AMS 700™

Inflatable Penile Prosthesis with TENACIO™ Pump

TABLE OF CONTENTS

REUSE WARNING 1
DEVICE DESCRIPTION 1
System Description 1
Contents 6
Materials 6
Operating Principle 7
Non-Pyrogenic 7
User Information 7
INTENDED USE 7
INDICATIONS FOR USE 7
CONTRAINDICATIONS 7
WARNINGS 7
PRECAUTIONS 8
Device-Related 8
Patient-Related 8
InhibiZone-Related 9
SILICONE INFORMATION 9
MRI SAFETY INFORMATION 9
ADVERSE EVENTS 10
CLINICAL STUDIES 13
HOW SUPPLIED 17
Device Details 17
Handling and Storage 18
OPERATIONAL INSTRUCTIONS 18
PREPARATION 19
PROCEDURE 19
SIZING 22
POST-PROCEDURE 41
PATIENT COUNSELING INFORMATION 42
EXPECTED LIFETIME OF THE IMPLANT 43
IMPLANTABLE DEVICE PATIENT INFORMATION 43
IMPLANT CARD INSTRUCTIONS 43
TROUBLE SHOOTING 43
PRODUCT REPLACEMENT INFORMATION 44
WARRANTY 44
SYMBOL DEFINITIONS 44

℞ ONLY

Caution: Federal Law restricts this device to sale by or on the order of a physician.

REUSE WARNING

Contents supplied STERILE using steam or an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, call your Boston Scientific representative.

For single patient use only. Do not reuse, reprocess or resterilize. 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 resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

DEVICE DESCRIPTION

System Description

The AMS 700 Inflatable Penile Prosthesis with TENACIO Pump is an implantable, closed, fluid-filled system (Figure 1) consisting of:

- Two cylinders with optional Rear Tip Extenders (RTEs)
- One TENACIO Pump
- One reservoir

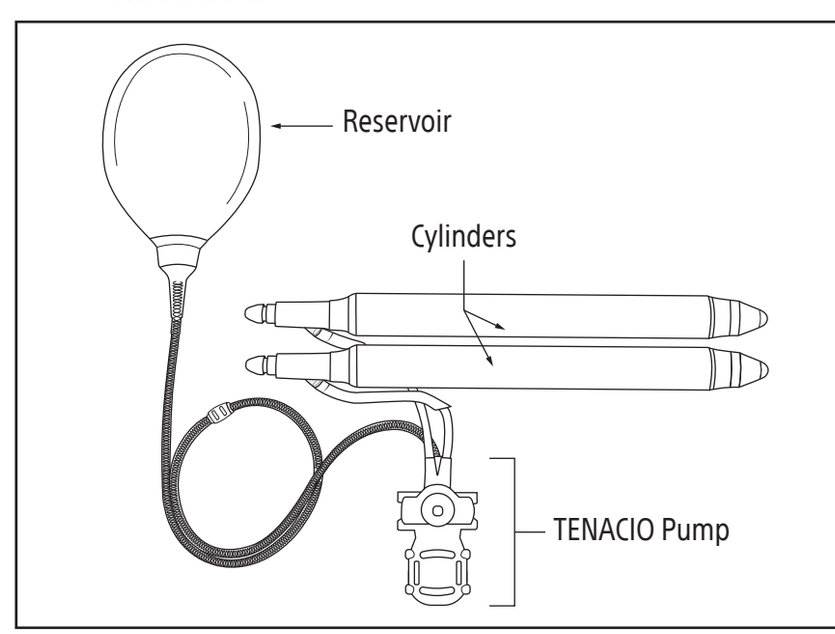

Figure 1. AMS 700 Inflatable Penile Prosthesis with TENACIO Pump

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Black (K) ΔE ≤5.0

The reservoir stores the fluid that fills and expands the penile cylinders. The patient operates the pump to inflate or deflate the cylinders. The cylinders are inflated by multiple squeezes of the pump bulb, which transfers fluid from the reservoir to the cylinders making the penis erect (Figure 2). The cylinders are deflated by squeezing the deflation button. This transfers fluid back into the reservoir making the penis flaccid (Figure 3). The penis can be made more flaccid by squeezing the penis; thereby transferring additional fluid to the reservoir. All components are connected by kink resistant tubing. The AMS 700 Inflatable Penile Prosthesis components are also available with InhibiZone[1], an antibiotic treatment of rifampin (rifampicin) and minocycline hydrochloride (minocycline HCl). For more information, please refer to the InhibiZone Antibiotic Treatment section.

[1]InhibiZone Antibiotic Treatment is not available in all markets.

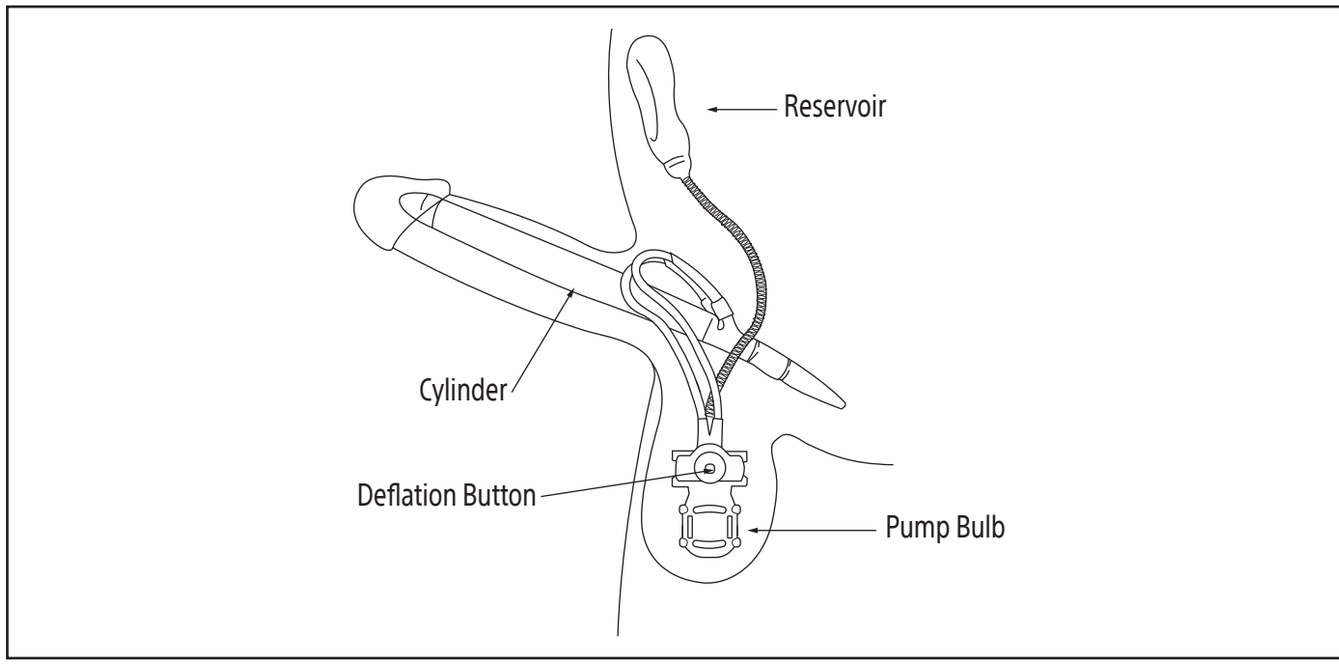

Figure 2. AMS 700 with TENACIO Pump: Inflated

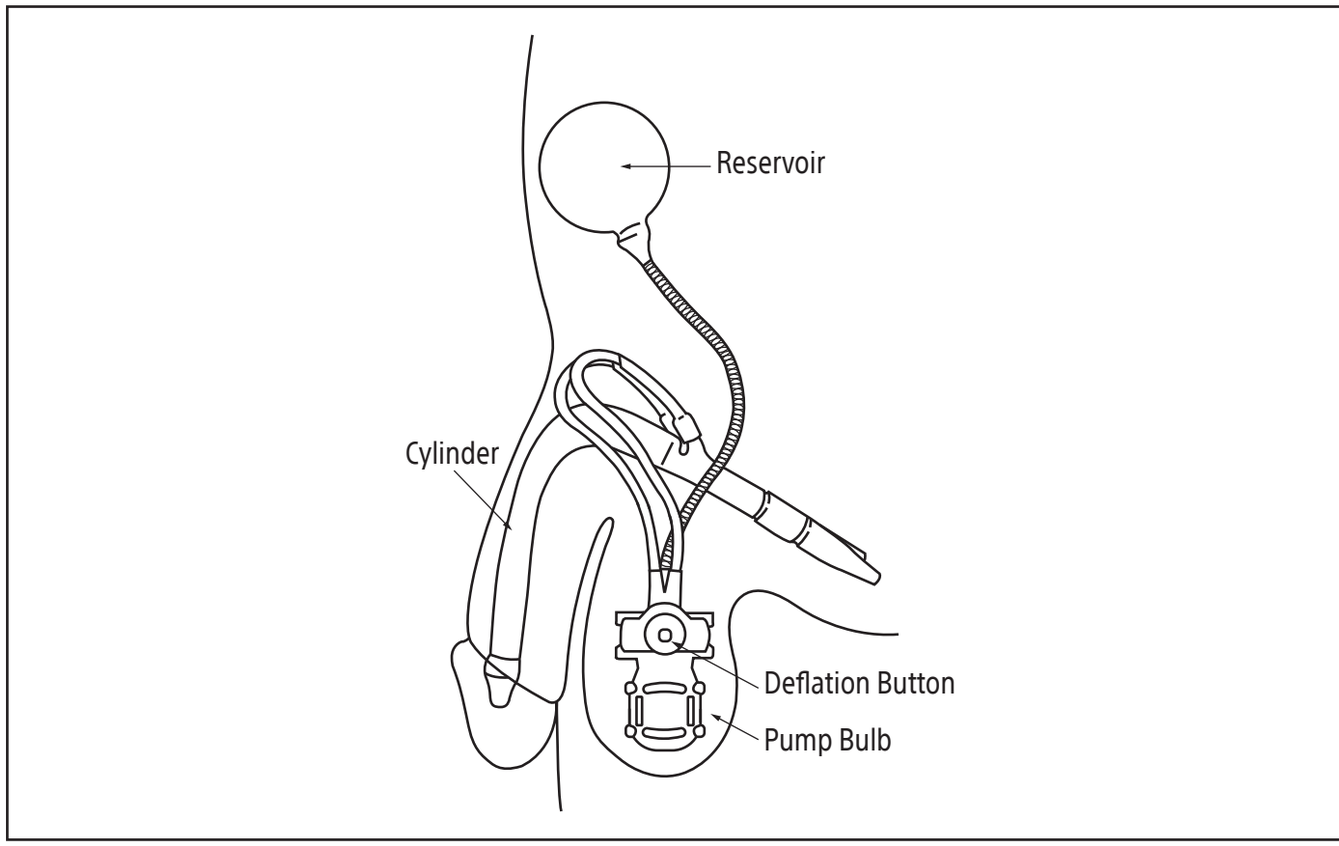

Figure 3. AMS 700 with TENACIO Pump: Deflated

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The AMS 700 Inflatable Penile Prosthesis product line includes the following products: AMS 700 CX, AMS 700 CXR, and AMS 700 LGX. The AMS 700 Inflatable Penile Prosthesis with TENACIO Pump is available with or without preconnected cylinders and pump and for either an infrapubic or penoscrotal approach. The available configurations are shown in Table 1.

Table 1. AMS 700 Inflatable Penile Prosthesis Product Line

			Kink Resistant Tubing Length			AMS 700 Cylinder Reservoir Recommendations		
						Spherical		Conceal (Low Profile)
Model/ Cylinder Expansion	Cylinder Diameter	Cylinder Length	Preconnected[1]		Non-preconnected Cylinders and Pump	65 mL	100 mL	100 mL
			Penoscrotal	Infrapubic				
AMS 700 CX (Girth expansion only)	12 mm deflated; 18 mm inflated[2]	12 cm	9 cm	18 cm	30 cm	√		√
		15 cm	9 cm			√		√
		18 cm	10 cm			√		√
		21 cm	12 cm				√	√
		24 cm	14 cm				√	√
AMS 700 LGX (Length and girth expansion)	12 mm deflated; 18 mm inflated[2]	12 cm	9 cm	18 cm	30 cm	√		√
		15 cm	9 cm			√		√
		18 cm	10 cm				√	√
		21 cm	12 cm				√	√
AMS 700 CXR (Girth expansion only)	9.5 mm deflated; 14.5 mm inflated[2]	10 cm	9 cm	15 cm	18 cm	√		√
		12 cm				√		√
		14 cm				√		√
		16 cm				√		√
		18 cm				√		√

[1] With preconnected cylinders and pump
[2] The inflated girth can vary ± 2 mm, in diameter

Cylinders

Each cylinder (Figure 4) includes:

- Solid silicone elastomer inner tube with Parylene coating on inside and outside surfaces
- Woven stretch fabric cylinder (located between the inner and outer tubes)
- Solid silicone elastomer outer tube with Parylene coating on the inside surface
- One silicone, clear, kink resistant tube per cylinder
- One protective ePTFE (expanded polytetrafluoroethylene) sleeve per cylinder
- One 3-0 braided, nonabsorbable, PTFE-coated polyester traction suture per cylinder

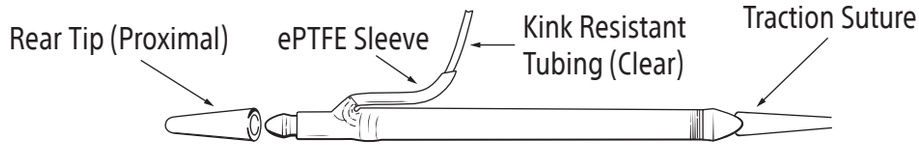

Figure 4. AMS 700 Inflatable Penile Prosthesis Cylinder

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Cylinders are available in several lengths and diameters, depending on the model number. Optional Rear Tip Extenders (RTEs) are provided and, when applied, are attached to the proximal end of the cylinder in a combination appropriate for the patient's anatomical length. The AMS 700 CXR penile prosthesis may be appropriate for a patient with an anatomy that requires shorter and narrower cylinders. It may also be useful for penile prosthesis reimplantation procedures.

All cylinders are sterilized via an ethylene oxide (EO) process.

Rear Tip Extenders

Rear tip extenders (RTEs) are available to extend and customize cylinder length, if desired. RTEs are available in non-stackable and stackable designs. A stackable RTE (available only in a 1.5 cm length) is attached directly to the proximal cylinder end, alone or in combination with (and distal from) a single, non-stackable RTE (available in 0.5, 1.0, 2.0, 3.0, 4.0, 5.0, and 6.0 cm lengths). Alternatively, a single, non-stackable RTE can be attached directly to the proximal cylinder end.

All RTEs are sterilized via a steam sterilization process.

TENACIO Pump

The TENACIO Pump (Figure 5) includes:

- One pump bulb
- One deflation button
- Three silicone, kink resistant tubes (two clear and one black color-coded)

The TENACIO Pump is used with all models of AMS 700 cylinders. The single, black color-coded kink resistant tubing connects the pump to the reservoir. Clear tubing connects the pump to each cylinder. In the preconnected system, the TENACIO Pump and cylinders are connected.

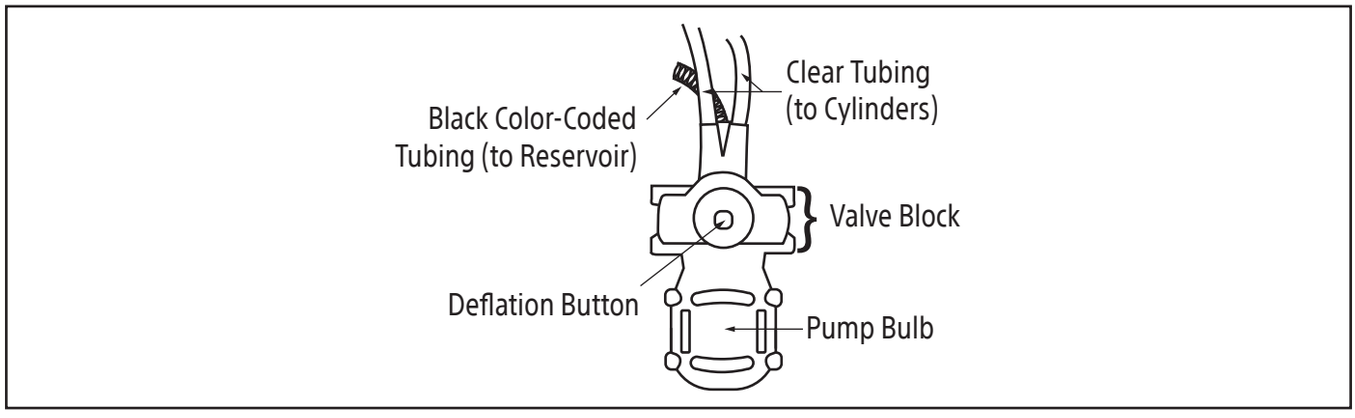

Figure 5. Features of the TENACIO Pump

All TENACIO Pumps and preconnected systems are sterilized via an ethylene oxide (EO) process.

Reservoir

The reservoir (Figure 6) includes:

- One fluid storage silicone reservoir, coated on the inside surface with Parylene (provides wear protection)
- One silicone, black color-coded kink resistant tube that connects the reservoir to the pump
- Two size options:
  - 65 mL (Spherical Reservoir, only)
  - 100 mL (Spherical Reservoir or Conceal Low Profile Reservoir*)

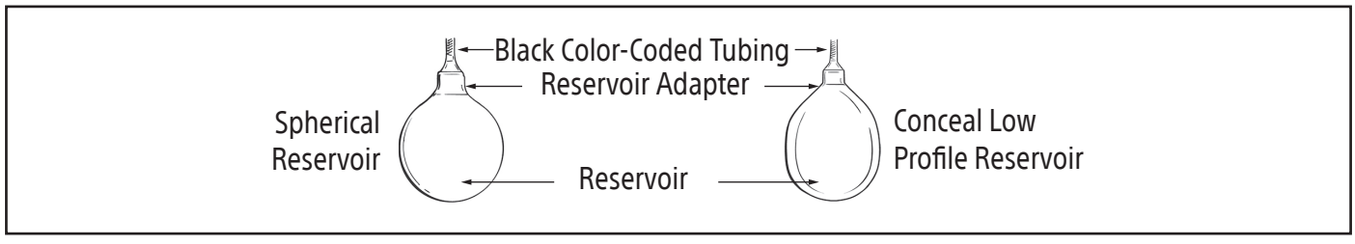

Figure 6. AMS 700 Reservoirs: Spherical and Conceal

* The Conceal Reservoir is not available in all markets

All reservoirs are sterilized via an ethylene oxide (EO) process.

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AMS 700 Accessory Kit

The AMS 700 Accessory Kit is provided sterile using a steam sterilization process and contains the materials needed for one implant procedure. The kit contains the following disposable items:

Special Purpose Needles

- Two 15-gauge disposable blunt tip needles (for filling components)
- Two 22-gauge disposable blunt tip needles (for flushing particulate matter and air from tubing)
- One pair of Keith Needles (for transporting the cylinder traction sutures through the glans)

Hemostat Shods

- Four 13 cm lengths of tubing (for covering the tips of hemostats used to prepare components – tubing shod hemostats help protect the prosthesis tubing from damage)

Tubing Connection Accessories

- Four straight Quick Connect Window Connectors
- Three right angle Quick Connect Window Connectors
- One collet holder with eight collets
- Three straight Suture-Tie Connectors
- Two right-angle Suture-Tie Connectors
- One tubing plug (to prevent fluid from entering or leaving the prosthesis during revision surgeries)

Proximal Tool

- The Proximal Tool is designed to facilitate the insertion of the proximal portion of the cylinder into the corpora and may also be used to assist in closing (Figure 7).

Figure 7. Proximal Tool

InhibiZone Antibiotic Treatment

InhibiZone is a formulation of minocycline HCl and rifampin antibiotics. The antibiotic dosage present on the AMS 700 is intended to act on organisms that come into contact with the surface of the device during implant. Regardless of component configuration, the AMS 700 (consisting of a reservoir, TENACIO Pump, and two cylinders) contains ≤33 mg rifampin and ≤12 mg minocycline HCl. This represents less than 2% of an oral dose exposure for a complete course of rifampin or minocycline HCl, with the maximum dose calculated for the most common device configuration's average concentration plus one standard deviation.

Clinical evidence of the InhibiZone effectiveness is provided by a post-market analysis, which included a comprehensive review of more than 43,000 patients in the Boston Scientific (BSC) Patient Information Form database. This analysis shows a significant improvement in the rate of revisions due to infection for patients with original or revision procedures for the AMS 700 with InhibiZone (as well as patients with diabetes who received an original AMS 700 with InhibiZone) compared to those who received an AMS 700 without InhibiZone.

Existing prophylactic antibiotic protocols should be maintained as determined by the physician and/or institution.

Parylene Coating

Parylene coating is a medical grade polymer designed to reduce wear occurrences on a variety of surface and texture materials. Within the AMS 700 Inflatable Penile Prosthesis cylinders, an innovative micro-thin Parylene coating is applied to each side of the internal cylinder surface and to the internal surface of the outer cylinder. All AMS 700 Reservoirs are coated on the inside surface with Parylene.

