VIPER
Sacral-Alar-Iliac Fixation
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### TABLE OF CONTENTS

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>INTRODUCTION</td>
<td>2</td>
</tr>
<tr>
<td>POTENTIAL SAI TECHNIQUE ADVANTAGES</td>
<td>3</td>
</tr>
<tr>
<td>SURGICAL TECHNIQUE</td>
<td></td>
</tr>
<tr>
<td>Patient Positioning and Exposure</td>
<td>5</td>
</tr>
<tr>
<td>Starting Point</td>
<td>6</td>
</tr>
<tr>
<td>SAI Trajectory</td>
<td>7</td>
</tr>
<tr>
<td>Probe Screw Path</td>
<td>9</td>
</tr>
<tr>
<td>Guide Wire Insertion and Tapping</td>
<td>10</td>
</tr>
<tr>
<td>Screw Placement</td>
<td>11</td>
</tr>
<tr>
<td>Rod Placement</td>
<td>13</td>
</tr>
<tr>
<td>REMOVAL INSTRUCTIONS</td>
<td>14</td>
</tr>
<tr>
<td>REFERENCES</td>
<td>15</td>
</tr>
<tr>
<td>INDICATIONS AND CONTRAINDICATIONS</td>
<td>16</td>
</tr>
</tbody>
</table>
INTRODUCTION

The VIPER® SAI Screw is the first implant designed specifically for the Sacral-Alar-Iliac technique for sacropelvic fixation. Fusions of the lumbosacral spine continue to be a challenging area in spine surgery. The complex local anatomy, unique biomechanical forces, and poor bone quality of the sacrum are just a few of the many reasons why fusions of the lumbosacral spine have been notoriously difficult to perform.

There exist various types of lumbosacral and sacropelvic fixation implants and techniques, all having their respective advantages and disadvantages. The Sacral-Alar-Iliac technique evolved out of these techniques. Its method of screw placement is a reproducible technique for achieving stable pelvic fixation that minimizes the risk of pseudarthrosis at the lumbosacral junction. The VIPER SAI Screw is optimized for Sacral-Alar-Iliac placement vis-à-vis a favored angle polyaxial head, smooth shank and robust drive feature. The in-line nature of this anchor allows not only stabilization but also correction of pelvic sagittal or coronal deformities.
POTENTIAL SAI TECHNIQUE ADVANTAGES

**Midline approach**
- Reduces the amount of soft tissue dissection to decrease the risk of wound complication, infection and blood loss
- May assist in preserving an intact fascial layer for closure

**Sacral starting point**
- Notching the posterior ilium is not necessary, which may reduce postoperative pain
- Low-profile construct with starting point 15 mm deep to the PSIS

**In-line construct**
- Eliminates the need for offset connectors, providing more ability to manipulate pelvis in correcting deformity
- Biomechanically stable construct*

**Can be performed via open or MIS techniques**

* As compared to traditional approach. Data on file.
VIPER SAI SCREW FEATURES AND ADVANTAGES

• VIPER SAI Screw head features:
  – Favored angle, which ensures alignment with other implants and proper rod seating
  – Compatible with 5.5 rod systems
  – Robust T27 drive feature to withstand additional torque

• Smooth shank portion of the VIPER SAI Screw may prevent screw threads from irritating the sacroiliac joint

• The VIPER SAI Screw offers a low profile with the ability to connect directly to the rod without the use of lateral connectors

• The cannulated shank of the VIPER SAI Screw provides compatibility with both VIPER and EXPEDIUM® Spine System instrumentation for open, MIS or hybrid techniques

The Screws are particularly suited for:
• Long fusions to the sacrum
• High-grade spondylolisthesis
• Complex lumbosacral deformities
• Flat-back syndrome requiring corrective osteotomy
• Distal lumbar kyphosis requiring correction
• Pelvic obliquity correction
• Additional bone fixation needed in situations of deformity correction
Depending on surgeon preference, this technique can be accomplished via a traditional open procedure or by utilizing a minimally invasive surgical approach.

1

Patient Positioning and Exposure

The patient should be in a prone position on a radio-lucent table, permitting AP and lateral imaging using uniplanar or biplanar x-ray and/or CT. Padding can be used to support the iliac crest. Ensure that the pelvis is as neutral as possible with minimal rotation, while optimizing the patient’s position in the sagittal plane. The patient’s position should allow access for palpating the greater trochanter.

Extend the midline skin incision to expose the dorsal foramina of the sacrum, specifically the S1 and S2 foramina. Additional lateral dissection to the iliac crest is not needed for this technique.

