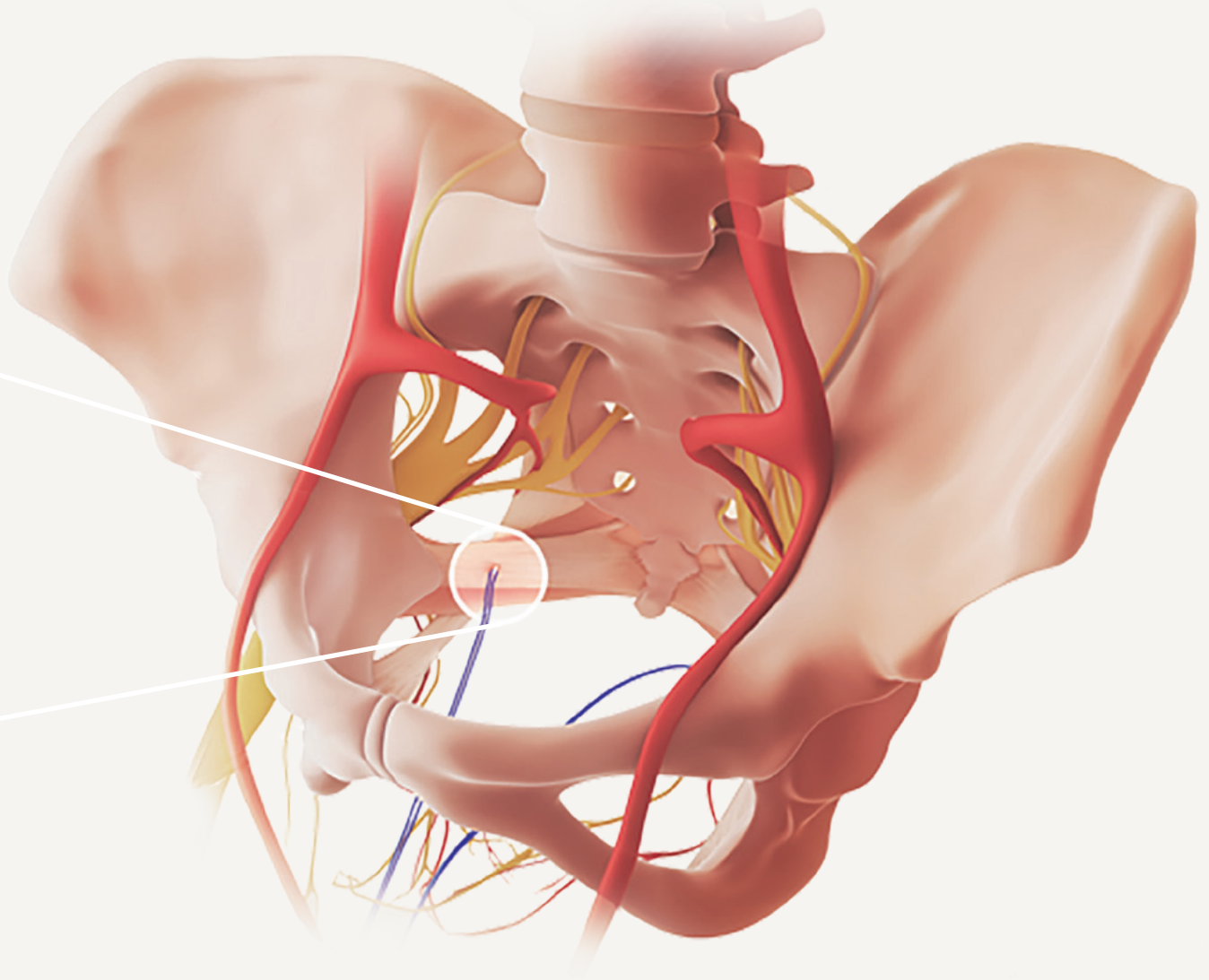


Saffron

Fixation System

Saffron anchor placement_



Colpopexy repair pain data_

Available literature for **suture-capture** based colpopexy repair pain data

Author and Title	Journal	Year	Site of Pain	Pain Rate	Time-frame	Device Used
Alex Mowat A descriptive study on the efficacy and complications of the Capio™ (Boston Scientific) suturing device for sacrospinous ligament fixation ¹	<i>The Australian and New Zealand Journal of Obstetrics and Gynecology</i>	2018	Buttock	15.9%	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	<i>American Journal of Obstetrics and Gynecology</i>	2018	Gluteal	26.9%	6 weeks	Capio
Cecile Unger Gluteal and Posterior Thigh Pain in the Postoperative Period and the Need for Intervention After Sacrospinous Ligament Colpopexy ³	<i>FPMRS</i>	2014	Gluteal/posterior thigh	15.3%	6 weeks	Capio

1. Alex Mowat, Vivien Wong, Judith Goh, Hannah Krause, Anita Pelecanos, Peta Higgs, 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. doi: 10.1111/ajo.12720.

2. Cecile A. Ferrando, Mark D. Walters, A randomized double-blind placebo-controlled trial on the effect of local analgesia on postoperative gluteal pain in patients undergoing sacrospinous ligament colpopexy, *Am J Obstet Gynecol* 2018 Jun;218(6):599.e1-599.e8. doi: 10.1016/j.ajog.2018.03.033

3. Cecile A. Unger, Mark D. Walters, Gluteal and Posterior Thigh Pain in the Postoperative Period and the Need for Intervention After Sacrospinous Ligament Colpopexy, 2014 Jul-Aug;20(4):208-11. doi: 10.1097/SPV.0000000000000091

4. Andre Plair, Whitney Smith, Katherine Hines, Jeffrey Schachar, Candace Parker-Autry, Catherine Matthews, Gluteal and Posterior Thigh Pain From a Suture Compared With an Anchor-Based Device in Patients Undergoing Sacrospinous Ligament Fixation, *Obstet Gynecol.* 2022 Jan 1;139(1):97-106. doi: 10.1097/AOG.0000000000004629

