

AMS 800™ Artificial Urinary Sphincter System for Male Patients

Prescriptive Information

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

Indications

The AMS 800 is used to treat urinary incontinence due to reduced outlet resistance (intrinsic sphincter deficiency) following prostate surgery.

Contraindications

1. This device is contraindicated in patients whom the physician determines to be poor candidates for surgical procedures and/or anesthesia due to physical or mental conditions.
2. This device is contraindicated in patients with urinary incontinence due to or complicated by an irreversibly obstructed lower urinary tract.
3. This device is contraindicated in patients with irresolvable detrusor hyperreflexia or bladder instability.
4. 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.
5. 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

Erosion may be caused by infection, pressure on the tissue, improper cuff sizing, improper balloon selection, tissue damage, and component malposition. Failure to evaluate and promptly treat erosion may result in substantial worsening of the condition, leading to infection and/or loss of tissue.

The implanter should check that there is an adequate amount of bulbospongiosus muscle to surround and support a bulbous urethral cuff implant. Thinner spongiosum typically occurs toward the distal end of the bulbous urethra, and implantation of the cuff where the spongiosum is thin increases the chance of erosion and other complications. This warning is especially important for double cuff implants, where the second cuff is placed distal to the first implanted cuff.

Patients with urinary tract infections, diabetes, spinal cord injuries, open sores, or skin infections in the region of the surgery have an increased risk of infection associated with a prosthesis. Appropriate measures should be taken to reduce the likelihood of infection. Infection that fails to respond to antibiotic therapy may result in removal of the prosthesis. Infection followed by explantation of the device may result in scarring which may make subsequent reimplantation more difficult.

Poor bladder compliance or a small fibrotic bladder may require some measure of intervention including, in some cases, augmentation cystoplasty before implanting the prosthesis.

Patients with urge incontinence, overflow incontinence, detrusor hyperreflexia or bladder instability should have these conditions treated and controlled (or resolved) prior to implantation of the device.

This device contains solid silicone elastomers. The risks and benefits of implanting this device in patients with documented sensitivity to silicone should be carefully considered.

Previous patient history of an adverse reaction to any radiopaque solution precludes their use as a filling medium for the prosthesis. Instead, sterile normal saline should be used to fill the device.

Do not pass a catheter or any other instrument through the urethra without first deflating the cuff and deactivating the device to prevent potential damage to the urethra or the AMS 800 AUS.

Adequate manual dexterity, strength, motivation, and mental acuity are required for proper use of the device. Surgical complications, or physical or psychological complications (such as any progressively degenerative disease), if they occur, may affect the use of the system. Continued improper use may lead to revision or removal of the prosthesis. Removal of the device without timely reimplantation of a new device may complicate subsequent reimplantation. The timing of reimplantation should be determined by the treating physician based on the patient's medical condition and history.

Any mechanical malfunction that does not permit the transfer of fluid from the cuff to the balloon may result in outflow obstruction. Mechanical events should be evaluated carefully by the treating physician, and the patient should consider risks and benefits of treatment options, including removal or revision surgery.

If a hypersensitivity reaction develops to a device treated with InhibiZone, the cuff and pump should be removed and the patient treated appropriately.

Precautions

Patient Related

1. Patients with urinary tract infections, diabetes, spinal cord injuries, open sores, or skin infections in the region of the surgery have an increased risk of infection associated with a prosthesis. Appropriate measures should be taken to reduce the likelihood of infection. Infection that fails to respond to antibiotic therapy may result in removal of the prosthesis. Infection followed by explantation of the device may result in scarring which may make subsequent reimplantation more difficult.
2. Poor bladder compliance or a small fibrotic bladder may require some measure of intervention including, in some cases, augmentation cystoplasty before implanting the prosthesis.
3. Patients with urge incontinence, overflow incontinence, detrusor hyperreflexia or bladder instability should have these conditions treated and controlled (or resolved) prior to implantation of the device.
4. This device contains solid silicone elastomers. The risks and benefits of implanting this device in patients with documented sensitivity to silicone should be carefully considered.

5. Previous patient history of an adverse reaction to any radiopaque solution precludes their use as a filling medium for the prosthesis. Instead, sterile normal saline should be used to fill the device.

InhibiZone™ Related

1. InhibiZone does not replace normal antibiotic protocols. Continue using any prophylactic protocols normally used for urological surgical procedures.
2. Components with InhibiZone are treated with a combination of rifampin and minocycline HCl. The contraindications, warnings, and precautions regarding the use of these antimicrobial agents apply, and should be followed for the use of this device, although systemic levels of minocycline HCl and rifampin 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 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 methoxyflurane 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.
7. 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.
8. InhibiZone components should not be soaked in saline or other solutions prior to implantation. The components may be briefly rinsed or dipped into a sterile solution, immediately prior to implant, if desired.

Surgery Related

1. Improper cuff sizing, improper balloon selection, or other causes may result in tissue erosion, migration of components, or continued incontinence.

2. Component migration can occur if the cuff is sized improperly, if the pump or balloon is not positioned correctly, or if the tubing lengths are incorrect. Migration can result in pain, complications, device malfunction and surgical revision.
3. Unsuccessful outcomes have been reported due to improper surgical technique, such as anatomical misplacement of components, improper sizing and/or filling of components, as well as tubing kinks. Product wear, component disconnection, or other mechanical problems may lead to malfunctioning of the components and leakage of fluid.
4. Tubing kinks may result if the connecting tubing is cut to an improper length during the implant procedure.

Device Related

1. Quick Connect Window Connectors should not be used in revision procedures involving previously implanted component tubing. Suture-Tie Connectors should be used in revision procedures. The Quick Connect system may be used in revision surgeries when all previously implanted components are removed and replaced with new components.
2. The stainless steel tubing plugs in the Deactivation Package contain nickel, which may cause an allergic reaction in individuals with nickel sensitivity.
3. If the deactivation valve is closed when the cuff is inflated, fluid cannot transfer from the cuff to the balloon and sustained outflow obstruction may arise as a result:
 - a. In the event of large pressures within the bladder, automatic pressure relief that normally occurs with the device would be prevented. Cycling the device can relieve the outflow obstruction.
 - b. Cycling the device may be difficult if deactivation occurs when the pump bulb is deflated. If unable to cycle the device, squeezing the sides adjacent to the deactivation button will allow fluid to fill the pump bulb and then the pump can be cycled normally.
 - c. Release of the deactivation valve may require greater pressure than that used to cycle the device.
4. System pressure changes may occur over time if you fill the balloon with radiopaque solution of incorrect concentration. Follow the instructions in the Operating Room Manual to prepare the radiopaque solution with the correct concentration.

Potential Adverse Events

The following adverse events have been associated with the use of this product: adhesion, allergic reaction, bladder spasms, bleeding, contracture, deep vein thrombosis, dehiscence, delayed wound healing, difficult activation, difficult deactivation, dysuria, edema, erosion, exposure to biohazardous material, fibrosis, fistula formation, foreign body/unretrieved device fragment, hematoma, hematuria, herniation, herniation of the device, hydrocele, impaired device function, infection, limited urethral coaptation (may be due to device leak, sizing, malfunction, malposition of components, placement, or other causes), malfunction, malposition of components, mechanical malfunction or mechanical difficulty, migration of component, nerve injury, overactive bladder, pain/discomfort, patient dissatisfaction, prolonged procedure, unintended surgical damage (perforation or injury to the bladder,

urethra, nerves, vessels, or other local structures), urethral atrophy, urethral stricture, urinary retention, and urinary urgency.

This is not a complete list of precautions. All precautions can be found in the product labeling supplied with each device.

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

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