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Professional Education

Saffron™ Fixation System

Saffron™ Fixation System

Distinguished faculty

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Account affiliation

City, ST

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Physician presentation disclaimer

The following materials are presented for general information purposes only. Coloplast is compensating me for this professional education [or training] presentation.

There are certain segments that I may personalize, based upon my own experience in performing this procedure. These will be distinguished as such during the presentation. To the extent they go beyond Coloplast's written materials, these should be recognized as my individual medical opinions and not the opinions or endorsements of the company.

It is obvious with this, and every other surgical procedure, that you use your own independent judgment that you have received sufficient information and training to proficiently perform the procedure. This lecture and demonstration is intended as a supplement to your own education and training and is not a substitute for your own medical judgment.

I have provided substantial time for questions in this presentation and encourage and welcome any questions that you have.

Objectives

Communicate Pelvic Organ Prolapse **prevalence and need**

Convey the importance of the **Saffron™ Fixation system and design**

Analyze the data and competitive market

Agenda

01. Pelvic Organ Prolapse prevalence and need
02. Importance of design
03. Pre-clinical data
04. Competitive comparison and data
05. Procedural steps
06. Procedural video

01

Pelvic organ prolapse

Prevalence and need

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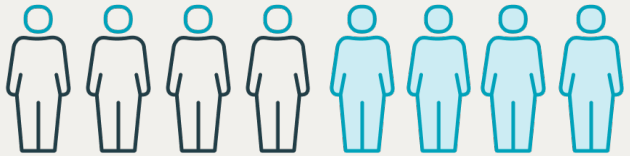
Pelvic organ prolapse (POP) prevalence

About

50% ***of US women 50-79 years of age***

will experience some form of prolapse[1]



The number of women in the US with symptomatic POP will be almost **5 million** by 2050[2]

[1] Barber, M.D., Maher, C. Epidemiology and outcome assessment of pelvic organ prolapse. *Int Urogynecol J* 24,1783-1790 (2013).
[2] Wu JM. Forecasting the prevalence of pelvic floor disorders in US women: 2010 to 2050. *Obstet Gynecol.* 2009;114(6)1278-83.

Coloplast's commitment_

Improve treatment options
for women

Provide better solutions
for surgeons

Focus to reduce costs
to the system

Pelvic organ prolapse repair options

Transabdominal

Restorelle® Y-Mesh

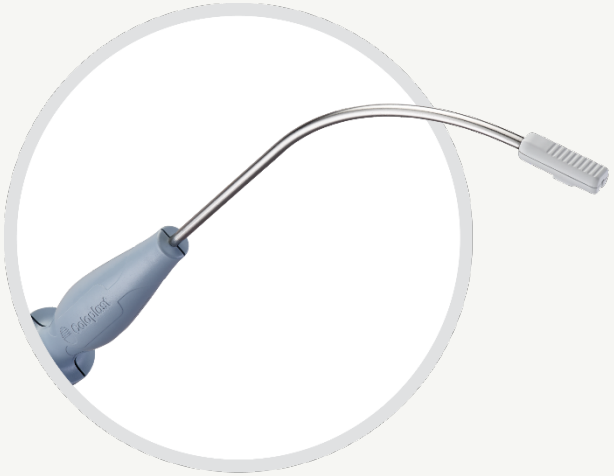
Transvaginal

Axis™ Allograft

Suspend® Allograft

Fixation

Saffron™ Fixation



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Innovating in pelvic floor reconstruction

Saffron™ Fixation System:

- Suture fixation tool
- Implantable anchors
- Used with native tissue or in conjunction with a biologic graft

