DIMA

DESARROLLO E INVESTIGACIÓN
MÉDICA ARAGONESA

ANCHORSURE ®

INSTRUCTIONS FOR USE

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Important:

CAUTION: Federal law (U.S.) restricts the sale of this device to or by order of a physician.

Physicians should be trained in the treatment of pelvic floor disorders and in management of complications resulting from these procedures.

Read this document carefully. Failure to follow instructions may cause malfunction and/or patient injury.

Description of the device:

Single use only.

Components:

1. - Monofilament polypropylene suture:
Monofilament polypropylene suture USP-0 is used for soft tissue fixation in the pelvic region.

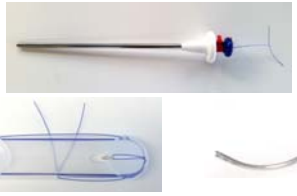
2. - Anchor:
Anchor is to be fixed to the pelvic floor ligaments.

3. - Anchoring Handle:
The Anchoring Handle allows Anchor placement to the pelvic floor ligament.

4. - Surgical Needle:
The Surgical Needle is used to fix the monofilament polypropylene suture to soft tissue in the pelvic region.

ANCHORSURE Accessory Options:

1. – Ref: A-SURE:
Contains a preloaded Anchoring Handle, an extra Anchor and a surgical needle.



2. –Ref: A-SURE02:
Contains 2 Anchors.

Intended use:

ANCHORSURE is intended for attaching sutures to ligaments of the pelvic floor.

Contraindications:

Do not implant ANCHORSURE:

- in patients undergoing anticoagulation therapy
- in pregnant women or women considering future pregnancies
- in patients with autoimmune disease affecting connective tissue
- in infants or children
- in patients with pre-existing conditions that pose surgical risks

Warnings and precautions:

1.- This product is presented sterile and must be sterile before its use. Before opening, the package must be inspected to check that it is not damaged and sterility is not compromised.
2.- This product is not reusable. ANCHORSURE cannot be re-sterilized. Reject and do not use any unpackaged or damaged system.
3.- Strict aseptic measures must be taken during the surgical procedure.
4.- Implant ANCHORSURE with proper surgical procedures, avoid contamination and infections.
5.- Inform the patient that dysuria, hematuria or any other adverse effect must be communicated to the surgeon as soon as possible.
6.- Retro pubic post-operative bleeding may occur. Observe any signs or symptoms before patient's discharge.
7.- It is recommended that patients avoid strenuous physical activity including sports (for example biking, jogging, etc.) for a minimum of two months after surgery. It is also recommended to avoid sexual intercourse during the first two months after surgery.
8.- The date of the last revision of this document is on the last page. If more than 24 months have passed since the last revision date, please contact the manufacturer or distributor to receive the updated document if available.
9.- It is recommended to pay special attention and take the appropriate measures to avoid risks during surgery in patients with urinary tract infection or obstruction, renal insufficiency, undergoing concomitant bowel surgery or in the presence of an active infection, cancer, radiated patients, or any other patient condition that may be affected by the use of the Anchorsure.

Adverse reactions:

1.- Vessel or nerve punctures may occur during the ANCHORSURE placement. The repair of the damage may require surgical intervention.
2.- Temporary irritation of surrounding tissue or adverse reactions to the foreign body may occur.
3.- As a foreign body, ANCHORSURE may stimulate a pre-existing infection.
4.- In the event that the patient suffers complications or reactions caused by any of the components, the system must be explanted immediately.
5.- The device may produce pain, tissue irritation, fistula formation or material extrusion.

Surgical Technique:

Before using ANCHORSURE the doctor must read and understand this document.

Anesthetics and antibiotic therapy:
The surgical technique to implant the device can be performed under regional or general anesthesia. It is recommended to follow the antibiotic protocol dictated by the hospital.
Anchor Placement:
Introduce the Anchoring Handle into pararectal space, position the tip of the handle over the pelvic floor ligament. Firmly press the Anchoring Handle against the ligament. Advance the anchor delivery shaft to deliver the anchor completely. Withdraw the Anchoring Handle from the patient and secure the proximal traction sutures with forceps. Connect the suture tip to the curved needle and suture the pelvic floor desired tissue to the ligament.

Materials used in manufacturing:

Suture:
Polypropylene monofilament

Anchor:
PEEK

Anchoring Handle:
Stainless Steel AISI 303
POM

Sterilization:

ANCHORSURE is sterilized by Ethylene Oxide.
This product is a single use device and it must not be re-sterilized or re-used.
Do not use if the package has been damaged.

Storage:

Store the ANCHORSURE at a temperature lower than 40ºC, far from humidity, heat and direct light. Do not use after the expiration date detailed on the package.

Single use product:

The ANCHORSURE device is intended to be used once only for a single patient. Do not reuse, reprocess or re-sterilize ANCHORSURE. Reuse, reprocessing or re-sterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or re-sterilization may also create a risk of contamination of the device and/or patient infection or cross-infection, including, but not limited to the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient. After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

Last Update of the Instructions for Use:

Date of the last review: March 2016

Manufacturer information:

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