Altis® Single Incision Sling System

Clinical Summary from Investigational Device Exemption Study

The clinical study of the Altis Sling System was a prospective, single arm, non-randomized, multi-center trial conducted at 17 sites in the US and Canada. The objective of the study was to assess safety and efficacy of the Altis single incision sling system for females with SUI. A total of 113 women were implanted with the Altis Sling. The median age for the women enrolled in the study was 54.5 years (range = 25.3 – 89.3). The median body mass index (BMI) was 29.9 (range = 20.0-55.8). Enrolled patients presented with the following history of stress urinary incontinence:

Stress Urinary Incontinence (SUI) History	% of Patients
Hypermobility	81.4% (92/113)
Without hypermobility	19.5% (22/113)
Mixed incontinence	37.2% (44/113)
Overactive bladder	5.3% (6/113)

The study's primary effectiveness objective was improvement in subject continence status measured by reduction in 24-hour pad weight. At 6 months, 88 of 103 evaluable subjects showed >50% reduction in pad weight compared to baseline.

Secondary effectiveness endpoints included cough stress test (CST) at 6 months, assessment of subject Quality of Life (QOL) through validated questionnaires at 6 months, and voiding diaries were evaluated using performance goals. All results were statistically significant.

CST, UDI-6, IIQ-7, Voiding Diary

Endpoint	Success	Lower 95.81% CL	p-value
Cough Stress Test[1]	92.2% (95/103)	86.1%	<0.0001
UDI Score[2]	88.6% (93/105)	81.8%	<0.0001
IIQ Score[3]	93.3% (97/104)	87.4%	<0.0001
Voiding Diary[4]	88.0% (81/92)	80.6%	<0.0001

[1]Percent of subjects with negative cough stress test at 6 months
[2]Percent of subjects with ≥ 50% reduction in UDI Score at 6 months
[3]Percent of subjects with ≥ 50% reduction in IIQ Score at 6 months
[4]Percent of subjects with ≥ 50% reduction in number of incontinence episodes at 6 months

Device related events included 4 mesh extrusions (3.5%) and one case (0.9%) each of dyspareunia, retention, UTI, inflammation, worsening OAB, and decreased urine stream. There were two device and/or procedure related serious adverse events: hematoma requiring hospitalization following a second sling revision due to urinary outlet obstruction, and a vaginal mesh extrusion for which explant surgery was indicated.

Conclusions: The Altis Sling System performs as well as or better than the legally marketed predicate devices based on bench testing, biocompatibility testing, simulated use testing, and clinical study results.

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