Instructions for Use

IMPORTANT MEDICAL INFORMATION
Instructions for Use

SIMPARO ANCHOR LINE FIXATION SYSTEM
Models # SALFS-001 & SALFS-002

SIMPARO ANCHOR LINE FIXATION SYSTEM – EXTRACTION KIT
Model # SALFS-003

DESCRIPTION:

The human thumb has a considerable multiplanar range of motion allowing for grasping and pinching capabilities. Dexterity of this joint may be limited by trauma or disease such as osteoarthritis (OA) in the first carpometacarpal (CMC) joint where the thumb metacarpal articulates with the trapezium in the wrist. Treatment of this painful arthritic condition typically involves excision of the trapezium (trapeziectomy). After the trapeziectomy, the surgeon will implant a device such as the Simparo Anchor Line Fixation System to provide stabilization and maintain alignment during the healing process.

The Simparo Anchor Line Fixation System is a device that consists of two titanium anchors, joined together by a continuous loop of number 2 non-absorbable multi-filament polyethylene suture. The index anchor with attached suture is preloaded on a driver and deployed into a pre-drilled index hole in the second metacarpal. The index anchor is inserted into the base of the index metacarpal and the driver removed.

The thumb anchor is located in a foam block in the handle of the driver and the operative suture is attached. The thumb anchor slides down the 2 operative limbs of the suture, positioned on the thumb driver and partially deployed into the pre-drilled hole at the base of the thumb metacarpal. The suture slack is removed, the anchor is tightened into the base of the thumb metacarpal and the thumb driver is removed. Then the two exiting suture limbs are tied with four square knots within the arthroplasty space and trimmed.

The Simparo Anchor Line Fixation System – Extraction Kit consists of an index anchor driver and a thumb anchor driver only.

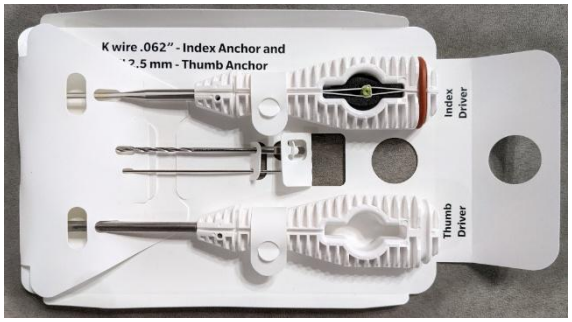

Figure 1. Simparo Anchor Line Fixation System (SALFS-001/SALFS-002)

SIMPARO ANCHOR LINE FRACTURE FIXATION SYSTEM MATERIAL SPECIFICATIONS:

The materials used in the Simparo Anchor Line Fixation System and Simparo Anchor Line Fixation System – Extraction Kit are common to other marketed orthopedic implants. Stainless Steel, Titanium/Titanium Alloys and PEEK are often used in orthopedic implants such as plates and screws, hip stems and spinal implants.

The common materials used to manufacture the Simparo Anchor Line Fixation System and Extraction Kit are industry standards.

Table A: Material of Construction

Implant Device	**Material**
Index Anchor 5mm	Titanium Alloy Ti 6Al-4V Medical Grade
Thumb Anchor 5mm	Titanium Alloy Ti 6Al-4V Medical Grade
Thumb Anchor Washer	PEEK
Suture #2 Braided	Polyethylene UHMWP "Force Fiber
K-Wire .062"	Stainless Steel 304 Trocar point
Instruments	**Material**
Index Handle/Driver Shaft	Polycarbonate/Stainless Steel 465
O-Ring securing suture on the Index Handle	High Temperature/High Purity Silicone
Foam Block	Closed Cell Foam (PE-Cross Linked) Plastazote PE
Thumb handle/Driver Shaft	Polycarbonate/Stainless Steel 465
Drill Bit	(Product Class HWE – Class I Exempt) SS 304

GENERAL PRODUCT INFORMATION:

The Simparo Anchor Line Fixation System and the Extraction Kit are used by surgeons that have adequate training and have received information regarding this product.

Through the advancement of surgical devices, surgeons are provided a tool for correcting a patient's anatomical situation (deformity, trauma, disease) to elevate the patient's pain.

The surgeon should be aware of the following:

- The device is the correct size, shape and design necessary for a successful patient outcome.
- The implant requires proper placement, and the bone support is adequate to secure the anchors.
- The surgeon should consider the patient's activity level. The patient/guardian must understand the limitations following surgery and rehabilitation.
- The surgeon should conduct appropriate tests where material sensitivity is a concern.

