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THE SACROILIAC (SI) JOINT
is increasingly understood to be a source of chronic low back, thigh, and buttocck pain in up to 30% of patients presenting with this complaint.\(^1\) Despite the relatively high prevalence of SI joint dysfunction, it remains underdiagnosed and undertreated.

The SI joints are load-bearing joints that connect the ilium to the sacrum on either side of the lower spine with a strong, ligamentous complex. The SI joint range of motion is limited to 2-4 degrees\(^2\) with the greatest flexibility occurring during pregnancy and childbirth. The SI joints support the weight of the upper body and function as shock absorbers to transfer forces to the lower limbs.

The most common cause of painful SI joint dysfunction results from trauma. Other contributing factors are degenerative changes resulting from childbearing, osteoarthritis, infection, inflammatory arthritis, and tumor.\(^1\) Adjacent joint disease following lumbar or lumbosacral fusion may also contribute to SI joint pain.\(^3\) SI joint pain is more commonly experienced unilaterally but may also occur bilaterally.

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The Inferior-Posterior surgical approach provides direct access to the articular portion of the SI joint through an anatomic window superior to the posterior inferior iliac spine (PIIS) and inferior to the posterior superior iliac spine (PSIS). The Catamaran Fixation Device is delivered via the Inferior-Posterior approach and follows the trajectory of the SI joint space away from critical neural and vascular structures. The bony anatomy in this region is optimal for SI joint fixation because the subchondral bone is thick and strong.

The Catamaran SI Joint Fusion System was developed as a less invasive alternative to traditional open SI joint surgery. The goal of the Catamaran procedure is to rigidly transfix and immobilize the SI joint in patients with SI joint disruptions and degenerative sacroiliitis when nonoperative treatments have failed to improve the symptoms.

The Catamaran Fixation Device is manufactured from medical grade ASTM F136-compliant titanium alloy (Ti6Al-4V ELI) and consists of two hollow, fenestrated pontoons connected by a transfixing osteotome bridge.

The implant pontoons are 10mm in diameter and are available in two lengths (30mm and 40mm) to accommodate patient anatomy.

During the surgical procedure, autologous bone graft is packed into the implant pontoons to help promote arthrodesis.

The Catamaran Fixation Device is intended for single use.

As with all surgical procedures and permanent implants, there are risks and considerations associated with surgery and use of the Catamaran Fixation Device. Please review the Instructions For Use provided with the Catamaran Fixation Device and Catamaran Fusion System for warnings, precautions, and risks.

**INDICATIONS FOR USE**

The Catamaran SI Joint Fusion System is intended for sacroiliac joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroiliitis.

**CONTRAINDICATIONS**

The Catamaran SI Joint Fusion System is contraindicated in patients with the following conditions:

- Skeletally immature spine
- Deformity
- Severe osteoporosis
- Morbid obesity
- Tumor resection
- Active infection at the treatment site
PATIENT SELECTION
The patient should be counseled on the risks and potential benefits of SI joint fusion surgery with the Catamaran SI Joint Fusion System prior to making an informed decision to elect SI joint fusion surgery.

Before undergoing SI joint fusion surgery, a thorough preoperative assessment of the patient should be conducted to determine whether this procedure is indicated and to confirm the patient is a good candidate for surgery. SI joint fusion surgery should not be considered until all reasonable nonoperative treatments have been attempted without resolution.

PREOPERATIVE PATIENT EVALUATION

Preoperative evaluation should include:
1. Diagnostic evaluation to confirm the SI joint is the source of pain.
2. Imaging including radiography of the pelvis; AP MRI of the lumbar spine and pelvis (if appropriate); CT of pelvis and/or SI joint SPECT-CT should be performed when appropriate.
3. General physical examination to confirm the patient can withstand the surgical procedure and follow postoperative instructions.
4. Laboratory testing as is standard prior to skeletal surgery.

