(12) STANDARD PATENT (11) Application No. **AU 2011265712 B2**
(19) AUSTRALIAN PATENT OFFICE

(54) Title
Systems for facet joint treatment

(51) International Patent Classification(s)
A61F 2/44 (2006.01) ***A61F 2/46*** (2006.01)

(21) Application No: **2011265712** (22) Date of Filing: **2011.05.24**

(87) WIPO No: **WO11/159440**

(30) Priority Data

(31) Number	(32) Date	(33) Country
13/084,104	**2011.04.11**	**US**
61/355,140	**2010.06.15**	**US**

(43) Publication Date: **2011.12.22**
(44) Accepted Journal Date: **2015.10.08**

(71) Applicant(s)
Zyga Technology, Inc.

(72) Inventor(s)
Assell, Robert;Beaubien, Brian;Dickhudt, Eugene

(74) Agent / Attorney
AJ PARK, L 9 Nishi 2 Phillip Law St, Canberra, ACT, 2601

(56) Related Art
US 2009/0138053
US 2009/0306671

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
22 December 2011 (22.12.2011)

PCT

(10) International Publication Number
WO 2011/159440 A1

(51) International Patent Classification:
A61F 2/44 (2006.01) *A61B 18/16* (2006.01)
A61F 2/46 (2006.01) *A61B 18/18* (2006.01)

(21) International Application Number:
PCT/US2011/037737

(22) International Filing Date:
24 May 2011 (24.05.2011)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
61/355,140 15 June 2010 (15.06.2010) US
13/084,104 11 April 2011 (11.04.2011) US

(71) Applicant *(for all designated States except US)*: **ZYGA TECHNOLOGY, INC.** [US/US]; 700 Tenth Avenue South, Suite 400, Minneapolis, Minnesota 55415 (US).

(72) Inventors; and
(75) Inventors/Applicants *(for US only)*: **ASSELL, Robert** [US/US]; 1206 Bayard Avenue, St. Paul, Minnesota 55116 (US). **BEAUBIEN, Brian** [US/US]; 287 Baker Street East, St. Paul, Minnesota 55107 (US). **DICKHUDT, Eugene** [US/US]; 6449 Langer Lane, Lino Lakes, Minnesota 55038 (US).

(74) Agents: **BONDI, Michael A.** et al.; DICKE, BILLIG & CZAJA, PLLC, 100 S. Fifth Street, Suite 2250, Minneapolis, Minnesota 55402 (US).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PE, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Declarations under Rule 4.17:

— *as to the identity of the inventor (Rule 4.17(i))*

— *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))*

Published:

— *with international search report (Art. 21(3))*

— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))*

(54) **Title**: SYSTEMS FOR FACET JOINT TREATMENT

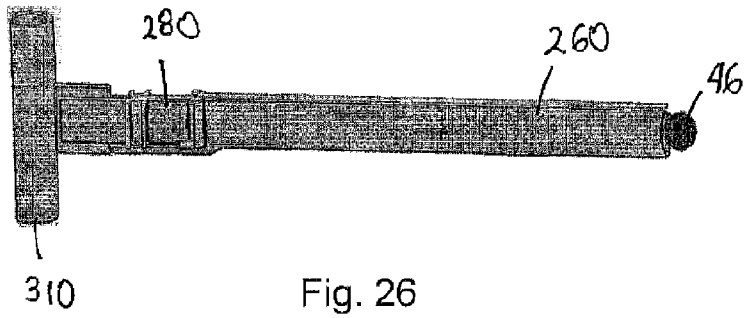

Fig. 26

(57) **Abstract**: A system for treating a facet joint of a patient. The facet joint includes a superior articular face and an inferior articular face. The system includes a resurfacing device, an implant insertion tool and a guide cannula. The resurfacing device is positionable between a superior articular face of a facet joint and an inferior articular face of a facet joint. The implant insertion tool is adapted to engage the resurfacing device. The guide cannula has a passage extending therethrough. The guide cannula passage is adapted to receive at least a portion of the resurfacing device and the implant insertion tool.

WO 2011/159440 A1

SYSTEMS FOR FACET JOINT TREATMENT

REFERENCE TO RELATED APPLICATION

[0001] This application claims priority to U.S. Provisional Application Number 61/355,140, which was filed on June 15, 2010, the contents of which are incorporated herein by reference.

FIELD OF THE INVENTION

[0002] An embodiment of the invention relates to a system for treating facet joint pain. More particularly, the invention relates to an implant system for treating facet joint pain.

BACKGROUND OF THE INVENTION

[0003] Within the next ten years, more than seventy million people will join the ranks of seniors. In an aging population, the articular cartilage that allows bones to smoothly move over each other wears down with time and disease, and like many tissues in the body, articular cartilage has a limited ability to heal itself.

[0004] At this time, options that help to relieve severe degenerative joint pain, or osteoarthritis, include joint replacement or fusion. As examples, approximately 200,000 total knee joint replacement operations and over 300,000 hip joint replacement operations are performed annually. While these operations are generally effective at treating the affected joint, these artificial joint implants typically only last about 10-15 years.

[0005] Chronic lower back pain also affects both work force productivity and healthcare expense. There are currently over 500,000 surgical procedures performed annually in the United States in an attempt to alleviate lower back pain even though such

surgical procedures are typically only performed after the failure of more conservative therapy such as bed rest, pain and muscle relaxant medication, physical therapy or steroid injection. The source of this pain may originate from dysfunction among a plurality of anatomical structures (as described below) that are comprised in the spine, including facet joints.

[0006] To understand spinal biomechanics, and the impacts of dysfunction in therapy, it is useful to first consider the spinal anatomy. The vertebrae of the spine are conventionally subdivided into several sections. Moving from the head (cephalad) to the tailbone (caudal), the sections are cervical, thoracic, lumbar, sacral, and coccygeal.

[0007] Regardless of location, each vertebra forms two pedicles and two laminae that combine to define a spinal foramen in which the spinal cord is protected. Extending laterally from the pedicles are two transverse processes. Extending from the mid-line of the vertebra where the two laminae meet is a spinous process. These three processes serve as a connection point for ligaments and muscles.

[0008] Adjacent vertebrae are separated by an intervertebral disc and surfaces of the adjacent vertebrae form portions of two facet joints by and between the two vertebrae. Relative to a spinal segment consisting of an intermediate vertebra, an immediately adjacent cephalad vertebra, and an immediately adjacent caudal vertebra, the intermediate vertebra forms portions of four facet joints; namely, two facet joints with the cephalad vertebra, and two facet joints with the caudal vertebra.

[0009] With the above background in mind, FIGS. 1A and 1B illustrate a facet joint 20 composed of a superior articular facet 22 and an inferior articular facet 24. The superior articular facet 22 is formed by the vertebral level below the intervertebral disc (i.e., a superior articular facet projects upward from the junction of the lamina and the pedicle), whereas the

inferior articular facet 24 is formed by the vertebral level above the intervertebral disc (i.e., an inferior articular facet projects downward).

[0010] On the superior articular facet 22 is a superior articular face 26, and on the inferior articular facet 24 is an inferior articular face 28. Facet joints are oriented obliquely to the sagittal plane, and the joint space itself is curved from front to back. The more posteriorly located inferior face 28 is convex, whereas the more interiorly located superior face 26 is concave.

[0011] The facet joint 20 is a synovial joint that is defined by the two opposing bony faces 26, 28 with cartilage 30 between them and a capsule 32 around the joint 20. More specifically, synovial fluid 34 is contained inside the joint 20 by the capsule 32, that is otherwise a water-tight sac of soft tissue and ligaments that fully surrounds and encloses the joint 20, and keeps the joint faces 26, 28 lubricated.

[0012] The ends of the bone articular facets 22, 24 that make up the synovial facet joint 20 are normally covered with the articular, hyaline cartilage 30 that allows the bony faces 26, 28 to glide against one another, providing the flexibility that allows the movement of vertebral bodies relative to one another.

[0013] As indicated above, there are two facet joints between each pair of vertebrae, one on each side (located posterior and lateral of the vertebral centerline), from the top and bottom of each vertebra. The joints combine with the disc space to create a three-joint complex at each vertebral level, and each joint extends and overlaps neighboring vertebral facet joints, linking each other and hence the vertebra together.

[0014] The assembly of two vertebral bodies, the interposed spinal disc and the attached ligaments, muscles, and facet joints (inferior articulating processes that articulate with the superior articular processes of the next succeeding vertebra in the caudal direction) is referred to as a "spinal motion segment." Each motion segment contributes to the overall

flexibility of the spine and contributes to the overall ability of the spine to provide support for the movement of the trunk and head, and in particular, the facet joints limit torsional (twisting) motion.

[0015] When the facets of one or more vertebral bodies degenerate or otherwise become damaged such that the vertebrae no longer articulate or properly align with each other, there is a resulting loss of mobility and pain or discomfort. The functional role of the facet joints in a spinal motion segment is thus relevant to an understanding of the operative and functional advantages of the facet joint systems and methods disclosed herein, which achieve dynamic stabilization and mobility preservation without constraining motion in any plane.

[0016] As indicated above, facet joints are located on the posterior column of the spine. The context of this discussion: "anterior" refers to in front of the spinal column, and "posterior" refers to behind the column; "cephalad" means towards a patient's head (sometimes referred to as "superior"); and "caudal" (sometimes referred to as "inferior") refers to the direction or location that is closer to the patient's feet.

[0017] Facet joints can be arthritic due to degeneration with aging, trauma, or disease (e.g., pathologies that include inflammatory, metabolic, or synovial, disorders). In addition, fractures, torn ligaments, and disc problems (e.g., dehydration or herniation) can all cause abnormal movement and alignment, putting extra stress on the surfaces of the facet joint.

[0018] The physiological response to this extra pressure is the development of osteophites, i.e., bone spurs. As the spurs form around the edges of the facet joint, the joint becomes enlarged, a condition called hypertrophy, and eventually the joint surfaces become arthritic. When the articular cartilage degenerates or wears away, the bone underneath is uncovered and rubs against bone. The joint thus becomes inflamed, swollen, and painful.

[0019] Facet joint arthritis is a significant source of neck and back pain, and is attributable to about 15-30% of persistent lower back pain complaints. Upon failure of conservative treatment for facet joint pain such as intra-articular steroids/local anesthetic injections administered under fluoroscopic guidance, some patients with chronic pain may eventually require surgical intervention for facet joint arthritis including, for example, facet rhizotomy; facet ectomony to remove the facet joint to reduce pressure on the exiting nerve root; total joint replacement or facet arthrodesis (i.e., fixation leading to fusion, where the two articulating surfaces of the joint remain immobile or grow solidly together and form a single, solid piece of bone); etc.

[0020] While these surgical procedures may alleviate back pain, many joint replacements and all fusions do not restore the normal physiological function and motion attributable to healthy anatomical form. Rather, they often significantly alter spinal biomechanics that can in turn cause or exacerbate co-existing spinal instabilities and degeneration at other spinal levels or in other joints associated with spinal motion.

[0021] There is a cause-and-effect relationship among intervertebral disc integrity, facet loads, and spinal degeneration. Specifically, the progressive loss of disc height with disc degeneration often also alters the facet joint's mechanical ability as the facet joints degenerate or dislocate, and ligaments lose elasticity and their load-carrying ability. More specifically, with disc-space narrowing, as frequently occurs with degenerative disc disease, there is an increased load in the facet joints, especially in extension, and concomitant degeneration of the facet joints and capsules.

[0022] Since the facet joint capsules are primarily loaded in flexion and in rotation, and the facet joints are the primary resistors against rotational or torsional forces (e.g., normally, the facet joints control approximately 30% of axial rotation), facet joint degeneration significantly alters spinal mobility.

[0023] The need to provide minimally invasive therapies that provide pain relief while restoring and preserving the biomechanical function of the physiological facet joints is paramount to overall spinal mobility, and to date, therapies have not adequately satisfied all of these issues, as noted below.

[0024] One therapy, facet rhizotomy, involves techniques that sever small nerves that go to the facet joint. The intent of the procedure is to stop the transmission of pain impulses along these nerves. The nerve(s) is identified using a diagnostic injection. Then, the surgeon inserts a large, hollow needle through the tissues in the low back. A radiofrequency probe is inserted through the needle, and a fluoroscope is used to guide the probe toward the nerve. The probe is slowly heated until the nerve is severed.

[0025] Another technique using pulsed radiofrequency does not actually burn the nerve, rather it is believed to stun the nerve. Yet another technique involves denervation by probe tip freezing, and still another procedure involves carefully controlled injection of botox toxin to treat muscle spasm, a protective reflex that may occur when the facets are inflamed that in turn causes the nearby muscles that parallel the spine to go into spasm.

[0026] While these procedures may provide pain relief, they do not address ongoing joint degeneration (e.g., wear on articulating surfaces), which leads to kinematic and biomechanical dysfunction that may in turn lead to transition syndrome (i.e., progression of degeneration and pain to other joints) at other levels.

[0027] While certain clinicians have advocated prosthetic total joint replacement of damaged facet joints, in practice, it is difficult to implement such a prosthesis for a variety of reasons including the variability of facet joint geometry from facet joint to facet joint, and the high level of interaction between the facet joint and the other components in the spinal column.

[0028] Moreover, joint replacement is a highly invasive and time-consuming procedure, requiring pre-preparation of joint surfaces and removal of bone, and thus there are associated risks, including blood loss and morbidity, increased anesthesia time, and increased convalescence time.

[0029] A related therapeutic treatment of the facet joint entails the provision of an artificial facet joint where the inferior facet segment, the mating superior facet segment, or both, are covered with a cap (i.e., over all, or substantially all, of the facet). One such device and related method of implantation is described in Fitz, U.S. Patent No. Re 36,758.

[0030] While potentially viable, the capping of the facet segments has several potential disadvantages. Clinical concerns are believed to result from the disruption of the periosteum and ligamentum teres femoris, both serving a nutrition delivery role to the femoral head, thereby leading to avascular necrosis of the bony support structure for the cap.

[0031] Another potential disadvantage of facet capping is that to accommodate the wide variability in anatomical morphology of the facets, not only between individuals, but also between levels within the spinal column, a very wide range of cap sizes and shapes is required.

[0032] Even further, implantation of the caps, such as those described in U.S. Patent No. Re 36,758, cannot be performed on a minimally-invasive basis, and entail fairly significant preparatory steps at the implantation site (e.g., removal and/or re-shaping of bone). At least with use of caps over osteoarthritic femoral heads, the capping of articular bone ends has sometimes experienced clinical failure by mechanical loosening.

[0033] Another therapeutic treatment of the facet joint is to affix the superior articular process to the inferior articular process using a facet screw. Although the fixation therapy may alleviate symptoms associated with a degenerated facet joint, it also sacrifices some of

the ability of the motion segment to move and thus sacrifices some of the ability of the spinal column to move in a natural manner.

[0034] Central and lateral spinal stenosis (joint narrowing), degenerative spondylolisthesis, and degenerative scoliosis may all result from the abnormal mechanical relationship between the anterior and posterior column structures and induce debilitating pain.

