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Spinal surgery methods and devices

Abstract

Disclosed methods, devices and systems are suitable for performing a minimally-invasive procedure for accessing the intervertebral space along an oblique pathway with an insertion instrument that holds a disc implant, and reorienting the angular relationship between instrument and implant while the implant is inside the body (for example at or within the disc space).

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Background/Summary

CROSS-REFERENCE TO RELATED APPLICATIONS (1) This application is a continuation of U.S. patent application Ser. No. 17/209,874 (now U.S. Pat. No. 11,969,359) filed on Mar. 23, 2021, which is a divisional application of U.S. patent application Ser. No. 16/149,108 (now U.S. Pat. No. 10,959,860) filed on Oct. 1, 2018, which is a continuation of U.S. patent application Ser. No. 15/235,957 (now U.S. Pat. No. 10,085,854) filed on Aug. 12, 2016, which is a continuation of U.S. patent application Ser. No. 13/239,014 (now U.S. Pat. No. 9,451,940) filed on Sep. 21, 2011, which is a continuation of U.S. patent application Ser. No. 13/133,909 having a 371(c) date of Sep. 23, 2011, which is a Rule 371 U.S. National Stage of International Patent Application No. PCT/US2009/069476 filed on Dec. 23, 2009, which claims priority to U.S. Provisional Patent Application No. 61/178,315, filed on May 14, 2009, and U.S. Provisional Patent Application No. 61/140,926, filed on Dec. 26, 2008, all of which are incorporated herein by reference.

BACKGROUND OF THE INVENTION
1. Field of the Invention
(1) Spinal surgery methods and devices are disclosed for repairing damaged or deteriorated vertebrae at the lower lumbar levels, such as in the L5-S1 intervertebral space.
2. Description of the Relevant Art
(2) The vertebral column is the central pillar of the body. It is a generally flexible column that bears tensile and compressive loads, permits bending motions, and provides an attachment site for ribs, muscles and other structures. The vertebral column includes irregular bones called vertebrae that are separated by fibrocartilaginous structures known as intervertebral discs. There are seven vertebral, twelve thoracic, five lumbar, five sacral, and four coccygeal vertebrae. A typical vertebra consists of a rounded anterior body and a posterior vertebral arch that together form a protective structure around the vertebral canal that contains the spinal cord.
(3) The intervertebral discs can be damaged or undergo degeneration, which often results in painful and sometimes debilitating nerve impingement syndromes. It is sometimes necessary to surgically replace the native disc with prosthetic disc implants to relieve the pain, restore the functional mechanics of the vertebral column, and promote fusion between adjacent vertebral bodies. Procedures such as total disc arthroplasty (disc replacement) have used a direct anterior approach orthogonal to the midline of the vertebral body, but such procedures require unfettered anterior spinal exposure for precise midline placement of the prosthetic disc. The major vascular structures that run along the anterior spine must be mobilized to achieve this exposure, which typically requires the assistance of a vascular surgeon. The procedure also causes significant surgical disruption of the anterior annular element around the disc.
(4) Bertagnoli has described an anterolateral transpsoatic approach (ALPA) for implantation of prosthetic disc replacement devices. The patient is positioned in a supine position on the operating table, with the arms in abduction. The target disc level is localized through bi-planar fluoroscopy, and an inflatable bladder is placed beneath the level of interest to permit additional lordosis. An anterolateral incision is made on the left side for access to lumbar intervertebral spaces, while the incision is made on the right side for access to L5-S1. The fascia of the external oblique muscle is opened along the direction of its fibers and the muscle is split. The retroperitoneal space is entered and the peritoneal sac mobilized away from the overlying fascia to develop an operative pathway along the anterior aspect of the psoas muscle to the lateral aspect of the intervertebral space. The

target zone for annulotomy is from the one o'clock to three o'clock position above the L5-S1 level, which leaves the anterior longitudinal ligament intact and avoids mobilizing the iliac vessels. At the L5-S1 level the target annulotomy zone is from the eight o'clock to ten o'clock position with mobilization of the iliac vessel toward the midline. Injury to the left iliac vessel is an unfortunate complication of such procedures. Additional information about anterolateral approaches to spinal surgery at the L4-L5 level is found in Bertognali et al, U.S. Pat. No. 7,326,216.

(5) A minimally invasive procedure promoted by Nuvasive, Inc. uses a direct lateral, retroperitoneal approach to access the intervertebral discs above the L5-S1 level with minimal muscular disruption. The patient is placed in a lateral decubitus position and the direct lateral incision is made in the axillary line. Another incision is made posterior to the lateral border of the erector spinae muscle, and finger dissection is conducted through this opening to the retroperitoneal space. The index finger of the surgeon sweeps the peritoneum anteriorly and palpates the psoas muscle. A dilator instrument is then introduced through the direct lateral incision and the index finger then guides the dilator instrument to the psoas muscle. The fibers of the psoas muscle are then split using blunt dissection and EMG monitoring to minimize damage to the nerves of the lumbar plexus that run through the posterior psoas muscle. A tissue distraction and tissue retraction assembly are then used to help establish an operative corridor to the direct lateral aspect of the intervertebral space at about the 3 o'clock position, as shown in U.S. Pat. No. 7,207,949. The direct lateral retroperitoneal approach to the L5-S1 space has not been possible because the anterior superior iliac spine obstructs a direct lateral approach to the L5-S1 intervertebral space. Hence approaches to the L5-S1 space typically use a standard anterior approach. For a laterally positioned patient, an extremely large sigmoidal incision has been required, with subsequent reflection of all the overlying musculature to expose the L5-S1 space.

(6) It would therefore be useful to provide a minimally invasive approach to the L5-S1 space that minimizes injury to the blood vessels and nerves around the vertebral bodies. It would also be helpful to perform such a procedure in a manner that minimizes retroperitoneal scarring and damage to other body structures. Minimally invasive surgical approaches to the intervertebral spaces in the past have also been limited by the need to insert the prosthetic disc implant either into the front portion, posterior portion, or the side of the disc space to achieve stable placement of the prosthetic implant. It would therefore be useful to have a procedure that could avoid such a limitation at any vertebral level.

SUMMARY OF THE INVENTION

(7) The inventor has found it is advantageous to provide a method, device and system that permit an angle between a disc implant and insertion instrument to be altered without removing the implant from the intervertebral space. This new surgical approach also removes the native disc contents from a generally lateral direction, which permits the peritoneal contents to fall out of the surgical field, while also taking advantage of the mechanics of anterior interbody surgery.

(8) Disclosed methods, devices and systems are suitable for performing a minimally-invasive procedure for accessing the intervertebral space along an oblique pathway with an insertion instrument that holds a disc implant, and reorienting the angular relationship between instrument and implant while the implant is inside the body (for example at or within the disc space). In some disclosed embodiments, a prosthetic disc implant is inserted diagonally within the disc space, and the implant is then pivoted to a medial-lateral orientation within the disc space. The invention is particularly useful for accessing the L5-S1 intervertebral space along an anterolateral pathway to the anterior aspect of the spine, placing a prosthetic disc implant diagonally within the intervertebral space, and pivoting the implant within the disc space. However the method can also be used at other vertebral levels. In one embodiment, the oblique pathway has a caudal or cephalad-directed component, and the implant can be repositioned into a transverse anatomic plane through the intervertebral space.

(9) In one embodiment, an implant is positioned in the intervertebral disc space of a laterally

positioned subject by accessing the anterior face of the spinal disc intervertebral space, between the L5 and S1 vertebrae, from an anterolateral retroperitoneal approach. An oblique operative corridor is then established to the anterior face of the spinal disc space by introducing a retractor instrument anterolaterally to the spinal disc space, for example anterior to the anterior superior iliac spine, and in some instances between the level of the anterior superior iliac spine and the anterior inferior iliac spine. The spinal disc contents are removed from the intervertebral space through the operative corridor, and an elongated implant is introduced through the operative corridor into the intervertebral space diagonally (at an angle). The elongated implant is then pivoted within the intervertebral space to eventually position the implant substantially medial-laterally within the intervertebral space and achieve midline symmetric distribution of the mechanical load on the implant. The ability to pivot the implant within the intervertebral space permits the elongated implant to be generally aligned with the insertion instrument and advanced into the body through a relatively narrow operative corridor, then turned to its final position within the intervertebral space.

(10) In a disclosed embodiment, the retractor instrument includes a proximal handle portion and a distal retractor blade portion that carries opposing ipsilateral and contralateral vascular retractor blades that are placed between the right and left iliac vessels and moved apart from one another to retract the right and left iliac vessels away from the anterior face of the spinal disc intervertebral space. A particular example of the retractor instrument has an ipsilateral arm on which the ipsilateral blade is mounted and a contralateral arm on which the contralateral blade is mounted. The retractor blades are placed between the right and left iliac vessels to move them away from one another to expose the anterior surface of the spine as the ipsilateral and contralateral arms of the retractor instrument move the retractor blades apart. For example, the blades of the retractor instrument are positioned at the anterior face of the vertebral body adjacent the anterior longitudinal ligament, and the retractor blades are spread to expose an area from about the 10 o'clock to 2 o'clock position of the vertebral body.

(11) The elongated implant may be advanced into the intervertebral space through the operative corridor defined by the arms of the retractor instrument by securing the implant to a distal end of an elongated rigid introducer instrument and advancing the implant on the introducer instrument through the operative corridor to the anterior face of the intervertebral space at an oblique angle so that the implant enters the disc space diagonally. The angle between the implant and the introducer is then selectively changed to pivot the implant in one or more subsequent steps into the medial-lateral position for symmetric midline placement within the intervertebral space. In some embodiments the introducer instrument has a distal docking element that selectively docks with an interface element of the implant in a series of preselected positions to alter the angle between the implant and the introducer instrument. For example, the docking element is a plurality of docking pins on the tip of the introducer element, and the interface element is a corresponding series of docking holes that cooperatively mate to hold the implant in preselected angular orientations to the introducer instrument.

