Brief Summary Document

Overview

Product

AMS 700™ with MS Pump™ Inflatable Penile Prosthesis	IFU #51828058-01A
AMS 700™ Inflatable Penile Prosthesis with TENACIO™ Pump	IFU #51558342-01A

Rx Statement

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a licensed practitioner.

Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.

INTENDED USE/INDICATIONS FOR USE

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.

Indication 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, or to 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 this device will make latent natural or spontaneous erections, as well as other interventional treatment options, impossible.
- 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.
- Improper measurement technique, positioning, or sizing may reduce cylinder life.
- 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.
- 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.
- 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.
- 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.
- 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

- 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.
- Devices with 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.

ADVERSE EVENTS

A clinical trial was conducted to determine the safety and effectiveness of the AMS 700™ 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 3 and 4 of the MS Pump IFU and Tables 5 and 6 of the TENACIO IFU, were noted during the duration of this clinical trial for all enrolled patients.

- Urogenital Pain (Typically Associated with Healing Process)
- Urogenital Edema
- Urogenital Ecchymosis
- Reservoir Encapsulation (persistent in 11/19 cases)
- Patient Dissatisfaction (With Length, Ability to Use and Nonspecific Reasons)
- Auto-Inflation
- Mechanical Malfunction (Leaks, Incomplete Inflation/Deflation, Kinking)
- Urination Impaired (Slow Stream, Split Stream, Voiding Difficulties or Obstructive Symptoms)
- Urogenital Erythema
- Joint Pain, Swelling, or Stiffness
- Decreased Penile Sensation
- Urogenital Hematoma
- Abnormal Ejaculation (Delayed, Burning, or General Nonspecific Problems)
- Infection
- Dysuria
- Penile Curvature
- Application Site Reaction (Wound Separation, Delay in Cutaneous Closure)
- Erosion/Extrusion (Pump/Cylinder)
- Paresthesia
- Urogenital Inflammation
- Adhesion of the Pump/Scrotum
- Device Malposition
- Device Migration (Pump/Cylinder)
- Transient Urinary Retention
- Urinary Frequency
- Weakness
- Abnormal Sexual Function

- Device Cylinder Aneurysm/Bulge
- Dizziness
- Dry Mouth
- Hematuria
- Low Grade Fever
- Memory Difficulties
- Pelvic Pain
- Rheumatoid Arthritis
- Other

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
- Vertigo

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
- Vessel Trauma

MH-545408-AE DEC 2024