Tritanium® PL Posterior Lumbar Cage

Surgical technique
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Sigurd Berven, MD
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Thomas Mroz, MD
John Rhee, MD
Tritanium technology overview

Tritanium is Stryker’s proprietary titanium alloy material built using Laser Rapid Manufacturing (LRM). This material has been used to create a cage that consists of a unique configuration of both solid and porous material surfaces.

- Highly porous titanium alloy on top and bottom of implant and all sides of internal graft window
- Solid-tipped, precisely angled serrations on the superior and inferior surfaces designed for bidirectional fixation and to maximize surface area for endplate contact with the implant
- Thin layer of solid material to provide smooth surface during insertion and reduce potential to catch soft tissue
- Smooth wedge nose to facilitate insertion
- Large window to reduce stiffness of cage and help with assessment on different imaging modalities
The following technique describes the unilateral insertion of a single implant into the disc space through a posterior lumbar interbody fusion (PLIF) approach, transforaminal lumbar interbody fusion (TLIF) approach or anywhere in between based on the pathology being addressed and surgeon preference. This technique may be performed through an open, less invasive or minimally invasive procedure.

Minimally invasive surgical procedures, without compromising surgical goals, may:

- Reduce incision size
- Reduce blood loss
- Reduce infection
- Lead to faster patient recovery
- Reduce pain
- Reduce hospital stay
- Spare muscle (Multifidus)
- Reduce reoperations

Note: This surgical technique is intended as a guide only. It is recommended that the surgeon be thoroughly trained before proceeding. The surgeon must consider the particular needs of each patient and make the appropriate adjustments when necessary and as required.

Please refer to the Tritanium PL Instructions For Use for complete information on indications, contraindications, precautions, warnings, potential adverse effects, sterilization and packaging.
Tritanium PL

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Description

The Tritanium PL posterior lumbar cages are rectangular-shaped interbody fusion devices intended for use as an aid in spinal fixation. These implants are constructed out of Stryker’s proprietary Tritanium technology. Tritanium is a novel highly porous titanium material designed for bone in-growth and biological fixation. These implants are offered in a variety of widths, lengths, heights and lordotic angles designed to adapt to a variety of patient anatomies. The implants have serrations on the superior and inferior surfaces designed for bidirectional fixation and to maximize surface area for endplate contact with the implant. The implants have ergonomically shaped anterior edges to facilitate cage insertion with preservation of endplates and flat posterior edges. The implants have a large central opening spanning endplate to endplate for graft containment and to aid in fusion throughout the interbody cage. Tritanium PL cage system is comprised of Tritanium PL cages as well as surgical instruments from other Stryker systems.
Surgical technique

Step 1: Exposure open approach
The patient is placed under anesthesia and positioned in the prone position prepped and draped in the usual sterile manner for posterior fusion with supplemental fixation (Figure 1).

The surgical approach to implant a Tritanium PL cage can be performed using a standard open, less invasive or minimally invasive procedure, from the patient’s left or right side. Typically, cage insertion is performed from the symptomatic side in patients with radiculopathy or on the concavity in patients with segmental coronal deformity. This technique describes an open surgical procedure.

This technique describes an open TLIF procedure placing a Tritanium PL cage obliquely across the disc space. The incision is made over the spinous process of the level above the index disc level and extends to the spinous process of the level below (Figure 2). Sharp paraspinal, subperiosteal dissection is performed exposing the facets of the level above and the facets at the operative level. Care must be taken to avoid damage to the facet capsules at the unfused level above. Unless the surgeon intends to perform concomitant intertransverse fusion, the transverse processes need not be exposed. Exposure to the tips of the transverse processes will permit a posterolateral fusion in addition to the interbody fusion.
**Note:** The remaining steps in this surgical technique are similar in open, less invasive and minimally invasive PLIF and TLIF surgical procedures. All images in this technique guide depict an open procedure for image clarity. The Tritanium PL cage system lends itself to minimally and less invasive techniques. These techniques rely on proprietary access systems and specialized tools, the use of which is best depicted in their individual technique guides. Please refer to Stryker’s retractor system surgical technique guides, including LITE Pedicle Based Retractor, LITE Mid-Line Retractor and LITE Decompression Tubes, for additional information and detailed images on less invasive and minimally invasive PLIF and TLIF procedures. In a minimally invasive TLIF procedure, the incision may be made at the midline or approximately 4cm off midline with a more lateral trajectory in line with the disc space (Figure 3).

