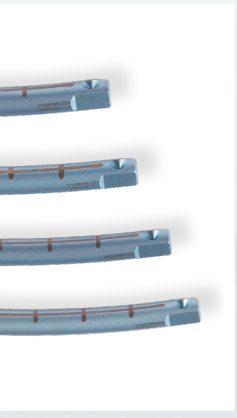
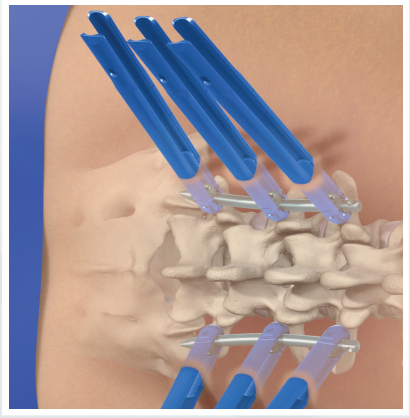
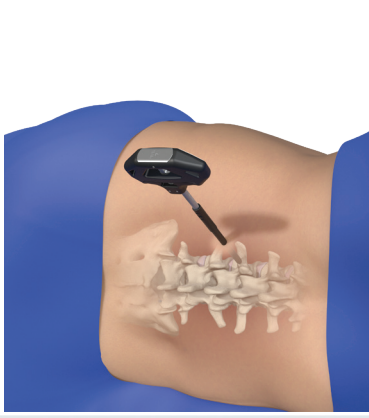
Vital™ MIS Spinal Fixation System

Single Position Lateral Interbody Fusion

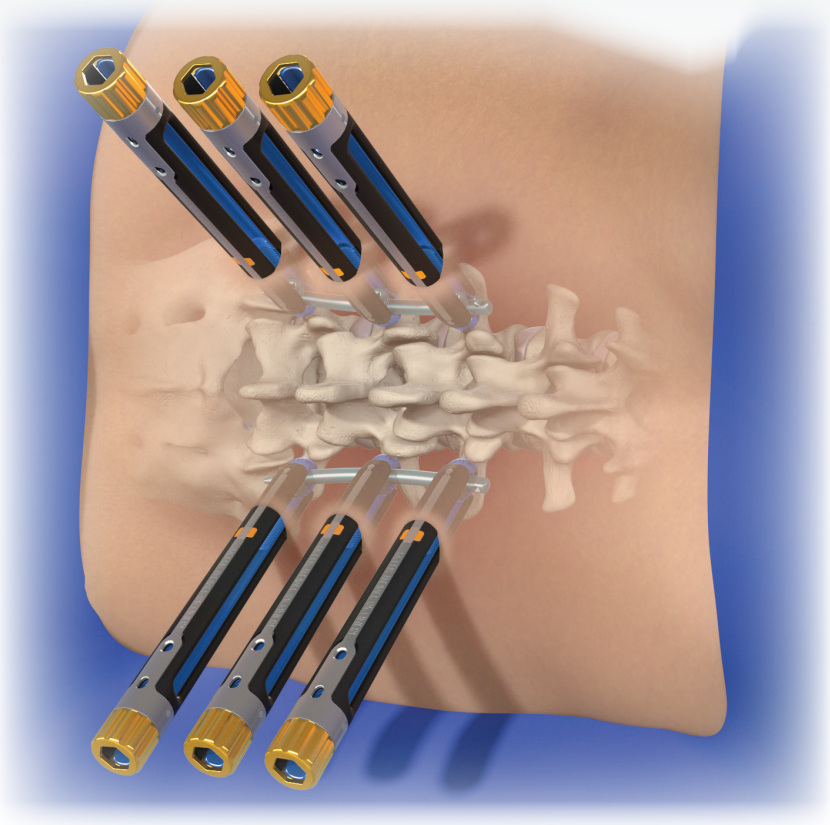
Surgical Technique Guide







ZimVie



The Vital MIS Spinal Fixation System is a percutaneous screw delivery system that offers a broad range of cannulated implants and specialized instrumentation for a minimalized, percutaneous or mini-open approach. The system was designed to provide surgeons with the flexibility to utilize instrumentation based on their personal technique, preference and specific patient needs.

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ZimVie Spine does not practice medicine. This technique was developed in conjunction with health care professionals. This document is intended for surgeons and is not intended for laypersons. Each surgeon should exercise his or her own independent judgment in the diagnosis and treatment of an individual patient, and this information does not purport to replace the comprehensive training surgeons have received. As with all surgical procedures, the technique used in each case will depend on the surgeon's medical judgment as the best treatment for each patient. Results will vary based on health, weight, activity and other variables. Not all patients are candidates for this product and/or procedure.

