



Tenon Medical, Inc. Catamaran® JIB Kit Surgical Technique Manual Addendum

The Tenon Medical Catamaran JIB Kit is an additional tray set of instruments and accessories to be used in conjunction with the Tenon Medical Catamaran® SI joint Fusion System.

This Addendum does not offer complete guidance for the Catamaran SI joint Fusion System and Catamaran® Fixation Device implantation; it only describes the detailed steps for the use of the Catamaran JIB Kit. For complete guidance on surgical techniques, please refer to the Surgical Technique Manual STM001.

The Catamaran JIB Kit consists of 7 components (Table 1).

Table 1. Catamaran JIB Kit

ACCESS INSTRUMENTS and ACCESSORY	GRAFT COLLECTION ACCESSORIES
1 LP Access Sleeve	6 Graft Remover
2 LP Drill Guide	7 Loader Funnel
3 LP Inserter	
4 LP Inserter Screw	
5 K-Wire Driver (Accessory)	

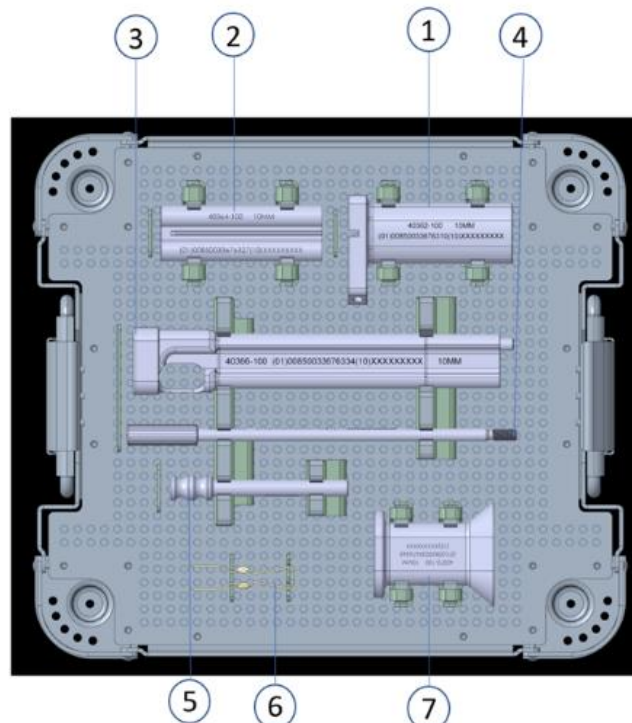


Figure 1. Catamaran JIB Kit Sterilization Tray Configuration

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For Customer Service and Reporting of Complaints or Adverse Events:

Use the following for information for customer service, including ordering, reporting complaints, or adverse events, and general information regarding Tenon Medical or products and services:

Tenon Medical
104 Cooper Court
Los Gatos, CA 95032
Direct: 408.649.5760
Fax: 408.649.5756

Manufactured for:

Tenon Medical
104 Cooper Court
Los Gatos, CA 95032
Direct: 408.649.5760
Fax: 408.649.5756

Introduction

Use of This Manual

This manual provides details specific to the Catamaran JIB Kit. This kit is designed to be used with the Catamaran SI Joint Fusion System.

Refer to the Catamaran SI Joint Fusion System Surgical Technique Manual STM001 and Instructions for Use IFU001 for full surgical procedure steps, information, warnings, precautions, and risks.

Refer to the Catamaran JIB Kit Instructions for Use, IFU002, for information on cleaning and sterilization.

General Warnings and Precaution:

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.

Failure to properly follow all instructions may lead to injury and improper functioning of the system. Avoid exerting excessive force as breakage or damage may occur when an instrument is subjected to excessive or inappropriate loads and / or angles.

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

Device Description:

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.

Procedural Steps

Refer to the Catamaran SI Joint Fusion System Manual STM001 for complete surgical procedure steps. The following steps should be followed when using the Catamaran JIB Kit, starting at Step 6 from STM001.

STEP 6 CATAMARAN JIB KIT SURGICAL TECHNIQUE Assemble the LP Access Sleeve and LP Drill Guide

The LP Access Sleeve Assembly



Figure 2. LP Access Sleeve | 40362



LP Drill Guide | 40364

Thread the Access Sleeve Handle into the LP Access Sleeve (Figure 3). 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.