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Contents

The following is a list of the AMS 700 Inflatable Penile Prosthesis with TENACIO Pump components and accessories:

(2) Cylinders
(1) TENACIO Pump
(1) Reservoir
Kink Resistant Tubing (KRT)
Connectors to attach ends of the kink resistant tubing

Optional Rear Tip Extenders: (2) 0.5 cm, (2) 1 cm, (2) stackable 1.5 cm, (2) 2 cm, (2) 3 cm, (2) 4 cm, (2) 5 cm, (2) 6 cm

AMS 700 Accessory Kit:

(4) Straight Quick Connect Window Connectors
(3) Right Angle Quick Connect Window Connectors
(3) Straight Suture-Tie Connectors
(2) Right Angle Suture-Tie Connectors
(8) Collets
(1) Collet Holder
(2) 22 Gauge Blunt Tip Needles
(2) 15 Gauge Blunt Tip Needles
(2) Keith Needles
(4) 13 cm Lengths of Tubing
(1) Tubing Plug
(1) Proximal Tool

Materials

The AMS 700 with and without InhibiZone utilize the same materials with the same surface areas. AMS 700 with InhibiZone (including reservoir, pump, and two cylinders), regardless of configuration, contains ≤ 33 mg Rifampin (CAS # 13292-46-1) and ≤12 mg Minocycline HCl (CAS # 10118-90-8) which represents less than 2% of oral dose exposure for a complete course of Rifampin or Minocycline HCl with the maximum dose calculated for the most common device configuration's average content plus one standard deviation.

This device is composed of a number of materials, including solid silicone elastomers and a fluorosilicone lubricant. The tubing plug and Keith needles are composed of stainless steel and therefore may contain cobalt.

Table 2: Implantable Materials in AMS 700 System plus AMS 700 Accessory Kit (if using Quick Connect window connectors)

Implantable Material	Patient Contacting Surface Area (sq cm)	% Patient Contacting Surface Area Implant Material / Total Implantable Patient Contacting Surface Area
Silicone	612.00	92.85
Expanded PTFE	33.50	5.08
Polyamide	0.03	Trace
316 Stainless Steel[1]	0.52	0.08
Polyacetal	13.06	1.98
Total Implantable	**659.11**	**100**

[1] Implantable stainless steel is attributable to the tubing plug included in the AMS 700 Accessory Kit. The tubing plug is used to plug component kink resistant tubing in the event of revision surgery when the physician decides to preserve and maintain that component.

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Table 3: Implantable Materials in AMS 700 System plus AMS 700 Accessory Kit (if using Suture-Tie connectors)

Implantable Material	Patient Contacting Surface Area (sq cm)	% Patient Contacting Surface Area Implant Material / Total Implantable Patient Contacting Surface Area
Silicone	612.00	94.54
Expanded PTFE	33.50	5.18
Polyamide	0.03	Trace
316 Stainless Steel[1]	0.52	0.08
Polyacetal	1.27	0.20
Total Implantable	**647.32**	**100**

[1] Implantable stainless steel is attributable to the tubing plug included in the AMS 700 Accessory Kit. The tubing plug is used to plug component kink resistant tubing in the event of revision surgery when the physician decides to preserve and maintain that component.

Materials of Animal Origin

Information concerning materials of animal origin in the AMS 700 Inflatable Penile Prosthesis components follows:

- InhibiZone treated components may contain a non-viable derivative of porcine origin or a bovine milk derivative.
- The Quick Connect Window Connectors (straight and right angle) and the collets contain a non-viable tallow derivative.

Operating Principle

The reservoir stores the fluid that fills and expands the penile cylinders. The patient operates the TENACIO Pump to inflate or deflate the cylinders. The cylinders are inflated by multiple squeezes of the pump bulb, which transfers fluid from the reservoir to the cylinders making the penis erect. The cylinders are deflated by squeezing the deflation button. This transfers fluid back into the reservoir making the penis flaccid. The penis can be made more flaccid by squeezing the penis; thereby transferring additional fluid to the reservoir. All components are connected by kink resistant tubing.

Non-Pyrogenic

The devices covered by this Instructions for Use document are non-pyrogenic.

User Information

The implantation of this device is to be performed only by physicians who are knowledgeable regarding the use and placement of an inflatable penile prosthesis. This manual is not intended to be a complete reference.

Post procedure, this implant is intended to be operated by the adult male patient.

INTENDED USE

The AMS 700 Inflatable Penile Prosthesis is designed to provide the patient with control over the erect and flaccid states of his penis.

INDICATIONS FOR USE

The AMS 700 Inflatable Penile Prosthesis is intended for use in the treatment of chronic, organic, male erectile dysfunction (impotence).

CONTRAINDICATIONS

- The implantation of this device is contraindicated in patients who have active urogenital infections or active skin infections in the region of surgery.
- The implantation of the InhibiZone version of this device is contraindicated in patients with known allergy or sensitivity to rifampin, minocycline HCl, or other tetracyclines.
- The implantation of products with InhibiZone is contraindicated in patients with systemic lupus erythematosus because minocycline HCl has been reported to aggravate this condition.

WARNINGS

- The implantation of a penile prosthesis will make latent natural or spontaneous erections impossible.
- The implantation of a penile prosthesis may make some erectile dysfunction treatment options impossible.

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- Men with diabetes, spinal cord injuries, or open sores may have an increased risk of infection associated with a prosthesis.
- Failure to evaluate and promptly treat erosion may result in a substantial worsening of the condition leading to infection and loss of tissue.
- Implantation of a penile prosthesis may result in penile curvature or scarring.
- This device contains solid silicone elastomer. The risks and benefits of implanting this device in patients with documented sensitivity to silicone should be carefully considered.
- Pre-existing abdominal or penile scarring or contracture may make surgical implantation more complicated or impractical.
- If a hypersensitivity reaction develops to a device treated with InhibiZone, the penile prosthesis should be removed, and the patient treated appropriately.

PRECAUTIONS

Surgery-Related

- 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.
- Migration of the device components can occur if the cylinders are improperly sized, if the pump or the reservoir is not positioned properly, or if the tubing lengths are incorrect.
- Removal of an implanted prosthesis without timely reimplantation of a new prosthesis may complicate subsequent reimplantation or may make it impossible.
- Improper measurement technique, positioning, or sizing may reduce cylinder life.
- Unsuccessful outcomes have been reported due to improper surgical technique, anatomical misplacement of components, improper sizing and filling of components, or tubing kinks.
- Implantation of AMS 700 LGX cylinders in patients with Peyronie's disease may not provide a satisfactory result.

Device-Related

- Quick Connect Window Connectors, provided in the AMS 700 Accessory Kit, should not be used in revision procedures involving previously implanted component tubing. In this situation the Quick Connect Window Connectors may be less effective.
- Some of the materials used in the construction of this device have been shown to cause minor irritation when implanted in animals. Therefore, implantation of this device may cause minor irritation or discomfort in some patients.
- The stainless-steel tubing plug(s) in the AMS 700 Accessory Kit and Deactivation Package contains nickel, which may cause an allergic reaction in individuals with nickel sensitivity.
- The AMS 700 Inflatable Penile Prothesis should be filled with sterile normal saline. Some patients may have a hypersensitivity to contrast media.
- Do not use product that has damaged or open packaging, as sterility may be compromised.
- CXR RTEs are not compatible with CX or LGX cylinders. CX/LGX RTEs are not compatible with CXR cylinders.
- Verify proper attachment of RTEs by spinning them once seated. Properly attached RTEs should spin freely without accidental disengagement or material bulging.
- Do not stack the CX, LGX, or CXR RTEs with the exception of the 1.5 cm RTE. The locking ring on all other RTE lengths will not engage with the smooth outer surface of the RTE, which may result in the RTE disconnecting.

Patient-Related

- Adequate patient manual dexterity and strength are required for proper device inflation and deflation.
- Mental or psychological conditions, such as senile dementia, may inhibit the patient's successful operation of the prosthesis.
- Trauma to the pelvic or abdominal areas, such as impact injuries associated with sports (e.g., bicycle riding), may result in damage or malfunction of the prosthesis and/or surrounding tissues, which may necessitate surgical correction, including replacement of the device.

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- The contour, elasticity, and dimension of the tunica albuginea may limit the length and/or diameter expansion of the AMS 700 Inflatable Penile Prosthesis cylinders.
- The implantation of this device should only be considered in patients whom the physician determines are adequate surgical candidates.
- Use of injection therapy concurrently with the penile prosthesis may damage the prosthesis. Patients should not use injection therapy after they receive their implant.

InhibiZone-Related

- InhibiZone does not replace normal antibiotic protocols. Continue using any prophylactic antibiotic protocols used when implanting an AMS 700.
- The AMS 700 with InhibiZone is impregnated with a combination of rifampin and minocycline HCl. The contraindications, warnings, and precautions regarding the use of these antimicrobial agents apply and should be adhered to for the use of the AMS 700, although systemic levels of minocycline HCl and rifampin in patients receiving this device are unlikely to be detected.
- Use of the AMS 700 with InhibiZone should be carefully considered in patients with hepatic or renal disease, as rifampin and minocycline HCl can cause additional stress on the hepatic or renal systems.
- Patients who receive an AMS 700 with InhibiZone and are also taking methoxyflurane should be carefully monitored for signs of renal toxicity.
- Patients who receive an AMS 700 with InhibiZone and are also taking warfarin should have their prothrombin time monitored, because tetracyclines have been reported to slow coagulation.
- Use of the AMS 700 with InhibiZone should be carefully considered in patients using thionamides, isoniazid, and halothane, due to potential hepatic side effects that have been reported in patients using these drugs and higher doses of rifampin.
- InhibiZone should not come into contact with ethyl alcohol, isopropyl alcohol or other alcohols, acetone or other nonpolar solvents. These solvents may remove the antibiotics from the device.
- InhibiZone components should not be soaked in saline or other solutions prior to implantation. The components may be briefly rinsed or dipped in a sterile solution immediately prior to implantation, if desired.

SILICONE INFORMATION

This device is composed of a number of materials, including solid silicone elastomers and a fluorosilicone lubricant. Silicone gel is not a component in the materials of this device.

Silicone elastomers have been commonly used in a variety of biomedical devices for over 45 years and are used as a biocompatibility reference against which new materials are tested. Silicone fluids have an extensive history of use in medical devices.

Scientific literature has included reports of adverse events and other observations in patients with implantable silicone devices. As reported, these events/observations indicate "allergic-like" symptoms and in other cases a symptom complex associated with immunological disorders. No causal relationship has been established between these events and silicone elastomer or fluorosilicone lubricant.

There are reports of malignant tumor formation in laboratory animals only, not humans, associated with implants of relatively large size. Many different materials are associated with this effect in animals, silicone elastomers among them. No such effect has been described in humans.

Extensive testing was conducted on all materials that comprise the AMS 700 Inflatable Penile Prosthesis. This testing indicated no toxicological response attributable to the materials. However, some of the materials caused minor irritation when implanted in animals.

Silicone elastomer particulate shedding and particulate migrations to regional lymph nodes have been reported in the literature from penile implants. There are no known clinical sequelae to this phenomenon.

MRI SAFETY INFORMATION

Table 4 provides the MRI parameters for patients with an AMS 700 IPP with TENACIO Pump. The patient may be safely scanned under these conditions regardless of cylinder type/size, reservoir type/size, RTEs, connector type, or if there is a tubing plug implemented. Failure to follow these conditions may result in injury.

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Table 4. MRI parameters for patients with an AMS 700 IPP with TENACIO Pump.

Static Magnetic Field Strength (B_0)	1.5 T or 3.0 T
MR Scanner Type	Cylindrical
B_0 Field Orientation	Horizontal
Maximum Spatial Field Gradient	40 T/m (4,000 gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	There are no Transmit Coil restrictions
RF Receive Coil Type	Any
Operating Mode	Normal Operating Mode
Maximum Whole-Body SAR	2 W/kg (Normal Operating Mode)
Scan Duration	2 W/kg whole-body average SAR for 60 minutes of continuous RF (a sequence or back-to-back series/scan without breaks)
MR Image Artifact	The presence of this implant may produce an image artifact that extends approximately 33 mm from the device

If information about a specific parameter is not included, there are no conditions associated with that parameter.

ADVERSE EVENTS

A clinical trial was conducted from January 31, 1995 to October 24, 2002 to determine the safety and effectiveness of the AMS 700 Inflatable Penile Prosthesis. This trial involved only devices without InhibiZone. A total of 300 patients were enrolled with follow-up out to 5 years for 126 patients. There were 18 patient deaths during the trial. No deaths that occurred during the duration of the clinical study were attributed to the device implantation or use.

The Adverse Device Events (ADE), detailed in Tables 5 and 6, were noted during the duration of this clinical trial for all enrolled patients.

Table 5: Clinical Trial Adverse Device Events

ADE	# Patient (%)**	Mean Onset Time in Days (Range in Days)
Urogenital Pain (Typically Associated with Healing Process)	160 (53.3 %)	21 (0 – 876)
Urogenital Edema	106 (35.3 %)	8 (0 – 722)
Urogenital Ecchymosis	30 (10.0 %)	4 (0 – 150)
Reservoir Encapsulation (persistent in 11/19 cases)	19 (6.3 %)	275 (38 – 1731)
Patient Dissatisfaction (With Length, Ability to Use and Nonspecific Reasons)	18 (6.0 %)	384 (0 – 1830)
Auto-Inflation	17 (5.7 %)	141 (0 – 608)
Mechanical Malfunction (Leaks, Incomplete Inflation/Deflation, Kinking)	13 (4.3 %)	905 (0 – 1915)
Urination Impaired (Slow Stream, Split Stream, Voiding Difficulties or Obstructive Symptoms)	11 (3.7 %)	239 (0 – 930)
Urogenital Erythema	10 (3.3 %)	36 (0 – 320)
Joint Pain, Swelling, or Stiffness	9 (3.0 %)	609 (1 – 1592)
Decreased Penile Sensation	7 (2.3 %)	124 (0 – 214)
Urogenital Hematoma	7 (2.3 %)	4 (0 – 25)
Abnormal Ejaculation (Delayed, Burning, or General Nonspecific Problems)	6 (2.0 %)	409 (40 – 1797)
Infection	6 (2.0 %)	216 (9 – 716)

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ADE	# Patient (%)**	Mean Onset Time in Days (Range in Days)
Dysuria	5 (1.7 %)	231 (2 – 684)
Penile Curvature	5 (1.7 %)	144 (0 – 257)
Application Site Reaction (Wound Separation, Delay in Cutaneous Closure)	4 (1.3 %)	14 (0 – 30)
Erosion/Extrusion (Pump/Cylinder)	4 (1.3 %)	425 (72 – 1066)
Paresthesia	4 (1.3 %)	490 (0 – 1897)
Urogenital Inflammation	4 (1.3 %)	12 (0 – 27)
Adhesion of the Pump/Scrotum	3 (1.0 %)	13 (10 – 19)
Device Malposition	3 (1.0 %)	278 (43 – 574)
Device Migration (Pump/Cylinder)	3 (1.0 %)	210 (40 – 548)
Transient Urinary Retention	3 (1.0 %)	85 (3 – 248)
Urinary Frequency	3 (1.0 %)	277 (99 – 409)
Weakness	3 (1.0 %)	1072 (519 – 1592)
Abnormal Sexual Function	2 (0.7 %)	239 (128 – 349)
Device Cylinder Aneurysm/Bulge	2 (0.7 %)	945 (110 – 1780)
Dizziness	2 (0.7 %)	929 (7 – 1850)
Dry Mouth	2 (0.7 %)	1721 (1592 – 1850)
Hematuria	2 (0.7 %)	902 (13 – 1791)
Low Grade Fever	2 (0.7 %)	13 (7 – 18)
Memory Difficulties	2 (0.7 %)	1318 (1107 – 1592)
Pelvic Pain	2 (0.7 %)	270 (42 – 498)
Rheumatoid Arthritis	2 (0.7 %)	281 (189 – 372)
Other	22 (7.0 %)	N/A

** Percentages based on total number of patients implanted (300).

Table 6: Resolution of Adverse Device Events

ADE	Method of Resolution					
	# Patient (%)	Surgical	Medication	Other[1]	No Medical Intervention	Continuing
Urogenital Pain	160 (53.3 %)	1 %	31 %	0 %	68 %	11 %
Urogenital Edema	106 (35.3 %)	0 %	3 %	11 %	86 %	2 %
Urogenital Ecchymosis	30 (10.0 %)	0 %	0 %	0 %	100 %	0 %
Reservoir Encapsulation	19 (6.3 %)	5 %	0 %	0 %	95 %	58 %
Patient Dissatisfaction	18 (6.0 %)	0 %	0 %	0 %	100 %	56 %
Auto-Inflation	17 (5.7 %)	0 %	0 %	0 %	100 %	35 %
Mechanical Malfunction	13 (4.3 %)	46 %	0%	8%	46%	62%
Urination Impaired	11 (3.7 %)	0 %	64 %	9 %	27 %	0 %

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ADE	Method of Resolution					
	# Patient (%)	Surgical	Medication	Other[1]	No Medical Intervention	Continuing
Urogenital Erythema	10 (3.3 %)	10 %	30 %	0 %	60 %	0 %
Joint Pain, Swelling, or Stiffness	9 (3.0 %)	0 %	11 %	11 %	78 %	67 %
Decreased Penile Sensation	7 (2.3 %)	0 %	0 %	0 %	100 %	72 %
Urogenital Hematoma	7 (2.3 %)	0 %	0 %	0 %	100 %	0 %
Abnormal Ejaculation	6 (2.0 %)	0 %	17 %	0 %	83 %	17 %
Infection	6 (2.0 %)	67 %	33 %	0 %	0 %	17 %
Dysuria	5 (1.7 %)	0 %	60 %	0 %	40 %	0 %
Penile Curvature	5 (1.7 %)	0 %	0 %	0 %	100 %	60 %
Application Site Reaction	4 (1.3 %)	0 %	25 %	0 %	75 %	25 %
Erosion/ Extrusion	4 (1.3 %)	100 %	0 %	0 %	0 %	0 %
Paresthesia	4 (1.3 %)	0 %	0 %	0 %	100 %	50 %
Urogenital Inflammation	4 (1.3 %)	0 %	50 %	0 %	50 %	0 %
Adhesion of Pump/Scrotum	3 (1.0 %)	0 %	0 %	0 %	100 %	33 %
Device Malposition	3 (1.0 %)	67 %	0 %	0 %	33 %	0 %
Device Migration	3 (1.0 %)	100 %	0 %	0%	0%	0 %
Transient Urinary Retention	3 (1.0 %)	0 %	0 %	100 %	0 %	0 %
Urinary Frequency	3 (1.0 %)	0 %	33 %	0 %	67 %	67 %
Weakness	3 (1.0 %)	0 %	0 %	67 %	33 %	67 %
Abnormal Sexual Function	2 (0.7 %)	0 %	0 %	0 %	100 %	100 %
Device Cylinder Aneurysm/ Bulge	2 (0.7 %)	50 %	0 %	0 %	50 %	50 %
Dizziness	2 (0.7 %)	0 %	0 %	0 %	100 %	50 %
Dry Mouth	2 (0.7 %)	0 %	0 %	0 %	100 %	100 %
Hematuria	2 (0.7 %)	0 %	50 %	0 %	50 %	50 %
Low Grade Fever	2 (0.7 %)	50 %	50 %	0 %	0 %	0 %
Memory Difficulties	2 (0.7 %)	0 %	0 %	0 %	100 %	0 %
Pelvic Pain	2 (0.7 %)	0 %	0 %	0 %	100 %	50 %

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ADE	Method of Resolution					
	# Patient (%)	Surgical	Medication	Other[1]	No Medical Intervention	Continuing
Rheumatoid Arthritis	2 (0.7 %)	0 %	0 %	0 %	100 %	100 %
Other	22 (7.0 %)	N/A	N/A	N/A	N/A	N/A

[1] Other treatments included back brace, physical therapy, urine culture, ice packs, elevation, hot soaks, hot sitz bath, manual manipulation, patient education, filliforms and followers, foley catheter, ultrasound/CT scan, and cystoscopy.

The following "Other" adverse device events (in alphabetical order) each occurred in less than 0.5 % of the patients: Alopecia, Back Pain, Cellulitis, Depression, Diabetes Mellitus, Epigastric Pain, Eye Disorder, Eye Pain, Fecal Incontinence, Fibrosis, Glans Hypermobile Dorsally, Kidney Calculus, Libido Decreased, Migraine, Necrosis, Phimosis, Photosensitivity Reaction, Pump Fixation, Thickening of the Skin, Urinary Tract Infection, Urinary Urgency, and Vertigo.

A total of 22 patients underwent revision surgeries in the 5-year study period. Information on device revisions is described in the Clinical Studies section.

The following adverse events (in alphabetical order) may have been associated with the use of this product: Bleeding, Cavernosal Crossover, Exposure to Biohazardous Material, Granuloma Formation, Ischemia, Non-Rheumatoid Arthritis Immune-Related Tissue Disorders, Pain (which may be prolonged or severe), Perforation or Injury of Bladder, Corpus Cavernosum, Nerve, Tunica, or Urethra, Prolonged Procedure, Seroma, Thrombosis, Ulceration, Unretrieved Device Fragment, Vascular Compromise, Ventral Chordee, and Vessel Trauma.

CLINICAL STUDIES

A clinical trial was undertaken from January 31, 1995 to October 24, 2002 to demonstrate that the AMS 700 Inflatable Penile Prosthesis Product Line provides an erection that is suitable for intercourse and has acceptable rates of surgical revision and significant clinical events associated with the implantation and use of these devices. This trial included only devices without InhibiZone. This trial was also designed to demonstrate that the implantation of these devices does not negatively impact the sexual satisfaction, psychological well-being, self-esteem, or quality of life of patients who receive these devices. It was a prospective, multicenter cohort trial in which the patients served as their own control. The choice of device model implanted (i.e., AMS 700 CX, AMS 700 CXM, AMS 700 Ultrex, AMS 700 Ultrex Plus) was at the discretion of the patient and implanting physician.