Vital MIS Implant Features

Integrated Extension Tabs

Fully machined integrated extension tabs remove the concern for weld breaks.

Open extended tab design allows for increased visualization and easier placement of percutaneous rods.

- 30 mm of integrated reduction threads.

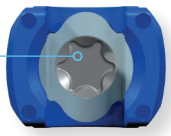
Multiple Instrument Connection Features

- The multiple pedicle screw head connection points allow various instruments to quickly and securely attach, simplifying manipulation maneuvers.
- After the disposable, integrated extension tabs have been removed, all Vital (open) instrumentation is compatible with Vital MIS screws.

Fully Threaded Cannulated Dual-lead Screw Shank

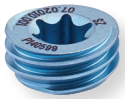
- Self-tapping fully threaded cannulated screw shank designed to improve the starting characteristics and improve bone screw fixation while reducing insertion torque.
- Improves surgeon efficiency by allowing pedicle screw insertion twice as fast as comparable single lead pedicle screws without sacrificing pull-out strength.[1]

T27 Hexalobe Drive Feature



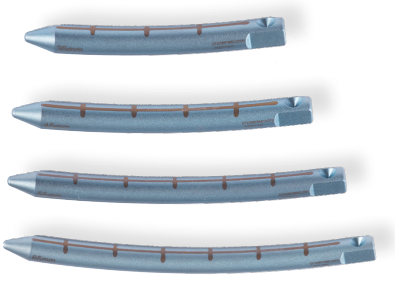
- Screws and closure tops utilize a T27 drive feature (one of the largest in the industry): 30% stronger than a T25 (MDT), 90% greater strength than a T20 (D/S).

Dual-lead Reverse Angle Thread Closure Top



- Dual-lead reverse angle thread designed to improve engagement, advance quickly and help prevent head splay.
- Closure top design supports loosening after final tightening and re-tightening of closure top without performance loss.

Percutaneous Rod Options



- Pre-bent and straight rod options standard in the set.
- Pre-bent rods can attach to rod holders in either lordotic or kyphotic orientation to accommodate thoracic or lumbar curves.

Pedicle Access Tool (PAT)

- Minimizes steps by combining a pedicle targeting needle and a tap into one instrument.

Pedicle Access Screw Insertion Tool (PASIT)

- Minimizes steps by providing a direct-to-screw insertion option for surgeons.

Reinforcement Sleeve

- Connects to the head of the pedicle screw (below perforation), adding strength to the extended tabs to allow for reduction, compression and distraction maneuvers.

Multiple Rod Inserters

- Standard thru-tip option allows the tip of the rod inserter to pass through the extended tabs of the pedicle screw for direct rod placement.

Standard thru-tip

- Standard stop-tip option provides a positive stop against the head of the pedicle screw aiding in proper rod placement.

Standard stop-tip

- Rod forceps allow for direct placement of a rod in mini-open/Wiltse approach.

