Single Incision Slings

Evolution of Slings in the Treatment of Female SUI

Coloplast

Distinguished Faculty_

Faculty Name, MD, FACOG, FACS

Account Affiliation

City, ST

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Physician Presentation Disclaimer_

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It is obvious with this, and every other surgical procedure, that you use your own independent judgment that you have received sufficient information and training to proficiently perform the procedure. This lecture and demonstration is intended as a supplement to your own education and training and is ***not a substitute for your own medical judgment.***

I have provided substantial time for questions in this presentation and encourage and welcome any questions that you have.

Objectives_

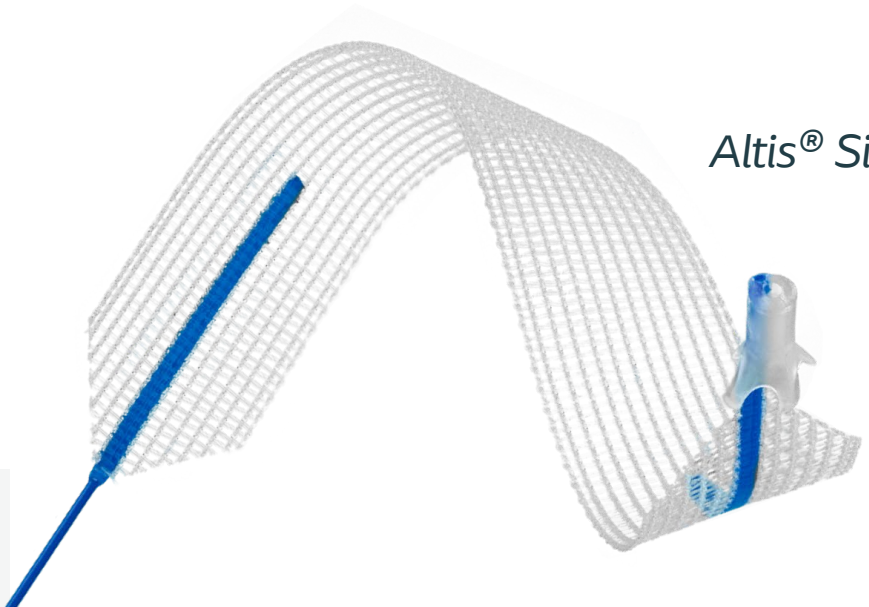
01. Communicate the prevalence of SUI and Coloplast's SUI Mesh options

02. Convey the importance of and data supporting single incision slings

03. Analyze the fundamentals of the Altis® Single Incision Sling procedure

Agenda_

1. SUI Prevalence and Evolution
2. Coloplast SUI Mesh- Options and Properties
3. Altis® Single Incision Sling Introduction
4. Why is Altis® different?
5. Pathway to Market
6. Post-Market Clinical Data
7. Why Altis®?
8. Patient Journey
9. Procedural Video



Altis® Single Incision Sling

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SUI Prevalence

and Evolution

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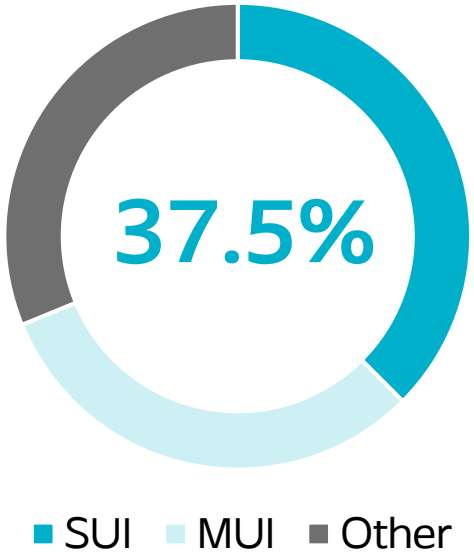
SUI Prevalence_

Approximately 78 million women

in the U.S. suffer from urinary incontinence[1]

1. Patel UJ, Godecker AL, Giles DL, Brown HW. Updated Prevalence of Urinary Incontinence in Women: 2015-2018 National Population-Based Survey Data. *Female Pelvic Med Reconstr Surg.* 2022 Jan 12

SUI Prevalence_



37.5% of these women are suffering from SUI

31.3% from MUI[1]

However, **less than 1%** go on to have surgery[2], despite low quality of life, including depression and anxiety[3].

1. Patel UJ, Godecker AL, Giles DL, Brown HW. Updated Prevalence of Urinary Incontinence in Women: 2015-2018 National Population-Based Survey Data. Female Pelvic Med Reconstr Surg. 2022 Jan 12
2. Clarivate data accessed March 17, 2022.
3. Kinjo M, Masuda K, Nakamura Y, Taguchi S, Tambo M, Okegawa T, Fukuhara H. Effects on Depression and Anxiety After Mid-Urethral Sling Surgery for Female Stress Urinary Incontinence. Res Rep Urol. 2020 Oct 19;12:495-501. doi: 10.2147/RRU.S270915. PMID: 33117749; PMCID: PMC7585269.

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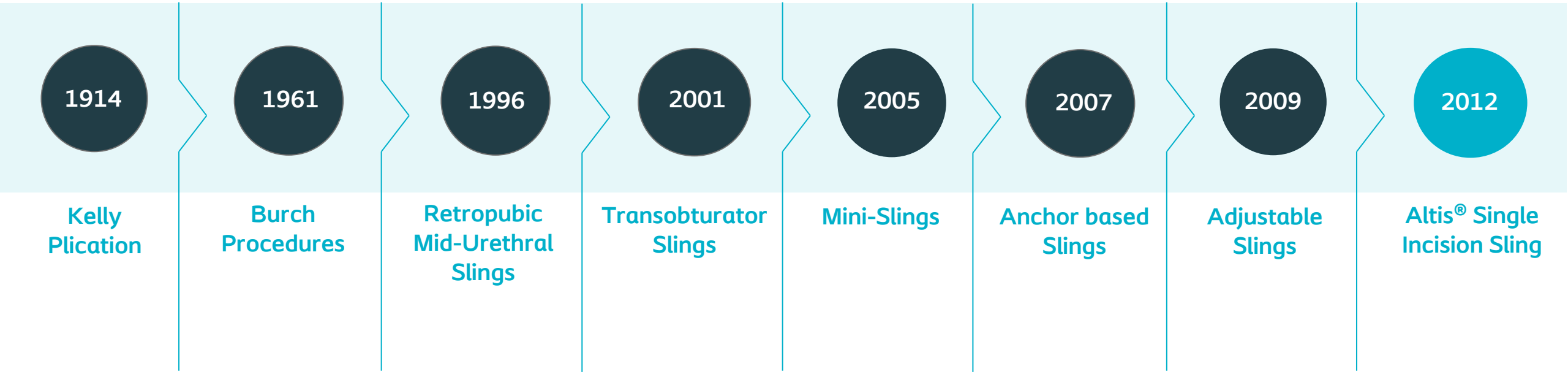
Evolution of Surgical Treatment for SUI_



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Coloplast SUI Mesh

Design Properties

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Coloplast SUI Mesh Options_

Altis®

Single Incision Sling System

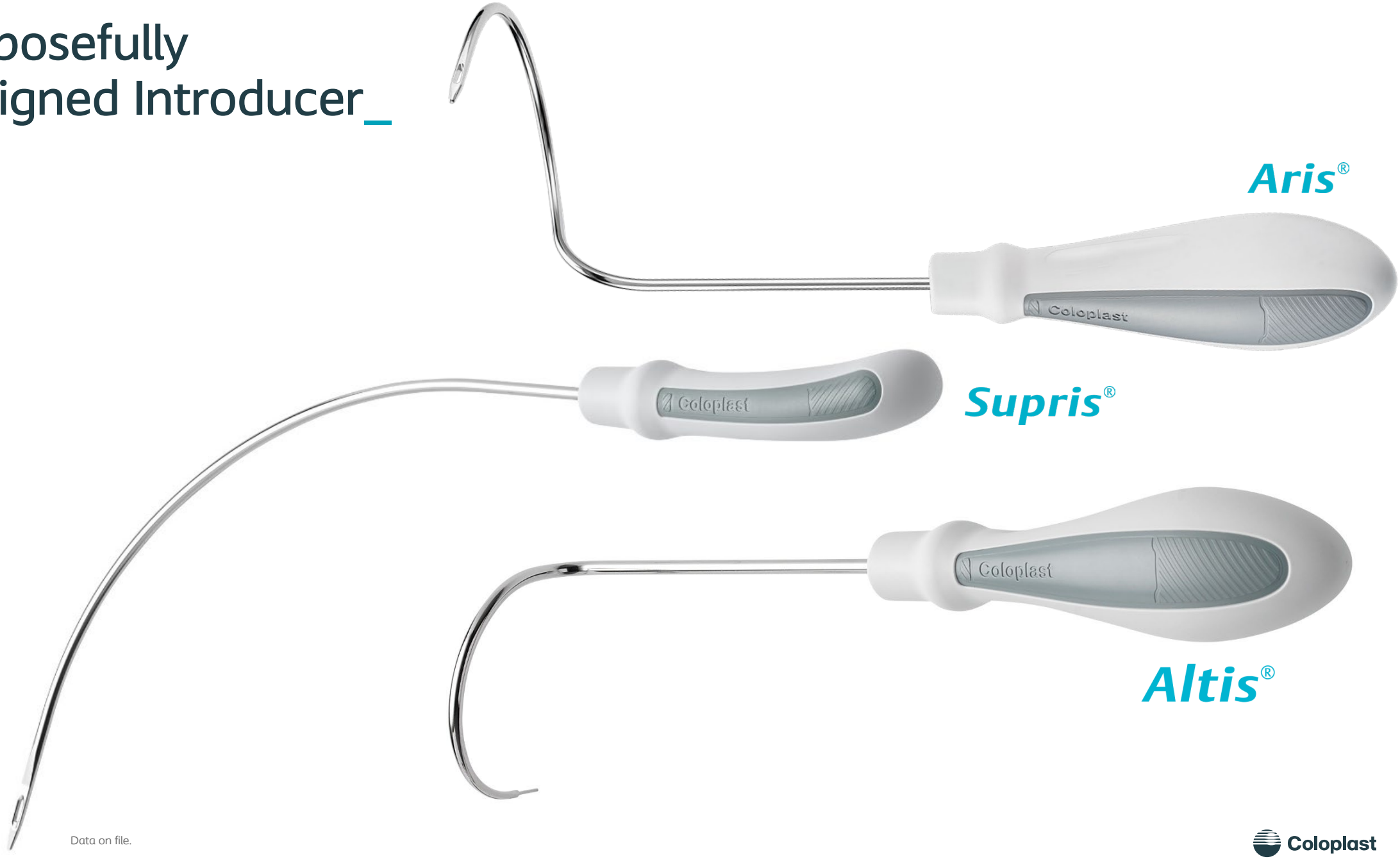
Aris®

Transobturator Sling System

Supris®

Retropubic Sling System

Purposefully Designed Introducer_



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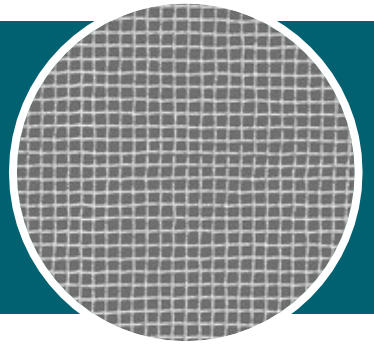
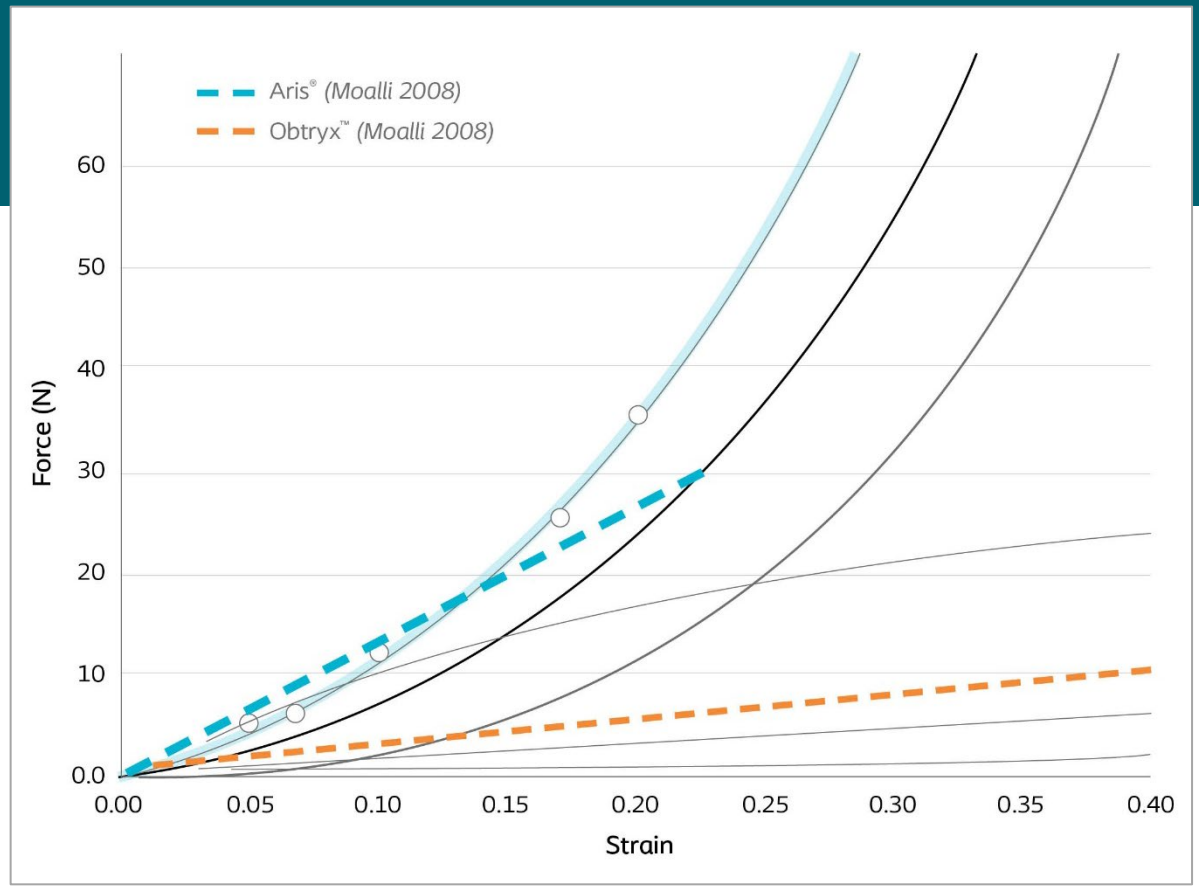
Coloplast SUI Mesh_



Purposefully designed mesh

- Tensile property is designed to emulate the **pubourethral ligament**
- Provides **support** and **stability** to the urethra



Brandao 2015 Biomechanical study on the bladder neck and urethral positions: simulation of impairment of the pelvic ligaments.

