INSTRUCTIONS FOR USE

Catamaran® SI Joint Fusion System

℞only **CAUTION: Federal (U.S.) law restricts this device to sale by or on the order of a physician.**

IMPORTANT NOTICE:

It is highly recommended that the physician adheres to the instructions, precautions, contraindications, and warnings outlined in this document.

DEVICE DESCRIPTION:

The Catamaran SI Joint Fusion System includes the Catamaran Fixation Device and the following surgical instruments required to perform Inferior-Posterior Sacroiliac Fixation surgery: Access, Drill & Delivery, Bone Graft Packing, and Extraction instruments. The Catamaran Fixation Device is manufactured from medical grade ASTM F136-compliant titanium alloy (Ti6Al-4V ELI) and consists of two hollow barrels connected by a bridge. The implant barrels are 10mm in diameter and are available in two lengths: 30mm and 40mm. During the surgical procedure, autologous bone graft is packed into the implant barrels. The surgical instruments are manufactured from stainless steel. The Catamaran Fixation Device is intended for single use only. The instruments include single-use only and reusable instruments. All components of the Catamaran SI Joint Fusion System are provided NON-STERILE and must be cleaned and sterilized by the user prior to use according to instructions included in this document.

INDICATIONS FOR USE:

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

CONTRAINDICATIONS:

Patients with the following conditions:

- Skeletally immature spine
- Deformity
- Severe osteoporosis
- Morbid obesity
- Tumor resection
- Active infection at the treatment site

IMPLANTED DEVICE IDENTIFICATION CARD:

An Implanted Device Identification Card is included with the Catamaran SI Joint Fusion System. This is to be completed and given to the patient with instructions to keep the card as a record of surgery with a metallic implant.

WARNINGS:

- Patient sensitivity to implant materials should be considered and assessed prior to surgery.
- Due to immobilization of the SI joint, female patients of childbearing potential should be 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.
- All reusable instruments in the Catamaran System must be cleaned and sterilized between uses according to the instructions provided in this document. All unused implants and single use instruments must be re-sterilized prior to use according to the instructions provided in this document.
- Instruments should be checked closely prior to use. **If any discoloration is noted, the instrument should be discarded and a new instrument selected for clinical use to eliminate any potential risks associated with instrument oxidation.**

PRECAUTIONS:

- Carefully read the Instructions for Use and Surgical Technique Manual prior to device implantation. Observe all warnings and precautions noted in these documents. Failure to do so may result in complications or injury.
- Do **not** use this product if you have not been trained in its use.
- Correct positioning of the patient is required. The patient must be placed in a flat position on the surgical table prior to beginning the procedure. Failure to do so may result in incorrect positioning of the implant.
- The Catamaran Fixation Device should be implanted only under fluoroscopic visualization.
- The Catamaran Fixation Device should not extend beyond the mid S1 body, as this places it at risk of breaching into the pelvis.
- All components of the Catamaran SI Joint Fusion System are provided NON-STERILE and must be cleaned and sterilized prior to use according to the instructions included in this document.
- Inspect the surgical instruments, implants and sterilization tray for damage, wear, contamination, and malfunctioning parts. In case of visible debris and/or residues, the components must be cleaned again. Components with debris that cannot be removed or show signs of damage should not be used.
- Use only the Catamaran SI Joint Fusion System surgical instruments to implant the Catamaran Fixation Device.
- The Catamaran SI Joint Fusion System includes single-use and reusable instruments as specified in Table 1 of this document.
- Inspect the Catamaran Fixation Device and surgical instruments prior to use for corrosion or damage that could hamper function.
- Do not use damaged or worn instruments. Protect the Catamaran Fixation Device and surgical instruments from contact with objects that can damage the surface finish.
- For safe and effective use of the Catamaran SI Joint Fusion System, the physician should be familiar with the recommended surgical technique for this system. Incorrect size selection, placement, positioning, or seating of the implant may

result in suboptimal loading conditions, which could affect the long-term service life of the implant. Preoperative x-rays should be measured in all planes to determine optimal implant length and what size implants might be needed during the surgical procedure.

- Postoperative care is the responsibility of the individual physician.
- 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-weightbearing or partial weightbearing for a period of time in accordance with standard medical practice.
- Heavy physical activity may result in excessive stress on the implant and SI joint and may have the potential to cause failure of the device. Patients should be instructed on the limitations of a metallic implant as it may not be as strong as normal, healthy bone and may loosen or fracture if excessive loading or movement is placed on it through weight or activity.
- Patients who smoke may have an increased incidence of pseudoarthrosis and should be cautioned on the potential consequences.