Note: The AMS 700 TENACIO Pump was not available at the time the clinical study was conducted. However, based on the similarities between the AMS 700 TENACIO Pump and the AMS 700 Inflate/Deflate Pump, the clinical results also apply to this new model.

Note: The AMS 700 LGX Preconnected was not available at the time the clinical study was conducted. However, since providing the AMS 700 LGX in preconnected form is not expected to affect the safety and effectiveness of the prosthesis, these clinical results also apply to the new model.

Note: The AMS 700 CXR was not available at the time the clinical study was conducted. However, based on the similarities between the AMS 700 CXR and the AMS 700 CXM models, the clinical results also apply to this new model.

Note: The Conceal Low Profile Reservoir* was not available at the time the clinical study was conducted. However, based on similarities between the Conceal Low Profile Reservoir and the spherical reservoir, the clinical results also apply to this new model.

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*Not available in all markets.

Three hundred male patients, over 21 years of age (range 32 years to 79 years), were enrolled in this study. The majority of study participants were White (85.3 %), with African Americans making up 14.3 % of the study population followed by Hispanics (0.3 %). All patients with diagnosed organic erectile dysfunction were eligible for enrollment, if they did not present with a history of allergy/sensitivity to silicone, preexisting autoimmune or connective tissue diseases, or active urogenital infection.

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All safety-related data, diagnoses, and health status evaluations were captured on detailed case report forms. The investigators' professional evaluation of the erections provided by the IPPs (Inflatable Penile Prosthesis) after implantation and their suitability for intercourse was the primary efficacy endpoint. The number of surgical revisions performed and reported by the investigators was the primary safety endpoint. Patient self-evaluations from four validated outcome instruments were the secondary efficacy endpoints (concerning quality of life, self-esteem, psychological well-being, and sexual satisfaction and functioning).

This clinical trial provided the following results through the 5-year evaluation for the first 126 patients to reach this postsurgical follow-up.

Physician Assessment of Device Function

One hundred twenty-six devices were evaluated at the 5-year follow-up, of which 123 (97.6 %) could be inflated. Of these 123 devices, all (100 %) were determined to provide an erection suitable for intercourse. However, it should be noted that this analysis does not include the following information regarding device malfunctions: (i) 3 of the 123 devices found to be functioning properly at the 5-year exam were surgically revised prior to this exam to correct a mechanical malfunction and (ii) 3 additional devices not evaluated at the 5-year follow-up exam were also surgically revised due to mechanical malfunction. These cases of device revision are discussed further in the next section.

Surgical Revisions

The incidence of revisions was evaluated in the 126 patients with follow-up out to 5 years, as well as 16 additional patients who experienced one or more revision surgeries and did not reach the 5-year follow-up exam (a revision is considered any urogenital surgical intervention that is related to the function, placement, or site reaction to the implanted device). Of these 142 patients, 22 (15.5 %; 95% confidence interval = 21.5 %) experienced a total of 26 revision surgeries, and 120 (84.5 %) were not revised.

The average time to the first revision surgery was 15 months (ranging from 0.9 months to 60.1 months). Of the 26 revision surgeries, there were 5 revisions due to "Infection," 2 for "Infection/ Erosion," 2 for "Migration/Malposition," 2 for "Erosion," 2 for "Malposition," 7 for "Mechanical Malfunction," 2 for "Fibrous Capsular Complication," 2 for "Reimplantation Following Previous Revision," and 2 due to reasons listed as "Other." The "Other" reasons for revision surgeries included 1 for cylinder kink/ auto-inflation and 1 for corporal body aneurysm. In 5 of these revision surgeries, no device components were explanted or replaced. The components were manipulated/ repositioned but were not removed.

Patient Evaluation of Quality of Life, Self-esteem, Psychological and Sexual Well-Being

In accordance with the study protocol, overall health-related quality of life (using the Medical Outcomes Study Health Survey [MOS-20]), self-esteem (using the Rosenberg Self-esteem Scale), psychological well-being (using the Brief Symptom Inventory), and sexual functioning and satisfaction (using the Sexual History Form) were evaluated in patients through 2 years, post-implantation. Throughout the 2-year follow-up period, patient quality of life, self-esteem, and psychological well-being were determined to be equivalent to the preimplant state. Sexual functioning and sexual satisfaction, on the other hand, was significantly improved over the preimplant state.

Antibiotic Human Clinical Experience

A post market analysis was conducted to evaluate the effect of the InhibiZone antibiotic treatment on reducing the incidence of penile implant infections, which consisted of a comprehensive review of more than 43,000 patients from the BSC Patient Information Form (PIF) database. This analysis shows a significant improvement in the rate of revisions due to infection for patients with original AMS 700 Inflatable Penile Prosthesis InhibiZone implants or revision AMS 700 Inflatable Penile Prosthesis InhibiZone implants compared to those who received an AMS 700 without InhibiZone. Further, patients with diabetes who received original AMS 700 Inflatable Penile Prosthesis with InhibiZone implants also demonstrate significant improvement in the rate of revisions due to infections, compared to those who received the AMS 700 without InhibiZone treatment. The data set included PIF data for patients who underwent an AMS 700 Inflatable Penile Prosthesis implant surgery in the United States from May 1, 2001, through September 1, 2007. The most common reason for implantation of an AMS 700 was recorded as "organic" on the PIFs (Table 7). Post prostatectomy, vascular disease, and diabetes were also commonly reported as the etiology leading to the need for the AMS 700.

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Table 7: Etiology for AMS 700 Implant Patients

Description	InhibiZone		Non-InhibiZone		Mixed	
	#	%	#	%	#	%
Original AMS 700 Implant						
Diabetes Mellitus*	4,977	17.7 %	627	17.7 %	177	18.1 %
Peyronie's Disease	2,553	9.1 %	328	9.2 %	102	10.4 %
Post Prostatectomy	7,215	25.7 %	819	23.1 %	242	24.7 %
Vascular Disease	4,037	14.4 %	576	16.2 %	120	12.3 %
Other	1,107	3.9 %	151	4.3 %	50	5.1 %
Organic	8,185	29.2 %	1,046	29.5 %	288	29.4 %
Total	28,074	100.0 %	3,547	100.0 %	979	100.0 %
Revision or Replacement AMS 700 Implant						
Diabetes Mellitus	1,979	16.2 %	349	15.4 %	63	15.2 %
Peyronie's Disease	1,243	10.2 %	208	9.2 %	40	9.6 %
Post Prostatectomy	2,016	16.5 %	330	14.5 %	68	16.4 %
Vascular Disease	2,566	21.0 %	599	26.4 %	101	24.3 %
Other	1,034	8.5 %	184	8.1 %	34	8.2 %
Organic	3,378	27.7 %	602	26.5 %	109	26.3 %
Total	12,216	100.0 %	2,272	100.0 %	415	100.0 %
TOTAL	40,290		5,819		1,394	

Note: None or more than one etiology could be selected for each patient; therefore, the numbers of patients within each subgroup by etiology above may not be identical to the number of patients in each life table analysis.

* The diabetes subgroup with an original implant was identified and analyzed as a specific high-risk subgroup.

Three patient populations were analyzed in this PIF analysis: the first group included all patients with an AMS 700 Inflatable Penile Prosthesis original implant between May 1, 2001, and September 1, 2007. A subgroup of these AMS 700 Inflatable Penile Prosthesis original implant patients included all patients with diabetes. The third group included all patients with an AMS 700 Inflatable Penile Prosthesis revision implant (removing or replacing all or part of an earlier implanted device) between May 1, 2001, and September 1, 2007. An event was recorded for any revision surgery with a surgery reason recorded as infection, mechanical malfunction, fluid loss, erosion, patient dissatisfaction, or other. Revision surgeries were tracked through December 1, 2007, when the reporting period was closed. When multiple reasons were listed for one revision surgery (e.g., infection, device malfunction, erosion, etc.), the individual revision surgery was counted and included in the data for each of the indicated revision reasons. Thus, all revisions that report some presence of infection will be captured in the infection category presented in this analysis (even if multiple other reasons for the revision surgery are listed).

Life tables were constructed, and the log rank test was used to compare the device survival distributions between the Treatment (InhibiZone) and Control (non-InhibiZone) groups. All significance tests were performed at an alpha level of 0.05. For original implants, device survival distributions were defined as the time between the implantation of the original device in the analysis period and the first replacement, revision, or removal of any component of the device due to infection, malfunction, fluid loss, erosion, patient dissatisfaction, or other reason (the Original Implant Group). For revision surgery patients, device survival distributions were created for the time between the implantation of the revision device and the next revision device due to infection, malfunction, fluid loss, erosion, patient dissatisfaction, or other reason (the Revision Surgery Group). The study also included a subgroup of patients who received a penile implant after spinal cord injury. However, this aspect of the analysis continues to be unknown, since there were too few patients in this group to be able to determine valid conclusions.

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Original Implant Patient Group

Among the original implant patients, a total of 31,328 (98.7 %) patient devices did not have any events reported due to infection and were censored during the timeframe of this report. A total of 338 (1.2 %) device events were due to infection in the InhibiZone treated group while 84 (2.5 %) were due to infection in the non-InhibiZone treated group. Life table analyses compared the rates of revision surgery due to infection for original InhibiZone or non-InhibiZone treated implants. In this device survival analysis with infection as the reason for the revision surgery, InhibiZone treated AMS 700 Devices had a significantly better survival than non-InhibiZone treated devices among original implant patients (p<0.0001) (Figure 8).

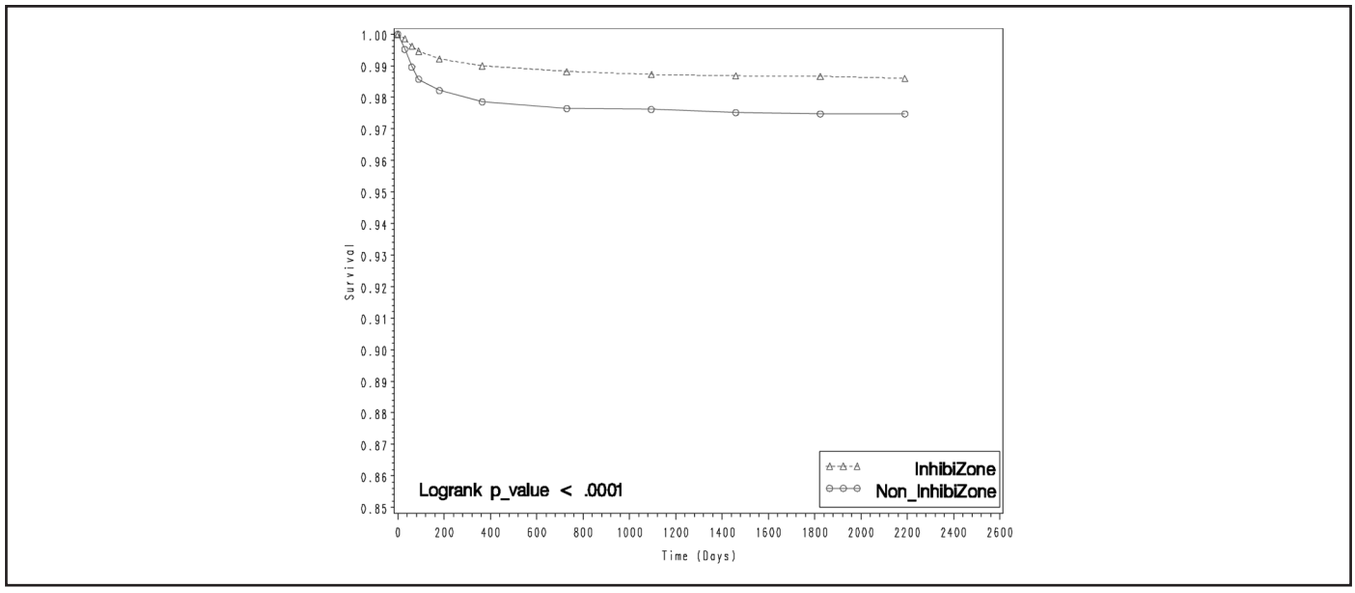

Figure 8. Device survival—freedom from revision due to infection among original implant patients

Diabetic Original Implant Patient Group

Among the subgroup of original implant patients who had diabetes, a total of 5604 diabetic patients included 4977 (88.8 %) with InhibiZone treated devices and 627 (11.2 %) with non-InhibiZone treated devices. A total of 5508 (98.3 %) diabetic patient devices did not have any events due to infection during the timeframe of this report. Only 71 (1.4 %) infection device events were in the InhibiZone treated group while 25 (4.0 %) events were in the non-InhibiZone treated group. Life table analyses compared rates of revision surgery due to infection for diabetic patients. InhibiZone treated devices had significantly better survivals than non-InhibiZone treated devices among diabetic patients (p<0.0001) (Figure 9).

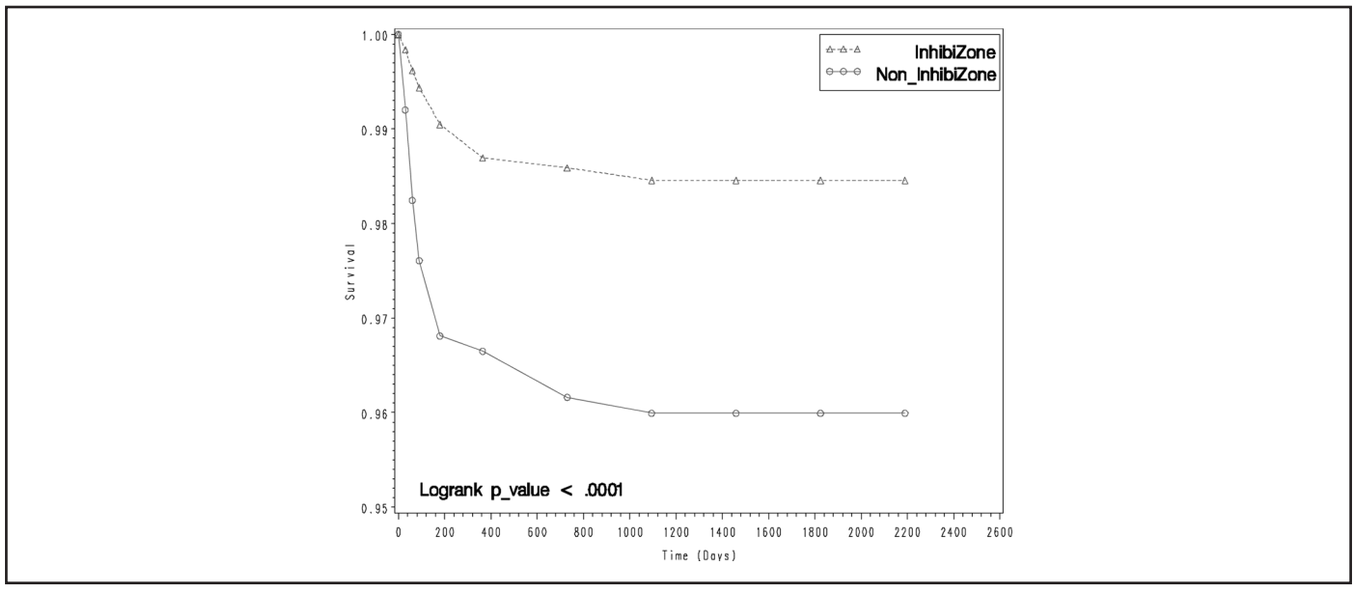

Figure 9. Device survival—freedom from revision due to infection among diabetic patients

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Revision Surgery Implant Group

Among the revision surgery implant patients, a total of 10,769 (97.3 %) patient devices did not have any events due to infection and were censored during the timeframe of this report. Only 229 (2.5 %) infection device events occurred in the InhibiZone treated group while 66 (3.7 %) infection events occurred in the non-InhibiZone treated group. Life table analysis compared the rates of revision surgery due to infection for InhibiZone or non-InhibiZone treated implants among revision surgery implant patients. In this device survival analysis with infection as the reason for the revision surgery, InhibiZone treated AMS 700 devices had a significantly better survival than non-InhibiZone treated devices among revision surgery implant patients (p=0.0252) (Figure 10).

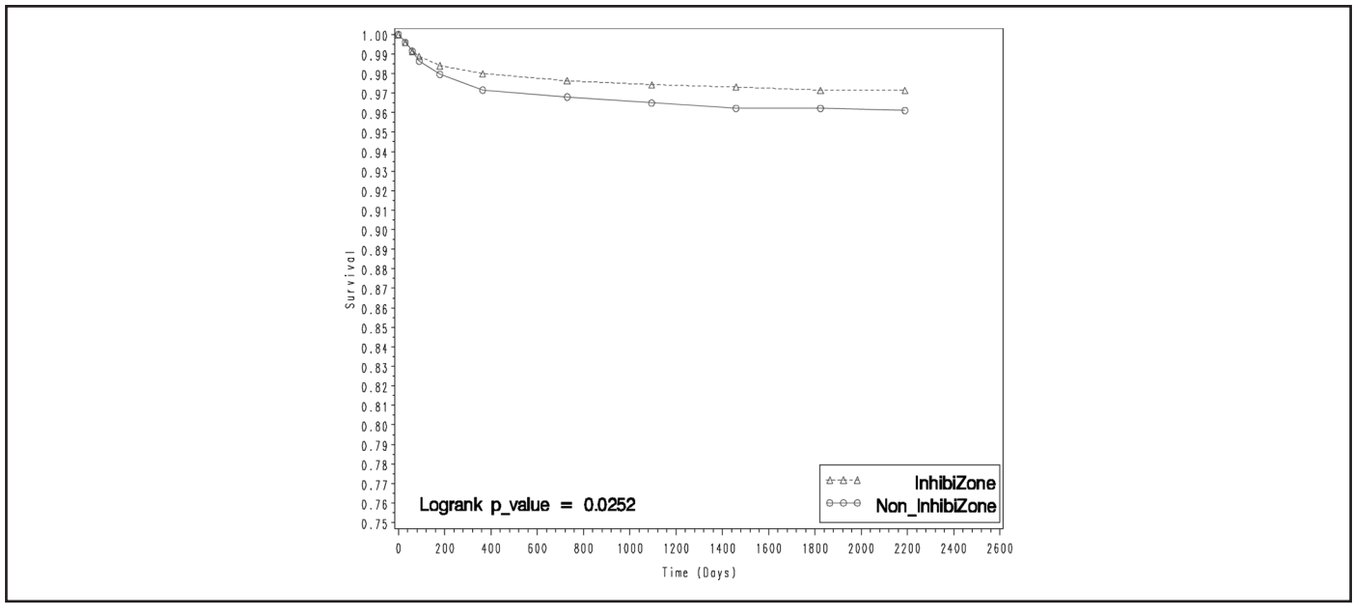

Figure 10. Device survival—freedom from revision due to infection among revision surgery implant patients

In conclusion, this human clinical evidence from the InhibiZone PIF analysis indicates the revisions due to infection were significantly lower among patients who received an AMS 700 treated with InhibiZone when compared to a nontreated AMS 700. This reduced rate of revisions subsequent to infection for the AMS 700 treated with InhibiZone when compared to a nontreated AMS 700 was reported for original as well as revision implants and included the high-risk subgroup of original implant patients who had diabetes. The analysis supports the following conclusions:

- No significant differences were found between InhibiZone treated and untreated AMS 700 Inflatable Penile Prosthesis for overall rates of revision due to mechanical malfunction, fluid loss, erosion, patient dissatisfaction, or all other reasons.
- Use of InhibiZone results in a significant reduction in the rate of revision due to device-related infection among penile prosthesis implants.
- Use of InhibiZone results in a significant reduction in the rate of revision due to device-related infection among penile prosthesis implants in diabetic patients.
- Use of InhibiZone results in a significant reduction in the rate of revision due to device-related infection in original and revision penile prosthesis implants.

HOW SUPPLIED

Device Details

The AMS 700 Inflatable Penile Prosthesis and Accessory Kit components are provided sterile.

- Do not use if package is damaged or unintentionally opened before use.
- Do not use if labeling is incomplete or illegible.
- Do not use the device if past the "Use By" date.

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Handling and Storage

- InhibiZone treated components: Keep dry and protect from light. Recommended storage at 25 °C (77 °F); excursions permitted to 15 °C-40 °C (59 °F-104 °F).
- Non-InhibiZone treated cylinders: Protect from light. Other non-InhibiZone treated components have no special handling or storage requirements.

Supplemental Surgical Tools

The following BSC surgical tools used to help facilitate implantation of the AMS 700 Inflatable Penile Prosthesis may be ordered separately.

Non-Sterile Tools

The following tools are provided non-sterile and must be sterilized before use (for reprocessing information, refer to the instructions manual provided with the tools):

- Quick Connect Assembly Tool

  There are two systems for connecting components and tubing for the AMS 700 Inflatable Penile Prosthesis.
  - Quick Connect Window Connectors (provided sterile)
  - Suture-Tie Connectors (provided sterile)

    In order to use the Quick Connect Window Connectors in the Accessory Kit, the Quick Connect Assembly Tool must be ordered. This is a reusable stainless-steel instrument used to close the connectors. The Quick Connect Assembly Tool is shipped non-sterile and may be re-sterilized. Quick Connect Window Connectors should not be used on revision surgeries, except when all previously implanted components are removed and replaced with new components.
- Insertion Package (2 stainless steel Tubing Passers)
- Closing Tool
- Furlow Insertion Tool
- Sizer

  Contents:

  (1) 9.5 mm Sizer

  (1) 12 mm Sizer

Sterile Tools

The following is provided sterile using an ethylene oxide sterilization process and is intended for single use only:

- SKW Deep Scrotal Retraction System

The following are provided sterile using a steam sterilization process and are intended for single use only:

- Disposable Dilators
- Deactivation Package

  Contents:

  (3) Tubing Plugs

  (1) Straight Suture-Tie Connector

  The Deactivation Package is not required for an initial implant. The Package contains 3 stainless steel tubing plugs and 1 straight Suture-Tie Connector which may be used to prevent fluid from entering or leaving the prosthesis during revision surgeries.