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


Saffron™
Fixation System

02

Importance of design

Saffron™ Fixation System

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Saffron™ Fixation System

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

Designed for:
ease and reliability
in prolapse repair

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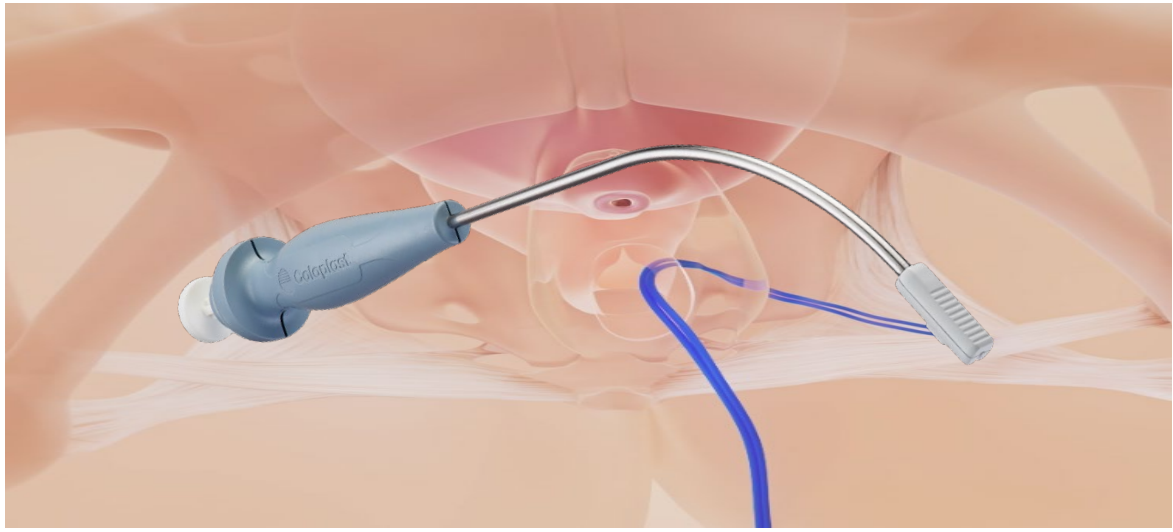
Saffron™ Fixation System Design

Intuitive design, that is easy to hold & deploy with the use of your choice of suture & needle

Benefits of the **Curved Shaft & Small Distal Tip** include:

- Smooth entry into dissection
- Easy navigation in SSL
- Perpendicular placement of SSL
- Precise anchor targeting
- Consistent anchor placement



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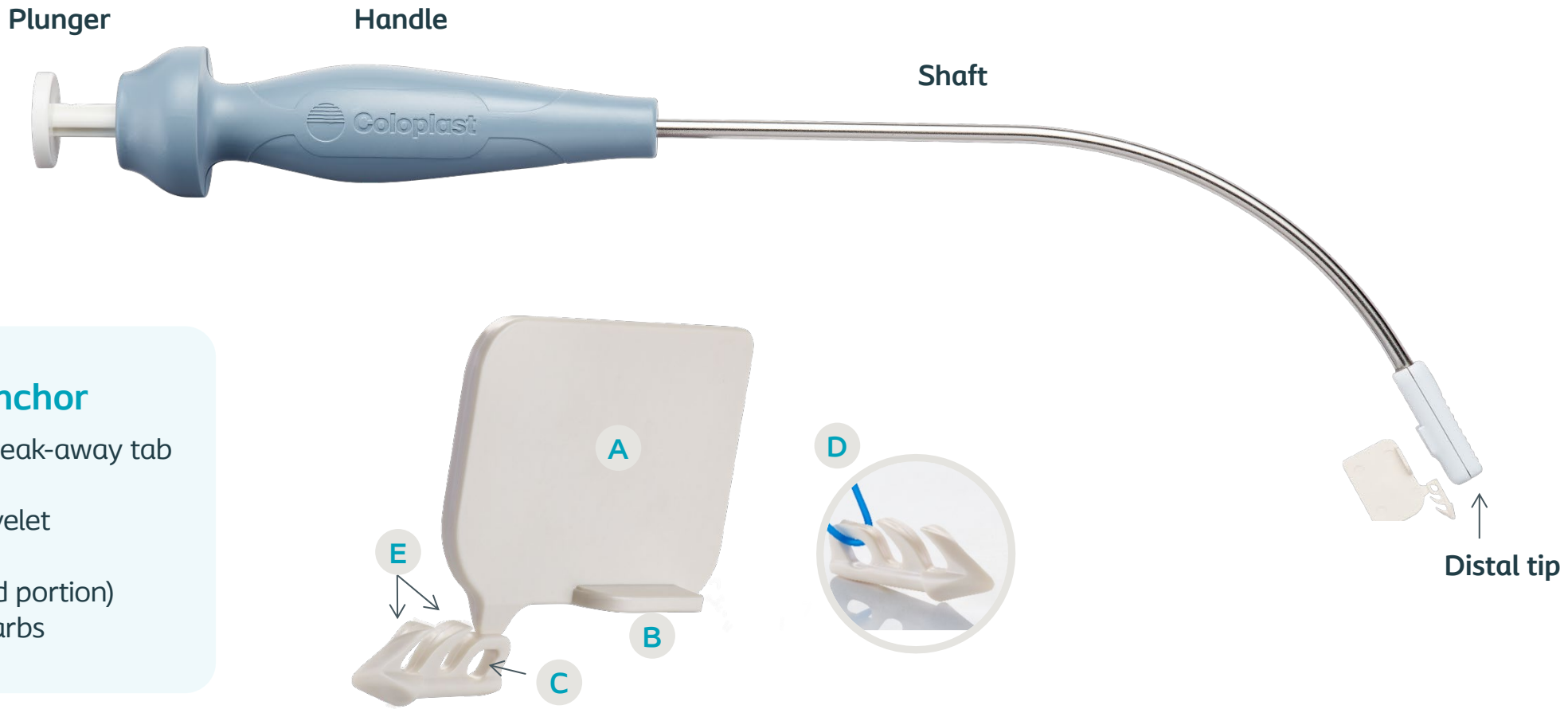
Saffron™ tool and anchor design



