04. PRODUCT INFORMATION

Product Name: Infla10® Three-piece Inflatable Penile Prosthesis

Brand Name:

Infla10® Three-piece Inflatable Penile Prosthesis
Rapid-Pump™
NarrowBody™ Cylinders
Easy-Click™ Connectors
ConnectSecure ™ Extenders
AdaptiveReservoir™
Infla10® Accessory Kit

04.01. Product Description

04.01.01. Models, Sizes and Model Differences

- Infla10® Three-piece Inflatable Penile Prosthesis is available in a variety of lengths ranging from 12 cm to 24 cm. Infla10® AX (Anatomical Expansion) model offers girth expansion and length expansion. Infla10® is also available with NarrowBody™ cylinders in a variety of lengths ranging from 10 cm to 16 cm. All standard and NarrowBody™ cylinders are provided pre-connected to the pump. *ConnectSecure™ RTE provides a secure and rigid connection. In addition to these components, an accecory kit that includes the cylinder protector tool, blunt tip needles for filling the device (15-Gauge) and flushing air and blood from the tubes (22-Gauge) is available.*

Product Name	Models	Product Code	Diameters	Length	ConnectSecure™ Rear Tip Extenders
Infla10® Sterile Inflatable Penile Prosthesis	Infla10® Inflatable Penile Prosthesis Infrapubic Approach	INF1012-IP	18 mm	12 cm	0.5 cm / 1cm 1.5 cm / 2 cm 3 cm / 4 cm 5 cm / 6 cm
		INF1015-IP	18 mm	15 cm	
		INF1018-IP	18 mm	18 cm	
		INF1022-IP	18 mm	22 cm	
		INF1024-IP	18 mm	24 cm	

Infla10® Sterile Inflatable Penile Prosthesis	Infla10® Inflatable Penile Prosthesis Penoscrotal Approach	INF1012-PS	18 mm	12 cm	0.5 cm / 1cm 1.5 cm / 2 cm 3 cm / 4 cm 5 cm / 6 cm
		INF1015-PS	18 mm	15 cm	
		INF1018-PS	18 mm	18 cm	
		INF1022-PS	18 mm	22 cm	
		INF1024-PS	18 mm	24 cm	
	Infla10® Anatomical Expansion Inflatable Penile Prosthesis Infrapubic Approach	INF1012AX-IP	18 mm	12 cm	0.5 cm / 1cm 1.5 cm / 2 cm 3 cm / 4 cm 5 cm / 6 cm
		INF1015AX-IP	18 mm	15 cm	
		INF1018AX-IP	18 mm	18 cm	
		INF1022AX-IP	18 mm	22 cm	
		INF1024AX-IP	18 mm	24 cm	
	Infla10® Anatomical Expansion Inflatable Penile Prosthesis Penoscrotal Approach	INF1012AX-PS	18 mm	12 cm	0.5 cm / 1cm 1.5 cm / 2 cm 3 cm / 4 cm 5 cm / 6 cm
		INF1015AX-PS	18 mm	15 cm	
		INF1018AX-PS	18 mm	18 cm	
		INF1022AX-PS	18 mm	22 cm	
		INF1024AX-PS	18 mm	24 cm	
	Infla10® NarrowBody™ Inflatable Penile Prosthesis Infrapubic Approach	INF1010NB-IP	15 mm	10 cm	0.5 cm / 1cm 1.5 cm / 2 cm 3 cm / 4 cm 5 cm / 6 cm
		INF1012NB-IP	15 mm	12 cm	
		INF1014NB-IP	15 mm	14 cm	
		INF1016NB-IP	15 mm	16 cm	

Infla10® Sterile Inflatable Penile Prosthesis	Infla10® NarrowBody™ Inflatable Penile Prosthesis Penoscrotal Approach	INF1010NB-PS	15 mm	10 cm	0.5 cm / 1cm
		INF1012NB-PS	15 mm	12 cm	1.5 cm / 2 cm
		INF1014NB-PS	15 mm	14 cm	3 cm / 4 cm
		INF1016NB-PS	15 mm	16 cm	5 cm / 6 cm

Product Name	Models	Reservoir Product Code	Volume
Infla10® Reservoir	Reservoir	INF10RS-65	65 ml
	AdaptiveReservoir™	INF10RS-70	70 ml
	AdaptiveReservoir™	INF10RS-110	110 ml

