Saffron™

Fixation System

Pelvic Organ Prolapse

Coloplast

Saffron™

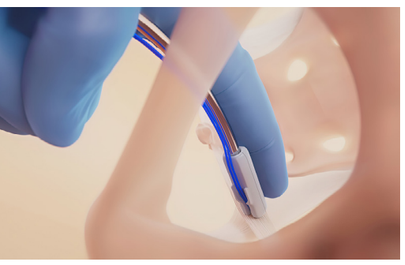
Designed for ease and reliability in prolapse repair

The Saffron™ Fixation System *consists of a suture fixation tool and implantable anchors designed for transvaginal pelvic organ prolapse repair, used with native tissue or in conjunction with an allograft.*

Smooth, secure anchor design with the smallest polymeric anchor volume available.

Consistent, reliable deployment

- Intuitive design, easy to hold and deploy
- Better at maintaining distal tip placement than Capio, Anchorsure and Digitex*
- Provides tactile confirmation that anchor has been deployed
- Design enables consistent anchor placement and precise anchor targeting
- Fixation strength exceeds requirement for prolapse repair



Ease of navigation

- Unique curved design allows for easy navigation to the sacrospinous ligament
- Small distal tip for smooth entry into the dissection
- Design enables perpendicular placement on the ligament

*Data on file.

Saffron has a

43%

smaller distal tip

*than Capio™ Slim**

Saffron Fixation Tool

Saffron Anchor

Device images are not to scale and are for illustrative purposes only.

More choice and control

- Use with your choice of commercially available sutures
- Accommodates most off-the-shelf sutures up to size 0 in any material or length (excluding barbed sutures)
- A wide array of needles can be used for the repair

Use your preferred sutures and needles.

Ordering Information

Saffron™ Fixation System

Product	Product Code	Purchase UOM	Qty per UOM
Saffron Fixation Tool	**520340**	EA	1
Saffron Anchor	**520350**	Box	12

Discover the unique advantages of Saffron at http://coloplast.to/saffron

SAFFRON™ FIXATION SYSTEM BRIEF STATEMENT

Indications

The Saffron Fixation System is indicated for the attachment of suture to ligaments of the pelvic floor.

Contraindications

The Saffron Fixation System is contraindicated in patients with one or more of the following conditions:

- Pregnancy or desire for future pregnancy
- Potential for further growth (e.g., adolescents)
- Documented hypersensitivity or allergic reaction to polysulfone
- Active infection, including untreated urinary tract and/or infection in operative field
- Patients with untreated or serious anticoagulant disorders
- Autoimmune disease affecting connective tissue
- Any condition, including known or suspected pelvic pathology, which could compromise implant or implant placement
- Applications requiring placement of suture into or through bone

Warnings

It is the responsibility of the physician to advise prospective patients prior to surgery, of the warnings associated with the use of this product and the associated surgical risks.

- The Saffron Fixation System should only be used by physicians experienced in the surgical procedures and techniques involving transvaginal placement of permanent anchors.
- The risks and benefits of using the Saffron Fixation System should be considered in patients.
- As with all surgical procedures, patients with certain underlying conditions can be more susceptible to postoperative bleeding, impaired blood supply, compromised/delayed healing, or other complications and adverse events.
- Patient counseling should include a discussion that Saffron Anchors are permanent.
- Future pregnancy could negate the benefits of this surgical procedure.
- Permanent anchor complications may result in one or more revision surgeries which may lead to removal of one or more Saffron Anchors. Complete removal of the Saffron Anchor(s) may not always be possible, and removal may not fully correct these complications. There may be unresolved pain with or without anchor explant.
- Patients should be instructed to report bleeding, pain, abnormal vaginal discharge, or signs of infection at any time.

Precautions

It is the responsibility of the physician to advise prospective patients prior to surgery, of the precautions associated with the use of this product and the associated surgical risks.

- Previous pelvic floor reconstruction may make the placement of Saffron Anchor(s) more difficult.

Potential Complications

Adverse events are known to occur with transvaginal pelvic organ prolapse repair. Adverse events following pelvic organ prolapse surgery may be localized, systemic, de novo, worsening, acute, chronic, or permanent.

Adverse events may include but are not limited to: Anchor migration, exposure, extrusion into the vagina or other structures or organs, bladder storage symptoms (e.g., increased daytime frequency, urgency, nocturia, overactive bladder, urinary incontinence), bleeding/hemorrhage/hematoma, delayed/impaired/abnormal wound healing, dyspareunia, fistula formation, infection, inflammation, irritation of surrounding tissue and/or foreign body reaction, pain, perforation or injury to adjacent muscles, nerves, vessels, structures or organs (e.g., bone, bladder, urethra, ureters, bowel, rectum, vagina), scarring, sexual dysfunction, and voiding symptoms (e.g., dysuria, urinary retention, incomplete emptying, bladder outlet obstruction, straining, position-dependent voiding, slow stream).

The information provided is not comprehensive with regard to product risks. For a comprehensive listing of indications, contraindications, warnings, precautions, and adverse events refer to the product's Instructions for Use. Alternatively, you may contact a Coloplast representative at 1-800-258-3476 and/or visit the company website at www.coloplast.com.

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

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