5. David E. Rapp, Ashley B. King, Bruce Rowe, Jeff P Wolters, Comprehensive evaluation of anterior elevate system for the treatment of anterior and apical pelvic floor descent: 2-year followup, *J Urol* 2014 Feb;191(2):389-94. doi: 10.1016/j.juro.2013.08.023

6. Edward J. Stanford, Robert D. Moore, Jan-Paul W. R. Roovers, Christophe Courtieu, James C. Lukban, Eduardo Bataller, Bernhard Liedl, Suzette E. Sutherland, 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. doi: 10.1097/SPV.0b013e318278cc29

7. Stanford EJ, Moore RD, Roovers J-PWR, Giudice T, Lukban JC, Bataller E, Mayne C, Sutherland S., 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

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.

Available literature for **anchor-based** colpopexy repair pain data

Title	Journal	Year	Site of Pain	Pain Rate	Time-frame	Device Used
Andre Plair Gluteal and Posterior Thigh Pain From a Suture Compared With an Anchor-Based Device in Patients Undergoing Sacrospinous Ligament Fixation ⁴	<i>Obstetrics & Gynecology</i>	2022	Gluteal/posterior thigh	0%	6 weeks	AnchorSure®
David E. Rapp Comprehensive Evaluation of Anterior Elevate System for the Treatment of Anterior and Apical Pelvic Floor Descent: 2-Year Follow up ⁵	<i>Journal of Urology</i>	2014	Buttock/leg	2.5%	2 weeks	Elevate Anterior/Apical Prolapse Repair System
E.J. Stanford Elevate Anterior/Apical: 12-Month Data Showing Safety and Efficacy in Surgical Treatment of Pelvic Organ Prolapse ⁶	<i>FPMRS</i>	2013	Buttock	3.9%	12 months	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 ⁷	<i>Journal of Minimally Invasive Gynecology</i>	2011	Buttock	3.5%	1 year	Elevate Anterior/Apical Prolapse Repair System

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
05/19/2022
PM-22168

Saffron anchor placement

The Saffron **anchor-based** fixation system in Figure 1 shows how the distance between the anchor and the surrounding nerves and vessels **exceeds 10 mm**.

