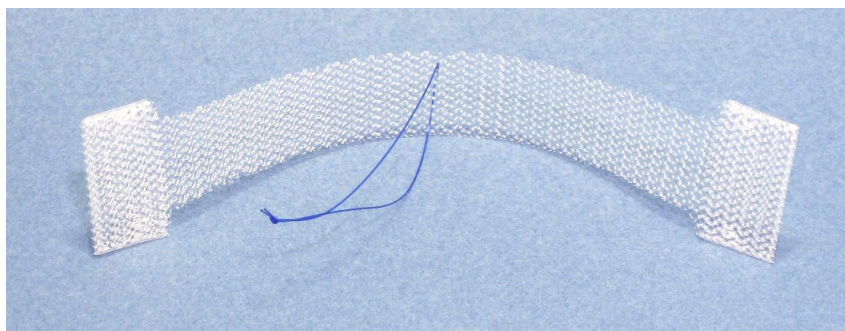


NEEDLELESS SLING



INSTRUCTIONS FOR USE



MANUFACTURING

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NEEDLELESS SLING

INSTRUCTIONS FOR USE

ENGLISH

CAUTION: Federal law restricts use of this device to physicians trained in the procedures and techniques for implanting suburethral slings and managing complications from gynecological use of surgical mesh.

IMPORTANT

Please, read the Instructions for Use carefully. Not following the indications in the user instructions may cause malfunctioning of the system, injury or damage to the patient.

These instructions for use explain the common steps for implanting the Needleless Sling. These instructions for use do not substitute a training to correct SUI (Stress Urinary Incontinence). The device should only be used by doctors trained in the treatment of this condition, more specifically in the use of this device, and by following the instructions for use.

Considering that each individual patient may present special anatomical conditions, it is imperative that the surgeon understands and plans for the safe and effective placement of the device. As with any surgical intervention, special circumstances may also be presented during the surgery; in such cases the medical specialist will be responsible for deviating from the instructions as necessary to ensure patient safety and health.

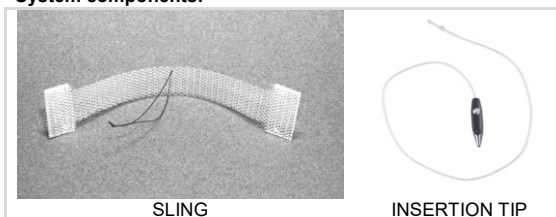
INDICATIONS FOR USE

Needleless Sling is intended for treatment of stress urinary incontinence (SUI) for female urinary incontinence resulting from urethral hypermobility and / or intrinsic sphincter deficiency.

DESCRIPTION OF THE DEVICE

This device has been designed for single-use only.

System components:



CONTRAINDICATIONS

Do not implant Needleless Sling:

- 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 undergoing anticoagulation treatments.
- in patients who suffer urinary tract infections or obstructions.
- in pregnant women or women who are considering future pregnancies.
- in patients with renal insufficiency.
- in patients with immune diseases.
- in patients who are still growing or less than 18 years of age.
- in sub-urethral or peri-urethral areas with signs of tissue necrosis.
- in patients with known sensitivity or allergy to device materials.
- in patients undergoing concomitant bowel surgery.
- in patients that already have a system implanted for urinary incontinence or vaginal prolapse.

WARNINGS AND PRECAUTIONS

Pre-operative:

- The patient should be counseled that there are alternatives to incontinence mesh surgeries, and the reason for choosing a mesh sling should be explained. Such alternatives include but are not limited to: Biofeedback, pelvic floor exercises (Kegel exercises), behavioral modification, pessary/vaginal tampon, transurethral bulking agents, medication, electrical stimulation and/or pads.
The patient may also be offered non synthetic mesh surgical options (e.g.: fascial sling or native tissue repair).
- Conservative, non-invasive treatments should be recommended before choosing a suburethral sling implant.
- Obtain patient consent of surgery with an understanding of the postoperative risks and potential complications of mesh surgery.
- Patient counseling should include a discussion that the sling to be implanted is a permanent implant, and that some complications associated with the implanted mesh may require additional surgery that may or may not correct the complication. A multi-disciplinary team of physicians is recommended for patient counseling.
- The physician must determine the risks that should be included in the patient informed consent.
- Users must be familiar with the surgical technique for bladder neck suspensions and must be adequately trained in the placement of Needleless Sling implantation procedure before employing the device.
- 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.
- The user must be qualified to manage any complications or adverse events associated to the device and the surgical procedure.
- As anatomy of individual patients may vary greatly, for each procedure it is important that the intended plans for device advancement and the intended place for mesh placement are planned and known for each individual patient. Employment of imaging methods before and after mesh placement may aid in proper mesh placement and confirm absence of injury to non-target anatomical structures.
- The risks and benefits of performing the Needleless Sling procedure in patients with the following conditions should be carefully considered by the physician:
 - Patients with other pelvic floor meshes;
 - Overweight patients;
 - Concomitant pelvic organ surgery;
 - Patients with conditions that would compromise healing (in patients who suffer cancers of the vagina, cervix, or uterus or in patients who have received radiation in the area of treatment, etc.) and;
 - Patients with mild to light SUI.
- Needleless Sling is not recommended for women in the first two years after their last pregnancy.

NEEDLELESS SLING

INSTRUCTIONS FOR USE

ENGLISH

- Special care should be taken in patients with conditions that may be aggravated by their placement in modified dorsal lithotomic position.
- This product is sterile and must remain sterile before its use. Inspect the package before its opening. Be sure the package is not damaged and sterility is not compromised.
- Do not reuse or resterilize this device. No component of the Needleless Sling system is reusable. 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. Prophylactic antibiotics can be administered according to the physician's usual practice.
- Good surgical practices should be followed for management of contaminated or infected wounds with particular attention to the possibility of mesh infection.
- Avoid excess tension of the mesh to minimize urinary retention, bowel obstruction or the possibility of damage to tissues or internal organs. Mesh must not be placed in direct contact with bowel or visceral organs, including urinary bladder.
- Take special care during surgical intervention to avoid perforation of bladder, bowel, urethra, vaginal wall, intestine and other internal pelvic structures as well as damage of nerves, blood vessels, pubic bone, or mechanical disruption of the tissue. Attention to local anatomy and sling placement will minimize risks.
- Intra-operative bleeding may occur.
- Excluding forceps, which are for sling placement, no other devices such as clamps, staples or clips should be used on/with the mesh, as mechanical damage may occur. Damage to the device could cause system failure. No data is available on the use of the sling with tissue adhesives and is not recommended.
- The Insertion Tip and midline blue thread are not permanent implants. Cut and withdraw the midline blue thread and completely withdraw the Insertion Tip (if used) before closing the vaginal wall.
- The discarded device components (midline blue thread, Insertion Tip) may be a potential biohazard. Handle and dispose of the discarded components in accordance with any local and federal laws regarding medical waste and disposal requirements for sharp devices, to prevent unnecessary injury or harm.

Post-operative:

- Instruct the patient to report dysuria, hematuria, paresthesia, or any other abnormal symptoms to the surgeon as soon as possible.
- Post-operative 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 (e.g.: heavy lifting) or partake in any moderate to high intensity sporting activity (e.g.: biking, jogging, etc.) for at least a minimum of two months. It is also recommended that patients avoid sexual intercourse during the first two months after surgery.
- The device is provided with multiple, product ("hospital") labels of which must be included in the patient medical file as well as administered to the patient for easy identification of the implant.

POTENTIAL ADVERSE REACTIONS

Known risks of surgical procedures for the treatment of incontinence include:

- Temporary surrounding tissue irritation, allergic reaction or adverse reactions to foreign bodies may occur. These reactions may produce infection, inflammation, recurrence of the incontinence, discomfort and/or pain, adhesion formation, dysuria, bleeding, hematuria, fistulas, hematomas, hemorrhage, erythema, abscess, edema and/or seromas.
- As a foreign body, the device could stimulate a pre-existing infection, or suffer rejection.
- Extrusion, exposure, and/or migration of the mesh from the desired location. The device may also produce erosion through the vagina, urethra, bladder or other surrounding tissues or structures. Mesh contraction (shrinkage) is associated with vaginal tightening, vaginal shortening and vaginal pain.
- Voiding dysfunction/de novo incontinence in the form of urgency, frequency or nocturia may appear after the intervention.
- Failure of the procedure resulting in continued or worsening urinary incontinence.
- Excess tension on the mesh may produce temporary or permanent urinary tract obstruction and retention.
- Altered bladder and/or bowel function. Problems defecating.
- Acute and/or chronic pain.
- Nerve damage, neuromuscular problems.
- Atrophic vaginitis or symptoms like redness, itching, burning or dryness of the vagina.
- Vaginal spotting, bleeding, abnormal discharge, or scarring.
- Dyspareunia. Sexual partners may experience discomfort, irritation and/or pain during sexual activity.
- Foreign body sensitivity or palpability, discomfort.