Data on file.

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Coloplast SUI Mesh_

Pore Size ~374 µm[1]

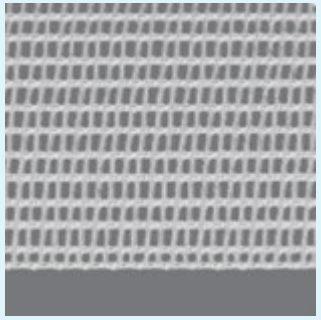
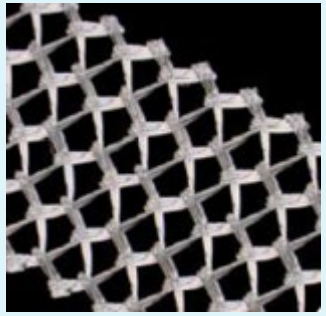
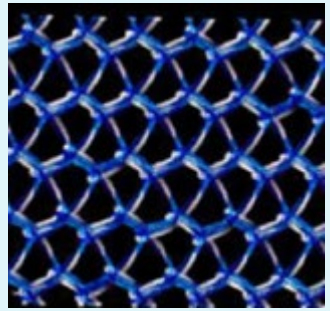
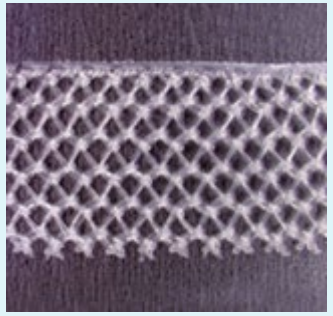
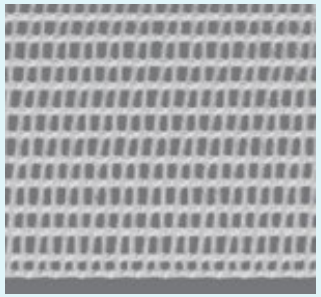
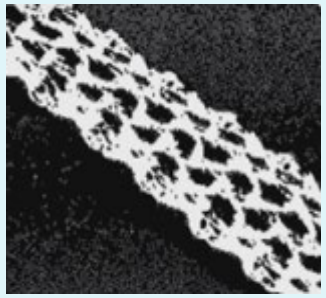
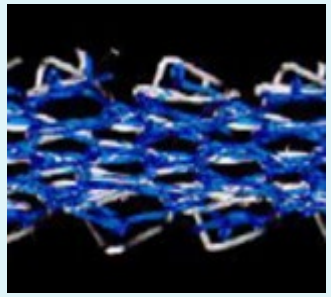
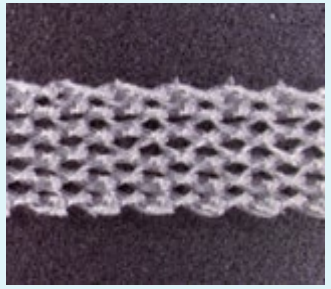
- Macrophages and neutrophils need pore dimensions **greater than 10 µm** to reach small bacteria[2]
- Amid's Type I mesh classification: **75 µm** pores
- Coloplast mesh is approximately **5x larger** than what is required for tissue ingrowth

1. Data on file at Coloplast
2. Amid 1997 Classification of biomaterials and their related complications in abdominal wall hernia surgery

Rationale of Sling with Low Elasticity_

*Pores and mesh width **do not experience significant distortion or narrowing** with tensile load application*

*Coloplast SUI mesh **maintains integrity under 2 lbs of force**[1]*

	Altis® Single Incision Sling Supris® Retropubic Kit Aris® Transobturator Kit **from Coloplast**[1,2]	**Obtryx™** Transobturator Mid-Urethral Sling System **Boston Scientific**[1,2]	**GYNECARE TVT™** Obturator System Tension-Free Support for Incontinence **Ethicon**[1,2]	**Desara® Sling** **Caldera**[1,2]
0 LBF.				
2 LBF.				

*All images are **8x** magnification*

1. Coloplast Internal Data
2. Trademarks are the property of their respective owners

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Supris® Retropubic Sling System

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Supris® Retropubic Sling System_

- Predictable and accurate tension-free adjustment
- Dual-use introducers can be used for both Bottom-Up and Top-Down approaches
- Full length sheathless sling

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Aris® Transobturator Sling System

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Aris® Transobturator Sling System_

- Outside-In approach
- Choice of flat curve or helical introducers
- Full length sheathless sling
- 9 year data—largest, longest randomized trial of female TOT slings demonstrating consistent results at year three and beyond[1]

1. Karmakar D, Mostafa A, Abdel-Fattah M. Long-term outcomes of transobturator tapes in women with stress urinary incontinence: E-TOT randomised controlled trial. BJOG 2017;124:973–981.

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Why is the Altis® Single Incision Sling different?

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Altis® Single Incision Sling

Introducer Animation

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Altis® Single Incision Sling

Dynamic Anchor Animation

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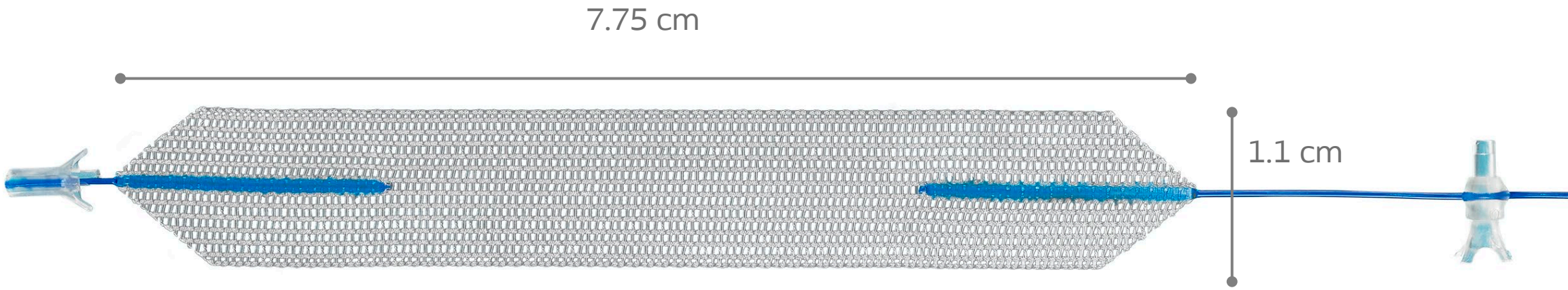
Altis® Single Incision Sling_



1. Data on file with Coloplast

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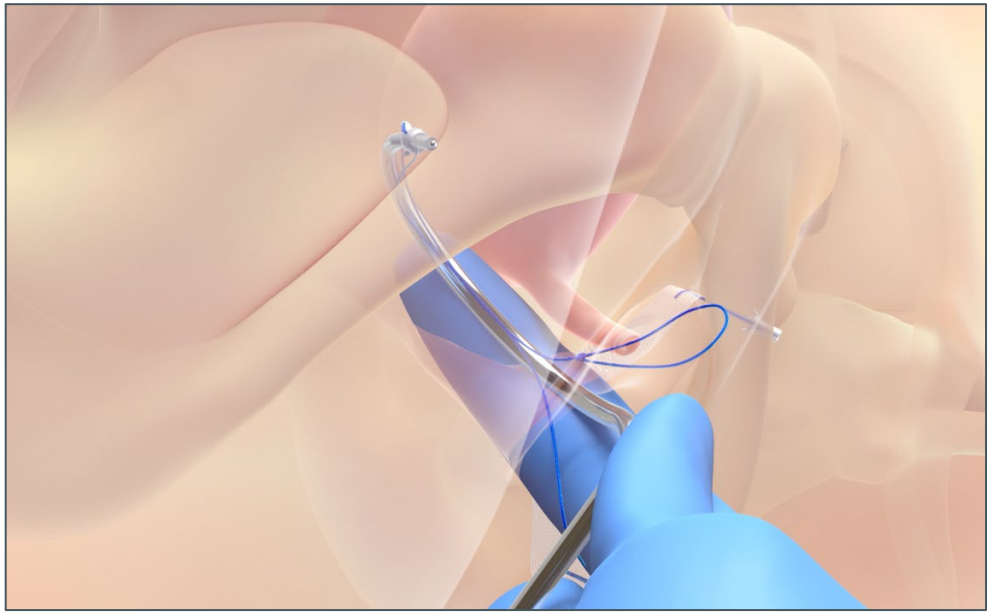
Reproducible Insertion_

Patented helical introducer makes the surgical procedure predictable, accurate and reproducible



Altis®
Single Incision Sling System

Data on file with Coloplast

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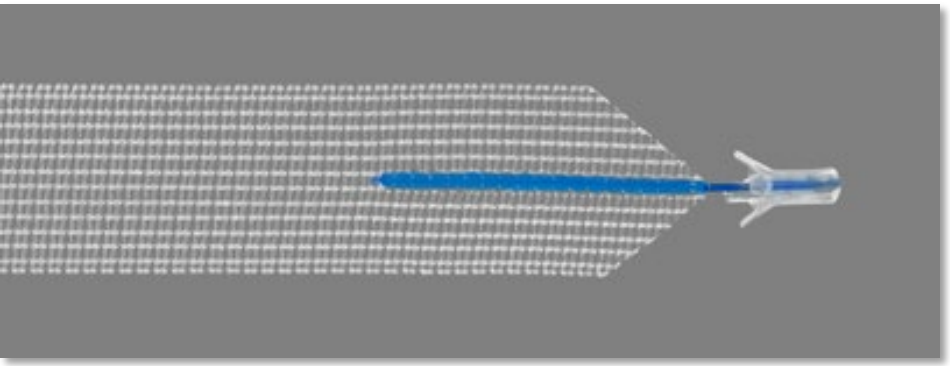
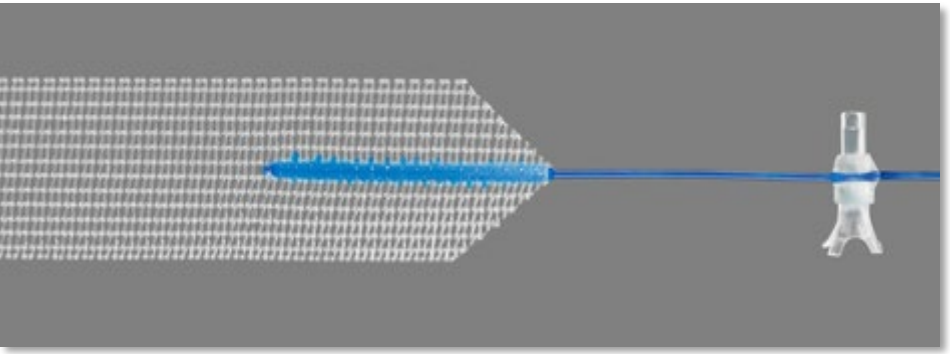
Altis® Single Incision Sling Anchor Components_

Static Anchor



Dynamic Anchor



Allows for **precise** and **secure** obturator membrane **placement**

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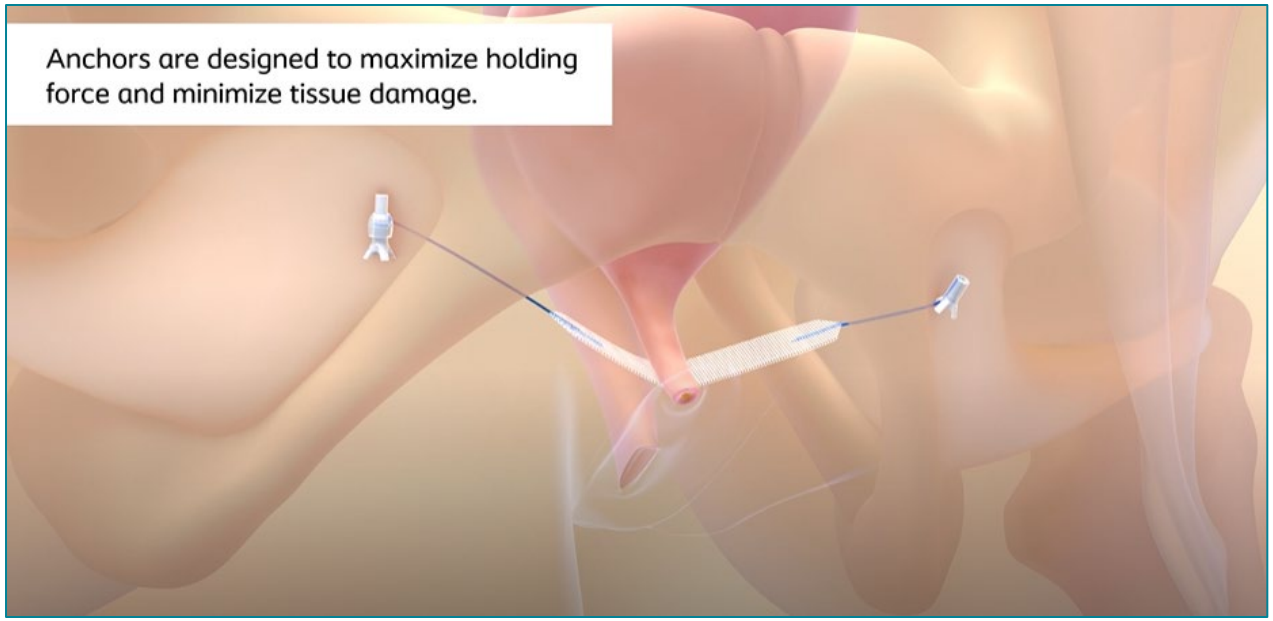
Altis® Single Incision Sling Anchor Strength_

Engineered to withstand pull out forces of greater than

2.0 lbs which is **4x** greater than any typical pelvic strain.



