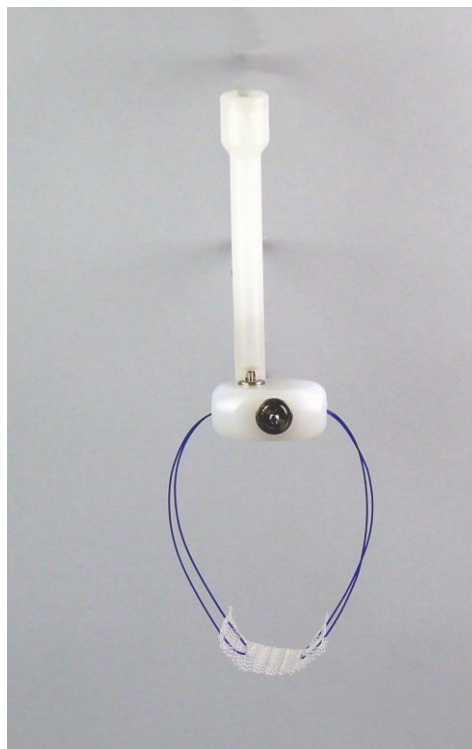


REMEEEX SYSTEM

FOR FEMALE URINARY INCONTINENCE



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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CAUTION: Federal law restricts the use of this device to physicians trained in 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 Remeex System. 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

The Remeex System is intended to be used as a pubourethral sling for treatment of female stress urinary incontinence (SUI) resulting from urethral hypomobility or hypermobility and/or intrinsic sphincter deficiency.

DESCRIPTION OF THE DEVICE

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

REMEEX SYSTEM

(Includes: Varitensor + Manipulator + 2 Disconnectors + Screwdriver + Sling + Passers composed of 2 needles and 1 handle)

1.- Varitensor: The permanently implanted part of the system which permits the physician to adjust the Sling tension.

2.- Manipulator: The part of the system which permits the Varitensor to be adjusted from outside the body to increase or decrease the Sling tension. Before the patient is discharged from the hospital, the Manipulator is disconnected from the Varitensor and removed from the patient using the Disconnector (the Manipulator comes connected to the Varitensor from the manufacturer).

3.- Disconnector: The part of the system that is used to disconnect or connect the Manipulator to the Varitensor. The system includes 2 Disconnectors.

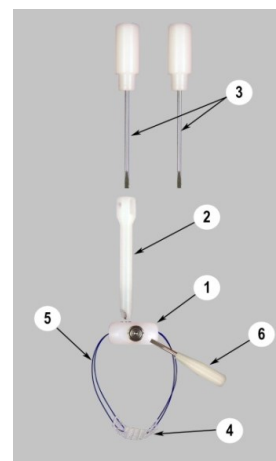
4.- Sling: A 15 x 32 mm polypropylene monofilament mesh connected to two monofilament Traction Threads. The Sling will be connected to the Varitensor by the Traction Threads.

5.-Traction Threads: The Sling will be connected to the Varitensor by the Traction threads. The Traction Threads come connected to the Sling from the manufacturer.

6.- Screwdriver: The Screwdriver is used to tighten the Fixation Screw (frontal screw of the Varitensor which fixes the Traction Threads).

7.- Passers: The detachable, single-use, retropubic Passers are used during the surgical procedure to drive the Traction Threads through to the abdominal wall.

Ref: SREM-01



DESCRIPTION OF THE ACCESSORIES USED WITH THE DEVICE

Accessories - Not included - Sold separately:

READJUSTMENT KIT

Ref : AR-01

The Readjustment Kit is composed of a Manipulator and 2 Disconnectors for medium to long-term Remeex Sling readjustment. The Readjustment Kit sterile and is single-use only.



READJUSTMENT KIT LONG

Ref : AR-01L

The Readjustment Kit Long is composed of a longer and stronger Manipulator and 2 longer Disconnectors for medium to long-term Remeex Sling readjustment. The Readjustment Kit Long is provided sterile and is single-use only.



