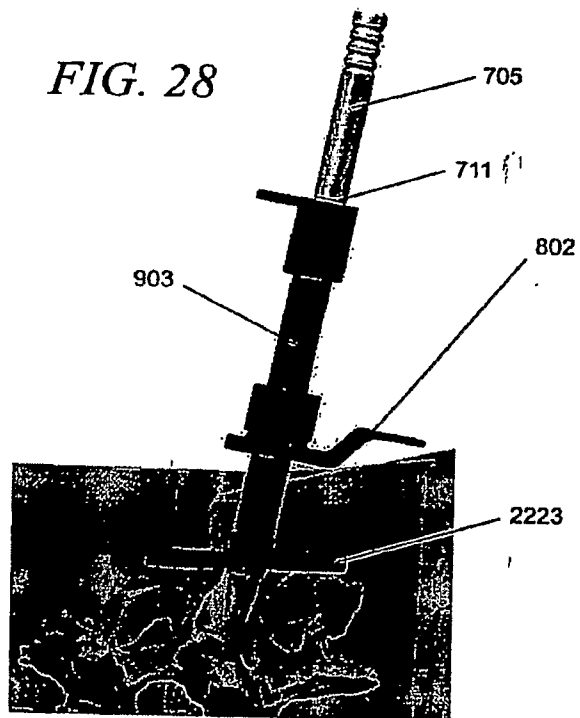


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FIG. 27F

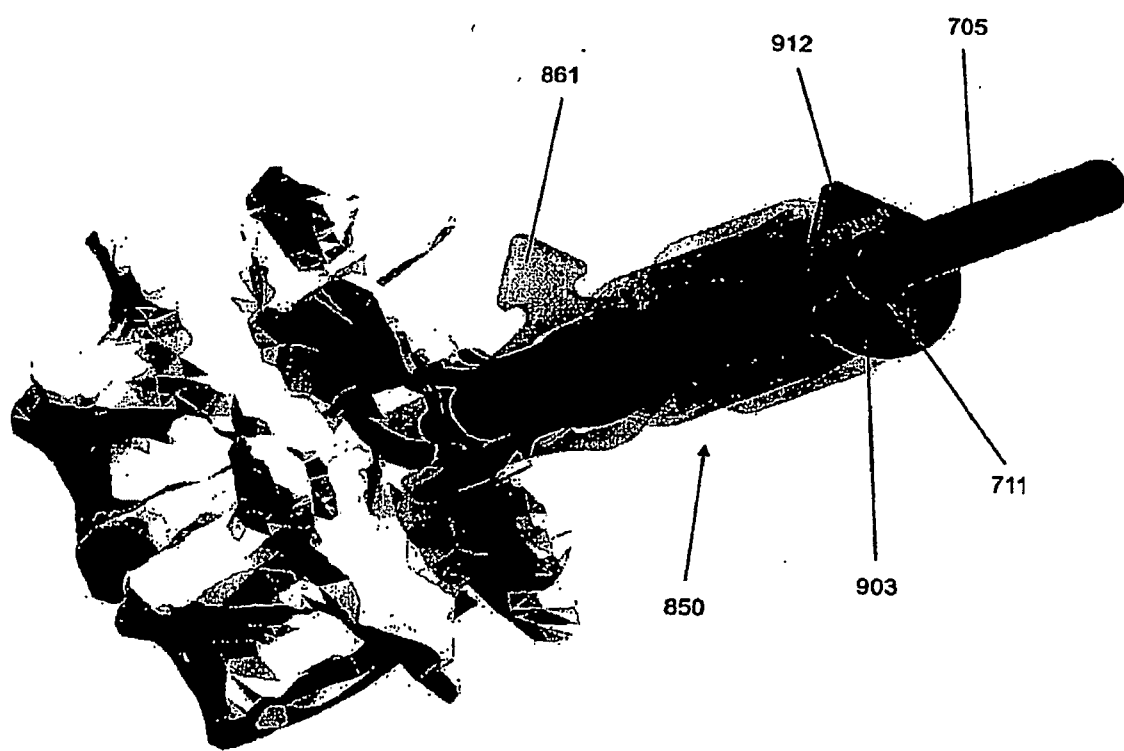


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FIG. 