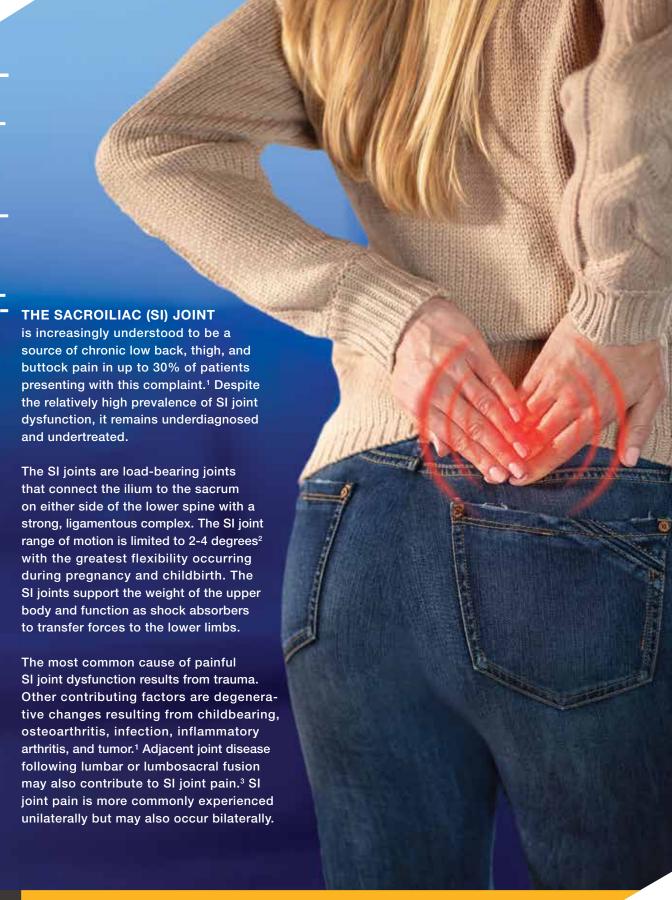




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^{1.} Cohen, et al. Sacroiliac joint pain: a comprehensive review of epidemiology, diagnosis, and treatment. Expert Rev Neurother. 2013;13(1):99-116.

^{2.} Sturesson, et al. Movements of the sacrolliac joints. A roentgen stereophotogrammetric analysis. Spine, 1989 Feb; 14(2):162-5.

^{3.} DePalma, et al. Etiology of chronic low back pain in patients having undergone lumbar fusion. Pain Med. 2011;12(5):732.

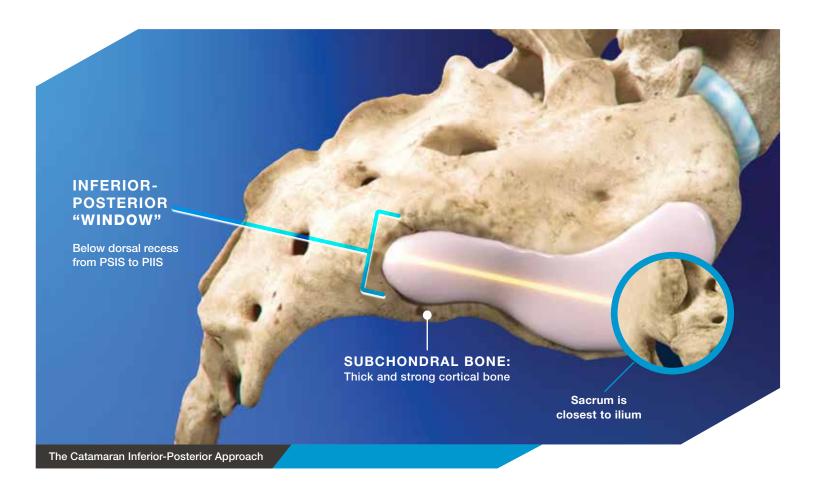
TENON MEDICAL

Inferior-Posterior Approach

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).4

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.4

Inferior-Posterior Approach allows the Catamaran implant to follow the trajectory of the joint.



^{4.} Donner, EJ. Posterior Inferior Approach, Minimally Invasive Surgery. In Dall, B. (Ed.) Surgery for Painful, Dysfunctional Sacroiliac Joint. Springer International Publishing. 2014

ABOUT THE

Catamaran SI Joint Fusion System



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 SI Joint 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

Preoperative Preparation



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

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.

