

Transvaginal Repair of anterior pelvic organ prolapse

OULTRA-LIGHTWEIGHT MESH

Clinical investigations have demonstrated that higher mesh weight and relatively stiff meshes may cause complications due to the mismatching between mechanical properties of the mesh and pelvic floor _(1, 2). **Calistar S is an innovative mesh for transvaginal repair of anterior pelvic organ prolapse.** The implant is characterized by a macroporous, monofilamentous, ultra-lightweight knitted in the central part of the mesh. With its **ultra-lightweight and flexible design**, its large pore size up to 4 mm and its reinforced frame, Calistar S convinces with superior anatomic outcome and minimized rates of adverse events (4).



OCALISTAR S IN DAILY CLINICAL PRACTICE

- Recurrent anterior compartment prolapse with or without involvement of the apical vaginal wall
- Complex primary anterior compartment prolapse with or without involvement of the apical vaginal wall

TREATMENT FOR RECURRENT & COMPLEX ANTERIOR PELVIC ORGAN PROLAPSE

Calistar S is intended for the transvaginal reestablishment and reinforcement of the physiological anatomy of the pelvic floor. It is intended for non-fertile (3) women with anterior pelvic organ prolapse (POP) with or without involvement of the apical vaginal wall, in both recurrent prolapse or primary POP when other surgical procedures are expected to fail (3).

SAFECTIVENESS AND SAFETY OF ANTERIOR POP REPAIR VIA TRANSVAGINAL ROUTE

A total of 107 non-fertile women who underwent transvaginal POP repair with Calistar S for either recurrent (87%) or complex (13%) anterior POP with a mean follow-up of 19 months were enrolled in a multicenter cohort trial. The average time for Calistar S implantation was only 38 minutes and there were no intraoperative complications. Treatment success was 98% defined by POP-Q \leq 1, and quality of life improved significantly (p < 0.001). Exposure rates were very low (5.6%) and the estimate of exposure-free survival was promising (93% after 36 months). Importantly, none of the patients who developed mesh exposure required further surgery. Furthermore, complications were rare and surgical re-interventions for complications were deniable. In conclusion, Calistar S can be considered effective and safe in women with recurrent or complex anterior POP

1: Roman S, Mangir N, MacNeil S. Designing new synthetic materials for use in the pelvic floor: what is the problem with the existing polypropylene materials? Curr Opin Urol. 2019; 29(4):407-413. /2: Dykes N, Karmakar D, Hayward L. Lightweight transvaginal mesh is associated with lower mesh exposure rates than heavyweight mesh. International urogynecology journal. 2020. /3: Calistar S Instructions for Use 2020. /4: Marschke J, Tunn R, Mörgeli C, Kolterer A, Naumann G. Ultra-lightweight mesh Calistar S for transvaginal mesh repair in recurrent and complex anterior pelvic organ prolapse: a multicenter cohort study. 45th IGUA Meeting – Virtual 2020.

◎ CALISTAR S IMPLANT

The **Calistar S implant** is composed of biocompatible type 1 macroporous, monofilamentous polypropylene with two anterior attachment arms and two posterior mesh arms. With its ultra-lightweight, flexible central part and its reinforced frame, it provides:

- Better tissue integration
- Reliable four-point fixation in order to resist a pull-out force exceeding up to four times the maximum abdominal pressure.
- Repair of the anterior compartment independently of involvement of the apical vaginal wall
- Uterus sparing procedure without increasing the risk for repeated surgery

◎ IMPLANT COMPONENTS

- Outer frame: lightweight (55 69 g/m2), macroporous (117 – 861 μm) polypropylene mesh
- Central mesh: ultra-lightweight (14 18 g/m2), macroporous (1769 – 3985 μm) polypropylene mesh
- Removable polypropylene sutures for correction of the anterior anchor position
- Anterior attachment arms
- Posterior mesh arms

TISSUE ANCHORING SYSTEM TAS

The **TAS** was developed to provide a reliable fixation to the sacrospinous ligament (SSL). 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 theanchor, the TAS provides:

- Highest pull-out force and accuracy
- Reliable fixation
- Safety with regard to vascular and neural structures

◎ RETRACTABLE INSERTION GUIDES – RIG

The **Retractable Insertion Guides** were developed to reach the targeted areas for performing an accurate and safe anchor insertion. The configuration of the large RIG, with its protective tube, guarantees the integrity of surrounding tissue during the implantation of the TAS into the sacrospinous ligament. The small RIG was developed to place the anterior attachment arms of the implant into the internal obturator muscle. Its curved design facilitates the introduction and placement of the anchor in the correct angle.

With their ergonomic design, small diameter and retractable mechanism for connecting and releasing the anchors, both RIGs provide:

- Precision and safety in surgical maneuvers
- Reduction of surgical dissection to a minimum
- Total control of connection and release of anchors



SINGLE INCISION. FUNCTIONAL. SAFE. EFFECTIVE.

© CONTRAINDICATIONS & PRECAUTIONS

Calistar S must not be used in:

- Fertile women
- 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 Calistar S should be based on a thorough patient assessment along with the patient's individual characteristics and preferences. The following items must also be considered:

- Calistar S 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 Calistar S.

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

ORDERING INFORMATION



Order number: KIT-CALISTAR-S

- 1 Calistar S Implant (Ref: CALISTAR-S)
- 3 Tissue Anchoring Systems (Ref.: TAS)
- 1 Retractable Insertion Guide designed for TAS implantation (Ref.: DPN-MNL)
- 1 Retractable Insertion Guide designed for the implantation of the anterior attachment arms (Ref.: DPN-MNC)
- 1 Knot Pusher (Ref.: KP)

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