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INSTRUCTIONS FOR USE

Stitch Cerclage - Suture Tapes

GENERAL INFORMATION

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

INDICATIONS FOR USE

Stitch Cerclage - Suture Tapes are indicated in orthopedic surgeries as bone fixation cerclage, specifically:

- Sternotomy indications including the "rewiring" of osteomized sternums;
- Repair of long bone fractures due to trauma or reconstruction.

CONTRAINDICATIONS

Patients who present any of the clinical conditions described below should not undergo the procedure using the product. Contraindications include those listed below, but are not limited to:

- Allergic reactions or hypersensitivity to UHMWPE cerclage material;
- Patients with acute or chronic bone infection;
- Patients with diseases or any clinical condition that may compromise the bone consolidation process.
- Spinal fixation applications and osteoporosis or insufficient bone quality.

DEVICE DESCRIPTION

Stitch Cerclage - Suture Tapes are indicated in orthopedic surgeries for internal fixation of discontinued bone structures. The surgical sutures and tapes are made of UHMWPE (ultra-high molecular weight polyethylene), the needles are made in AISI300 steel series, according to the standard ASTM F899 and cerclage is assembled on an ABS loader.

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, batch, 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. Traceability tags shall be fixed to the following locations:

- The tag number 1, obligatorily, in the patient's medical record;
- The tag number 2, in the report delivered to the patient;
- The tag number 3, in the tax documentation that generates the collection to the paying source;
- The tag number 4, available for supplier control (registration distribution history);
- The tag number 5, provided for the control of the doctor.

It is a 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.

HOW SUPPLIED

They are found in a variety of diameters to meet the range of anatomies of the patients, it is provided in sterile condition sterilized by Ethylene Oxide. The instruments are provided non-sterile and should be sterilized before use.

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HANDLING, CONSERVATION, STORAGE AND TRANSPORT

The hospital is responsible for the handling, conservation and storage of products from the moment they are received and must ensure that the manufacturer's recommendations are followed and that the product maintains its original characteristics.

The product must be preserved, handled and transported in a way that prevents any damage or alteration to its characteristics and packaging.

The product must be preserved and stored in its original packaging until the moment of use, with due care from 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.

The product must be handled exclusively by professionals from the medical-hospital area, duly trained, qualified and familiar with the technique and procedures involved.

The effects of vibration, shocks, faulty seating and inadequate stacking during transportation must be avoided. Storage outside these conditions can generate risks to the procedure and to the patient.

SURGICAL TECHNIQUE

1. Analyze the type of cerclage to be used (internal fixation of diaphyseal fractures of the femur and humerus or sternum closure);
2. Apply the product to the desired region, in order to perform the planned cerclage technique using passers appropriate to the bone anatomy;
3. Use the tensioner to obtain adequate tension;
4. Cut the needle and any excess tape and discard;
5. Multiple tapes may be implanted depending on the surgical planning performed.

Only surgeons qualified and trained in bone fixation may use the product, including orthopedists and cardiovascular surgeons.

Not to be used in conjunction with other bone fixation implants, like plates.

Note: The surgeon must be aware of all recommendations described in the product's "Instructions for Use" and other information described on the label. Please check the complete surgical technique on the GMReis website or by email at qualidade@gmreis.com.br.

CAUTION/PRECAUTIONS

The patient must be warned by the surgeon in charge about the risks of the surgeries and the consequences of the factors mentioned in the contraindications and undesirable side effects, as well as the possible complications that may arise.

The patient must be warned by the surgeon in charge about the limits of his/her initial activities and about his/her rehabilitation in order to protect the surgery performed.

The patient must be informed that the implant will not have the same characteristics as natural tissue, and that there may be failures in the positioning of the implantable component, resulting from excessive physical activity, trauma or other degenerative diseases, which may lead to a revision procedure.

It is the responsibility of the surgeon in charge to make the post-operative recommendations, follow-ups and clinical progress of the patient.

It is important for the patient to be aware that failure to follow the post-operative recommendations may lead to the failure of the procedure.

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CRITERIA FOR SIZE SELECTION, SHAPE AND DESIGN ASSOCIATED WITH THE BONE CONSOLIDATION SUCCESS

It is the responsibility of the surgeon in charge of the procedure, the size selection of the implantable component most appropriate for the use, which must be done based on radiological studies pre-operative and the indication of the correct use. The right selection of the implant is extremely important and should consider the biomechanical aspects, the size and shape of the bone structure to be treated, which corresponds to the size and the model of the implant selected.

Product load restrictions

STITCH CERCLAGE tapes are indicated for internal fixation of diaphyseal fractures of the femur and humerus and sternal closure using cerclage techniques.

The application of forces exerted when handling the product, or its improper handling, may compromise the integrity of the product and its mechanical characteristics, leading to the tape breaking or the needle coming loose during the surgical procedure.

WARNINGS

- This device is intended to be used by a trained medical professional.
- Do not re-sterilize this device.
- Once open, discard unused suture.
- The sutures must never be re-used.
- Detailed instructions on the use and limitations of this device should be given to the patient.
- In handling this or any other suture material, care should be taken to avoid damage from handling. Avoid crushing or crimping damage due to application of surgical instruments such as forceps or needle holders.
- Surgeons must apply their professional judgment when determining the appropriate sized device based on the specific indication, preferred surgical technique, and patient history.
- The safety and effectiveness of these devices for use as an artificial ligament or tendon has not been established; hence, the device should not be used for those applications.

