



Rigicon Pty Ltd
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For immediate release

The innovative prosthetic urology portfolio from Rigicon receives marketing approval in Australia

Norwood SA, February 8, 2021

Rigicon Inc., with its global headquarters in NY, USA, announces that their innovative prosthetic urology portfolio received marketing approval from Australia (Australian Government Department of Health Therapeutic Goods Administration)

The following implant options from Rigicon are now available for specialized surgeons and patients in Australia:

- » Infla10[®] Inflatable Penile Prosthesis Models
- » Rigi10[™] Malleable Penile Prosthesis
- » Conti[®] Artificial Urinary Sphincter Models
- » Testi10[™] Testicular Prosthesis Models

With this approval, Rigicon becomes the first medical device solutions provider in the Australian market with a diverse and complete portfolio of men's health treatment options.

Rigicon Australia

Rigicon will carry out its operations directly from its local headquarters located in Norwood, SA, to ensure sustainable access to Rigicon's high-quality treatment options and "customer-first" service mentality.

Rigicon will continue to invest in the Australian Economy by hiring local talent and investing in local facilities.

Rigicon is committed to increasing disease awareness for Erectile Dysfunction and Urinary Incontinence by developing patient-focused online/offline platforms and full cooperation with

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leading scientific communities in the region (i.e., The Urological Society of Australia and New Zealand (USANZ)) and globally. (e.g., American Urological Association and the European Association of Urology)

Infla10® Inflatable Penile Prosthesis Models

Infla10® Three-Piece Inflatable Penile Prosthesis is indicated for patients suffering from organic erectile dysfunction (impotence) and are candidates for penile prosthesis implantation.

Infla10® cylinders are designed for a natural feel in a deflated/flaccid state and satisfactory rigidity in the erected state.

Reinforced with the proprietary 4th layer, Infla10® cylinders offer durability.

Infla10® pump is easy to locate and manipulate, even for patients with limited manual dexterity. The pump requires fewer pumps to make the cylinders rigid and equipped with a single press deflate button for easy deflation.

Infla10® Anatomical Expansion model is the world's only inflatable penile prosthesis model that can offer girth and length expansion and a hydrophilic coating.

Rigi10™ Malleable Penile Prosthesis

Rigi10™ Malleable Penile Prosthesis is designed for the treatment of organic “erectile dysfunction” in men.

Rigi10™ is easy to implant, easy to use, and easy to conceal. The Flexible Rod Technology enables higher bending angles with no spring-backs.

Rigi10™ continues to offer good rigidity and concealment even after repeated cycles of use.

Rigi10™ is offered in 6 different diameters and two sizes for a better fit to the patient's anatomy.

Conti® Artificial Urinary Sphincter Models

ContiClassic® Artificial Urinary Sphincter and ContiReflex® Artificial Urinary Sphincter are implant devices that treat Urinary Incontinence (UI). Conti® Artificial Urinary Sphincter Systems are indicated to treat urinary incontinence due to intrinsic sphincter deficiency in cases such

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as incontinence following prostate surgery. Conti® Artificial Urinary Sphincter Systems are designed to restore the function of the normal (healthy) urinary sphincter that restricts urine flow out of the bladder.

Conti® Artificial Urinary Sphincter Systems offer unique features for the treatment of UI. ContiReflex® AUS offers sophisticated intra-abdominal pressure regulation via its innovative pressure regulating balloon design.

Conti® Artificial Urinary Sphincter Systems are designed to offer robust solutions to conventional AUS systems' physiological and mechanical problems. Both AUS models are designed to reduce urethral erosion and device fluid-loss, the two most common causes of treatment failure.

Conti® Artificial Urinary Sphincter Systems are available in a broad and new range of cuff sizes to offer the best fit to the patient's urethral anatomy.

Additionally, the innovative design of the EasyClick™ Y-connectors will facilitate double occlusive cuff placement for patients with very severe UI.

