Instruction for Use – LoopLoc CL Fixation System

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Descriptions:
The LoopLoc CL fixation system is a sterile, single-use device. It provides the orthopedic surgeon a means of accurate suture fixation in reconstructive surgery. The fixation device is composed of two components: a suture loop and metal button.

AT001	LoopLoc CL Fixation System 12mm, 15mm, 20mm, 25mm, 30mm, 35mm, 40mm
AT010	Loop Button
AT084	LoopLoc - II (Loop with UFiber Tape)
AT078	LoopLoc XL - Button Extender
AT043.1	SlideRope - Adjustable Loop (1 SIDE SUTURE)
AT043.2	SlideRope - Adjustable Loop (2 SIDE SUTURE)
AT069	SlideRope-TAD - Adjustable Loop for Tibial Attachable Disk

Material:
Titanium According to ASTM F136 or ISO 5832-3
Ultra-High Molecular Weight Polyethylene (UHMWPE) According to ASTM F2848

Intended Users:
The device is intended for use by health care professionals in accordance with these instructions for use. The use environment is a professional healthcare facility. Procedures will be performed by the surgeon's preferred technique.

Intended Use:
The fixation device is intended use for fixation or reattachment of tendons, ligaments and soft tissue to bone during orthopaedic reconstruction procedures.

Indications for Use:
Knee: ACL/PCL Reconstruction or Repair

Contraindications:
- Surgical procedures other than those listed in the indications of use section.
- Insufficient quality or quantity of bone or soft tissue.
- Blood supply limitations and previous infections, which may tend and retard healing.
- Any infection.
- Foreign body sensitivity, where material sensitivity is suspected, appropriate tests should be made and sensitivity ruled out prior to implantation.
- Surgical procedures other than those listed in the indications for use.
- Any case where the implant components selected for use would be too large or too small to achieve a successful result.

Adverse Event:
- Non-union or delayed union, which may lead to breakage of the implants.
- Bending or fracture of implants.
- Breakage of the suture can occur.
- Loosening or migration of the implants.
- Mild Inflammatory reaction.
- Foreign body reaction.
- Infection, both deep and superficial.
- Allergic reaction.
- Inadequate healing.
- Intra operative or post-operative bone fracture and/or postoperative pain.

Note: Additional surgery may be necessary to correct some of these adverse events.

Warning:
- Do not use if package is damaged. Do not use if the product sterilization barrier or its packaging is compromised.
- Contents are sterile unless package is opened or damaged. For single use only. Discard any open, unused product. Do not use after the expiration date.
- Do not clean, resterilize, or reuse the device, as this may damage or compromise the performance resulting in product malfunction. Failure, or patient injury and also expose the patient to the risk of transmitting infectious diseases.
- It is the surgeon's responsibility to be familiar with the appropriate surgical techniques prior to use of this device.
- Product must be stored in the original sealed pouch.
- Correct selection of the implants is extremely important. The potential for success in soft tissue to bone fixation is increased by the selection of the proper type of implant. While proper selection can help minimize risks, neither the device nor grafts, when used are designed to withstand the unsupported stress of full weight bearing, load bearing or excessive activity.
- Any decision to remove the implants should take into consideration the potential risk to the patient of a second surgical procedure. Device removal should be followed by adequate postoperative management.
- Incomplete anchor insertions may result in poor anchor performance.
- Breakage of suture anchor can occur if predrilling is not performed prior to implantation.
- Associated instruments for suture anchors are sold separately and are provided NON-STRILE. These instruments must be properly cleaned and sterile prior to us.