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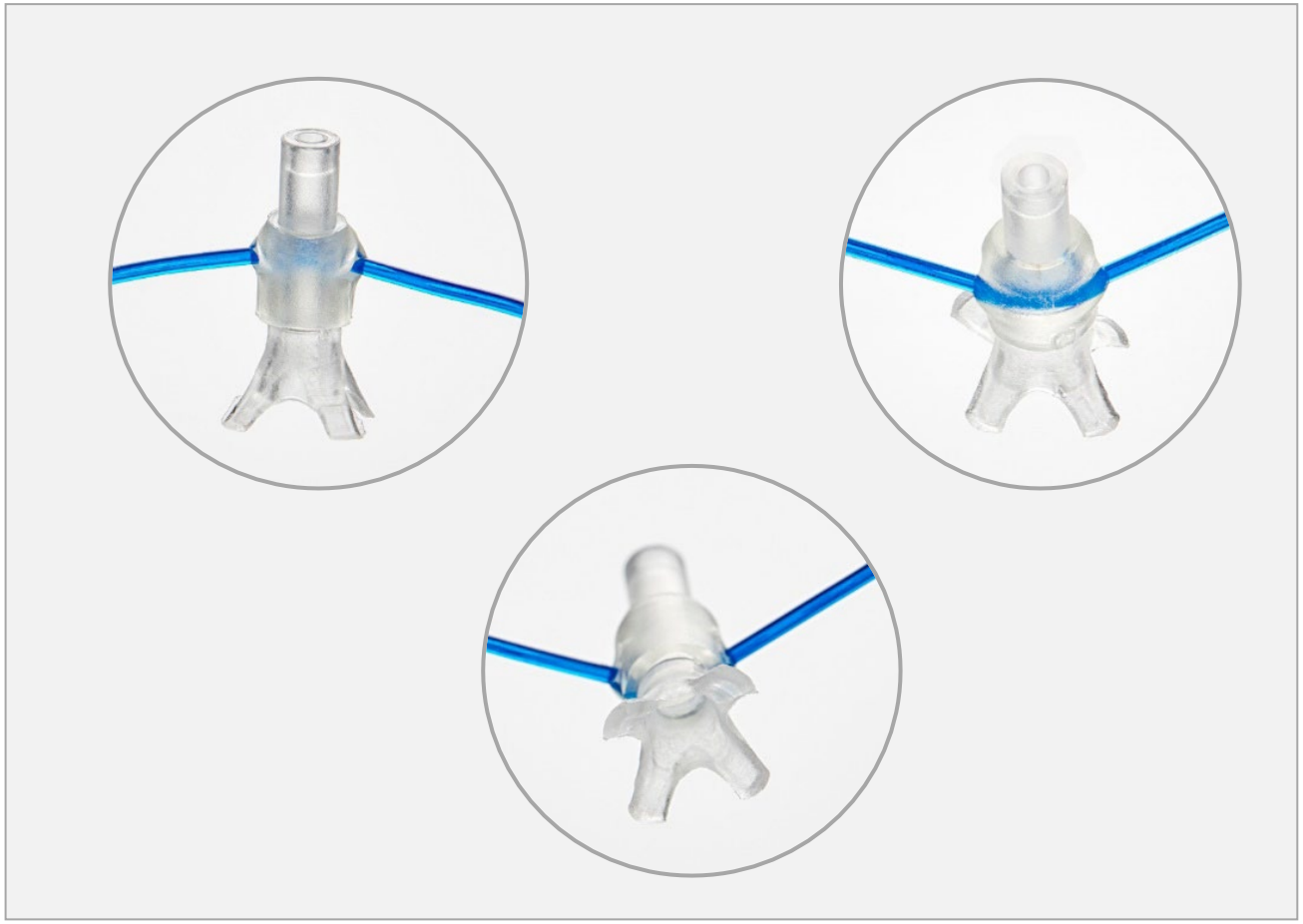
Altis® Single Incision Sling Adjustability_

Dynamic anchor allows for intraoperative adjustability, tensioning and customization for each patient



Pathway to Market

Altis® Single Incision Sling

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Altis® Single Incision Sling Clinical Timeline_

2010 Altis Single Incision Sling IDE Study Initiated

2011 **Safety Communication and Analysis Issued**

2012 **Postmarket Surveillance Studies Ordered**

Altis Single Incision Sling receives FDA 510(k) clearance*

2013 Altis Single Incision Sling 522 order received

2020 Altis Single Incision Sling 522 12-month results published
Journal of Minimally Invasive Gynecology

2021 Altis Single Incision Sling 522 Study completed

2023 Altis Single Incision Sling 522 36-month results published
Neurourology and Urodynamics

*US Commercial Launch (2010 Canada / 2011 Europe)

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Altis® Single Incision Sling IDE Study Design_

Only sling with a premarket **IDE** study

Baseline Characteristics	Implanted Subjects (n=113)
Age (years)	54.5 ± 14.0
BMI (kg/m2)	31.2 ± 6.8
Baseline Incontinence Diagnosis SUI MUI	 62.8% (n=71) 37.2% (n=42)

17 sites (16 United States and 1 Canada) • **Patient follow-up** at 3-mo, 6-mo, 12-mo and 24-mo

Trial reflected first implant experiences with Altis® for all investigators

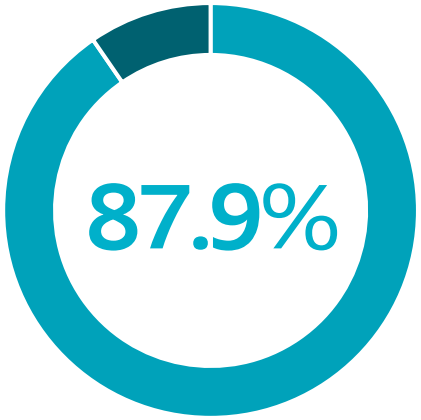
Kocjancic E, Erickson T, Tu LM, Gheiler E, Van Drie D. *Two-year outcomes for the Altis® adjustable single incision sling system for treatment of stress urinary incontinence.* Neurourol Urodyn. 2017 Aug;36(6):1582-1587

Altis® Single Incision Sling 24-Month IDE Objective Measures_

Cough Stress Test (CST)	CST performed **six times in two different positions** 1 2 3 — IN LITHOTOMY 4 5 6 — STANDING	*researchers typically use just* **one CST in a single position** 1 — IN LITHOTOMY
Pad Weight Testing	Evaluated effectiveness using **24-hour pad weight testing** - Assessing stress component of incontinence - Contribution of the urge component	*Other studies have used* **one-hour pad weight testing**

Altis® Single Incision Sling IDE 24 Month Outcomes

Altis® has proven efficacy



Negative CST

24-hour pad weight success
(≥50% reduction)

Kocjancic E, Erickson T, Tu LM, Gheiler E, Van Drie D. *Two-year outcomes for the Altis® adjustable single incision sling system for treatment of stress urinary incontinence.* Neurourol Urodyn. 2017 Aug;36(6):1582-1587

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Altis® Single Incision Sling IDE 24 Month Outcomes

Significant reduction in median scores (p<0.0001)

Median UDI-6 score value at

55.5 Baseline

5.6 24-month

Median IIQ-7 score value at

57.0 Baseline

0.0 24-month

Kocjancic E, Erickson T, Tu LM, Gheiler E, Van Drie D. *Two-year outcomes for the Altis® adjustable single incision sling system for treatment of stress urinary incontinence.* Neurourol Urodyn. 2017 Aug;36(6):1582-1587

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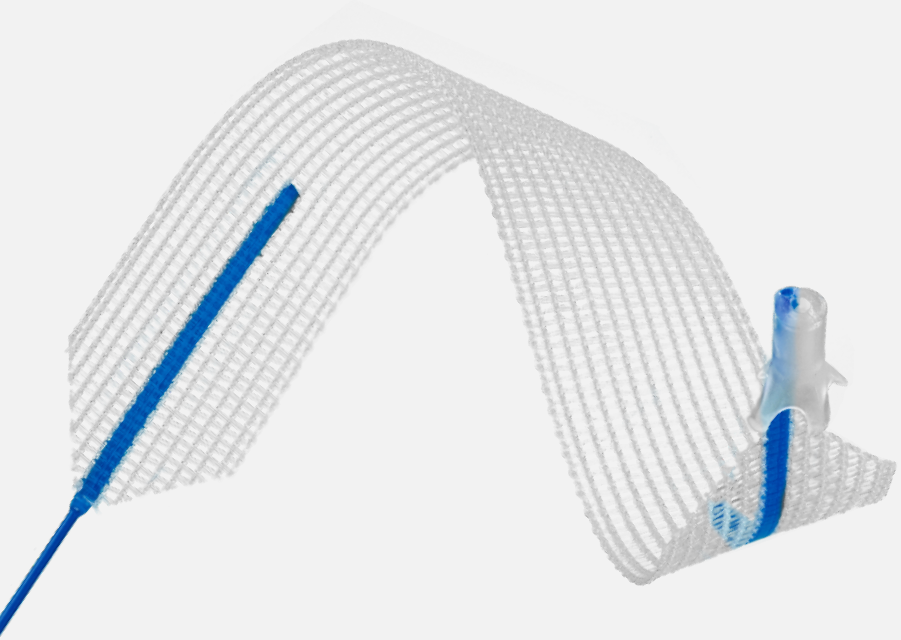

Kocjancic E, Erickson T, Tu LM, Gheiler E, Van Drie D. *Two-year outcomes for the Altis® adjustable single incision sling system for treatment of stress urinary incontinence.* Neurourol Urodyn. 2017 Aug;36(6):1582-1587

Altis® Single Incision Sling IDE 24 Month Outcomes

No Altis experience

This trial reflected **first implant experiences** with Altis for all investigators

Adverse events*

Non-pelvic pain – other (9) 8%
Mesh extrusion (4) 3.5%
Pelvic/urogenital pain (4) 3.5%

Zero

No new device *or* procedure-related complications between the 12 and 24 month visits

*AEs with incidence >3% are represented. For full list of post-operative complications please refer to full IDE manuscript.

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Post-Market Clinical Data

Altis® Single Incision Sling

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Altis® Single Incision Sling_

The **only** single incision sling with an IDE and 522 study.

What is a 522 Study?

The FDA ordered postmarket surveillance studies ("522 studies") by manufacturers of urogynecologic surgical mesh devices to address specific safety and effectiveness concerns related to mini-sling devices for SUI and surgical mesh used for transvaginal repair of POP.

Data from the studies will enable the agency to better understand the safety and effectiveness profiles of these devices.

Altis® Single Incision Sling 522 Study Overview_

522 Altis Post-Market Surveillance Study through 36 months.

Prospective, multi-center, nonrandomized study

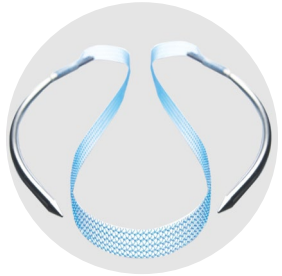
355 Women underwent sling procedures

32 Physicians

23 Different sites (US & Canada)

Slings Tested

Single Incision Sling:
Altis®



Comparator:
Full length retropubic & transobturator slings

Timeframe Observed

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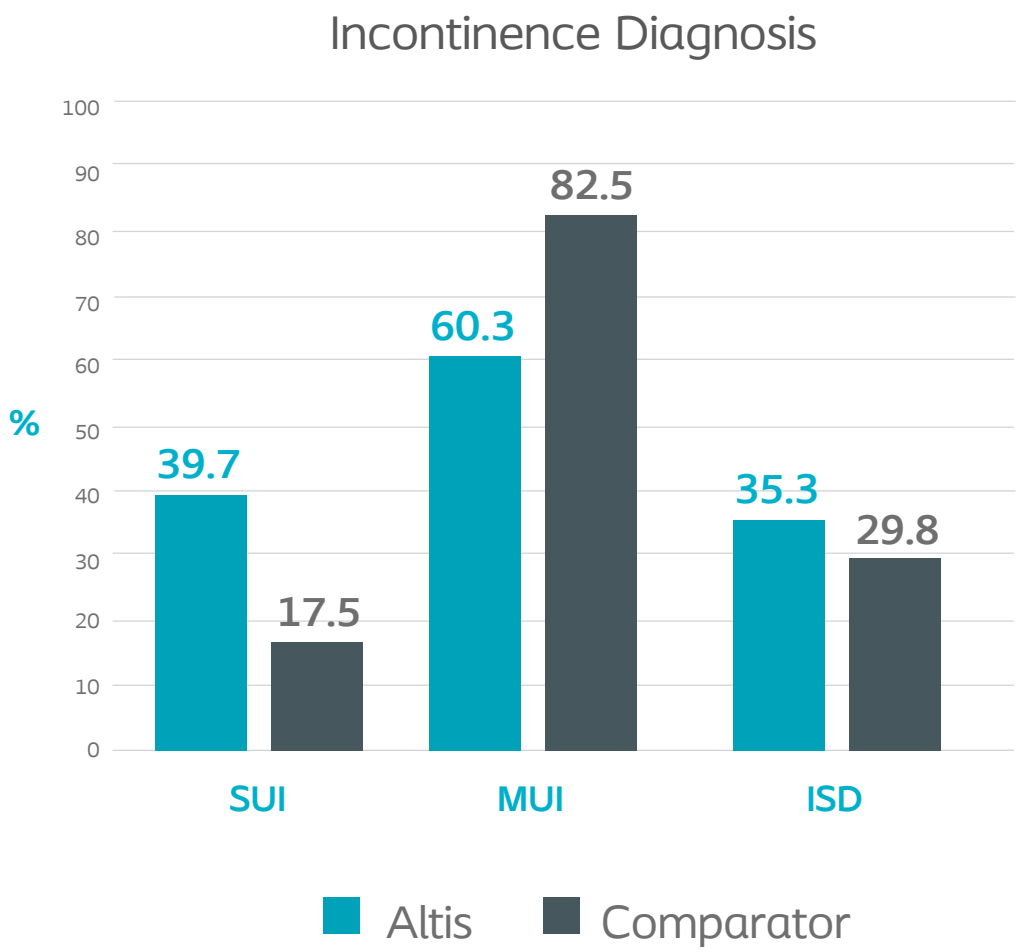
Altis® Single Incision Sling 522 Study Patient Demographics_

Altis Single Incision Sling (n=184)

56.2 Years (11.4)
30.0 BMI (5.8)

Comparator (n=85 Retropubic; n=86 Transobturator)

53.3 Years (12.3)
31.8 BMI (7.6)



Erickson T, Roovers JP, Gheiler E, Parekh M, Parva MM, Hanson C, McCrery R, Tu LM. A multi-center prospective study evaluating efficacy and safety of a single-incision sling procedure for stress urinary incontinence. J Minim Invasive Gynecol. 2020 Apr 19. pii: S1553-4650(20)30189-8.