The following are provided sterile using an e-beam sterilization process and are intended for single use only:

- Furlow Disposable Insertion Tool

OPERATIONAL INSTRUCTIONS

Supplies and Instrument Requirements

Instruments normally required for a urological surgical procedure are recommended. In addition to the AMS 700 Inflatable Penile Prosthesis components, the RTEs, and Accessory Kit, the following sterile set up is needed:

- Sterile normal saline (filling and flushing solution)
- Two 60 mL and two 10 mL syringes (for filling and flushing prosthesis components)

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- Eight mosquito hemostats (for clamping tubing when prepared with shods)
- One straight pair of clean, sharp scissors for trimming tubing
- Disposable Dilators or a set of corporal dilators for dilating the corpora cavernosa
- One furlow insertion tool (for passing traction sutures through the glans)
- Corporal length measuring instrument
- Quick Connect Assembly Tool (only needed for Quick Connect Window Connectors)
- Antibiotic solution for irrigation

PREPARATION

Open the AMS 700 Accessory Kit

1. Remove the tray from the box in the operating room
2. Remove the inner tray from outer tray, using appropriate sterile technique, and place the inner tray on a sterile, lint free Mayo stand.
3. Open the inner tray.

Note: Record the part and serial lot/numbers of the Accessory Kit on the Patient Information Form (PIF). The adhesive label at one end of the outer box and the small removable labels on the side of the plastic trays contain the part and serial/lot numbers. This information is also listed on the Tyvek lid of the outer tray.

Prepare the Hemostats

Use the following procedure to cover the hemostats with the blue tubing provided in the Accessory Kit:

1. Place blue tubing on both jaws of the mosquito hemostats to fully cover the serrated surfaces.
2. Clamp the jaws together one notch only, to prevent excessive pressure on the tubing.
3. Trim the tubing at each jaw tip with sharp, clean scissors.
4. Reserve one pair of straight scissors as "clean" tubing scissors throughout the procedure. These will be used for trimming tubing prior to connecting.

Prepare the Patient

Before surgery, take adequate steps to limit the risk of postoperative infection.

CAUTION: Using a device with InhibiZone does not change the need to follow normal hospital protocols for prophylactic antibiotic administration.

Once the patient is in the operating room, shave the abdominal and genital area. Following the shave, scrub the area using the approved hospital preoperative scrub procedure.

Establish the sterile field, drape, and prepare the patient. Throughout the procedure, flush the surgical site with copious amounts of broad-spectrum antibiotics. Position the patient according to the preferred surgical approach: infrapubic or penoscrotal.

PROCEDURE

Surgical Approaches

The following descriptions are an overview of the infrapubic and penoscrotal surgical approaches.

Infrapubic Approach

All of the AMS 700 components can be implanted through an infrapubic incision. When preconnected, be certain that the cylinder/TENACIO Pump package is labeled **Infrapubic**.

Penoscrotal Approach

It is also possible to implant all of the AMS 700 components through a penoscrotal incision. When preconnected, be certain the cylinder/pump package is labeled **Penoscrotal**.

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Make the Incision and Dissect

1. Place a Foley catheter to facilitate urethra identification. The Foley catheter can help decompress the bladder and avoid bladder injury during reservoir placement.
2. Make the appropriate incision for the surgical approach chosen.

Infrapubic: Make a 4 cm to 5 cm longitudinal or transverse incision, at the symphysis pubis (Figure 11). Avoid the midline neurovascular bundle.

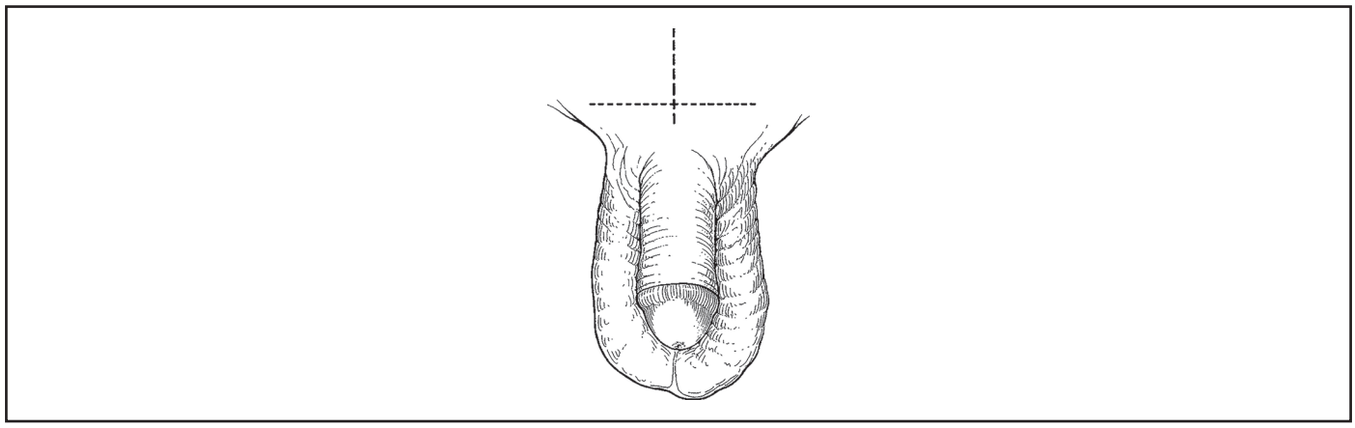

Figure 11. Infrapubic: Identify incision site

Penoscrotal: Make a 2 cm to 3 cm incision through the median raphe of the scrotum at the penoscrotal junction.

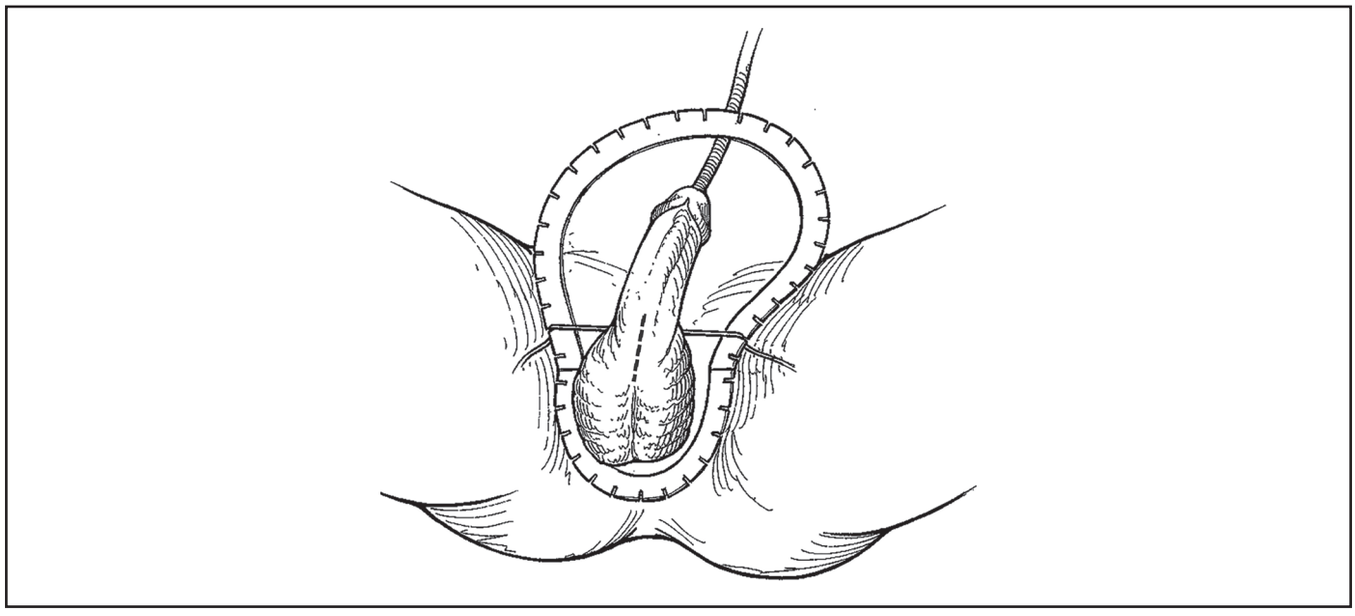

Figure 12. Penoscrotal: Identify incision site

- If using the SKW Deep Scrotal Retraction System, place the retractor on the patient with the large ring toward the patient's head (cephalad) and the smaller ring toward the patient's feet (caudal) (Figure 12).
- Position the penile strap in the first slot of the retractor ring above the hinges.
- Place the sharp hook in the meatus to put the penis on stretch in the 12 o'clock position.
- Make a high scrotal incision and move the incision onto the penis. While holding the incision on the penis, place hooks at 1, 5, 7, 11, 3, and 9 o'clock (Figure 12).

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Black (K) ΔE ≤5.0

- Laterally retract the corpus spongiosum to avoid damaging the urethra (Figure 13).

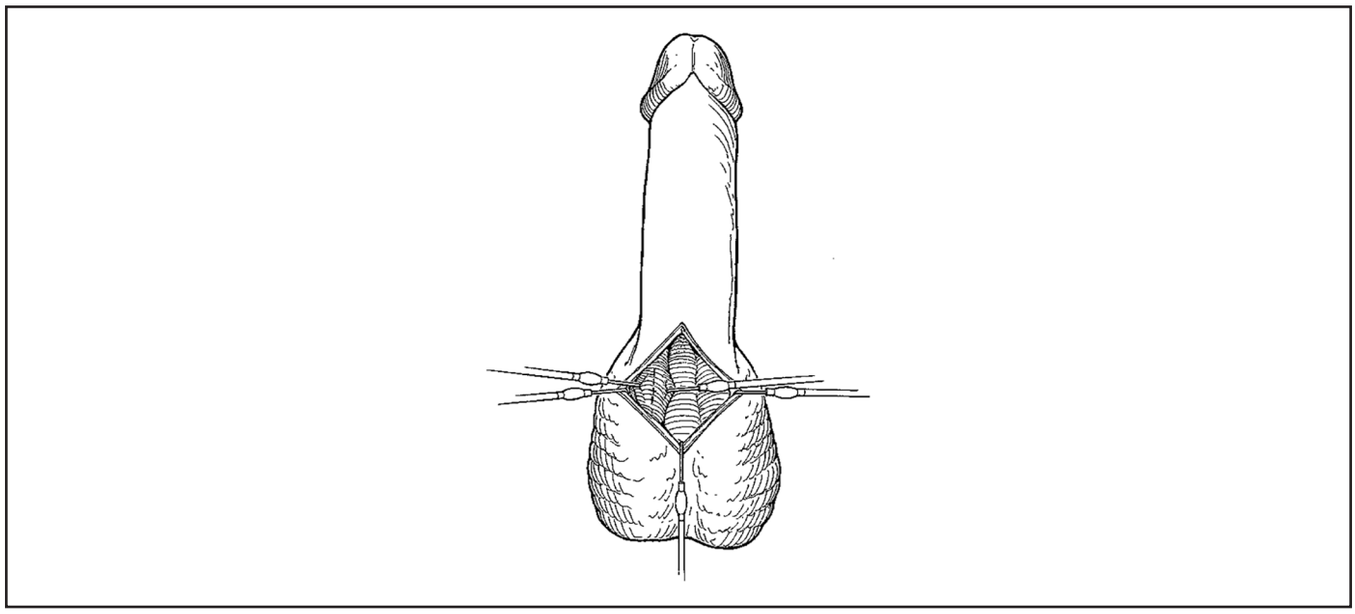

Figure 13. Penoscrotal: Retract corpus spongiosum

3. Dissect through Dartos fascia and Buck's fascia to expose the tunica albuginea.
4. Place stay sutures.
5. Make an incision into one of the corpora cavernosa (Figure 14). As a general rule, the corporotomy is best placed when two-thirds of the total corporal measurement is distal from the incision and one-third is proximal. This facilitates the placement of the cylinders and may avoid the need to extend the corporotomy during the procedure.

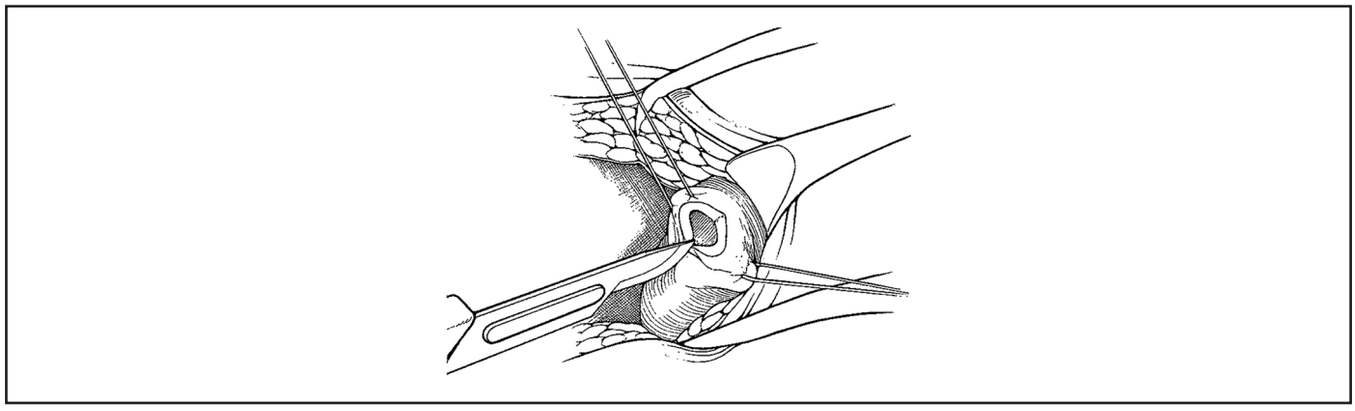

Figure 14. Make corporotomy

Dilate and Size

1. Using a series of dilation tools, dilate the proximal corpus cavernosum (toward the crus) to at least 11 mm, if the cylinder tubing will exit directly from the corporotomy; larger if the tubing will be inside the proximal corpus cavernosum. Dilate the distal corpus cavernosum to at least 12 mm to create a space for inserting a penile cylinder.

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2. After dilating one corpus cavernosum, incise and dilate the adjacent corpus cavernosum following the same procedure (Figures 15 and 16).

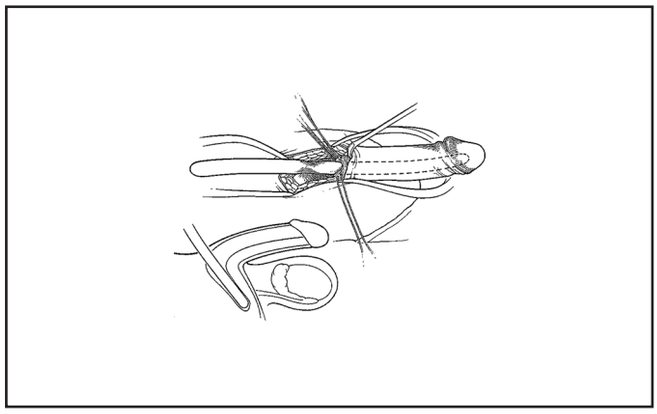

Figure 15. Infrapubic: Dilate

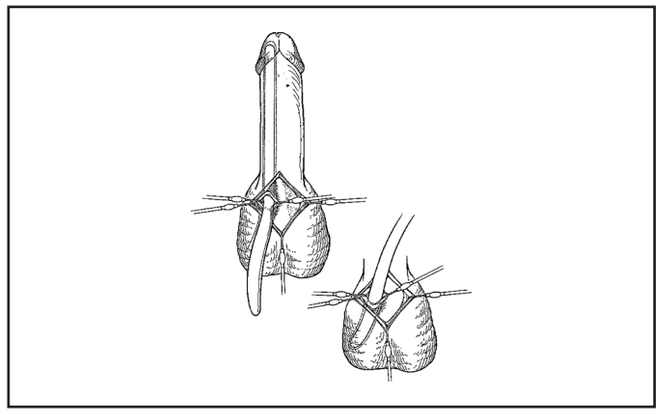

Figure 16. Penoscrotal: Dilate

3. Measure each corpus cavernosum length, proximally and distally, using a corporal length measuring instrument, slightly stretching the penis during this process (Figures 17 and 18).These measurements help the physician select cylinders and RTEs that fit the patient's anatomy. If the corpora cavernosa are unevenly sized or the measuring instrument cannot reach mid glans, consider dissecting through the fibrotic tissue as needed.

Note: Measuring both directions from one of the stay sutures provides consistency. However, when using an AMS 700 LGX, some physicians choose to measure distally from the distal edge of a 2 cm corporotomy and proximally from the proximal end of a 2 cm corporotomy, for optimal cylinder sizing.

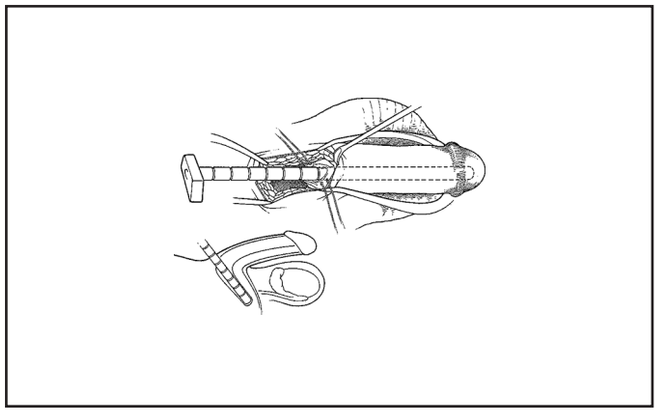

Figure 17. Infrapubic: Size

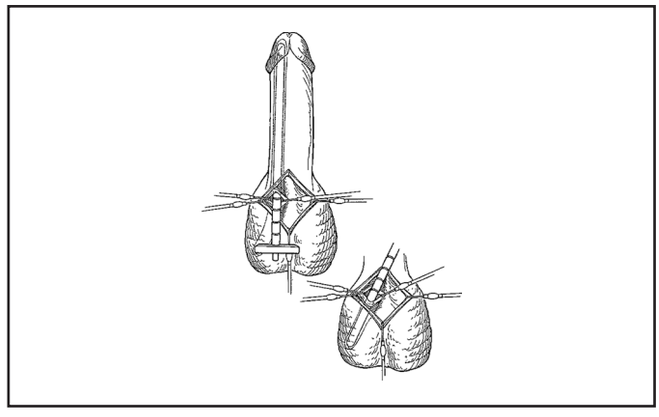

Figure 18. Penoscrotal: Size

Select the Appropriate Cylinder and RTE Sizes

For the most accurate corporal sizing, RTEs may be utilized for adding a minor amount of length.

SIZING

AMS 700 CXR with TENACIO Pump

The proximal portion of the CXR cylinder is approximately 0.7 cm longer than the CX and LGX cylinders. Sizing using Method A (see below) is recommended and will result in tubing that exits from the corporotomy.

AMS 700 CX with TENACIO Pump and AMS 700 LGX with TENACIO Pump

There are two methods available when selecting cylinder sizes for the AMS 700 CX and LGX Prosthesis. Each surgeon's own implanting experience will determine which technique is used.

Rear Tip Extenders (RTEs)

Sizing to the 0.5 cm can be achieved, if desired, by attaching the 0.5 cm, the 1.5 cm, or for lengths longer than 1.5 cm, by stacking one additional whole centimeter length RTE to the 1.5 cm RTE.

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Except for the 1.5 cm RTE, the RTEs cannot be stacked due to an internal interlocking design. Select the appropriate RTE length and attach the RTE to the cylinder, twisting the RTE onto the cylinder to provide a tactile indication of a proper connection. The RTE is correctly attached when the groove on the cylinder engages the corresponding locking ring on the RTE, resulting in a smooth outer profile.

CAUTION: Do not stack the RTEs other than the 1.5 cm RTE. If other sizes of RTEs are stacked, the locking mechanism will not engage and the RTEs may not stay connected.

CAUTION: CXR RTEs are not compatible with CX or LGX cylinders. CX/LGX RTEs are not compatible with CXR cylinders.

Sizing Method A

Method A reduces the length of the solid proximal portion of the cylinders in the shaft of the penis and allows the tubing sleeve to contact a portion of the expandable shafts of the cylinders (Figure 19). As the tubing is partially buried in the corpora, using Method A has the potential to increase the likelihood of tubing compression or kinking, which may reduce fluid flow. If you believe the tubing is kinked, attempt to gently straighten it.

