EnPlace®

Pelvic ligament fixation system

INSTRUCTIONS FOR USE

Device Description

EnPlace is a single use trans-vaginal pelvic floor repair system which enables delivery of a tissue Anchor to the ligaments of the pelvic floor.

The Anchors are pre-loaded inside the device Shaft and are ready for use.

A Finger Guide is also supplied, as an accessory for the device, to be used as a guide channel for better handling of EnPlace.

Intended Use / Indications for Use

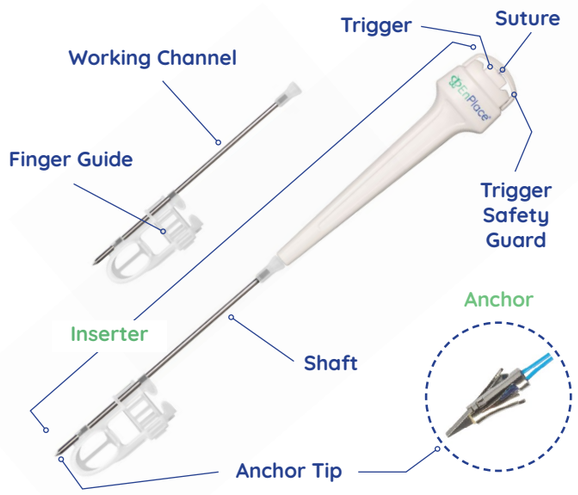
The EnPlace system is intended for attaching sutures to ligaments of the pelvic floor.

CAUTION: Federal law (U.S) restricts this device to sale by or on the order of a physician.

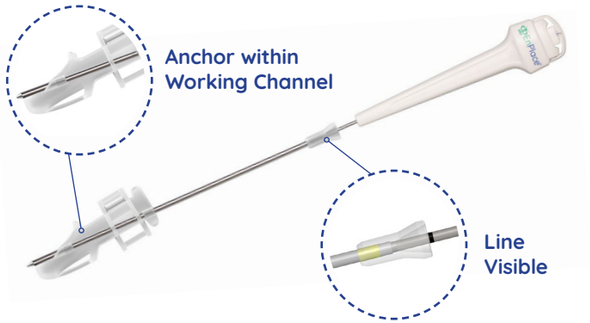
Physicians should be trained in the treatment of pelvic floor disorders and in management of complications resulting from these procedures.

Read this document carefully.
Failure to follow instructions may cause malfunction and / or patient injury.

Device Components



When the “exit” line is visual the anchor is within the Working Channel and no tissue trauma will occur. Once the line is covered by the port, the needle is exposed distally and tissue trauma is possible.



Contents

The EnPlace device package contains one kit, supplied in a sterile blister pack.

Each kit contains the following:

- 2 EnPlace Inserters with pre-loaded Anchor and Suture
- 2 Finger Guides (Left & Right)

Contraindications

The EnPlace Implant is NOT intended for use on the following:

- Do not use the EnPlace device on patients undergoing anticoagulation therapy.
- Do not use the EnPlace device on patients with an autoimmune disease affecting connective tissue.
- Do not use the EnPlace device on patients under 18 years.
- Do not use the EnPlace device on patients with pre-existing conditions that pose an unacceptable surgical risk.
- Do not use the EnPlace device on patients with known Nickel or Ni / Ti allergy.
- Do not use the EnPlace device on pregnant women or those considering future pregnancy.

Warnings and Precautions

It is imperative that the surgeon and operating room staff are fully conversant with the appropriate surgical technique for treating pelvic organ prolapse (POP) via anchoring to the pelvic ligaments.