Precautions:
- Do not reuse implants. While implant may appear undamaged, previous stress may have created imperfections that would reduce the service life of the implants. Do not treat with implants that have been, even momentarily, placed in different patient.
- Instruments are available to aid in the accurate implantation of internal fixation devices. Intraoperative fracture or breaking of instruments has been reported. Surgical instruments are subject to wear with normal usage. Instruments, which have experienced extensive use or excessive force, are susceptible to fracture. Surgical instruments should only be used for their intended purpose.
- All trail, packaging and instrument components must be removed prior to closing the surgical site: do not implant.
- Do not use sharp instruments to manage or control the suture.
- Hard bone condition require preparation by predrilling the insertion site to reduce the potential to torsional overload. Predrilling extracts the core

diameter of the suture anchor and creates a countersink broach for insertion of the device tip. Predrilling with the appropriate drill bit is the preferred method of site preparation.
- Excessive force during insertion can cause failure of the suture anchor or insertion device. A two finger AO technique should be used to insert the anchor.
- User shall not be altering implant or instrumentation. Otherwise, performance may be compromised.
- Postoperative range of motion is to be determined by physician.

How Supplied:
- The Devices are individually packed in protective packaging that is labelled to its contents properly.
- All supplied implants are intended for single use only.
- Device is supplied sterile, for single use only.

Storage:
Proper storage of device is crucial to maintain their surface finish, configurations, sterility, material integrity and overall safety until they are used in surgical procedures. Below are the recommended storage conditions based on industry standards and best practices:
- Store in a dry, clean and dust-free environment to minimize the risk of contamination.
- Avoid direct exposure to sunlight or intense artificial light to prevent degradation of packaging materials.
- Use shelves or cabinets that elevate implants off the ground to reduce contamination risks. Open shelving is preferable to promote ventilation.
- Limit access to storage areas to minimize unnecessary handling and reduce the risk of contamination.
- Implement a First In, First Out (FIFO) system to ensure that older implants are used before newer ones, minimizing the risk of using expired products.

Note: Always refer guidelines and relevant industry standards for specific storage and handling requirements.

Device Selection:
The selection of the proper size, shape, and design of the implant for each patient is crucial to the success of the procedure. Metallic surgical implants are subject to repeated stresses in use, and their strength is limited by the need to adapt the design to the size and shape of human bones. Unless great care is taken in patient selection, proper placement of the implant, and post-operative management to minimize stresses on the implant, such stresses may cause metal fatigue and consequent breakage, bending or loosening of the device before the healing process is complete, which may result in further injury or the need to remove the device prematurely.

Instruction for Use:
- Over drill the drill tip passing pin with the 4.5 mm endoscopic cannulated drill bit, Measure the total femoral channel length using the graduated markings on the drill bit at the moment of cortical breakthrough. or remove the drill bit and use the depth probe.
- Measure the intra-articular distance between the proximal end of the tibial tunnel and the distal end of the femoral socket. Also measure the length of the graft.
- Determine the estimated graft insertion lengths for the tibial tunnel and femoral socket by subtracting the intra-articular distance from the total graft length and dividing the remainder in half for equal tibial and femoral insertion.
- Select the suitable size fixation device by subtracting the estimated graft insertion length for the femoral socket from the total length of the femoral channel.
- Drill the femoral socket 6 mm deeper than the desired insertion of the graft to create a space to accommodate the turning radius of the fixation device
  CAUTION: The maximum recommended graft diameter to use with the 10 mm fixation device is 9 mm.
  CAUTION: Ensure the endoscopic cannulated drill bit does not breach the femoral cortex, otherwise the femoral fixation with fixation device will be compromised. If the femoral cortex is breached then the fixation system (6-10 mm tunnels) can be used Refer to the instructions to use for fixation system for further information.
- Pass the graft through the loop of the fixation device and then suture the tibial side.
- Using a marker, place a line on the graft indicating the desired length of insertion, and another line 6 mm more distal to indicate the point at which the fixation device can be rotated.
- One outside hole of the fixation system to lead and pass the fixation device /graft construct. Another suture to the opposite outside hole of the fixation device to rotate the fixation device as it exits the anterolateral femoral cortex. Both sutures are passed through the eyelet of the drill tip passing pin.
- The drill tip passing pin is used for passage, piercing the quadriceps and skin proximally. The lead suture is pulled first. Advancing the device/graft construct into the femoral tunnel. As the second distal marking line on the graft reaches the internal femoral aperture, the trailing suture is pulled, rotating the fixation device immediately external to the femur.
- Tensioning the tibial side causes the graft to retreat 6 mm, locking it in place. X-ray or fluoroscopy will confirm the position of the fixation device on the anterolateral femoral cortex.

