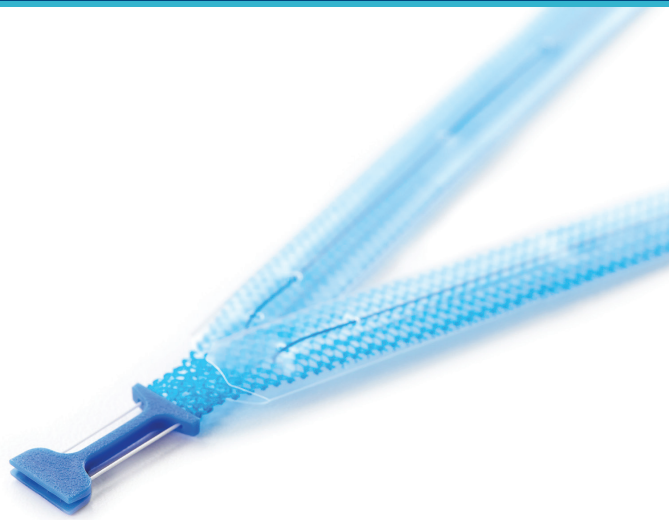
# Ultra Retropubic Mid-urethral Sling Product Family



## Introduction

The purpose of this value analysis brief is to illustrate the potential clinical and economic value of Ultra Retropubic Mid-urethral Sling Product Family. This brief is based on market research, bench testing, clinical literature and health economics data.*

## Background

**Stress Urinary Incontinence is incredibly common, but it isn't normal.**

One in two women suffer from bladder leakage, often caused by a condition called Stress Urinary Incontinence (SUI).[1] SUI has a dramatic impact on quality of life, but it can be treated long-term with a short, outpatient sling procedure.

**Since 1995, Boston Scientific has made significant investments in pelvic floor research and innovation, which have resulted in best-in-class solutions for women and the doctors who treat them.**

**Clinical research:** millions in post-market studies and decades of research on our products as well as numerous ongoing sponsored research studies

**Physician and patient education:** World-class in-person and on-demand training to support physicians as all stages of their careers, and robust education to help patients understand their conditions and take action

**R&D and innovation:** 25+ years of physician-driven, customer-centric innovation

**Society partnerships:** Collaboration to further clinical evidence and training

**Health economics and market access:** Dedicated team to help shape reimbursement policy and expand access to care

Our investment in the pelvic floor space, paired with more than 200 physician touchpoints, has resulted in the new Ultra Retropubic Mid-Urethral Sling Family, which offers an enhanced sling delivery system that's designed for consistent sling placement.

# Consistent. Innovative. Precise.

## Physician-Driven, Patient-Centered Features

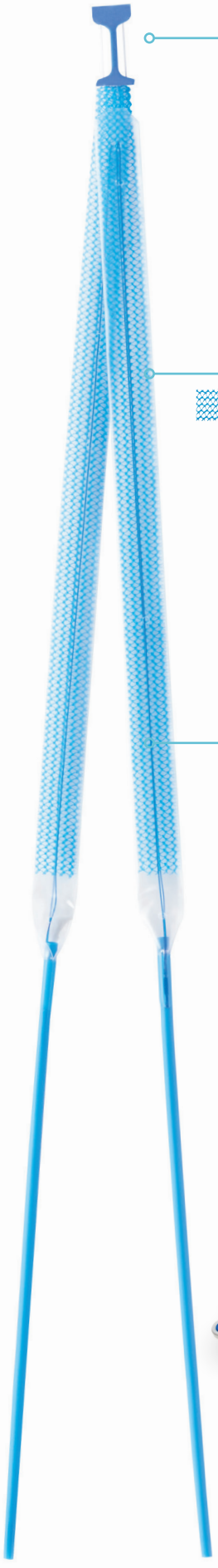
Fueled by physician insights and feedback, Ultra innovation is designed to **improve provider experience** by enhancing sling delivery to drive procedural efficiency, mesh visualization and tensioning consistency.

Advantage mesh is supported by **more than 100 publications to date.**

Advantage mesh has been used in **more than 1 million slings.**

Centering tab and sleeve removal technique are **consistent across surgical approaches**, enabling facilities to **streamline training** for residents and fellows. Achieving consistency across the Boston Scientific mid-urethral sling family, Ultra innovation is featured with:

- Advantage™ Ultra Transvaginal Mid-Urethral Sling System
- Advantage Fit™ Ultra Transvaginal Mid-Urethral Sling System
- Lynx™ Ultra Suprapubic Mid-Urethral Sling System



**Sleek, suture-released centering tab** provides physicians with:

- 1 cm exposed mesh designed for better visualization of the surgical field
- One-step removal process
- Ability to visualize tensioning and centering after sleeve removal

**Clinically supported Advantage™ optical blue mesh** is made of the same material as the patented clear mesh. The optical blue color enhances intra-operative visibility of mesh against the urethra, which may make it easier to locate post-operatively, if needed.