Rod forceps

Preoperative and Intraoperative Preparation

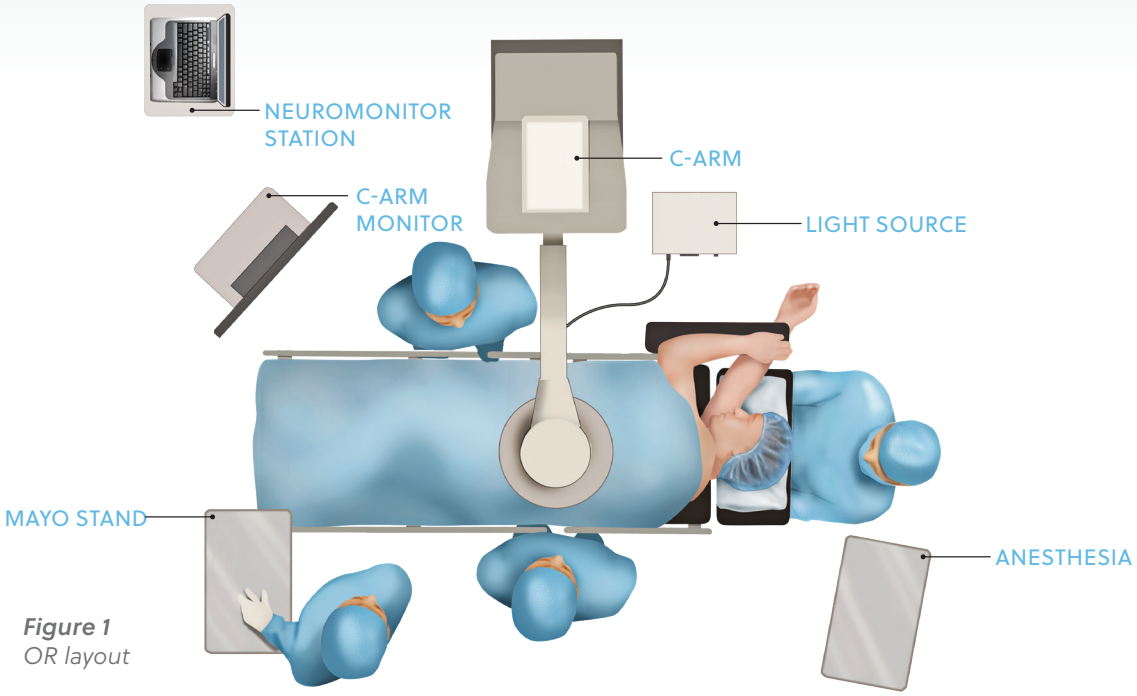


Figure 1
OR layout

Preoperative Preparation

- The primary surgeon must be fully experienced with the required spinal fusion techniques, as well as the lateral surgical approach to the spine.
- Surgical site access is dependent upon the level and indication(s) being treated. Adequate planning should be done to ensure safe and proper access to the surgical site for lateral interbody placement and MIS posterior fixation.
- Preoperative imaging studies of the anatomy should be examined to:
  - Ensure that the range of implant sizes is appropriate for the patient's anatomy at the proposed operative levels.
  - Give special consideration to L4–L5, ensuring that height of the iliac crest will not prevent access to the L4–L5 disc space.
  - Review anatomy and determine the best approach (i.e., left or right, concave vs. convex side of deformity).

Intra Operative Preparation

- All imaging studies should be available for both planning and intraoperative review of the patient's anatomy.
- The operative suite should be laid out such that it is conducive to the lateral approach procedure (Figure 1).

Patient Preparation

Neuromonitoring may be selected at the surgeon's discretion. If neuromonitoring is to be used, a neurophysiologist or neuromonitoring technician should apply electrodes to the patient prior to patient positioning.

Tip: *If neuromonitoring is selected, it is important to discuss with the anesthesiologist that the patient is not to be administered paralytics during the procedure. A "train of four" test will help ensure an absence of paralytics.*

Figure 2
Patient positioning and taping

Patient Positioning

- Place the patient in a lateral decubitus (90°) position on a radiolucent surgical table such that the patient's greater trochanter is directly over the break in the table.
- The patient should be positioned no more than 3-5 in. from the edge of the table to ensure adequate access to the pedicles for posterior MIS pedicle screw fixation. If appropriate, the surgical table should be reversed prior to positioning the patient so that fluoroscopy may be used.

Tips:

- Considerations for left- vs. right-side positioning:
  - When anatomy allows, a left-sided approach is preferred.
  - Previous surgeries or anatomical factors may dictate approaching from the patient's right side.
- As needed, use an axillary roll under the axilla, and a hip bump underneath the patient's greater trochanter. The hip bump may be removed prior to posterior fixation.
- Place pillows under the head, between the knees and under the upper arm.
- Cover sensitive areas as needed with a towel prior to taping. 3-inch silk surgical tape is recommended.
- Secure the patient to the table using surgical tape per the following (Figure 2):
  a. Directly across the table, just below the tip of the iliac crest and below table break.
  b. Directly across the table, over the thoracic region just underneath the arm.
  c. Just superior and anterior to tip of the iliac crest, down to the foot of the table (posterior), around the corner of the table and back to the tip of the iliac crest.
  d. Just superior and posterior to tip of the iliac crest, down to the foot of the table (anterior), around the corner of the table and back to the tip of the iliac crest.
  e. From the tip of the iliac crest, straight down to the end of the table.
  f. From the anterior edge of the table, over the knee and along the lower leg to the posterior, inferior corner of the table.
- The pelvis should now be tilted away from the spine by lowering the table's "foot" end or the patient's legs.

