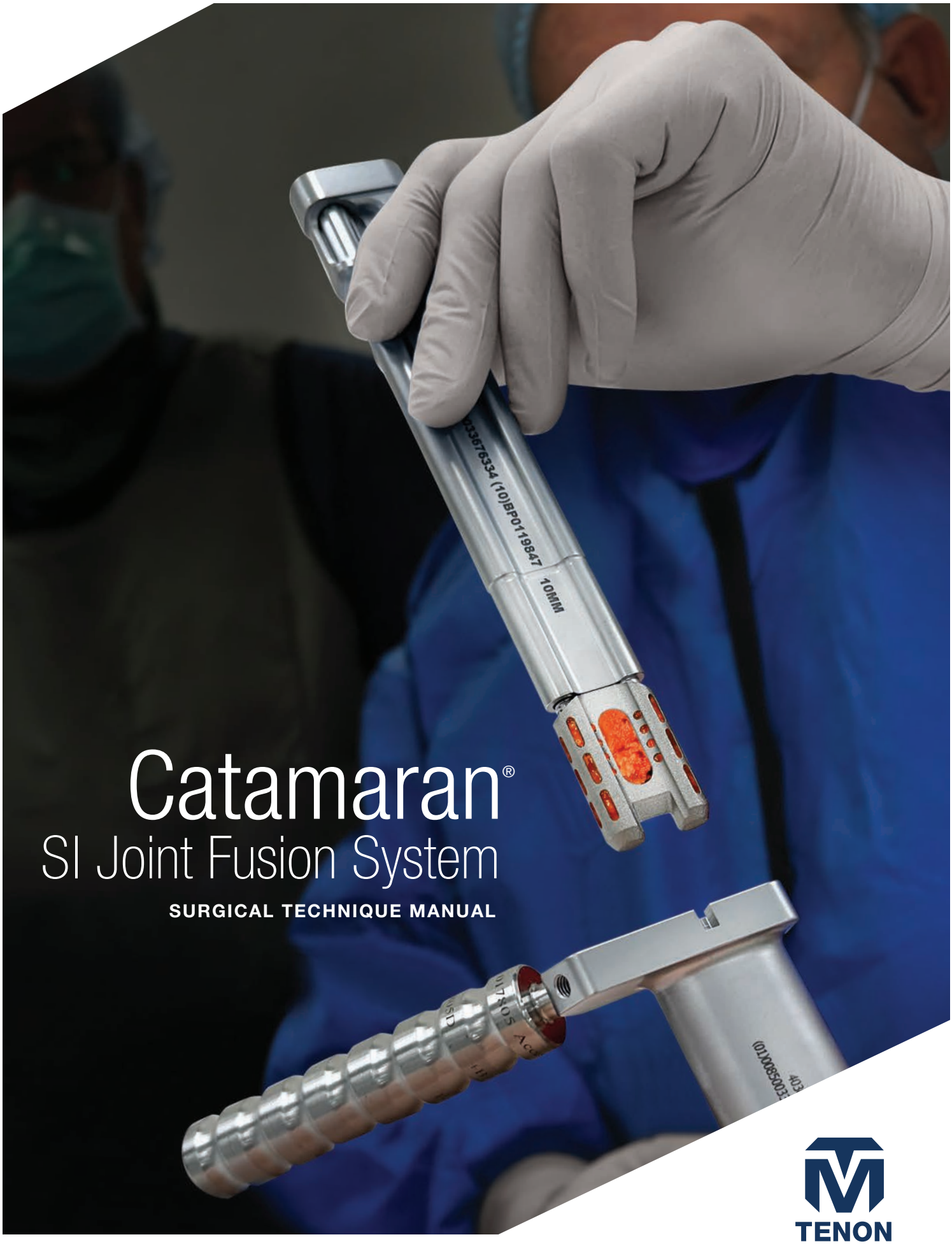
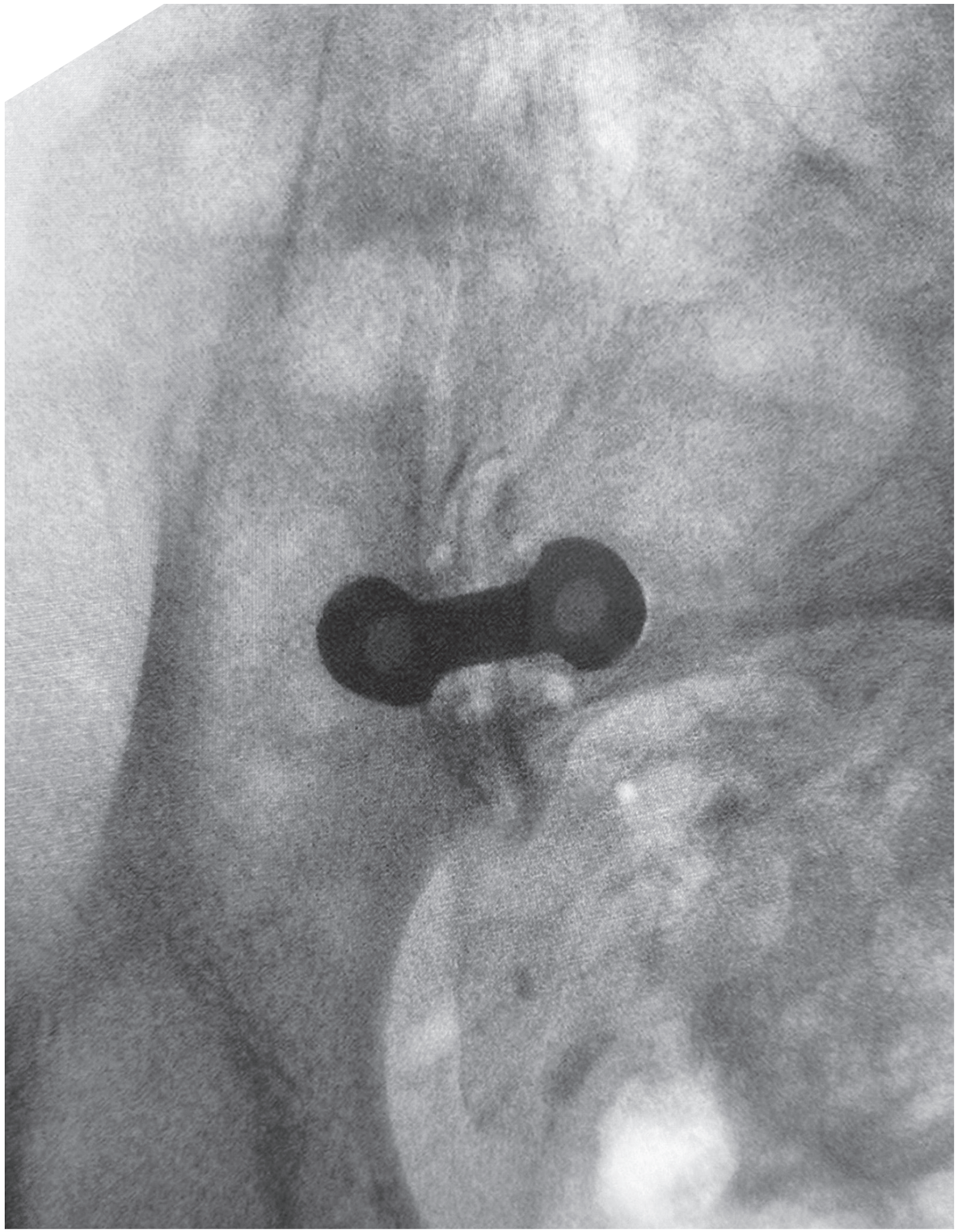


