Intended Use/Indications for Use

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

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.

Contents

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

Each kit contains the following:

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

Contraindications

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

- Patients who are pregnant or planning to become pregnant.
- Patients with a known allergy to nickel or Nitinol.
- Patients with bowel problems, urinary tract infection or any other patient condition that may be affected by the use of the EnPlace system.
- Any patient with another medical condition that may affect the integrity of the Anchor.

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.
- 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 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. It is recommended to avoid sexual intercourse during the first month of the postoperative period.

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.

When the “exit” line is visual the anchor is within the Work 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.

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 un-packed or damaged EnPlace systems.
- Strict aseptic measures must be taken during the surgical procedure.
- Informed 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.

Materials Used in Manufacturing:

- Suture: Poliglecaprone monofilament
- Anchor: Nickel – Titanium alloy (Nitinol)

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 25ºC, far from humidity, heat and direct light.

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.

Potential Adverse Reactions:

- Vessels and/or nerves, bowel and urinary tract injury may occur during the placement of the EnPlace Anchor.

The EnPlace system is intended for use on the following:

- Patients with known autoimmune disease affecting connective tissue.
- Patients undergoing anticoagulation therapy.
- Patients with pre-existing infection.
- Patients with known Nickel or Ni / Ti allergy.
- Patients with bowel problems, urinary tract infection or any other patient condition that may be affected by the use of the EnPlace system.

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 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. It is recommended to avoid sexual intercourse during the first month of the postoperative period.
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.


4. Introduce the Finger Guide until it reaches the site for anchoring.

5. Slide the Applicator through the Work 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.

8. Firmly push the Trigger, without moving the Anchor Tip.

9. Lower the Trigger Safety Guard to expose the Anchor Tip.

10. Firmly pull the Trigger, deploying the Anchor into the ligament without moving the Anchor Tip.

11. Withdraw the EnPlace Applicator and Finger Guide from the vaginal orifice and secure the proximal traction Sutures with forces. Then verify the initial pull out force by gently pulling the Sutures.

12. Continue with the procedure, as performed routinely, by attaching the EnPlace anchored Sutures to an appropriate centropelvic anchoring point on the pelvic floor.

Magnetic Resonance Imaging Safety Information

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 SAR 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 Finger Guide) for the EnPlace Anchor in the MRI system room is unknown and these items have not been evaluated for magnetic field interaction or artifacts. Therefore, these items should not be used in the MRI environment.