Rigicon®

Innovative Urological Solutions

RIGI10™

HYDROPHILIC

MALLEABLE PENILE PROSTHESIS

INSTRUCTIONS FOR USE

℞ ONLY

Table of Contents

Symbols on Label

	Manufacturer Information
	The authorized representative in the European Community.
	Date of Manufacture
	Use by YYYY-MM-DD
	LOT Number
	Do Not Reuse
	Do Not Resterilize
	Sterilized Using Ethylene Oxide
	Consult Instructions for Use
	Prescription
	Caution
	Do not use if package is damaged
	Temperature limit
	Keep dry
	Keep away from sunlight
CE 2764	CE Mark

EC- REP Information:

Rigicon BV:

Saturnusstraat 46-62, 2132 HB Hoofddorp, Netherlands

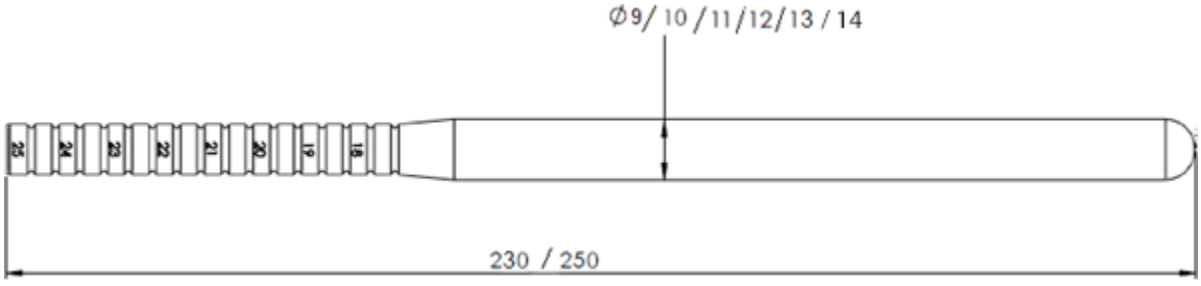
1. General Information About the Device

1.1. Intended Use

Rigi10™ Hydrophilic 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

Rigi10™ Hydrophilic Malleable Penile Prosthesis is a surgical device that allows an impotent patient 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 prosthesis is sterile and single use. It is available in different sizes consisting of six diameters and two lengths. Please see the diagram above. 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.

The package of Rigi10™ Hydrophilic Malleable Penile Prosthesis consists of two rods, and extenders. There are four pieces of extenders (two pieces Ex0.5 and two pieces Ex1.0) in each package. The product is supplied to the market in a sealed, double pouch and inside a protective carton box.

Rigi10™ Hydrophilic and Nitinol Hydrophilic Malleable Penile Prosthesis is available in following sizes:

Product Catalogue Code	*Prosthesis Product Code*	Prosthesis diameters	Prosthesis Lengths	Extenders
Rg09-H	*RG1009H*	9 mm	23 cm	*Ex0.5* *Ex1.0* 0.5 and 1cm
Rg10-H	*RG1010H*	10 mm		
Rg11-H	*RG1011H*	11 mm	25 cm	
Rg12-H	*RG1012H*	12 mm		
Rg13-H	*RG1013H*	13 mm		
Rg14-H	*RG1014H*	14 mm		
Rg09-NH	*RG1009NH*	*9 mm*	23 cm	*Ex0.5* *Ex1.0* 0.5 and 1cm
Rg10-NH	*RG1010NH*	*10 mm*		
Rg11-NH	*RG1011NH*	*11 mm*	25 cm	
Rg12-NH	*RG1012NH*	*12 mm*		
Rg13-NH	*RG1013NH*	*13 mm*		
Rg14-NH	*RG1014NH*	*14 mm*		

1.3. Mechanism of Action

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

Rigi10™ Hydrophilic Malleable Penile Prosthesis and Hydrophilic Nitinol Malleable Penile Prosthesis are 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.

It is designed for the treatment of organic erectile dysfunction (impotence) in 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

3. Contraindications

The device is contraindicated for patients:

- Whom the physician determines as 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

- The prosthesis is designed to be implanted as a pair of matched rods unless otherwise recommended by the surgeon. A single implanted rod may not be adequate to achieve sexual intercourse and may have a negative 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, and tearing or ripping of the device during or after implantation

- The complications listed above may necessitate surgical revision or removal of the prosthesis.

4.1. 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 treated 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.

4.2. Migration

Migration occurs when the prosthesis moves from the original anatomical position it was placed. This may result in surgical revision, psychological/physiological complications, or device malfunction. Migration may occur if the rods are sized improperly.

4.3. Device Sizing

Sizing of the device is important for successful results. Selection of improper rod size or mispositioning of the rods which are inserted into the corpora cavernosa may result in migration or buckling of the rods and reduce product life.

4.4. Operational Technique

Incorrect measurement, inappropriate rod size selection and 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.

4.5. 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 the biomedical sector. Scientific literature indicates that adverse events and other complications may occur in patients with implantable silicone devices. According to scientific reports, the adverse events/complications include allergic symptoms related to immunological disorders, however these are not linked to the usage of silicone material.

There are reports on malignant tumor formation in laboratory animals due to inadequate material size. Formation of malign tumor in animals can be caused by various materials such as silicone elastomers. However, no tumor formation in humans has been previously reported due to silicone elastomers.

Comprehensive tests including cytotoxicity, implantation, sensitization, irritation, subchronic toxicity, acute systemic toxicity and genotoxicity were performed on silicone material used in the manufacturing of the prosthesis. These tests have shown that silicone material has no toxic effect on animals. There are literature data about silicone particle migration to lymph nodes and particle shedding on penile prosthesis.