Catamaran®

SI Joint Fusion System

SURGICAL TECHNIQUE MANUAL

TENON MEDICAL®



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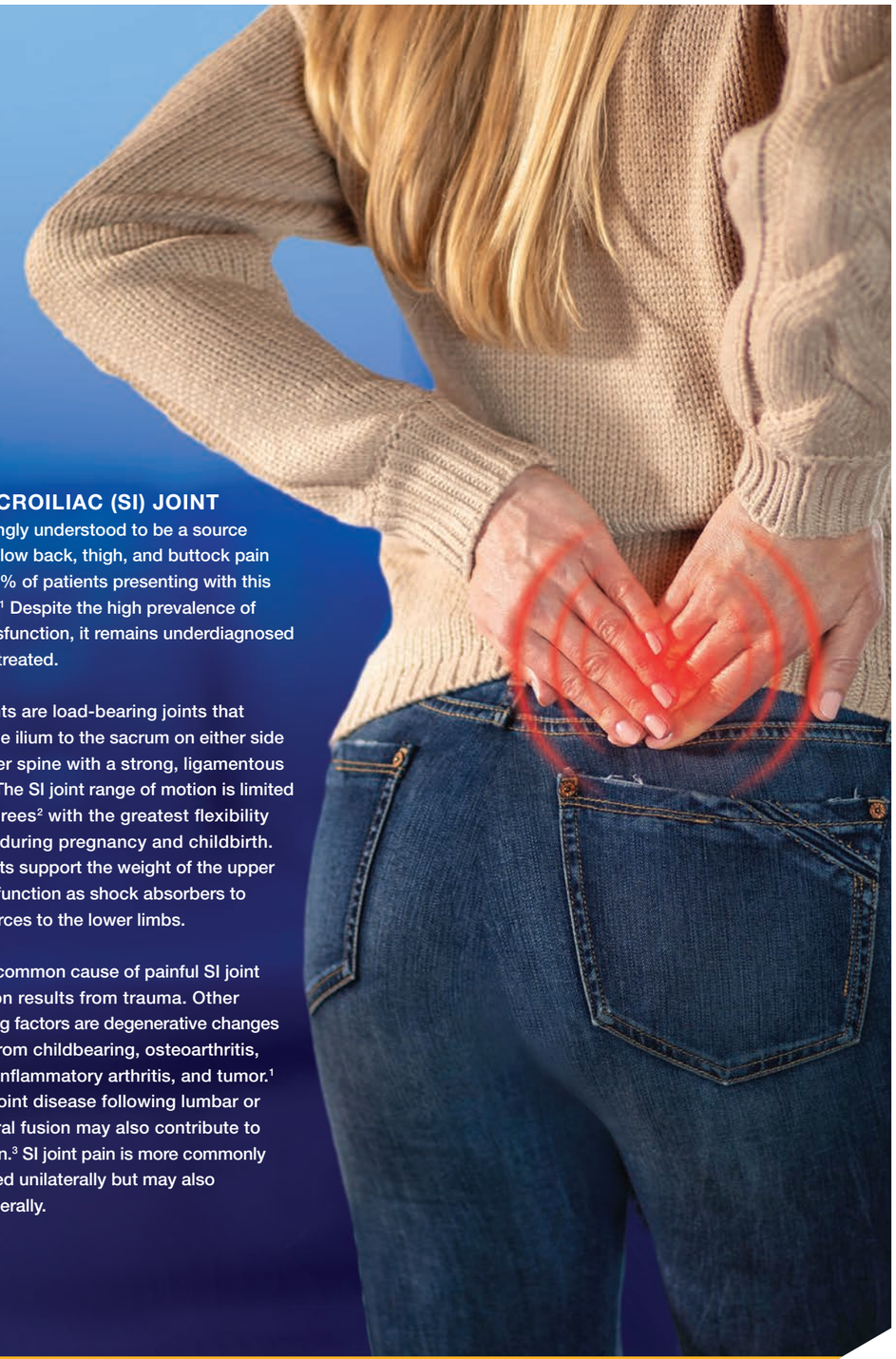


THE SACROILIAC (SI) JOINT is increasingly understood to be a source of chronic low back, thigh, and buttock pain in up to 30% of patients presenting with this complaint.[1] Despite the high prevalence of SI joint dysfunction, it remains underdiagnosed and undertreated.

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.

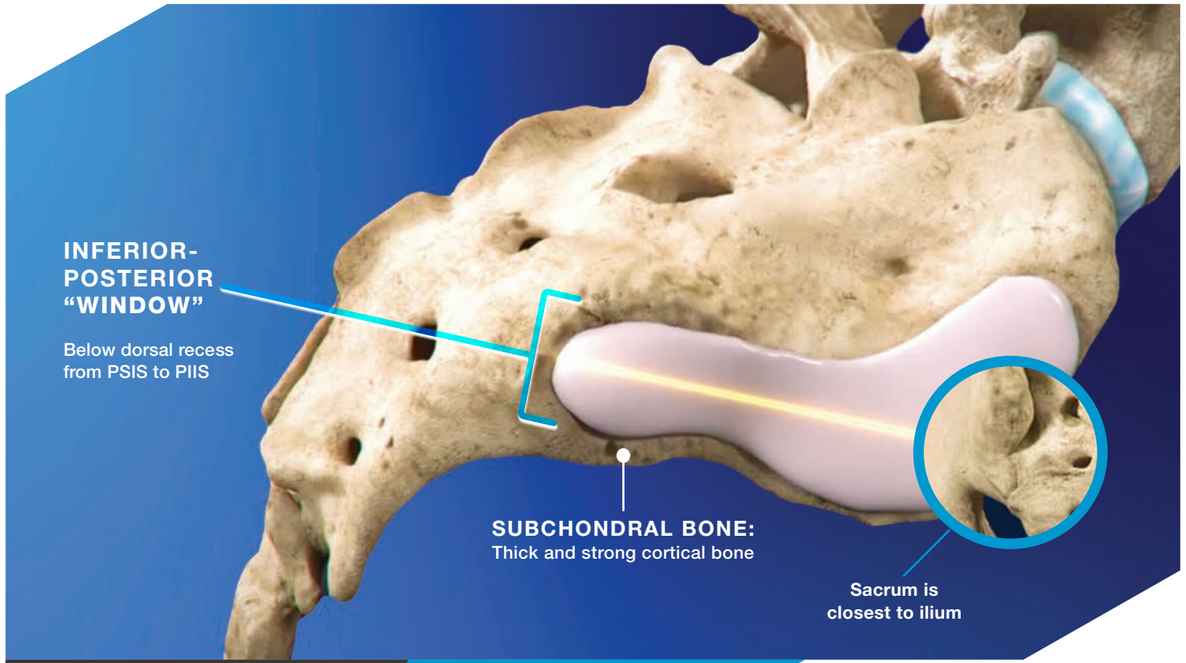
1. Cohen, et al. Sacroiliac joint pain: a comprehensive review of epidemiology, diagnosis, and treatment. Expert Rev Neurother. 2013;13(1):99–116.
2. Sturesson, et al. Movements of the sacroiliac joints. A roentgen stereophotogrammetric analysis. Spine.1989 Feb;14(2):162-5.
3. DePalma, et al. Etiology of chronic low back pain in patients having undergone lumbar fusion. Pain Med. 2011;12(5):732.

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.



The Catamaran Inferior-Posterior Approach

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 FIXATION DEVICE

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 either 10mm or 7.5mm 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 Tenon Medical Catamaran SI Joint Fusion System is intended for sacroiliac joint fusion for conditions including:

- **Sacroiliac joint disruptions and degenerative sacroiliitis**
- **To augment immobilization and stabilization of the sacroiliac joint in skeletally mature patients undergoing sacropelvic fixation as part of a lumbar or thoracolumbar fusion.**

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 suitable 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:

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.

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

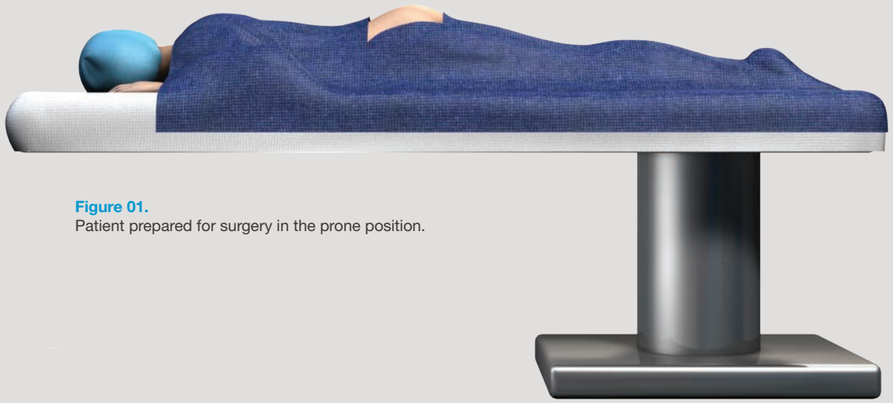


Figure 01.
Patient prepared for surgery in the prone position.

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 1) Identify & align the alar boundary and 2) Assess dysmorphism.

Imaging Overview

GENERAL IMAGING GUIDANCE AND REMINDERS

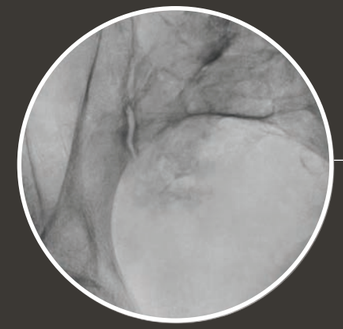
The following instructions establish the anatomic landmarks, skin entry point, and Inferior-Posterior delivery of the Catamaran Fixation Device utilizing two-dimensional fluoroscopy.