- The patient should be thoroughly evaluated, and if any of the following are identified, SI joint surgery should not be performed:
- Inability or refusal to comply with instructions related to surgery and/or postoperative care.
- Insufficient bone quality, impaired bone metabolism, or evidence of impaired healing.
- Insufficient bone stock, defect, or deformity in the sacral or iliac bone that would impede or impair surgery or healing.
- Tumor, inflammation, or infection in the lower spine, hip, or pelvic region.
- Active infection.
- Prior repeated failed attempts to fixate the SI joint.
- 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.
- See the contraindications for a full list of conditions for which Catamaran should not be used.

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.



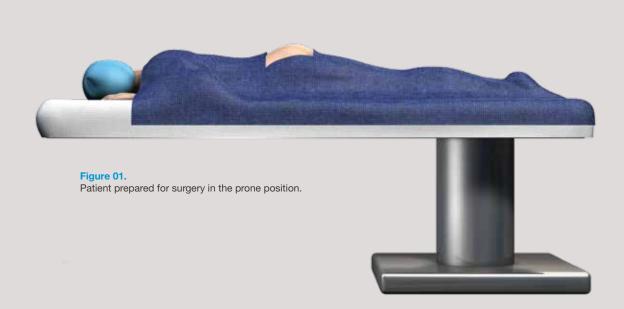
Operating Room Preparation

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.



FLUOROSCOPICALLY CONFIRM PATIENT POSITIONING



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 landmarks, skin entry point, and Inferior-Posterior delivery of the Catamaran **Fixation Device utilizing**

- IT IS CRITICAL to understand the threedimensional anatomy of the SI joint and to apply this understanding to two-dimensional imaging.
- **CRITICAL BONY LANDMARKS TO IDENTIFY ON FLUOROSCOPY:**
 - Ventral border of the sacrum
 - Sacral promontory
 - **Alar boundary**
 - Parallel boundaries of the sacrum and ilium that form the SI joint
 - Sacral Foramina

MODIFIED OUTLET VIEW

To draw sagittal skin line





30 DEGREES CEPHALAD



MODIFY 10 DEGREES

MODIFIED INLET VIEW

To draw axial line





30 DEGREES CAUDAD



MODIFY 10 DEGREES

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).

FLUOROSCOPICALLY ALIGN THE JOINT

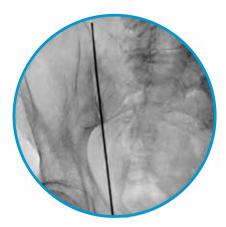


Figure 02. True outlet view typically shows the SI joint as two lines (front and back of the joint).

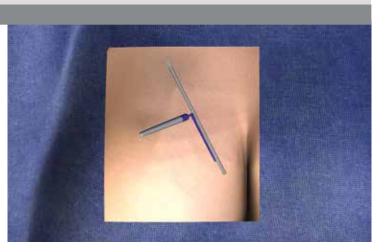


Figure 03 Modified outlet view shows aligned SI joint.

ESTABLISH THE SAGITTAL LINE



Fluoroscopically align the Ball Tip Probe to establish sagittal line.



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.

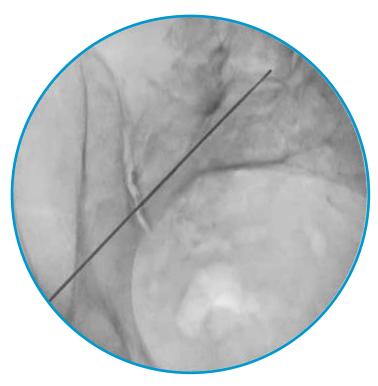


Figure 06. Fluoroscopically align the Ball Tip Probe to establish the axial line.

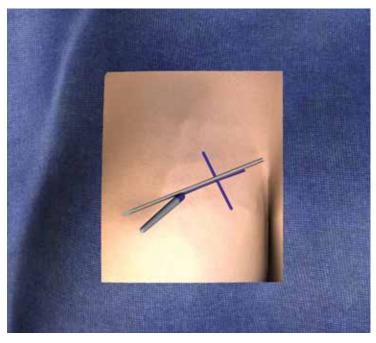


Figure 07. Use a skin marker to draw the axial line on the skin.