### Step 2: Preparation of facet joints

At the operative level, both facet capsules should be removed completely. This is typically accomplished using a cauterity device. The facet is prepared for fusion by removing the articular cartilage from the facet joint with a burr, rongeur or other appropriate instrument (Figure 5). The inferior and superior articular facets are removed on the side of the TLIF. Complete facetectomy of the contralateral side may permit increased restoration of segmental lordosis.
Step 3: Insertion site preparation: Facet sparing or transforaminal
The Tritanium PL cage may be inserted into the disc space using either a facet sparing (similar to a posterolumbar interbody fusion, PLIF) or a transforaminal (TLIF) approach. For the TLIF approach, at the appropriate level(s), an osteotome may be used to remove the inferior articular process of the cephalad vertebra. If an osteotome is used, this may be done with two cuts (Figure 6):
- One vertical cut just medial to the facet extending superiorly to the superior border of the facet
- One horizontal cut directed laterally towards the foramen

Once both cuts are made, the inferior articulating process of the cephalad vertebra may be removed with a kerrison. The lateral edge of the ligamentum flavum can then be visualized. A curette may be used to release (but not resect) the ligamentum flavum from the superior lamina of caudal vertebra allowing for distraction. The ligamentum flavum may be preserved to minimize exposure of the neural elements, but resection of the ligamentum flavum is often required for adequate neural compression.

Step 4: Distraction
Minimal distraction may be required to insert the interbody implant. If distraction is needed to insert the implant, there are several techniques that can be utilized including: pedicle screw distraction, distraction between bony elements and/or distraction with a positioning device. Distraction should be removed when the implant is in the interbody space to minimize external compressive forces on the interbody space.
Step 5: Discectomy and endplate preparation

Access to the disc space is achieved through an annulotomy made lateral to the posterior longitudinal ligament. Using a scalpel, vertical cuts are made parallel to the dura and laterally in the foramen from the endplate of the cephalad vertebra to the endplate of the caudal vertebra. Additional cuts extend horizontally along the endplates of the vertebrae, connecting the vertical cuts (Figure 7). Access to the disc space may also be gained using an osteotome at the superior endplate of the lower vertebra. The annulus and any accessible disc material are removed with a pituitary rongeur (Figure 8).

Note: The Tritanium PL cages come in 9mm and 11mm width options. It is recommended that the annulotomy be at least as wide as the implant in order to facilitate insertion of the implant. If using a 9mm wide Tritanium PL cage, the annulotomy should be at least 9mm wide. If using an 11mm wide Tritanium PL cage, the annulotomy should be at least 11mm wide.

Note: Throughout the remainder of the procedure, care must be taken to avoid unintentional disruption of the remaining lateral, anterior or posterior annulus.

Note: Disc removal and endplate preparation instrumentation is available in the Reliance Total PLIF Instrument set, the Reliance LITE Instrument set and the LITE Decompression Instrument set.

If osteophytes are present, sharp excision with an osteotome or kerrison punch will provide a larger entry portal if desired.

A curette, endplate shaver or narrow cobb elevator is used to elevate disc material from the endplates of the vertebral bodies. Angled curettes can also be used to elevate the disc from the endplates. An easily missed portion of the disc lies posteriorly and centrally within the disc space, just ventral to the spinal canal. Special effort should be directed to disc removal in this zone to provide optimal surface area for interbody fusion. Straight and angled pituitary rongeurs should be used to remove the disc. Additionally, multiple passes with the straight and angled curettes may be necessary to ensure adequate discectomy. Fluoroscopy may help in ensuring an adequate discectomy while limiting the risk of unintentional disruption to the ventral, lateral or posteromedial annulus.
Step 6: Sizing the disc space
The disc space height can be sized using a series of paddle distractors, reamer distractors or trials. The paddle distractor, reamer distractor or trial size is serially increased until the appropriate fit within the disc space is achieved. The paddle distractor, reamer distractor or trial should fit snugly within the disc space with distraction released. Care must be taken to not damage the dense cancellous bony surface of the endplate to optimize the interface between the endplate and the implant (Figure 9).