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
5. Posterior Superior Iliac Spine (PSIS)

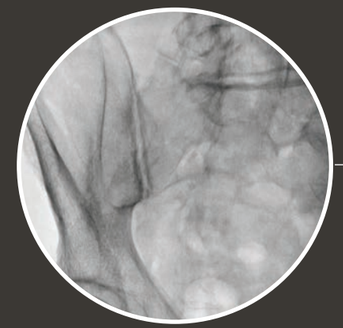
MODIFIED INLET VIEW
Alignment of Pelvic floor/Entry Point



~15-30 DEGREES CAUDAD

MODIFY (Oblique) ~0-20 DEGREES

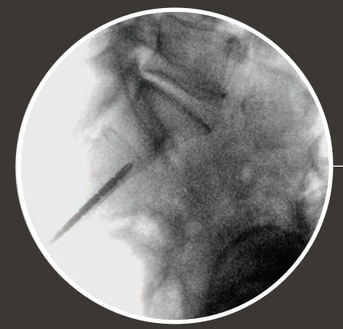
MODIFIED OUTLET VIEW
Confirming Medial/Lateral Trajectory



~15-30 DEGREES CEPHALAD

MODIFY (Oblique) ~0-20 DEGREES

LATERAL VIEW
To determine Angle and Depth



Establish the Skin Entry

FLUOROSCOPIC IMAGING:

MODIFIED INLET VIEW

Rotate the C-Arm caudal until the pelvic floor aligns. Tilt (oblique) the C-arm approximately 15-30° from a true anteroposterior (AP) position, contralateral to the operating side, until the joint aligns.

Optional: Identify and mark the skin directly below the posterior superior iliac spine (PSIS). A second line parallel to the pelvic floor is then marked.

Position the tip of the Graduated Guide Wire inferior to the PSIS. Make a small stab incision (approximately 1cm) at the marked location. Maintaining the tip position, carefully insert the Graduated Guide Wire through the skin and down towards the bone. Slightly medialize the hand while inserting to “dock” the Graduated Guide Wire firmly against the bone (Figure 02). Confirmation of the entry point is achieved when the guidewire appears as a “dot” view on fluoroscopy (Figure 03).

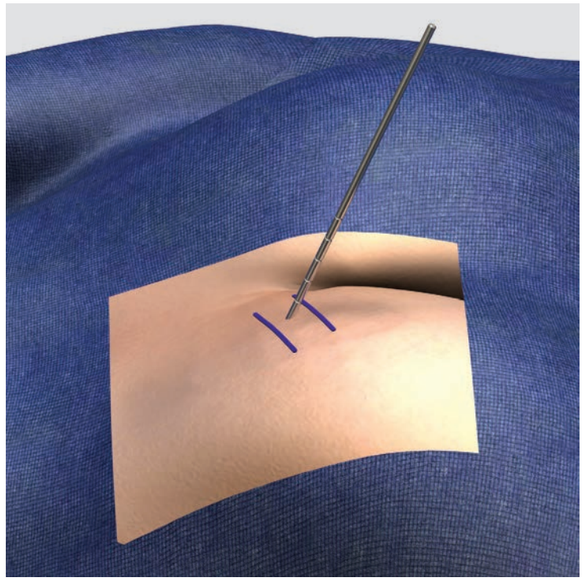


Figure 02.
Stab incision to reach desired entry.

NOTES:

Document the final C-arm position for future reference.

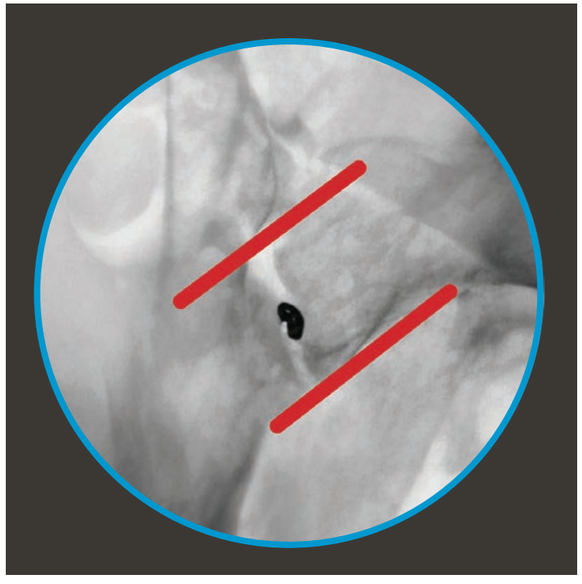


Figure 03.
Modified Inlet View showing docked point.

Aligning the SI Joint

FLUOROSCOPIC IMAGING:

MODIFIED OUTLET VIEW

Switch to an Outlet view by rotating the C-Arm cephalad while maintaining the same oblique angle as in the Inlet view. Utilize fluoroscopy to confirm the medial/lateral trajectory of the Graduated Guide Wire. Once confirmed to be within the joint and away from neural structures, use a small mallet to gently advance the guidewire 1-2cm for secure docking (Figure 04).

NOTE:

Document the final C-arm position for future reference.

CAUTION:

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

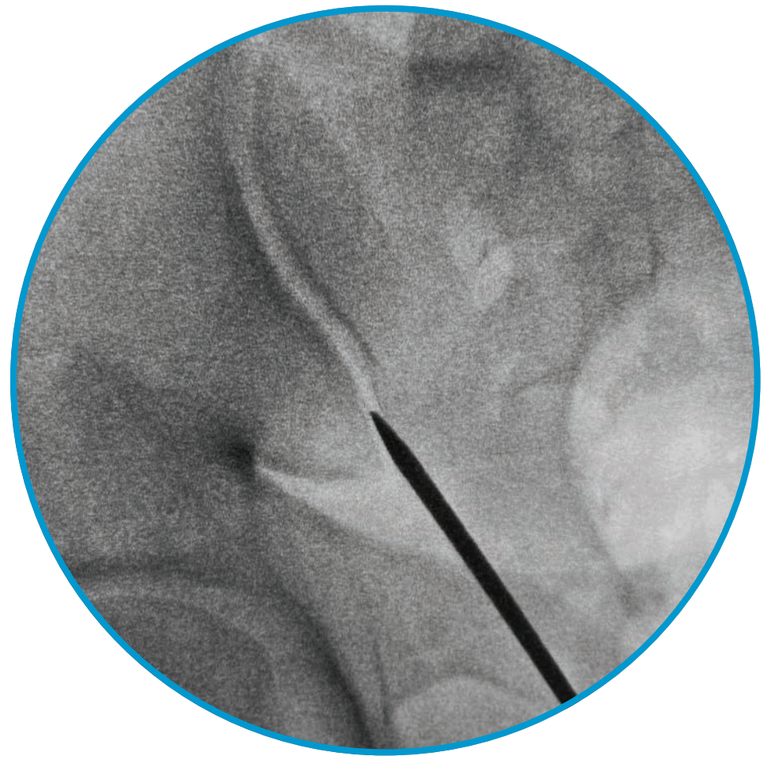


Figure 04.
Anchor the Graduated Guide Wire in the SI joint space.

Advance the Graduated Guide Wire

FLUOROSCOPIC IMAGING:

MODIFIED LATERAL VIEW

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 should be into mid-point of the S1 Sacral body, approximately 5mm short of the most inferior alar boundary (Figure 05).

Make a skin incision that allows for blunt dissection down to the bone to facilitate proper placement of the Access Sleeve.

CAUTION:

Do not advance beyond the alar boundary.

NOTE:

If the alar boundaries are not aligned, confirm in the modified Outlet view that the Graduated Guide Wire is just past the S1 Foramen.

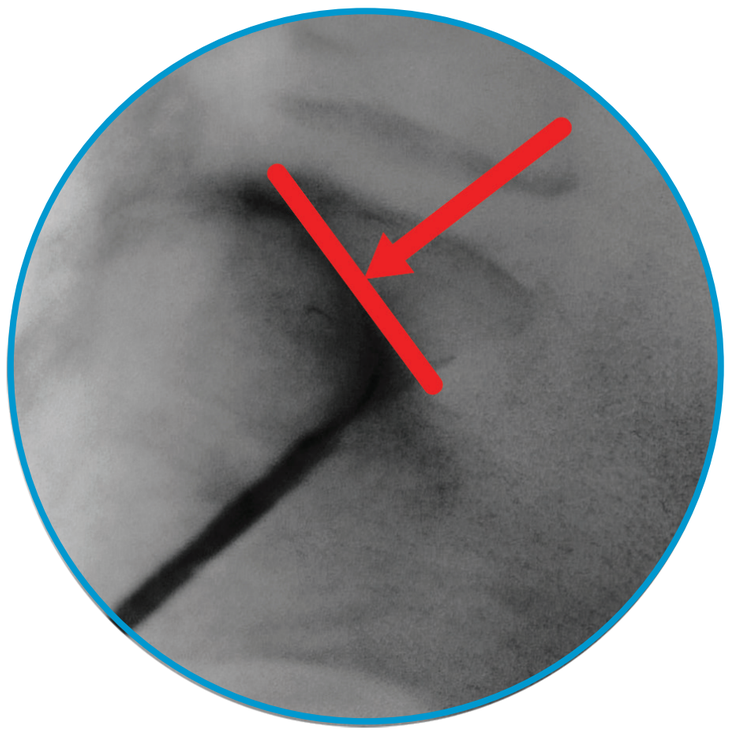


Figure 5.
Lateral view arrow indicating the alar boundary.

