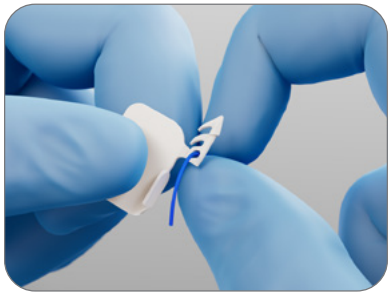
Saffron™

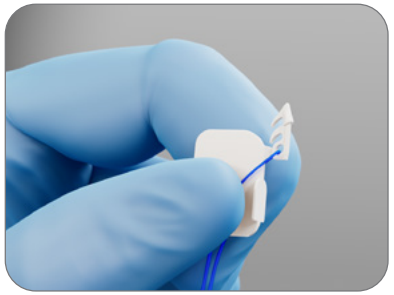
Saffron Fixation System

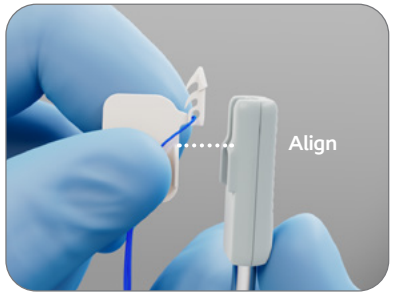
Anchor Loading Guide



STEPS 1 & 2

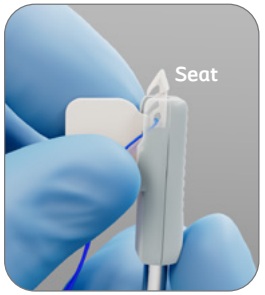
1. Select desired suture, size 0 or smaller (not included).
2. While holding anchor by the anchor tab, thread suture through Saffron Anchor eyelet.

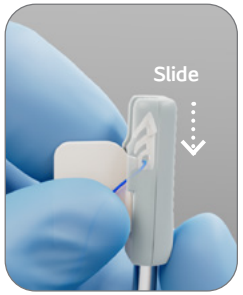




STEP 3

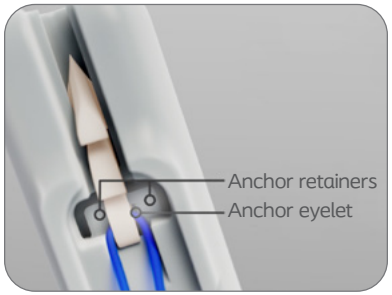
Grasp the suture and Saffron anchor tab at the corner, keeping the suture taut and away from the anchor barbs. **Align** the sled of the anchor tab with the loading rails on the distal tip.





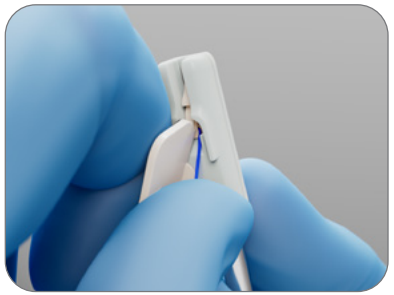
STEP 4

Seat the anchor into the deployment tool distal tip. **Slide** the anchor all the way back into the anchor retainers until a click is felt and/or heard. The sled of the anchor tab should slide past the loading rails completely.



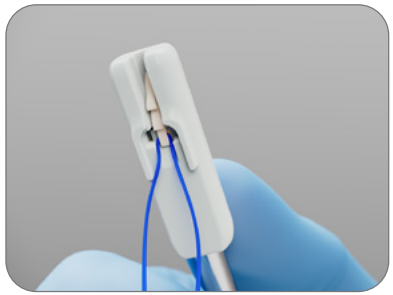
STEP 5

Verify that the anchor is fully seated in the anchor retainers and the suture is threaded through the anchor eyelet.



STEP 6

Twist the anchor tab like a key to break it away from the anchor. Discard the anchor tab. The break-away tab portion of the anchor is not intended for implantation and should be discarded.



STEP 7

The anchor is now fully loaded and is ready to be inserted into the tissue.

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Device Overview

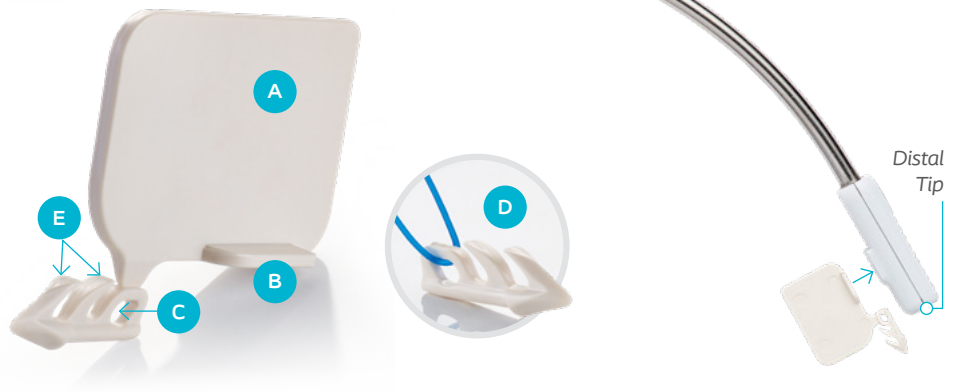
Saffron Fixation Tool

Shown smaller than actual size.

Saffron Anchor

Shown larger than actual size.

A. *Anchor break-away tab*
B. *Sled*
C. *Anchor eyelet*
D. *Anchor (implanted portion)*
E. *Anchor barbs*



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.

PM-22168

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