VICTO

Adjustable Artificial Sphincter

## ORDERING **INFORMATION**

### Starter Kits

| DESCRIPTION | CUFF SIZE | CODE |
|---|---|---|
| VICTO STARTER KIT 3.7 | 3.7 | KIT-VICTO-37 |
| VICTO STARTER KIT 4.0 | 4.0 | KIT-VICTO-40 |
| VICTO STARTER KIT 4.5 | 4.5 | KIT-VICTO-45 |
| VICTO STARTER KIT 5.0 | 5.0 | KIT-VICTO-50 |
| VICTO STARTER KIT 5.5 | 5.5 | KIT-VICTO-55 |

### Accessories Kit

| DESCRIPTION | CODE |
|---|---|
| VICTO ACCESSORIES KIT | KIT-AC-02 |

victosphincter.com

Magnetic Resonance (MR) Environment
Non-clinical testing has demonstrated that Victo is MR conditional.
A patient with this device can be scanned safely under the following conditions:

MR

- Static magnetic field of 1.5 Tesla and 3 Tesla, with
- Maximum spatial field gradient of 12,800 G/cm (128 T/m)
- Maximum force product of 231 $T^2/m$
- Theoretically estimated maximum whole body averaged (WBA) specific absorption rate (SAR ) of < 2 W/kg (Normal Operating Mode)

Promedon
Urology and Pelvic Floor

Company information: Distribution EMEA & APAC | Promedon GmbH | orders@promedon.com | Phone: +49 8031 900 400 | Fax: +49 08031 900 4040 | An der Alten Spinnerei 5 | 83059 Kolbermoor | GERMANY
**Manufactured by:** PROMEDON S.A. | www.promedon-upf.com

B-31-111(01)/FSD00000317/MAR2022

CE 0197

VICTO

Adjustable Artificial Sphincter

# TAKING THE ARTIFICIAL URINARY SPHINCTER CONCEPT TO **THE NEXT LEVEL**

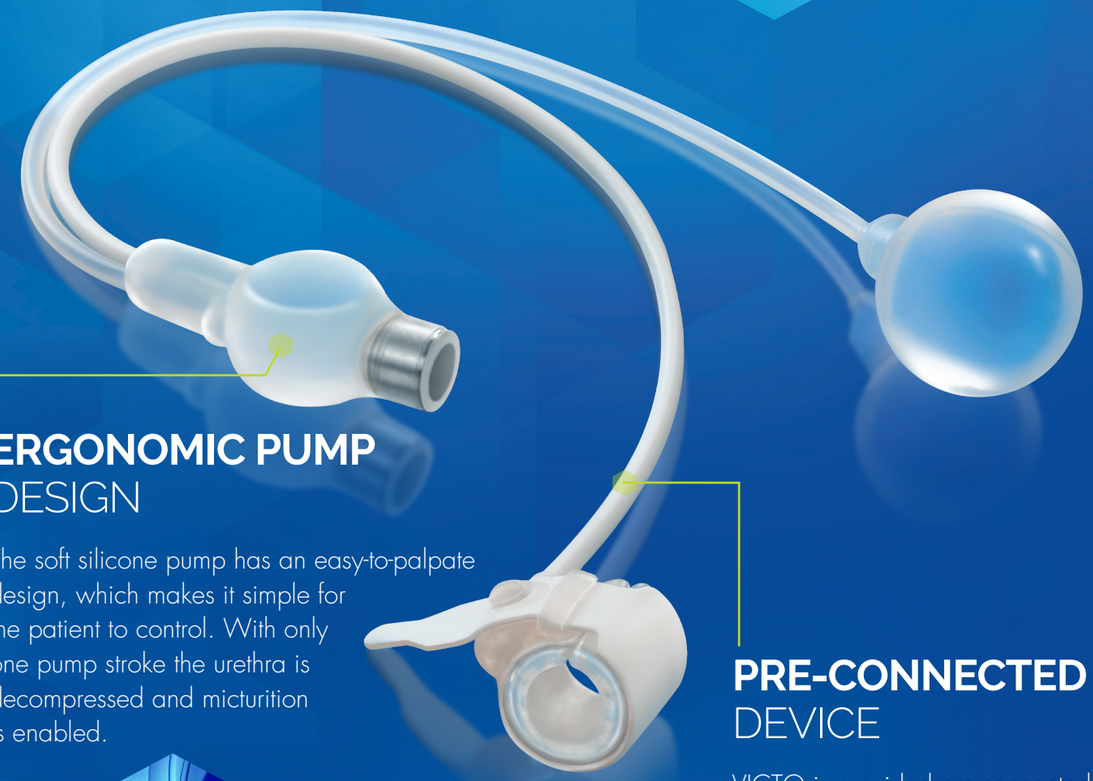
- Minimally invasive adjustment procedure
- Pre-connected device
- Ergonomic pump design

# **VICTO** ARTIFICIAL URINARY SPHINCTER.

VICTO is a preconnected artificial urinary sphincter that enables pressure adjustments with a minimally invasive ambulant procedure.

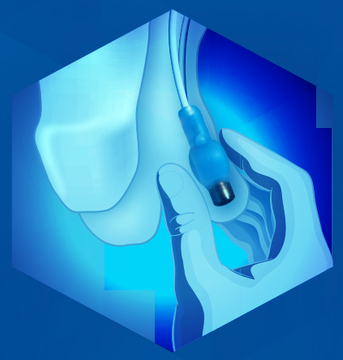
## **MINIMALLY INVASIVE** ADJUSTMENT PROCEDURE

With its unique pump design, the system pressure in VICTO can easily be adjusted through the self-sealing port, in an outpatient and easy-to-perform procedure.



## **ERGONOMIC PUMP** DESIGN

The soft silicone pump has an easy-to-palpate design, which makes it simple for the patient to control. With only one pump stroke the urethra is decompressed and micturition is enabled.



## **PRE-CONNECTED** DEVICE

VICTO is provided pre-connected, ready for filling and implantation.

**VICTO** is available in 5 different cuff sizes, which can be selected intraoperatively using the cuff size selection tape, provided in the Accessories kit.

3.7 CM

4.0 CM

4.5 CM

5.0 CM

5.5 CM

## **ACTIVATION & ADJUSTMENT** PROCEDURE

Preparation during surgery: +13ml

Activation +4ml

Individual adjustments(+1ml), if needed

4-6 weeks

**NEEDLE RECOMMENDATION:**
The usage of a non-coring needle 25G is recommended for the filling or liquid removal procedures performed during the Victo activation, adjustment or deactivation.

## **INTENDED** USE

VICTO is intended for the reestablishment of urinary continence in the defined patient population.

## **INDICATIONS**

VICTO is indicated for the treatment of male stress urinary incontinence.

## **CONTRAINDICATIONS**

- Uncontrolled overactive bladder
- Untreated or irreversible infravesical obstruction
- Impaired cognitive or manual abilities which may affect manual dexterity or motivation, and prevent the patient from operating the device
- Untreated acute urinary tract infection or active infection at the surgical sites or systemic infections (sepsis)
- Known allergy to silicone or titanium
- Patients with stricture/stenotic disease

  Patients whom the surgeon determines to be not suitable due to risks associated with open surgical procedures, and/or with the patients' medical history (physical or mental problems)
- Prior abdominal surgery, status post peritonitis, and other conditions resulting in peritoneal adhesions, fibrosis, scars that could potentially interfere with the correct functioning of the pressure regulating balloon