SURGEON DESIGNERS

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CONTRIBUTING SURGEON

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OR SETUP

This surgical technique for the VIPER® F₂ Transfacet Pedicular System will focus on an MIS approach, though it can also be performed open or mini-open*. VIPER F₂ is indicated for use in the L1-S1 lumbar levels.

The patient should be positioned prone lying face down on a radiolucent table. A Jackson table is recommended to maintain the lordotic nature of the lumbar spine.

Fluoroscopy is strongly recommended throughout the procedure to aid with facet targeting, proper trajectory, guidewire placement and final confirmation of screw placement. If possible, biplanar fluoroscopy should be utilized throughout this procedure to help maximize efficiency and accuracy.

*Non-cannulated drill bits are available for open and mini-open techniques if desired.
FLUOROSCOPIC PLANNING

Pre-operative imaging is recommended, combined with an on-table assessment, to plan optimal trajectories and incision location.

Use A/P and lateral fluoroscopy to identify and target the appropriate level. Ensure that the C-Arm is positioned correctly for the targeted level by adjusting the position of the C-Arm until both endplates are parallel and the spinous process is equidistant from the center of each pedicle when viewed on A/P fluoroscopy.
**FLUOROSCOPIC PLANNING**

Once an optimal image is obtained, use a surgical marker to note the key anatomic landmarks noted below:

1. Identify the inferior border of the spinous process at the appropriate level above the desired surgical level.

   *For the L4-L5 and L5-S1 surgical levels, an incision at the L3 spinous process typically allows for proper trajectory. For the L3-L4 surgical level, a midline incision at the L2 spinous process is recommended. Adjust appropriately for lordosis and patient depth.*

   Using a guidewire, mark a midline, 20mm vertical line from the inferior aspect of the spinous process up to the middle of the spinous process to note on the skin where the incision will be. (See Figures 1a & 1b)

2. Using fluoroscopy, place a guidewire vertically on the skin, bisecting the pedicle at the operative level in the coronal plane. Mark the line vertically through the pedicle. (See Figures 2a & 2b)
**FLUOROSCOPIC PLANNING**

3. Using fluoroscopy, place a guidewire horizontally to bisect the inferior pedicle at the operative level in the axial plane. Mark a 20mm, horizontal line bilaterally that intersects with the line from step 2. (See Figures 3a & 3b)

![Figure 3a](image1)

![Figure 3b](image2)

4. To approximate trajectory, place a guidewire diagonally from the center of the midline incision mark to the intersection of the vertical and horizontal lines marked on the inferior pedicle (crosshairs) at the surgical level. Take an A/P fluoroscopic image to visualize the approximate trajectory from midline to the pedicle. (See Figures 4a & 4b) This trajectory should be replicated during Jamshidi needle and guidewire placement. A skin mark may also be made at this point.

![Figure 4a](image3)

![Figure 4b](image4)
**PRE-OPERATIVE IMPLANT SIZING**

- Make a vertical skin incision over the identified midline surgical marking. Incision size will depend on desired polyaxial ring size. For the small polyaxial ring make a 16mm incision, for the large use a 20mm incision. Be sure to also incise the fascia at this point to anticipate the sequential dilation steps.

- 13mm polyaxial ring: 16mm incision
- 16mm polyaxial ring: 20mm incision

**NOTE:** Note that the 5mm and 6mm screws can be used with either size polyaxial ring.
JAMSHIDI NEEDLE PLACEMENT

- Place a Jamshidi needle immediately lateral to the spinous process on the marked surgical side. Advance the Jamshidi needle through the fascia and move the needle following the angle of the planned trajectory.

- Use the pre-identified marking points to guide the Jamshidi needle from incision towards the pedicle.

- Make sure that the inferior endplate of the superior vertebral body is perpendicular on an A/P fluoroscopic view. Advance the Jamshidi needle through soft tissues and dock the tip at the junction of the lamina and the inferior facet, aiming for the pedicle. Confirm this placement and trajectory on A/P view. At this point the tip of the Jamshidi needle should be in line with the inferior endplate of the superior vertebral body.

- Gently push down on the inferior facet with the Jamshidi needle to both feel the facet capsule and to prevent the needle from skiving off the desired bony entry point.

NOTE: Optionally, draw a line on the needle at 5 and 10mm above the skin. This will help visually approximate depth and potentially reduce fluoroscopic imaging needed.
JAMSHIDI NEEDLE PLACEMENT

- Confirm the trajectory of the Jamshidi needle on a lateral fluoroscopic view. Adjust the trajectory if necessary to aim towards the pedicle. Using A/P fluoroscopy, advance the Jamshidi needle into and through the inferior facet (advancing the Jamshidi needle into the superior facet is optional).

