Fusion ORTHOPEDICS

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LapiLock - 4D Advanced Bunion Surgery

CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician.

DESCRIPTION OF THE MEDICAL DEVICE:
LapiLock is a nonpowered hand-held orthopedic manual surgical instrument. This class 1 medical device is used with 2.0mm Guide Wires and 2.0mm Olive Wires in order to manipulate various bones in the foot and ankle. LapiLock was reviewed and cleared by the FDA within the IntraLock 510(k) K210159 on July 23, 2021.

INDICATIONS FOR USE
LapiLock is intended for tissue and bone manipulation. This bone positioner is specifically used to help position and prepare the 1st Metatarsocunieform joint for arthrodesis. Previously cleared Fusion Orthopedics fixation (class 2 medical devices) should be used in conjunction with LapiLock to fuse the 1st Metatarsocunieform joint.

CONTRAINDICATIONS
- Any active or suspected latent infection or marked local inflammation around the affected area.
- Compromised vascularity that would inhibit adequate blood supply to the fracture or the operative site.
- Bone stock compromised by disease, infection or prior implantation that can not provide adequate fixation of the devices.
- Material sensitivity, documented or suspected.
- Obesity. An overweight or obese patient can produce loads on the implant that can lead to failure of the fixation of the device or to failure of the device itself.
- Patients having inadequate tissue coverage over the operative site.
- Implant utilization that would interfere with anatomical structures or physiological performance.
- Any mental or neuromuscular disorder which would create an unacceptable risk of fixation failure or complication in postoperative care.

PRECAUTIONS
Only experienced surgeons should use LapiLock with specific training in treating its associated indications. Because of the technically demanding nature of procedure, surgeons should preoperatively plan to ensure that the risks presented to the patient are minimized. Pre-operative assessment of the suitability of the patients' anatomy for accepting implants is made on the basis of X-Rays, CT scans and other radiological studies.

Only patients that meet the criteria described in the Indications for Use section should be selected. Under no circumstances should damaged components or surgically excised components be used. Instruments that have already been in contact with body fluids or body tissues must not be resterilized and are for single use only.

ADVERSE EFFECTS
- Tissue damage resulting from improper placement of implants or instruments
- Infection
- Hematoma
- Allergy
- Thrombosis
- Pain, discomfort or wound healing complications at the surgical site
- Misalignment of anatomical structures
- Bone non-union or delayed union
- Dislocation, migration and/or subluxation of implant from improper positioning, trauma, loss of fixation and/or muscle and fibrous tissue laxity
- Implant fracture

Adverse effects may necessitate re-operation, revision or removal surgery, arthrodesis of the involved joint, and/or amputation of the limb.

DIRECTIONS FOR USE
All LapiLock components should be carefully inspected to ensure proper working condition. Critical areas, including joint surfaces, should be checked for wear, damage or irregularities. Damaged or broken LapiLock components must not be used and should be returned to Fusion Orthopedics for evaluation. Before using LapiLock, the surgeon should be thoroughly familiar with the LapiLock Surgical Technique Guide. Pre-Operative planning by the surgeon should determine the system and size of permanent fixation. An adequate supply of the implant sizes should be available prior to surgery, including larger and smaller sizes than those expected to be used. To view all of the availble forms of fixation visit www.fusionorthopedics.com/fusionorthopedics.com/lapilock.

For complete instructions regarding the proper use and application of LapiLockm, please refer to the LapiLock Surgical Technique Guide. A comprehensive manual can be found at www.fusionorthopedics.com/library.

CARE AND HANDLING
LapiLock instruments described in this package insert are either provided sterile or non-sterile as indicated on the individual product's label. Instruments that are presented in instrument trays are provided non-sterile.

Devices in sterile packaging should be inspected to ensure that the packaging has not been damaged or previously opened. Sterile implants and instruments should not be used after the expiration date. If the outer package, seal, or inner package integrity has been compromised, sterilization cannot be assured and the device should not be used. Contact the manufacturer for further instructions. The devices should be opened using aseptic OR technique; they should only be opened after the correct size has been determined.

Devices labeled for single-use only should never be reused. The mechanical characteristics of sterile instruments and implants may be altered if they are re-used as this would compromise device integrity, performance, and standards conformance. Reuse of these devices may potentially result in serious patient harm. Examples of hazards related to the reuse of these devices include, but are not limited to: significant performance degradation, cross-infection, and contamination.

Devices provided non-sterile should be processed according to the recommended parameters outlined (below) in the instructions for use and according to standard hospital procedure. LapiLock Instruments provided non-sterile should be stored in the original packaging until cleaned and sterilized. Implants and instruments should be stored at room temperature.

MAGNETIC RESONANCE (MRI) COMPATIBILITY
The LapiLock Instruments have not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of LapiLock Implants in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

STERILIZATION, CLEANING AND DISINFECTION
PREPARATION FOR CLEANING:
Clean the device until there is no visual contamination of the instruments directly after application (within a maximum of 2 h).

