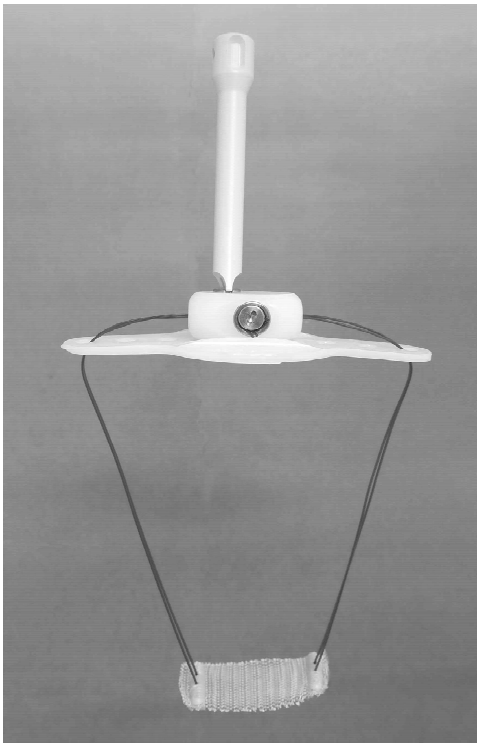
DIMA DESARROLLO E INVESTIGACIÓN
MÉDICA ARAGONESA S.L.

MALE REMEEX SYSTEM



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 pubourethral slings and managing complications from urological use of surgical mesh.

IMPORTANT

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

This document intends to explain the instructions for use of the Male Remeex System for the treatment of male urinary incontinence. These instructions for use do not substitute a training to correct SUI (Stress Urinary Incontinence). Male Remeex System should only be used by doctors instructed in the treatment of this type of pathology and more specifically, in the use of this device.

These instructions for use explain the common steps for implanting the Male Remeex System. 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 be 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

Male Remeex System is intended to be used as a pubourethral sling for the treatment of male stress urinary incontinence.

DESCRIPTION OF THE DEVICE

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

Male Remeex System

1.- Varitensor: Is a permanently implanted part of the system which permits the physician to change the tension of the Traction Threads of the Sling.

2.- Manipulator: Is 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 hospital, the Manipulator is disconnected from the Varitensor using the Disconnector and removed from the patient. (The Manipulator comes connected to the Varitensor from manufacturer).

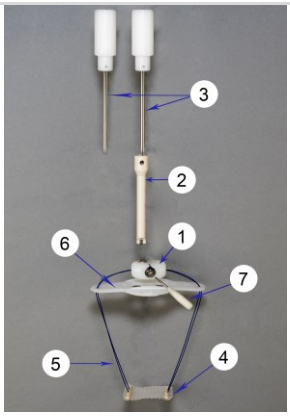
3.- Disconnector: Is the part of the system that is used to disconnect or connect the Manipulator to the Varitensor. The system includes 2 Disconnectors.

4.- Sling: Is a polypropylene monofilament mesh of 18 x 33 mm connected to the 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.- Base Plate: Is a base which lies under the Varitensor to better support it over the fascia of the rectus abdominal muscles, where it remains permanently implanted.

7.- Screwdriver: The screwdriver is used to tighten the Fixation Screw, the screw of the Varitensor which fixes the Traction Threads.

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



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DESCRIPTION OF THE ACCESSORIES USED WITH THE DEVICE

Accessories - Not included - Sold separately:

READJUSTMENT KIT **Ref : AR-01P**
The Readjustment Kit is composed of a Manipulator and 2 Disconnectors for medium to long-term Remeex Sling readjustment. The Readjustment Kit is provided sterile and is single-use only.

READJUSTMENT KIT LONG **Ref : AR-01L**

The Readjustment Kit Long is composed of a longer 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-07**
The Thread Passer is a 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.

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 the patient with renal insufficiency.
- In patients with immune deficiency.
- In patients who are still growing or less than 18 years of age.
- If the fascia of the abdominal rectus muscle is damaged or does not offer normal resistance.
- 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.