- Advance the needle slowly and incrementally to avoid damaging the facet.

- Once in optimal position, remove the inner stylet of the Jamshidi needle.
**DRILLING AND PLACING GUIDEWIRE**

- Insert a sharp tip guidewire into the Jamshidi needle and take a lateral fluoroscopy shot to visualize the desired trajectory. Confirm trajectory on A/P fluoroscopy.

- Using a high-speed, cannulated power drill with needle driver attachment (not included in the VIPER F2 Set), advance the guidewire across both inferior and superior facets, into and through the pedicle. The **guidewire should be advanced under lateral fluoroscopy**. The guidewire should not be advanced past the posterior one-third of the vertebral body.

  **NOTE:** A change in resistance may occur as the guidewire is drilled into the cortex at the superior facet. Continue drilling until the guidewire is docked at the posterior one-third of the vertebral body.
INITIAL DILATOR ASSEMBLY AND INSERTION

The VIPER F₂ System features two different polyaxial ring options to optimize the construct for different patient pathologies: the silver 13mm polyaxial ring and the gold 16mm polyaxial ring. Each polyaxial ring size requires the use of different dilators and ports. Choose the correct dilators and port based on polyaxial ring selection.
(Refer to page 20)

**Dilation**

- Prior to dilation, reconfirm trajectory on A/P fluoroscopy.

- Insert the inner stylet into the outer cannula of the SPOTLIGHT® polyaxial ring dilator and use downward pressure to "snap" and lock the two pieces together.

- Advance the SPOTLIGHT polyaxial ring dilator assembly over the guidewire until the distal tip of the instrument contacts the facet.

**NOTE:** When dilating, avoid placing off-axis forces on the guidewire. If necessary, use lateral and A/P fluoroscopy to ensure no bending of the wire. These off-axis forces should be avoided throughout the subsequent steps and whenever placing instruments over the wire.
INITIAL DILATOR ASSEMBLY AND INSERTION

- Push down on the outer cannula until it separates from the inner stylet and advances to the facet. Remove the inner dilator stylet, leaving the outer cannula in place.

- Confirm placement with lateral and A/P fluoroscopy.

NOTE: If the cannula is not fully flush to the bone, the SPOTLIGHT polyaxial ring handle can be used to push the dilator down to the facet.
CANNULATED DRILL BIT PLACEMENT

The VIPER F₂ Implants have 5mm and 6mm diameter options. Select the proper cannulated drill bit according to the desired VIPER F₂ Screw diameter.

- Attach the drill bit to a cannulated power drill.* Place the cannulated high-speed drill assembly over the wire and through the first dilator. Avoid off-axis forces so as not to bend the guidewire.

- Under power, advance the drill bit through the facets and into the pedicle. Lateral fluoroscopy should be used while drilling. The drill bit should not be advanced past the posterior wall of the vertebral body.

NOTE: Significant resistance may be encountered when drilling through the superior facet; typically the resistance will decrease once the pedicle has been reached. The cannulated drill bit has a maximum drill depth of 40mm.

NOTE: The drill bits match the minor diameter of their corresponding screw:

- 3.66mm inner diameter = 5mm screw
- 4.06mm inner diameter = 6mm screw

NOTE: Cannulated power drill is not included in the VIPER F₂ set.
CANNULATED DRILL BIT PLACEMENT

- Remove the cannulated drill bit, leaving the guidewire in place. When removing the cannulated drill bit from the guidewire, reverse the high-speed drill and hold the guidewire in place while backing the drill out of the bone. Take a lateral fluoroscopic image to ensure no loss of guidewire placement.
**FACET TAPPING**

The VIPER F2 Screw is a self-tapping screw. Choose whether or not to tap based on the bone quality of the patient.

- While controlling the cannula, advance the appropriate size cannulated self-drilling tap over the guidewire, through the inferior and superior facets by turning the tap in a clockwise manner.

  **NOTE:**  The outer diameters of the VIPER F2 taps are undersized by .5mm:
  - 5mm tap = 4.5mm outer diameter
  - 6mm tap = 5.5mm outer diameter

- It is recommended that fluoroscopy be used while tapping to monitor the depth of the tap and ensure the guidewire is not unintentionally advanced. While tapping, care should also be taken to avoid unintentional guidewire advancement or rotation. Do not advance the tap beyond the tip of the guidewire as doing so may result in unintentional wire removal.

