

Rigi10™ Malleable Penile Prosthesis

Safety Information

Indications

The device is indicated for implantation into the corpora cavernosa of the penis in men who are diagnosed as having erectile dysfunction. The malleable penile prosthesis is implanted to provide adequate penile rigidity for sexual intercourse.

It is designed for the treatment of organic, erectile dysfunction (impotence) of men due to:

- Pelvic fracture
- Spinal cord injury or disease
- Prostatectomy
- Multiple sclerosis
- Diabetes mellitus,
- Arteriosclerosis and hypertensive vascular disease,
- Priapism
- Peyronie's disease
- Selectively for psychogenic impotence

Contraindications

It is contraindicated for the patients:

- The implantation of this device is contraindicated in patients who have active urogenital infections or active skin infections in the region of the surgery.

- Whose total corporal length is less than the cylinder size.
- Sensitive to silicone materials
- Patients with neurogenic bladder and/or urinary obstruction
- Patients who are elected by the urologist as inadequate mentally or physiologically and having silicone material allergy for operation cannot be operated because of contraindications states.
- Implantation of the malleable penile prosthesis is contraindicated in patients who require repeated urethral endoscopic protocols.
- Patients who wish to retain the probability of latent, natural or spontaneous erectile ability or other interventional therapy options cannot be operated by urologist because of contraindications states.
- The implantation of the malleable penile prosthesis is contraindicated with a malleable penile prosthesis for patients who have compromised tissue and cannot resist the permanent pressure.

Warnings

- The malleable penile prosthesis is designed to be implanted as a pair of matched cylinders. A single implanted cylinder may not be adequate to achieve sexual intercourse and may have an adverse effect on the reliability of the device.
- Known and potential complications include, but are not limited to, infection, erosion, migration, extrusion, mechanical malfunction, patient dissatisfaction, adverse tissue reaction, allergic reaction, prolonged or intractable pain, urinary obstruction, silicone particle migration, And other complications: O post-operative bleeding, hematoma, penile edema, penile necrosis/gangrene, perforation of the corpora or the urethra, inability to adequately dilate the corpora, incorrect sizing of the implant, and tearing or ripping of the device during or after implantation

Precautions

Surgery Related

- Direct contact of surgical instruments to the malleable penile prosthesis may result in damage, rendering it unsuitable for implantation.
- During insertion, do not over bend cylinders beyond their natural U-shape as it may damage the malleable penile prosthesis and shorten its product life.

- Do not trim the distal or proximal ends of the cylinders, or the rear tip extenders. Trimming will damage the device.
- Careful intraoperative sizing is required to ensure proper device operation and to minimize the occurrence of sizing related complications such as migration and/or extrusion.

Device Related

- Implantation of a malleable penile prosthesis that has been in previous contact with or contaminated by body tissue or fluid, regardless of intervening, cleaning, or sterilization, is prohibited.
- The device is presented in a double pouch package and inside a protective carton box. The package should be checked in terms of damaging, tearing and puncture. Do not use the damaged, teared and punctured packages.
- Before unpacking, the expiry date of the product should be checked. Do not use the products which have passed the expiration date. Sterilization of the products which have passed the expiration date is not being guaranteed.
- Products which are removed from patients should be disposed as medical waste within the framework of legal procedures.

Patient Related

- Before operation, the urologist should decide and evaluate whether the patient is available for treatment of erectile dysfunction or not.
- A thorough preoperative consultation should include a discussion between patient and physician of all available treatment options and their risks and benefits.
- Sufficient patient skill and strength are required for the appropriate device position.
- Uncircumcised patients may have an increased risk of postoperative complications with the sub-coronal approach. Surgeons may wish to discuss performing a circumcision to reduce the risks of post-operative complications associated with this approach.
- Some malleable penile prosthesis operations can be complex or unpractical for patients who have penile scarring or contractor.
- Some adverse events can be occurred like urethral bleeding, pain, phimosis not high several, hematoma after operation.
- If the patient had been done revision surgery, they can live differences such length, flaccidity, sensation and girth associated with using new malleable penile prosthesis.
- Physiology and psychology states can hinder the successful operation of the device.