28D



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FIG. 29

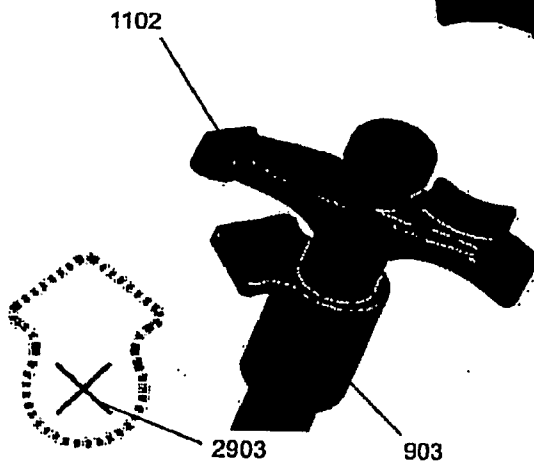
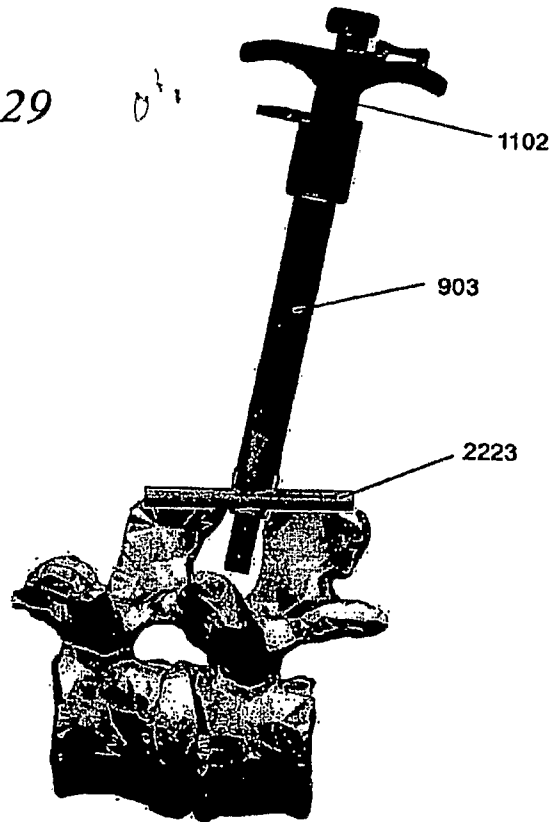


