Rigicon®

Innovative Urological Solutions

Instructions for Use

Infla10®

Three-Piece
Inflatable Penile Prosthesis

℞ ONLY

℞ ONLY	Caution: Federal law (U.S.) restricts this device to sale by or on the order of a physician
	Manufacturer Information
EC REP	The 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
	Caution
	Do not use if package is damaged
	Temperature limit
	Keep dry
	Keep away from sunlight
CE 2764	CE Mark

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NOTE: Please refer to the Operating Room Protocol for further information on the implantation of Infla10® Three-Piece Inflatable Penile Prosthesis.

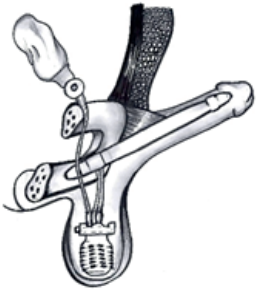
DEVICE DESCRIPTION

Infla10® Three-Piece Inflatable Penile Prosthesis is available for patients who are candidates for penile prosthesis implantation for the treatment of Erectile Dysfunction. This device provides voluntary control of penile erection.

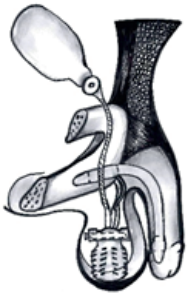
Infla10® Three-Piece Inflatable Penile Prosthesis is a self-contained, fluid-filled system that consists of two cylinders, a pump and a reservoir. Two inflatable silicone elastomer penile cylinders are implanted in the corpora cavernosa of the penis. The cylinders are attached to a pump, which is placed in the patient's scrotum, and the pump is connected to a fluid reservoir that is implanted underneath the abdominal muscles of the patient. The reservoir contains a valve, which is intended to minimize the probability of involuntary auto-inflation. The reservoir is filled with sterile saline solution. All components are connected via kink-resistant tubes that are responsible for the fluid distribution between the cylinders, the pump, and the reservoir.

Repeated squeezing and releasing of the pump, which is located in the scrotum, transfers the fluid from the reservoir to the cylinders in the penis. The penis enlarges and becomes erect as the penile cylinders fill with fluid from the reservoir.

The pump and the cylinders are pre-connected, and the reservoir is connected to the pump inlet tubing using the EasyClick™ Connector during implantation. All components of Infla10® Three-Piece Inflatable Penile Prosthesis incorporate a hydrophilic coating on external surfaces. The hydrophilic coating (HydroShield™) offers the surgeons (i.e. urologists) the freedom to choose their preferred aqueous solution. Hydrophilic coating facilitates the rapid and strong absorption of the preferred aqueous solution on the device and may promote easier device implantation.



Erect state with Infla10®



Flaccid state with Infla10®

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INFLA10® MODELS, SIZES AND MODEL DIFFERENCES

Infla10® X Three-Piece Inflatable Penile Prosthesis Infrapubic Approach						
Product Code	**INF1012-IP**	**INF1015-IP**	**INF1018-IP**	**INF1020-IP**	**INF1022-IP**	**INF1024-IP**
Diameter	12 mm	12 mm	12 mm	12 mm	12 mm	12 mm
Length	12 cm	15 cm	18 cm	20 cm	22 cm	24 cm

Infla10® X Three-Piece Inflatable Penile Prosthesis Penoscrotal Approach						
Product Code	**INF1012-PS**	**INF1015-PS**	**INF1018-PS**	**INF1020-PS**	**INF1022-PS**	**INF1024-PS**
Diameter	12 mm	12 mm	12 mm	12 mm	12 mm	12 mm
Length	12 cm	15 cm	18 cm	20 cm	22 cm	24 cm

Infla10® AX Three-Piece Inflatable Penile Prosthesis Infrapubic Approach						
Product Code	**INF1012-AX-IP**	**INF1015-AX-IP**	**INF1018-AX-IP**	**INF1020-AX-IP**	**INF1022-AX-IP**	**INF1024-AX-IP**
Diameter	12 mm	12 mm	12 mm	12 mm	12 mm	12 mm
Length	12 cm	15 cm	18 cm	20 cm	22 cm	24 cm

Infla10® AX Three-Piece Inflatable Penile Prosthesis Penoscrotal Approach						
Product Code	**INF1012-AX-PS**	**INF1015-AX-PS**	**INF1018-AX-PS**	**INF1020-AX-PS**	**INF1022-AX-PS**	**INF1024-AX-PS**
Diameter	12 mm	12 mm	12 mm	12 mm	12 mm	12 mm
Length	12 cm	15 cm	18 cm	20 cm	22 cm	24 cm