Saffron anchor

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

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

03

Pre-clinical data

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Saffron™ pre-clinical article[1]

Study objective

- Demonstrate the efficacy and safety of anchor deployment and suture fixation for pelvic organ prolapse repair using the Saffron™ Fixation system

Study design

- Pre-clinical, observational human cadaver study

Designed to measure

- Correct anchor placement identified by palpation, then dissection
- The distance between anchors and vulnerable structures in the pelvic cavity
- The holding force of the fixated anchors

International Urogynecology Journal
https://doi.org/10.1007/s00192-022-05444-7

ORIGINAL ARTICLE

A novel anchoring system for pelvic organ prolapse repair: an observational study

Heather van Raalte[1] · Nina Bhatia[2] · Jeffrey Mangel[3] · Hugo Ryckebusch[4] · Jan-Paul Roovers[5,6]

Received: 11 October 2022 / Accepted: 12 December 2022

Abstract
Introduction and hypothesis 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.

Keywords Anchoring device · Native tissue surgery · Pelvic organ prolapse · Sacrospinous ligament fixation · Safety

Introduction

Pelvic organ prolapse (POP) is a prevalent condition, with 1 in 10 women requiring surgical correction during their lifetime [1]. Sacrospinous ligament (SSL) fixation intending to optimize apical suspension has become the cornerstone of successful vaginal prolapse surgery [2]. Precise and reliable fixation is vital for good surgical outcomes and several suturing and anchoring devices have been introduced over the years to facilitate precise and reliable fixation [3, 4]. From a safety standpoint, it is critical that fixation devices minimize possible hazard to nerves and vessels (particularly the pudendal nerve and inferior gluteal artery) that are closely related to the SSL [5–7].

Limitations of available fixation devices include suboptimal ergonomics, which may limit precision, larger anchor size, limited suture choice, and risk of anchor dislocation in response to increased abdominal pressure. There is a paucity of evidence demonstrating the clinical efficacy, safety, or superiority of device performance, and there remains a lack of documentation regarding the development and engineering rationale of available devices. Coloplast Corp. (Minneapolis, MN, USA) developed the Saffron™ Fixation System with the intent of generating an anchoring device that overcomes the shortcomings of existing devices. We present the results of human cadaver studies to evaluate the performance of this innovative anchoring device.

