

bonecam® Suture Anchor & Delivery System

Instructions for Use

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A. Device Description

The bonecam Suture Anchor & Delivery System is for use in fixation of soft tissue to bone in the knee, shoulder, hip, foot/ankle, elbow, and hand/wrist. The bonecam Suture Anchor & Delivery System consists of a single anchor with integrated multiple suture attachments. The anchors are provided loaded on individual inserters with integrated sutures with or without needles, sterile, for single use only.

Contents

1 ea. – Non-absorbable bonecam suture anchor made from Zeniva® ZA-500 or ZA-600 PEEK (polyetheretherketone) from Solvay.

1 ea. – Single-use disposable inserter [ABS plastic (Handle) and Stainless Steel (Shaft).

2 ea. – Braided, uncoated, sutures made from UHMWPE with or without stainless steel needles.

Refer to individual bonecam suture anchor delivery system product labels for material, diameter and length of anchor, size of attached sutures, and needle attachment.

B. Indications for Use

The bonecam family of suture anchors are intended for use in soft tissue to bone fixation in areas such as the shoulder, elbow, knee, hip, foot/ankle, & hand/wrist.

C. Contraindications

- Anatomy 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 bonecam Anchor.
- Pathologic changes in the soft tissues being fixated to bone that would prevent their secure fixation by the bonecam Suture Anchor.
- Comminuted bone surface that would militate against secure fixation of the bonecam 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.
- bonecam Suture Anchors are not designed for and should never be used to attach artificial ligaments.

D. 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.

E. Warnings

- No modification to the device should be made prior to implantation
- bonecam 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.
- Postoperatively and until healing is complete, fixation provided by this device should be considered as temporary and may not withstand weight 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. 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.
- Patient sensitivity to the device materials should be considered prior to implantation. See Adverse Effects.
- Impacting anchor off-axis of the pilot hole during insertion may result in anchor damage or premature anchor pullout

F. 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.

G. 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.

H. Material Specifications

Refer to the packaging label for the materials.

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

I. Cleaning (Reusable Instruments)

The reusable instruments for the bonecam 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.

J. Sterilization (Reusable Instruments)

The reusable instruments for the bonecam Suture Anchors that are delivered non-sterile 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

K. Storage Conditions

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

L. 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
 i	Consult instructions for use		Do not reuse
 !	Caution		Sterilized by Ethylene Oxide gas
	Date of manufacture		Manufacturer
	Keep Dry		Prescription use only



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