POSSIBLE RISKS:

This section does not include all possible adverse events that can occur with any surgery. General surgical risks should be explained to the patient prior to surgery. The following are important considerations specific to metallic internal stabilization devices. As with other surgical procedures used to treat SI joint conditions, the risks associated with the Catamaran SI Joint Fusion System surgical procedure include, but are not limited to:

- Malposition of the device
- Device migration, subsidence, loosening, or fracture
- Chronic inflammation (foreign body reaction, bursitis) or allergic reaction related to the device
- Muscle and tissue injury or damage
- Infection
- Hematoma or bleeding
- Unsatisfactory clinical results that may include increased pain, flare-up of symptoms and/or non-union
- Fracture and/or erosion of the sacrum or ilium
- Neurological compromise
- Nerve root irritation
- Vascular injury
- Gastrointestinal injury
- Genital-urinary injury
- Osteolysis surrounding the implant
- Inability to complete the implantation of the device, which may require the use of another treatment modality to complete the therapy
- Additional surgical intervention due to any of the above factors (includes reoperation or supplemental fixation)

MRI SAFETY INFORMATION

MR Conditional Information	
MR Safety Information  **MR Conditional**	The CATAMARAN SI Joint Fixation Implant is MR Conditional. A patient with the CATAMARAN SI Joint Fixation Implant may be safely scanned under the following conditions. Failure to follow these conditions may result in injury to the patient.
Parameter	***Condition***
Nominal Values of Static Magnetic Field (T)	1.5-Tesla or 3.0-Tesla
Maximum Spatial Field Gradient (T/m and gauss/cm)	50-T/m (5,000-gauss/cm)
Type of RF Excitation	Circularly Polarized (CP) (i.e., Quadrature-Transmission)
Transmit RF Coil Information	There are no transmit RF coil restrictions. Accordingly, the following may be used: body transmit RF coil and all other RF coil combinations (i.e., body RF coil combined with any receive-only RF coil, transmit/receive head RF coil, transmit/receive knee RF coil, etc.)
Operating Mode of MR System	Normal Operating Mode
Maximum Whole Body Averaged SAR	2-W/kg
Limits on Scan Duration	Whole body averaged SAR of 2-W/kg for 60 minutes of continuous RF exposure (i.e., per pulse sequence or back-to-back sequences/series without breaks)
MR Image Artifact	The presence of this implant produces an imaging artifact.

HOW SUPPLIED / STORAGE AND HANDLING:

The Catamaran Fixation Device and surgical instruments are **supplied non-sterile and must be sterilized prior to use** according to the sterilization instructions provided in these Instructions for Use.

The Catamaran Fixation Device and specified instruments are intended for single use only. Reusable instruments must be cleaned and re-sterilized following these instructions prior to clinical use. Unused single use Catamaran Fixation Devices and single use instruments must be re-sterilized following sterilization instructions provided in these Instructions for Use.

The Catamaran Fixation Device and surgical instruments should be correctly stored in the supplied sterilization tray. Care should be taken to ensure that the components are not damaged. Store in a cool, dry place.

CATAMARAN SI JOINT FUSION SYSTEM COMPONENTS:

Catamaran Fixation Device

The Catamaran Fixation Device (implant) is manufactured from medical grade, ASTM F136-compliant titanium aluminum alloy (Ti6A1-4V ELI) and is available in the sizes shown in Table 1.

Catamaran SI Joint Instruments

The Catamaran SI Joint Instruments are required for implantation of the Catamaran Fixation Device. These instruments are grouped into four categories as shown in Table 1.