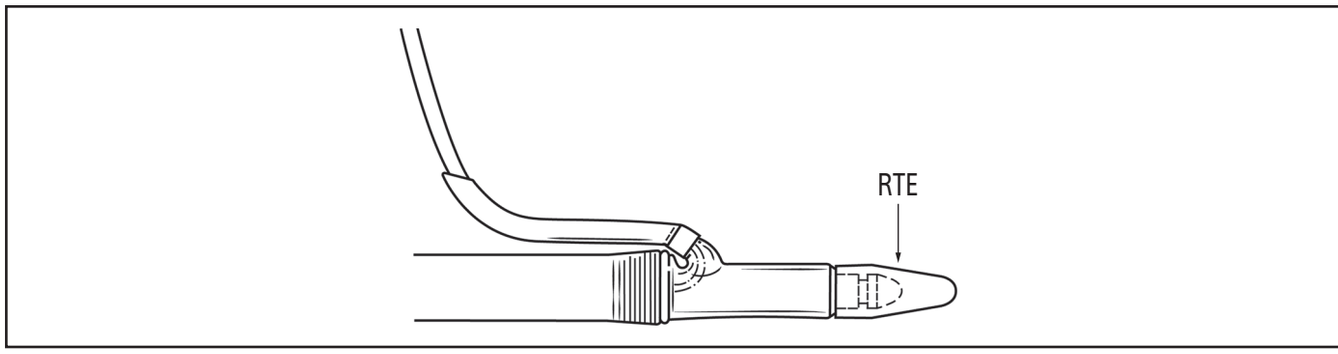

Figure 19. Method A

1. Calculate the Total Corporal Length (distal + proximal)	
Example	
Distal Corporal Length	12 cm
Proximal Corporal Length	+7 cm
Total Corporal Length	19 cm
2. Select the closest cylinder size that is shorter than or equal to the Total Corporal Length. Add RTEs, if necessary, to fit the patient's anatomy.	
Example	
Total Corporal Length	19 cm
Selected Cylinder Length	-18 cm
RTE Length	1 cm

Sizing Method B

Method B allows the tubing to exit directly from the corporotomy (Figure 20). Follow the formula described below to select the appropriate cylinder length and number of RTEs. If necessary, extend the length of the corporotomy.

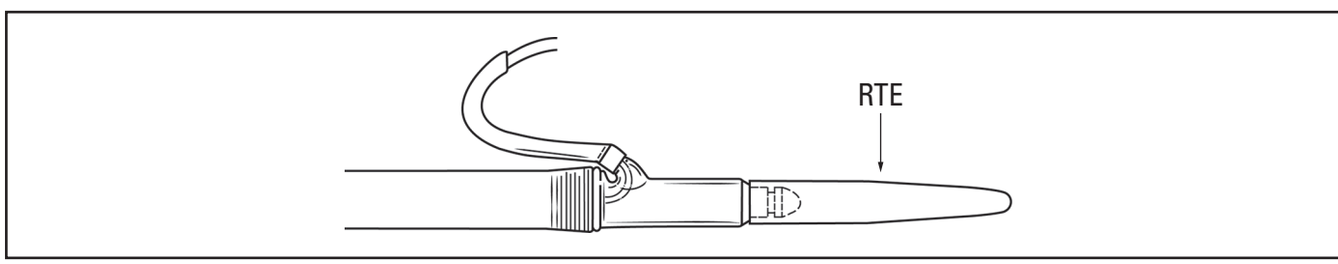

Figure 20. Method B

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1. Calculate the Total Corporal Length (distal + proximal)	
Example	
Distal Corporal Length	12 cm
Proximal Corporal Length	+7 cm
Total Corporal Length	19 cm
2. Subtract 2 cm from the Total Corporal Length to obtain an Adjusted Measurement.	
Total Corporal Length	19 cm
	-2 cm
Adjusted Measurement	17 cm
3. Select the closest cylinder size that is shorter than or equal to the Adjusted Measurement.	
Example	
Adjusted Measurement	17 cm
Selected Cylinder Length	15 cm
4. Subtract the selected Cylinder Length from the Total Corporal Length to determine the length of the RTEs.	
Example	
Total Corporal Length	19 cm
Selected Cylinder Length	-15 cm
RTE Length	4 cm

Note: Do not open any component packages until the cylinder length is confirmed.

Unpack the Components

The AMS 700 Inflatable Penile Prosthesis components are packaged in sterile pouches, except the RTEs, which are packaged in sterile trays. Keep the sterile products in their boxes or plastic travel cases until they are in the operating room.

1. Remove the product from the outer travel case or box in the operating room.
2. For products in pouches, remove the sterile inner pouch from the outer pouch and place it on a sterile, lint free Mayo stand.

CAUTION: Do not place cloth towels on the Mayo stand. They may transfer lint to the components.

3. When ready to prepare the components, open the inner pouches and place the components on the sterile, lint free Mayo stand. If RTEs are used, open the sterile tray(s), and place the RTEs on the sterile, lint free Mayo stand.

Note: Record the part and serial/lot numbers and the size of the components on the Patient Information Form (PIF). The small, removable adhesive labels list the part and serial/lot numbers and the size of the components.

Prepare the Components

If using preconnected components, follow the preparation steps for the preconnected TENACIO Pump and cylinders and the reservoir. If using non-preconnected components, follow the preparation steps for the reservoir, the non-preconnected cylinders, and the non-preconnected TENACIO Pump.

Boston Scientific recommends that all components of the AMS 700 be prepared with sterile normal saline. The sterile normal saline must remain free of debris, which can block fluid flow through the components.

Components that are treated with InhibiZone should not be submerged in sterile normal saline.

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Black (K) ΔE ≤5.0

CAUTION: Soaking InhibiZone impregnated devices in saline (or similar solution) will cause the antibiotics to diffuse from the device into the solution. This will cause the solution to turn orange and will reduce the concentration of antibiotics on the prosthesis.

Prepare the Preconnected TENACIO Pump and Cylinders

The AMS 700 CX, CXR, and LGX Preconnected Penile Prosthesis cylinders with the TENACIO Pump are provided preconnected. The only connection required is between the pump and the reservoir.

The following instructions outline the preparation of the prosthesis to ensure that the air is removed from the cylinders and pump before the reservoir is connected.

Attach the RTEs to the cylinders, if needed, twisting the RTEs onto the proximal end of the cylinders to provide a tactile indication of a proper connection.

1. Partially fill a graduate with sterile normal saline.
2. Submerge the single, black color-coded tubing from the pump into the sterile normal saline.

CAUTION: To avoid damaging the TENACIO Pump, do not inject fluid into the reservoir line of the pump using a syringe.

3. Hold the TENACIO Pump so the deflate button is on top (up) and the pump bulb is on the bottom (below) (Figure 21 and Figure 22).
4. Fully depress the deflation button once and release.
5. For the first pump, give the pump bulb a firm squeeze and then release to allow the pump bulb to refill. Continue pumping to allow the pump bulb to completely fill with fluid, taking note to remove large air bubbles (Figure 22).

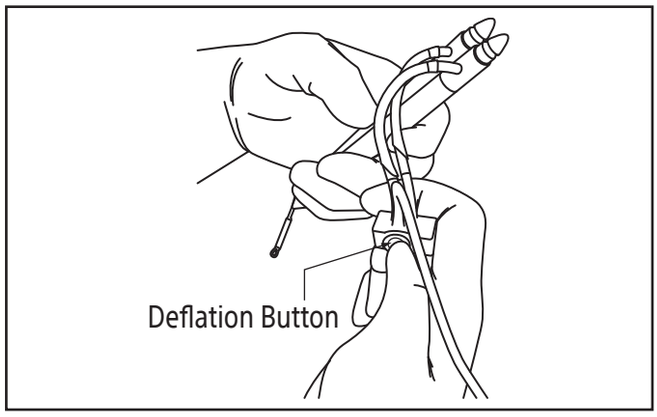

Figure 21. Deflation button location and cylinder position

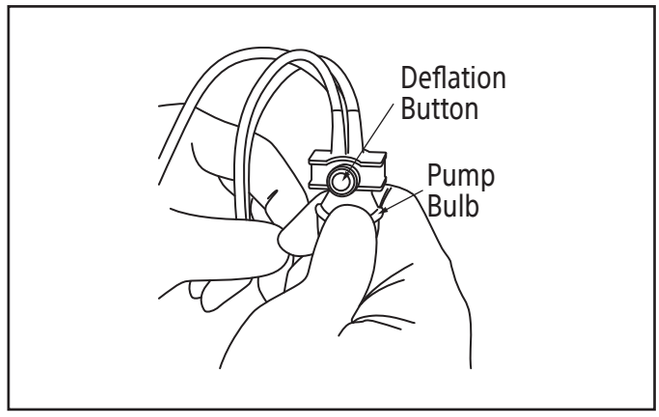

Figure 22. TENACIO Pump bulb squeeze grip position

Note: Step 5 is important in order to lubricate the valves of the TENACIO Pump for further preparation.

Note: If fluid does not appear in the pump bulb or if the bulb does not fully fill with fluid, squeeze the deflation button once more and release. This will reset the pump.

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Black (K) ΔE ≤5.0

6. To remove air from the pump bulb and the fluid pathways, fully compress the bulb to a flat condition (Figure 23).

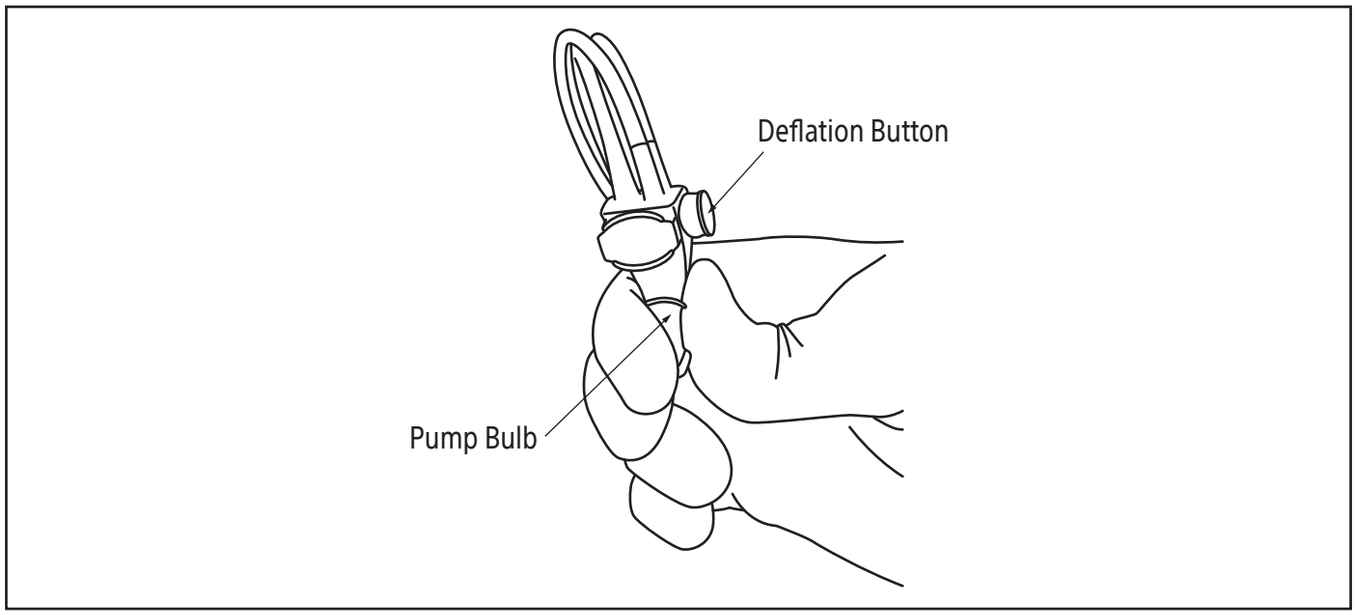

Figure 23. TENACIO Pump bulb squeeze grip position with fully compressed pump bulb

7. Compress the pump bulb using firm and quick compressions until the cylinders are rounded and the pump bulb is hard to squeeze. Allow the pump bulb to fully refill prior to each squeeze.
8. While holding the cylinders with the rear tips facing up and the rear tip tubing exit on top (Figure 21), depress the deflation button to allow the air to be expelled from the components.
9. Repeat steps 6 and 8 until no bubbles are noted in the graduate during deflation.
10. Squeeze the cylinders to remove the remaining fluid from the cylinders.

Note: Some small bubbles may still be present in the tubing, this is acceptable and will not affect long term pump performance.

---

11. With the black color-coded tubing end still submerged in the saline, use a blue shod mosquito hemostat to clamp (1 notch only) the black color-coded tubing 2.5 cm from the open end.

CAUTION: Do not advance the hemostat's ratchet more than one notch. Excessive pressure will permanently damage the tubing.

---

12. For components treated with InhibiZone, place the empty cylinders and filled TENACIO Pump onto an empty sterile tray, empty kidney basin, or sterile Mayo stand. Do not submerge the components in saline.

CAUTION: Soaking InhibiZone impregnated devices in saline (or similar solution) will cause the antibiotics to diffuse from the device into the solution. This will cause the solution to turn orange and will reduce the concentration of antibiotics on the device.

---

13. For non-InhibiZone treated components, submerge the empty cylinders and filled TENACIO Pump into a kidney basin of sterile normal saline or sterile normal saline mixed with an antibiotic solution.

Prepare the Reservoir

1. Attach a 15 gauge blunt tip needle to a 60 mL syringe and partially fill it with sterile normal saline.
2. Hold the reservoir in the non-dominant hand and squeeze the air out of the reservoir.
3. Holding the reservoir, attach the partially filled syringe to the reservoir.

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4. Use the partially filled syringe to aspirate all air from the reservoir (Figure 24).

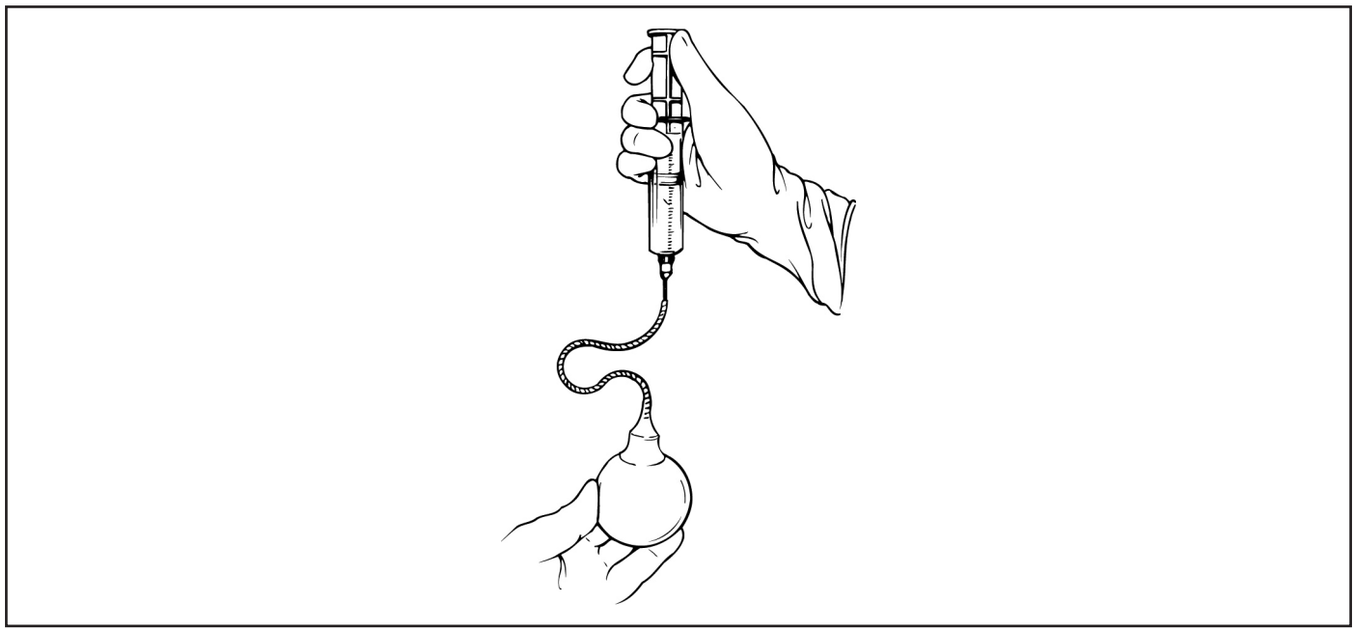

Figure 24. Aspirate air from the Reservoir

5. After the air has been removed, inject sterile normal saline (approximately 20 mL-30 mL) without injecting an air bubble.
6. Using your thumb, press in on the side of the reservoir to form it into a bowl shape.
7. Aspirate all remaining saline and air out of the reservoir and into the syringe, stopping when the syringe plunger encounters resistance and/or the reservoir makes a flattened bowl shape. Leave the reservoir in the flattened bowl shape.

CAUTION: Do not over aspirate to prevent air from being drawn into the reservoir through its semi-permeable silicone elastomer.

---

8. Holding the syringe plunger up with the thumb, clamp tubing (one notch only) 2.5 cm from the blunt needle tip using a blue shod mosquito hemostat. Remove the 15-gauge needle and syringe.

CAUTION: Do not advance the hemostat's ratchet more than one notch. Excessive pressure may permanently damage the tubing.

---

9. For a reservoir treated with InhibiZone, place the reservoir onto an empty sterile tray, empty kidney basin, or sterile Mayo stand. Do not submerge the reservoir in saline.

CAUTION: Soaking InhibiZone impregnated devices in saline will cause the antibiotics to diffuse off of the device into the solution. This will cause the solution to turn orange and will reduce the concentration of antibiotics on the device.

---

10. For a non-InhibiZone treated reservoir, submerge the reservoir into a kidney basin of sterile normal saline or of sterile normal saline mixed with an antibiotic solution.

Prepare the Non-preconnected Cylinders

Attach the RTEs to the cylinders, if needed, twisting the RTEs onto the proximal end of the cylinders to provide a tactile indication of a proper connection.

1. Attach a 15-gauge blunt tip needle to a 60 mL syringe that is partially filled with sterile normal saline.
2. Hold the cylinder in the non-dominant hand and squeeze out the air.
3. Holding the cylinder, attach the partially filled syringe to the cylinder.

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Black (K) ΔE ≤5.0

4. Use the partially filled syringe to aspirate all air from the cylinder, and then slowly fill the cylinder with sterile normal saline (approximately 20 mL-30 mL) without injecting an air bubble.

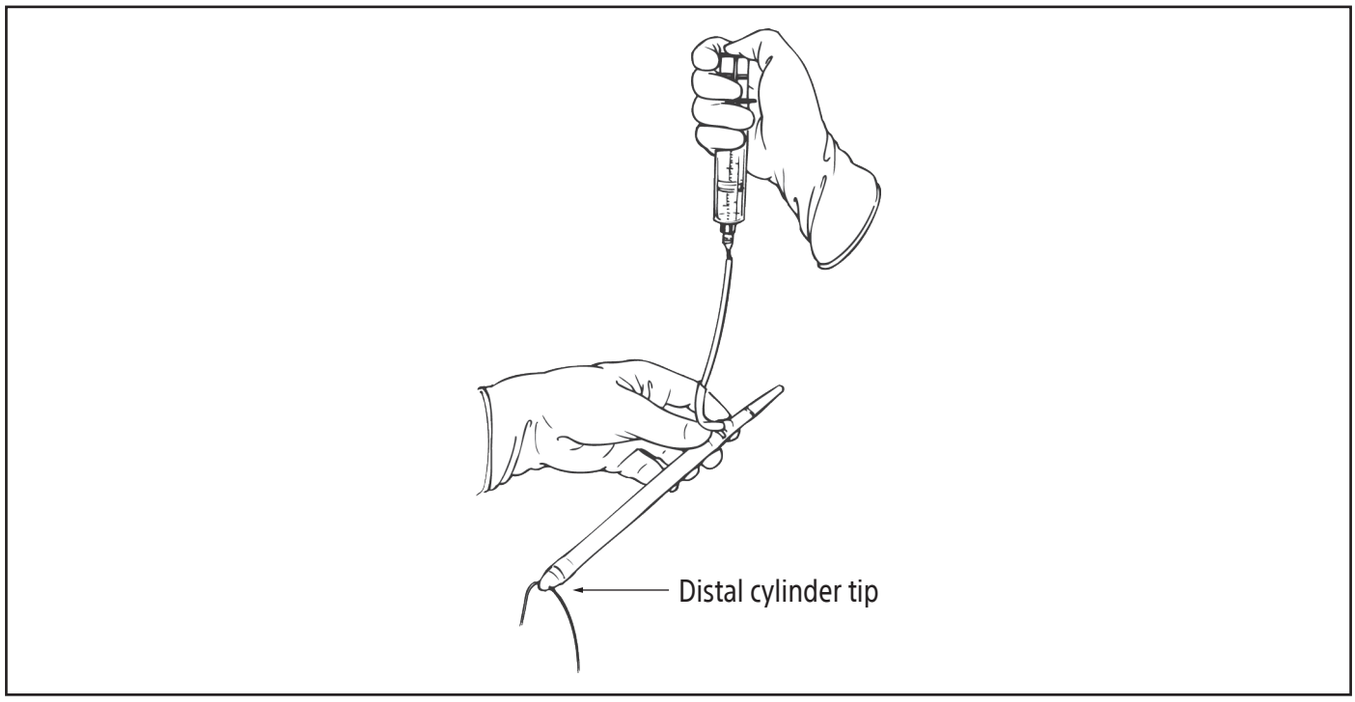

Figure 25. Fill the cylinder with the distal tip pointing down

- Hold the cylinder from the proximal end with the distal tip pointing down to allow the distal portion of the cylinder to fill first (Figure 25).
- Inject sterile normal saline into the cylinder until it is rounded out.
- Aspirate all air from the cylinder with the syringe.

5. You may repeat this process, if needed to remove air from the cylinder.
6. Aspirate all sterile normal saline and air from the cylinder until it is flat, or until the syringe plunger meets resistance.

CAUTION: Do not over aspirate to prevent air from being drawn into the cylinder through its semi-permeable silicone elastomer.

---

7. Holding the syringe plunger up with your thumb, clamp the tubing (1 notch only) 2.5 cm from the needle tip using a blue shod mosquito hemostat. Remove the 15-gauge needle and syringe.

CAUTION: Do not advance the hemostat's ratchet more than one notch. Excessive pressure may permanently damage the tubing.

---

8. For a cylinder treated with InhibiZone, place the cylinder onto an empty sterile tray, empty kidney basin, or sterile Mayo stand. Do not submerge the cylinders in saline (or similar solution).

