Facet Fixation System

Surgical Technique

SeaSpine

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Facet Fixation System

The SeaSpine® Facet Fixation System is intended to stabilize the lumbar spine as an adjunct to fusion. The implant provides transfacet or translaminar facet fixation to limit spinal flexion/extension and promote bone fusion.

The system consists of titanium screws and washers, and instrumentation for operative site access, bone preparation, and screw insertion. The system is packaged in a single tray for transportation, cleaning and sterilization.

Design Rationale

The SeaSpine Facet Fixation System was designed to streamline facet fixation through minimal instruments and straightforward implants.

System Features

- 4.5mm screw diameter
- Partially and Fully threaded shaft
- Screw lengths:
  - » 26-46mm (4mm increments)
  - » 50, 55mm
- Washer for greater surface area and load distribution
  - » Fixation spikes for off-axis fixation
- Titanium alloy for biocompatibility and x-ray visualization
- Internal and external features for multiple insertion options

Surgical Technique

STEP 1 Preoperative Planning and Patient Positioning

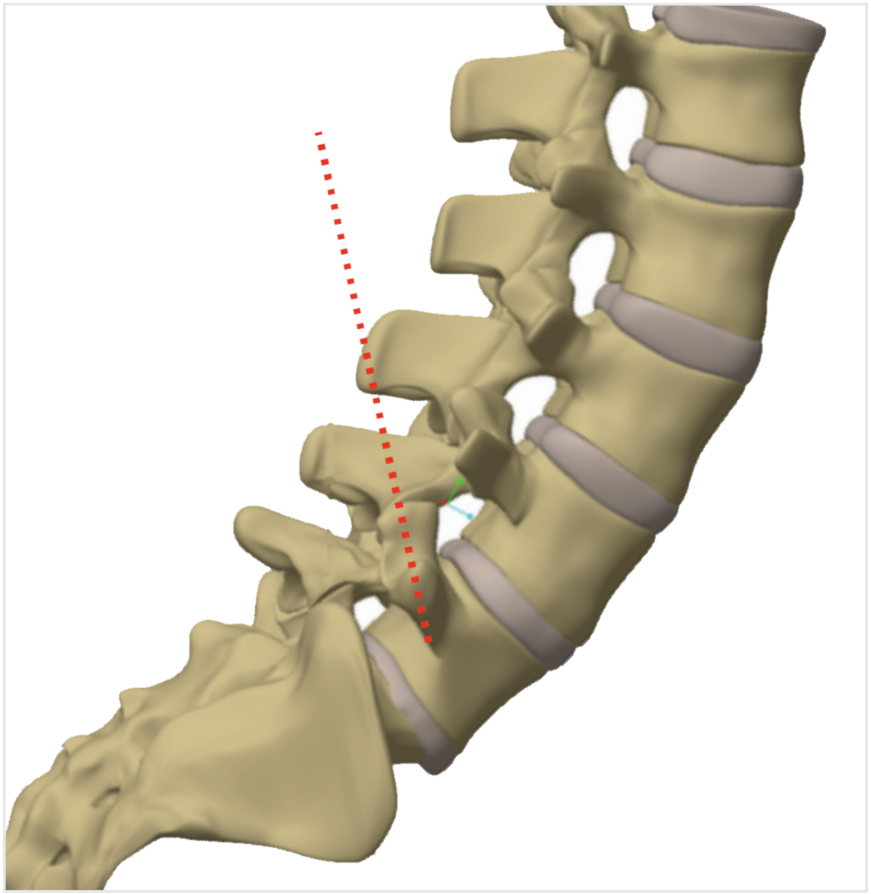
Medial-lateral and anterior-posterior X-rays, CT scans and MRI images may be used to help determine damaged intervertebral disc space, endplate angulation and potential instability. These images may also be useful to approximate the correct implant size.

STEP 2 Incision, Approach and Site Preparation

Transfacet Technique

Utilizing fluoroscopy, identify the operative level, plan screw trajectories and location of incisions.

Make a 10mm vertical skin incision over the identified entry site. A 10mm incision will accommodate the facet screw washer. In anticipation of sequential dilation steps, incise the fascia.



STEP 2 Incision, Approach and Site Preparation continued

Translaminar Technique

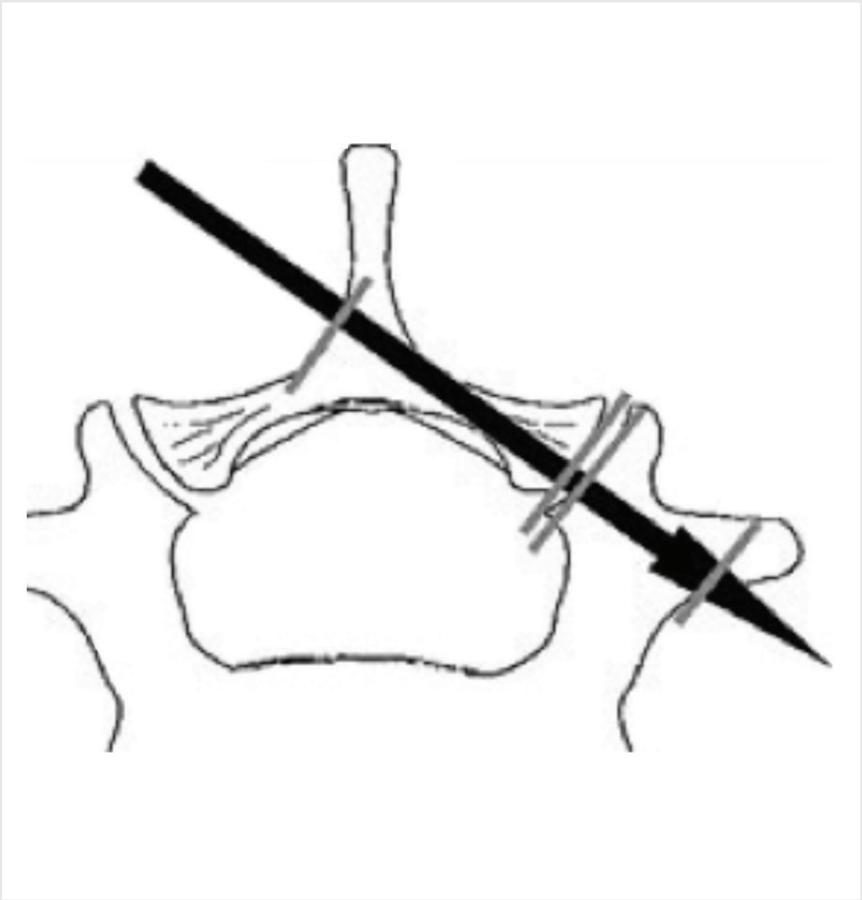
Utilizing fluoroscopy, identify the operative level, plan screw trajectories and location of incisions. Screws can be placed through an open midline or percutaneous approach. Trajectories should allow screws to cross within the spinous process and through the facets.

