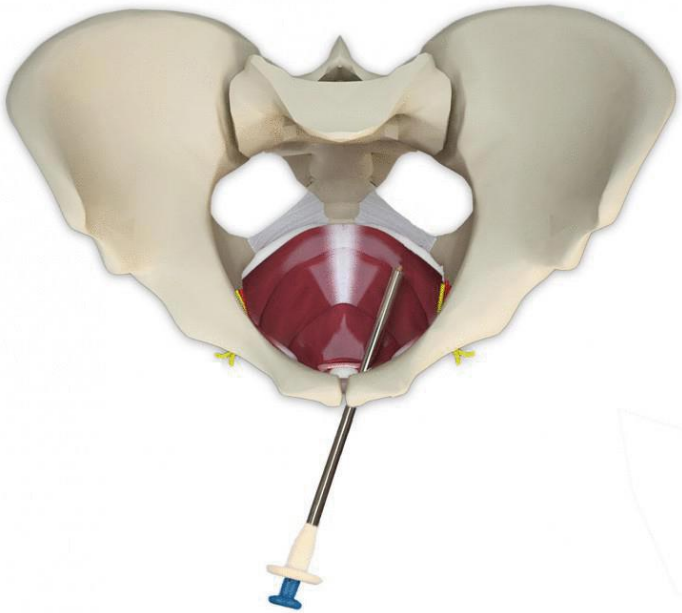
ANCHORSURE

SAFE AND EASY ANCHOR FIXATION



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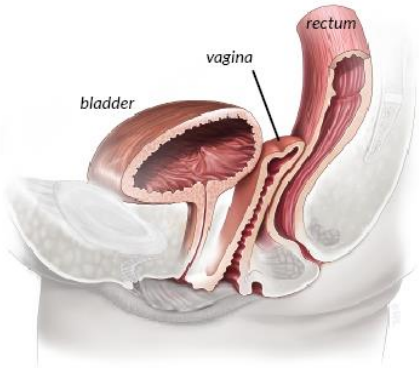
APICAL PROLAPSE

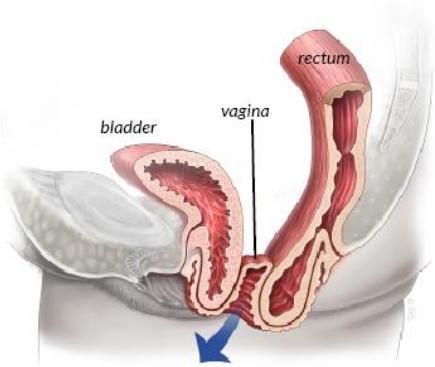
Three types of prolapse can occur in the apical compartment:

- Uterine prolapse.
- Vaginal vault prolapse (after hysterectomy)
- Small bowel prolapse (entrocele).

We will not focus on the enterocele. The surgical techniques for its vaginal and laparoscopic treatment are not interesting to our products.



Vagina Vault without prolapse



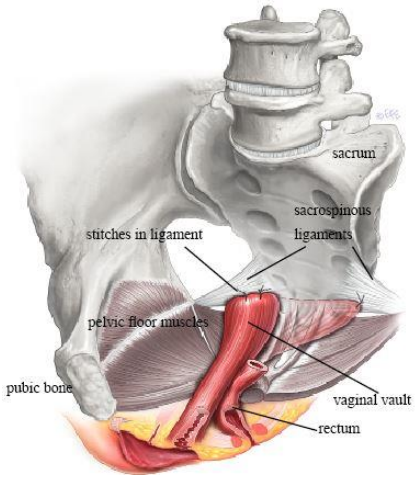
Severe vaginal vault prolapse, with anterior and posterior prolapse

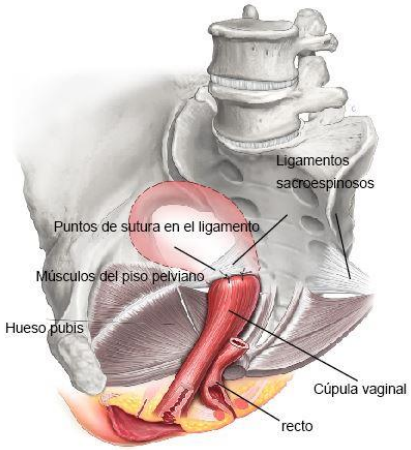
SACROSPINOUS LIGAMENT FIXATION

The **SACROSPINOUS LIGAMENT FIXATION (SSLF)** is a transvaginal surgery designed to reposition the uterus or vagina vault.