Notes:
- If performing the technique utilizing a minimally invasive approach, begin with a midline 2–3 cm skin incision.
- Beware of occult midline sacro-laminar defects.
2 Starting Point

Stand on the contralateral side of the patient to identify the starting point. The anatomical landmarks are the S1 and S2 dorsal foramina. Find the midpoint between the S1 and S2 dorsal foramina and the lateral border of the foramen. Your starting point is where these two lines intersect (Fig. 2). Note that the entry point may vary with the local anatomy of the patient. This starting point should be in line with the S1 pedicle screw.

Tip: If the pelvis is asymmetrical in the transverse plane, the starting point may need to vary in the mediolateral plane. This is common in patients with genetic or neuromuscular disorders.
3

SAI Trajectory

The following are key points for the proper trajectory of the SAI technique:

• Major Alar projection (forms upper part of iliopectineal line)
• 20–30° caudal – guided by posterior surface of the sacrum
• 40–50° vertical to the horizontal plane
• Aim for anterior inferior iliac spine, which can be found by palpating the top of the greater trochanter (Fig. 3)
• The pathway (trajectory) passes immediately above the sciatic notch
Fluoroscopy can be helpful identifying the appropriate trajectory. The C-Arm should be oriented in the intended trajectory of the implant. Position the C-Arm above the starting point. Next, angle the C-Arm 20–30° caudal (Fig. 4) and 40–50° to the vertical plane (Fig. 5), aiming for the anterior inferior iliac spine (AIIS). With this trajectory, the iliac teardrop should be visible on your AP fluoroscopic image (Fig. 7 and 8). Also note the anterior view of the pelvis and iliac teardrop in Figure 6.
4

Probe Screw Path

- Use an awl and probe or pelvic 2.5 mm drill bit. The chosen trajectory should be lateral and approximately 40–50° relative to the horizontal line connecting the posterior superior iliac spine (PSIS) and 20–30° caudal from straight lateral (Fig. 9 and 10). This trajectory will vary with pelvic obliquity and lumbar lordosis.
- Fluoroscopy is very helpful, and an AP view showing the pelvis and the sciatic notch is most beneficial. The path of the probe or drill should be within 20 mm of the greater sciatic notch and aiming toward the anterior inferior iliac spine (AIIS).
- If using a drill, feel for the bony end point following each advancement of the drill. Once the drill crosses the sacroiliac joint, a 3.2 drill bit is used to guard against breaking the smaller bit in the ilium. An awl is another option, which helps to establish the trajectory in the dysplastic pelvis.
- A teardrop fluoroscopic image at this stage will help ensure the anterior posterior trajectory within the thickest part of the ilium, without cortical breach.
- Use a ball tip probe to palpate the course of the screw and confirm the bony end point. Note the appropriate screw length as denoted on the ball tip probe or on the tap.

Tips:
- Bony resistance should be felt at all times. If not, assess trajectory via teardrop view or redirect.
- The drill or probe should always be above the sciatic notch.
- Beware of premature lateral exit of the ilium. If a breach should occur, a “fresh” trajectory can often be obtained by varying the starting point cranio-caudally.
5
Guide Wire Insertion and Tapping

A guide wire can be utilized by placing it through the probed or drilled hole to preserve the trajectory established (Fig. 11). Confirm guide wire position with fluoroscopy.

Next, tap the hole using the same size pedicle tap as the intended screw diameter. While advancing the tap, ensure that the guide wire does not also advance.

Notes:
• Tapping is the key to successfully implanting screws into the ilium in either a minimally invasive or open fashion. Be sure to tap line-to-line as the VIPER SAI taps are already undersized.
• As the pelvic wing tends to be a highly cortical structure, it is important to tap the full distance for the screw. Tapping the full distance will help to avoid imparting high torsional forces onto the implant.
6 Screw Placement

Select the appropriate VIPER SAI Screw diameter and length. The threaded portion of the VIPER SAI Screw changes with screw length, as noted in the table below.

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<th>VIPER SAI Screw Length (mm)</th>
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</tr>
</thead>
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</tr>
<tr>
<td>110</td>
<td>73</td>
</tr>
</tbody>
</table>

Assemble the handle to the SAI Quick Connect Polyaxial Driver and thread it into the head of the VIPER SAI Screw (Fig. 12 and 13).