PREOPERATIVE PLANNING
Carefully review all preoperative radiographs to understand the individual patient’s SI joint anatomy, and confirm the patient is a good candidate for Inferior-Posterior sacroiliac surgery. A CT scan with coronal sagittal reconstruction and/or MRI of the pelvis is recommended for preoperative planning and to evaluate for any SI joint abnormalities.

The patient should be thoroughly evaluated, and if any of the following are identified, SI joint surgery should not be performed:

1. Inability or refusal to comply with instructions related to surgery and/or postoperative care.
2. Insufficient bone quality, impaired bone metabolism, or evidence of impaired healing.
3. Insufficient bone stock, defect, or deformity in the sacral or iliac bone that would impede or impair surgery or healing.
4. Tumor, inflammation, or infection in the lower spine, hip, or pelvic region.
5. Active infection.
6. Prior repeated failed attempts to fixate the SI joint.
7. Pregnancy. Females of childbearing potential should be further cautioned that vaginal delivery may not be advisable following SI joint surgery. If the patient does become pregnant, it is further advised that the patient consult with her attending OB/GYN prior to delivery to determine whether Caesarean section is recommended.
8. See the contraindications for a full list of conditions for which Catamaran should not be used.

CAUTION: Do not use this system unless you have been properly trained in its use.
Operating Room Preparation

PATIENT POSITIONING
Inferior-Posterior SI joint surgery is performed with the patient in the prone position on a standard spinal surgery procedure table (e.g., Jackson table). Ensure the patient is lying flat on the table. Correct positioning of the patient is critical for access and intraoperative imaging.

FLUOROSCOPE SETUP
Ensure the fluoroscope is positioned on the side of the OR table opposite the patient’s operative side. Check the fluoroscope to ensure it can be rotated 30+ degrees from vertical around the operating table.

Figure 01.
Patient prepared for surgery in the prone position.

FLUOROSCOPICALLY CONFIRM PATIENT POSITIONING

FLUOROSCOPIC IMAGING: TRUE AP AND TRUE LATERAL VIEWS
Take true AP and lateral fluoro views to confirm the patient is aligned on the surgical table in a true prone position with no malpositioning (Figure 01). Use the true lateral view to identify the alar boundary.
Imaging Overview

GENERAL IMAGING GUIDANCE AND REMINDERS

The following instructions establish the anatomic landmarks, skin entry point, and Inferior-Posterior delivery of the Catamaran Fixation Device utilizing two-dimensional fluoroscopy.

IT IS CRITICAL to understand the three-dimensional anatomy of the SI joint and to apply this understanding to two-dimensional imaging.

CRITICAL BONY LANDMARKS TO IDENTIFY ON FLUOROSCOPY:

1. Ventral border of the sacrum
2. Sacral promontory
3. Alar boundary
4. Parallel boundaries of the sacrum and ilium that form the SI joint
5. Sacral Foramina

MODIFIED OUTLET VIEW
To draw sagittal skin line

MODIFIED INLET VIEW
To draw axial line

LATERAL VIEW
To determine depth
Establish the Sagittal Skin Line

**FLUOROSCOPIC IMAGING:**

**MODIFIED OUTLET VIEW**

The SI joint can vary in shape and does not align with the axis of the spine. In the true outlet view, two lines representing the front and back of the SI joint are typically seen (Figure 02). Move to a traditional Outlet View (30° tilt from a true AP). Modify the Outlet View with an approximate 10° rotation of the C-arm to align the joint (Figure 03). The exact degree of C-arm modification required to achieve this view is specific to the individual patient’s anatomy, and a brief live fluoro may assist in the process.

**NOTE:**

Record the C-arm position for future reference.

Once the aligned joint is in view, place the Ball Tip Probe on the skin and fluoroscopically align it with the joint (Figure 04). This establishes the sagittal line to mark the skin for the trajectory. Use a skin marker to trace the Ball Tip Probe to indicate the joint trajectory (Figure 05).

**ESTABLISH THE SAGITTAL LINE**

**FLUOROSCOPICALLY ALIGN THE JOINT**

Figure 02.
True outlet view typically shows the SI joint as two lines (front and back of the joint).

