

SUMMARY OF WARNINGS, PRECAUTIONS AND CONTRAINDICATIONS

For the Elevate Anterior and Posterior Prolapse Repair System

As with any surgical procedure, inherent risks are present. Some of the most severe risks associated with the Elevate procedure include perforation of the urethra, bladder and bowel, erosion of the mesh through neighboring tissue, and infection. If infection or erosion occur, the entire mesh may have to be removed or revised. Prolapse repair may unmask pre-existing incontinence.

For a complete list of indications, contraindications, warnings and precautions, contact your AMS representative or refer to the product Instructions for Use available on www.amslabeling.com.

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

NOTE: The clinical studies listed were chosen by AMS based on their clinical significance for the Elevate product.



KEY CLINICAL STUDIES

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Abstract	Outcomes
<i>Elevate Anterior & Apical 12 Mo Follow-Up</i>	Objective Cure Rate: • Anterior: 87.4%, Apical: 95.9%
First Author	Subjective Cure Rate: • All QOL scores were significantly improved from baseline • 121 (96.8%) felt that they were some or a lot improved • 118 (94.4%) were moderately, very or extremely satisfied
<i>Stanford EJ ICS 2011</i>	Complications: • 8 (5.6%) UTIs and mesh extrusion (each) • 6 (4.2%) dyspareunia • 5 (3.5%) buttock pain, <i>de novo</i> SUI and urinary retention (each) • 3 (2.1%) hematoma and granuloma formation (each) • All other AEs at <2%
Study Purpose	Key Takeaways
Assess safety and efficacy of Elevate Anterior & Apical	Twelve month data shows that Elevate Anterior & Apical is effective with few complications, low mesh extrusion rates and high patient satisfaction.
Study Design	
• Prospective, multi-center study • 142 patients (125 at 12 mo)	

Manuscript	Outcomes
<i>Elevate Anterior & Apical 12 Mo Follow-Up</i>	Objective Cure Rate: • 91.7%
First Author	Subjective Cure Rate: • 98.4%
<i>Moore R Int Urogynecol J 2011</i>	Complications: • 3 (5%) vaginal pain and <i>de novo</i> SUI (each) (resolved with physical therapy) • 1 (1.6%) <i>de novo</i> Urge, recurrent prolapse and dyspareunia (each) • 0 mesh extrusion
Study Purpose	Key Takeaways
Analyze safety and efficacy	Initial Anterior Elevate system results show the procedure to be safe and early efficacy is promising.
Study Design	
• Retrospective, single-center study • 60 patients (13.4 month mean follow-up (3 mo – 24 mo))	

Abstract	Outcomes
<i>Elevate Anterior & Apical 6 and 12 Mo Follow-Up Results</i>	Objective Cure Rate: • 91.2% at 1 year
First Author	Subjective Cure Rate: • QOL was improved from baseline significantly (p<0.05) by PFDI-20, PISQ-12, and PFIQ-7 • No patients complained of bulge in vagina at 6 months or 1 year follow-up
<i>Courtieu C IUGA 2011</i>	Complications: • 6 buttock pain • 4 (4.3%) dyspareunia • 2 bladder injuries • 1 pelvic hematoma • 5 worsened or <i>de novo</i> SUI • 4 transient urinary retention • 3 <i>de novo</i> posterior stage II prolapse • 1 (1.3%) mesh extrusion (3 mo)
Study Purpose	Key Takeaways
Assessment of safety, anatomical efficacy and functional results	Results of Elevate Anterior & Apical are comparable to those obtained with transobturator meshes, with excellent functional results on QOL questionnaires. There was a low rate of extrusion.
Study Design	
• Prospective, single-center study • 95 patients (77 at 6 mo, 45 at 12 mo)	

Abstract	Outcomes
<i>Elevate Anterior & Apical 3 Mo Follow-Up</i>	Objective Cure Rate: • 100%
First Author	Subjective Cure Rate: • Mean postoperative VAS score was 1.5 ± 1.7 (P<0.001) when compared with pre-op score
<i>Ricci L IUGA 2011</i>	Complications: • 3 <i>de novo</i> SUI • 0 mesh extrusion • 2 <i>de novo</i> UUI • 0 <i>de novo</i> dyspareunia
Study Purpose	Key Takeaways
To determine the morbidity and short-term efficacy	Elevate Anterior is a promising technique.
Study Design	
• Prospective, multi-center study • 27 patients (>3 mo follow-up)	

Abstract	Outcomes
<i>Elevate Apical & Posterior 24 Mo Results</i>	Objective Cure Rate: • Posterior: 91.5%, Apical: 88.2%
First Author	Subjective Cure Rate: • Significant improvement was seen in all QOL questionnaires at 24 months. 92.0% of subjects would recommend the procedure to a friend.
<i>Lukban J ICS 2011</i>	Complications: • 11 (7.9%) mesh erosion (no explants) • 3 (2.2%) constipation and buttock pain (each) • 2 (1.4%) vaginal infection, hematoma, UTI and superficial wound dehiscence (each) • All other complications <1%
Study Purpose	Key Takeaways
Assess the safety, efficacy and quality of life	Elevate Apical and Posterior was shown to provide long term safety and effectiveness.
Study Design	
• Prospective, multi-center study • 139 patients (113 at 24 mo follow-up)	

Abstract	Outcomes
<i>Elevate Apical & Posterior 12 Mo Results</i>	Objective Cure Rate: • 97.8% at 1 year
First Author	Subjective Cure Rate: • No sexual change pre-and post-op and VAS (p<0.05)
<i>Raut N ICS-IUGA 2010</i>	Complications: • 2 (4.0%) mesh erosion • 1 (2.2%) buttock pain • 1 (2.2%) blood loss >500ml
Study Purpose	Key Takeaways
To determine the safety and efficacy and also the PROMS following prolapse repair with the Elevate Apical & Posterior system	Elevate Apical and Posterior system is safe and effective in the management of posterior compartment prolapse repair. Our study also concludes that this repair system is associated with an overall improvement in the state of health.
Study Design	
• Prospective, single-center study • 45 patients (4 and 12 mo follow-up)	

Abstract	Outcomes
<i>Elevate Apical & Posterior Results at 12 Mo</i>	Objective Cure Rate: • Posterior: 100%, Apical: 98%
First Author	Subjective Cure Rate: • Not studied
<i>Dhingra C Female Pelvic Med Reconstruc Surg 2010</i>	Complications: • 3 (2.8%) granulation tissue • 1 (1.4%) mesh erosion • 1 (1.4%) partial explant to 1 year due to abscess • 2 (2.0%) pelvic hematoma • 1 (1.4%) injury to rectum
Study Purpose	Key Takeaways
To evaluate the safety and efficacy of Elevate for posterior and/or apical vaginal prolapse	Elevate Apical and Posterior appears to be safe, provides equivalent anatomical results in posterior and/or apical vaginal wall prolapse to graft techniques that require passage through pelvic musculature.
Study Design	
• Retrospective study • 102 patients (3 mo, 6 mo - 73% and 12 mo - 41% follow-up)	