



Safyre
Adjustable Sling System

ADJUSTABLE SYSTEM POR FEMALE SUI

Promedon
— People + Innovation



ADJUSTABILITY

The **Safyre Adjustable Sling System** has, as a unique feature, a precisely controlled intraoperative and postoperative adjustability (if necessary). Tension adjustments can be performed according to the needs and conditions of each patient.

VERSATILITY

The **Safyre Adjustable Sling System** offers, in its three versions, a complete and easy-to-use surgical kit that facilitates safe, reproducible, and minimally invasive procedures for either a retropubic or transobturator approach.

SOLID CLINICAL SUCCESS

The **Safyre Adjustable Sling System** has been tried in tens of thousands of patients worldwide and achieved a "95% clinical success rate".¹

The Safyre Adjustable Sling System allows the surgeon to optimize the results obtained with conventional polypropylene vaginal tapes, due to its unique feature of postoperative adjustability.

"...the number of women reporting cure of stress leakage was 103 (59%) in the vaginal tape arm..." (British Medical Journal, July 2002 - "Prospective multicentre randomised trial of tension-free vaginal tape and colposuspension as primary treatment for stress incontinence" - Ward, Karen; Hilton, Paul on behalf of the United Kingdom and Ireland Tension-free Vaginal Tape Trial Group).

"The question remains as to what should be done with patients who remain incontinent after vaginal tape surgery..." (European Urology Supplements I (2002), 38-40 - "Stress Incontinence: New developments in the Post-TVT World" - Bart Bemelmans, Unit for Functional Urology, Universal Medical Center, Nijmegen, The Netherlands).

It has been successfully implanted in more than 100,000 patients.²

RELIABILITY

The optimal porosity and density, combined with low elasticity, make the Safyre sub-urethral mesh a very reliable material, offering the best conditions for tissue in-growth and minimizing the risk of erosion and infection.

A reliable mesh and the polydimethylsiloxane elastomer fixation arms make the Safyre Adjustable Sling unique in design and functionality.

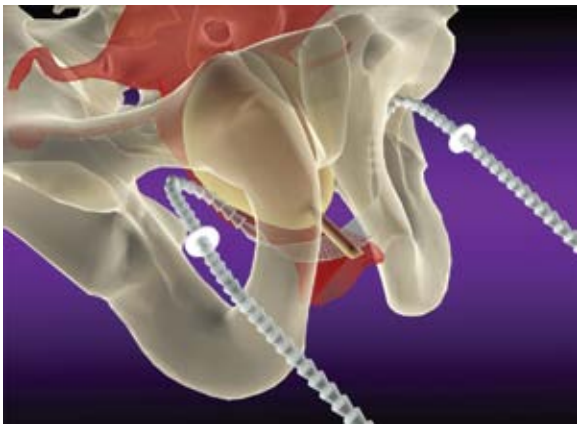
1. Paulo C.R. Palma, Miriam Dambros, Cássio Z. Riccetto, Marcelo Thiel and Nelson Netto Jr. "The Ibero-American experience with a re-adjustable minimally-invasive sling". British Journal of Urology 2005: 95, 341-345.

2. Data on File. Promedon.



FOR TRANSOBTURATOR APPROACH

The Safyre T Plus Adjustable Sling System is the latest step in the evolution of transobturator slings, combining the safety of the transobturator approach and an optimized adjustability.



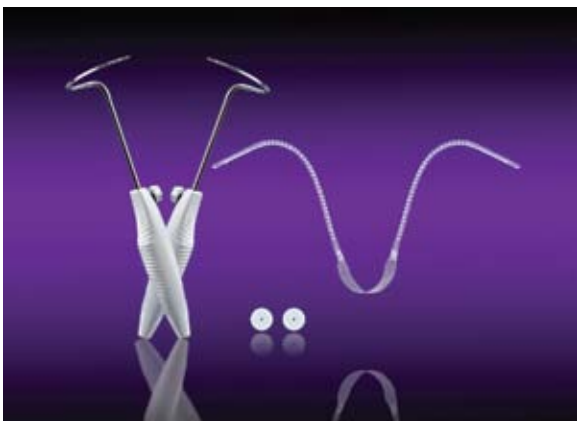
Optimized Adjustability

- The advanced system allows tensioning according to the patient needs. The surgical kit includes rings that help keep the desired tension intra-operatively and, if necessary, postoperatively.



Highly-Evolved Tunneling System

- The anatomically designed tunneling system uses needles with a unique semi-circular design which simplifies surgical movement. The differential diameter -3.25 and 4 mm. facilitates minimal invasiveness and easy handling of the needles during implantation.



