

AMS 700[®] with MS Pump[®] *Penile Prosthesis Product Line* Instructions for Use

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CAUTION: Federal law (U.S.) restricts this device
to sale by or on the order of a physician.

AMS

Solutions for Life[®]

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AMS 700[®] with MS Pump[®]

Penile Prosthesis Product Line

Instructions for Use

NOTE: Refer to the Operating Room Manual for further information on the AMS 700[®] product line and their implantation.

DEVICE DESCRIPTION

The AMS 700[®] Series Inflatable Penile Prosthesis product line includes the AMS 700 LGX[®] Preconnect, AMS 700[®] CX Preconnect, AMS 700 LGX[®], AMS 700[®] CX, AMS 700[®] CXM, and the AMS 700[®] CXR Penile Prosthesis. These configurations are also available with InhibiZone[®], an antibiotic impregnation of rifampin (rifampicin) and minocycline.* These prostheses are closed fluid-filled systems consisting of a pair of cylinders, optional rear tip extenders, a pump, and a fluid reservoir. All components are connected by kink-resistant tubing. The cylinders are inflated as fluid is pumped from the reservoir, creating an erection. They are deflated as fluid is transferred back to the reservoir, making the penis flaccid once again. This device contains solid silicone elastomer. These devices are for men who, after appropriate patient history and diagnostic evaluations as well as discussions with the urologist about other alternative treatment methods, are determined to be suitable candidates for implantation surgery.

INDICATIONS FOR USE

The AMS 700 Series Inflatable Penile Prosthesis product line 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 (rifampicin), or to minocycline, or other tetracyclines.

The implantation of products with InhibiZone is contraindicated in patients with systemic lupus erythematosus because minocycline has been reported to aggravate this condition.

* not available in all markets.

WARNINGS

1. Implantation of the device will make latent natural or spontaneous erections, as well as other interventional treatment options, impossible.
2. Men with diabetes, spinal cord injuries, or open sores may have an increased risk of infection associated with a prosthesis.
3. Failure to evaluate and promptly treat erosion may result in a substantial worsening of the condition leading to infection and loss of tissue.
4. Implantation of a penile prosthesis may result in penile shortening, curvature or scarring.
5. 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.
6. Pre-existing abdominal or penile scarring or contracture may make surgical implantation more complicated or impractical.
7. If a hypersensitivity reaction develops to a device coated with InhibiZone, the penile prosthesis should be removed and the patient treated appropriately.

PRECAUTIONS

Surgery Related

1. 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.
2. 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.
3. Removal of an implanted prosthesis without timely reimplantation of a new prosthesis may complicate subsequent reimplantation or may make it impossible.
4. Improper measurement technique, positioning or sizing may reduce cylinder life.
5. Unsuccessful outcomes have been reported due to improper surgical technique, anatomical misplacement of components, improper sizing and filling of components, or tubing kinks.
6. Implantation of AMS 700 LGX Cylinders in patients with Peyroine's disease may not provide a satisfactory result.

Device Related

1. AMS Quick Connect Sutureless Window Connectors should not be used in revision procedures involving previously implanted component tubing. In this situation the Quick Connect Sutureless Window Connectors may be less effective.

2. 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.
3. Devices in the AMS 700 product line should be filled with sterile, normal saline. Some patients may have a hypersensitivity to contrast media.
4. Do not use product that has damaged or open packaging, as sterility may be compromised.
5. Devices with InhibiZone should not come into contact with ethyl alcohol, isopropyl alcohol or other alcohols, acetone or other non-polar solvents. These solvents may remove the antibiotics from the device.
6. 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 implant, if desired.
7. CXR RTEs are not compatible with CX or LGX cylinders.
8. Verify proper attachment of RTEs by spinning them once seated. Properly attached RTEs should spin freely without accidental disengagement or material bulging.
9. Do not stack the CX, LGX or CXR Snapcone RTEs with the exception of the 1.5cm. The locking ring will not engage with the smooth outer surface of the RTE, which may result in the RTE disconnecting.

Patient Related

1. A thorough preoperative consultation should include a discussion between patient and physician of all available treatment options and their risks and benefits.
2. Adequate patient manual dexterity and strength are required for proper device inflation and deflation.
3. Mental or psychological conditions, such as senile dementia, may inhibit the patient's successful operation of the prosthesis.
4. Trauma to the pelvic or abdominal areas, such as impact injuries associated with sports (e.g. bicycle riding), can result in damage of the implanted device and/or surrounding tissues. This damage may result in the malfunction of the device and may necessitate surgical correction, including replacement of the device.
5. The contour, elasticity and dimension of the tunica albuginea may limit the length and/or diameter expansion of the AMS 700 cylinders.
6. The implantation of this device should only be considered in patients whom the physician determines are adequate surgical candidates.

