Rigicon®
American Urological Solutions

ContiClassic® Artificial Urinary Sphincter Safety Information

Indications

ContiClassic® Artificial Urinary Sphincters (AUS) is used to treat urinary incontinence due to intrinsic sphincter deficiency in cases such as incontinence following prostate surgery.

Causes of Urinary Incontinence:

• Changes with age

• Enlarged prostate

• Prostate Cancer

• Obstruction

• Neurological disorders

Contraindications

The ContiClassic® AUS is contraindicated in patients with:

• Urinary incontinence due to or complicated by an irreversibly obstructed lower urinary tract.

• Irresolvable detrusor hyperreflexia or bladder instability.

• In patients whom the physician determines to be poor candidates for surgical procedures and/or anesthesia due to physical or mental conditions.

• Known sensitivity to silicone rubber.

• Acute urinary tract infection which may lead to post-operative complications.

Warnings

• 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.

• 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.

• Poor bladder compliance or a small fibrotic bladder may require some measure of intervention including, in some cases, augmentation cystoplasty before implanting the prosthesis.

• 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.
• 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 device.

• This device contains solid silicone elastomers. The risks and benefits of implanting this device in patients with documented sensitivity to silicone should be carefully considered.

• 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.

• 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 overflow obstruction.

• The implanter should check that there is an adequate amount of spongiosus 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.

Reuse of the single use device may create a potential harm to the user.

Reprocessing, washing, disinfection and /or sterilization of ContiClassic® may compromise product characteristics and cause additional risks of physical harm and / or infection.

Precautions

The implantation of this device should only be considered for patients determined as suitable surgical candidates by the specialized physician.

Physicians implanting ContiClassic® Artificial Urinary Sphincter should be familiar with current practices in patient measuring techniques, implant size determination, and performing the surgery.

Removal of an implanted ContiClassic® Artificial Urinary Sphincter without timely reimplantation of a new prosthesis may complicate subsequent reimplantation or even may make it impossible.

Patient Related

• Patient selection requires thorough preoperative consultation and evaluation by the physician.

• Patients should be counseled in order to have a realistic expectation of the physical, psychological, and functional outcome of the implantation of ContiClassic® AUS. Although the prosthesis is designed to restore urinary control, some patients continue to have a degree of incontinence after this procedure.

• Patients may experience pain when the device is activated in the postoperative period and during periods 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.

• 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.

• 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.

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

• 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 prosthesis. The physician should advise patients of these possibilities and warn them to avoid trauma to these areas.

• Consideration should be given to the diameter of the implanted occlusive cuff relative to catheters or other trans-urethral 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.

Surgery Related

• Proper surgical technique, proper sizing, filling and anatomical placement of the device components are vital for successful outcomes.

• The device should be carefully examined prior to and during the surgical procedure to ensure the structural integrity of the device is not compromised. A damaged device or a device on which repairs have been attempted should not be implanted.

• Improper reservoir placement or filling technique can result in spontaneous unintended inflation or deflation of the cylinders that may result in unintended partial or full erections.

• Improperly sized cylinders, improper positioning of the pump or the reservoir, or incorrect tubing lengths can result in migration of the reservoir or the pump.

• Prostheses of incorrect length may result in voiding difficulties, inflammation, pressure necrosis and erosion into the urethra or through the tunica albuginea of the corpus cavernosum, SST deformity, buckling of the cylinders.

• Cylinder life may be reduced due to improper measurement technique, positioning or sizing.

• NarrowBody™ cylinders should only be used in patients with compromised corpora cavernosa and smaller anatomies. Do not use narrow cylinders in patients with normal anatomies.

• Extreme care should be taken when manipulating the device with blunt instruments and device components should not be handled with sharp-cornered instruments to avoid tearing, warping or nicking.

• Surface contaminants (e.g. talc, lint, fingerprints) can cause foreign body reactions. Contaminants should be avoided with utmost care. Any nick or split in the device creates a potential for mechanical failure and can serve as a collection point of debris which could cause foreign body reactions or be a locus for infection.

Device Related

• Improper cuff sizing, improper balloon selection, or other causes may result in tissue erosion, migration of components, or continued incontinence.

• 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.

• Unsuccessful outcomes may result from improper surgical technique, improper sterile technique, anatomical misplacement of components, improper sizing and/or filling of components.

• 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

• Use sterile, isotonic or normal saline to fill the implant. Some patients may have a hypersensitivity to contrast media.

• The components of this device are manufactured and tested for assembly/use with their specified Rigicon® devices. The use of Rigicon® components with other manufacturers' components has not been tested and is not recommended.

• Do not use product with damaged or open packaging, as sterility may be compromised.

• Due to the hydrophilic coating on all components of ContiClassic® will be slippery when wet and care should be taken when handling them.