FIG. 29A

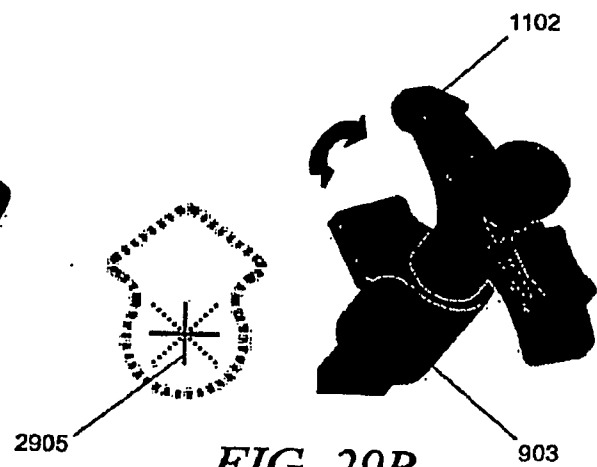
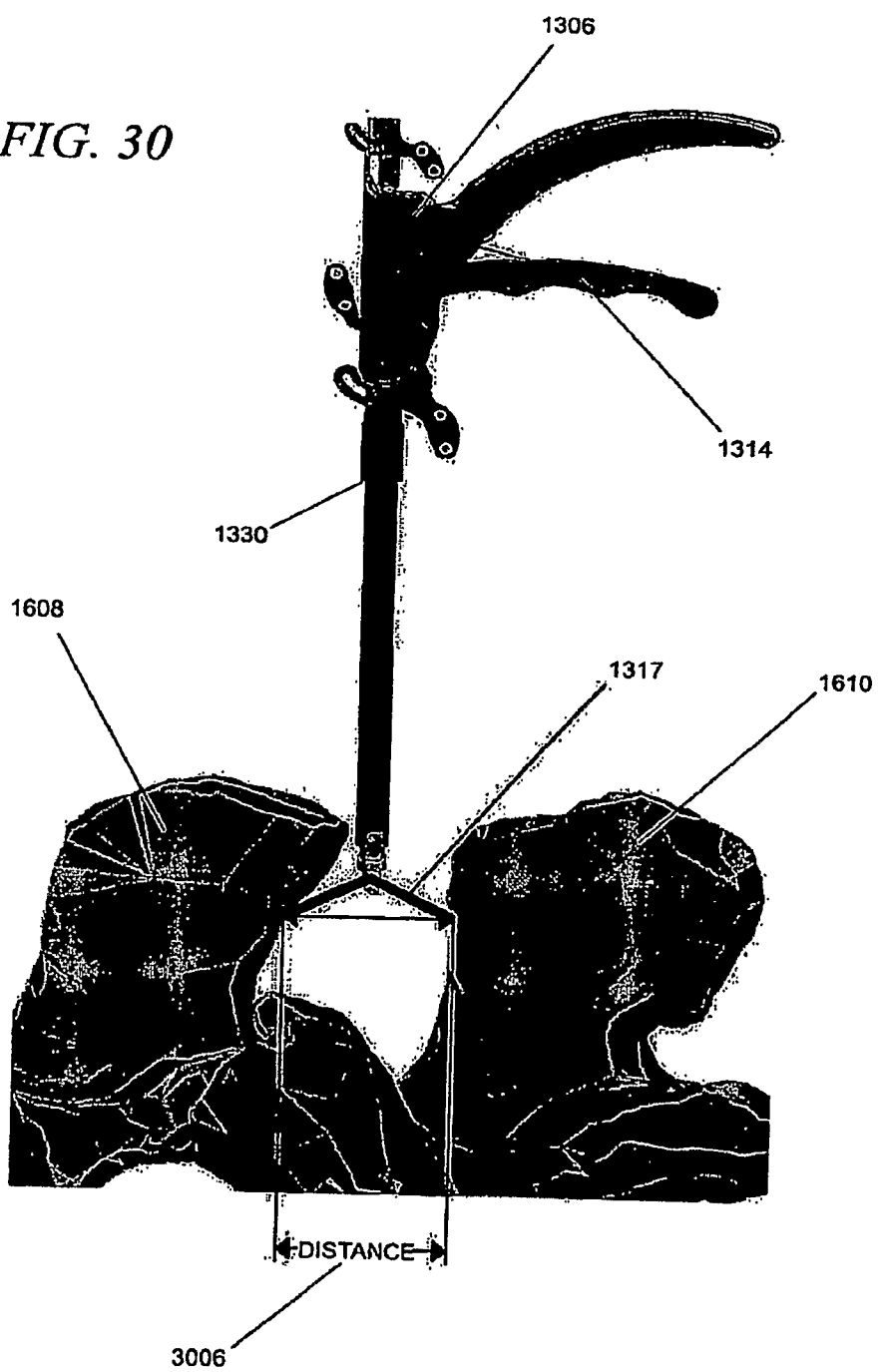