CAUTION: Soaking InhibiZone impregnated devices in saline will cause the antibiotics to diffuse off of the device into the solution. This will cause the solution to turn orange and will reduce the concentration of antibiotics on the device.

---

9. For a non-InhibiZone treated cylinder, submerge the cylinder in a kidney basin of sterile normal saline or sterile normal saline mixed with an antibiotic solution.
10. Prepare the other cylinder in the same manner.

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Prime the Non-Preconnected TENACIO Pump

1. Partially fill a graduate with sterile normal saline.
2. Submerge the pump's three tubing ends into sterile normal saline (Figure 26).

CAUTION: To avoid damaging the TENACIO Pump, do not inject fluid into the reservoir line of the pump using a syringe.

3. Hold the TENACIO Pump so the deflation button is on top and the pump bulb is on the bottom (Figure 22).
4. Fully depress the deflation button once and release.
5. For the first pump, give the pump bulb a firm squeeze and then release to allow the pump bulb to refill. Continue pumping to allow the pump bulb to completely fill with fluid, taking note to remove large air bubbles (Figure 22).

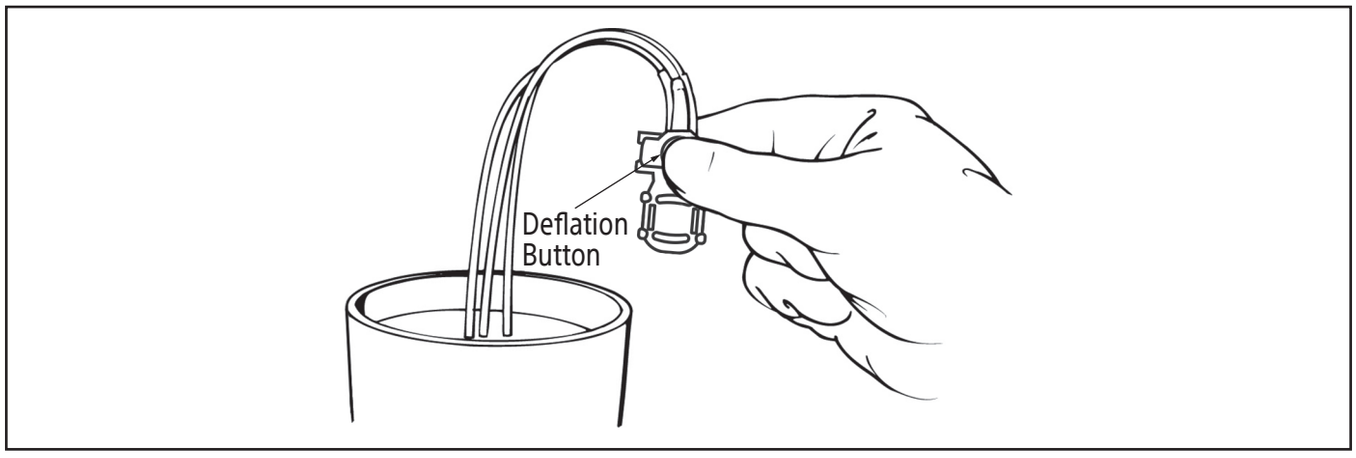

Figure 26. Squeeze the deflation button and release

Note: Step 5 is important in order to lubricate the valves of the pump for further preparation.

Note: If fluid does not appear in the pump bulb or if the bulb does not fully fill with fluid, squeeze the deflation button once and release. This will reset the TENACIO Pump.

6. To remove air from the pump bulb and the fluid pathways, fully compress the bulb to a flat condition (Figure 23).
7. Compress the pump bulb using firm and quick compressions while allowing the pump bulb to fully refill prior to each subsequent squeeze.
8. Repeat steps 6 through 7 until no bubbles are noted in the graduate during deflation.

Note: Some small bubbles may still be present in the tubing, this is acceptable and will not affect long term TENACIO Pump performance.

9. With the tubing still in the fluid, use 3 blue shod mosquito hemostats to clamp (1 notch only) each of the 3 tubes 2.5 cm from the open end.

CAUTION: Do not advance the hemostat's ratchet more than one notch. Excessive pressure will permanently damage the tubing.

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10. For a TENACIO Pump treated with InhibiZone, place the pump onto an empty sterile tray, empty kidney basin, or sterile Mayo stand. Do not submerge the pump in saline (or similar solution).

CAUTION: Soaking InhibiZone impregnated devices in saline (or similar solution) will cause the antibiotics to diffuse off of the device into the solution. This will cause the solution to turn orange and will reduce the concentration of antibiotics on the device.

---

11. For a non-InhibiZone treated TENACIO Pump, submerge the filled pump into a kidney basin of sterile normal saline or sterile normal saline mixed with an antibiotic solution.

Insert the Cylinders

Refer to the Furlow Disposable Insertion Tool Instructions for Use, when applicable.

A traction suture has been placed through the distal tip of each cylinder. Depending on surgeon preference, either before or after inserting the cylinder into the crus, complete the following steps:

1. Use the Furlow Insertion Tool (Figure 27) and Keith Needle to help introduce the cylinders into the corpora cavernosa.

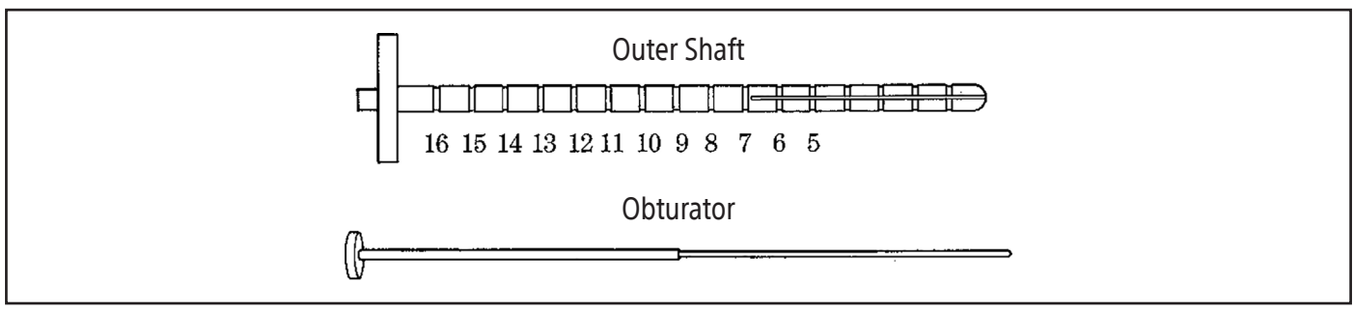

Figure 27. Furlow Insertion Tool

2. To help prevent cross over through the intercavernous septum when placing the first cylinder, a dilator or other surgical tool may be placed in the contralateral corpus cavernosum.
3. Check the function of the Furlow Insertion Tool by withdrawing the obturator to the locking groove, for the "retracted" position, and then fully insert the obturator until the tip appears at the end.

Note: Keith Needles are included in the AMS 700 Accessory Kit.

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4. Withdraw the obturator to the "retracted" or "locked" position. Pass both ends of the cylinder traction suture (approximately 10 cm) through the eye of a Keith Needle (Figure 28).

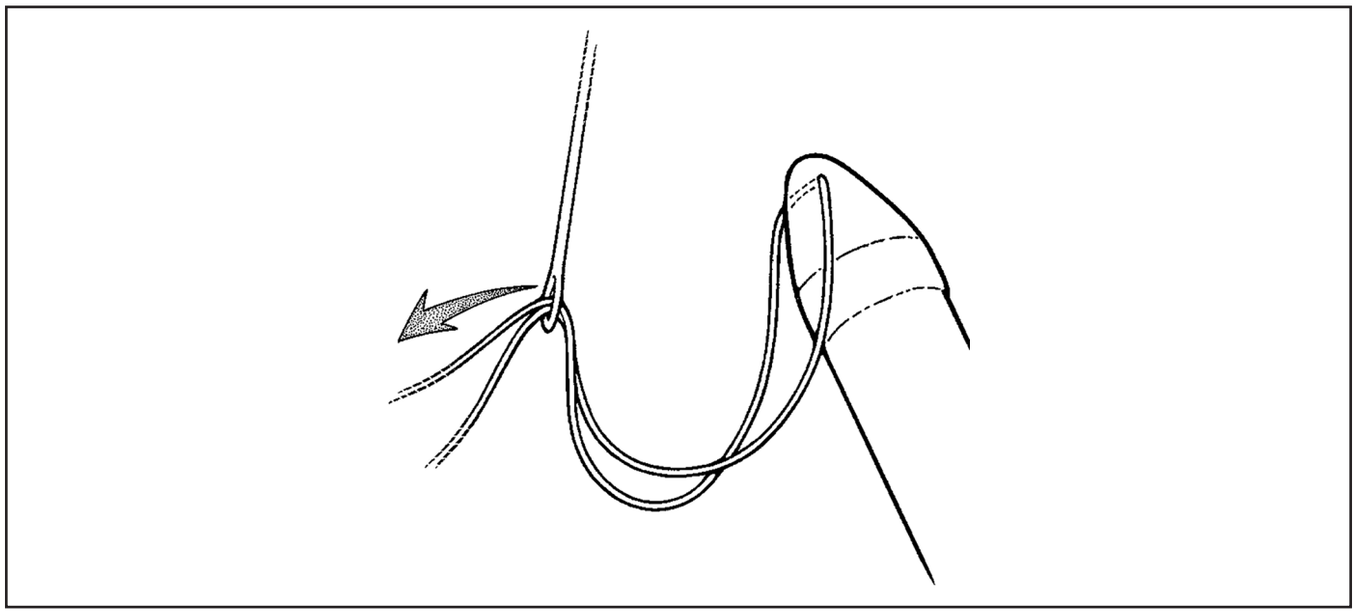

Figure 28. Insert traction suture into Keith Needle

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Black (K) ΔE ≤5.0

5. Load the blunt end of this needle into the Furlow Insertion Tool (Figure 29) and place the suture into the tool slot.

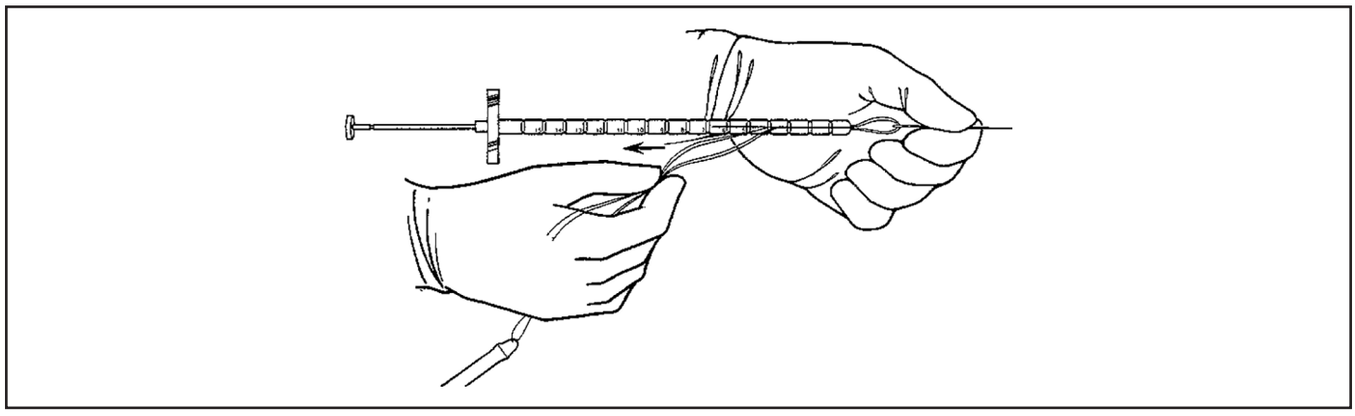

Figure 29. Load Keith Needle

6. Completely retract the suture into the slot and fully draw the needle into the barrel of the tool.
7. Hold the four strands of suture against the tool and insert the tool into the distal portion of the corporal body until the front tip is at mid glans.

Note: It is imperative that patient's penis is aligned symmetrically with his body and that the location of the glans puncture is satisfactorily identified before pushing the needle through the glans. The Furlow Insertion Tool should be in the ipsilateral corpora at the distal tip.

Note: If you cross over through the intercavernous septum to the contralateral side, remove, place the dilator into the contralateral side and reposition the Furlow Insertion Tool on the ipsilateral side. No repair is necessary.

---

8. Place the penis on a mild stretch; push the needle through the glans by fully inserting the obturator into the barrel.
9. Grasp the needle with a needle holder or mosquito hemostat and pull it completely through the glans.
10. Detach the needle from the suture and remove the needle from the area to prevent any accidental cylinder punctures.
11. Attach a tubing-covered hemostat to the traction suture to prevent inadvertent retraction through the glans.
12. Insert the front tip of the cylinder into the corporotomy.
13. Gently push the cylinder distally into place from the corporotomy.

Note: Use the traction suture to guide the cylinder until the front tip is placed at mid glans. Take care not to twist the cylinder as it is being placed.

---

14. Carefully assess the front tip position of the cylinder at mid glans to verify proper cylinder placement.

Note: Take care to leave the traction suture in place through the glans to allow the cylinder to be repositioned. If repositioning or more dilation is required, the cylinder should simply be pulled out of the corporal body.

---

15. Before placing the proximal end of the cylinder, slightly retract the distal tip of the cylinder several centimeters in the proximal direction.

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Black (K) ΔE ≤5.0

16. Fold the cylinder back on itself, and then push the proximal end of the cylinder into the crus while gently stretching the distal penis (Figures 30 and 31). Alternatively, place the "U" shaped portion of the proximal tool at the junction between the output tube and cylinder and use the tool to push the proximal end of the cylinder into the crus while gently stretching the distal penis. The flatter side of the tool should face toward the cylinder.

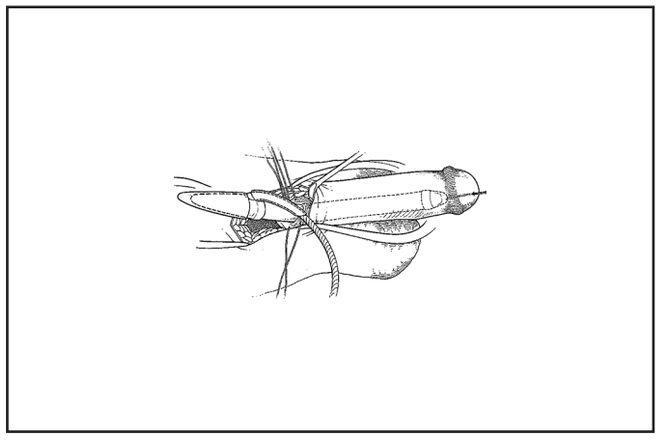

Figure 30. Infrapubic: Insert cylinders

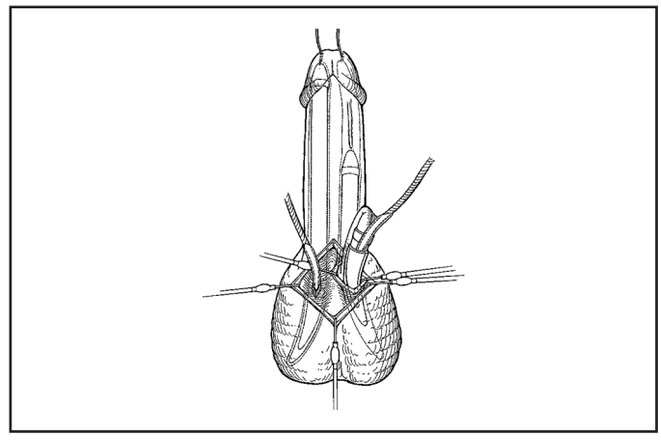

Figure 31. Penoscrotal: Insert cylinders

17. Once the proximal portion of the cylinder is in place, reposition the distal portion at mid glans by gently pulling on the traction suture.
18. Assess the cylinder length for satisfactory fit within the corpora cavernosa by ensuring that the distal tip is snugly at mid glans, the cylinder lies within the corporotomy, and the proximal end is firmly against the crus. If not satisfactory, remove the cylinder, adjust the length as needed, and re-implant.
19. Repeat the procedure to insert the remaining cylinder into the other corporal body.

Perform the Inflate/Deflate Test for Non-preconnected Cylinders

An optional inflate/deflate test to ensure nonconnected cylinder integrity after placement may be performed. The test may be conducted before or after the corporotomies are closed. If performed before closure, place the thumb and another finger over the corporotomy sites before inflation.

20. Remove the blue shod mosquito hemostats from the cylinder tubing.
21. Flush the cylinder tubing with sterile normal saline using a 22-gauge blunt tip needle on a 10 mL syringe (Figure 32).

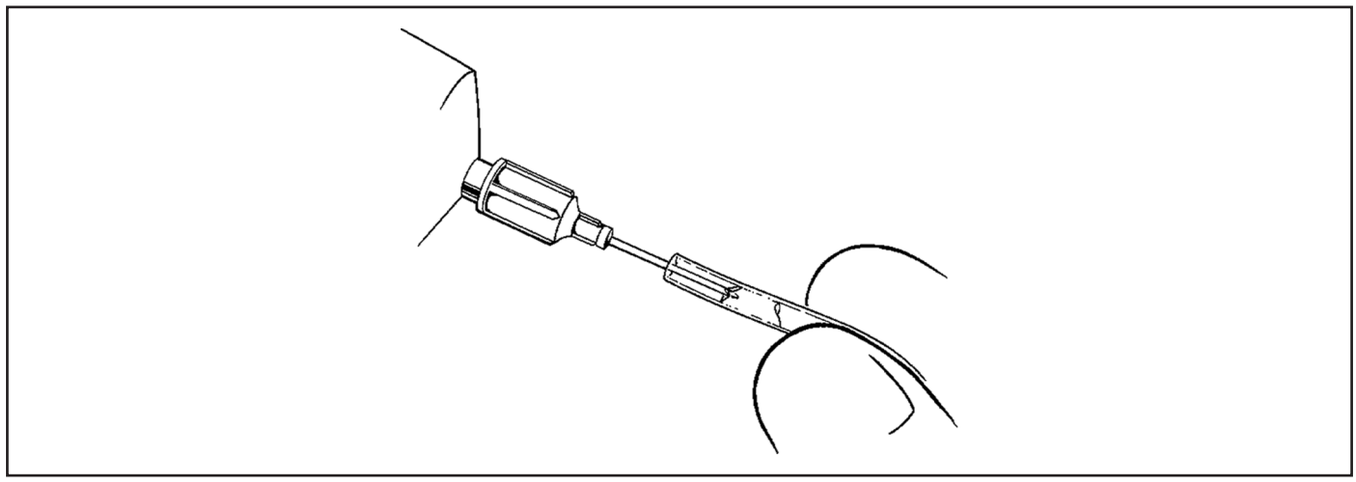

Figure 32. Flush tubing

22. Attach a 15 gauge blunt tip needle to a 60 mL syringe and fill it with 55 mL of sterile normal saline. Prepare another 60 mL syringe in this manner.

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23. Attach the 60 mL syringes to the cylinders.
24. Inflate the cylinders to evaluate erection quality.

Note: Check for placement of the cylinder tip, any cylinder buckling, kinking, or disruption of the suture line, or fluid leakage from the cylinder.

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25. Deflate to evaluate flaccidity.
26. For each cylinder, reclamp the cylinder tubing (one notch only) 2.5 cm from the needle top using a blue shod mosquito hemostat. Remove the 15-gauge needle and syringe.

IMPLANT THE RESERVOIR

Infrapubic Implantation

1. Create a defect in the rectus fascia and a pocket in the prevesical space under the rectus muscle and insert the reservoir.

Note: The reservoir tubing may be routed through the rectus fascia using a Tubing Passer. When using a Tubing Passer, the tubing should be placed on the knobbed end of the passer and passed through the fascia. As an alternative, route the tubing directly through the midline between the rectus muscles.

Penoscrotal Implantation

1. Create a defect in the transversalis fascia through the external inguinal ring (Figure 33). This defect provides access to the prevesical space. You may find access to the inguinal ring and prevesical space easier when using a baby Deaver retractor provided in the SKW Retractor Kit. The Deaver is placed in the inguinal ring and retracted cephalad, revealing the inguinal ring. Once the pocket is created in the prevesical space, use your finger to place the reservoir into the space.

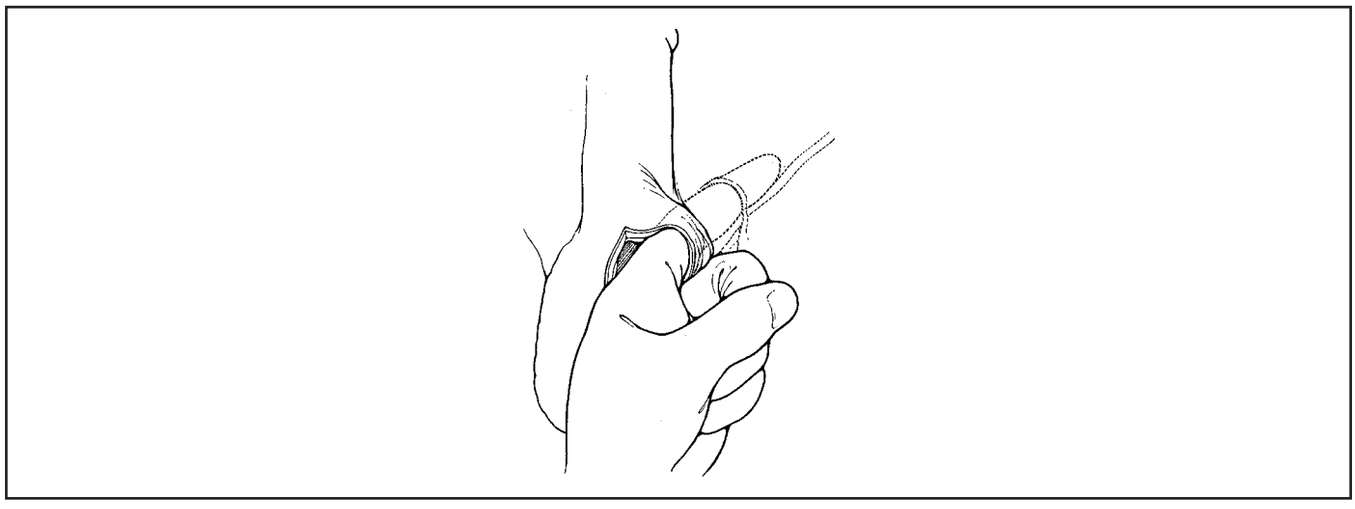

Figure 33. Create defect

Note: Alternatively, the prepared reservoir may be placed in the prevesical space through a small inguinal incision. Make a defect in the prevesical space under the rectus muscle large enough to accommodate the reservoir without putting pressure on it. Then insert the reservoir.