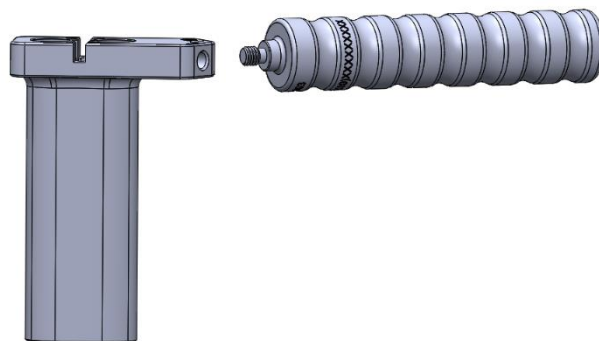


Figure 3. Thread Access Sleeve Handle into LP Access Sleeve

Insert the LP Drill Guide into the LP Access Sleeve (Figure 4). The LP Drill Guide lip facilitates the removal of the LP Drill Guide from the LP Access Sleeve from either orientation.

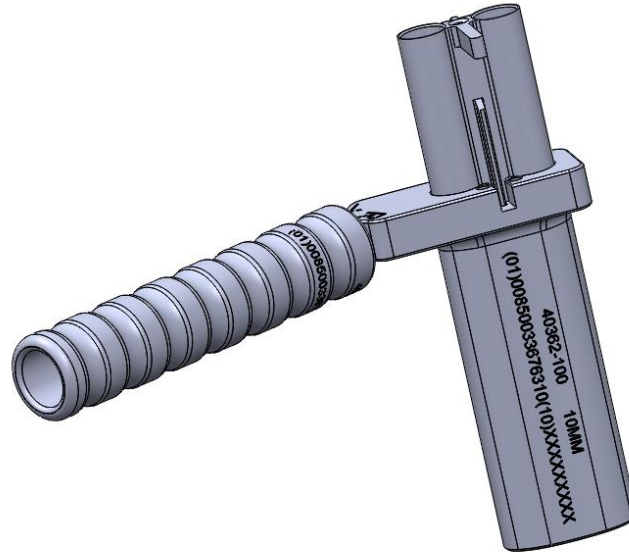


Figure 4. Insert LP Drill Guide into LP Access Sleeve

STEP 7 CATAMARAN JIB KIT SURGICAL TECHNIQUE

Insert LP Access Sleeve Assembly

Place the LP Drill Guide over the Graduated Guide Wire, ensuring the Graduated Guide Wire is in the center hole. Position the LP Access Sleeve Assembly with the handle pointing away from the midline and perpendicular to the axis of the spine (Figure 5).

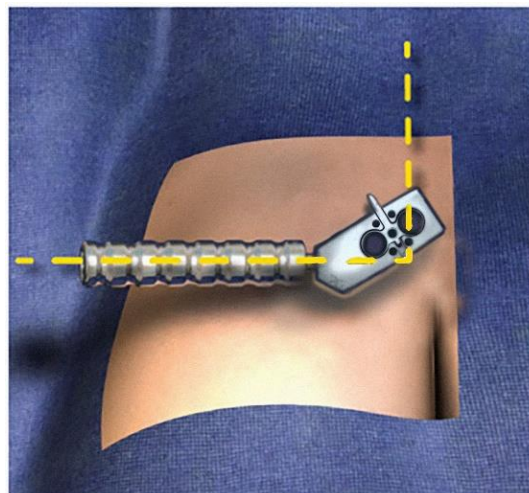


Figure 5. Handle Perpendicular to Spine

Place all four K-Wires through the holes on the LP Access Sleeve (Figure 6). Avoiding the Graduated Guidewire, gently tap the K-Wires to initially secure the LP Access Sleeve. Once secure, the K-Wire Driver can be used to aid in driving the K-Wires into the bone (Figure 7).

Caution: Place K-Wires under fluoroscopy and verify adequate bone purchase.