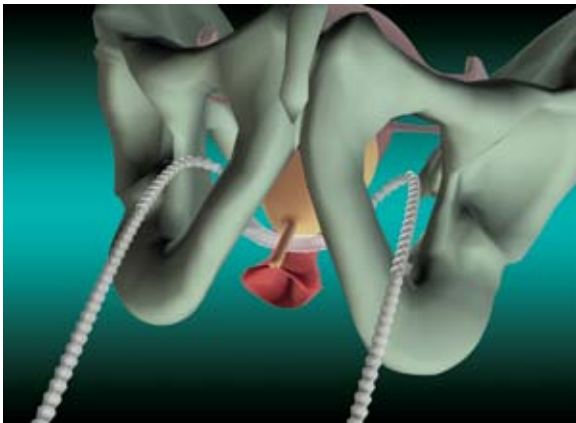
The Safyre T Plus Adjustable Sling System includes:

- 1 Safyre T Plus Adjustable Sling made of a macroporous monofilament polypropylene mesh as a sub-urethral support, connected to two fixation arms made from solid polydimethylsiloxane elastomer. The sling fixation arms are made up of a multiple cone structure.
- 2 Semi-Circular Needles with ergonomic handles. The handles facilitate maneuverability during rotational surgical movements.



FOR TRANSOBTURATOR APPROACH

The Safyre T Adjustable Sling System is the ideal treatment for female stress urinary incontinence through the transobturator approach when a hooked needle is the chosen instrument.



Straight-Forward Procedure

- The Safyre T Adjustable Sling System allows for a fast and straight-forward transobturator procedure.



Ergonomic Needle System

- The System includes one hooked needle to use for both left and right sides in the transobturator approach. The needle enables easy and accurate placement of the sling.



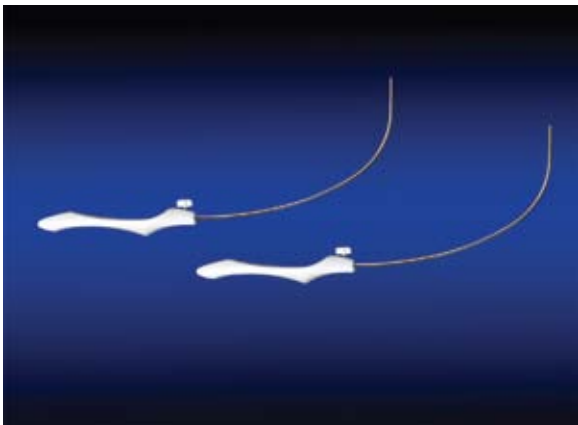
The Safyre T Adjustable Sling System includes:

- 1 Safyre T Adjustable Sling made of a macroporous monofilament polypropylene mesh as a sub-urethral support, connected to two fixation arms made from solid polydimethylsiloxane elastomer. The sling fixation arms are made up of a multiple cone structure.
- 1 Hooked Needle with ergonomic handle. The design of the handle facilitates maneuverability during insertion.



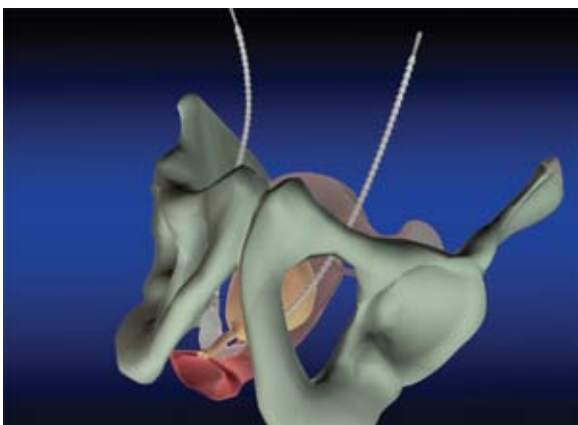
FOR VAGINAL/SUPRAPUBIC APPROACH

When the choice is to use a retropubic sling, the Safyre VS Adjustable Sling System is the best option due to its unique features and versatility.



One System, Two options

- Due to the exclusive needle design, the Safyre VS Adjustable Sling System can be used for either the vaginal or the suprapubic approach. The 3.5 mm pair of needles enables minimally invasive, safe and accurate placement of the sling.



Adjustability

- The Safyre VS Adjustable Sling System allows for an effective coaptation of the urethra due to the "U" location of the implant and the possibility of postoperative adjustments when a tension-free sling is insufficient.



The Safyre VS Adjustable Sling System includes:

- 1 Safyre VS Adjustable Sling made of a macroporous monofilament polypropylene mesh as a sub-urethral support, connected to two fixation arms made from solid polydimethylsiloxane elastomer. The sling fixation arms are made up of a multiple cone structure.
- 2 Curved Needles with ergonomic handles, especially designed for insertion maneuvers.



ORDERING INFORMATION

Safyre T Plus Adjustable Sling System

Order Number: KIT-TP-01

1 Safyre T Plus Sling: S-85-AF

2 T Plus Needles: DPN-HA

2 Pairs of Rings (Washers): AR-TP

Safyre T Adjustable Sling System

Order Number: KIT-T-01

1 Safyre T Sling: S-52-AF

1 T Needle: DPN-TA

Safyre VS Adjustable Sling System

Order Number: KIT-VS-01

1 Safyre VS Sling: S-42-AF

1 Set of VS Needles: DPN-SA



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B-30-27 (02) / 7-Apr-15