WARNINGS AND PRECAUTIONS

Pre-operative:
- The patient should be counselled that there are alternatives to Male Remeex System surgery, and the reason for choosing this readjustable sling option should be explained. Such alternatives include but are not limited to: other pubourethral & non-adjustable slings, pads, pharmaceuticals, penile clamps, urethral catheters or condoms, artificial urinary sphincter (urniary cuff), transurethral bulking agents and/or behavioral modification (e.g.: electrostimulation).
- Conservative, non-invasive treatments should be recommended before choosing a pubourethral 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 SUI surgery, 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 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 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-target anatomical structures.
- Special care should be taken in patients with conditions that may be aggravated by their placement in modified dorsal lithotomic position.
- This product is provided sterile and must be sterile before its use. Before opening the product, the package must be inspected to check it is not damaged and sterility is not compromised.
- Do not reuse or resterilize the single use components of the product. 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 these 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.
- Intraoperative bleeding may occur.
- Take special care during surgical intervention to avoid perforation of bladder, bowel, urethra, 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 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 counterclockwise) 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 by covering the surgical field with appropriate sterile materials.
- To disconnect the external Manipulator from the Varitensor, gently pull on the Manipulator while rotating the Disconnector until the point mark of the Disconnector 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, 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, cystoliths, 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 hemorrhaging occurs.
- Post-operative perineal pain is a common side effect. The patient should inform the physician if the pain becomes severe, so that it may be treated or alleviated.
- 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.
- 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.
- 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 male SUI sling:
- Acute inflammatory tissue reaction/swelling and transitory local irritation, allergic reaction or other adverse reactions to foreign bodies may occur.
- Infection, hardening of the device caused by fibrosis, inflammation/swelling or edema, recurrence of the incontinence, discomfort and/or pain, adhesion formation, dysuria, bleeding, hematuria, fistulas, erythema, hematomas, hemorrhage, abscess, and/or seromas.
- As a foreign body, the device could stimulate a pre-existing infection, suffer rejection.
- The device may produce erosion, extrusion and/or migration of the mesh.
- Failure of the procedure resulting in continued or worsening urinary incontinence.
- Detrusor overactivity could occur. Voiding dysfunction, de novo incontinence in the form of urgency, frequency or nocturia may appear after the intervention.
- Altered bladder and/or bowel function. Problems defecating.
- Excess tension on the mesh may produce temporary or permanent urinary tract obstruction and retention.
- Acute and/or chronic pain.
- Nerve damage, neuromuscular problems.
- Dyspareunia.
- 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, Base Plate and/or the Sling 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 Male Remeex System the doctor must read and understand the instructions for use.

Anaesthetics and antibiotic therapy:
The surgical procedure to implant the Male 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 implant site:

1.- Abdominal Incision: Make a small transversal incision at the abdominal midline, 2 cm over the pubis. Then open the fat until the fascia of the abdominal rectal muscles is clearly visible.

2.- Perineal Incision: With the patient in the Lithotomic position, perform a longitudinal perineal incision of approximately 6 cm and dissect subcutaneous structures until the angle between the bulb cavernous and isquio cavernous muscle is identified. Dissect the perineal body to allow free urethral mobilization.

3.- Insertion of the Remeex Passers through the Retzius space: Remeex Passers are necessary for device delivery. They are used to drive the Traction Threads through the fascia of the abdominal rectal muscles. Insert Remeex Passers from the angle between the bulb cavernous and isquio cavernous up to the abdominal incision. The Remeex Passers may be connected to a handle which is used to help drive the needles and succeed in crossing the fascia of the abdominal rectal muscles. The needle tip of the Remeex Passers must show up at the abdominal incisions at least 2 cm lateral to the midline of the abdominal incision. The same maneuver is performed in the contra lateral side. Avoid going too lateral on the pelvic side wall to avoid injury of the pelvic vessels and be sure to stay away from the peritoneal wall. Bladder mobilization techniques may also be used to avoid bladder perforation.

4.- Cystoscopy: Perform a cystoscopy to determine the bladder integrity, and assure that the bladder is not perforated. If perforated, repair as necessary, withdraw the Remeex Passer and repeat step three (3).

Placement of the Male Remeex System:
1.- Placement of the Sling and Traction Threads: After removing the Sling form the sterile container, position the Sling at the bulbar urethra. Then place the Traction Threads of the Sling through the holes at the proximal end of each Remeex Passer. Move the Remeex Passers forward by pushing them from the perineal region or pulling them from the abdominal site 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. Then fix the Sling at the bulbar urethra muscle with two absorbable suture knots to avoid antero-posterior or lateral displacement of the Sling. The Sling must be in full contact with the bulbar urethra muscle.

2.- Varitensor and Base Plate placement: Before starting this part of the surgery, the surgeon and the assistant need to change the surgical gloves to avoid contaminating the Varitensor. Insert the Traction Threads through the lateral holds of the Base Plate and 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 Base Support and the Varitensor until they rest over the fascia of the abdominal rectus muscles, where they will remain for future adjustment. During the Manipulator rotation operation, it is very important to maintain a slight upward pull on the Varitensor, using the other hand. This minimal tension is optimal for permitting the Traction Threads to be wound properly into the Varitensor.

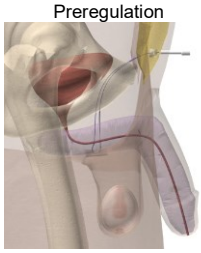
3.- Perineal and abdominal incision closure: Close the abdominal incision with the Manipulator protruding perpendicular to the abdominal wall. Close the perineal incision.

Post-surgical regulation and Manipulator disconnection:
The following morning, through a urethral catheter, fill the bladder with 300 c.c. of saline, and then 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 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 counter-clockwise, helping to descend the urethra using a rigid probe. To disconnect the Manipulator from the Varitensor, insert the Disconnector inside the Manipulator and rotate the Disconnector 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 he 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*.