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Springer

Note: *Both anterior and posterior approaches were tested for anchor insertion efficacy*

[1] van Raalte H, Bhatia N, Mangel J, Ryckebusch H, Roovers JP. A novel anchoring system for pelvic organ prolapse repair: an observational study. *Int Urogynecol J.* 2023 Jul;34(7):1593-1598.

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Publication key points

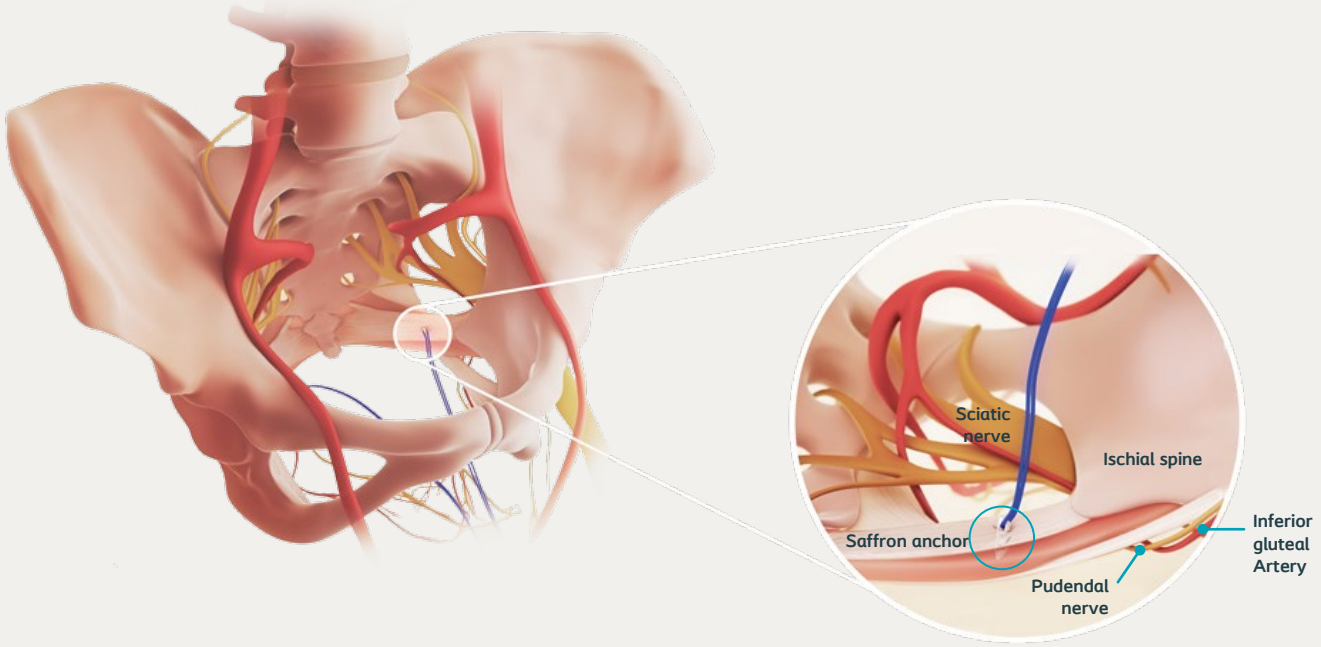
Efficacy results

- 19 of 20 anchors were correctly placed
- **Mean pull-out force of 18 Saffron anchors tested was 4.02lbs +/- 1.26lbs** (17.9N +/- 5.6N)
  - *The holding force required for pelvic floor repair is 2.25lbs (10N)*

Safety results[1]

Mean distance between anchors and surrounding nerves and vessels is

greater than or equal to 10 mm



[1] van Raalte H, Bhatia N, Mangel J, Ryckebusch H, Roovers JP. A novel anchoring system for pelvic organ prolapse repair: an observational study. *Int Urogynecol J.* 2023 Jul;34(7):1593-1598.

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Saffron™ pre-clinical article[1]

Conclusion

> *The **innovative anchoring device** that was developed appeared to enable precise and solid anchor placement in the SSL*

[1] van Raalte H, Bhatia N, Mangel J, Ryckebusch H, Roovers JP. A novel anchoring system for pelvic organ prolapse repair: an observational study. *Int Urogynecol J.* 2023 Jul;34(7):1593-1598.