[0035] More recently, a percutaneously-implantable, facet joint stabilization device has been developed, and is described in U.S. Application Serial No. 12/238,196 (filed September 25, 2008 and entitled "Method and Apparatus for Facet Joint Stabilization"), the teaching of which are incorporated herein by reference. The facet joint stabilization device generally entails a superior body and an inferior body that, when combined, form an exteriorly threaded device.

[0036] When inserted into the joint space, the inferior and superior bodies establish an engaged relationship with the corresponding inferior and superior bony faces of the facet joint anatomy, respectively, and are somewhat slidable relative to one another to facilitate near normal facet joint motion ability. While viable, areas for improvement remain, including retention, long-term functioning, and insertion techniques.

[0037] As the present disclosure contemplates accessing various vertebral elements and joints through a preferred approach that comes in from a percutaneous posterior approach, "proximal" and "distal" are defined in context of this channel of approach. Consequently, "proximal" is closer to the beginning of the channel and thus closer to the clinician, and "distal" is further from the beginning of the channel and thus more distant from the clinician.

[0038] When referencing access or delivery tools, "distal" would be the end intended for insertion into the access channel, and "proximal" refers to the opposing end, generally the

end closer to the handle of the delivery tool. When referencing implants, generally "distal" would be the leading end first inserted into the joint and "proximal" refers to the trailing end, generally in an engagement with a deployment tool.

[0039] In light of the above, a need exists for additional therapies applicable to facet joints to stabilize and augment the facet joint in alleviating problems without initial resort to the more radical therapies of replacing the facet joint with a prosthesis and/or fixation of the facet joint and the inherent loss of natural movement of that motion segment.

SUMMARY OF THE INVENTION

[0039a] In accordance with a first aspect of the invention, there is provided a system for treating a facet joint of a patient, wherein the facet joint includes a superior articular face and an inferior articular face, wherein the system comprises: an implant that is configured to be positioned between a superior articular face of a facet joint and an inferior articular face of the facet joint, wherein the implant has a plurality of teeth on at least one surface thereof, wherein the implant exhibits sufficient flexibility to transition from a relatively flat state to an inserted state in which the implant substantially matches any multi-planar curvatures of the superior articular face and wherein the implant comprises a first engagement feature; an implant insertion tool that is adapted to engage the implant, wherein the implant insertion device comprises a second engagement feature that is capable of mating with the first engagement feature and wherein a force to separate the first engagement feature and the second engagement feature after mating is at least 1 Newton; and a guide cannula having an internal passage extending therethrough, wherein the guide cannula passage is adapted to receive at least a portion of the implant and the implant insertion tool.

[0039b] In accordance with a second aspect of the invention, there is provided a system for treating a facet joint of a patient, wherein the facet joint includes a superior articular face

and an inferior articular face, wherein the system comprises: an implant configured to selectively conform to a shape of at least one of a superior articular face of a facet joint and an inferior articular face of the facet joint, wherein the implant comprises a first engagement feature; and an implant insertion device having a second engagement feature that is capable of mating with the first engagement feature, wherein a force to separate the first engagement feature and the second engagement feature after mating is at least 1 Newton.

[0039c] In accordance with a third aspect of the invention, there is provided a kit for treating a facet joint of a patient, wherein the facet joint comprises a superior articular face and an inferior articular face, wherein the kit comprises: a superior implant configured to selectively transition to a shape that at least partially conforms to a shape of a superior articular face of a facet joint; an inferior implant configured to selectively transition to a shape that at least partially conforms to a shape of an inferior articular face of the facet joint, wherein the superior implant is separate from the inferior implant; and an insertion tooling set comprising: a delivery cannula having an internal passage, a guide cannula having an internal passage; and an implant insertion device sized to be slidably received within the delivery cannula passage; wherein the kit is configured to provide an insertion arrangement in which the superior implant, the inferior implant and the implant insertion device are slidably received within the delivery cannula passage, wherein the superior implant and the inferior implant are stacked against one another adjacent a distal region of the implant insertion device.

[0040] Some aspects in accordance with the disclosure relate to a system for treating a facet joint of a patient. The facet joint anatomy includes opposing, superior and inferior articular faces. With this in mind, the system includes a superior resurfacing device and an inferior resurfacing device.

[0041] The superior resurfacing device has a superior resurfacing body configured to selectively transition to a shape conforming to a shape of the superior articular face of the facet joint. Similarly, the inferior resurfacing device includes an inferior resurfacing body configured to selectively transition to a shape conforming to a shape of the inferior articular face of the facet joint.

[0042] In this regard, each of the resurfacing bodies exhibits sufficient flexibility to transition from a relatively flat state to an inserted state in which the resurfacing body substantially matches any multi-planar curvatures and concavities of the corresponding facet joint articular face in the presence of compressive forces associated with a typical, adult human facet joint.

[0043] With this construction, the system is capable of establishing a new sliding interface within the facet joint via articulating surfaces of the resurfacing bodies, thereby

eliminating the pain-causing, bone-on-bone articular interface associated with the natural anatomy. Further, by conforming to the natural shape associated with the native facet joint articular faces, the system of the disclosure can be inserted on a minimally-invasive basis, and restructuring (e.g., removal) of the natural bony interface is not required.

[0044] In some embodiments, the resurfacing bodies are identical, each consisting of a disc-like body having a thickness in the range of between about 0.25 and about 4 millimeters. In related embodiments, the resurfacing bodies are formed of polyetherketone (PEK) -based material, such as or polyetheretherketone (PEEK).

[0045] In yet other embodiments, the resurfacing bodies provide an articulating surface and a plurality of teeth projecting in a direction opposite the articulating surface; the plurality of teeth serve to establish engagement with the corresponding facet joint articular face upon insertion.

[0046] Yet other aspects in accordance with principles of the disclosure relate to methods for treating facet joint pain of a patient, and include inserting a superior resurfacing body into the facet joint and into engagement with the superior articular face of the facet joint articular anatomy. In this regard, the superior resurfacing body transitions from a relatively flat state to an insertion state upon insertion to the facet joint, substantially conforming to a shape of the superior facet joint face in response to compressive forces of the facet joint.

[0047] An inferior resurfacing body is inserted into the facet joint and into engagement with an inferior facet joint articular face. As part of this insertion, the inferior resurfacing body transitions from a relatively flat state to an insertion state that substantially conforms to a shape of the inferior articular face in response to compressive forces of the facet joint.

[0048] Upon final insertion, an articulating surface of the superior resurfacing body slidably abuts an articulating surface of the inferior resurfacing body, thereby relieving facet

joint pain. In some embodiments, the method is characterized by the absence of surgical removal of normal bone of the facet joint, and the resurfacing bodies are inserted simultaneously via a percutaneous technique.

[0049] Yet other aspects in accordance with principles of the present disclosure relate to a kit for treating a facet joint of a patient. The kit includes a treatment system as described above (e.g., a superior resurfacing device having a superior resurfacing body, and an inferior resurfacing device having an inferior resurfacing body), along with an insertion tooling set. The insertion tooling set may include a delivery cannula and an implant insertion tool.

[0050] The delivery cannula has a distal end and defines an internal passage that is open at the distal end. The implant insertion tool is sized to be slidably received within the passage. With this construction, the kit is configured to provide an insertion arrangement in which the resurfacing devices and the implant insertion tool are slidably received within the passage, with the resurfacing devices being stacked against one another adjacent the distal end and a distal region of the implant insertion tool abutting the resurfacing devices opposite the distal end of the cannula. In some embodiments, the resurfacing devices each have a recess to receive a finger formed by the implant insertion tool to achieve selective engagement therebetween.

BRIEF DESCRIPTION OF THE DRAWINGS

[0051] The accompanying drawings are included to provide a further understanding of embodiments and are incorporated in and constitute a part of this specification. The drawings illustrate embodiments and together with the description serve to explain principles of embodiments. Other embodiments and many of the intended advantages of embodiments will be readily appreciated as they become better understood by reference to the following

detailed description. The elements of the drawings are not necessarily to scale relative to each other. Like reference numerals designate corresponding similar parts.

[0052] Fig. 1A is a simplified cross-sectional view of a human spinal segment illustrating anatomy of native facet joints with which the systems and methods of the present disclosure are useful in treating.

[0053] Fig. 1B is an enlarged view of one facet joint of the segment of FIG. 1A.

[0054] Fig. 2 is a perspective view of a resurfacing body according to an embodiment of the invention.

[0055] Fig. 3 is a side view of the resurfacing body of Fig. 2.

[0056] Fig. 4 is top view of another configuration of the resurfacing body having a tab extending therefrom.

[0057] Fig. 5 is a sectional view of the resurfacing body taken along a line A—A in Fig. 4.

[0058] Fig. 6 is a perspective view of the resurfacing body of Fig. 4.

[0059] Fig. 7 is a top view of another configuration of the resurfacing body having a tab extending therefrom.

[0060] Fig. 8 is a sectional view of the resurfacing body taken along a line A—A in Fig. 7.

[0061] Fig. 9 is a perspective view of the resurfacing body of Fig. 7.

[0062] Fig. 10 is a top view of a guide probe assembly according to an embodiment of the invention.

[0063] Fig. 11 is a sectional view of the guide probe assembly taken along a line A—A in Fig. 10.

[0064] Fig. 12 is an enlarged sectional view of a tip portion of the guide probe assembly.

[0065] Fig. 13 is a side view of a guide probe assembly according to an alternative embodiment of the invention.

[0066] Fig. 14 is a perspective view of a guide cannula for use in conjunction with an embodiment of the invention.

[0067] Fig. 15 is a side view of the guide cannula of Fig. 14.

[0068] Fig. 16 is a side view of a delivery cannula according to an embodiment of the invention.

[0069] Fig. 17 is a side view of an implant insertion tool according to an embodiment of the invention.

[0070] Fig. 18 is a side view of an implant insertion tool according to an alternative embodiment of the invention.

[0071] Fig. 19 is a side view of an implant insertion tool according to another alternative embodiment of the invention.

[0072] Fig. 20 is a side view of an implant countersink positioner according to an embodiment of the invention.

[0073] Fig. 21 is a top view of the resurfacing device positioned adjacent to a distal end of the implant insertion tool.

[0074] Fig. 22 is a perspective view of the resurfacing device in engagement with an extension on the distal end of the implant insertion tool.

[0075] Fig. 23 is a perspective view of the delivery cannula inserted into the guide cannula.

[0076] Fig. 24 is a perspective view of the implant insertion tool in an initial position where the resurfacing device is inside of the delivery cannula and where the delivery cannula is inside of the guide cannula.

[0077] Fig. 25 is a perspective view of the implant insertion tool in an inserted position where the resurfacing device is partially extending beyond the distal end of the delivery cannula.

[0078] Fig. 26 is a perspective view of the implant insertion tool in a partially retracted position where the resurfacing device is moved beyond the delivery cannula for implanting the resurfacing device in the facet joint.

[0079] Fig. 27 is a side view of a leaflet retractor tool for use in withdrawing the implant insertion tool from the delivery cannula.

[0080] Fig. 28 is a perspective view of the guide probe assembly inserted into the facet joint and the guide cannula being inserted over the guide probe assembly.

[0081] Fig. 29 is a sectional view of the resurfacing device that has been implanted in one of the facet joints.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0082] One embodiment of an implant system 40 in accordance with principles of the invention and useful for treating a facet joint of a patient is illustrated in Fig. 2. The implant system 40 may include a superior resurfacing device 42 and an inferior resurfacing device 44.

[0083] As illustrated in Fig. 2, the superior resurfacing device 42 may be positioned on top of the inferior resurfacing device 44 so that the superior resurfacing device 42 and the interior resurfacing device 44 are oriented in opposite directions as the superior resurfacing device 42 and the inferior resurfacing device 44 would be oriented during the implantation process. Details on the various components of the resurfacing devices 42, 44 are provided below.

[0084] In certain embodiments, the resurfacing devices 42, 44 may be substantially similar to each other where the superior resurfacing device 42 is placed adjacent to a superior

facet joint articular face (e.g., the superior articular face 26 of Fig. 1B), and the inferior resurfacing device 44 is placed adjacent to an inferior facet joint articular face (e.g., the inferior articular face 28 of Fig. 1B).

[0085] The resurfacing devices 42, 44 may be capable of substantially conforming to the naturally-occurring shape or curvature of the facet joint anatomy. The resurfacing devices 42, 44 thereby replace the bone-on-bone interface of the natural facet joint in a manner achieving normal or near normal mobility.

[0086] While not required, the resurfacing devices 42, 44 may be substantially similar to each other in some embodiments. As such, the following description of the superior resurfacing device 42 is equally applicable to the inferior resurfacing device 44.

[0087] The resurfacing device 42 consists of a resurfacing body 46. In certain embodiments described below, one or more additional components can be attached to, or extend from, the resurfacing body 46. In certain embodiments, the resurfacing body 46 may have a disc-like shape, that includes a base web 50 and a plurality of teeth 52 (referenced generally).

[0088] The base web 50 defines opposing major surfaces 54, 56, as illustrated in Fig. 3, with the first major surface 54 providing or serving as an articulating surface (e.g., articulates relative to a corresponding articulating surface of the inferior resurfacing device 44 (Fig. 2)) as described below. Thus, the first major surface 54 may also be referenced as the "articulating surface" of the resurfacing body 46. The plurality of teeth 52 may project from the second major surface 56 in a direction that is generally opposite the first major surface 54.

[0089] With specific reference to Figs. 2 and 3, the base web 50 defines an outer perimeter 58 of the resurfacing body 46. In certain embodiments, the outer perimeter 58 may have a generally circular shape that generally conforms to a shape of the facet joint in which

the resurfacing body is to be implanted. In other embodiments, the perimeter may have an oval-like shape (relative to a top or bottom plan view). The resurfacing device 44 may be formed with other shapes, examples of which include square, rectangular, hexagonal and curvilinear.

[0090] An overall size or footprint of the resurfacing body 46 is defined by the outer perimeter 58 and can vary depending upon a size of the facet joint being treated, but is generally relatively small, especially as compared to conventional facet joint prostheses and/or capping devices. As is noted above, the resurfacing body 46 should be large enough to prevent bone-to-bone contact in the facet joint.

[0091] In certain embodiments, a diameter of the resurfacing body 46 may be in the range of between about 3 millimeters and about 15 millimeters. In other embodiments, the diameter of the resurfacing body may be in the range of between about 5 millimeters and about 10 millimeters.

[0092] Facet joint treatment systems in accordance with this invention may be provided to a treating clinician with two or more different superior resurfacing devices 42 (and two or more different inferior resurfacing devices 44) each having a differently-sized resurfacing body 46.

[0093] Examples of the sizes of the resurfacing bodies include about 5 millimeters, about 8 millimeters, about 10 millimeters and about 12 millimeters. The treating clinician may select the most appropriately sized resurfacing device for implantation based upon an evaluation of the facet joint to be treated.

[0094] While it is desirable for the resurfacing body 46 to be sufficiently large to prevent bone-to-bone contact within the facet joint, the resurfacing body 46 should not be too large such that the resurfacing body 46 extends beyond the facet joint as such a condition

could result in damage to the tissue adjacent to the facet joint where the resurfacing body 46 is implanted.