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Convincing Results_

Altis® performs similarly to full length retropubic and transobturator slings in:

SAFETY

EFFECTIVENESS

PATIENT SATISFACTION

Tu LM, Gheiler E, Hanson CE, et al. Management of female stress urinary incontinence with single-incision mini-sling (Altis®): 36 month multicenter outcomes. Neurourology and Urodynamics. 2023 Aug 9. https://doi.org/10.1002/nau.25256

Proven Safety_

Device and/or Procedure-Related Serious Adverse Events (SAE) Through 36 Months

Data for the treated population are presented as the number of subjects (%)

	Altis®	Comparator
Pelvic/urogenital pain (groin)	1 (0.5%)	0 (0.0%)
Urinary retention/obstruction requiring surgery	1 (0.5%)	0 (0.0%)
Bleeding, hematoma or hemorrhage	0 (0.0%)	1 (0.6%)
Delayed wound healing	0 (0.0%)	1 (0.6%)
Mesh exposure (extrusion)	0 (0.0%)	1 (0.6%)
Perforation, bladder	0 (0.0%)	1 (0.6%)
Total subjects that experienced a SAE	**2 (1.1%)**	**4 (2.3%)**

Revision/resurgery*	1 (0.5%)	7 (4.1%)

*Statistically significant, P<0.001

Compared to full length retropubic and transobturator slings, Altis®:

- Had **similarly** low rates of serious device and/or procedure-related adverse events
- **Zero cases** of mesh exposure, extrusion or erosion

Tu LM, Gheiler E, Hanson CE, et al. Management of female stress urinary incontinence with single-incision mini-sling (Altis®): 36 month multicenter outcomes. Neurourology and Urodynamics. 2023 Aug 9. https://doi.org/10.1002/nau.25256

Hanson, C, Erickson, T., McCrery R. Patient satisfaction and quality of life in a multicenter prospective study of single incision mini-sling (Altis®) in the management of female stress urinary incontinence. Journal of Urology. 2023 Apr 29. e516 Vol 209, No. 4S, Supplement.

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Proven Safety_

Relevant Device and/or Procedure-Related Nonserious Adverse Events (AE) Through 36 Months

Data for the treated population are presented as the number of subjects (%), significance was defined as $p \leq 0.05$

	Altis®	Comparator
Urinary retention/obstruction	9 (4.9%)	3 (1.8%)
Recurrent incontinence	2 (1.1%)	7 (4.1%)
Vaginal blood spotting	1 (0.5%)	1 (0.6%)
Delayed wound healing	0 (0.0%)	1 (0.6%)
"Button hole in Fornix"	0 (0.0%)	1 (0.6%)
Infection	0 (0.0%)	1 (0.6%)
Other urinary problems		
Voiding dysfunction	1 (0.5%)	0 (0.0%)
Urgency worsening	0 (0.0%)	2 (1.2%)
Dysuria	1 (0.5%)	1 (0.6%)
Pain		
Pelvic/urogenital (groin) pain	7 (3.8%)	4 (2.3%)
Dyspareunia, de novo	3 (1.6%)	2 (1.2%)
Dyspareunia, worsening	1 (0.5%)	1 (0.6%)
Vaginal pain	1 (0.5%)	0 (0.0%)
Pain at incision site	0 (0.0%)	1 (0.6%)
Extremity pain		
Hip pain	7 (3.8%)	0 (0.0%)
Leg pain	4 (2.2%)	0 (0.0%)
Hip and leg pain	3 (1.6%)	0 (0.0%)
Sciatica	1 (0.5%)	0 (0.0%)
Calf pain	0 (0.0%)	1 (0.6%)
Abdominal pain		
Lower abdominal pain	1 (0.5%)	0 (0.0)%
Lower abdomen cramping	0 (0.0%)	1 (0.6%)

Altis® performed **similarly** to full length retropubic and transobturator with respect to device and/or procedure related AEs through 36 months.

Tu LM, Gheiler E, Hanson CE, et al. Management of female stress urinary incontinence with single-incision mini-sling (Altis®): 36 month multicenter outcomes. Neurourology and Urodynamics. 2023 Aug 9. https://doi.org/10.1002/nau.25256

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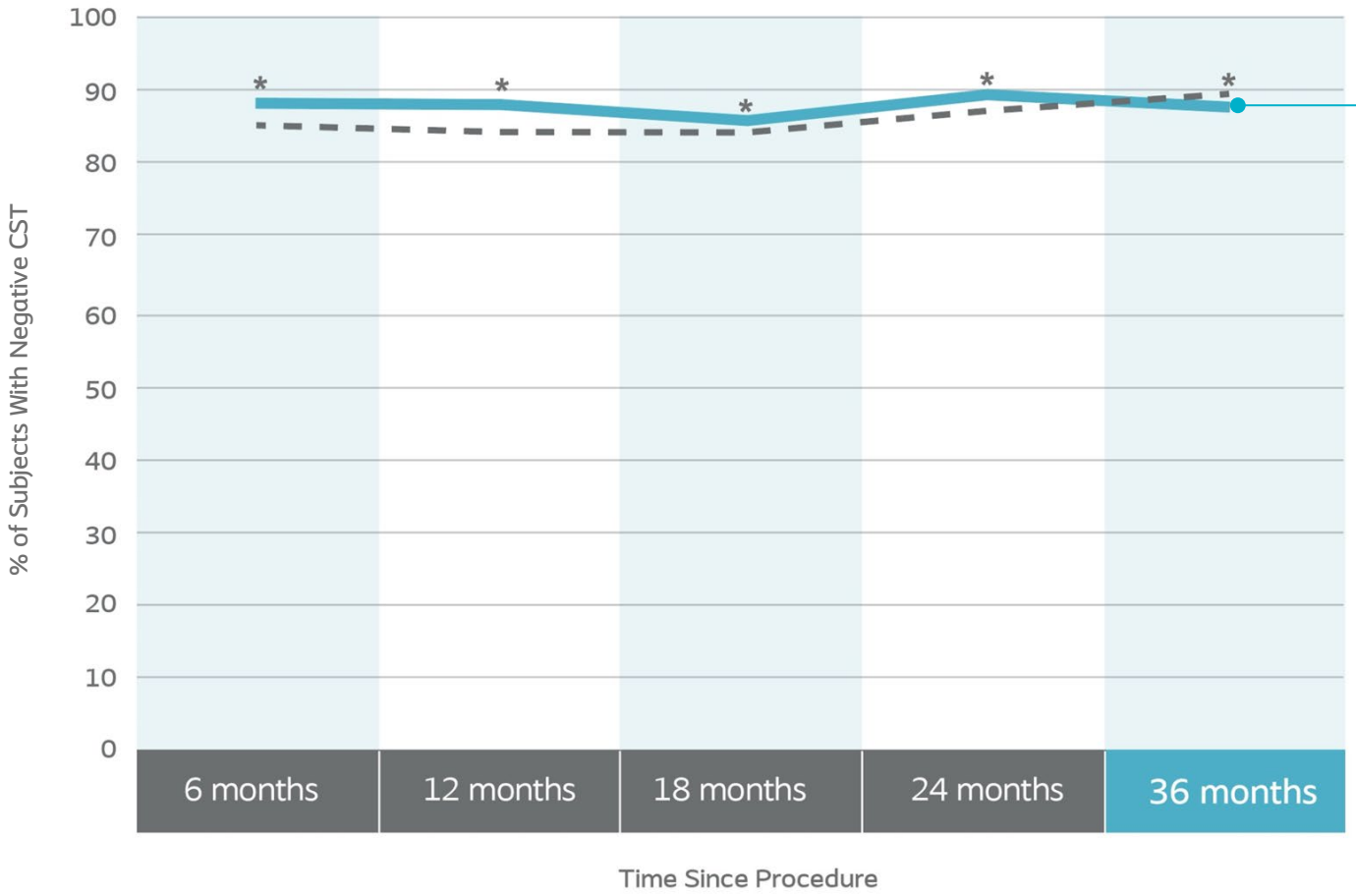
Proven Effectiveness_

Negative Cough Stress Test (CST) through 36 months

Data for the treated population are presented as numbers (%). Significance $p \leq 0.050$

**p Value for categorical variables is a difference in proportions noninferiority test between groups with a noninferiority margin of 0.15*



87.1%

CST demonstrated Altis® was similar to retropubic and transobturator slings (p<0.001).

Altis performed **similarly** to the Comparator arm at every study visit and rates of negative CST remained **above 80%** for both groups (p<0.001).

Altis® ——— Comparator - - - -

Tu LM, Gheiler E, Hanson CE, et al. Management of female stress urinary incontinence with single-incision mini-sling (Altis®): 36 month multicenter outcomes. Neurourology and Urodynamics. 2023 Aug 9. https://doi.org/10.1002/nau.25256

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Proven Satisfaction_

Proven efficacy with patient reported subjective outcomes and high patient satisfaction for Altis.

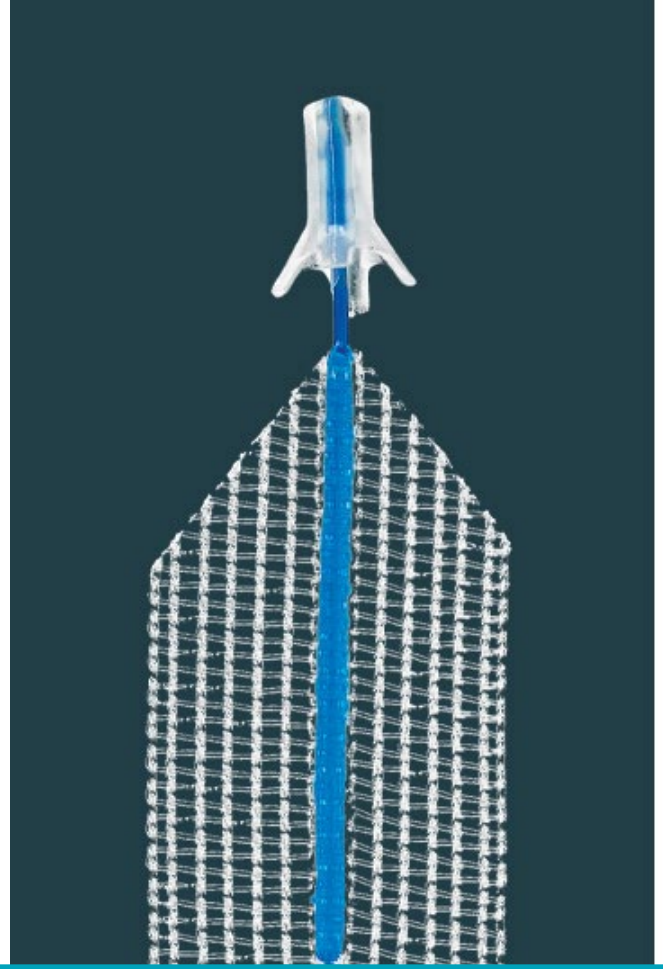
	ALTIS® SINGLE INCISION SLING		RETROPUBIC AND TRANSOBTURATOR	
	Baseline	24 months[1]	Baseline	24 months[1]
Patient Global Impression of Improvement (PGI-I) "Very Much Better" or "Much Better"	-	**91.2%**	-	**91.3%**
Urogenital Distress Inventory (UDI-6)	50.3 (20.0)†	9.1 (15.2)†	56.4 (21.2)†	10.0 (14.2)†
Incontinence Impact Questionnaire (IIQ-7)	56.7 (27.0)†	5.0 (14.7)†	59.3 (24.7)†	7.5 (15.8)†

†Standard deviation

Subjective outcome measures collected included patient global impression of improvement (PGI-I), urogenital distress inventory (UDI-6), Incontinence Impact Questionnaire – Short Form (IIQ-7), Surgical Questionnaire (SSQ-8), and visual analog scale for pain (VAS). At 24 months, Altis is comparable to full-length retropubic and transobturator slings.

1. Data on file.

Erickson T, Roovers JP, Gheiler E, Parekh M, Parva MM, Hanson C, McCrery R, Tu LM. A multi-center prospective study evaluating efficacy and safety of a single-incision sling procedure for stress urinary incontinence. J Minim Invasive Gynecol. 2020 Apr 19. pii: S1553-4650(20)30189-8.