1. The SSL is accessed where one to three permanent or slow-absorbing sutures (PDS) are attached.
2. This sutures are threaded through the vagina vault or uterus and drived to the SSL to correct the prolapse.

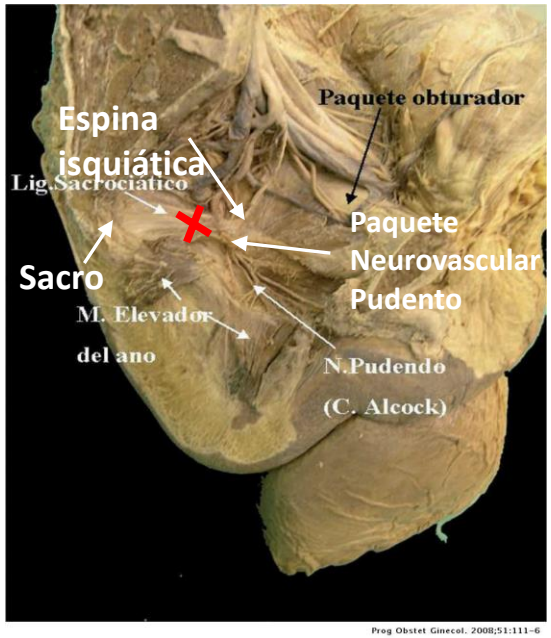
This technique was described BY Kurt Richter in 1968 and ever since we call it **Richter Tecnique.** Also called vaginal vault native tissue repair.

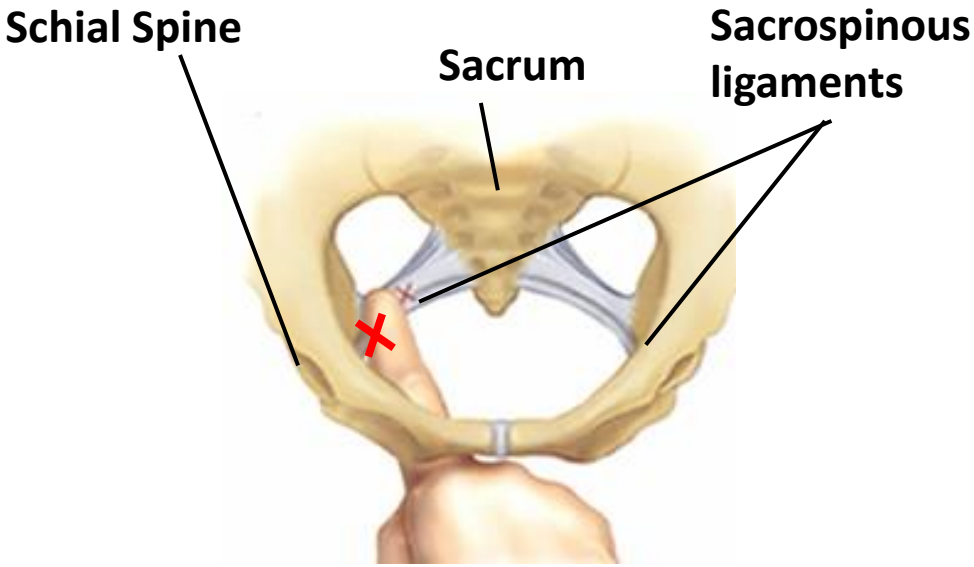




SACROSPINOUS LIGAMENT FIXATION

- The sacrospinous ligament (SSL) is, due to its position in the deep pelvis, a good support for vaginal fixation of the organs of the apical compartment.
- It measures between 4 - 5 cm and between 6 - 8 mm wide in its narrowest section.
- The pudendal neurovascular bundle passes behind the SSL in its most lateral stretch, next to the schial spine.
- To avoid pain and bleeding we should target the fixation 2 cm away from the schial spine.