- Proper surgical procedures must be used to avoid contamination and infection.
- The EnPlace system is supplied sterile. Immediately before opening the unit’s sterile pack, visually inspect the pack to assure that the pack is intact and undamaged, verifying that the EnPlace system’s sterility is not compromised.
- The EnPlace system is **NOT** reusable. EnPlace cannot be re-sterilized. Discard and do not use any unpacked or damaged EnPlace systems.
- Strict aseptic measures must be taken during the surgical procedure.
- Inform the patient that significant bleeding, pain, fever, abdominal swelling, weakness, or any other adverse effect must be communicated to the surgeon as soon as possible.
- Pelvic post-operative bleeding and intestinal injury may occur. Observe any signs or symptoms before patient’s discharge.
- It is recommended that patients avoid physical stress or sport activities (for example biking, jogging, etc.) for a minimum of one month after surgery. It is also recommended to avoid sexual intercourse during the first month of the postoperative period.
- It is recommended to pay special attention and take the appropriate measures to avoid risks during surgery in patients with bowel problems, urinary tract infection or obstruction, renal and or liver insufficiency, undergoing concomitant bowel surgery or treated by radiation.
- Special care should also be taken in patients with an active infection, cancer, or any other patient condition that may be affected by the use of the EnPlace system.
- The penetration limit mechanism of action requires the use of the Finger Guide. If the decision is not to use the Finger Guide, please take caution when puncturing the ligament.

Limitations:
The biocompatibility Risk Assessment for the EnPlace Nitinol Anchor has determined that a maximum of 11 Anchors per patient may be implanted.

Potential Adverse Reactions:

- Vessels and / or nerves, bowel and urinary tract injury may occur during the placement of the EnPlace Anchor. Any damage inflicted that requires surgical intervention, should be managed.
- Using the EnPlace system may cause temporary irritation of surrounding tissue and / or foreign body reaction.
- As a foreign body, the EnPlace Anchor may exacerbate a pre-existing infection.
- If a patient suffers complications or reactions caused by any of the components, the implants should be removed.
- The device may cause pain, tissue irritation, fistula formation.
- If Anchor removal is indicated, dissection of the Anchor from the sacrospinous ligament with a surgical scalpel incurs risk of injury to the ligament itself as well as injury to the rectum, ureter, and the abundant nerves and blood vessels (inferior gluteal vessels, hypogastric venous plexus, pudendal nerves/vessels) in close proximity to the ligament.

Materials Used in Manufacturing:
Suture: Polypropylene monofilament
Anchor: Nickel – Titanium alloy (Nitinol)
Delivery Handle: Stainless Steel AISI 316L & Makrolon 2458
Finger Guide: TM9Med & Stainless-Steel AISI 316L

How Supplied and Storage Instructions:
The EnPlace system is supplied sterile by Ethylene Oxide processing.

Warning: Do not use if the package has been damaged.

Storage: Store the EnPlace system at a temperature lower than 25°C, far from humidity, heat and direct light. **Do not use after the expiration date detailed on the package.**

Single Use Product:
The EnPlace system is intended to be used only once for a single patient. **DO NOT** reuse, reprocess or re-sterilize. Reuse, reprocessing or re-sterilization may compromise the

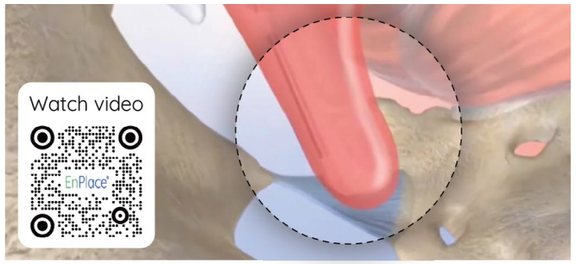
structural integrity of the device and/or lead to device failure, which in turn, may result in patient injury, illness or death. Reuse, reprocessing or re-sterilization may also create a risk of contamination of the device and/or patient infection or cross-contamination, including, but not limited to the transmission of infectious disease(s) from one patient to the other. Contamination of the device may lead to injury, illness or death of the patient. After use, dispose of product and packaging in accordance to hospital, administrative and/or local government policy.

Procedure:
Before using the EnPlace system, the physician must read and understand this document.

Anesthetics and Antibiotic Therapy:
The surgical technique to implant the device can be performed under regional or general anesthesia. It is recommended to follow the antibiotic protocol dictated by the hospital (or surgeon).

Anchor Placement

1. Choose the site of anchoring, on the selected pelvic ligament, based on palpation and pre-procedure vaginal ultrasound (if performed).
2. Prepare the surgical field and the site of anchoring.
3. Place the Finger Guide on the corresponding index finger (RIGHT Finger Guide for RIGHT index finger for fixation of the patient's RIGHT ligament and LEFT Finger Guide for LEFT index finger for fixation of the patient's LEFT ligament). Extend the index finger to the distal tip of the Finger Guide and then wrap the tensioning strap around the Finger Guide and secure it to the appropriate notch for comfort and tightness.
4. Introduce the Finger Guide until it reaches the site for anchoring.