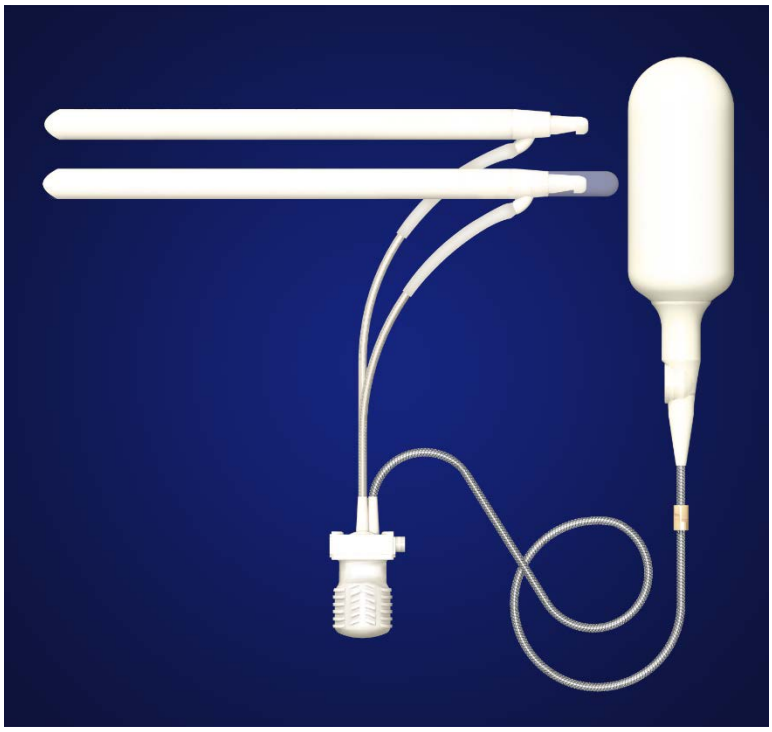


***Fig-1: Infla10®** Inflatable Penile Prosthesis*

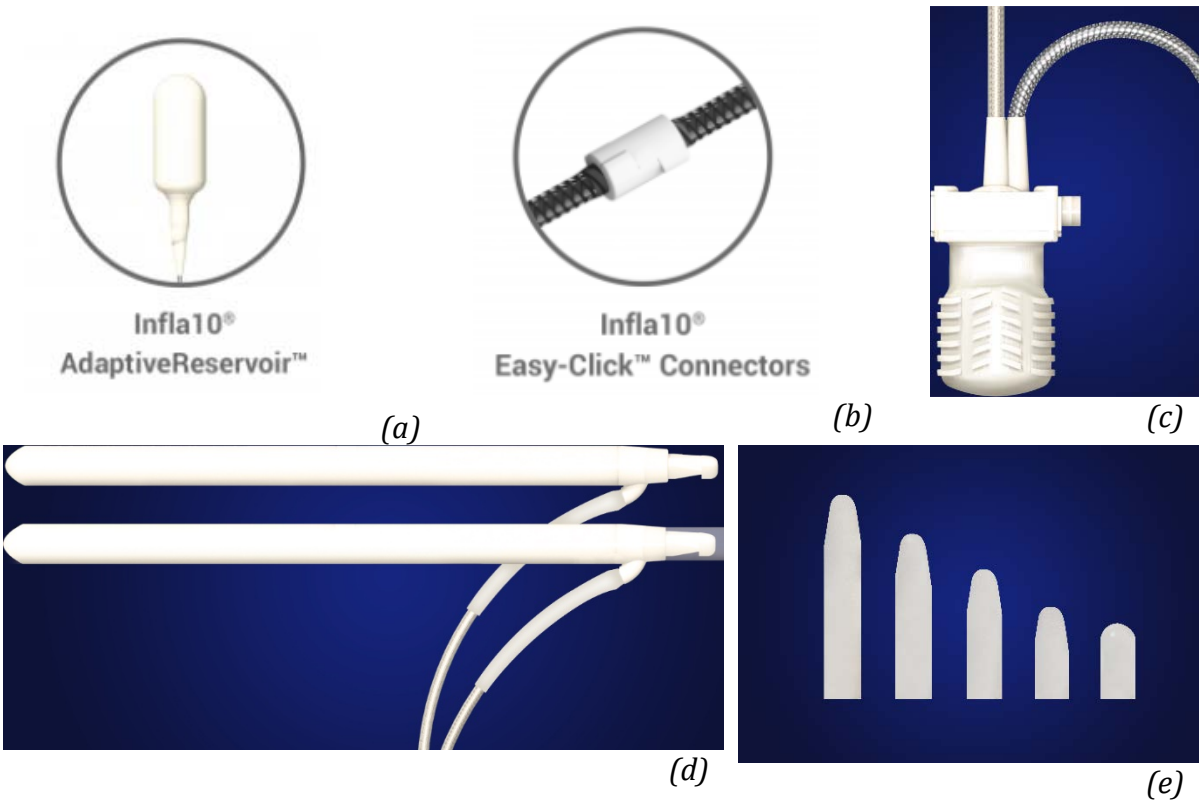


Fig-2: *(a) AdaptiveReservoir™; (b) EasyClick™ Connectors; (c) RapidPump™; (d) Cylinders; (e) ConnectSecure ™ Extenders*

