

AMS 700™ Inflatable Penile Prosthesis

Prescriptive Information

Refer to the device instructions for use for complete directions on device use.

Intended Use

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

Indications

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 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

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 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 Peyronie's disease may not provide a satisfactory result.

Device Related

1. AMS Quick Connect Sutureless 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 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. CX/LGX RTEs are not compatible with CXR 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 RTEs with the exception of the 1.5 cm. The locking ring will not engage with the smooth outer surface of the RTE, which may result in the RTE disconnecting.

Patient Related

- 1.. Adequate patient manual dexterity and strength are required for proper device inflation and deflation.
2. Mental or psychological conditions, such as senile dementia, may inhibit the patient's successful operation of the prosthesis.
3. 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.
4. The contour, elasticity, and dimension of the tunica albuginea may limit the length and/or diameter expansion of the AMS 700 cylinders.
5. The implantation of this device should only be considered in patients whom the physician determines are adequate surgical candidates.
6. 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 HCl (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 HCl 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 HCl 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).
7. 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.

8. 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.

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

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