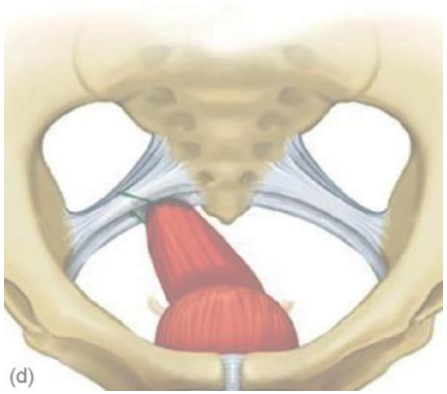
✗ → Fixation placement

RICHTER - MONOLATERAL OR BILATERAL

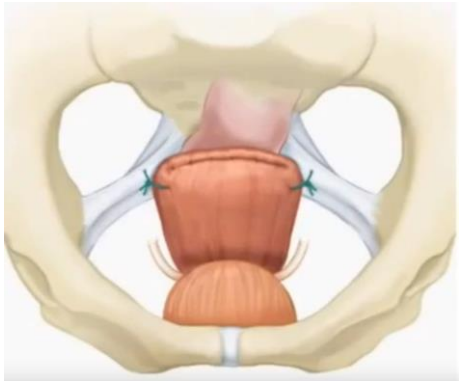
The vaginal vault fixation to the SSL can be done monolateral or bilateral.

Bilateral technique is more anatomic reconstruction than monolateral but increases the tension on the stitches and perhaps increasing the risk of recurrent prolapse.

“The literature, in general, is in favor of the monolateral technique because of the reduction of surgery time and less morbility”*.



Monolateral fixation



Bilateral fixation

VAGINAL HYSTERECTOMY + PROPHYLACTIC RICHTER

To prevent the appearance of a vaginal vault prolapse Vaginal Hysterectomy (VH), it is always necessary to finish the VH with a colposuspension technique. There are two options:

- **McCall Culdoplasty**: consisting on fixation of the vaginal vault to the uterosacral ligaments and the closure of the Douglas space with the uterosacrals in the midline.

- **Richter**:
  - Some authors defend prophylactic Richter after VH.
  - Others affirm that due to the low rate of vaginal vault prolpase after VH it's not a necessary treatment.

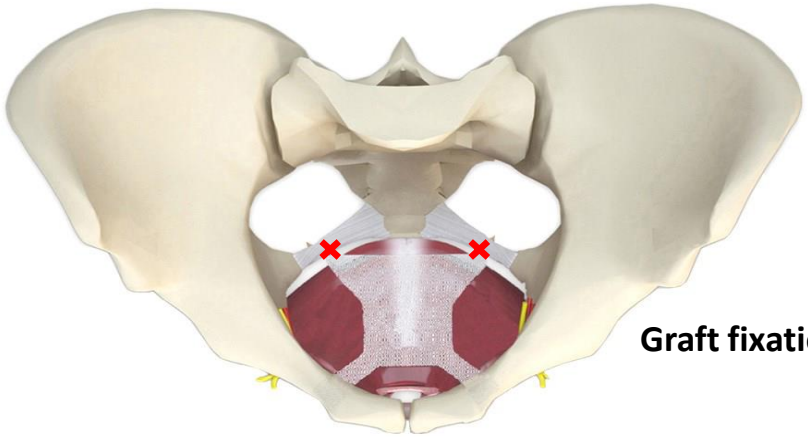
VAGINAL REPAIR WITH MESH

Another technique option for the correction of apical prolapse is using a mesh that supports the apical - anterior + apical – posterior + apical compartments.

The mesh will be fixed to the SSL using sutures and the prolapsed organ will be fixed to the central area of the mesh. Finally, mesh + prolapsed organ will be driven to the SSL ligament to complete the reconstruction.

The mesh can be:

- Synthetic (Ex: polypropylene)
- Biologic (ex: colagen)



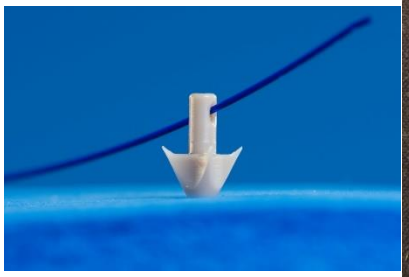
Graft fixation to the SSL

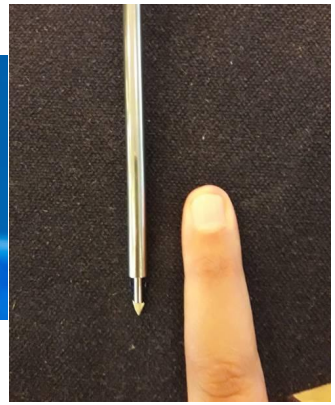
TYPES OF FIXATION

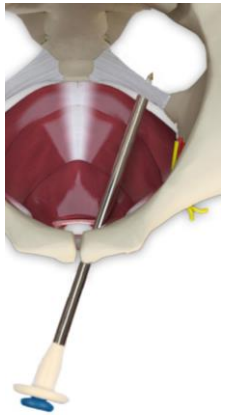
We can divide the types of fixation to the SSL in two groups depending on the device used:

Anchor fixation:

- The fixation consist of going through the SSL with an anchor connected to a suture thread. This thread will help to fix biologic graft or to suture the organ itself.
- As the anchor is only going through the SSL by one unique insertion point, there is less risk of having ligament entrapment and the related post-op pain.
- The fixation is done with a 5mm diameter applicator.