7. Use of injection therapy concurrently with the penile prosthesis can damage the prosthesis. Patients should not use injection therapy after they receive their implant.

InhibiZone Related

1. InhibiZone does not replace your normal antibiotic protocols. Continue using any prophylactic protocols normally used when implanting an inflatable penile prosthesis.
2. Because the products with InhibiZone are impregnated with a combination of rifampin (rifampicin) (a derivative of rifamycin B) and minocycline (a derivative of tetracycline), the contraindications, warnings and precautions regarding the use of these antimicrobial agents apply and should be adhered to for the use of this device, although systemic levels of minocycline and rifampin (rifampicin) in patients receiving this device are unlikely to be detected.
3. Use of products with InhibiZone should be carefully considered in patients with hepatic or renal disease, as use of rifampin (rifampicin) and minocycline can cause additional stress on the hepatic and renal systems.
4. Patients who receive a device with InhibiZone and are also taking methoxyflourane should be carefully monitored for signs of renal toxicity.
5. Patients who receive a device with InhibiZone and are also taking warfarin should have their prothrombin time monitored, because tetracyclines have been reported to slow coagulation.
6. Use of products 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 (rifampicin).

ADVERSE EVENTS

A clinical trial was conducted to determine the safety and effectiveness of the AMS 700 Series of inflatable penile prostheses. This trial involved only devices without InhibiZone. A total of 300 patients were enrolled with follow-up out to 5 years for 126 patients. The Adverse Device Effects, detailed in the table below, were noted during the duration of this clinical trial for all enrolled patients.

AMS CLINICAL TRIAL ADVERSE DEVICE EFFECTS

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)
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).

RESOLUTION OF ADVERSE DEVICE EFFECTS

ADE	# Patient (%)	Method of Resolution				
		Surgical	Medication	Other	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%
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%
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 effects (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 Hypermobility Dorsally, Kidney Calculus, Libido Decreased, Migraine, Necrosis, Pump Fixation, Phimosis, Photosensitivity Reaction, Thickening of the Skin, Urinary Tract Infection, Urinary Urgency, and Vertigo.

The following risks of inflatable penile implants or their materials have been reported in the medical literature but did not occur during the prospective study: granuloma formation, non-rheumatoid arthritis immune-related tissue disorders, ischemia, seroma, ulceration, vascular compromise, and ventral chordee.

There were eighteen patient deaths during the course of the trial. No deaths that occurred during the duration of the clinical study were attributed to the device implantation or use.

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

CLINICAL STUDIES

A clinical trial was undertaken to demonstrate that the AMS 700 product line provides an erection that is suitable for intercourse and has acceptable rates of surgical revision and of 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 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, multi-center cohort trial in which the patients served as their own control. The choice of device model implanted (i.e. 700 CX, 700 CX Preconnect, 700 CXM, 700 Ultrex, 700 Ultrex Plus) was at the discretion of the patient and implanting physician.

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

NOTE: The AMS 700 LGX Preconnect 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.*

** not available in all markets*

Three hundred male patients, over 21 years of age, were enrolled in this study. All patients with diagnosed organic erectile dysfunction were eligible for enrollment, if they did not present with a history of allergy/sensitivity to silicone, pre-existing autoimmune or connective tissue diseases or active urogenital infection.

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 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 on four validated outcome instruments were the secondary efficacy endpoints (concerning quality of life, self-esteem, and sexual satisfaction and functioning).

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

Physician Assessment of Device Function

One hundred twenty-six devices were evaluated at the five-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 five-year exam were surgically revised prior to this exam to correct a mechanical malfunction, and (ii) 3 additional devices not evaluated at the five-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 five years, as well as 16 additional patients who experienced one or more revision surgery and did not reach the five-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 twenty-six revision surgeries, there were five (5) revisions due to "Infection"; two (2) for "Infection/Erosion"; two (2) for "Migration/Malposition", two

(2) for “Erosion”, two (2) for “Malposition”; seven (7) for “Mechanical Malfunction”, two (2) for “Fibrous Capsular Complication”, two (2) for “Reimplantation Following Previous Revision”, and two (2) due to reasons listed as “Other”. The “Other” reasons included Cylinder kink/auto-inflation (1), Corporal body aneurysm (1). In five 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 two years post-implantation. Throughout the two-year follow-up period, patient quality of life, self-esteem, and psychological well being were determined to be equivalent to the pre-implant state. Sexual functioning and sexual satisfaction, on the other hand, was significantly improved over the pre-implant state.