Model Differences

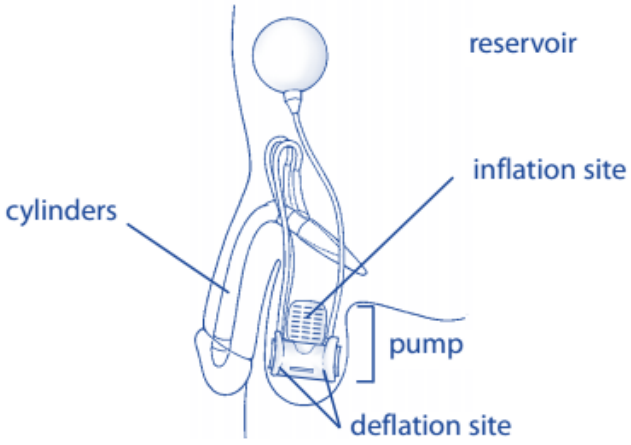
- **Infla10® NarrowBody™** cylinders are available for use in patients with compromised corpora cavernosa and patients who require a narrower cylinder due to their anatomy.
- **Infla10® Inflatable Penile Prosthesis** has **"-AX" (Anatomical Expansion)** variants. The difference that distinguishes the AX variant from other Infla10® models is that the AX model cylinders offers length expansion aside from girth expansion.
- INF10XX-**IP** and INF10XX-**PS** are different from each other due to surgical approach. The device is available for both common surgical approaches. IP indicates that the device is designed for infrapubic surgical approach while PS indicates that the device is designed for Penoscrotal approach.
- *There are three different sizes of **Infla10® Reservoir;** 65 ml, 70 ml and 110 ml. The **AdaptiveReservoirs™** with a volume of 70 ml and 110 ml have a rectangular design while the Reservoir with 65 ml volume has a spherical design.*

Rigicon, Inc. does not plan to develop any model and designs related to the product.
The package of Infla10® Inflatable Penile Prosthesis consists of two cylinders, a pump and a reservoir, extenders with different sizes and an accessory kit. Polyester suture, 0.0 (for positioning of cylinder by tensile strength, after implantation it is removed from tip of the cylinders) is presented in outer package. There are 8 extenders in each package. The product is supplied to the market in a sealed, double pouch and inside a protective carton box. Each variant of the product is presented in this package.

04.01.02. 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 is responsible for the fluid distribution between the cylinders, the pump and the reservoir. Different sizes of extenders are available to adjust the length of prosthesis according to the corporal length of the patient. EasyClick™ Connectors is used for connecting with kink-resistance tubes of reservoir and kink-resistance tubes of pump.

- RapidPump™
- Reservoir
- NarrowBody™ Cylinders
- EasyClick™ Connectors
- ConnectSecure ™ Extenders



04.01.03. Software, Accessories, Instruments and Devices used together

The device does not have an embedded software.

Infla10® Accessory Kit

The extenders are accessories of this product. There are 8 extenders in each package. The pump and the cylinders are pre-assembled and the reservoir is connected to the pump inlet tubing following implantation, using components of the assembly kit. Accessory kit contains the components necessary to assemble and implant an Infla10® device. Standard accessory kit contains the following components:

- Cylinder protector tool to protect the cylinders during suturing procedure
- Blunt Tip Needles for filling the device (15-Gauge) and flushing air and blood from the tubes (22-Gauge)

Minimum Required Surgical Instruments:

- Scalpel blades of two different sizes (one for corporotomy and one for skin incision)
- Curved Nelson-Metzenbaum Dissecting Scissors
- Straight Mayo scissors for cutting the sutures
- Preferred small retractors (e.g. Army, Navy, paediatric Deaver, “S”, or Richardson)
- At least 10 pairs of Mosquito haemostats
- Preferred tissue forceps
- One Babcock clamp
- Right angle clamps
- Preferred suction tips
- Metal basins (min. 500 ml)
- Furlow insertion tool
- Set of Hegar dilators (7mm - 12mm)
- 16F Foley catheter
- Irrigation syringe (60 cc)
- Preferred wound drainage catheter (Mini-vac or Hemovac)
- 1000 ml sterile normal saline

Device related Instruments:

- Straight Mayo scissors for cutting the tubing
- Graduated pitcher or basin for preferred aqueous solution
- Metal basins or graduates for device filling solution
- 60cc Luer Lock syringe
- 10 cc Luer Lock syringe for irrigation prior to connection
- 3 pairs of mosquito clamps

** All of these instruments must be sterile.*

A polyester suture (0.0, for positioning of cylinder by tensile strength, after implantation it is removed from tip of the cylinders) is pre-connected to tip of the cylinders.

Ref.: *[1] J Sex Med 2012; 9: 2467–2474. DOI: 10.1111/j.1743-6109.2012.02819.x*

[2] J Sex Med 2011;8: 310–314; DOI: 10.1111/j.1743-6109.2010.02064.x

[3] Equivalent and similar devices Instruction for use documents.

[4] Three-piece Inflatable Penile Prosthesis: Surgical Techniques and Pitfalls, Journal of Surgical Technique and Case Report | Jul-Dec 2011 | Vol-3 | Issue-2 (page 77)

04.01.04. Product Position on the Market and CE Marking Information

The device received initial CE-marking from Notified Body – 2764 recently. There are currently no sales.

04.01.05. Device Group

The device belongs to the Non-active urologic soft tissue implants.

04.02. Intended Purpose of the Device

Medical 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 of Erectile Dysfunction (impotence):

- prostatectomy,
- diabetes mellitus,
- arteriosclerosis,
- hypertensive vascular disease.
- pelvic fracture
- priapism
- Peyronie's disease
- spinal cord injury or disease,
- multiple sclerosis,
- psychogenic

Ref.: [1] J Sex Med 2011;8: 310–314; DOI: 10.1111/j.1743-6109.2010.02064.x

[2] Archivio Italiano di Urologia e Andrologia 2016; 88, 2; DOI: 10.4081/aiua.2016.2.122

[3] International Journal of Impotence Research (2015), 1–5; doi:10.1038/ijir.2015.33

[4] Urol Clin N Am 38 (2011) 217–225; doi:10.1016/j.ucl.2011.02.009

04.02.01. Patient Populations

Male patients who have experienced problems with erection is appropriate for this prosthesis. The patients who are considered for an inflatable penile prosthesis should have the manual dexterity required to operate the device.