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

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

In cases in which the mesh needs to be removed in part or whole, significant dissection may be required.

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/or removal of the device.

SURGICAL TECHNIQUE

Before using Needleless Sling the doctor must read and understand this document.

Anaesthetics and antibiotic therapy:

The surgical technique to implant Needleless Sling can be performed under local, regional or general anaesthesia. It is recommended to follow the surgical implants antibiotic protocol dictated by the hospital.

Surgical technique:

With the patient in lithotomic position, inject local anaesthesia at the anterior vaginal wall.
Make a 2 cm longitudinal incision at the middle line of the anterior vaginal wall.

Dissect the para urethral submucosa with Mayo scissors until the tip of the scissors is in contact with the inferior pubic ramus. Do not dissect the fascia with Mayo scissors. Expand the submucosal space by a wide retrodissection while withdrawing the Mayo scissors to create enough space for the mesh to be absolutely flat under the urethra. Insert surgical forceps (Crawford) into one of the terminal pockets of the sling, opening the forceps inside the pocket to gather mesh, closing them to fold the pocket, and to minimize the width of the sling tip. Insert the sling through the submucosal dissection (in the direction of 10 o'clock for the right side of the patient and 2 o'clock for the left side of the patient). Push the mesh pocket through the fascia into the internal obturator muscle to the point where the central sling traction thread is 0.5 to 1cm from the urethral midline. Open the surgical forceps to release the mesh pocket.

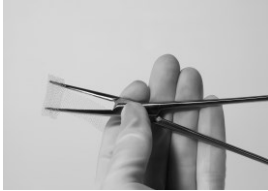
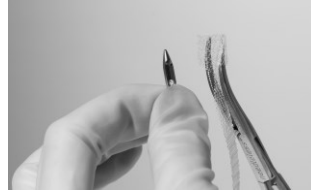
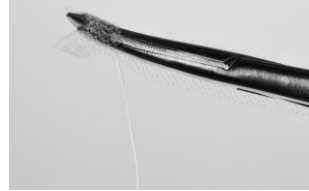
NEEDLELESS SLING INSTRUCTIONS FOR USE

ENGLISH

Close and pull the forceps out of the vaginal surgical incision maintaining the mesh in place. Repeat the same maneuver on the contra lateral side and continue with forceps penetration up to the point where the central traction thread of the mesh is at the middurethral line. A Mosquito clamp can be placed on the central traction thread to better control the center of the mesh.

Sling repositioning maneuvers can be performed by further pushing the sling pocket with the tip of the forceps. Assure that the sling is fully extended, in full contact with the submucosa and centered at the mid urethral line.

HOW TO USE THE INSERTION TIP



MATERIALS USED IN MANUFACTURING

Patient-contacting materials:

Sling: Polypropylene monofilament mesh and thread (blue)

Insertion Tip: Stainless Steel* and multifilament ultra high molecular weight polyethylene (UHMWPE) thread

No phthalates, latex or other hazardous materials are used in the manufacture of the Needleless Sling-implant components.

*Stainless steel components contain nickel

STERILIZATION

Needleless Sling 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 packaging 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

Needleless Sling device is intended to be used once only for a single patient. Do not reuse, reprocess or resterilize Needleless Sling. Reuse, reprocessing or resterilization 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 resterilization 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



SERIAL NUMBER



DO NOT REUSE



MEDICAL DEVICE



UNIQUE DEVICE IDENTIFIER



DO NOT RESTERILIZE



DO NOT USE IF PACKAGE IS
DAMAGED



CONSULT INSTRUCTIONS
FOR USE



USE BY DATE



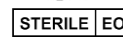
MANUFACTURER



KEEP DRY



KEEP AWAY FROM SUNLIGHT



STERILIZED USING ETHYLENE OXIDE