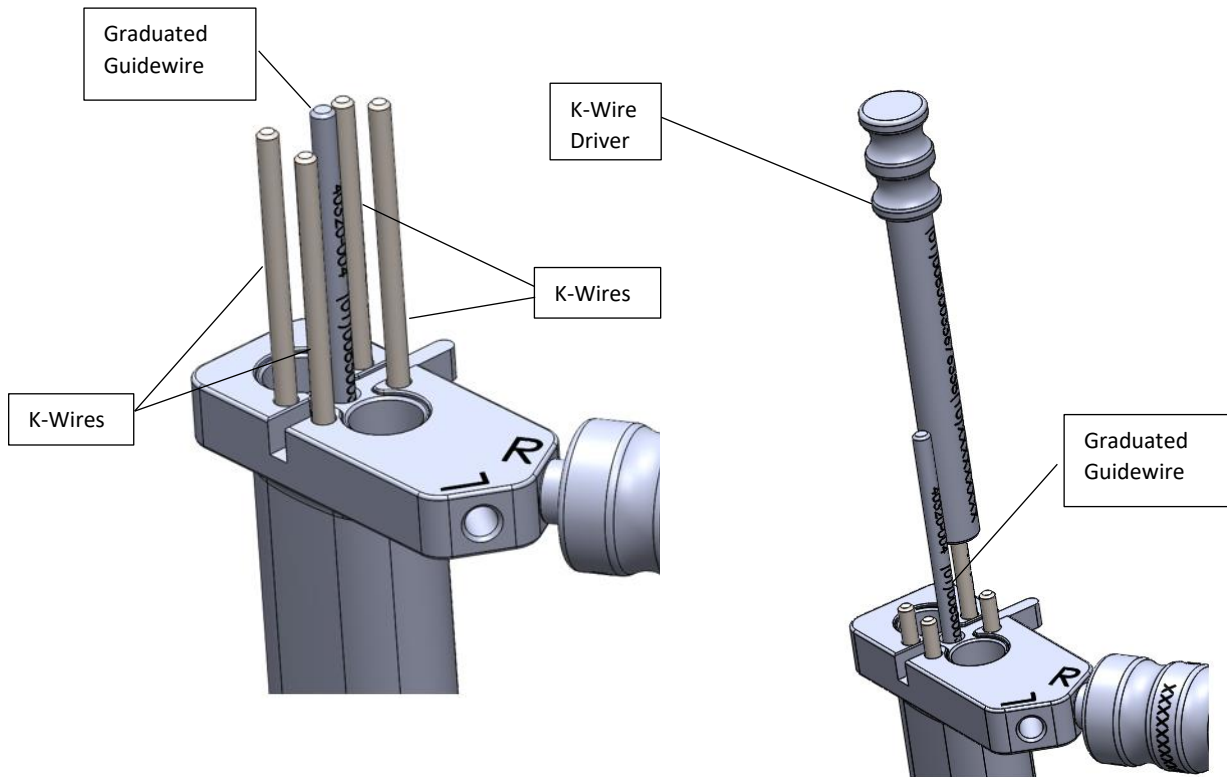


Figure 6. Anchor LP Access Sleeve with K-wires

Figure 7. Use K-wire Driver to Drive K-wires into Bone

After stabilizing the LP Access Sleeve refer to **STM001** for **STEP 8 & STEP 9** to determine drill depth and Catamaran Fixation Device length and for drilling the pontoon channels.

After drilling each pontoon channel, as directed in STM001, the Graft Remover and Loader Funnel can be used to collect the autograft from the drill bit and load the bone material into the implant.

Graft Collection

Place the Catamaran Fixation Device into the Loader Funnel with the open ends of the pontoons facing up (Figure 8).

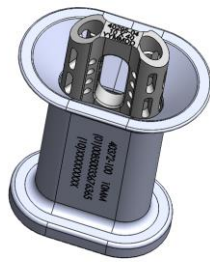


Figure 8. Place Catamaran Fixation Device into Loader Funnel

After drilling the first hole, clip the Graft Remover onto the drill (Figure 9). 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 10).

