MINIMAL INVASIVE.
UTEROUS SPARING.
SIMPLE. ANATOMICALLY ADVANTAGEOUS.

CONTRAINDICATIONS & PRECAUTIONS

Splentis must not be used in:

- Fertile women
- Women with post-(total) hysterectomy vaginal vault prolapse
- Patients with any active or latent infection of the vagina, cervix or uterus
- Patients with previous or current vaginal, cervical or uterine cancer
- Previous, current or planned pelvic radiation therapy
- Known allergy to polypropylene

The implantation of Splentis should be based on a thorough patient assessment along with the patient's individual characteristics and preferences. The following items must also be considered:

- Splentis must ONLY be used by surgeons experienced in transvaginal pelvic floor reconstruction
- The surgical technique brochure must be read and understood PRIOR to the first implantation of Splentis

For further precautions and warnings, we refer to our Instruction for Use

ORDERING INFORMATION

Splentis
POP TISSUE ANCHORING SYSTEM

Order number: KIT-UT-01

- 1 Reinforcement implant (Ref.: MSAP)
- 1 Dispenser Unit with three Tissue Anchoring Systems (Ref.: TAS)
- 1 Retractable Insertion Guide designed for TAS implantation (Ref.: DPN-MNL)
- 1 Knot Pusher (Ref.: KP)

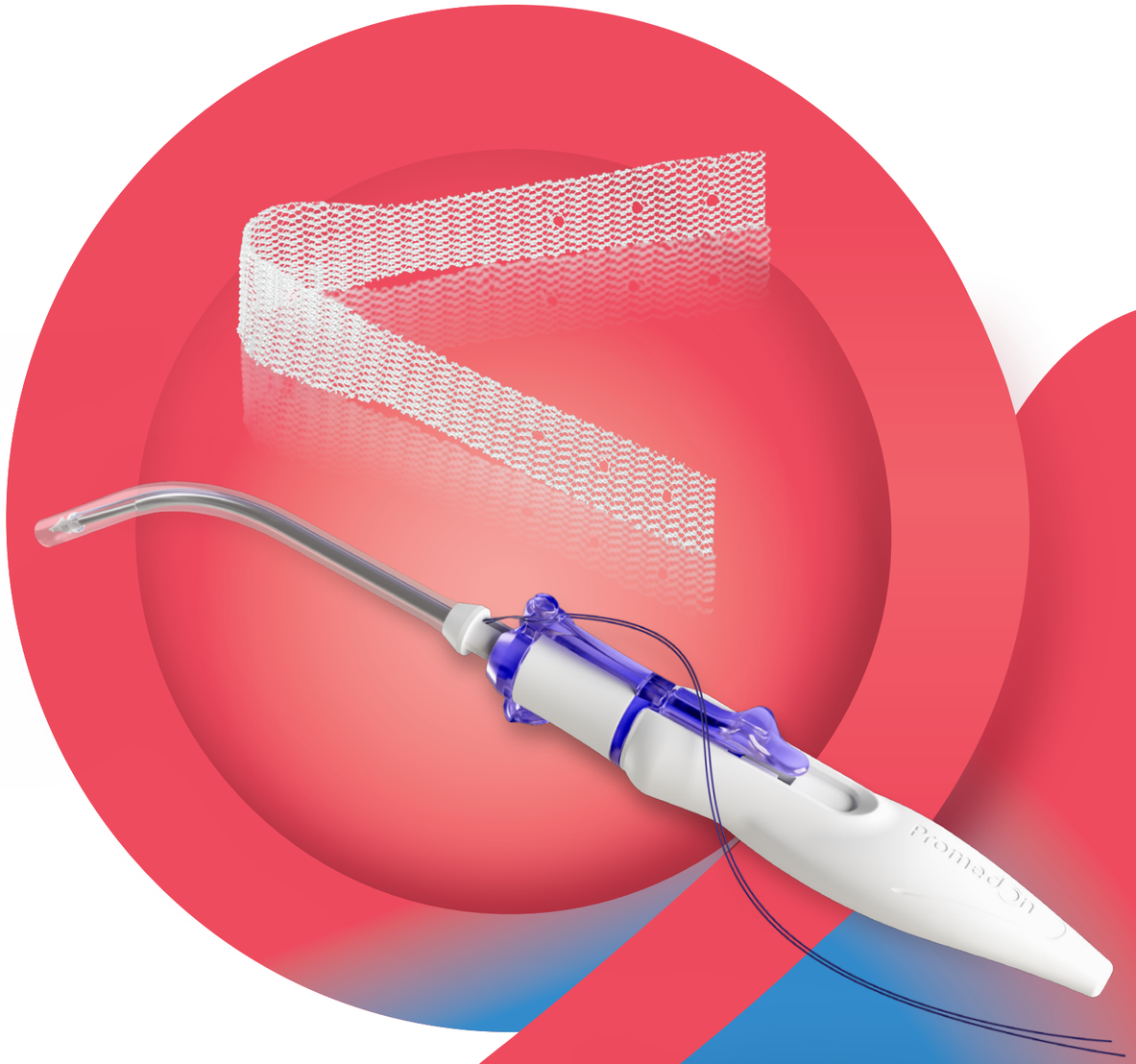
CE 0197 PSD-00000054 (02) / MAR-2024

Promedon
Urology and Pelvic Floor

www.promedon-upf.com

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

Splentis
POP TISSUE ANCHORING SYSTEM



Transvaginal Repair of Apical Pelvic Organ Prolapse

SINGLE INCISION APICAL REPAIR

SPLENTIS is a single incision repair system, indicated for transvaginal bilateral sacrospinous hysteropexy in combination with anterior colporrhaphy of uterine prolapse in non-fertile women [1]. With its sling alike configuration, minimal amount of alloplastic material and the fixation to the anterior supravaginal portion of the cervix, the utilization of Splentis demonstrates excellent treatment success while minimizing adverse events [2,3].