  **NOTE:** Typically, the hardest bone and resistance will be encountered about 5-10mm short of desired screw length. Use caution not to bend or kink the guidewire while advancing the tap.
SEQUENTIAL DILATION AND PORT PLACEMENT

- Place the SPOTLIGHT polyaxial ring second dilator over the first dilator. If necessary, use the SPOTLIGHT polyaxial ring handle to advance the dilator through soft tissue and down to the bone.

- Place the SPOTLIGHT polyaxial ring port over the first and second dilators, using the fixed handle to advance the port down to the bone.
SEQUENTIAL DILATION AND PORT PLACEMENT

- Take lateral and A/P fluoroscopy shots to confirm
  1) the dilators and port are correctly placed
  2) there has been no unintentional advancement of the guidewire
  3) the final screw placement will conform to the proper trajectory into the pedicle

- Remove the first and second dilators from inside the port. Leave the port in place.


**VIPER F₂ SCREW LOADING**

- Select the desired polyaxial ring and place it into the assembly block.

- Slide the selected screw size (blue = 5mm diameter; green = 6mm diameter) over the polyaxial ring so that the VIPER F₂ Screw sits loosely above the polyaxial ring in the loading block.

- Attach the straight handle onto the cannulated self-retaining screwdriver. Insert the distal end of the screwdriver shaft into the top of the screw head and push down to fasten the screw to the polyaxial ring. An audible click can be heard when the polyaxial ring loads successfully onto the screw head.

- The F₂ screw and polyaxial ring is now assembled. The polyaxial ring is designed to remain mobile on the head of the screw when assembled.

**NOTE:** Once assembled, if a selected polyaxial ring needs to be removed from the head of the screw, please see polyaxial ring removal instructions. DO NOT REUSE OR RESTERILIZE a polyaxial ring once it has been removed from the screw. The removed polyaxial ring should be discarded immediately.
**VIPER F2 SCREW INSERTION**

- Using the cannulated self-retaining screwdriver, guide the screw and polyaxial ring assembly over the guidewire and through the SPOTLIGHT polyaxial ring port, down to the bone. Thread the assembly through the inferior and superior facets into the pedicle by turning the handle clockwise. Be sure to avoid unintentional advancement and rotation of the guidewire. Placement and depth of the screw can be monitored and confirmed using lateral fluoroscopy. The distal tip of the screw should reach the junction of the pedicle and the vertebral body.

  **NOTE:** The VIPER F2 screw features dual lead threads and will advance more quickly than a single lead screw. Be sure not to over-insert the screw to maintain adequate bony purchase.

- The guidewire should be removed once the VIPER F2 Screw has gained bony purchase in the pedicle. This can be accomplished manually with a heavy needle driver or by reversing a cannulated power drill with needle driver attachment (not included in the VIPER F2 Set).

- The VIPER F2 polyaxial ring should seat against the top of the inferior facet, and the ring’s teeth should engage the inferior articular surface to provide additional fixation. Once the polyaxial ring is seated, compress the facet joint until fully lagged by advancing the screw no more than a half turn. Take care to not overtighten once the polyaxial ring is fully engaged. Confirm both screw and polyaxial ring placement with lateral fluoroscopy.

  **NOTE:** Tactile feedback should indicate when the polyaxial ring seats.

- Once the VIPER F2 Screw is inserted to the desired depth, remove the self-retaining screwdriver by lightly wiggling the driver back and forth to disengage it from the screw head.

- Remove the SPOTLIGHT polyaxial ring port.
CONFIRMATION OF IMPLANT PLACEMENT

- Confirm the appropriate implant positioning with fluoroscopy to make sure that the facet joint is fully lagged and that the screw has been sufficiently locked into the desired position. Use an oblique fluoroscopic angle to assess full lagging of the facet joint.

- Use the same midline skin incision to place a second VIPER F2 Screw on the opposite side of the spinous process.
## PRODUCT CATALOG

### IMPLANTS (STERILE)

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<th>Description</th>
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<td>1757-10-130S</td>
<td>13mm Polyaxial Ring</td>
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<td>1757-10-160S</td>
<td>16mm Polyaxial Ring</td>
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<td>1757-10-520S</td>
<td>5 X 20mm Cannulated Screw</td>
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### INSTRUMENTS

