FEMSelect EnPlace

October 2024

Device Overview

Pelvic organ prolapse (POP) refers to the descent of female pelvic organs, leading to a protrusion of the vagina and/or uterus. This typically involves the descent of the bladder, uterus, or vaginal cuff following a hysterectomy. Factors such as vaginal delivery, hysterectomy, chronic straining, aging, and connective tissue abnormalities can predispose some women to disruptions or dysfunctions in the levator ani complex (the funnel-shaped group of muscles in the lower pelvis) and the connective tissue attachments of the vagina, resulting in prolapse. [1] Current medical practice holds that a transabdominal sacrocolpopexy, whether conducted laparoscopically or robotically, is regarded as the gold standard for treating pelvic organ prolapse. [2] The FEMSelect EnPlace is a minimally invasive system for apical organ prolapse procedures that utilizes a meshless and minimal dissection ligament fixation approach. [3] Featuring a patented delivery system for guiding, inserting, and deploying the anchor unit, the anchor is designed to be inserted through the vaginal wall and secured to the pelvic floor ligament for stabilization. [4] Per the manufacturer, benefits include potential preservation of the uterus, same-day surgery, “no scarring”, and the ability to resume most activities within days. [4]

Actions for Consideration

PARTNER

ENGAGE SUBJECT MATTER EXPERTS
Evaluate plans for device use and implementation. Collaborate with gynecology, operating room leaders, and quality to assess.

CONSIDER GUIDELINES FOR USE
With multiple options available for treatment, consider criteria for appropriate indications and populations for use.

UNDERSTAND CONCERNS
Encourage open dialogue and assessments with key departments Leverage a physician champion as a peer liaison.

CONNECT

SEEK CLINICAL IMPACT
Assess FEMSelect’s EnPlace potential to impact outcomes and patient satisfaction compared to current practices. Include evaluation regarding impact with potential learning curve of new practices.

CONDUCT ANALYSIS
In addition to clinical impact, analyze the costs of current treatment options for POP and conduct a cost analysis to assess the financial impact, including reimbursement potential.

DETERMINE POPULATION
Collaborate with key stakeholders to identify the ideal patient population.

COMMUNICATE

EDUCATE AND TRAIN
Share details about available training and promote hands-on demonstrations to help users become familiar with the product. Ensure supplier engagement.

PLAN AHEAD
Consider trialing if consensus is not attained in analysis. Create and share plan to continue ongoing education about product, use, & outcomes.

FOLLOW-UP FOR FEEDBACK
Establish a continuous feedback loop to address challenges, outcomes, and any concerns after implementation. Report metrics regularly.

Professional Society Statements & Clinical Practice Guidelines

The American College of Obstetricians and Gynecologists and the American Urogynecologic Society

The POP practice bulletin reviewing "information on the current understanding of POP in women and to outline guidelines for diagnosis and management that are consistent with the best available scientific evidence" may be found here. [5]

Clinical Evidence

Several published studies on the use of the FEMSelect EnPlace device exist; however, these studies include authors who were involved in the device's development. The following is a selection of available evidence.

A 2023 retrospective cohort study conducted by Gold et al. included 123 participants with stage III or IV apical POP who underwent sacrospinous ligament (SSL) fixation using EnPlace. [6] The patients were categorized into two sub-groups: 91 patients with stage III–IV uterine prolapse and 32 patients with stage III–IV vault prolapse. Follow-up assessments were conducted at 6 weeks, 3 months, and 6 months after surgery. The postoperative evaluation included anatomical and functional cure rates, as well as pain, dyspareunia, lower urinary tract symptoms, and any additional complications. Results of the study found that of "91 patients with preoperative uterine prolapse, eight (8.8%) patients developed a recurrent uterine prolapse during the 6-month follow up. Of 32 patients with preoperative vault prolapse, two (6.3%) had a recurrent vault prolapse." [6] Limitations included the use of retrospective data, the absence of validated questionnaires, and a relatively short follow-up period. In addition, it is important to note that one of the authors is the founder and Medical Director of FEMSelect. [6]

