AdVance™ Male Sling System

Prescriptive Information

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

Indications

The AdVance Male Sling System is intended for the placement of a suburethral sling for the treatment of male stress urinary incontinence (SUI).

Contraindications

Contraindications associated with the use of the AdVance Male Sling System include:

• Patients with urinary tract infections.

• Patients with blood coagulation disorders.

• Patients with a compromised immune system or any other condition that would compromise healing.

• Patients with renal insufficiency and upper urinary tract relative obstruction.

Warnings and Precautions

General

• Only physicians who have been trained as to its use should use the AdVance Male Sling System.

• The AdVance Male Sling System must not be re-sterilized or re-used.

• Inspect the packaging for visible damage prior to use. Any damage to the sterile barriers renders the device non-sterile.

• Do not use product beyond the indicated expiration date.

• Only the innermost pouch may be introduced into the sterile field.

• The implantation of this device should only be considered for patients whom the physician determines are appropriate surgical candidates.

• The risks and benefits of using the AdVance Male Sling System procedure on patients with blood coagulation disorders should be carefully considered.

• The risks and benefits of using the AdVance Male Sling System procedure on patients with compromised immune systems or any other conditions that would compromise healing should be carefully considered.

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• The risks and benefits of using the AdVance Male Sling System procedure on patients with renal insufficiency and upper urinary tract obstruction should be carefully considered.

• Physicians should be familiar with surgical procedures and techniques involving non-absorbable meshes before using the AdVance Male Sling System device.

• Good surgical practice should be followed for management of contaminated or infected wounds.

• Urinary tract infection should be treated prior to implantation.

• The possibility of urgency incontinence should be carefully considered before a sling implant is conducted.

• It is recommended that good bladder function (bladder capacity >250ml and post void residual urine <50 ml) be demonstrated by candidates for a male sling.

• It is recommended that the presence of bladder neck or urethral strictures be ruled out for male sling candidates.

• It is recommended that a condition involving cystitis, urethritis or prostatitis be ruled out for male sling candidates.

• It is recommended that detrusor instability of a neurological origin be ruled out for male sling candidates.

• A 6 month period of non-invasive treatment (e.g., behavior modification, bladder exercises, biofeedback, extra corporeal magnetic stimulation of the pelvic floor, or drug therapy) is recommended before a sling implant is considered for males with stress urinary incontinence.

• Acute inflammatory tissue reaction and transitory local irritation has been reported with the use of the absorbable suture.

Procedural

• Check for bleeding and pelvic organ dysfunction due to intra-operative vessel or nerve damage associated with anomalous location, during needle passage through the medial area of the obturator foramen membrane.

• Do not insert the AdVance Male Sling System needles with an approach that deploys the needle from the perineum to the obturator.

• It is important to verify the tension and placement of the sling prior to closure.

• Take care to avoid vessel perforation. Observe patient for any signs of retropubic or periurethral bleeding.

• The correct use of the device should avoid perforation of the urethra, bladder or bowel during needle placement.

• Do not remove the plastic sheath until the sling is in its desired position.

• Do not contact the sling with any staples, clips, or other instruments, which may damage the mesh.

Post Procedure

• If subsequent infection occurs, the entire sling may have to be removed or revised.

• After several (2-3) weeks post-implant, the mesh becomes fixated by in-growth of surrounding tissues and cannot be entirely removed. However, the urethral repositioning may be reversed by cutting through the center of the mesh to release the tension.

• Patients should be counseled on abstaining from heavy lifting, strenuous exercise, and intercourse for a minimum of 6 weeks. Patients may return to other normal daily activities at the physician's discretion, often one to two weeks post procedure.

• If dysuria, bleeding, or other problems occur, the patient should be instructed to call the surgeon immediately.

Device Related

• Do not open the secondary compartment of the external pouch. It contains a drying agent (desiccant) that is included as part of the pouch packaging and is not for use with the device. Open the external pouch from the end with the angled, peelable seal only.

• Do not re-sterilize or re-use this device. The AdVance Male Sling System is intended for single use only. No portion of this device is reusable.

• Non-functional instruments should not be used and should be returned to AMS.

• Do not use any part of the AdVance Male Sling System beyond the indicated expiration date.

Do not use the AdVance Male Sling System if the package is opened or damaged, as sterility may be compromised.

• To maintain sterility, only the innermost package of the sling should be introduced into the sterile field.

• Store the AdVance Male Sling System in a clean, dry, area away from direct sunlight and at room temperature.

Adverse Events

• As with all implants, local irritation at the wound site and/or a foreign body response may occur.

• Tissue responses to the implant could include extrusion, erosion through the urethra or other surrounding tissue, migration of the device from the desired location, fistula formation and inflammation. The occurrence of these responses may require removal of the entire sling.

• Like all foreign bodies, the sling may allow an existing infection to propagate.

• Incorrect sling tension may cause temporary or permanent lower urinary tract obstruction and retention.

Known risks of surgical procedures for the treatment of incontinence include allergic reaction, bleeding, device migration, erosion, exposure to biohazardous material, hematoma, infection, injury (urethra, corpus spongiosum, nerve), malposition, pain, pelvic organ dysfunction, perforation, prolonged procedure, scar tissue, toxicity, unretrieved device fragment, and complete failure of the procedure, resulting in incontinence and mild to moderate urinary incontinence due to incomplete support or overactive bladder.

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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