



Premarket Notification 510(k) - FDA GMReis Suture Anchors IFU

GENERAL INFORMATION

- Single-use product, do not reuse, even if it is in perfect condition;
- Sterile supplied product by ETO;
- Prohibited reprocessing.

INDICATIONS FOR USE

The GMReis Suture Anchors is intended to be used for soft tissue reattachment in the elbow, shoulder, hand, wrist, foot, ankle, knee, and hip. Specific indications are listed below:

Elbow: Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction.

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

Hand/Wrist: Scapholunate Ligament Reconstruction, Repair/Reconstruction of collateral ligaments, Repair of Flexor and Extensor Tendons at the PIP, DIP and MCP joints for all digits, tendon transfers, Carpal Ligament Reconstruction and Carpometacarpal joint arthroplasty (basal thumb joint arthroplasty).

Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Metatarsal Ligament Repair, Hallux Valgus reconstruction, tendon transfers, Mid-foot reconstruction.

Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis.

Hip: Capsular repair, acetabular labral repair.

PURPOSE OR INTENDED USE OF THE PRODUCT

The success of the treatment is directly related to the appropriate surgical technique applied by the surgeon and the correct choice of implants, following their characteristics: model, shape, type, dimensions, etc. The size and anatomy of the bone structures are the main factors in the definition of the implants to be used. It is possible to see below, for each type of suture, the indication of the implantation site.

PHYSICAL PRINCIPLE AND TECHNOLOGY FUNDAMENTALS DESCRIPTION, APPLIED TO ITS WORKING AND ACTION

The product enables the fixation of soft tissue to the cancellous bone, promoting its stabilization. For this, an anchor is inserted into the bone, and the surgical suture attached to this anchor are tied to the tissue in order to lead tissue fixation.

GM dos Reis Industria e Comercio Ltda.

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Website: www.gmreis.com.br

TECHNICAL SPECIFICATION OF THE MATERIAL MANUFACTURING

The Suture Anchors GMREIS are manufactured with the following raw materials:

- PEEK Anchor made of PEEK (Polyetheretherketone), according to ASTM F2026.

MARKING

The implantable components are identified by marking laser with the following information:

- Batch of product;
- Product Code;
- Logo of the GMReis brand.

STERILIZATION METHOD

The products are supplied sterile, by ethylene oxide, according to ISO 11135 - "Sterilization of health care products - Ethylene oxide Part 1: Requirements for development, validation and routine control of the sterilization process for medical devices" and must be maintained in its original packaging until the moment of its use.

PRODUCT TRACEABILITY PROCEDURE

The Identification and traceability of the product are ensured through a set of 05 adhesive tags contained in the package, along with the instructions for use and the implant, such as: name, model, code, allotment, product registration and manufacturer identification. In this way it is possible to make the reverse path and reach a production, raw material, suppliers, and other quality controls established in the GMReis Quality System. It is the responsibility of the medical and hospital staff (the custodians of patient information and records), the tag fixation on the surgical description sheet or a section of the medical chart. GMReis recommends that the patient receive this information, receiving a certificate stating one of the traceability adhesive tags.

PRESENTATION FORM OF THE MEDICAL PRODUCT

The product is for single use, supplied sterile by ETO, properly identified, presented in 4 levels of packaging.

Primary: blister pack or surgical grade paper, containing an ETO integrating seal;

Secondary: Surgical grade paper;

Tertiary: outer carton for packaging, properly labeled on the reverse.

Finally, the outer carton is wrapped in a thermo-shrinkable polyolefin film constituting the quaternary packaging of the product.

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The product is accompanied by 5 traceability tags and a manual on how the user can obtain the Instructions for Use of the product, in non-printed form, at no additional cost, including shipping.

