Zimmer Facet Screw System
Surgical Technique

- Description, Indications & Contraindications .............................................. 3
- Surgical Technique ........................................................................................................ 4
- Alternate Insertion Technique Options ................................................................. 7
- Tray Layouts .................................................................................................................. 8
- Instrument Visual Guide ............................................................................................ 9
- Warnings and Precautions ......................................................................................... 10
Description, Indications & Contraindications

DESCRIPTION

The Zimmer Facet Screw System consists of partially-threaded screws, and hand instruments. Various forms and sizes of these screws are available, so that adaptations can always be made to take into account the pathology and anatomy of an individual patient. All components are made of Ti6Al4V ELI, a titanium-based alloy which complies with ASTM F136.

INDICATIONS FOR USE

The Zimmer Facet Screw System is intended for posterior fixation to the lumbar spine (L1 to S1 inclusive). The system is intended for bilateral, transfacet fixation of the facet joint in order to provide stability for fusion. The system is indicated for posterior surgical treatment of any or all of the following at the L1 to S1 (inclusive) spinal levels:

• Degenerative disc disease (as defined by back pain of discogenic origin with degeneration of the disc as confirmed by patient history and radiographic studies),
• Degenerative disease of the facets with pain and/or instability on plain flexion and extension lateral radiographs where there is movement of the vertebral bodies relative to each other of more than 4mm,
• Trauma (i.e., fractures and/or dislocations),
• Spondylolisthesis,
• Spondylolysis,
• Pseudoarthrosis and/or failed previous fusions.

CONTRAINDICATIONS

Contraindications for the Zimmer Facet Screw System are similar to those of other systems of similar design, and include, but are not limited to:

1. Active infectious process in the patient, particularly in or adjacent to the spine or spinal structures.
2. Morbid obesity.
4. Grossly distorted anatomy due to congenital abnormalities.
5. Any medical or surgical condition which would preclude the potential benefit of spinal implant surgery.
6. Rapid joint disease, bone absorption, osteopenia, osteomalacia, or osteoporosis. Osteopenia or osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction and/or the amount of mechanical fixation.
7. Suspected or documented metal allergy or intolerance.
8. Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.
9. Use of these implants is relatively contraindicated in patients whose activity, mental capacity, mental illness, alcohol or drug abuse, occupation or life-style may interfere with their ability to follow post-operative instructions.
10. Any time implant utilization would interfere with anatomical structures or expected physiological performance.
11. Any case not needing a bone graft and fusion or where fracture healing is not required.
12. Other medical or surgical conditions which would preclude the potential benefit of spinal implant surgery such as the presence of tumors, congenital abnormalities, elevation of white blood cell count (WBC), or a left shift in the WBC differential count.
**Surgical Technique**

**Patient Positioning**

Step 1

The patient is positioned on the operating table in the prone position. The patient should be positioned to minimize intra-abdominal pressure to avoid venous congestion and excess intra-operative bleeding and allow adequate ventilation under anesthesia. The patient’s hips should be extended to preserve lumbar lordosis for fusion and instrumentation of the lumbosacral region.

**Exposure**

Step 2

The surgical approach is carried out through a standard midline incision to the spinal column over the anatomic position of the spinous process. The exposure of the spinous process should extend one additional level. The laminae, pedicles, superior and inferior facets of the levels to be fused should be visualized directly and/or by intraoperative fluoroscopy. (Fig. 1)

**Note:** For the percutaneous surgical approach, a 12mm skin incision is recommended for each facet screw.

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**Instruments**

- **K-wire (500mm)**
  - 07.02214.015
  - (X063-0063)
- **Inner Dilator**
  - 07.02214.009
  - (X063-0035)
Step 3
Appropriate arthrodesis and interbody fusion with a load-bearing construct should be performed prior to screw placement. Care should be taken to avoid any removal or anatomic compromise of the facet joints. Anterior column support and meticulous fusion techniques are required for a successful procedure. (Fig. 2)

Step 4
Under fluoroscopic guidance, a K-wire, Drill and Drill Outer Dilator are placed over the superior facet with a trajectory into the inferior facet and the inferior proximal pedicle. A transfacet rather than a translaminar approach is recommended. Care must be taken to avoid over-drilling into any structure outside of the cortical bone margin. (Fig. 3)

NOTE: Ensure the Long Drill Outer Dilator is used with the Cannulated Drill for appropriate drilling depth.