For this use only running water or a disinfectant solution; the disinfectant should be aldehyde-free (otherwise fixation of blood impurities), possess a fundamentally approved efficiency, be suitable for the disinfection of instruments and be compatible with the instruments. For manual removal of impurities only a soft brush or a clean soft tissue is to be used, in no case metal brushes or steel wool.
Rinse all lumens five (5) times by application of a single-use syringe (minimum volume 10ml).

MANUAL CLEANING:
1. Soak instruments for a minimum of five (5) minutes in enzymatic detergent made with potable water.
2. Deliberately brush and pay considerable attention to areas of a high exposure, accumulation, or retention of soil.
3. Rinse thoroughly with warm water. Final rinses conducted with warm (30º C. to 40º C.) purified water (reverse osmosis processed, or better), with a minimum rinse time of 30 seconds.
4. Check the instruments for visible soil (see "Verifying Cleaning"). Repeat cleaning if soil is visible.

For Devices with challenging design features (cannulations, annodized color bands, handle interfaces, hinged instruments, instruments with crevices):

1. Immerse instrument and soak for a minimum of five (5) minutes in enzymatic detergent.
2. Use cleaning brushes/pipe cleaners to remove additional soil from challenging design features and areas of high exposure, accumulation, or retention of soil such as: cannulations, annodized color bands, handle/ chuck interfaces, hinged instruments, or instruments with crevices.
   a. Scrub interfaces several times using a twisting action if possible. If components of the instrument can be retracted or moved, it is necessary to retract or open the part in order to access and clean these areas.
   b. Scrub inside cannulas/holes with a tight-fitting brush or pipe cleaner using a twisting action. The brush or pipe cleaner should be of an appropriate size to ensure that full depth of the feature is reached.
   c. Scrub around hinged/mating surface areas with a brush or pipe cleaner.
   d. Scrub all crevices, such as those found around color bands, using a cleaning brush or pipe cleaner.
3. Sonicate instrument in its fully opened position for a minimum of 15 minutes in an ultrasonic cleaner containing warm enzymatic detergent.
4. Rinse thoroughly with warm water, making sure to irrigate the challenging design features. If the components of the instrument are moveable or can be retracted, it is necessary to retract or open the part for thorough rinsing at these locations. Blind holes should be repeatedly filled and emptied.
5. Check instruments for visible soil (see "Verifying Cleaning"). Repeat cleaning if soil is visible.

VERIFYING CLEANING
1. After thoroughly cleaning, visually inspect devices under normal lighting for the removal of visible soil.
2. **Optional:** For difficult to view design features, such as cannulation, apply 3% hydrogen peroxide. Bubbling is indicative of the presence of blood.

Note: Rinse the instruments thoroughly with warm water following hydrogen peroxide testing. Repeat cleaning if not visibly clean and re-inspect.

INSPECTION AND FUNCTION TESTING

Device/Feature	Flaw
All reusable devices	Visually inspect for damage or wear.
Hinged instruments	Check for smooth movement of hinge without excessive "play."
Locking mechanisms	Check for action.
Cutting features	Check edges for distortion/large nicks. Edges should be continuous.
Trials	Articular surfaces should be smooth and free of cracks and deep nicks.
Mating parts	Check to make sure that mating parts fit together without complications.
Reamer/drill bits	Inspect "chuck" end for burrs and distortion that might hinder insertion into a drill.
Hammering surfaces	Inspect for burrs and large nicks.
Driving instruments	Inspect plastic ends for cracks and large nicks.
Metal surfaces	Inspect for corrosion and major deformation.

STERILIZATION
Sterilize devices inside their respective trays using gamma irradiation according to the following parameters:

Sterilization Method	Gravity Steam	Pre-Vacuum Steam
Wrapping	Single or Double	Single or Double
Exposure Temperature	132°C (270°F)	132°C (270°F)
Minimum Cycle Time	15 minutes	4 minutes
Minimum Dry Time	30 minutes	30 minutes

The wrap should be FDA cleared for the proposed cycle specifications

WARNING: Total drying time depends on several factors. These include but are not limited to: altitude, humidity, type of wrap, preconditioning, size of chamber, mass of load, material of load, and placement in chamber. Verify that drying time set in each autoclave yields dry surgical equipment.

MAINTENANCE:
If any of the instruments exhibit any of the flaws listed above adequately dispose of the devices.
For more information regarding cleaning and sterilization of the LapiLock Implants or Instruments, please visit www.fusionorthopedics.com/cleaning.

CUSTOMER SERVICE
For further information regarding LapiLock or a copy of the LapiLock Surgical Technique Guide please contact Fusion Orthopedics USA, LLC, your local Fusion Orthopedics Distributor, or visit fusionorthopedics.com. The Graphical Symbols for Medical Labeling Glossary can be found at fusionorthopedics.com/library. Any complaints or concerns can be reported at fusionorthopedics.com/customerproductfeedback.

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