Rigicon®

Innovative Urological Solutions

Instructions for Use

Rigi10™

Malleable Penile Prosthesis

℞ ONLY

	Manufacturer
EC REP	Authorized representative in the European Community
	Date of Manufacture
	Use by YYYY-MM-DD
LOT	LOT Number
	Do Not Reuse
	Do Not Resterilize
STERILE EO	Sterilized Using Ethylene Oxide
	Consult Instructions for Use
R_X Only	Caution: Federal Law (U.S.) restricts this device to sale by or on the order of a physician
	Caution
	Do not use if package is damaged
	Temperature limit
	Keep dry
	Keep away from sunlight
CE	CE Mark

EC-REP Information: Rigicon BV:
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Hoofddorp, Netherlands

1. GENERAL INFORMATION ABOUT THE DEVICE

1.1. INTENDED USE

The Rigicon Inc. Rigi10™ malleable penile prosthesis is intended for implantation into the corpora cavernosa of the penis in men who are diagnosed with erectile dysfunction. The prosthesis is implanted to provide adequate penile rigidity for sexual intercourse.

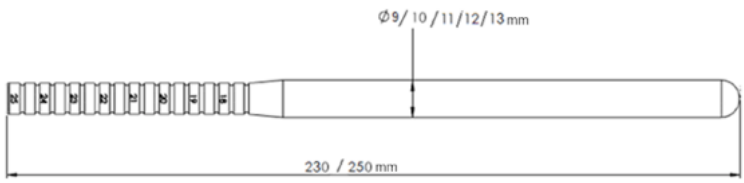
1.2. DEVICE DESCRIPTION AND CHARACTERISTICS

The malleable penile prosthesis is a surgical device that allows an impotent male to achieve an erection. The malleable penile prosthesis consists of two cylindrical rods that are always hard but pliable.
All components are concealed within the body and cannot be seen from the outside.

The two rods are implanted into the corpora cavernosa which are located on each side of the penis. No tissue is removed to implant the prosthesis. The prosthesis simply occupies spaces that were previously filled with blood when the patient was potent. It does not disrupt the flow of urine or ejaculate and it does not alter the sensation of the penis.

The prosthesis is sterile and single use. It is available in different sizes consisting of five diameters and two lengths. Please see the diagram below. Each prosthesis comes with two different extender sizes to adjust the length of the prosthesis according to the corporal length of the patient. The extenders are easy to connect/assemble.

The prosthesis is non-pyrogenic. The color of the prosthesis is white.



Rigi10™ Malleable Penile Prosthesis

Product Code	Prosthesis Diameters	Prosthesis Lengths	Extenders
RG1009	9 mm	23 cm	Ex0.5 Ex1.0 0.5 cm and 1 cm
RG1010	10 mm		
RG1011	11 mm	25 cm	
RG1012	12 mm		
RG1013	13 mm		

1.3. PROCEDURE

The corpora cavernosa is dilated by the surgeon with dilation instruments to determine the correct diameter and to create space for the prosthesis. The surgeon measures the length of the dilated corpora cavernosa with a sizer instrument. Then, the surgeon chooses the correct prosthesis diameter and sizes it (adjusts the length) to fit the patient's anatomy. If necessary, the extenders can be added to the cylinders to increase the length of the prosthesis. Once the prosthesis has been correctly sized, the surgeon implants the prosthesis into the dilated corpora cavernosa. After the prosthesis is implanted into the penis, an erection can be obtained by the patient due to the rigidity of the prosthesis.

2. INDICATIONS FOR USE

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

The prosthesis is designed for the treatment of organic erectile dysfunction in men due to:

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

3. CONTRAINDICATIONS

The device is contraindicated for patients:

- Whom the physician determines is physically or mentally not a suitable candidate,
- Whom the physician determines to be a poor candidate due to risks associated with open surgical procedures,
- With active urogenital infections or skin infections in the region of the surgery,
- Whose total corporal length is less than the shortest cylinder length (the penis length is too short for the implant),
- Sensitive to silicone materials,
- Who require repeated endoscopic procedures,
- With a neurogenic bladder,
- Who have compromised tissue and as a result cannot withstand constant pressure,

4. WARNINGS

Known and potential complications include, but are not limited to:

4.1. OPERATIONAL TECHNIQUE

The prosthesis is designed to be implanted as a pair of matched cylindrical rods. A single implanted rod may not be adequate to achieve sexual intercourse and may have an adverse effect on the reliability of the device. Accurate sizing of the prosthesis is important for a successful outcome. Incorrect measurement, inappropriate rod size selection or malpositioning of the rods which are inserted into the corpora cavernosa can result in migration or buckling of the rods and reduce product life. There should be no unnecessary cuts or abrasions on the prosthesis and it should be positioned properly within the corpora cavernosa.

