



Tenon Medical, Inc.

Catamaran® JIB Kit

INSTRUCTIONS FOR USE

R_xonly *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, contraindications, warnings, and precautions outlined in this document.

DEVICE DESCRIPTION:

The Catamaran JIB Kit includes a set of instruments and accessories to be used in conjunction with the Catamaran® SI Joint Fusion System. Refer to IFU001 for the Instructions on the Catamaran SI Joint Fusion System. All components of the Catamaran JIB Kit 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.

INTENDED USE:

The Catamaran JIB Kit is intended to be used in conjunction with the Catamaran SI Joint Fusion System for accessing the implant site, implant delivery and to facilitate bone graft removal and insertion into the implant.

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

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 components in the Catamaran JIB Kit must be cleaned and sterilized between uses according to the instructions provided in this document.
- All components should be checked closely prior to use. **If any discoloration is noted, the component should be discarded and a new component selected for clinical use to eliminate any potential risks associated with component oxidation.**

PRECAUTIONS:

- Carefully read the Catamaran JIB KIT Instructions for Use (IFU002) and Surgical Technique Manual (STM002), as well as the Catamaran SI Joint Fusion Instructions for Use (IFU001) and Surgical Technique Manual (STM001) 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 JIB Kit 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 and JIB Kit surgical instruments and accessories to implant the Catamaran Fixation Device.
- The Catamaran JIB Kit includes both single-use and reusable components as specified in Table 1 of this document.
- Inspect the Catamaran JIB Kit components prior to use for corrosion or damage that could hamper function.
- Do **not** use damaged or worn components. Protect the Catamaran Fixation Device, and surgical instruments and accessories 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)

MR SAFETY AND COMPATIBILITY:

MR Conditional Information	
 <p>MR Safety Information</p>	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.
MR Conditional 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:

All components of the Catamaran JIB Kit are provided **NON-STERILE** and must be cleaned and sterilized by the user prior to use according to the instructions included in this document.

The Catamaran JIB Kit components include both single use and reusable instruments and accessories. Reusable components must be cleaned and resterilized between patient use following these instructions.

The Catamaran JIB Kit components 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 JIB KIT COMPONENTS:

Table 1. Catamaran JIB Kit		
Access Instruments and Accessories		
40362	LP Access Sleeve	Reusable
40364	LP Drill Guide	Reusable
40366	LP Inserter	Reusable
40368	LP Inserter Screw	Reusable
40370	K-Wire Driver (Accessory)	Reusable
Graft Collection Accessories		
40372	Loader Funnel	Reusable
40374	Graft Remover	Single Use

STERILIZATION:

The Catamaran JIB Kit components are provided **NON-STERILE** and must be cleaned and steam sterilized prior to use.

Single-use Accessories: The single-use accessories are intended to be used surgically one time and then properly disposed of. Unused accessories may be resterilized for future use. Single-use accessories include: Graft Remover.

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

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

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

Place the Catamaran JIB Kit components (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 Catamaran JIB Kit components. The process parameters in Table 2 have been 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 / accessories. To reassemble, twist the component in a clockwise direction.

Table 2. Recommended Sterilization Parameters

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

WARNINGS/PRECAUTIONS:

- Do **not** use any other sterilization method for the Catamaran JIB Kit.
- The use of flash sterilization is not recommended for reusable components.
- Do **not** attempt to reuse single-use components.
- Do **not** use damaged or worn components. Inspect the Catamaran JIB Kit reusable components for corrosion or wear that could hamper the function of the components prior to use.
- Use only the Sterilization Tray provided with the Catamaran JIB Kit.

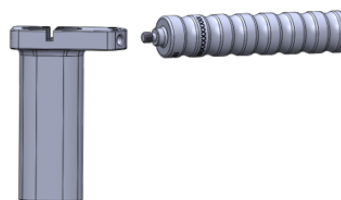
CLEANING INSTRUCTIONS FOR REUSABLE INSTRUMENTS:

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

Disassembly:

The LP Access Sleeve should be disassembled prior to cleaning by twisting the instrument component in a counterclockwise direction (see Figure 1).

Figure 1. LP Access Sleeve separated into two 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.

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 (STM001) and the Catamaran JIB Kit Surgical Technique Manual Addendum (STM002).

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.
	Used by Prescription Only	Federal Laws (USA) restricts this device to sale by or on the order of a physician

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/gal
Wash 1	02:00	65.5°C	Prolystica 2X Enzymatic 1/8 oz/gal
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 components 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.**



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