Figure 9. Measuring Tritanium PL cage length using trial

Trials
Choose a Trial and insert into the disc space. Attach the Trial to the T-Handle.

Note: The Trial footprint is available in all height and width offerings; however, it is only available in a length of 20mm. A ridge exists on the post of the trial at 25mm and 30mm, and is designed to assist the surgeon in determining which implant length is appropriate from radiographic images.

Note: Tritanium PL cages are available in 23mm and 28mm lengths.

Note: The Trials should be evaluated under fluoroscopic imaging to determine the proper fit and placement of the final implant.
Note: If the surgeon utilizes the AVS Navigator Dynamic Distractor, 48394005, to determine the implant height, carefully and slowly expand the Dynamic Distractor as to not over distract the disc space or violate the endplates. Reference the AVS Navigator Surgical Technique Guide for instruction on assembly, use, disassembly, cleaning and sterilization.

Step 7: Tritanium PL cage sizing and preparation
It is recommended to choose a cage that is equivalent to the final Trial height or final distractor used. The implant sizing is based on the fit and feel of either the final Trial or distractor.
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How to open the pouch containing the Tritanium PL cage

The Tritanium PL cages are sterile packaged. Select the appropriate implant size and verify before opening the packaging.

To remove the cage from the pouch:
1. Remove the large flap from the cross strap.

2. Hold the top of the cutout with one hand while holding the smaller flap on the opposite side with the other.

3. Pull the top of the cutout and small flap away from each other until the pouch opens.

4. Remove the cage from the pouch.
To assemble the Inserter:
1. Remove the Inserter, including the Inner Shaft, from the Instrument Tray.

Note: The PEEK Spacer Inserters from the AVS PL and UniLIF systems are the same Inserters used to implant the Tritanium PL cages.

2. Place the threaded end of the Inner Shaft through the center opening on the back of the appropriate Inserter.

Refer to the table to determine the appropriate Inserter used with the cage size selected by the surgeon.

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<td>9-14mm</td>
<td>Inserter 11</td>
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**Step 8: Assemble Tritanium PL cage to Inserter**

Align the threaded distal tip of the Inner Shaft with the threaded hole on the selected cage. Secure the cage to the Inserter by turning the knob on the Inner Shaft until the implant is tightly connected.

**Note:** The AVS PL Inserter is held disassembled in the Instrument Tray for cleaning and sterilization purposes.

**Note:** Make sure the Inner Shaft is completely seated by pressing down on the proximal end until the Inner Shaft bottoms out within the Inserter. This will allow the distal end of the Inner Shaft to fully protrude providing the necessary surface area to securely load the implant (Figure 10).
Place the Tritanium PL cage in the **Graft Block**, and pack it with autogenous or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft using the **Graft Compactor**. The compacted graft should be flush with the upper and lower surfaces of the implant, to later be in contact with the endplates (Figure 11).

**Step 9: Tritanium PL cage insertion**
Carefully insert the cage gently and progressively into the disc space using a mallet when necessary. Optimal positioning may be facilitated by directing the implant obliquely until it contacts the ventral annulus (Figure 12). If difficulty is encountered while inserting the implant, it most likely represents contralateral disc material which may be blocking passage of the implant, inadequate distraction, an undersized annulotomy or oversized implant.

Check for adequacy of the discectomy and be sure distraction, if used, is maintained. Then, reposition the implant as needed. The distraction, if used, should be released to facilitate optimal placement of the implant.

**Note:** Final cage position may vary depending on surgeon preference.
The recommended insertion angle for the obliquely lordotic PL implants is approximately 30° off midline. The circular dimple feature on the posterior end of the lordotic 28mm implants is designed to help determine the orientation of the lordosis. To help ensure the lordosis is restored in the desired plane, the circular dimple must be towards the lateral aspects in an oblique insertion (Figure 13).

**Note:** Nerves or the spinal cord could interfere with implant insertion - Retractors similar to the Reliance PL Nerve Root Retractors (48360300, 48360310 and 48360320) or Reliance LITe Penfields (48066104 and 48066204) can be used.