Assemble the Access Sleeve and Drill Guide

The Access Sleeve Assembly

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 06).

Insert the Drill Guide into the Access Sleeve (Figure 06). The Drill Guide lip facilitates the removal of the Drill Guide from the sleeve from either orientation.

Catamaran® SE
SI Joint Fusion System

NOTE:

When utilizing the Catamaran SE (Figure 6A), employ the Access Sleeve Positioner in lieu of the Access Sleeve Handle throughout the surgical procedure as outlined in the surgical technique manual.

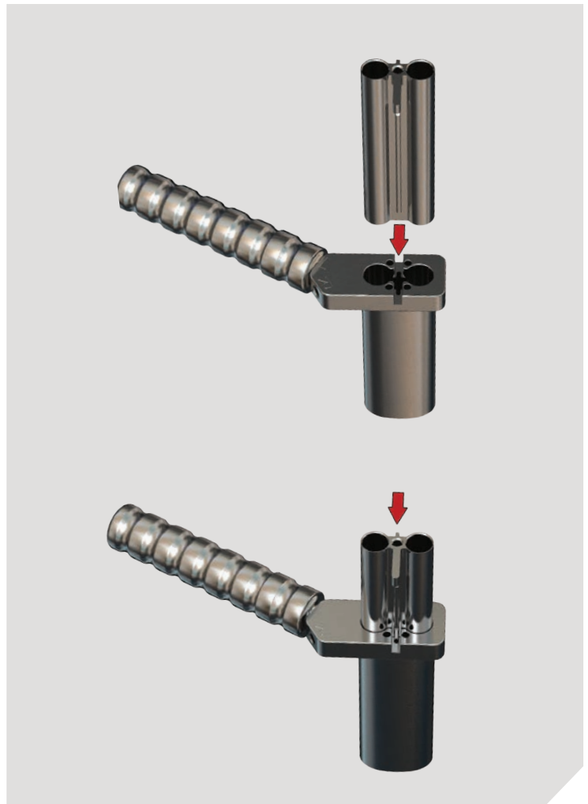


Figure 6.
Thread the Access Sleeve Handle into the Access Sleeve and insert Drill Guide into Access Sleeve.

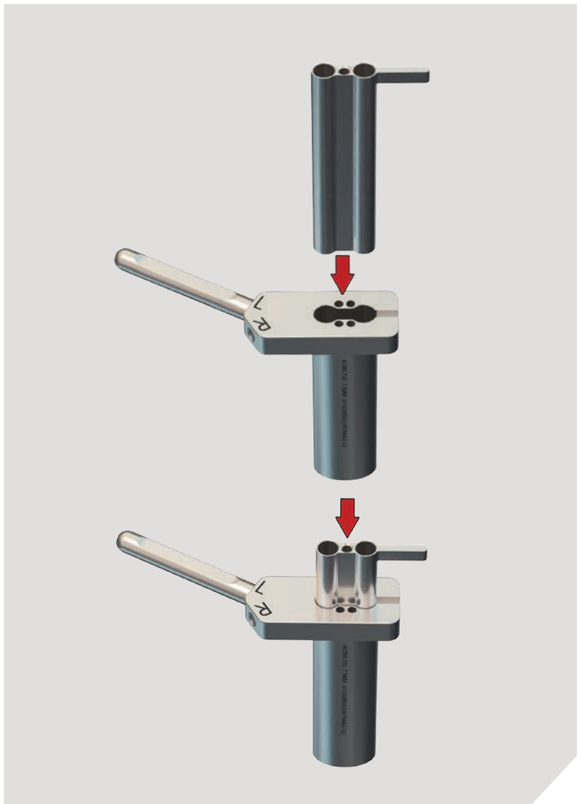


Figure 6A.
Thread the Access Sleeve Positioner into the Access Sleeve and insert Drill Guide into Access Sleeve.

Insert Access Sleeve Assembly

Place the Drill Guide over the Graduated Guide Wire, ensuring the Graduated Guide Wire is in the center hole. Start by positioning the Access Sleeve Assembly on the bone, with the handle perpendicular to the axis of the spine. (Figure 07). A Lateral view image can be obtained to ensure the Access Sleeve is in contact with bone (Figure 08).

In the Modified Inlet view, obtain a Barrel view fluoroscopic image. This view confirms proper transfixing of the SI joint through the Drill Guide, with visualization into both the Sacrum and Ilium (Figure 09). Carefully place a single K-Wire through the Access Sleeve on the Sacral side, avoiding interference with the Graduated Guide Wire. Gently tap the K-Wire into the bone to initially secure Access Sleeve.

Rotate the Access Sleeve as needed to assure the Drill Guide holes transfix the SI joint. Once secure, the K-Wire Driver can be used to aid in driving the initial K-wire into the bone (Figure 10). Take another Barrel view to confirm the position of the Access Sleeve and then finish securing with additional K-wires.

CAUTION:

Place K-wires under fluoroscopy and verify adequate bone purchase.

CAUTION:

For optimal placement and to avoid interference with the Drill Bit, ensure the Graduated Guide Wire is not visualized within the barrel view on fluoroscopy. If the Graduated Guide Wire is visible, adjust its position until it is no longer visible within the barrel.

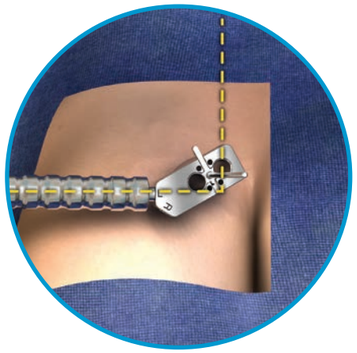


Figure 7.
Handle perpendicular to Spine.

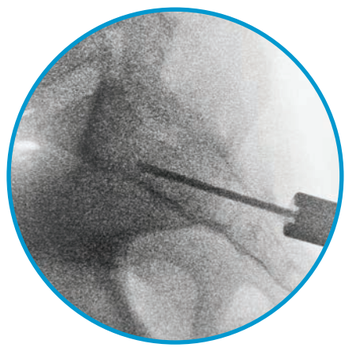


Figure 8.
Lateral view to ensure Access sleeve is touching bone.

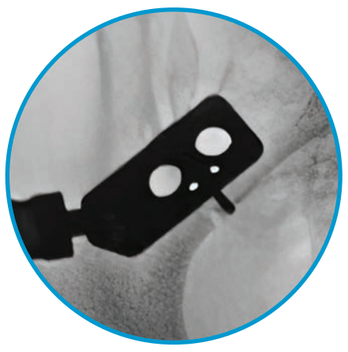


Figure 9.
Confirmation that the Drill Guide holes transfix the Sacrum and Ilium.

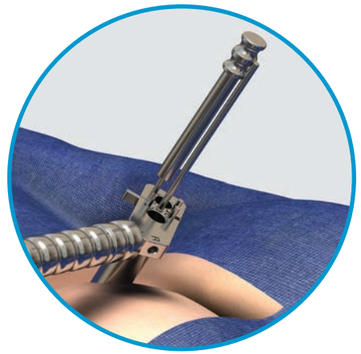


Figure 10.
Use the K-wire Driver to drive the K-wires into the Bone.

Utilize Guide Wire Graduations to Determine Drill Depth and Catamaran Fixation Device Length

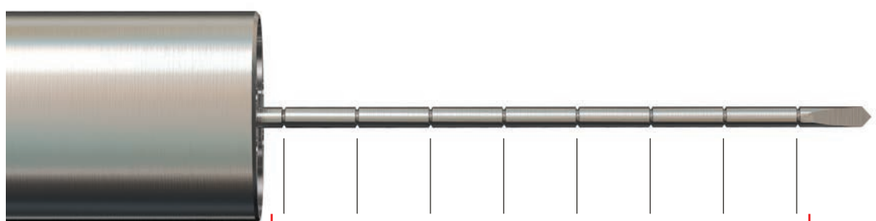


Figure 11.
Graduated Guide Wire with 10mm increment marks.

The Graduated Guide Wire is marked in 10mm increments (Figure 11). 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.

