

EnPlace[™]
SIMPLE, STRONG AND SECURE

Pelvic ligament fixation system

Instructions for Use

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.

Instructions for Use

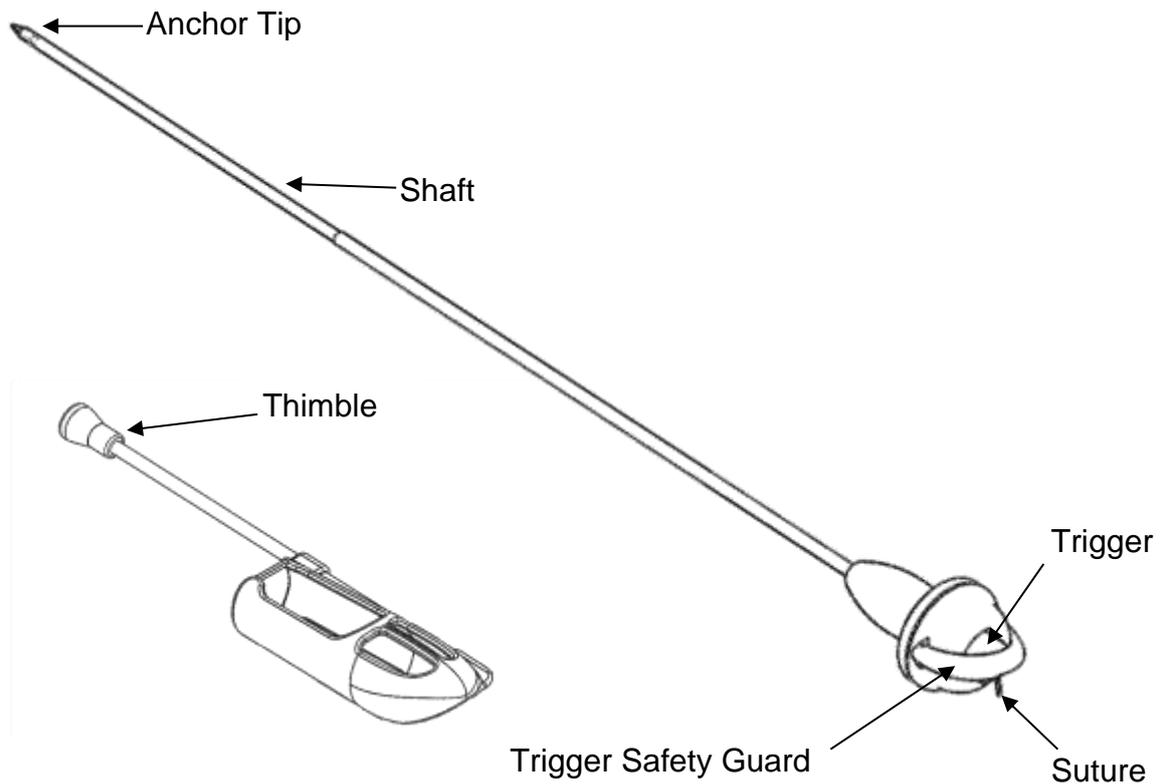
Device Description

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

The anchors are pre-loaded inside the device shaft and are ready for use.

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

Device Components



Contents

The EnPlace™ device package contains three kits, each kit is supplied in a sterile blister pack.

Each kit contains the following:

- 2 EnPlace™ devices with pre-loaded anchor and suture
- 2 Thimbles (L & R)

Intended Use / Indications for Use

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

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 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. The EnPlace™ cannot be re-sterilized. Discard and do not use any unpacked or damaged 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 two months after surgery. It is also recommended to avoid sexual intercourse during the first two months 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 channel limiter mechanism of action requires the use of the thimble if the decision is not to use thimble, please take caution when puncturing the ligament.

Limitations

- The biocompatibility Risk Assessment for the EnPlace™ Nitinol Anchor has determined that a maximum of 4 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 Polyoxymethylene (POM)

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 40°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.

Anchor Placement

1. Choose the site of anchoring, on the selected pelvic floor ligament, based on palpation and pre-procedure vaginal ultrasound (if performed).
2. Prepare the surgical field of the site of anchoring.
3. Place the thimble on the index finger of the dominant hand (optional) or just use your index finger as support for the end of the shaft to ensure that the tip safely reaches the anchor site.

Note: If the thimble is being used, slide the shaft trough the introducer located on the side of the thimble.

4. Introduce the EnPlace™ device until the anchor tip reaches the site for anchoring.



5. Position the Anchor tip over the selected pelvic floor ligament anchoring point (such as the Sacro-spinous ligament).



6. Firmly press the EnPlace™ anchor tip and shaft against the ligament puncturing the ligament with the Anchor tip. The device is designed to allow a limited penetration which should provide a firm attachment without the risk of over-penetration.



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

7. Lower the Trigger Safety Guard to expose the Trigger.



8. Push the Trigger, deploying the Anchor into the ligament.



9. Withdraw the EnPlace™ shaft from the anchoring site and secure the proximal traction sutures by a forceps. Then verify the initial pull out force by gently pulling the sutures.

10. Continue with the procedure, as performed routinely, by attaching the anchors to an appropriate centro-apical anchoring point at the pelvic floor.
11. 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., applicator and thimble) 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



Catalog Number



Manufacturer



Batch Code



CAUTION: USA Federal Law restricts the sale, distribution, or use of this device to, by, or on the order of a physician.



Use By Date



Do Not Reuse



Caution



Sterilized using Ethylene Oxide



Consult Instructions For Use



Do Not Use if Package is Damaged

Manufacturer Information

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