Sterilization Procedure:
Implants are provided sterile. Check the package labelling for more information. Devices that are provided in a terminally sterilized configuration should never be re-sterilized under any conditions.

Instruments are must be sterile and cleaned prior to surgical use. Remove packing of before cleaning.
We are suggesting following parameter for the sterilization that protects the integrity of the devices, Re sterilization is possible up to 200 cycles.

Method	Cycle	Temperature	Pressure	Exposure time
Moist Heat (Steam)	Pre vacuum	121 Deg °C.	15 lb	30 Minutes*

Note: Because of the many variables involved in sterilization, each medical facility should calibrate & verify this sterilization process (Eg: temperature, time) used for their devices.

Preoperative:
- Carefully screen the patient, choosing only those that fit the indications described above.
- If device is provided non-sterile and should be stored in its original packaging until sterilized. Prior to use, each implant must be sterilized according to standard hospital procedure. See "Sterilization" section for details.
- Device should not be scratched, bent repeatedly or otherwise damaged. Store away from corrosive environments.
- An adequate inventory should be available at surgery than the exact device expected to be used.
- All components and instruments should be cleaned and sterilized prior to each use. Additional sterile components should be available in case of an unexpected need.

Intraoperative:
- Instructions should be carefully followed.

- Device surface should not be scratched or notched since such actions may reduce the functional strength of the construct.
- Proper handling of the devices before and during the operation is crucial.
- Before closing the incision, check each device to make sure that none have loosened.

Postoperative:

- The patient should be advised about the advantages and disadvantages of device and of any postoperative limitations.
- The patient should be advised about weight bearing and load bearing stresses on the device which could affect secure bone healing.
- To achieve best results, the patient should not be exposed to excessive mechanical vibrations. The patient should not smoke or consume alcohol during the healing process.
- The patient should be advised on their limitations and taught to compensate for this permanent physical restriction in body motion
- If a non-union develops, or if the components loosen, the devices should be revised or removed before serious injury occurs. Failure to immobilize the non-union, or a delay in such, will result in excessive and repeated stresses on the device.

Magnetic Resonance Imaging (MRI) Safety:
Device made from non-ferromagnetic materials like Titanium (ASTM F136 or ISO 5832-3) and PEEK (ASTM F2026) are MRI Compatible as per researches carried out worldwide according to specific condition for patients undergoing MR procedures. Hence, MJ Surgical need not been evaluated for safety and compatibility in the MR environment. MJ Surgical device has also not been tested for heating and migration in the MR environment.
However, Patients who have used device made from ferromagnetic materials like S.S. 316L (ISO 5832-1) are warned not to entre area with electromagnetic or magnetic fields.

Safe Disposal:
This single use device may be a potential biohazard and should be handled in accordance with accepted medical practice and applicable local and national requirements.

Traceability:
There is always a lot/batch number on the label provided for each MJ Surgical devices. This label with lot/batch number must be attached to the file of the patient in order to trace back production details. For the same reason distributional documents have to be maintained for 15 years.

Limited Warranty and Disclaimer:
Devices warranty to the original purchased against defects in workmanship and materials. Any other express or implied warranties, including warranties of merchantability or fitness are hereby disclaimed.

For Further Information:
If further information, including warranty, on this device is needed, contact MJ Surgical Customer Service at +91-9426086742, info@mjsurgical.com or an authorized representative

Symbols:

 *Manufacturer*	 *Lot No.*	 *Reference No.*	 *Medical Device*
 *Precaution*	 *European Conformity*	 *Do Not Use If Package Is Damaged*	 *Use By Date*
 *Instructions For Use*	 *Keep away from Sunlight*	 *Do not re-use*	 *EO Sterile*
 *Instruction For Use*	 *European Authorized Representative*	 *Country of Manufacturer*	 *Keep Dry*