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O.I.C. Cage
PLIF Surgical Technique

- O.I.C. PEEK
- O.I.C. Titanium

Acknowledgements

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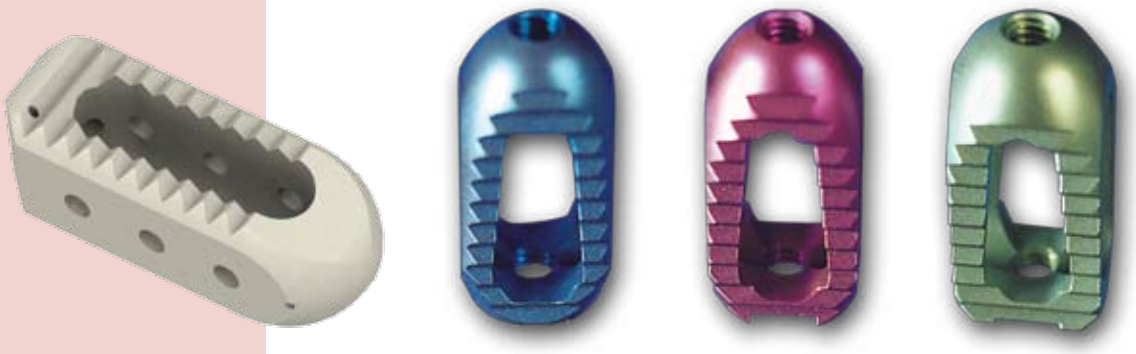
Additionally, Stryker Spine wishes to thank the global OIC PEEK Cage System surgeon panel for their dedication to the development of the OIC PEEK Cage System.

Table of Contents

PLIF Surgical Technique

Posterior Lumbar Interbody Fusion Technique

The following technique describes a bilateral, open PLIF technique. This technique may be applied bilaterally to any lumbar interbody space, based on the pathology being addressed and surgeon preference, and this technique may be performed through an open or minimally invasive approach. In an open or minimally invasive PLIF procedure, the interbody space is generally approached from a direct posterior approach and two O.I.C Cages are inserted in parallel across the disc space.



Description

The O.I.C Cage is an interbody fusion device intended for use as an aid in spinal fixation. This hollow, rectangular implant is offered in a variety of lengths, heights and lordotic angles to adapt to a variety of patient anatomies. It has serrations on the superior and inferior surfaces of the implant for fixation, an ergonomically shaped anterior edge, and a flat posterior edge. Radiopaque markers have been embedded within the implant which are designed to allow for visualization in radiographic images.

Posterior Interbody Fusion with the Stryker O.I.C Cage

Eeric Truumees, MD

Posterior interbody fusion techniques are increasingly recommended by spine surgeons. Improved surgical techniques and improved interbody implants are among the reasons interest in these techniques is increasing. Posterior interbody procedures provide both posterior and anterior stabilization through a single incision.

Posterior interbody fusion represents a spectrum of techniques. These procedures can be performed as a PLIF, or Posterior Lumbar Interbody Fusion, through a paramedian annulotomy. Alternatively, TLIF, or Transforaminal Lumbar Interbody Fusion, utilizes a farther lateral annulotomy, collinear with the pedicle. In reality, any point between the paramedian and far lateral approach can be selected. What one surgeon may call a TLIF might be termed a PLIF by another.

These procedures can be done through traditional open approaches, or they can be performed through tubular retractors in a nearly percutaneous manner, or virtually every point in between.

The posterior interbody fusion surgeon has a number of other choices as well. A variety of cage materials and geometries are available for single or paired implantation. Typically, adjunctive stabilization is sought with transpedicular instrumentation. The graft material employed will also vary from iliac crest autograft to local bone.

Rationale of Posterior Interbody Surgery

Appropriate cage selection requires an understanding of the rationale and biomechanics of interbody procedures. Interbody techniques place the fusion mass under compression and this region has better vascularity than does the posterolateral, inter-transverse space. These techniques afford the surgeon 360° access to the motion segment without a separate, anterior approach.

The disadvantages of these procedures need to be considered as well. For PLIF procedures, the surgeon must be careful to avoid excessive nerve root retraction in order to avoid postoperative epidural fibrosis. In TLIF procedures, the sensitive dorsal root ganglion must be protected. Both procedures require segmental destabilization from facet removal.

Goals, Indications & Contraindications

Regardless of the exact method selected, the goals of posterior interbody surgeries are to achieve a solid, stable arthrodesis of the spinal segment while maintaining proper disc height and restoring sagittal plane alignment. Indications include:

1. Degenerative Disc Disease
2. Grade 1 Spondylolisthesis

Interbody fusions are also added to longer posterolateral fusions when additional anterior column stability is required. For example, in patients with marginal sagittal balance a TLIF/PLIF may prevent post-operative flat-back.

Posterior interbody procedures are not appropriate in every clinical situation, however. A number of relative contraindications must be considered when recommending a specific surgical strategy.

Similarly, while osteoporotic patients are often more fragile overall, if interbody implants are required, the larger footprint of an ALIF cage is less likely to subside than a posterior cage. Alternatively, a bilateral approach may be considered in patients with borderline bone quality.

Finally, both PLIF and TLIF procedures must be undertaken with great care in patients with extensive epidural scarring. In those cases, safe dural retraction required for PLIF may be difficult. In TLIF cases, extensive epidural scarring limits the extent to which safe interbody distraction can be achieved.