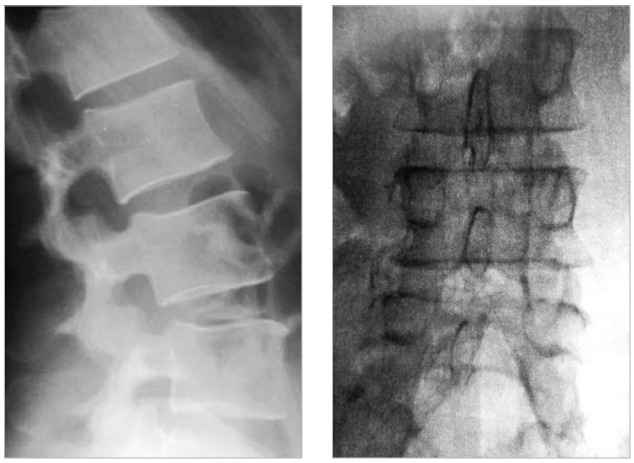


Figure 3
Examples of true lateral and A/P images

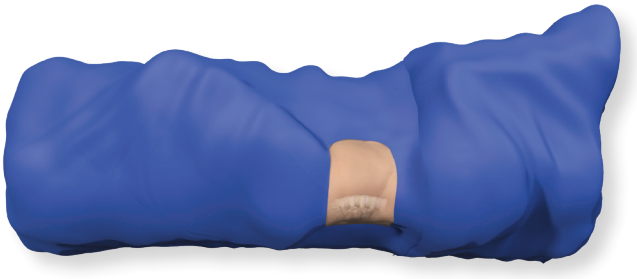


Figure 4

Patient Positioning (continued)

- Now that the patient has been secured to the table, adjust the table so that true lateral and anterior-posterior (A/P) images may be obtained when the C-arm is set at 90° and 0° respectively.

  Note: *True A/P orientation of the surgical level has been achieved when the spinous process is centered directly between the pedicles, the pedicles appear round and the endplates are distinguished as a solid line on the A/P radiograph/fluoro.*

- True lateral and A/P images may require adjusting the bed position separately for each level.
- True lateral orientation is noted by observing a sharp view of the endplates at the operative level and when the neural foramina align perfectly on the lateral radiograph/fluoro (Figure 3).
- Drape and prep the surgical site for the lateral procedure and MIS posterior fixation procedure (Figure 4).
- Perform lateral interbody procedure.

Preoperative Planning

The following Surgical Technique Guide Supplement describes the recommended placement and use of the Vital MIS Spinal Fixation System guidewires with the patient in the lateral position.

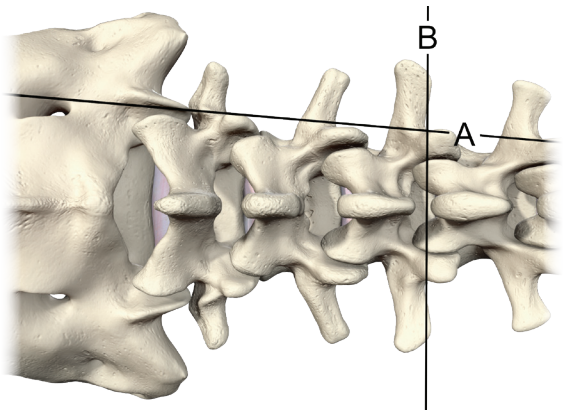


Figure 5

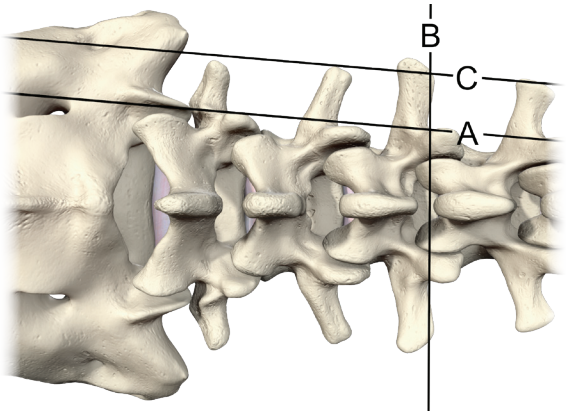
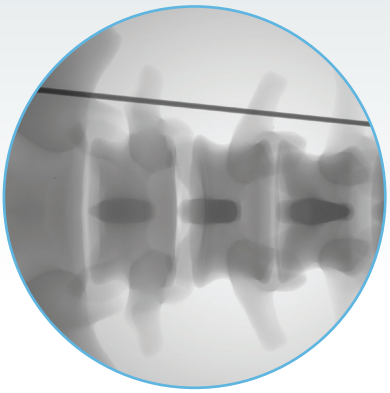