Ref.: [1] J Sex Med 2011;8: 310–314; DOI: 10.1111/j.1743-6109.2010.02064.x (patient and Surgeons (i.e. urologists) selection)

[2] Urol Clin N Am 38 (2011) 217–225; doi:10.1016/j.ucl.2011.02.009

04.02.02. Intended User

The device shall be implanted by surgeons (i.e. urologists).

Ref.: J Sex Med 2011;8: 310–314; DOI: 10.1111/j.1743-6109.2010.02064.x (patient and Surgeons (i.e. urologists) selection)

04.02.03. Repeat Applications, Including Any Restrictions as to the Number or Duration of Reapplications

Re-application is possible for this product. However, restrictions about re-application is decided by the surgeon (i.e. urologists).

04.02.04. 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;
- neurogenic bladder and/or urinary obstruction;
- Total corporal length less than the cylinder size.

**** The AX variants of Infla 10® cannot be implanted in patients with Peyronie's disease. AX variants are contraindicated for patients with Peyronie's disease (Ref.: Journal of Medicine and Life Vol. 5, Issue 3, July-September 2012, pp.280-282, "Penile prosthesis in the surgical treatment of Peyronie's disease").*

Ref.: [1] Urologia. 2017 Apr 20:0. doi: 10.5301/uj.5000240

[2] J Sex Med 2012; 9: 2467–2474. DOI: 10.1111/j.1743-6109.2012.02819.x

[3] THE JOURNAL OF UROLOGY Vol. 190, 2183-2188, December 2013; http://dx.doi.org/10.1016/j.juro.2013.06.084

[4] *Urol Clin N Am 38 (2011) 217–225; doi:10.1016/j.ucl.2011.02.009.*

04.02.05. Precautions and Warnings Required by The Manufacturer

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

Surgeons (i.e. urologists) implanting penile prostheses should be familiar with current practices in patient measuring techniques, implant size determination, and performing the 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 with 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 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 penile prosthesis. Injection therapy can damage the prosthesis.
- If the patient has prostate disease, before implantation of inflatable penile prosthesis, they should be prostate surgery.

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.

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 an adverse effect on the reliability of the device.
- 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.

Post-operative Warnings for patients

- *Postoperative care is 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 then completely deflated the day after surgery and left deflated as this fills the reservoirs and prevents the normal capsule from forming around a deflated reservoir.*
- *The device is not further activated until scrotal oedema and pain have subsided. Most patients begin inflation and deflation of the device in the third or fourth week after surgery. In patients with prolonged scrotal oedema or tenderness, this manoeuvre has been delayed indefinitely without adverse functional or cosmetic results.*
- *The cylinders must remain deflated and the reservoir component totally inflated until the third or fourth week after surgery. This helps prevent the normal capsule formation from hindering reservoir inflation and cylinder deflation when the prosthesis is operated, and helps prevent auto inflation caused by the capsule. Postoperative care and instructions should be discussed with and understood by the patient prior to surgery.*

Ref.: [1] Urologia. 2017 Apr 20:0. doi: 10.5301/uj.5000240 (precautions related surgical procedure)
[2] J Sex Med 2012; 9: 2467–2474. DOI: 10.1111/j.1743-6109.2012.02819.x (precauitons by urologist in terms of surgery evaluation)
[3] J Sex Med 2013;10:2855–2860. DOI: 10.1111/jsm.12009 (usage precauitons)

[4] *Instruction for use Titan®, Titan® OTR and Titan® Touch Inflatable Penile Prosthesis document*

04.02.06. Single Use / Reusable

The device is single-use only.

04.03. General Description of the Medical Device

A Concise Physical and Chemical Description

Rigicon® offers the Infla10® Inflatable Penile Prosthesis (IPPs) for patients that need surgical intervention for the management of Erectile Dysfunction. This device provides the patient with voluntary control of the penis.

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. The fluid reservoir contains a valve, which is intended to minimize the probability of involuntary auto-inflation. The fluid reservoir is filled with a sterile saline solution. All components are connected via kink-resistant tubes that is responsible for the fluid distribution between the cylinders, the pump and the reservoir.

Repeated squeezing of the pump 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-assembled and the reservoir is connected to the pump inlet tubing following implantation, using components of the assembly kit. Accessory kit contains the components necessary to assemble and implant an Infla10® device. All components of Infla10® incorporate a hydrophilic coating on the external surfaces. The hydrophilic coating (HydroShield™) offers the Surgeons (i.e. urologists) the freedom to choose their patient-antibiogram-modified or preferred aqueous solution. Hydrophilic Coating facilitates the rapid and strong absorption of the preferred antibiotic solution on the device and may promote easier device implantation.

Chemical description in terms of raw material is defined in next sections.

Others (Sterility, Shelf life, Radioactivity etc.)

The device is sterilized with EtO method. The shelf life of the product is 5 years. The product may remain in the penile during patient lifetime until there will observe undesired effects.