Decision Making

Surgeons planning posterior interbody fusions have a number of options in their approach to fit the pathology to be addressed. For example, the relative location of the dorsal root ganglion at the operative level may affect the medial-lateral approach angle to the disc space. Similarly, the width of the lateral pars and the pelvis may render PLIF or TLIF more appropriate in a given patient. In males with a narrow pelvis, the L5-S1 disc space may be more easily accessed through a paramedian (PLIF) approach. In the upper lumbar spine (L3-4 and above), the narrow pars and smaller canal to dural diameter ratio makes TLIF the preferred approach in most cases.

Other choices include the selection of graft material and the indications for posterolateral fusion. Important decisions include cage selection. The ideal posterior interbody cage provides solid structural support until the fusion mass solidifies. The cage geometry should be optimized for adequate endplate coverage. Overly large cages are difficult to insert and risk traction injuries to the nerves. Modern cage designs are often tapered to ease insertion.

The ideal interbody fusion cage is mechanically compatible with the surrounding bone. That is, the stiffness or modulus of elasticity should approximate the host bone. The cage must be biologically compatible with little cage/host reactivity or rejection. Finally, the ideal interbody cage is radiographically compatible. Metallic cages are quite strong and resist compression failure, but are markedly stiffer than the surrounding bone, increasing the risk of subsidence.* Moreover, these cages yield streak artifact in CT studies and bloom in MRI studies which limits the surgeon's ability to assess decompression and fusion status post-operatively. Today, PEEK (Poly-Ether-Ether-Ketone) cages offer excellent compression resistance while approximating the modulus of elasticity of the host bone*. Moreover, PEEK is radiolucent allowing easy postoperative assessment of fusion.

Posterior interbody fusion cages come in a number of shapes. Among the earliest cages were threaded cylinders. These confer high stability once implanted because of a strong bone implant junction, but also confer the highest risk of nerve injury during insertion because of their shape.

*Data on file at Stryker Spine.

Given the frequency of concomitant pedicle screw instrumentation, these large cages are not mechanically necessary. Vertical cylinders were recommended by Harms for TLIF procedures, but their endplate contact areas are limited thereby limiting maintenance of height and segmental lordosis.

Today, most typically rectangular cages are employed because they offer the greatest flexibility in insertion. They can be placed unilaterally or bilaterally and from a variety of angles. Geometrically, they confer outstanding endplate coverage while requiring little nerve root retraction for insertion.

Technique Pearls

Regardless of the approach, open vs. MIS, TLIF vs. PLIF, a number of technique tips apply in every interbody fusion procedure. First, even when open technique is employed, careful attention to soft tissue handling will improve posterior muscular function and decrease pain. Of course, the most important soft tissues are the nerves. Safer posterior lumbar interbody fusion techniques require identification of the exiting and traversing nerves. In TLIF, the exiting root and dorsal root ganglion are identified. In both cases, careful control of local, epidural bleeders through bipolar electrocautery, thrombin soaked gelfoam, or other means will allow improved visualization through the critical steps of disc space preparation and cage instertion.

Second, even when an MIS approach is used, an adequate job must be performed mechanically. That is, cages must be sized to fit the interspace and screws must be sized to fit the pedicle. If, in a given case, full disc space debridement cannot be performed through a less invasive approach, the incision should be opened to insure that that annular tension is restored and the optimal cage is implanted. Often, resection of surrounding endplate osteophytes will improve visualization into the disc space to confirm debridement and, subsequently, cage sizing. Some surgeons prefer to apply bone wax to bleeding bone surfaces in the canal after the cage has been inserted.

Third, a wide near total discectomy must be performed. The disc space around the cage(s) should be packed with graft material.

Fourth, while removal of the endplate cartilage is critical, it is important to protect the boney endplates. Focal disruption of the endplate should result in selection of a new cage trajectory. Placement of the cage over a disrupted endplate may lead to early subsidence and a higher risk of cage migration.

Fifth, ideal placement of the cage(s) in the interspace may vary depending on the patient's needs. For example, if the goal is to maximize segmental lordosis, anterior cage placement may be preferred. On the other hand, posterior placement may allow for improved foraminal decompression.

Conclusions

The Stryker O.I.C Cage portfolio is designed to afford the surgeon an excellent tool for stabilization of the anterior column from a posterior approach. This stabilization may be helpful in off-loading posterior instrumentation, increasing foraminal height, or improving spinal alignment. After proper disc space preparation, the O.I.C Cage helps to provide an ideal geometry for safe insertion while maintaining excellent endplate coverage.

Step 1
Approach

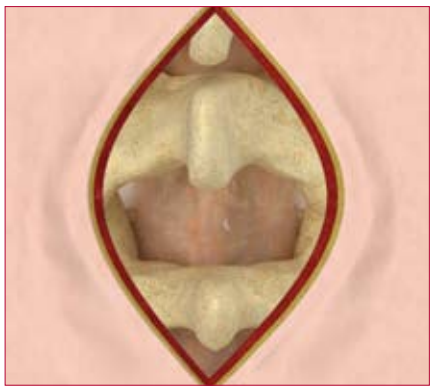


Figure 1 - Expose laminae and articular processes.

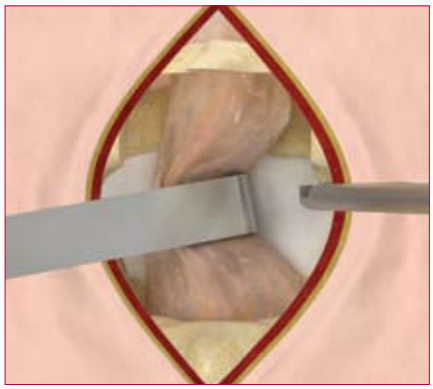


Figure 2 - Excise laminae and articular processes.