Open: make a small vertical midline incision and expose the spinous processes and lamina in a standard fashion.

Percutaneous: make a 10mm vertical skin incision over the identified entry sites.

Ensure the first screw entry point is slightly caudal or cephalad to allow room for the second screw on the contra lateral side.

NOTE Depending on anatomy and surgeon preference, screws may be placed slightly dorsal to the lamina until crossing the facet.



STEP 3 Access Needle Placement

Advance the access needle through the fascia (Transfacet Technique) or lamina (Translaminar Technique) following the planned screw trajectory. Confirm placement and trajectory on A/P view.

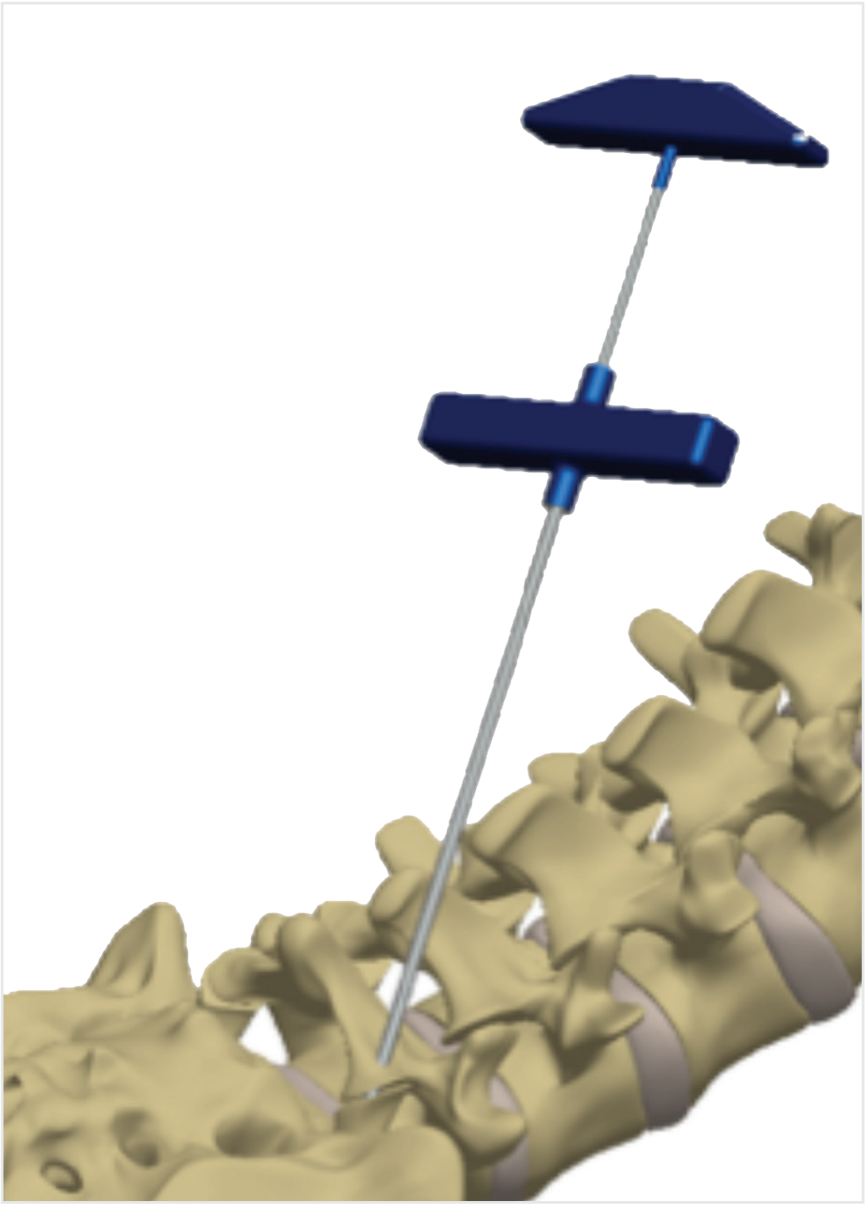
To prevent skiving off the entry point, push the inferior facet with the needle.

Confirm trajectory of the needle on lateral view. Adjust trajectory if necessary.

NOTE For Transfacet Technique, trajectory is aimed towards the pedicle.

Using A/P view, advance the needle slowly through the inferior facet.

Remove the inner stylet, if being used.

