FaSet™

Facet Fixation System

Translaminar Approach

REV A – US ONLY

DIO MEDICAL®

CONTENTS

Images may not look the same as the actual product.

This surgical tech guide alone may not offer all information, or knowledge, required to perform spinal surgery, thus additional instruction, or performance, of an experienced surgeon is recommended.

IMPLANT OVERVIEW

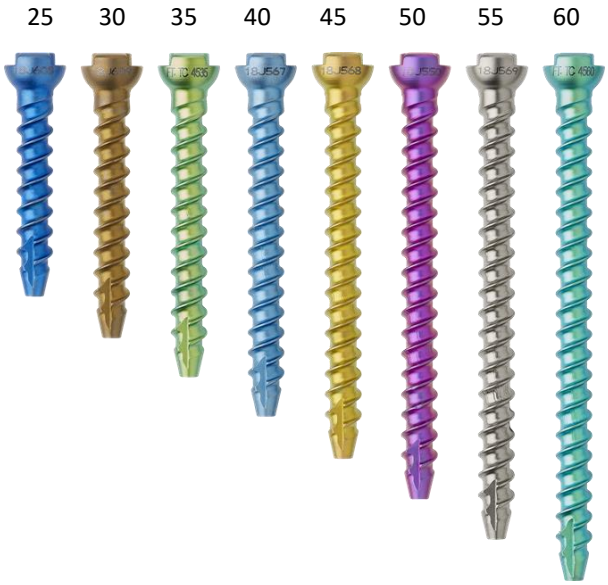
FEATURES & BENEFITS

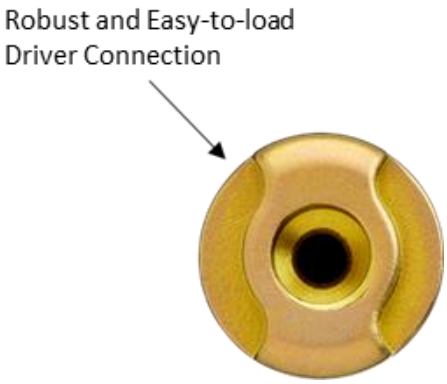
- Low profile screw design for less tissue damage
- Dual thread screws for easier and faster insertion and better tactile feel
- Multiple screw types provides broader options
- Unique feature for secure screw and driver connection
- Snap fit washer for easy assembly
- Ridged undersurface to allow for better washer engagement with bone
- Washer angulation up to 25°
- Streamlines instrumentation for easier and faster implantation

SCREWS

- 4.5 mm and 5.0 mm diameter
- Length from 15 to 60mm (2mm increments)
- Cannulated and non-cannulated
- Color coded for easy identification per length (see image below)

SCREWS LENGTH





SURGICAL TECHNIQUE

STEP 1: PATIENT POSITIONING

The patient is placed under anesthesia and positioned prone position on a radiolucent OR table. To obtain optimal visualization of the spine, the OR table should have enough clearance available for a fluoroscopic C-arm to rotate freely for A/P, oblique and lateral views. Accurate visualization of anatomic landmarks and fluoroscopic visualization of the facet joints is imperative for using the FaSet Fixation System

STEP 2: APPROACH

The technique for the translaminar approach is a cross-table technique for both mini-open and percutaneous methods. Using A/P and lateral fluoroscopic views, locate the starting point at the ipsilateral (to the surgeon side) junction of the spinous process to the medial lamina. For the mini-open technique, the incision is identical to that used for a bilateral laminotomy to expose the junction of the spinous process and lamina bilaterally and exposing bilateral facet joint. In a thin patient the incision is 3-4 cm in length. In the obese and morbidly obese patient, the incision is approximately 6 cm in length. Flouroscopy with a marker is used to confirm the spinal levels for fixation.