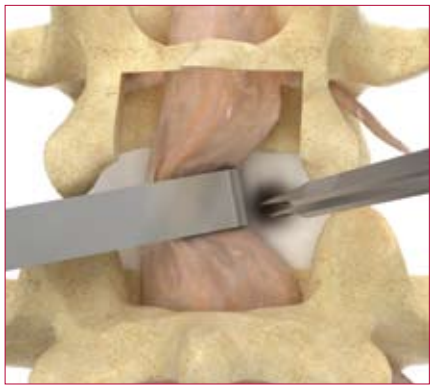


Figure 3 - Cauterize epidural venous plexus.

Open Approach
The PLIF approach can be performed using standard open or minimally invasive techniques. The laminae and articular processes are exposed laterally to the base of the transverse processes. (Fig. 1)

The spinal canal is then opened by excision of the laminae and articular processes. (Fig. 2)

The laminectomy is extended laterally to the medial edge of the pedicle, which is located by palpation with a spatula.

The excision also includes half of the inferior articular process of the superior vertebra.

The superior articular process of the inferior vertebra is progressively resected until the preforaminal portion of the nerve root is visible. The origin of the inferior nerve root is also well exposed.

Great care is taken to verify the mobility of the right and left nerve roots prior to applying distraction to the disc space.

Before accessing the posterior part of the disc, the epidural venous plexus should be carefully cauterized with the bipolar forceps. (Fig. 3)

Minimally Invasive Approach
The minimally invasive PLIF approach is performed using a standard, bilateral technique. Minimally invasive systems, which can be used include, but are not limited to, the Stryker Luxor System. Please refer to the Luxor surgical technique for additional information on minimally invasive approaches.

NOTE: *The remaining steps in the surgical technique are similar in both open and minimally invasive approaches. All images in this technique, however depict an open approach for image clarity and simplicity. Please refer to the Luxor surgical technique for additional information on minimally invasive approaches and detailed minimally invasive images.*

Step 2
Discectomy

A dura matter retractor is used to retract the dura medially, exposing the posterior part of the disc. In most cases this retractor is placed at the origin of the inferior nerve root. (Fig. 4)

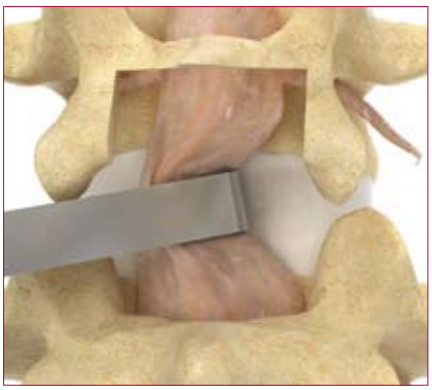


Figure 4 - Retract the dura mater.

Using a thin-bladed scalpel (#11), a circular incision approximately one centimeter in diameter is made in the annulus fibrosus. (Fig. 5)

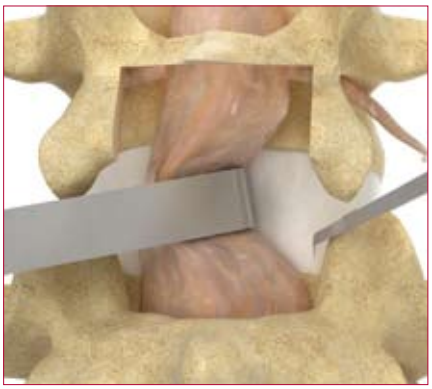


Figure 5 - Make circular incision in annulus fibrosus.

Introduce a series of curettes. (Fig. 6)

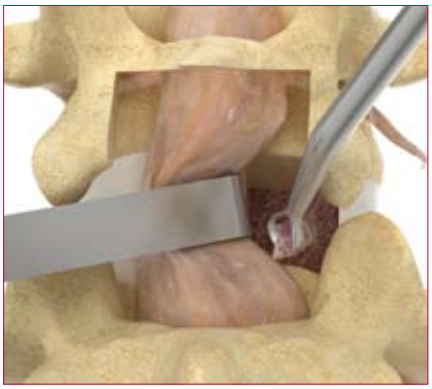


Figure 6 - Introduce curettes.

The disc fragments are removed with the pituitary rongeur. (Fig. 7)

NOTE: *Keep the neural elements in view throughout this phase of the procedure.*

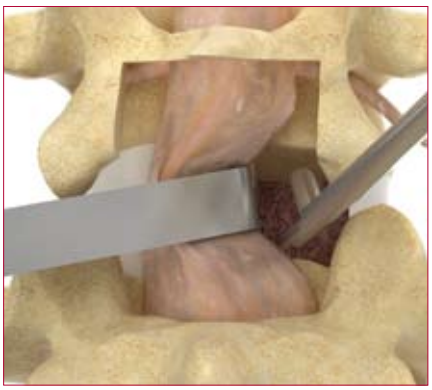


Figure 7 - Remove disc fragments.

Step 3
Preparation of Insertion Site

Figure 8a - Insert reamer-distractor into disc space.

Figure 8b - Turn instrument 90° to distract and scrape the endplates.

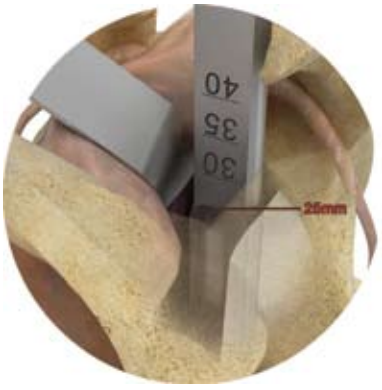


Figure 8c - Measure depth.

Once an effective discectomy is performed, the disc space and endplates must be prepared for implant insertion. Preparation of the insertion site may be divided into two phases, distraction and endplate preparation.

Since techniques vary depending upon surgeon preference two different types of instrumentation are available for distraction.