THREAD PASSER

Ref : AR-03

The Thread Passer is an Ø3.5mm stainless steel needle. It is provided non-sterile, and is reusable. The Thread Passer must be cleaned and sterilized before first and all subsequent uses.



PASSER HANDLE

Ref : AR-05

The Passer Handle is a polymeric "t-handle" to be used with the AR-03 Thread Passer. It is provided non-sterile, and is reusable. The Passer Handle must be cleaned and sterilized before first and all subsequent uses.



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 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 are less than 18 years of age.
- if the fascia of the rectus abdominal muscles is damaged or does not offer enough resistance.
- in sub-urethral or peri-urethral areas with signs of tissue necrosis.
- in patients with known sensitivity or allergies to Remeex System materials.
- in patients undergoing concomitant bowel surgery.
- in patients that already have a system implanted for urinary incontinence or vaginal prolapse.

WARNINGS AND PRECAUTIONS

Preoperative:

- The patient should be counseled that there are alternatives to incontinence mesh surgeries, and the reason for choosing an adjustable mesh sling should be explained. Such alternatives include but are not limited to: Biofeedback, pelvic floor exercises (Kegel exercises), behavioral modification, pessary/vaginal tampons, transurethral bulking agents, medication, electrical stimulation and/or pads. The patient may also be offered a non-adjustable sling or alternatively, non-mesh surgical options (e.g.: fascial sling, stitches).
- 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 implant 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 Remeex System 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 Remeex System 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.
- Remeex System device 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 Remeex 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 Passer 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 contact any part of the Sling mesh with any staples, clips, or clamps as mechanical damage to the mesh may occur. No data is available on the use 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.
- Do not turn the Manipulator without complete control. It is crucial to record the number of turns, the direction of the turns (both clockwise or counter-clockwise) and the date that it has been performed.
- While the external Manipulator is connected to the Varitensor, take the appropriate aseptic techniques and conditions to avoid contamination and infection at the site. The appropriate cleaning of the abdominal site must be performed by the appropriate medical personnel. During this time when the Manipulator and Varitensor are connected, the abdominal area must be protected using aseptic technique while covering the surgical field with appropriate sterile materials.
- To disconnect the external Manipulator from the Varitensor, gently pull on the Manipulator while rotating the Disconnecter until the point mark of the Disconnecter is aligned with the line mark of the Manipulator. Do not apply excessive pressure during this procedure.
- Clamps should only be used on the Traction Thread ends. The use of clamps could damage or weaken the strength of the Traction Threads. Damage to the Traction Threads between the Sling and the ends could cause system failure.
- The Passers, Manipulator, Disconnectors and Screwdriver are not permanent implants.
- During the readjustment procedure, take special care to avoid damaging the Traction Threads. Damage to the Traction Threads could cause system failure.
- The use of electrocautery is not recommended during the readjustment procedure given that the device material is sensitive to excessive temperatures and may cause further risks to the patient, product and/or healthcare specialist.
- The loosening and falling of the Fixation Screw into the surgical field could occur if surgeon mistakenly unscrews instead of tightening. Without the Fixation Screw, the Traction Threads cannot be fixed to the Varitensor.
- The Manipulator must not be connected to the Varitensor more than 3 consecutive days.
- The discarded device components (excess Traction Thread, Manipulator, Disconnectors, Screwdriver 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.
- Traction Threads may fracture in case of overload due to overexertion of the patient.
- 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.
- Sling tension-level readjustments may be made throughout the lifetime of the patient. However, wound dehiscence and/or infection may occur if the surgeon performs an incision for readjustment before the previous incision wound has healed completely.

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, 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 Varitensor and/or the mesh need 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 Remeex System the doctor must read and understand the instructions for use.

Anaesthetics and antibiotic therapy:

The surgical procedure to implant the Remeex System can be performed under regional or general anesthesia. It is advisable to use the hospital antibiotic protocol for implants.

