

ANCHORSURE®

INSTRUCTIONS FOR USE



MANUFACTURING

Desarrollo e Investigación Médica Aragonesa S.L.
Polígono Industrial Mediavega, Parcela 2.8
50300 Calatayud (Zaragoza)
Spain
Tel: +34-976-884065
Fax : +34-976-891872
E-mail: dimasl@dimasl.com



DISTRIBUTION

Productos Especiales de Neomedic International S.L.
C/ Maestrat, nº 41-43 1º
08225 Terrassa (Barcelona)
Spain
Tel: +34-93-7804505
Fax: +34-93-7806105
E-mail: info@neomedic.com

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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.

INTENDED USE

Anchorsure is intended for attaching suture to ligaments of the pelvic floor.

CONTRAINDICATIONS

Do not implant Anchorsure:

- in patients with pre-existing conditions that pose an unacceptable surgical risk as determined by the Physician, including comorbidities that may compromise tissue healing.
- in patients who are undergoing anticoagulation treatments.
- in patients who suffer urinary tract infections or obstructions.
- in pregnant women or women that are considering future pregnancies.
- if the patient suffers renal insufficiency.
- in patients with immune deficiency.
- in patients who are still growing or less than 18 years of age.
- in areas with signs of tissue necrosis.
- in patients with known sensitivity or allergy to system materials.
- in patients undergoing concomitant bowel surgery.
- in patients that already have a system implanted for vaginal prolapse or urinary incontinence.

WARNINGS AND PRECAUTIONS

Pre-operative:

- The patient should be counseled that there are alternatives to pelvic floor surgery, and the reason for choosing surgery should be explained. Such alternatives include but are not limited to: Pelvic Floor Exercises (Kegel exercises), Pessary/Vaginal Tampon, and/or behavioral modification (electrostimulation).
- Obtain patient consent of surgery with an understanding of the postoperative risks and potential complications of pelvic floor surgery.
- Patient counseling should include a discussion that the device to be implanted is a permanent implant, and that some complications associated with the implant may require additional surgery that may or may not correct the complication.
- The physician must determine the risks that should be included in the patient informed consent.
- The device must only be used by doctors trained in the placement of this device. It is mandatory to know the operational principles of the device.
- The device must only be implanted by doctors who are qualified to carry out the required surgical technique.
- Surgical risks not associated directly with the use of the device, its function, or method of implantation require understanding and consideration by a qualified surgeon who is knowledgeable of anatomy, medical treatments and procedures for conditions appropriately treated with this device.
- As anatomy of individual patients may vary greatly, for each procedure it is important that the intended plans for device advancement and the intended location for product placement are planned and known for each individual patient. Employment of imaging methods before and after product placement may aid in proper product placement and confirm absence of injury to non-targeted anatomical structures.
- Special care should be taken in patients with conditions that may be aggravated by their placement in modified dorsal lithotomy position.
- This product is provided sterile and must be sterile before its use. Before opening the product the package must be inspected to ensure it is not damaged and that the sterility is not compromised.
- This product is not reusable. Anchorsure cannot be re-sterilized. Reject and do not use any unpackaged system.
- The date of the last revision of this document is included in this Instructions For Use. If more than 24 months have passed since the last revision date, please contact the manufacturer or distributor to receive the updated Instructions For Use.

Intra-operative:

- This product is an implant that must be implanted in an operating theatre. Use strict aseptic and antibiotic coverage measures during the surgical procedure.
- Good surgical practices should be followed for management of contaminated or infected wounds with particular attention to the possibility of product infection.
- Intra-operative bleeding may occur.
- Take special care during surgical intervention to avoid laceration, perforation or damage of nerves, blood vessels, arteries, bladder, urethra, intestines and other pelvic structures. Mechanical disruption of the tissue may occur.
- Cystoscopy should be performed to confirm bladder integrity.
- The used components may be a potential biohazard. Handle and dispose of the Anchoring Handle, excess Suture, and any other used components in accordance with any local and federal law regarding medical waste, with special attention to disposal requirement for sharp devices, to prevent unnecessary injury or harm.
- Mechanical damage may occur if affixing any part of the product with any staples, clips, or clamps. Clamps should only be used on the suture ends. The use of clamps could damage or weaken the strength of the suture. Cut and discard the area of the suture that is damaged. Damage to the suture could cause system failure.
- When connecting the suture to the surgical needle, only the suture end should be inserted into the eye. Insertion of the suture into the eye of the surgical needle could possibly damage the suture and cause system failure. Therefore, if the suture end has been damaged during insertion, the damaged area should be cut and discarded.
- Avoid excess tension of the Suture to minimize the possibility of Suture damage.
- Take special care to avoid tighten the Suture by pulling only one end. The Suture could disengage from the Anchor and it will no longer be possible to reconnect the Suture to the Anchor.