Figure 03.
Modified outlet view shows aligned SI joint.

Figure 04.
Fluoroscopically align the Ball Tip Probe to establish sagittal line.

Figure 05.
Use a skin marker to draw the sagittal line on the skin.
Establish the Axial Skin Line

**FLUOROSCOPIC IMAGING: MODIFIED INLET VIEW**

Move to a traditional Inlet View (30° tilt from a true AP). Starting from the true inlet view, slowly rotate the C-arm approximately 10° into the Modified Inlet View. The posterior and anterior aspects of the pelvic floor will be aligned establishing the pelvic rim. The C-arm view is now parallel to the ventral surface of the sacrum. Identify the ventral margin of the SI joint extending up the PIIS and slightly lateral. Under fluoroscopy, align the Ball Tip Probe at the midpoint between the dorsal recess and the pelvic floor (Figure 06). The Ball Tip Probe should be positioned approximately at a 30° angle relative to the axis of the spine. **This establishes the axial line to mark the skin for incision and angle.** Use a surgical skin marker to trace the Ball Tip Probe along the axial line, intersecting the sagittal line (Figure 07). Where the line intersects is the joint entry point (Figure 08).

**NOTE:**

*Record the C-arm position for future reference.*

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**Figure 06.**
Fluoroscopically align the Ball Tip Probe to establish the axial line.

**Figure 07.**
Use a skin marker to draw the axial line on the skin.

**Figure 08.**
The intersection of the sagittal and axial lines represents the joint entry point.
STEP 3  CATAMARAN SURGICAL TECHNIQUE

Dock the Graduated Guide Wire and Establish Trajectory

Initial Stab Incision

Make a stab incision (approximately 1cm) to allow the Graduated Guide Wire to reach the desired entry point in the SI joint (Figure 09).

Figure 09.
Stab incision to reach desired entry point.

FLUOROSCOPIC IMAGING:
MODIFIED OUTLET VIEW
(Previously established C-arm position)

The Modified Outlet View will provide a direct and aligned view of the SI joint. Advance the Graduated Guide Wire into the joint along its trajectory, approximately 1cm so that it is firmly docked (Figure 10).

Figure 10.
Anchor the Graduated Guide Wire in the SI joint space.

FLUOROSCOPIC IMAGING:
MODIFIED INLET VIEW
(Previously established C-arm position)

The alignment of the joint in the Modified Inlet View confirms the proper entry point of the Graduated Guide Wire. (Figure 11).

Figure 11.
The posterior and anterior aspects of the pelvic floor will be aligned.
STEP 3  CATAMARAN SURGICAL TECHNIQUE

Dock the Graduated Guide Wire and Establish Trajectory (Cont’d)

Grasp the end of the Graduated Guide Wire with a long Kelly clamp (Figure 12). Make slight adjustments to the Graduated Guide Wire until it appears as a tight dot under fluoroscopy at the joint entry. This confirms the trajectory of the Graduated Guide Wire relative to the long axis of the SI joint (Figure 13).

Use a small mallet to gently advance the Graduated Guide Wire into the SI joint an additional 1-2cm. This action requires very little force. Advance the Graduated Guide Wire only enough to dock it more firmly in place.

CAUTION:
Do not advance the Graduated Guide Wire so far that the trajectory cannot be easily adjusted.

Figure 12.
Adjust the Graduated Guide Wire trajectory using a Kelly clamp.

Figure 13.
The entry point is confirmed when the Graduated Guide Wire appears as a dot under fluoro.
In the Lateral View, confirm the depth and accuracy of the Graduated Guide Wire's superior and inferior trajectory.

In this view, identify the alar boundary. The Graduated Guide Wire must not advance beyond this point. Any advancement beyond the alar line indicates a potential breach into the pelvis. The final depth for the Graduated Guide Wire is 5mm to 10mm short of the most inferior alar boundary. If necessary, confirm the placement of the Graduated Guide Wire using the modified outlet and lateral views (Figure 14).

