Spectra™ Concealable Penile Prosthesis

Prescriptive Information

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

Indications

The Spectra™ Concealable Penile Prosthesis is a sterile, non-pyrogenic, single-use implant that is intended for use in the treatment of chronic, organic, erectile dysfunction (impotence) in men who are determined to be suitable candidates for implantation surgery.

Contraindications

• The implantation of this device is contraindicated in patients who have active urogenital infections or active skin infections in the region of surgery.

• Implantation of this device is contraindicated in patients whose proximal corporal length measurement is less than the proximal rigid section of the Spectra cylinders (5 cm for the 9.5 mm diameter, and 6 cm for the 12 mm and 14 mm diameter).

• Implantation of this device is contraindicated in patients whose total intracorporal length is not within the range of 12 cm to 27.5 cm.

• The implantation of this device is contraindicated in patients whom the physician determines to be poor candidates due to risks associated with open surgical procedures and /or the patient's medical history (physical and mental conditions), or with sensitivity to silicone materials.

• Implantation of the device is contraindicated in patients who require repeated endoscopic procedures.

• Patients who have compromised tissue and as a result cannot withstand constant pressure should not be implanted with a Spectra penile prosthesis.

Warnings

The Spectra prosthesis is designed to be implanted as a pair of matched cylinders. A single implanted cylinder may not be adequate to achieve sexual intercourse and may have an adverse effect on the reliability of the device.

Known and potential complications include, but are not limited to infection, erosion, migration, extrusion, mechanical malfunction, patient dissatisfaction, adverse tissue reaction, allergic reaction, prolonged or intractable pain, urinary obstruction, silicone particle migration, and other complications (e.g., post-operative bleeding, hematoma, penile edema, penile necrosis/gangrene, perforation of the corpora or the urethra, inability to adequately dilate the corpora, incorrect sizing of the implant, and tearing or ripping of the device during or after implantation).

The complications listed above may necessitate surgical revision or removal of the prosthesis.

MH-491201-AA AUG 2017

Product Life

The Spectra Concealable Penile Prosthesis is intended as a prosthetic device which restores to the patient an important physiological function. As with any penile rigidity implant, this device is subject to wear and eventual failure over time. It is not possible to predict how long an implanted prosthesis will function in a particular patient.

Patients should be advised that the implant is not considered a lifetime prosthesis and additional surgery for replacement and removal may be necessary.

Currently, there is no data on the revision rate for this device. However, in a study of the Dura II penile prosthesis (similar to this device), the revision rate was reported as 5.1% after two years post-implant for 196 patients. There were no mechanical failures reported.1

Mechanical Malfunction

Product wear, mechanical, or performance malfunctions may occur that could render the prosthesis inadequate for sexual intercourse or concealment. Malfunctions may include fracture of the prosthesis, difficulty or changes in the ability to position the prosthesis, changes in rigidity or column strength of the prosthesis, or breach of the outer silicone layer which may lead to surgical intervention or removal of the prosthesis.

Mechanical events should be evaluated carefully by the treating physician and the benefits and risks of treatment options, including revision surgery, should be considered.

Infection

As with any surgical implantation, the surgery required to implant this device can result in infection. Men with existing medical conditions such as diabetes, spinal cord injuries, open sores or skin infections in the region of the surgery, or urinary tract infections may increase the risk of prosthetic-associated infections.

Appropriate measures should be taken to reduce the likelihood of infection, such as use of sterile techniques and appropriate antibiotic prophylaxis. The patient should be monitored for infection and treated appropriately.

Infection that fails to respond to antibiotic therapy may result in removal of the prosthesis. Implantation of a new device may be contraindicated at the time of removal for infection.

Infection followed by explantation of the device may result in scarring, which may make subsequent re-implantation more difficult.

Erosion

Erosion, which is the breakdown/disruption of tissue planes adjacent to the device, can occur with the device. Erosion may be caused by infection, pressure, improper sizing, tissue damage, and cylinder misplacement. The most frequently reported sites associated with cylinder erosion are the glans, the urethra, or the skin. In any case of erosion, the physician must evaluate and decide whether repair and/or removal is necessary.

Failure to timely evaluate and treat the erosion may result in a substantial worsening of the condition leading to infection and loss of tissue.

Migration

Migration is the movement or displacement of components within the space in which they were implanted and can result in surgical revision, pain, psychological/medical complications (such as floppy glans), or device malfunction.

Migration can occur if the cylinders are improperly sized.

Silicone

This device is composed of a number of materials, including solid silicone elastomers. Silicone gel is not a component in the materials of this device.

Silicone elastomers have been commonly used in a variety of biomedical devices for over 40 years and are used as a biocompatibility reference against which new materials are tested.

Scientific literature has included reports of adverse events and other observations in patients with implantable silicone devices. As reported, these events/observations indicate “allergic-like” symptoms and in other cases a symptom complex associated with immunological disorders. No causal relationship has been established between these events and silicone elastomers.