SUI mini-slings **are as effective** as traditional mid-urethral slings **over a 36-month** timeframe

April 11, 2024:

Evaluation of Final Results of the 522 Studies for SUI Mini-Slings and the FDA's Literature Review

Tu LM, Gheiler E, Hanson CE, et al. Management of female stress urinary incontinence with single-incision mini-sling (Altis®): 36 month multicenter outcomes. Neurourology and Urodynamics. 2023 Aug 9. https://doi.org/10.1002/nau.25256

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Single Incision Slings vs. Retropubic RCT

Dr. Catherine Matthews (PI)

Abstract presented at SGS 2024

Coloplast

Randomized Trial of Retropubic Versus Single-incision Mid-Urethral Sling (Altis® Single Incision Sling) for Concomitant Management of Stress Urinary Incontinence During Native Tissue Vaginal Repair

Study Objective

- To assess outcomes of retropubic (RP) versus single-incision mid-urethral slings (Altis Single Incision Sling) placed at the time of native tissue vaginal repair

Study Design

- RCT: single-blinded, Sham incisions, 1-year follow-up
- Multicenter: 7 U.S. academic centers

Primary Outcome Measures

- Abnormal urinary tract infection: bothersome SUI symptoms, SUI retreatment or intervention for urinary retention (e.g. sling lysis)

Secondary Outcome Measures

- Patient global impression of bladder function (PGI-I)
- Surgeon ease of use of the sling

Timeline

- Study start: December 2018
- Enrollment completed: January 2023
- Study completion: January 2024

Study found on ClinicalTrials.gov Retropubic vs. Single-Incision Mid-Urethral Sling for Stress Urinary Incontinence - Full Text View - ClinicalTrials.gov
Study Sponsor Wake Forest University Health Sciences

Key Results_

Patient Population

- N=280 enrolled, 256 randomized (mean age 67±12 years)
- Majority white, non-smoking, obese women with symptomatic SUI (75%), bothersome UUI (50%)

Few Lost to follow-up

- At 6-weeks post-op 95% and at 1-year post-op 94%

Key Findings

- Abnormal bladder function: 25% Altis vs 20% RP sling (3 vs 1 retreatment SUI, 2 vs 2 sling lysis)
- PGI-I (very satisfied & satisfied): 71% Altis vs 67% RP sling (p=0.43)
- Median surgeon ease of sling use: 8 [7-10]Altis vs. 9 [8-10] RP sling (p=0.03)
- AEs: 24 (16%) Altis vs 14 (9%) RP slings (95% CI, 0.95-3.29; p=0.7), majority UTIs (18% vs 10%, p=0.07)
- No difference between intra-op injuries (p=0.06) but all bladder trocar injuries occurred in RP group (0% vs 6%)
- No difference in SAEs between groups. 1 pelvic hematoma after RP sling requiring surgery

Takeaways_

- **Altis® Single Incision Sling was non-inferior to RP**:
  For women undergoing vaginal POP repair, Altis was non-inferior to RP sling for abnormal bladder function: SUI symptoms, SUI retreatments and sling lysis

- **Ease of use was rated highly, even by surgeons with less Altis experience**

- **High patient satisfaction:**
  Overall patient satisfaction was rated ”very high” or ”high” in both the Altis and RP sling groups

- **AEs were similar between groups**

- **SAEs similar, but bladder perforation and 1 hematoma requiring surgical intervention in the RP group**

Single Incision Slings Pragmatic RCT

Dr. Abdel- Fattah(PI)

Published in NEJM 2022

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Single incision mini-slings for stress urinary incontinence in women - *Dr. Abdel-Fattah(PI)*

Study Objective

- Compare the effectiveness and safety of single incision (SI) mini-slings with those of standard mid-urethral slings

Study Design

- **Pragmatic**, noninferiority, randomized trial comparing SI mini-slings with standard mid-urethral slings among women with SUI
- Enrollment completed at 21 centers in the UK with 36 months of follow-up

Primary Outcome Measure

- Patient-reported success, defined as a response of ”very much improved” or ”much improved” on the PGI-I at 15-months*

*All other responses (improved, same, worse, much worse, and very much worse) were considered to indicate treatment failure

Abdel-Fattah M, Cooper D, Davidson T, Kilonzo M, Hossain M, Boyers D, Bhal K, Wardle J, N'Dow J, MacLennan G, Norrie J. Single incision mini-slings for stress urinary incontinence in women. N Eng J Med. 2022;386:1230-1243.

Key Results_

Patient Population

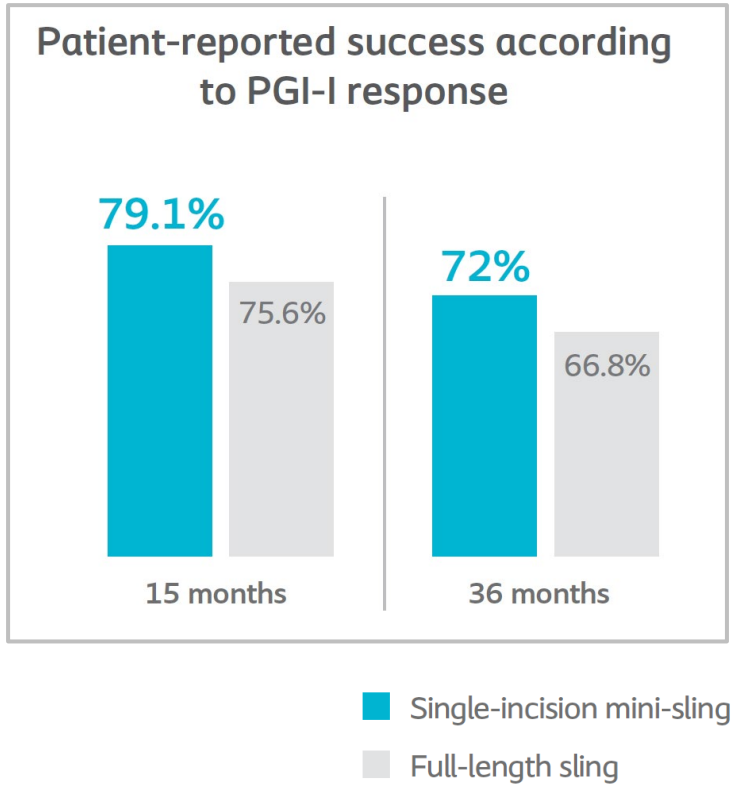
- N=298 patients assigned to receive single incision (SI) mini-slings
- N=298 patients assigned to receive standard mid-urethral slings

Patient Retention *(those who completed the PGI-I at 15-months)*

- N=268 SI mini-sling patients
- N=250 standard mid-urethral sling patients

Key Findings

- **At 15 months:**
  - **Success as measured by the PGI-I was reported by 79.1% in the SI group and by 75.6% in the standard mid-urethral sling group**
  - Success as measured with a 24-hour pad test occurred in 85.7% in the the SI mini-sling group and in 75.5% in the standard mid-urethral sling group
- **At 36 months**, a low percentage of patients had received further surgery for SUI (2.5% of the SI mini-sling patients and 1.1% of the standard mid-urethral sling patients)



Abdel-Fattah M, Cooper D, Davidson T, Kilonzo M, Hossain M, Boyers D, Bhal K, Wardle J, N'Dow J, MacLennan G, Norrie J. Single incision mini-slings for stress urinary incontinence in women. N Eng J Med. 2022;386:1230-1243.

Dyspareunia & Pain_

- Adverse events and serious adverse events were similar between groups
- At 36 months, tape or mesh exposure occurred in 3.3% of SI mini-sling group and 1.9% of the mid-urethral sling group
- No change in rate of **dyspareunia** was noted following mini-sling placement at 15 months

Dyspareunia	Mini-sling group *(Coloplast Altis & Bard Ajust)* % (n/N)	Mid-urethral sling group % (n/N)	P-value
Baseline	17.2% (25/145)	14.5% (21/145)	
15 months	17.2% (25/145)	5.5% (8/145)	0.008
36 months	11.7% (17/145)	4.8% (7/145)	0.01

- No significant difference in the incidence of **groin or thigh pain** between or within groups at 15 or 36 months

Groin or thigh pain	Mini-sling group *(Coloplast Altis & Bard Ajust)* % (n/N)	Mid-urethral sling group % (n/N)	P-value
15 months	14.9% (41/276)	11.9% (31/261)	0.14
36 months	14.1% (39/276)	14.9% (39/261)	0.61

Abdel-Fattah M, Cooper D, Davidson T, Kilonzo M, Hossain M, Boyers D, Bhal K, Wardle J, N'Dow J, MacLennan G, Norrie J. Single incision mini-slings for stress urinary incontinence in women. N Eng J Med. 2022;386:1230-1243.

Key Takeaways_

- Non-inferiority:
  This pragmatic RCT comparing a SI mini-sling to RP sling for isolated SUI demonstrated noninferiority at 15-months and 36-months post-surgery

- Longevity of successful outcomes:
  72% of SI mini-sling patients continued to report success at 36 months post-surgery

- Quality of life and sexual function outcomes were similar between groups

- SAEs were similar between groups

Abdel-Fattah M, Cooper D, Davidson T, Kilonzo M, Hossain M, Boyers D, Bhal K, Wardle J, N'Dow J, MacLennan G, Norrie J. Single incision mini-slings for stress urinary incontinence in women. N Eng J Med. 2022;386:1230-1243.

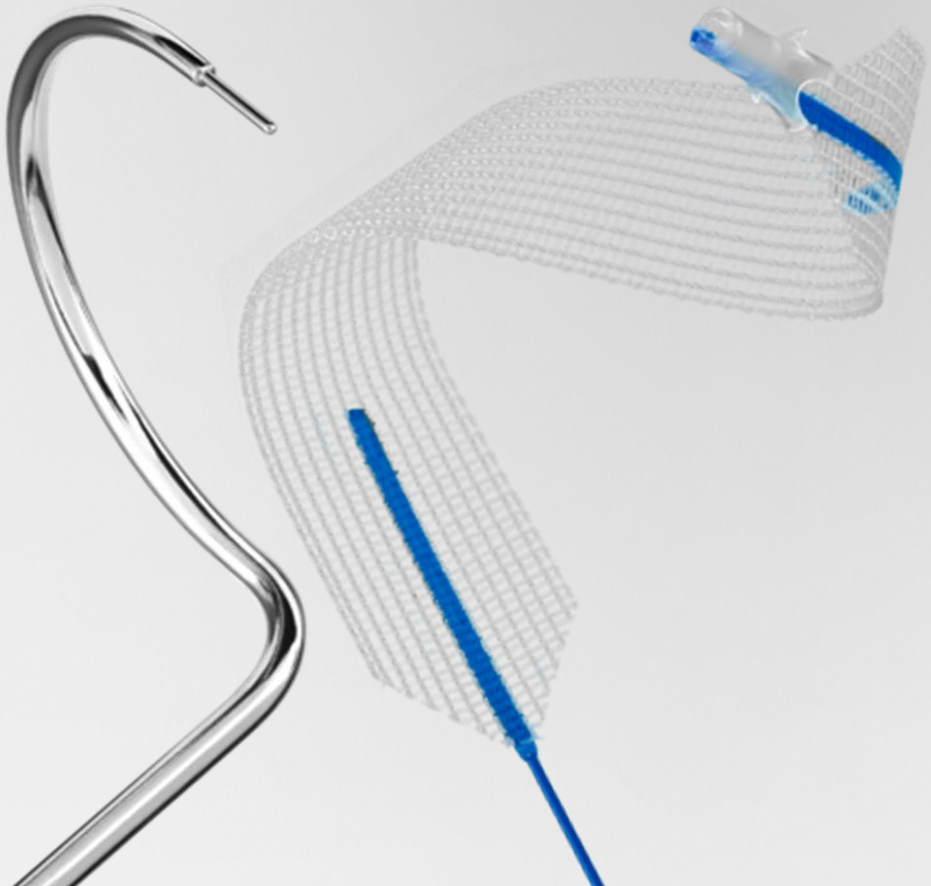
Why Altis®?

Coloplast

The most

rigorously studied

single incision sling in the U.S.



#1 single incision sling in the U.S.

More than 50 Altis® studies

More than 3000

Patients have been treated
in Altis clinical studies worldwide

FDA Reviewed

The only sling with prospective, multicenter clinical trial data reviewed by FDA to support market clearance

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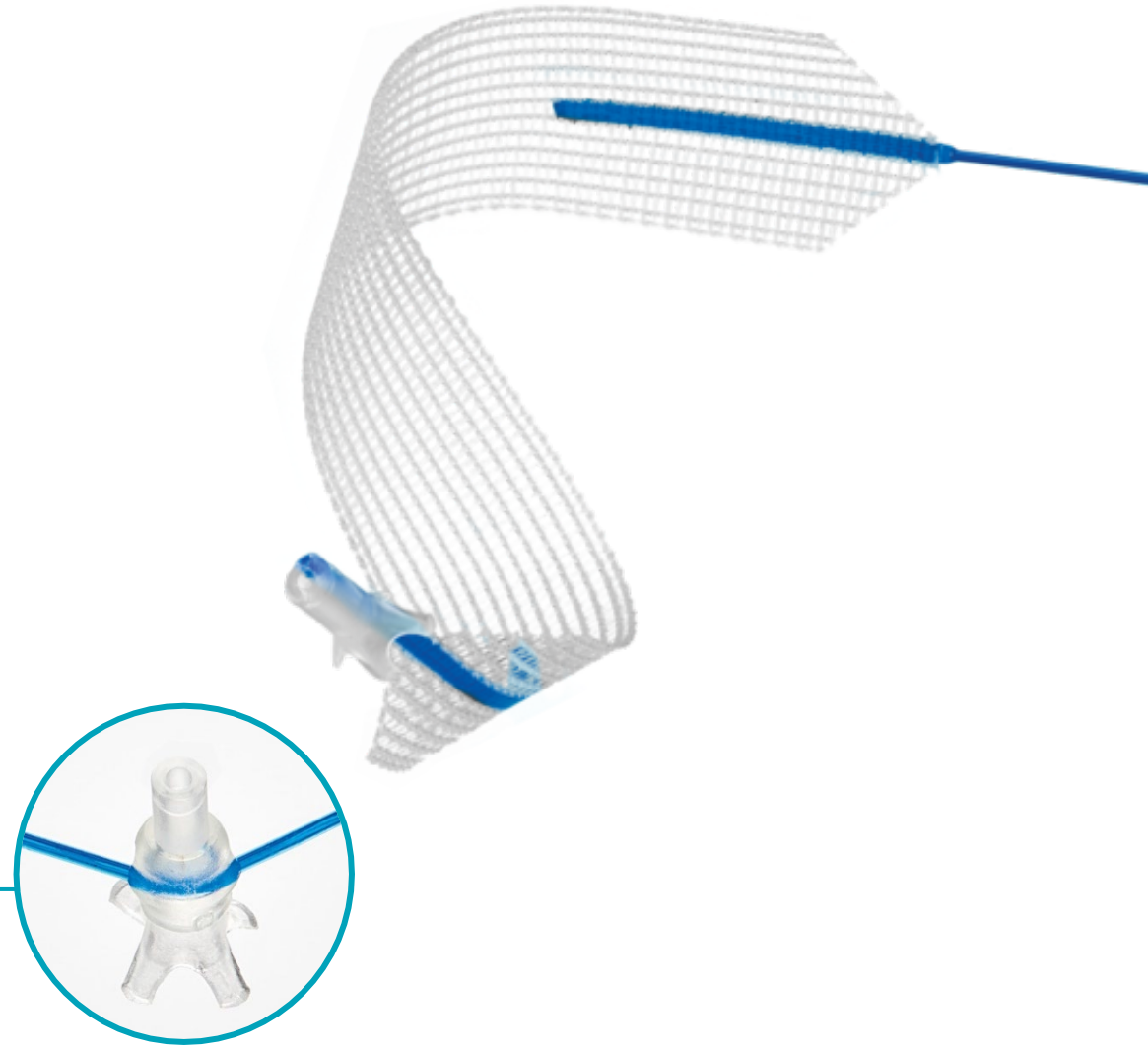
Altis® Single Incision Sling System_

- **LESS INVASIVE**
  One incision. Less tissue trauma. Speed up procedure time and deliver a better patient experience.[1,2]

- **STABLE SUPPORT**
  Patented, flexible, lightweight mesh is the thinnest available, allowing support of the urethra.[1]

- **REPRODUCIBLE INSERTION**
  Patented helical introducer makes the surgical procedure predictable, accurate and reproducible.[1]

- **PRECISE TENSIONING**
  Place the device, then control the adjustable tensioning.[1]



1. Data on file.
2. Mostafa A et al.. Single-incision mini-slings versus standard midurethral slings in surgical management of female stress urinary incontinence: an updated systematic review and meta-analysis of effectiveness and complications. *Euro Urology*. 2014;65(2):402-427. doi:10.1016/j.eururo.2013.08.032.