**CAUTION:**
Do not advance beyond the alar boundary.

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**STEP 5**

**Make the Skin Incision**

Once the entry point and trajectory is established, extend the skin incision 2cm bilaterally of the skin entry point at a 30° angle from the sagittal midline (Figure 15). This will match the angle of the Access Sleeve.

Once the incision is made, dissect down to the joint following the angle of the Graduated Guide Wire.
Assemble the Access Sleeve and Drill Guide

Thread the Access Sleeve Handle into the Access Sleeve. If working on the right side of the patient, thread the Access Sleeve Handle into the hole marked with an R. If working on the left side of the patient, thread the Access Sleeve Handle into the hole marked with an L (Figure 16).


The Access Sleeve Assembly

![Image of Access Sleeve Assembly](image)

**Figure 16.** Insert Drill Guide into Access Sleeve.
Place the Drill Guide over the Graduated Guide Wire, ensuring the Graduated Guide Wire is in the center hole. Position the Access Sleeve Assembly with the handle pointing away from the midline and perpendicular to the axis of the spine (Figure 17).

Stabilize the Access Sleeve orientation by driving a minimum of three K-wires through the most medial insertion points of the Access Sleeve (Figure 18).

**CAUTION:**

Place K-wires under fluoroscopy and verify adequate bone purchase.
Utilize Guide Wire Graduations to Determine Drill Depth and Catamaran Fixation Device Length

The Graduated Guide Wire is marked in 10mm increments (Figure 19). As seen on lateral fluoroscopy, count the visible marks from the distal tip of the Graduated Guide Wire upward to confirm the appropriate drill depth.

To determine the optimal Catamaran Fixation Device length, place the Temporary Pin into the ilium side of the Drill Guide until it rests on the ilium. Take a lateral fluoro image. In this view, the Temporary Pin tip will cover a portion of the Graduated Guide Wire. Count the remaining visible marks on the Graduated Guide Wire to determine the length of the Catamaran Fixation Device (Figure 20).
STEP 9  CATAMARAN SURGICAL TECHNIQUE

Drill the Pontoon Channels

Based on the previous measurements using the Graduated Guide Wire, choose the desired drill bit length (50mm, 60mm or 70mm) and attach it to the available power system.

Place Drill Bit into Drill Guide drilling sacral side first. Use the Modified Outlet view to ensure Drill Bit will not compromise the sacral neuroforamen.

Switch to the lateral view to continue drilling. Do not proceed beyond the alar boundary (Figure 21).

CAUTION:

Drill under fluoroscopy at all times.

Remove the Drill Bit without reversing its rotation. This will help harvest the most autograft on the Drill Bit. Carefully collect all bone material for packing into the implant. (Figure 22).

Figure 21.
Final drilling depth.

Figure 22.
Harvest autograft from Drill Bit.
STEP 9  CATAMARAN SURGICAL TECHNIQUE

Drill the Pontoon Channels (Cont’d)

Use the Ball Tip Probe to ensure the anterior cortex has not been breached (Figure 23).

Repeat the drilling process for the second pontoon channel into the ilium and collect the autograft for packing into the implant. Use the Ball Tip Probe to ensure the anterior cortex has not been breached.

Place the Temporary Pin into the sacral pontoon channel as additional support to maintain the Drill Guide position while drilling into the ilium (Figure 24).

Using the assembled Funnel and Bone Pusher, pack autograft from the Drill Bit into the implant (Figure 27). Take care to leave the proximal portion of the pontoons free of autograft to ensure a firm interface with the Inserter.

Cannulate the Inserter Screw through the Inserter. Attach the Catamaran Fixation Device onto the distal end of the Inserter Handle. Align the boss into the one pontoon and thread the Insertion Screw into the other pontoon.