Table 1. Catamaran SI Joint Fusion System		
Catamaran Fixation Device		
40295-03	10mm x 30mm Implant (2)	Single Use
40295-04	10mm x 40mm Implant (2)	Single Use
Catamaran SI Joint Surgical Instruments		
Access Instruments		
40316	Access Sleeve	Reusable
40318	Access Sleeve Handle	Reusable
40320	Graduated Guide Wire (2)	Single Use
40322	K-Wire (6)	Single Use
40326	Drill Guide	Reusable
Drill & Delivery Instruments		
40328	Drill Bit, 50mm	Reusable
40329	Drill Bit, 60mm	Reusable
40330	Ball Tip Probe	Single Use
40331	Drill Bit, 70mm	Reusable
40332	Temporary Pin	Reusable
40334	Inserter	Reusable
40336	Inserter Screw	Reusable
40338	Hex Key	Reusable
Bone Graft Packing Instruments		
40344	Bone Pusher Head	Single Use
40346	Bone Pusher Rod	Single Use
40340	Funnel Tube	Reusable
40342	Funnel Cone	Reusable
Extraction Instruments		
40348	Extraction Fork	Reusable
40350	Extraction Screw	Single Use
40352	Slap Hammer	Reusable
40354	Slap Hammer Rod	Reusable
40356	Slap Hammer Flange	Reusable

STERILIZATION:

The Catamaran SI Joint Fusion System, including Fixation Device and instruments, is provided non-sterile and must be sterilized prior to use using steam sterilization.

Single-use Instruments and Implants: The single-use instruments and implants are intended to be used surgically one time and then properly disposed of or implanted (Catamaran SI Joint Fixation Device). Unused instruments and implants may be re-sterilized for future clinical use. Single-use instruments include: Graduated Guide Wires, K-wires, Bone Pusher Rod and Head, Ball Tip Probe. The Extraction Screw is intended for single use only.

Reusable Instruments: Before sterilization and reuse, inspect all reusable instruments for possible damage, wear, or non-functioning parts. Carefully inspect critical, inaccessible areas, joints, and all movable parts. Damaged or defective instruments should **not** be used or processed for reuse. Sterilization of all reusable instruments should only be performed after instrument cleaning in accordance with the recommended cleaning instructions provided in this document.

NOTE: Instruments with multiple components are shipped disassembled and should remain disassembled for sterilization.

NOTE: Any disassembled instruments should remain disassembled during sterilization and reassembled after sterilization, in preparation for the next patient use. To reassemble, twist the instrument component in a clockwise direction.

Place the Catamaran Fixation Device and instruments (single-use and reusable) into the provided Sterilization Tray and double wrap with woven or nonwoven sterilization wrap for sterilization.

NOTE: Only commercially available, FDA-cleared, medical grade steam sterilization wraps or other FDA-cleared sterilization accessories that have been validated to allow sterilant penetration as well as sterility maintenance should be utilized. The package should be prepared using the AAMI double wrap or equivalent method.

NOTE: For further details, refer to the Sterilization Tray Configuration Section of these instructions.

Steam autoclave (moist heat) sterilization using a pre-vacuum (forced air removal) cycle is recommended. Installation, care, and maintenance of sterilizers must be conducted according to ANSI/AAMI ST79. Tenon Medical has validated an autoclave cycle for sterilization of the complete sterilization tray with implants and instruments. The process parameters in Table 2 are validated and recommended by Tenon Medical for sterilization. Follow all autoclave manufacturer instructions for recommended maximum sterilization load, installation, calibration, and maintenance.

Sterilization is recommended using the parameters provided in Table 2.

Verify components are in working order prior to next patient use. Reassemble any disassembled instruments. To reassemble, twist the instrument component in a clockwise direction.

Table 2. Recommended Sterilization Parameters

Method	Moist Heat Sterilization According to ANSI/AAMI ST79
Cycle	Pre-vacuum
Temperature	132°C (270°F)
Exposure Time	4 minutes (minimum)
Drying Time	45 minutes (minimum, in chamber)

PRECAUTIONS/WARNINGS:

- Do not use any other sterilization method for the Catamaran Fixation Device or associated instruments.
- The use of flash sterilization is not recommended for reusable instruments.
- Do **not** attempt to reuse single-use instruments that have been used in a prior patient surgery.
- Do **not** use damaged or worn instruments. Inspect the Catamaran SI Joint System reusable instruments for corrosion or wear that could hamper function of the instruments prior to use.
- Use only the Instrument Sterilization Tray provided with the Catamaran System.

CLEANING INSTRUCTIONS FOR REUSABLE INSTRUMENTS:

Once used in surgery and exposed to bodily fluids, the Catamaran Fixation Device and single-use instruments should not be cleaned and reused. The following cleaning instructions are specific only to the reusable instruments that are part of the Catamaran System. The reusable instruments should be cleaned before sterilization between clinical procedures in accordance with the following instructions.