The intersection of the sagittal and axial lines represents the joint entry point.

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).

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).

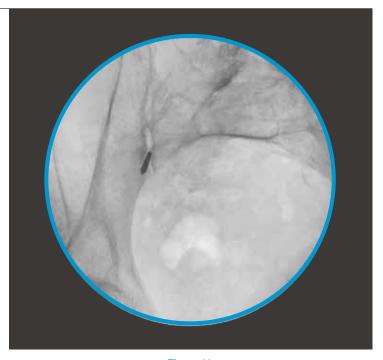


Figure 11. The posterior and anterior aspects of the pelvic floor will be aligned.

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

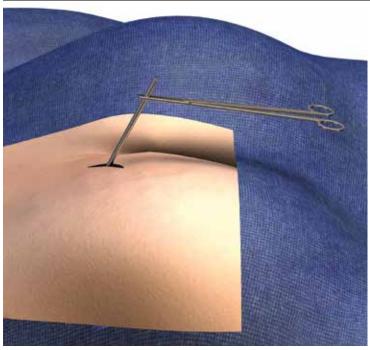


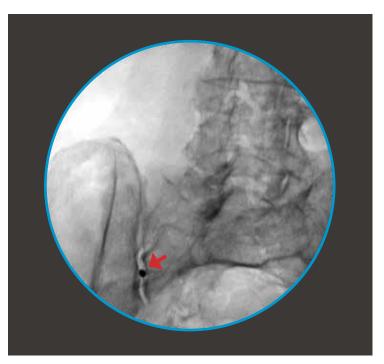
Figure 12. Adjust the Graduated Guide Wire trajectory using a Kelly clamp.

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.



The entry point is confirmed when the Graduated Guide Wire appears as a dot under fluoro.

Advance the Graduated Guide Wire

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.

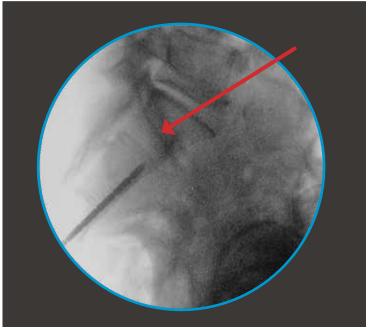


Figure 14. Lateral view with arrow indicating the alar boundary.

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.

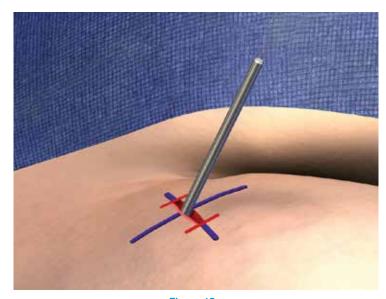


Figure 15 Extend skin incision 2cm bilaterally of the Graduated Guide Wire along the axial line.

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).

Insert the Drill Guide into the Access Sleeve. The Drill Guide lip facilitates the removal of the Drill Guide from the sleeve from either orientation.

The Access Sleeve Assembly

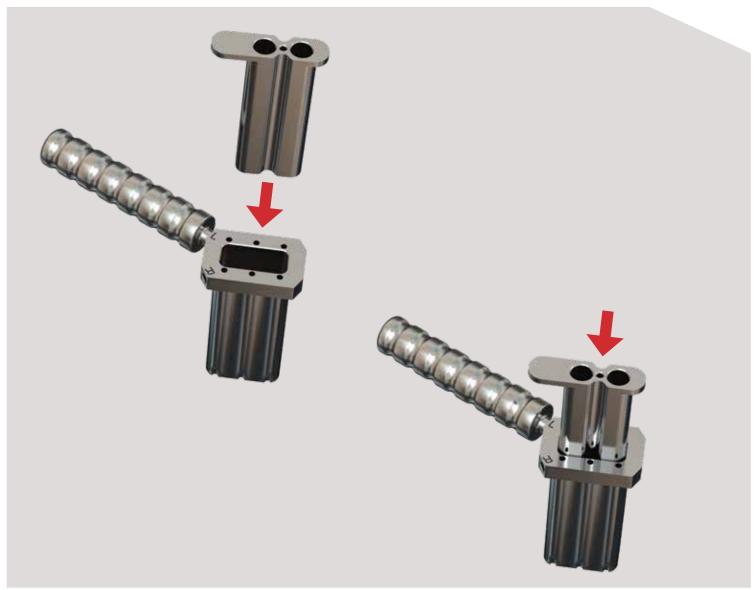


Figure 16. Insert Drill Guide into Access Sleeve.