- Reamer-distractors
  (one single instrument)
- Distractors and reamers
  (two separate instruments)

NOTE:
It is also possible to distract the intervertebral space with the aid of posterior fixation hardware. Distraction can be applied and constantly maintained through the pedicle screws. In addition, an interspinous distractor or interlaminar distractor may be used.

Option 1:
Use of the Reamer-Distractor

One side of the working end has a smooth surface that may be applied to the endplates to distract the intervertebral space. The other side has two cutting edges that scrape the endplates.

The smallest reamer-distractor is inserted "horizontally" into the intervertebral space; the widest part of the instrument facing medial/lateral and the thinnest part facing superior/inferior. (Fig. 8a)

Turning the instrument 90° (this position will be called "vertical") distracts the intervertebral space and scrapes the endplates. (Fig. 8b)

The graduation marks on the instrument indicate the depth of the opening in the disc. When 20mm long Cages are to be used, it is recommended that the posterior wall of the vertebral body be flush with the 25mm mark on the reamer-distractor.

For 25mm long Cages, it is recommended that the posterior wall of the vertebral body be flush with the 30mm mark on the reamer-distractor.

For 30mm and 33mm long Cages, it is recommended that the posterior wall of the vertebral body be flush with the 35mm mark on the reamer-distractor. (Fig. 8c)

The endplates are scraped by rotating the reamer-distractor clockwise or counterclockwise. (Fig. 9)

After three or four turns the reamer-distractor is pulled straight out with no rotation. Examination of the material removed with the reamer-distractor helps to determine whether the endplates have been sufficiently prepared. If the material removed with the reamer-distractor is white (debris from the annulus fibrosus or cartilage), a larger reamer needs to be used to reach the subchondral bone.

Reamer-distractors of progressively increasing size are inserted serially on the right and left, widening the intervertebral space until the optimal distraction is achieved. The final reamer-distractor is temporarily left in the vertical position on the contralateral side to maintain the disc space distraction. (Fig. 10)

Figure 9 - Rotate reamer-distractor to scrape endplates.

Figure 10 - Serial insertion of reamer-distractors to widen the intervertebral space.

Curettes may be used to complete the preparation of the parts of the endplates that are not accessible with the reamer-distractor. (Fig. 11a & 11b)

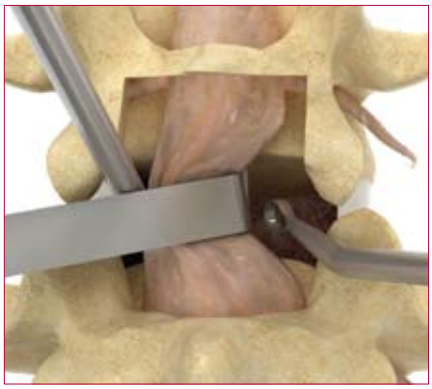


Figure 11a - Further preparation of the endplates using a curette.

Figure 11b - Sagittal view.

Step 3

Preparation of Insertion Site

Figure 12a - Insertion of distractor into disc space.

Figure 12b - Turn instrument 90° to distract the disc space.

Option 2:
Use of the Separate Distractors and Reamers

The distractors are smooth and rounded and are designed to reduce the risk of injury to the endplates during distraction of the intervertebral space.

The smallest distractor is used first.

A small distractor is inserted "horizontally" into the intervertebral space and then turned 90° to distract it. (Fig. 12a & 12b)

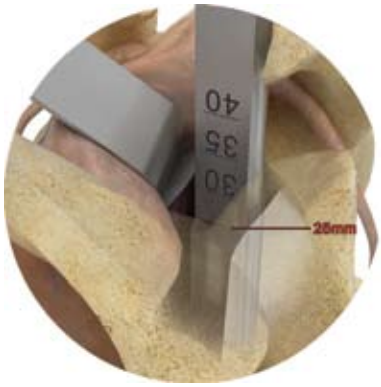


Figure 12c - Measure depth.

The graduations on the instrument indicate the depth of the opening made in the disc. If using a 20mm long cage, it is recommended that the posterior wall of the vertebral body be flush with the 25mm mark on the distractor. For the 25mm long cage, it is recommended that the posterior wall of the vertebral body be flush with the 30mm mark on the distractor.

For 30mm and 33mm long cages, it is recommended that the posterior wall of the vertebral body be flush with the 35mm mark on the distractor. (Fig. 12c)

Figure 13 - Serial insertion of paddle distractors to widen the disc space.

Distractors of progressively increasing size are inserted alternatively on the right and left widening the intervertebral space until optimal distraction is achieved. (Fig. 13)

The tension on the nerve roots is constantly monitored during distraction. The final distractor is temporarily left in position to maintain the disc space distraction.

A reamer, of the same size as the distractor that is left in place, is inserted by gentle impaction without rotation. This precautionary measure is taken to prevent contact of the cutting edges of the reamer with the dura mater or nerve roots. (Fig. 14a)

The endplates are scraped by rotating the reamer clockwise or counterclockwise. (Fig. 14b) After three or four turns the reamer is pulled straight out with no rotation. Examination of the material removed helps to determine whether the endplates have been sufficiently prepared. If the material removed from the reamer is white (debris from the annulus fibrosus or cartilage), a larger reamer needs to be used to reach the subchondral bone.

Figure 14a - Gentle impaction without rotation.

Figure 14b - Rotate clockwise to scrape endplates.