(12) In some disclosed embodiments, the implant is an elongated elastomeric member that has a top bearing face, a bottom bearing face, a front face, a rear face, an ipsilateral face and a contralateral face. The rear face of the implant may be substantially flat. The contralateral face of the implant may be rounded (particularly at its corners that adjoin the front and rear faces) to minimize trauma induced by advancing the implant diagonally into the intervertebral space at the oblique angle, and using the ipsilateral face to function as an impact hinge or pivot point as the implant is moved in one or more realignments from the oblique to medial-lateral orientation. The ipsilateral end of the implant may have a pivot axis and an interface element, such as multiple pairs of spaced docking holes arranged on a curved surface that extends partially circumferentially around the pivot axis. The selected pairs of spaced docking holes are positioned to mate with the docking element of the introducer instrument, such as a pair of docking pins that extend from a distal tip of the introducer instrument.

(13) In some embodiments the implant tapers in height from its front face to rear face, and/or medially to laterally, and it may be a partially hollow member in which the top face and bottom face are substantially open and separated by an internal divider wall that extends from the front face to the rear face to form a contralateral and ipsilateral window though the implant to promote the growth of bone within the implant. In some disclosed embodiments, the implant is a slightly compressible member in which the front face is convex and the ipsilateral face includes the interface element that mates with the docking element. The external surfaces of the implant (such as the top and bottom faces of the implant) have protuberances that help frictionally engage the implant to adjoining vertebral bodies, and also promote bone growth into the implant. The protuberances may have a variety of shapes, such as grooves or corrugations, but a frustopyramidal protuberance is believed to be particularly suitable. The retractor instrument may also take a variety of forms, but certain disclosed embodiments have an ipsilateral arm that is shorter than the contralateral arm. A retractor blade on the ipsilateral arm therefore extends a shorter distance from the handle than the retractor blade on the contralateral arm. This asymmetric arrangement permits the retractor instrument to be advanced diagonally through the body from an anterolateral entrance point through the abdominal wall to the anterior aspect of the vertebral body. Since the contralateral arm is longer than the ipsilateral arm, the retractor blades at the anterior vertebral body span the anterior face of the vertebral body, for example from the 10 o'clock to 2 o'clock positions. The retractor blades may be curved outwardly from a longitudinal axis of the retractor instrument to help minimize damage to the blood vessels as they are retracted. A thin shim with a tapered tip may be inserted into the intervertebral space and mounted to the ipsilateral blade to retain the instrument in its desired angular orientation and distract adjacent vertebral bodies (such as L5 and S1) apart from one another during the procedure. The shim curves inwardly into the disc space, toward the midline of the body, away from the ipsilateral retractor blade, and toward a longitudinal axis of the retractor instrument. The shim has a height sufficient to maintain the adjacent vertebral bodies spaced from one another while a trial spacer and subsequent disc implant are pivoted into place within the disc space. The present disclosure also includes a system for positioning an implant in an intervertebral space of a subject. In certain disclosed embodiments, the system includes the retractor instrument for establishing an operative corridor to the anterior face of the intervertebral space. The retractor instrument has a proximal handle portion and a distal retractor blade portion that includes opposing ipsilateral and contralateral arms that are movable toward and away from one another to define a portion of the operative corridor therebetween. In certain embodiments, the ipsilateral retractor blade is carried by the ipsilateral arm, and a contralateral vascular retractor blade is carried by the contralateral arm. The contralateral arm and blade are longer than the ipsilateral arm and blade so that the retractor instrument can be introduced at an oblique angle with the two retractor blades spaced apart on the anterior aspect of the vertebral body.

(14) The system also includes the introducer instrument for advancing an elongated prosthetic spinal disc implant between the arms and blades of the retractor instrument to the intervertebral space at an oblique angle so that the implant enters the intervertebral space diagonally. The introducer instrument is capable of pivoting the implant in the intervertebral space, for example by connecting docking pins on a tip of the introducer instrument to different sets of corresponding docking holes on the implant. The docking pins selectively mate with the different sets of docking holes on the implant to maintain the implant at different fixed angles to the introducer instrument. By mating the docking pins with different docking holes, the implant can be pivoted within the intervertebral space to move it from its initial diagonal orientation to a medial-lateral orientation generally symmetric with respect to the axis of the vertebral column. In certain embodiments, the system also includes the implant which has a top bearing face, a bottom bearing face, a front face, a rear face, an ipsilateral face and a contralateral face. The implant's contralateral face may be rounded to minimize trauma induced by advancing the implant diagonally into the intervertebral space and pivoting it around a pivot axis within the intervertebral space. The implant has an

interface element for coupling with the introducer instrument and pivoting the implant within the disc space. For example, the interface element includes multiple pairs of spaced docking holes arranged on a curved surface that extends partially circumferentially around the pivot axis, and selected pairs of spaced docking holes are positioned to mate with the docking element of the introducer instrument. In certain disclosed embodiments, the implant tapers in height from the front face to the rear face. The implant may also be a partially hollow member in which the top face and bottom face are substantially open and may be separated by an internal divider wall that extends from the front face to the rear face to define the ipsilateral and contralateral windows therebetween for promoting tissue growth within the implant.

(15) Another aspect of the invention is the prosthetic implant itself, the retractor itself, and the introducer element itself.

Description

BRIEF DESCRIPTION OF THE DRAWINGS

(1) Advantages of the present invention will become apparent to those skilled in the art with the benefit of the following detailed description of embodiments and upon reference to the accompanying drawings in which:

(2) FIG. **1**A illustrates a patient positioned in a right lateral decubitis position for minimally-invasive spinal surgery using a retroperitoneal approach;

(3) FIG. **1**B is a schematic top view illustrating the anatomy of the L5 vertebra;

(4) FIG. **1**C is a schematic perspective view of the human body illustrating several anatomic reference planes;

(5) FIG. **2**A is a schematic cross-sectional view of the abdomen at the level of the L5-S1 intervertebral space illustrating the left anterolateral displacement of the peritoneum and the right anterolateral introduction of a dilator through an incision toward the L5-S1 space under the guidance of a surgeon's finger introduced through a lateral incision;

(6) FIG. **2**B is an isolated perspective view illustrating the components and use of an initial distraction assembly that includes a K-wire, an initial dilating cannula with handle, and a split-dilator housed within the initial dilating cannula;

(7) FIG. **2**C is an isolated perspective view illustrating the K-wire and split-dilator of the initial distraction assembly with the initial dilating cannula and handle removed;

(8) FIG. **3**A is a view similar to FIG. **2**A, but showing introduction of a minimally invasive retractor instrument through the right anterolateral incision, and its positioning at the L5-S1 intervertebral space with the right and left iliac vessels retracted away from the anterior spine;

(9) FIG. **3**B is an isolated schematic end view of the retractor blades on the retraction instrument, illustrating the greater curvature of the shorter retraction blade;

(10) FIG. **4**A is a front elevation view of a shim for placement on the ipsilateral blade of the retractor instrument;

(11) FIG. **4**B is a side view of the shim of FIG. **4**A;

(12) FIG. **4**C is a top view of the shim of FIGS. **4**A and **4**B;

(13) FIG. **5**A is a perspective fragmentary view of the pelvis and the sacro-lumbar segment of the spinal column illustrating the bifurcation of the iliac vasculature along the anterior aspect of the spinal column;

(14) FIG. **5**B is a front view of FIG. **5**A with the iliac vessels retracted to expose the L5-S1 disc space;

(15) FIG. **6** is a perspective view of an introducer instrument for guiding an implant to a spinal disc space, showing the implant connected to the introducer instrument for movement about a pivot axis;

(16) FIG. **7** is an isolated perspective view of the introducer instrument;
(17) FIG. **8** is an enlarged, fragmentary view of the tip of the introducer instrument of FIG. **7** illustrating the instrument interface of the implant, and showing the pins on the distal tip of the instrument for connection to positioning holes on the implant;
(18) FIG. **9** is an enlarged, fragmentary view of the implant held in a fixed angular position relative to the introducer element by the pins of the instrument interface locked into a preselected set of positioning holes on the implant;
(19) FIG. **10**A is a perspective view of a first embodiment of the implant, showing the implant interface surface in which pairs of pin receiving holes are arranged at different angles around the interface surface to hold the implant at variable fixed angles relative to the longitudinal axis of the introducer instrument;
(20) FIG. **10**B is an end view of the implant of FIG. **10**A, illustrating a tapered height of the implant;
(21) FIG. **11**A is a top view of an embodiment of an implant;
(22) FIG. **11**B is a side view of an embodiment of the implant of FIG. **11**A;
(23) FIG. **11**C is an end view of an embodiment of the implant of FIG. **11**A;
(24) FIG. **12** is a perspective view of a second embodiment of the implant;
(25) FIG. **13** is a schematic top perspective view of the pelvis with a retractor instrument introduced obliquely into the subject's body along an anterolateral operative trajectory, and with the introducer instrument advanced through the operative corridor defined by the retractor instrument. A trial spacer is attached to the distal end of the introducer instrument for introduction diagonally into the L5-S1 intervertebral space;
(26) FIG. **14**A is an enlarged top view of the L5-S1 disc space shown in FIG. **13**, illustrating the rounded contralateral face of the trial spacer impacting the far lateral aspect of the apophyseal ring;
(27) FIG. **14**B is a view similar to FIG. **14**A, but illustrating adjustment of the angle between the introducer instrument and the body of the trial spacer by repositioning the pins on the tip of the instrument in a different set of pin receiving holes on the trial spacer;
(28) FIG. **14**C is a view similar to FIG. **14**A, but illustrating progressive reorientation of the trial spacer in a generally medial-lateral orientation within the intervertebral space;
(29) FIG. **15** is a view similar to FIG. **13**, but showing a subsequent step of the procedure in which the introducer instrument has advanced an implant to the disc space;
(30) FIGS. **16**A, **16**B and **16**C are top views of the L5-S1 disc space, illustrating progressive reorientation of the implant within the disc space by repositioning of the pins on the tip of the introducer instrument in different sets of pin receiving holes on the implant;
(31) FIG. **17** is an enlarged top view of the L5-S1 disc space illustrating the implant in position within the disc space;
(32) FIG. **18**A is a front elevation view of a shim for placement on the ipsilateral blade of the retractor instrument;
(33) FIG. **18**B is a side view of the shim of FIG. **18**A;
(34) FIG. **18**C is a top view of the shim of FIGS. **4**A and **4**B;
(35) FIG. **19**A is a perspective view of an embodiment of an implant;
(36) FIG. **19**B is a side view of an embodiment of the implant of FIG. **19**A;
(37) FIG. **19**C is an end view of an embodiment of the implant of FIG. **19**A;
(38) FIG. **20** is a top view of the L5-S1 disc space, illustrating orientation of the implant of FIG. **11**A within a disc space;
(39) FIG. **21** is a perspective view of a portion of a retraction instrument with a pair of blades provided at a distal end;
(40) FIG. **22** is a top view of the retraction instrument of FIG. **21**, showing a mechanism for moving the retractor blades;
(41) FIG. **23**A is a perspective view of a blade for use with a retraction instrument;