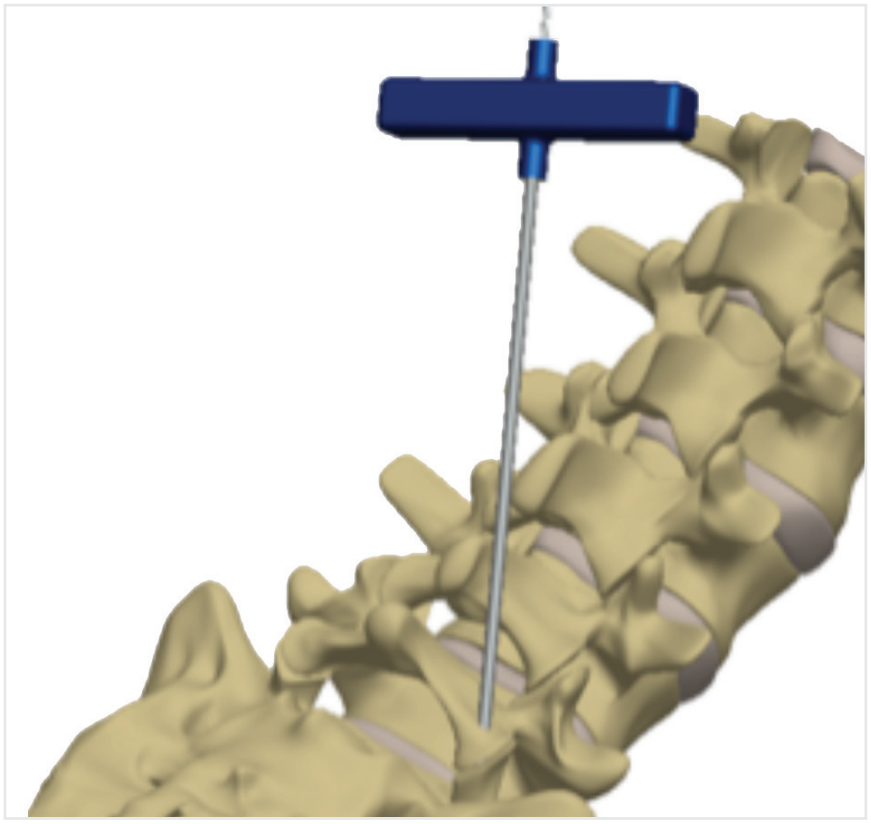


STEP 4 Guidewire Placement

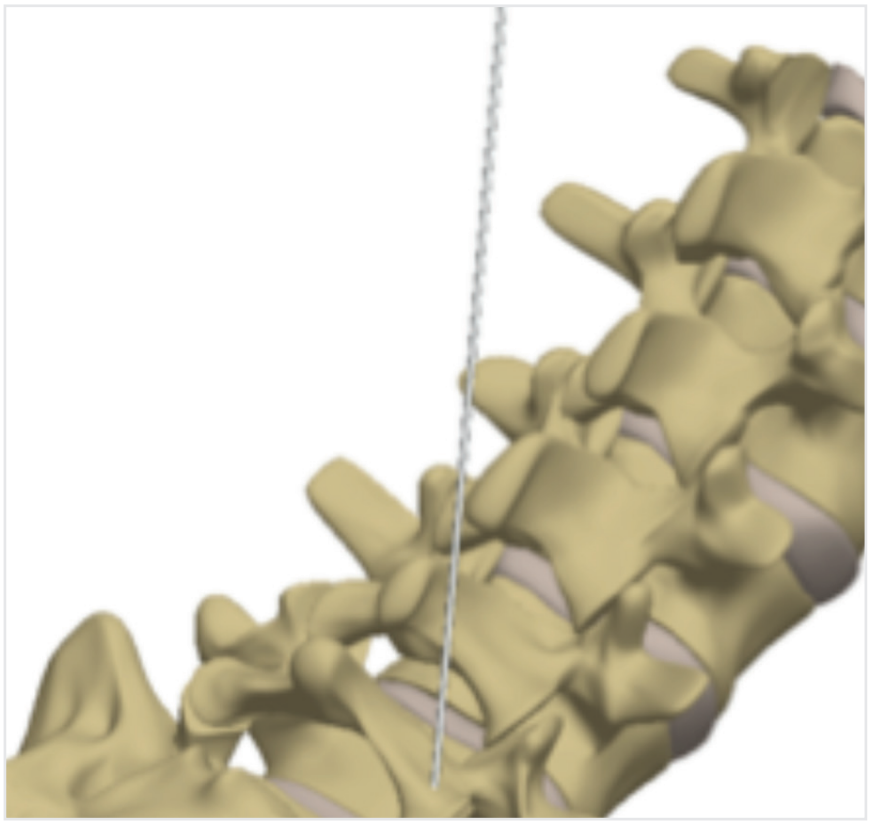
Insert a guidewire into the access needle and take a lateral fluoro shot to visualize the desired trajectory. Confirm on A/P view.

Advance the guidewire into the superior facet. View advancement under lateral view.

NOTE Change in resistance may be felt as the guidewire is advanced into the cortex of the superior facet.



Once the guidewire is anchored, the access needle can be removed.

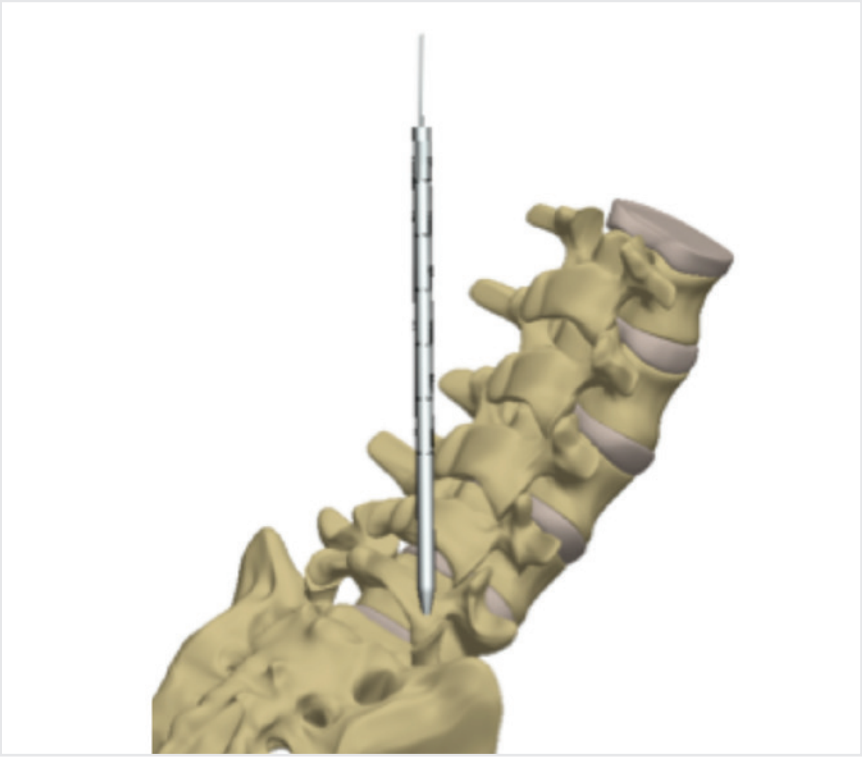


STEP 5 Dilation (for Percutaneous Approach)

Small Dilator

Advance the small dilator over the guidewire until the distal tip contacts the facet (Transfacet Technique) or spinous process (Translaminar Technique).