Curettes may be used to complete the preparation of the parts of the endplates that are not accessible with the reamer. (Fig. 15a & 15b)

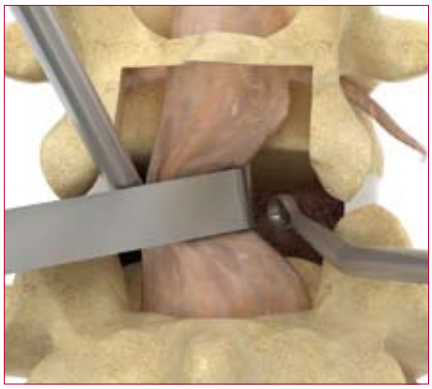


Figure 15a - Further preparation of the endplates using a curette.

Figure 15b - Sagittal view.

Step 4

Preparation of the Cage

PEEK O.I.C. and Titanium O.I.C.

Figure 16 - Cage assembled to Impactor.

The Cage must be of the same size as the final reamer or reamer-distractor.

The cage is screwed onto the cage impactor and slipped into the cage support, where it is filled with pieces of autologous bone or other bone grafting material. (Fig.16)

NOTE:

- *All 8mm and 9mm wide cages should be assembled to the PEEK Spacer Inserter 8, 9.*
- *All 11 mm wide cages should be assembled to the PEEK Spacer Inserter 11 or the PEEK Cage Impactor.*
- *Implants with lengths of 30mm and 33mm which are 6mm, 7mm and 8mm in height should be assembled to the PEEK Spacer Inserter 8,9.*

PEEK O.I.C. and Titanium O.I.C.

Figure 17 - Bone graft is compacted into the Cage.

The compacted graft should be flush with the upper and lower surfaces of the cage, to be in contact with the endplates. (Fig.17)

Step 5
Placement of the Cage

To ensure that the intervertebral space is accessible, the contralateral distractor is left in place during the Cage placement.

The position of the Cage corresponds to that of the handles of the PEEK Spacer Inserter or Impactor.

The implant is correctly oriented when the handle faces superiorly/inferiorly. (Fig.18)

PEEK O.I.C. Option

Figure 18 - Correct orientation of the PEEK Spacer Inserter or Impactor with the Impant.

The Cage must be inserted gently and progressively. Its serrated sides should be positioned to face the endplates. (Fig. 19 & 19b)

NOTE: *The neural elements should be kept in view during Cage implantation.*

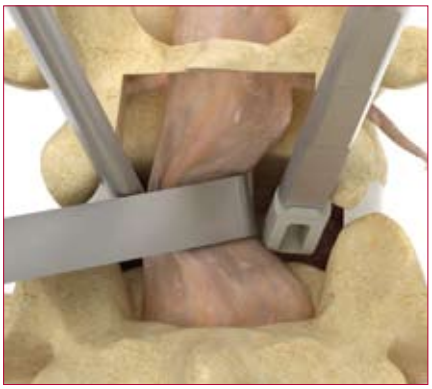


Figure 19a - Insertion of a PEEK Cage.

Titanium O.I.C. Option

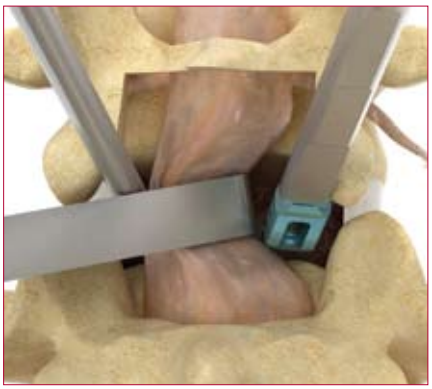


Figure 19b - Insertion of a titanium Cage.

The Cage distracts the endplates, due in part to its bulleted ogival or wedge shape.

Figure 20 - Unscrew Cage Impactor.

Figure 21a - Approach of final Impactor.

Figure 21b - Tamp into final position.

Once inserted, the posterior end of the cage should lie between 2mm-4mm anterior to the posterior vertebral body wall. The Cage Inserter or Impactor is then unscrewed. (Fig. 20)

Because it is essential to maintain the proper depth of cage insertion, a Final Impactor is provided to gently tamp the cage to its final position after the primary cage impactor has been removed. (Fig. 21a & 21b)

Figure 22a - PEEK O.I.C. PLIF

Figure 22b - Titanium O.I.C. PLIF

The distractor is removed and the steps are repeated on the contralateral side of the intervertebral space. (Fig. 22a & 22b)

In the PEEK impants, there are two tantalum markers, oriented perpendicular to each other, embedded in the implant to help visually confirm its position under fluoroscopy. One marker is positioned horizontally at the end of the wedge nose, and the other marker is positioned vertically at the posterior aspect of the implant. (Fig. 23)

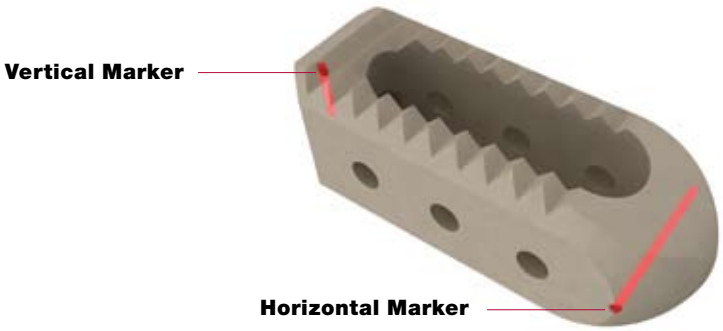


Figure 23 - Markers on implant.

