Rigicon

American Surgical Solutions

MALLEABLE PENILE PROSTHESIS

INSTRUCTION FOR USE

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Symbols on Label

EC-REP Information:

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	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
	Caution
	Do not use if package is damaged
	Temperature limit
	Keep dry
	Keep away from sunlight
CE 2292	CE Mark

1. General Information About the Device

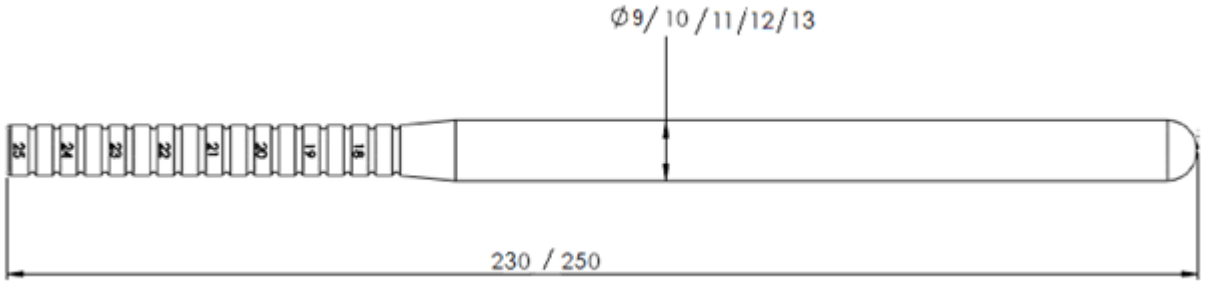
1.1. Intended Use

The Rigicon Inc. – Malleable Penile Prosthesis is intended for implantation into the corpora cavernosa of the penis in men who are diagnosed as having erectile dysfunction. The prosthesis is implanted to provide adequate penile rigidity for sexual intercourse.

1.2. Device Description and Characteristics

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

The penile implant cylinders reside in the penis on either side of the penis. No tissue is removed to place the cylinders; the cylinders simply occupy spaces that were previously filled with blood, when one was potent. The cylinders do not disrupt the flow of urine or ejaculate. The cylinders do not alter the sensation of the penis. The cylinders also do not affect tumescence of the glans of the penis.



Malleable Penile prosthesis, sterile, single – use implant consisting of three different sizes of malleable penile prosthesis with extenders to adjust the length of prosthesis according to the corporal length of the patient. Suitable for each individual's corporal length. They provide easy connection.

The product is manufactured as white.

There are three models and different sizes for Malleable Penile Prosthesis in the following sizes:

Rigi10 Malleable Penile Prosthesis

Product Catalogue Code	*Prosthesis Product Code*	Prosthesis diameters	Prosthesis Lengths	Extenders
Rg1009	Rigi10-09	9 mm	23 cm	*Ex0.5* *Ex1.0* 0.5 and 1cm
Rg1010	Rigi10-10	10 mm		
Rg1011	Rigi10-11	11 mm	25 cm	
Rg1012	Rigi10-12	12 mm		
Rg1013	Rigi10-13	13 mm		

RigiSoft Malleable Penile Prosthesis

Product Catalogue Code	*Prosthesis Product Code*	Prosthesis diameters	Prosthesis Lengths	Extenders
RgS09	RigiSoft-09	9 mm	23 cm	*Ex0.5* *Ex1.0* 0.5 and 1cm
RgS10	RigiSoft-10	10 mm		
RgS11	RigiSoft-11	11 mm	25 cm	
RgS12	RigiSoft-12	12 mm		
RgS13	RigiSoft-13	13 mm		

Rigi11 Malleable Penile Prosthesis

Product Catalogue Code	*Prosthesis Product Code*	Prosthesis diameters	Prosthesis Lengths	Extenders
Rg1109	Rigi11-09	9 mm	23 cm	*Ex0.5* *Ex1.0* 0.5 and 1cm
Rg1110	Rigi11-10	10 mm		
Rg1111	Rigi11-11	11 mm	25 cm	
Rg1112	Rigi11-12	12 mm		
Rg1113	Rigi11-13	13 mm		

Model Differences

Rigi10 is comprised of a stainless-steel rod with titanium cap.