04.03.01. Mechanism of Action and Principles of Operation

Fluid is moved into the penile cylinders from the reservoir by squeezing the pump bulb in the scrotum repeatedly. The pump has a one-way valve that is manually deactivated. As the fluid fills the cylinders, they inflate causing an erection which can be maintained for as long as desired. A flaccid state is reinstated when the one-way valve, which is located in the pump, is manually deactivated allowing fluid from the cylinders to return to the reservoir.

Ref.: [1] *J Sex Med 2012; 9: 2467–2474. DOI: 10.1111/j.1743-6109.2012.02819.x (evaluation by urologist)*

[2] *Coloplast Titan ® OTR A Guide to Penile Implant document*

Principle of Operation

Pre- Operative Considerations

- Proper patient selection is significant prior to implantation of the malleable penile prosthesis.
- Before 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 Surgeons (i.e. urologists) should scrub their hands for 10 minutes.
- In the operating room:
  - Patient can use parenteral antibiotics according to urologist's discretion.
  - The patient's genital areas should be shaved.
  - The skin should be prepared with a 10-minute scrub of providone-iodine soap

Intra- Operative Procedures

Operational Methods

There are two operational methods for the Inflatable Penile Prosthesis:

1. Infrapubic
2. Penoscrotal

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 be determined depending the length of the corpora cavernosa.
- The corpora cavernosa should be dilated distally and proximally using Hegar™ dilators.
- The corpora cavernosa should be dilated proximally by promoting the dilator to the ischial tuberosity.
- Corpora should be dilated distally by feeling the dilator at mid-glans by hand.
- It should be dilated 1 mm above the diameter of the device planning to be implanted.
- After dilatation, to determine the diameter of the cylinders to use the urologist should select two Hegar™ dilators whose total diameter equals the total diameter of the prosthesis to be implanted.
- The urologist should insert the Hegar™ dilators into the corpora cavernosa side by side and evaluate overall fit appropriately. Repeat this step for both the distal and proximal ends.

Diameter Adjustment

- Infla10® Three-piece inflatable penile prosthesis has two different diameter sizes. (12 mm and 10 mm for NarrowBody™ Cylinders)

Measuring the Length of the Corpora Cavernosa

- The tapered end of the sizer is inserted into the proximal part of the corpora cavernosa. Then, the sizer which has a curved and blunt end is inserted into the most distal part of corpus cavernosum and the distal measurement is read. Afterwards, the 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 to the extra length desired must be selected for extending the length of the prosthesis. The extenders should be placed on the proximal end of the prosthesis.

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, a rigidity test is carried out for determining the functionality of the device. The penis is bent down for the concealed position and straightened for the erect position. Afterward, the buckling test is performed. While the penis is in the up position, the glans is pressed against with the palm of the hand to confirm adequate rigidity.
- Closing
  - The corporotomy is closed with a 3.0 polydioxanone or 3.0 polyglyconate suture
  - The facia and skin are closed using an acceptable surgical technique.

Rigicon, Inc., has a manual for surgeons (i.e. urologists). Detailed information related to surgical operation is available in the document which is presented in TF-04.08 IFU / INF10-ORP.

Post- Operative Considerations

- Catheter usage should be minimized.
- Routine wound care should be done.
- The sexual activity can start 4-6 weeks after operation.
- All patient trainings should be completed to ensure proper and effective use of the new device.

Ref.: [1] *Urologia. 2017 Apr 20:0. doi: 10.5301/uj.5000240* (surgical technic),

[2] *Urol Clin N Am 38 (2011) 217–225; doi:10.1016/j.ucl.2011.02.009* (surgical technic).

04.03.02. The Contents of the Product

The device has no substance contents. The information about including a medicinal substance, animal tissues or blood components, phthalates and PFOS (perfluoroctansulfonates) is given the declarations which is located in **TF-04.06 Declarations**.

04.03.03. Intended Performance

The device is intended for the treatment of erectile dysfunction. Erectile dysfunction, although does not directly threaten the survival of the patient but has profound effects on physical and psychosocial health and affects the quality

of life of patients negatively. The clinical benefits of penile prosthesis implantation are documented to show both physiological and psychological improvements for patients. After implantation, relationship with partner and the QoL of the patient are affected positively. So, psychosocial health of the patient will also improve. In terms of both clinical performance and clinical safety, the device shall provide good quality of life to patients.

04.03.04. Adverse Effects and Complications

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 oedema,
- 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.

Ref.: [1] *J Sex Med 2012; 9: 2467–2474. DOI: 10.1111/j.1743-6109.2012.02819.x*
[2] *THE JOURNAL OF UROLOGY Vol. 190, 2183-2188, December 2013; http://dx.doi.org/10.1016/j.juro.2013.06.084*
[3] *J Sex Med 2013;10:2855–2860. DOI: 10.1111/jsm.12009*
[4] *Transl Androl Urol 2017;6 (Suppl 5): S832-S848; doi: 10.21037/tau.2017.06.07.*
[5] *Scandinavian Journal of Urology, 2014; 48: 105–109; DOI: 10.3109/21681805.2013.808695.*

04.03.05. Drug Interactions

There is no drug interaction related using device.