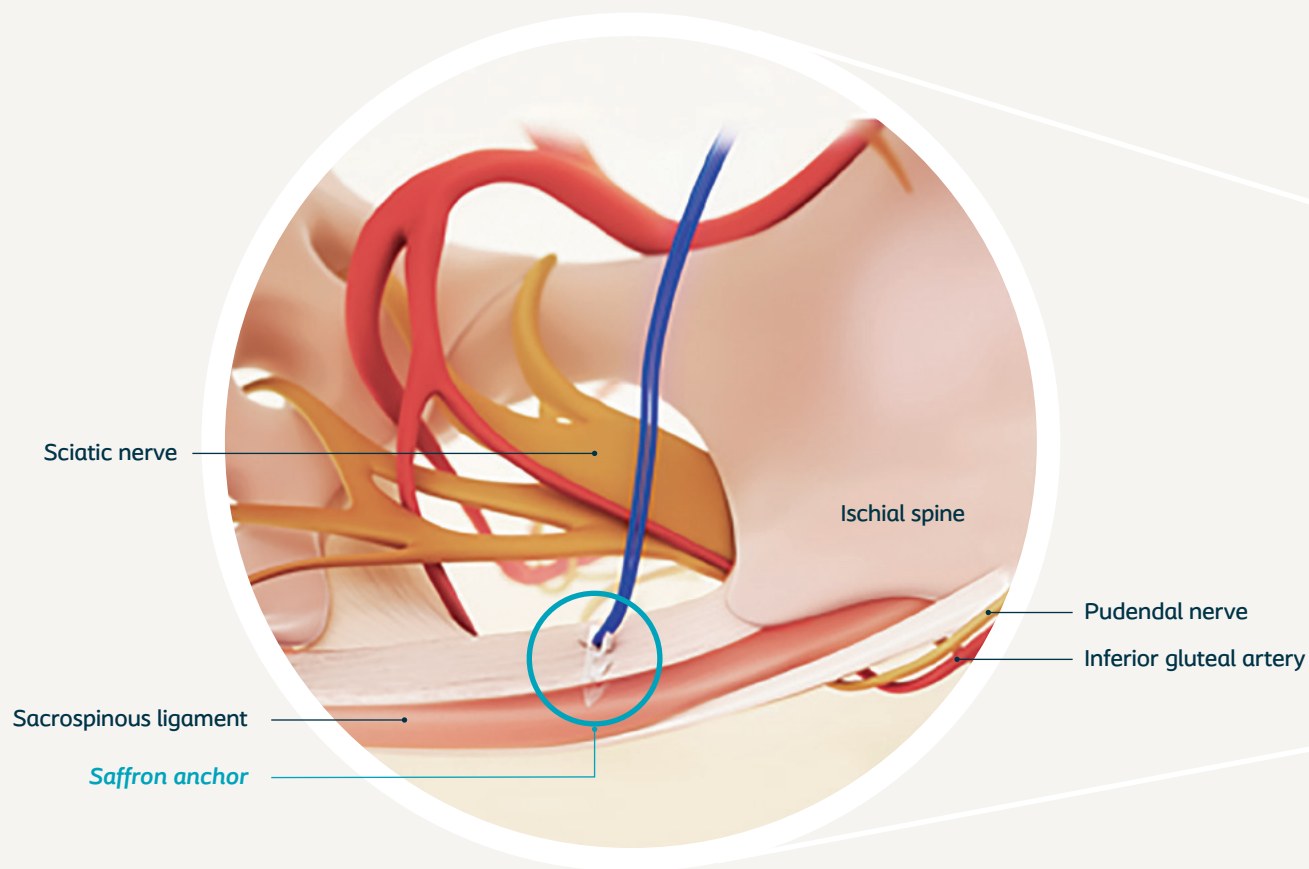


Figure 1