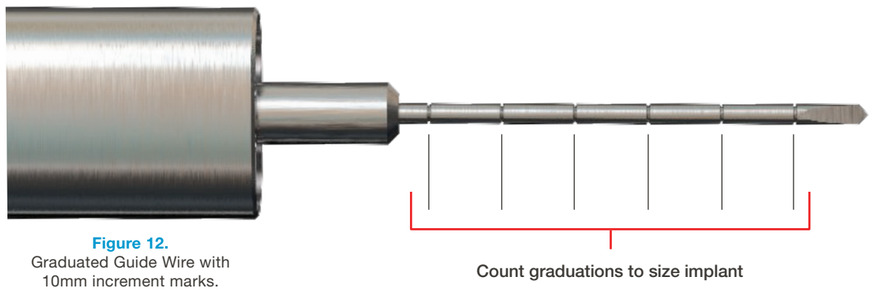


Figure 12.
Graduated Guide Wire with 10mm increment marks.

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 12).

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.

NOTE:

When employing the Catamaran SE system, only a single drill bit (Drill Bit, 73mm) is required.

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 (Figure 13).

Switch to the Lateral view to continue drilling. Do not proceed beyond the alar boundary (Figure 14).

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.

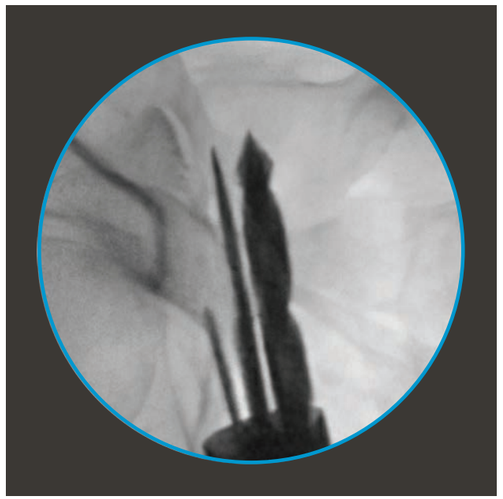


Figure 13.
Drill bit on Sacral side.

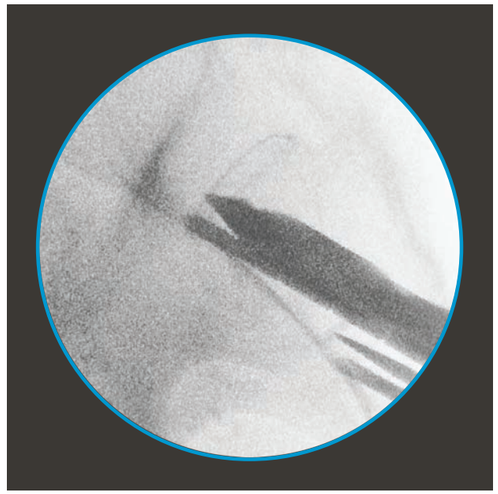


Figure 14.
Final Drilling depth.

Graft Collection

Place the Catamaran Fixation Device into the Loader Funnel with the open ends of the pontoons facing up (Figure 15).

Figure 15.
Place Catamaran Fixation Device into Loader Funnel.

Drill the Pontoon Channels *(cont.)*

After drilling the first hole, clip the Graft Remover onto the drill (Figure 16). Hold the drill over the Loader Funnel. Keeping your fingers away from the sharp drill edges, rotate the Graft Remover clockwise down the length of the drill removing all the graft and placing it into the Catamaran Fixation Device (Figure 17).

Figure 16.
Harvest autograft from Drill Bit.

Figure 17.
Load autograft into the Implant.

Use the Ball Tip Probe to ensure the anterior cortex has not been breached (Figure 18).

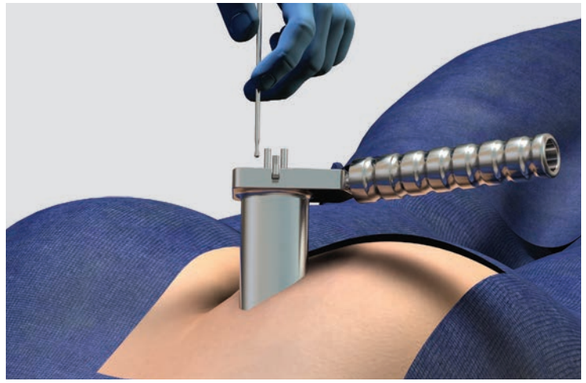


Figure 18.
Use the Ball Tip Probe to confirm the integrity of the anterior cortex.

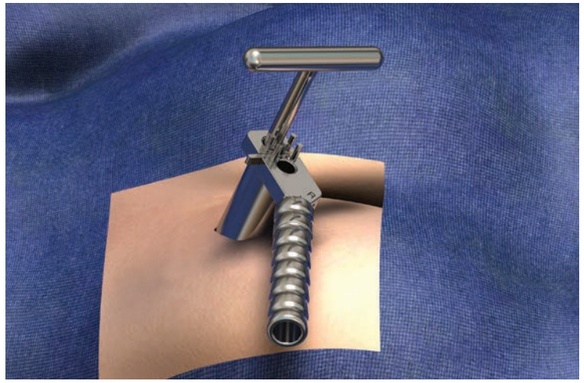


Figure 19.
Place Temporary Pin into drill hole to retain the Drill Guide position.

Place the Temporary Pin into the sacral pontoon channel as additional support to maintain the Drill Guide position while drilling into the Ilium (Figure 19).

Repeat the same process for the ilial side drill hole.

Prepare the Implant for Delivery

Cannulate the Inserter Screw through the Inserter. Attach the Catamaran Fixation Device onto the distal end of the Inserter Handle (Figure 20). 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. The Hex Key may be used to tighten the device. **DO NOT OVERTIGHTEN.** Ensure a straight angle implant-to-Inserter interface.

With the Inserter attached, remove the implant from the Loader Funnel. The implant is now ready for delivery into the drilled pontoon channels and SI joint.

Remove the Temporary Pin, Drill Guide and Graduated Guide Wire, leaving the Access Sleeve and K-wires firmly in place (Figures 21 and 22).

Figure 20.
Attach Catamaran Fixation Device to Inserter Handle.

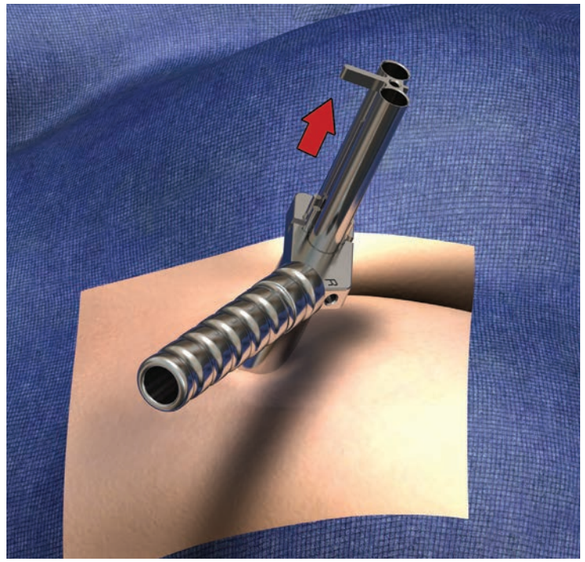


Figure 21.
Remove Drill Guide.

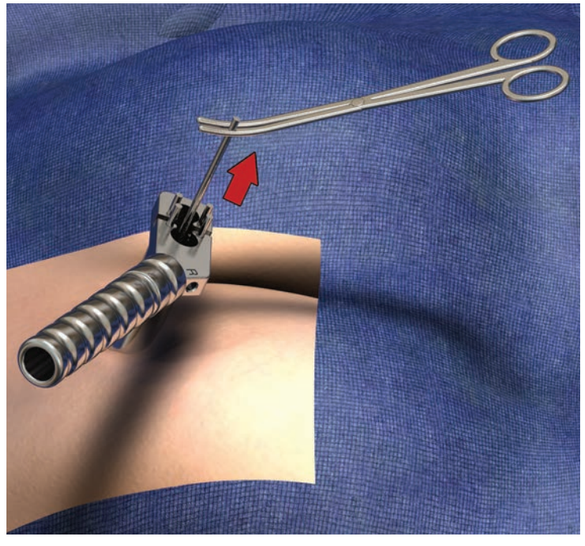


Figure 22.
Remove Graduated Guide Wire in an axial direction, avoiding excessive lateral movement.

Deliver the Catamaran Fixation Device and Confirm Placement

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 23 and 24).

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 23).