(42) FIG. **23**B is a rear view of the blade of FIG. **23**A; and
(43) FIG. **23**C is a top view of the blade of FIG. **23**A.
(44) While the invention may be susceptible to various modifications and alternative forms, specific embodiments thereof are shown by way of example in the drawings and will herein be described in detail. The drawings may not be to scale. It should be understood, however, that the drawings and detailed description thereto are not intended to limit the invention to the particular form disclosed, but to the contrary, the intention is to cover all modifications, equivalents, and alternatives falling within the spirit and scope of the present invention as defined by the appended claims.

DETAILED DESCRIPTION OF THE EMBODIMENTS

(45) It is to be understood the present invention is not limited to particular devices or methods, which may, of course, vary. It is also to be understood that the terminology used herein is for the purpose of describing particular embodiments only, and is not intended to be limiting. As used in this specification and the appended claims, the singular forms “a”, “an”, and “the” include singular and plural referents unless the content clearly dictates otherwise. Furthermore, the word “may” is used throughout this application in a permissive sense (i.e., having the potential to, being able to), not in a mandatory sense (i.e., must). The term “include,” and derivations thereof, mean “including, but not limited to.” The term “coupled” means directly or indirectly connected.
(46) Embodiments of the invention are disclosed herein for accessing an intervertebral space, such as the L5-S1 space, and implanting a prosthetic disc implant within that space. The disclosed devices, methods and systems are suitable for use in a minimally invasive procedure for repairing degenerated or otherwise injured intervertebral discs.
(47) General Overview of the Surgical Procedure
(48) The method generally includes initially accessing the intervertebral space using a retroperitoneal lateral approach. Then, with a finger-directed dilator or other suitable instrument, the distal retroperitoneum is swept anteriorly to expose an eventual channel to a direct approach to L5-S1. In most people, the direct approach to L5-S1 is anterior to the anterior superior iliac spine, or between the anterior superior iliac spine and the anterior inferior iliac spine. An incision is then made to open this channel, and blunt dilators are directed in an oblique direction directly to the mid-anterior aspect of L5-S1, for example between the 10 o'clock and 2 o'clock position. Fluoroscopic guidance may be used in accordance with known techniques to assist in advancing and positioning the dilators.
(49) A retractor is then advanced over the dilators. In certain embodiments, the blades of the retractor are translucent so that the retracted contents can be seen through the blades. In contrast to existing retractors used in minimally invasive spinal surgery, the blades are shaped so that the curvature of the retractor blades conforms to the unique shape of the anatomy for the approach described herein, and is particularly suitable for use in this portion of the spine. For example, the ipsilateral blade may be shorter than the contralateral blade, and the ipsilateral blade may be more arcuate with a steeper curve as compared to the less curved, straighter contralateral blade. In one embodiment, the blades can accommodate a xenon light source for visualization in the cavity.
(50) Once the retraction blades are advanced to the anterior aspect of the spine (for example between the 10 o'clock and 2 o'clock positions at the L5-S1 intervertebral space), the retractor blades are positioned below the iliac bifurcation between the right and left iliac vessels. The retractor blades are moved apart to increase exposure of the anterior vertebral column. A docking shim that is angled away from the ipsilateral blade and toward the disk space is placed in the intervertebral space to secure the retractor in position and maintain distraction of the vertebral bodies. If the small middle sacral artery is viewable in the midline, the surgeon may choose to ligate or electrocauterize this small vessel.
(51) The procedure provides a relatively large window within which a discectomy and reconstruction can be carried out. The tools used for the discectomy may be slightly angled

(relative to tools used for existing techniques) to maximize disc removal from an oblique direction. Trial spacers and final disc implants have a unique design suited to the trajectory of the implantation, as described in greater detail below. Radiopaque markers may be included on the trial spacers and implants (for example at its corners) to enable the structures to be visualized under fluoroscopy.

(52) One or more trial spacers are then introduced into the evacuated disc space to help select an appropriate size implant. During introduction of the trial spacer or final implant, the initial insertion trajectory is oblique, resulting in diagonal entry of the trial spacer into disc space with impaction of the contralateral face of the implant or trial spacer to the far lateral aspect of the apophyseal rings (for example of LS-S1). The angle of impaction is then reoriented so that the portion of the trial spacer or implant that is present in the more anterior portion of the intervertebral space is impacted posteriorly on the apophyseal ring by using the contralateral side as a swivel point. Under fluoroscopic control, final seating of the implant or trial spacer is achieved. Once the final implant is in place, retraction is slowly released by allowing the retraction blades to move toward one another to check for any residual bleeding. The retractor is then slowly removed so that the skin closure of the percutaneous incision can be carried out.

(53) This general summary of the procedure is illustrated in more detail in the following sections of this specification.

(54) Positioning the Patient and Relevant Spinal Anatomy

(55) As shown in FIG. **1**A, a patient **20** is placed in a direct right lateral decubitis position with the patient's right side down on an operating table **22** and the left side up. A bolster pillow **24** is placed at the waist of patient **20** to bend the body at that point, which elevates and tilts the pelvis **26** of patient **20**. Pelvis **26** is schematically shown in FIGS. **1**, SA and SB to include an ileum **28**, with an iliac crest **30**, anterior superior iliac spine **32**, and anterior inferior iliac spine **34**. A notch **36** (FIGS. SA and SB) is formed between the superior and inferior iliac spines **32**, **34**. The spinal anatomy is schematically illustrated in FIG. **1**A, wherein the sacrum **38** is shown connected to the LS vertebra **40**. Higher levels of lumbar and thoracic vertebrae are shown superior to the LS disc. The anatomy of the LS vertebra is illustrated in more detail in FIG. **1**B, wherein the vertebra includes an anterior vertebral body **42** and a posterior vertebral arch **44** that cooperatively define spinal foramen **46**. Vertebral body **42** includes a circumferential apophyseal ring **48**, while vertebral arch **44** includes a spinous process **50**, right transverse process **52** and left transverse process **54**. Positions around vertebral body **42** can be designated arbitrarily by hours of the clock, with anterior-most position **56** designated the twelve o'clock position. Hence an anterior face of vertebral body **42** is designated herein as the face **58** that extends from about the ten o'clock position **60** to the two o'clock position **62**. The axis of the vertebral column is located generally at the center of vertebral body **42**.

(56) To clarify some of the terms in this specification, the anatomic planes of the body in the standard anatomical position are shown in FIG. **1**C. In general anatomic terminology, “superior” means closer to the head, “posterior” means closer to the posterior surface of the body, “anterior” means closer to the anterior surface of the body, “cephalad” means toward the head, “caudad” means toward the feet. The anatomic reference planes in FIG. **1**C are the “coronal plane” that separates the body into anterior and posterior halves, and the “median plane” that separates the body into right and left parts. A transverse plane is shown, which is any plane that is perpendicular to the coronal and median planes; multiple transverse planes exist at different levels of the body. With reference to the coordinate planes of FIG. **1**C, the “noon” position is on the front of the body along the A-P (anterior-posterior) line at which the median plane intersects a transverse plane. The three and six o'clock positions are along the L-M (lateral-medial) line at the intersection of the transverse and coronal planes.

(57) An “oblique plane” is any plane that is at an angle (not within or parallel) to any one of the coronal, median or transverse planes. Hence an operative corridor is “oblique” if it is an oblique plane. An oblique angle can lie in one of the illustrated coronal, median or transverse planes, be

parallel to one or two of those planes, or be outside of (and not parallel) to all three of them. For instance, an oblique pathway P**1** to an intervertebral space can extend in a transverse plane at a non-zero angle to the median plane. Alternatively, an oblique pathway P**2** can extend at a non-zero angle to the transverse, coronal and median planes.

(58) Additional pertinent anatomy at the anterior aspect of the spine is illustrated in FIGS. **5**A and **5**B, which shows the aortic bifurcation **64** into the right and left common iliac arteries **66**, **68**, each of which divides into an external iliac artery **66***a*, **68***a* and an internal iliac artery **66***b*, **68***b*. Accompanying common iliac veins **67**, **69** are also shown in FIG. **5**A. The descending aortic artery, bifurcation **64**, and the bifurcated iliac vessels are at the anterior face of the vertebral bodies, and have complicated surgical approaches that attempt to access the anterior vertebral body to repair a damaged spinal disc. The L5-S1 intervertebral space **70** is shown in FIG. **5**A without retraction of the iliac vessels, and in FIG. **5**B with retraction of the iliac vessels to expose L5-S1 intervertebral space **70**.