On a true lateral fluoroscopic view of implants centered from left to right within the disc space, the vertical posterior markers and anterior horizontal markers will appear as depicted. (Fig 24 & 25)

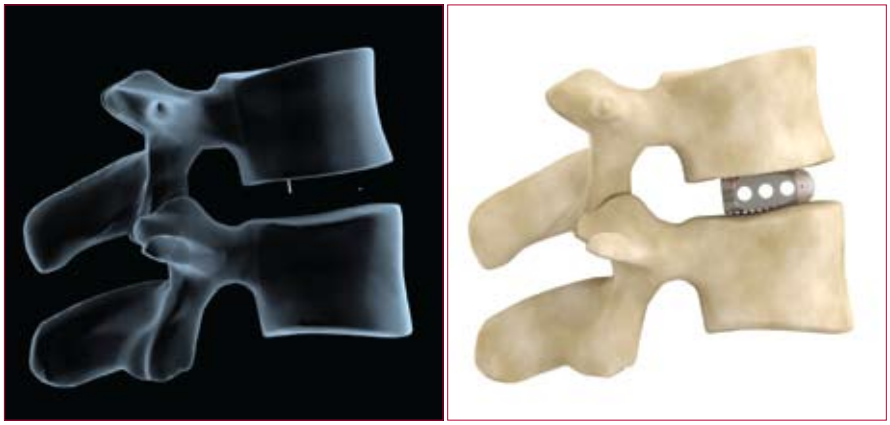


Figure 24 - Sagittal perspective of properly positioned O.I.C PEEK Cages.

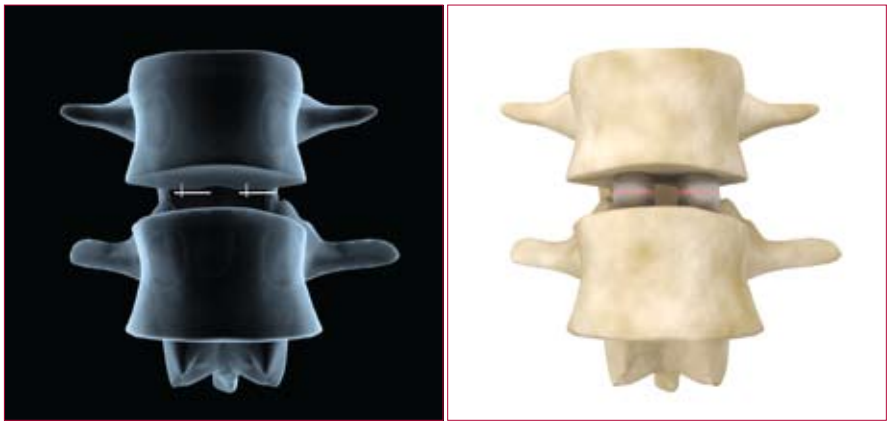


Figure 25 - Anterior/posterior perspective of properly positioned O.I.C PEEK Cages.

INTRAOPERATIVE RESCUE:
The O.I.C Cage Impactor or PEEK Spacer Inserter can be used to rescue the implant if deemed medically necessary. Align the outter chamfered shaft with the contours of the implant and thread the internal shaft into the implant and remove it. A blunt nerve hook may also be used.

Step 6
Osteosynthesis

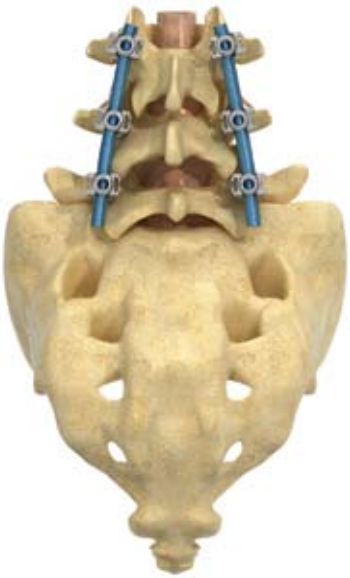


Figure 26 - Add posterior fixation.

The operation systematically ends via fixation with posterior osteosynthesis hardware. The construct is then placed under compression to ensure proper contact between the vertebral endplates and the bone graft material inside of the Cages. (Fig. 26)

The O.I.C. Cages are intended to be used with supplemental spinal fixation systems that have been cleared for use in the lumbosacral spine (i.e., posterior pedicle screw and rod systems). Please refer to the surgical technique of any additional Stryker System before use.

PEEK Cage

Reference Numbers

Without lordosis - 0°

Width 09 mm - Length 20mm

Ref.	Description (height x length x lordosis-width)
6760090	Cage 9x20x0° - 9
6760100	Cage 10x20x0° - 9
6760110	Cage 11x20x0° - 9
6760120	Cage 12x20x0° - 9
6760130	Cage 13x20x0° - 9
6760140	Cage 14x20x0° - 9
6760150	Cage 15x20x0° - 9
6760160	Cage 16x20x0° - 9

Width 11 mm - Length 20mm

Ref.	Description (height x length x lordosis-width)
673090	Cage 9x20x0° - 11
673100	Cage 10x20x0° - 11
673110	Cage 11x20x0° - 11
673120	Cage 12x20x0° - 11
673130	Cage 13x20x0° - 11
67310140	Cage 14x20x0° - 11
67310150	Cage 15x20x0° - 11
67310160	Cage 16x20x0° - 11

Width 08 mm - Length 25mm

Ref.	Description (height x length x lordosis-width)
6765090	Cage 9x25x0° - 8
6765100	Cage 10x25x0° - 8
6765110	Cage 11x25x0° - 8
6765120	Cage 12x25x0° - 8
6765130	Cage 13x25x0° - 8
6765140	Cage 14x25x0° - 8
6765150	Cage 15x25x0° - 8
6765160	Cage 16x25x0° - 8

Width 11 mm - Length 25mm

Ref.	Description (height x length x lordosis-width)
6730900	Cage 9x25x0° - 11
6731000	Cage 10x25x0° - 11
6731100	Cage 11x25x0° - 11
6731200	Cage 12x25x0° - 11
6731300	Cage 13x25x0° - 11
67315140	Cage 14x25x0° - 11
67315150	Cage 15x25x0° - 11
67315160	Cage 16x25x0° - 11