Coloplast

The Altis® Single Incision Sling System may be an optimal sling choice vs full length slings for providers and patients_

Minimally invasive and safe[1]

Better patient experience[2,3]

Shorter procedure time[2,4]

Cost Savings[2,3, 5-8]

† Approximate cost to the patient over 5-years

1. Tu LM, Gheiler E, Hanson CE, Jalkut M, McCrery R, Parekh M, Parva M, Erickson T. Management of female stress urinary incontinence with single-incision mini-sling (Altis®): 36 month multicenter outcomes. *Neurourol Urodyn*. 2023 Aug 9. doi: 10.1002/nau.25256. Epub ahead of print. PMID: 37555436. 2. Abdel-Fattah M, Cooper D, Davidson T, Kilonzo M, Hossain Md. Single-Incision Mini-Slings for Stress Urinary Incontinence in Women. The New England Journal of Medicine. 2022;386. 1230-1243.10.1056/NEJMoa2111815. 3. Mostafa A, Lim CP, Hopper L, Madhurvata P, Abdel-Fattah M. Single-incision mini-slings versus standard midurethral slings in surgical management of female stress urinary incontinence: an updated systematic review and meta-analysis of effectiveness and complications. Euro Urology. 2014;65(2):402-427. doi:10.1016/j.eururo.2013.08.032. 4. Lucente et al. Single incision midurethral sling site of care: office based ambulatory surgical unit versus hospital based ambulatory surgical unit setting. JMIG 2023 Apr 11. S1553-4650(23)00156-5. Chang, OH; Cadish, LA; Kailasam, A; Ridgeway, BM; Shepherd, JP, Impact of the availability of midurethral slings on treatment strategies for stress urinary incontinence: a cost-effectiveness analysis, BJOG: An International Journal of Obstetrics & Gynaecology, John Wiley & Sons, Inc, Publication Date: 1/10/2022, Volume: 129, Issue: 3, Pages: 500-508, DOI: 10.1111/1471-0528.16850, PMID: 34314554. 6. CMS-1753-FC | CMS. 7. Boyers D, Kilonzo M, Mostafa A, Abdel-Fattah M. Comparison of an adjustable anchored single-incision mini-sling, Ajust,® with a standard mid-urethral sling, TVT-O™: a health economic evaluation. BJU Int. 2013 Dec;112(8):1169-77. doi: 10.1111/bju.12388. PMID: 24053310. 8. Capobianco G, Saderi L, Dessole F, Petrillo M, Dessole M, Piana A, Cherchi PL, Dessole S, Sotgiu G. Efficacy and effectiveness of bulking agents in the treatment of stress and mixed urinary incontinence: A systematic review and meta-analysis. Maturitas. 2020 Mar;133:13-31. doi: 10.1016/j.maturitas.2019.12.007. Epub 2019 Dec 11. PMID: 32005420

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Patient Journey

Patient Selection, Implantation, Post-Procedure

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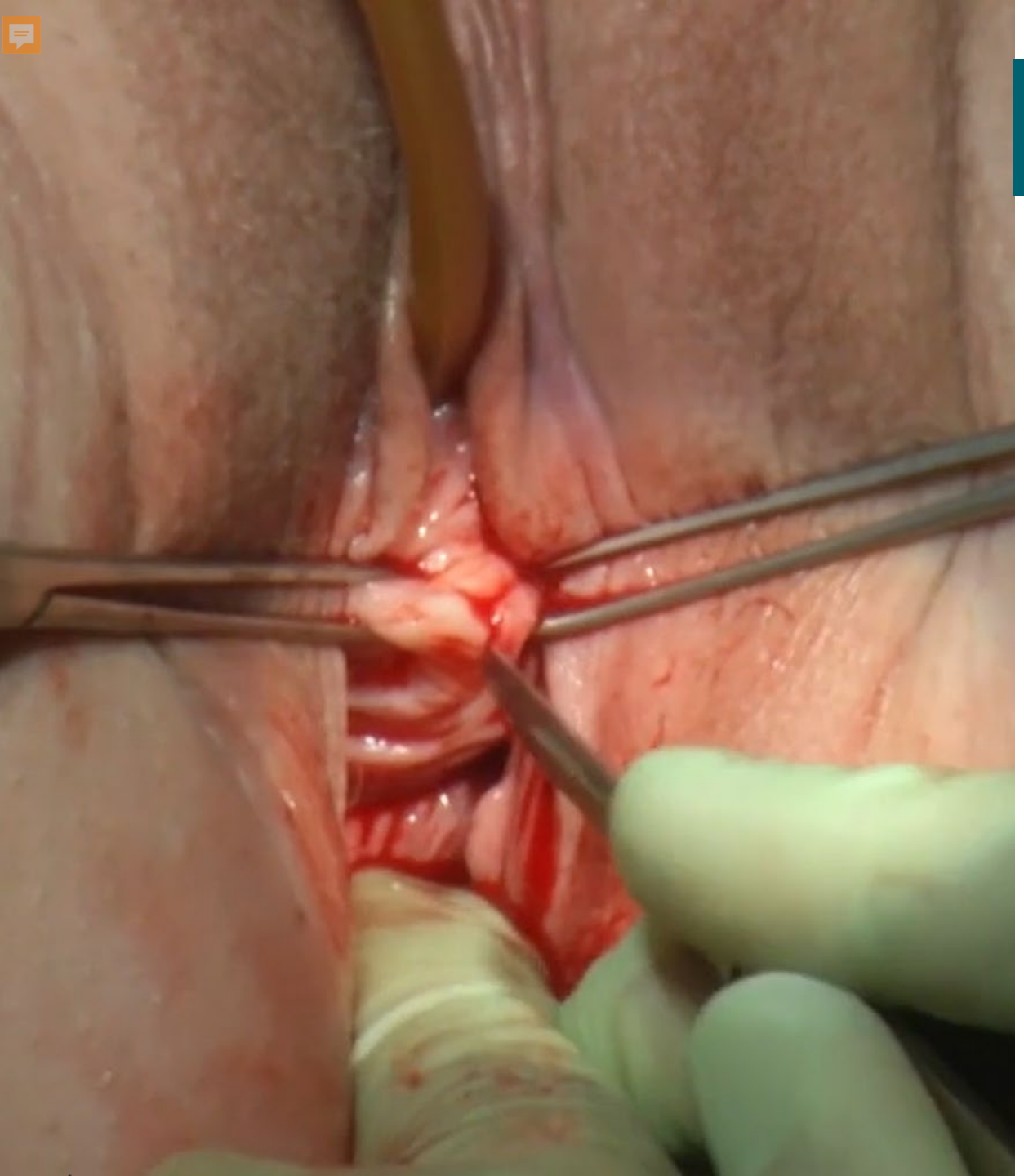
Patient Selection_

Indication: The Altis Single Incision Sling System is indicated for the treatment of female stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency(ISD).

Keys to Implantation

Altis® Single Incision Sling

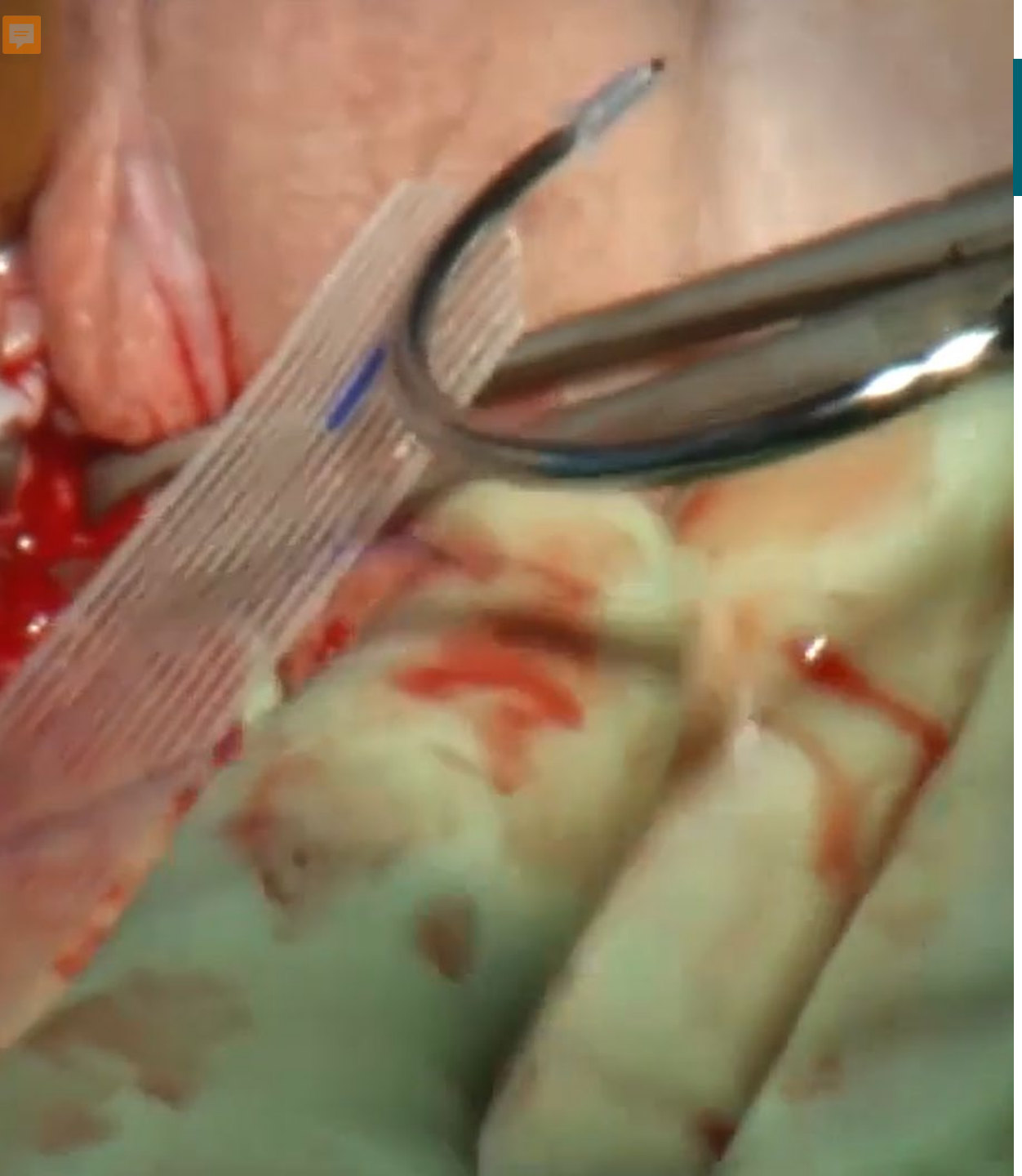
Coloplast



Keys to Implanting_

Incision and Dissection

- Perform hydro-dissection
- Make 1.5 cm long midurethral incision
- Dissect back to the ipsilateral ischiopubic ramus (at least 1.5 cm wide), which allows the sling to lay flat in the dissected plane



Keys to Implanting_

Implant the Static Anchor First

- Place static non-tensioning anchor on introducer and ensure introducer tip exits the top of the anchor
- Place the introducer/sling into the midline vaginal incision
- Align the introducer shaft parallel to the ipsilateral ischiopubic ramus