FIG. 29B

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FIG. 30



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FIG. 30A

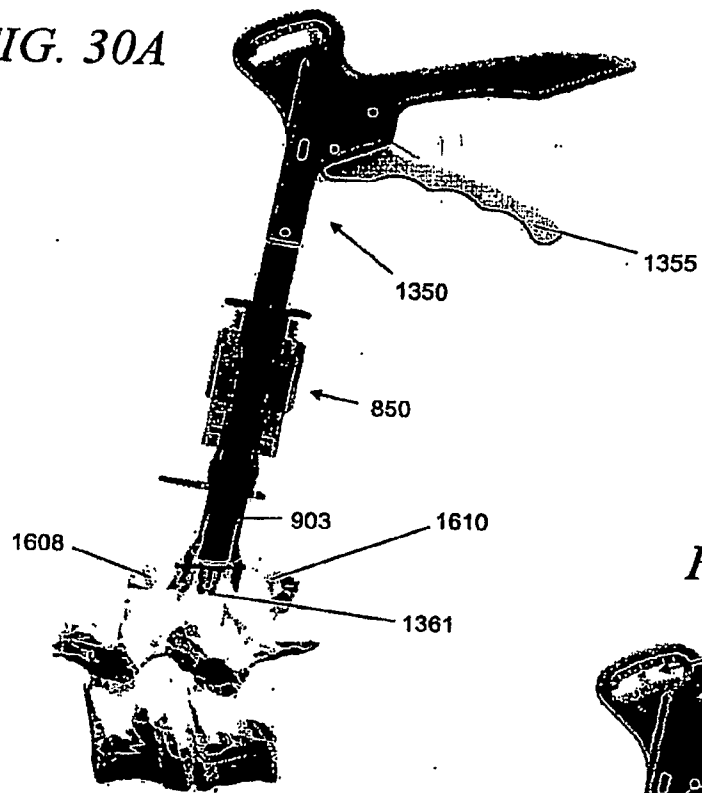
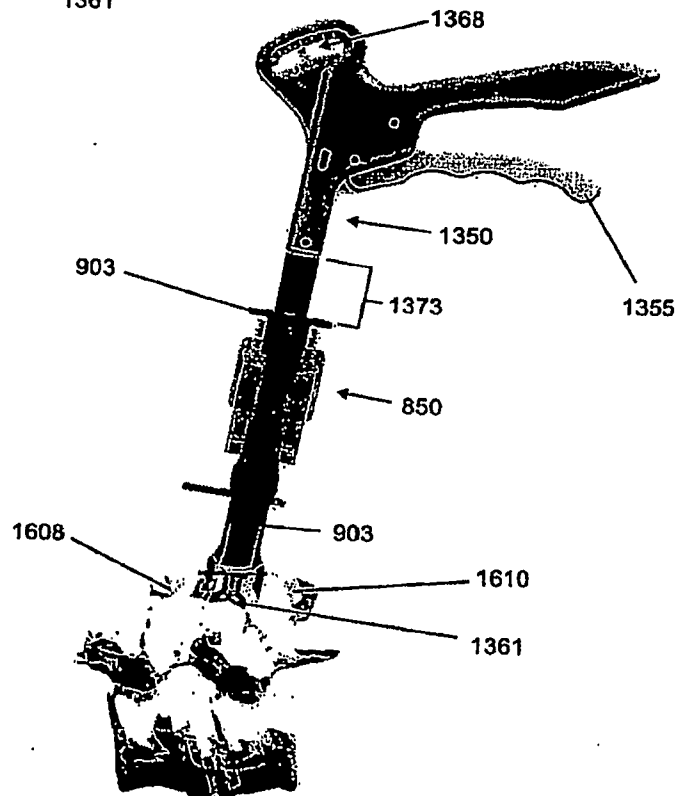