Width 11 mm - Length 30mm

Ref.	Description (height x length x lordosis-width)
6731060	Cage 6x30x0° - 11
6731070	Cage 7x30x0° - 11
6731080	Cage 8x30x0° - 11
6731090	Cage 9x30x0° - 11
6731100	Cage 10x30x0° - 11
67311100	Cage 11x30x0° - 11
6731120	Cage 12x30x0° - 11
6731130	Cage 13x30x0° - 11

Width 11 mm - Length 33mm

Ref.	Description (height x length x lordosis-width)
6733060	Cage 6x33x0° - 11
6733070	Cage 7x33x0° - 11
6733080	Cage 8x33x0° - 11
6733090	Cage 9x33x0° - 11
6733100	Cage 10x33x0° - 11
67331100	Cage 11x33x0° - 11
6733120	Cage 12x33x0° - 11
6733130	Cage 13x33x0° - 11

Lordosis - 4°

Width 09 mm - Length 20mm

Ref.	Description (height x length x lordosis-width)
6760074	Cage 7x20x4° - 9
6760084	Cage 8x20x4° - 9
6760094	Cage 9x20x4° - 9
6760104	Cage 10x20x4° - 9
6760114	Cage 11x20x4° - 9
6760124	Cage 12x20x4° - 9
6760134	Cage 13x20x4° - 9
6760144	Cage 14x20x4° - 9
6760154	Cage 15x20x4° - 9
6760164	Cage 16x20x4° - 9

Width 11 mm - Length 20mm

Ref.	Description (height x length x lordosis-width)
673094	Cage 9x20x4° - 11
673104	Cage 10x20x4° - 11
673114	Cage 11x20x4° - 11
673124	Cage 12x20x4° - 11
673134	Cage 13x20x4° - 11
67310144	Cage 14x20x4° - 11
67310154	Cage 15x20x4° - 11
67310164	Cage 16x20x4° - 11

Width 08 mm - Length 25mm

Ref.	Description (height x length x lordosis-width)
6765074	Cage 7x25x4° - 8
6765084	Cage 8x25x0° - 8
6765094	Cage 9x25x4° - 8
6765104	Cage 10x25x4° - 8
6765114	Cage 11x25x4° - 8
6765124	Cage 12x25x4° - 8
6765134	Cage 13x25x4° - 8
6765144	Cage 14x25x4° - 8
6765154	Cage 15x25x4° - 8
6765164	Cage 16x25x4° - 8

Width 11 mm - Length 25mm

Ref.	Description (height x length x lordosis-width)
6730904	Cage 9x25x4° - 11
6731004	Cage 10x25x4° - 11
67311104	Cage 11x25x4° - 11
6731204	Cage 12x25x4° - 11
6731304	Cage 13x25x4° - 11
67315144	Cage 14x25x4° - 11
67315154	Cage 15x25x4° - 11
67315164	Cage 16x25x4° - 11

Lordosis - 8°

Width 09 mm - Length 20mm

Ref.	Description (height x length x lordosis-width)
6760098	Cage 9x20x8° - 9
6760108	Cage 10x20x8° - 9
6760118	Cage 11x20x8° - 9
6760128	Cage 12x20x8° - 9
6760138	Cage 13x20x8° - 9
6760148	Cage 14x20x8° - 9
6760158	Cage 15x20x8° - 9
6760168	Cage 16x20x8° - 9

Width 11 mm - Length 20mm

Ref.	Description (height x length x lordosis-width)
67310098	Cage 9x20x8° - 11
67310108	Cage 10x20x8° - 11
67310118	Cage 11x20x8° - 11
67310128	Cage 12x20x8° - 11
67310138	Cage 13x20x8° - 11
67310148	Cage 14x20x8° - 11
67310158	Cage 15x20x8° - 11
67310168	Cage 16x20x8° - 11

Width 08 mm - Length 25mm

Ref.	Description (height x length x lordosis-width)
6765098	Cage 9x25x8° - 8
6765108	Cage 10x25x8° - 8
6765118	Cage 11x25x8° - 8
6765128	Cage 12x25x8° - 8
6765138	Cage 13x25x8° - 8
6765148	Cage 14x25x8° - 8
6765158	Cage 15x25x8° - 8
6765168	Cage 16x25x8° - 8

Width 11 mm - Length 25mm

Ref.	Description (height x length x lordosis-width)
67315098	Cage 9x25x8° - 11
67315108	Cage 10x25x8° - 11
67315118	Cage 11x25x8° - 11
67315128	Cage 12x25x8° - 11
67315138	Cage 13x25x8° - 11
67315148	Cage 14x25x8° - 11
67315158	Cage 15x25x8° - 11
67315168	Cage 16x25x8° - 11

Titanium Cage
Reference Numbers

• Blue 0° • Pink 4° • Green 8°

Ref.	Description (height - lordosis)	
672009	Cage 9-0°	length 25 mm
672010	Cage 10-0°	length 25 mm
672011	Cage 11-0°	length 25 mm
672012	Cage 12-0°	length 25 mm
672013	Cage 13-0°	length 25 mm
672109	Cage 9-4°	length 25 mm
672110	Cage 10-4°	length 25 mm
672111	Cage 11-4°	length 25 mm
672112	Cage 12-4°	length 25 mm
672113	Cage 13-4°	length 25 mm
672210	Cage 10-8°	length 25 mm
672211	Cage 11-8°	length 25 mm
672112	Cage 12-8°	length 25 mm
672213	Cage 13-8°	length 25 mm
672214	Cage 14-8°	length 25 mm
672811	Cage 9-4°	length 20 mm
672812	Cage 10-4°	length 20 mm
672813	Cage 11-4°	length 20 mm
673124	Cage 12-4°	length 20 mm
673134	Cage 13-4°	length 20 mm