HANDLING, CONSERVATION, STORAGE AND TRANSPORT

The hospital is responsible for the steps of handling, conservation and storage of products from receipt, ensuring that the manufacturer's recommendations are respected too, and that the product maintains the original characteristics established. The product must be preserved, handled and transported in order to prevent any damage or modification to its characteristics and packaging. The product must be preserved and stored in its original packaging until use, with due care in the medical-hospital area, in a clean, dry, ventilated environment, protected from sunlight and free from contaminating substances (acid and organic vapors), and with controls, recommended, at room temperature.

Exclusively professionals in the hospital area, properly trained, empowered and familiar with the technique and the procedures involved, must do the handling of the product.

Vibrations effects, shocks, defective seating and improper stacking during transportation should be avoided. Storage outside these conditions may create risk to the procedure, and patient.

CAUTION/PRECAUTIONS

These implants are designed to support physiological loads when implanted for the stabilization of a certain ligament structure and may rupture until full tissue integration/regeneration occurs. Overloads and mechanical manipulation efforts (i.e., torsion, bending, traction, etc.) exerted during implantation compromise its mechanical characteristics, which can lead to early failure of the implant and/or inserter, as well as breakage during implantation.

It is recommended to release the load after the period established by the surgeon for complete recovery of the treated tissue.

The implants are designed as aids to the natural consolidation process but are not intended to replace anatomical structures or support body weight in the presence of incomplete consolidation.

The time during which such care should be maintained depends on the specific characteristics of each procedure and must be carefully delineated by the surgeon in charge. Similarly, postoperative care and rehabilitation will depend on innumerable variables that cannot be delineated in this document, and which are the absolute responsibility of the multidisciplinary team that cares for the patient. Until full load is released, the patient should follow the surgeon's recommendations.

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PATIENT INSTRUCTIONS

The patient should be warned about the limits of its initial activities and about their rehabilitation to protect the surgery performed by the surgeon in charge.

Excessive initial activities can affect the positioning of the implantable component or affect the supporting bone and/or ligament structure, making the review procedure more difficult and premature.

The patient should be warned about the risks of surgery, secondary effects, or undesirable side effects and that the reconstruction carried out with the implant will not present the same physical characteristics of the natural tissue, and there may be failures of the implantable component, resulting from abnormal physical activities, trauma or referring to degenerative diseases.

The patient must be instructed by the surgeon in charge to use adequate external support (such as splints or boots), if necessary, for the time stipulated by the surgeon in charge, as well as to restrict physical activities that put the implant at risk or that allow movements at the site of the implant.

It is important that the patient is aware that the implant has a useful life of 90 (ninety) days and should be warned that if ligament reconstruction does not occur in this period, the implants may loosen, rupture or break, especially if the postoperative recommendations, excessive physical therapy load and/or poor implant positioning, accidents as well as other causes.

The surgeon in charge is responsible to make the postoperative recommendations, accompaniments, clinical evolution and radiological of the patient.

The patient should be informed that, despite of the raw material used for the implant manufacturer is biocompatible, side effects may occur or adverse reactions in more sensitive patients, such as:

- Sensibility to the material;
- Allergic reactions;
- Bone deformity in the place of the implementation;
- Incomplete bone consolidation;

SIDE EFFECTS/ADVERSE EVENTS:

- Pain, discomfort, and abnormal sensations due to the presence of the implant;
- Infections, both deep and superficial;
- Allergies and other reactions with implanted materials.
- Hydrarthrosis (accumulation of fluid in joint cavities);
- Foreign body reactions;

NOTE 1: A second surgery may be needed to repair the secondary effects

NOTE 2: Smokers, elderly patients, and who suffer from degenerative disease or metabolic dysfunction, have greater difficulties in achieving tissue integration/regeneration, consequently there are greater chances of rupture or loosening of the implants, and not achieving tissue integration/regeneration.

WARNINGS:

- An internal fixation device must never be reused;
- Do not re-sterilize this device;
- Foreign body sensitivity. Where material sensitivity is suspected, appropriate tests should be made, and sensitivity ruled out prior to implantation.

WARNING REGARDING THE PRODUCT CONDITION WHICH RESTRICT THE USE

The product should not present any visual abnormality in its surface, as risks, failures, dirt or other.