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

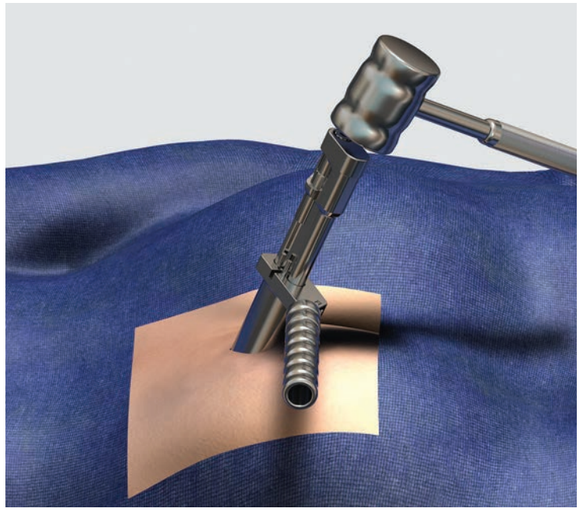


Figure 23.
Tap the Catamaran Fixation Device to the desired depth.

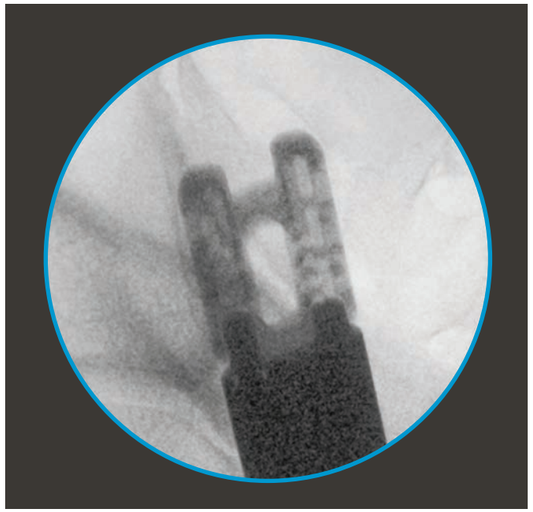


Figure 24.
Modified outlet view to confirm medial to lateral trajectory.

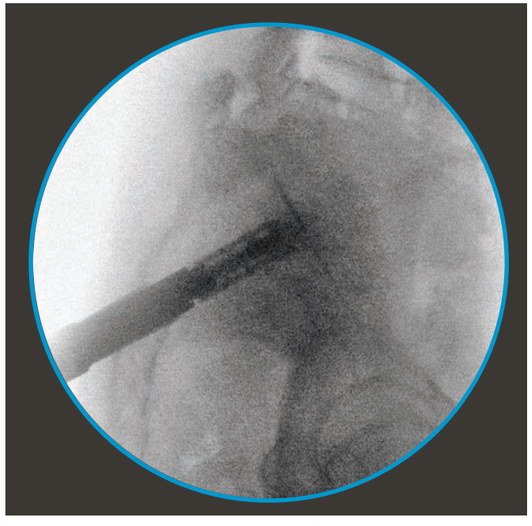


Figure 25.
Lateral view to confirm device depth.

Use fluoroscopy to confirm device position (Figure 24 and Figure 25).

Deliver the Catamaran Fixation Device and Confirm Placement *(Cont.)*

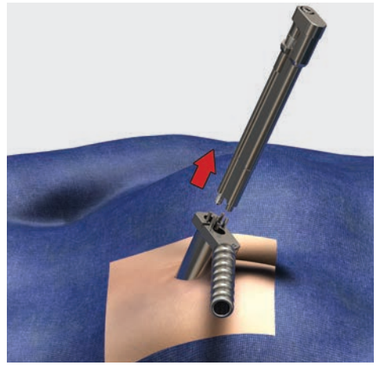


Figure 26.
Lateral view to confirm device depth.

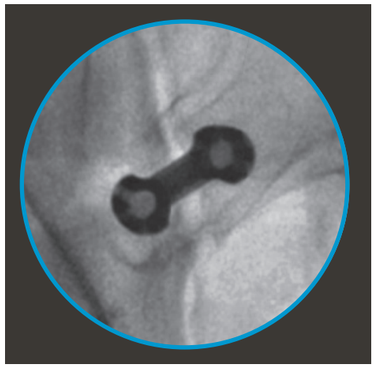


Figure 27.
MODIFIED INLET VIEW
Catamaran Fixation Device placement confirmed under fluoroscopy.

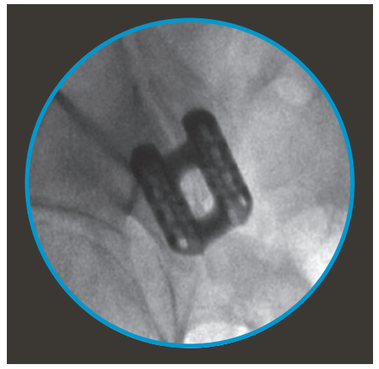


Figure 28.
MODIFIED OUTLET VIEW
Catamaran Fixation Device placement confirmed under fluoroscopy.

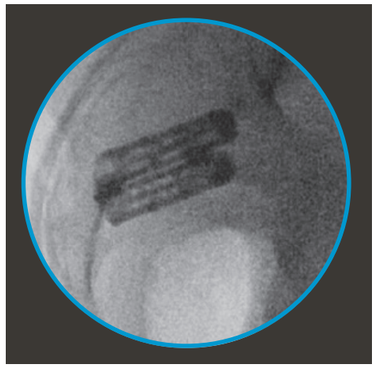


Figure 29.
LATERAL VIEW
Catamaran Fixation Device placement confirmed under fluoroscopy.

Post-pack the Catamaran Fixation Device

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

POST OPERATIVE 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® SE
SI Joint Fusion System

Additional autograft may be post packed with the Dual Port Loader and Graft Inserter (Figure 30A). Complete the surgery using the standard wound closure protocols.

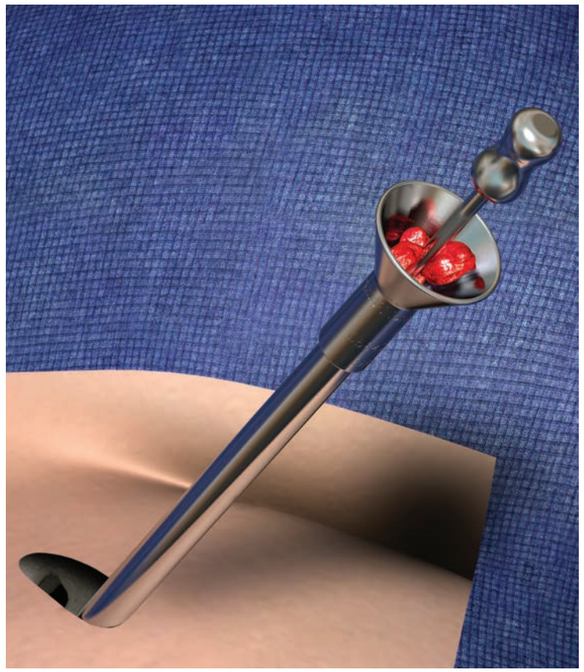


Figure 30.
Use Catamaran Bone Pusher to post-pack the implant.

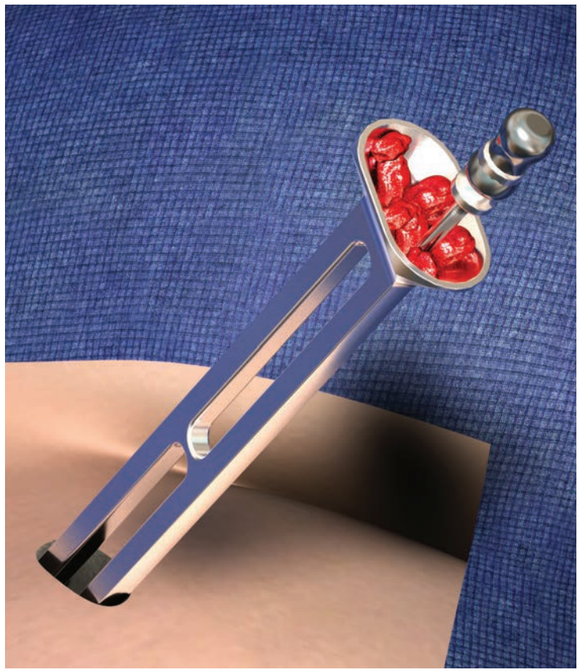


Figure 30A.
Use Catamaran Graft Inserter to post-pack the implant.

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

Catamaran Fixation Device Extraction

In all cases, the first and best option for removal is using 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 31). 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 the 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 extract and remove the Catamaran Fixation Device (Figure 32).

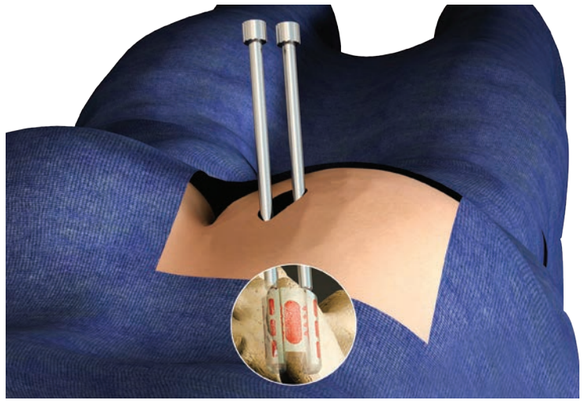


Figure 31.
Extraction Screws fitted into implant pontoons for removal.

