

Surgical
Technique
& Ordering
Information

ZYGOLOC[™]
FACET FUSION SYSTEM

ZYGOLOC™

FACET FUSION SYSTEM

PIONEERING FACET FUSION TECHNOLOGY

INTRODUCTION

The **ZYGOLOC™ Facet Fusion System** is a structural implant and insertion system that offers enhanced biomechanical support and biological fusion capability indicated for use in conjunction with traditional pedicle screw and rod fixation.

The novel ZYGOLOC™ cage design features a total of eight graft fusion windows, a roughened external surface to promote bony ongrowth and an external circumferential thread feature to provide initial stability. The Zygoloc™ Facet Fusion Cage permits a standardized and reproducible surgical technique to enhance posterior spinal fusion.

Finite element modeling studies, bench top biomechanical studies, and clinical fusion studies with follow up exceeding two years have demonstrated the success of the ZYGOLOC™ Facet Fusion Cage.

This Surgical Technique and Guide describes the key implant and instrumentation that are specific to the **ZYGOLOC™ Facet Fusion System**

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SPINAL TRAUMA TREATMENT

USING THE ZYGOLOC™ FACET FUSION SYSTEM

History of Presenting Pathology

- A 65 year old male presented after 10/52 constant low back pain (LBP) following a fall.
- The patient reported increasingly severe radiating right sided leg and buttock pain.
- Imaging revealed an L2 crush fracture, fractured L1 spinous process and a long standing L4 wedge fracture that was asymptomatic.
- Comparative films before and after presentation showed a stable appearance of L4 and further collapse with retropulsion of an endplate fragment at L2.

Treatment Method

- The surgical goal was to stabilize and prevent further collapse of the grossly unstable L2 fracture.
- An L1—L3 posterior spinal fusion was performed utilizing pedicle screws and rods.
- Due to the unstable nature of the injury, ZygoLoc™ Facet Fusion Cages were inserted into all facet joints between L1 and L3.
- Fusion material was also laid down in the Posterolateral Gutter region.
- Operative time in total was 120 minutes with minimal blood loss. No operative complications were reported.

Follow-Up Results

- The patient was ambulating post-op on day 4 and discharged home on day 7.
- At the time of discharge the patient reported a marked improvement in pain and stability.
- At 2 month follow up the patient reported nil pain with no current use of medication. Post operative films revealed no signs of further vertebral collapse.



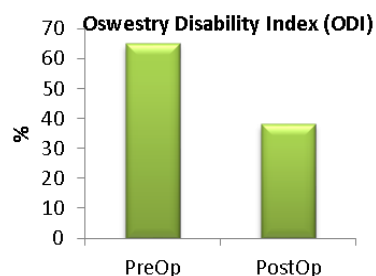
Figure 1: Lateral CT Pre-Op



Figure 2: AP X-ray Post-Op



Figure 3: Lateral X-ray Post-Op



SPINAL DEFORMITY TREATMENT

USING THE ZYGOLOC™ FACET FUSION SYSTEM

History of Presenting Pathology

- A 28 year old female social worker arrived at the Emergency Department after a jet ski accident in 2010.
- The patient was neurologically intact. Central thoracic back pain was reported by the patient.
- CT, MRI and X-ray images revealed a T9 crush fracture with 40% vertebral height loss.
- A pre-existing Kyphoscoliosis of T5-T11 was also identified with a Cobb angle of 70°, exaggerated by the segmental deformity of the T9 vertebrae.