Surgical technique:

Preparation of the implanted site:

1.- Abdominal Incision: With the patient in the lithotomic position, make a small transversal incision at the abdominal midline, 2 cm over the pubis. Dissect the fatty tissue until the fascia of the abdominal rectal muscles is clearly visible.

2.- Vaginal Incision: With the patient in lithotomic position, perform a longitudinal incision at the midline of the anterior vaginal wall at the mid-urethral level. Dissect the paraurethral spaces to prepare the passage of the Passer needle to the abdominal site.

3.- Insertion of the Passer needles through the Retzius space: Passers are necessary for device delivery. They are used to drive the Traction Threads through the fascia of the abdominal rectal muscles. Insert the Passer needles in the para-urethral spaces, through the Retzius space, maintaining the tips away from the urethra and in continuous contact with the posterior wall of the pubis, until the tip of the Passer can be clearly seen at the abdominal incision. The Passers may be connected to the detachable T-handle which is used to help drive the needles and succeed in crossing the fascia of the abdominal rectal muscles. Bladder perforation may be avoided by leaving 3cm of distance between both needle tips when crossing the fascia of the abdominal rectal muscles. Take precautions to avoid going too lateral or too posterior in order to avoid blood vessels, bowel or other structural damage. Bladder mobilization techniques may also be used to avoid bladder perforation.

4.- Cystoscopy: Perform a cystoscopy to check the bladder integrity, and assure that the bladder is not perforated. If it has been perforated, withdraw the Remeex Passer and repeat step 3.

Placement of the Remeex System for Female Urinary Incontinence:

1.- Placement of the Sling and Traction Threads: After removing the Sling from the sterile package, position the Sling at the midline of the anterior vaginal wall incision, at the level of the mid urethra. Then place the Traction Threads of the Sling through the holes in the proximal end of each Passer needle. Move the Passers forward by pushing them through the Retzius space towards the abdominal site incisions or pulling them from the abdominal side until the Traction Threads appear at the abdominal incision. The surgical assistant should clamp the Traction Thread ends with a mosquito clamp. Do not clamp the Traction Threads in any other area apart from the tip. Fix the Sling with two absorbable suture knots to avoid Remeex Sling antero-posterior or lateral displacement of the Sling. The Sling must be in full contact with the suburethral tissue.

2.- Varitensor placement: Before starting this part of the surgery, the surgeon and the assistant need to change the surgical gloves to avoid contaminating the Varitensor with the vaginal flora. After removing the Varitensor and Manipulator from the sterile packaging, transport it to the abdominal surgical field. Insert the Traction Threads through the Varitensor's respective lateral reception holes, so that the Traction Threads come out through the central outcome hole (at the Varitensor midline). Before inserting the Traction Threads through the Varitensor, align the marks of the external ring of the Fixation Screw by rotating the Manipulator. (The marks need to be horizontally aligned with the Traction Thread reception holes). Once this step is completed, have the surgical assistant hold the Varitensor prosthesis in the midline, 4 cm over the fascia of the abdominal rectal muscles, and then fix the Traction Threads by tightening the Fixation Screw. Verify that the same length of Traction Thread has been left at each side between the Varitensor and the fascia. Cut and discard the excess Traction Thread protruding

from the Fixation Screw. Rotate the Manipulator clockwise, winding the Traction Threads into the Varitensor, which will lower the the Varitensor until they rest over the fascia of the abdominal rectus muscles, where it will remain for future adjustment. During the Manipulation rotation operation, it is very important to maintain a slight upward pull on the Varitensor, using the other hand. This minimal tension is optimal and permits the Traction Threads be wound properly into the Varitensor.

3.- Vaginal and abdominal incision closure: Close the abdominal incision with the Manipulator protruding perpendicular to the abdominal wall. Close the vaginal incision.

