apollo®

Medial Suture Anchor, XT Suture Anchor, Knotless Anchor, Medial With Needles

Indications for Use

Para obtener la versión en español de estas instrucciones de uso, viste nuestro sitio web www.maruho-medical.com/ifu

A. Device Description

The apollo Medial Suture Anchor, XT Suture Anchor, Knotless Anchor, and Medial With Needles Delivery Systems are delivery systems for anchors for use in fixation of ligament, tendon, bone, or soft tissue to bone in knee, shoulder, foot/ankle, elbow, and hand/wrist procedures. These anchors consist of cannulated anchors with integrated suture attachment or separate suture punch eyelet. The Anchors are provided loaded on individual inserters with and without integrated sutures, with and without needles, sterile, for single use only.

Contents

- 1 ea. – Single use disposable inserter [ABS plastic (Handle), Stainless Steel (Shaft and Punch), Ethylene Propylene (Suture Retention O-Ring)], Non-absorbable Medial Suture Anchor, XT Suture Anchor, or Knotless Anchor made from ZENIVA™ ZA-500, ZA-600, PEEK (polyetheretherketone) from SOLVAY ADVANCED POLYMERS or Titanium 6AL-4V ELI, and sutures or tape made from UHMWPE with or without stainless steel needles (needles available on medial with needles only). Refer to individual Medial Suture Anchor delivery system, XT Suture Anchor delivery system, Knotless Anchor delivery system, or Medial With Needles delivery system product labels for material, diameter and length of anchor.

B. Indications – apollo Medial, Medial With Needles, and apollo XT Suture Anchor

The apollo Medial, Medial With Needles, and apollo XT Suture Anchors are intended for:

Shoulder

- Rotator Cuff Repair
- Bankart Repair
- SLAP Lesion Repair
- Biceps Tenodesis
- Acromio-Clavicular Separation Repair
- Deltoid Repair
- Capisular Shift or Capsulolabral Reconstruction

Foot/Ankle

- Lateral Stabilization
- Medial Stabilization
- Achilles Tendon Repair

Knee

- Medial Collateral Ligament Repair
- Lateral Collateral Ligament Repair
- Posterior Oblique Ligament Repair
- Illiotibial Band Tenodesis

Elbow

- Biceps Tendon Reattachment
- Ulnar or Radial Collateral Ligament Reconstruction

Hip

- Capsular Repair
- Acetabular Labral Repair

C. Indications – apollo Knotless Anchor

The apollo Knotless Anchor is indicated for:

Shoulder

- Rotator Cuff Repair
- Bankart Repair
- SLAP Lesion Repair
- Biceps Tenodesis
- Acromio-Clavicular Separation Repair
- Deltoid Repair
- Capsular Shift or Capsulolabral Reconstruction

Wrist/Hand

- Scapholunate Ligament Reconstruction
- Ulnar/Radial Collateral Ligament Reconstruction

Foot/Ankle

- Lateral Stabilization
- Medial Stabilization
- Achilles Tendon Repair/Reconstruction
- Hallux Valgus Reconstruction
- Mid- and Forefoot Reconstruction

Elbow

- Biceps Tendon Reconstruction
- Ulnar or Radial Collateral Ligament Reconstruction
- Lateral Epicondylitis Repair **(PEEK Anchor Only)**

Knee

- Medial Collateral Ligament Repair
- Lateral Collateral Ligament Repair
- Posterior Oblique Ligament Repair
- Joint Capsule Closure
- Iliotibial Band Tenodesis
- Patellar Ligament/Tendon Repair

D. Contraindications

- Procedures other than those listed in the Indications section.
- Pathologic conditions of bone such as cystic changes or severe osteopenia that would impair its ability to securely fix the apollo Anchor.
- Pathologic changes in the soft tissues being fixated to bone that would prevent their secure fixation by the apollo Anchor.
- Comminuted bone surface that would militate against secure fixation of the medial suture anchor.
- Physical conditions that would eliminate or tend to eliminate adequate implant support or retard healing, i.e., blood supply limitation, previous infection, etc.
- Conditions which tend to limit the patient's ability to restrict activities or follow directions during the healing period.
- apollo Anchors are not designed for and should never be used to attach artificial ligaments.

E. Adverse Effects

- Infections, both deep and superficial.
- Foreign body reactions.
- Adverse reactions to implant materials have sometimes necessitated the removal of the implant. Patient sensitivity to device materials must be considered prior to implantation.
- **Metal implants only:** Shoulder dislocation/subluxation.

F. Warnings

- No modification to the device should be made prior to implantation.
- apollo Anchors are designed to anchor into cortical or cancellous bone. Bone quality must be adequate to allow proper and secure anchor placement. Incomplete insertion or poor bone quality may result in anchor pullout.
- Immediate range of motion should be avoided to allow biological bony/soft tissue healing.
- An internal fixation device must never be reused.
- **Metal implants only:** All metallic implant devices used for this surgical procedure should have the same metallurgical composition.
- Postoperatively and until healing is complete, fixation provided by this device should be considered as temporary and may not withstand weigh bearing or other unsupported stress. The fixation provided by this device should be protected. The postoperative regimen prescribed by the physician should be strictly followed to avoid adverse stresses applied to the device.
- Pre-operative and operating procedures, including knowledge of surgical techniques and proper selection and placement of the device, are important considerations in the successful utilization of this device. The appropriate delivery system is required for proper implantation of the device.
- Any decision to remove the device should take into consideration the potential risk to the patient of a second surgical procedure.

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Device removal should be followed by adequate postoperative management.