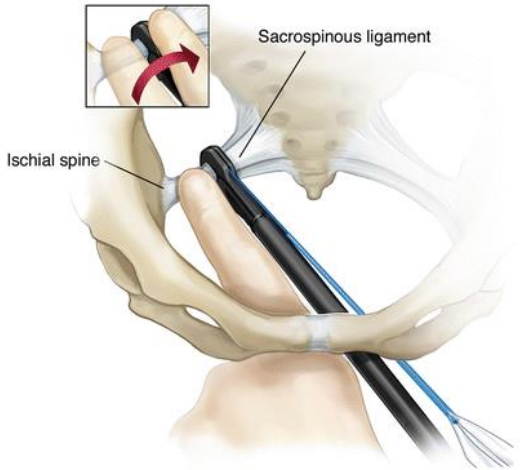


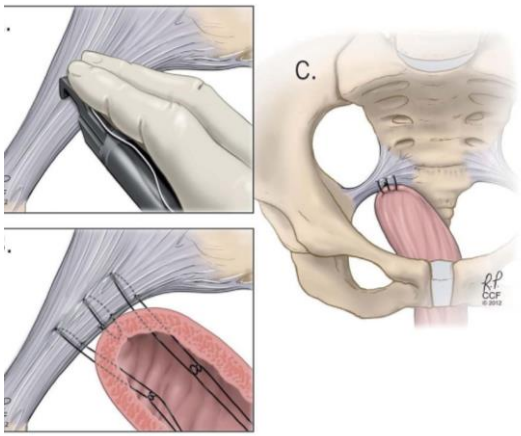


TYPES OF FIXATION

Suturing fixation:

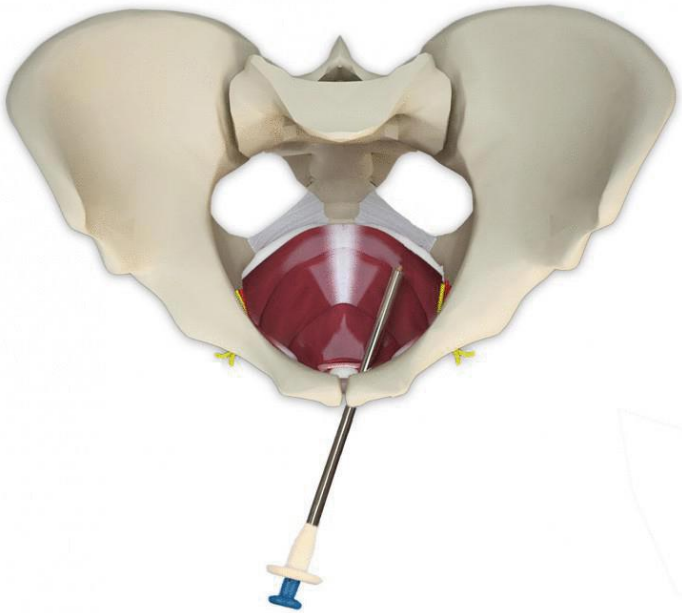
- This fixation consist in fixing a suture around the ligament like a regular stitch but using a bulky applicator to reach the SSL.
- This suture will be used to fix a biologic graft or directly the prolapsed organ tissue.
- The suture is going around the ligament which increases the risk of ligament and nerve entrapment that creates post-op pain.
- A bigger dissection is needed.





ANCHORSURE

SAFE AND EASY ANCHOR FIXATION



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¿WHAT IS IT?

ANCHORSURE

- It’s a vaginal approach minimal invasive **sacrospinous fixation device** for the treatment of prolapse.
- **Anchor fixation** (currently in the market there are suturing devices and anchor systems)
- It can be used to fix synthetic mesh, biologic graft or to perform a vaginal vault native tissue repair (Richter technique).