Post surgical regulation and Manipulator disconnection:

The following morning, fill the bladder with 300 c.c. of saline through a urethral catheter and ask the patient to stand up and perform Valsalva maneuvers. If necessary, rotate the Manipulator clockwise checking continence level every 4 complete turns, until continence is achieved. Invite the patient to urinate and measure the residual in the bladder after urination. If residual is less than 100 c.c. disconnect the Manipulator and discharge the patient. If residual is more than 100 c.c., decrease the Sling tension by rotating the Manipulator counterclockwise, helping to descend the urethra using a rigid probe. To disconnect the Manipulator from the Varitensor, insert the Disconnecter inside the Manipulator and rotate the Disconnecter ¼ of a turn in relation to the Manipulator while slightly pulling the Manipulator. *It is important to explain to the patient that even though she is leaving the hospital with continence, some degree of incontinence may re-appear during the first month after the intervention. If this is the case, it is possible to re adjust the Sling level by means of a minor surgical procedure.*

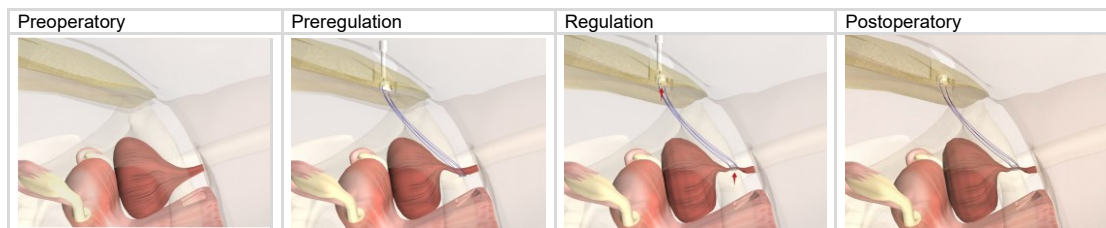
Medium-Long term ability to readjust the sling support level:

(For medium-long term readjustment, wait at least 30 days from hospital discharge to ensure that the patient is completely recovered from surgery).

Remeex System offers the possibility to modify the Sling support level whenever needed throughout the patient's lifetime. During the month following the surgical procedure the tissue inflammation will diminish considerably, the manipulated organs will return to their normal anatomical position and the patient will return to her normal physical activity level. Some patients may show some degree of incontinence, in which case the Sling can be readjusted to restore continence by performing a minor surgical procedure. This is accomplished using the single-use, pre-sterilized Remeex Readjustment Kit which contains 1 Manipulator and 2 Disconnectors.

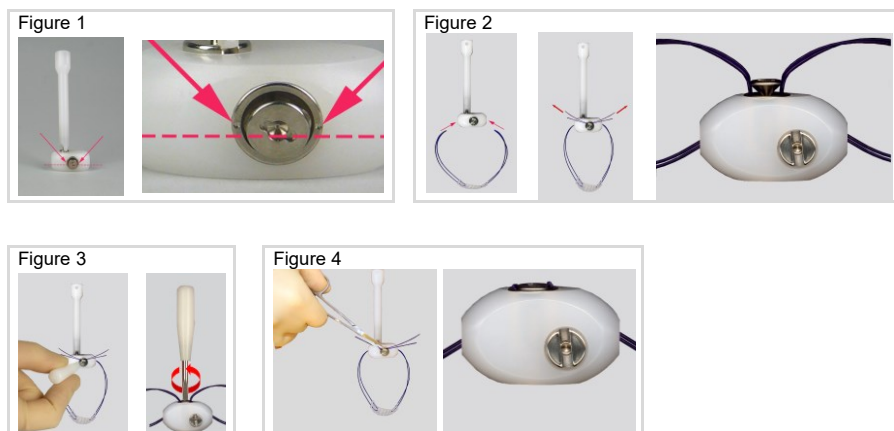
Sling Level Readjustment: In an appropriate surgical environment, after injecting local anaesthesia, make a minimal incision at the abdominal midline, just over the pubis in order to localize the Varitensor. Connect the sterile Manipulator to the implanted Varitensor and close the incision with the Manipulator protruding from the abdomen.