FIG. 30B



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FIG 31A

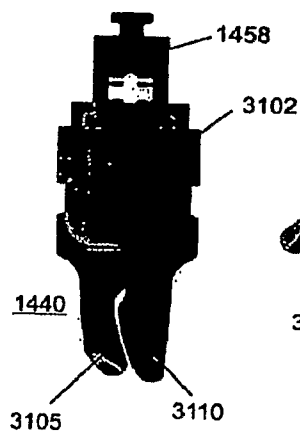


FIG 31C

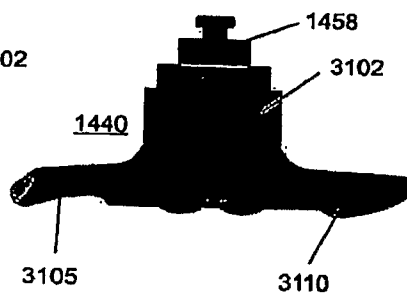


FIG 31E

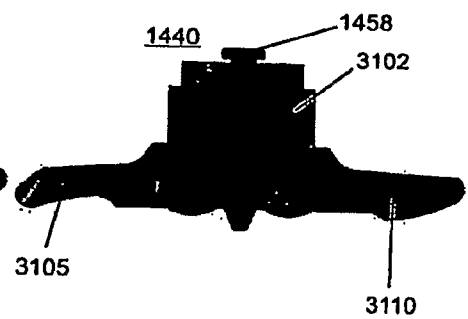


FIG 31B

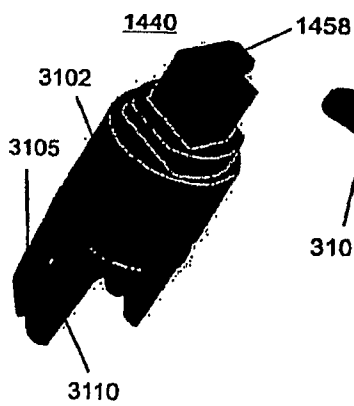


FIG 31D

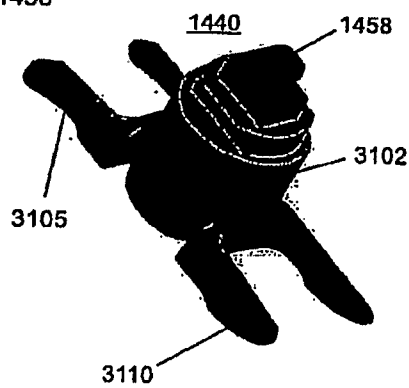
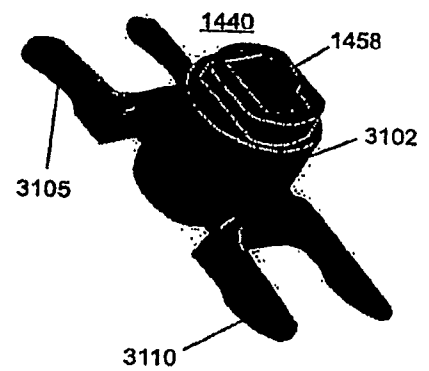


FIG 31F



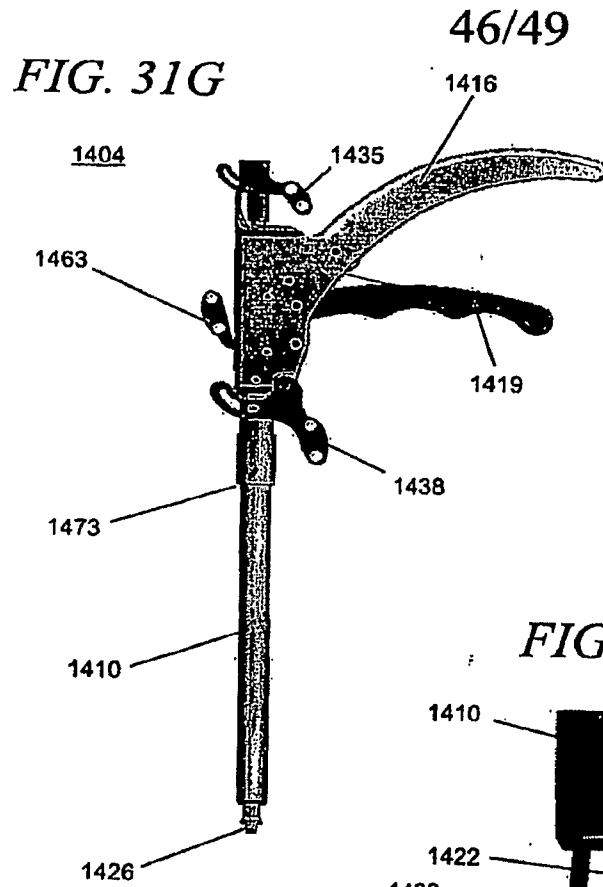


FIG. 31I

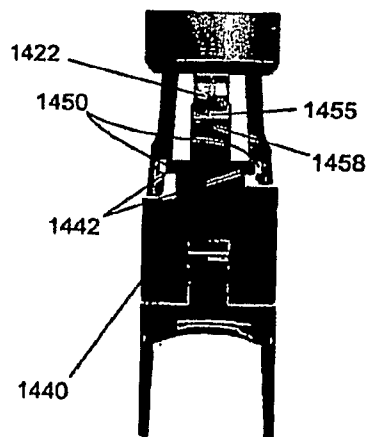
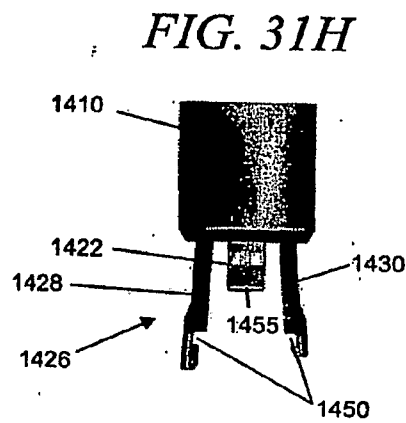