The implantable components that exhibit abnormalities in their surface should be destroyed and disposed of according to the procedure of "Destruction and disposal".

FACTORS THAT MAY CAUSE THE IMPLANT TO A POSSIBLE BREACH, LOOSENING, DISPLACEMENT OR HEATING WHICH SHOULD BE INFORMED TO THE PATIENT

The following are the main factors that, alone or in combination, can lead the implantation of a premature failure (breakage, loosening or migration).

- Disregard with the postoperative recommendations;
- Metabolic disorders;
- Diabetes;
- Smoking;
- Patients accident (e.g., falls, accidents...);
- Failure in surgical technique;
- Inappropriate choice of implant;
- Failure to use orthosis/immobilization techniques after surgery;
- Excessive load or inappropriate activity;
- Osteoporosis;
- Practice of intense physical activity;
- Practice of physical activity prior to the surgeon release;

PROCEDURE FOR DISPOSAL TO ENSURE THE DESTRUCTION OF THE PRODUCT

The implants which for some reason were not used during the surgery and had the package open or suffered damage and/or falls may not be re-used and/or re-sterilized and should be discarded in the hospital as the medical procedure hospital and/or local law or as instructed by the Commission of Hospital Infection Control. The methods and procedures for product disposing should ensure the complete mischaracterization of it, preventing any possibility of reuse. The adulteration of the product is the sole responsibility of the hospital institution, as well as the methods and procedures for disposing used. It is recommended that they be deformed with molders or twistors until is clearly identified that the product is inappropriate for your use, ensuring that the product may not be used or improperly reused.

CONTRAINDICATIONS

The patients who present some clinical condition described below, should not be subject to the procedure with the use of the product. The contraindications include those listed below, but are not limited to:

- Pregnancy;
- Insufficient bone quality or quantity to receive the product;
- Limitations in blood supply and/or previous infections that may delay recovery;
- Patients in conditions that may compromise implant fixation such as osteoporosis, osteopenia and pathological conditions in soft tissues;
- Patients unable to follow the postoperative recommendations, including those who abuse drugs, tobacco and/or alcohol;
- Patients in inadequate physical conditions to undergo the surgical procedure and;
- Spinal procedures (e.g. This device is not for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.);
- Attachment of artificial ligaments or other implants;
- The use of this device may not be suitable for patients with insufficient or immature bone. The physician should carefully assess bone quality before performing orthopedic surgery on patients who are skeletally immature. The use of this medical device and the placement of hardware or implants must not bridge, disturb or disrupt the growth plate.

DETAILED INFORMATION ON THE CHARACTERISTICS OF ALL PARTS, ACCESSORIES AND MATERIALS DESTINED TO BE USED WITH THE PRODUCT**ADMISSIBLE COMBINATIONS WITH OTHER MATERIALS**

Combination with other materials is not recommended. The surgeon is entirely responsible for the risks inherent in the combination with other materials.

The product should only be deployed with the specific instruments, by GMReis Brand.

USEFUL INFORMATION TO PREVENT RISKS ARISING OUT OF THE IMPLANTATION**IMPLANTATION RISK**

To reduce the risks of implementing the product, the recommendations regarding the indications for use, contraindications and the information described in the "Instruction for Use" must be followed. Detailed instructions on the use and limitations of the product must be given to the patient.

Preoperative and operating room-related procedures, including knowledge of surgical techniques, proper implant size selection, and proper implant implantation, are important considerations for successful use of this device. Do not use the product if the date marked on the label has expired or if the packaging is damaged.

Note: The device may break / rupture or become damaged as a result of excessive activity or trauma. This situation may cause the device to fail, requiring a new surgery for removal.

ASSESSMENT OF THE PRODUCT DEPLOYED

After the deployment, in the intra-operative the responsible professional should perform radiological control to verify the correct positioning of the product. The professional responsible must make, and it is his/her responsibility, the clinical and radiological assessments after the surgical procedure, in the frequency stipulated by him, to check the condition of the implant and the bone healing. If the product find itself outside the correct placement, or present any non-compliance, it is the responsibility of the surgeon take the more appropriate corrective action.

