



# Instructions For Use

**CAUTION:**

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.

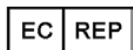
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0044 Date of CE authorization: June 2018

## Instructions for Use

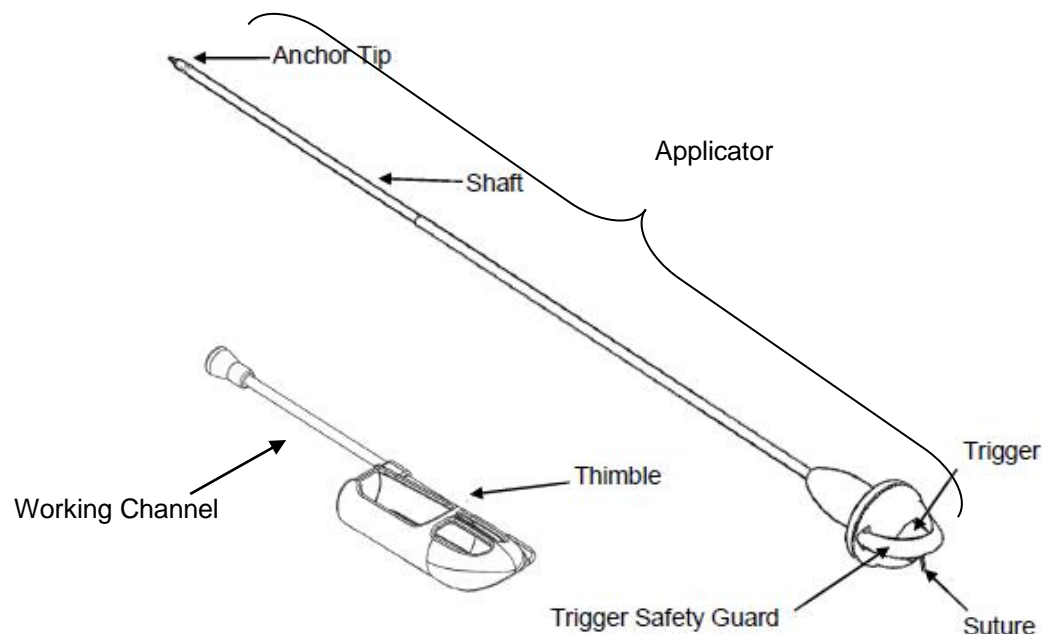
### Device Description

The EnPlace™ is a single use trans-vaginal device for the repair of pelvic organ prolapse (POP) by anchoring sutures to ligaments of the pelvic floor.

The EnPlace™ device comprises three main elements: a delivery system (“applicator”), an anchor-suture unit (pre-loaded in the delivery system) and a thimble with working channel.

The EnPlace™ is a single use implant, with associated accessories, supplied sterile, pre-loaded with the anchor-suture and ready for use.

### Device Components



#### Delivery system (applicator):

The applicator is a single hand operated, cylindrical straight stainless-steel shaft, that, upon insertion and guidance to the ligament enables the deployment and attachment of the pre-loaded anchor-suture unit at the designated position on ligament.

#### Suture attached to anchor:

The anchor is a sharp needlepoint nitinol element that is self-piercing through the designated location on the ligament. When released from the applicator, the anchor's spurs spring open on both sides, preventing release from the ligament. The anchor is attached to a polypropylene-monofilament suture at its distal end, which is exposed following retrieval of the applicator, enabling suturing and fixation of the prolapsed pelvic organ as intended for reconstruction.

#### Thimble (Working Channel):

The thimble is mounted on the surgeon's index finger and is coupled with a working channel to facilitate guidance of the applicator tip based on palpation of the target location with the index finger. There are two different thimbles - one for the right-hand and one for the left hand.

## Contents

The EnPlace™ device package contains three kits, each kit is supplied sterile within a pouch package.

Each kit contains the following:

- 2 EnPlace™ applicators, each with pre-loaded anchor-suture unit
- 2 Working Channels (Left & Right)

## Indications for Use

The EnPlace™ system is indicated for use in female patients suffering from apical central pelvic floor prolapse, with or without anterior and/or posterior pelvic floor compartment prolapses, after hysterectomy or with the uterus in situ, with or without urinary or fecal leakage – thus complying with the general requirements for centro-apical pelvic support.

## Intended Use

The EnPlace™ is a minimally invasive trans-vaginal device intended for the repair of pelvic organ prolapse (POP) by anchoring sutures to ligaments of the pelvic floor.

### Intended Users:

The EnPlace™ device is intended for professional use by Urogynecologist surgeons, Gynecologic surgeons, Urologic surgeons, Colorectal surgeons, Pelvic floor surgeons and General surgeons only.

### Intended patient population:

Women age 18 years and older, any weight and physical activity, diagnosed with centro-apical pelvic floor prolapse are candidates for the EnPlace™ system.

## Contraindications

The EnPlace™ is **NOT** intended for use in the following patients:

- Women undergoing significant anticoagulation therapy;
- Women with active autoimmune disease affecting connective tissue;
- Women under 18 years;
- Women with pre-existing conditions that pose an unacceptable surgical risk;
- Women with known Nickel or Ni / Ti allergy;
- Relative contraindication in pregnant women.

## 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 the sacro-spinous ligament or other pelvic ligaments.
- Proper surgical procedures must be used, to avoid contamination and infection.
- The EnPlace™ system should be used by surgeons knowledgeable in pelvic surgeries, who are trained in the use of the EnPlace™ system.
- 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™ system cannot be re-sterilized. Discard and do not use any unpacked or damaged systems.