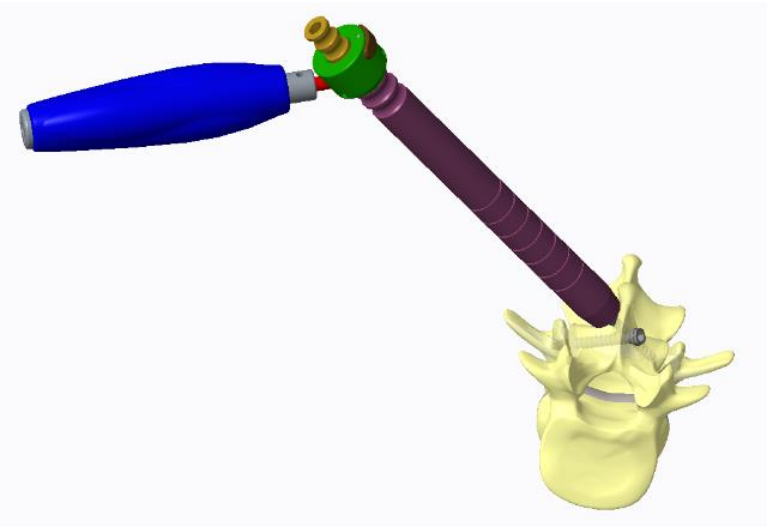
STEP 3: JAMSHIDI NEEDLE and K-WIRE INSERTION

Once the appropriate starting point is identified under AP and lateral images, one can then drill the K-wire either transfacet or translaminar approach. Introduce a Jamshidi Needle via a small stab wound and follow the angle of the planned trajectory. Make sure that the inferior endplate of the superior vertebral body is perpendicular on an A/P fluoroscopic view. The starting point for the incision is typically at the midline (or slightly contralateral in obese patients). Advance the Jamshidi needle through the soft tissues and dock the needle tip on the inferior articular process. Confirm the trajectory on Lateral and A/P fluoroscopy. Gently push down on the inferior facet with the Jamshidi needle.

(*Note: Remove the inner stylet from Jamshidi needle and insert the K-wire into the outer stylet of Jamshidi needle. Ensure that the K-wire does not advance more than 10mm past the tip of the needle. Confirm the protrusion with fluoroscopy. Once the K-wire is placed, remove the Jamshidi Needle entirely.)

STEP 4: DILATION

The patient is placed under anesthesia and positioned prone position on a radiolucent OR table. To obtain optimal visualization of the spine, the OR table should have enough clearance available for a fluoroscopic C-arm to rotate freely for A/P, oblique and lateral views. Accurate visualization of anatomic landmarks and fluoroscopic visualization of the facet joints is imperative for using the FaSet Fixation System