RESTRICTIONS AND INSTRUCTIONS ON THE DAMAGE OF THE PACKAGING

In the circumstances described below, the product must be unusable and discarded, as the procedure of destruction and disposal:

- The sealing area of the package is violated.
- Any one of the packages present physical damage;
- The label or identification code is unreadable and
- Date of validity is expired.

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RESTRICTIONS ON REUSE

It is not allowed any reuse of the product, even if this present to be in perfect condition. The reuse does not guarantee the performance given by GMReis to the product, being free of any responsibility about this act.

ADDITIONAL INFORMATION ABOUT THE PROCEDURE BEFORE USING THE PRODUCT

Upon opening the package, check the superficial condition of the product as deformations, stains, scratches or any other type of superficial alteration or defect. The product packaging must be disposed of in accordance with the medical-hospital procedure and/or local law or as instructed by the Hospital Infect Control Commission.

MRI SAFETY INFORMATION

The PEEK Anchors implantable device is made only of polymers with PEEK as its main component, making the material safe for exposure to MRI environments.

SPECIFIC GUIDANCE TO THE PHYSICIAN REGARDING THE REPORTING OF ADVERSE EVENTS

If the product presents adverse events not reported in the instructions for use or there are technical complaints about the product, the physician should immediately contact the manufacturer through the GM Reis Customer Service (SAC), in addition to notifying the competent sanitary authority. To ensure the traceability of the product, the physician should continue as the "Procedure for product traceability". The traceability of the product is ensured by the 05 traceability tags, provided within the packaging, along with the instructions for use, as described in the topic "Product Traceability Procedure".

CUSTOMER COMPLAINT

If the medical product presents a risk specific unpredictable, being outside of its specifications or being generated any dissatisfaction, directly notify the GM Reis Customer Service (SAC). The product should be sent cleaned and packed in plastic bag, properly identified and with the description of non-compliance to the following address: G. M. dos Reis Indústria e Comércio Ltda - Pierre Simon de Laplace Avenue, no. 600 Lot 3 - Block F - 9677 - TECHNOPARK – Zip Code: 13069-320 – Campinas – SP – BRAZIL or directly notify at Telephone Number:(0xx19)3765-9900/ E-mail: sac@gmreis.com.br.

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GENERAL INFORMATION - REPROCESSING**Non-sterile Instruments:**

Point of Use Preparation for Reprocessing: Remove excess body fluids and tissue from instruments with a disposable, non-shedding wipe. Place devices in a basin of distilled water or in a tray covered with damp towels. Do not allow saline, blood, body fluids, tissue, bone fragments or other organic debris to dry on devices prior to cleaning.

Cleaning process is the first step in effectively reprocessing devices. Adequate sterilization depends on thoroughness of cleaning.

Cleaning and sterilization processes in this IFU have been validated and demonstrate that soil and contaminants have been removed leaving the devices effectively free of viable microorganisms.

It is recommended that all new relevant clinical practice guidelines be followed as per the CDC guidance, "Guideline for Disinfection and Sterilization in Healthcare Facilities".

It is recommended to rinse the device components with water that meets 'critical water' specifications in accord with AAMI ST108 "Water for the reprocessing of medical devices.

Devices are usually supplied in sets and subdivided into trays and cases in which the devices may be arranged by size or in the order needed for a specific surgical procedure and should be used to transportation and storage.

Devices Preparation:

Cleaning, inspection, and sterilization must be performed by hospital personnel trained in the general procedures involving contaminant removal.

Before use, medical devices must be cleaned to ensure that there is no risk to the patient from the transmission of infectious agents and other residues that could become toxic.

Cleaning Instructions for non-sterile devices:

Devices must be thoroughly cleaned prior to sterilization.

Disconnect all handles/knobs prior to cleaning.