## Instructions For Use

- Strict aseptic techniques must be used 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 immediately.
- 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 that patients avoid sexual intercourse during the first two months of the post-operative period.
- It is recommended that surgeons pay special attention and take appropriate precautions to avoid risks during surgery in patients with bowel issues, urinary tract infection or obstruction, renal insufficiency or liver disease, undergoing concomitant bowel surgery or treated by radiation. Special care should also be taken in patients with active infections, cancer, or any other patient condition that may affect the EnPlace™ system.
- There are special considerations when performing this procedure in pregnant women.
- The channel limiter mechanism of action, which limits the depth of insertion of the anchor-suture unit beyond the ligament, requires use of the thimble and working channel.

## 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

- Vessel, nerve, 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 pre-existing infections.
- If a patient suffers complications or reactions caused by any of the EnPlace™ components, the implants should be removed.
- The device may cause pain, tissue irritation or fistula formation.

## 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 higher than -10°C and lower than 40°C, far away from humidity, heat and direct light.

**Warning:** Do not use after the expiration date listed 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, or with local anesthesia combined with sedation.

It is recommended that the antibiotic protocol dictated by the hospital be followed.

### Anchor Placement

1. Choose the site of anchoring, on the selected pelvic floor ligament, based on palpation and pre-procedural vaginal ultrasound (if performed).
2. Prepare the surgical field of the site of anchoring.
3. Place the thimble on the index finger of the same hand as the side of the patient operation and slide the shaft through the introducer located on the side of the thimble at the end of the shaft. When introducing the thimble armed index finger into the patient's vaginal cavity, insert laterally, follow the bony pelvic sidewall up to the Iliac spine and identify by palpation the sacrospinous ligament, which emerges medially, then aim the working channel opening to the ligament's center, in both dimensions: mediolateral and cephalo-caudal. Having identified the midpoint of the ligament, sweep along the ligament to push midline structures, particularly the rectum, medially away from the point of insertion in the ligament, move back along the ligament to its midpoint, guide the thimble's working channel to that precise point on the ligament, and ensure that the tip safely reaches the anchor site.
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 against the ligament and puncture the ligament with the anchor tip. The device is designed to allow a limited penetration, which provides a firm attachment without the risk of over-penetration of the ligament and surrounding tissue.

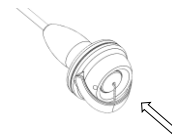
**Caution:** Ensure that the anchor tip is in direct contact with the ligament without involvement of other surrounding tissue by using the thimble to track along the ligament and sweep surrounding tissue out of the way.



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



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



9. Withdraw your hand together with the EnPlace™ thimble and applicator from the vagina. Then verify secure fixation of the anchor-suture unit by gently pulling the sutures.
10. Continue with the pelvic organ prolapse repair procedure, as routinely performed. The usual method of securing the sutures to the vaginal apex is to use a virgin needle to pass the supportive polypropylene nonabsorbable suture backwards through its entering point through the vaginal wall and medially and then through the cervical isthmus tissue, taking a significant 'bite' of the cervical fibrotic tissue, and then out to the vaginal cavity, through a small posterior colpotomy prepared before. The polypropylene suture may also be attached to the uterine cervix, or, if the patient has had a hysterectomy, the suture may be attached to the remnants of the utero-sacral ligaments, to the serosa of the vaginal apex, or to the vagina wall or any other appropriate centro-apical anchoring point within the pelvic floor. The polypropylene suture should be tied appropriately; 7 knots are recommended to avoid spontaneous loosening and untying of the knots. The small posterior colpotomy incision should be closed with absorbable 00 suture.
11. In the unlikely event that the anchor needs to be removed after placement, please use a small surgical scalpel blade to gently cut around the anchor within the ligament. This should free the anchor and you should be able to pull the anchor out using the suture attached to it. You can use the suture as a guide if you need to dissect a path to the ligament and the anchor. (The dissection is done the same way as performed to reach the sacro-spinous or other ligament for fixation).

## ***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, the maximum temperature rise is not expected to exceed 2.5°C after 15-minutes of continuous scanning (i.e., per pulse sequence).




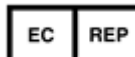













In non-clinical testing, the image artifact caused by the EnPlace™ Anchor extends approximately 10-mm from the device when imaged using a gradient echo pulse sequence and a 3-Tesla MR system.

**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.

### Disclaimer

The recommended labeling information is provided as an example of proper labeling for this product based on the latest information from the Food and Drug Administration and the American Society for Testing and Materials (ASTM) International, Designation: F2503 Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment. The issued labeling may be modified by the manufacturer, as needed. The manufacturer of this product is ultimately responsible and liable for damages involved in the use of the MRI-related labeling. The author or Shellock R & D Services, Inc. shall not be held liable for the product labeling or damages related to the use of this labeling.

## Symbols Used in EnPlace™ Labeling

	Catalog Number		Manufacturer
	Batch Code (YYMMX-00X)		Authorized representative in the European community
	Use By Date (YYYY-MM-DD)		CAUTION: USA Federal Law restricts the sale, distribution, or use of this device to, by, or on the order of a physician.
	Caution		Do Not Reuse
	Consult Instructions For Use		Do Not Re-Sterilize
	Do Not Use if Package is Damaged or Open		Sterilized Using Ethylene Oxide
	MRI Conditional		Keep dry
	Keep Away From Sunlight		Temperature Limitation
	CE marking of conformity		