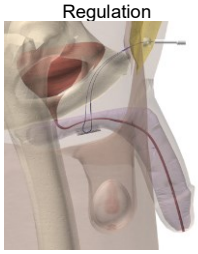
Medium-Long term ability to readjust the sling support level:
(For medium-long term readjustment, wait at least 30 days from hospital discharge to ensure that the patient is completely recovered from surgery).
Male Remeex System offers the possibility to modify the Sling support level whenever needed throughout patient's life. During the month following the surgical procedure to implant Male Remeex System, the tissue inflammation will diminish considerably, the manipulated organs will return to their normal anatomical position and the patient will return to his normal physical activity level. In this situation, some patients may show some degree of incontinence in which case the sling can be readjusted to restore continence performing a minor surgical procedure. This is accomplished using the single-use, pre-sterilized Remeex System 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 locate 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 Manipulator clockwise checking continence level every 4 complete turns, until continence is achieved (there is no leakage). 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 Disconnector inside the Manipulator and rotate the Disconnector ¼ of a turn in relation to the Manipulator while slightly pulling the Manipulator. Close the abdominal incision.

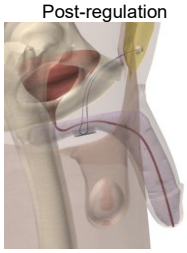
Preregulation



Regulation



Post-regulation



MECHANICAL FUNCTION STEP-BY-STEP

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 Thread fixation with Fixation Screw.
Figure 4.- Cutting of the excess Traction Threads.
Figure 5.- Sling level regulation by rotating the Manipulator.
Figure 6.- Disconnector insertion into the Manipulator.
Figure 7.- 90º rotation of the Disconnector in relation to the Manipulator.
Figure 8.- Disconnection of the Manipulator.

Figure 1

Figure 2

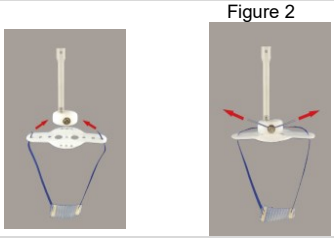


Figure 3

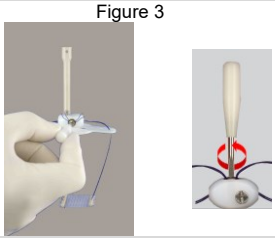


Figure 4

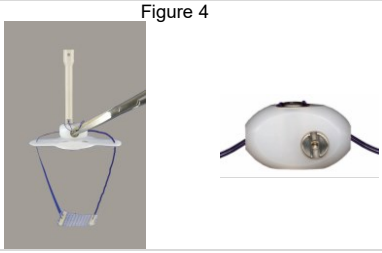


Figure 5

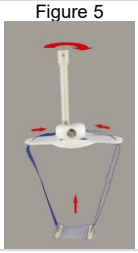


Figure 6

Figure 7

Figure 8

MECHANICAL CHARACTERISTICS / SPECIFICATIONS

External Manipulator function: Every 360º turn of the external Manipulator causes an increase or decrease of the Sling's suspension level by approximately 1mm.
Wind up capacity: The wind up capacity of the Varitensor is of 10cm of the 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
Base plate, Varitensor: Ultra high molecular weight polyethylene (UHMWPE), Titanium,
Manipulator: Polyetheretherketone (PEEK), Ultra high molecular weight polyethylene (UHMWPE), Titanium
Sling: Polypropylene monofilament mesh, polyetheretherketone (PEEK) spreader bars, polyvinylidene fluoride (PVDF) Traction Threads
Passers*: Stainless steel

No phthalates, latex or other hazardous materials are used in the manufacture of the Male Remeex System implant components.
**Stainless steel components contain nickel*

STERILIZATION

Male Remeex System is sterilized by Ethylene Oxide.
This product is a single use device and must not be re-sterilized or re-used.
Do not use if the packaging has been damaged.

STORAGE

It is recommended to store Male Remeex System 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

With the exception of the reusable surgical instruments, the device is intended to be used only once and for a single patient. Do not reuse, reprocess or resterilize. 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 cause 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
SN — SERIAL NUMBER
UDI — UNIQUE DEVICE IDENTIFIER
MD — MEDICAL DEVICE
DO NOT REUSE
DO NOT RESTERILIZE
DO NOT USE IF PACKAGE IS DAMAGED AND CONSULT INSTRUCTIONS FOR USE
DISTRIBUTOR
CONSULT INSTRUCTIONS FOR USE
USE BY DATE
MANUFACTURER
KEEP DRY
STERILE EO — STERILIZED USING ETHYLENE OXIDE
KEEP AWAY FROM SUNLIGHT
SINGLE STERILE BARRIER SYSTEM