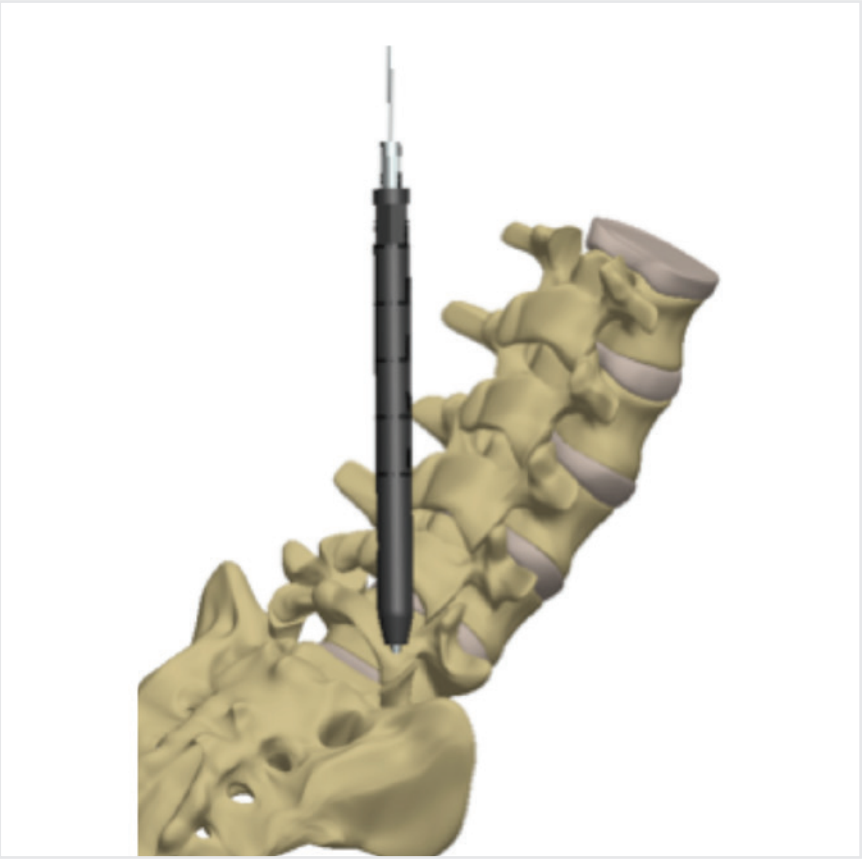
During dilation, monitor the guidewire to ensure it does not bend.



Medium Dilator

Similarly advance the medium dilator over the small dilator.

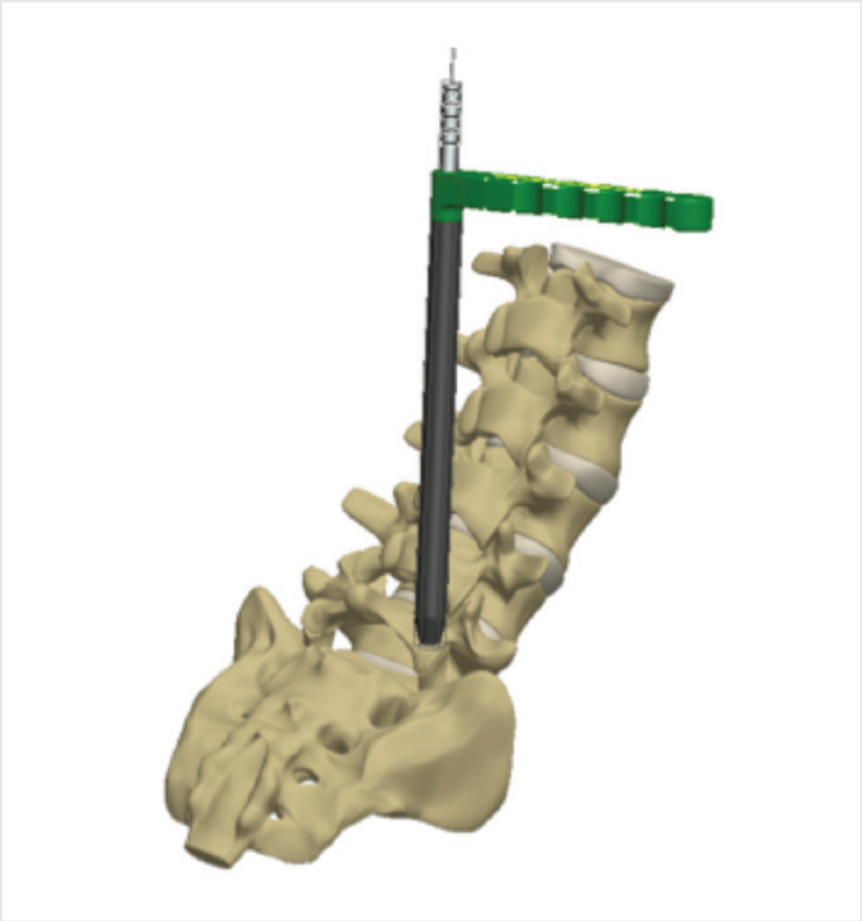
Once the medium dilator is placed, the small dilator may be removed.



STEP 5 Dilation (for Percutaneous Approach) continued

Dilator Handle

The dilator handle can be attached to the medium dilator for ease of handling.



STEP 6 Drill

Place the appropriate cannulated drill over the guidewire and through the medium dilator. Ensure the guidewire is not bent.

Advance the drill through the facets to the appropriate depth. Monitor drill location on lateral view with fluoroscopy.

NOTE For Transfacet Technique, drill into the pedicle. The cannulated drill should not advance beyond the posterior wall of the vertebral body. Depth markings on the drill indicate the appropriate length screw.

Reverse the Cannulated Drill, holding the guidewire in place while removing the drill. Confirm guidewire placement.