(59) Additional pertinent perispinal anatomy is shown in FIGS. **2**A and **3**A, wherein right and left common iliac arteries **66**, **68** and veins **67**, **69** are shown in their normal anatomic position on the anterior aspect of the spine. The nucleus pulposus **72** of the L5-S1 intervertebral disc is illustrated, as are the right and left psoas muscles **74**, **76**, the right and left erector spinae muscles **78**, **80** and the right and left transversospinalis muscles **82**, **84**. The peritoneum **86**, which is normally adjacent and adherent to the retroperitoneal structures, is shown in FIGS. **2**A and **3**A after it has been moved anteriorly and separated from the retroperitoneal structures on the right side of the body to clear an operative pathway to the L5-S1 intervertebral space.

(60) Access to Retroperitoneal Space and Establishing Operative Corridor to Intervertebral Space

(61) The surgeon palpates the subject to locate the position of the anterior superior iliac spine **32**, and an initial incision **90** (FIG. **1**) is made at this point in the mid-axillary line, as in a standard retroperitoneal approach. As shown in FIG. **2**A, blunt finger dissection is directed caudally in the retroperitoneal plane to connect to a point that is parallel the L5-S1 disc space, just anterior to ileum **28**. The surgeon's finger **94** sweeps peritoneum **86** anteriorly, moving it away from the ileum **28** and the retroperitoneal structures in the right side of the abdominal cavity. A second skin incision **92** (FIGS. **1**A and **2**A) is then made inferior to first incision **90**. Second incision **92** is anterior to first incision **90**, between the anterior axially line and the sheath of the rectus abdominis muscle, and is approximately 3-5 cm in length. Second incision **92** is made at the level of the L5-S1 disc space, which is determined fluoroscopically prior to making the incision. FIG. **2**B illustrates an initial access assembly **100** for accessing the targeted intervertebral space, such as the L5-S1 intervertebral space. Although a particular device and method are described for accessing the L5-S1 intervertebral space, the disclosed invention is not limited to use of this particular device and method. The term “accessing” the intervertebral space or its face is meant to broadly include any device and/or method for establishing a pathway from a surface incision to the disc space or its face. Illustrated access assembly **100** includes a K-wire **102**, an initial dilating cannula **104** with handle **106**, and a split-dilator **108** housed within the initial dilating cannula **104**. The entire assembly **100** is advanced under fluoroscopic guidance through the tissue towards the surgical target site (i.e. annulus). This may be accomplished using a nerve detection and/or direction device as described in U.S. Pat. No. 7,207,949, although the nerve detection capability is not necessary. Initial dilating assembly **100** is advanced until the distal ends of split-dilator **108** and initial dilator **104** are positioned within the disc space. The initial dilator **104** and handle **106** are then removed (FIG. **2**C) to leave split-dilator **108** and K-wire **102** in place. Split-dilator **108** is thereafter split such that the respective halves **108***a*, **108***b* are separated from one another to distract tissue in a generally cephalad-caudal fashion relative to the target site as described in more detail in U.S. Pat. No. 7,207,949. Split dilator **108** may thereafter be relaxed (allowing the dilator halves **108***a*, **108***b* to come together) and rotated approximately 90 degrees such that the dilator halves **108***a*, **108***b* are disposed in a transverse anatomic plane. Once rotated in this manner, the dilator halves **108***a*, **108***b*

are again separated to distract tissue in the transverse plane. Each dilator half **108***a*, **108***b* may be provided with one or more electrodes (preferably at their distal regions) equipped for use with a nerve surveillance system, such as, by way of example, the Neuro Vision System, although the nerve monitors are optional.

(62) Progressively larger dilators (not shown) may be used to further establish the operative pathway. The dilators are labeled with depth markings to help assure insertion of the successive dilators to the appropriate depth. The dilators are introduced obliquely into the body along a diagonal pathway from incision **92** to the anterior aspect of the spine to enter the intervertebral space between the twelve o'clock and two o'clock positions. The particularly illustrated pathway is generally in a transverse plane at the level of L5-S1, but at an angle to (and between) the coronal and median planes (for example in the direction of the pathway P**1** in FIG. **1**C). However, the pathway can also be at an angle to the transverse plane as well (for example, at the same angle as pathway P**2** in FIG. **1**C). The dilator pathway helps determine the eventual operative corridor that is established by placement of retraction instrument **110**. However, in some embodiments, the retraction instrument **110** can itself establish the operative corridor without the initial use of the dilators.

(63) In the illustrated embodiment, one of more of the dilators is left in place to serve as a guide for insertion of a retractor instrument **110** (FIG. **3**A). Retraction instrument **110** includes a proximal handle portion **112** and a distal retractor blade portion **114** that includes opposing contralateral retraction arm **116** and ipsilateral retraction arm **118**, which respectively carry a terminal contralateral retraction blade **120** and ipsilateral retraction blade **122**. Each of blades **120**, **122** is curved longitudinally away from the axis of elongated retractor instrument **110** (FIG. **3**A), and is additionally curved radially (FIG. **3**B). As shown in FIGS. **3**A and **3**B, ipsilateral retraction blade **122** is shorter and has a greater cross-sectional (radial) curvature than contralateral retraction blade **120**. In addition, ipsilateral blade **122** has a greater longitudinal curvature than contralateral blade **120**.

(64) A pair of angled extension members **117**, **119** can extend from handle portion **112** to improve the access angle provided by the retractor instrument. Conventional retraction instruments are not well suited for approaches that are not directly lateral to an implantation site. The increased distance from the handle to the blades and the change in angle provided by extension members **117**, **119** improve access to the implantation sites for the methods described herein.

(65) In particular, extension members **117**, **119** can extend from handle portion **112** such that they are substantially parallel to one another and form an angle of between about 45 and 80 degrees from a plane formed by a surface of handle portion **112** to which extension members abut and from which extension members extend. As shown in FIG. **22**, extension member **119** is preferably shorter than extension member **117**. If desired, a central angled extension member **121** can be provided between extension members **117**, **119** to receive another blade member. Arms **116**, **118** (FIG. **3**A) are coupled to extension members **117**, **119**, respectively.

(66) Arms **116**, **118** and their respective retraction blades **120**, **122** can be moved toward and away from one another by the movement of handles **124**, **126**, generally as shown in U.S. Pat. No. 7,207,949. Preferably, handles **124**, **126** are coupled to a gear mechanism that converts the movement of the handles toward each other into linear movement of retraction arms **116**, **118** away from one another to widen the distance between those arms without rotating them. The distance between handles **124**, **126** can be adjusted and fixed by rotation of knobs **134**, **136**.

(67) The retraction instrument **110** is placed in cannulated fashion over the dilators with the shorter ipsilateral arm/retraction blade on the ipsilateral side of the operative corridor.

(68) Retraction instrument **110** is slightly opened by moving handles **124**, **126** toward one another so that opposing retraction arms **116**, **118** move farther apart without rotation of the retraction arms. A standard xenon light source is carried by the instrument, and it is used for visualization of the anatomy at the distal tip of the instrument to position the retractor blades between the bifurcation of

the right and left common iliac arteries and veins. The foot of ipsilateral blade **122** is placed beneath the ipsilateral vasculature (the right side for the approach illustrated in FIG. **3**A) and the foot of contralateral blade **120** is placed under the contralateral vasculature (the left side for the approach illustrated in FIG. **3**A). Handles **124**, **126** are then moved closer together and fixed in position to move retraction arms **116**, **118** away from one another and create surgical exposure of the anterior spine by moving ipsilateral vessels **66**, **67** posteriorly and laterally with ipsilateral blade **122**, and by moving contralateral vessels **68**, **69** anteriorly and laterally with contralateral blade **120**. Handles **124**, **126** can be moved and fixed in different positions by rotation of knobs **134**, **136**.

(69) FIGS. **5**A and **5**B illustrate retraction of the iliac vasculature to expose the L5-S1 intervertebral space; FIG. **5**B also shows the trajectory along which retraction instrument **110** may be advanced. FIG. **5**A shows the iliac vasculature running along the anterior spine near the front of the L5-S1 intervertebral space **70**. FIG. **5**B illustrates the iliac vessels retracted away from the anterior face of the spine by the retractor instrument **110** (not shown). A trajectory along which retractor instrument **110** may be introduced is shown by arrow **128** in FIG. **5**B. The illustrated trajectory is from anterolateral incision **92** through the region of notch **36** between interior superior iliac spine **32** and anterior inferior iliac spine **34**. This trajectory contrasts with trajectory **130** (dotted line in FIG. **5**B) taken by prior minimally invasive direct lateral surgeries for the L4-L5 disc space from the axillary line.

(70) According to one aspect of the invention, once satisfactory ipsilateral vascular retraction is achieved, a shim **132** (FIGS. **3**A and **4**A, **4**B, **4**C) is inserted along the ipsilateral blade and advanced to position shim **132** within the anterolateral region of the LS-S1 disc space. Referring to FIGS. **22** and **23**A-**23**C, blades **120**, **122** can each be provided with a slot **133** for receiving a shim **132**. FIG. **22** illustrates blade **122** with a shim **132** in slot **133**, while blade **120** of FIG. **22** is shown without a shim or other structure positioned within its respective slot **133**.

(71) Shim **132** is an elongated plate with a substantially planar proximal portion **130***a* and a curved distal portion **130***b*. The curved distal portion **130***b* also tapers to a pointed distal tip **131** that is designed for introduction into an intervertebral space. The substantially planar proximal portion of shim **132** has a height h greater than its thickness t to minimize obstruction of access to the disc space when the shim is in place, and the height of the shim narrows anteriorly to pointed distal tip **131**. Shim **132** further has a reversed curvature, in that its distal portion **130***b* is curved away from ipsilateral retraction blade **122** and toward contralateral retraction blade **120**.