Complex instruments, such as those with, cannulas, hinges, retractable features, mated surfaces, and textured surface finishes, require special attention during cleaning. Brush tight tolerance areas with an appropriately sized brush (soft bristle brush nylon) and flush using a water jet or syringe where debris could become trapped.

Ensure all moving parts of instruments are cleaned at both extents.

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Handle all products with care. Mishandling may lead to damage and possible improper functioning.

Clean the instruments, trays and inserts using only recommended cleaning solutions.

Visual inspection must be performed at each cleaning to determine if an instrument is acceptable for use. If an instrument is not acceptable for use, replace it with a new piece.

NOTE 1: The information on concentration, temperature, quality water, exposure time and cycles used in the equipment, follow the instructions for use and labels according to products manufacturer.

Manual Cleaning

In a sink the devices must be rinsed in running water to remove excess soil or contaminants.

Prepare a Prolystica® Steris enzymatic detergent solution according to the label instructions using distilled water at a concentration of 4 mL of detergent per liter of water (4 mL/1L).

Then, with a soft bristle brush nylon soaked in the prepared solution, brush the devices

Wash the devices with running water and repeat the brushing process as many times as necessary.

Finally, wash the devices with distilled water and dry and protected place.

Preparation of detergent and disinfectant solutions

Prepare a solution at a concentration of 4 mL of detergent per liter of water (4 mL/1L) of Prolystica® Steris enzymatic detergent using potable water heated between 35°C and 65°C.

Prepare another solution at a concentration of 5% neutral detergent according to the label instructions (50 mL of detergent for each liter of water) using potable water heated between 35°C and 65°C.

Prepare a disinfectant solution at a concentration of 29.6 mL of disinfectant to 3.78 L of water of Vesta Syde SQ disinfectant according to label instructions using potable water.

Washing

Pre-rinse the devices in running water to remove excess of soil or contaminants.

Then, immerse the devices in the prepared enzymatic detergent solution for at least 10 minutes.

After the action time, brush the items with the neutral detergent solution.

Finally, wash them in running water and drain them on absorbent paper to remove excess water.

Disinfection

Immerse the devices in disinfectant solution in containers for at least 10 minutes.

After the time, wash the devices with running critical water.

With the aid of absorbent paper, dry the devices.

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The cleaning process is illustrated in Figure 03

INSPECTION, MAINTENANCE, TESTING

Carefully inspect each device to ensure that all visible contamination has been removed. If contamination is noted repeat the cleaning/disinfection process.

Check the action of moving parts (e.g., hinges, box-locks, connectors, sliding parts, etc.) to ensure smooth operation throughout the intended range of motion also visually inspect for completeness, damage and/or excessive wear, unacceptable deterioration such as corrosion, discoloration and pitting.

STERILIZATION/RESTERILIZATION

Instruments should be autoclave sterilized using the following validated cycle parameters. The hospital is responsible for sterilization before surgery, through the method he finds more convenient and secure, while respecting the technical standards and current sanitary regulations. The sterilization procedures as well as the quality and the training of staff involved in this process is sole responsibility of the health service. GMReis recommends the following validated cycle:

STEAM STERILIZATION CYCLES - FOR NON-STERILE PRESENTATION

Type: humid heat

Cycle: gravitational

Temperature: 121°C (250°F)

Exposure Time: 30 minutes

Minimum Drying Time: 15 – 30 min.

The product must be wrapped with an FDA-cleared wrap.

Additional information regarding sterilization is described in ISO 17665-1- "Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices".