**Note:** To visually confirm the lordosis is restored in the desired plane, the implant must be inserted with the circular dimple feature towards the lateral aspects in an oblique insertion.

**Note:** Fluoroscopy may be useful in determining the appropriate trajectory for insertion of the implant and appropriate final positioning. Care should be taken to prevent the instrument from pushing too far anteriorly.

**Caution:** In patients with compromised bone integrity, be mindful that the implant is in apposition to dense bone to maximize distraction of the interbody space and to avoid possible implant subsidence.

Based on surgeon preference, the PL Impactor or the AVS Navigator Footed Tamp may be used to gently tamp the implant to its final position.
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Note: The Tritanium PL cage can be used for a traditional PLIF approach with two implants placed in a straight orientation bilaterally within the disc space (Figure 14).

The correct position of the implant should be confirmed by direct visualization of implant location and/or with lateral and anterior-posterior fluoroscopic images (Figures 15 and 16).
**Note:** For intraoperative removal of the cage, when deemed medically necessary, use the AVS PL Inserter still attached to the implant to remove the cage from the disc space. If needed, a mallet or slap hammer can be used. If the cage has been removed intraoperatively, it should not be re-inserted into the disc space as this may affect the performance of the implant.

With the desired position achieved, detach the AVS PL Inserter from the implant by turning the knob on the Inner Shaft in a counterclockwise direction.

**Step 10: Placement of bone graft**

Autograft and/or allogenic bone graft may be placed in the interbody space prior to insertion of the implant. The cage should be filled with bone graft prior to insertion. Additional bone graft may be placed lateral or dorsal to the implanted cage.
Step 11: Posterior fusion
The Tritanium PL cages are to be used with supplemental fixation that is intended for use in the lumbosacral spine. If pedicle screws were not inserted earlier in the procedure, insert pedicle screws at this point or other appropriate supplemental fixation. Compression of the pedicle screws or interspinous device may be used to create segmental lordosis of the segment fused (Figure 17).

The remaining bone graft may be placed in the decorticated facets to promote fusion.

Intraoperative coronal and sagittal radiographic views should be used to confirm satisfactory position of the Tritanium PL cage, supplemental fixation and bone graft.

Note: Choices for supplemental spinal fixation systems include, but are not limited to, Stryker’s pedicle screw or interspinous process fixation plate systems (Xia, Radius, Trio, Techtonix, UniVise and ES2). Please refer to the respective surgical techniques of the above mentioned supplemental fixation systems for additional information on implantation.
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**Step 12: Closure**
Check the foramen and TLIF site for any bone fragments or extraneous soft tissue. Once satisfactory decompression of the exiting and traversing nerve roots is confirmed, the wound should be closed in a routine manner.

**Step 13: Revision**
A surgical revision may be indicated for many reasons including new or unresolved pain or neurological symptoms, changes in implant positioning, non-union or incomplete fusion, etc. If necessary, the Tritanium PL cage can be removed with the use of the AVS PL Inserter and a mallet or slap hammer. The surgeon must use his/her professional judgment to determine the appropriate revision strategy taking into consideration the patient’s health, the nature of the problem and/or implant failure, the patient’s bone quality and the surgeon’s expertise with other spinal treatments and instrumentation.

**Revision guidelines:**
1. Soft tissue around the surface of the implant should be removed.
2. An osteotome or rongeurs can be used to remove any bony tissue secured to the implant.
3. The AVS PL Inserter is reattached to the implant to remove it from the surgical site.
4. A mallet or slap hammer can be used to aid in withdrawal of the implant.