Post-operative:

- Instruct the patient to report dysuria, hematuria, paresthesia, or any other abnormal symptoms to surgeon as soon as possible.
- Post-operative retropubic bleeding may occur. Observe any signs or symptoms before discharging the patient. The patient must be instructed to contact the surgeon immediately if any hemorrhaging occurs.
- Patient should report incontinence, voiding dysfunction or problems defecating to the surgeon as soon as possible.
- It is recommended that patients do not overly exert themselves physically or partake in any strenuous sporting activity (for example biking, jogging, etc.) for at least a minimum of two months following surgery. It is also recommended to avoid sexual intercourse during the first two months after surgery.

ADVERSE REACTIONS

- Temporary surrounding tissue irritation, allergic reaction or adverse reactions to foreign bodies may occur. Other reactions may include: erosion, infection, inflammation, recurrence of the pathology, pain and/or discomfort, dysuria, hematuria, fistulas, hematomas, hemorrhage, erythema, abscesses, and/or seromas.
- As a foreign body, Anchorsure could stimulate a pre-existing infection.
- Failure of the procedure resulting in continued or worsening of the pathology.
- Altered bladder and/or bowel function.
- Dyspareunia.
- Vaginal discharge, bleeding.

As with all surgical interventions, the patient is at risk of:

- Wound site complications (i.e.: excess granulation formation, wound dehiscence).
- Scarring.
- Physical deformity.
- Emotional problems.

The occurrence of adverse reactions may require revisions and/or realization of specific, additional treatments, including but not limited to: antibiotics, blood transfusions, intravenous (IV) therapy, drainage, multiple restoration surgeries, and removal of the device.

DESCRIPTION OF THE DEVICE

This device has been designed for a single use.

Anchorsure is a sacrospinous-ligament (SSL) fixation system. It is composed of an anchor which is secured to the SSL using a specially designed applicator (Anchoring Handle), and an attached monofilament Suture.

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 references:

1. - Ref: A-SURE:

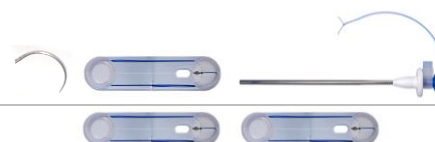
Contains:

- a preloaded Anchoring Handle
- an additional Suture and Anchor
- a Surgical Needle

2.- Ref: A-SURE02:

Contains:

- 2 Sutures and 2 Anchors.



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.

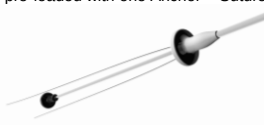
Loading the Anchoring Handle

The Anchoring Handle is composed of two parts: an inner rod and an outer tube, each with a polymer grip/trigger button. Inner: trigger button with two linear grooves; Outer: grip with round, central aperture.

Surelift Anchorsure system kit includes an assembled Anchoring Handle, pre-loaded with one Anchor + Suture. To load additional Anchor + Suture:



1. Place the Anchor into the tip of the Anchoring Handle's inner rod, with each end of the Suture passing through the lateral grooves in the tip.



2. With the Anchor loaded onto the tip of the Anchoring Handle's inner rod, insert the inner rod into the outer tube through the round opening in the grip.



3. Once the Anchoring Handle is assembled and loaded with an Anchor, be sure to insert each end of the monofilament Suture into the lateral grooves of the trigger button.

MATERIALS USED IN MANUFACTURING

Patient-contacting materials

Suture: polypropylene monofilament
Anchor: polyetheretherketone (PEEK)
Anchoring Handle: stainless steel*

Anchorsure is free of phthalates, latex and other hazardous materials.

*Stainless steel components contain nickel

STERILIZATION

Anchorsure is sterilized with Ethylene Oxide.

This product is a single use device and must not be re-sterilized or re-used.

Do not use if the package has been damaged.

STORAGE

It is recommended to store the product in a dry place at room temperature, away from 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.

SYMBOLS USED ON PRODUCT LABELS



CATALOGUE NUMBER



CONSULT INSTRUCTIONS FOR USE



SERIAL NUMBER



USE BY DATE



UNIQUE DEVICE IDENTIFIER



MANUFACTURER



MEDICAL DEVICE



KEEP DRY



DO NOT REUSE



DO NOT RESTERILIZE



DISTRIBUTOR



STERILIZED USING ETHYLENE OXIDE



SINGLE STERILE BARRIER SYSTEM WITH PROTECTIVE PACKAGING INSIDE



KEEP AWAY FROM SUNLIGHT



DO NOT USE IF PACKAGE IS DAMAGED AND CONSULT INSTRUCTIONS FOR USE



INFORMATION WEBSITE FOR PATIENTS