Finger tighten the Inserter Screw into the Catamaran Fixation Device until the device fits snugly. **DO NOT OVERTIGHTEN** to ensure a straight angle implant-to-Inserter interface. The implant is now ready for delivery in the drilled pontoon channels and SI joint.
STEP 11  CATAMARAN SURGICAL TECHNIQUE

Deliver the Catamaran Fixation Device

Place the Inserter with the loaded Catamaran Fixation Device into the Access Sleeve. With the Access Sleeve acting as a guide, position the Catamaran Fixation Device pontoons into the drilled pontoon channels. In the Modified Outlet View, use a mallet to seat the Inserter with attached Catamaran Fixation Device and ensure optimal medial/lateral trajectory for the transfixing osteotome bridge to capture the SI joint (Figure 28 and 29).

Unthread the Inserter Screw (if necessary, use the Hex Key) and remove the Inserter assembly from the Catamaran Fixation Device. Remove the Access Sleeve and K-wires (Figure 31).

Once the optimal positioning is confirmed with the Modified Outlet View, move the C-arm to a Lateral View and impact the implant to the desired depth (Figure 28).

WARNING: Inserting the implant past the correct depth may result in anterior bone fracture and/or displacement.

Use fluoroscopy to confirm device position (Figure 29 and Figure 30).

Figure 28.
Tap the Catamaran Fixation Device to the desired depth.

Figure 29.
Modified outlet view to confirm medial to lateral trajectory.

Figure 30.
Lateral view to confirm device depth.

Figure 31.
Remove the Access Sleeve and K-wire.
Confirm Placement of the Catamaran Fixation Device

Confirm final implant placement. (Figure 32)
Post-pack the Catamaran Fixation Device

Figure 33. MODIFIED OUTLET VIEW:
Catamaran Fixation Device placement confirmed with fluoroscopy.

Figure 34. LATERAL VIEW:
Catamaran Fixation Device placement confirmed with fluoroscopy.

Figure 35. Use Bone Pusher to post-pack the implant.

Additional autograft may be post-packed with the Funnel and Bone Pusher. Complete the surgery using standard wound closure protocols.

Postoperative Care

The patient should be informed of the limitations of this type of SI joint implant and cautioned that physical activity and full weight bearing have been associated with premature failure of similar SI joint devices. Based on the individual patient, the attending clinician may require non-weight bearing or partial weight bearing for a period of time in accordance with standard medical practice. Once full weight bearing is achieved, a physical therapy regimen should commence.4

Catamaran Fixation Device Extraction

In all cases, the first and best option for removal is through the use of the Extraction Screws. If the Catamaran Fixation Device cannot be removed using the Extraction Screws, other methods including removing bone surrounding the device may be performed.

NOTE:
If permanently removing the Catamaran Fixation Device, use clinical judgment to dictate the proper method for stabilizing the SI joint and filling the resulting bone void.

• Prepare the Catamaran Fixation Device pontoons for the Extraction Screws, if necessary.

• Thread the Extraction Screws into the pontoons of the Catamaran Fixation Device until firmly snug (Figure 36). Use the 4.0mm Hex Key to firmly engage the extraction screws into the pontoons.

• Assemble the Slap Hammer Extraction System by first threading the Slap Hammer Rod into the top of the Extraction Fork.

• Next, cannulate the Slap Hammer over the Slap Hammer Rod and let it sit on the Extraction Fork.

• Insert the threaded portion of the Access Sleeve Handle through the hole of the Slap Hammer Flange.

• Attach Slap Handle Flange to the Slap Handle Rod utilizing the Access Sleeve Handle.

NOTE:
Ensure markings on Slap Hammer Flange are facing up.