Alternatively, if the AVS PL Inserter cannot be reattached to the implant, forceps or other manual surgical instruments may be used to grasp and extract the implant.
Tritanium PL sterile packaged cages

Reference number | Description Height x Length x Lordotic angle - Width
--- | ---
48950070 | 7 x 23 x 0 - 9 Posterior Lumbar Cage
48950080 | 8 x 23 x 0 - 9 Posterior Lumbar Cage
48950090 | 9 x 23 x 0 - 9 Posterior Lumbar Cage
48950100 | 10 x 23 x 0 - 9 Posterior Lumbar Cage
48950110 | 11 x 23 x 0 - 9 Posterior Lumbar Cage
48950120 | 12 x 23 x 0 - 9 Posterior Lumbar Cage
48950130 | 13 x 23 x 0 - 9 Posterior Lumbar Cage
48950140 | 14 x 23 x 0 - 9 Posterior Lumbar Cage

Lordotic angle - 6°

Width: 9 mm

Reference number | Description Height x Length x Lordotic angle - Width
--- | ---
48950076 | 7 x 23 x 6 - 9 Posterior Lumbar Cage
48950086 | 8 x 23 x 6 - 9 Posterior Lumbar Cage
48950096 | 9 x 23 x 6 - 9 Posterior Lumbar Cage
48950106 | 10 x 23 x 6 - 9 Posterior Lumbar Cage
48950116 | 11 x 23 x 6 - 9 Posterior Lumbar Cage
48950126 | 12 x 23 x 6 - 9 Posterior Lumbar Cage
48950136 | 13 x 23 x 6 - 9 Posterior Lumbar Cage
48950146 | 14 x 23 x 6 - 9 Posterior Lumbar Cage

Width: 11 mm

Reference number | Description Height x Length x Lordotic angle - Width
--- | ---
48951070 | 7 x 23 x 0 - 11 Posterior Lumbar Cage
48951080 | 8 x 23 x 0 - 11 Posterior Lumbar Cage
48951090 | 9 x 23 x 0 - 11 Posterior Lumbar Cage
48951100 | 10 x 23 x 0 - 11 Posterior Lumbar Cage
48951110 | 11 x 23 x 0 - 11 Posterior Lumbar Cage
48951120 | 12 x 23 x 0 - 11 Posterior Lumbar Cage
48951130 | 13 x 23 x 0 - 11 Posterior Lumbar Cage
48951140 | 14 x 23 x 0 - 11 Posterior Lumbar Cage

Lordotic angle - 6°

Width: 9 mm

Reference number | Description Height x Length x Lordotic angle - Width
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48951076 | 7 x 23 x 6 - 11 Posterior Lumbar Cage
48951086 | 8 x 23 x 6 - 11 Posterior Lumbar Cage
48951096 | 9 x 23 x 6 - 11 Posterior Lumbar Cage
48951106 | 16 x 23 x 6 - 11 Posterior Lumbar Cage
48951116 | 11 x 23 x 6 - 11 Posterior Lumbar Cage
48951126 | 12 x 23 x 6 - 11 Posterior Lumbar Cage
48951136 | 13 x 23 x 6 - 11 Posterior Lumbar Cage
48951146 | 14 x 23 x 6 - 11 Posterior Lumbar Cage
### Tritanium PL Surgical technique

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Important product information for Tritanium PL
Sterile product

Material
The Tritanium PL cages are manufactured out of Titanium Alloy Ti6Al4V (ASTM F1472).

U.S.A and Canada Indications
The Tritanium PL cage is an intervertebral body fusion device indicated for use with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft when used as an adjunct to fusion in patients with degenerative disc disease (DDD) at one level or two contiguous levels from L2 to S1.

DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The DDD patients may also have up to Grade I spondylolisthesis at the involved level(s). These patients should be skeletally mature and have six months of nonoperative therapy.

Additionally, the Tritanium PL cage can be used as an adjunct to fusion in patients diagnosed with degenerative scoliosis.

The Tritanium PL cage is to be implanted via a posterior approach.

The Tritanium PL cage is intended to be used with supplemental spinal fixation systems that have been cleared for use in the lumbosacral spine.

Indications Outside U.S.A. and Canada
The Tritanium PL cage is an intervertebral body fusion device indicated for the treatment of spondylolisthesis, degenerative spine disorders and discal and vertebral instability, and may also be used in cases of spine revision surgery. Packing bone graft material within the implant is recommended.

The Tritanium PL cage is to be implanted via a posterior approach.

The Tritanium PL cage is intended for use with supplemental fixation.

General conditions of use
The implantation of intervertebral body fusion devices must be performed only by experienced spinal surgeons having undergone the necessary specific training in the use of such systems because this is a technically demanding procedure presenting a risk of serious injury to the patient.

