MALE REMEEX SYSTEM

PATIENT IMPLANT INFORMATION

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The purpose of this document is to ensure the safety and effectiveness of Male Remeex System. It provides information regarding proper use, as well as potential risks and benefits of the device.

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.

1.- DEVICE DESCRIPTION

You have been treated with the Male Remeex System to help manage male stress urinary incontinence, which is the unintentional loss of urine during everyday activities such as coughing, laughing, walking, or lifting.

What is the Male Remeex System?

The Male Remeex System is a medical device that includes a surgical mesh sling. This sling is placed under the urethra (the tube that carries urine out of the body) to support it when pressure is applied to the bladder, like during movement or physical effort. It works like a small hammock that helps keep it closed when needed, to avoid urine loss.

Why did you receive it?

The Male Remeex System is typically used in male who suffer from stress urinary incontinence (SUI) resulting from intrinsic sphincter deficiency following prostate surgery.

The physician should evaluate type and severity of incontinence in order to consider Male Remeex System as a treatment.

How is the Male Remeex System different?

Unlike other slings, the Male Remeex System can be adjusted after surgery. This means that if the support needs to be increased or reduced, your doctor can do it without needing another major operation (typically, any future adjustments are due to recurrent leakage however a reduction in support could be required if urinary retention or problems emptying the bladder are present).

This permits the sling to provide just the right amount of support to help improve urine control based on your individual needs.

What about the adjustments?

The first adjustment is normally done within the first few days after surgery, based on how you are feeling and your ability to hold urine.

After that, some men may need one or more additional adjustments, while others may not need any further changes at all.

The important thing is that your implant can be regulated even months or years later if necessary, helping to maintain long-term results.

Materials used in the device

Male Remeex System is made of different materials. In the following table, materials for the permanent implantable and non-implantable components are specified:

Permanent Implantable Components	Non-Implantable Components
Ultra-High Molecular Weight Polyethylene (UHMWPE)	Stainless Steel*
Titanium	Polypropylene
Polypropylene	Polyoxymethylene (POM)
Polyether Ether Ketone (PEEK)	Ultra-High Molecular Weight Polyethylene (UHMWPE)
Polyvinylidene fluoride (PVDF) *With blue colorant*	Titanium
	Polyether Ether Ketone (PEEK)

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

Possible Side Effects or Complications

As with any surgery, there are some risks or side effects that may occur. Below is a list of possible issues that could happen after an operation with the Male Remeex System, bearing in mind that most complications are rare and the benefits of the device outweigh the potential risks:

Possible problems related to the device or the surgical procedure:

- **Body reactions**: The body may respond to the device with acute inflammation, swelling, short-term local irritation, allergic reaction, or other negative responses to the presence of a foreign object.
- **Infections or rejection**: Infection after receiving a surgical implant could occur. Additionally, because the device is a foreign object, it could worsen a pre-existing infection or, in rare cases, be rejected by the body.
- **Bleeding and other complications**: That may include hardening of the mesh due to scar tissue (fibrosis), inflammation or swelling (including edema), return of urine leakage (incontinence), discomfort or pain, tissues sticking together (adhesions), painful or difficult urination (dysuria), bleeding, blood in the urine (hematuria), abnormal passages between organs (fistulas), blood collection under the skin (hematomas), severe bleeding (hemorrhage), collection of pus (abscess), or fluid accumulation (seroma).
- **Mesh movement**: The mesh may wear through surrounding tissue (erosion), come out through nearby tissues (extrusion), or shift from its original place (migration).
- **New urgency symptoms**: A new need to urinate suddenly and urgently (urge incontinence) may appear after the procedure.
- **Procedure failure**: The treatment may not work as expected, and urine leakage may continue or worsen.
- **Urination problems**: Some people may have trouble starting, continuing, or fully emptying the bladder (voiding dysfunction). If the mesh is too tight, it may block the urinary tract, causing difficulty or inability to urinate, either temporarily or permanently.
- **Bladder or bowel changes**: There may be changes in urination or bowel habits, including problems with defecation.
- **Pain**: Pain may appear shortly after surgery (acute) or persist over time (chronic).

- **Nerve or muscle issues**: There may be nerve damage or problems with muscles and coordination (neuromuscular issues).
- **Pain during sex**: Some patients may experience pain during sexual activity (dyspareunia).
- **Foreign body sensation**: Some may feel the presence of the implant inside the body or experience general discomfort due to it.

General surgical risks (not specific to this device):

- **Problems with the wound**: Such as delayed healing or reopening of the surgical cut.
- **Scarring**: The formation of visible scars.
- **Changes to the body's appearance**: Slight deformity or changes in the shape of the area.
- **Emotional impact**: It is normal to feel emotional stress or frustration if complications occur.

If part or all of the device needs to be removed:

In rare cases, if any of the implantable components needs to be taken out, this may require additional surgery/surgeries to remove it safely.

Other possible treatments if problems occur:

If other problems occur, you may need revisions and/or additional treatments such as: antibiotics, blood transfusions, intravenous medication, drainage of fluids or further surgeries (e.g.: possible removal of the device).

2.- AFTER THE SURGERY

Once the Male Remeex System has been implanted, it is important to follow certain recommendations to ensure a smooth recovery and proper long-term function of the device.

