INSTRUCTIONS FOR USE

KeeL-LocK® Implant System

MANUFACTURER

CrossRoads Extremity Systems
6423 Shelby View Drive, Suite 101
Memphis, TN 38134 USA
+1 901-221-8406

CAUTION: Federal Law (U.S.) restricts this device to the sale, distribution, and use by or on the order of a physician.

DEVICE DESCRIPTION

Implants

The KeeL-LocK® Implant System gives the surgeon a means of bone fixation in the management of bone fractures and reconstruction surgery. The KeeL-LocK® Implant System includes implants and the related instruments needed for implantation. Prior to implantation, the legs of the implant are held substantially parallel to facilitate insertion into the prepared bone. Once implanted and released from the insertion device, the legs of the implant will move towards each other in a converging fashion. This movement creates compression across the adjoining bone members. The amount of compression will vary depending on the spatial orientation of the bones, bone quality, surgical technique, etc. Implant components are provided sterile and are intended for single use only.

Instrument System

Instruments used with the KeeL-LocK® Implant System include the following: Reamer Guide, Reamer, Temporary Fixation Pin, broach guide, broach, tamp, and Inserter. Instrument components are provided sterile.

INDICATIONS

The KeeL-LocK® Implant System is indicated for hand and foot bone fragment osteotomy fixation and joint arthrodesis.

CONTRAINDICATIONS

Contraindications for the KeeL-LocK® Implant System are as follows:

- Comminuted bone surface that would prevent proper clip placement.
- Pathological bone conditions that would prevent secure clip fixation
- Active or suspected infection
- Physiological or psychological conditions that limit the patient's ability and/or willingness to follow instructions during the healing process.
- Inadequate skin, bone, or neurovascular status
- Skeletally immature patients with open epiphyses
- Sensitivity to metals, including nickel.

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

WARNINGS

- Surgeon familiarity with the device, instrumentation, and surgical technique prior to surgery is crucial to proper device installation.
- As with any implant system, the implants cannot be expected to replace normal healthy bone or withstand the stress placed upon the device by full or partial weight-bearing or load bearing in the presence of nonunion, delayed union or incomplete healing. Therefore, it is important that immobilization of the treatment site using routine methods be maintained until bone healing has occurred.
- Reduction of the site should be achieved and maintained prior to implanting the device. The compressive force of the implant should not be relied upon to achieve closure or reduction of a fracture line.
- Any additional processing or reprocessing of the implant may affect the material properties of the nitinol potentially reducing the effectiveness of the implant.
- Reamers are designed for use specifically with the supplied guides. Re-use or reprocessing may affect the compatibility with other instruments and usability of the instruments.
- If it is suspected that sterilization is compromised prior to implantation, another sterile implant should be used. Product should not be re-sterilized.
- The KeeL-LocK® Implant System has not been evaluated for safety and compatibility in the MR environment. The KeeL-LocK® Implant System has not been tested for heating or migration in the MR environment.
- The expiration date listed on the package label should be verified prior to use. If expired, another sterile kit within expiration date should be used.

Dispose of used device in accordance with healthcare facility policy and local regulations.

COMPLICATIONS

Surgical procedures involving these devices should not be attempted by physicians unfamiliar with possible adverse clinical events which may occur during or after the procedure and could require additional surgery for implant revision.

The anticipated adverse device effects are the same as those associated with the currently available nitinol bone staple fixation procedures.

ADVERSE EVENTS

The following list includes potential complications typically associated with surgical intervention utilizing nitinol fixation devices.

- Prolonged healing
- Failure or breakage of the implant or part of the implant
- Damage to nerves and vessels
- Infection, painful, swollen or inflamed implant site
- Loosening or dislocation of the implant requiring revision surgery
- Edema
- Delayed union or malunion
- Allergic reaction(s) to implant material(s)
- Muscle tendon impalement and excessive operative bleeding
- Nonunion pseudoarthrosis development and persistence and failure of the bone regenerating satisfactorily
- Loss of bone mass
- Venous thrombosis, pulmonary embolism, cardiovascular problems
- Inability to compress the bone surface due to poorly fixated implant

Adverse Events related to KeeL-LocK® Implant System

No additional risks are associated with KeeL-LocK® Implant System.