Disassembly:

The Access Sleeve, Extraction Slap Hammer, and Funnel should be disassembled prior to cleaning by twisting the instrument component in a counterclockwise direction (see Figures 1, 2, and 3).

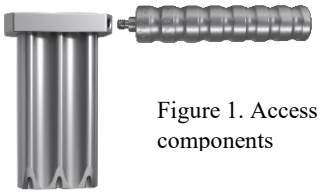

Figure 1. Access Sleeve separated into two components

Figure 2. Funnel separated into two components

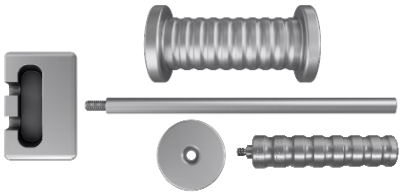

Figure 3. Extraction Slap Hammer separated into five components

Only cleaning agents with proven efficacy (FDA approved/cleared) should be used. All cleaning agents should be prepared at the use dilution and temperature recommended by the manufacturer. Softened tap water may be used to prepare cleaning agents. Use of recommended temperatures is important for optimal performance of cleaning agents. Fresh cleaning solution should be prepared when existing solution becomes grossly contaminated (bloody and/or turbid).

Manual Pre-cleaning:

Do not allow saline, blood, body fluids, tissue, bone fragments or other organic debris to dry on instruments prior to cleaning.

1. Rinse instruments under running tap water for a minimum of 3 minutes to remove gross soil.
2. While rinsing, brush all exterior sites with a soft bristled M16 brush for a minimum of 1 minute. Brush the lumen four times using a 3mm x 12inch, lumen brush.
3. While rinsing, flush a minimum of 360mL per instrument using a 60mL syringe. Ensure all spaces and lumens are flushed.
4. Transfer the instruments to the washer for processing according to the instructions in Table 3.

Table 3. Mechanical Washer Instructions (Motor speed: high):

Phase	Recirculation Time (min)	Temperature	Detergent Type and Concentration
Pre-wash 1	02:00	Cold tap water	N/A
Enzyme	02:00	Hot tap water	Prolystica 2X Enzymatic 1/8 oz/gallon
Wash 1	02:00	65.5°C	Prolystica 2X Enzymatic 1/8 oz/gallon
High Purity Rinse	01:00	RO/DI or higher water quality	N/A
Drying	07:00	90°C	N/A

Components must be completely dry before the autoclave sterilization cycle. Dry the devices thoroughly with a clean lint-free cloth or filtered pressurized air.

Inspect all components for any residual contamination. If contamination is seen, repeat cleaning steps. Verify components are in working order prior to next patient use.

NOTE: Any disassembled instruments should remain disassembled during sterilization and reassembled after sterilization, prior to the next patient use. To reassemble, twist the instrument component in a clockwise direction.

Precautions:

1. **The Catamaran Fixation Device should not extend beyond the mid S1 body, as this places it at risk of breaching into the pelvis.**
2. **Always drill under fluoroscopy to verify drill hole depth.**
3. **Always tap the Fixation Device under fluoroscopy to verify position. Inserting the device beyond the correct depth may result in anterior bone fracture and/or displacement.**

DIRECTIONS FOR USE:

1. Only one (1) implant per sacroiliac joint is recommended for treatment.
2. For detailed surgical technique information, refer to the Catamaran SI Joint Fusion System Surgical Technique Manual.

GRAPHIC SYMBOL KEY:

Symbol	Title of Symbol	Description of Symbol
	Batch Code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	Catalogue Number	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	Caution	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
	Do not use if package is damaged	Indicates a medical device that should not be used if the package has been damaged or opened.
	Non-sterile	Indicates a medical device that has not been subjected to a sterilization process.
	Manufacturer	Indicates the medical device manufacturer, as defined in EU directives 90/385/EEC, 93/42/EEC and 98/79/EC.
	Do not re-use	Indicates the medical device is intended for single patient use only and not for re-use.
	MR Conditional	The Catamaran SI Joint Fixation Implant is MR Conditional. A patient with the Catamaran SI Joint Fixation Implant may be safely scanned under the conditions described in this Instruction for Use. Failure to follow these conditions may result in injury to the patient.
	Used by Prescription Only	Federal Laws (USA) restricts this device to sale by or on the order of a physician

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