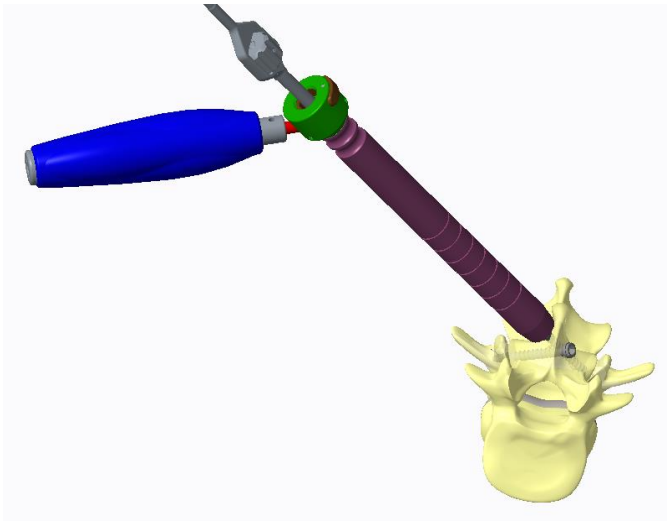
STEP 5: AWL, DRILL and TAP

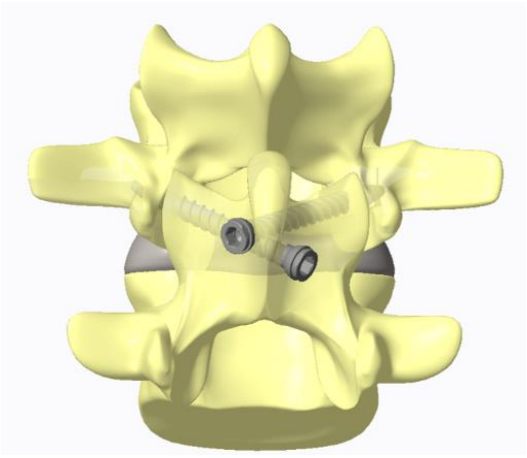
Select the proper cannulated drill bit according to the desired FaSet Screw Diameter. Securely attached the Ratcheting Handle to the Cannulated Drill. Slide Dill with Ratcheting Handle over the K-wire and through the Dilator Large (or DTS Guide). To measure the Drill depth, check the laser marking on the Drill bit. Also, confirm with lateral and A/P fluoroscopy view. Remove the Drill with Ratcheting Handle and leave the K-wire in place. Insert the corresponding Tap with Ratchet handle. To measure the Tap depth, check the laser marking on the Tap. Also, confirm with lateral and A/P fluoroscopy views.

(*Note: Cannulated instruments are not mandatory for both open or mini-open procedure)

STEP 6: SCREW INSERTION

Align the left and right ledge of the screw-head with the Screw Driver distal tip arms of the outer shaft of the Driver. Once both arms of Screw Driver sit properly, the inner shaft of the driver which has threads can be advanced into the screw-head thread portion by turning the knob clockwise on the Screw Driver. Ensure that the screw-head is securely assembled to the Screw Driver.
Drive the assembly (Screw and Screw Driver) over the K-wire and through Dilator Large (or DTS Guide). Placement and depth of the screw can be monitored and confirmed by fluoroscopy. The K-wire can be removed once the screw is secure within the desired anatomy. Also, disengage the Screw Driver from the screw by turning the knob of the Screw Driver counterclockwise.





Final Construct

STEP 7: CLOSURE

The operative site should be closed per hospital protocol and the surgeon's discretion.

STEP 8: POSTOPERATIVE CARE

Following are few of the recommended steps:

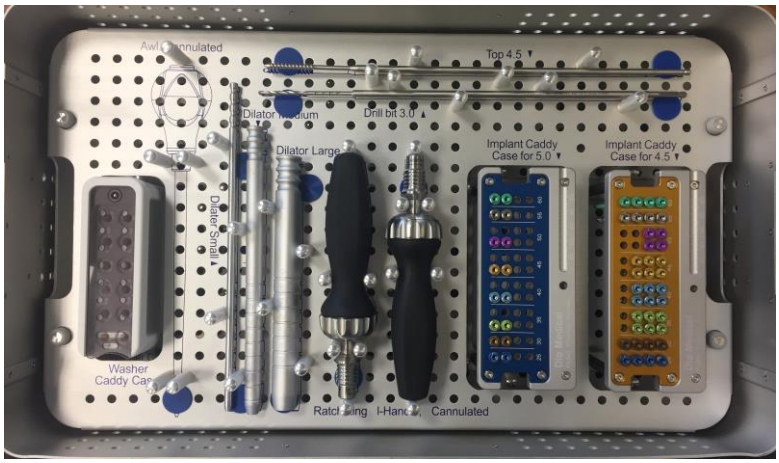
- Prior to adequate fusion healing, the physician may prescribe an additional external support (e.g. brace) to allow full weight bearing.
- Take anteroposterior and lateral X-rays to ensure correct positioning of the interbody cages and facet screws before mobilization of the patient.
- Routine monitoring of the vital signs, and of the hemodynamic and neurologic status of the patient should be done per hospital protocol and the surgeon's discretion.
- Pain Medication per hospital protocol and the surgeon's discretion.
- Diet is restricted to small amounts of liquids until return of bowel function per hospital protocol and the surgeon's discretion.
- The patient is encouraged to ambulate as soon as possible based on the activity level determined by the surgeon

STEP 9: IMPLANT REMOVAL (OPTIONAL)