4.2. INFECTION

Implantation of the prosthesis may result in infection. As with each surgical prosthesis, patients with diabetes, skin infection in the surgical area, open sores or urinary tract infections can have an increased risk of prosthetic associated infections. The use of sterile techniques and appropriate antibiotic prophylaxis will reduce the risk of infection. The patient should be monitored for any infection risk and cured accordingly. If the infection does not respond to treatment, it can result in the removal of the prosthesis from the patient and the implantation of a new prosthesis can be contraindicated. Infection can result in scarring that can cause re-implantation to be more difficult.

4.3. MIGRATION / EXTRUSION

Migration or extrusion occurs when the prosthesis moves from the original anatomical position it was placed. This may result in the need for a surgical revision. Migration or extrusion may occur from improper sizing of the prosthesis.

4.4. EROSION

Erosion is the breakdown/disruption of the tissues around the prosthesis and may occur after placement. Erosion can be caused by tissue injury, inappropriate sizing, inappropriate positioning, infection or pressure. The most common areas experiencing erosion are the glans, urethra and skin. The physician should evaluate each case and decide whether or not to remove the prosthesis. If erosion occurs and has not been evaluated or treated in a timely manner, it can result in a substantially worsening case and can lead to infection and loss of tissue.

4.5. SENSITIVITY TO SILICONE MATERIAL

Silicone is used in the manufacturing process of the prosthesis. For many years, silicone elastomers have been commonly used as a biocompatible material in a variety of biomedical sectors. Scientific literature indicates there can be adverse events and other complications for patients with implantable silicone devices. According to these reports, the adverse events/complications specify allergic symptoms related to immunological disorders and have no relevance between the events and the silicone material. Comprehensive tests including cytotoxicity, implantation, sensitization, irritation, subchronic toxicity, acute systemic toxicity and genotoxicity were performed on silicone material which is used for manufacturing of the prosthesis.

4.6. LIFE EXPECTANCY OF THE PRODUCT / MECHANICAL FAILURES

The prosthesis is not a lifetime device. It will experience fatigue over time. As with other medical devices, product wear and mechanical problems can occur after a period of usage. The prosthesis may break as a result of excessive bending. If a rod is broken, it may be difficult for the patient to manipulate the prosthesis adequately to achieve an effective erection. Cylinders with a broken rod may no longer hold their position after being bent. The broken tip of a rod may tear the silicone and consequently damage penile tissue. If this is the case, the prosthesis must be removed and possibly replaced with a new prosthesis depending upon the patient's health. The broken rod will be detectable through X-ray. It is not possible to predict how long an implanted prosthesis will function in a particular patient. Patient should be advised that the implant is not considered a lifetime prosthesis and additional surgery for replacement and removal may be necessary.

4.7. PAIN

The physician should counsel the patient with regard to the severity and duration of post-operative pain and the level of expected pain during the normal healing process to give the patient a sense of the normal healing process. Pain may occur after implantation and during periods of initial usage by the operator. Pain with a severity or duration beyond that which is expected in a given patient can be symptomatic of medical complications or mechanical device malfunction and may lead to medical or surgical intervention. Cases related to chronic pain associated with device implantation have been reported. There have been some reports that a prosthesis has been removed due to unknown pain and medical complications.

4.8. OTHER COMPLICATIONS

Other complications include:

- Post-Operative bleeding,
- Hematoma,
- Penile edema,
- Urinary obstruction,
- Penile necrosis/gangrene,
- Silicone particle migration,
- Adverse tissue reaction,
- Phimosis,
- Patient dissatisfaction,
- 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 implantation

Complications listed above may necessitate surgical revision or removal of the prosthesis.

5. PATIENT EXPECTATIONS

Correct patient expectations should be maintained. The physician should provide the patient candidate with the Information For Patients Considering Rigicon Inc. Rigi10™ Malleable Penile Prosthesis booklet prior to the surgery. The patient candidate should have plenty of time to review the information and discuss the information with their physician and sexual partner.
Managing expectations will include:

- functionality (how it works),
- physical (the look of the penis),
- psychological (how the patient thinks and feels about the prosthesis),

It is important to inform the patient that the prosthesis will experience fatigue over time and that it is not a lifetime device. Other important information will include the following:

After implantation, the prosthesis may result in:

- a shorter or curved penis,
- less girth (width),
- scarring
- difficulty concealing or hiding the prosthesis while wearing certain clothes.

