Ophira®

MINISLINGSYSTEM

THE SMALLEST SYSTEM. THE GREATEST SOLUTION.

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Continued research into female urinary incontinence has led to a minimally-invasive treatment solution

Initial stages of management of urinary incontinence through surgical correction used **colposuspension techniques**.
Retropubic midurethral sling implants without tension followed as a hammock-like device to support the urethra. With this knowledge came the advent of the transobturator approach, which was considered a highly useful option.
Today, innovative techniques and new materials have given way to the latest chapter of this treatment evolution:
the single incision technique for implanting midurethral slings.

Ophira Mini Sling System represents a notable advance in the evolution of treating female urinary incontinence. Ophira is a minimally-invasive treatment with local anesthesia, a single and very small incision, short surgical time, less pain and bleeding, and rapid patient recovery. This procedure represents an advance toward the outpatient procedure for SUI [1].

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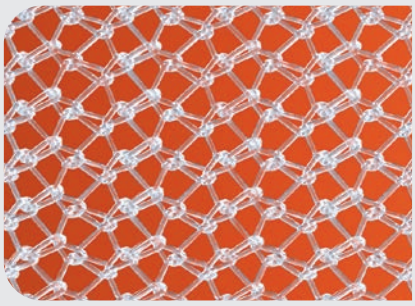
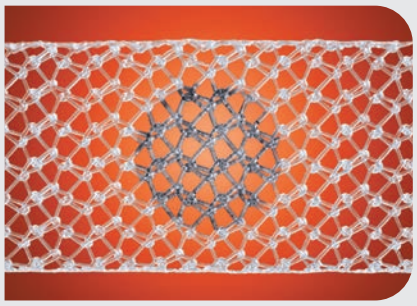
EVOLVING THE TREATMENT OF FEMALE URINARY INCONTINENCE

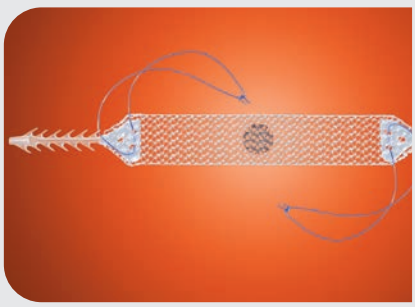
Ophira is a single incision mini sling developed for the treatment of female urinary incontinence.
Made of a100% Type 1 polypropylene mesh suburethral area and two fixation arms, the Ophira System includes a Retractable Insertion Guide used for precise sling placement. Through a single incision and accurate insertion, Ophira offers an efficient procedure and consistent clinical results.

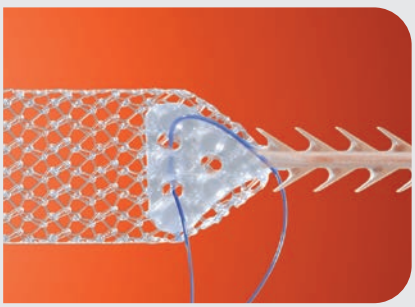
IMPROVING MATERIALS AND DESIGN FOR BETTER PERFORMANCE





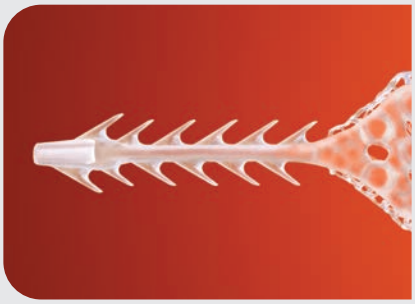
Ophira, with its Type 1 polypropylene mesh and its thermo-sealed edges, offers an excellent balance of the main biomechanical requirements: tissue integration and low elasticity.
An easily identifiable mark in the center helps to achieve a symmetrically centered location for the proper placement of the sling.



