CLINICAL PUBLICATION SUMMARY

A Novel Anchoring System for Pelvic Organ Prolapse Repair: An Observational Study

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STUDY SUMMARY

Objective: Sacrospinous ligament (SSL) fixation is an effective and widely used vaginal procedure for correcting apical prolapse. The Saffron™ Fixation System (Coloplast Corp., Minneapolis, MN, USA) is a new anchoring device aimed at facilitating a durable, easy, and short procedure for SSL fixation with the goal of minimizing operative complications. The objective was to demonstrate the efficacy and safety of anchor deployment and suture fixation for pelvic organ prolapse repair using the Saffron Fixation System.

Methods: An observational human cadaver study was conducted to measure the distance between anchor location and anatomical landmarks in the pelvis, and the holding force of the fixated anchors. Anchors were placed in four human cadavers by different implanters. The pull-out force of these anchors was measured to assess efficacy (three cadavers by three implanters) and the distance between anchors and primal vessels and nerves was measured to assess safety (one cadaver by one implanter).

Results: Nineteen out of 20 anchors (95%) were correctly placed as judged by independent assessment performed by non-implanting surgeons. Distance between anchors and surrounding nerves and vessels exceeded 10 mm. Mean (SD) pull-out force was 17.9 (5.6) N.

Conclusion: The innovative anchoring device that was developed appeared to enable precise and solid anchor placement in the SSL. Future clinical studies are needed to explore if the theoretical advantages of this device translate to improved clinical outcomes in comparison with available suturing and anchoring devices.

KEY RESULTS

Accuracy of Anchor Insertion

95%

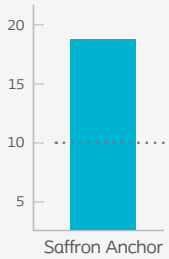
19 out of 20 anchors were correctly placed

Safety of Anchor Insertion

Distance between anchors and surrounding nerves and vessels exceeded

10 mm

Pull Out Force

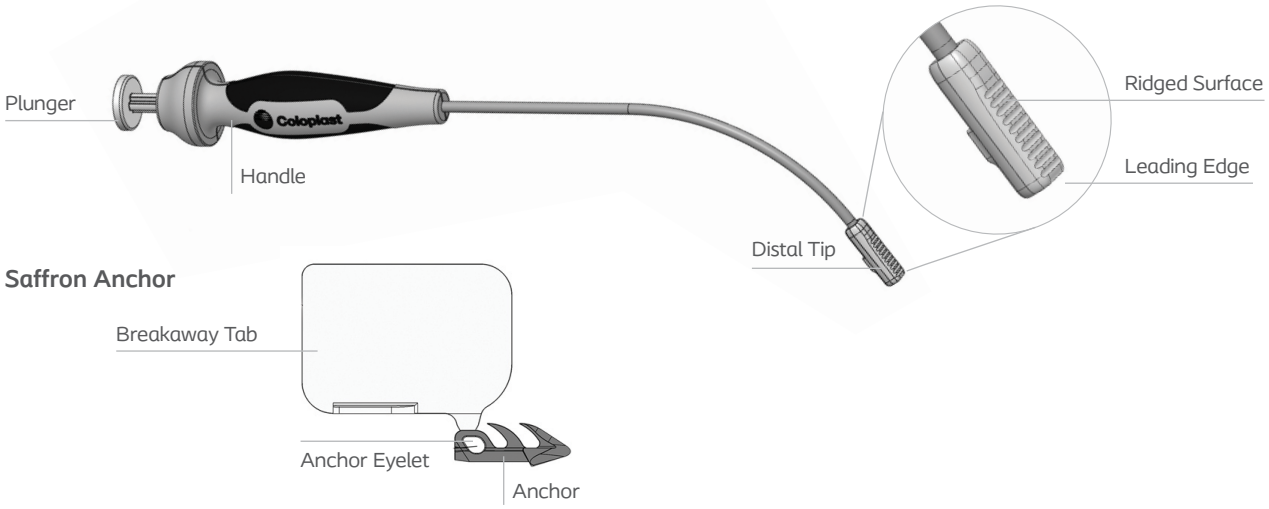


Mean (SD) pull-out force was 17.9 (5.6) N, or 4.02 lbs

10N required for apical support

Coloplast

SAFFRON FIXATION SYSTEM



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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