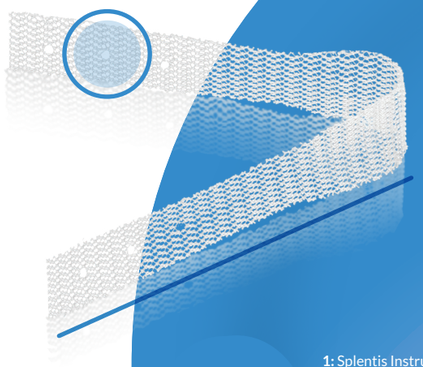
ADVANTAGEOUS ANATOMICAL RESULTS

Splentis provides uterine suspension by bridging the distance between the cervix and the sacrospinous ligaments bilaterally. The apical fixation provides a physiologic, central position while preserving uterine mobility. It proved excellent clinical outcome by simultaneously minimizing the advent of adverse events by avoiding direct contact to the vaginal wall [2].

EFFECTIVENESS AND SAFETY OF HYSTEROPEXY VIA VAGINAL ROUTE

A total of 103 non-fertile women with a median age of 68 years who underwent transvaginal POP repair with Splentis for primary apical POP were enrolled in a monocentric cohort trial. The median time of surgery was 22 minutes and there were no intraoperative complications, particularly no cases of injury to surrounding vessels or organs. An additional anterior colporrhaphy was performed in 102 (99%) patients. After a median follow-up of 17 months the absence of a vaginal bulge symptom was reported by 91 (89.2%) patients and no patient required repeat surgery due to prolapse recurrence, indicating a treatment success in 91 patients. Subjectively, a total of 99 (97.1%) patients reported treatment success. Exposure occurred in three patients (2.9 %), whereas further surgery was mandatory in two patients (1.9%) and one patient (1.4%) presented complete remission by conservative treatment. In conclusion, Splentis can be considered effective and safe in non-fertile women with apical POP [3].

- Lightweight mesh (55-69 g/m²), pore size 117 – 861 µm
- Mesh arms with orientation marks for symmetrical implantation



SPLENTIS REINFORCING IMPLANT

Splentis is composed of biocompatible, lightweight, type 1 (macroporous, monofilamentous) polypropylene. It was developed to provide a physiological anatomical position of the uterus by bilateral sacrospinous fixation through the anterior approach. With its sling alike configuration, Splentis uses the lowest amount of alloplastic material to achieve a reliable physiological apical suspension in a central position.

- Minimal utilisation of foreign material
- No fixation to the vaginal wall
- Descent of the uterus or uterine cervix
- Apical suspension by fixation to the anterior supravaginal portion of the cervix and the sacrospinous ligament bilaterally.

1: Splentis Instructions for Use 2024. **2:** Naumann, G. et. al.: Positive effects of vaginal bilateral hysteropexy with Splentis-tape on prolapse symptoms and quality of life in women with severe pelvic organ prolapse; Geburtshilfe Frauenheilkd 2018, 78(10):219-220.
3: Naumann, G., et al. A novel bilateral anterior sacrospinous hysteropexy technique for apical pelvic organ prolapse repair via the vaginal route: a cohort study. Arch Gynecol Obstet (2022)

TISSUE ANCHORING SYSTEM – TAS

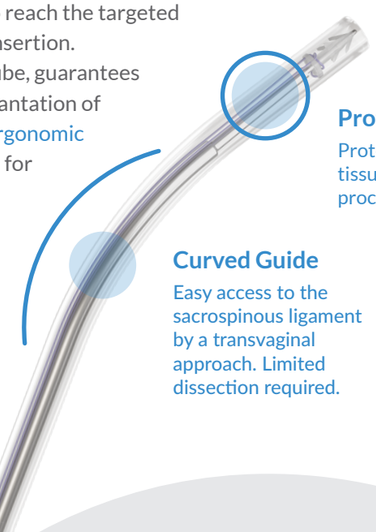
The TAS was developed to provide a reliable fixation to the sacrospinous ligament. The TAS is composed of a polypropylene anchor with an attached polypropylene suture. With its six circumferentially arranged polypropylene spikes and the safety stop at the bottom of the anchor, the TAS provides:

- High pull-out force and accuracy
- Reliable fixation
- Safety with regard to vascular and neural structures, due to the additional protection tube provided for the implantation procedure

RETRACTABLE INSERTION GUIDE – RIG

The Retractable Insertion Guide was developed to reach the targeted area for performing an accurate and safe anchor insertion. The configuration of the RIG, with its protective tube, guarantees the integrity of surrounding tissue during the implantation of the TAS into the sacrospinous ligament. With its ergonomic design, small diameter and retractable mechanism for connecting and releasing anchors, it provides:

- Precision and safety in surgical maneuvers
- Minimal dissection requirement
- Total control of connection and release of TAS Anchors



Protective Tube
Protection of surrounding tissue during implantation procedure

Curved Guide
Easy access to the sacrospinous ligament by a transvaginal approach. Limited dissection required.

Protective tube lock and release mechanism
Easy locking and releasing of the protective tube

Retractable Mechanism
Simple insertion and release of anchor

Ergonomic Handle
Easy and safe handling

SPLENTIS IN DAILY CLINICAL PRACTICE

- Descent of the uterus
- Descent of the uterine cervix after subtotal (supracervical) hysterectomy