**Lay-flat, two-sleeve design** delivers a slim, smooth surface during tissue interaction.

Includes **established and trusted trocar** delivery devices.

## Potential Clinical and Economic Benefits to Institutions

### Equivalent Pricing

Enhanced delivery system at no additional cost as compared to Boston Scientific's legacy retropubic mid-urethral slings (MUS).

### Impact to Institutions

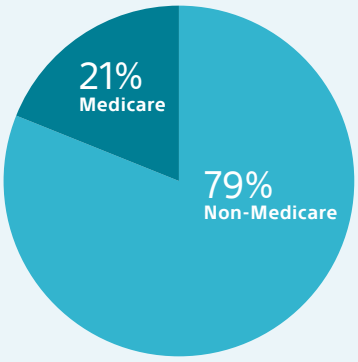
Growing reimbursement, favorable payer mix and site of service suggest that sling procedures, within the urology service line, remain a great place to prioritize therapies for patients.

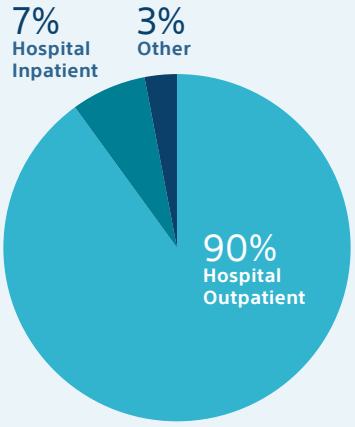
### Site of Service

- 90% of all sling procedures are performed in the hospital outpatient site of service which is a potentially less costly site of service for these procedures.[2,3]
- When compared with inpatient, outpatient MUS site of service decreased complication rates, readmissions and reoperations.[4]

### Favorable Payer Mix

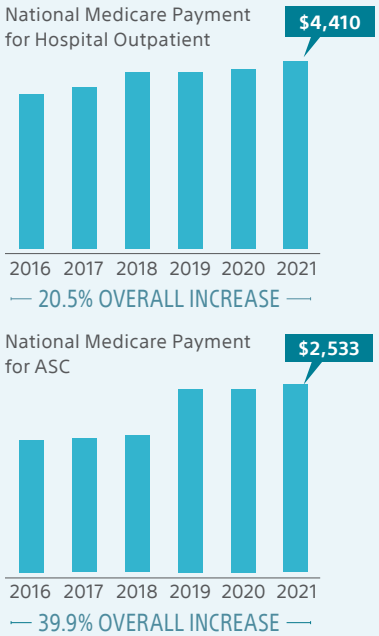
- Nationally, 79% of sling operations are performed among the non-Medicare population.[2] Prevalence of stress urinary incontinence peaks around age 40-49,[5] and typically this age group is insured under private insurance.
- On average, private payers reimburse at 200% of Medicare rates for outpatient services.[6]