The information contained in the Package Insert is necessary but not sufficient for the use of this device. This information is in no sense intended as a substitute for the professional judgment, skill and experience of the surgeon in careful patient selection, preoperative planning and device selection, knowledge of the anatomy and biomechanics of the spine, understanding of the materials and the mechanical characteristics of the implants used, training and skill in spinal surgery and the use of associated instruments for implantation, securing the patient’s cooperation in following an appropriately defined post-operative management program and conducting scheduled post-operative follow-up examinations.

Caution
• Federal law (U.S.A.) restricts this device to sale by or on the order of a licensed physician.
• This device is not intended for anterior surgical implantation.
• This device is provided STERILE. Do not use if package is opened or damaged or after the “Use by” date on the label has expired.
• The Tritanium PL cages have not been evaluated for safety and compatibility in the MR environment. Tritanium PL cages have not been tested for heating or migration in the MR environment.
• Based on the fatigue testing results, the physician/surgeon must consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact the performance of the intervertebral body fusion device.
• The implantation of the intervertebral body fusion device must be performed only by experienced spinal surgeons with specific training in the use of this device because this is a technically demanding procedure presenting a risk of serious injury to the patient.
• Potential risks identified with the use of this intervertebral body fusion device, which may require additional surgery, include: device component fracture, loss of fixation, pseudoarthrosis (i.e. non-union), fracture of the vertebral, neurological injury, and vascular or visceral injury.
• Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.
• The components of the system should not be used with components of any other system or manufacturer. Any such use will negate the responsibility of Stryker for the performance of the resulting mixed component implant.
• Do not mix metals (e.g. Titanium based devices with stainless steel items). Some corrosion occurs on all implanted metals and alloys. Contact of dissimilar metals, however, may accelerate corrosion. Corrosion may accelerate fatigue fracture of implants, and cause metal compounds to be released into the body.

Infection
Transient bacteremia can occur in daily life. Dental manipulation, endoscopic examination and other minor surgical procedures have been associated with transient bacteremia. To help prevent infection at the implant site, it may be advisable to use antibiotic prophylaxis before and after such procedures.

Instruments
Instruments are provided by Stryker and must be used to assure accurate implantation of the device. While rare, intraoperative fracture or breakage of
instruments can occur. Instruments which have experienced extensive use or excessive force are more susceptible to fracture depending on the operative precaution, number of procedures, and disposal attention. Instruments must be examined for wear or damage prior to surgery.

Reuse
Never reuse or re-implant spinal surgical implants. These could become contaminated resulting in infection. In addition, even though the device appears undamaged, it may have small defects which could compromise structural integrity reducing its service life and/or leading to patient injury.

Surgeons must verify that the instruments are in good condition and operating order prior to use during surgery.

Handling
Correct handling of the implant is extremely important. The operating surgeon must avoid notching or scratching the device.

Allergy and hypersensitivity to foreign bodies
When hypersensitivity is suspected or proven, it is highly recommended that the tolerance of the skin to the materials that make up the implants be checked before they are implanted.

Contraindications
Contraindications may be relative or absolute. The choice of a particular device must be carefully weighed against the patient’s overall evaluation. Circumstances listed below may reduce the chances of a successful outcome:
- The Tritanium PL cage should not be implanted in patients with an active infection at the operative site.
- The Tritanium PL cage is not intended for use except as indicated.
- Marked local inflammation.
- Any abnormality present which affects the normal process of bone remodeling including, but not limited to, severe osteoporosis involving the spine, bone absorption, osteopenia, primary or metastatic tumors involving the spine, active infection at the site or certain metabolic disorders affecting osteogenesis.
- Any mental or neuromuscular disorder which would create an unacceptable risk of fixation failure or complications in postoperative care.
- Open wounds.
- Pregnancy.
- Inadequate tissue coverage over the operative site.
- Any neuromuscular deficit which places an unsafe load level on the device during the healing period.
- Obesity. An overweight or obese patient can produce loads on the spinal system which can lead to failure of the fixation of the device or to failure of the device itself.
- A condition of senility, mental illness, or substance abuse. These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions in the use of the implant, leading to failure or other complications.
- Foreign body sensitivity. Where material sensitivity is suspected, appropriate tests must be made prior to material selection or implantation.
- Other medical or surgical condition which would preclude the potential benefit of spinal implant surgery, such as the presence of tumors, congenital abnormalities, elevation of sedimentation rate unexplained by other diseases, elevation of white blood cell count (WBC), or marked left shift in the WBC differential count.
- Prior fusion at the levels to be treated.