COMPLETE SYSTEM

Anchor + permament suture

Applicator

Free needle

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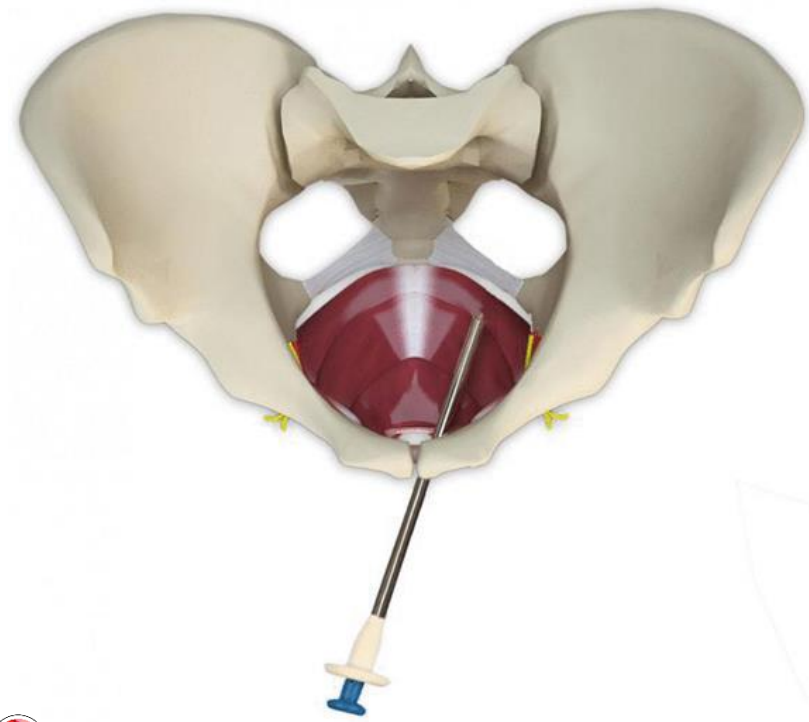
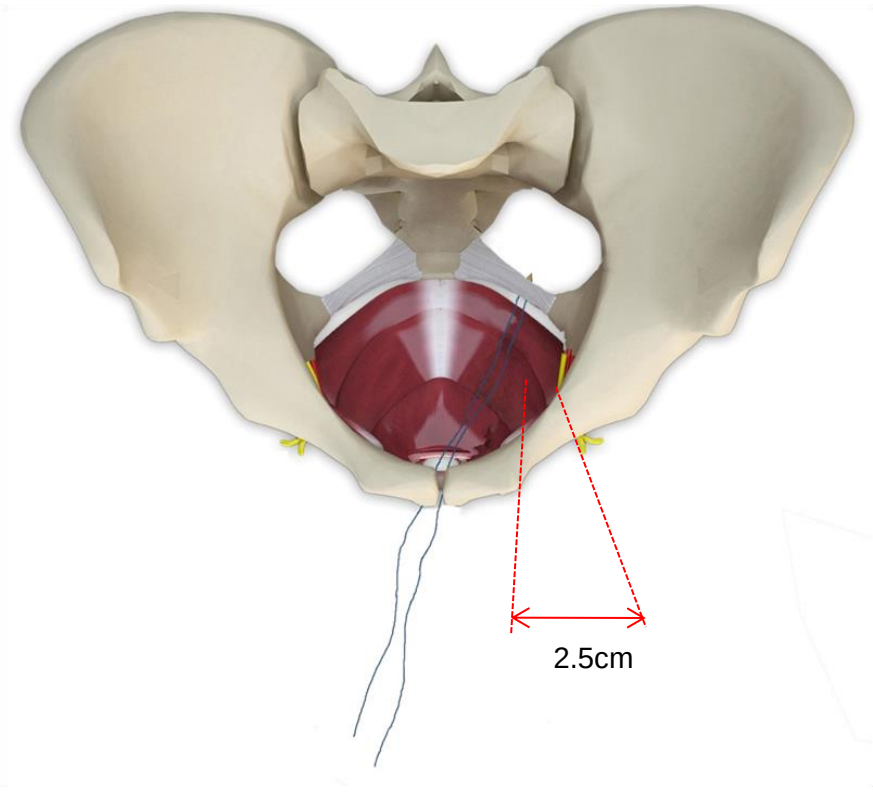
THE ANCHOR