4.6. Shelf Life of Product

Rigicon Inc. – Hydrophilic Malleable Penile Prosthesis is designed as a prosthesis which provide the patient with significant physiological penile functionality. As in any biomedical prosthesis, erosion of the device may occur, which may result in device malfunction. It is impossible to predict the longevity of the product implanted into the patient body. The patient must be informed about the lifetime of the product.

4.7. Patient Expectations

The patient should be informed about the usage of hydrophilic malleable penile prosthesis; physical, psychological, and functional aspects of the treatment and the product.

Penile prosthesis implantation may result in penile shortening, scarring and curvature. After operation, erection of the penis implanted with penile prosthesis can be different from natural (not-implanted) penile erection. The reason behind this is that implantation may result in less girth, less firmness, a shorter penis and reduced sensation. The information about cosmetic expectation should be also given to the patient in regard to skin scarring and difficulty in concealing the penile prosthesis in some cases.

The penile prosthesis will not provide rigidity to the glans and can result in floppy glans and lack of rigidity in the corpus spongiosum.

4.8. Erosion

Erosion is the breakdown/disruption of the tissues around the device and may occur after implantation of the device. Erosion may occur due to tissue injury, improper sizing, malpositioning of the device, infection, or pressure. The most common areas experiencing erosion are the glans, skin, or urethra.

The surgeon should evaluate the case and comment whether remove or repair the device is necessary or not in a case of erosion. If erosion occur and be not evaluated or be not treated in time can result in substantial worsening of the case leading to infection and loss of tissue.

4.9. Pain

Pain may occur after implantation and during periods of initial usage by the operator. Cases related to the pain caused by prosthesis have been reported. The physician should counsel the patient with regards to the severity and duration of the post-operative pain and the level of expected pain during the normal healing process to give a patient a sense of the normal healing process. 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.

5. Precautions

5.1. Surgery Related

- Direct contact of surgical instruments to the 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 prosthesis and shorten its product life.
- Do not trim the distal part that is above the ribbed/trimmable part of the proximal end of the rod, or the rear tip extenders. Trimming this part will result in damage to the prosthesis.
- 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.

5.2. Device Related

- Implantation of a 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 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 guaranteed.
- Products which are removed from patients should be disposed as medical waste within the framework of legal procedures.

5.3. Patient Related

- Prior to 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 appropriate device positioning.
- 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 prosthesis operations can be complex or unpractical for patients who have penile scarring or contracture.
- Some adverse events may occur such as urethral bleeding, pain, mild phimosis, or hematoma after operation.
- If patient has previously undergone revision surgery, patients may experience differences in their penile length, girth, flaccidity, and sensation after penile prosthesis implantation
- Physiology and psychology states can hinder the successful operation of the device.

6. Pre- Operative Considerations

CAUTION: Rigi10™ Hydrophilic Malleable Penile Prosthesis is to be implanted only by physicians who are knowledgeable in the use of penile prostheses (e.g. urologists).

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 for staining.

7. Intra- Operative Procedures

Operational Methods

There are three operational methods for Rigi10™ Hydrophilic Malleable Penile Prosthesis;

1. Suprapubic,
2. Penoscrotal,
3. Subcoronal

Dissection

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

Corporotomy

Make a 2-4 cm incision in corpus cavernosum.

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

Rigicon Inc. – Hydrophilic Malleable and Hydrophilic Nitinol Malleable prosthesis is available in 6 diameter sizes. This includes 9mm, 10mm, 11mm, 12mm, 13mm and 14mm. 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.

Length Adjustment

The extender which is equal the extra length desired must selected for extending a pair of rods with rear tip extenders.

Insertion of the Prosthesis

The prosthesis is inserted according to the preferred operational method. The conoid tip of the rod is located in the proximal part of the corpus cavernosum and curved tip of the rod is located in distal part of the corpus cavernosum.

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 3.0 polydioxanone or 3.0 polyglyconate which is commonly used by urologist.
- The facia and skin are closed according to the per urologist protocol.

8. Post- Operative Considerations

- Catheter usage should be minimized.
- Wound care should be done.
- The sexual activity can start 4-6 weeks after operation.
- Education about using new penile prosthesis should be taken.

9. Magnetic Resonance Imaging (MRI) Important Safety Information

Non-clinical testing has demonstrated that the Rigi10H® Hydrophilic Malleable Penile Prosthesis is MR Conditional.

Patients who have been implanted with the Rigi10H® Hydrophilic 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 2.0 W/kg for 15 minutes of scanning (i.e. per pulse sequence) (Normal Operating Mode)

Under the scan conditions defined above, the Rigi10H® Hydrophilic 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 Rigi10H® Hydrophilic 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

10. Supply

WARNING: Contents are supplied STERILE. Do not use if sterile barrier is damaged. If damage is found, please contact Rigicon®, Inc.

For single patient use only. Do not reuse, reprocess or re-sterilize. Reuse, reprocessing or re-sterilization 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.

11. 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.

Rigicon, Inc.

2805 Veterans Memorial Highway Suite 5,
Ronkonkoma, NY 11779, United States of America
e-mail: operations@rigicon.com **/ Phone:** +1 (888) 202-9790

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

RG10H-IFU, REV.07, REV.DATE: 17.12.2021

2805 Veterans Highway Suite 5, Ronkonkoma, NY 11779,
United States of America
operations@rigicon.com / Phone: +1 888 202 9790
www.rigicon.com

EC REP
Rigicon BV. ;
Saturnusstraat 46-62, 2132 HB Hoofddorp, Netherlands