MINIMAL INVASIVE. SINGLE INCISION SIMPLE. CLINICALLY PROVEN

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CONTRAINDICATIONS & PRECAUTIONS

Ophira should be used only by surgeons familiar with the procedures and techniques for implanting Ophira. Careful patient selection and complete diagnostic evaluation are essential prior to surgery.

Ophira should not be prescribed if there are infectious processes, especially in the genital system or in the urinary tract.

Ophira should not be used for patients

- on anticoagulant therapy
- with current urinary infection or,
- during pregnancy,
- with known sensitivity or allergy to polypropylene products,
- with pre-existing conditions that pose an unacceptable surgical risk. In order to avoid complications

In order to avoid complications, please consider all warnings and precautions, which are stated in the IFU.

ORDERING INFORMATION



Order number: KIT-OT-01

1 Ophira Mini sling: S-38-AF

1 Retractable Insertion Guide: DPN-MN



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Urology and Pelvic Floor

MINISLINGSYSTEM

Minimal Invasive Stress Urinary Incontinence



SINGLE INCISION STRESS URINARY INCONTINENCE TREATMENT

The Ophira sling is intended to be used for the treatment of female stress urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency (1). The Mini Sling with its two fixations arms on each side, is fixated to both internal obturator muscles and allows to create support underneath the urethra while using only one incision for the implantation.

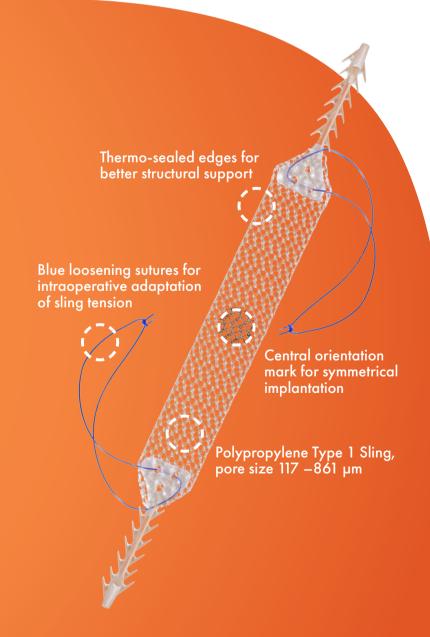
CONSISTENT CLINICAL RESULTS

Clinical evidence obtained with Ophira Mini Sling System is consistent in different centers around the world. Ophira offers a safe and effective method for the treatment of female stress urinary incontinence (2). Compared to transobturator and retropubic suburethral slings, Ophira shows no inferiority regarding success rate at mid term follow-up (3,4,5,6,7). The major advantage is the possibility of performing this procedure under regional or local anaesthesia (5). The vaginal sling application of Ophira led to a further reduction of complications by avoiding the retropubic or transobturator space (6). Its unique fixation system results in immediate high efficacy (8).



MINI SLING IMPLANT

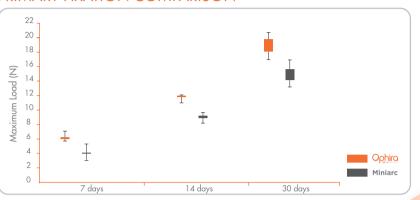
Ophira, with its Type 1 polypropylene mesh and its thermosealed edges, offers an excellent balance of the main biomechanical requirements: tissue integration and low elasticity. An easily identifiable mark in the center helps to achieve a symmetrically centered location for the proper placement of the sling. Additionally, Ophira is equipped with blue loosening sutures inserted in the base of both fixation arms, giving the ability to correct excessive tension during the procedure for optimal suburethral support. Therefore, the tension of the sling can be customized to the given patient individual characteristics.



FIXATION SYSTEM

Ophira's fixation system has an unique and innovative design with multiple fixation points along its self-fixating arms. It offers a high pull out force and reliability in its primary fixation. A reliable primary fixation is important for the outcome of the treatment. The Ophira Minisling System offers a safe and simple way to achieve a correct and precise sling placement (3).

PRIMARY FIXATION COMPARISON (9)



INSERTION GUIDE

The Retractable Insertion Guide (RIG) is designed to provide control and easy handling that allows a precise and minimally invasive implantation technique. The anti-rotational assembly system on the tip of the retractable insertion guide goes along with the anti-rotational connector of the fixation arm and ensures that the minisling can be implanted without positioning complications. With its 2.2 mm diameter and anatomical curvature the RIG enables the surgeon to implant the fixation arms safe and efficiently in the right anatomical direction, while having a very short blind passage.

Anti-rotational assembly system Ensure twist-free implantation Curved guide Follows the right direction for implantation to the internal obturator. Retractable mechanism Simple insertion and release of the fixation system

Ergonomic handle

Easy and safe handling

15.000 +
Ophira Minislings
implanted

OPHIRA IN DAILY CLINICAL PRACTICE

Ophira has been developed to be used for the treatment of female stress urinary incontinence.