Rigicon®

Innovative Urological Solutions

ContiReflex®

Artificial Urinary Sphincter

Instructions for Use

℞ ONLY

Symbols on Label

	Manufacturer Information
	The authorized representative in the European Community.
	Date of Manufacture
	Use by YYYY-MM-DD
	LOT Number
	Do Not Reuse
	Do Not Resterilize
	Sterilized Using Ethylene Oxide
	Consult Instructions for Use
	Prescription
	Caution
	Do not use if package is damaged
	Temperature limit
	Keep dry
	Keep away from sunlight
	CE Mark

EC-REP Information:

Rigicon B.V:

Saturnusstraat 46-62, 2132 HB Hoofddorp, Netherlands

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ContiReflex®

Artificial Urinary Sphincter

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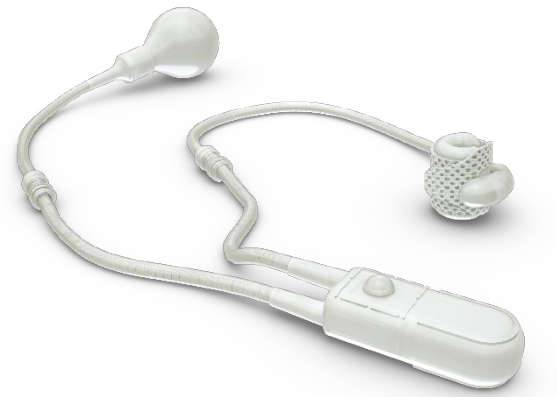
CAUTION: Federal law restricts this device to sale by or on the order of a physician.

NOTE: Please refer to the *Operating Room Protocol* for further information on the implantation of ContiReflex® Artificial Urinary Sphincter.

Device Description

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

ContiReflex® is a self-contained, fluid-filled system that consists of an occlusive cuff, a control pump and a pressure regulating balloon. The cuff can be placed around either the bladder neck or bulbous urethra. The occlusive cuff is attached to a control pump, which is placed in the patient's scrotum, and the control pump is connected to a pressure regulating balloon that is implanted underneath the abdominal muscles of the patient. The pressure regulating balloon is filled with sterile saline solution. All components are connected via kink-resistant tubes, responsible for the fluid distribution, and the EasyClick™ connectors.



Conti® Artificial Urinary Sphincter

ContiReflex® AUS has been developed to maintain continence by simulating the function of the urethral sphincter. The device keeps the urethra closed with the help of the urethral cuff and prevents the passage of urine. The pressure in the cuff is regulated by the Pressure Regulating Balloon(PRB). Patient deflates the occlusive cuff by squeezing the control pump located in the scrotum. The repeated squeezing of the control pump transfers the fluid inside the cuff to the Pressure Regulating Balloon, leaving the cuff empty and consequently allowing voiding. The occlusive cuff re-inflates through the slow bleed valve to keep the urethra closed.

All components of ContiReflex® incorporate a hydrophilic coating (HydroShield™) on the external surfaces. HydroShield™ offers the physicians the freedom to choose their preferred aqueous solution and facilitates the rapid and strong absorption of the solution on the device and may promote easier device implantation.

ContiReflex® Artificial Urinary Sphincter Models

Conti® Artificial Urinary Sphincter has two models; ContiClassic® Artificial Urinary Sphincter and ContiReflex® Artificial Urinary Sphincter. ContiReflex® model offers additional intra-abdominal pressure regulation via its novel pressure-regulating balloon and control pump design. ContiReflex® AUS is available with Occlusive Cuffs in a variety of sizes ranging from 3.5 cm to 13 cm. There are two Occlusive Cuff models which are specified as Regular and Angled. The angled occlusive cuff model has the ability of angled belting the bulbous urethra by this way ambient pressure and belting process of the urethra are properly provided. ContiReflex® has its own specific control pumps and pressure-regulating balloons.

Product Code	Product Name
CTR-PRB49	ContiReflex® Pressure Regulating Balloon 40 – 49 cm H_20
CTR-PRB59	ContiReflex® Pressure Regulating Balloon 50 – 59 cm H_20
CTR-PRB69	ContiReflex® Pressure Regulating Balloon 60 – 69 cm H_20
CTR-PRB79	ContiReflex® Pressure Regulating Balloon 70 – 79 cm H_20
CTR-PRB89	ContiReflex® Pressure Regulating Balloon 80 – 89 cm H_20
CTR-OC35	ContiRegular® Occlusive Cuff 3.5 cm
CTR-OC375	ContiRegular® Occlusive Cuff 3.75 cm
CTR-OC40	ContiRegular® Occlusive Cuff 4.0 cm
CTR-OC425	ContiRegular® Occlusive Cuff 4.25 cm
CTR-OC45	ContiRegular® Occlusive Cuff 4.5 cm
CTR-OC475	ContiRegular® Occlusive Cuff 4.75 cm
CTR-OC50	ContiRegular® Occlusive Cuff 5.0 cm
CTR-OC55	ContiRegular® Occlusive Cuff 5.5 cm
CTR-OC60	ContiRegular® Occlusive Cuff 6.0 cm
CTR-OC65	ContiRegular® Occlusive Cuff 6.5 cm
CTR-OC70	ContiRegular® Occlusive Cuff 7.0 cm