[0095] For reasons that are set forth in more detail below, the resurfacing body 46 may incorporate one or more features dictating a preferred insertion orientation and/or direction. For example, the resurfacing body 46 may be more readily inserted into, and subsequently retained within, a facet joint in a particular orientation.

[0096] Relative to the configuration of Figs. 2 and 3, the outer perimeter 58 can be described as generally defining a leading or distal end 70, a trailing or proximal end 72, and opposing sides 74, 76. During an insertion procedure, the resurfacing body 46 may be oriented such that the leading end 70 is initially inserted into the facet joint, followed by the trailing end 72.

[0097] In addition to the teeth 52 having a structure corresponding with these designations (and thus the intended insertion direction and orientation described below), the trailing end 72 can form or define an engagement feature 80, as illustrated in Fig. 2, that promotes desired interaction with a separately-provided insertion tool, which is discussed in more detail below.

[0098] In certain embodiments, the engagement feature 80 is an aperture that includes at least two aperture regions 81a, 81b. The first aperture region 81a may intersect the outer perimeter 58 or edge proximate the trailing end 72. The second aperture region 81b is in communication with the first aperture region 81a and is oriented on a side of the first aperture region 81a that is opposite the outer perimeter 58.

[0099] The first aperture region 81a may have a width that is smaller than a width of the second aperture region 81b. The shape of the engagement feature 80 thereby provides a partially enclosed aperture to facilitate attachment of the resurfacing body 46 to the implant insertion tool during the insertion process.

[0100] A force to separate the resurfacing body 46 from the implant insertion tool should be sufficiently large so that the resurfacing body 46 does not inadvertently separate from the implant insertion tool 312. In certain embodiments, the force to separate the resurfacing body 46 from the implant insertion tool 312 is at least 1 Newton. In other embodiments, the force to separate the resurfacing body 46 from the implant insertion tool 312 is between about 1 Newton and about 10 Newtons. In still other embodiments, the separation force is about 5 Newtons.

[0101] The separation force may be affected by a difference in the sizes of the widths of the first aperture region 81a and the second aperture region 81b and the width of the extension. The separation force may also be affected by other factors such as the rigidity of the resurfacing body 46 and the extension on the implant insertion tool 312. For example, if the resurfacing body 46 or the extension is fabricated from a flexible material, the separation force may be lower if the resurfacing body 46 or the extension is fabricated from a relatively rigid material.

[0102] The engagement feature 80 may be formed at the same time the other portions of the resurfacing body 46 are formed such as by molding. Alternatively, the engagement feature 80 may be formed after the resurfacing body 46 is formed such as by stamping out the region that defines the first aperture region 81a and the second aperture region 81b.

[0103] It is possible to use other techniques for maintaining the resurfacing device 46 in engagement with the implant insertion tool 312 during the process of inserting the resurfacing device 46 into the facet joint. An example of one such alternative attachment technique is attaching the resurfacing device 46 and the implant insertion tool 312 with a frangible connection. When a force that is greater than a threshold force, the frangible connection may be severed to thereby allow the implant insertion tool 312 to be removed while leaving the resurfacing body 46 in the facet joint. In certain embodiments, the force to

sever the frangible connection is at least 1 Newton. In other embodiments, the force to sever the frangible connection is between about 1 Newton and about 10 Newtons. In still other embodiments, the separation force is about 5 Newtons.

[0104] In certain embodiments, the base web 50 has, in some constructions, a relatively uniform thickness (e.g., nominal thickness variation of +/- 0.05 mm), as illustrated in Fig. 3. The base web 50 forms the articulating surface 54 to be relatively smooth. This smoothness attribute is, at least in part, a function of the material employed for the resurfacing body 46 as described below.

[0105] In other embodiments, the articulating surface 54 of the base web 50 may be coated with a separate layer that provides enhanced frictional (i.e., lower coefficient of friction) and wear characteristics. An example of one such material have a low coefficient of friction is polytetrafluoroethylene (PTFE), which is available under the designation TEFLON.

[0106] The plurality of teeth 52 project from the second major surface 56 of the base web 50. These teeth 52 may have a variety of forms. In some embodiments, the teeth 52 are arranged to form or define discrete zones or teeth sets, such as the first, second and third teeth sets 90, 92, 94 generally identified in Fig. 2.

[0107] The first teeth set 90 may be centrally located along the base web 50 extending between the leading and trailing ends 70, 72. Individual teeth of the first teeth set 90 may be generally identical. More particularly, each of the teeth may include a leading face 98 and a trailing face 100 that extends from the second major surface 56 and intersect at a tip 102. The leading face 98 may be oriented more proximate the leading end 70 (as compared to the trailing face 100), whereas the trailing face 100 may be oriented more proximate the trailing end 72.

[0108] With these designations in mind, the teeth may be constructed to define an insertion direction whereby an angle α formed by the leading face 98 relative to the second major surface 56 is smaller than an angle β formed by the trailing face 100 relative to the second major surface 56.

[0109] In these configurations, the leading face 98 may have a more gradual slope relative to the leading end 70 as compared to a slope of the trailing face 100 relative to the trailing end 72 such that the tooth 96a more overtly engages a separate structure, such as the facet joint superior face (not shown) at and along the trailing face 100 as compared to the leading face 98.

[0110] In some configurations, the angle α defined by the leading face 98 may be in the range of 20°-60°, whereas the angle β defined by the trailing face 100 is approximately 90°. Suitable angles may be affected by a variety of factors such as the material from which the resurfacing body 46 is fabricated. Regardless, and returning to FIG. 2, the remaining teeth of the first teeth set 90 may be aligned with one another in two or more rows as shown.

[0111] The second teeth set 92 and the third teeth set 94 may be formed at or along the opposing sides 74, 76, respectively, as illustrated in Fig. 2. In this regard, while the individual teeth of the second and third sets 92, 94 may have the non-symmetrical relationship described above with respect to the tooth discussed above, an exterior face 104 associated with each tooth of the second and third teeth sets 92, 94 establish an angle of extension relative to the second major surface 56 that approaches 90°.

[0112] With this but one acceptable construction, the second and third teeth sets 92, 94 overtly resist side-to-side displacement of the resurfacing body 46 relative to a corresponding facet joint face following insertion. For example, the second teeth set 92 may resist leftward displacement of the resurfacing body 46, whereas the third teeth set 94 may resist rightward displacement.

[0113] In certain embodiments, each tooth of the plurality of teeth 52 may have an identical, or nearly identical, height (or extension from the second major surface 56), as illustrated in Fig. 3. In other embodiments, the teeth of the first teeth set 90 may have an elevated height as compared to teeth of the second and third teeth sets 92, 94, and combine to define a tapering height of the resurfacing body 46 from the leading end 70 to the trailing end 72.

[0114] Stated otherwise, and relative to the illustrated embodiment in which the first major surface 54 is planar, a height of the leading tooth 96a is greater than a height of a trailing tooth 96b. For example, the tips 102 associated with the teeth of the first teeth set 90 combine to define a hypothetical plane P. The plane P is, in some embodiments, non-perpendicular relative to a plane of the first major surface 54, combining with the first major surface 54 to define an included angle Δ in the range of between about 1° and about 5°.

[0115] In other embodiment, other angles are also contemplated where the teeth 52 have substantially similar heights. In certain embodiments, the tallest tooth 96a may be provided at the leading end 70 that ultimately is located opposite the point of insertion into the facet joint. As a result, the leading tooth 96a may establish a more rigid engagement with the corresponding facet joint face to thereby overtly resist displacement upon final insertion.

[0116] The base web 50 and the teeth 52 combine to define an overall thickness T of the resurfacing body 46. For example, a lateral distance between the first major surface 54 and the tip 102 of the "tallest" tooth 96a. As described in greater detail below, a desired conformability characteristic of the resurfacing body 46 is influenced by the overall thickness T and the base web thickness t, and thus the overall thickness T is selected, along with other parameters, to effectuate the desired degree of conformability.

[0117] In some constructions, the overall thickness T of the resurfacing body 46 is between about 0.25 millimeters and about 4 millimeters, although other dimensions are also

contemplated. As a point of reference, the overall thickness T associated with the resurfacing body 46 selected by the treating clinician for insertion into a particular facet joint may vary as a function of other procedures associated with the insertion.

[0118] For example, where the resurfacing body 46 is inserted into a facet joint without any overt tissue removal prior to insertion, the overall thickness T can be between about 0.5 millimeters and about 2.5 millimeters. If the insertion procedure entails first removing cartilage (or other tissue) from the facet joint, a larger version of the resurfacing body 46 can be inserted, such that the overall thickness T of the resurfacing body 46 is between about 0.5 millimeters and about 3 millimeters.

[0119] The resurfacing devices 42, 44, and thus the corresponding resurfacing bodies 46, may be integrally formed of a robust material that achieves desired conformability. The resurfacing body 46 in accordance with this invention maintains its structural integrity (i.e., little or no wear) without adhesive or cohesive damage when subjected to typical articulation of the facet joint with movement of the patient.

[0120] In some constructions, the resurfacing devices 42, 44 may be formed of an implantable-grade plastic, although other materials such as metal are also available. For example, the resurfacing devices 42, 44 may be made from the polyetherketone (PEK) family of plastics, which have strength, wear, flexibility, and biocompatibility properties appropriate for insertion into, and long-term functioning within, the facet joint.

[0121] Polyetheretherketone (PEEK) has been found to provide not only the conformability attributes described below, but also long-term mechanical strength and resistance to wear. Additional materials may be incorporated, such as those exhibiting radio-opacity properties. For example, the resurfacing devices 42, 44 may be formed from a radio-opaque mineral (e.g., barium)-loaded PEK composition.

[0122] Visualization may also be provided via one or more radio-opaque marker bands (e.g., platinum marker band). The marker band(s) can be embedded within the resurfacing device 42, 44. For example, a radio-opaque rod may be inserted into a hole formed in the resurfacing device 42, 44, as illustrated in Fig. 5. Alternatively, the radio-opaque material may be inserted around a perimeter of the resurfacing device 42, 44.

[0123] The selected materials, shapes, and dimensions associated with the resurfacing body 46 of each of the resurfacing devices 42, 44 impart or create a conformability property to the resurfacing body 46 sufficient to allow the resurfacing body 46 to "match" the multi-planar concavity associated with a native facet joint articular face anatomy.

[0124] With the resurfacing device 42, 44 embodiment of Fig. 2, the resurfacing body 46 forms an entirety of the corresponding resurfacing device 42, 44. In other embodiments described below, one or more additional components may be included with the resurfacing body 46, such that the following explanation of conformability is specifically applicable to the resurfacing body 46, but may also apply equally to the resurfacing devices 42, 44 as a whole.

[0125] In general terms, "conformability" may be inversely proportional to bending stiffness of the resurfacing body 46 during insertion, and may be increased as the resurfacing body 46 heats to body temperature and is allowed to creep. From a clinical perspective, "conformability" of the resurfacing body 46 entails the resurfacing body 46 conforming to a radius of curvature of the C-shaped or J-shaped portions of the articular joint such as the concave-shaped superior articular face 26 of Fig. 1B or the convex-shaped inferior articular face 28 of Fig. 1B.

[0126] As a point of reference, the minimum radius of curvature of the human facet joint in the transverse plane is on the order of 20 millimeters, with a lower bound (10th percentile) on the order of 7 millimeters. The radius of curvature will vary with the vertebral

level and the patient's specific anatomy and disease state. Preparation of the facet joint prior to insertion of the resurfacing devices 42, 44 may also change the radius of curvature.

[0127] A range of curvature radii of 7 millimeters to infinity (i.e., flat facet anatomy) can be accommodated by the resurfacing devices 42, 44 of the present disclosure. There also may be curvature in the sagittal plane; the conformable nature of the resurfacing body 46 of the present disclosure is capable of substantially "matching" any sagittal plane curvature as well.

[0128] With the above understandings in mind, the conformability characteristic of the resurfacing body 46 is sufficient such that the resurfacing body 46 readily transition from the relatively flat state illustrated in Fig. 2 to an inserted state (not shown but reflected, for example, in Fig. 30) in which the resurfacing body 46 substantially matches or mimics the naturally-occurring shape (e.g., radius of curvature of curved portions) of the facet joint face to which the resurfacing body 46 is secured. In this regard, the facet joint 20 (Fig. 1B) is subject to, or experiences, various loads that effectuate compressive forces at the region of interface between the superior and inferior articular faces 26, 28 (Fig. 1B).

[0129] These physiologic forces across the facet joint 20 will vary with activity, posture, body loads, and muscle forces, and tend to be between about 7% and about 14% of body load when standing. However, in the prone, slightly flexed position during surgery/implantation, these loads may be as little as zero. The intrinsic forces will be generated as the resurfacing device 42, 44 (and thus the corresponding resurfacing body 46) are inserted and the capsule 32 (Fig. 1B) is tensioned. Compression of the underlying cartilage and subchondral bone, slight flexion, or laminar strains may result and would accommodate some thickness of the devices 42, 44. However, separation/posterior translation of the superior facets would be required to accommodate a large portion of a collective thickness of the devices 42, 44.

[0130] Compressive loads normal to and across the articular faces 26, 28 will be generated upon separation/posterior translation of the superior facets due to joint capsule tensioning. The conformable nature of the resurfacing body 46 is such that in the presence of these typical compressive forces, the resurfacing body 46 will transition from the relatively flat state to the inserted state in which the resurfacing body 46 substantially matches the geometry of the facet joint surface to which the resurfacing body 46 is secured.

[0131] For example, the resurfacing body 46 will flex to conform with a macroscopic shape/contour of the native articular face to which the resurfacing body 46 is applied, but may not conform to the microscopic variations in the native articular face because of small deviations due to cartilage defects, bony fissures, or small voids during preparation of the joint (typically between about 0.05 millimeters and about 0.5 millimeters in width).

[0132] This process will occur as the compressive forces applied by the ends of the hypothetical concave region of one facet articular surface (e.g., the superior articular surface 26) and the center of the corresponding convex surface on the opposing articular facet (e.g., the inferior articular surface 28) generate a bending moment on the resurfacing body 46 that produces strain to conform the resurfacing body 46 to the native anatomy.

[0133] As used through this specification, a resurfacing body that conforms to the minimum radius of curvature of an adult human facet joint under normal physiologic forces (e.g., between about 180 and about 450 Newtons/millimeter per segment assuming a net 1 millimeter posterior shear translation) without deviations from the articular surface to which the resurfacing body is applied of greater than 1 millimeter is defined as being "conformable" and "substantially matching" the multi-planar curvatures of a facet joint.

[0134] Alternatively, a resurfacing body sized for placement within an adult human facet joint and exhibiting a Conformability Factor (described below) of not more than 100 Newtons is also defined as being "conformable" and "substantially matching" the multi-

planar curvatures of a facet joint in accordance with the present disclosure. In some embodiments, resurfacing bodies in accordance with the present disclosure exhibit a Conformability Factor of not more than 50 Newtons, and in other embodiments not more than 25 Newtons.