RigiSoft is manufactured as without rod.

Rigi11 is comprised of a silver rod and PTFE cap.

1.3. Mechanism of Effect

The spongious tissue of cavernosa is dilated by the surgeons (two channels in the shaft of the patient's penis which fill with blood when the patient has a natural erection) and measured the length of the dilated area and implanted the same size penile prosthesis to fit the anatomy (if needed the extenders can be added to the cylinders) and the prosthesis provide erection to the patient. After the product is inserted into the penile, the erection is successfully provided due to the rigidity of the material.

2. Indications

The device is indicated for implantation into the corpora cavernosa of the penis in men who are diagnosed as having 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) 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

RigiSoft assures a reduction in the venous bed and in the quota of tissue to be expanded by a reduced arterial flow ensuring support to the physiological erection.

3. 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 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 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 prosthesis is contraindicated with malleable penile prosthesis for patients who have compromised tissue and cannot resist permanent pressure.

4. Warnings

- The 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, 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

The operation need to implant this product may result in infection as with each surgical prosthesis. Patients with diabetes, skin infection in surgery area, spinal cord injuries, open sores or urinary tract infections can have an increased risk of prosthetic associated infections. Using of sterile techniques and appropriate antibiotic prophylaxis should reduce the infection risk by taking appropriate measures. The patient should be monitored for any infection risk and cured correctly.

The infection which do not responded the treatment can result in removing of the prosthesis from patient and using of the new device can be contraindicated at that

time. After explantation of the device, infection can result in scarring that can subsequent re-implantation more difficult.

4.2. Migration

Migration is the displacement of the extenders/jacket or movement in the space in which implanted there and may result in surgical revision, psychological/physiological complications or device malfunction. Migration may occur if the rods are sized wrongly.

4.3. Device Sizing

Sizing of the device is significant for resulting successfully. Measurement wrongly, inappropriate rod size selection or malpositioning of the rods which is inserted into the corpora cavernosa can result in migration or buckling of the rods and reduce product life.

4.4. Operational Technic

Associated with operational technic, there are some reports for of operational technic containing of inappropriate sizing, cuts/abrasions of the prosthesis, malpositioning of the prosthesis.

4.5. Silicone (material)

Silicone is used for manufacturing of this product. Silicone elastomers is used commonly in a variety of biomedical sector for a long time and is used as a biocompatibility materials. Scientific literatures show us adverse event and other complications on patients with implantable silicone devices. According to the reports, these adverse events/complications specify allergic symptoms and symptom complex related with immunological disorders. But, there is no relevance between these events and silicone material. There are reports related malignant tumor in only scientific research animals arising from inappropriate size. Malign tumor in animals can occur arising from many different materials like silicone elastomers and etc. But no effects like this has been reported before in humans.

Comprehensive tests including cytotoxicity, implantation, sensitization, irritation, Subcronic toxicity, acute systemic toxicity and genotoxicity tests were performed on silicone material which is used for manufacturing. These tests are shown that there is no toxic effect on animals related with silicone material. In literatures, silicone particle migration to regional lymph nodes and particle shedding on penile prosthesis have been reported.

4.6. Shelf Life of Product

Rigicon Inc. – Malleable Penile Prosthesis is designed as a prosthesis which cures the patient a significant physiological function. As in each biomedical prosthesis, the device is exposed to erosion and be unsuccessful function in time. It is impossible to predict that how long the product can be implanted in a patient. The patient must be informed about lifetime of the product.

4.7. Patient Expectations

To inform about correct expectation of the physical, psychological and functional treatment and usage of the malleable penile prosthesis, patient should be informed.

Implanted penile prosthesis can result in penile shortening, scarring and curvature. After operation, the implanted penile erection can be different from not implanted penile erection (natural) because of reduced sensations, shorter, have less girth and less firm. The information about cosmetic expectation is also given the patient, for example, skin scarring and lack of concealability of penile prosthesis.

The penile prosthesis will not provide rigidity to the glans and can result in a floppy glans and lack of rigidity of the corpus spongiosum. The penile looseness is less than before to implantation.

4.8. Erosion

Erosion is the breakdown/disruption of the tissues around the device and may occur after placement the device. Erosion can be occurred by tissue injury, inappropriate sizing, malpositioning of the device, infection and pressure. The common reported field related with erosion is the glans, skin or urethra.