Figure 6

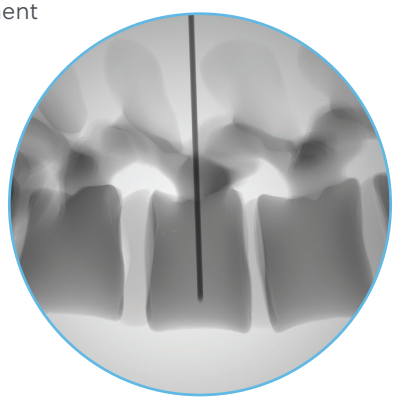
Patient Marking

- Fluoroscopically locate the pedicle's lateral border by placing a guidewire in a cephalad/caudal orientation on the skin.
- With a sterile pen, mark a vertical line, line "A," on the skin.
- Position the guidewire perpendicular to "A" and with a slightly superior bias over the pedicle.
- Confirm fluoroscopically and mark with a horizontal line on the skin, line "B" (Figure 5).
- Repeat marking line "B" for each vertebral body to be instrumented, first ensuring to reposition the C-arm for proper A/P view of each level.
- The intersection of lines "A" and "B" marks the optimal pedicle entry.
- Due to the depth of soft tissue and muscle, draw a second vertical line 2 cm–3 cm lateral to line "A." This is line "C," and delineates the incision site (Figure 6).
- An oblique view directly down the pedicle can also be utilized to identify the ideal skin entry point.

  Note: *Greater subcutaneous tissue requires greater lateral distance skin incision.*



A/P Alignment



Lateral Alignment

Figure 7

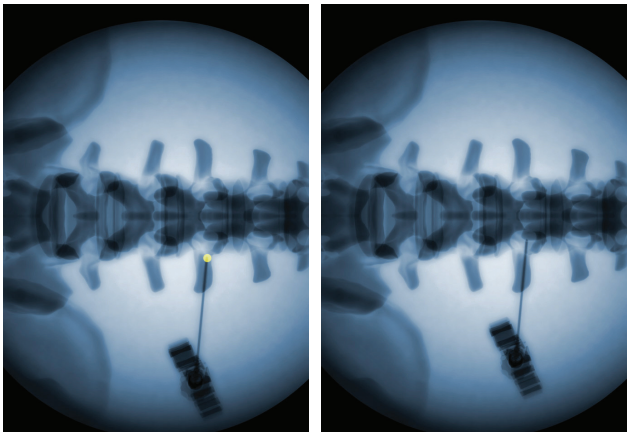


Figure 8

Pedicle Targeting

- When visualizing the anatomy, the superior endplates on the A/P radiograph should be parallel, as well as showing perfect symmetry of the pedicles in their relation to the spinous process (Figures 7).

  Note: *When targeting the S1 pedicle, a Ferguson view is recommended.*

- On the lateral radiograph, the endplates and pedicles should be parallel to ensure that the depth trajectory of the instrumentation is in-line with the A/P radiograph (Figure 7).
- A spinal needle can be utilized to localize the anatomy and verify the trajectory required for the individual pedicles.
- Upon confirmation of the trajectory, the skin can be marked accordingly for the incision.
- Due to the nature of the pedicle anatomy, care should be taken to ensure that the starting point of the targeting needle begins in the proper trajectory and plane (Figure 8).