Insert Access Sleeve Assembly

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.

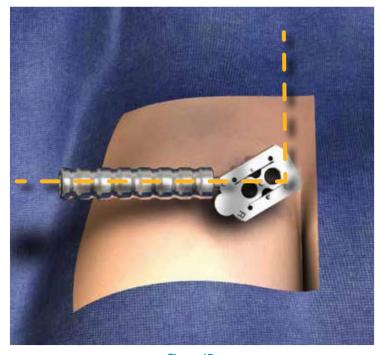


Figure 17. Handle perpendicular to the spine.

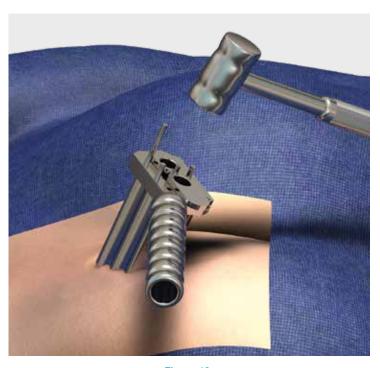
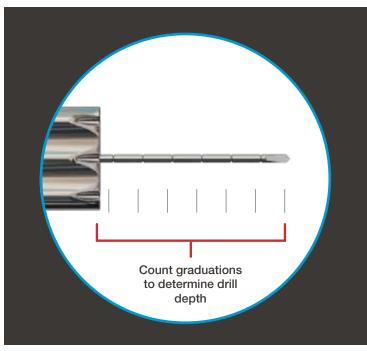


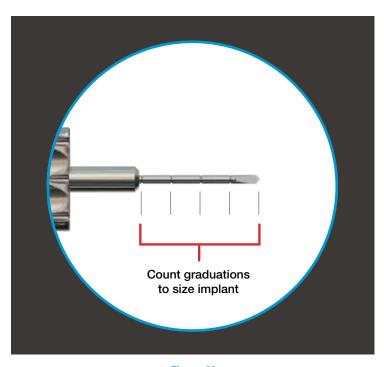
Figure 18. Anchor Access Sleeve with K-Wires.

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.

Figure 19. Graduated Guide Wire with 10mm increment marks.



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).

Figure 20. Count visible marks to determine the length of the Catamaran Fixation Device.

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.



Figure 21. Final drilling depth.

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 22. Harvest autograft from Drill Bit.

Drill the Pontoon Channels (Cont'd)

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

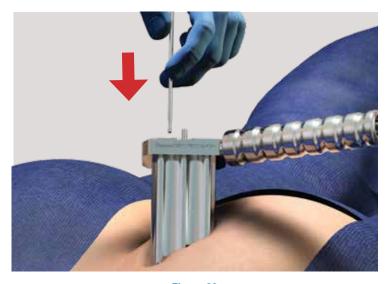


Figure 23. Use the Ball Tip Probe to confirm the integrity of the anterior cortex.

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).

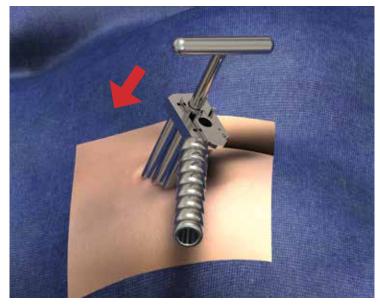


Figure 24. Place Temporary Pin into drill hole to retain the Drill Guide position.

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.



Figure 25. Remove Drill Guide.

Remove the Temporary Pin, Drill Guide, and Graduated Guide Wire, leaving the Access Sleeve and K-wires firmly in place (Figures 25 and 26).

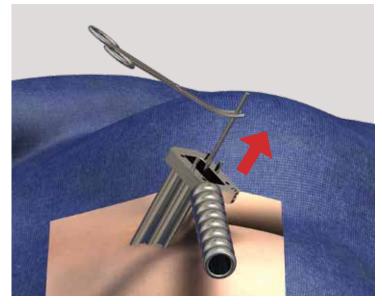


Figure 26. Remove Graduated Guide Wire in an axial direction, avoiding excessive lateral movement.