Infla10® NarrowBody™ Three-Piece Inflatable Penile Prosthesis Infrapubic Approach				
Product Code	**INF1010-NB-IP**	**INF1012-NB-IP**	**INF1014-NB-IP**	**INF1016-NB-IP**
Diameter	10 mm	10 mm	10 mm	10 mm
Length	10 cm	12 cm	14 cm	16 cm

Infla10® NarrowBody™ Three-Piece Inflatable Penile Prosthesis Penoscrotal Approach				
Product Code	**INF1010-NB-PS**	**INF1012-NB-PS**	**INF1014-NB-PS**	**INF1016-NB-PS**
Diameter	10 mm	10 mm	10 mm	10 mm
Length	10 cm	12 cm	14 cm	16 cm

ConnectSecure™ Rear Tip Extenders							
Product Code	**RTE05**	**RTE10**	**RTE15**	**RTE20**	**RTE30**	**RTE40**	**RTE50**	**RTE60**
Diameter	0.5 cm	1 cm	1.5 cm	2 cm	3 cm	4 cm	5 cm	6 cm

Infla10® Accessory Kit	
Product Code	**INF10AK**

Infla10® Extender Fixation	
Product Code	**INF10-EF**

Infla10® Reservoir			
Product Code	**INF10RS-65**	**INF10RS-70**	**INF10RS-110**
Volume	65 ml	70 ml	110 ml

Infla10® X and AX Three-Piece Inflatable Penile Prosthesis is available in 6 different lengths; 12 cm, 15 cm, 18 cm, 20 cm, 22 cm, and 24 cm. Infla10® Three-Piece Inflatable Penile Prosthesis is also available with NarrowBody™ cylinders in 4 different lengths; 10 cm, 12 cm, 14 cm, and 16 cm. All X, and NarrowBody™ cylinders are provided pre-connected to the pump. ConnectSecure™ Rear Tip Extenders (RTE) are used to add length to the cylinders.

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MODEL DIFFERENCES

- Anatomical eXpansion cylinders offer longitudinal expansion in addition to girth expansion. The longitudinal expansion capacity of the AX cylinders depends on the anatomy of the patient.

- NarrowBody™ cylinders are available for patients with narrower anatomies or compromised corpora cavernosa.

- IP and PS in product codes define the surgical method the device is designed for implantation. IP stands for the infrapubic surgical approach. PS stands for the penoscrotal surgical approach.

- There are three different sizes of the Infla10® Reservoir; 65 ml, 70 ml, and 110 ml. The reservoirs with a volume of 70 ml, and 110 ml have a rectangular design while the reservoir with 65 ml volume has a spherical design.

INDICATIONS

Infla10® Three-Piece 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® Three-Piece Inflatable Penile Prosthesis is contraindicated in patients with:

- an active infection, especially urinary tract or genital infection;
- a documented sensitivity to silicone;
- neurogenic bladder and/or urinary obstruction
- total corporal length shorter than the cylinder size

COMPONENTS OF THE DEVICE

Infla10® is a self-contained, fluid-filled system that consists of two cylinders, a pump and a reservoir. Two inflatable silicone elastomer penile cylinders are implanted in the corpora cavernosa of the penis. The cylinders are attached to a pump, which is placed in the patient's scrotum, and the pump is connected to a fluid reservoir that is implanted underneath the abdominal muscles of the patient. All components are connected via kink-resistant tubes that enable the fluid distribution between the cylinders, the pump and the reservoir. Different sizes of extenders are available to adjust the length of the prosthesis to fit the total corporal length of the patient. EasyClick™ Connector is used for connecting the tubes from the reservoir and the pump.

The components of the device are

- Cylinders (X, Anatomical eXpansion, or NarrowBody™)
- RapidPump™
- Infla10® Reservoir (65 ml, 70 ml, 110 ml)
- EasyClick™ Connector
- ConnectSecure™ Rear Tip Extenders (0.5 cm, 1 cm, 1.5 cm, 2 cm, 3 cm, 4 cm, 5 cm, and 6 cm.)

SOFTWARE, ACCESSORIES, INSTRUMENTS AND DEVICES USED TOGETHER

This device does not have an embedded software.