(72) The curvature of the distal portion of shim **132** is relatively slight, being only 5-15 degrees out of the plane of the planar proximal portion **130***a* of shim **130**. Alternatively, as shown in FIGS. **18**A, **18**B, and **18**C, shim **132** can be substantially straight along its entire length. Shim **132** is attached to ipsilateral blade **120** to help lock retractor instrument **110** in position until removal of the instrument is desired, and distracts the adjacent vertebral bodies (such as L5 and S1) to restore disc height. Shim **132** can be coupled to ipsilateral blade **120** and/or contralateral blade **122** in a variety of manners. In a preferred embodiment, shim **132** comprises a projecting portion **135** that projects outward from a surface of shim **132**. Projecting portion **135** can be a spring-loaded member that is biased outward from the surface of shim **132**.

(73) In use, shim **132** can be positioned in a slot **133** and secured thereto to the respective blade (e.g., blade **122** in FIG. **23**C).

(74) As shown in FIGS. **21** and **23**B, a plurality of spaced detents or openings **137** can extend along the length of a rear side **139** of blade **122** to receive projecting portion **135** and secure shim **132** to blade **122**. When projecting portion **135** is in a locked position (i.e., with projecting portion **135** extending at least partially through a detent **137**), shim **132** is restricted from moving relative to blade **122**. To adjust the position of shim **132** relative to blade **122**, projecting portion **135** can be pushed inward towards the surface of shim **132**, moving projecting portion **135** out of detent **137** and releasing shim **132** from blade **122**. Once projecting portion **135** is released from detent **137**,

shim **132** can be moved into another position along blade **122** by pushing or otherwise directing shim **132** downward along the length of blade **122**. This process can be repeated until shim **132** is secured to blade **122** in a desired position.

(75) Shim **132** also rigidly couples ipsilateral retractor blade **122** in fixed relation relative to the vertebral bodies, and helps ensure that surgical instruments employed within the operative corridor are not advanced outside the operative corridor, thereby avoiding inadvertent contact with the exiting nerve roots and vasculature during the surgery. Once the operative corridor is established, any of a variety of surgical instruments, devices, or implants may be passed through and/or manipulated within the operative corridor depending upon the given surgical procedure.

(76) Superior and inferior soft tissue retractors (not shown) may also be placed as needed for retraction for any creeping retroperitoneal contents to allow creation of a box-type approach to the L5-S1 disc space. Discectomy is than carried out in a conventional fashion to evacuate as much of the disc and interspace contents as possible. The handle portion **112** may be coupled to any number of mechanisms for rigidly registering it in fixed relation to the operative site, such as through the use of an articulating arm mounted to the operating table **22**.

(77) Introducer Instrument

(78) Once the discectomy has been completed, trial implants are introduced into the L5-S1 disc space **70** to select an appropriate size final implant, and a final implant is then introduced into the disc space.

(79) FIGS. **6**-**9** illustrate an introducer instrument **140** for introducing implants into the disc space. Instrument **140** includes a rigid sheath **142** (FIGS. **6**-**7**) that is sufficiently long to reach the L5-S1 disc space **70**. A longitudinal axis **144** of sheath **142** is illustrated by a dashed line. Instrument **140** is provided with a proximal handle **146** that is coupled to a rotatable shaft **147** (FIG. **8**) inside a ridged collar **148** (FIG. **7**) so that shaft **147** can be rotated within sheath **142** by rotating handle **146** as collar **148** is grasped by the surgeon's hand to maintain collar **148** stationary. As shown in FIG. **7**, an externally threaded rod **150** projects from a cylindrical distal tip **152** of sheath **142** along longitudinal axis **144** on sheath **142**. A pair of small coupling pins **154**, **156**, which are smaller than threaded rod **150**, project from distal tip **152** on either side of rod **150** in a fixed spaced alignment generally along a common plane that bisects shaft **142** along its axis **144**. Coupling pins **154**, **156** are substantially shorter and of much smaller diameter than the threaded rod **150**. For example, coupling pins are less than 25% or even 10% of the diameter and length of threaded rod **150** projecting from the tip **152** of instrument **140**.

(80) As shown best in FIG. **8**, threaded rod **150** is connected to rotatable shaft **147** by a reduced diameter step-down extension **158** that projects out of distal tip **152** of sheath **142** to provide a gap between threaded rod **150** and the face **160** of distal tip **152**. Distal tip **152** (and pins **154**, **156** that it carries) can be selectively advanced toward and retracted from implant **172** in a pathway generally parallel to longitudinal axis **144** by rotating handle **146**. As handle **146** rotates counterclockwise, it drives shaft **147** to turn threaded rod **150** and loosen the connection between rod **150** and a threaded opening in the implant. Since pins **154**, **156** have a much shorter axial length than threaded rod **150**, only slight loosening of the threaded rod is required to disengage pins **154**, **156** from the implant. Once pins **154**, **156** are disengaged from the implant, they can be repositioned in another set of openings on the implant to change the angle between instrument **140** and the implant. Handle **146** is then rotated clockwise to tighten the pins in their new openings to fix the new angular relationship between instrument **140** and the implant.

(81) Threaded rod **150** and coupling pins **154**, **156** form an example of a docking element of introducer instrument **140**. The docking element selectively docks with an interface element **170** of an implant **172**, as shown in FIG. **9**. The docking element docks at a plurality of positions with interface element **170** to selectively alter an angle between implant **172** and introducer instrument **140**. Implant **172** has a pivot axis **174** around which implant **172** may be pivoted relative to longitudinal axis **144** of instrument **140**.

(82) An example of an implant **172** is shown in greater detail in FIGS. **10**A and **10**B, where implant **172** has a top bearing face **176**, a bottom bearing face **178**, a front face **180**, a rear face **182**, an ipsilateral face **184** and a contralateral face **186**. A rotation pin **188** extends between top and bottom faces **176**, **178** and rotates relative to implant **172**; pivot axis **174** of implant **172** extends along the axis of rotation pin **188**. Interface element **170** (FIGS. **9** and **10**A) has a recessed slot **190** between top and bottom faces **176**, **178** that provides access to the side of rotation pin **188** in which an internally threaded opening **191** is provided which has threads that are complementary to the external threads of rod **150** of introducer instrument **140**. An upper arcuate lip **192** and lower arcuate lip **194** form slot **190** cooperatively therebetween. Lips **192**, **194** are spaced from and generally parallel to the outer walls of rotation pin **188**. Lips **192**, **194** of interface element **170** each have a series of spaced docking holes that form paired upper and lower sets of spaced holes arranged on the curved surfaces of the lips. These docking holes extend partially circumferentially around pivot axis **174**, and selected pairs of spaced docking holes are positioned to mate with the docking element of introducer instrument **140**. This docking is illustrated in greater detail in FIG. **9** wherein face **160** of distal tip **152** is curved to fit in register with the curved faces of lips **192**, **194** with pin **154** in an upper member of a docking pair of holes on upper lip **192** and pin **156** (not shown in FIG. **9**) in a corresponding aligned lower member of the docking pair of holes on lower lip **194**. Interface element **170** therefore includes spaced docking holes that extend partially circumferentially around pivot axis **174** so that selected pairs of docking holes are positioned to mate with the docking element of introducer instrument **140**.
(83) In use, introducer instrument **140** is secured to an implant **172** by threading rod **150** into opening **191** of rotation pin **188** by rotating handle **146** to turn shaft **147** within sheath **142**. Handle **146** is rotated until implant **172** is tightly secured to distal tip **152** and pins **154**, **156** are aligned with and inserted within a pair of the upper and lower aligned docking holes. The angular relationship between instrument **140** and implant **172** can be altered by slightly unscrewing threaded rod **150** from threaded opening **191**. This action moves face **160** of distal tip **152** sufficiently out of engagement with interface element **170** to disengage pins **154**, **156** from a first set of docking holes without completely disconnecting instrument **140** from implant **172**. The implant **172** and instrument **140** can then pivot relative to one another until sheath **142** is again advanced to engage coupling pins **152**, **154** with a new pair of docking holes by rotating handle **146** to once again securely engage instrument **140** to implant **172**, so that the implant is fixed at a new angular relationship with the instrument.
(84) Although a particular embodiment of the device is illustrated in which the angular relationship between instrument **140** and implant **172** can be selectively altered, many other means for varying this angular relationship to pivot the implant are contemplated. For example, rotation of handle **146** can actuate a gear that pivots implant **172**, or handle rotation can actuate a cam that selectively moves pins **154**, **156** to selectively engage and disengage them from interface element **170**. Alternatively the tip of instrument **140** can fit into a slot within implant **172** to pivot the implant as instrument **140** is moved from the contralateral to the ipsilateral arm of the retractor instrument. In other embodiments, a universal joint is provided between the instrument **140** and implant **172** to selectively pivot the implant relative to the instrument. Different numbers and arrangements of the pins can also be provided. Electronic devices can also be used that rotate the implant in the plane of the disc space while maintaining the instrument within the operative pathway defined between the retraction blades of instrument **140**.
(85) The Implant
(86) Additional features of implant **172** are shown in detail in FIGS. **10** and **11** to illustrate details that make the implant particularly suitable for insertion and progressive pivoting of the implant within the L5-S1 disc space, as described in greater detail below. The implant tapers in height from the height h**1** of front face **180** to height h**2** of rear face **182**, and is elongated in a direction transverse to the direction of tapering height. Hence front face **180** and rear face **182** are longer

than ipsilateral and contralateral faces **184**, **186**. The implant material is made of a generally compressible or elastomeric material. Front face **180** is generally convex, ipsilateral face **184** includes interface element **170**, rear face **176** is generally flat, and contralateral face **186** is rounded at its front and rear edges to minimize impact damage to spinal structures as the implant is introduced into the disc space and pivoted into position. Implant **172** is also partially hollow and may have ipsilateral and contralateral windows **200**, **202** extending between top and bottom faces **176**, **178**. The windows are formed by an internal divider wall **204** that extends from the front to rear of implant **172** and substantially bisects the implant into ipsilateral and contralateral halves. However, ipsilateral window **200** is smaller than contralateral window **202** because a portion of the ipsilateral half of implant **172** is occupied by rotation pin **188** and the structure that supports it. The windows **200**, **202** provide communication between the open bottom and top faces of the implant to promote ingrowth of tissue within and through implant **172**.

