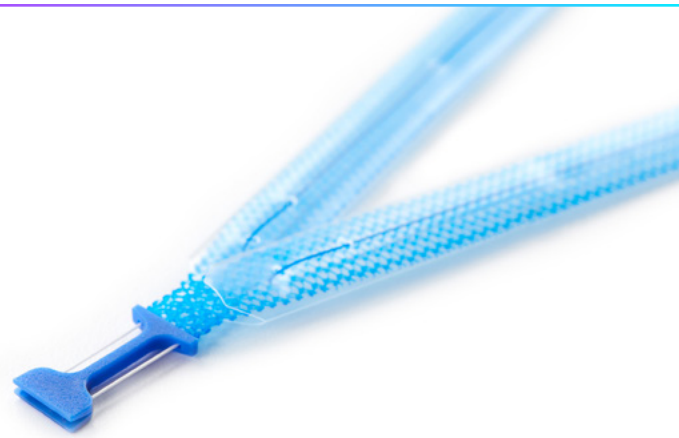
Boston Scientific
Advancing science for life™

Ultra™

Retropubic Mid-Urethral Sling Family



Introduction

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

Background

Stress urinary incontinence is 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 may have a negative impact on quality of life, but it can be treated long-term with an outpatient sling procedure.

Since 1995, Boston Scientific has made significant investments in pelvic floor research and innovation, which have resulted in impactful solutions for women and the physicians who treat them.

Clinical research: Millions in post-market studies and decades of research on Boston Scientific's female slings and pelvic floor reconstruction technologies, including numerous ongoing investigator-sponsored research studies

Physician and patient education: In-person and on-demand virtual training to support physicians at all stages of their career and robust education to help patients understand their condition and take action

Research and development: Turning customer and patient needs into meaningful innovation for 25+ years

Society support: Collaboration to further clinical evidence and training

Health economics and market access: Dedicated team that provides market insights on procedural trends and reimbursement support

Consistent. Innovative. Precise.

Physician-driven, patient-centered innovation

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 across the Ultra Sling Family.

Advantage mesh is documented in **more than 100 publications to date.**[2]

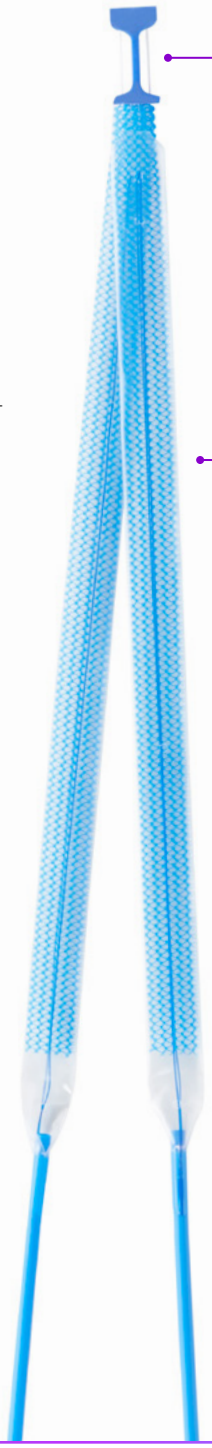
Advantage mesh has been used in **more than 1 million slings.**[2]

Centering tab and sleeve removal technique are **consistent throughout the Ultra Sling Family**, which may make **training residents and fellows more efficient.**

Achieving consistency across the Boston Scientific mid-urethral sling family, Ultra innovation is used in:

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

Includes the same, unchanged trocar delivery devices



Sleek, suture-released centering tab

Provides physicians with:

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

Clinically supported Advantage™ optical blue mesh

Offers the same material and features as the patented Advantage clear mesh in an optical blue color, enhancing intra-operative visibility of mesh against the urethra.

Lay-flat, two-sleeve design

Designed to deliver a slim, smooth surface during tissue interaction.

Potential clinical and economic benefits to institutions

Equivalent pricing

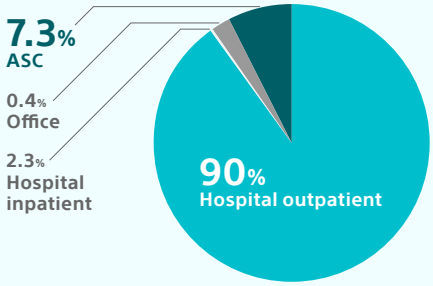
Enhanced delivery system at no additional cost as compared to Boston Scientific's legacy retropubic mid-urethral slings (MUS).

Impact to institutions

Growing reimbursement, as well as favorable payer mix and site of service are potential benefits of MUS procedures.