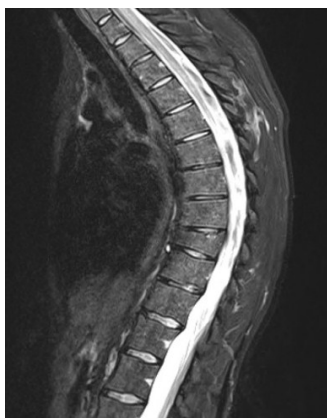


Figure 1: Lateral MRI Pre-Op

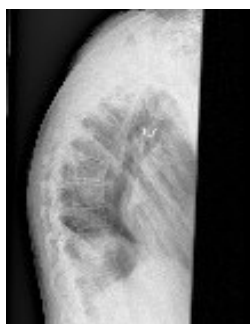


Figure 2: Lateral X-ray Pre-Op

Treatment Method

- A T3—L2 Posterior Spinal Fusion was performed to prevent further wedging of the T9 vertebra and deformity progression.
- Four proximal hooks and nine pedicle screws were inserted. Rods were contoured to match patient alignment. With gentle further correction all setscrews were inserted and tightened. A crosslink was placed in the thoracic region .
- Eight Zygoloc™ Facet Cages were placed in the distal thoracolumbar region of the construct. Additionally two Zygoloc™ Cages were inserted to provide fusion and stability where pedicle screws had not been inserted at one level within the construct.
- Operative time was 180 minutes with 300ml blood loss. No surgical complications were reported.



Figure 3: Axial CT Post-Op 6 months

Follow Up Results

- The patient was ambulating on postoperative day 4.
- At 2 month post op the patient reported marked improvement with little to no pain. An impressive correction of the patients kyphotic angle was noted.
- The most recent follow up reported no signs of further vertebral collapse or progression of her deformity.

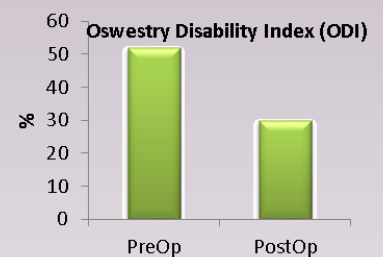


Figure 4: A/P X-ray Post-Op



Figure 5: Lateral X-ray Post-Op

SPINAL DEGENERATIVE TREATMENT

USING THE ZYGOLOC™ FACET FUSION SYSTEM

History of Presenting Pathology

- A 67 year old male was admitted to hospital with right sided thigh and groin pain.
- Investigation with MRI scanning revealed a focal right disc prolapse at L2/3 with foraminal stenosis causing L2 nerve root compression.
- The patient was administered a nerve block and discharged with analgesia for further follow up.
- The patient then presented to the Emergency Department with increasingly severe pain and was no longer able to manage at home.



Figure 1: Lateral MRI Pre-Op

Treatment Method

- The patient was booked for an L2-3 Posterior Spinal Lumbar Interbody Fusion.
- A total of four pedicle screws were inserted into the L2-3 pedicles and fixed with rods and setscrews.
- A laminectomy for decompression was performed with bilateral facet preservation.
- A thorough discectomy was performed.
- Two 7mm wide VERTELOC™ Interbody cages were packed with bone graft and inserted into the disc space.
- Two ZYGOLOC™ Facet Fusion Cages were inserted into the preserved facet joints.

Follow Up Results

- The patient was ambulating on postoperative day 3.
- On follow up the patient reported no referred groin pain and complete relief of his referred L2 nerve root symptoms.

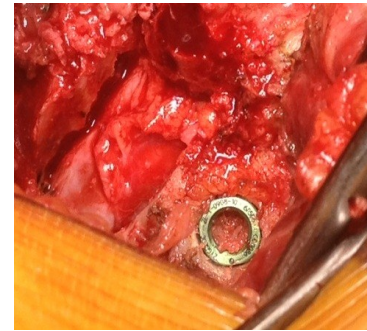


Figure 2: Intraoperative view of the Zygoloc™ cage insitu

INDICATIONS

All single and multilevel posterior pedicle screw and rod constructs in the thoracic, lumbar and sacral spine where fusion is required.

Degenerative, trauma, tumour and deformity pathology in adjunct to posterior instrumentation.

Relative osteoporotic vertebral bone.

In conjunction with all interbody fusion constructs – including Posterior Lumbar Interbody fusion (PLIF) where both facets are preserved and Transforaminal Lumbar Interbody Fusion (TLIF) where a single Zygoloc™ Facet Fusion Cage can be used to augment the pedicle instrumentation at the retained facet joint.