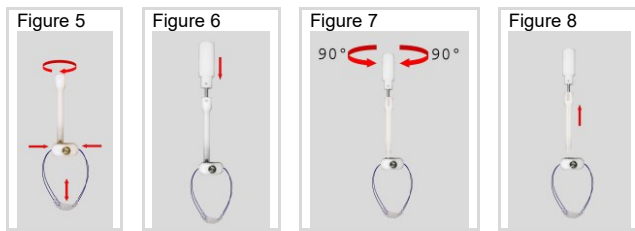
The Sling readjustment is performed with the patient in standing position, performing the normal pressure maneuvers that cause the patient to become incontinent. Fill the bladder with 300 c.c. of saline through a urethral catheter and ask the patient to stand up and perform Valsalva maneuvers. If necessary, rotate the Invite the patient to urinate and measure the residual in the bladder after urination. If residual is less than 100 c.c. disconnect the Manipulator from the Varitensor, close the incision and discharge the patient. If residual is more than 100 c.c., decrease the Sling tension by rotating the Manipulator counterclockwise, helping to descend the urethra using a rigid probe. To disconnect the Manipulator from the Varitensor, insert the Disconnecter inside the Manipulator and rotate the Disconnecter ¼ of a turn in relation to the Manipulator while slightly pulling the Manipulator. Close the abdominal incision.



Mechanical function steps:

- Figure 1.- Horizontal alignment of the external ring marks of the Fixation Screw by rotating the Manipulator.
- Figure 2.- Passing of the Traction Threads through the Varitensor.
- Figure 3.- Traction Threads fixation with Fixation Screw.
- Figure 4.- Cutting of the excess Traction Threads.
- Figure 5.- Sling level regulation by rotating the Manipulator.
- Figure 6.- Disconnecter insertion into the Manipulator.
- Figure 7.- 90° rotation of the Disconnecter in relation to the Manipulator.
- Figure 8.- Disconnection of the Manipulator.





MECHANICAL CHARACTERISTICS / SPECIFICATIONS

External manipulator function: Every 360° turn of the external Remeex Manipulator causes an increase or decrease of the Sling suspension level of approximately 1mm.

Wind up capacity: The wind up capacity of the Remeex Varitensor is 15 cm of Traction Threads per each side.

Maximum traction stress: The Varitensor can support the force of 18 Newtons produced by the Traction Threads, with a minimum safety coefficient of 5.

MATERIALS USED IN MANUFACTURING

Patient contacting materials

Varitensor and Manipulator: Ultra-high molecular weight Polyethylene (UHMWPE), Titanium

Sling: Polypropylene monofilament mesh, polyvinylidene fluoride (PVDF) monofilament Traction Threads

Passers*: Stainless steel

No phthalates, latex or other hazardous materials are used in the manufacture of The Remeex System implant components.

*Stainless steel components contain nickel

STERILIZATION

Remeex System is sterilized by Ethylene Oxide. Certain components are 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 DISCLAIMER

With the exception of the reusable surgical instruments, Remeex System device is intended to be used only once for a single patient. Do not reuse, reprocess or resterilize Remeex System. 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

REF	CATALOGUE NUMBER		DISTRIBUTOR		SINGLE STERILE BARRIER SYSTEM
SN	SERIAL NUMBER		CONSULT INSTRUCTIONS FOR USE		INFORMATION WEBSITE FOR PATIENTS
UDI	UNIQUE DEVICE IDENTIFIER		USE BY DATE		
MD	MEDICAL DEVICE		MANUFACTURER		
	DO NOT REUSE		KEEP DRY		
	DO NOT RESTERILIZE		STERILIZED USING ETHYLENE OXIDE		
	DO NOT USE IF PACKAGE IS DAMAGED AND CONSULT INSTRUCTIONS FOR USE		KEEP AWAY FROM SUNLIGHT		