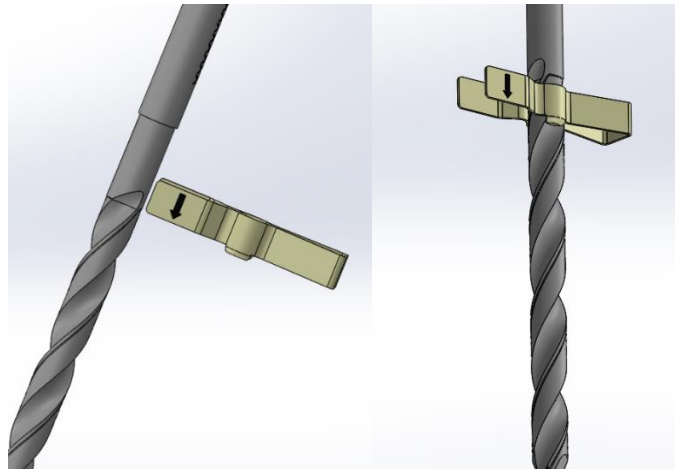


Figure 9. Harvest autograft from Drill Bit.

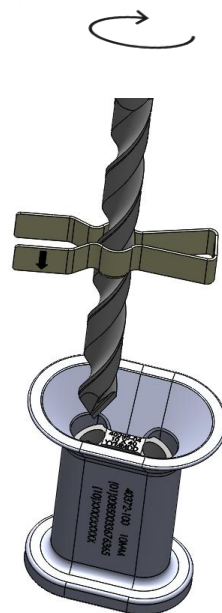


Figure 10. Load autograft into the Implant.

Repeat the same process for the second drill hole.

Using the 4 mm Hex Key or Bone Pusher Rod, pack the graft into the pontoons. Take care to leave the proximal threaded portion of the pontoons free of autograft to ensure a firm interface with the LP Inserter.

STEP 10 CATAMARAN JIB KIT SURGICAL TECHNIQUE

Prepare the Implant for Delivery

Cannulate the LP Inserter Screw through the LP Inserter. Attach the Catamaran Fixation Device onto the distal end of the Inserter Handle (Figure 11). Align the boss into the one pontoon and thread the LP Insertion Screw into the other pontoon.

Finger tighten the LP 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.

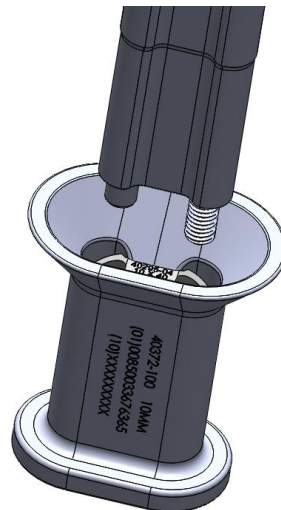


Figure 11. Attach Catamaran Fixation Device to Inserter Handle

With the LP Inserter attached, remove the implant from the Loader Funnel. The implant is now ready for delivery into the drilled pontoon channels and SI joint. Refer to implantation **STEPS 11 – 13** in **STM001** to complete the surgical procedure.

Catamaran JIB Kit

The Catamaran JIB Kit includes the following stainless steel surgical instruments and accessories designed to be used with the Catamaran SI Joint Fusion System.

LP ACCESS INSTRUMENTS and ACCESSORY

The LP Access Instruments and Accessory, when used with the Access Sleeve Handle, Graduated Guide Wire, and K-Wires 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.



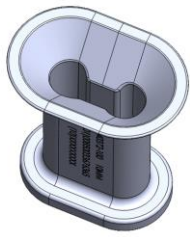
LP Inserter | 40366 | Reusable



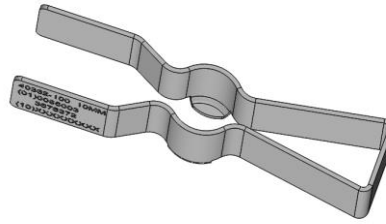
LP Inserter Screw | 40368 | Reusable

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 JIB Kit are provided **NON-STERILE** and must be cleaned and sterilized prior to use. Please review the **Instructions For Use IFU002** provided with this kit for cleaning and sterilization instructions. The surgical instruments and accessories are manufactured from stainless steel.



Tenon Medical
104 Cooper Ct.
Los Gatos, CA 95032
(408) 649-5760