Fill the Reservoir

Use two 60 mL syringes with 1 mL gradations when filling the 65 mL or 100 mL reservoir.

1. Remove the blue shod mosquito hemostat from the reservoir tubing.
2. Flush the reservoir tubing with sterile normal saline using a 22-gauge blunt tip needle on a 10 mL syringe.

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3. Using the 60 mL syringe and a 15-gauge blunt tip needle, fill the reservoir with the appropriate amount of sterile normal saline. Generally, the amount of fluid should be equivalent to the size of the reservoir (65 mL or 100 mL). The 100 mL Conceal Low Profile Reservoir can be filled up to 100 mL to accommodate all cylinder sizes.
4. Using a blue shod mosquito hemostat, re-clamp (one notch only) the reservoir tubing 2.5 cm from the tip of the needle. Remove the 15-gauge needle and syringe.

Note: Do not allow excess tubing to lie on the reservoir.

Close the Corporotomies

1. Close the tunica albuginea with either a running horizontal mattress stitch or preplaced sutures, with meticulous attention to hemostasis.

Note: If using a mattress stitch, you may place the winged end of the Reusable Closing Tool or the foot of the disposable Proximal Tool over the cylinder to protect it while suturing. Move the tool along the incisions with each stitch to protect the cylinder.

Implant the TENACIO Pump

1. Use blunt dissection to form a pocket in the most dependent portion of the scrotum (Figures 34 and 35). The TENACIO Pump may also be placed in a dependent position between the two testicles.

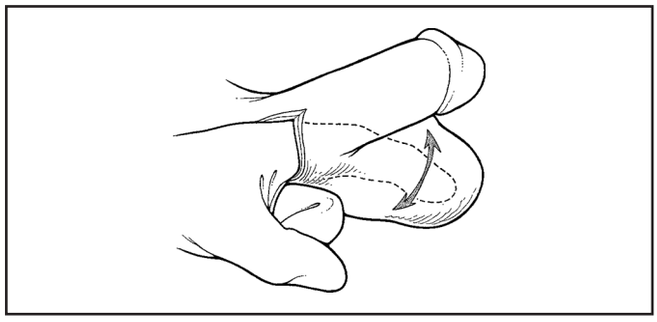

Figure 34. Infrapubic: Blunt dissection

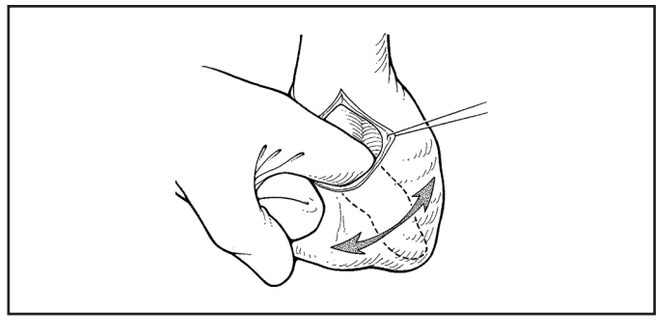

Figure 35. Penoscrotal: Blunt dissection

2. Insert the pump into the scrotal pocket.
3. Apply Allis or Babcock clamps to the pump tubing through the scrotal skin to hold the pump in place during the remainder of the procedure.
4. A suture may be placed to secure the TENACIO Pump in the scrotum, if desired.
5. Ensure that the length of the tubing between the cylinders and the TENACIO Pump fits the patient's anatomy.
   - If using a nonconnected system, make the connections between the cylinders and pump.
   - The length of the tubing between the AMS 700 preconnected cylinders and the TENACIO Pump can be shortened using the AMS 700 Accessory Kit.

Refer to the instructions on making connections in the Connect the Tubing section.

Note: Extra tubing between the Preconnected TENACIO Pump and cylinders of the AMS 700 CX, CXR, and LGX may be tucked within the surrounding tissues.

Complete the Surrogate Reservoir Test

Before connecting the tubing between the TENACIO Pump and reservoir, perform a surrogate reservoir test to ensure that the TENACIO Pump and cylinders work well together.

CAUTION: To avoid damaging the TENACIO Pump, don't inject fluid into the black color-coded reservoir line of the pump using a syringe.

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Black (K) ΔE ≤5.0

1. Submerge the black color coded reservoir tubing of the TENACIO Pump into a basin with at least 55 mL of sterile normal saline.
2. Remove the blue shod mosquito hemostat from the tubing and squeeze the pump inflation bulb to inflate the cylinders, making the penis erect.
3. Confirm that the cosmetic result is satisfactory. Cylinders should be rigid without bending or buckling.
4. Deflate the cylinders by squeezing the TENACIO Pump's deflation button.
5. Remove all of the fluid from the cylinders, by gently squeezing the penis/cylinders to return the fluid to the basin. Evaluate flaccidity.
6. With the tubing still in the saline, reclamp the reservoir tubing with a blue shod mosquito hemostat.

Connect the Cylinders and Reservoir

After successfully completing the surrogate reservoir test, connect the TENACIO Pump and the reservoir. Refer to the instructions on making connections in the Connect the Tubing section.

Connect the Tubing

1. Connect the component tubing using Quick Connect Window Connectors or Suture-Tie Connectors, after the cylinders, reservoir, and TENACIO Pump are implanted and the testing described earlier in this manual has been completed.

CAUTION: Quick Connect Window Connectors should not be used in revision procedures involving previously implanted component tubing.

Note: Use either straight connectors or right angle connectors, depending on the surgeon's technique and the patient's anatomy.

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2. If desired, the protective ePTFE sleeve on the cylinder tubing may be peeled back if it interfaces with a connection.
3. Gently grasp the sleeve at the tab and peel the sleeve away from the tubing.
4. Once the sleeve has been peeled to the desired length, excess sleeve material may be cut.

CAUTION: Do not remove so much ePTFE sleeve material that bare input tubing touches the expandable shaft of the cylinder.

Using Quick Connect Window Connectors

Note: The Quick Connect System components cannot be resterilized. Conventional hospital sterilization will damage the connector components. However, the Quick Connect Assembly Tool may be resterilized. For reprocessing information, refer to the instructions manual provided with the tool.

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1. Cut the tubing with straight scissors to fit the patient's anatomy, making sure the cut end is square (Figure 36).

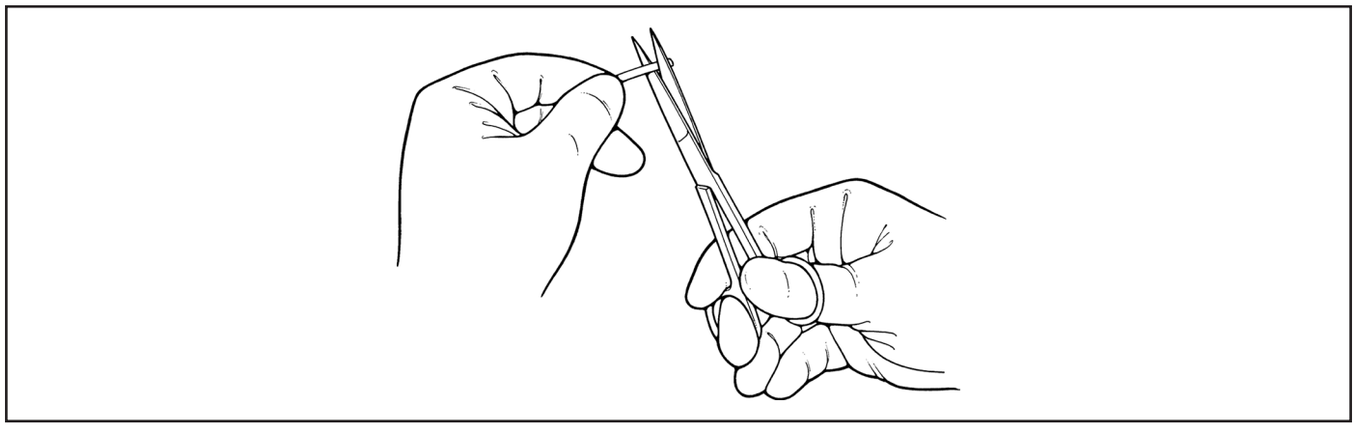

Figure 36. Cut the tubing squarely

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Black (K) ΔE ≤5.0

2. Clamp the tubing using blue shod mosquito hemostats.
3. Insert the small diameter portion of the collet holder into the tubing.
4. Slide a collet onto the tubing (Figure 37), making sure that the teeth of the collet face toward the open tubing end. Repeat with the end of the other tubing.

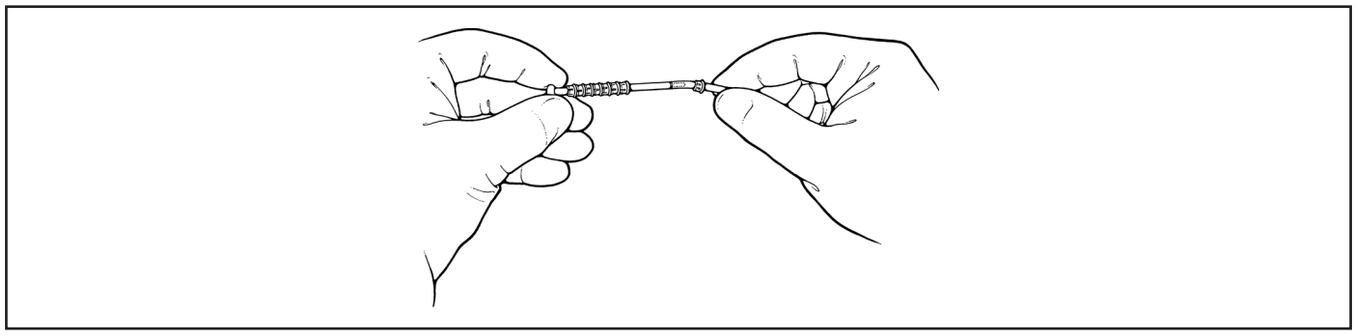

Figure 37. Slide a collet onto each end of the tubing

5. Flush each end of the tubing with sterile normal saline to remove particulate matter and air using a 22-gauge blunt tip needle.
6. Firmly push one end of the tubing to the middle wall of the connector (Figure 38) and check the tubing placement through the connector window.

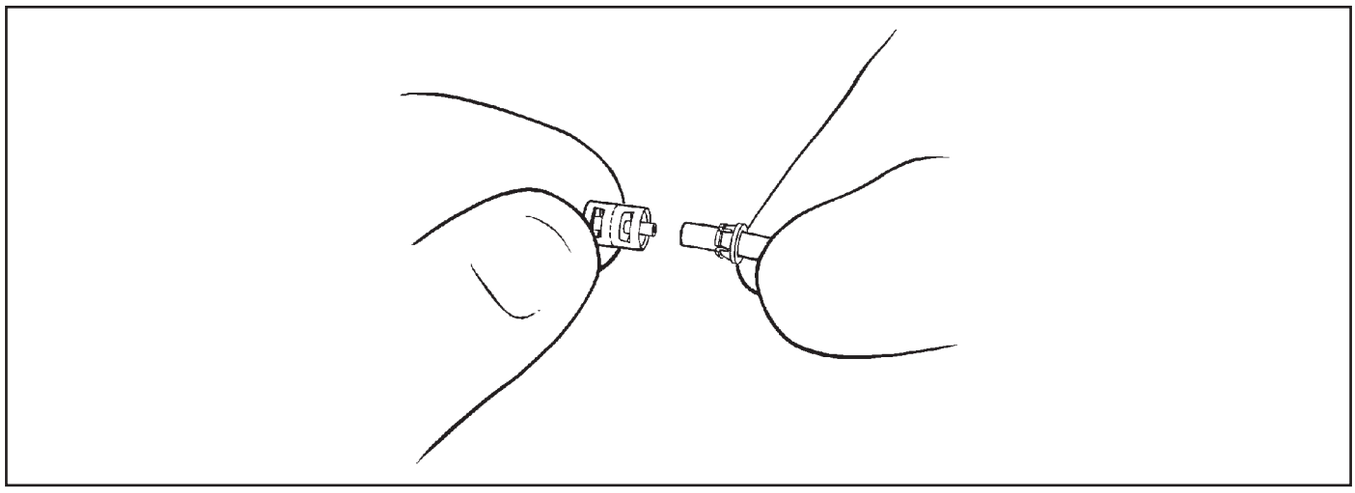

Figure 38. Firmly push the first end of the tubing onto the connector

7. Flush the end of the connector with sterile normal saline to remove particulate matter and air using the 22-gauge blunt tip needle.
8. Firmly push the other end of the tubing to the middle wall (Figure 39). Check the connector windows to make certain both tubing ends are still touching the middle walls of the connector.

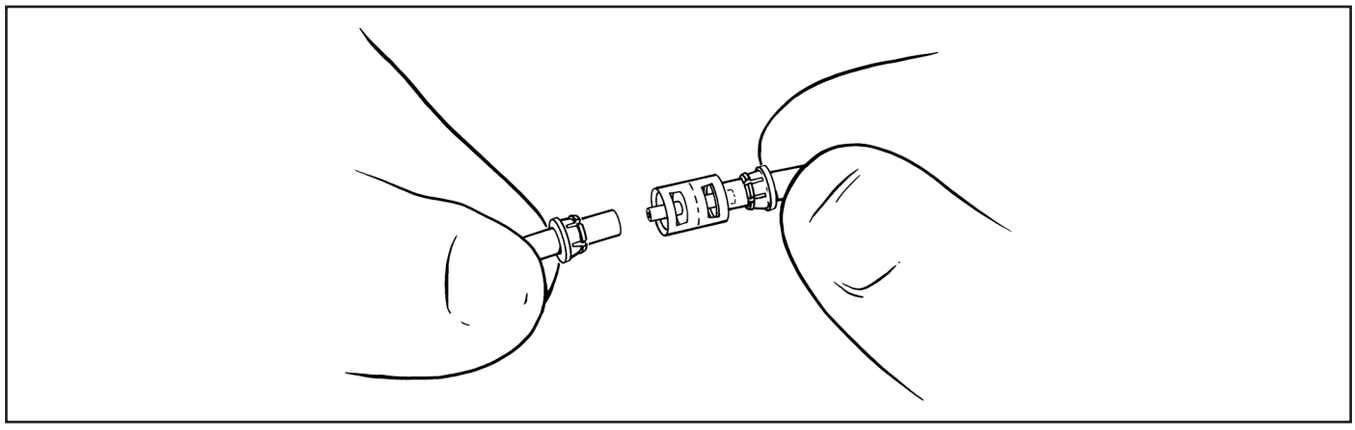

Figure 39. Firmly push the remaining tubing onto the connector

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9. Slide the collets towards the connector until the collet teeth touch the connector (Figure 40).

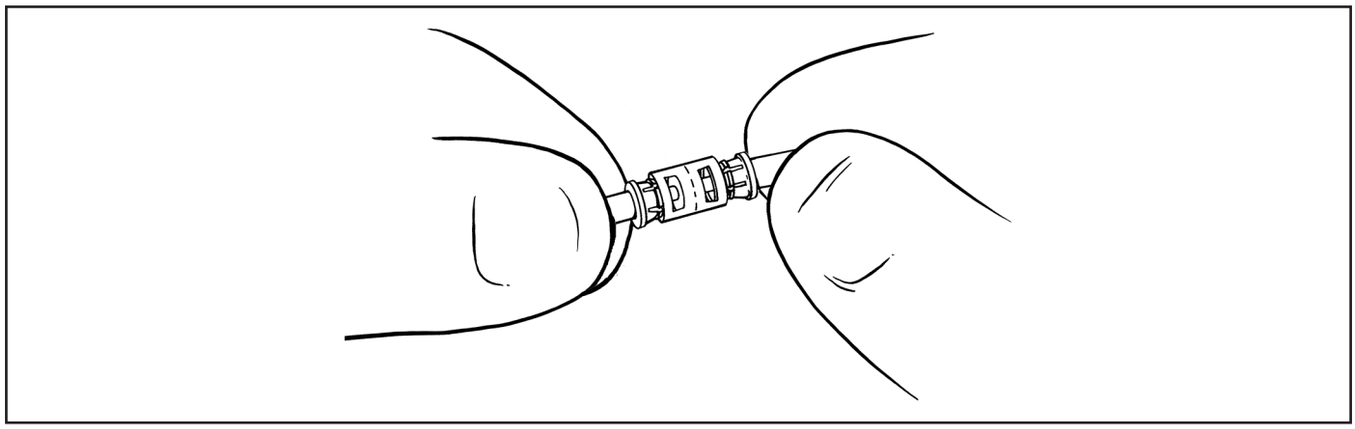

Figure 40. Slide the collets towards the connector until the teeth touch

10. Place the tubing connection in the Quick Connect Assembly tool jaw (Figure 41).

CAUTION: Check the tubing before closing the assembly tool. The tubing must not be trapped between the assembly tool jaw and the connector. The tubing must exit straight from the ends of the connector, through the slots in the assembly tool.

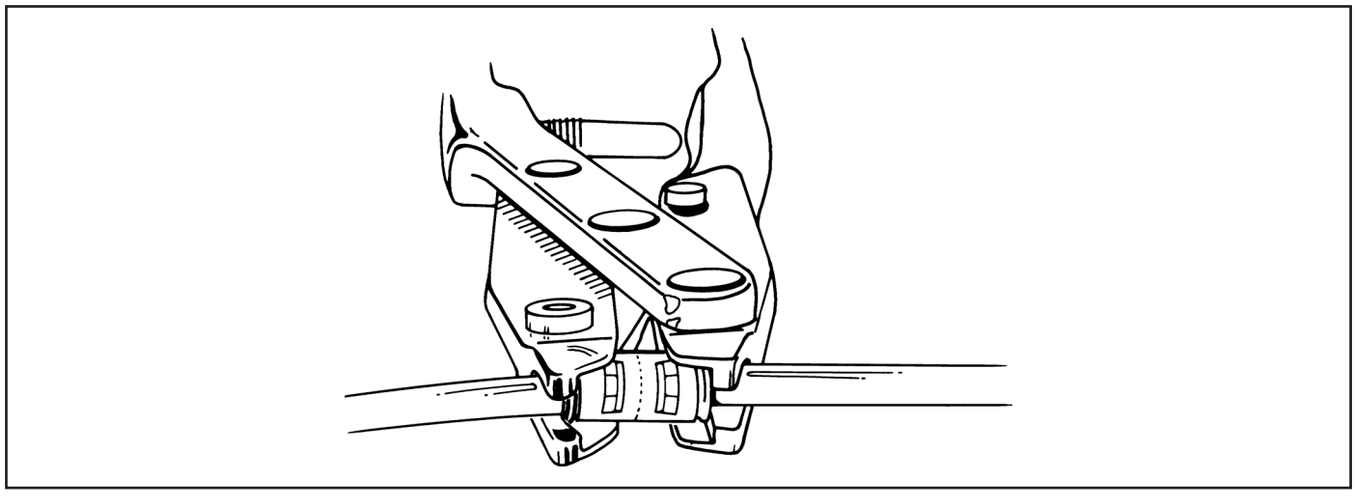

Figure 41. Place the connection in the tool jaw with the tubing exiting straight from the connector ends

11. Squeeze the tool handles until the closure stop touches the opposite handle. Do not hold the tubing connection while squeezing the tool jaw as this could cause misalignment. Check that all of the collet teeth are entering the connector before completing the connection.

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12. When using a right angle connector, the Quick Connect Assembly tool must be used twice, once on each end of the connector. Again, make certain the tubing is touching the middle wall on both sides of the connector. The closure stop of the assembly tool must touch the opposite handle each time a connection is made (Figure 42).