04

Competitive comparison and data

Fixation systems

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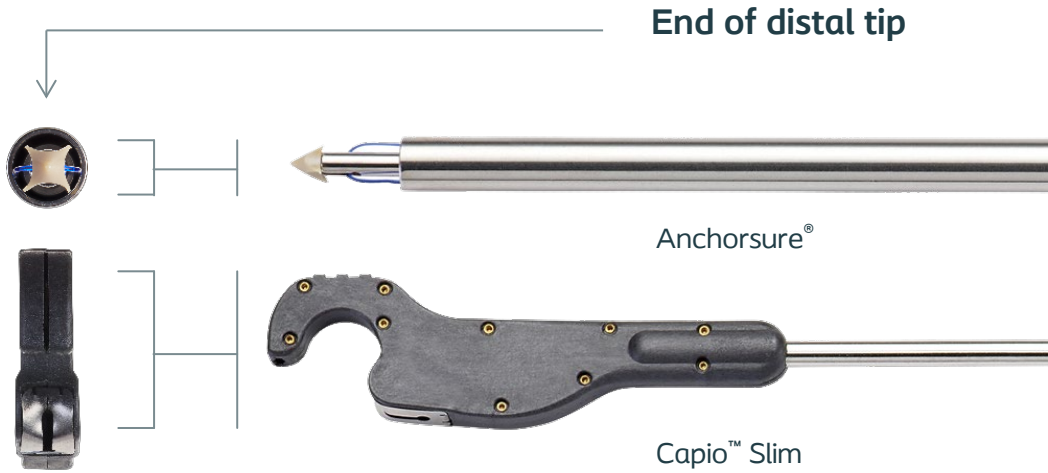
Saffron™ Fixation System vs. Capio™ Device and Anchorsure® System

Shaft Angle

- The curvature of the device allows for ease of navigation & perpendicular placement on the SSL

Distal Tip/Anchor Size

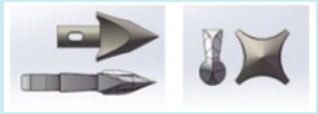
- Saffron has a smaller distal tip than Capio and smaller anchor volume than Anchorsure[1]



Saffron total implanted anchor volume is

15%

Smaller than Anchorsure[1]



Saffron has a

43%

Smaller distal tip than Capio™ Slim[1]

[1] Data on file.

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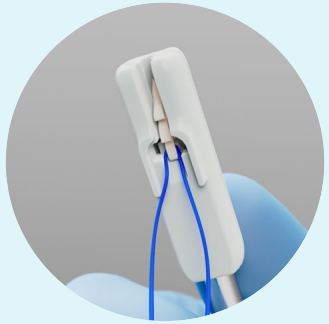
Saffron™ Fixation System vs. Capio™ Device and Anchorsure® System



Suture/anchor security post-loading

The Saffron Anchor won't fall out once loaded

- The Capio bullet may dislodge from device prior to deployment
- The Anchorsure anchor can fall off device prior to deployment

Deployment

Saffron offers proven consistent anchor deployment[1], while Capio **misfires almost 20%** of the time

[1] Data on file.

Available literature for anchor-based colpopexy repair pain data

Lead author	Title	Journal	Year	Pain rate	Site of pain	Timeframe	Device used
Collin M. McKenzie	Sacrospinous Ligament Fixation Using an Anchor Versus Suture-Capturing Device: A Prospective Cohort Study[1]	*FPMRS*	2022	**0%**	N/A	1 year	Anchorsure
David E. Rapp	Comprehensive Evaluation of Anterior Elevate System for the Treatment of Anterior and Apical Pelvic Floor Descent: 2-Year Follow-up[2]	*Journal of Urology*	2014	**2.5%**	Buttock/leg	2 weeks	Elevate Anterior/ Apical Prolapse Repair System
Edward J. Stanford	Elevate Anterior/Apical: 12-Month Data Showing Safety and Efficacy in Surgical Treatment of Pelvic Organ Prolapse[3]	*FPMRS*	2013	**3.9%**	Buttock	6 weeks	Elevate Anterior/ Apical Prolapse Repair System
E.J. Stanford	One-Year Safety and Efficacy of Elevate® Anterior and Apical (EAA) with IntePro® Lite™ in the Surgical Treatment of Pelvic Organ Prolapse[4]	*Journal of Minimally Invasive Gynecology*	2011	**3.5%**	Buttock	1 year	Elevate Anterior/ Apical Prolapse Repair System