A 2022 single-center longitudinal prospective study by Ben Zvi et al. included a total of 13 patients with advanced POP who received the EnPlace implant, although two of them were lost to follow-up. [7] Follow-up ranged from 42–57 months (with a median of 51 months) with assessments occurring at 4–6 weeks, 3 months, and 6 months. Outcome measurements included rates of anatomical and functional cure, levels of post-operative pain and dyspareunia, urinary symptoms, and incidence of post-operative complications. Surgical success rate was reported at 92.3% as one patient required an additional prolapse surgery. [7] One of the authors is the founder and Medical Director of FEMselect, and no other authors note any conflict of interest. [7]

Systematic search terms: FEMSelect, EnPlace, Pelvic organ prolapse repair. **Databases:** PubMed, Medline, CINAHL. **Studies published from:** 2019 to 2024.

See Reference section for complete listing of research sources.

Clinical Insights: HealthTrust Physician Advisors

A panel of gynecologists within our HealthTrust Physician Advisor Network offered the following insights with regard to the use of FEMSelect EnPlace treatment for pelvic organ prolapse. [8]

Physician Advisor Insights

Advantages

- Potential to improve minimally invasive surgical treatment of prolapse
- Potential to reduce operative time and length of stay
- Can be done concomitantly with other prolapse procedures

Disadvantages

- Success rates are not based on large statistically significant studies
- Attachment of sutures is performed blindly, which could lead to higher operative complications

Patient Populations

- Patients with pelvic organ prolapse - uterine prolapse or vaginal vault prolapse after hysterectomy
- Medically complex patients or poor surgical candidates who would not tolerate more extensive procedure

General Insights

- Need for training to gain familiarity with the product and safely deploy
- Long term studies are needed to validate smaller studies and product claims

Member Insights: HealthTrust Member Network

Members of the HealthTrust member network provided insights and feedback on the use of this product. [9]

Member Insights

Advantages

- Minimally invasive
- Alternative to repair using mesh products
- Potential quicker healing time
- Potential shorter length of stay
- Potential for less scarring and post-operative complications
- Product ease of use
- Potential outcomes including improved fecal and urinary continence, improvement of self body image

Disadvantages

- Potentially cost prohibitive
- May not have enough patient volume to support adoption
- Training and in-servicing due to new technique
- Potential learning curve issues
- Adoption may be difficult due to physician preference

FDA Approval

FDA 510K Approval (K160569) of FEMSelect EnPlace was received in 2016 (under the previous name NeuGuide) as indicated for "attaching sutures to ligaments of the pelvic floor." Found here. [10]

Contraindications [4]:

- Patients undergoing anticoagulation therapy
- Patients with an autoimmune disease affecting connective tissue
- Patients under 18 years
- Patients with pre-existing conditions that pose an unacceptable surgical risk
- Patients with known nickel allergy
- Pregnant women or those considering future pregnancy

Summary

1. FEMSelect's EnPlace has the potential to enhance minimally invasive surgical treatment for prolapse, possibly leading to shorter operative times and reduced hospital stays.
2. The target patient population includes individuals with POP, specifically uterine prolapse or vaginal vault prolapse, following a hysterectomy.
3. Further studies are necessary to validate the performance claims, as the success rates are not derived from large, statistically significant research.

HealthTrust Clinical Resources

Allow us to connect you with the resources you need. Examples for this category include resources on value analysis and product trials.

ASK A QUESTION | PROVIDE YOUR FEEDBACK | SHARE YOUR VOICE | NETWORK WITH PEERS

PERSONALIZED REQUEST SERVICE & RESOURCE LIBRARY

www.hpginsights.com

PEER NETWORKING

www.huddle.healthtrustpg.com
App store: "HealthTrust Huddle"

References

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