INTENDED USE:

The Simparo Anchor Line Fixation System, when used for fixation of bone-to-bone or soft-tissue to-bone, is intended as an anchor fixation system, a distribution bridge, or for distributing suture tension over areas of ligament or tendon repair.

INDICATIONS FOR USE:

The Simparo Anchor Line Fixation System is indicated for carpometacarpal (CMC) joint arthroplasty as an adjunct in the suspension of the thumb metacarpal during the healing process of hematoma distraction arthroplasty by providing stabilization at the base of the first and second metacarpals when the trapezium has been excised due to osteoarthritis.

PERFORMANCE:

Misuse of the device or patient noncompliance may adversely affect performance. In no case does the Simparo Anchor Line Fixation implant replace a healthy bone structure.

CONTRAINDICATIONS:

- Insufficient quantity or quality of bone.
- Blood supply limitations which may retard healing.
- Previous or active infection
- Foreign body sensitivity. Where material sensitivity is suspected, appropriate tests should be made, and sensitivity ruled out prior to implantation.
- Foreign body reactions.
- Conditions that tend to limit the patient’s ability or willingness to restrict activities or follow directions during the healing period.
- Do not use for surgeries other than those indicated

Contraindications may be absolute or relative and are left to the discretion of the surgeon.

CONDITIONS PRESENTING INCREASED RISK:

- Active Infection
- Blood supply limitation that may delay healing
- Inadequate skin, bone or neurovascular status
- Active fever
- Foreign body reaction

POTENTIAL COMPLICATIONS AND ADVERSE REACTIONS:

Any surgical procedure has the potential for complications. The risks and complications with the Simparo Anchor Line Fixation System include the following:

- Infection or painful, swelling or inflammation at implant site
- Damage or fracture to the implant
- Surgical error in implantation of the implant
- Loosening or dislocation of the implant requiring revision surgery
- Allergic reaction to the implanted material

WARNINGS:

The Simparo Anchor Line Fixation System is intended for Single Use Only. If opened but not used may not be resterilized or reused.

PRECAUTIONS:

Surgeons are advised to review the Simparo Anchor Line Fixation System Surgical Technique prior to performing surgery.

CAUTION STATEMENT:

The Simparo Anchor Line Fixation System has not been evaluated for safety and compatibility in the MRI environment.

PREOPERATIVE:

- Proper understanding of the device and technique is essential.
- Patient selection should be in accordance with the listed indications and contraindications for use of the device.
- Upon arrival of the system at the hospital/surgical center inspect the device for damage during shipment that may increase the likelihood of fragmentation during the procedure.
- Inspect the sterile pouch for any holes or damage that may compromise sterility.

INTRAOPERATIVE:

- Use the Anchor Line Fixation System in accordance with labeled recommendations, manufacturer's instructions for use and the surgical technique.
- Check implantation under Fluro.
- As with all forms of thumb CMC joint arthritis reconstruction, the surgeon must avoid over-tightening the suspension sling. This is accomplished by keeping gentle axial distraction force and adduction of the thumb metacarpal as the sling is tightened and secured, ensuring a small amount of slack in the suspension sling, to allow stability and full abduction.
- Tie 4 square knots and check the range of motion clinically and under fluoroscopy to confirm full motion and no impingement.

POSTOPERATIVE:

The surgeon should provide directions and warning to the patient/guardian regarding:

- Restricted Activity
- Adverse Effects
- Length of time for healing to occur
- Physical Therapy

PACKAGING:

The components of the Simparo Anchor Line Fixation System components are inserted onto a backer card and sealed into a Tyvek pouch.

CLEANING:

This device is provided clean and ready for single patient use. No components should be re-cleaned or re-used.

STERILIZATION:

This device is sterilized by Ethylene Oxide gas. Check the package labeling for more information. This device should never be re-sterilized under any conditions.

STORAGE:

The Simparo Anchor Line Fixation System and Simparo Anchor Line Fixation Systems are sterile devices. The systems should be stored in a dry environmentally controlled area. The devices should not be used if any damage occurs to the packaging during storage or after the expiration date.

PACKAGING AND LABELING :

Simparo devices should only be accepted if the factory packaging and labeling are intact.

Contact Simparo Customer Service if the received package is opened or altered.

Manufactured and Distributed By:

9 Dauphin St
3rd Floor
Mobile, AL 36602

251-301-7931

SimparoSurgical.com/IFU

SYMBOLS KEY

REF	Catalog number		Manufacturer
LOT	Lot Number		Do not reuse
QTY	Quantity	STERILE EO	Sterilized by EtO
	Use by		Caution: Consult accompanying documents
	Consult instructions for use		Do not use if product is broken, damaged or open
Rx	Rx Only		

Document L-10114 Revision C, 4/19/2026