

Calistar

SINGLE INCISION POP REPAIR SYSTEM



NEW GENERATION OF PELVIC ORGAN PROLAPSE SOLUTIONS

Calistar Single Incision POP Repair System

is indicated for anterior and apical prolapse repair (Calistar A), as well as posterior and apical prolapse repair (Calistar P) by reinforcing the support structures of the pelvic floor. The procedure is performed through a single vaginal incision.

Single incision: minimally invasive prolapse repair

- Decreased operative and hospitalization time.
- Rapid patient recovery.



Precise implantation: Retractable Insertion Guide and TAS Anchors



Retractable Insertion Guide (RIG):

- High precision connection between the RIG and the implant.
- Controlled release of implant fixation arms and TAS anchors, and proper implant placement at targeted anatomical landmarks.

BENEFITS

- Comfort and safety in surgical maneuvers.
- Possibility to choose the right approach for each patient.
- Total control of retention and release of TAS anchor.

Reliable fixation: unique anchoring system



TAS (Tissue Anchoring System) anchors

- Implant securely adheres to surrounding tissue.
- 6 fixating points at 360° and a safety stop provides strong and safe anchorage to sacrospinous ligaments.

BENEFITS

- Certainty and simplicity for SSL fixation.
- Durable results.
- Low complication rate.

Optimal implant design: stabilized correction of a wide range of defects

- Design of 6-mm orifices in the central portion of implant.⁽¹⁾
- Posterior fixation arms with special design for efficient attachment to De Lancey's Level 1.

BENEFITS

- Facilitates tissue ingrowth.
- Possibility to choose the right elevation of vaginal apex for each patient.



A solution for every condition



Remarkable anatomical and functional outcomes for anterior and apical prolapse repair

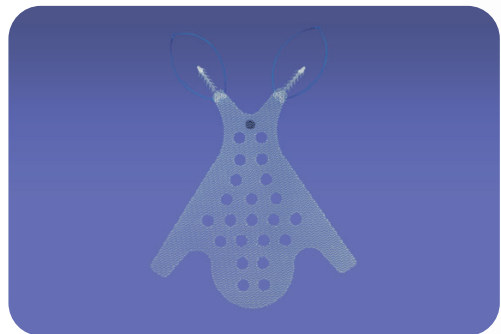
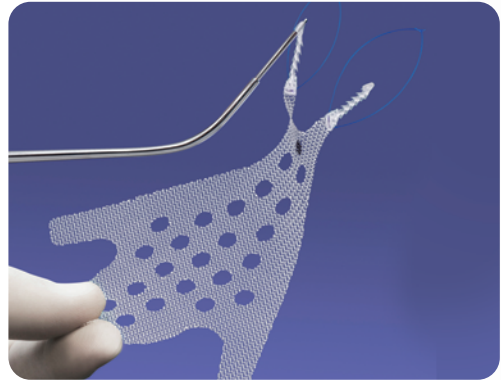
- Achieved by fixing the implant to De Lancey's Level I (sacrospinous ligaments), pericervical structures and mid urethra support.
- Unique and innovative feature: significant reduction in the incidence of SUI post-correction of the prolapse by the tension-free support of the mid urethra.

Accurate Surgical Technique

- Specially designed instrumentation allows for secure and highly precise implantation to sacrospinous ligaments and internal obturator muscles.

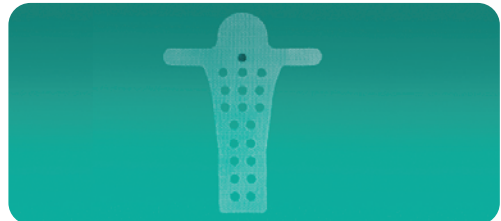
Stability, Adjustability and Simplicity

- Innovative multipoint anchoring system of the anterior arms provide a highly reliable primary fixation.⁽²⁾
- Intra-operative adjustability: loosening loops on fixation arms allow tension adjustments at the suburethral support.
- Easily identifiable central mark to achieve a symmetric centered implant placement under the mid urethra.



Minimally invasive surgery for posterior and apical prolapse repair

- Secure attachment to sacrospinous ligaments through the TAS anchors.
- New technique significantly reduces the risk of nerve or vessels damage.
- Specific design for an accurate fitting to De Lancey's Level I and II.



Proven efficacy: clinical results

Simultaneous single-incision transvaginal mesh to treat anterior and apical prolapses - a midterm results ⁽³⁾

Prospective study / N= 95 pts.
Max. follow-up: 24 months.

POP-Q points

	Pre	Post
Aa	+ 1.8	- 2.0
Ba	+ 3.0	- 2.6
C	+ 0.5	- 6.4
D	- 2.4	- 7.3
ICQ-SF	13.7	1.6

- 84.3% women were considered cured from anterior prolapse.
- 95.5% women were considered cured from apical prolapse.
- SUI was cured in 82.9% from the pre-diagnosed group.

Severe posterior and apical prolapse correction through single incision ⁽⁴⁾

Patients with posterior and apical prolapse POP-Q stage 3.

Results:

90% of patients were considered cured (POP-Q posterior/apical stage 0 or 1).

1. Palma P, Siniscalchi R, Riccetto C, Maciel L, Soarez M, Del Fabro I. Division of female Urology, Universidade Estadual de Campinas, Brazil. Biomechanical effects of the inclusion of the standardized orifices on the integration of monofilament polypropylene meshes: in vivo study. *Actas Urol Esp.* 2011 NovDec;35(10):599-604. doi: 10.1016/j.acuro.2011.06.014. Epub 2011 Aug 10.

2. Siniscalchi R T1, Dias F G F1, Fabro I D2, Santos A C P D1, Palma P1, Riccetto C1. 1. Division of Urology, University of Campinas – Unicamp, 2. Division of Engineering, University of Campinas – Unicamp. Mechanical properties of mini sling fixation devices: Ophira® versus Mini Arc®. 41st Annual ICS Meeting. Glasgow, UK. Abstract# 13016.

3. Palma P1, Riccetto C1, Altuna S2, Barreiro T1, Sardi J3, Ledesma M4, Triginelli S5, Monteiro M5, State University of Campinas - Unicamp – Brazil. Hospital Universitario Austral Bs As – Argentina. Hosp. Británico, Buenos Aires, Argentina. Clinica Sucre Córdoba – Argentina. Federal Univ. of Minas Gerais, Belo Horizonte, Brazil. Simultaneous Single-incision Transvaginal Mesh To Treat Anterior And Apical Prolapses - A Midterm Results IUGA Dublin. Abstract #470. 2013.

4. Riccetto, C., Palma, P., Tcherniakovsky, M., Barreiro, T., Souza, R., Lopez, F., Herrmann, V. University of Campinas, Dept. of Surgery - Division of Urology, Campinas, Brazil. Transvaginal single incision implant for severe apical and posterior prolapses: initial results of a prospective multicentre trial. 41st Annual ICS Meeting. Glasgow, UK. Abstract#818.



ORDERING INFORMATION

Calistar A - Apical and Anterior Vaginal Prolapse Repair

ORDER NUMBER: KIT – CALISTAR A

- 1 CALISTAR A Anterior Vaginal Prolapse Implant
- 3 TAS (Tissue Anchoring System) anchors with sutures
- 1 Retractable Insertion Guide

Calistar P - Apical and Posterior Vaginal Prolapse Repair

ORDER NUMBER: KIT – CALISTAR P

- 1 CALISTAR P Posterior Vaginal Prolapse Implant
- 3 TAS (Tissue Anchoring System) anchors with sutures
- 1 Retractable Insertion Guide



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