SYMBOLISM OF LABELLING

The graphic symbols used in labelling are in accordance with the ISO 15223 Standard and ASTM F2503-13, as follows:

Table 1 - Labeling symbols

Symbol	Description	Symbol	Description
	Date of Manufacture		Batch number
	Manufactured by		Caution "see instructions for use"
	Use-by date		Keep away from sunlight
	Keep dry		Do not use if package is damaged
	Prescription use only		Do not resterilize
	Sterile by Ethylene Oxide		Product catalogue number
	Do not reuse		MR Safe
	Unique Device Identifier		

USER WARNING

These Instructions for Use are available in format that is not printed, through the electronic address of the manufacturer: <http://www.gmreis.com.br/produtos/IFU>. The Instructions for use provided will always be in accordance with the current latest version. If there is interest from the user, the Instructions for Use may be available in printed format, without additional cost. Ask for free by e-mail: sac@gmreis.com.br.

COMPANY NAME / MANUFACTURER NAME:

GM dos Reis Indústria e Comércio Ltda.

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Caution: Federal (USA) law restricts this device to be sold by or on the order of a licensed physician.

PEEK ANCHORS, Revision: 00 - August 21, 2025

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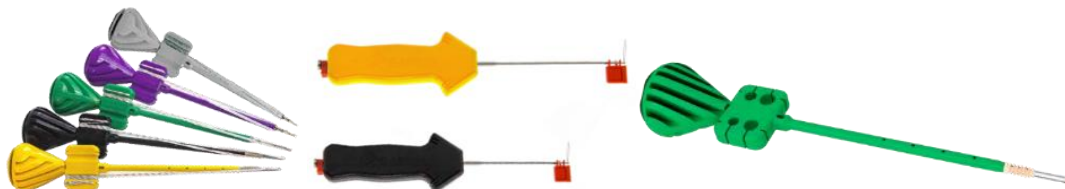
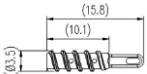


Figure 1 - PEEK Anchor Inserters (Fastlock, Presslock and Tenolock)

Table 2 - FASTLOCK anchor models

FASTLOCK		
320-35485-PB-SA	FASTLOCK - KNOTLESS PEEK ANCHOR Ø3.5x4.0/8.5mm WITH OPEN EYELET AND 2.0mm WHITE/BLACK TAPE	
320-35085-SA	FASTLOCK - KNOTLESS PEEK ANCHOR Ø3.5x4.0/8.5mm WITH OPEN EYELET AND 2.0mm WHITE/BLUE TAPE	
320-35485-SA	FASTLOCK - KNOTLESS PEEK ANCHOR Ø3.5x4.0/8.5mm WITH OPEN EYELET	
320-351580-PE3	FASTLOCK - KNOTLESS PEEK ANCHOR Ø3.5x10.1/15.8mm WITH CLOSED EYELET	
320-351580-PE2	FASTLOCK - KNOTLESS PEEK ANCHOR Ø3.5x10.1/15.8mm WITH CLOSED EYELET AND WHITE/BLACK TAPE	
320-351580-PE1	FASTLOCK - KNOTLESS PEEK ANCHOR Ø3.5x10.1/15.8mm WITH CLOSED EYELET AND WHITE/BLUE TAPE	
320-475191-PE3	FASTLOCK - KNOTLESS PEEK ANCHOR Ø4.75x15.0/19.1mm WITH CLOSED EYELET	
320-475191-PE5	FASTLOCK - KNOTLESS PEEK ANCHOR Ø4.75x15.0/19.1mm WITH CLOSED EYELET AND WHITE/BLACK TAPE	

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320-475191-PE4	FASTLOCK - KNOTLESS PEEK ANCHOR $\varnothing 4.75 \times 15.0/19.1$ mm WITH CLOSED EYELET AND WHITE/BLUE TAPE	
320-55191-PE2	FASTLOCK - KNOTLESS PEEK ANCHOR $\varnothing 5.5 \times 15.0/19.1$ mm WITH CLOSED EYELET	
320-55191-PE3	FASTLOCK - KNOTLESS PEEK ANCHOR $\varnothing 5.5 \times 15.0/19.1$ mm WITH CLOSED EYELET AND WHITE/BLACK TAPE	
320-55191-PE4	FASTLOCK - KNOTLESS PEEK ANCHOR $\varnothing 5.5 \times 15.0/19.1$ mm WITH CLOSED EYELET AND WHITE/BLUE TAPE	