INFLA10® THREE-PIECE INFLATABLE PENILE PROSTHESIS ACCESSORIES

The ConnectSecure™ rear tip extenders are accessories of this product. There are 8 sizes of extenders (0.5 cm, 1 cm, 1.5 cm, 2 cm, 3 cm, 4 cm, 5 cm, and 6 cm.) 1.5 cm rear tip extender is stackable. The pump and the cylinders are pre-connected, and the reservoir is connected to the pump inlet tubing during implantation. The Accessory kit contains the components necessary to assemble and implant an Infla10® Three-Piece Inflatable Penile Prosthesis. For more detailed information on the components of the accessory kit please refer to the Operating Room Protocol.

PATIENT POPULATION

Patients experiencing problems with having and or maintaining an erection might be suitable candidates for Inflatable Penile Prosthesis implantation. The candidate patient must have the required manual dexterity to operate the implanted device.

INTENDED USER

Infla10® Three-Piece Inflatable Penile Prosthesis must be implanted by specialized surgeons (i.e. urologists).

REPEAT APPLICATIONS, INCLUDING ANY RESTRICTIONS AS TO THE NUMBER OR DURATION OF REAPPLICATIONS

Re-application is possible for this device. The implanting surgeon (i.e. urologist) must decide on the restrictions of re-application.

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 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 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 a negative effect on the reliability of the device.
- The reuse of this single-use device may create potential harm to the user. Reprocessing, washing, disinfection and /or sterilization of Infla10® Three-Piece Inflatable Penile Prosthesis may compromise product characteristics and cause additional risks of physical harm and/or infection.

POST-OPERATIVE WARNINGS FOR PATIENTS

- Postoperative care should be determined by the treating physician. In general, antibiotics are administered intravenously for 48 hours and oral antibiotics are given for 5 days after discharge from the hospital. The prosthesis cylinders are left partially inflated at the time of surgery. The cylinders are completely deflated the day after surgery and left at this flaccid state during the healing period.

- The device is not activated until scrotal edema and pain have subsided. Most patients begin inflation and deflation of the device in the third or fourth week after surgery.

- The cylinders must remain deflated and the reservoir inflated until the third or fourth week following surgery. This helps the prevention of capsule formation around the reservoir. Capsule formation hinders reservoir inflation and cylinder deflation and may cause auto inflation.

- Postoperative care and instructions should be discussed with the patient prior to surgery.

PRECAUTIONS

The implantation of this device should only be considered for patients determined as suitable surgical candidates by the specialized surgeon (i.e. urologist).

Physicians implanting penile prostheses should be familiar with current practices in patient measuring techniques, implant size determination, and performing penile prosthesis implantation surgery. Removal of an implanted prosthesis without timely reimplantation of a new prosthesis may complicate subsequent reimplantation or even may make it impossible.

PATIENT RELATED

- The surgeon (i.e. urologist) 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 to implanted prosthesis (i.e. device revision).
- Proper device inflation and deflation requires manual 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 prosthesis.
- The length and/or diameter expansion of the cylinders may be limited by the contour, elasticity, and dimension of the patient's anatomy (i.e. tunica albuginea)

- Post-op trauma to the pelvic or abdominal areas can result in damage to 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 penile prosthesis. Injection therapy can damage the prosthesis.

- If the patient is also diagnosed with prostate diseases, the surgical operation on the prostate should be carried out prior to the implantation of the inflatable penile prosthesis.

SURGERY RELATED

- Proper surgical technique, proper sizing, filling, and anatomical placement of the device components are essential 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 the migration of the reservoir or the pump.

- Cylinders 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, and 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 narrower anatomies. Do not use NarrowBody™ 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.
- Implantation of Infla10® Anatomical eXpansion cylinders in patients with Peyronie's disease may not provide satisfactory results.

DEVICE RELATED

- Use sterile, isotonic, or normal saline to fill the implant.
- 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 products with damaged or open packaging, as sterility may be compromised.

- Due to the hydrophilic coating on all components (including the EasyClick™ connector and the RTEs) Infla10® Three-Piece Inflatable Penile Prosthesis will be slippery when dipped in an aqueous solution and care should be taken when handling them.

- Rigicon recommends the use of the AdaptiveReservoir™ with 110 ml capacity with cylinder sizes of 18 cm and above (i.e. 18 cm, 20 cm, 22 cm, and 24 cm cylinders). Cylinder size and reservoir volume selection is at the implanting surgeon's discretion.

