

AMS 800™ Urinary Control System for Male Patients

Prescriptive Information

Refer to the device directions 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

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. Erosion may be caused by infection, pressure on the tissue, improper cuff sizing, improper balloon selection, tissue damage, and component misplacement. The cuff may erode around the urethra or bladder neck. The control pump may erode through the scrotum. The pressure-regulating balloon may erode into the bladder. Acute urinary tract infection can interfere with proper functioning of the device and may lead to erosion of the urethra in the cuff area. Failure to evaluate and promptly treat the erosion may result in a substantial worsening of the condition leading to infection and/or loss of tissue.
3. Poor bladder compliance or a small fibrotic bladder may require some measure of intervention including, in some cases, augmentation cystoplasty before implanting the prosthesis.
4. 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.

5. 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.
6. This device contains solid silicone elastomers. This device does not contain silicone gel. The risks and benefits of implanting this device in patients with documented sensitivity to silicone should be carefully considered.
7. Surgical, physical, psychological, or mechanical complications, if they occur, may necessitate 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.
8. Product wear, component disconnection or other mechanical problems may lead to surgical intervention. Mechanical complications may include malfunctioning of the components and leakage of fluid. 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 revision surgery.
9. Previous patient history of adverse reaction(s) to radiopaque solution precludes its use as a filling medium for the prosthesis. Instead, saline should be used to fill the device.
10. 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.
11. If a hypersensitivity reaction develops to a device coated with InhibiZone, the cuff and pump should be removed and the patient treated appropriately.

Precautions

Patient Related

1. Patient selection requires thorough preoperative consultation and evaluation by the physician.
2. Patients should be counseled in order to have a realistic expectation of the physical, psychological, and functional outcome of the implantation of an AMS 800. Although the prosthesis is designed to restore urinary control, some patients continue to have a degree of incontinence after this procedure.
3. Patients may experience pain when the device is activated in the postoperative period and during the period of initial use. Cases of chronic pain associated with device have been reported. Pain with a severity or duration beyond what is expected may require medical or surgical intervention. Patients should be counseled on expected postoperative pain including severity and duration.
4. Tissue fibrosis, previous surgery, or previous radiation therapy in the area of the implant may preclude implantation of a cuff at the bulbous urethra or bladder neck.
5. Any progressively degenerative disease, e.g. multiple sclerosis, may limit the future usefulness of the implanted prosthesis as a treatment for the patient's urinary incontinence.

6. Adequate manual dexterity, strength, motivation, and mental acuity are required for proper use of the device.

7. Trauma or injury to the pelvic, perineal or abdominal areas, such as impact injuries associated with sports, can result in damage to 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. The physician should advise patients of these possibilities and warn them to avoid trauma to these areas.

8. Consideration should be given to the diameter of the implanted occlusive cuff relative to catheters or other transurethral devices. When fully deflated, the inside diameter of the smallest occlusive cuff (3.5cm) generally exceeds 28F. Additional clearance is required to accommodate the patient's urethral tissue between the trans-urethral device and the occlusive cuff. Urethral tissue thickness is patient specific and requires a physician's assessment to determine its impact on sizing.

InhibiZone™ Related

1. 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.

2. Patients who receive a device with InhibiZone and are also taking methoxyflourane should be carefully monitored for signs of renal toxicity.

3. 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.

4. 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.

5. 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.

6. 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.

7. InhibiZone does not replace your normal antibiotic protocols. Continue using any prophylactic protocols normally used for urological surgical procedures.

8. Because products with InhibiZone are 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 this device, although systemic levels of minocycline HCl and rifampin in patients receiving this device are unlikely to be detected.

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 may result from improper surgical technique, improper sterile technique, anatomical misplacement of components, improper sizing and/or filling of components.
4. Although reinforced tubing has been designed to be more resistant to tubing kinks, tubing kinks may still result from tailoring the connecting tubing to an improper length during the implant procedure.

Device Related

1. 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.
2. 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: bladder spasms, bleeding, contracture, deep vein thrombosis, delayed wound healing, difficult activation, difficult deactivation, dysuria, edema, exposure to biohazardous material, extrusion, fibrosis, fistula formation, foreign body/unretrieved device fragment, hematoma, hematuria, herniation, herniation of the device, hydrocele, impaired device function, infection, limited urethral coaptation, migration, nerve injury, overactive bladder, pain/discomfort, patient dissatisfaction, perforation, positional incontinence, recurrent incontinence, swelling, tissue erosion, tissue erosion/infection, urethral atrophy, urethral injury, urethral stricture, urge de novo, urinary retention, wound dehiscence, wound infection.

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

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

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