CONTRAINDICATIONS

Bilateral pars intra-articular defects

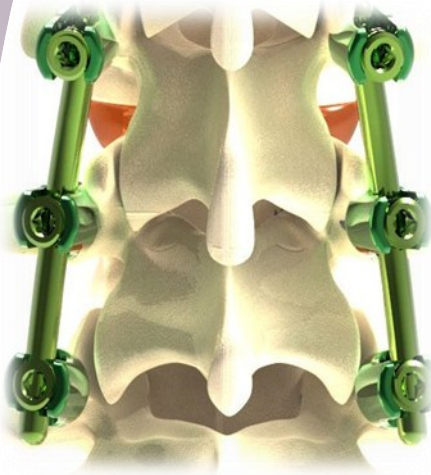
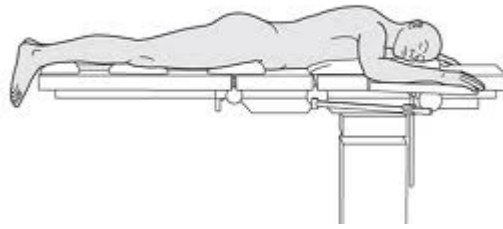
Note: The described technique presents only a few of the many approaches to stabilization and fusion of the posterior thoracolumbar spine. The surgeon is encouraged to utilize the Zygoloc™ Facet Fusion System with those techniques that most favor the desired surgical result.

Operative Technique

Open

Step 1 OT Setup

Position the patient prone on a suitable operating table under usual conditions.



Step 2 Site Preparation

Insert the posterior pedicle screw and rod construct over one or more levels as indicated as per relevant surgical technique.

Perform any correction of the necessary spinal levels required as per surgical technique.

Hint

Be sure to place pedicle screw entry point as lateral as possible to expose as much facet joint medially. Polyaxial screws are recommended for this technique.

Step 3 Hole Preparation Option 1

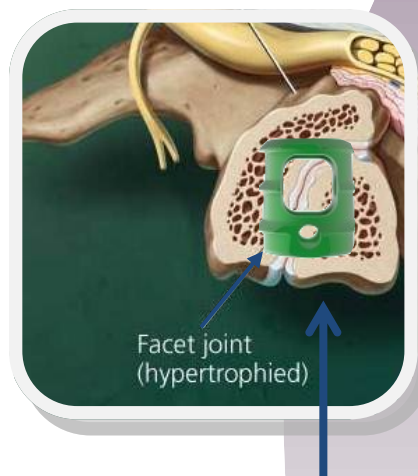
Using the recommended high speed drill attachment mill the hole within the facet joint crossing the two articulating surfaces. **The use of high flow irrigation must be utilized to prevent thermal necrosis during this high speed milling technique.** It is recommended to position the starting point for the hole at either the 10 o'clock or 2 o'clock position relative to the pedicle screw. The facet joint is commonly more cephalad and medial to the caudal pedicle screw head in a one level construct.



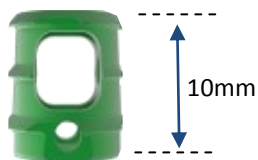
Operative Technique

Open

The trajectory for the hole is forgiving. Pending individual patient anatomy in the lower lumbar spine a typical posterior to anterior direction usually creates a hole that crosses the oblique joint successfully. This permits point contact of the Zygoloc™ Facet Fusion Cage across a large surface area of each side of the sub-chondral (bony) articular surface of the facet joint.



A posterior to anterior trajectory typically creates a hole that crosses the oblique joint successfully.



Step 3 Hole Preparation Option 2

A standard drill with chuck adaptor will be necessary for this alternative milling method.

Select an 8-9mm Zygoloc™ Burr. These are typically provided boxed and sterile. Attach the Burr to the Zygoloc™ Drill Shaft by inserting the T-end of the Burr into the shaft and turning 45° clockwise. Attach the drill shaft with attached burr into the Jacobs chuck and securely tighten.

Utilizing the Zygoloc™ Drill Guide advance the drill to create the hole. The drill guide will not allow the burr to advance past 15mm.

Note: Implant length is 10mm.

Operative Technique

Open

Usually a complete bony wall is made in the milling technique that traverses both superior and inferior articular processes of the facet joint. However in a small number of patients a small deficiency in the wall of the facet joint hole may be encountered. It is acceptable to implant the device. The hole must cross both articular processes AND the hole must permit a reasonable hold on the Zygoloc™ cage.

Step 4 Cage Loading

Load the Zygoloc™ cage into the loading block exposing the open end. Guide the cage inserter into the open end of the cage and lightly push down. Tactile feedback should be a firm self retaining fit between implant and inserter.