Insert the screw aiming for the AIIS with the trajectory within 20 mm above the greater sciatic notch. Before screw is fully seated, remove the guide wire to prevent bending or breakage.
Using the teardrop view, confirm screw placement with fluoroscopy. Note figures 14–16, which show proper VIPER SAI Screw placement from the axial, posterior and lateral viewpoints.
Rod Placement

Choose a rod length that will span the full length of the construct. Sagittally contour the rod before implanting. No additional contouring of the rod should be necessary to allow for placement in the VIPER SAI Screw heads.

Tip: If compression or distraction is required, additional rod length may be needed. The additional rod may be buried in the sacrum via the Jackson technique. It is also helpful to allow for at least 1 cm of rod distal to the screw at the end of the construct to prevent loosening.

Check that the VIPER SAI screws are in line with the S1 screws and proximal screws in the construct. Utilizing the favored angle feature, adjust the screw head so the etched lines denoting the location of the favored angle are on the lateral side of the screw head. This orientation of the screw head should facilitate placement of the rods. Rods can be inserted from caudal to cranial (most common) or from cranial to caudal in case of severe proximal deformity.

Using the VIPER SAI Stabilizer, insert the set screw to capture the rod. Tighten the set screw to affix the rod to the distal VIPER SAI Screw and continue in a cephalad direction, capturing the rod to the rest of the screws in the construct.

Once the rod has been captured, the set screws can be final-tightened.

Tip: Alignment with the upper screws may be improved by recessing the VIPER SAI Screw.

See VIPER® 2 System and EXPEDIUM® System Surgical Technique Guides for additional information.
If a decision is made to remove the implants after solid fusion occurs, the following steps should be taken after the implant is exposed.

1. Clean debris/tissue from the set screws.
2. Loosen set screws with the X25 Screw Driver.
   If counter-torque is needed, use the Rod Stabilizer and remove.
3. Once the set screws are removed, the rod can be removed.
4. Remove the polyaxial screws by using the SAI Quick Connect T27 Polyaxial Driver.
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INDICATIONS AND CONTRAINDICATIONS

**Indications**
The VIPER Spine System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine.

The VIPER Spine System is intended for noncervical pedicle fixation and nonpedicle fixation for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor, pseudarthrosis; and failed previous fusion in skeletally mature patients.

When used in a posterior percutaneous approach with MIS instrumentation, the VIPER System is intended for noncervical pedicle fixation and nonpedicle fixation for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor, pseudarthrosis; and failed previous fusion in skeletally mature patients.

**Contraindications**
Disease conditions that 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.

Any entity or condition that totally precludes the possibility of fusion, i.e., cancer, kidney dialysis, or osteopenia is a relative contraindication. Other relative contraindications include obesity, certain degenerative diseases, and 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. See also the WARNINGS, PRECAUTIONS AND POSSIBLE ADVERSE EFFECTS CONCERNING TEMPORARY METALLIC INTERNAL FIXATION DEVICES section of this insert.
WARNINGS, PRECAUTIONS, AND POSSIBLE ADVERSE EFFECTS CONCERNING TEMPORARY METALLIC INTERNAL FIXATION DEVICES

Following are specific warnings, precautions, and possible adverse effects that should be understood by the surgeon and explained to the patient. These warnings do not include all adverse effects that can occur with surgery in general, but are important considerations particular to metallic internal fixation devices. General surgical risks should be explained to the patient prior to surgery.

Warnings

1. CORRECT SELECTION OF THE IMPLANT IS EXTREMELY IMPORTANT. The potential for satisfactory fixation is increased by the selection of the proper size, shape, and design of the implant. While proper selection can help minimize risks, the size and shape of human bones present limitations on the size, shape and strength of implants. Metallic internal fixation devices cannot withstand activity levels equal to those placed on normal healthy bone. No implant can be expected to withstand indefinitely the unsupported stress of full weight bearing.

2. IMPLANTS CAN BREAK WHEN SUBJECTED TO THE INCREASED LOADING ASSOCIATED WITH DELAYED UNION OR NONUNION. Internal fixation appliances are load-sharing devices which are used to obtain alignment until normal healing occurs. If healing is delayed, or does not occur, the implant may eventually break due to metal fatigue. The degree or success of union, loads produced by weight bearing, and activity levels will, among other conditions, dictate the longevity of the implant. Notches, scratches or bending of the implant during the course of surgery may also contribute to early failure. Patients should be fully informed of the risks of implant failure.