[0135] It has surprisingly been found that forming the resurfacing body 46 (and thus either of the resurfacing devices 42, 44 of the one embodiment of Fig. 2) of PEEK and with the footprint size and thickness dimensions described above achieves the desired conformability characteristics, long-term resistance to wear, and facet joint stabilization following insertion.

[0136] Another embodiment of the resurfacing body 46 is illustrated in Figs. 4-6. The resurfacing body 46 may have a similar over shape and a similar tooth pattern to the resurfacing body illustrated in Figs. 2-3 except as noted below.

[0137] The resurfacing body 46 may include a radio opaque marker 82 placed therein. The radio opaque marker 82 may be utilized to monitor the location of the resurfacing body 46 is implanted in a non-invasive manner as the radio opaque marker 82 may be viewed using many different types of imaging conventionally used in the medical field.

[0138] The radio opaque marker 82 should be sufficiently large to facilitate viewing the radio opaque marker using conventional medical imaging techniques. However, the radio opaque marker 82 should be sufficiently small such that the radio opaque marker 82 does not impede the flexibility of the resurfacing body 46 after implantation. Alternatively or additionally, the radio opaque marker 82 may be fabricated from a flexible material that does not impede the ability of the resurfacing body 46 to flex after implantation.

[0139] While it is possible to incorporate the radio opaque marker 82 during the process used to fabricate the resurfacing body 46, it is also possible to insert the radio opaque marker 82 into the resurfacing body 46 after fabrication.

[0140] One such suitable technique for inserting the radio opaque marker 82 into the resurfacing device includes forming an aperture in the resurfacing body 46. In certain embodiments, the aperture may be formed using a drill.

[0141] In certain embodiments, the radio opaque marker 82 may be placed into the resurfacing body 46 from a trailing end 72 thereof proximate a center line of the resurfacing body 46. Using such a configuration provides the resurfacing body 46 with symmetry to assist in evaluating the position of the resurfacing body 46 based upon medical imaging of the radio opaque marker 82.

[0142] The placement of the radio opaque marker 82 in the resurfacing body 46 should be relatively accurate such that the radio opaque marker 82 does not extend through one of the surfaces of the resurfacing body 46. Such an occurrence could lead to degradation of the resurfacing body 46 or could cause damage to the tissue in the facet joint that is adjacent to the resurfacing body 46.

[0143] To ensure that the radio opaque marker 82 does not extend through the upper surface of the resurfacing body 46, an additional material region 84 may be provided in the region adjacent to the radio opaque marker 82, as illustrated in Figs. 4 and 5. The radio opaque marker 82 may be placed at an approximately equal distance between the upper and lower surfaces of the resurfacing body in the additional material region 84.

[0144] An elongated tab 86 may extend from the trailing end 72 of the resurfacing body 46. The elongated tab 86 could be used in the manufacturing process and then be severed from the other portions of the resurfacing body 46 once manufacturing is completed. Alternatively, the elongated tab 86 may be used in conjunction with the insertion of the resurfacing body 46 into the facet joint as opposed to the implantation system described herein. In such instances, a line of weakening may be provided where the elongated tab 84 intersects the resurfacing body 46.

[0145] Another embodiment of the resurfacing body 46 is illustrated in Figs. 7-9. The resurfacing body 46 may have a similar over shape and a similar tooth pattern to the resurfacing body illustrated in Figs. 2-3 except as noted below.

[0146] The resurfacing body 46 may include a radio opaque marker 82 placed therein. The radio opaque marker 82 may be utilized to monitor the location of the resurfacing body 46 is implanted in a non-invasive manner as the radio opaque marker 82 may be viewed using many different types of imaging conventionally used in the medical field. The features and placement of the radio opaque marker 82 are similar to the features and placement of the radio opaque marker 82 in the embodiment of the resurfacing body 46 illustrated in Figs. 4-6

[0147] An elongated tab 86 may extend from the trailing end 72 of the resurfacing body 46. The structure and function of the elongated tab 86 may be to the structure and function of the elongated tab 86 in the embodiment of the resurfacing body 46 illustrated in Figs. 4-6.

[0148] The resurfacing body 46, and thus the system 40, may be delivered to, and inserted within, a facet joint in a variety of manners via various instrumentations sets or systems. Components of one useful insertion tooling set are discussed below.

[0149] One of the important aspects of accurately delivering the resurfacing body 46 is to not only accurately locate the desired facet joint but also to accurately position the resurfacing body delivery system with respect to the facet joint to permit the resurfacing body 46 to be accurately inserted into the facet joint.

[0150] In certain embodiments, a guide probe assembly 200, as illustrated in Figs. 10-11, may be initially used to locate the region in the facet joint where the resurfacing device 46 is to be inserted. The guide probe assembly 200 may include a guide probe shaft 202 and a guide probe tip 204 that extends from a distal end of the guide probe shaft 202.

[0151] The guide probe shaft 202 may have a substantially rectangular profile, as illustrated in Figs. 10 and 11. Forming the guide probe shaft 202 with the substantially rectangular profile enables the guide cannula 260 to slide over the guide probe assembly 200 after the guide probe assembly 200 is positioned with the guide probe tip 204 at least partially in the facet joint, as is discussed in more detail herein. This process reduces the time associated with implanting the resurfacing body 46 when compared to an implantation system that does not utilize this insertion process.

[0152] To minimize the size of the incision that is formed in the patient, the guide probe shaft 202 may be formed with a width and a height that is approximately equal to a width and a height of the resurfacing body 46.

[0153] In certain embodiments, the guide probe shaft 202 has a width of between about 5 millimeters and about 20 millimeters. In other embodiments, the guide probe shaft 202 has a width of about 12 millimeters.

[0154] In certain embodiments, the guide probe shaft 202 has a thickness of between about 0.20 millimeters and about 10 millimeters. In other embodiments, the guide probe shaft 202 has a thickness of about 2 millimeters.

[0155] The guide probe shaft 202 is formed with a length that enables a proximal end of the guide probe shaft 202 to be positioned outside of the patient's body when the distal end of the guide probe shaft 202 is adjacent the facet joint. Such a configuration facilitates the surgeon or other person who is using the guide probe assembly 200 to accurately position the guide probe assembly 200 with respect to the facet joint.

[0156] In certain embodiments, the guide probe shaft 202 has a length of between about 10 centimeters and about 30 centimeters. In other embodiments, the guide probe shaft 202 has a length of about 23 centimeters.

[0157] The distal end of the guide probe shaft 202 may include a tapered region 206, as illustrated in Figs. 10-11, to provide a transition between the guide probe shaft 202 and the guide probe tip 204. The length of the tapered region 206 may depend on a variety of factors such as a difference in the width and the height of the guide probe shaft 202 and the guide probe tip 204.

[0158] The guide probe shaft 202 may be fabricated from a relatively rigid material to facilitate the use of the guide probe shaft 202 to locate the facet joint using the guide probe tip 204. In certain embodiments, the guide probe shaft 202 may be fabricated from stainless steel. In other embodiments, it is possible to fabricate the guide probe shaft 202 from a non-metallic material such as plastic.

[0159] An important criterion is that the guide probe shaft 202 be fabricated from a material that is biocompatible. If it is desired to reuse the guide probe shaft 202 for multiple surgical procedures, the guide probe shaft 202 should be capable of withstanding repeated sterilization processes such as by using an autoclave.

[0160] The guide probe tip 204 is operably connected to the proximal end of the guide probe shaft 202. In certain embodiments, the guide probe shaft 202 has an aperture 210 formed in the distal end thereof. This aperture 210 is adapted to receive a portion of the guide probe tip 204.

[0161] The portion of the guide probe tip 204 that extends into the aperture 210 may have a length that is greater than a length of the guide probe tip 204 that extends beyond the proximal end of the guide probe shaft 202 to enhance the ability of the guide probe tip 204 when attempting to locate a desire location in the facet joint.

[0162] Forming the guide probe tip 204 separate from the other portions of the guide probe assembly 200 enables guide probe tips 202 having different widths and/or lengths to be

used depending on the size, shape and location of the facet joint in which the resurfacing device is being inserted.

[0163] The guide probe tip 204 may have a thickness and a width that are both smaller than a thickness and a width of the guide probe shaft 202. In certain embodiments, the guide probe tip 104 has a width of between about 5 millimeters and about 20 millimeters. In other embodiments, the guide probe tip 104 may have a width that is about 9 millimeters.

[0164] In certain embodiments, the guide probe tip 204 may have a thickness of between about 0.10 millimeters and about 0.50 millimeters. In other embodiments, the guide probe tip 204 may have a thickness of about 0.20 millimeters.

[0165] The guide probe tip 204 may be formed with a proximal end that is not pointed. Forming the guide probe tip 204 with this configuration at the proximal end minimizes the potential that the guide probe tip 204 will damage or other negatively impact the tissue in the facet joint or surrounding the facet joint.

[0166] In certain embodiments, it is possible for the proximal end of the guide probe tip 204 to be sharpened such that the guide probe tip 204 may be used to cut tissue when attempting to access the facet joint.

[0167] The guide probe tip 204 may be fabricated from a material that is rigid but which is flexible. Forming the guide probe tip 204 from a flexible material enhances the ability of the guide probe tip 204 to be positioned at least partially in the facet joint as an initial step in implanting the resurfacing body 46.

[0168] In certain embodiments, the guide probe tip 204 is fabricated from a metallic material such as stainless steel. It is also possible to fabricate the guide probe tip 204 from a non-metallic material using the concepts of the invention.

[0169] An important criterion is selecting the material that is used to fabricate the guide probe tip 204 is that the material be biocompatible. If it is desired to reuse the guide

probe tip 204 for multiple surgical procedures, the guide probe tip 204 should be capable of withstanding repeated sterilization processes such as by using an autoclave.

[0170] The guide probe tip 204 may be attached to the guide probe shaft 202 using at least one fastening device 212. In certain embodiment at least two of the fastening devices 212 are used to attached the guide probe tip 204 to the guide probe shaft 202.

[0171] The fastening device 212 may have a variety of different configurations. In one configuration, the fastening device 212 frictionally engages the guide probe shaft 202 through the aperture formed therein. Alternatively, the fastening device 212 may have a threaded side surface that enables the fastening device 212 to be screwed into the guide probe shaft 202 having an aperture with a complementary shape.

[0172] As an alternative to the configuration of the guide probe assembly 200 configuration illustrated in Figs. 10-12, alternative configurations of the guide probe assembly 200 may be utilized in conjunction with the concepts of the invention. One such alternative configuration of the guide probe assembly is illustrated at 240 in Fig. 13. The guide probe assembly 240 includes an elongated main portion 242 and a handle portion 244 that is attached to a proximal end of the main portion 242.

[0173] The main portion 242 may have a configuration that is similar to the guide probe shaft 202 illustrated in Figs. 10-11. While Fig. 13 illustrates that the main portion 242 does not have a separate tip portion, it is possible to adapt the concepts of this embodiments to encompass a separate tip portion so that the tip portion may possess different physical characteristics that the main portion 242 from which the tip portion extends. Even when a separate tip portion is not provided, a proximal end of the main portion 242 may be tapered to facilitate guiding the guide probe assembly 240 to a desired location in the facet joint.

[0174] The handle portion 244 enhances the ability to grasp the guide probe assembly 240 during the insertion process. In certain embodiments, the handle portion 244 may have a

width that is greater than a width of the main portion 242. The handle portion 244 may also have a thickness that is greater than a thickness of the main portion 242.

[0175] The guide probe assembly 240 may be used in conjunction with the guide probe assembly 200. In such a configuration, the main portion 242 may be placed adjacent to the guide probe assembly 200. When used in this configuration, the main portion 242 and the guide probe assembly 200 may be thinner than with the separately used configuration so that the main portion 242 and the guide probe assembly 200 may both fit inside of the guide cannula 260.

[0176] This configuration may utilize the handle portion 244 for guiding the distal end of the guide probe assembly 200 into a position within the facet joint. Thereafter, the guide probe assembly 240 may be withdrawn. Next, the guide cannula 260 may be placed over the guide probe assembly 200.

[0177] The delivery system may include a guide cannula 260, as illustrated in Figs. 14 and 15. The guide cannula 260 has an internal passage 262 that extends from a proximal end to a distal end thereof. In certain embodiments, the passage 262 may have a generally rectangular configuration.

[0178] A width of the passage 262 is smaller than a width of the delivery cannula 280. In certain embodiments, the width of the passage 262 may be between about 3 millimeters and about 15 millimeters. In other embodiments, the width of the passage 262 is between about 5 millimeters and about 10 millimeters.

[0179] A height of the passage 262 is smaller than a height of the delivery cannula 280. In certain embodiments, the height of the passage 262 may be between about 0.50 millimeters and about 5 millimeters. In other embodiments, the height of the passage 262 is about 2 millimeters.

[0180] To facilitate accurately positioning the guide cannula 260 with respect to the facet joint, the proximal end of the guide cannula 260 may have a concave surface 266. The concave surface 266 may at least partially receive a convex surface of the facet joint to thereby prevent the guide cannula 260 from moving laterally with respect to the facet joint and thereby enhance the ability to accurately insert the resurfacing device into the facet joint.

[0181] The guide cannula 260 may include a first stop mechanism 270 proximate a distal end thereof. The first stop mechanism 270 limits a distance the delivery cannula 280 may be inserted into the guide cannula 260. In certain embodiments, the first stop mechanism 270 engages a stop surface 286 that extends from an outer surface of the delivery cannula 280 proximate a distal end thereof.

[0182] The guide cannula 260 may also include a second stop mechanism 272 extending from the proximal end thereof. The second stop mechanism 272 limits a distance the implant insertion tool 300 may be inserted into the guide cannula 260 to thereby prevent over-insertion of the resurfacing device 46 into the facet joint. The second stop mechanism 272 may engage a shoulder 320 on the implant insertion tool 310 when the implant insertion tool 310 has been extended a desired distance into the guide cannula 260.

[0183] To enhance the ability to use the different components of the system, the second stop mechanism 272 may be positioned in a spaced-apart relationship with respect to the first stop mechanism 270. In certain embodiments, a spacing between the first stop mechanism 270 and the second stop mechanism 272 is between about 1 centimeter and about 5 centimeters.

[0184] The guide cannula 260 thereby facilitates extending the guide probe shaft 202 into the proximal end of the rectangular passage 262 until the proximal end of the guide cannula 260 is adjacent to the facet joint. Thereafter, the guide probe assembly 200 may be

withdrawn from the guide cannula 260 by pulling the distal end of the guide probe assembly 200.

[0185] The guide cannula 260 may be fabricated with a length that enables the distal end to be positioned proximate to the facet joint where the implant is to be inserted while the proximal end is positioned outside of the person's body. In certain embodiments, the guide cannula 260 may have a length of between about 10 centimeters and about 30 centimeters.

[0186] The delivery cannula 280 may have a generally rectangular profile with a width and a height that are both slightly smaller than the width and the height of the guide cannula 260. This configuration enables the delivery cannula 280 to be inserted into the guide cannula 260 after the guide stop assembly 200 has been removed from the guide cannula 260.

[0187] The delivery cannula 280 has an internal passage 282 that extends from a proximal end to a distal end thereof. In certain embodiments, the passage 282 may have a generally rectangular configuration.