- Detailed instructions on the use and limitations of the device should be given to the patient.
- This is a single use device. Reuse of this device could result in failure of the device to perform as intended and could cause harm to the patient and/or user.
- This device has not been evaluated for safety and compatibility in the magnetic resonance (MR) environment. This device has not been tested for heating or migration in the MR environment. If the implant is manufactured from a metallic material, surgeons can expect that MR artifacts will be present during routine MR imaging.
- **Metal Implants Only:** Removal of supplemental fixation, if applicable, after healing. If the supplemental fixation is not removed following the completion of its intended use, any of the following complications may occur: (1) Corrosion, with localized tissue reaction or pain; (2) Migration of implant position resulting in injury; (3) Risk of additional injury from postoperative trauma; (4) Bending, loosening, and/or breakage, which could make removal impractical or difficult; (5) Pain, discomfort, or abnormal sensations due to the presence of the device; (6) Possible increased risk of infection; and (7) Bone loss due to stress shielding. The surgeon should carefully weigh the risks versus the benefits when deciding whether to remove the implant. Implant removal should be followed by adequate postoperative management to avoid re-fracture.
- Patient sensitivity to the device materials should be considered prior to implantation. See Adverse Effects.

G. Precautions

U.S. Federal law restricts this device to sale by or on the order of a physician.

- Surgeons are advised to review the product-specific surgical technique prior to performing any surgery. Detailed surgical techniques in print and electronic formats are available. Or, contact your representative for an onsite demonstration.
- **Sterile Units Only:** Contents are sterile unless package is opened or damaged. DO NOT RESTERILIZE. For single use only. Discard any open, unused product. Do not use after the expiration date.
- Prior to use, inspect the device to ensure it is not damaged. Do not use a damaged device.
- Under insertion of the device may leave the proximal end of the implant protruding beyond the cortical bone, which could potentially cause soft tissue irritation and/or pain post-operatively.
- Excessive force should not be placed on the delivery instrument.
- Careful attention should be paid to asepsis and avoidance of anatomical hazards.
- After use, this device may be a potential biohazard and should be handled in accordance with accepted medical practice and applicable local and national requirements.

H. Packaging and Labeling

- Implant devices should be accepted if the factory packaging and labeling arrive intact.
- Contact Customer Service if package has been opened or altered.

I. Material Specifications

Refer to the packaging label for the materials.

The device is made of titanium or polyetheretherketone (PEEK). Sutures are made of braided Ultra High Molecular Weight Polyethylene and polyester or polypropylene.

J. CLEANING (Reusable Instruments)

The instruments for the apollo Suture Anchors that are delivered non-sterile should be cleaned in accordance with the following cleaning instructions:

1. Wipe outer surfaces of Instrument with isopropyl alcohol (IPA), minimum concentration 70%.
2. Soak: Prepare an enzymatic detergent-based cleaning solution, per the manufacturer's instructions. Fully immerse the Instrument in the solution for a minimum of 1 minute or longer if recommended by the cleaning agent's manufacturer. After the soak, brush the components with a soft bristle brush to wash external surfaces of the Instrument with the cleaning solution.
3. Rinse: Rinse the Instrument by holding under running water for at least one minute or until cleaning solution residues are no longer visible.
4. Rinse: Prepare at least 50cc's of enzymatic detergent-based cleaning solution, per the manufacturer's instructions. Decontaminate cannulas and lumen by flushing them with a sterile syringe and using a pipe cleaner.
5. Rinse: Rinse the Instrument thoroughly under running tap water for at least one minute.
6. Ultrasound: Prepare another batch of enzymatic detergent-based cleaning solution to fill an ultrasonic cleaning tank. Place the flushed Instrument in the ultrasonic cleaner and sonicate for 10 minutes minimum.
7. Final Rinse: Use distilled water, deionized water, sterilized water, or water otherwise controlled for bacterial endotoxins, to rinse the Instrument. Rinse in cool or tepid running water for at least 1 minute, or longer if necessary, to remove visible signs of cleaning solution. Ensure that rinse water flows liberally into blind holes, recesses, and crevices.
8. Dry: Allow Instrument to air-dry.
9. Inspect: Inspect the Instrument. If any soil or fluid is visible, repeat the cleaning procedure above, with fresh batches of cleaning solution.
10. Verify mechanical function of Instrument. Do not continue to sterilization (below) if the device does not function properly, or if it is visibly damaged.

K. Sterilization (Reusable Instruments)

The instruments for the apollo Suture Anchors are delivered non-sterile and should be sterilized in accordance with the following steam and dry time specifications:

Cycle Type	Cycle Time	Temperature	Packaging	Dry time
Pre-vacuum	4 minutes	132° C	Double Autoclave Wrap	30 minutes

L. Disposal

All disposable instruments and single use anchors should be disposed of properly and in accordance with the facility's sharps protocol.

M. Storage Conditions

All devices must be stored in the original unopened packaging, away from moisture and should not be used after the expiration date.

N. Information

Surgeons are advised to review the product specific surgical technique prior to performing any surgery. Detailed surgical techniques are available in print and electronic formats. Or, contact your authorized representative for an onsite demonstration.

If further information is needed, contact maruho medical Customer Service or your authorized representative.

REF	Catalog number		Do not use if package is damaged
LOT	Batch code		Expiration date
	Consult instructions for use		Do not reuse
	Caution	STERILE EO	Sterilized by Ethylene Oxide gas
	Date of manufacture		Manufacturer
	Keep Dry	Rx	Prescription use only

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