Surgical Technique

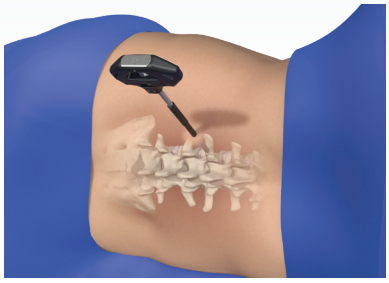


Figure 9

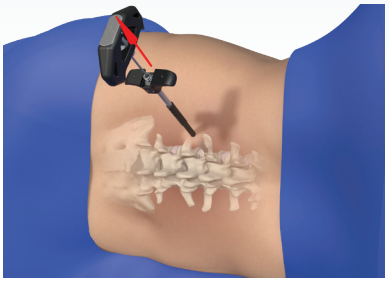


Figure 10

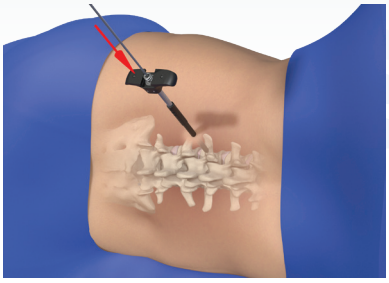


Figure 11

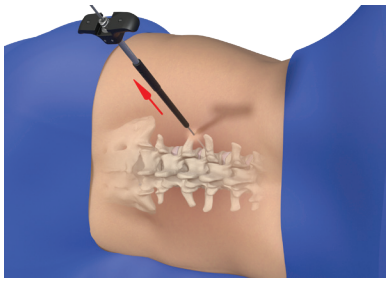


Figure 12

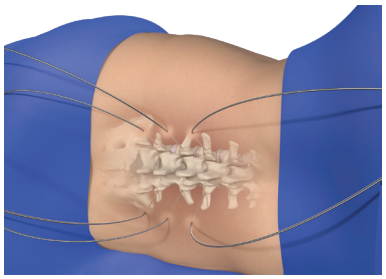


Figure 13

Note: *Please see Vital MIS Surgical Technique Guide for full instructions on tapping, pedicle screw placement, percutaneous rod placement and full instructions on the Vital MIS Spinal Fixation System.*

Pedicle Preparation

- Make an incision in the skin and fascia approximately 16 mm wide for each screw.
- Place a targeting needle on the pedicle, advancing it into the pedicle, paying attention to follow the pedicular column (Figure 9). Final position is verified via A/P and Lateral fluoroscopic imaging.

  Tip: *From a true A/P view, the proper starting point is at the intersection of the facet and transverse process. On the right side, this is the 3 o'clock position on the lateral wall of the pedicle and on the left side, this is the 9 o'clock position on the lateral wall of the pedicle.*
- The pedicle is perforated with the targeting needle and the needle is advanced into the vertebral body following the pedicle trajectory. This trajectory is typically parallel to the endplate with 10° to 12° of lateral to medial angulation.
- Remove the inner stylus of the targeting needle (Figure 10).
- With the inner stylus of the targeting needle removed, place the guidewire within the needle cannula (Figure 11).

  Tip: *The guidewire slap hammer may be utilized for more control when introducing or removing the guidewire.*

  Note:*The guidewire should be placed so that the distal end is approximately 60-70% across the vertebra.*

  Note:*There are both trocar and blunt tip guidewires available in the set.*
- Remove the lower portion of the targeting needle, taking care that the guidewire maintains purchase in the vertebra (Figure 12). For the "floor side" pedicles, care should be taken during the MIS fixation procedure to ensure that surgical instruments do not fall onto the floor.
- Repeat pedicle targeting and preparation for all indicated levels (Figure 13).

Important Information on the Vital MIS Spinal Fixation System

Vital

The Vital Spinal Fixation System is a subsystem of the Vitality Spinal Fixation System.

Device Description

The Vitality Spinal Fixation System is a thoracolumbar and sacroiliac fixation system designed to aid in the surgical correction of several types of spinal conditions. The system consists of a variety of spinal rods, pedicle screws, hooks and connectors intended only to provide temporary stabilization during the development of a solid fusion of the spine with bone graft. The system can be rigidly locked into a variety of configurations, with each construct being customized to the patient's anatomy. All implants are single use only and should not be reused under any circumstances. The implant system is intended to be removed after solid fusion has occurred.

The system also includes instrumentation for insertion, securing and removal of the implants. All implants are made from medical grade titanium alloy; select rods are also available in medical grade cobalt chromium alloy. Implants made from medical grade titanium, medical grade titanium alloy, and medical grade cobalt chromium may be used together. Never use titanium, titanium alloy and/or cobalt chromium with stainless steel in the same implant construct. The Vitality Spinal Fixation System is compatible with components from other cleared spinal fixation systems. See Indications below.

Indications

The Vitality Spinal Fixation System implants are non-cervical spinal fixation devices intended for posterior pedicle screw fixation (T1 S2/ilium), posterior hook fixation (T1 L5), or anterolateral fixation (T8 L5). Pedicle screw fixation is indicated for skeletally mature patients and for adolescent patients.

These devices are indicated as an adjunct to fusion for all of the following indications: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), deformities or curvatures (i.e., scoliosis, kyphosis and/or lordosis, Scheuermann's Disease), tumor, stenosis, pseudoarthrosis and/or failed previous fusion. When used as an adjunct to fusion, the Vitality Spinal Fixation System is intended to be used with autograft and/or allograft.

In addition the Vitality Spinal Fixation System is intended for treatment of severe spondylolisthesis (Grade 3 and 4) of the L5–S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft, having implants attached to the lumbosacral spine and or ilium with removal of the implant after attainment of a solid fusion. Levels of pedicle screw fixation for these patients are L3-sacrum/ilium.

