

KIM® (Knotless Incontinence Mesh)

INSTRUCTIONS FOR USE



MANUFACTURING

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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 KIM (Knotless Incontinence Mesh). 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

KIM (Knotless Incontinence Mesh) is a surgical mesh kit for treatment of female stress urinary incontinence resulting from urethral hyper mobility and / or intrinsic sphincter deficiency.

DESCRIPTION OF THE DEVICE

This device has been designed for a single-use only. System components:

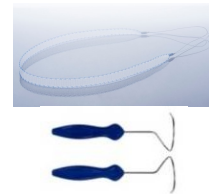
KIM (Knotless Incontinence Mesh) kit**Ref: KIM01/OID5**

All components are provided sterile and are single-use.

1.- Sling: Polypropylene monofilament Sling for female urinary incontinence treatment, which permits the patient continence control by providing extra support to the urethra.

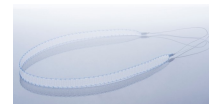
2.- Passers: A pair of Passers.

Two stainless steel transobturator Thread Passer needles. They are used during the surgical procedure to drive the sling traction threads through the obturator foramina.

**KIM (Knotless Incontinence Mesh) sling****Ref: KIM-01**

KIM Sling is provided sterile and is single use.

Polypropylene monofilament Sling for female urinary incontinence treatment, which permits the patient continence control by providing extra support to the urethra. Passers are necessary to drive the KIM Sling traction threads through the obturator foramina.

**CONTRAINDICATIONS**

Do not implant the device:

- 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.
- 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 sub-urethral or peri-urethral areas with signs of tissue necrosis.
- in patients with known sensitivity or allergy to KIM (Knotless Incontinence Mesh) 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 an implantable 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 device 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 KIM (Knotless Incontinence Mesh) 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 the 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 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 KIM (Knotless Incontinence Mesh) 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.
- KIM (Knotless Incontinence Mesh) sling is not recommended for women in the first two years after their last pregnancy.
- 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.
- Do not reuse or resterilize this device. No component of the KIM (Knotless Incontinence Mesh) system is reusable. Reject and do not use any unpackaged system.
- Before surgery, remove and discard protective tips on the Passers, if applicable.
- 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 product infection.
- Cystoscopy should be performed to confirm bladder integrity after the needle-passage, as well as a digital rectal exam for detection of rectal perforation.
- 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.
- Intra-operative bleeding may occur.
- 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 proper passage of needles will minimize risks.
- Do not affix any part of KIM (Knotless Incontinence Mesh) with any staples, clips, or clamps as mechanical damage to the mesh and/or anchor may occur. No data is available on the use

KIM (Knotless Incontinence Mesh) INSTRUCTIONS FOR USE

ENGLISH

of the sling with tissue adhesives and is not recommended.

- Omitting the vaginal and skin incisions to insert the Passers may result in excessive force and could cause injury to the patient.
- The Transition Cones, the Traction Thread loops are not permanent implants.
- The discarded device components (Traction Thread, Transition Cones and Passers) may be a potential biohazard. The Passers have sharp tips, which could potentially protrude when not in use. Handle and dispose of the Passers, as well as the other 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 urinary incontinence with a mid-urethral sling 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. Hardening of the mesh caused by fibrosis.
- 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, removal of the device.

SURGICAL TECHNIQUE

Before using KIM (Knotless Incontinence Mesh) the doctor must read and understand this document.

Anaesthetics and antibiotic therapy:

The surgical technique can be performed under regional or general anesthesia. It is recommended to follow the hospital implants antibiotic protocol.

KIM(Knotless Incontinence Mesh) placement: (TransObturator Technique)

1.- Vaginal Incision: With the patient in the gynecological position, prepare the surgical field by Auvard Speculum. Start by making a 2 cm longitudinal incision at the anterior vaginal wall, preparing the submucosal space to present the best possible view of the urethral tract.

2.- Make a mark inside the groin creases, at the level of the clitoris laterally. Perforate the skin with a 0.5 cm scalpel stab to help entering the passers. Introduction of the KIM passer from this described entry point of the obturator foramen to the vaginal incision.

3.- Cystoscopy: Perform a cystoscopy to determine the bladder integrity, and assure that the bladder is not perforated. If perforated, withdraw the passer and repeat step two (2).

4.- Placement of the KIM (Knotless Incontinence Mesh): Connect the traction threads of the KIM to the tip of the passers and pull the traction threads by withdrawing the passers through the skin. Position the KIM at the mid urethra with no tension, and close the vaginal incision. Cut the excess of KIM protruding out off the skin of the patient and close the minimal skin incisions.

MATERIALS USED IN MANUFACTURING

Patient-contacting materials

Sling: Polypropylene monofilament mesh

Traction Threads: Ultra high molecular weight polyethylene (UHMWPE)

Transition Cones: Polyoxymethylene (POM)

Passers*: Stainless Steel

No phthalates, latex or other hazardous materials are used in the manufacture of the KIM (Knotless Incontinence Mesh) implant components.

*Stainless steel components contain nickel

STERILIZATION

KIM (Knotless Incontinence Mesh) 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

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 DISCLAIMER

KIM (Knotless Incontinence Mesh) device is intended to be used only once for a single patient. Do not reuse, reprocess or re-sterilize KIM (Knotless Incontinence Mesh) system. 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



STERILIZED USING ETHYLENE OXIDE



SERIAL NUMBER



USE BY DATE



SINGLE STERILE BARRIER SYSTEM WITH
PROTECTIVE PACKAGING INSIDE



UNIQUE DEVICE IDENTIFIER



MANUFACTURER



KEEP AWAY FROM SUNLIGHT



MEDICAL DEVICE



KEEP DRY



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



DO NOT REUSE



DO NOT RESTERILIZE