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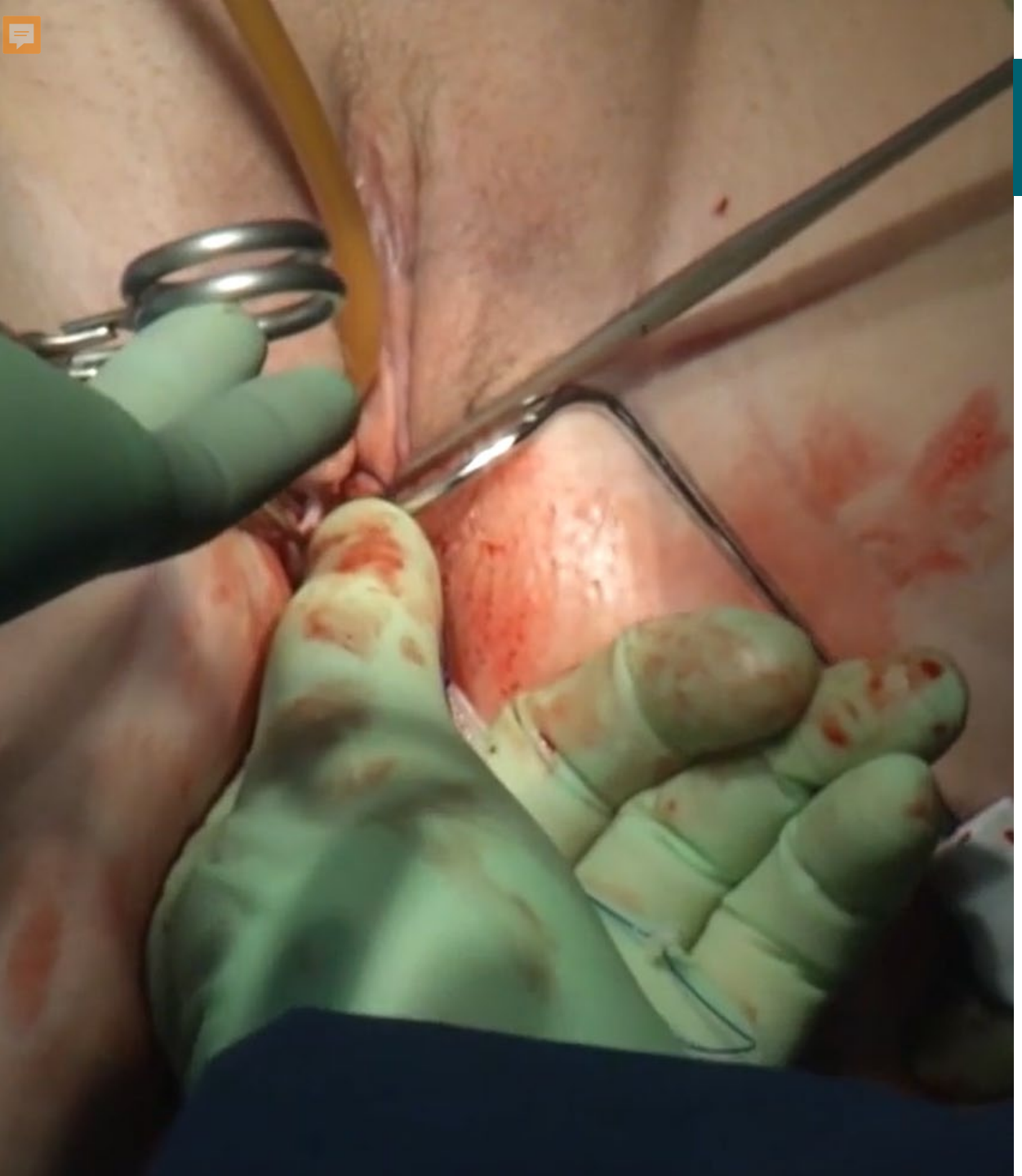
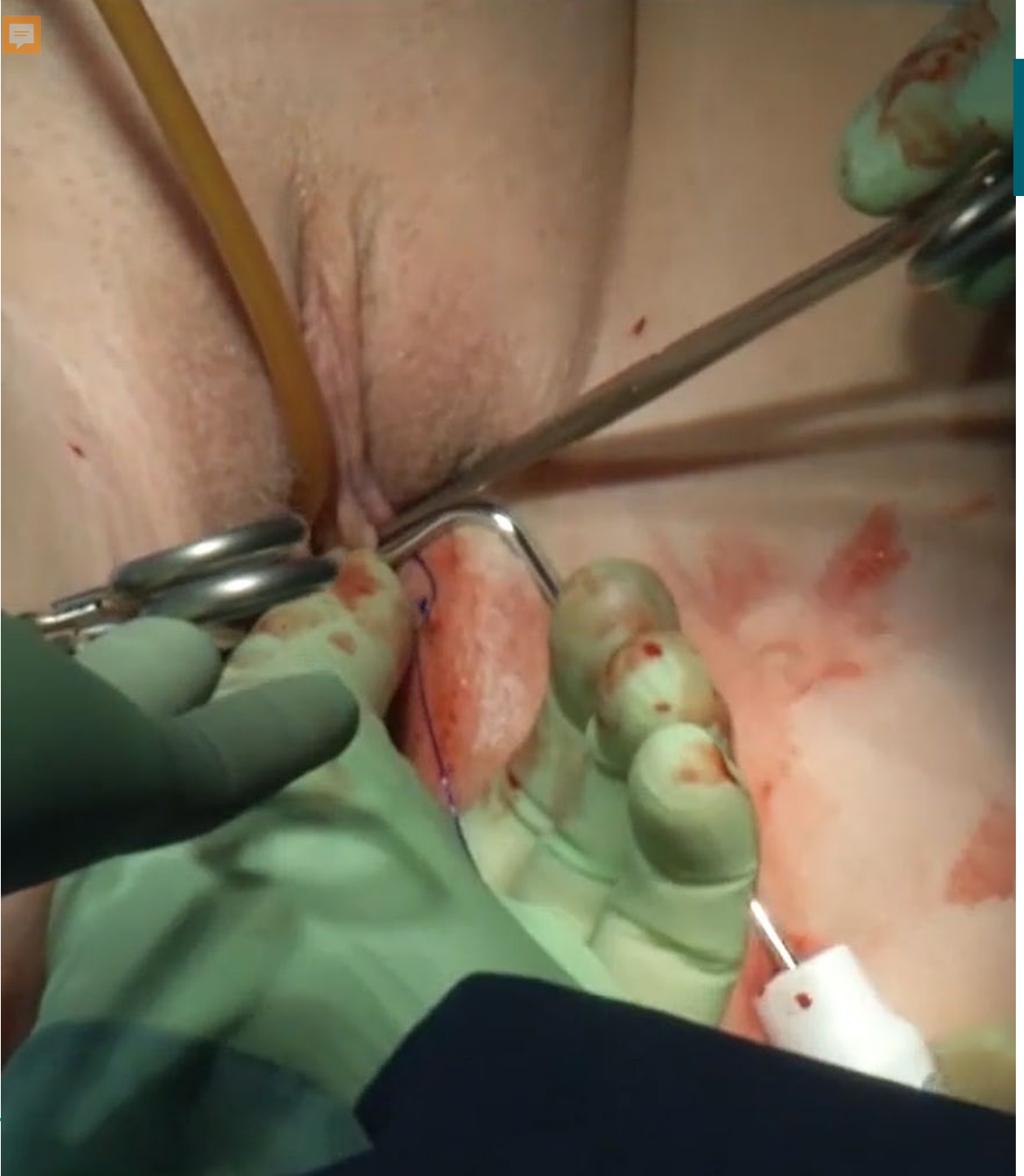


Keys to Implanting_

Introducer Placement

- Pass the introducer/anchor tip proximal to the cephalad posterior border of the ischiopubic ramus
- Press the arc of the introducer to advance the tip into the obturator internus
- Avoid a twisting motion
- Keep introducer against the body and parallel with the ipsilateral ischiopubic ramus



Keys to Implanting_

Obturator Membrane

- Make a ¼ turn toward patient's midline
- A "pop" should be felt as the anchor implants through the obturator membrane
- Grey bar of introducer faces up

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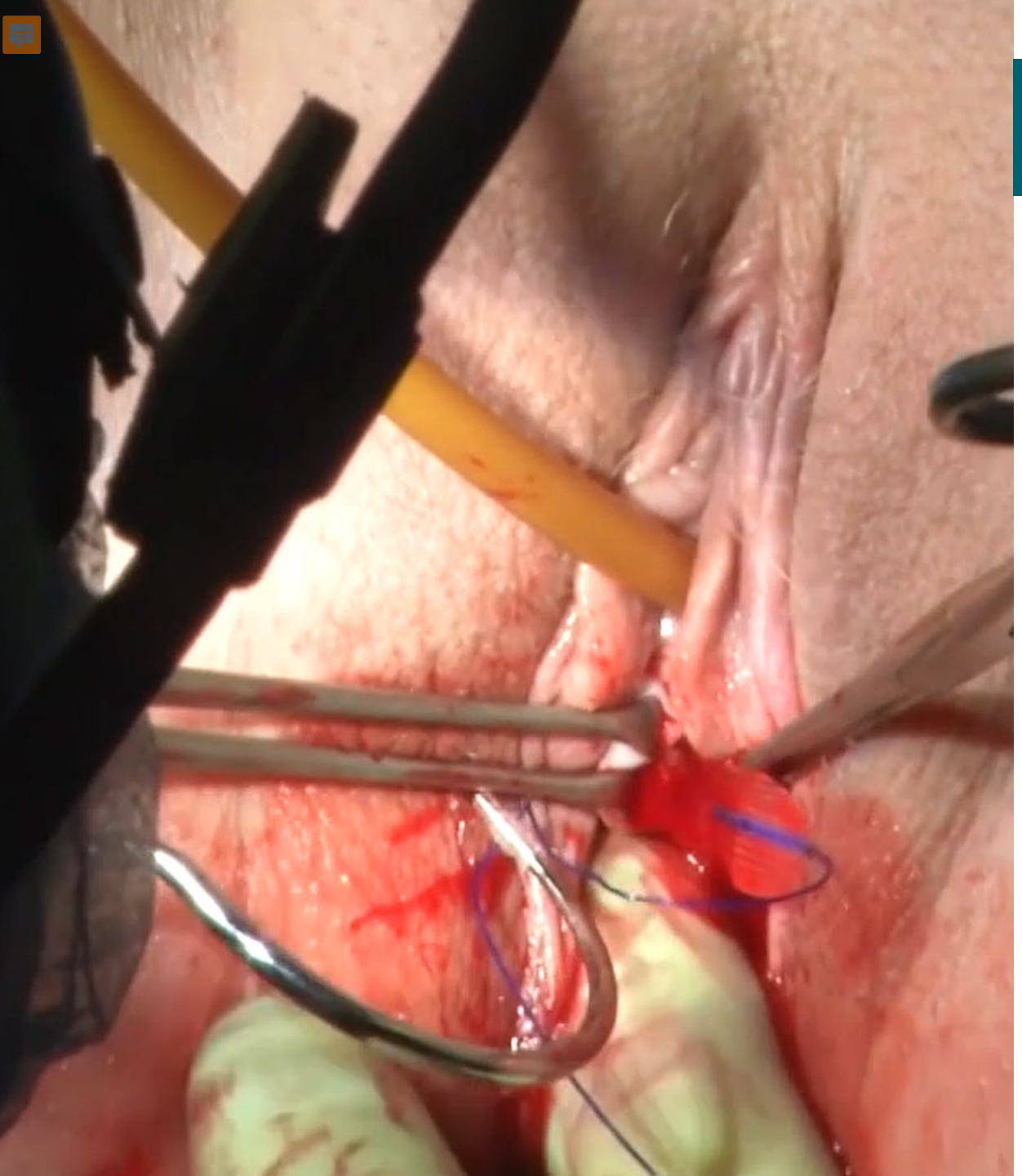

Keys to Implanting_

Dynamic Anchor

- Repeat steps using the dynamic anchor on the contralateral side with the opposite introducer

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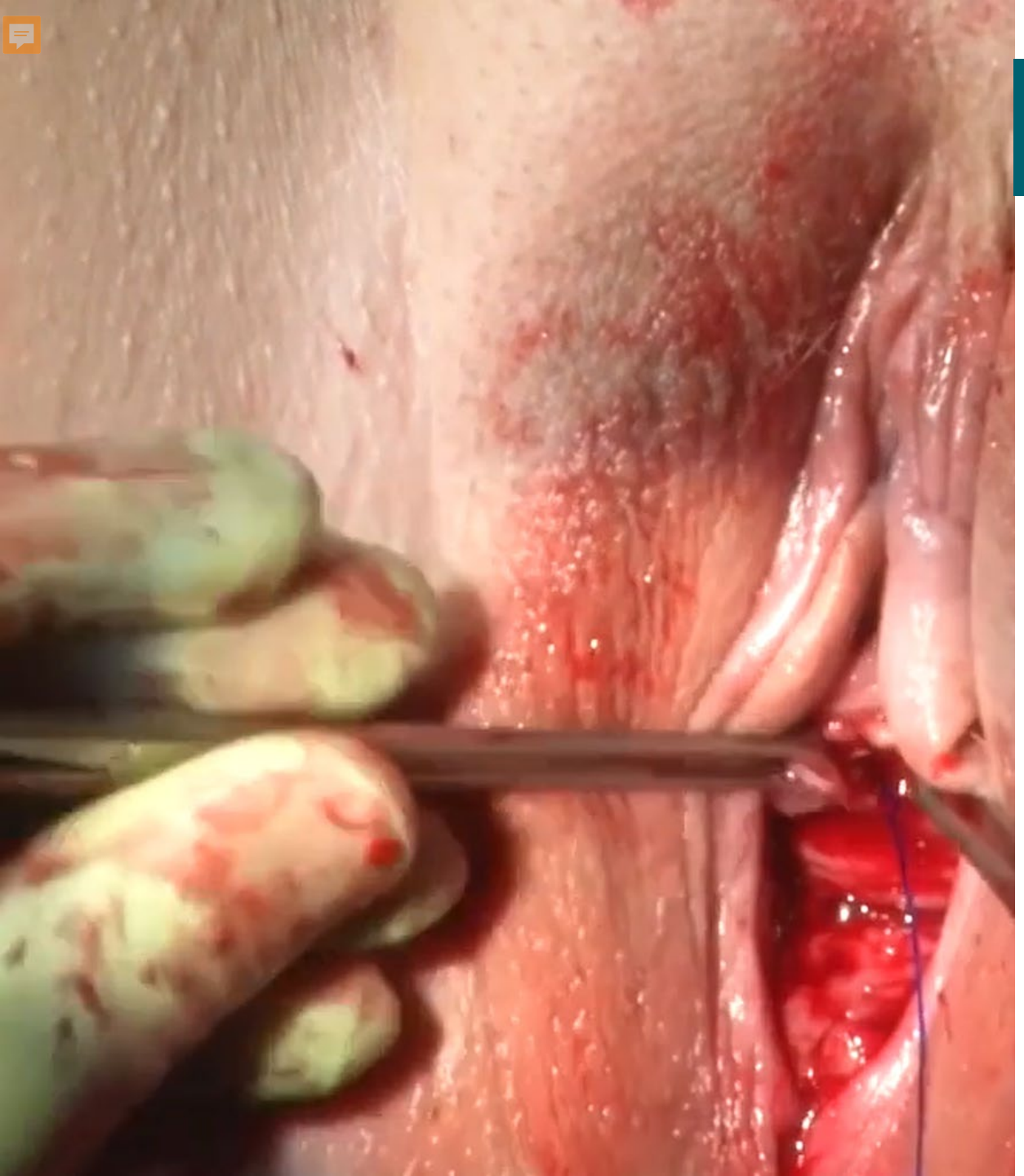

Keys to Implanting_

Tensioning

- Ensure that the sling is lying flat under urethra tension free
- If folding or curling is observed, widen dissection until sling lies flat
- Adjust the sling by pulling the suture loop slowly across the patient's midline until desired support is reached
- To loosen sling, use a blunt instrument between the sling and urethra and gently pull down on the sling

Altis® Single Incision Sling Implantation Physician Tips and Tricks

- Patient positioning
- Wide dissection
- Step by step technique
- Over/Under rotation
- Cystoscopy
- Cutting the suture
- Closing the incision

Post-Procedure_

Peri-Surgical Care

Patient Aftercare

Patient Feedback

Altis® Single Incision Sling

Procedural Video

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Questions?