04.04. Product MDD Classification and Rule

The product class is determined as **Class IIb** according to the **Rule 8** of 93/42/EEC – Annex IX, Classification Rules, which is:

All implantable devices and long-term surgically invasive devices are in Class IIb unless they are intended:
— to be placed in the teeth, in which case they are in Class IIa,
— to be used in direct contact with the heart, the central circulatory system or the central nervous system, in which case they are in Class III,
— to have a biological effect or to be wholly or mainly absorbed, in which case they are in Class III,
— or to undergo chemical change in the body, except if the devices are placed in the teeth, or to administer medicines, in which case they are in Class III.

When the scope of the rule is considered, our product;

- *Infla10® Three-piece Inflatable Penile Prosthesis,*
- *NarrowBody™ Cylinders,*
- *Rapid-Pump™,*
- *AdaptiveReservoir™,*
- *ConnectSecure ™ Extenders,*
- *Accessory kit.*

is not in direct contact with the heart, the central circulatory system or the central nervous system and it is not placed in the teeth. So, ***Class IIb*** *is selected based on being invasive, implantable and has long-term surgically usage.*

04.05. Biocompatibility Classification

Clinical Classification according to Table 1 of EN ISO 10993-1:2009	
Category	Implant Device
Contact	**Implant Device** *(Tissue)* *The device contacts with silicone material, that is inserted in to the penis and intra-abdominal directly.* *Other materials of the product;* *For example;* *- Polyethyleneterephthalate (PET) inside in kink-resistant-tube is not connected to the body directly,* *- Connectors are made of polyether ether ketone (PEEK) and it contacts the abdominal region.* *- Inner/outer pumps are made from silicone and contacts with the scrotum. There are springs and pins inside in pump. They are made from 316 stainless steel.* The device is implantable.
Contact Duration	C — Permanent (> 30 days)

Biocompatibility Test Results are provided in the Test Reports below:

Annex - II	**Biocompatibility Evaluation Report**
	Irritation Test
	Cytotoxicity Test
	Sensitization Test
	Acute Systemic Toxicity
	Subcronic Toxicity
	Genotoxicity
	Implantation

04.06. Conformity Assessment Method

Medical Devices Directive 93/42/EEC Annex II (Excluding Section 4).

04.07. Product GMDN Code and Description

GMDN Code	***36250 - Prosthesis, internal, penile, inflatable***
Description	An Internal device indicated for erectile impotence, used to achieve penile tumescence and rigidity. The device is a hydraulic system, made out of

	silicone rubber and/or another polymer. It consists of one or two inflatable cylinders implanted in the penis, connected to a reservoir containing fluid, e.g. saline with/without radiopacifier, implanted in the abdomen, and a subcutaneous manual pump implanted in the scrotum.

04.08. Product Performance Criteria

The performance criteria of our product are determined according to the ease of users, risk situations and features of the device. Considering these, the table is prepared as following:

TF – 04.11 Annex I Essential Requirements
TF – 04.05 Harmonized Applicable Standards List

NO	CRITERIA	CLAIM
1	Horizontal Penile Lie	The purpose of Simulated Life/Fatigue Testing is to determine whether the proposed device can withstand the cyclical forces that occur when a patient alters the position of his penis over the expected lifetime of the device. ***@ different pressure (10,15,20) for 18 cm: ~ 4 – 8 displacement angle (unloaded)*** ***@ different pressure (10,15,20) for 18 cm: ~ 10 – 13 displacement angle (loaded)***
2	Longitudinal Column Load Testing	To replicate resistance to bending with gravity or penile lie, it was examined in terms of horizontal rigidity. It was looked at change in device angle in a loaded and an unloaded setting in the form of a cantilever test. ***Variable pressures to generate kinking, with pressures ranging from 1.7 lb to 2.2 lb***
3	Pump functional test	The pump must function in every sexual intercourse during the lifetime of the product.

The biomechanical test reports are located in **TF – 04.15 ANNEXES – Annex III Biomechanical Evaluation Report**.

04.09. Product Safety Criteria

The safety criteria of our product are determined according to the ease of users, risk situations and features of the device. Considering these, the table is prepared as following:

TF – 04.11 Annex I Essential Requirements
TF – 04.05 Harmonized Applicable Standards List

NO	CRITERIA	CLAIM
1	Sterilization	After production, the product is sterilized to not cause complications. ***Ref.: 04.15 ANNEXES – Annex VIII Sterilization validation report***

2	Pump functionality	The pump must function in every sexual intercourse during the lifetime of the product. ***Ref.: 04.15 ANNEXES – Annex III Biomechanical evaluation report***
3	Biocompatible material	Silicone elastomers have been commonly used in biomedical devices for over forty years. This material should not be caused allergic reaction on patients. ***Ref.: 04.15 ANNEXES – Annex II Biocompatibility evaluation report and ANNEX V- Raw Material and Component Certificates***
4	Microbiological control	After production, the products should be controlled as microbiologically (<100 cfu). ***Ref.: 04.15 ANNEXES – Annex VIII Sterilization validation report / Bioburden test***
5	Leakage	The reservoir shall not be leakage during lifetime. ***Ref.: 04.15 ANNEXES – Annex III Biomechanical evaluation report***
6	Not explode of the reservoir	The reservoir shall not be exploded. ***Ref.: 04.15 ANNEXES – Annex III Biomechanical evaluation report***

Performance and safety criteria have been supported a literature.