HOW SUPPLIED, CLEANING AND STERILIZATION

Implants

The implants are provided sterile to the end user.

Implant packaging and implants should be inspected to ensure there is no damage. If the implants' packaging or implants' integrity has

been compromised use an alternate item and contact the manufacturer for further instructions.

Implants are for single use only.

Instrument System
Instruments are provided sterile or non-sterile to the end user. Instrument packaging and instruments should be inspected to ensure there is no damage. If the instruments' packaging or instruments' integrity has been compromised, contact the manufacturer for further instructions.

CARE AND CAUTION

- All instruments for the KeeL-LocK® Implant System are provided sterile for single use only or non-sterile.
- Inspect the sterile packaging used for the implants and instruments prior to use. If the packaging and/or seal is damaged, sterilization may be compromised and the implant and/or instrument should not be used.
- KeeL-LocK® Implant System implants and instruments may be stored at room temperature.
- The mechanical characteristics and performance of the sterile implants may be altered if re-sterilized. Since this could potentially adversely affect device integrity and performance, CrossRoads warns against resterilization of its single use implants.

Some instruments may be provided non-sterile to the end user and must be cleaned and sterilized before each use in accordance with the instructions below.

Cleaning

1. **Disassemble** all components as per manufacturer instructions (if appropriate). **Open** all hinged instruments.
2. **Rinse** with cold tap water to remove gross contamination.
3. **Bathe** in an enzymatic detergent solution prepared per manufacturer directions for 5 minutes.
4. **Scrub** thoroughly with a soft brush and/or pipe cleaner; repeatedly flush any very narrow lumens with enzymatic detergent solution using a syringe.
5. **Rinse** with cold tap water for a minimum of one minute; use a syringe to repeatedly flush any very narrow lumens.
6. **Bathe** in a detergent solution prepared per manufacturer directions for 5 minutes.
7. **Scrub** thoroughly with a soft brush and/or pipe cleaner; repeatedly flush any very narrow lumens with detergent solution using a syringe.
8. **Rinse** thoroughly /flush with deionized / reverse osmosis (RO/DI) water.
9. **Sonicate** for a minimum of 10 minutes in an enzymatic detergent solution prepared per manufacturer directions.
10. Rinse thoroughly /flush with RO/DI water.
11. **Dry** with a clean, soft, absorbent, disposable cloth.
12. **Visually inspect** for cleanliness. All visible surfaces, internal and external, should be visually inspected. If necessary reclean until it is visibly clean.

Note: Brushes (i.e. pipe cleaners) could be used for cleaning most lumens; however, the use of a syringe to flush narrow lumens with diameters less than or equal to 0.041 inches is recommended.

The minimum recommended steam sterilization conditions for **reusable instruments** are as follows:

FOR PREVACUUM STEAM STERILIZATION ONLY:

1. Double wrap the assembled tray in a FDA cleared wrap or FDA cleared sterilization container.

2. Autoclave according to the following parameters:

Steam Sterilization – PREVACUUM

Cycle Type	Parameter	Minimum Set Point
Prevacuum 270 ˚F (132 ˚C)	Exposure Temperature	270˚F (132˚C)
	Exposure Time	4 minutes
	Dry Time	20-30 minutes

3. After sterilization, remove the component from its wrapping or container using accepted sterile technique with powder-free gloves.

Ensure that the component is at room temperature prior to use. Avoid contact with hard objects that may cause damage.

These recommendations are consistent with ANSI/AAMI ST79 guidelines and have been developed and tested using specific equipment.

Due to variations in environment and equipment, it must be demonstrated that these recommendations produce sterility in your environment. If processing conditions, wrapping materials, or equipment changes occur, the effectiveness of the sterilization process must be demonstrated.