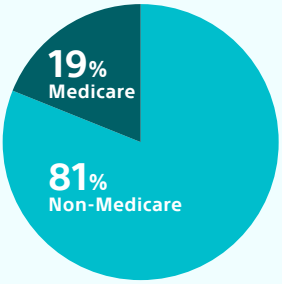
Site of service

90% of all mid-urethral sling procedures in 2021 were performed in the hospital outpatient site of service[3] which is a potentially less costly site of service compared to hospital inpatient procedures.[4]



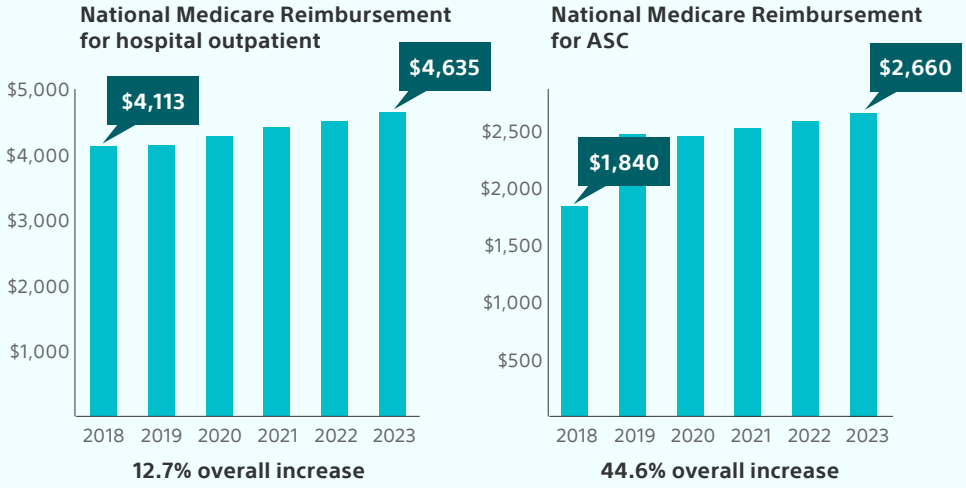
Favorable payer mix

- In the US in 2021, 81% of patients undergoing mid-urethral sling procedures were non-Medicare patients.[3] Prevalence of stress urinary incontinence peaks around age 40-59,[5] and the majority of this age group is insured under private insurance.[6]
- On average, private payers reimburse at 264% of Medicare rates for outpatient services according to an analysis performed by Kaiser Family Foundation.[7]



Increased reimbursement

Medicare national average reimbursement for mid-urethral sling surgery, to treat SUI, has seen an overall increase from 2018 to 2023 in both the hospital outpatient department[8] and in the ambulatory surgical center (ASC)[9].



Conclusion

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

References:

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. *J Urol*. 2011;186:589–593.
2. Data on file with Boston Scientific.
3. Boston Scientific HEMA 2021 All Sites All Payers Datacube.
4. Growth in outpatient care: The role of quality and value incentives. A report by the Deloitte Center for Health Solutions. (n.d.). Available at: https://www2.deloitte.com/content/dam/insights/us/articles/4170_Outpatient-growth-patterns/DI_Patterns-of-outpatient-growth.pdf. Accessed September 28, 2022.
5. Minassian VA, Stewart WF, Wood GC. Urinary incontinence in women. *Obstet Gynecol*. 2008;111(2 Pt 1):324–331.
6. Health Insurance Coverage: Early Release of Estimates From the National Health Interview Survey, 2021. Available at: https://www.cdc.gov/nchs/data/nhis/earlyrelease/insur202205.pdf. Accessed May 16, 2023.
7. How Much More Than Medicare Do Private Insurers Pay? A Review of the Literature. Kaiser Family Foundation. Available at: https://www.kff.org/medicare/issue-brief/how-much-more-than-medicare-do-private-insurers-pay-a-review-of-the-literature. Accessed May 16, 2023.
8. Centers for Medicare Medicaid Services. Hospital Outpatient PPS. Accessed July 2023. https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps
9. Centers for Medicare Medicaid Services. Ambulatory Surgical Center (ASC) Payment. Accessed July 2023. https://www.cms.gov/medicare/medicare-fee-for-service-payment/ascpayment.

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 January 2023 but is subject to change without notice. Rates for services are effective January 1, 2023.

CAUTION: 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.

CAUTION: For Female Mid-Urethral Slings: Federal (US) law restricts this device to sale by or on the order of a physician trained in use of surgical mesh for repair of stress urinary incontinence.

Please refer to the instructions for use for this product for complete Indications for Use, Contraindications, Warnings, Precautions, Adverse Events, and Instructions prior to using this product.

Boston Scientific
Advancing science for life™

Boston Scientific Corporation
300 Boston Scientific Way
Marlborough, MA 01752-1234
www.BostonScientific.com

WH-1093204-AB AUG 2023