There are reports of malignant tumor formation in laboratory animals only, not humans, associated with implants of relatively large size. Many different materials are associated with this effect in animals, silicone elastomers are among them. No such effect has been described in humans.

Extensive testing has been conducted on all materials that comprise the AMS penile prostheses product lines. This testing has indicated no toxicological response attributable to the materials. However, some of the materials caused minor irritation when implanted in animals.

Silicone elastomer particulate shedding and particulate migrations to regional lymph nodes have been reported in the literature on penile implants. There are no known clinical sequelae to this phenomenon.

Revision Surgery

The risk of surgical revision or device removal is common to all devices. Generally, surgical revision or removal of penile prostheses is performed to address other complications.

However, the patient may elect to have the device removed due to patient dissatisfaction unrelated to safety or efficacy. Removal of an implanted prosthesis, for any reason, without timely re-implantation of a new prosthesis may substantially complicate re-implantation or make it inappropriate.

The patient must be informed that a penile prosthesis is subject to wear and that eventual failure is expected over time. It is not considered a lifetime prosthesis. The patient should be made fully aware that additional surgery for replacement and removal may be necessary.

Patient Expectations

Patients should be counseled in order to have a realistic expectation of the physical, psychological, and functional outcome of the implantation of a rigid penile prosthesis.

Implantation of a penile prosthesis may result in penile shortening, curvature, or scarring. The prosthetic erection may differ from the patient's original, natural erection in that it may be shorter, less firm, have less girth, and reduced sensations.

Realistic cosmetic expectations should be communicated to the patient and should include the potential for skin scarring and lack of concealability.

The implantation of a penile prosthesis will not provide rigidity to the glans, and may result in a floppy glans and lack of rigidity of the corpus spongiosum. Penile flaccidity will be less than prior to implantation.

Loss of Latent Erectile Capability

Penile prosthesis implantation may result in the loss of any natural or latent spontaneous erectile capacity.

Device Sizing

Proper sizing of the device is critical to a successful outcome. Improper measurement, inappropriate cylinder size selection, or malpositioning of the cylinders within the corpora cavernosa may result in migration or buckling of the cylinders or reduce cylinder life.

Pain

Device implantation may result in pain at the operative sites during the post-implantation period and during periods of initial use. Cases have been reported of chronic pain associated with device implantation.

Pain with a severity or duration beyond that which is expected in a given patient can be symptomatic of medical complications or mechanical device malfunction, which may lead to medical or surgical intervention. There are also reports of patients without known medical complications who elected to have a functional device removed due to unresolved pain.

Patients should be counseled on expected post-operative course of pain, including severity and duration, to get a sense of the normal healing process.

Surgical Technique

Unsuccessful outcomes have been reported due to improper surgical technique which compromises the integrity of the device (including cuts or abrasions of the device), anatomical misplacement of the device, or improper sizing of cylinders.

Precautions

Surgery Related

Direct contact of surgical instruments to the prosthesis may result in damage, rendering it unsuitable for implantation.

During insertion, **do not** over bend cylinders beyond their natural U-shape as it may damage the prosthesis and shorten its product life.

Do not trim the distal or proximal ends of the cylinders, or the rear tip extenders (RTEs). Trimming will damage the device.

Careful intraoperative sizing is required to ensure proper device operation and to minimize the occurrence of sizing-related complications such as migration and/or extrusion.

Device Related

Implantation of a penile prosthesis that has been in previous contact with or contaminated by body tissue or fluid, regardless of intervening, cleaning, or sterilization, is prohibited.

Spectra RTE Kits, 720170-01 and 720171-01, are **only** compatible with the 9.5 mm diameter Spectra cylinders. **Do not** use them with the 12 mm or 14 mm Spectra cylinders. (See "Spectra Dimensional Specifications" section for details.)

Spectra RTEs, 72404320-4326 and 72404330, are **only** compatible with the 12 mm and 14 mm diameter Spectra cylinders. **Do not** use these RTEs with the 9.5 mm Spectra cylinders. (See "Spectra Dimensional Specifications" section for details.)

Do not stack the Spectra RTEs on each other, with the exception of the 1.5 cm RTE. The internal locking ring of the RTE will not engage with the smooth outer surface of other size RTEs. Improper attachment will result in the RTE disconnecting and/or bulging.

The articulating segments of the Spectra penile implant may produce vibration and/or sound during movement. This is normal and may be detected physically or audibly by some patients.

The total length of RTEs and the proximal rigid section of the cylinders should not extend beyond the penoscrotal junction.

The AMS Sizers are provided non-sterile.

Patient Related

A thorough preoperative consultation between patient and physician should include a discussion of all available treatment options and their risks and benefits.

Adequate patient education is required to ensure safe, effective patient use.

Uncircumcised patients may have an increased risk of post-operative complications with the sub-coronal approach. Surgeons may wish to discuss performing a circumcision to reduce the risks of post-operative complications associated with this approach.

Patients must have sufficient strength and/or dexterity to position the device.

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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