SUPPLEMENTARY CLINICAL INFORMATION

Although it is not feasible to predict exactly how long an implanted penile prosthesis will function in a particular patient, American Medical Systems, Inc. has assembled a set of data on device removals and revisions to help gain insight into the product performance over time.

The following two tables provide an estimate of the long-term rates of device removals and revisions for Ultrex and CX models. The first data set comes from Patient Information Forms (PIFs) submitted to AMS by physicians for surgical procedures requiring parts replacement under AMS warranty (Table 1). All forms reporting devices implanted between January 1993 and December 2000 were included in a life table analysis that was used to calculate the revision rates for each category. Revision surgeries may not be reported to AMS.

Therefore, the incidence of surgeries after original implant would likely be underreported, if one were to rely solely on the PIF data. AMS also assembled a second set of data directly from a retrospective review of physicians’ medical records (Table 2). These medical records capture each surgery performed by that physician after original implant for any reason.

NOTE: These analyses did not include the AMS 700 with MS Pump, snapcone cylinders, or parylene coated components.

NOTE: These analyses did not include the AMS Conceal Low Profile Reservoir.

PIF Study

Table 1: Revision rates based on PIF data:*

Reason for Removal or Replacement Surgery	700 CX Revision Rate (5 YRS) n=12,080	700 Ultrex Revision Rate (5 YRS) n=20,438
Mechanical Revision	5.6%	4.8%
Removal for Infection	2.2%	2.0%
Removal for Erosion	1.4%	1.0%
Migration/Malposition of Component	0.5%	0.5%
Cylinder Aneurysm	0.5%	0.5%
Other Reasons	3.6 %	2.9%
ALL REASONS**	11.6%	9.8%

* Interpretations of the PIF data may be limited by a number of factors:

- Statistics are based only on surgery data voluntarily reported to AMS by hospitals and physicians in the U.S. as part of the AMS Product Replacement. Because surgeries may not be reported to AMS, the number of patients implanted and the incidence of removal/replacement surgery may actually be higher.
- These statistics pertain only to the incidence of removal/replacement surgery and not to the current functioning of devices which have not been removed.

** The total may be less than the sum of the category percentages because more than one reason can be reported for any revision.

Medical Records Study

Table 2: Revision rates based on medical records data**

Reason for Removal or Replacement Surgery	700 CX Revision Rate (5 YRS) n=512	700 Ultrex Revision Rate (3 YRS) n=155
Mechanical Revision	9.4%	3.2%
Removal for Infection	2.9%	2.0%
Removal for Erosion	2.4%	1.6%
Migration/Malposition of Component	2.8%	0.7%
Cylinder Aneurysm	0.6%	0.0%
Other Reasons	2.1%	4.0%
ALL REASONS	18.1%	10.4%

** Interpretations of the medical record data may be limited by several factors:

- These percentages reflect the known revisions performed by the original implant physicians.
- These statistics pertain only to the incidence of removal/replacement surgery and not to the current functioning of devices which have not been removed.

NOTE: The amount for "ALL REASONS" is lower than the total of the individual percentages due to the incidence of multiple reasons for removal/replacement surgery.

ANTIBIOTIC INFORMATION

The antibiotics present in InhibiZone, minocycline and rifampin (rifampicin), are well characterized and have been in use for years. The dosage present on the penile prostheses is intended to act on organisms that attempt to colonize the device. The AMS 700 components are treated with very low levels of antibiotics. AMS provides numerous completed configurations of the AMS 700 to individualize treatment; however, a complete device (reservoir, pump and two cylinders), regardless of configuration, represents less than 2% of oral dose exposure for a complete course of rifampin (rifampicin) or minocycline. Although the quantity of antibiotics on individual AMS 700 components may vary, average quantities on the most common device configurations have approximately 27mg (SD plus or minus 6) rifampin (rifampicin) and 11mg of minocycline (SD plus or minus 1). The following in vitro data are available, but their clinical significance is unknown. No clinical studies have been performed to evaluate the effect of the antibiotic surface treatment on reducing the incidence of penile implant infections, but early published data is promising. (Ref. Carson, CC. Efficacy of antibiotic impregnation of inflatable penile prostheses in decreasing infection in original implants. *J Urol.* 2004; 171: 1611-1614.) (Ref. Droggin, D, Shabsigh, R, Anastasiadis, AG, Antibiotic coating reduces penile prosthesis infection. *J Sex Med* 2005; 2: 565-568.)