Figure 32.
Extraction Fork fitted over Extraction Screws.

Catamaran SE SI Joint Fusion System Catamaran SE Fixation Intraoperative Device Extraction

- Prepare the Catamaran Fixation Device pontoons for the Insertion Screws, if necessary.
- Thread the Insertion Screws into the pontoons of the Catamaran Fixation Device until firmly snug. Use the 4.0mm Hex Key to firmly engage the insertion screws into the pontoons.
- Slide the forked end of the tool onto the heads of the Insertion Screws.
- Next, tap the strike plate end of the Intraoperative Extraction Tool with a large mallet to withdraw device.
- Stop tapping on the strike plate when the implant is withdrawn to the proper position.

NOTE:

In the event of post-operative Catamaran SE implant removal, a Catamaran Extraction Kit must be requested. Detailed instructions for kit utilization can be found in Step 11.

Catamaran Sterilization Tray Configuration

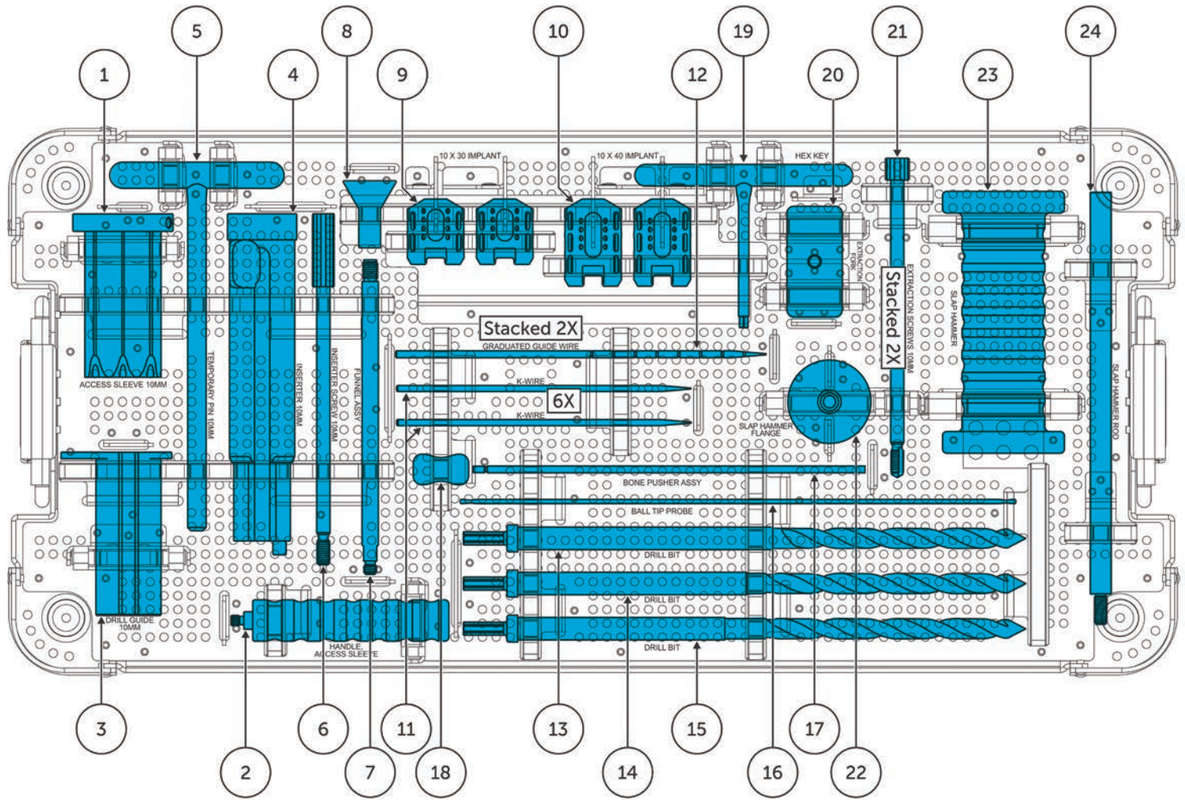


Table 1. Sterilization Tray Placement Key

ACCESS INSTRUMENTS	CATAMARAN FIXATION DEVICES	DRILL & DELIVERY 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

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

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

Catamaran
SI Joint Surgical Instruments (Cont.)

JIB KIT STERILIZATION TRAY CONFIGURATION

The Catamaran JIB Kit contains lower profile (LP) versions of the Access Sleeve (LP Access Sleeve) and Drill Guide (LP Drill Guide), and an extended length LP Inserter and LP Inserter Screw. These four reusable instruments are intended to be used in place of the corresponding four components from the Catamaran SI Joint Fusion System Tray to aid in preparing the pathway for drilling in the joint space as well as placing the Catamaran Fixation Device into position.

The K-Wire Driver is a reusable accessory tool to be used as an aid in the placement of the K-Wires through the LP Access Sleeve.

The Graft Remover and Loader Funnel accessories are used to aid in autograft collection and implant packing during the implant preparation stage of the procedure. The Loader Funnel is reusable, and the Graft Remover is single use.

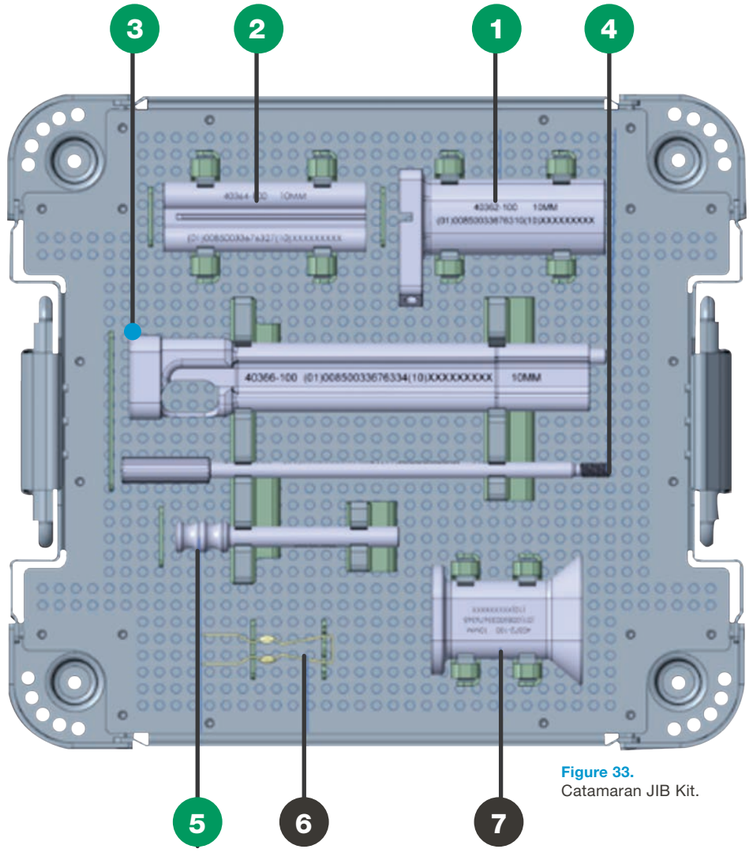


Figure 33.
Catamaran JIB Kit.

ACCESS INSTRUMENTS AND ACCESSORIES

1 LP Access Sleeve

2 LP Drill Guide

3 LP Inserter

4 LP Inserter Screw

5 K-Wire Driver (Accessory)

GRAFT COLLECTION ACCESORIES

6 Graft Remover

7 Loader Funnel

Jib Kit SI Joint Surgical Instruments

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.

LP Access Sleeve | 40362 | Reusable

LP Drill Guide | 40364 | Reusable

K-Wire Driver (Accessory) | 40370 | Reusable

DELIVERY INSTRUMENTS

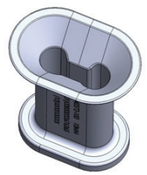
The Delivery instruments are used for placement and delivery of the Catamaran Fixation Device to the SI joint stabilization site.

LP Inserter | 40366 | Reusable

Inserter Screw | 40368 | Reusable

BONE GRAFT PACKING ACCESSORIES

The Bone Graft Packing accessories are used for removing autologous bone graft material from the drill bit and packing the material into the Catamaran Fixation Device prior to implantation.



Loader Funnel | 40372 | Reusable

Graft Remover | 40374 | Single Use

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.