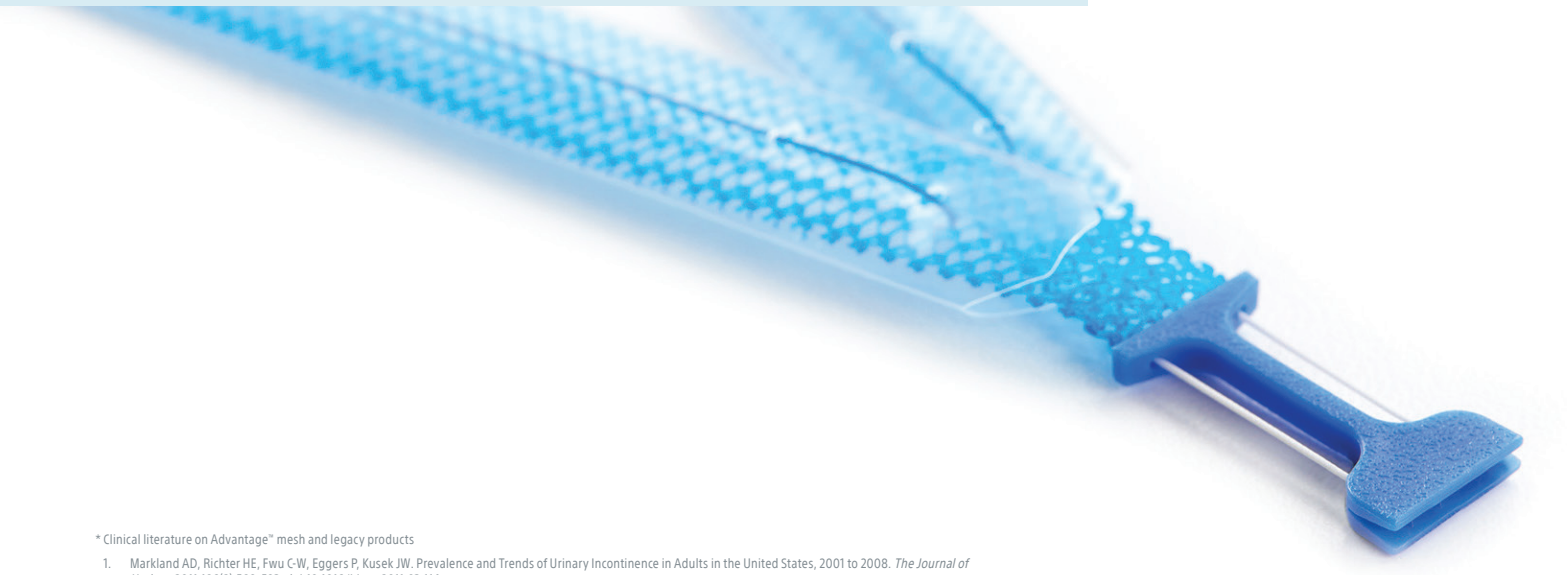

### Increased Reimbursement

- Medicare national average reimbursement in the hospital outpatient department and in the ambulatory surgical center (ASC) for MUS surgery for SUI is steadily increasing year-over-year.[2]
- CPT code 57288 has increased an average of 3.16% over the last 6 years (2016 – 2021) in the hospital outpatient department and has increased an average of 5.76% over the last 6 years (2016-2021) in the ASC.[2]
- The Centers for Medicare and Medicaid Services (CMS) continues to ensure that ASCs remain competitive, to increase choices of site of care and encourage site neutrality.[7] This resulted in a sharp increase in one year, between 2018–2019, of 35%.[2]
- National Medicare Payment for hospital outpatient is $4,410 and National Medicare Payment for the ASC is $2,533.[8]



## Conclusion

Fueled by physician insights and feedback, the Ultra Retropubic Mid-Urethral Sling Product Family enhances sling delivery to drive greater procedural efficiency, mesh visualization and tensioning consistency. Paired with Boston Scientific's clinically supported Advantage™ optical blue mesh, the Ultra Retropubic Mid-Urethral Sling Family is designed for more precise sling placement.



* Clinical literature on Advantage™ mesh and legacy products


1. Markland AD, Richter HE, Fwu C-W, Eggers P, Kusek JW. Prevalence and Trends of Urinary Incontinence in Adults in the United States, 2001 to 2008. *The Journal of Urology.*2011;186(2):589-593. doi:10.1016/j.juro.2011.03.114.
2. Boston Scientific HEMA 2012-2018 All Sites All Payers Datacube
3. Growth in outpatient care: The role of quality and value incentives A report by the Deloitte Center for Health Solutions. (n.d.). https://www2.deloitte.com/content/dam/insights/us/articles/4170_Outpatient-growth-patterns/DI_Patterns-of-outpatient-growth.pdf
4. Slopnick EA, Hijaz AK, Nguyen CT, Abouassaly R, Gonzalez CM, Mahajan ST, Henderson JW, Bream MJ, Kim SP. National Surgical Trends and Perioperative Outcomes of Midurethral Sling Placement for Stress Urinary Incontinence. Urology. 2017 Jan;99:57-61. doi: 10.1016/j.urology.2016.07.027. Epub 2016 Sep 23. PMID: 27669653. National Surgical Trends and Perioperative Outcomes of Midurethral Sling Placement for Stress Urinary Incontinence - Urology (goldjournal.net)
5. Minassian, V. A., Stewart, W. F., & Wood, G. C. (2008). Urinary Incontinence in Women. Obstetrics & Gynecology, 111(2, Part 1), 324–331. doi: 10.1097/01.aog.0000267220.48987
6. White, C, et al. High and Varying Prices for Privately Insured Patients Underscore Hospital Market Power. Center for Studying Health System Change. Research Brief no. 27. September 2013
7. https://www.cms.gov/newsroom/fact-sheets/cms-finalizes-medicare-hospital-outpatient-prospective-payment-system-and-ambulatory-surgical-center
8. https://www.bostonscientific.com/content/dam/bostonscientific/Reimbursement/Urology/pdf/Pelvic_Health_Coding_and_Payment_Guide.pdf