After implantation, the:

- prosthesis will not improve sexual drive or the skill to achieve an orgasm and ejaculate,
- prosthesis will prevent the patient from having the capability of a natural erection,

6. PRECAUTIONS

6.1. SURGERY RELATED

- Direct contact of surgical instruments with the prosthesis may result in damage, rendering it unsuitable for implantation.
- Do not trim the distal end of the rods, or the rear tip extenders. Trimming these parts will result in damage to the prosthesis.
- Careful intra-operative sizing is required to ensure proper prosthesis implantation. This will minimize complications such as migration, extrusion and erosion.
- Perforation of the corpora cavernosa or the urethra should be avoided.
- Inability to adequately dilate the corpora cavernosa will cause difficulty in implanting the prosthesis.
- Tearing or ripping of the prosthesis during implantation may result in damage, rendering it unsuitable for implantation.

6.2. DEVICE RELATED

- Any implantation of a penile prosthesis which has been previously in contact with or contaminated by body tissue or fluid is prohibited regardless of cleaning, or resterilization.
- The prosthesis is presented in a double pouch package and inside a protective carton box. The package should be checked in terms of damage, tearing and puncture. Do not use damaged, torn or punctured packages.

- Before unpacking, the expiration date of the prosthesis should be checked. Do not use products past their expiration date.
- Prosthesis which are removed from patients should be disposed of as medical waste within the framework of legal procedures.

6.3. PATIENT RELATED

- Before the procedure, the surgeon should evaluate the patient's status and decide whether the patient is a candidate for the implantation of the penile prosthesis.
- A complete pre-operative consultation should include a discussion between the patient and the physician on the risks and benefits for all of the available treatment options.
- Sufficient patient skills (dexterity) are required to function the device properly.
- 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 risk of post-operative complications associated with this approach.
- Penile prosthesis operations can be complex or unpractical for patients who have penile scarring or contracture.
- Post-operatively some adverse events can occur such as infection, pain, migration/extrusion, erosion, sensitivity to silicone material, mechanical failures, post-operative bleeding, hematoma, penile edema, urinary obstruction, penile necrosis/gangrene, silicone particle migration, adverse tissue reaction, phimosis and patient dissatisfaction.

7. PRE-OPERATIVE CONSIDERATIONS

CAUTION: Rigi10™ Malleable Penile Prosthesis is to be implanted only by physicians who are knowledgable in the use of penile prostheses (e.g. urologists). This document is not intended to be a complete reference.

Proper patient selection is important before the implantation of the prosthesis.

Prior to the operation:

- The urine of the patient should be sterile.
- An antimicrobial shower should be given the night before the operation.
- An antibacterial prophylaxis should be given to the patient.
- The surgeon should scrub their hands for 10 minutes.

In the operating room:

- Parenteral antibiotics can be used on the patient according to the surgeon's discretion.
- The patient's genital area should be shaved.
- The skin should be prepared with a 10 minute scrub of providone-iodine soap.

8. INTRA-OPERATIVE PROCEDURES

Operational Method
There are three operational methods for the malleable penile prosthesis:

1. Suprapubic
2. Penoscrotal
3. Subcoronal

Dissection
After selecting the operational method, make a skin incision. To expose the tunica albuginea, dissect through Buck's fascia.

Corporotomy
Make a 2-4 cm incision in the corpus cavernosa.

Dilatation
The corpora cavernosa should be dilated both distally and proximally using Hegar dilators or equivalent instrumentation. It should be dilated proximally by promoting the dilator to the ischial tuberosity and distally by feeling the dilator at mid glans by hand. It is important not to perforate the distal end of the corpora cavernosa. The corpora cavernosa should be dilated 1mm above the diameter of the prosthesis intended to be implanted. Once the diameter of the corpora cavernosa has been determined, the surgeon should insert two dilators. One into each corpora cavernosa. The surgeon should insert the dilators into the corpora cavernosa side by side to evaluate the overall positioning and fit. Repeat this step for both the distal and proximal ends.

Diameter Selection
The prosthesis is available in 5 different diameter sizes. This includes 9mm, 10mm, 11mm, 12mm and 13mm. The diameter of the prosthesis should be selected based upon the anatomy of the patient.

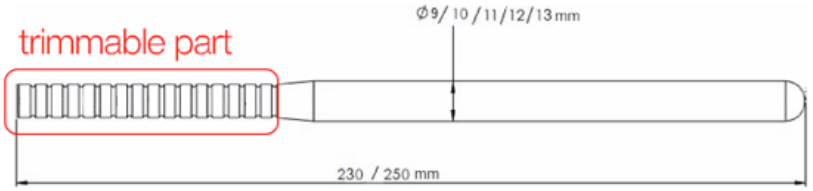
Measuring the Length of the Corpora Cavernosa
To determine the length of the corpora cavernosa, a sizer instrument is used. The sizer has a centimeter scale etched along the length of the instrument. The sizer should be placed in the distal corpora cavernosa and the measurement should be read. Then, the sizer should be placed in the proximal corpora cavernosa and the measurement should be read. Afterward, both the distal length and the proximal length should be added together to determine the appropriate length of the prosthesis needed to accommodate the patient anatomy.