ADVERSE EVENTS

The following potential adverse events may be experienced by patients:

- Scrotal swelling
- Auto inflation
- Urogenital Ecchymosis
- Discomfort
- Angulation/curvature
- Edema
- Device malfunction
- Chronic pain
- Difficulty with ejaculation
- Transient urinary retention
- Fever
- Migration
- Patient dissatisfaction
- Infection
- Deflation
- Hematoma
- Wound leakage
- Bleeding
- Delayed wound healing
- Phimosis
- Sensory loss
- Cylinder aneurysm
- Fibrous capsule formation

- Over/under inflation
- Erosion
- Scrotal erythema
- Genital Change
- Inguinal hernia
- Other device-related events

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:

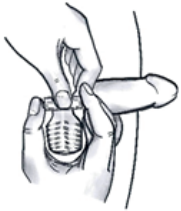
- post-operative bleeding,
- hematoma,
- penile edema,
- penile necrosis/gangrene,
- perforation of the corpora or the urethra,
- inability to adequately dilate the corpora,
- incorrect sizing of the implant,
- tearing or ripping of the device during or after implantation.

The complications listed above may necessitate surgical revision or removal of the prosthesis. Implantation of a penile prosthesis may result in penile shortening, curvature, or scarring.

MECHANISM OF ACTION

Fluid is transferred into the penile cylinders from the reservoir by squeezing and releasing the pump bulb in the scrotum repeatedly. (See Drawing 1) As the fluid fills the cylinders, they inflate and result in a voluntary erection. A flaccid state can be achieved by pressing the deflation button located on the pump and allowing fluid from the cylinders to transfer back to the reservoir. (See Drawing 2)

Drawing 1



Drawing 2

PRINCIPLE OF OPERATION

Please refer to the Operating Room Protocol for table and instrument set-up and further information on the implantation of Infla10® Three-Piece Inflatable Penile Prosthesis.

MAGNETIC RESONANCE IMAGING (MRI) IMPORTANT SAFETY INFORMATION

Non-clinical testing has demonstrated that the Infla10® Inflatable Penile Prosthesis product line is MR Conditional.

Patients who have been implanted with the Infla10® Inflatable Penile Prosthesis product line 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 720 Gauss/cm or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2.9W/kg for 15 minutes of scanning (i.e. per pulse sequence) (Normal Operating Mode)

Under the scan conditions defined above, the Infla10® Inflatable Penile Prosthesis product line is expected to produce a maximum temperature rise of less than or equal to 1.9˚C after 15 minutes of continuous scanning (i.e. per pulse sequence).

MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the Infla10® Inflatable Penile Prosthesis. Therefore, optimization of MR imaging parameters to compensate for the presence of this device may be necessary.

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

HOW SUPPLIED

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

All components of the system are supplied STERILE and nonpyrogenic in a double- wrap packaging system. Components of the Infla10® Three-Piece Inflatable Penile Prosthesis are sterilized by the following methods:

Product	Sterilization Method	Symbol
Infla10® Three-Piece Inflatable Penile Prosthesis Cylinders and Pump	Ethylene Oxide	STERILE EO
Infla10® Reservoir	Ethylene Oxide	STERILE EO
Infla10® Accessory Kit	Ethylene Oxide	STERILE EO
Infla10® ConnectSecure™ Rear Tip Extenders	Ethylene Oxide	STERILE EO

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.

STORAGE

Store the device in a clean, dry, dark area at room temperature (0-25°C).

OTHERS (SHELF LIFE AND PACKAGE)

The shelf life of the product is 5 years. The product may remain implanted over the patient's lifetime until any undesired effects are observed.

The product is supplied to the market in a sealed, double pouch and inside a protective carton box.

The package of Infla10® Three-Piece Inflatable Penile Prosthesis consists of; Infla10® Three-Piece Inflatable Penile Prosthesis with two cylinders, RapidPump™ and the Infla10® reservoir and the Infla10® Accessory Kit.

Infla10® Three-Piece Inflatable Penile Prosthesis (with two cylinders pre-connected to the pump) and Infla10® reservoir are used together. Infla10® Reservoir and the Infla10® Accessory Kit can be sold separately in separate packages.

DISCLAIMER

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

WARRANTY & PRODUCT REPLACEMENT

To activate the warranty of the device, the Patient Surgery Form must be filled out and filed with Rigicon, Inc.

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