[0188] A width of the passage 282 is smaller than a width of the main portion 312 of the implant insertion tool 310. In certain embodiments, the width of the passage 282 may be between about 3 millimeters and about 15 millimeters. In other embodiments, the width of the passage 282 is between about 5 millimeters and about 10 millimeters.

[0189] A height of the passage 282 is smaller than a height of the main portion 312 of the implant insertion tool 310. In certain embodiments, the height of the passage 282 may be between about 0.5 millimeters and about 5 millimeters. In other embodiments, the height of the passage 282 is about 2 millimeters.

[0190] Proximate the proximal end of the delivery cannula 280, the sides of the passage 282 may be removed so that an upper face and a lower face of the delivery cannula 280 define a pair of arms. When the implant insertion tool 310 is inserted into the delivery

cannula 280, at least a part of the shoulder portion 320 may have a width that is greater than the width of the delivery cannula 280, as illustrated in Fig. 24. This configuration thereby limits the distance that the implant insertion tool 310 may be inserted into the delivery cannula 280.

[0191] The delivery cannula 280 may include a pair of leaflets 284 that extend from a distal end thereof. The leaflets 284 may be fabricated from a resilient material. The leaflets 284 may be initially positioned adjacent each other.

[0192] The leaflets 284 may have a width that is approximately the same as a width of the resurfacing body 46. A distal end of the leaflets 284 may be curved. The curved distal end of the leaflets 284 thereby minimizes damage to the superior articular face and the inferior articular face of the facet joint as the leaflets are moved into a position at least partially within the facet joint to provide an opening in the facet joint that is adapted to receive the resurfacing body 46.

[0193] The leaflets 284 may deflect away from each other as the resurfacing body 46 and the distal end of the implant insertion tool 310 extend therebetween. The leaflets 284 thereby enable maintaining the resurfacing body 46 in engagement with the implant insertion tool 310.

[0194] The force required to separate the leaflets 284 should be sufficiently large so that the leaflets 284 are retained in the closed configuration. However, the force should not be too great such that it is difficult for the resurfacing body 46 to be urged between the leaflets 284 during the implantation process or that the leaflets 46 damage the resurfacing body 46 when passing between the leaflets 284.

[0195] Proximate the proximal end of the delivery cannula 280, a stop mechanism 286 may extend from at least one outer surface of the delivery cannula 280. The stop

mechanism 286 may be an elevated region that is oriented generally transverse to an axis of the delivery cannula 280.

[0196] In certain embodiments, the stop mechanism 286 may comprise two elevated regions that are mounted in a spaced-apart configuration, as illustrated in Fig. 16. The two elevated regions thereby define a channel 288 that extends therebetween. The channel 288 is adapted to receive a portion of a leaflet retractor tool 360, which may be used to withdraw the delivery cannula 280 from the guide cannula 260.

[0197] The stop mechanism 286 engages the first stop mechanism 270 on the guide cannula 260. The stop mechanism 286 thereby limits a distance to which the delivery cannula 280 may be inserted into the guide cannula 260.

[0198] An embodiment of the invention may also include an implant insertion tool 310, as illustrated in Fig. 17. The implant insertion tool 310 may include a main portion 312 and a handle portion 314 that is attached to a proximal end of the main portion 312.

[0199] The main portion 312 may have a width and a height that are slightly smaller than the width and the height of the delivery cannula 280. This configuration enables the main portion 312 to be placed inside of and slide with respect to the delivery cannula 280 during the process of inserting the resurfacing body 46.

[0200] In certain embodiments, the width of the main portion 312 may be between about 3 millimeters and about 15 millimeters. In other embodiments, the width of the main portion 312 is between about 1 millimeter and about 5 millimeters.

[0201] In certain embodiments, the height of the main portion 312 may be between about 0.5 millimeters and about 5 millimeters. In other embodiments, the width of the main portion 312 is about 2 millimeters.

[0202] Proximate the intersection with the handle portion 314, the main portion 312 may include a shoulder 320 extending from at least one side thereof. The shoulder 320 may

be used to limit a distance to which the implant insertion tool 310 may be inserted into the delivery cannula by engaging the second stop mechanism 272 on the guide cannula 260.

[0203] The handle portion 314 may be oriented generally perpendicular to the main portion 312. The handle portion 314 thereby provides an enlarged surface that may be used to grasp the implant insertion tool 310 and thereby facilitates manipulating the implant insertion tool 310. In certain embodiments, the length of the handle portion 314 may be between about 5 centimeters and about 15 centimeters.

[0204] A distal end 322 of the main portion 312 may include a concave surface 323 that is curved to at least partially conform to a surface of the resurfacing body 46. The concave surface thereby enhances the ability to retain the resurfacing body 46 in a desired position with respect to the implant insertion tool 310

[0205] To further enhance the ability to maintain the resurfacing body 46 in a desired location with respect to the implant insertion tool 310, an extension 324 may extend from the distal end 322. The extension 324 is adapted to engage the engagement feature 80 that is provided in the resurfacing body 46.

[0206] The extension 324 may have a shape that is similar to but slightly smaller than the engagement feature 80. In particular, the extension 324 may include a first extension region 326a and a second extension region 326b.

[0207] The first extension region 326a has a width that is smaller than the width of the first aperture region 81a. The second extension region 326b has a width that is larger than the width of the first aperture region 81a and smaller than the width of the second aperture region 81b. This configuration enables the extension 324 to be retained in the engagement feature 80 to prevent the resurfacing body 46 from being separated from the implant insertion tool 310. More details on the relative size of the engagement feature 80 and the extension 324 are discussed above.

[0208] Figs. 21 and 22 illustrate the relationship between the resurfacing body 46 and the implant insertion tool 310. In Fig. 21, the resurfacing body 46 is placed adjacent to but spaced-apart from the implant insertion tool 310. In Fig. 22, the resurfacing body 46 is in engagement with the implant insertion tool 310 such that the extension 324 extends into and engages the engagement feature 80. The shape of the engagement feature 80 may be approximately the same as the shape of the extension 324.

[0209] Since the accurate placement of the resurfacing body 46 within the facet joint plays an important role in successfully treating the patient, the implant insertion tool 310 is configured to be inserted into the delivery cannula 280 and the guide cannula 260 until the handle portion 314 engages the second stop mechanism 272 on the guide cannula 260. This configuration protects against inadvertent over insertion of the resurfacing body 46.

[0210] In certain situations depending on the shape of the facet joint where the resurfacing body 46 is being implanted, it may be desired to insert the resurfacing body 46 to different distances in the facet joint. To facilitate accurately inserting the resurfacing body 46 to a desired depth, embodiments of the invention utilize implant insertion tools 330 and 340, as illustrated in Figs. 18 and 19. These implant insertion tools 330, 340 provide for selected countersinking of the resurfacing body 46 in the facet joint.

[0211] Other than the features set forth below, the implant insertion tools 330, 340 have a similar configuration to the implant insertion tool 310 illustrated in Fig. 17. The implant insertion tool 330 in Fig. 18 includes a countersink extension 332 that extends from the distal end thereof. The countersink extension 332 may have a concave end surface 334 that with a curvature that is similar to a curvature of the resurfacing body 46.

[0212] Similar to the embodiment in Fig. 17, an extension 336 is provided on the countersink extension 332 that facilitates attachment of the resurfacing implant 46 to the implant insertion tool 330.

[0213] The end surface 334 is spaced apart from the concave surface 322. In certain embodiments, the distance between the end surfaces may be between about 1 millimeter and about 10 millimeters. In other embodiments, the distance between the end surfaces may be about 3 millimeters.

[0214] The countersink extension 332 may have a width and a height that are smaller than the width and the height of the main portion 312. Such a configuration minimizes the potential of contact between the countersink extension 332 and the tissue within the facet joint, as such contact could cause undesirable side effects.

[0215] The implant insertion tool 340 in Fig. 19 is similar to the implant insertion tool 330 in Fig. 18 except that the countersink extension 342 is slightly longer. In certain embodiments, the countersink extension 342 may have a length of about 5 millimeters.

[0216] It is also possible to utilize a countersink positioner 350, as illustrated in Fig. 20 in conjunction with positioning the resurfacing body 46 at a desired location within the facet joint. The countersink positioner 350 is similar to the implant insertion tool 330 illustrated in Fig. 18 except that the countersink positioned 350 does not include an extension extending from a distal end thereof.

[0217] The countersink positioner 350 may thereby be utilized after the resurfacing body 46 has been inserted into the facet joint when it is recognized that the resurfacing body 46 is not inserted far enough into the facet joint. After removing the implant insertion tool 310 from the delivery cannula 280, the countersink positioner 350 is inserted into the delivery cannula 280.

[0218] Similar to the handle portion 314 on the implant insertion tool 310 limiting a distance that the implant insertion tool 310 may be inserted into the delivery cannula 280, the handle portion 352 on the countersink positioner 350 limits the distance that the countersink

positioner 350 may be inserted into the delivery cannula 280 so that the resurfacing body 46 may be accurately positioned within the facet joint.

[0219] In operation, an incision is made in the patient proximate to the facet joint where it is desired to implant the resurfacing body 46. The guide probe assembly 200 is inserted into the patient so that the guide probe tip 204 can be used to identify the joint line in the facet joint.

[0220] Next, the guide cannula 260 is slid over the guide probe assembly 200, as illustrated in Fig. 28, until the distal end of the guide cannula 260 is adjacent to the facet joint. The guide probe assembly 200 thereby enables the guide cannula 260 to be accurately and quickly placed in the location for the implanting process.

[0221] The guide probe assembly 200 is then withdrawn from the guide cannula 260 with care being exercised to maintain the guide cannula 260 in a stationary position with respect to the facet joint. Thereafter, the delivery cannula 280 is inserted into the guide cannula 260 until a rib 281 on the delivery cannula 280 engages the first stop mechanism 270, as illustrated in Fig. 23. The first stop mechanism 270 thereby limits the distance to which the delivery cannula 280 may be inserted into the guide cannula 260.

[0222] In this configuration, the leaflets 284 extend from the distal end of the guide cannula 260. As the distal end of the guide cannula 260 is adjacent to the facet joint, the leaflets 284 extend into the facet joint to cause a region to be formed where the resurfacing body 46 may be inserted in subsequent operations.

[0223] Next, the resurfacing body 46 is positioned adjacent to the distal end of the implant insertion tool 310 so that the extension 324 extends into the engagement feature 80, as illustrated in Fig. 22. The implant insertion tool 310 is then inserted into the proximal end of the delivery cannula 280.

[0224] When the implant insertion tool 310 is almost completely inserted into the delivery cannula 280, the resurfacing body 46 is recessed in the delivery cannula 280, as illustrated in Fig. 24.

[0225] In some embodiments, it may be desirable to use a leaflet spreader (not shown) that maintains the leaflets 284 in a spaced apart configuration such that the resurfacing body 46 may be positioned between the leaflets 284. If it is desired to use the leaflet spreader, the loading process may be changed slightly so that the resurfacing body 46 is attached to the implant insertion tool 310 and then the implant insertion tool 310 is inserted into the delivery cannula 280.

[0226] The insertion of the implant insertion tool 310 is continued until the resurfacing body 46 begins to extend from the distal end of the delivery cannula 280, as illustrated in Fig. 24. At this time, the shoulder 320 engages the second stop mechanism 272 to limit the distance to which the implant insertion tool 310 may be inserted into the delivery cannula 280. As noted above, the leaflets 284 are deflectable to provide a space for the resurfacing body 46 to be inserted into the facet joint.

[0227] Next, the delivery cannula 280 is urged away from the facet joint, as illustrated in Fig. 26. This motion causes the leaflets 284 to be retracted to within the delivery cannula 280. The facet joint returns to its initial position, which causes the resurfacing body 46 to fill the space between the bones.

[0228] In certain circumstances, it may be desirable to use a leaflet retractor tool 360 such as is illustrated in Fig. 27 to cause the delivery cannula 280 to be urged away from the facet joint. The leaflet retractor tool 360 includes a first handle section 362 and a second handle section 364 that are pivotally mounted with respect to each other.

[0229] The first handle section 362 engages the handle portion 314 on the implant insertion tool 310. In certain embodiments, the handle portion 314 may have an aperture that

extends therethrough and the first handle section 362 may be extended through the aperture to secure the leaflet retractor tool 360 with respect to the implant insertion tool 310.

[0230] Thereafter, an end of the second handle section 364 engages a lip 366 extending from the delivery cannula 280 proximate a proximal end thereof. The second handle section 364 is pivoted with respect to the first handle section 362 as indicated by arrow 368. This pivoting motion causes the delivery cannula 280 to be urged away from the facet joint so that the leaflets 284 are retracted to within the guide cannula 260. This motion is towards the facet joint to reduce the potential that the guide cannula 260 is moved from its desired position against the facet joint during the implanting process.

[0231] Thereafter, the implant insertion tool 310 may be separated from the resurfacing body 46 using a gentle pull away from the resurfacing body 46 to leave the resurfacing devices 42, 44 in the facet joint as illustrated in Fig. 29. The implantation process is thereby complete. Medical imaging may be used to evaluate whether the resurfacing body has been accurately implanted prior to removing the guide cannula 260 from adjacent to the facet joint.

[0232] In the preceding detailed description, reference is made to the accompanying drawings, which form a part hereof, and in which is shown by way of illustration specific embodiments in which the invention may be practiced. In this regard, directional terminology, such as "top," "bottom," "front," "back," "leading," "trailing," etc., is used with reference to the orientation of the Figure(s) being described. Because components of embodiments can be positioned in a number of different orientations, the directional terminology is used for purposes of illustration and is in no way limiting. It is to be understood that other embodiments may be utilized and structural or logical changes may be made without departing from the scope of the present invention. The preceding detailed

description, therefore, is not to be taken in a limiting sense, and the scope of the present invention is defined by the appended claims.

[0233] It is contemplated that features disclosed in this application, as well as those described in the above applications incorporated by reference, can be mixed and matched to suit particular circumstances. Various other modifications and changes will be apparent to those of ordinary skill.

[0234] The term "comprising" as used in this specification and claims means "consisting at least in part of". When interpreting statements in this specification and claims which include "comprising", other features besides the features prefaced by this term in each statement can also be present. Related terms such as "comprise" and "comprised" are to be interpreted in a similar manner.

[0235] In this specification, where reference has been made to patent specifications, other external documents, or other sources of information, this is generally for the purpose of providing a context for discussing the features of the invention. Unless specifically stated otherwise, reference to such external documents is not to be construed as an admission that such documents, or such sources of information, in any jurisdiction, are prior art, or form any part of the common general knowledge in the art.

THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:

1. A system for treating a facet joint of a patient, wherein the facet joint includes a superior articular face and an inferior articular face, wherein the system comprises:

an implant that is configured to be positioned between a superior articular face of a facet joint and an inferior articular face of the facet joint, wherein the implant has a plurality of teeth on at least one surface thereof, wherein the implant exhibits sufficient flexibility to transition from a relatively flat state to an inserted state in which the implant substantially matches any multi-planar curvatures of the superior articular face and wherein the implant comprises a first engagement feature;

an implant insertion tool that is adapted to engage the implant, wherein the implant insertion device comprises a second engagement feature that is capable of mating with the first engagement feature and wherein a force to separate the first engagement feature and the second engagement feature after mating is at least 1 Newton; and

a guide cannula having an internal passage extending therethrough, wherein the guide cannula passage is adapted to receive at least a portion of the implant and the implant insertion tool.