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Altis® Single Incision Sling System - Brief Statement

Indications
The Altis Single Incision Sling System is indicated for the treatment of female stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency (ISD).

Contraindications
It is the responsibility of the physician to advise the prospective patients prior to surgery, of the contraindications associated with the use of this product. The Altis Single Incision Sling System is contraindicated for use in patients with one or more of the following conditions:

- Pregnancy or desire for future pregnancy
- Potential for further growth (e.g., adolescents)
- Known active urinary tract infection and/or infection in operative field
- Taking anti-coagulant therapy
- Abnormal urethra (e.g., fistula, diverticulum)
- Any condition, including known or suspected pelvic pathology, which could compromise implant or implant placement
- Documented hypersensitivity or allergic reaction to polypropylene or polyurethane

Warnings
It is the responsibility of the physician to advise prospective patients prior to surgery, of the warnings associated with the use of this product and the associated surgical risks.
The Altis Single Incision Sling System should only be used by physicians experienced in the surgical procedures involving transvaginal placement of non-absorbable, synthetic mesh slings. A thorough assessment of each patient should be made to determine the suitability of a synthetic mesh sling procedure.
The patient should be counseled that alternative incontinence treatments may be appropriate prior to surgical intervention.
Obtain patient consent prior to surgery and ensure that the patient understands the postoperative risks and potential complications of transvaginal mesh sling surgery and that the Altis implant is permanent.

Serious mesh associated complications may result in one or more revision surgeries which may lead to partial or complete removal of the mesh. Complete removal of the mesh may not always be possible or advisable, and removal may not fully correct these complications. There may be unresolved pain with or without mesh explant. De novo complications and recurrence or worsening of SUI can occur.

Patient-Related Warnings
As with all surgical procedures, patients with certain underlying conditions may be more susceptible to postoperative bleeding, impaired blood supply, compromised/delayed healing, mesh sling exposure or other complications and adverse events.

The risks and benefits of using Altis should be considered in patients with:

- Age-related underlying conditions
- Autoimmune disease
- Coagulation disorder
- Connective tissue disorder
- Debilitated or immunocompromised state
- Diabetes
- Pelvic radiation therapy or chemotherapy
- Physical characteristics (e.g., body mass index)
- Renal insufficiency
- Smoking-related underlying conditions
- Urinary tract anomalies

Any future pregnancy could negate the benefits of this surgical procedure. Patients should report bleeding, pain, abnormal vaginal discharge or signs of infection at any time.

Altis® Single Incision Sling System - Brief Statement

Potential Complications
Adverse events are known to occur with transvaginal synthetic sling procedures and implants and may include:

Abnormal vaginal discharge, abscess, adhesion, allergic reaction, hypersensitivity, or maladaptive immune response, bladder storage symptoms (e.g., increased daytime frequency, urgency, nocturia, overactive bladder, urinary incontinence), bleeding/hemorrhage or hematoma, delayed/impaired/abnormal wound healing, dyspareunia, exposure, extrusion, or erosion of mesh sling or suture into the vagina or other structures and organs, fistula formation, granuloma/scar tissue formation, hispareunia (male partner pain with intercourse), infection, inflammation/irritation, necrosis, neuromuscular disorder, pain, palpable mesh (patient and/or partner), pelvic/urogenital pain, perforation or injury to adjacent muscles, nerves, vessels, structures, or organs (e.g., bone, bladder, urethra, ureters, bowel, vagina), scarring, seroma, sexual dysfunction, sling migration, tensioning suture exposure, ureteral obstruction, urinary tract infection, vaginal tightening/shortening, voiding symptoms (e.g., dysuria, urinary retention, incomplete emptying, bladder outlet obstruction, straining, position-dependent voiding, slow stream) or wound dehiscence.

The information provided is not comprehensive with regard to product risks. For a comprehensive listing of indications, contraindications, warnings, precautions, and adverse events refer to the product's Instructions for Use. Alternatively, you may contact a Coloplast representative at 1-800-258-3476 and/or visit the company Website at www.coloplast.com.

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

Minneapolis, MN
PM-03363 04.2024

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Supris® Retropubic Sling System - Brief Statement

Indications
The Supris Retropubic Kit consists of the Supris implantable midurethral support sling and disposable introducers for placement using a "top-down" or "bottom-up" retropubic surgical approach. The Supris sling and introducers are indicated for the surgical treatment of female stress urinary incontinence (SUI), resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

Contraindications
It is the responsibility of the physician to advise the prospective patients or their representatives, prior to surgery, of the contraindications associated with the use of this product. The Supris Retropubic Kit is contraindicated for use in patients with the following conditions:

- Pregnancy or desire for future pregnancy
- Potential for further growth (e.g., adolescents)
- Known active urinary tract infection and/or infection in operative field
- Taking anti-coagulant therapy
- Abnormal urethra (e.g., fistula, diverticulum)
- Intraoperative urethral injury
- Any condition, including known or suspected pelvic pathology, which could compromise implant or implant placement
- Sensitivity/allergy to polypropylene

Warnings and Precautions
It is the responsibility of the physician to advise the prospective patients or their representatives, prior to surgery, of the warnings and precautions associated with the use of this product and the associated surgical risks.

Warnings
The Supris Retropubic Kit should only be used by physicians familiar with the surgical procedures and techniques involving transvaginal placement of non-absorbable, synthetic mesh slings and who have adequate education and experience in the treatment of female SUI.

A thorough assessment of each patient should be made to determine the suitability of a synthetic mesh sling procedure.

The patient should be counseled that alternative incontinence treatments may be appropriate, and the reason for choosing a mesh sling procedure should be explained.

Obtain patient consent prior to surgery and ensure that the patient has an understanding of the postoperative risks and potential complications of transvaginal mesh sling surgery.

Patient counseling should include a discussion that the sling to be implanted is a permanent implant and that some complications associated with the implanted mesh sling may require additional surgery; repeat surgery may not resolve these complications. Serious adverse tissue responses or infection may require removal of mesh, and complete removal of the sling may not always be possible. Individuals may have varying degrees of collagen laydown that may result in scarring.

As with all surgical procedures, patients with certain underlying conditions may be more susceptible to postoperative bleeding, impaired blood supply, compromised/delayed healing, or other complications and adverse events.

The risks and benefits of using Supris should be considered in patients

Supris® Retropubic Sling System - Brief Statement

Any future pregnancy could negate the benefits of this surgical procedure. Patients should report any bleeding, pain, abnormal vaginal discharge or sign of infection that occur at any time.

Do not use product that has damaged or opened packaging, or has expired, as sterility may be compromised.

The procedure to insert the Supris sling requires good knowledge of pelvic anatomy and the correct use of the introducer needles in order to avoid damage to adjacent anatomical structures.

Potential Complications
Adverse events are known to occur with transvaginal synthetic sling procedures and implants. Adverse events following mesh implantation may be de novo, persistent, worsening, transient, or permanent.

Adverse events may include but are not limited to: abscess (acute or delayed), adhesion/scar formation, allergy, hypersensitivity or other immune reaction, bleeding, hemorrhage or hematoma, bowel obstruction, dehiscence, delayed wound healing, extrusion, erosion or exposure of mesh sling into the vagina or other structures or organs, fistula formation, infection, inflammation (acute or chronic), local irritation, necrosis, de novo and/or worsening dyspareunia, neuromuscular symptoms (acute or chronic), pain (acute or chronic), partner pain and/or discomfort during intercourse, perforation or injury of soft tissue (e.g., muscles, nerves, vessels), structures, or organs (e.g., bone, bladder, urethra, ureters, vagina), seroma, sling migration, bladder storage dysfunction (e.g., increased daytime frequency, urgency, nocturia, overactive bladder, urinary incontinence), ureteral obstruction, urinary tract infection, voiding symptoms (e.g., dysuria, urinary retention, incomplete emptying, straining, positional voiding, weak stream), granulation tissue formation, palpable mesh (patient and/or partner), sexual dysfunction, vaginal discharge (abnormal) and vaginal scarring or tightening.

The occurrence of these events may require one or more revision surgeries, including removal of the sling.

Complete removal of the sling may not always be possible, and additional surgeries may not always fully correct the complications.

There may be unresolved pain with or without mesh sling explantation.

The information provided is not comprehensive with regard to product risks. For a comprehensive listing of indications, contraindications, warnings, precautions, and adverse events refer to the product's Instructions for Use. Alternatively, you may contact a Coloplast representative at 1-800-258-3476 and/or visit the company Website at www.coloplast.com.

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

Minneapolis, MN
PM-04431 04.2021

Coloplast

Aris® Transobturator Sling System - Brief Statement

Indications
The Aris Transobturator Kit consists of the Aris implantable midurethral support sling and disposable introducers. The Aris sling and introducers are indicated for the surgical treatment of all types of stress urinary incontinence (SUI) and for female urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency. The introducer is a surgical instrument designed to assist in correct placement of a sling.

Contraindications
It is the responsibility of the physician to advise the prospective patients or their representatives, prior to surgery, of the contraindications associated with the use of this product. The Aris Transobturator Kit is contraindicated for use in patients with the following conditions:

- Pregnancy or desire for future pregnancy
- Potential for further growth (e.g., adolescents)
- Known active urinary tract infection and/or infection in operative field
- Taking anti-coagulant therapy
- Abnormal urethra (e.g., fistula, diverticulum)
- Intraoperative urethral injury
- Any condition, including known or suspected pelvic pathology, which could compromise implant or implant placement
- Sensitivity/allergy to polypropylene

Warnings and Precautions
It is the responsibility of the physician to advise the prospective patients or their representatives, prior to surgery, of the warnings and precautions associated with the use of this product and the associated surgical risks.

Warnings
The Aris Transobturator Kit should only be used by physicians familiar with the surgical procedures and techniques involving transvaginal placement of non-absorbable, synthetic mesh slings and who have adequate education and experience in the treatment of female SUI.

A thorough assessment of each patient should be made to determine the suitability of a synthetic mesh sling procedure.

The patient should be counseled that alternative incontinence treatments may be appropriate, and the reason for choosing a mesh sling procedure should be explained.

Obtain patient consent prior to surgery and ensure that the patient has an understanding of the postoperative risks and potential complications of transvaginal mesh sling surgery.

Patient counseling should include a discussion that the sling to be implanted is a permanent implant and that some complications associated with the implanted mesh sling may require additional surgery; repeat surgery may not resolve these complications. Serious adverse tissue responses or infection may require removal of mesh, and complete removal of the sling may not always be possible. Individuals may have varying degrees of collagen laydown that may result in scarring.

As with all surgical procedures, patients with certain underlying conditions may be more susceptible to postoperative bleeding, impaired blood supply, compromised/delayed healing, or other complications and adverse events.

Aris® Transobturator Sling System - Brief Statement

The risks and benefits of using Aris should be considered in patients.

Any future pregnancy could negate the benefits of this surgical procedure. Patients should report any bleeding, pain, abnormal vaginal discharge or sign of infection that occur at any time.

Do not use product that has damaged or opened packaging, or has expired, as sterility may be compromised.

The procedure to insert the Aris sling requires good knowledge of pelvic anatomy and the correct use of the introducer needles in order to avoid damage to adjacent anatomical structures.

Potential Complications
Adverse events are known to occur with transvaginal synthetic sling procedures and implants. Adverse events following mesh implantation may be de novo, persistent, worsening, transient, or permanent.

Adverse events may include but are not limited to: abscess (acute or delayed), adhesion/scar formation, allergy, hypersensitivity or other immune reaction, bleeding, hemorrhage or hematoma, dehiscence, delayed wound healing, extrusion, erosion or exposure of mesh sling into the vagina or other structures or organs, fistula formation, infection, inflammation (acute or chronic), local irritation, necrosis, de novo and/or worsening dyspareunia, neuromuscular symptoms (acute or chronic), pain (acute or chronic), partner pain and/or discomfort during intercourse, perforation or injury of soft tissue (e.g., muscles, nerves, vessels), structures, or organs (e.g., bone, bladder, urethra, ureters, vagina), seroma, sling migration, bladder storage dysfunction (e.g., increased daytime frequency, urgency, nocturia, overactive bladder, urinary incontinence), ureteral obstruction, urinary tract infection, voiding symptoms (e.g., dysuria, urinary retention, incomplete emptying, straining, positional voiding, weak stream), granulation tissue formation, palpable mesh (patient and/or partner), sexual dysfunction, vaginal discharge (abnormal) and vaginal scarring or tightening.

The occurrence of these events may require one or more revision surgeries, including removal of the sling.

Complete removal of the sling may not always be possible, and additional surgeries may not always fully correct the complications.

There may be unresolved pain with or without mesh sling explantation.

The information provided is not comprehensive with regard to product risks. For a comprehensive listing of indications, contraindications, warnings, precautions, and adverse events refer to the product's Instructions for Use. Alternatively, you may contact a Coloplast representative at 1-800-258-3476 and/or visit the company Website at www.coloplast.com.

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

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