Table 3: In vitro Zones of Inhibition for Device Samples* with InhibiZone Treatment

Organism	Mean (mm)	S. D (mm)	Number of Isolates
Staphylococcus epidermidis	22.6	2.9	21
Staphylococcus aureus	17.5	5.0	25
Escherichia coli**	6.5	2.6	24
Enterococcus faecalis**	4.8	6.7	21
Candida albicans**	0.1	0.4	21
Proteus mirabilis**	0.6	1.0	17

* obtained using standardized KRT test samples containing 12 µg minocycline and 26 µg rifampin (rifampicin)

** the isolates tested were not susceptible to rifampin (rifampicin) and/or minocycline control disks

An animal infection study was conducted using 11 rabbits. Five rabbits were implanted subcutaneously with 6 test samples each and five rabbits were implanted subcutaneously with 6 control samples each. One rabbit received three test samples and three control samples. The test samples were portions of an InhibiZone treated AMS 700 Pump and the control samples were portions of a standard AMS 700 Pump without InhibiZone. All samples were soaked in a 10^3 - 10^4 CFU solution of staphylococcus aureus, Sheretz strain for 8 hours. Samples were then allowed to dry for 30 minutes prior to surgical placement in the rabbit. After 2 days, all samples were removed and observed for growth on the samples. The number of coated samples that were infected was statistically significantly lower than the number of control samples that were infected.

PATIENT COUNSELING INFORMATION

Patients should be counseled in order to have a realistic expectation of the physical, psychological and functional outcome 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.

An appropriate patient history, including history of personality disorders, and diagnostic work-up should be a part of the patient decision making process.

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.

Implantation of a penile prosthesis may result in penile shortening, curvature or scarring. The prosthetic erection may differ from the patient's original, natural erection in that it may be shorter, less firm, have less girth, and reduced sensations. Realistic cosmetic expectations should be communicated to the patient and should include the potential for skin scarring, scrotal deformity, pump bulge in the scrotum, lack of concealability and other possible adverse events. Patients should also be aware that penile prostheses are not considered to be lifetime implants.

Improper implantation of a penile prosthesis may not provide rigidity to the glans, which may result in a floppy glans and may result in a lack of rigidity of the corpus spongiosum. Penile flaccidity may be less than it was before implantation.

Patients who undergo revision surgery may notice a change in the character of their erection compared to their previous implant, which may include differences in sensation, length, girth, rigidity, and/or flaccidity.

It is also important that the physician discusses with the patient the possibility of an allergic reaction to the materials in the device (See Silicone Information).

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 40 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 casual 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 has been conducted on all materials that comprise the prostheses in the AMS 700. This testing has 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 on penile implants. There are no known clinical sequelae to this phenomenon.

MAGNETIC RESONANCE IMAGING (MRI) INFORMATION

Several studies regarding MRI and the AMS 700 product line (or similar AMS products) have concluded that the presence of an AMS prosthesis will not produce harmful effects during scanning. These studies were conducted by Robert C. Lange, Ph.D., Yale University and Frank G. Shellock, Ph.D., Cedars-Sinai Medical Center, Los Angeles. Dr. Lange produced his study for American Medical Systems and Dr. Shellock produced his studies independently for publication in American Journal of Roentgenology (AJR) and Radiology.¹⁻³

In these studies, the metallic components in AMS implants were subjected to magnetic field strengths up to 1.5 Tesla and showed no unsafe magnetic interaction. The small stainless steel components in AMS prostheses may distort the uniform magnetic field in the vicinity of the implant; though it is unlikely that these components will interfere with normal MRI. However, the complete compatibility profile of these products within a MRI field has not been established.

¹ Shellock F, MR Imaging of Metallic Implants and Materials: A Compilation of the Literature, AJR, October 1988.

² Shellock F, MR Imaging and Biomedical Implants, Materials and Devices: An Updated Review, Radiology, 1991, Vol 180, pp. 541-550.

³ Shellock F, MR Procedures and Biomedical Implants, Materials and Devices: 1993 Update, Radiology, 1993, Vol. 189, pp. 587-599.

INVENTORY RETURNS AND PRODUCT REPLACEMENT INFORMATION

In the United States

Before returning any components, whether explanted or unused (sterile or nonsterile), customers must fill out the Return Goods Form located on the last page of the Patient Information Form.

Follow all of the instructions on the form carefully, and be sure that the components have been thoroughly cleaned before returning them to AMS.

In all cases, obtaining credit or percentage of credit for a returned component is subject to approval under the terms of the AMS Return Goods Policy and the AMS Product Warranty Policy. For complete information regarding these policies, contact the AMS Customer Service Department.

Outside the United States

Customers outside of the United States should contact their local AMS Representative prior to returning any product.

This document is written for professional medical audiences. Contact American Medical Systems for lay publications.

American Medical Systems periodically updates product literature. If you have questions about the currency of this information, contact American Medical Systems.

HOW SUPPLIED AND STORAGE

WARNING: Contents supplied STERILE. Do not use if sterile barrier is damaged. If damage is found, call your AMS 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. After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.



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