2. The system of claim 1, wherein the implant comprises a first resurfacing portion and a second resurfacing portion.

3. The system of claim 1, wherein:

the first engagement feature comprises a first aperture region and a second aperture region, wherein the first aperture region intersects an edge of the implant and

wherein the second aperture region is in communication with the first aperture region; and

the second engagement feature comprises a first extension region and a second extension region, wherein the second extension region is attached to the implant insertion device and wherein the first extension region is attached to the second extension region opposite the implant insertion device.

4. The system of claim 1, wherein the implant insertion tool further comprises:

a main portion having a proximal end and a distal end;

a handle portion attached to the main portion proximate the proximal end; and

a shoulder portion extending from at least one of the main portion and the handle portion, wherein the shoulder portion has a width that is greater than a width of the main portion.

5. The system of claim 1, wherein the implant and the implant insertion tool are slidably mounted with respect to the guide cannula and wherein the guide cannula has a concave distal surface that at least partially conforms to an edge of the implant.

6. The system of claim 1, and further comprising a guide probe assembly that includes a guide probe tip, wherein the guide probe assembly has a width that is smaller than a width of the guide cannula passage, wherein the guide probe assembly has a height that is smaller than a height of the guide cannula passage, wherein the guide probe tip is removably mounted to the guide probe assembly and wherein a width of the guide probe tip is smaller than the width of the guide probe assembly and wherein a height of the guide probe tip is smaller than the height of the guide probe assembly.

7. The system of claim 1, and further comprising a delivery cannula having an internal passage extending therethrough, wherein the delivery cannula passage is adapted to receive at least a portion of the implant and the implant insertion tool and wherein the guide cannula passage is adapted to receive the delivery cannula, wherein the delivery cannula comprises a pair of leaflets mounted proximate a distal end thereof and wherein the leaflets are fabricated from a resilient material and wherein the guide cannula is slidably mounted with respect to the delivery cannula and wherein the implant and the implant insertion tool are slidably mounted with respect to the delivery cannula.

8. The system of claim 1, and further comprising a retractor tool that comprises:

a first handle section that is capable of engaging the implant insertion tool; and

a second handle section operably connected to the first handle section, wherein the second handle section is capable of engaging the delivery cannula and wherein the first handle section is pivotally mounted to the second handle section.

9. A system for treating a facet joint of a patient, wherein the facet joint includes a superior articular face and an inferior articular face, wherein the system comprises:

an implant configured to selectively conform to a shape of at least one of a superior articular face of a facet joint and an inferior articular face of the facet joint, wherein the implant comprises a first engagement feature; and

an implant insertion device having a second engagement feature that is capable of mating with the first engagement feature, wherein a force to separate the first engagement feature and the second engagement feature after mating is at least 1 Newton.

10. The system of claim 9, wherein:

the first engagement feature comprises a first aperture region and a second aperture region, wherein the first aperture region intersects an edge of the implant and wherein the second aperture region is in communication with the first aperture region; and

the second engagement feature comprises a first extension region and a second extension region, wherein the second extension region is attached to the implant insertion device, wherein the first extension region is attached to the second extension region opposite the implant insertion device, wherein a width of the first aperture region is smaller than a width of the second aperture region, wherein a width of the first extension region is larger than a width of the second extension region and wherein the width of the first aperture region is larger than the width of the first extension region.

11. The system of claim 9, wherein the implant comprises a first resurfacing portion and a second resurfacing portion, wherein the first engagement feature is formed in at least one of the first resurfacing portion and the second resurfacing portion, wherein first resurfacing body and the second resurfacing body each comprise a first side and a second side, wherein the first side has a plurality of teeth extending therefrom, wherein the second side is substantially flat, wherein the first resurfacing body exhibits sufficient flexibility to transition from a relatively flat state to an inserted state in which the first resurfacing body substantially matches any multi-planar curvatures of the superior articular face; and wherein the second resurfacing body exhibits sufficient flexibility to transition from a relatively flat state to an

inserted state in which the second resurfacing body substantially matches any multi-planar curvatures of the inferior articular face.

12. The system of claim 11, wherein the plurality of teeth comprise a first set of teeth, a second set of teeth and a third set of teeth, wherein the first set of teeth are oriented differently than the second set of teeth and the third set of teeth, wherein the first resurfacing body and the second resurfacing body each define an anchoring surface and an articulating surface and wherein the system is configured such that upon insertion into a facet joint, the articulating surfaces abut one another in a sliding interface.

13. The system of claim 11, wherein an end of the implant insertion device includes a concave region that corresponds to at least a portion of an edge of the implant, wherein the implant exhibits a Conformability Factor of not more than 100 N, wherein the implant is formed of polyetherketone-based plastic, wherein at least one of the teeth is defined by a leading face and a trailing face, an angle defined by the leading face and a plane of the first major surface being smaller than an angle defined by the trailing face and the plane of the first major surface such that the at least one tooth more overtly resists movement of the corresponding resurfacing body relative to a corresponding facet joint articular face in a first direction as compared to a second, opposite direction and wherein the plurality of teeth include:

a first teeth set, each tooth of the first teeth set defining a first angle of extension relative to the second major surface; and

a second teeth set, each tooth of the second teeth set defining an angle of extension relative to the first major surface differing from the first angle of extension, wherein each tooth of the first teeth set includes a leading face more proximate

the leading end and a trailing face more proximate the trailing end, the leading and trailing faces intersecting at a tip opposite the first major surface, and further wherein a length of the leading face is greater than a length of the trailing face such that the corresponding tooth defines a direction of insertion of the corresponding resurfacing body from the leading end to the trailing end and wherein the base web defines a substantially uniform thickness and the plurality of teeth include a first tooth proximate the leading end and a second tooth proximate the trailing end, a height of the first tooth being greater than a height of the second tooth.

14. A kit for treating a facet joint of a patient, wherein the facet joint comprises a superior articular face and an inferior articular face, wherein the kit comprises:

a superior implant configured to selectively transition to a shape that at least partially conforms to a shape of a superior articular face of a facet joint;

an inferior implant configured to selectively transition to a shape that at least partially conforms to a shape of an inferior articular face of the facet joint, wherein the superior implant is separate from the inferior implant; and

an insertion tooling set comprising:

a delivery cannula having an internal passage,

a guide cannula having an internal passage; and

an implant insertion device sized to be slidably received within the delivery cannula passage;

wherein the kit is configured to provide an insertion arrangement in which the superior implant, the inferior implant and the implant insertion device are slidably received within the delivery cannula passage, wherein the superior implant and

the inferior implant are stacked against one another adjacent a distal region of the implant insertion device.

15. The kit of claim 14, wherein at least one of the superior implant and the inferior implant comprises a first engagement feature, wherein the implant insertion device comprises a second engagement feature that is capable of mating with the first engagement feature, wherein a force to separate the first engagement feature and the second engagement feature after mating is at least 1 Newton and wherein the superior implant and the inferior implant are each formed of a polyetherketone-based material.