Step 5
After confirmation of appropriate depth, a 4.5mm tap is used to create threading and an appropriately sized screw is introduced over the K-wire into the superior facet. (Fig. 4)

Placement of Bone Graft

Drilling

Tapping

Instruments

Graft Packer 07.02214.012 (X063-0040)
Dilator Handle 07.02214.013 (X063-0045)
Ratcheting Driver Handle 07.02214.001 N60000473
Drill Outer Dilator, Long 07.02214.010 X063-0036
Cannulated Drill 07.02214.006 X063-0028
Tap 07.02214.007 (X063-0029)
Step 6
Attach the Screwdriver to the screw by fully seating the drive in the screw head and turning the Screwdriver sleeve counterclockwise.

The screw should be rotated gradually under biplanar fluoroscopic guidance to confirm distal entry into the inferior facet. The screw should be rotated until the screw head contacts the superior facet. Over-tightening of the screw can result in facet fracture. Bilateral screws are required for adequate fixation strength. (Fig. 5)

NOTE: An optional washer may be used with the facet screw. (Fig. 8)

Step 7
Anteroposterior and lateral radiography should be performed to confirm screw position. Additionally, neurophysiologic testing of the screw is recommended to confirm that there is no nerve root conductance. (Fig. 6)

Instruments

Ratcheting Driver Handle
07.02214.001
M60000473

Screwdriver
07.02214.005
X063-0025
Optional Open Technique

If using an open midline surgical approach without K-wires, shorter non-cannulated instruments may be used for drilling and tapping.

Screw Placement with Optional Washer

If desired, an optional 10mm washer may be implanted with the Zimmer Facet Screw.

Instruments

- Ratcheting Driver Handle
  - 07.02214.001
  - N60000473

- Drill Outer Dilator, Short
  - 07.02214.011
  - (X063-0038)

- Drill
  - 07.02214.006
  - (X063-0028)
Tray Layouts

Zimmer Facet Screw System Instruments and Implants 07.02213.400

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Instrument Visual Guide

K-Wire Trocar, 500mm
07.02214.015
(X063-0063)

K-Wire Blunt, 500mm
07.02214.017
(X063-0073)

Cannula Cleaner, 300mm
07.02214.002
(N60001000)

Rasp
07.02214.016
(X063-0066)

Cannulated Bone Awl
07.02214.003
(X010-0169)

Ratcheting Driver Handle
07.02214.001
(N60000473)

Dilator Handle
07.02214.013
(X063-0045)

Inner Dilator
07.02214.009
(X063-0035)

Drill Outer Dilator, Long
07.02214.010
(X063-0036)

Drill Outer Dilator, Short (Open Approach)
07.02214.011
(X063-0038)

Cannulated Drill
07.02214.006
(X063-0028)

Drill (Open Approach)
07.02214.008
(X063-0031)

Tap
07.02214.007
(X063-0029)

Screwdriver
07.02214.005
(X063-0025)

Mallet
07.02214.014
(X063-0055)

Graft Packer
07.02214.012
(X063-0040)
Warnings and Precautions

**WARNINGS:**
Potential risks associated with the use of this system, which may require additional surgery, include; device component neurological injury, and vascular or visceral injury. Discard all damaged or mishandled implants. Never reuse an implant, even though it may appear undamaged.

Internal fixation devices cannot withstand activity and load levels equal to those placed on normal healthy bone. Until maturation of the fusion mass is confirmed, do not subject this device to the stress of full weight bearing, or implant failure may result.

Contouring and bending of a system component may reduce its fatigue strength and cause failure under load. If spinal screws are bent or otherwise damaged during insertion or adjustment, they must not be implanted and must be replaced.

**Mixing Metal:** some degree of corrosion occurs on all implanted metal and alloys. Contact of dissimilar metals, however, may accelerate this corrosion process. The presence of corrosion may accelerate fatigue fracture of implants, and the amount of metal compounds released into the body system will also increase. Internal fixation devices, such as rods, hooks, screws, etc., which come in contact with other metal objects, must be made from like or compatible metals. Because different manufacturers employ different materials, varying tolerances and manufacturing specifications, and differing design parameters, the components of Zimmer Facet Screw System should not be used in conjunction with components from any other manufacturer’s spinal system.