Prepare the Implant for Delivery

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.

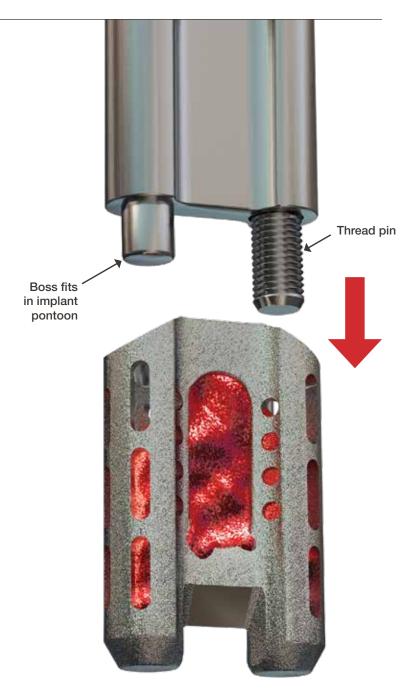


Figure 27. Pack autograft into bridge and pontoons.

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).



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

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



Figure 30. Lateral view to confirm device depth.

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).

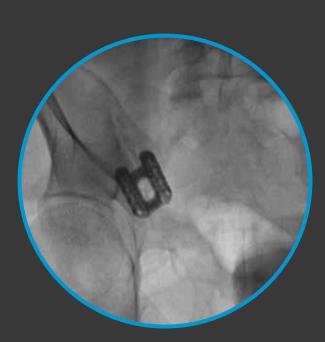


Figure 31. Remove the Access Sleeve and K-wire.

Confirm Placement of the Catamaran Fixation Device



Post-pack the Catamaran **Fixation Device**



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



LATERAL VIEW: Catamaran Fixation Device placement confirmed with fluoroscopy.

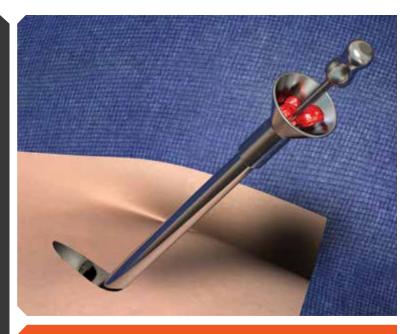




Figure 35. Use Bone Pusher to post-pack the implant.

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 activity and full weight bearing have been associated 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,

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).



Figure 36. Extraction Screws fitted into implant pontoons for removal.



Figure 37. Extraction Fork fitted over Extraction Screws.