2011265712 14 Jan 2013

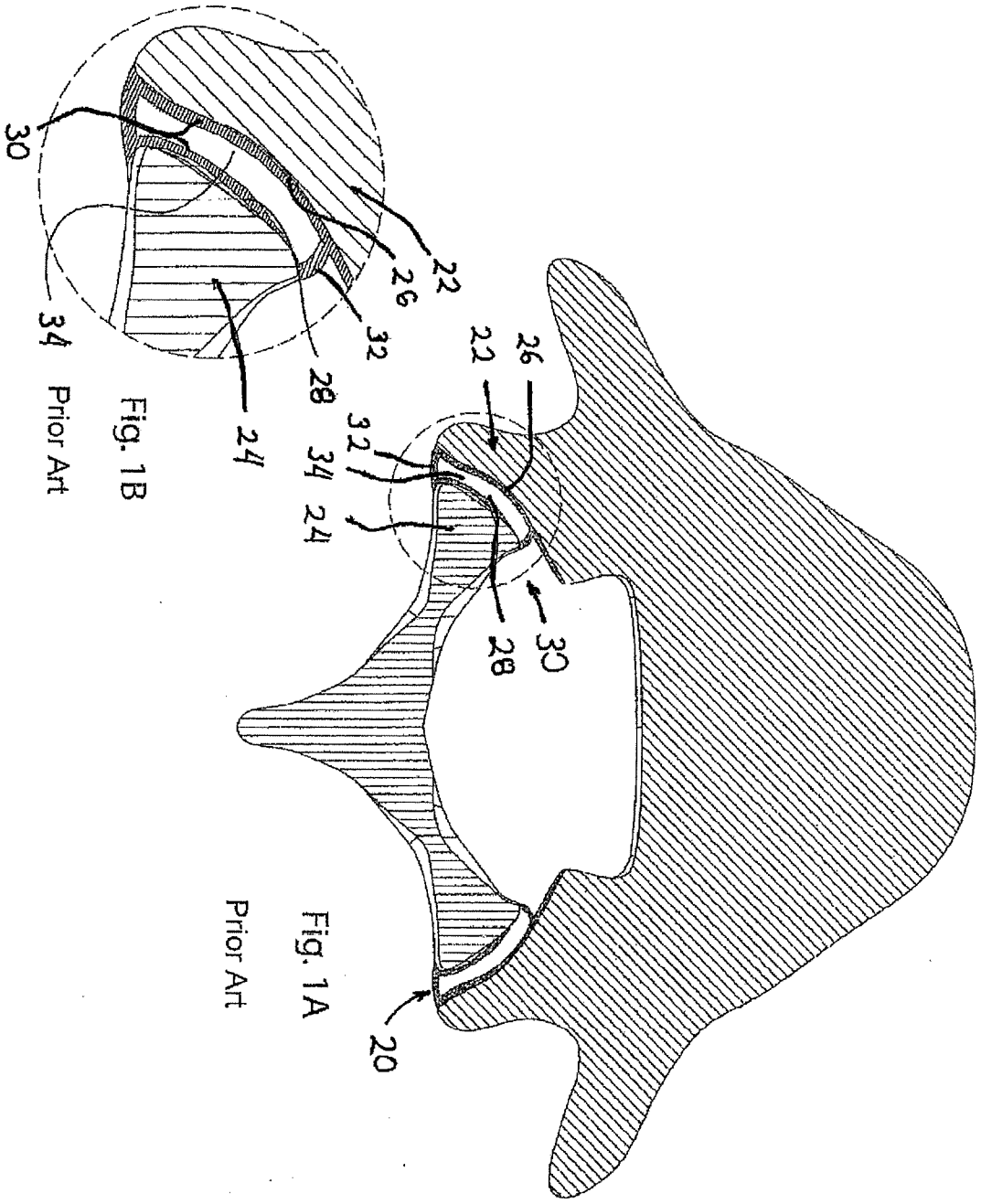

Fig. 1A Prior Art

Fig. 1B Prior Art

2011265712 14 Jan 2013

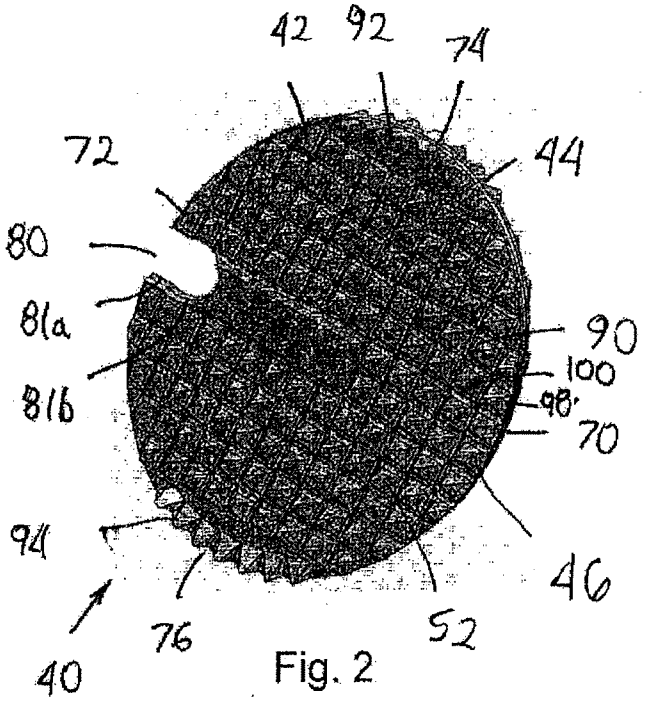

Fig. 2

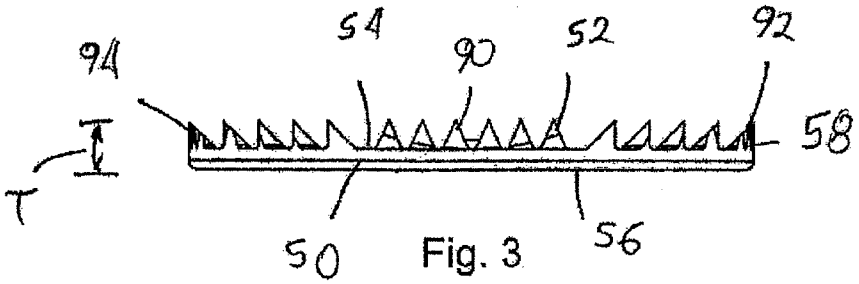

Fig. 3

2011265712 14 Jan 2013

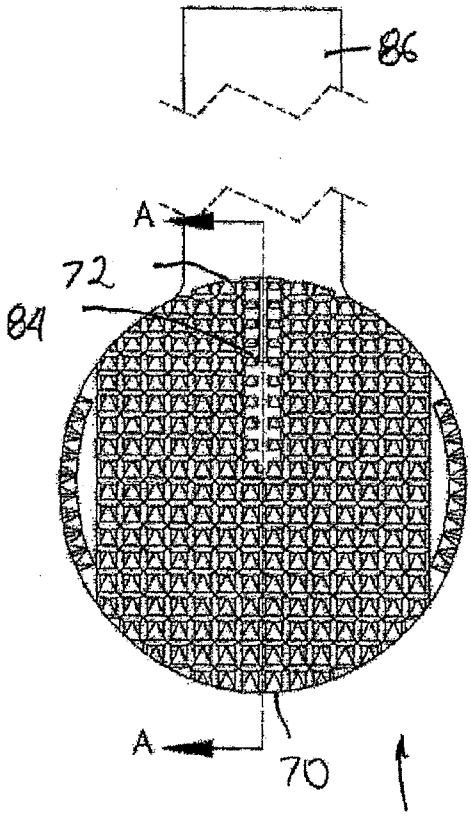

Fig. 4

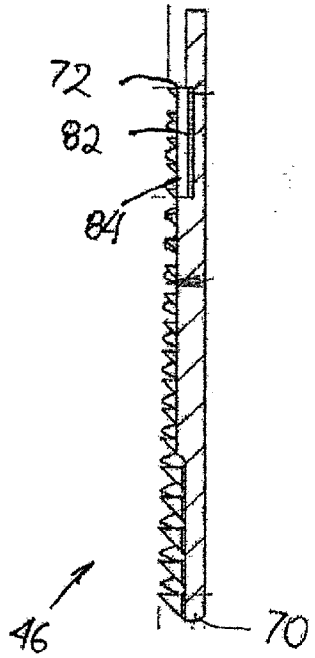

Fig. 5

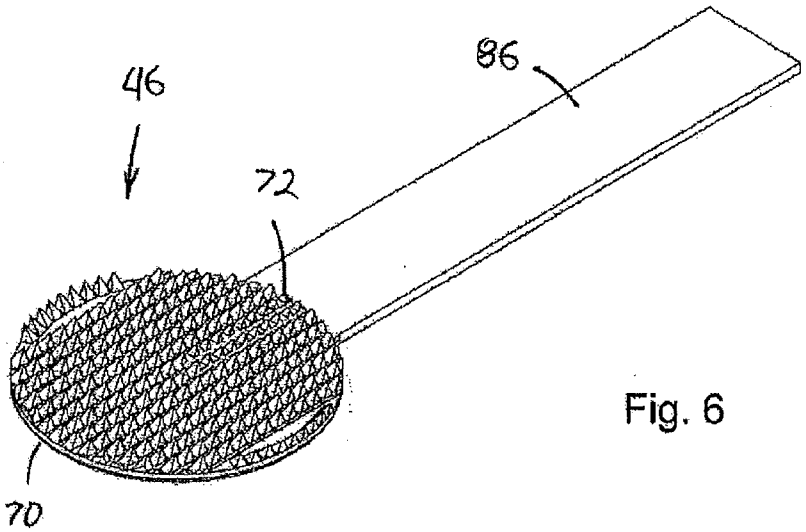

Fig. 6

2011265712 14 Jan 2013

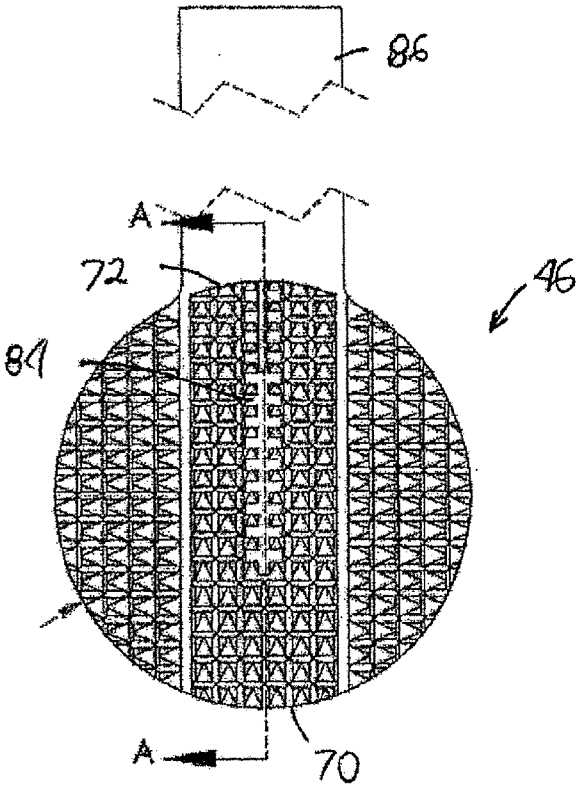

Fig. 7

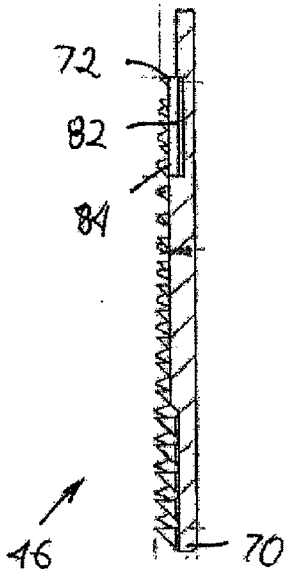

Fig. 8

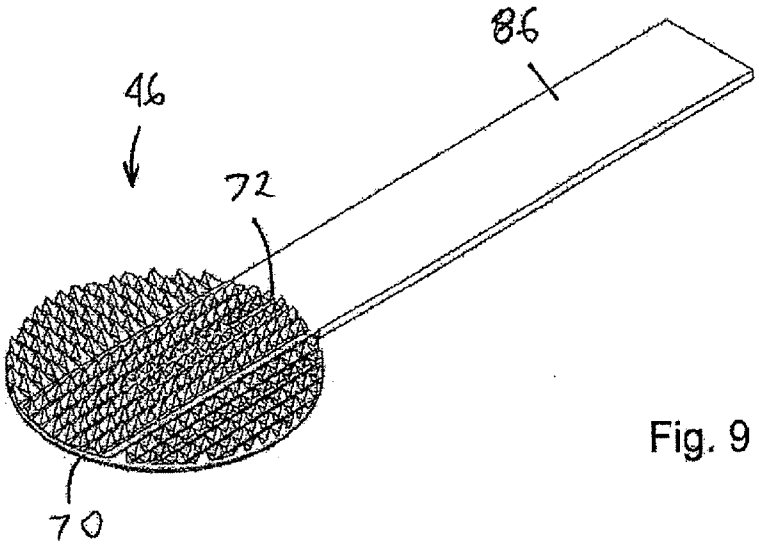

Fig. 9

2011265712 14 Jan 2013

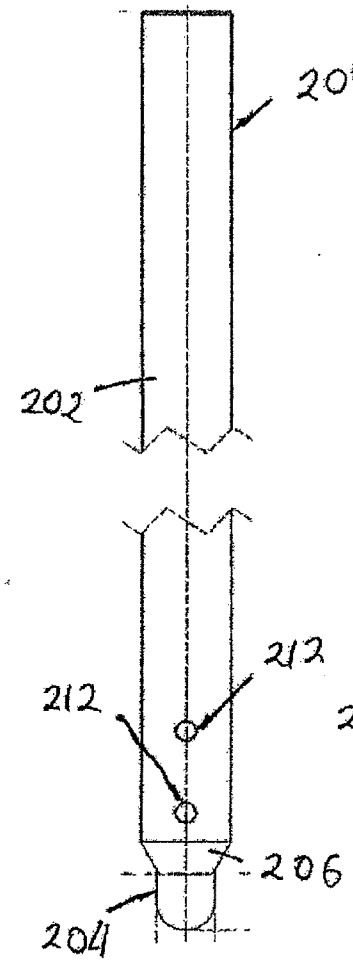

Fig. 10

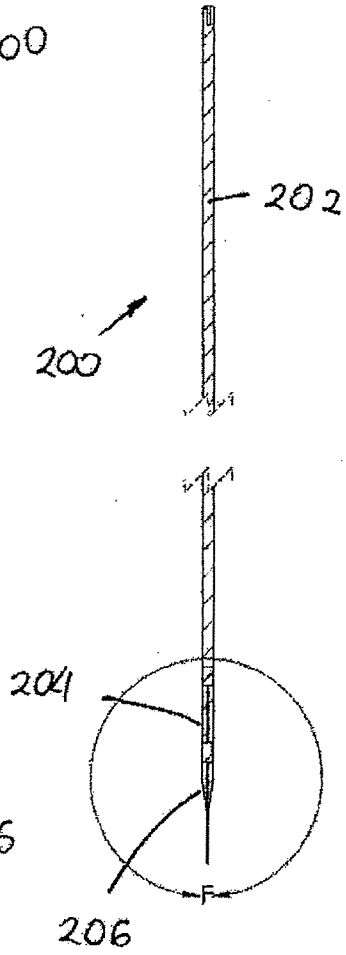

Fig. 11

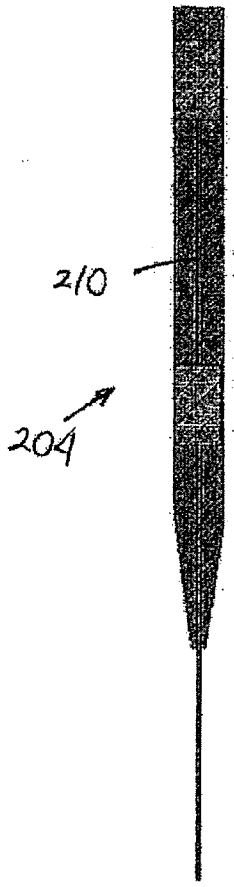

Fig. 12

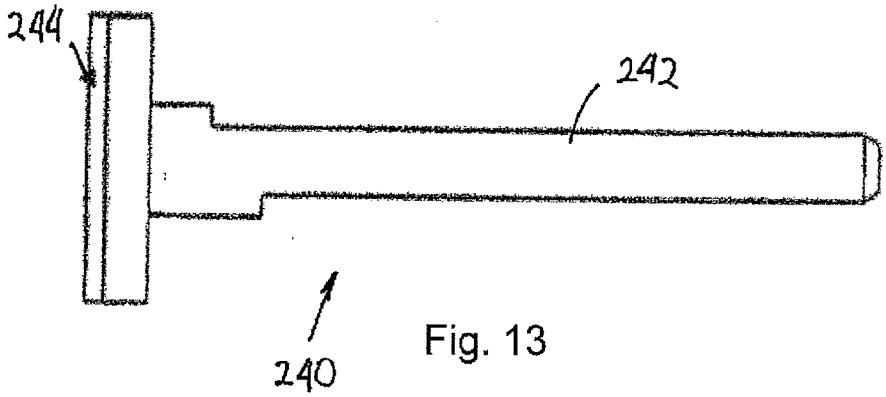

Fig. 13

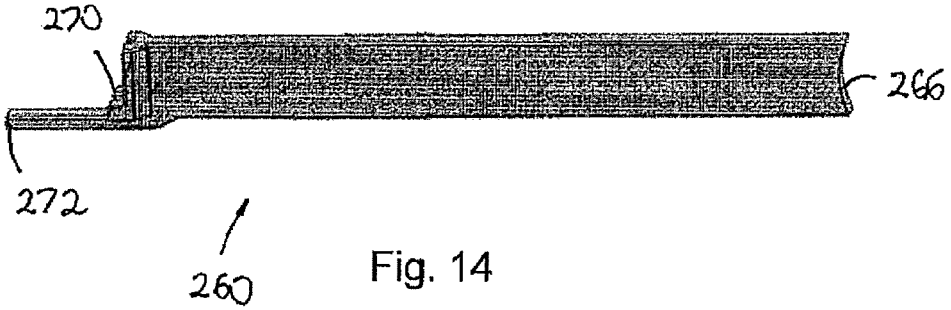

Fig. 14