FIG. 31J

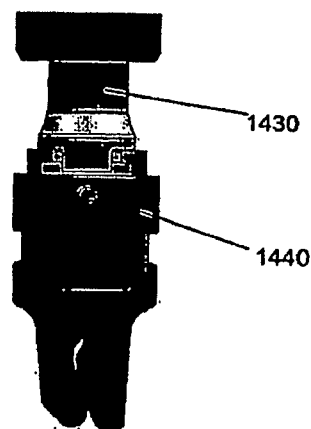


FIG. 31K

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FIG. 32A

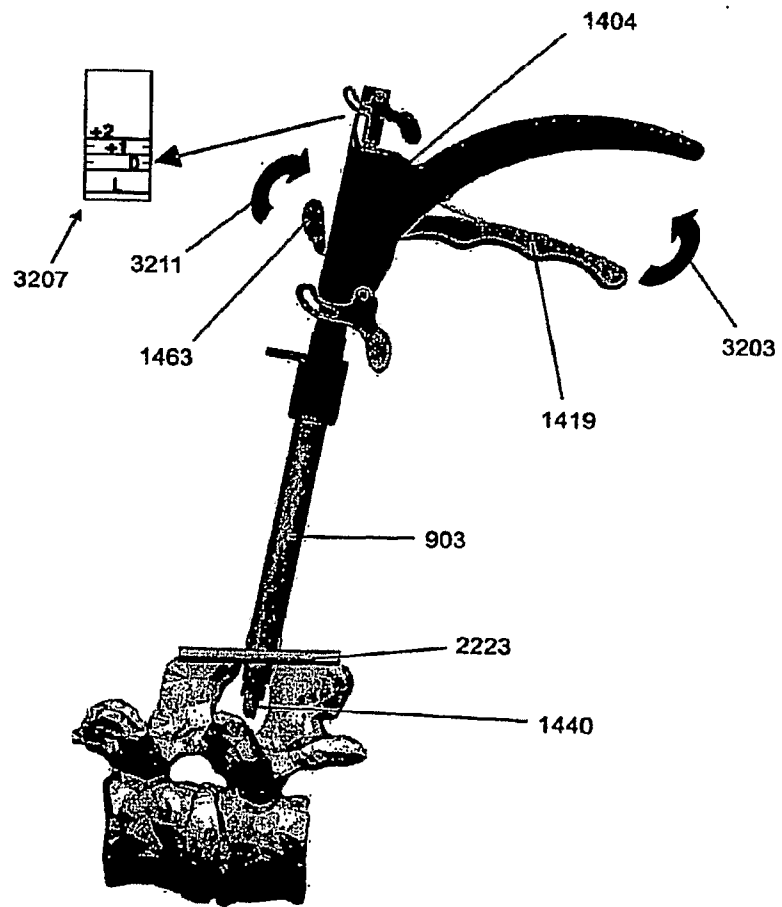
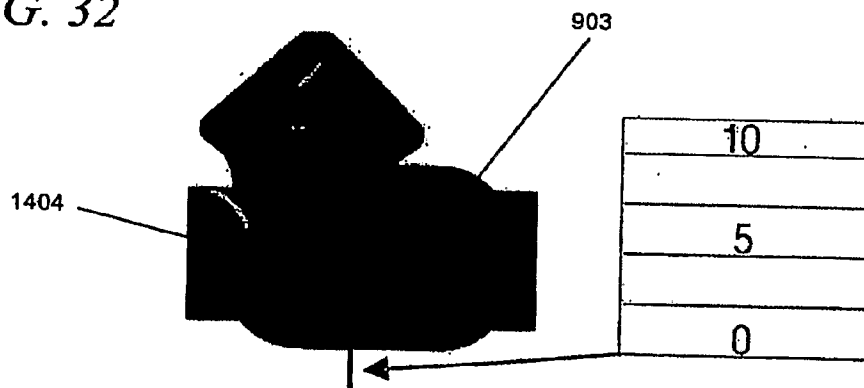