The urologist 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 can be occurred after implantation and during periods of initial usage at operational area. Cases related to the pain caused by prosthesis have been reported.

The severity and duration of the pain can occur as unexpended on patient. The reason for this, it can be medical complication or mechanical malfunction of device symptomatically that can cause medical or operational intervention. Some reports

that have a functioning prosthesis removed because of unknown pain and medical complications on patient exist. Training related with expected pain containing of severity and duration after operation should be given to patient.

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 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.

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 noy use the products which have passed the expiration date. Sterilization of the products which have passed the expiartion date is not be guaranteed.
- Products which are removed from patients should be disposed as medical waste within the framework of legal procedures.

5.3. 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 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 can be occurred like urethral bleeding, pain, phimosis not high several, hematoma after operation.
- If patient had been done revision surgery, they can live differences such length, flaccidity, sensation and girth associated with using new prosthesis.
- Physiology and psychology states can hinder the successful operation of the device.

6. Pre- Operative Considerations

The selection of the appropriate patient is significant before the operation of Malleable penile prosthesis.

Before the operation:

- The urine of the patient should be sterile.
- An antimicrobial shower should be taken at night before operation.
- An antibacterial prophylaxis should be received the patient.
- The urologist should scrub by hand for 10 minute.

In the operating room:

- Patient can use parenteral antibiotics according to urologist's discretion.
- The patient should be shaved.
- The skin of the penile should be prepared by staining for 10 minutes by hand scrub.

7. Intra- Operative Procedures

Operational Methods

There are five methods for Malleable Penile Prosthesis operations:

1. Suprapubic,
2. Perineal,
3. Penoscrotal,
4. Subcoronal,
5. Mid-shaft

Dissection

- After selection of operational methods, make a skin incision.
- For exposing the tunica albuginea, dissect through Buck's fascia.

Corporotomy

Make a 2-4 cm incision in corpus cavernosum.

Dilatation

- The appropriate size should determine for patient due to the fact that differences of corpora cavernosa from patient to patient.
- Corpora should be dilated distally and proximally with using Hegar dilators as far as patient's physically allows.
- It should be dilated proximally by promoting the dilator to the ischical tuberosity.
- Corpora should be dilated distally by feeling the dilator at mid-glans.
- It should be dilated 1 mm above the diameter of the device to be implanted.
- After dilatation, to determine the diameter of the cylinders to use:
    - The urologist should select two Hegar dilator which total diameter equals the total diameter of the prosthesis to be implanted.
    - The urologist should insert the Hegar dilators into the Corpora cavernosa and evaluate appropriately.

Diameter Adjustment

Rigicon Inc. – Malleable prosthesis has 5 diameter sizes. The outer silicone jacket must be removed to achieve two small diameters. The edge of a blunt scissors favorably a bandage scissors is removed by the urologist with caution, under the proximal end of the jacket. The scissors should be slide slowly throughout the entire length of the rod. The urologist should be attention to not scratch the surface of the prosthesis. After the cutting full length of the jacket, the jacket is peeled and discarded.

Measuring the Length of the Corpora Cavernosa

The tapered end of the sizer is inserted into the proximal part of the corpus cavernosum. Then, the sizer which has curved and blunt end is inserted into the most distal part of corpus cavernosum and the distal measurement is read. After that, corresponding centimeter scale for the blunt end which is etched on the opposite side of the sizer is used from the proximal measurement scale. The two measurements are added for calculating the total length of the corpus cavernosum.

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 inserting of the prosthesis, rigidity test is carried out for determining device approximately and function: the penile is twisted down for concealed position and straightened for the erect position. After that, the test which show that there is no buckling is performed: while the penile is in the up position, the glans are pressed against with the palm of the hand for confirming wrong rigidity.

Closing

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

8. Post- Operative Considerations

- Catheter usage should be reduced.
- 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. How Supplied and Storage

WARNING: Contents supplied STERILE. Do not use if sterile barrier is damaged. If damage is found, call our company.

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.

Store 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

For to activate the warranty of the implant, Patient Infromation Form must be filled and filed to Rigicon,Inc.

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

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