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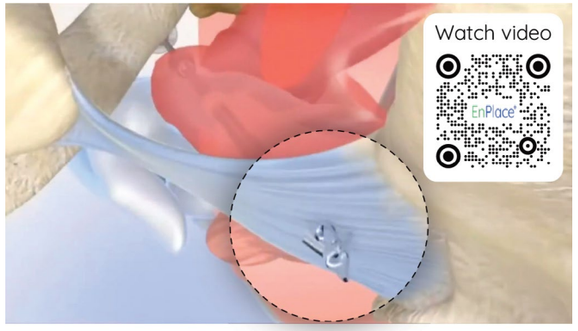
5. Slide the Inserter through the Working Channel located on the lateral side of the Finger Guide
6. Position the Anchor Tip over the selected pelvic ligament anchoring point (such as the sacrospinous ligament).
7. Firmly press the Finger Guide against the vaginal wall and the EnPlace Anchor Tip against the ligament until puncturing and penetrating through the ligament with the Anchor Tip. The device is designed to allow a limited penetration which should provide a firm fixation without the risk of over-penetration.

   Caution: Ensure Anchor Tip is in direct contact with the ligament without involvement of other surrounding tissue.



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8. Lower the Trigger Safety Guard to expose the Trigger, without moving the Anchor Tip.

9. Firmly push the Trigger, deploying the Anchor into the ligament without moving the Anchor Tip.

10. Withdraw the EnPlace Applicator and Finger Guide from the vaginal orifice and secure the proximal traction Sutures with forceps. Then verify the initial pull out force by gently pulling the Sutures.
11. Continue with the procedure, as performed routinely, by attaching the EnPlace anchored Sutures to an appropriate centro-apical anchoring point on the pelvic floor.
12. In the unlikely event that the Anchor needs to be removed after placement, the Anchor could be difficult to locate and reach within the ligament and removal could be complicated by inflammation and scar tissue. A forceful pull on the Suture could cause the Suture to tear, making the Anchor difficult to reach. Dissection of the Anchor from the sacrospinous ligament with a surgical scalpel incurs risk of injury to the ligament itself as well as injury to the rectum, ureter, and the abundant nerves and blood vessels (inferior gluteal vessels, hypogastric venous plexus, pudendal nerves/ vessels) in close proximity to the ligament.

MRI Safety Information

MR Conditional

Non-clinical testing demonstrated that the EnPlace Anchor is MR Conditional. A patient with this device can be scanned safely, immediately after placement under the following conditions:

- Static magnetic field of 1.5-Tesla and 3-Tesla.
- Maximum spatial gradient magnetic field of 4,000- Gauss/ cm (40-T/m) or less.
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 4-W/kg for 15 minutes of scanning (i.e., per pulse sequence) in the First Level Controlled Operating Mode of operation for the MR system.
- Under the scan conditions defined for the EnPlace Anchor is expected to produce a maximum temperature rise of 2.5°C after 15-minutes of continuous scanning (i.e., per pulse sequence).

In non-clinical testing, the image artifact caused by the EnPlace Anchor extends approximately 10-mm from the device when imaged using a gradient echo pulse sequence and a 3-Tesla MR system.

Additional Information:
The safety of using the delivery system (e.g., Inserter and Finger Guide) for the EnPlace Anchor in the MR system room is unknown and these items have not been evaluated for magnetic field interactions, heating, or artifacts. Therefore, these items should not be used in the MRI environment.

Symbols Used in EnPlace Labeling

REF	Catalog Number
LOT	Batch Code
	Use By Date
	Caution
	Consult Instructions For Use
	Do Not Use if Package is Damaged
	Manufacturer
Rx Only	**CAUTION:** USA Federal Law restricts the sale, distribution, or use of this device to, by, or on the order of a physician.
	Do Not Reuse
STERILE EO	Sterilized using Ethylene Oxide

Manufacturer Information

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