Sizing the Prosthesis (Length)
Once the length of the corpora cavernosa has been determined, the prosthesis can be trimmed to the appropriate length. The prosthesis comes in two lengths. This includes 23cm and 25cm. The length is determined by the diameter of the prosthesis.

23cm = 9mm & 10mm
25cm = 11mm, 12mm and 13mm

The 9mm and the 10mm diameter prosthesis are 23cm long and the 11mm, 12mm and the 13mm diameter prosthesis are 25cm long.

The prosthesis can be trimmed by cutting the proximal end of the prosthesis to achieve the appropriate length. The proximal end of the prosthesis is ribbed and is illustrated in the diagram below (trimmable part). Each rib is 1/2cm apart. Surgical scissors or a scalpel can be used to trim the prosthesis. The use of an extender is optional. Do not trim any part where the malleable core is located which is opposite the ribbed area. Only the trimmable part (ribbed area) shown in the diagram should be trimmed.



Length Adjustment
An extender can be used to add length to the prosthesis. The extenders come in two lengths. They are available in 0.5cm and 1.0cm. Each prosthesis comes with two of each size of the extenders. If the surgeon wants to add length to the prosthesis, they should choose the extender with the length (0.5cm or 1.0cm) they intend to add. The extenders should be placed over the proximal end of the prosthesis. The proximal end is the trimmable part (ribbed) illustrated in the diagram above.

Insertion of the Prosthesis
The prosthesis should be inserted according to the operational method preferred by the surgeon. The distal end of the prosthesis (non trimmable part & not ribbed) should be placed in the distal corpora cavernosa. The proximal end of the prosthesis

(trimmable part & ribbed) should be placed in the proximal corpora cavernosa.

Intraoperative Testing
After insertion of the prosthesis, a rigidity test should be performed to confirm the functionality of the prosthesis. The penis is bent down for the concealed position and then straightened into the erect position. Afterward, the buckling test should be performed. While the penis is in the erect position, the palm of the surgeon's hand is pressed against the glans to confirm adequate rigidity.

Closing
The corporotomy is closed with sutures which are commonly preferred by the surgeon. The facia and skin are closed using an acceptable surgical technique.

9. POST-OPERATIVE CONSIDERATIONS

- The physician should counsel the patient with regard to the severity and duration of post-operative pain and the level of expected pain during the normal healing process.
- The physician should counsel the patient with regard to the possible need of antibiotic prophylaxis for future dental or other procedures.
- The physician should provide preferred recommendations to the patient for the proper care of the surgical site. The physician may administer routine wound care and educate the patient on the correct way to urinate during the healing process and how to recognize the early signs of infection.
- Catheter usage should be minimized.
- Education regarding the use of the new penile prosthesis should be given to the patient.
- Sexual activity can start 4-6 weeks after the operation.

10. MAGNETIC RESONANCE IMAGING (MRI)

IMPORTANT SAFETY INFORMATION
Non-clinical testing has demonstrated the Rigi10™ malleable penile prosthesis is **MR Conditional.**

Patients who have been implanted with the Rigi10™ Malleable Penile Prosthesis can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5 T and 3.0 T
- Maximum spatial field gradient of 4,000 Gauss/cm (40 T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2W/kg for 15 minutes of scanning (i.e. per pulse sequence) (Normal Operating Mode)

Under the scan conditions defined above, the Rigi10™ malleable penile prosthesis is expected to produce a maximum temperature rise of less than or equal to 1.6°C after 15 minutes of continuous scanning (i.e. per pulse sequence).

In non-clinical testing, the image artifact caused by the Rigi10™ malleable penile prosthesis extends approximately 55 mm from the device when imaged with a gradient echo pulse sequence and a 3.0 T MRI system.

If you have further questions about the compatibility of the prosthesis and the MRI, please contact the Rigicon, Inc. Company or e-mail operations@rigicon.com

11. SUPPLY AND STORAGE

WARNING: Contents are supplied STERILE. Do not use if sterile barrier is damaged. If damage is found, please call your Rigicon representative.

The prosthesis is supplied for single patient use only. Do not reuse, reprocess or re-sterilize. 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 re-sterilization may also create a risk of contamination of the device. After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

Store the device in a clean, dry, dark area at room temperature.

DISCLAIMER:

The manufacturer Rigicon Inc. reserves the right to make technical or design changes as part of the device's continual improvement process.

Warranty & Product Replacement
In order to activate the warranty of the implant, the Patient Surgery Form must be filled out and filed with Rigicon, Inc.

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Customers outside the United States and Canada should contact their local Rigicon Representative

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