Catamaran® SI Sterilization Tray Configuration

SI Joint Fusion System

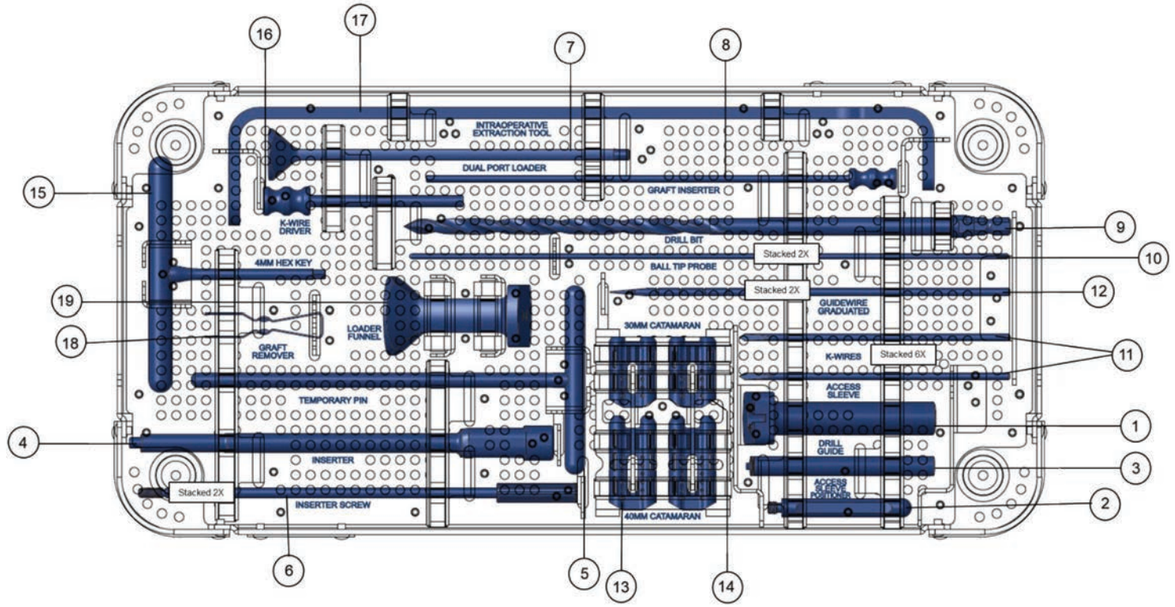


Table 2. Sterilization Tray Placement Key

ACCESS INSTRUMENTS	CATAMARAN FIXATION DEVICES	DRILL & DELIVERY INSTRUMENTS	BONE GRAFT PACKING INSTRUMENTS	EXTRACTION
1 Access Sleeve	13 Fixation Device, 40MM (2)	4 Inserter	7 Dual Port Loader	17 Intraoperative Extraction Tool
2 Access Sleeve Positioner	14 Fixation Device, 30MM (2)	5 Temporary Pin	8 Graft Inserter	
3 Drill Guide		6 Inserter Screw (2)	18 Graft Remover	
11 K-wire (6)		9 Drill Bit, 73MM	19 Loader Funnel	
12 Graduated Guide Wire (2)		10 Ball Tip Probe (2)		
16 K-Wire Driver		15 Hex Key, 4MM		

Catamaran® SE
SI Joint Fusion System

SI JOINT SURGICAL INSTRUMENTS

The Catamaran SE 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

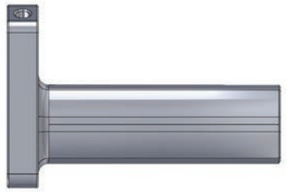
To accommodate patient anatomy, the Catamaran Fixation Device is available in two sizes, 30mm and 40mm.

Fixation Device 30MM (2) | 40295-01 | Single Use

Fixation Device 40MM (2) | 40295-02 | 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 | 40386 | Reusable

Access Sleeve Positioner | 40392 | Reusable

Drill Guide | 40388 | Reusable

K-wire (6) | 40322 | Single Use

Graduated Guide Wire (2) | 40320 | Single Use

K-Wire Driver | 40396 | Reuseable

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 | 40382 | Reusable

Temporary Pin | 40394 | Reusable

Inserter Screw (2) | 40384 | Reusable

Drill Bit 73MM | 40390 | Reusable

Ball Tip Probe (2) | 40330 | Single Use

Hex Key | 40338 | Reusable

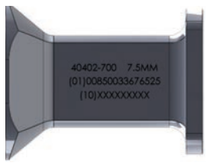
BONE GRAFT PACKING INSTRUMENTS

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.

Dual Port Loader | 40406 | Reusable

Graft Inserter | 40408 | Reusable

Graft Remover | 40404 | Reusable



Loader Funnel | 40402 | Reusable

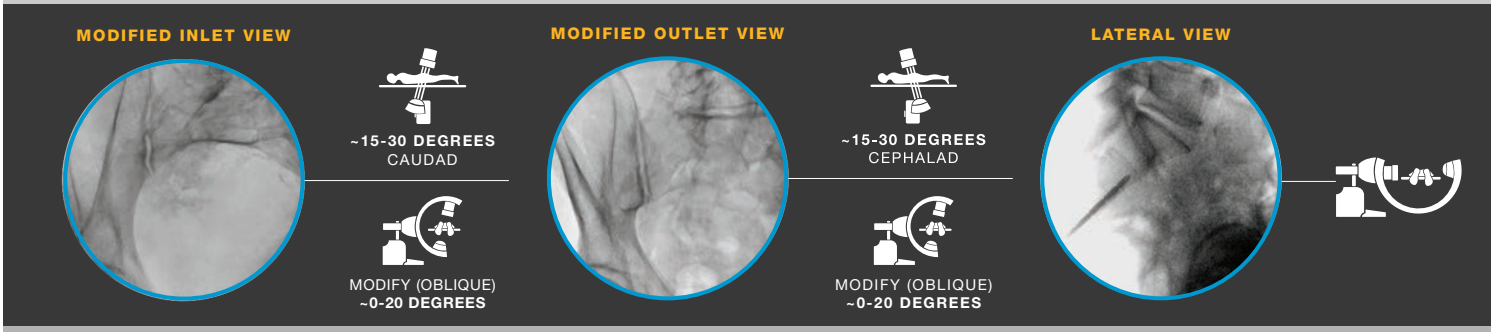
EXTRACTION INSTRUMENT

The Intraoperative Extract instrument is included in the event the Catamaran Fixation Device requires removal or repositioning.

Interoperative Extraction Tool | 40410 | Single Use

Catamaran SI Joint Imaging Overview

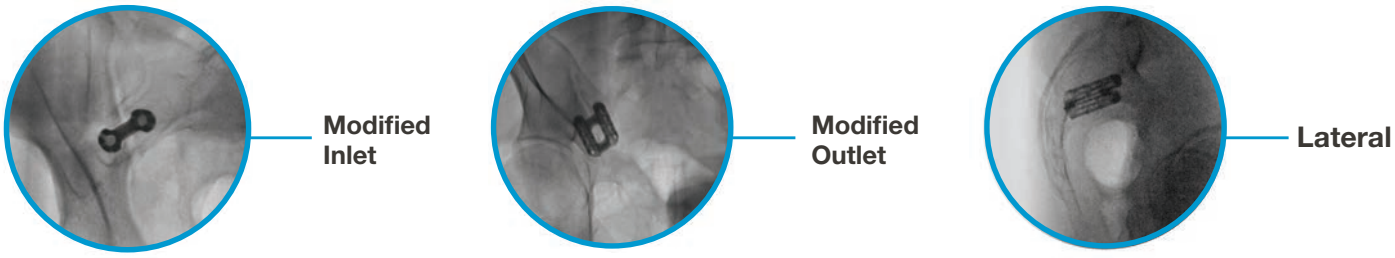
FLUOROSCOPIC IMAGING VIEWS



PROCEDURAL IMAGING SEQUENCE

STEP	VIEW	ACTION
1.	**Neutral AP**	Confirm pelvis is straight.
2.	**Lateral**	Align alar lines, assess dsymorphism.
3.	**Modified Inlet**	Establish skin entry: mark lines just below dorsal recess & just above pelvic floor, parallel to floor. Roll tip of spinal needle between marked lines until tip is positioned between lines. Lift hand and needle up at this point. Gently dock.
4	**Modified Outlet**	Confirm medial/lateral trajectory of guide wire –slight tap of guide wire.
5.	**Lateral**	Advance guide wire along pelvic rim towards sacral promontory. Stop short of aligned alar boundaries.
6.	**Modified Inlet**	Place one k wire on sacral side. Rotate access sleeve to “double barrel” view & confirm bone coverage. Finish securing access sleeve with additional k wires.
7.	**Modified Outlet**	Begin drilling to confirm medial/lateral trajectory.
8.	**Lateral**	Finish drilling and confirm depth is short of alar boundary.
9.	**Modified Outlet**	Begin implantation.
10.	**Lateral**	Finish implantation.

FINAL IMPLANT VIEWS



TENON MEDICAL®

Catamaran® SI Joint Fusion System

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