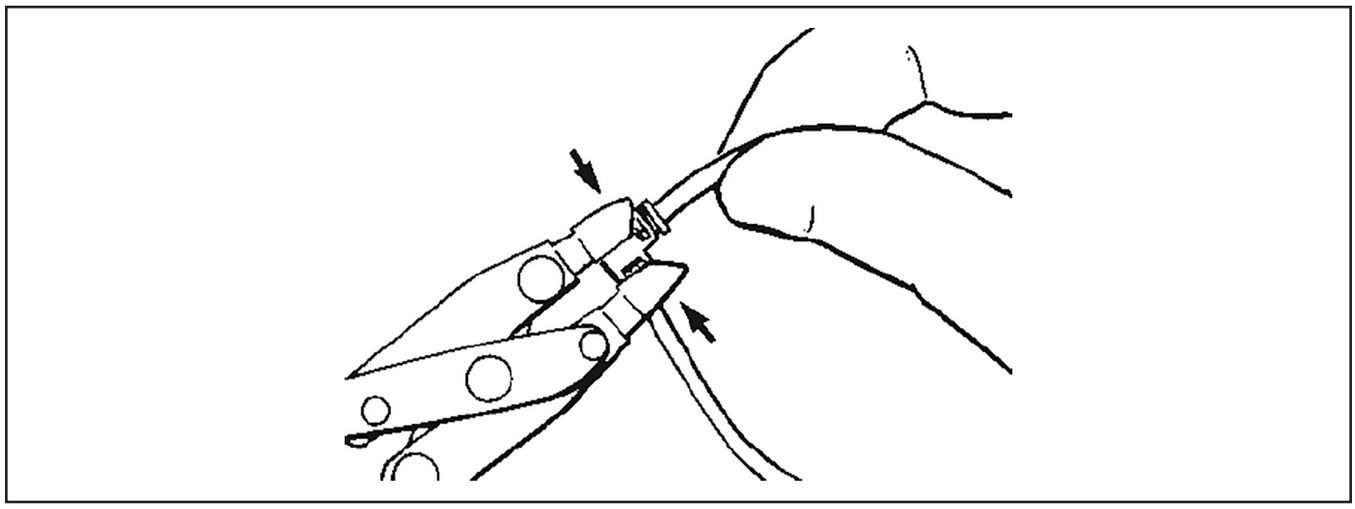

Figure 42. Use the tool twice when using a right angle connector – once on each connector end

13. After using the Quick Connect Assembly Tool, the tubing should bulge through the connector windows. This indicates that the tubing is still firmly pressed against the middle wall of the connector. The end of the collet outside of the connector should be parallel to and almost flush with the end of the connector. This indicates that the collet has been inserted completely into and attached to the connector. Give the tubing on both ends of the connector a firm pull to confirm a good connection has been made.
14. If any of the collet teeth did not enter the connector, if the connection pulled apart when tested, or if the connector is damaged, cut out the connection and make a new one.

Suture Tie Connectors

1. Cut the tubing (Figure 36) to fit the patient's anatomy.
2. All connections using Suture-Tie Connectors are tied with 3-0 nonabsorbable polypropylene. Clamp the component tubing using blue shod mosquito hemostats.
3. Use a 22-gauge blunt tip needle to flush the tubing ends with sterile normal saline to remove particulate matter and air before connecting.
4. Push the tubing over the ends of the connector so that they meet at the center hub of the connector.

Note: Make sure the tubing is on the connector straight.

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5. Use a double-throw overhand surgeon's knot followed by a minimum of two single throws to attach the tubing to the connector (Figure 43).

Note: The suture should crimp, but not cut the tubing.

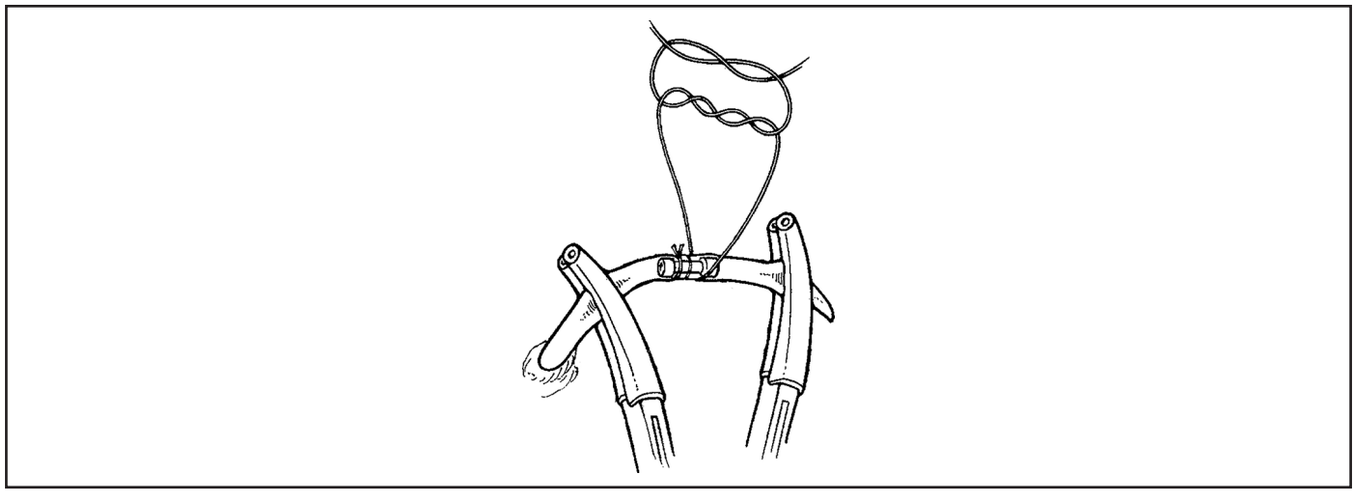

Figure 43. Tie suture

6. Pass the suture 180° and use the same tying technique on the opposite side of the connector. Use another suture and repeat on the opposite end of the connector.

Complete the Final Inflate/Deflate Test

1. After all the components are connected, completely inflate and deflate the cylinders at least once to ensure the device is functioning properly, to check the quality of the erection, and to evaluate flaccidity.

Note: The erect penis should present a satisfactory cosmetic result.

Note: The flaccid penis should lie close to body when deflated. There may be some swelling that precludes a good flaccid result.

Note: If erect or flaccid results are not acceptable, check the amount of fluid in the reservoir and adjust the volume if necessary.

2. Before ending the procedure, squeeze the TENACIO Pump bulb to allow the cylinders to partially inflate so that some fluid still remains in the cylinders postoperatively. This will ensure the cylinder capsules are large enough to prevent resistance to inflation.

CAUTION: Forces applied to the TENACIO Pump bulb should be minimized to reduce the risk of autoinflation during the healing period.

3. Close the incision in a fashion that prevents the connectors from rubbing on the tubing.

Note: Some physicians close the dartos fascia in two layers with absorbable suture and then close the skin.

4. Cut one end of traction suture approximately 2 cm from the glans; pull it out slowly to minimize trauma to the glans and the front tip of the cylinder.

Note: Do not remove the traction sutures from the cylinders until completion of the surgery should the cylinders need to be repositioned. The suture is non-absorbable and must be removed from the glans.

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5. Wound dressing can be applied, and the cylinders can remain partially inflated (Figure 44).

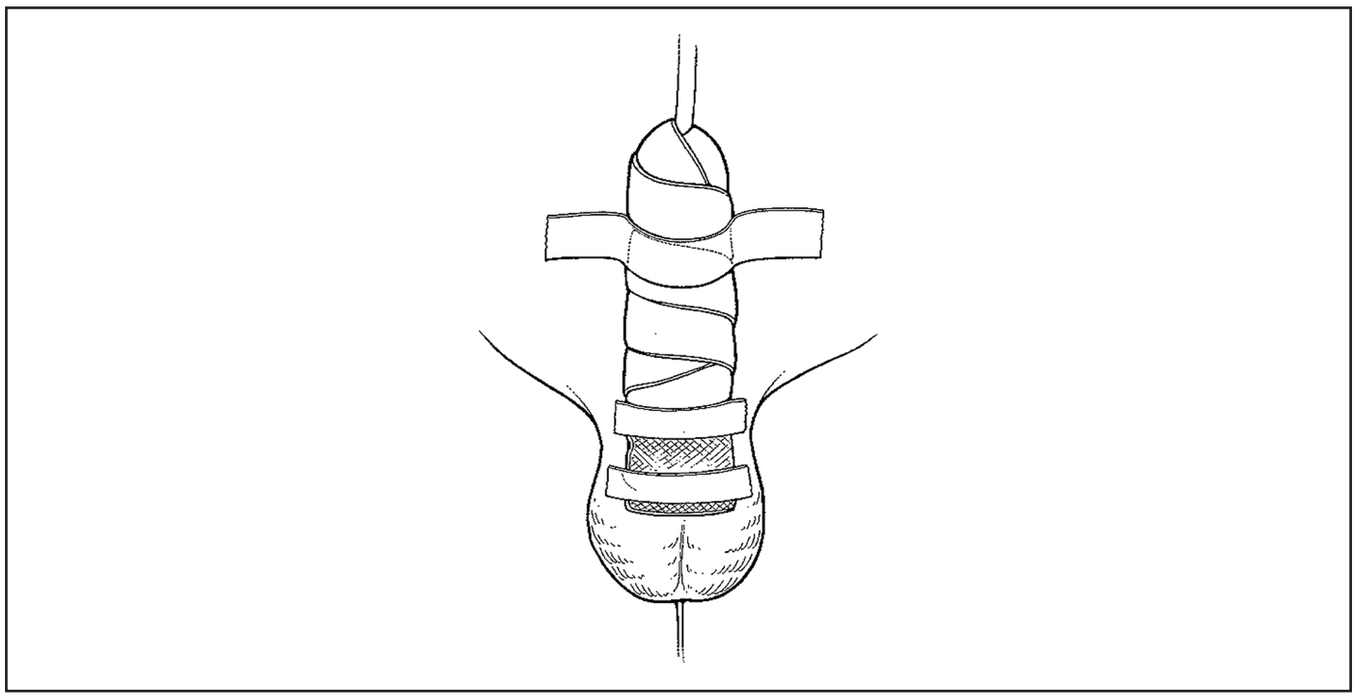

Figure 44. Wound dressing (example)

6. Support the penis on the lower abdomen.
7. A drain may be placed for 12 hours-24 hours, if desired.

Disposal

To minimize the risk of infection or microbial hazards after use, dispose device and packaging as follows: After use, device and packaging may contain biohazardous substances. Any device and packaging that came into contact with biohazardous substances should be treated and disposed of as biohazardous waste or be treated and disposed of in accordance with any applicable hospital, administrative, and/or local government regulations. Use of a biohazardous container with biological hazard symbol is recommended. Untreated biohazardous waste should not be disposed of in the municipal waste system.

This device contains a sharps hazard. Take precautions to ensure that sharps are handled properly. Dispose of all sharps directly into a sharps disposal container labeled with a biological hazard symbol. Sharps waste should be safely disposed of using available sharps waste channels in accordance with hospital, administrative, and/or local government policy.

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POST-PROCEDURE

Immediately Postoperative

After 24 hours, remove the dressing. Support the penis on the abdomen for four to six weeks to help promote a straight erection.

After the Patient is Released from the Hospital

The patient is usually discharged the same day or within 24 hours.

After the patient has returned home and the swelling from the surgery has subsided, the physician may ask the patient to pull down on the TENACIO Pump located in the scrotum to properly position it. Positioning the TENACIO Pump makes it easier for the patient to locate the TENACIO Pump.

The frequency of positioning the TENACIO Pump is up to the physician. Some physicians have their patients position the TENACIO Pump daily.

To position the TENACIO Pump in the scrotum, a patient should be told to:

- Locate the TENACIO Pump in the scrotum.
- Grasp the pump firmly on each side of the valve block and above the TENACIO Pump bulb. Carefully pull the TENACIO Pump down in the scrotum. The patient should gently pull the pump into a position close to the outer scrotal wall.

CAUTION: Forces applied to the TENACIO Pump bulb should be minimized to reduce the risk of autoinflation during the healing period.

After three to six weeks, the physician may instruct the patient to begin cycling the device for the first time.

To cycle the device, the patient inflates and deflates the prosthesis several times. It may be painful for the patient the first few times that he inflates and deflates the device. However, after the postoperative healing period, the pain should subside.

Instruct the patient to inflate and deflate the prosthesis several times daily. This is intended to encourage maximum pseudocapsule development and reservoir capacity.

Four to six weeks postoperatively, determine if the patient is ready to use the device:

- Check the incision site to be sure that it has healed properly. There should be no redness, swelling, or drainage. Any of these findings may indicate that an infection is present, and it should be treated promptly with antibiotics.
- Ask the patient about pain when cycling the device and observe the patient inflating and deflating the device.
- If the patient is unable to inflate the device and you believe the tubing may be kinked, Boston Scientific recommends trying the pull-stretch technique: the patient's penis is pulled-stretched out, up, down and side to side 2-3 times, which may allow the cylinders to be inflated. This technique may resolve the issue by slightly modifying tubing placement to optimize fluid flow.

After determining that the patient knows how to operate the device and that the device is functioning correctly, inform the patient that it is possible to have gentle intercourse. Advise the patient not to inflate the device for long periods of time when not in use.

If the patient is familiar with injection therapies for erectile dysfunction, remind the patient that such therapies can cause damage to the penile prosthesis, and should not be used.

The TENACIO Pump valving system resists elevated reservoir pressure. However, there is the possibility that the device could automatically inflate during the immediate postoperative period and the patient may have to return to the office for deflation.

Evaluating Long-term Function and Placement

After the post-operative healing period, it is advised that the physician continue to have contact with the patient at least on an annual basis to evaluate the function of the device and the implant site.

Auto-inflation may occur for a variety of reasons. If this occurs, verify that the patient is squeezing the deflation button, rather than other features of the TENACIO pump.

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If the patient is having mechanical difficulty with the device, or there is infection or erosion present, revision surgery may be necessary.

Any serious incident that occurs in relation to this device should be reported to Boston Scientific and the relevant local regulatory authority.

Device Removal

When considering removal of a penile prosthesis, thorough exam and review of medical history and prior penile prosthesis operative notes (if possible) will guide the surgical removal approach. Providers should clearly inform the patient of the risks and benefits of removal, replacement, or revision. It is critical to understand and account for all previously implanted prosthesis components, including the number of RTEs utilized, particularly in the event of infection. Regardless of the presence or absence of clinical signs of infection, mechanical lavage of the implant site(s) for removal, replacement, or revision may mitigate future infection. Full removal and concomitant replacement can be performed, at surgeon discretion, as can removal without replacement. For non-infected patients undergoing a surgical revision procedure, a surgeon may choose to drain, insert a tubing plug, and leave the reservoir in place, as a means to minimize reoperative insult. Replacement of a pump or reservoir at a contralateral location can also be considered. Doing so should be explicitly documented in the patient's medical record, to inform any future operative procedures.

PATIENT COUNSELING INFORMATION

Prior to the use of this device, discuss the benefits and risks of the AMS 700 and the alternate therapies available for the treatment of erectile dysfunction.

Patients should be counseled in order to have a realistic expectation of the physical, psychological, and functional outcomes of the implantation. The risks, benefits, and potential adverse events of all available treatment options should be discussed with the patient and considered by the physician and patient when choosing a treatment option. A discussion concerning the patient's preference for which side of their body where the pump should be placed, may be appropriate.

Some patients may become dissatisfied by the presence of the prosthetic device in their body. This issue should be discussed with the patient prior to the surgery. Patient dissatisfaction may lead to device removal. Patients should also be aware that the AMS 700 is not considered to be a lifetime implant.

Brief the patient on any contraindications, warnings, precautions, adverse events, and post-procedure instructions outlined in this document that are of relevance to the patient.

Explain that AMS 700 is MR conditional and inform them of the guidelines outlined in the MRI section of this document.

Advise the patient when moderate and strenuous activities, as well as intercourse, may be resumed. If discomfort while urinating, bleeding, or other problems occur, the patient should contact their physician.

It is also important that the physician discuss with the patient the possibility of an allergic reaction to the materials in the device.

Patients should be counseled on expected postoperative pain including severity and duration.

Patients may experience pain when the device is activated in the postoperative period and during periods of initial use. Pain with a severity or duration beyond what is expected may require medical or surgical intervention.

Advise the patient to use caution regarding impact sports or trauma to the surgical area - possible avoidance may be recommended after surgery, as this may alter the implanted device.

Advise the patient to notify the physician of any changes in manual dexterity, strength, and mental acuity as these conditions may affect proper use of the device.

Advise patients receiving an InhibiZone treated implant who are also taking warfarin that their prothrombin time should be monitored because tetracyclines have been reported to slow coagulation.

Advise the patient to notify physician of any redness, tenderness, swelling, or drainage at rest or when cycling their device. Any of these things may indicate that an infection is present and may require treatment. Ask the patient about tenderness and/or discomfort when cycling the device.

Provide the patient with the completed implant card and advise that it be carried permanently in order to inform others of the device in case of an emergency.

After the post-operative healing period, it is advised that the physician continue to have contact with the patient at least on an annual basis to evaluate the function of the device and the implant site. Advise patients to notify physician of any changes in device function and implant site appearance between annual visits.

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Black (K) ΔE ≤5.0

EXPECTED LIFETIME OF THE IMPLANT

The AMS 700 is not intended to be a lifetime implant. As with any mechanical implant, the device will be subject to wear through normal daily use which will vary by patient use. As such it is possible the system components or the entire system may require replacement or removal over time.

The AMS 700, with and without InhibiZone, system reliability has been verified to be at least 1,000 inflation / deflation cycles as demonstrated by testing of system functional performance, which equates to 2 erect states per week for 10 years.

IMPLANTABLE DEVICE PATIENT INFORMATION

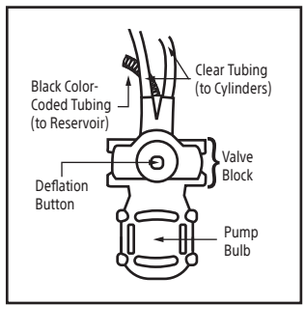
Advise the patient that additional information may be available to them on the Boston Scientific website (www.bostonscientific.com/patientlabeling).

IMPLANT CARD INSTRUCTIONS

- Apply the peel-off labels from the product onto the supplied patient implant card.
- Fill in the implant date, patient name, and physician information.
- Provide to patient.

TROUBLE SHOOTING

Table 8. During Surgery

Problem	What to Do
Cylinders and TENACIO Pump (Refer to Figure 45)	
Sized incorrectly	Re-dilate and resize. Remove the cylinder(s) and add or subtract RTEs to adjust the length. If unable to adjust the length with RTEs, remove the cylinder(s) and replace with cylinder(s) of the appropriate size.
Difficult to inflate	Squeeze the deflation button to "reset" the TENACIO pump. For the first pump, give the pump bulb a firm squeeze and then release to allow the pump bulb to refill.
Punctured	Remove damaged cylinder(s) and replace
Won't inflate	• Check that all hemostats are off the tubing. • Determine that the tubing is not kinked. If it is kinked, gently straighten it. • Check that the cylinder has not buckled. If the cylinder has buckled, be sure that it has been inserted properly. • If the cylinders still will not inflate, remove the pump from the scrotum and try to prime the pump outside of the body with the pump tubing submerged in a basin of sterile normal saline. • If the pump still will not prime, replace it with a new pump. • If the cylinders still will not inflate, remove and replace them.
Won't deflate  **Figure 45. Features of the TENACIO Pump**	• Check that all hemostats are off the tubing. • Determine that the tubing is not kinked. If it is kinked, gently straighten it. • Check that the tubing between the TENACIO Pump and the cylinders is clear of debris. If there is debris in the tubing, clamp the tubing with tubing covered hemostats, remove the connector, flush the system, and reconnect the system. • Check that the cylinders are properly sized and are positioned without kinks. • Make sure the deflate button was fully depressed. • Squeeze only the deflation button and do not squeeze the pump bulb. This should allow the cylinders to deflate normally. • If the cylinders still will not deflate, remove the pump from the scrotum and try to prime it outside of the body with the pump tubing submerged in a basin of sterile normal saline. • If the pump still will not prime, replace it with a new pump. • If the cylinders still will not deflate, remove and replace them.

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Problem	What to Do
Reservoirs	
Won't fill	• Check that the reservoir adaptor is not rolled over onto the reservoir. The reservoir adaptor should follow the tubing exit path through the fascia layer. If this does not address the problem, remove and replace with a new reservoir. • Make sure there is adequate space for the reservoir (i.e., not in scar tissue).
Punctured	Remove damaged reservoir and replace.

Table 9. Post-surgery

Problem	What to Do
Cylinders difficult to inflate or pump won't inflate cylinders	• Squeeze the deflation button to refill the pump bulb. Then give the pump bulb a firm squeeze and release to allow the pump bulb to refill.
Cylinders will not inflate	• The tubing may be kinked. The following pull-stretch technique may modify the tubing placement to optimize fluid flow and open the lumens of the tubing to the cylinders: The patient's penis is pulled- stretched out, up, down, and side to side 2-3 times.

PRODUCT REPLACEMENT INFORMATION

For more information about the replacement of an AMS 700, component or accessory, please contact a Boston Scientific representative or local distributor. Replacement may require the return of product to Boston Scientific in accordance with the applicable Boston Scientific Corporation Product Replacement Policy for Implanted Devices.

WARRANTY

For device warranty information, visit (www.bostonscientific.com/warranty).

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SYMBOL DEFINITIONS

Commonly used medical device symbols that appear on the labeling are defined at www.bostonscientific.com/SymbolsGlossary.

Additional symbols are defined at the end of this document.

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Store at 25 °C (77 °F); excursions permitted to 15-40 °C (59-104 °F).

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This document is applicable to the following products:

720182-01	72404172	72404293	72404406	72404450	72404467
720185-01	72404173	72404294	72404407	72404451	72404468
72400095	72404174	72404320	72404408	72404452	72404469
72403872	72404175	72404321	72404420	72404453	72404480
72404010	72404241	72404322	72404429	72404455	72404481
72404011	72404242	72404323	72404430	72404456	72404482
72404012	72404243	72404324	72404431	72404457	72404483
72404013	72404244	72404325	72404432	72404458	72404484
72404014	72404271	72404326	72404433	72404460	72404485
72404043	72404272	72404330	72404434	72404461	72404486
72404155	72404273	72404400	72404435	72404462	72404487
72404156	72404274	72404401	72404436	72404463	72404488
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