HydroShield™ Hydrophilic Coating

All components of the **Infla10® Inflatable Penile Prosthesis Models, Rigi10™ Malleable Penile Prosthesis, and Conti® Artificial Urinary Sphincter Systems** are offered with the HydroShield™ hydrophilic coating, giving the physician freedom to choose the aqueous solution for dipping the devices before implantation.

Testi10™ Testicular Prosthesis Models

Testi10™ Testicular Prosthesis Models are indicated for patients diagnosed with testicular agenesis or patients whose testicle or testicles were surgically removed due to several pathologies. The prosthesis is also indicated for replacement.

Testi10™ Testicular Prosthesis has two models: Silicone-filled and Saline-Filled.

Testi10™ Testicular Prostheses are offered in 5 size options.

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About erectile dysfunction

Erectile dysfunction, or ED, is the inability to achieve or sustain an erection suitable for sexual intercourse. ED is a common male sexual disorder and may maintain a permanent course as some men cannot have an erection for the remaining part of their life. ED might have a profound impact on the quality of life and social relationships of the patient.

ED may be caused by various diseases and disorders, including heart disease, diabetes, pelvic area damage due to surgery, accidents or radiation therapy, benign prostatic hyperplasia (BPH, which is a non-cancerous enlargement of the prostate tissue), disorders associated with low testosterone levels, Parkinson's disease, and other neurologic diseases.

According to Healthdirect Australia, It is estimated erectile dysfunction affects about 1 million men in Australia

About inflatable and malleable penile prostheses

A penile prosthesis is a medical device that allows an impotent man to achieve an erection on demand. The inflatable penile prosthesis consists of three components: two inflatable cylinders, a pump, and a reservoir. The malleable implant consists of two rods that are always hard but pliable. All components are concealed within the body and cannot be seen from the outside. The penile implant cylinders/rods reside in the erectile chambers of the penis located on either side. No tissue is removed to place the cylinders/rods; they occupy spaces previously filled with blood when potent. The rods do not disrupt the flow of urine or ejaculate.

The cylinders/ rods do not alter the sensation of the penis.

Penile implant surgery is considered a gold standard therapy for men with erectile dysfunction.

About Urinary Incontinence

Urinary incontinence (UI) is the involuntary loss of urine. Patients suffering from UI are unable to control the release of urine from the bladder. While Stress Urinary Incontinence is the most common type, there are different types of urinary incontinence. Stress urinary incontinence is the unexpected leakage of urine when an outside pressure occurs with heavy lifting, coughing, sneezing, laughing, or exercise. This external pressure causes the already weakened bladder to leak urine.

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Weakened urinary sphincters may be caused by:

- Surgery in the pelvic area or the prostate
- Injury to the urethra
- Medicines
- Being overweight
- Changes with age
- Other causes

Urinary incontinence is a significant problem, affecting tens of millions of patients. UI is estimated to affect 1 out of 10 males, with increasing prevalence associated with aging.

Men with Urinary Incontinence have a higher rate of depression and are more likely to decrease participation in activities (e.g., decrease work hours, change employment, or take voluntary early retirement)

About Artificial Urinary Sphincter

Artificial Urinary Sphincter (AUS) is a medical device specifically designed to treat urinary incontinence. Artificial Urinary Sphincter is a surgical treatment option when non-surgical or behavioral treatment options fail. AUS will mimic a healthy urinary sphincter (the two muscles controlling the exit of urine from the bladder through the urethra). AUS will close the urethra preventing urine leakage. The patient will squeeze a pump located in his scrotum to release the cuff over the urethra and void. The cuff will return to its closed state in around 2 minutes to prevent urine leakage after voiding. The artificial urinary sphincter is widely regarded as the gold standard for the treatment of Urinary Incontinence.

About Rigicon

Rigicon is exclusively focused on designing, manufacturing, and marketing innovative pelvic urology solutions. Our mission is to be the one-stop source for a comprehensive portfolio of products and services and make high quality innovative pelvic urology solutions accessible to all customers.

Find out more at pr@rigicon.com | www.rigicon.com.au | www.rigicon.com

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