3. MIXING METALS CAN CAUSE CORROSION. There are many forms of corrosion damage and several of these occur on metals surgically implanted in humans. General or uniform corrosion is present on all implanted metals and alloys. The rate of corrosive attack on metal implant devices is usually very low due to the presence of passive surface films. Dissimilar metals in contact, such as titanium and stainless steel, accelerate the corrosion process of stainless steel and more rapid attack occurs. The presence of corrosion often accelerates fatigue fracture of implants. The amount of metal compounds released into the body system will also increase. Internal fixation devices, such as rods, hooks, etc., which come into contact with other metal objects, must be made from like or compatible metals.

4. PATIENT SELECTION. In selecting patients for internal fixation devices, the following factors can be of extreme importance to the eventual success of the procedure:

A. The patient’s weight. An overweight or obese patient can produce loads on the device that can lead to failure of the appliance and the operation.

B. The patient’s occupation or activity. If the patient is involved in an occupation or activity that includes heavy lifting, muscle strain, twisting, repetitive bending, stooping, running, substantial walking, or manual labor, he/she should not return to these activities until the bone is fully healed. Even with full healing, the patient may not be able to return to these activities successfully.

C. A condition of senility, mental illness, alcoholism, or drug abuse. These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions in the use of the appliance, leading to implant failure or other complications.

D. Certain degenerative diseases. In some cases, the progression of degenerative disease may be so advanced at the time of implantation that it may substantially decrease the expected useful life of the appliance. For such cases, orthopaedic devices can only be considered a delaying technique or temporary remedy.

E. Foreign body sensitivity. The surgeon is advised that no preoperative test can completely exclude the possibility of sensitivity or allergic reaction. Patients can develop sensitivity or allergy after implants have been in the body for a period of time.

F. Smoking. Patients who smoke have been observed to experience higher rates of pseudarthrosis following surgical procedures where bone graft is used. Additionally, smoking has been shown to cause diffuse degeneration of intervertebral discs. Progressive degeneration of adjacent segments caused by smoking can lead to late clinical failure (recurring pain) even after successful fusion and initial clinical improvement.
**Precautions**

1. **SURGICAL IMPLANTS MUST NEVER BE REUSED.** An explanted metal implant should never be reimplanted. Even though the device appears undamaged, it may have small defects and internal stress patterns which may lead to early breakage. Reuse can compromise device performance and patient safety. Reuse of single-use devices can also cause cross-contamination leading to patient infection.

2. **CORRECT HANDLING OF THE IMPLANT IS EXTREMELY IMPORTANT.** Contouring of metal implants should only be done with proper equipment. The operating surgeon should avoid any notching, scratching or reverse bending of the devices when contouring. Alterations will produce defects in surface finish and internal stresses which may become the focal point for eventual breakage of the implant. Bending of screws will significantly decrease the fatigue life and may cause failure.

3. **CONSIDERATIONS FOR REMOVAL OF THE IMPLANT AFTER HEALING.** If the device is not removed after the completion of its intended use, any of the following complications may occur:
   (1) Corrosion, with localized tissue reaction or pain; (2) Migration of implant position resulting in injury; (3) Risk of additional injury from postoperative trauma; (4) Bending, loosening, and/or breakage, which could make removal impractical or difficult; (5) Pain, discomfort, or abnormal sensations due to the presence of the device; (6) Possible increased risk of infection; and (7) Bone loss due to stress shielding. The surgeon should carefully weigh the risks versus benefits when deciding whether to remove the implant. Implant removal should be followed by adequate postoperative management to avoid refracture. If the patient is older and has a low activity level, the surgeon may choose not to remove the implant, thus eliminating the risks involved with a second surgery.

4. **ADEQUATELY INSTRUCT THE PATIENT.** Postoperative care and the patient's ability and willingness to follow instructions are among the most important aspects of successful bone healing. The patient must be made aware of the limitations of the implant, and instructed to limit and restrict physical activities, especially lifting and twisting motions, and any type of sports participation. The patient should understand that a metallic implant is not as strong as normal healthy bone and could loosen, bend and/or break if excessive demands are placed on it, especially in the absence of complete bone healing. Implants displaced or damaged by improper activities may migrate and damage the nerves or blood vessels. An active, debilitated, or demented patient who cannot properly use weight-supporting devices may be particularly at risk during postoperative rehabilitation.

5. **CORRECT PLACEMENT OF ANTERIOR SPINAL IMPLANT.** Due to the proximity of vascular and neurologic structures to the implantation site, there are risks of serious or fatal hemorrhage and risks of neurologic damage with the use of this product. Serious or fatal hemorrhage may occur if the great vessels are eroded or punctured during implantation, or are subsequently damaged due to breakage of implants, migration of implants, or if pulsatile erosion of the vessels occurs because of close apposition of the implants.