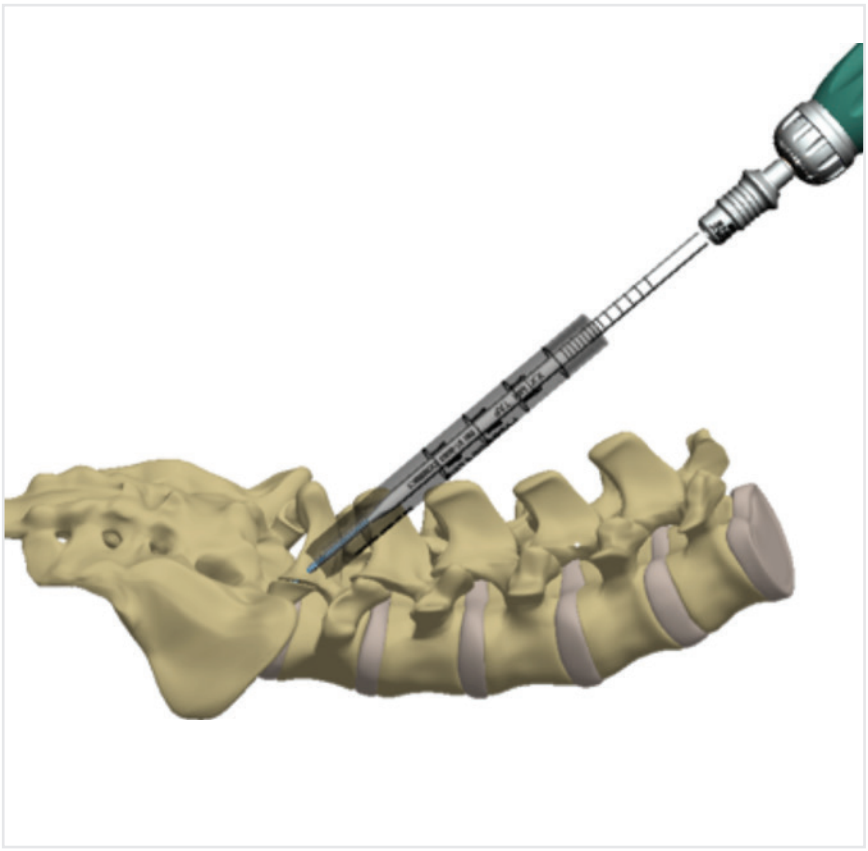
STEP 7 Tap

Place the appropriate cannulated tap over the guidewire and through the medium dilator. Ensure the guidewire is not bent. Tap through both facets.

NOTE For Transfacet Technique, tap into the pedicle.

Depth markings on the tap indicate the appropriate length screw.

Reverse the tap and hold the guidewire in place while removing the tap. Confirm guidewire placement.

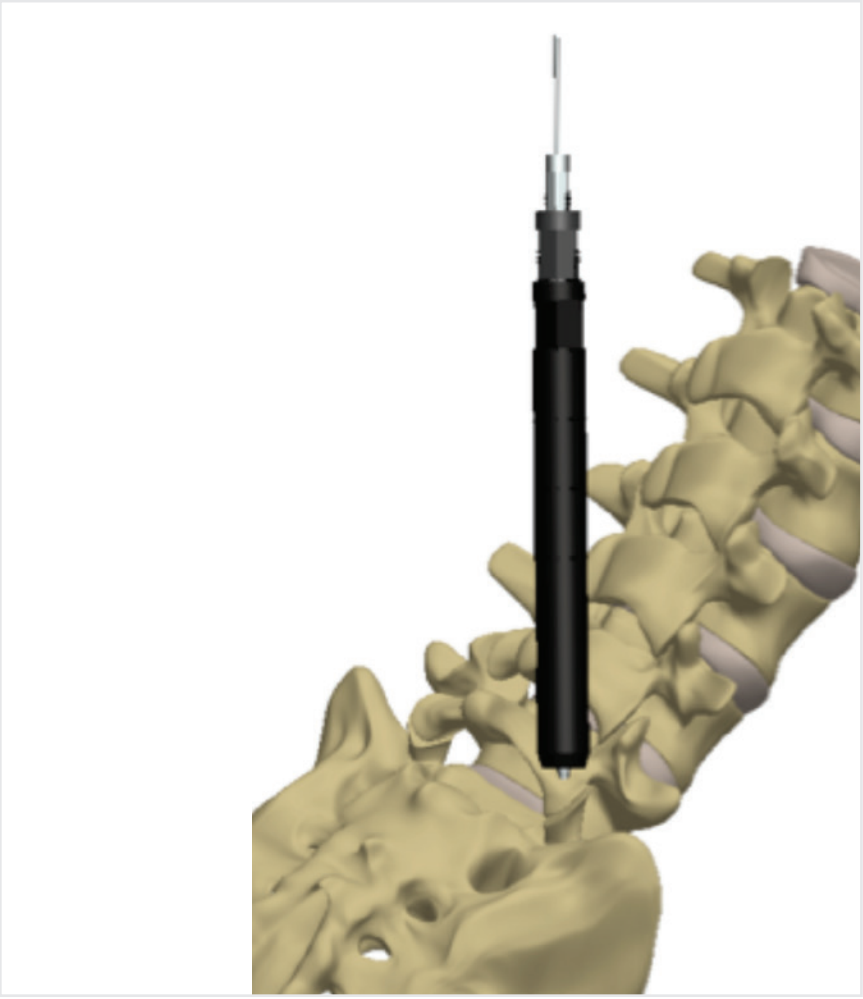


STEP 8 Large Dilator

If used, remove the dilator handle.

Insert the large dilator over the medium dilator. Advance the large dilator until the distal tip contacts the facet (Transfacet Technique) or spinous process (Translaminar Technique).

After large dilator placement, remove the medium dilator. The dilator handle can be attached to the large dilator for ease of handling.

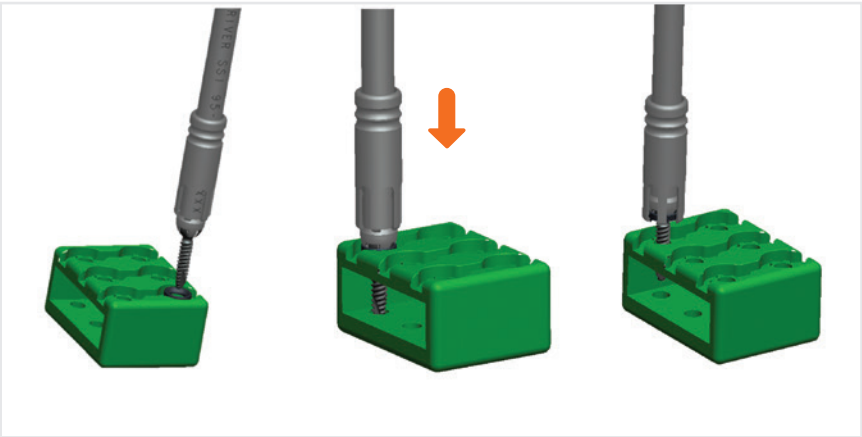


STEP 9 Screw Loading

Insert the universal driver shaft into the universal driver handle, turning the knob clockwise to engage threads. Place the washer retaining sheath over the universal driver handle. Place screw driver assembly over the desired screw and secure screw by turning the knob clockwise.

