

Instruction for Use – Mini-Protoza-PK : Suture Anchor

MJ SURGICAL, Plot No 268, Main Road, Opp. Road No 3, GIDC Kathwada, Ahmedabad, Gujarat -382430, India

Descriptions:

Mini-Protoza-PK : Suture Anchor is sterile, single-use, preloaded device which consist of a Mini-Protoza-PK Suture Anchor with attached non-absorbable sutures assembled to an insertion device.

AT028	Mini-Protoza-PK : Suture Anchor 2.8mm, PEEK (Loaded with 1pc UFiber#2)
AT029	Mini-Protoza-PK : Suture Anchor 3.0mm, PEEK (Loaded with 2pc UFiber#2)
AT082	Mini-Protoza-PK : Suture Anchor 3.0mm, PEEK (Loaded with 2pc UFiber#2 with Needle)
AT083	Mini-Protoza-PK : Suture Anchor 3.0mm, PEEK (Loaded with 1pc UFiber#2 And 1pc UFiber Tape 1.4mm with Needle)
AT030	Mini-Protoza-PK : Suture Anchor 3.5mm, PEEK (Loaded with 2pc UFiber#2)
AT096	Mini-Protoza-PK : Suture Anchor 3.5mm, PEEK (Loaded with 2pc UFiber#2 with Needle)
AT097	Mini-Protoza-PK : Suture Anchor 3.5mm, PEEK (Loaded with 1pc UFiber#2 And 1pc UFiber Tape 1.4mm with Needle)

Material:

PEEK According to ASTM F2026

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.

Intended Use:

Provide secure reattachment of soft tissue to bone. Attachment of soft tissue is performed by the surgeon's preferred technique.

Indications for Use:

Shoulder: Rotator Cuff Repair, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-clavicular Sepa-ration Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction

Foot Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Hallux Valgus Reconstruction, Mid-foot Reconstruction, Metatarsal Ligament Repair/Tendon Repair and Bunionectomy

Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis, Secondary Fixation for ACL/PCL Reconstruction or Repair, Meniscal Root Repair

Hand Wrist: Scapholunate Ligament Reconstruction, Ulnar or Radial Collateral Ligament Reconstruction

Elbow: Biceps Tendon Reattachment, Tennis Elbow Repair, Ulnar or Radial Collateral Reconstruction, Lateral Epicondylitis Repair

Hip: Capular Repair, Acetabular Labral Repair

Other orthopedic procedures requiring soft tissue fixation to bone

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.

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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:

- Expose the surgical site using an open or arthroscopic approach.
- Prepare the bone surface and identify the desired anchor insertion site.
- Using the appropriate drill bit, spear, tap and punch (each sold separately) to prepare the anchor insertion site. (Caution: Hard bone conditions require preparation by predrilling or use of a tap or punch are recommended at insertion site to reduce the potential of torsional overload.)
- Using routine sterile technique to remove suture anchor with insertion device from the packaging.
- Establish axial alignment of the suture anchor to the hole. While stabilizing the insertion site, rotate the anchor clockwise into the hole with the insertion device using two-finger AO technique until desired placement is achieved by visual inspection. (Caution: Excessive force during insertion can cause failure of the suture anchor or insertion device.)
- First horizontal indicator line on the tip of the insertion device identifies the top of the anchor.
- Axial lines on the insertion device indicate suture orientation within the anchor.
- Disengage the suture anchor from the inserter.
- Confirm stable fixation by gently tensioning the sutures.
- Pass the repair sutures or suture tape through the soft tissue according to the selected repair technique.
- Tie secure surgical knots while maintaining appropriate tissue tension.
- Verify repair stability and tissue apposition through the appropriate range of motion.
- Close the surgical site following standard surgical procedures.
- Discard the insertion device.

Note: The exact surgical technique may vary depending on the anatomical location, anchor design, and surgeon preference.

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.

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- 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 enter 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's 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:

 <i>Manufacturer</i>	 <i>Lot No.</i>	 <i>Reference No.</i>	 <i>Medical Device</i>	 <i>UDI with barcode</i>
 <i>Precaution</i>	 <i>XXXX European Conformity</i>	 <i>Do Not Use If Package Is Damaged</i>	 <i>Expiry Date (DD-MM-YYYY)</i>	 <i>Single sterile barrier system with protective packaging outside</i>
 <i>Instructions For Use</i>	 <i>Keep away from Sunlight</i>	 <i>Do not re-use</i>	 <i>EO Sterile</i>	 <i>Do not Re-sterile</i>
 <i>only for prescription use</i>	 <i>European Authorized Representative</i>	 <i>Date of manufacture (DD-MM-YYYY)</i>	 <i>Keep Dry</i>	 <i>Packed Product Quantity</i>