(87) Top and bottom faces **176**, **178** are provided with protuberances **206** that also help promote bone growth into implant **172**. The protuberances may take a variety of shapes, but the illustrated frustopyramidal protuberances **206** are believed to be particularly suitable for this purpose.

(88) In addition to the implant, trial spacers are also provided to help assess the size of the disc space once the disc space contents have been evacuated but before the final implant is advanced into the disc space.

(89) FIGS. **11**A, **11**B, and **11**C illustrate another embodiment of an implant **272**. To facilitate comparison to implant **172**, FIGS. **11**A-C use reference numbers with the same two final digits for elements that are generally similar to elements identified in FIGS. **10**A and **10**B. Thus, implant **272** has a top bearing face **276**, a bottom bearing face **278**, a front face **280**, a rear face **282**, an ipsilateral face **284** and a contralateral face **286**. A rotation pin **288** extends between top and bottom faces **276**, **278** and rotates relative to implant **272**. Pivot axis **274** of implant **272** extends along the axis of rotation pin **288**.

(90) An interface element **270** (FIGS. **11**B and **11**C) has a recessed slot **290** between top and bottom faces **276**, **278** that provides access to the side of rotation pin **288** in which an internally threaded opening **291** is provided which has threads that are complementary to the external threads of rod **150** of introducer instrument **140**. An upper arcuate lip **292** and lower arcuate lip **294** form slot **290** cooperatively therebetween. For clarity, FIG. **11**B is shown without pin **288** fitted or received in implant **272**.

(91) Lips **292**, **294** of interface element **270** can have a series of spaced docking holes such as that shown in FIGS. **10**A and **10**B. Alternatively, as shown in FIGS. **11**B and **11**C, lips **292**, **294** can be formed without such docking holes. Instead, the introducer instrument can be shaped to contact a portion of the upper and/or lower curved faces of lips **292**, **294**, thereby forming a frictional fit between the convex face of implant **272** and a concave face **160** of the introducer instrument **140**. Thus, in use, introducer instrument **140** can be secured to implant **272** by threading rod **150** into opening **291** of rotation pin **288** by rotating handle **146** to turn shaft **147** within sheath **142**. When handle **146** is rotated a sufficient amount, implant **272** will be tightly secured to face **160** of distal tip **152**. The angular relationship between instrument **140** and implant **272** can be altered by slightly unscrewing threaded rod **150** from threaded opening **291**. This action moves face **160** of distal tip **152** sufficiently out of engagement of the frictional fit with interface element **270** (or other contacting portion of a surface of implant **272**). Implant **272** and instrument **140** can then pivot relative to one another until sheath **142** is again advanced to engage the instrument **140** and implant **272** in a frictional fit that is tight enough to restrict relative movement of the instrument **140** and implant **272**.

(92) As shown in FIGS. **11**B and **11**C, implant **272** can be constructed so that it is substantially the same thickness (height) along its length (FIG. **11**B), while at the same time varying in thickness (height) along its width (FIG. **11**C). In particular, as shown in FIG. **11**C, the thickness (height) of implant **272** can vary from a first larger height to a second smaller height to facilitate the

implantation of the device in the patient.
(93) Like implant **172**, implant **272** can be provided with protuberances **306** that help promote bone growth into implant **172**. As noted above, such protuberances can take a variety of shapes.
(94) Also like implant **172**, implant **272** can be at least partially hollow and can have one or more windows (e.g., windows **300**, **302**). Windows **300**, **302** can provide the same benefits as windows **200**, **202** in the previous embodiment, which is to provide communication between the open bottom and top faces of the implant to promote ingrowth of tissue within and through implant **272**. Implant **272** can also have one or more openings **303** that extend through a side wall of the implant to further promote ingrowth of tissue and to facilitate access to internal areas of implant **272** (e.g., access to one or both of windows **300**, **302**) when implant **272** is implanted in the body.
(95) Windows **300**, **302** can extend between top and bottom faces **276**, **278** as shown in FIG. **11**A. The windows can be formed by an internal divider wall **304** that substantially bisect the implant into two halves. Unlike divider wall **204** shown in FIG. **10**A, however, divider wall **304** preferably extends diagonally across implant **272** from an area adjacent or near the pin **288** to an area at or near contralateral face **286**. By extending generally diagonally across implant **272** as shown in FIG. **11**A, diagonal wall **304** can provide structural strength to the implant in the general direction of the force that will be applied to implant **272** during implantation. For example, as shown in FIG. **20**, divider wall **304** is located substantially in-line with the instrument **140**.
(96) FIG. **12** illustrates another version of an implant **220**. This implant is similar to that shown in FIGS. **10**-**11**, except it is substantially rectangular in shape instead of polygonal, and it has a rotation pin **222** with a pivot axis **224** that extends between a front and rear face of implant **220**. Rotation pin **222** includes an opening **226** (e.g., a threaded opening) for receiving a threaded distal end of introducer instrument **140**. As described above with respect to implant **172**, implant **220** can be secured to threading rod **150** by positioning rod **150** into opening **226** and rotating handle **146** to turn shaft **147** and tighten the distal end of the instrument (e.g., face **160**) to a facing surface of implant **220**.
(97) Because rotation pin **222** is positioned horizontally (FIG. **12**) rather than vertically (FIG. **10**A), implant **220** is therefore suitable for pivoting up and down with respect to introducer instrument **140** instead of from side-to-side as with implant **172**. It may also have varied dimensions medial to lateral as described for implant **172**, although other embodiments do not taper and are of uniform height. The embodiment of the implant shown in FIG. **12** is generally used in surgeries superior to the L5-S1 space, for example in the L4-L5 space or the L3-L4 space. By providing an implant that can pivot vertically, such as implant **220**, the implantation site can be more easily accessed from an incision point superior or inferior to the implantation site. For example, in use, the implant can be delivered to the implantation site from a location superior to iliac crest **30** and pivoted vertically into the desired position at the implantation site.
(98) As with the other implants described herein, implant **220** can be provided with one or more windows **228**, **230** and a plurality of protrusions **232** to promote the ingrowth of tissue. Implant **220** can also be provided with a plurality of docking holes **234** to help lock or secure implant **220** to a distal end of instrument **140**. Alternatively, implant **220** can be secured to the instrument **140** via a frictional fit or other similar mechanism. FIGS. **19**A, **19**B, and **19**C illustrate another embodiment of an implant that can pivot up and down (e.g., vertically), in a manner similar to that shown in FIG. **12**. Implant **320** is configured to receive a rotation pin (not shown) in a recess **322** between a top surface **324** and a bottom surface **326** of implant **320**. As described in other embodiments, implant **320** can include a plurality of windows **330**, **332** separated by a divider wall **334**. In addition, openings **336** can be formed in the side of the implant as shown in FIGS. **19**A and **19**B.
(99) Introducing the Trial Spacer and Disc Implant
(100) Once the operative corridor has been established by retraction instrument **110** and the operative field has been exposed, a trial spacer **210** is attached to introducer instrument **140** and advanced into the L5-S1 disc space as shown in FIG. **13**. The trial spacer is generally similar to

implant **174**, except it does not have the protuberances projecting from its top and bottom faces. For the initial introduction of trial spacer **210**, the spacer is directly laterally attached to instrument **110**. The direct lateral attachment is shown in FIG. **13**, wherein the longitudinal axis of sheath **142** is generally parallel to flat rear face **182** of implant **210**. Because of the anterolateral operative pathway to the disc space, trial implant **210** moves along a generally oblique or diagonal pathway into the disc space. The "oblique" pathway is one that travels diagonally within the body, for example in an oblique anatomic plane. The oblique pathway may be a diagonal pathway, for example between 15 and 45 or 60 degrees to a coronal plane of the body. In FIG. **13**, the oblique pathway is shown at an angle a of about 30 degrees to coronal plane **212** (FIG. **13**). The oblique pathway may be either in a transverse plane of the body, or above or below a transverse plane (for example between 15 and 45 or 60 degrees to a transverse plane of the body). However, in a particular disclosed embodiment of the method, fluoroscopy is used to detect the level of the target disc space (such as L5-S1) so that the instrument, spacer and implant can be introduced diagonally in the body, but generally in the plane of the L5-S1 disc space.

(101) As trial spacer **210** enters the illustrated L5-S1 disc space (FIGS. **13** and **14**A), contralateral face **186** impacts the posterior contralateral aspect of the disc space. The rounded edges of contralateral face **186** help avoid damage to the structures which the contralateral face **186** of the trial spacer encounters. The trial spacer is then progressively reoriented from its diagonal orientation in the disc space (FIG. **14**A) to a generally medial-lateral orientation (FIG. **14**C) by successively retracting sheath **142**, pivoting the trial spacer on rotation pin **188** by forcing contralateral face of trial spacer **210** against the postero lateral apophyseal ring and moving introducer instrument **140** toward ipsilateral retractor arm **118**, and repositioning coupling pins in a new set of docking holes that maintain the trial spacer in an intermediate position shown in FIG. **14**B. Sheath **142** is then retracted again, and the trial spacer pivoted on rotation pin **188** to the generally medial-lateral orientation (FIG. **14**C). As the trial spacer **210** moves from its initial diagonal to final medial-lateral orientation (with its flat rear face generally parallel to a coronal plane of the body), sheath **142** moves from a first position abutting contralateral retractor blade **120** (FIG. **14**A) to a second position abutting ipsilateral blade **122** (FIG. **14**C).