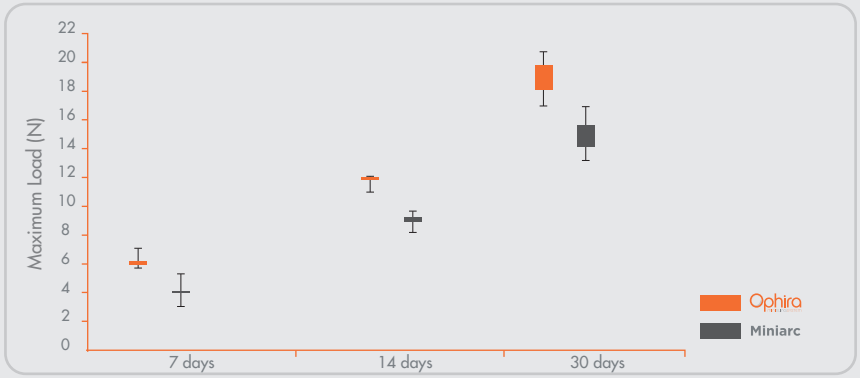


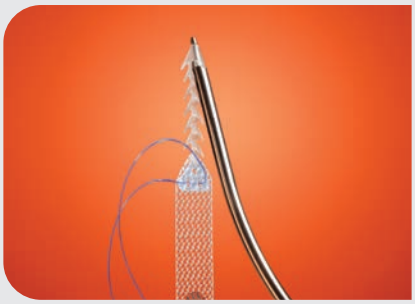
Ophira has blue loosening sutures inserted in the base of both fixation arms, giving the ability to correct excessive tension during the procedure for optimum suburethral support. The blue loosening sutures allow to customize the implant to the patient, and once in place yields a successful post-operative result and a better outcome.

ENHANCING FIXATION AND ADJUSTABILITY FOR A HIGHER LEVEL OF SAFETY



PRIMARY FIXATION COMPARISON[2]





Ophira's fixation system has an exclusive and innovative design with multiple fixation points along its self-fixating arms. Unlike other implants available on the market that present a single fixation point, Ophira's design offers a high pull out force and greater reliability in its primary fixation. A reliable primary fixation is critical for the final result of the treatment.

The Ophira System offers a safe and simple way to achieve a correct and precise sling placement. The connectors located at the ends enable the Retractable Insertion Guide to be inserted easily and safely.

MASTERING ERGONOMICS AND PRECISION FOR THE BEST CONTROL

Ophira Mini Sling System features an innovative anti rotational assembly system between the Retractable Insertion Guide (RIG) and the implant that allows a precise sling insertion.

The Retractable Insertion Guide is exclusively designed to give the best control and the greatest ease when applying the minimally invasive technique and when releasing Ophira in the correct position.

This instrument features an ergonomic handle ideal for minimally-invasive maneuvers. Its 2.2 mm diameter, anatomical curvature, and retractable mechanism make the Insertion Guide the ideal complement to the Ophira Single Incision Mini Sling for a complete system that allows to perform the single incision technique with efficiency and precision for remarkable results.

CONSISTENT CLINICAL RESULTS

Published clinical data from international multicentric research support Ophira efficacy with a maximum follow-up of 2 years.[3]

OVERALL SUCCESS RATE:	91.6%
n=	124 pts.
ICIQ-SF (0-21):	15.8 to 1.9
UDI-6 (0-18):	9.2 to 1.7
Mean operative time	17 minutes
Max. follow-up:	24 months

Clinical evidence obtained with Ophira Mini Sling System is consistent in different centers around the world. Ophira offers a safe and efficient method for the treatment of female stress urinary incontinence [4].
Compared to transobturator and retropubic suburethral slings, Ophira shows no inferiority regarding success rate at mid term follow-up [5,6,7,8,9]. The major advantage is the possibility of performing this procedure under local anaesthesia on an ambulatory basis with less blood loss [5]. The vaginal sling application of Ophira led to a further reduction of complications by avoiding the retropubic or transobturator space [8].
Its unique fixation system results in immediate high efficacy [10].