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<td>2757-10-072</td>
<td>SPOTLIGHT Small Polyaxial Ring First Dilator (Combo)</td>
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<td>2757-10-068</td>
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<td>2867-10-200</td>
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<td>VIPER 2 Ratcheting Modular T-Handle Cannulated</td>
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<td>2867-05-220</td>
<td>VIPER 2 Guidewire 1.45mm Blunt Threaded</td>
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<tr>
<td>2867-05-230</td>
<td>VIPER 2 Guidewire 1.45mm Sharp Threaded</td>
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INDICATIONS
The VIPER® F2 Facet Fixation System is intended to stabilize the spine as an aid to fusion by the transfacet fixation method only. Transfacet fixation: The screws are inserted bilaterally through the superior side of the facet, across the facet joint and into the inferior pedicle. This system is indicated for the posterior surgical treatment of any or all of the following at the L1 to S1 (inclusive) spinal levels:
1. Trauma, including spinal fractures and/or dislocations;
2. Spondylolisthesis;
3. Spondyloysis;
4. Pseudoarthrosis or failed previous fusions which are symptomatic or which may cause secondary instability or deformity;
5. Degenerative diseases which include: (a) degenerative disc disease (DDD) as defined by 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
(IFI) Disease conditions which have been shown to be safely and predictably managed without the use of internal fixation devices are relative contraindications to the use of these devices. Active systemic infection or infection localized to the site of the proposed implantation are contraindications to implantation. Severe osteoporosis is a relative contraindication because it may prevent adequate fixation of spinal anchors and thus preclude the use of this or any other spinal instrumentation system. Absence of posterior spinal elements including the pedicle, pars interarticularis, facet joints, spinous process and the majority of the lamina are contraindications to implantation. Any entity or condition that totally precludes the possibility of fusion, i.e. cancer, kidney dialysis, or osteopenia are relative contraindications. Other relative contraindications include obesity, certain degenerative diseases, or foreign body sensitivity. In addition, the patient's occupation or activity level or mental capacity may be relative contraindications to this surgery. Specifically, patients who because of their occupation or lifestyle, or because of conditions such as mental illness, alcoholism, or drug abuse, may place undue stresses on the implant during bony healing and may be at higher risk for implant failure.

WARNINGS
Correct placement of the device is essential to optimal performance. Use of the VIPER® F2 Facet Fixation System should only be undertaken after the surgeon has become thoroughly knowledgeable about the spinal anatomy and biomechanics, has had experience with posterior approach spinal surgeries, and has had hands-on training in the use of the device.
1. Correct selection of the implant is extremely important.
2. Implants can break when subjected to the increased loading associated with delayed union or nonunion.
3. Mixing metals can cause corrosion.
4. In selecting patients for internal fixation devices, the following factors can be extremely important to the eventual success of the procedure, including: the patient’s weight and occupation or activity; a condition of senility, mental illness, alcoholism, or drug abuse; certain degenerative diseases, foreign body sensitivity, smoking.

PRECAUTIONS
1. Surgical implants must never be reused.
2. Correct handling of the implant is extremely important.
3. If the device is not removed after the completion of its intended use; any of the following complications may occur: corrosion with localized tissue reaction or pain; migration of implant position resulting in injury; risk of additional injury from postoperative trauma; bending, loosening, and/or breakage, which could make removal impractical or difficult; pain, discomfort, or abnormal sensations due to the presence of the device; possible increased risk of infection; and bone loss due to stress shielding. The surgeon should carefully with the risks versus the benefits when deciding when to remove the implant.
4. Adequately instruct the patient. The patient must be made aware of the limitations of the implant, and instructed to limit and restrict physical activities.

Revision/Screw Removal:
ITEMS NEEDED:
- Self retaining screwdriver.
- The screwdriver tip should be in good condition.
REMOVAL TECHNIQUE:
- Thoroughly clean out the inside of the screw head.
- Insert the self retaining screwdriver ensuring the tip of the screwdriver is fully seated within the head of the screw. The shaft of the screwdriver should be aligned with the screw shank.
- Disengage the screw.
- Repeat for all screws.

Washer Removal:
ITEMS NEEDED:
- Screw Loading Block.
- Self retaining screwdriver.
- VIPER F2 Instrument Case.
REMOVAL TECHNIQUE:
- Place distal tip of screw into the corresponding diameter hole found inside the VIPER F2 Instrument Case. The holes will be located at the bottom of the inside of the tray, below the holder for the loading block.
- Align the side hole of the loading block with the top of the screw head.
- Push down on the loading block to disengage the washer from the screw head. Surgical gloves are required.
- DO NOT REUSE OR RESTERILIZE a washer once it has been removed from the screw. The removed washer should be discarded immediately.