- **Material: Peek** (Polyether Ether Ketone). Medical grade thermoplastic organic polymer
- **100% Biocompatible**
- **Maximum pull out force**: the tension needed to remove the anchor from the SSL is bigger than the traction force of the thread.
- **Compatible with any technique and sutures.**

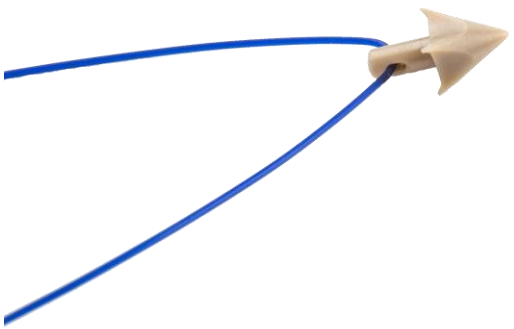
THE ANCHOR

The anchor must be placed at least 2cm away from the schial spine to avoid the vascular bundle.





THE SUTURE

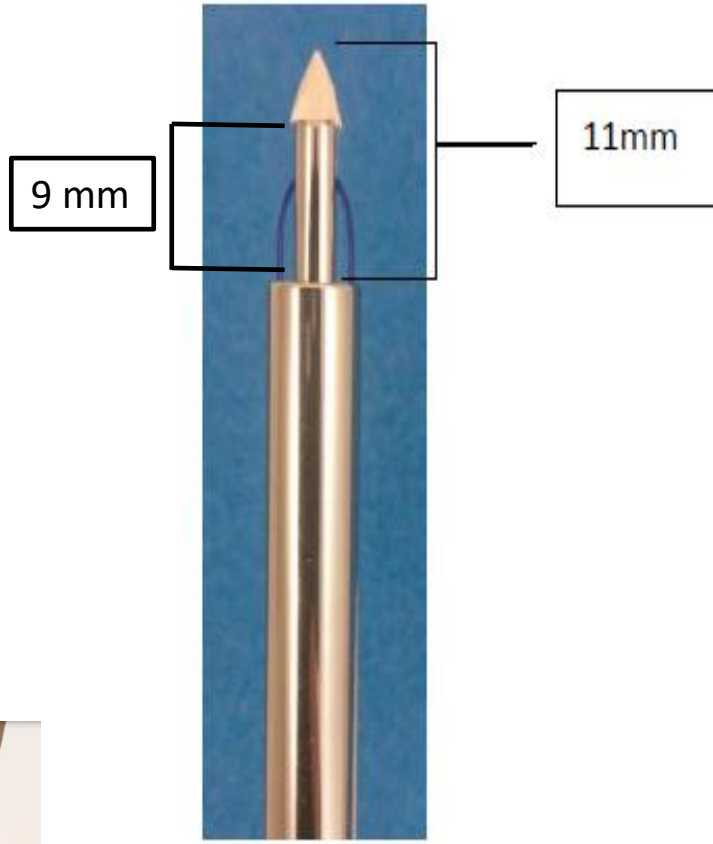


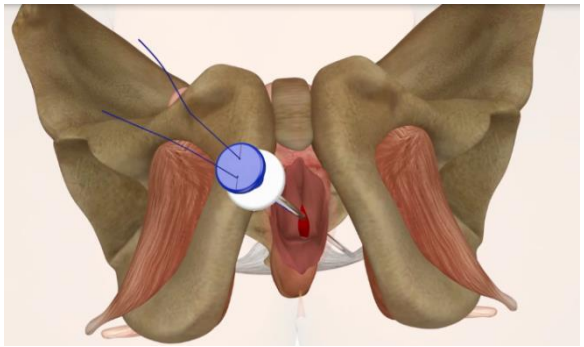
- **Material:** Polyvinyl Fluoride Monofilament (PVDF)
- **Non reabsorbible**
- **Suture size:** USP-0 (1-0)
- The anchor is not fix to the thread, therefore it can be changed by any other USP-0 suture.

Anchorsure is the only fixation device offering a **Pulley system.**
The system allows the surgeon to adjust the tension when driving the prolapsed organ into the deep pelvis towards the SSL.

THE APPLICATOR

- 5mm diameter straight applicator (minimum dissection and bleeding).
- The applicator has a **lenght limit control of 11mm**.
- The anchor form and the length of the applicator is designed to completely cross the ligament avoiding other tissues.