**Disclaimers:**
The following adverse events have been reported due to suburethral sling placement, any of which may be ongoing, but are not limited to: As with all implants, local irritation at the wound site and/or a foreign body response may occur, Foreign body reaction may be acute or chronic, Pain (pelvic, vaginal, groin/thigh, suprapubic, dyspareunia) (acute or chronic), Dyspareunia, Tissue responses to the mesh implant could include: erosion into organs (urethra, bladder or other surrounding tissues); exposure/extrusion into the vagina, Mesh contact with urine via erosion/exposure/extrusion may result in stone formation, scarring/scar contracture, Necrosis, fistula formation (acute or chronic), inflammation (acute or chronic), Mesh contracture, Tissue contracture, Vaginal shortening or stenosis that may result in dyspareunia and/or sexual dysfunction, Pain with intercourse that may not resolve, Exposed mesh may cause pain or discomfort to the patient's partner during intercourse, Sexual dysfunction, including the inability to have intercourse. Like all foreign bodies, the mesh may potentiate an existing infection. Allergic reaction has been reported. Known risks of surgical procedures for the treatment of incontinence include: pain, ongoing pain (pelvic, vaginal, groin/thigh, suprapubic, dyspareunia), Severe, chronic pain, Apareunia, Leg weakness, Infection, De novo detrusor instability, Complete failure of the procedure/failure to resolve a patient's stress urinary incontinence, Voiding dysfunction (incontinence, temporary or permanent lower urinary tract obstruction, difficulty urinating, pain with urination, overactive bladder, and retention), Bruising, bleeding (vaginal, hematoma formation), Abscess, Vaginal discharge, Dehiscence of vaginal incision, Edema and erythema at the wound site, Perforation or laceration of vessels, nerves, bladder, urethra or bowel may occur during placement. The following additional adverse events have been reported for the Solyx SIS System: Dysuria, Hematuria. The occurrence of these events may require surgical intervention and possible removal of the entire mesh. In some instances, these events may persist as a permanent condition after surgical intervention or other treatment. Removal of mesh or correction of mesh-related complications may involve multiple surgeries. Complete removal of mesh may not be possible and additional surgeries may not always fully correct the complications.

This information is intended solely to alert customers to potential economic opportunities. It is not meant to influence decisions regarding clinical care; decisions regarding the medical care of patients should only be made by licensed healthcare professionals and in the best interest of each individual patient. Nor is this information meant to be representative of the performance of any individual healthcare facility; individual results will vary.

Payer policies will vary and should be verified prior to treatment for limitations on diagnosis, coding, or site of service requirements. The coding options listed within this guide are commonly used codes and are not intended to be an all-inclusive list. We recommend consulting your relevant manuals for appropriate coding options.

Health economic and reimbursement information provided by Boston Scientific Corporation is gathered from third-party sources and is subject to change without notice as a result of complex and frequently changing laws, regulations, rules, and policies. This information is presented for illustrative purposes only and does not constitute reimbursement or legal advice. Boston Scientific encourages providers to submit accurate and appropriate claims for services. It is always the provider's responsibility to determine medical necessity, the proper site for delivery of any services, and to submit appropriate codes, charges, and modifiers for services rendered. It is also always the provider's responsibility to understand and comply with Medicare national coverage determinations (NCD), Medicare local coverage determinations (LCD), and any other coverage requirements established by relevant payers which can be updated frequently. Boston Scientific recommends that you consult with your payers, reimbursement specialists, and/or legal counsel regarding coding, coverage, and reimbursement matters. Boston Scientific does not promote the use of its products outside their FDA-approved label. Information included herein is current as of November 2020 but is subject to change without notice. Rates for services are effective January 1, 2021.

**CPT® Disclaimer**


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



Boston Scientific
Advancing science for life™


Boston Scientific Corporation
300 Boston Scientific Way
Marlborough, MA 01752
www.bostonscientific.com





WH-1093204-AA AUG 2021