POTENTIAL ADVERSE EVENTS

- Loosening and need for revision surgery.

MRI SAFETY INFORMATION

The implantable devices are made only in polymers with its main component the UHMWPE (Polyethylene Ultra-High Molecular Weight). Stitch Cerclage - Suture Tapes is MR Safe.

USER WARNING

These Instructions for Use are available on-line, through the electronic address of the manufacturer: <http://www.gmreis.com.br/produtos/IFU>, and can be checked in the search field by trade name, described on the label of the product packaging. 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

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

FURTHER INFORMATION

If the medical product presents a risk specific unpredictable, being outside of its specifications or being generated any dissatisfaction, directly notify the GM Dos Reis Customer Service.

GM Dos Reis Indústria e Comércio Ltda - Pierre Simon de Laplace Avenue, no.600 TECHNOPARK – CEP: 13069-320 – Campinas – SP – BRAZIL or directly notify at Telephone Number:+55 19 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 specifications for AAMI TIR34 "Water for the reprocessing of medical devices" for example, DI/RO water.

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.

NOTE: Any implant that has not been used, but has become soiled, should be handled according to hospital protocols. Refer to implant product inserts for any specific processing, cleaning, and sterilization instructions for that implant.

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 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 and flush using a water jet or syringe where debris could become trapped.

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

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 brush 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.

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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 were 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 on absorbent paper to remove excess water.

Disinfection

Immerse the devices in disinfectant solution in containers.

Wait the action time of 10 minutes.

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

With the aid of absorbent paper, dry the devices.

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.

Visually inspect for completeness, damage and/or excessive wear.

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.

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".

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SYMBOLS GLOSSARY

ISO 15223-1 and ASTM F2503-13.

Symbol	Description	Symbol	Description
	Date of Manufacture		Batch number
	Manufacturer and Date of Manufacture		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	Code	Product catalogue number
	Do not reuse		MR Safe

COMPANY NAME / MANUFACTURER NAME:

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STITCH CERCLAGE EN Revision: 00, December 12, 2024

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STITCH CERCLAGE**CODE****DESCRIPTION**

333-SCAB-25-1226CI	STITCH CERCLAGE - Suture Tape UHMWPE blue and white with 2,5mm with curved needle ½ 26mm cylindrical tip
333-SCBR-25-1226CI	STITCH CERCLAGE - Suture Tape UHMWPE white with 2,5mm with curved needle ½ 26mm cylindrical tip

STERNAL STITCH CERCLAGE**CODE****DESCRIPTION**

333-ECAB-25-1226CO	STERNAL STITCH CERCLAGE - Suture Tape UHMWPE blue and white with 2,5mm with curved needle ½ 26mm conventional tip
333-ECBR-25-1226CO	STERNAL STITCH CERCLAGE - Suture Tape UHMWPE white 2,5mm with curved needle ½ 26mm conventional tip
333-ECAB-25-1248CO	STERNAL STITCH CERCLAGE - Suture Tape UHMWPE blue and white 2,5mm with curved needle ½ 48mm conventional tip
333-ECBR-25-1248CO	STERNAL STITCH CERCLAGE - Suture Tape UHMWPE white 2,5mm with curved needle ½ 48mm conventional tip
333-ECBR-25-1226RB	STERNAL STITCH CERCLAGE - Suture Tape UHMWPE white 2,5mm with curved needle ½ 26mm blunt tip
333-ECAB-25-1226RB	STERNAL STITCH CERCLAGE - Suture Tape UHMWPE blue and white 2,5mm with curved needle ½ 26mm blunt tip
333-ECBR-25-1248RB	STERNAL STITCH CERCLAGE - Suture Tape UHMWPE white 2,5mm with curved needle ½ 48mm blunt tip
333-ECAB-25-1248RB	STERNAL STITCH CERCLAGE - Suture Tape UHMWPE blue and white 2,5mm with curved needle ½ 48mm blunt tip

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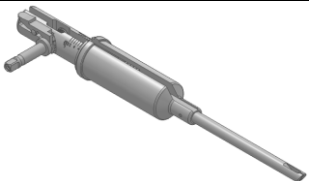
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CODE	DESCRIPTION	SIZE	MATERIAL	REGULATION NUMBER/PRODUCT CODE/CLASS	IMAGE
333-SC-100	Cerclage Tensioner	278,0mm x 32,0mm	Stainless Steel ASTM F899	888.4540 LXH CLASS I	
333-SC-200	T Ratchet Handle	117,0mm x 114,0mm	Stainless Steel ASTM F899 and Polymer Handle	888.4540 LXH CLASS I	
333-SC-310	Cerclage Passer - 40,0mm	255,0mm x 30,0mm	Stainless Steel ASTM F899 and Polymer Handle	888.4540 LXH CLASS I	
333-SC-320	Cerclage Passer - 55,0mm	263,0mm x 30,0mm	Stainless Steel ASTM F899 and Polymer Handle	888.4540 LXH CLASS I	
333-SC-330	Cerclage Passer - 70,0mm	270,0mm x 30,0mm	Stainless Steel ASTM F899 and Polymer Handle	888.4540 LXH CLASS I	

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