AMS Ambicor™ Penile Prosthesis

Prescriptive Information

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

Indications

The AMS Ambicor 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.

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.

Precautions

Surgery Related

1. Spontaneous unintended inflation or deflation of the cylinders may occur and may result in unintended partial or full erections.

2. Migration of the device components can occur if the cylinders are improperly sized, or if the pump is not positioned properly.

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.

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5. Unsuccessful outcomes have been reported due to improper surgical technique, anatomical misplacement of components, improper sizing of components, or tubing kinks.

Device Related

1. 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.

2. Do not use product that has damaged or open packaging, as sterility may be compromised.

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 area, 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 implantation of this device should only be considered in patients whom the physician determines are adequate surgical candidates.

Potential Adverse Events

The following events occurred during this clinical study but were classified by the Investigators as not related to the device or the implantation surgery: urethral stricture (9 cases), prostate cancer (4 cases), BPH (3 cases), incontinence (3 cases), urinary retention (3 cases), urinary tract infection (3 cases), abnormal prostate exam/PSA (2 cases), abnormal sexual function (2 cases), balanitis (2 cases), hematuria (2 cases), pain (2 cases), renal calculus (2 cases), abnormal ejaculation (1 case), bladder instability (1 case), bladder spasms (1 case), blood in urine (1 case), dysuria (1 case), edema (1 case), epididymal cyst (1 case), eroded artificial sphincter (1 case), erythema (1 case), infection (1 cases), inguinal hernia (1 case), nocturia (1 case), prostate nodule (1 case), prostatitis (1 case), pyuria (1 case), renal colic (1 case), renal insufficiency (1 case), testicular cyst (1 case), testicular hydrocele (1 case), trichomonas (1 case), urethral mucosal atrophy (1 case), urination impaired (1 case), urgency (1 case), and urosepsis (1 case).

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: genital changes, inguinal hernia, excessive fibrous capsular growth, erosion, abscess, ulceration, necrosis, vascular compromise, ventral chordee, ischemia, immune-related connective tissue disorders, and granulomas.

There were four 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 14 patients underwent revision surgeries in the study. Information on device revisions is described in the “Clinical Studies” section of the Instructions for Use.

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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