Ref.: *Scovell et. all. Longitudinal and Horizontal Load Testing of Inflatable Penile Implant Cylinders of Two Manufacturers: An Ex Vivo Demonstration of Inflated Rigidity, J Sex Med 2016;13:1750e1757.*

04.10. Critical Raw Material, Suppliers and Technical Specifications

**** Andromed Medikal A.Ş. is responsible for purchasing of critical raw material for our company.***

Critical Suppliers and Raw Materials Data Sheets are located in **TF – 04.15 ANNEXES / ANNEX IV** and **V** Critical Suppliers Contracts and Raw Material and Component Certificates.

The Product Technical Specifications

	TECHNICAL SPECIFICATIONS
INFLATABLE PENILE PROSTHESIS **INFLA10 AND INFLA10 NARROWBODY**	**Appearance:** White and transparent **Surface:** Smooth cylinders **Length and Diameters:** Different sizes are available. It is defined in section 04.01 (models and sizes) **Horizontal penile lie:** @ different pressure (10,15,20) for 18 cm: ~ 4 – 8 displacement angle (unloaded); ~ 10 – 13 displacement angle (loaded) **Longitudinal Column Load Testing:** from 1.7 lb to 2.2 lb * No leakage and no explode for reservoir

04.11. Technical Drawings

Technical drawings for Inflatable Penile Prosthesis are presented in the annex below.

TF – 04.15 ANNEXES / ANNEX XI Technical Drawing of Inflatable Penile Prosthesis

04.12. Field Information for Product Processes

Rigicon Inc.

***Headquarter Address**	:	2805 Veterans Highway Suite 13, Ronkonkoma, NewYork 11779 U.S.A
Phone	:	+1 631 630 2271
Web	:	www.rigicon.com
E-mail	:	info@rigicon.com
****Authorized Person**	:	Hüseyin LÜLECİ
Title	:	General Manager
Phone	:	+90 532 2151237
E-mail	:	hluleci@gmail.com
Authorized Person (2)	:	Melih LÜLECİ
Title	:	Quality Management Representative
Phone	:	+90 532 306 63 80
E-mail	:	ml@rigicon.com

** The address is the headquarter, design studies, production (re-labelling, re-packaging and final control and release) and warehouse address of company.*
***General manager is also responsible for product. If there is a feedback about product, the authorized person is Hüseyin Lüleci.*

Information about Work Environment

The manufacturing of the product is performed under cleanroom conditions. Packaging process is carried out in ISO 7 class. Production process (coating and press) is also performed in same cleanliness class (ISO 7). The entrance is ISO 8 class.

Information about cleanroom with details has been presented in **TF – 04.15 ANNEXES / ANNEX VI- Cleanroom Qualification Report.**

04.13. Coating Process and Validation

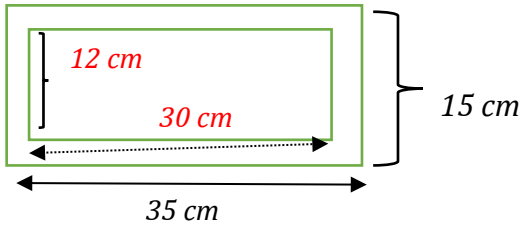
Coating process with PVP (polyvinylpyrrolidone) performed by sub-contractor UroAmerican Medikal A.Ş. The process was validated by our company. The information related coating process has been given in **TF – 04.15 ANNEXES / ANNEX X - Production Validation and Quality Control Documents.**

04.14. Packaging Information

The products are double-packaged with Wipak's (Tyvek Sterilization Rule BOPET/PE Film + Tyvek® 1073B, 100% HDPE) packages by using Gündem machine. Necessary

documentations are located in **ANNEX V – Raw Material and Component Certificates / Wipak** Documents. Packaging process was validated by our company. Validation procedure/protocol/report was prepared and located in **TF – 04.15 ANNEXES / Annex VII – Packaging Validation**.

The package dimensions are (for inner and outer packages):



*For transportation, shipping box with the dimensions of 14*14*22 inch is used.*

The package of Inflatable Penile Prosthesis consists of;

- Infla10® Three-piece Inflatable Penile Prosthesis with two cylinders, RapidPump™ pump and EasyClick™ Connectors;

Others are:

- Infla10® Reservoir,
- ConnectSecure™ Extenders,
- Infla10® Accessory Kit

Three-piece inflatable penile prosthesis (with two cylinders, pump and connectors) and reservoir are used together. Reservoir and accessory kit can be sold separately in separate packages.

04.15. Sterilization Information

This medical device is sterilized with Ethylene Oxide sterilization. Sterilization process is carried out by **Rigicon, Inc.** with **Zeoss machine** according to EN ISO 14937:2009. All

details about sterilization are located in **TF – 04.15 ANNEXES / ANNEX VIIII-Sterilization Validation File**. After sterilization, products are transported to Rigicon Inc.

04.16. Shelf Life Information

The shelf-life is determined as 60 months for sterile products as located in of **TF – 04.15 ANNEXES / ANNEX IX – Shelf Life Study File**. In case of the storage conditions which are mentioned in IFU and Label.