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(1) Palma P., Riccetto C., Reges R., Fraga R., Miyaoka R., Hermann V., Marcondes T. Arcus to arcus microsling: technique and preliminary results. Int Urogynecol J. 19: 1133-1136. DOI 10.1007/s00192-008-0595-x. **(2008)**

(2) Siniscalchi R T1, Dias F G F1, Fabro I D2, Santos A C P D1, Palma P1, Ricetto C1. 1. Division of Urology, University of Campinas – Unicamp, 2. Division of Engeneering, University of Campinas – Unicamp. Mechanical properties of mini sling fixation devices: Ophira® versus Mini Arc®. 41st Annual ICS Meeting. Glasgow, UK. Abstract #13016. **(2011)**

(3) Palma P1, Riccetto C1, Bronzatto E1, Castro R2, Altuna S3. 1. University of Campinas - UNICAMP, 2. Federal University of São Paulo - Unifesp – Brazil, 3. Austral University Hospital - Buenos Aires – Argentina. What is the best indication for single incision mini slings? Insights from 2 year follow-up multicentric international study. Int Urogynecol J. 2013 Oct 30. [Epub ahead of print]. DOI 10.1007/s00192-013-2242-4. **(2013)**

(4) Huebner Jana, Lobodasch Kurt, Brosche Torsten. DRK Krankenhaus Cemnitz-Rabenstein, Gynecology, Chemnitz, Germany. Experience with Vaginal Mini-Sling Ophira: First Interim Analysis.58. Kongress der Deutschen Gesellschaft für Gynäkologie und Geburtshilfe. Munich. Abstract #PO-Gyn 02.12. **(2010)**

(5) P. P. Smith, R. K. Dhillon, M. Baptiste and A.S. Arunkalaivanan. Comparison of single-incision mid-urethral tape (Ophira™) and transobturator tape (Obtryx™) sub-urethral sling procedures for female stress urinary incontinence. Journal of Clinical Medicine and Research. Vol. 5(4), pp. 53-57, June, 2013. DOI 10.5897/JCMR12.019. **(2013)**

(6) Arunkalaivanan A1;Smith P2;, Baptiste M3. 1. University of Melbourne, 2. University of Birmingham, 3. City Hospital. Single-Incision Midurethral Tape (Ophira™) Vs Transobturator Tape (Obtryx™): Prospective Comparative Study – 2 Year Follow-Up. 44th ICS Annual Meeting 2014. Rio de Janeiro, Brazil. Abstract #245. **(2014)**

(7) H. Enzelsberger1, I. Cemer 1, E. Kostersitz1, S. Enzelsberger2. Ophira® (Minisling) versus Monarc® (Tot) - A Prospective Randomized Study for the Treatment of Female Stress Urinary Incontinence at a follow-up of 20 months. 36th Annual Meeting of the International Urogynecological Association. Lisbon, Portugal. Abstract #281. **(2011)**

(8) Ahn J H1, Chung H S1. 1. Incheon Sarang Hospital. Comparison of Single-Incision Mid-Urethral Tape (Ophira) and Transobturator Tape (Safyre) suburethral sling procedures for female stress urinary incontinence. 44th ICS Annual Meeting 2014. Rio de Janeiro, Brazil. Abstract #263. **(2014)**

(9) Mehmet Bilgehan Yuksel, Osman Kose , Ayhan Karakose, Sacit Nuri Gorgel, Yuksel Yılmaz, Bilal Gumus. 2013 Turkey. The comparison of short term results of transobturatour tape and single incision midurethral sling procedures. Int J Women's Health Reproduction Sci Vol. 1, No. 3, Autumn 201. **(2013)**

(10) Pushkar D, Kasyan G, Godunov B, Gvozdev M, Lynova Y. MSMSU, Russia. Preliminary results of treatment of stress urinary incontinence with Ophira Mini-Sling. ICS/IUGA Meeting (Toronto, Canada) . Abstract #800. **(2010)**

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ORDERING INFORMATION

Ophira Mini Sling System
Order number: KIT-OT-01
1 Ophira Mini sling: S-38-AF
1 Retractable Insertion Guide: DPN-MN

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