CTR-OC75	ContiRegular® Occlusive Cuff 7.5 cm
CTR-OC80	ContiRegular® Occlusive Cuff 8.0 cm
CTR-OC85	ContiRegular® Occlusive Cuff 8.5 cm
CTR-OC90	ContiRegular® Occlusive Cuff 9.0 cm
CTR-OC95	ContiRegular® Occlusive Cuff 9.5 cm
CTR-OC100	ContiRegular® Occlusive Cuff 10 cm
CTR-OC110	ContiRegular® Occlusive Cuff 11 cm
CTR-OC120	ContiRegular® Occlusive Cuff 12 cm
CTR-OC130	ContiRegular® Occlusive Cuff 13 cm
CTA-OC35	ContiAngled® Occlusive Cuff 3.5 cm
CTA-OC375	ContiAngled® Occlusive Cuff 3.75 cm
CTA-OC40	ContiAngled® Occlusive Cuff 4.0 cm
CTA-OC425	ContiAngled® Occlusive Cuff 4.25 cm
CTA-OC45	ContiAngled® Occlusive Cuff 4.5 cm
CTA-OC475	ContiAngled® Occlusive Cuff 4.75 cm
CTA-OC50	ContiAngled® Occlusive Cuff 5.0 cm
CTA-OC55	ContiAngled® Occlusive Cuff 5.5 cm
CTA-OC60	ContiAngled® Occlusive Cuff 6.0 cm
CTA-OC65	ContiAngled® Occlusive Cuff 6.5 cm
CTA-OC70	ContiAngled® Occlusive Cuff 7.0 cm
CTA-OC75	ContiAngled® Occlusive Cuff 7.5 cm
CTA-OC80	ContiAngled® Occlusive Cuff 8.0 cm
CTA-OC85	ContiAngled® Occlusive Cuff 8.5 cm
CTA-OC90	ContiAngled® Occlusive Cuff 9.0 cm
CTA-OC95	ContiAngled® Occlusive Cuff 9.5 cm
CTA-OC100	ContiAngled® Occlusive Cuff 10 cm
CTA-OC110	ContiAngled® Occlusive Cuff 11 cm
CTA-OC120	ContiAngled® Occlusive Cuff 12 cm
CTA-OC130	ContiAngled® Occlusive Cuff 13 cm
CTC-CP	ContiClassic® Control Pump

CTR-CP	ContiReflex® Control Pump
CT-AK	Conti® Accessory Kit

Indications

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

Contraindications

The ContiReflex® 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.

Patient Population

Male, female, and child patients who experience problems with urinary incontinence may be suitable candidates for ContiReflex® AUS implantation. The patients considered for Conti® AUS should have the manual dexterity required to operate the device. The implantation of this device should only be considered for patients determined as suitable surgical candidates by the specialized surgeon (i.e. urologist).

According to investigated clinical articles and reviews; AUS operations are convenient for 4-17 years old child, under 4-years old child urologist must decide the urinary sphincter incontinence operations.

Precautions

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® and ContiReflex® 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

- 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® and ContiReflex® will be slippery when wet and care should be taken when handling them.
- If the deactivation valve is closed when the cuff is inflated, fluid cannot transfer from the cuff to the balloon and sustained outflow obstruction may arise as a result:
    - In the event of large pressures within the bladder, automatic pressure relief that normally occurs with the device would be prevented. Cycling the device can relieve the outflow obstruction.
    - Cycling the device may be difficult if deactivation occurs when the pump bulb is deflated. If unable to cycle the prosthesis, squeezing the sides adjacent to the deactivation button will allow fluid to fill the pump bulb and then the pump can be cycled normally.
    - Release of the deactivation valve may require greater pressure than that used to cycle the device.

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. Appropriate measures should be taken to reduce the likelihood of infection. Infection that fails to respond to antibiotic therapy may result in removal of the prosthesis. Infection followed by explantation of the device may result in scarring which may make subsequent reimplantation more difficult.
- 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. Failure to evaluate and promptly treat the erosion may result in a substantial worsening of the condition leading to infection and/or loss of tissue.
- 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. The timing of reimplantation should be determined by the treating physician based on the patient's medical condition and history.
- 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. Mechanical events should be evaluated carefully by the treating physician and the patient should consider risks and benefits of treatment options, including revision surgery.
- Previous patient history of adverse reaction(s) to radiopaque solution precludes its use as a filling medium for the prosthesis. Instead, saline should be used to fill the device.
- The implanter should check that there is an adequate amount of spongiosis muscle to surround and support a bulbous urethral cuff implant. A 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. This warning is especially important for double cuff implants, where the second cuff is placed distal to the first implanted cuff.