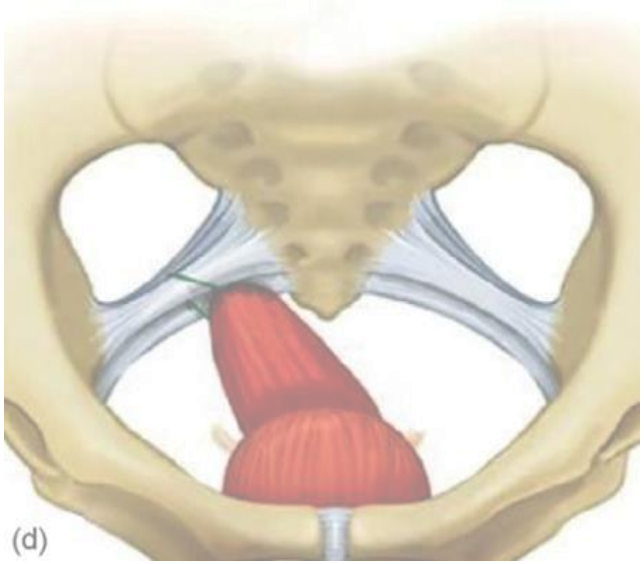




APPLICATIONS

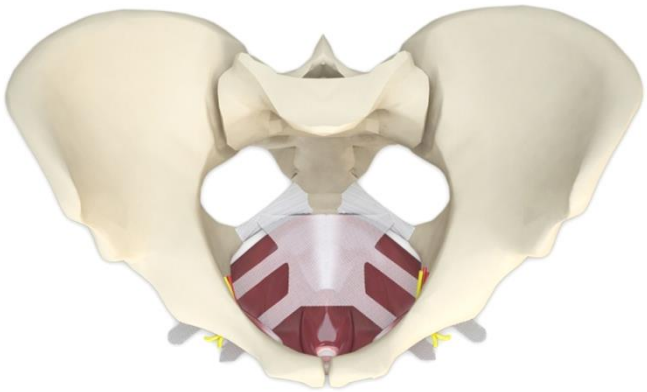
Anchorsure can be used for:

1. **Richter:** Native tissue repair suturing the vaginal vault and driving it to the SSL.

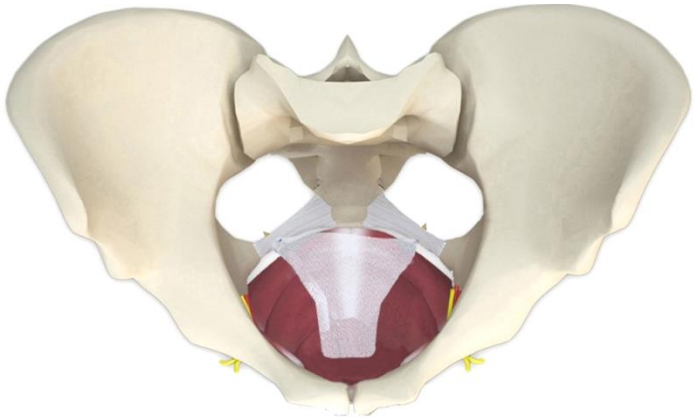


2. In combination with synthetic mesh or biologic graft:

Anterior + Apical prolapse



Posterior + Apical prolapse



ADVANTAGES AND BENEFITS

- Mínima invasive fixation system.
- Safer, easier and faster than any other SSL fixation device.
- Less trauma and pain because the fixation is not going around the ligament. Avoiding ligament entrapment and the related post-op pain.
- Less dissection which will reduce risk of bleeding.
- Palpate guided procedure, precise and simple.
- Compatible with all techniques

MATERIAL NEEDED IN THE OR

- **CPSAPLIC2AV**: Kit Anchorsure single use. Includes 1 applicator loaded with 1 anchor and suture + 1 anchor + free needle

 ANCHORING HANDLE, PRELOADED WITH ONE ANCHOR	 ANCHOR	 SURGICAL NEEDLE

SURGICAL TECHNIQUE

OPERATING ROOM REMINDERS

- We recommend the surgeon to stand up when doing the fixation of the Anchorsure.
- When deploying the anchor, keep some pressure to the external shaft of the applicator in order to make sure the anchor goes deep into the ligament.
- If the surgeon uses any type of forceps to clamp the thread, it's important to do it carefully as the thread can be damaged and break when doing the repair.