When used for posterior non-cervical pedicle screw fixation in pediatric patients, the Vitality System implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. The Vitality System is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

The use of the Vitality Spinal Fixation System in skeletally mature patients may include the fixation of the Instinct® Java™ Spinal Fixation System* hooks, APEX Spinal System™* hooks, or fixation of the Universal Clamp® Spinal Fixation System* to the rods of the Vitality Spinal Fixation System. The Vitality Spinal Fixation System may also be used in skeletally immature patients when connected with the Universal Clamp Spinal Fixation System.

In order to achieve additional levels of fixation in skeletally mature patients, the Vitality Spinal Fixation System may be connected to the Virage® OCT Spinal Fixation System* and the Instinct Java Spinal Fixation System offered by ZimVie Spine, using rod connectors.

* These optional components are not approved in all regions.

Contraindications

The Vitality System is not designed or sold for any use except as indicated. DO NOT USE THE VITALITY SYSTEM IMPLANTS IN THE PRESENCE OF ANY CONTRAINDICATION.

- Insufficient bone quantity, severe osteoporosis or other condition that might compromise rigid fixation of the device.
- A history of infection, active systemic infection or infection localized to the site of the proposed implantation.
- Suspected or documented metal allergy or intolerance.
- A disorder affecting the normal process of bone remodeling, including but not limited to severe osteoporosis involving the spine, excessive bone reabsorption, osteopenia, a primary or metastatic tumor involving the spine or certain metabolic disorders of osteogenesis.
- Iliac screws and offset connectors should not be used in cases of tumor or trauma of the sacrum, when additional screw fixation in S1 is not possible.
- Other relative contraindications include obesity, pregnancy, certain degenerative diseases, and foreign body sensitivity. In addition, the patient's occupation or activity level or mental capacity may be relative contraindications to this surgery. Specifically, some patients may, because of their occupation or lifestyle, or because of conditions such as mental illness, alcoholism or drug abuse, place undue stresses on the implant

Warnings and Precautions

Following are specific warnings, precautions and adverse effects associated with use of the Vitality System that should be understood by the surgeon and explained to the patients. General surgical risk should be explained to the patients prior to surgery.

- Implantation of the Vitality System should be performed only by experienced spinal surgeons.
- All implants are intended for single use only. Single-use devices should not be re-used. Possible risks associated with re-use of single-use devices include:
  - Mechanical malfunction
  - Transmission of infectious agents
- Metal sensitivity has been reported following exposure to orthopedic implants. The most common metallic sensitivities (nickel, cobalt and chromium) are present in medical grade stainless steel and cobalt-chrome alloys.
- Universal precautions should be observed by all end users that work with contaminated or potentially contaminated medical devices. Caution should be exercised when handling devices with sharp points or cutting edges to prevent injuries during and after surgical procedures and reprocessing.
- Warning: The safety and effectiveness of pedicle screw spinal systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are significant mechanical instability or deformity of the thoracic, lumbar and sacral spine secondary to severe spondylolisthesis (grades 3 and 4) of the L5–S1 vertebra, degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor and failed previous fusion (pseudoarthrosis). The safety and effectiveness of these devices for any other conditions are unknown.
- Warning: The safety and effectiveness of this device has not been established for use as part of a growing rod construct. The device is only intended to be used when definitive fusion is being performed at all instrumented levels.
- Additional Warnings for Pediatric Patients: The use of pedicle screw fixation in the pediatric population may present additional risks when patients are of smaller stature and skeletally immature. Pediatric patients may have smaller spinal structures (pedicle diameter or length) that may preclude the use of pedicle screws or

Important Information on the Vital MIS Spinal Fixation System *(continued)*

increase the risk of pedicle screw malpositioning and neurological or vascular injury. Patients who are not skeletally mature undergoing spinal fusion procedures may have reduced longitudinal spinal growth, or may be at risk for rotational spinal deformities (the "crankshaft phenomenon") due to continued differential growth of the anterior spine.

- Precaution: The implantation of pedicle screw spinal systems should be performed only by experienced spinal surgeons with specific training in the use of this pedicle screw spinal system because this is a technically demanding procedure presenting a risk of serious injury to the patient.
- Additional Precautions for Pediatric Patients: The implantation of pedicle screw spinal systems in pediatric patients should be performed only by experienced spinal surgeons with specific training in the use of this pedicle screw spinal system in pediatric patients because this is a technically demanding procedure presenting a risk of serious injury to the patient.