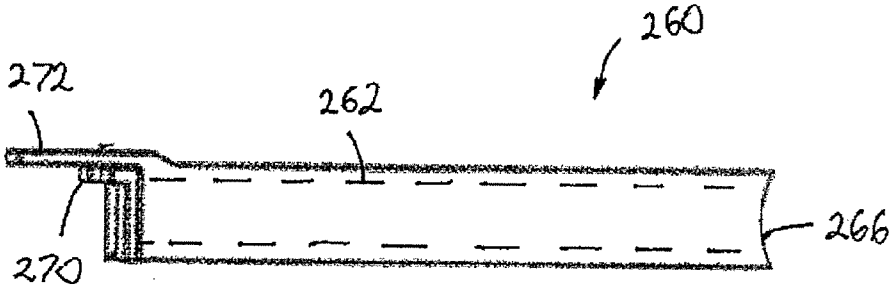

Fig. 15

2011265712 14 Jan 2013

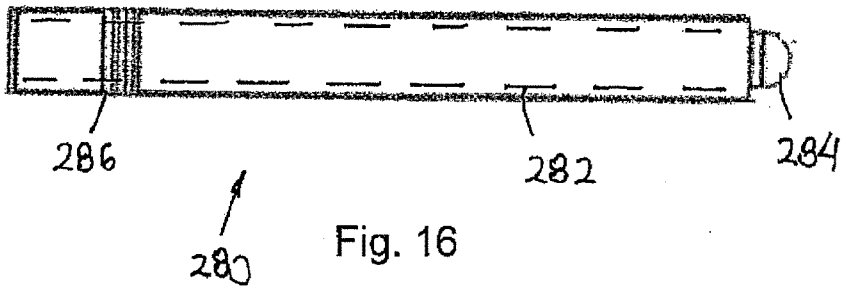

Fig. 16

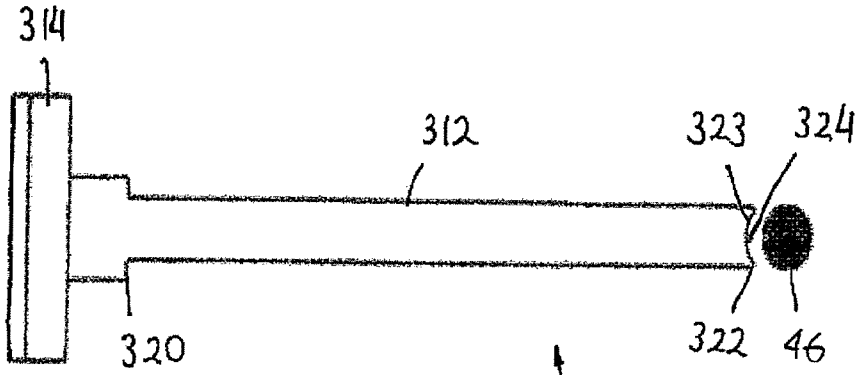

Fig. 17

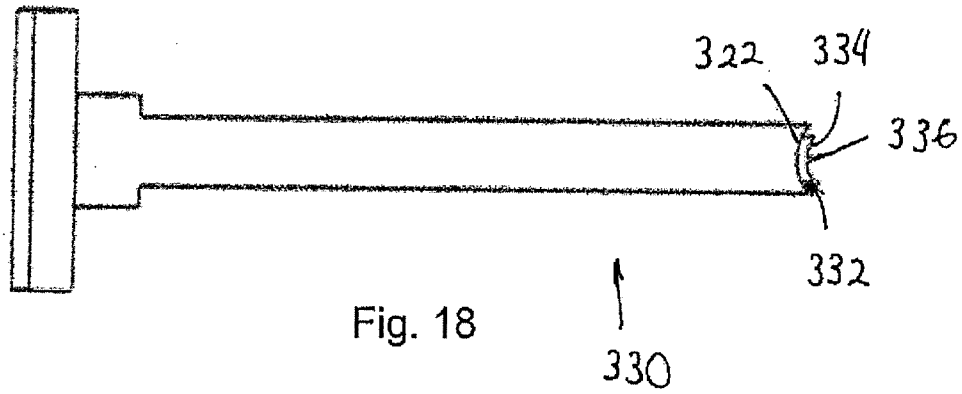

Fig. 18

2011265712 14 Jan 2013

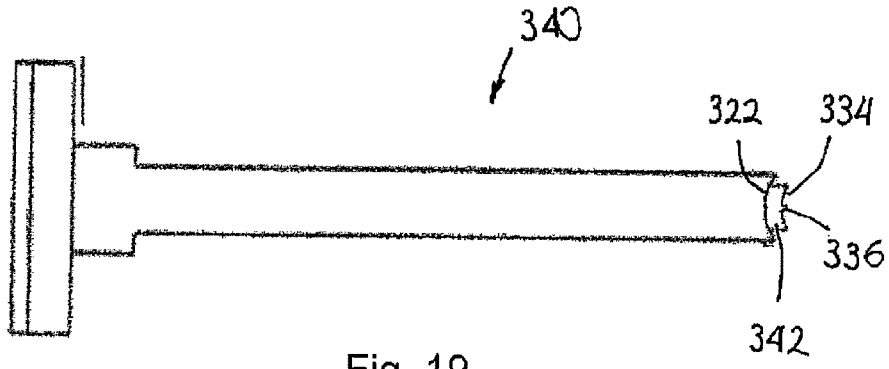

Fig. 19

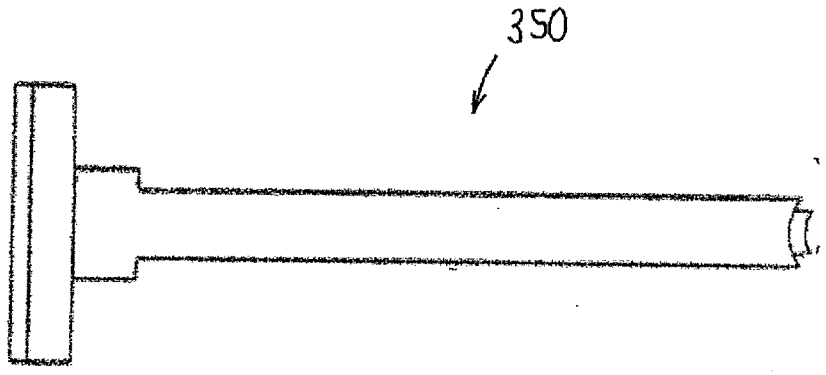

Fig. 20

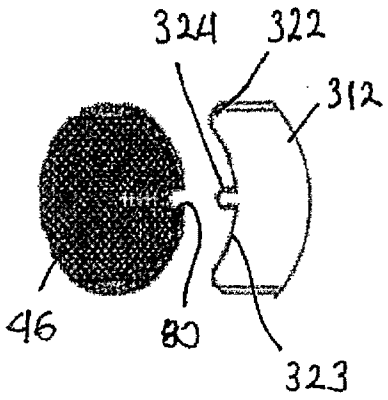

Fig. 21

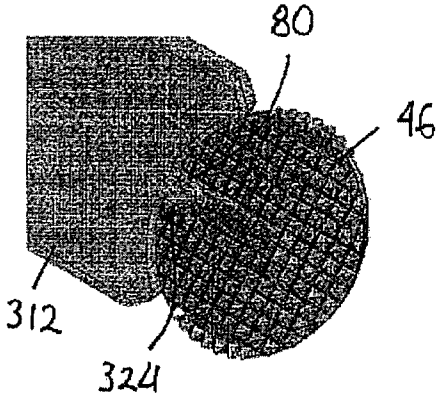

Fig. 22

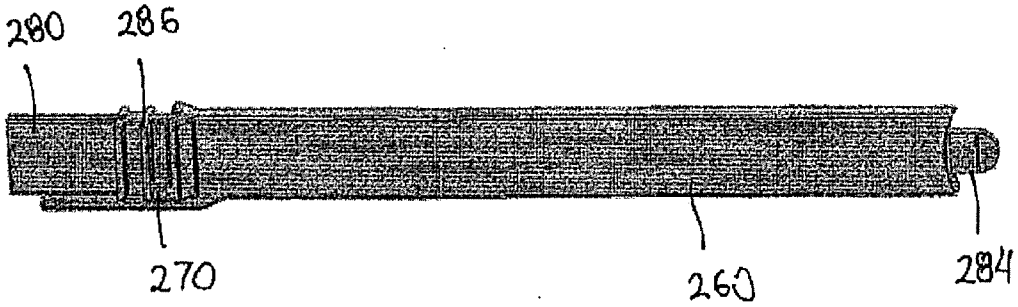

Fig. 23

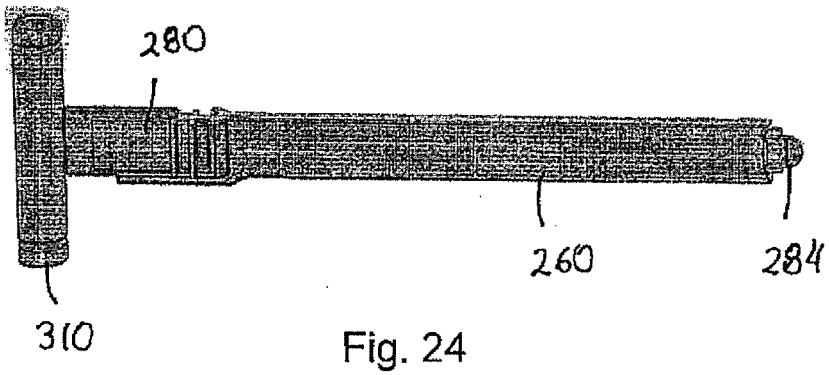

Fig. 24

2011265712 14 Jan 2013

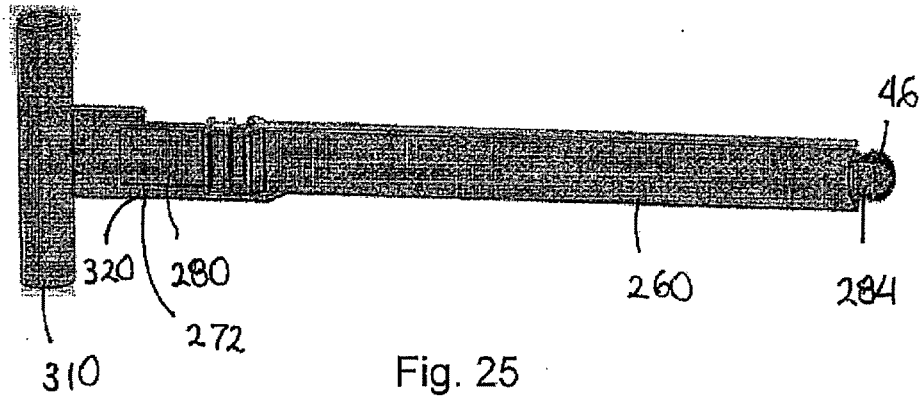

Fig. 25

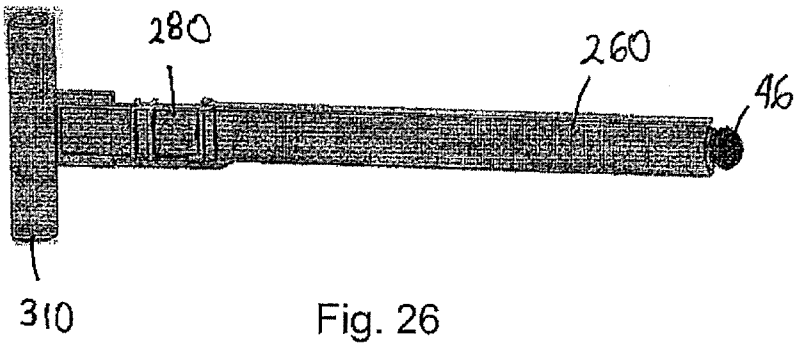

Fig. 26

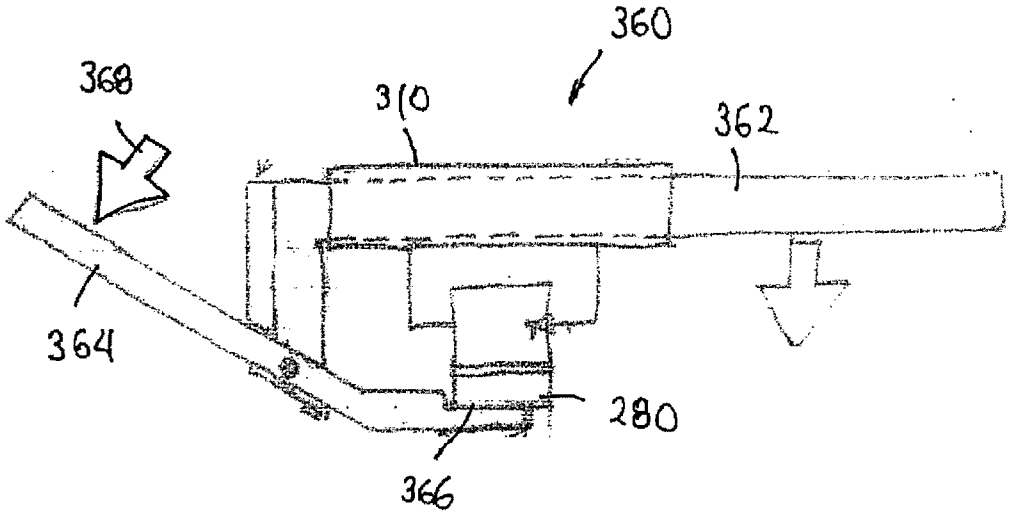

Fig. 27

2011265712 14 Jan 2013

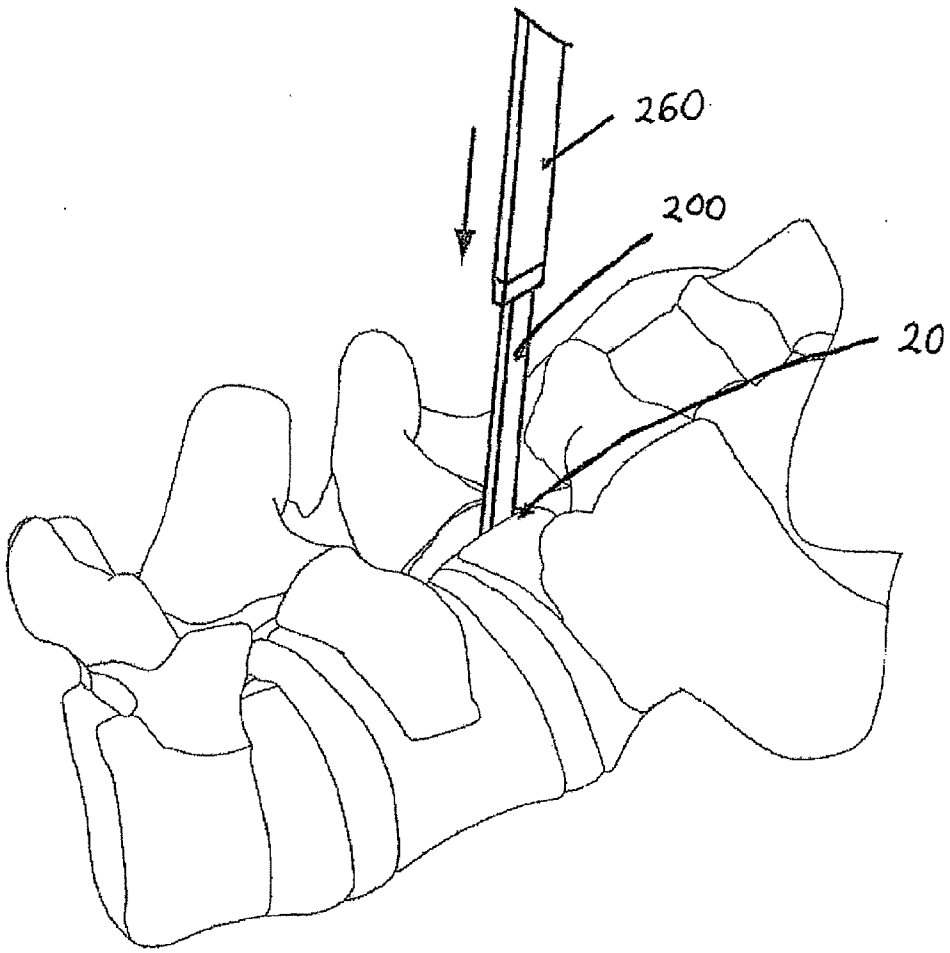

Fig. 28

2011265712 14 Jan 2013

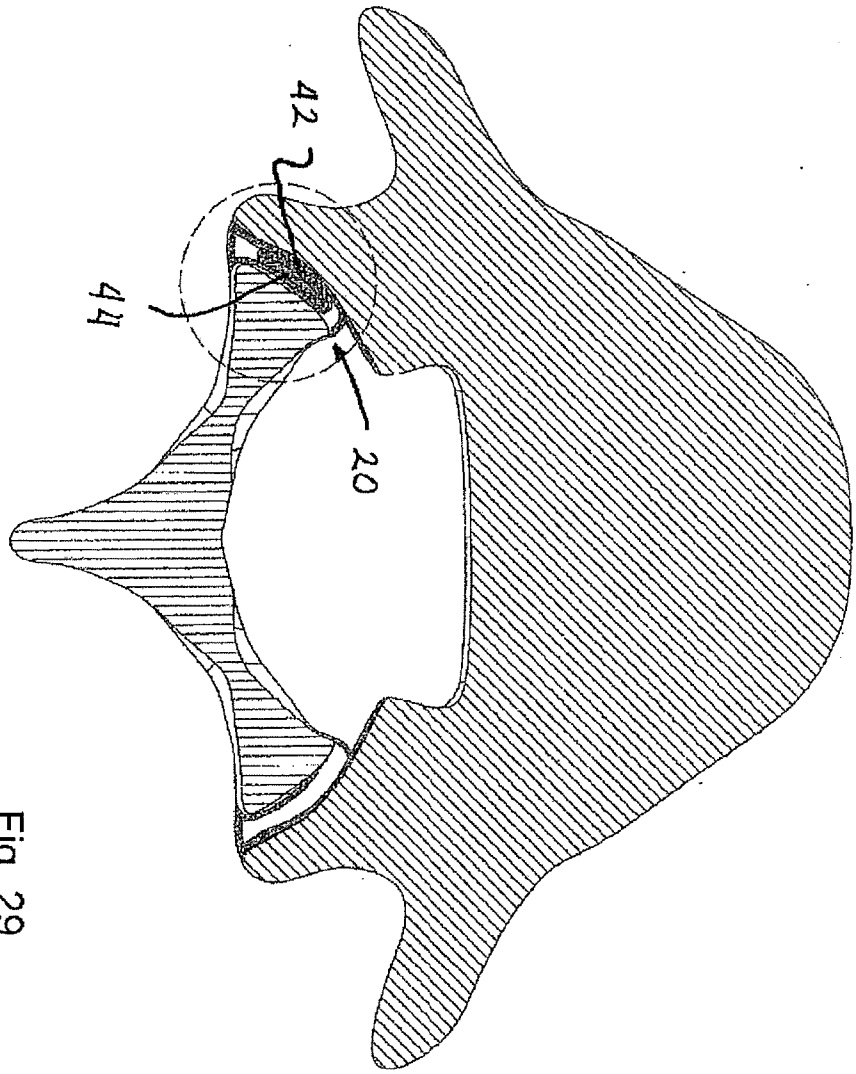

Fig. 29