Rigicon®
Innovative Urological Solutions

Infla10® Inflatable Penile Prosthesis Safety Information

Indications

Infla10® Inflatable Penile Prosthesis is indicated for patients suffering from organic erectile dysfunction (impotence) and are candidates for a penile prosthesis implantation.

Causes for Erectile Dysfunction (impotence)

- Prostatectomy,
- Diabetes mellitus,
- Arteriosclerosis,
- Hypertensive vascular disease,
- Pelvic fracture,
- Priapism,
- Peyronie's disease
- Spinal cord injury or disease,
- Multiple sclerosis,
- Psychogenic,

Contraindications

The Infla10® Inflatable Penile Prosthesis is contraindicated in patients with:

- An active infection, especially urinary tract or genital infection;
- A documented sensitivity to silicone;

• Patients with neurogenic bladder and/or urinary obstruction

• Total corporal length less than the cylinder size

Warnings

Implantation of the device may make natural or spontaneous erections impossible

• Future interventional treatment options may not be possible following device implantation

• Patients with diabetes, spinal cord injuries, open sores or immunocompromised hosts, may have an increased risk of infection associated with a Inflatable Penile Prosthesis.

• This device contains solid silicone elastomer. The risks and benefits of implanting this device in patients with documented sensitivity to silicone (e.g. lupus, scleroderma, or myasthenia gravis) should be carefully evaluated.

• Failure to evaluate and promptly treat erosion may result in a substantial worsening of the condition, leading to infection and loss of tissue.

• Implantation may be more complicated or impractical in patients with pre-existing abdominal or penile scarring or contracture.

• The Inflatable 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:

• 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

• Tearing or ripping of the device during or after implantation

• The complications listed above may necessitate surgical revision or removal of the Inflatable Penile Prosthesis.

• Implantation of a Inflatable Penile Prosthesis may result in penile shortening, curvature or scarring.

Reuse of the single use device may create a potential harm to the user. Reprocessing, washing, disinfection and /or sterilization of Infla10® may compromise product characteristics and cause additional risks of physical harm and / or infection.

Precautions

The implantation of this device should only be considered for patients determined as suitable surgical candidates by the specialized physician.

Physicians implanting penile prostheses should be familiar with current practices in patient measuring techniques, implant size determination, and performing the surgery.

Removal of an implanted Inflatable Penile Prosthesis without timely reimplantation of a new prosthesis may complicate subsequent reimplantation or even may make it impossible.

Patient Related

• The physician should discuss with the patient all available ED treatment options and their risks and benefits and carry out an in-depth pre-operative consultation. Patients should be notified of probable future surgeries related with implanted Inflatable Penile Prosthesis (i.e. device revision).

• Proper device inflation and deflation requires dexterity and adequate strength from the patient.

• Mental or psychological conditions (e.g. dementia, Alzheimer's disease) may hinder the patient's ability to successfully manipulate the Inflatable Penile Prosthesis.

• The length and/or diameter expansion of the Infla10® cylinders may be limited by the contour, elasticity, and dimension of the patient's tunica albuginea.

• Post-op trauma to the pelvic or abdominal areas can result in damage of the implanted device and/or surrounding tissues. This damage may result in the malfunction of the device and may necessitate surgical correction, including replacement of the device.

• Patients should not use injection therapy concurrently with the implanted Inflatable Penile Prosthesis. Injection therapy can damage the Inflatable Penile Prosthesis.

Surgery Related

• Proper surgical technique, proper sizing, filling and anatomical placement of the device components are vital for successful outcomes.

• The device should be carefully examined prior to and during the surgical procedure to ensure the structural integrity of the device is not compromised. A damaged device or a device on which repairs have been attempted should not be implanted.

• Improper reservoir placement or filling technique can result in spontaneous unintended inflation or deflation of the cylinders that may result in unintended partial or full erections.

• Improperly sized cylinders, improper positioning of the pump or the reservoir, or incorrect tubing lengths can result in migration of the reservoir or the pump.

• Prostheses of incorrect length may result in voiding difficulties, inflammation, pressure necrosis and erosion into the urethra or through the tunica albuginea of the corpus cavernosum, SST deformity, buckling of the cylinders.

• Cylinder life may be reduced due to improper measurement technique, positioning or sizing.

• NarrowBody™ cylinders should only be used in patients with compromised corpora cavernosa and smaller anatomies. Do not use narrow cylinders in patients with normal anatomies.

• Extreme care should be taken when manipulating the device with blunt instruments and device components should not be handled with sharp-cornered instruments to avoid tearing, warping or nicking.

• Surface contaminants (e.g. talc, lint, fingerprints) can cause foreign body reactions. Contaminants should be avoided with utmost care. Any nick or split in the device creates a potential for mechanical failure and can serve as a collection point of debris which could cause foreign body reactions or be a locus for infection.

Device Related

• Use sterile, isotonic or normal saline to fill the implant. Some patients may have a hypersensitivity to contrast media.

• The components of this device are manufactured and tested for assembly/use with their specified Rigicon® devices. The use of Rigicon® components with other manufacturers' components has not been tested and is not recommended.

• Do not use product with damaged or open packaging, as sterility may be compromised.

• Due to the hydrophilic coating on all components of Infla10® (including connectors and Rear Tip Extenders) will be slippery when wet and care should be taken when handling them.