Removal of an unloosened spinal screw may require the use of special instruments to disrupt the interface at the implant surface. This technique may require practice in the laboratory before attempted clinically. Any decision by a surgeon to remove the internal fixation 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. Implant removal should be followed by adequate postoperative management to avoid fracture.

**PRECAUTIONS**
When properly used, facet screws will provide temporary stabilization as an adjunct to spinal bone grafting processes. After solid fusion occurs, these devices serve no functional purpose and may be removed. In some cases, removal is indicated because the implants are not intended to transfer or to support forces developed during normal activities. Any decision to remove the device must be made by the physician and the patient. This decision should consider the patient’s general medical condition and the potential risk to the patient of a second surgical procedure.

The implants must be implanted only by experienced surgeons having undergone appropriate training in spinal surgery. Their use in implantation must be decided upon with regard to the surgical and medical indications, the potential risks, and limitations related to this type of surgery. The surgeon and patient should demonstrate knowledge of the contraindications, side effects, precautions, metallurgical and biological characteristics of the implants to be used. Zimmer Facet Screw System implants must not be used together with implants from a different source, a different manufacturer or made from a different material.

As with all orthopedic and neurosurgical implants, none of the Zimmer Facet Screw System components should ever be reused under any circumstances. Risks associated with reuse include infection, non-union (pseudarthrosis), serious patient injury or death.

Knowledge of surgical techniques, proper reduction, selection and placement of implants, and pre and post-operative patient management are considerations essential to a successful surgical outcome. Appropriate selection, placement and fixation of the spinal system components are critical factors which affect implant service life. As in the case of all prosthetic implants, the durability of these components is affected by numerous biologic, biomechanics and other extrinsic factors, which limit their service life. Accordingly, strict adherence to the indications, contraindications, precautions, and warnings for this product is essential to potentially maximize service life. (Note: While proper implant selection can minimize risks, the size and shape of human bones present limitations on the size, shape, and strength of the implants).

Patients who smoke have been shown to have an increased incidence of pseudoarthrosis.
Such patients should be advised of this fact and warned of the potential consequences. Patients with previous spinal surgery at the level to be treated may have different clinical outcomes compared to those without a previous surgery. Based on the fatigue testing results, the physician/surgeon should consider the level of implantation, patient weight, patient activity level, and other patient conditions, etc. which may have an impact on the performance of the system.

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) resultant forces can cause failure of the device. In some cases, progression of degenerative disease may be so advanced at the time of implantation that the expected useful life of the appliance may be substantially decreased. In such cases, orthopedic devices may be considered only as a delaying technique or to provide temporary relief. Patients should be instructed 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 patient should understand that a metallic implant is not as strong as normal, healthy bone and will bend, loosen or fracture if excessive demands are placed on it. An active, debilitated, or demented patient who cannot properly use weight supporting devices may be particularly at risk during postoperative rehabilitation.

Care must be taken to protect the components from being marred, nicked or notched as a result of contact with metal or abrasive objects. Alterations will produce defects in surface finish and internal stresses which may become the focal point for eventual breakage of the implant.

Due to the presence of implants, interference with roentgenographic, CT and/or MR imaging may result. The Zimmer Facet Screw System has not been evaluated for safety and compatibility in the MR environment. The Zimmer Facet Screw System has not been tested for heating or migration in the MR environment. It must be noted that there are several different manufacturers and generations of MRI systems available, and Zimmer Spine cannot make any claims regarding the safety of Zimmer Spine implants and devices with any specific MR system.

Physician Note: The physician is the learned intermediary between the company and the patient. The indications, contraindications, warnings, and precautions given in this document must be conveyed to the patient. If requested, additional information, including surgical technique manuals, may be obtained through corporate sales representatives.
Disclaimer:
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Caution: Federal (USA) law restricts this device to sale by or on the order of a physician. Please see the product Instructions for Use for a complete listing of the indications, contraindications, warnings, precautions and adverse effects.

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