Sterilization Tray Configuration

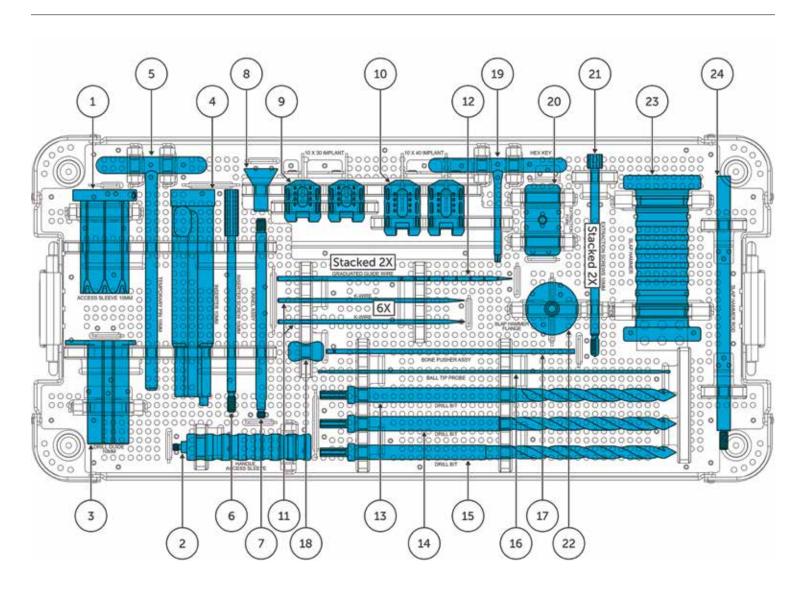


Table 1. Sterilization Tray Placement Key

ACCESS INSTRUMENTS	CATAMARAN FIXATION DEVICES	DRILL & ACCESS INSTRUMENTS	BONE GRAFT PACKING INSTRUMENTS	EXTRACTION
1 Access Sleeve	9 Fixation Device, 30MM (2)	4 Inserter	7 Funnel Tube	20 Extraction Fork
2 Access Sleeve Handle	10 Fixation Device, 40MM (2)	5 Temporary Pin	8 Funnel Cone	21 Extraction Screw (2)
3 Drill Guide		6 Inserter Screw	17 Bone Pusher Rod	22 Slap Hammer Flange
11 K-wire (6)		13 Drill Bit, 50MM	18 Bone Pusher Head	23 Slap Hammer
12 Graduated Guide Wire (2)		14 Drill Bit, 60MM		24 Slap Hammer Rod
		15 Drill Bit, 70MM		
		16 Ball Tip Probe		
		19 Hex Key, 4MM		

Catamaran SI Joint Surgical Instruments

The Catamaran SI Joint Fusion System includes the Catamaran Fixation Device and the following stainless steel surgical instruments required to perform the Inferior-Posterior sacroiliac fusion surgery.

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.



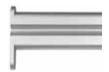
Access Sleeve | 40316 | Reusable



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



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



Hex Key | 40338 | Reusable



BONE GRAFT PACKING INSTRUMENTS

The Bone Graft Packing instruments are used for packing autologous bone graft material into the Catamaran Fixation Device both prior to and after implementation, as needed.



Funnel Cone | 40342 | Reusable

Funnel Tube | 40340 | Reusable



Bone Pusher Head | 40344 | Single Use

Bone Pusher Rod | 40346 | Single Use

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

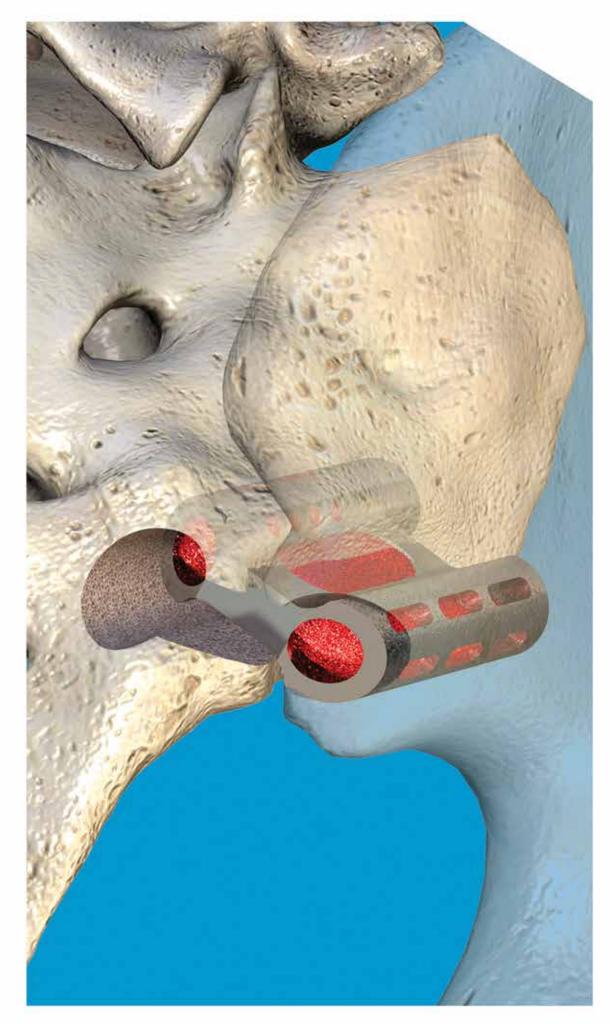


Slap Hammer Flange | 40356 | Reusable

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 SI Joint Fusion System for cleaning and sterilization instructions.

The surgical instruments are manufactured from stainless steel.



MRI SAFETY INFORMATION

The Catamaran SI Joint
Fixation Device has been
evaluated for safety and
compatibility in the MR
environment and is
MR Conditional. For
complete information on
MRI Safety, refer to the
Instructions for Use.



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