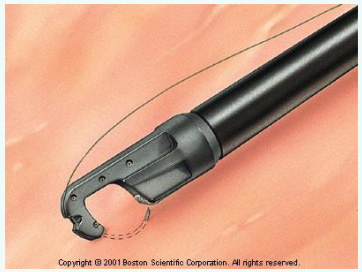
COMPETITORS

ANCHOR FIXATION

1. Promedon – **Splentis**

SUTURING DEVICES

2. Boston Scientific- **Capio**



3. AMI - **i-Stitch**

4. Coloplast - **Digitex**

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COMPETITORS

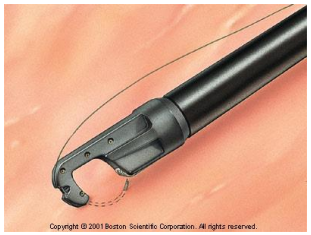
Boston- Capio

Coloplast- Digitex

Neomedic- Anchorsure

BENEFITS FOR THE HEALTHCARE PROFESSIONALS

BENEFITS ANCHORSURE VS SUTURES



- **Less Trauma and pain:**
  No nerve entrapment because Anchors are not squeezing the ligament
  Minimally invasive
  Reliable tissue anchor fixation

- **Less dissection:**
  Lower risk of bleeding
  More precision
  Easier to use
  Comfortable blind placement

SUTURES vs ANCHORSURE

Sutures : Capio (BSC)	Anchors : Anchorsure (Neomedic)+ Elevate (AMS)
Aust N Z J Obstet Gynaecol. 2018 Feb;58(1):119-124. doi: 10.1111/ajo.12720. Epub 2017 Sep 22. A descriptive study on the efficacy and complications of the Capio (Boston Scientific) suturing device for sacrospinous ligament fixation. Mowat A1, Wong V2, Goh J3, Krause H3, Pelecanos A4, Higgs P5. **Summary** N= 51 patients Patients with post-op pain = 84% After 7 weeks it reduces to 16%. 7% with analgesics Follow up = 17 months	J Urol. 2014 Feb;191(2):389-94. doi: 10.1016/j.juro.2013.08.023. Epub 2013 Aug 20. Comprehensive evaluation of anterior elevate system for the treatment of anterior and apical pelvic floor descent: 2-year followup. Rapp DE1, King AB2, Rowe B3, Wolters JP2. **Summary** N= 42 patients Patients with post-op pain = 7,14 % Follow up = 2 years
Female Pelvic Med Reconstr Surg. 2014 Jul-Aug;20(4):208-11. doi: 10.1097/SPV.0000000000000091. Gluteal and posterior thigh pain in the postoperative period and the need for intervention after sacrospinous ligament colpopexy. Unger CA1, Walters MD. **Summary** N= 242 patients Patients with post-op pain = 55,4 % After 6 weeks it reduces to 15.3% Follow up = 5 years	IUGA POSTER NDP 295 ANCHORSURE – NEOMEDIC INTERNATIONAL By E. KAPLAN; Ctr. For Advanced Gynecologic Surgery, Walnut Creek, CA. SYSTEM: OUTCOMES AND SAFETY PROFILE IN VAGINAL RECONSTRUCTIVE SURGERY **Summary** N= 300 patients Patients with post-op pain = 0.2% Follow up = Post-op

Average post-op pain after suturing devices:
15,7%

Average post-op pain after anchor devices :
4%

Utilizing suturing devices the post-op pain increases significantly and it remains until 7 weeks.

¿Do we want this for our patients?

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PATIENT BENEFITS

- Less pain
- Less risk of bleeding

BENEFITS FOR HEALTHCARE PROFESSIONALS

ANCHORSURE BENEFITS VS SPLENTIS

- 100% biocompatible material (PEEK vs Polypropylene)
    - More anchor strength than Splentis
- Pulley system (sliding suture), Splentis does not have it
    - Facilitates the adjustability of the mesh or the organ to fix
- Anchorsure applicator has a safety stop and ensures that we completely cross the ligament without reaching delicate structures. Splentis does not have an stop, which runs the risk of piercing the ligament not only with the anhor but also with the applicator, increasing the risk of injury to neighboring structures or of not penetrating the ligament.
    - Less risk of pain and more precision, Splentis more risk of pain.

KEY MESSAGES

- **Anchor fixation**
- **Minimal invasive – less bleeding**
- **No ligament entrapment - Less trauma and pain**
- **Palpate placement, easy, precise and comfortable**

THANK YOU

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