argus

adjustable system

PATIENT INFORMATION LEAFLET

Information only applicable for Australia

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DESCRIPTION

ARGUS is a permanent implant with two polydimethylsiloxane elastomer fixation arms made up of two regions, a lower smooth circular region and an upper region with multiple conical subunits, and a central radiopaque pad made of the same elastomer foam. This pad supports the bulbar urethra producing its coaptation passively and during stress. The system includes one pair of radiopaque rings (washers), also made of polydimethylsiloxane elastomer, which are placed in the fixation arms to adjust (tighten and loosen) the implant.

INDICATION FOR USE

ARGUS Adjustable System (KIT-M-01b) is used as a permanently implanted urethral support in men to treat stress urinary incontinence due to Intrinsic Sphincter Deficiency (e.g., after radical prostatectomy or transurethral resection of the prostate).

WARNINGS

The product should be used only by surgeons familiar with implantation procedures and techniques.
It must be used cautiously in diabetic patients.
It must be used cautiously in patients where the fascia of the rectus abdominis muscle is damaged or do not offer enough resistance.

When passing the needle, blood vessels, the bladder, intraperitoneal organs or nerves may be perforated or injured, which may require another surgical intervention for proper repair.
A cytoscopic check must be performed to ensure that the urethra and bladder are not injured and to rule out perforation after passing needles.
Adequate precautions must be taken to avoid contamination during the surgical procedure.
Like any foreign body, the implant may potentiate an existing infection.

MAGNETIC RESONANCE (MR) ENVIRONMENT

The implant does not affect and is not affected by magnetic resonance (MR) environments.

POSSIBLE COMPLICATIONS

The use of the implant may result in complications associated with the methods used during the surgical procedure, and/or complications that stem from the patient's level of intolerance to any foreign body implanted in the human body.
Some complications may require complete or partial removal of the implant.
Infections that do not respond to antibiotic treatment require the removal of the implant with the resulting recurrence of preoperative urinary incontinence.

Some patients may feel suprapubic, inguinal and perineal pain during the immediate postoperative period. Treatment with ANALGESICS and ANTIINFLAMMATORIES may be enough to relieve pain.

Complications reported with this or other implants include:

- Incision infection, including secondary necrosis.
- Incomplete control of postoperative urinary incontinence.
- Urethral erosion.
- Urinary fistula.
- Numbness.
- Suprapubic pain.
- Inguinal pain.
- Perineal pain.
- Urinary, purulent, serous, or bloody discharges.
- Suprapubic inflammation.
- Inguinal inflammation.
- Perineal inflammation.
- Injury to neighboring organs (vessels, nerves, bladder, etc.)
- Bladder instability.
- Osteomyelitis
- Urinary retention.
- Dysuria.

The postoperative formation of a fibrous tissue capsule around the implant is a normal physiological response to the implantation of a foreign body.

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INFORMATION FOR PATIENTS

Before surgery, the surgeon is responsible for informing patients or authorized persons about possible complications.
It is advisable that patients avoid lifting heavy weights or doing intense exercise involving effort (cycling, running, horseback riding, sexual intercourse, etc.) during the first six weeks after surgery.
The patient must contact the surgeon or the team that performed the surgery immediately in the event of:

- Dysuria (difficult or painful urination).
- Suprapubic, inguinal or perineal pain.
- Fever.
- Urinary, purulent, serous, or bloody discharges.
- Hemorrhages or other problems.

The implant allows post-surgery adjustment.

IMMEDIATE POST-OPERATIVE CARE

- A post surgery catheter may be used based on the surgeon's criteria.
- Antibiotic prophylaxis should be administered.
- Confirm the patient's ability to empty the bladder.
- Pain medication may be prescribed for short term pain management.

Any serious incident that occurs in relation to the device should be reported to Promedon: www.promedon-urologypf.com and to the Therapeutic Goods Administration: www.tga.gov.au

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