Your Implant Card

After surgery, you should receive an **implant card** that contains important information about the device placed in your body.

Please **carry this card with you at all times**, especially when you go to a hospital, clinic, or any healthcare provider. This is particularly important if you need to have a test such as a **magnetic resonance imaging (MRI)** scan.

MRI is a medical imaging test that uses strong magnetic fields. Although the Male Remeex System has been tested and is considered safe for MRI under specific conditions, the metal parts may slightly heat up during the scan and could affect the quality of the images. MRI conditions are specified at the end of this leaflet and in the Instructions for Use (IFU).

Always show your implant card before having an MRI.

Please make sure your doctor or radiologist is aware of the MRI conditions. Following these conditions ensures your safety during the scan.

Physical Activity and Recovery

To help your body heal properly and avoid damaging the device:

- **Avoid heavy physical activities** such as lifting heavy objects, cycling, jogging, or other moderate to intense exercise for at least **two months** after surgery.
- **Avoid sexual intercourse** during the first **two months** after the procedure to give your body time to heal.
- **Follow all your doctor's instructions** about rest, wound care, and any medications.

Follow-Up Appointments

Your doctor will plan follow-up visits after surgery to check your recovery and make sure the system is working correctly.

- These follow-ups may happen in the short, medium, and long term depending on your individual case.
- If needed, adjustments to the sling can be made throughout your life. However, it's important to wait until any surgical wounds are fully healed before performing a new adjustment, as doing it too early may cause infections or problems with the wound.

When to Contact Your Doctor

Please contact your doctor or healthcare team as soon as possible if you experience any of the following:

- Pain or burning when urinating (dysuria), blood in the urine (hematuria), or unusual tingling or sensations in the pelvic area.
- Bladder stones or any other symptoms that seem abnormal or new.
- Bleeding from the surgical area. If you notice this at home, **contact your doctor immediately**.
- Return of urine leakage (incontinence), difficulty urinating, or problems with defecation (constipation or straining).
- Any signs of infection (fever, unusual discharge, redness, or swelling).
- If you feel discomfort or suspect the threads of the sling have broken, especially after exerting yourself.
- Any new pain, discomfort, or changes that worry you.

3.- INCIDENT REPORTABILITY

The Physician(s) and patient should report any serious incident in relation to Male Remeex System to the manufacturer and the national health authority that have jurisdiction in your geographical region.

4.- SUMMARY OF SAFETY AND CLINICAL PERFORMANCE

The device summary of safety and clinical performance (SSCP) is made publically available through the European Database on Medical Devices (Eudamed).

You can access the Eudamed public website at the following link: https://ec.europa.eu/tools/eudamed and search for the Male Remeex System SSCP with the unique device identifier (UDI-DI): 843656835REMEEXMALEV7.

Until the public Eudamed database module allowing access to the SSCP is up and running, the SSCP may be available to the public upon request, by contacting the manufacturer.

5.- MRI SAFETY INFORMATION FOR HEALTHCARE PROFESSIONALS

MR Conditional: The permanent implant components of Male Remeex System may safely enter an MRI scanner environment only under the specific conditions outlined in the table below.

MR Safety Information

MR Conditional

A patient with a Male Remeex System manufactured by DIMA S.L. may be safely scanned under the following conditions. Failure to follow these conditions may result in injury to the patient and/or item malfunction. Additional MR Safety information may be found at www.dimasl.com or by emailing at dimasl@dimasl.com

Parameter	***Condition of Use / Information***
Static Magnetic Field Strength (B_0)	1.5 T, 3 T
Type of Nuclei	Hydrogen
Static Magnetic Field (B_0) Orientation	Horizontal, Cylindrical Bore
Maximum Spatial Field Gradient (SFG)	1.5 T: 81.96 T/m (= 8196 G/cm) 3 T: 40.97 T/m (= 4097 G/cm)
RF Transmit Coil	Integrated Whole Body Transmit RF coil and extremities local RF transmit coils.
RF Receive Coil	Any receive RF coil may be used.
MR System (RF) Operating Modes or Constraints	Normal Operating Mode
Patient Characteristics	Only one device implanted per patient.
Scan Duration and Wait Time	Maximum 1h of continuous scanning and wait 15 minutes of cooling period before resuming scanning. Note: Autoscanning / Autoscan Mode is considered continuous scanning. Note: Short pauses between scan sequences are considered part of the scan time.
MR Image Artifact	In non-clinical testing of a worst case product, the MR image artifact caused by the item extended approximately 13.5 mm from the item when imaged with a gradient echo pulse sequence and 17.5 mm with a spin echo pulse sequence both at 1.5 T MR system.

6.- SYMBOLS USED ON PRODUCT DOCUMENTATION

CATALOGUE NUMBER

SERIAL NUMBER

UNIQUE DEVICE IDENTIFIER

MEDICAL DEVICE

DISTRIBUTOR

MANUFACTURER

DATE OF IMPLANTATION

PATIENT NAME OR PATIENT ID

NAME/ADDRESS OF IMPLANTING HEALTHCARE INSTITUTION/PROVIDER

INFORMATION WEBSITE FOR PATIENTS

MR CONDITIONAL