Instrument
Reference Numbers

Ref.	Description	
873001	Titanium O.I.C.™ Container for Implants	
873002	Peek O.I.C.™ Container for Implants	
873003	O.I.C.™ Cages Container for Instruments	
873010	Triangular Curette	
873011	Dura Matter Retractor	
873012	Root Retractors	
873013	Cage Support	
873014	Final impactor	
873015	Graft Compactor	
873016	Titanium Cage Impactor	
873017	Peek Cage Impactor	
873(109)-(114)	Reamer 9-10-11-12-13-14 mm	
873(208)-(214)	Distractor 8-9-10-11-12-13-14 mm	
873(309)-(314)	Reamer-Distractor 9-10-11-12-13-14 mm	
48350951	PEEK Spacer Inserter 8,9 (Qty in set = 2)	
48350952	PEEK Spacer Inserter 11 (Qty in set = 2)	
48350923	Graft Compactor (Qty in set = 1)	
48350961	PL Graft Block (Qty in set = 1)	
48350911	PL Impactor (Qty in set = 1)	
48350001	11mm Implant Tray (Qty in set = 1)	
48350001	8,9mm Implant Tray (Qty in set = 1)	
48350001	AVS PL PEEK Conatainer (Qty in set = 1)	
48350010	0° Long Implant Caddy (Qty in set = 1)	
48350012	OIC PEEK Cages 0° Long Implant Lid (Qty in set = 1)	

Notes

INDICATIONS

The Stryker Spine O.I.C. PEEK cages are intervertebral body fusion devices indicated for use with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two levels from L2 to S1.

DDD is defined as back pain of discogenic origin with degeneration of the disc conformed 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.

The O.I.C. PEEK cages are to be implanted via posterior approach.

The O.I.C. PEEK cages are intended to be used with supplemental spinal fixation systems that have been cleared for use in the lumbosacral spine (i.e., posterior pedicle screw and rod systems).

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.

CAUTION

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 on 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 vertebrae, neurological injury, and vascular or visceral injury.

Specialized instruments are provided by STRYKER Spine and must be used to assure accurate implantation of the intervertebral body fusion device. While rare, intraoperative fracture or breakage of instruments can occur, instruments, which have experienced extensive use or extensive 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. Instruments for implantation of the O.I.C. PEEK cages are provided non-sterile and must be sterilized prior to use.

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

Specialized instruments are provided by STRYKER Spine 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 extensive force are more susceptible to fracture depending on the operative precaution, number of procedures, disposal attention. Instruments must be examined for wear or damage prior to surgery.

REUSE

An implant should never be reused. While it may appear undamaged, a used implant may have acquired blemishes or latent compromise of its integrity which would reduce its service life.

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:

- An active infection at the operative site.
- Use except as indicated.
- Marked local inflammation.
- Any abnormality present which affects the normal process of bone remodeling including, but not limited to, severe osteo porosis 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 postop erative care.
- Open wounds.
- Pregnancy.
- Patients having inadequate tissue coverage of 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. Obesity is de fined according to the W.H.O. standards.
- A condition of senility, mental illness, or sub stance abuse. These conditions, among oth ers, 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 sen sitivity is suspected, appropriate tests must be made prior to material selection or implan tation.
- 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 dif ferential count.

These contra-indications can 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 made 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 advice 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. Surgeons must advise patients of this fact and warn of the potential consequences. For diseased 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.

PREOPERATIVE 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 im plant (e.g., substantial walking, running, lift ing, or muscle strain) may be at increased risk for failure of the fusion and/or the de vice.
- 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 unre alistic functional expectations.
- A condition of senility, mental illness, chemi cal dependence or alcoholism. These conditions among others may cause the patients to ignore certain necessary limitations and pre cautions in the use of the implant, leading to failure and other complications.
- Foreign body sensitivity. Where material sen sitivity is suspected appropriate tests must 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 compo nents 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 or 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.

INTRAOPERATIVE 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 pro vided in the surgical technique brochure sup plied by STRYKER Spine.
- Discard all damaged or mishandled im plants.
- Never reuse an implant, even though it may appear undamaged.

POST OPERATIVE PRECAUTIONS

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 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;
- Peripheral neuropathies, nerve damage, het erotopic bone formation and neurovascular compromise, including paralysis;
- While the expected life of spinal implant components is difficult to estimate, it is finite.
  These components are made of foreign ma terials which are placed within the body for the potential fusion of the spine and reduc tion of pain. However, due to the many bio logical, mechanical and physicochemical fac tors which affect these devices but cannot be evaluated in vivo, the components cannot be expected to indefinitely withstand the activ ity 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 neurovas cular 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 fixa tion 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 im mediately 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 loosen ing may result from trauma, infection, bio logical complications or mechanical prob lems, with the subsequent possibility of bone erosion, vertebral endplate injury or pain.
- Serious complications may occur with any spinal surgery. These complications include, but are not limited to, genitourinary disorders; gastrointestinal disorders; vascular dis orders, including thrombus; bronchopulmonary disorders, including emboli; bursitis, hemorrhage, myocardial infarction, infection, paralysis or death.
- 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.

Adverse effects may necessitate reoperation or revision.

The surgeon must warn the patient of these adverse effects as deemed necessary.

IMPLANT REMOVAL

If fusion / bone graft growth occurs, the device will be deeply integrated into the bony tissues. As a result, the O.I.C. PEEK cage device 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 surgi cal 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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