Post-operative Warnings for Patients

- Postoperative care is determined by the treating physician. In general, antibiotics are administered intravenously for 48 hours and oral antibiotics are given for 5 days after discharge from the hospital.
- The device system must be left in the deactivated mode for four to six weeks following implantation. The device is not further activated until scrotal oedema and pain have subsided. In patients with prolonged scrotal oedema or tenderness, this maneuver has been delayed indefinitely without adverse functional or cosmetic results.
- The device system must be left in the deactivated mode for four to six weeks following implantation. This helps prevent the normal capsule formation from hindering balloon inflation when the prosthesis is operated, and helps prevent auto inflation caused by the capsule. Postoperative care and instructions should be discussed with and understood by the patient prior to surgery.

Adverse Events

The following potential adverse events may be experienced by patients:

- Bladder spasm
- Bleeding,
- De novo urge incontinence
- Deep vein thrombosis,
- Delayed wound healing
- Device malfunction
- Difficult activation
- Difficult deactivation
- Dysuria,
- Edema,
- Explantation
- Extrusion,
- Fibrosis,
- Fistula formation
- Fluid loss due to disruption of a connection
- Haematoma
- Hematuria,
- Herniation of the device,
- Hydrocele,
- Impaired device function,
- Infection
- Limited urethral coaptation,
- Mechanical failure
- Migration
- Nerve injury,
- Overactive bladder,
- Pain/discomfort
- Patient dissatisfaction
- Perforation,
- Positional incontinence,
- Recurrent incontinence,
- Swelling,
- Tissue erosion/infection
- Urethral atrophy
- Urinary retention
- Wound infection

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

How Supplied

WARNING: Contents are supplied STERILE. Do not use if sterile barrier is damaged. If damage is found, please contact Rigicon, Inc.

All components of the system are supplied STERILE and nonpyrogenic in a double-wrap packaging system. Components of the ContiReflex® AUS is sterilized by the following methods:

Product	Sterilization Method	Symbol
ContiReflex® Pressure Regulating Balloon	Ethylene Oxide	STERILE EO
ContiReflex® Occlusive Cuff	Ethylene Oxide	STERILE EO
ContiReflex® Control Pump	Ethylene Oxide	STERILE EO

For single patient use only.

Do not reuse, reprocess or re-sterilize. Reuse, reprocessing or re-sterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or re-sterilization may also create a risk of contamination of the device. After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

Magnetic Resonance Imaging (MRI) Important Safety Information

Non-clinical testing has demonstrated that the ContiReflex® Artificial Urinary Sphincter is MR Conditional.

Patients who have been implanted with the ContiReflex® Artificial Urinary Sphincter can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5 T and 3.0 T
- Maximum spatial field gradient of 720 Gauss/cm or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2.9W/kg for 15 minutes of scanning (i.e. per pulse sequence) (Normal Operating Mode)
- In non-clinical testing, the image artefact caused by the device extends approximately 9mm from the implanted device when imaged with a gradient echo sequence and a 3T MRI system.

Under the scan conditions defined above, the ContiReflex® Artificial Urinary Sphincter is expected to produce a maximum temperature rise of less than or equal to 2.0˚C after 15 minutes of continuous scanning (i.e. per pulse sequence). MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the ContiReflex® Artificial Urinary Sphincter. Therefore, optimization of MR imaging parameters to compensate for the presence of this device may be necessary. If you have further questions about the compatibility of the prosthesis and the MRI, please contact the Rigicon, Inc. Company or e-mail operations@rigicon.com.

Storage

Store the device in a clean, dry, dark area at room temperature (0-25°C).

Others (Shelf life and Package)

The shelf life of the product is 5 years. The product may remain implanted over the patient's lifetime until any undesired effects are observed.

The product is supplied to the market in a sealed, double pouch and inside a protective carton box.

The packages of Conti® AUS consists of; ContiClassic®, ContiClassic® WR and ContiReflex® Pressure Regulating Balloon, ContiRegular®, and ContiAngled® Occlusive Cuff, ContiClassic® and ContiReflex® Control Pump and the Conti® Accessory Kit.

ContiClassic® and ContiReflex® Pressure Regulating Balloon, Conti® Occlusive Cuff, ContiClassic® and ContiReflex® Control Pump and the Conti® Accessory Kit are used together.

All components can be marketed separately.

Disclaimer

The manufacturer Rigicon, Inc. reserves the right to make technical or design changes to the device as part of the device's continual improvement process.

Warranty & Product Replacement

In order to activate the warranty of the device, Patient Surgery Form must be filled out and filed with Rigicon, Inc.

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Customers outside the United States and Canada should contact their local Rigicon Representatives.

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