(102) Trial spacers of different sizes may be introduced into the disc space and pivoted from the diagonal to the medial-lateral orientation until a trial spacer of the appropriate size and height is found. Introducer instrument **140** is detached from trial spacer **210** by rotating handle to unscrew threaded **150** from the internally threaded opening of trial spacer **210** to secure different trial spacers until the correct one is found. The trial spacer is then withdrawn from the disc space and detached from introducer instrument **140**, and the final implant **172** is directly laterally attached to distal tip **152** of introducer instrument **140** (as illustrated in FIG. **15**) by rotating handle **146** to screw the threaded rod at the tip of instrument **140** into the internally threaded hole on the implant. With the implant **172** directly laterally attached to instrument **141**, the elongated implant **172** can be introduced through a relatively narrow operative pathway between the arms of retractor instrument **110**. FIG. **16**A illustrates the diagonal introduction of implant **172** into the disc space along the same pathway already described for trial spacer **210**. The implant enters the disc space with its flat rear face **182** at an angle of about 15-45 degrees (for example 30 degrees) to a coronal plane of the body. The implant is then progressively reoriented by retracting sheath **142**, pivoting implant **172** within the disc space, and advancing sheath **142** to reengage coupling pins **154**, **156** within a new set of docking holes to hold implant **172** in the intermediate orientation shown in FIG. **16**B wherein the implant is at an angle of about 15 degrees to a coronal plane of the body. Implant **172** can then be further reoriented in this fashion until sheath **142** contacts ipsilateral arm **118** of retractor instrument **110** (FIG. **16**C). Once implant **172** cannot be reoriented any further using the instrument, handle **146** is rotated to completely disengage introducer instrument **140** from implant **172**. Instrument **140** is then withdrawn from retractor instrument **110**.

(103) Additional positioning of implant **172** can be achieved by pushing it with the tip of

instrument **140**, or with other elongated instruments introduced through retractor instrument **110**. Retractor instrument **110** can then be removed from the body by moving arms **116**, **118** toward one another to reduce the width of instrument **110** then withdrawing it from the body. Normal closure of the surgical incisions on the body surface is then carried out.

(104) FIG. **20** illustrates implant **272** secured to instrument **140** and being delivered to an implantation site. The method of delivering implant **272** is substantially the same as the method of delivering implant **172**, which is described above and shown in FIGS. **15-17**.

(105) Implant **272** is desirably secured to the distal end of instrument **140** so that divider wall **304** is generally in-line with axis **350** of instrument **140**. In this manner, implant **272** can exhibit increased strength to ensure that it can withstand the impaction force, which is generally applied along the axis **350** to deliver implant **272** to the desired location in the body.

(106) The implants described herein can be coated with and/or impregnated with various elements to promote bone in-growth. In a preferred embodiment, stem cells can be delivered along with the implant (either delivered into openings in the implant or coated thereon) to improve and facilitate bone in-growth. In view of the many possible embodiments to which the principles of the disclosed invention may be applied, it should be recognized that the illustrated embodiments are only preferred examples of the invention and should not be taken as limiting the scope of the invention. Rather, the scope of the invention is defined by the following claims. We therefore claim as our invention all that comes within the scope and spirit of these claims.

Claims

1. A spinal implant system advanceable along an oblique anterolateral retroperitoneal operative corridor to an intervertebral disc space, the spinal implant system comprising: a spinal implant sized and shaped to be introduced into the intervertebral disc space via the oblique anterolateral retroperitoneal operative corridor, the spinal implant further sized and shaped to be repositionable within and to substantially occupy the intervertebral disc space, the spinal implant including: an implant body including: a top bearing face having upper bone engagement protuberances; a bottom bearing face located opposite the top bearing face, the bottom bearing face having lower bone engagement protuberances; an anterior face extending between the top bearing face and the bottom bearing face; a posterior face located opposite the anterior face, the posterior face extending between the top bearing face and the bottom bearing face; an ipsilateral face located between the anterior face and the posterior face, the ipsilateral face extending between the top bearing face and the bottom bearing face, the ipsilateral face including an upper arcuate lip and a lower arcuate lip; a contralateral face located between the anterior face and the posterior face opposite the ipsilateral face, the contralateral face extending between the top bearing face and the bottom bearing face; and a recessed slot formed along the ipsilateral face and located within the implant body between the top bearing face and the bottom bearing face; and a pin extending between the top bearing face and the bottom bearing face, the pin pivotable about a vertical pivot axis between a plurality of angular positions relative to the implant body, the pin including an internally threaded opening having a central axis oriented transverse to the vertical pivot axis, the internally threaded opening accessible via the recessed slot; and an introducer instrument configured to introduce the spinal implant into the intervertebral disc space via the oblique anterolateral retroperitoneal operative corridor, the introducer instrument further configured to reposition the spinal implant within the intervertebral disc space from an initial oblique orientation to a lateral orientation in which the posterior face of the spinal implant is substantially parallel to a coronal plane of the intervertebral disc space, the introducer instrument including: a sheath including a distal tip having a plurality of fixation protuberances, the sheath defining a longitudinal axis; and a rotatable shaft extending through the sheath, the rotatable shaft including an externally threaded end projecting externally from the distal tip past the fixation protuberances, wherein the externally threaded end of the rotatable shaft of the

introducer instrument is configured to threadedly mate with the internally threaded opening of the pin of the spinal implant while the externally threaded end is positioned within the recessed slot of the implant body of the spinal implant, wherein rotation of the rotatable shaft in a first rotational direction about the longitudinal axis while the externally threaded end is threadedly coupled to the internally threaded opening and the pin is positioned at a first angular position from among the plurality of angular positions advances the externally threaded end along the internally threaded opening, the advancement causing at least a first one of the plurality of fixation protuberances of the introducer instrument to engage the upper arcuate lip of the ipsilateral face of the spinal implant and at least a second one of the plurality of fixation protuberances of the introducer instrument to engage the lower arcuate lip of the ipsilateral face of the spinal implant in a manner that fixes the pin of the spinal implant relative to the implant body of the spinal implant at the first angular position and also fixes the introducer instrument relative to the spinal implant at the first angular position, wherein rotation of the rotatable shaft in a second rotational direction about the longitudinal axis opposite the first rotational direction while the pin and the introducer instrument are fixed at the first angular position retracts the externally threaded end along the internally threaded opening, the retraction causing the at least a first one of the plurality of fixation protuberances of the introducer instrument to disengage from the upper arcuate lip of the ipsilateral face of the spinal implant and the at least a second one of the plurality of fixation protuberances of the introducer instrument to disengage from the lower arcuate lip of the ipsilateral face of the spinal implant in a manner that releases the pin and the introducer instrument from the first angular position while the externally threaded end remains threadedly coupled to the internally threaded opening, wherein the pin can subsequently be pivoted relative to the implant body of the spinal implant via the introducer instrument from the first angular position to a second angular position from among the plurality of angular positions, the second angular position differing from the first angular position, wherein rotation of the rotatable shaft in the first rotational direction about the longitudinal axis while the externally threaded end remains threadedly coupled to the internally threaded opening and the pin is positioned at the second angular position fixes the pin of the spinal implant relative to the implant body of the spinal implant at the second angular position and also fixes the introducer instrument relative to the spinal implant at the second angular position.

2. The spinal implant system of claim 1, wherein the pin of the spinal implant is exposed along the ipsilateral face of the implant body through the recessed slot.

3. The spinal implant system of claim 1, further comprising a multi-blade retractor having at least first and second retractor blades that are sized to establish the oblique anterolateral retroperitoneal operative corridor to the intervertebral disc space.

4. The spinal implant system of claim 3, wherein the first retractor blade has a different tip shape than the second retractor blade such that the first retractor blade is configured to lateralize a left common iliac vein and a left common iliac artery, and the second retractor blade is configured to lateralize a right common iliac vein and a right common iliac artery.

5. The spinal implant system of claim 1, wherein the implant body has a longitudinal length that extends from the ipsilateral face to the contralateral face and that is configured to be arranged parallel to the coronal plane of the intervertebral disc space, wherein the implant body has a maximum width that extends from the posterior face to the anterior face and that is configured to be arranged parallel to a medial plane of the intervertebral disc space.

6. The spinal implant system of claim 1, wherein the vertical pivot axis is located between the anterior face and the posterior face and between the ipsilateral face and the contralateral face.

7. The spinal implant system of claim 1, wherein the recessed slot is located between the upper arcuate lip and the lower arcuate lip.