Preoperative and operating procedures, including knowledge of surgical techniques, good reduction, and proper selection and placement of the implants are important considerations in the successful utilization of the system in pediatric patients. The selection of the proper size, shape and design of the implant for each patient is crucial to the safe use of this device in pediatric patients.

Additional preoperative, intraoperative and postoperative warnings and precautions:

Preoperative

- Usage of automated cleaning processes without supplemental manual cleaning may not result in adequate cleaning of instruments.
- Proper handling, decontamination (including pre-rinsing, washing, rinsing and sterilization), storage and utilization are important for the long and useful life of all surgical instruments. Even with correct use, care and maintenance, they should not be expected to last indefinitely. This is especially true for cutting instruments (e.g., bone awls/drills) and driving instruments (e.g., drivers). These items are often subjected to high loads and/or impact forces. Under such conditions, breakage can occur, particularly when the item is corroded, damaged, nicked or scratched.
- Never use titanium, titanium alloy, and/or cobalt chromium with stainless steel in the same implant construct; otherwise, galvanic corrosion may occur.
- ZimVie does not specify the maximum number of times a re-usable instrument may be re-used. The useful life of these instruments is highly dependent on a number of factors including the frequency and manner in which they are used and the handling they experience in between uses. Inspection and, where appropriate, functional testing prior to using, is the best way to determine whether or not an individual device should be used.

Intraoperative

- If contouring of the implant is necessary for optimal fit, the contouring should be gradual and avoid any notching or scratching of the implant surface. Do not repeatedly or excessively bend the implant. Do not reverse bend the rods.
- Pedicle bone integrity should be verified.
- Care should be taken during pedicle preparation to avoid penetrating too deep.
- Care should be taken during bone preparation to avoid damage to the pedicle and to the surgical instruments.
- Care should be taken to minimize soft tissue damage during surgery.
- Care should be taken to avoid removing excess material from the lamina.
- Care should be taken to avoid cross-threading screws and closure tops.
- If any implant or instrument comes in contact with a non-sterile surface it should not be used.

Postoperative

- Adequately instruct the patient. Postoperative care and the patient's ability and willingness to follow instructions are one of the most important aspects of successful bone healing. The patient must be made aware of the limitations of the implant and that physical activity and full weight bearing have been implicated in fracture. The patient should understand that an implant is not as strong as normal, healthy bone and will fracture if excessive demands are placed on it in the absence of complete bone healing. An active, debilitated, or demented patient who cannot properly use weight-supporting devices may be particularly
  at risk during postoperative rehabilitation.
- The Vitality System is a temporary internal fixation device. Internal fixation devices are designed to stabilize the operative site during the normal healing process. After healing occurs, these devices serve no functional purpose and should be removed. Implant removal should be followed by adequate postoperative management to avoid fracture
  or refracture.

Adverse Effects

Complications and adverse reactions have been reported with the use of similar spinal instrumentation systems. These adverse effects, including the possibility of death, should be discussed with the patient prior to surgery.

- Non-union, delayed union
- Bending or fracture of implant. Fraying, kinking, loosening, bending or breaking of any or all implant components.
- Loosening of or migration of the implant
- Metal sensitivity or allergic reaction to a foreign body
- Infection
- Decrease in bone density due to stress shielding
- Pain, discomfort, or abnormal sensations due to the presence of the device
- Loss of the natural curvature of the spine
- Modification of the spinal geometric corrections of the vertebral and/or intervertebral height and/or of the reduction in spinal deformities
- Vascular and/or nerve damage due to surgical trauma or presence of the device.
- Neurological difficulties including bowel and/or bladder dysfunction, impotence, retrograde ejaculation and paraesthesia.
- Bursitis
- Dural leak
- Paralysis
- Death
- Erosion of blood vessels due to the proximity of the device, leading to hemorrhage and/or death
- Additional surgery may be required to correct any of these potential adverse effects
- Additional Potential Adverse Effects for Pediatric Patients:
  - Inability to use pedicle screw fixation due to anatomic limitations (pedicle dimensions, distorted anatomy)
  - Pedicle screw malpositioning, with or without neurological or vascular injury
  - Proximal or distal junctional kyphosis
  - Pancreatitis

Other adverse events related to pedicle screw fixation, such as screw or rod bending, breakage, or loosening, may also occur in pediatric patients and pediatric patients may be at increased risk for device-related injury because of their smaller stature.

For more information, visit ZimVie.com

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