NB: Bone graft or bone substitute may be packed into the cage prior to loading onto the cage inserter.

Step 5 Cage Insertion

Impact the Zygoloc™ Facet Fusion Cage with a mallet onto the impaction end of the insertion tool. The Zygoloc™ Facet Fusion cage has a press-fit implantation technique. Reversed circumferential press fit threads restrict the back-out of the cage once inserted into the prepared hole. Once impacted simply pull up on the insertion tool to release.



Operative Technique

Open

Step 6 Graft Insertion

Prepare desired bone graft material. The bone graft tamp may be utilized to ensure adequate material is packed firmly into the cage.

A check x-ray is recommended to confirm satisfactory placement of the implant.



Removal

Removal of the Zygoloc™ Facet Fusion Cage is possible at the time of surgery using a toothed forcep or an extraction hook. If difficulty is encountered, distraction on the pedicle screw construct (as per the relevant surgical technique) can aid removal.

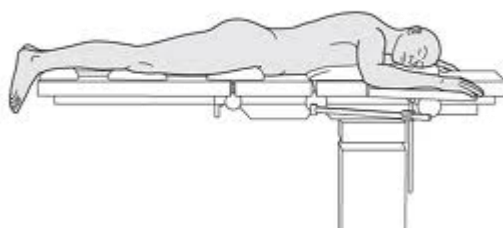
Operative Technique

MIS

Minimally invasive techniques, commonly referred to as MIS, have become an increasingly popular method of posterior spinal fusion. For the ideal pathology minimally invasive spinal surgery via a posterior approach is associated with reduced iatrogenic soft tissue injury that occurs with muscle stripping and retraction during traditional open approaches. Through evolving experience and education, it has become apparent that the major obstacle to minimally invasive fixation is achieving a minimally invasive fusion.

Step 1 OT Setup

Position the patient prone on a suitable operating table under usual conditions.



Hint

Any operating table used for spinal procedures will suffice, though the Jackson table offers an optimal amount of unrestricted fluoroscopic visualization.

On the surgeon's preferred side, position the rigid arm clamp on the table rail lateral to the mid or upper thigh of the patient to facilitate subsequent placement of the rigid arm assembly.



The rigid arm clamp can also be attached to the table rail once the surgical draping is completed. The clamp can be attached over the drapes. The sterile rigid arm can then be attached to the clamp. The rigid arm can now easily be adjusted within the sterile field. ***It is recommended to loosely attach the rigid arm to both the table attachment and the connection clamp before dilation and attachment of the selected port.***

Operative Technique

MIS

Step 2 Site Preparation & Targeting

Posterior instrumentation can be inserted via an open or minimally invasive (MIS) technique. Surgeons learn various techniques and develop their preferred method of choice for patient treatment based on individual pathology. Insert the posterior pedicle screw and rod construct over one or more levels as indicated as per the relevant surgical technique.

Perform any correction of the necessary spinal levels required as per the surgical technique.



Hint

Where guidewires for MIS screw insertion have been inserted and no further correction is to be obtained, dilation of the muscle over the guidewire while “wanding” the port up to the facet can be achieved. Dilation can also occur along side of the guidewire.

Step 3 Dilation & Depth Measurement

Dilation of the muscles that run parallel to the spine is the primary objective to gain access to the relevant facet joint. Intraoperative Fluoroscopy or Navigation is often used to accurately locate the desired level.

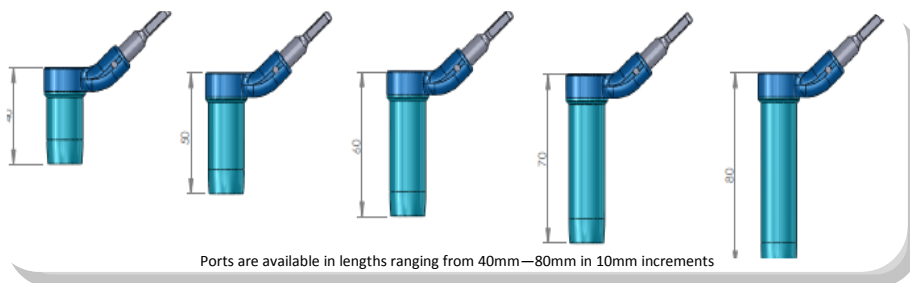
Once the initial skin incision is made, the first dilator is inserted. Once the initial dilator has bluntly penetrated the fascia, advance down to the bony anatomy. Ensure the initial dilator is fully seated against the bony anatomy. Use the initial dilator to palpate the anatomy in both the coronal and sagittal planes.