These contraindications may be relative or absolute and must be taken into account by the physician when making his decision. The above list is not exhaustive. Surgeons must discuss the relative contraindications with the patients.

Information for patients
The surgeon must discuss all physical and psychological limitations inherent to the use of the device with the patient. This includes the rehabilitation regimen, physical therapy, and wearing an appropriate orthosis as prescribed by the physician. Particular discussion should be directed to the issues of premature weight bearing, activity levels, and the necessity for periodic medical follow-up. The surgeon must warn the patient of the surgical risks and make them aware of possible adverse effects. The surgeon must warn the patient that the device cannot and does not replicate the flexibility, strength, reliability or durability of normal healthy bone, that the implant can break or become damaged as a result of strenuous activity or trauma, and that the device may need to be replaced in the future. If the patient is involved in an occupation or activity which applies inordinate stress upon the implant (e.g., substantial walking, running, lifting, or muscle strain) the surgeon must advise the patient that resultant forces can cause failure of the device. Patients who smoke have been shown to have an increased incidence of non-unions. Such patients should be advised of this fact and warned of the potential consequences. For patients with degenerative disease, the progression of degenerative disease may be so advanced at the time of implantation that it may substantially decrease the expected useful life of the appliance. In such cases, orthopaedic devices may be considered only as a delaying technique or to provide temporary relief. Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.

Pre-operative precautions
The surgical indication and the choice of implants must take into account certain important criteria such as:
- Patients involved in an occupation or activity that applies excessive loading upon the implant (e.g., substantial walking, running, lifting, or muscle strain) may be at increased risk for failure of the fusion and/or the device.
- Surgeons must instruct patients in detail about the limitations of the implants, including, but not limited to, the impact of excessive loading through patient weight or activity, and be taught to govern their activities accordingly. The procedure will not restore function to the level expected with a normal, healthy spine, and the patient should not have unrealistic functional expectations.
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• A condition of senility, mental illness, chemical dependence or alcoholism. These conditions among others may cause the patients to ignore certain necessary limitations and precautions in the use of the implant, leading to failure and other complications.
• Foreign body sensitivity. Where material sensitivity is suspected appropriate tests should be made prior to material implantation.
• Surgeons must advise patients who smoke have been shown to have an increased incidence of non-unions. Such patients must be advised of this fact and warned of the potential consequences.
• Care must be taken to protect the components from being marred, nicked, or notched as a result of contact with metal or abrasive objects.

The choice of implants
The choice of proper shape, size and design of the implant for each patient is crucial to the success of the surgery. The surgeon is responsible for this choice, which depends on each patient.

Patients who are overweight may be responsible for additional stresses and strains on the device which can speed up implant fatigue and/or lead to deformation or failure of the implants.

The size and shape of the bone structures determine the size, shape and type of the implants. Once implanted, the implants are subjected to stresses and strains. These repeated stresses on the implants must be taken into consideration by the surgeon at the time of the choice of the implant, during implantation as well as in the post-operative follow-up period.

Indeed, the stresses and strains on the implants may cause fatigue, fracture or deformation of the implants, before the bone graft has become completely consolidated. This may result in further side effects or necessitate the early removal of the osteosynthesis device.

Intra-operative precautions
• The insertion of the implants must be carried out using instruments designed and provided for this purpose and in accordance with the specific implantation instructions for each implant. Those detailed instructions are provided in the surgical technique brochure supplied by Stryker.
• Discard all damaged or mishandled implants.
• Never reuse an implant, even though it may appear undamaged.