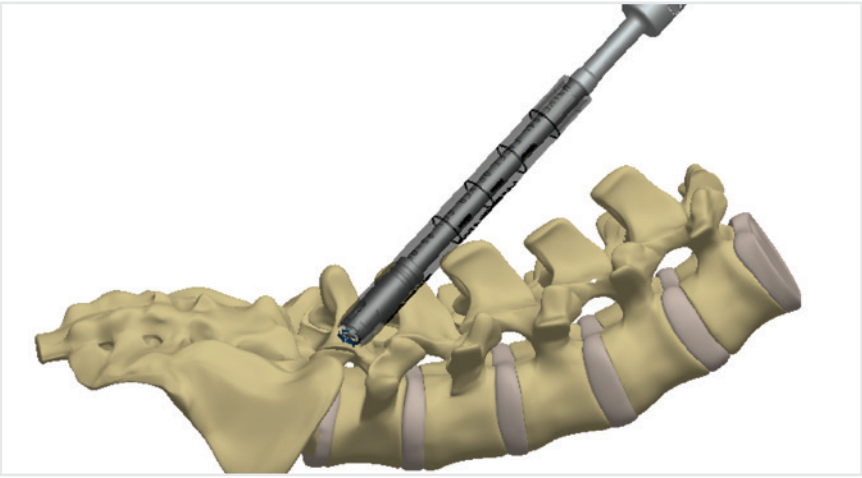
STEP 10 Washer Attachment

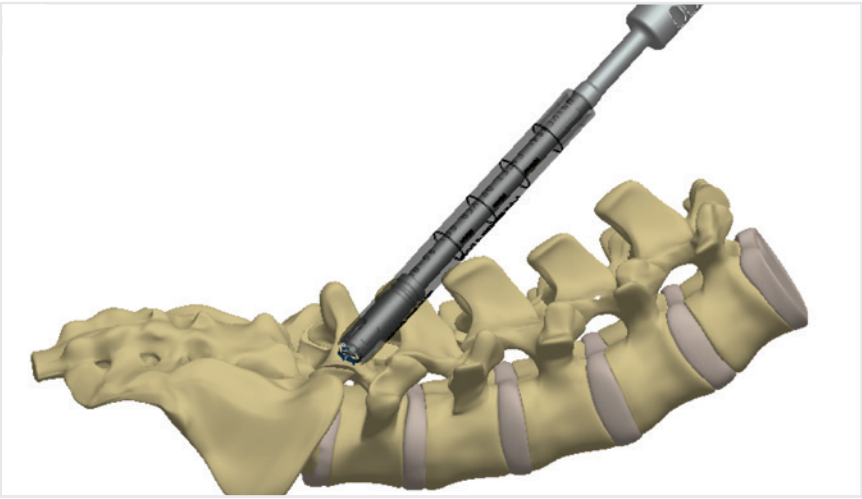
Washers are housed in a separate caddy. Slide the screw through the washer and lower the washer retaining sheath to secure the washer.



STEP 11 Screw Insertion

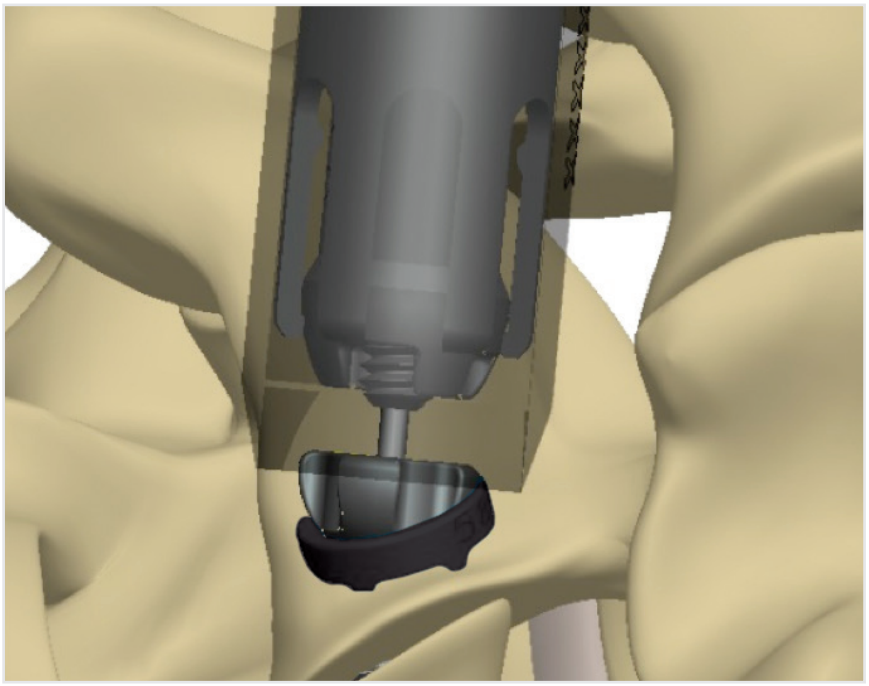
Place the screw over the guidewire and advance to the desired location. The guidewire should be removed once the screw has begun to purchase bone in the superior facet (or pedicle when using a Transfacet Technique).