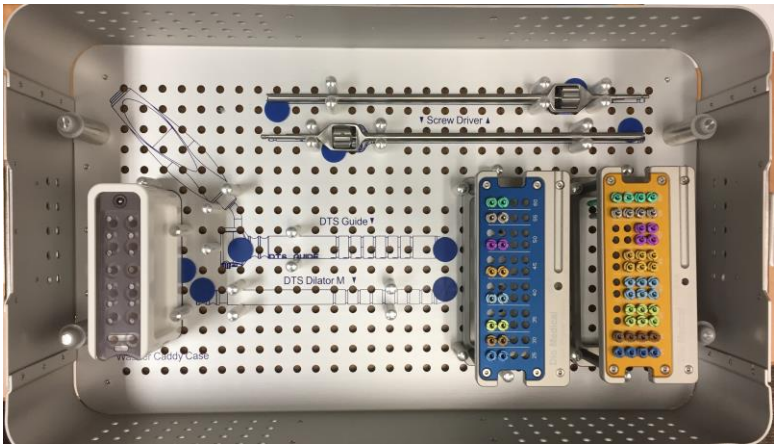
The insertion instruments can be used to engage the implant securely. The implant can then be extracted by following the implantation process in the reverse order. Optionally, other manual surgical instruments may be used to grasp and extract the implant.

INSTRUMENT LIST

Description	Set Qt'y
Awl, Cannulated	1
Dilator Small	1
Dilator AL Large	1
Dilator AL Medium	1
DTS Guide AL	1
DTS Dilator M AL	1
Drill bit 3.0	2
Tap 4.5	1
Screw driver	2
Ratcheting I-Handle, Cannulated	2
AL Case	1
Implant Caddy Case for 4.5	1
Implant Caddy Case for 5.0	1



TOP TRAY



BOTTOM TRAY

INSTRUCTION FOR USE

Indications For Use

The FaSet Fixation System is intended to stabilize the spine as an aid to fusion through bilateral immobilization of facet joints. The Facet Screw System is indicated for posterior surgical treatment with or without bone graft at single or multiple levels from C2 to S1 (inclusive). For transfacet fixation, the screws are inserted posteriorly through the superior side of the facet, across the facet joint, and into the pedicle. For translaminar facet fixation, the screws are inserted posteriorly through the lateral aspect of the spinous process, through the lamina, through the superior side of the facet, across the facet joint, and into the pedicle. The FaSet Fixation System is indicated for treatment for any or all of the following:

-Spondylolisthesis

-Pseudoarthrosis or failed previous fusions which are symptomatic or which may cause secondary instability or deformity

-Spondylolysis

-Degenerative Disk Disease (DDD) as defined by back pain of discogenic origin with degeneration of disk confirmed by history and radiographic studies and/or degenerative disease of the facets with instability

-Trauma including spinal fractures and/or dislocations.

Contraindications

- Any active or suspected latent infection in or about the spine.
- Any mental or neuromuscular disorder which would create an unacceptable risk of fixation failure or complications in postoperative care.
- Bone stock compromised by disease, infection or prior implantation which cannot provide adequate support and/or fixation to the devices.
- 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.
- Recent infection, fever, or leukocytosis.
- Bony abnormalities preventing safe screw fixation.
- Open wounds
- Metal sensitivity, documented or suspected
- Bone absorption, osteopenia and/or osteoporosis. (Osteoporosis is a relative contraindication, as the condition may limit the degree of correction obtainable and the amount of mechanical fixation.)
- Patient having inadequate tissue coverage over the operative site.
- Pregnancy
- Excessive local inflammation
- 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 sedimentation rate unexplained by other diseases, elevation of white blood cell count(WBC), or marked left shift in the WBC differential count.

Caution

- Federal law restricts this deveice to sale by or on the order of a physician/surgeon (Rx only)

Precautions

- 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.
- 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 they may substantially decrease the expected useful life of the appliance. In such cases, orthopedic devices may be considered only as a delaying technique or to provide temporary relief.
- Before clinical use, the surgeon should thoroughly understand all aspects of the surgical procedure and limitations of the spinal fixation systems requires detailed
- knowledge of spinal surgery. This device is recommended for use only by surgeons familiar with preoperative and surgical techniques, cautions, and potential risks associated with such spinal surgery. 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.
- 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.
- 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, bio-mechanic 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.

INSTRUCTION FOR USE

- 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.
- The implantation of the FaSet Fixation System should be performed only by experienced spinal surgeons with specific training in the use of this pedicle screw spinal system because this is a technically demanding procedure presenting a risk of serious injury to the patient.

NOTE

Indications

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