8. The spinal implant system of claim 1, wherein an outer surface of the upper arcuate lip and an outer surface of the lower arcuate lip are spaced apart from and extend generally parallel to an outer wall of the pin of the spinal implant that is exposed through the recessed slot of the implant

body.
9. The spinal implant system of claim 1, wherein the rotatable shaft is rotatable relative to the sheath.
10. The spinal implant system of claim 1, wherein the ipsilateral face of the implant body is parallel to the vertical pivot axis.
11. The spinal implant system of claim 1, wherein the posterior face of the implant body is flat.
12. The spinal implant system of claim 1, wherein the anterior face of the implant body has a front maximum height and the posterior face of the implant body has a rear maximum height, wherein the rear maximum height is less than the front maximum height.
13. The spinal implant system of claim 12, wherein the implant body tapers in height from the front maximum height of the anterior face to the rear maximum height of the posterior face.
14. A spinal implant system advanceable along an oblique anterolateral retroperitoneal operative corridor to an intervertebral disc space, the spinal implant system comprising: a spinal implant sized and shaped to be introduced into the intervertebral disc space via the oblique anterolateral retroperitoneal operative corridor, the spinal implant further sized and shaped to be repositionable within and to substantially occupy the intervertebral disc space, the spinal implant including: an implant body including: a top bearing face having upper bone engagement protuberances; a bottom bearing face located opposite the top bearing face, the bottom bearing face having lower bone engagement protuberances; an anterior face extending between the top bearing face and the bottom bearing face; a posterior face located opposite the anterior face, the posterior face extending between the top bearing face and the bottom bearing face; an ipsilateral face located between the anterior face and the posterior face, the ipsilateral face extending between the top bearing face and the bottom bearing face, the ipsilateral face including an upper arcuate lip and a lower arcuate lip; a contralateral face located between the anterior face and the posterior face opposite the ipsilateral face, the contralateral face extending between the top bearing face and the bottom bearing face; a recessed slot formed along the ipsilateral face and located within the implant body between the top bearing face and the bottom bearing face; and a tissue ingrowth window extending through the top bearing face and the bottom bearing face, the tissue ingrowth window located between the anterior face and the posterior face and between the contralateral face and the ipsilateral face; and a pin extending between the top bearing face and the bottom bearing face, the pin exposed along the ipsilateral face though the recessed slot, the pin pivotable about a vertical pivot axis between a plurality of angular positions relative to the implant body, the vertical pivot axis located between the anterior face and the posterior face and between the ipsilateral face and the contralateral face, the vertical pivot axis being parallel to the ipsilateral face, the pin including an internally threaded opening having a central axis oriented transverse to the vertical pivot axis, the internally threaded opening accessible via the recessed slot; and an introducer instrument configured to introduce the spinal implant into the intervertebral disc space via the oblique anterolateral retroperitoneal operative corridor, the introducer instrument further configured to reposition the spinal implant within the intervertebral disc space from an initial oblique orientation to a lateral orientation in which the posterior face of the spinal implant is substantially parallel to a coronal plane of the intervertebral disc space, the introducer instrument including: a sheath including a distal tip having a plurality of fixation protuberances, the sheath defining a longitudinal axis; and a rotatable shaft extending through the sheath, the rotatable shaft including an externally threaded end projecting externally from the distal tip past the fixation protuberances, wherein the externally threaded end of the rotatable shaft of the introducer instrument is configured to threadedly mate with the internally threaded opening of the pin of the spinal implant while the externally threaded end is positioned within the recessed slot of the implant body of the spinal implant, wherein rotation of the rotatable shaft in a first rotational direction about the longitudinal axis while the externally threaded end is threadedly coupled to the internally threaded opening and the pin is positioned at a first angular position from among the plurality of angular positions advances the externally threaded end along

the internally threaded opening, the advancement causing at least a first one of the plurality of fixation protuberances of the introducer instrument to engage the upper arcuate lip of the ipsilateral face of the spinal implant and at least a second one of the plurality of fixation protuberances of the introducer instrument to engage the lower arcuate lip of the ipsilateral face of the spinal implant in a manner that fixes the pin of the spinal implant relative to the implant body of the spinal implant at the first angular position and also fixes the introducer instrument relative to the spinal implant at the first angular position, wherein rotation of the rotatable shaft in a second rotational direction about the longitudinal axis opposite the first rotational direction while the pin and the introducer instrument are fixed at the first angular position retracts the externally threaded end along the internally threaded opening, the retraction causing the at least a first one of the plurality of fixation protuberances of the introducer instrument to disengage from the upper arcuate lip of the ipsilateral face of the spinal implant and the at least a second one of the plurality of fixation protuberances of the introducer instrument to disengage from the lower arcuate lip of the ipsilateral face of the spinal implant in a manner that releases the pin and the introducer instrument from the first angular position while the externally threaded end remains threadedly coupled to the internally threaded opening, wherein the pin can subsequently be pivoted relative to the implant body of the spinal implant via the introducer instrument from the first angular position to a second angular position from among the plurality of angular positions, the second angular position differing from the first angular position, wherein rotation of the rotatable shaft in the first rotational direction about the longitudinal axis while the externally threaded end remains threadedly coupled to the internally threaded opening and the pin is positioned at the second angular position fixes the pin of the spinal implant relative to the implant body of the spinal implant at the second angular position and also fixes the introducer instrument relative to the spinal implant at the second angular position.

15. The spinal implant system of claim 14, wherein the recessed slot is located between the upper arcuate lip and the lower arcuate lip.

16. The spinal implant system of claim 14, wherein an outer surface of the upper arcuate lip and an outer surface of the lower arcuate lip are spaced apart from and extend generally parallel to an outer wall of the pin of the spinal implant that is exposed through the recessed slot of the implant body.

17. The spinal implant system of claim 14, wherein the rotatable shaft is rotatable relative to the sheath.

18. The spinal implant system of claim 14, wherein the anterior face of the implant body has a front maximum height and the posterior face of the implant body has a rear maximum height, wherein the rear maximum height is less than the front maximum height.

19. The spinal implant system of claim 18, wherein the implant body tapers in height from the front maximum height of the anterior face to the rear maximum height of the posterior face.

20. A spinal implant system advanceable along an oblique anterolateral retroperitoneal operative corridor to an intervertebral disc space, the spinal implant system comprising: a spinal implant sized and shaped to be introduced into the intervertebral disc space via the oblique anterolateral retroperitoneal operative corridor, the spinal implant further sized and shaped to be repositionable within the intervertebral disc space, the spinal implant including: an implant body including: a top bearing face having upper bone engagement protuberances; a bottom bearing face located opposite the top bearing face, the bottom bearing face having lower bone engagement protuberances; an anterior face extending between the top bearing face and the bottom bearing face; a posterior face located opposite the anterior face, the posterior face extending between the top bearing face and the bottom bearing face, the posterior face being flat; an ipsilateral face located between the anterior face and the posterior face, the ipsilateral face extending between the top bearing face and the bottom bearing face, the ipsilateral face including an upper arcuate lip and a lower arcuate lip; a contralateral face located between the anterior face and the posterior face opposite the ipsilateral face, the contralateral face extending between the top bearing face and the bottom bearing face; a

recessed slot formed along the ipsilateral face between the upper arcuate lip and the lower arcuate lip, the recessed slot located within the implant body between the top bearing face and the bottom bearing face; and a tissue ingrowth window extending through the top bearing face and the bottom bearing face, the tissue ingrowth window located between the anterior face and the posterior face and between the contralateral face and the ipsilateral face; and a pin extending between the top bearing face and the bottom bearing face, the pin exposed along the ipsilateral face though the recessed slot, the pin pivotable about a vertical pivot axis between a plurality of angular positions relative to the implant body, the vertical pivot axis positioned between the anterior face and the posterior face and between the ipsilateral face and the contralateral face, the vertical pivot axis being parallel to the ipsilateral face, the pin including an internally threaded opening having a central axis oriented transverse to the vertical pivot axis, the internally threaded opening accessible via the recessed slot, wherein an outer surface of the upper arcuate lip and an outer surface of the lower arcuate lip are spaced apart from and extend generally parallel to an outer wall of the pin; and an introducer instrument configured to introduce the spinal implant into the intervertebral disc space via the oblique anterolateral retroperitoneal operative corridor, the introducer instrument further configured to reposition the spinal implant within the intervertebral disc space from an initial oblique orientation to a lateral orientation in which the posterior face of the spinal implant is substantially parallel to a coronal plane of the intervertebral disc space, the introducer instrument including: a sheath including a distal tip having a plurality of fixation protuberances, the sheath defining a longitudinal axis; and a rotatable shaft extending through the sheath, the rotatable shaft including an externally threaded end projecting externally from the distal tip past the fixation protuberances, wherein the externally threaded end of the rotatable shaft of the introducer instrument is configured to threadedly mate with the internally threaded opening of the pin of the spinal implant while the externally threaded end is positioned within the recessed slot of the implant body of the spinal implant, wherein rotation of the rotatable shaft in a first rotational direction about the longitudinal axis while the externally threaded end is threadedly coupled to the internally threaded opening and the pin is positioned at a first angular position from among the plurality of angular positions advances the externally threaded end along the internally threaded opening, the advancement causing at least a first one of the plurality of fixation protuberances of the introducer instrument to engage the upper arcuate lip of the ipsilateral face of the spinal implant and at least a second one of the plurality of fixation protuberances of the introducer instrument to engage the lower arcuate lip of the ipsilateral face of the spinal implant in a manner that fixes the pin of the spinal implant relative to the implant body of the spinal implant at the first angular position and also fixes the introducer instrument relative to the spinal implant at the first angular position, wherein rotation of the rotatable shaft in a second rotational direction about the longitudinal axis opposite the first rotational direction while the pin and the introducer instrument are fixed at the first angular position retracts the externally threaded end along the internally threaded opening, the retraction causing the at least a first one of the plurality of fixation protuberances of the introducer instrument to disengage from the upper arcuate lip of the ipsilateral face of the spinal implant and the at least a second one of the plurality of fixation protuberances of the introducer instrument to disengage from the lower arcuate lip of the ipsilateral face of the spinal implant in a manner that releases the pin and the introducer instrument from the first angular position while the externally threaded end remains threadedly coupled to the internally threaded opening, wherein the pin can subsequently be pivoted relative to the implant body of the spinal implant via the introducer instrument from the first angular position to a second angular position from among the plurality of angular positions, the second angular position differing from the first angular position, wherein rotation of the rotatable shaft in the first rotational direction about the longitudinal axis while the externally threaded end remains threadedly coupled to the internally threaded opening and the pin is positioned at the second angular position fixes the pin of the spinal implant relative to the implant body of the spinal implant at the second angular position and also

fixes the introducer instrument relative to the spinal implant at the second angular position that differs from the corresponding first angular position.

21. The spinal implant system of claim 20, wherein the rotatable shaft is rotatable relative to the sheath.

22. The spinal implant system of claim 20, wherein the anterior face of the implant body has a front maximum height and the posterior face of the implant body has a rear maximum height, wherein the rear maximum height is less than the front maximum height.

23. The spinal implant system of claim 22, wherein the implant body tapers in height from the front maximum height of the anterior face to the rear maximum height of the posterior face.