FIG. 32



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FIG. 32B

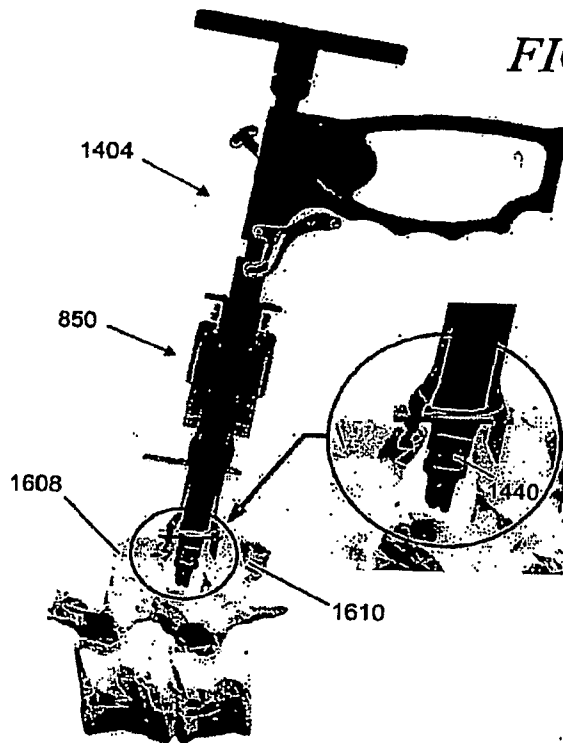
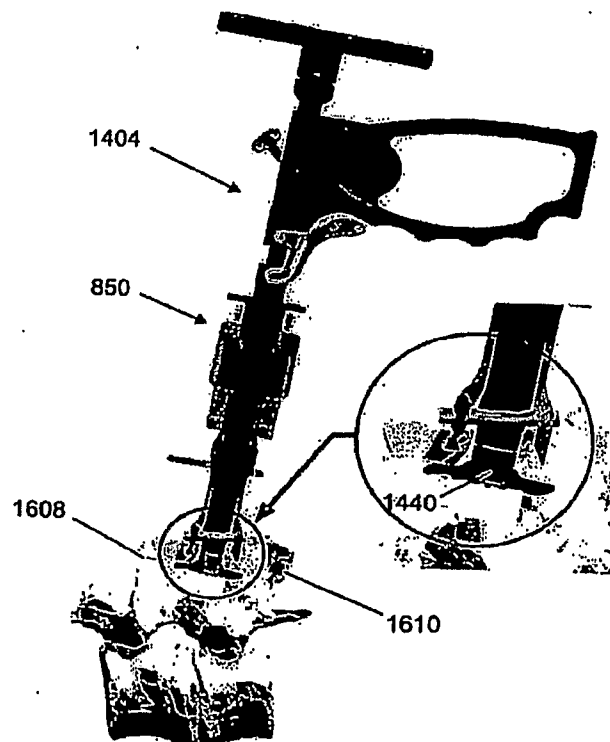


FIG. 32C



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FIG. 33

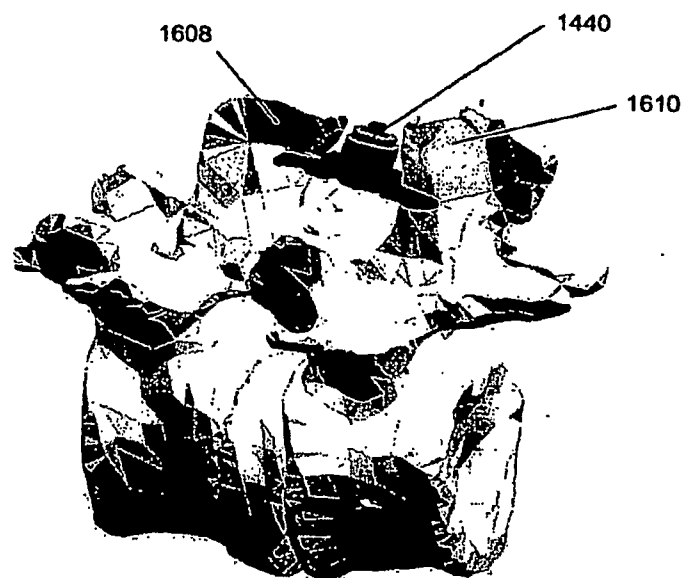


FIG. 34

