

MINIMAL INVASIVE . SINGLE INCISION  
SIMPLE . CLINICALLY PROVEN



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## CONTRAINDICATIONS & PRECAUTIONS

The decision to use the Ophira mini sling should be based on a thorough assessment of the patient as well as on the patient's individual characteristics and preferences. The surgical technique brochure must be read and understood BEFORE implanting Ophira for the first time.

Ophira must not be prescribed if untreated urinary tract infection, active infection at the surgical site or systemic infection (sepsis) is present.

Ophira must not be used in patients:

- who have a soft tissue pathologies at the intended implantation site
- who are pregnant,
- with known sensitivity or allergy to polypropylene products,

## ORDERING INFORMATION



Order number: KIT-OT-01

1 Ophira Mini sling: S-38-AF

1 Retractable Insertion Guide: DPN-MN

Manufactured by PROMEDON S.A. | [www.promedon-upf.com](http://www.promedon-upf.com)

**Promedon**  
Urology and Pelvic Floor

Company information: Distribution EMEA & APAC | Promedon GmbH | [orders@promedon.com](mailto:orders@promedon.com) | Phone: +49 8031 900 400 | Fax: +49 08031 900 4040 | An der Alten Spinnerei 5 | 83059 Kolbermoor | GERMANY

MINISLINGSYSTEM

Minimal Invasive  
Stress Urinary Incontinence  
Treatment



PSD-000000391 (01) / AUG-2022



**Ophira**®  
MINISLINGSYSTEM

## SINGLE INCISION STRESS URINARY INCONTINENCE TREATMENT

Ophira is a single incision mini sling developed for the treatment of female stress urinary incontinence. The Mini Sling with its two anchors 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 (1).

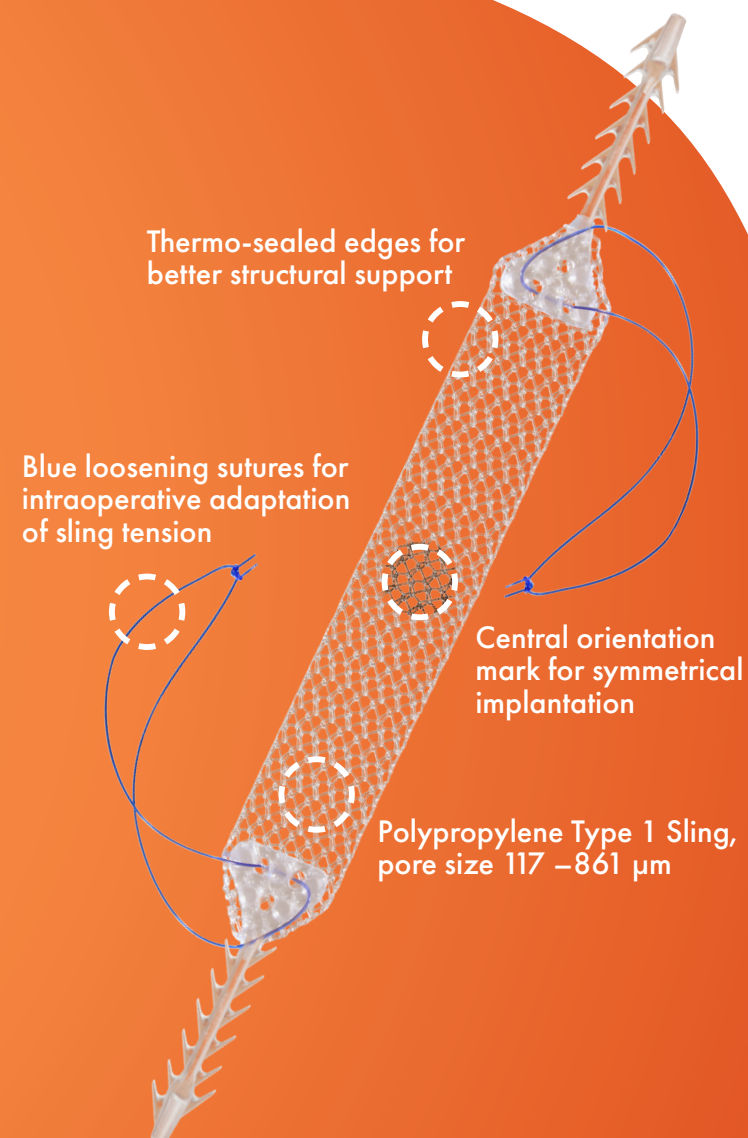
## CONSISTENT CLINICAL RESULTS

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 (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).

**Ophira**  
MINISLINGSYSTEM

## MINI SLING IMPLANT

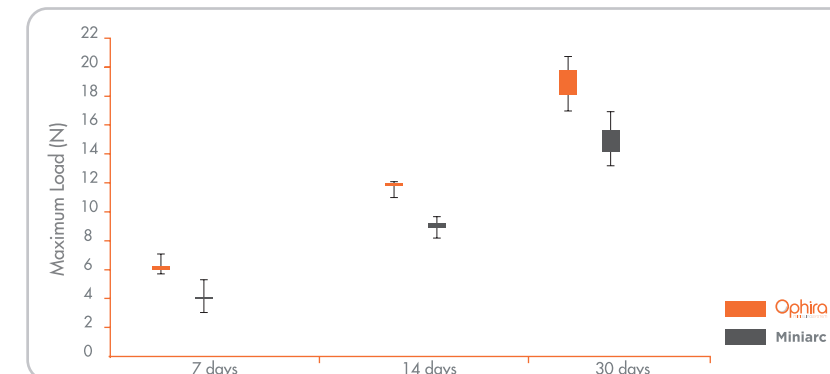
Ophira, with its Type 1 polypropylene mesh and its thermosealed edges, offers an excellent balance of the main biomechanical requirements: tissue integration and low elasticity. An easily identifiable mark in the center helps to achieve a symmetrically centered location for the proper placement of the 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 <sup>(9)</sup>



## INSERTION GUIDE

The Retractable Insertion Guide 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 therefore 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 anchors safe and efficiently in the right anatomical direction, while having a very short blind passage.

**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.

**Anti-rotational assembly system**  
Ensure twist-free implantation

**Curved guide**  
Pretends 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