[1] McKenzie, M. Sacrospinous Ligament Fixation Using an Anchor Versus Suture-Capturing Device: A Prospective Cohort Study· *Female Pelvic Med Reconstr Surg.* 2022 Mar 1;28(3):131-135
[2] Rapp, D. Comprehensive Evaluation of Anterior Elevate System for the Treatment of Anterior and Apical Pelvic Floor Descent: 2-Year Follow-up. *J Urol.* 2014 Feb;191(2):389-94
[3] Stanford, E. Elevate Anterior/Apical: 12-Month Data Showing Safety and Efficacy in Surgical Treatment of Pelvic Organ Prolapse. *Female Pelvic Med Reconstr Surg.* 2013 Mar-Apr;19(2):79-83
[4] Stanford, E. One-Year Safety and Efficacy of Elevate® Anterior and Apical (EAA) with IntePro® Lite™ in the Surgical Treatment of Pelvic Organ Prolapse. Abstracts / *Journal of Minimally Invasive Gynecology*. 18(2011) S47–S70

Available literature for suture capture-based colpopexy repair pain data

Lead author	Title	Journal	Year	Pain rate	Site of pain	Timeframe	Device used
Alex Mowat	A descriptive study on the efficacy and complications of the Capio (Boston Scientific) suturing device for sacrospinous ligament fixation[1]	*The Australian and New Zealand Journal of Obstetrics and Gynecology*	2017	**15.9%**	Buttock	6 weeks	Capio
Cecile Ferrando	A randomized double-blind placebo-controlled trial on the effect of local analgesia on postoperative gluteal pain in patients undergoing sacrospinous ligament colpopexy[2]	*American Journal of Obstetrics and Gynecology*	2018	**26.9%**	Gluteal	6 weeks	Capio
Cecile Unger	Gluteal and Posterior Thigh Pain in the Postoperative Period and the Need for Intervention After Sacrospinous Ligament Colpopexy[3]	*FPMRS*	2014	**15.3%**	Gluteal/ posterior thigh	6 weeks	Capio

[1] Mowat, A. A descriptive study on the efficacy and complications of the Capio (Boston Scientific) suturing device for sacrospinous ligament fixation. *Aust N Z J Obstet Gynaecol,* 2018 Feb;58(1):119-124
[2] Ferrando, C. A randomized double-blind placebo-controlled trial on the effect of local analgesia on the postoperative gluteal pain in patients undergoing sacrospinous ligament colpopexy. *Am J Obstet Gynecol.* 2018 Jun;218(6):599.e1-599.e8
[3] Unger, C. Gluteal and Posterior Thigh Pain in the Postoperative Period and the Need for Intervention After Sacrospinous Ligament Colpopexy. *Female Pelvic Med Reconstr Surg.* 2014 Jul-Aug;20(4):208-11

05

Procedural steps

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Saffron™ Fixation System procedural steps

4 Steps to successful anchoring:

1

The sacrospinous ligament should be **fully cleared of the overlying tissue**

2

The sacrospinous ligament should be **clearly identified from the surrounding tissue**

3

Identify the appropriate fixation point on ligament

- Place your guiding fingertip on the fixation point
- Replace your fingertip with the distal tip of the Saffron Fixation Device

4

Appropriate force should be used when deploying the anchor to ensure the anchor is sufficiently implanted

06

Procedural video

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Saffron™

Fixation System

Surgical Video

Costas A. Apostolis MD, FACOG, FPMRS

Akron, Ohio, U.S.A.

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.
Minneapolis, MN
PM-22168 05.2022

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PM-32660 07.2024