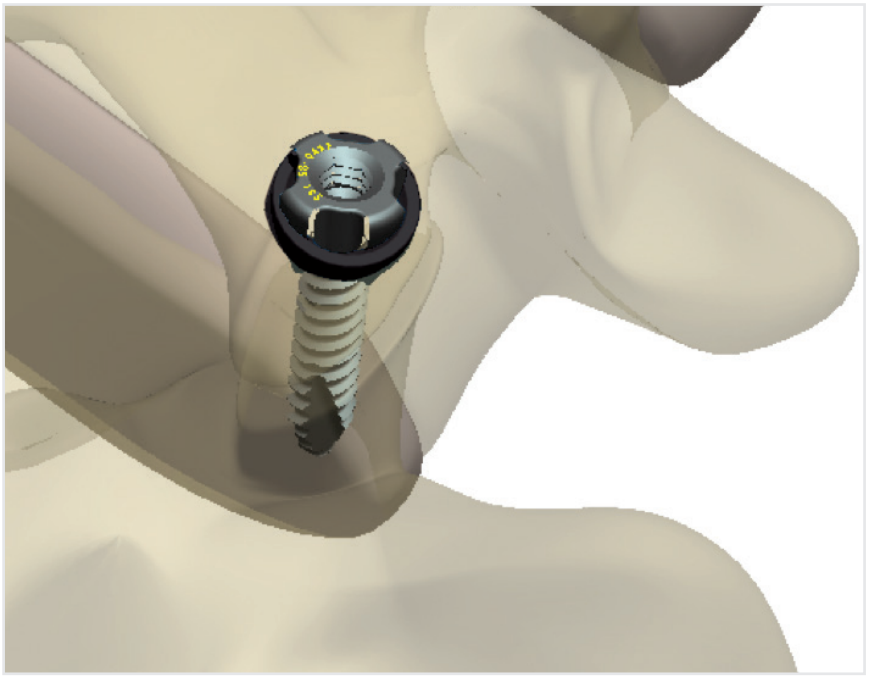


STEP 11 Screw Insertion continued

The washer will disengage from the washer retention sheath when the washer has bottomed out on the inferior facet.

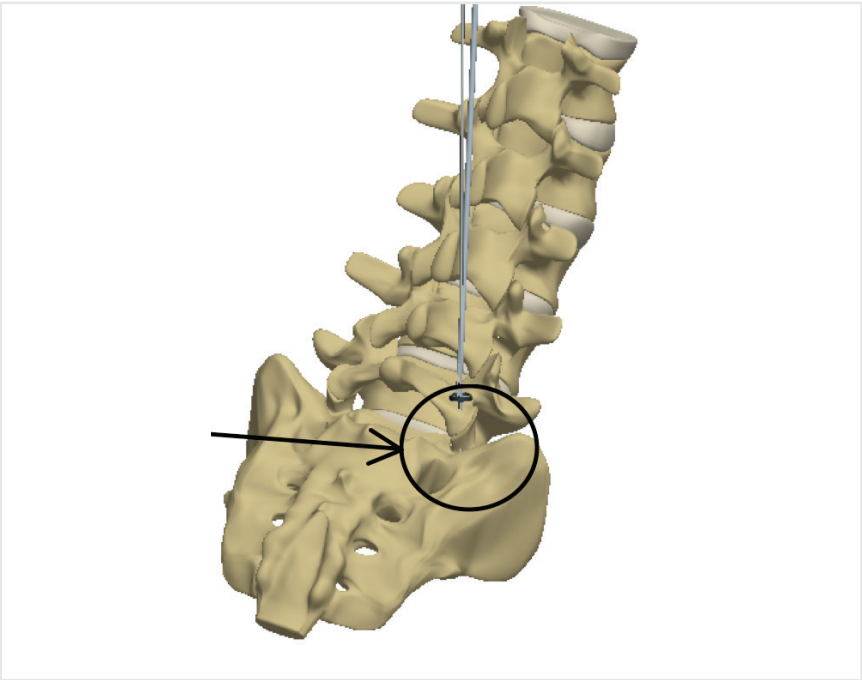


Once the screw is inserted to the desired depth, the driver knob can be turned counterclockwise to disengage the screw.



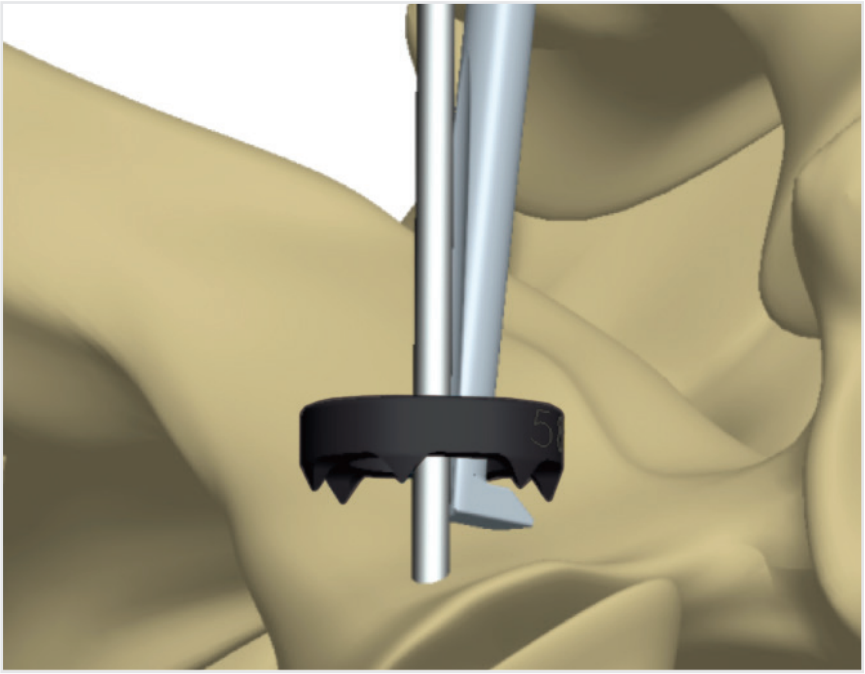
STEP 12 Removal

Remove tissue from the screw head. Mate the head of the screw with the tip of the universal driver and turn the driver knob clockwise to secure the screw. Rotate the driver handle counterclockwise to remove the screw.



Use forceps to grasp and remove the washer. Alternatively, use the washer retrieval tool as shown below:

Insert washer retrieval tool into washer opening. Use a guidewire to stabilize the washer while using the hook to engage the washer. Pull on the washer retrieval tool and remove the washer.



Indications for Use

The SeaSpine® Facet Fixation System is intended to stabilize the spine as an aid to fusion by two different fixation methods:

Transfacet fixation – The screws are inserted bilaterally through the superior side of the facet, across the facet joint and into the inferior pedicle.