MR SAFETY INFORMATION

The KeeL-LocK® Implant System has not been evaluated for safety and compatibility in the MR environment. These systems have not been tested for heating, migration, or image artifact in the MR environment. The safety of the KeeL-LocK™ Implant System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

.

OTHER SUPPLIES AND EQUIPMENT NEEDED

- Standard OR equipment used in patient preparation and surgical exposure.
- Power drill with pin driver attachment and AO quick connect attachment.

RECOMMENDED PROCEDURE

Steps for application of the KeeL-LocK® Implant System are as follows:

1. Reduce the osteotomy or fracture and hold in place. Center the Reamer Guide across the fusion site with both guide tubes against the bone.
2. Drill the first hole by advancing the reamer to the proper depth.
3. Place a Temporary Fixation Pin through the reamer guide into the drilled hole. Use this Temporary Fixation Pin to help maintain reduction while the second hole is drilled with the reamer to the proper depth.
4. Place a second Temporary Fixation Pin into the second hole and remove the reamer guide. Slide the broach guide over the Temporary Fixation Pins and impact the broach through the guide to prepare the bone for the KeeL-LocK® implant keel feature. The KeeL-LocK® Implant is then loaded on the

inserter. NOTE: Some kits in this system have implants pre-loaded onto inserters. Positioning the implant onto the inserter is not necessary with these kits.

5. While making sure that reduction is maintained; insert the legs of the KeeL-LocK® implant into the predrilled holes. Light tapping on the end of the Inserter may be helpful in advancing the KeeL-LocK® implant. The implant should be fully inserted until flush against the surface of the bone.
6. Rotate the inserter knob counterclockwise until pressure is released, then rotate the inserter counter-clockwise until the KeeL-LocK® implant releases. Proper placement can be confirmed radiographically.

REMOVAL

1. Expose the implant site and bridge of the implant.
2. Once exposed, remove the implant by installing the appropriately sized inserter and removal hook onto the implant and gently withdrawing the implant from bone. If the implant bridge is below the bone surface, utilize an osteotome to expose the bridge for removal.
3. If the inserter is unavailable at the time of removal, utilize forceps or pliers to grasp the center of the implant bridge. With the bridge grasped, pull up on the implant to remove.

SYMBOLS

Refer to package labels to determine which symbols are relevant to the device in the package.

	Caution consult accompanying documents
	Catalogue number
	Consult instructions for use
	Contents of package
	Do not reuse
	Lot number
	Manufacturer
	Sterilized using irradiation
	Prescription only - device restricted to use by or on the order of a physician
	Use By: YYYY-MM (YYYY is year; MM is month)

DISCLAIMER OF WARRANTY AND LIMITATION OF REMEDY

THERE IS NO EXPRESS OR IMPLIED WARRANTY, INCLUDING WITHOUT LIMITATION ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, ON CROSSROADS EXTREMITY SYSTEMS, LLC PRODUCT(S) DESCRIBED IN THIS PUBLICATION. UNDER NO CIRCUMSTANCES SHALL CROSSROADS EXTREMITY SYSTEMS, LLC BE LIABLE FOR ANY DIRECT, INCIDENTAL, OR CONSEQUENTIAL DAMAGES OTHER THAN AS EXPRESSLY PROVIDED BY SPECIFIC LAW. NO PERSON HAS THE AUTHORITY TO BIND CROSSROADS EXTREMITY SYSTEMS, LLC TO ANY REPRESENTATION OR WARRANTY EXCEPT AS SPECIFICALLY SET FORTH HEREIN.

Descriptions or specifications in CrossRoads Extremity Systems, LLC printed matter, including this publication, are meant solely to generally describe the product at the time of manufacture and do not constitute any express warranties.

CrossRoads Extremity Systems, LLC will not be responsible for any direct, incidental, or consequential damages resulting from reuse of the product.

KeeL-LocK® is a trademark of CrossRoads Extremity Systems, LLC

Product and/or its use are covered by patents pending.