Table 3 - PRESSLOCK anchor models

PRESSLOCK		
320-25080	PRESSLOCK - IMPACTED KNOTLESS PEEK ANCHOR $\varnothing 2.5 \times 4.7/8.0$ mm WITH CLOSED EYELET	
320-29125	PRESSLOCK - IMPACTED KNOTLESS PEEK ANCHOR $\varnothing 2.9 \times 7.5/12.5$ mm WITH CLOSED EYELET	
320-29155	PRESSLOCK - IMPACTED KNOTLESS PEEK ANCHOR $\varnothing 2.9 \times 10.5/15.5$ mm WITH CLOSED EYELET	
320-29155-SFPK-HIP	PRESSLOCK LONG - IMPACTED KNOTLESS PEEK ANCHOR $\varnothing 2.9 \times 10.5/15.5$ mm WITH CLOSED EYELET	

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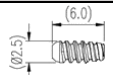
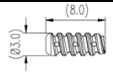
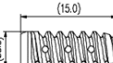
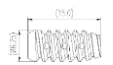
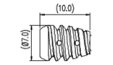
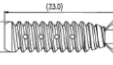
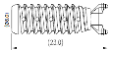
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Table 4 - TENOLOCK anchor models

TENOLock		
320-25080-FT	TENOLock - TENODESIS KNOTLESS PEEK ANCHOR WITH INSERTER Ø2.5x6.0mm	
320-30080-FT	TENOLock - TENODESIS KNOTLESS PEEK ANCHOR WITH INSERTER Ø3.0x8.0mm	
320-40010-FT	TENOLock - TENODESIS KNOTLESS PEEK ANCHOR WITH INSERTER Ø4.0x10.0mm	
320-4010-FT	TENOLock - TENODESIS KNOTLESS PEEK ANCHOR WITH INSERTER Ø4.0x10.0mm	
320-47515-FT	TENOLock - TENODESIS KNOTLESS PEEK ANCHOR WITH INSERTER Ø4.75x15.0mm	
320-5515-FT	TENOLock - TENODESIS KNOTLESS PEEK ANCHOR WITH INSERTER Ø5.5x15.0mm	
320-62515-FT	TENOLock - TENODESIS KNOTLESS PEEK ANCHOR WITH INSERTER Ø6.25x15.0mm	
320-7010-FT	TENOLock - TENODESIS KNOTLESS PEEK ANCHOR WITH INSERTER Ø7.0x10.0mm	
320-70230-FT	TENOLock TENODESIS KNOTLESS PEEK ANCHOR WITH INSERTER ø7.0x23.0mm WITH OPEN EYELET	
320-80230-FT	TENOLock - TENODESIS KNOTLESS PEEK ANCHOR WITH INSERTER ø8.0x23.0mm WITH OPEN EYELET	

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Premarket Notification 510(k) - FDA

GMReis Suture Anchors IFU

Table 4 - Instruments

CODE	DESCRIPTION	IMAGE
320-110-24	PRESSLOCK DRILL Ø2.4mm	
320-110-29	PRESSLOCK DRILL Ø2.9mm	
320-110-27	FASTLOCK DRILL Ø2.7x110.0mm	
320-110-27-C	FASTLOCK CANNULATED DRILL Ø2.7x110.0mm	
320-110-34	FASTLOCK DRILL Ø3.4x110.0mm	
320-110-37	FASTLOCK DRILL Ø3.7x110.0mm	
320-FL-35	FASTLOCK TAP Ø3.5mm	
320-FL-475	FASTLOCK TAP Ø4.75mm	
320-FL-55	FASTLOCK TAP Ø5.5mm	
320-FLP-475	FASTLOCK PUNCTURE Ø4.75mm	
320-FLP-55	FASTLOCK PUNCTURE Ø5.5mm	
320-PL-45	FASTLOCK PUNCTURE Ø4.5mm	
320-135	GUIDE WIRE Ø1,35mm	

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