Translaminar facet fixation – The screws are inserted bilaterally 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 inferior pedicle.

For both methods, this system is indicated for the posterior surgical treatment of any or all of the following at the L1 to S1 (inclusive) spinal levels:

- Trauma, including spinal fractures and/or dislocations;
- Spondylolisthesis;
- Spondylolysis;
- Pseudoarthrosis or failed previous fusions which are symptomatic or which may cause secondary instability or deformity;
- Degenerative disc disease which include:
  (a) degenerative disc disease (ddd) as defined by neck and/ or back pain of discogenic origin as confirmed by patient history with degeneration of the disc as confirmed by radiographic studies and/ or
  (b) degenerative disease of the facets with instability

Contraindications

Any medical or surgical condition which would preclude the potential benefit of spinal implant surgery is a contraindication. The following conditions may reduce the chance of a successful outcome and should be taken into consideration by the surgeon. This list is not exhaustive:

Absolute contraindications:
- Infection in or around the operative site
- Allergy or sensitivity to implant materials
- Any case not described in the indication

Relative contraindications:
- Local inflammation
- Morbid obesity
- Pregnancy
- Fever or leukocytosis
- Prior fusion at the level(s) to be treated
- Grossly distorted anatomy due to congenital abnormalities
- Rapid joint disease, bone absorption, osteopenia, and/or osteoporosis
- Elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count
- Any case not requiring bone graft and fusion or where fracture healing is not required
- Patients having inadequate tissue coverage over the operative site or where there is inadequate bone stock, bone quality, or anatomical definition
- Unsuitable or insufficient bone support
- Bone immaturity
- The patient's activity level, mental condition, occupation and/or a patient unwilling to cooperate with the postoperative instructions
- Any case where implant utilization would interfere with anatomical structures or expected physiological performance
- Use of incompatible materials from other systems

Warnings and Precautions

- Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without previous surgery. The safety and effectiveness of spinal systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are significant mechanical instability or deformity of the spine secondary to severe spondylolisthesis, degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor and failed previous fusion (pseudarthrosis). The safety and effectiveness of these devices for any other condition is unknown.
- The implantation of this system should 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.
- Based on the fatigue testing results, the surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact the performance of the system
- Ensure all implants, components or instruments are sterilized prior surgery. The use of non-sterile devices may lead to inflammation, infection or disease.
- Implants should never be reused under any circumstances. A used implant should be discarded. While the implant may appear undamaged, it may have small defects or internal stress patterns and if implanted, could fail to perform as intended and pose safety risks to the patient. The risks include, but are not limited to, mechanical failure, breakage, difficulty with implantation, incompatibility with mating components and infection.
- The safety and effectiveness of spinal systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are significant mechanical instability or deformity of the thoracic and lumbar spine secondary to degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor and failed previous fusion (pseudarthrosis). The safety and effectiveness of these devices for any other condition is unknown.
- To achieve the best results, unless otherwise specifically described in another SeaSpine document, do not use SeaSpine Facet Fixation System components in conjunction with components from any other system or manufacturer.

NOTE Mechanical and clinical testing indicates that the majority of the axial or compressive load is carried in the anterior column of the spine. When posterior instrumentation is utilized for spinal stability, adequate anterior column support is necessary, either by surgical intervention or existing anatomy. Failure to maintain a stable anterior column when using posterior instrumentation may lead to overstress of the posterior construct and implant failure.

A successful result will not be achieved in every instance of use of this device. Strict adherence by the patient to the instructions of the surgeon is necessary to insure the optimal result. Known conditions associated with poor or less than optimal results include malnutrition, cigarette smoking, obesity, and alcohol abuse.

SeaSpine Orthopedics Corporation does not practice medicine and does not recommend this or any other surgical technique for use on a specific patient. The surgeon who performs any procedure is responsible for determining and using the appropriate technique in each patient.

CAUTION Federal law restricts this device to sale by or on the order of a physician or practitioner.

Ordering Information

Reference	Description	Units/Set
58-0001	Serrated Facet Washer	10
4.5mm Fully Threaded Screws		
58-0426	Facet Screw, 4.5mm x 26mm	5
58-0430	Facet Screw, 4.5mm x 30mm	5
58-0434	Facet Screw, 4.5mm x 34mm	5
58-0438	Facet Screw, 4.5mm x 38mm	5
58-0442	Facet Screw, 4.5mm x 42mm	5
58-0446	Facet Screw, 4.5mm x 46mm	5
58-0450	Facet Screw, 4.5mm x 50mm	5
58-0455	Facet Screw, 4.5mm x 55mm	5
4.5mm Partially Threaded Screws		
58-1426	Facet Lag Screw, 4.5mm x 26mm	5
58-1430	Facet Lag Screw, 4.5mm x 30mm	5
58-1434	Facet Lag Screw, 4.5mm x 34mm	5
58-1438	Facet Lag Screw, 4.5mm x 38mm	5
58-1442	Facet Lag Screw, 4.5mm x 42mm	5
58-1446	Facet Lag Screw, 4.5mm x 46mm	5
58-1450	Facet Lag Screw, 4.5mm x 50mm	5
58-1455	Facet Lag Screw, 4.5mm x 55mm	5

Reference	Description	Units/Set
95-8001	Guidewire	5
95-8003	3.5mm Driver	1
95-8004	Cannulated Drill 4.5mm x 60mm	2
95-8006	Washer Retaining Sheath	2
95-8007	Facet Universal Driver Handle	2
95-8008	Facet Universal Driver Shaft	2
95-8009	Facet Access Needle	1
95-8010	Ratcheting Pineapple Handle	1
95-8011	T-Handle, Slim	1
95-8012	Access Needle Stylet	1
95-8014	Cannulated Tap 4.5mm x 60mm	1
95-8017	Small Dilator	1
95-8018	Medium Dilator	1
95-8019	Large Dilator	1
95-8020	Retrieval Tool	1
95-8021	Dilator Handle	1
95-8101	Facet Tray Base	1
95-8102	Facet Tray Insert	1
95-8103	Facet Tray Lid	1
95-8104	4.5mm Facet Screw Caddy	1
95-8105	4.5mm Facet Lag Screw Caddy	1
95-8106	Washer Caddy	1

For more information or to place an order, please contact:
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