Operative Technique

MIS

Continue sequential dilation by passing the next largest dilator over the previously inserted dilator.

It is recommended that the depth measurement be taken at the point where the skin contacts the dilator. Often it is more accurate to take this measurement from the second dilator as this will be flush to the bone. There are four dilators in total ranging from 5mm to 16mm. The last dilator corresponds to the port diameter with an outer diameter of 18mm.



Step 4 Port Insertion

Once the final dilator has been inserted and the depth has been determined select the corresponding port. Slide the port over the dilator until it contacts the bony surface. Whilst holding the port in place attach the rigid arm with the connection clamp to the port. Securely tighten.

The port is now in place for the remainder of the procedure. The sequential dilators can now be removed.

To adjust the position of the port at any time during the procedure, insert final dilator only. With downward pressure on the tube, loosen the rigid arm, reposition and retighten. Remove the final dilator. This action can be repeated at any time to allow for an alternative angle or field of view and permit additional exposure of the local spine region.



Quick Connect Rigid Arm and Connection Clamp

Operative Technique

MIS

Step 5 Hole Preparation

Using the recommended high speed drill attachment and the bayoneted drill sleeve mill the hole within the facet joint crossing the two articulating surfaces. **The use of high flow irrigation must be utilized to prevent thermal necrosis during this high speed milling technique.** A 'mixing cannula' or similar syringe extension may be needed to allow irrigation whilst maintaining visual access through the port.



View of milled facet joint through the MIS port

Step 6 Cage Loading

Load the Zygoloc™ cage into the loading block exposing the open end. For the MIS technique it is a recommend to pack as much graft into the cage before insertion allowing room for the tips of the insertion instrument within the cage. Guide the preferred MIS cage inserter into the open end of the cage and lightly push down. Tactile feedback should be a firm self retaining fit between the implant and the inserter.

Step 7 Cage Insertion

Gently impact the insertion instrument impaction plate with a mallet. Once satisfactory cage placement is achieved remove the inserter by gently pulling up on the handle. The cage will be released and remain insitu. The bone graft tamp may be utilized to deliver further graft material and ensure the graft is firmly packed into the cage.

Check fluoroscopy is recommended to ensure satisfactory placement of the cage.



ZygoLoc™ Facet Fusion System

Ordering Information

Reference	Description
Implants	
ZL-T-0908-10	Zygoloc™ Facet Cage 8-9mm (Green)
Hole Preparation	
9HM85	8.5mm Holemaker High speed Burr
132-062-022	Zygoloc™ 8-9mm Drill Bit
Core Instruments	
132-062-028	Graft Packing Jig
132-062-024	Zygoloc™ Drill Guide Long
132-062-014	Zygoloc™ Inserter 8-9mm
132-062-033	Bone Tamp
132-062-027	Zygoloc™ Drill Shaft Long





INDICATIONS

The Zygoloc™ Facet Fusion Cage is an implant used to stabilise the triple joint complex in the thoracolumbar spine during the development of facet joint arthrodesis. The device is intended to be implanted by a posterior approach using the corresponding Zygoloc™ instrument set. The Zygoloc™ Facet Fusion Cage is indicated for use in skeletally mature patients with the following conditions: Arthrodesis required at any paired vertebral bodies in the thoracolumbar spine, degenerative disc disease defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies, spinal stenosis, spinal deformities or curvatures, spondylolisthesis, pseudoarthrosis and failed previous fusion in skeletally mature patients.

The Zygoloc™ cage is to be used with complimentary posterior support in the form of pedicle screws and rods. The Zygoloc™ cage is intended to be used with bone graft materials and/or similar.

WARNINGS, PRECAUTIONS AND CONTRAINDICATIONS

Refer to the Zygoloc™ Facet Fusion System IFU for complete information.

IFU 131-111-001 Rev. A

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