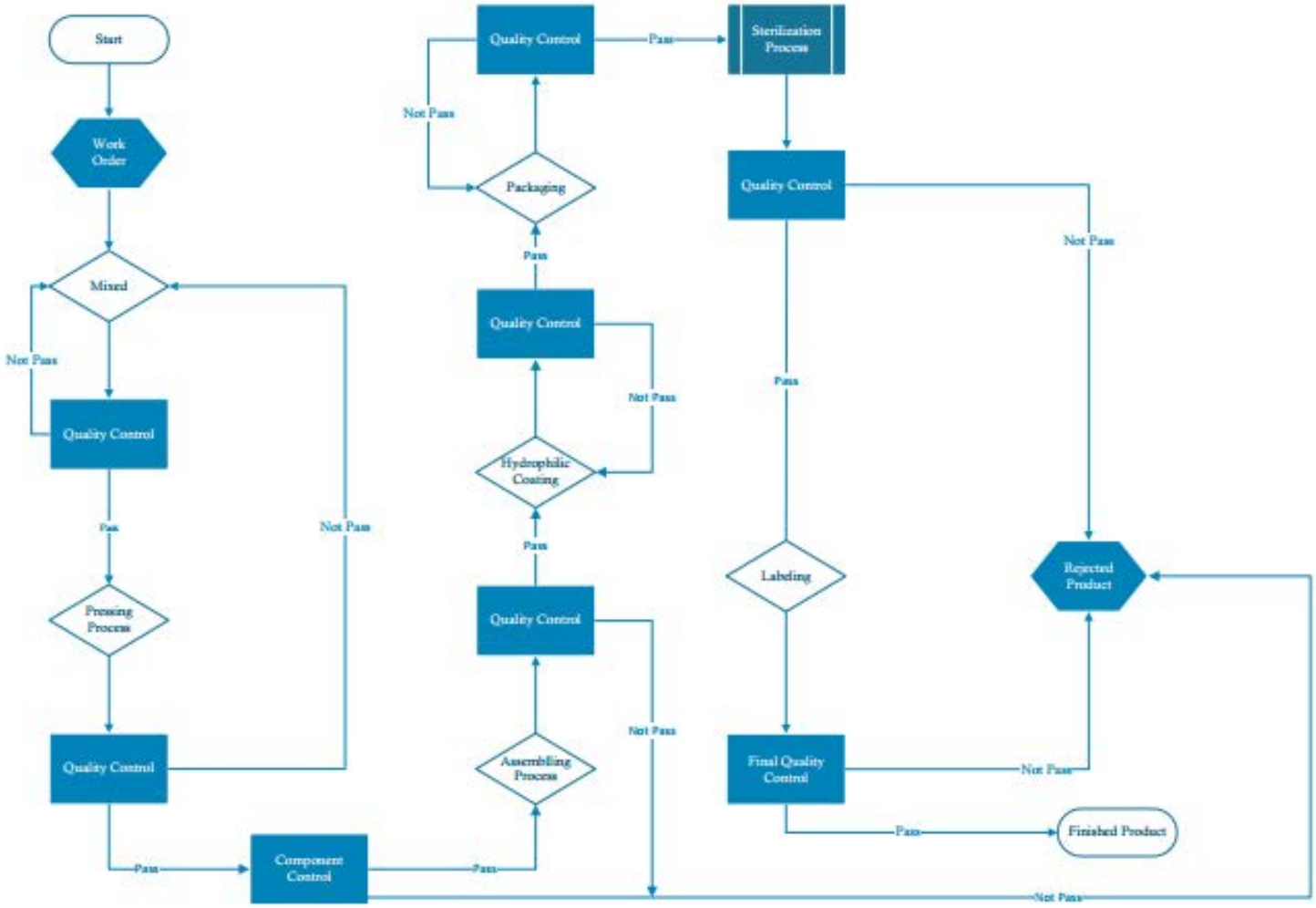
Hydrophilic coating does not affect the life-time of the product. The coating is eliminated in 24 hours.
Ref.: *L. Hunter and J. Fan, Waterproofing and breathability of fabrics and garments, Engineering Apparel Fabrics and Garments - 1st Edition – Elsevier, 30th May 2009.*

04.17. Storage Conditions

Products are stored at 0-25°C temperature and low humidity (35-60%RH) conditions before being shipped to the customer. Storage conditions are determined in **TF – 04.15 ANNEXES / Annex IX Shelf-Life Study File**.

04.18. Product Workflow Schema

The workflow for our products from raw material entry to the product delivery is provided in the schema below.
TF – 04.15 ANNEXES / ANNEX X – Process Validation, Production and Quality Control Documents / IA.07.03 Inflatable Penile Prosthesis IPP


Start
Work Order
Mixed
Not Pass
Quality Control
Pass
Not Pass
Pressing Process
Quality Control
Pass
Component Control
Pass
Assembling Process
Quality Control
Not Pass
Pass
Hydrophilic Coating
Not Pass
Pass
Quality Control
Not Pass
Packaging
Pass
Quality Control
Pass
Sterilization Process
Quality Control
Not Pass
Pass
Labeling
Final Quality Control
Not Pass
Pass
Rejected Product
Finished Product
Not Pass