Patient care following treatment
Prior to adequate maturation of the fusion mass, implanted spinal instrumentation may need additional help to accommodate full load bearing. External support may be recommended by the physician from two to four months postoperatively or until x-rays or other procedures confirm adequate maturation of the fusion mass; external immobilization by bracing or casting may be employed. Surgeons must instruct patients regarding appropriate and restricted activities during consolidation and maturation for the fusion mass in order to prevent placing excessive stress on the implants which may lead to fixation or implant failure and accompanying clinical problems.

Surgeons must instruct patients to report any unusual changes of the operative site to his/her physician. The physician must closely monitor the patient if a change at the site has been detected.

Adverse effects
Include but are not limited to:
• Late bone fusion or no visible fusion mass and pseudarthrosis;
• While the expected life of spinal implant components is difficult to estimate, it is finite. These components are made of foreign materials which are placed within the body for the potential fusion of the spine and reduction of pain. However, due to the many biological, mechanical and physicochemical factors which affect these devices but cannot be evaluated in vivo, the components cannot be expected to indefinitely withstand the activity level and loads of normal healthy bone;
• Superficial or deep-set infection and inflammatory phenomena;
• Allergic reactions to the implanted materials, although uncommon, can occur;
• Decrease in bone density due to stress shielding;
• Dural leak requiring surgical repair;
• Peripheral neuropathies, nerve damage, heterotopic bone formation and neurovascular compromise, including paralysis, loss of bowel or bladder function, or foot-drop may occur.
• Cessation of growth of the fused portion of the spine;
• Loss of proper spinal curvature, correction, height and/or reduction;
• Delayed Union or Nonunion:
Internal fixation appliances are load sharing devices which are used to obtain alignment until normal healing occurs. In the event that healing is delayed, does not occur, or failure to immobilize the delayed/ nonunion results, the implant will be subject to excessive and repeated stresses which can eventually cause loosening, bending or fatigue fracture. The degree or success of union, loads produced by weight bearing, and activity levels will, among other conditions, dictate the longevity of the implant. If a nonunion develops or if the implants loosen, bend or break, the device(s) must be revised or removed immediately before serious injury occurs;
• Neurological and spinal dura mater lesions from surgical trauma;
• Early loosening may result from inadequate initial fixation, latent infection, premature loading of the device or trauma. Late loosening may result from trauma, infection, biological complications or mechanical problems, with the subsequent possibility of bone erosion, or pain.
• Serious complications may occur with any spinal surgery. These complications include, but are not limited to, genitourinary disorders; gastrointestinal disorders; vascular disorders, including thrombus; bronchopulmonary disorders, including emboli; bursitis, hemorrhage, myocardial infarction, infection, paralysis or death.
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• Inappropriate or improper surgical placement of this device may cause distraction or stress shielding of the graft or fusion mass. This may contribute to failure of an adequate fusion mass to form.
• Intraoperative fissure, fracture, or perforation of the spine can occur due to implantation of the components. Postoperative fracture of bone graft or the intervertebral body above or below the level of surgery can occur due to trauma, the presence of defects, or poor bone stock.

Adverse effects may necessitate reoperation or revision. The surgeon must warn the patient of these adverse effects as deemed necessary.

Removal
If fusion / bone graft growth occurs, the device will be deeply integrated into the bony tissues. As a result, the Tritanium PL cage is not intended to be removed unless the management of a complication or adverse event requires the removal. Any decision by a physician to remove the device should take into consideration such factors as:
• The risk to the patient of the additional surgical procedure as well as the difficulty of removal.
• Migration of the implant, with subsequent pain and/or neurological, articular or soft tissue lesions
• Pain or abnormal sensations due to the presence of the implants
• Infection or inflammatory reactions
• Reduction in bone density due to the different distribution of mechanical and physiological stresses and strains.
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Surgical technique
A surgeon must always rely on his or her own professional clinical judgment when deciding whether to use a particular product when treating a particular patient. Stryker does not dispense medical advice and recommends that surgeons be trained in the use of any particular product before using it in surgery.

The information presented is intended to demonstrate the breadth of Stryker product offerings. A surgeon must always refer to the package insert, product label and/or instructions for use before using any Stryker product. Products may not be available in all markets because product availability is subject to the regulatory and/or medical practices in individual markets. Please contact your Stryker representative if you have questions about the availability of Stryker products in your area.

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