• Use the Slap Hammer to extract the Catamaran Fixation Device by repeatedly sliding the Slap Hammer towards the Slap Hammer Flange so that it contacts the Flange with enough force to fully explant and remove the Catamaran Fixation Device (Figure 37).
Sterilization Tray Configuration

Table 1. Sterilization Tray Placement Key

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<th>DRILL &amp; ACCESS INSTRUMENTS</th>
<th>EXTRACTION</th>
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<td>1 Access Sleeve</td>
<td>9 Fixation Device, 30MM (2)</td>
<td>11 K-wire (6)</td>
<td>19 Hex Key, 4MM</td>
</tr>
<tr>
<td>2 Access Sleeve Handle</td>
<td>10 Fixation Device, 40MM (2)</td>
<td>12 Graduated Guide Wire (2)</td>
<td>20 Extraction Fork</td>
</tr>
<tr>
<td>3 Drill Guide</td>
<td></td>
<td>13 Drill Bit, 50MM</td>
<td>21 Extraction Screw (2)</td>
</tr>
<tr>
<td>4 Inserter</td>
<td></td>
<td>14 Drill Bit, 60MM</td>
<td>22 Slap Hammer Flange</td>
</tr>
<tr>
<td>5 Temporary Pin</td>
<td></td>
<td>15 Drill Bit, 70MM</td>
<td>23 Slap Hammer</td>
</tr>
<tr>
<td>6 Inserter Screw</td>
<td></td>
<td>16 Ball Tip Probe</td>
<td>24 Slap Hammer Rod</td>
</tr>
<tr>
<td>7 Funnel Tube</td>
<td></td>
<td>17 Bone Pusher Rod</td>
<td></td>
</tr>
<tr>
<td>8 Funnel Cone</td>
<td></td>
<td>18 Bone Pusher Head</td>
<td></td>
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</tbody>
</table>
### CATAMARAN FIXATION DEVICES
To accommodate patient anatomy, the Catamaran Fixation Device is available in two sizes, 30mm and 40mm.

- **Fixation Device 30MM (2)** | 40295-03 | Single Use
- **Fixation Device 40MM (2)** | 40295-04 | Single Use

### ACCESS INSTRUMENTS
The Access instruments are used to access and visualize the SI joint stabilization site in preparation for drilling and placement of the Catamaran Fixation Device.

- **Access Sleeve** | 40316 | Reusable
- **Access Sleeve Handle** | 40318 | Reusable
- **Graduated Guide Wire (2)** | 40320 | Single Use
- **K-wire (6)** | 40322 | Single Use
- **Drill Guide** | 40326 | Reusable

### DRILL & DELIVERY INSTRUMENTS
The Drill & Delivery instruments are used to drill holes for placement of the Catamaran Fixation Device and to deliver the Fixation Device to the SI joint stabilization site.

- **Inserter** | 40334 | Reusable
- **Drill Bit 50MM** | 40328 | Reusable
- **Drill Bit 60MM** | 40329 | Reusable
- **Drill Bit 70MM** | 40331 | Reusable
- **Ball Tip Probe** | 40330 | Single Use
- **Inserter Screw** | 40336 | Reusable
- **Temporary Pin** | 40332 | Reusable
**CLEANING AND STERILIZATION**

All components of the Catamaran SI Joint Fusion System are provided **NON-STERILE**. Please review the **Instructions For Use** provided with the Catamaran Fixation Device and Catamaran Fusion System for cleaning and sterilization instructions. *The surgical instruments are manufactured from stainless steel.*

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**BONE GRAFT PACKING INSTRUMENTS**

The Bone Graft Packing instruments are used for packing autologous bone graft material into the Catamaran Fixation Device after implantation.

- **Funnel Cone** | 40342 | Reusable
- **Funnel Tube** | 40340 | Reusable
- **Bone Pusher Head** | 40344 | Single Use
- **Bone Pusher Rod** | 40346 | Single Use

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**EXTRACTION INSTRUMENTS**

Extraction instruments are included in the event the Catamaran Fixation Device requires removal or repositioning. The Access Sleeve Handle is used with the Slap Hammer assembly.

- **Extraction Screw (2)** | 40350 | Single Use
- **Extraction Fork** | 40348 | Reusable
- **Slap Hammer** | 40352 | Reusable
- **Slap Hammer Rod** | 40354 | Reusable
- **Slap Hammer Flange** | 40356 | Reusable
- **Hex Key** | 40338 | Reusable