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Health Products  
and Food Branch

Direction générale des produits  
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OTTAWA, Ontario  
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November 11, 2022

22-109746-906

To whom it may concern,

**Re: Health Canada will publish a summary safety review regarding standard synthetic mid-urethral slings**

As an ongoing commitment to openness and transparency, Health Canada would like to notify you that a summary safety review (SSR) regarding standard synthetic mid-urethral slings and their long-term safety and effectiveness will be published (see attached document). The SSR is intended to provide Canadians with a sufficient understanding of the safety review conducted by Health Canada, specifically what was assessed, what was found and what action was taken. The SSR will be posted in subsequent days.<sup>1</sup>

**This advance notification is being sent for your information only.** A broader dissemination to your members would be greatly appreciated.

Any question related to the SSR process or requests for further information on the safety review should be directed to the Marketed Health Products Directorate; e-mail: [hc.mhpdssrcoordinator-dpscreicoordinateur.sc@hc-sc.gc.ca](mailto:hc.mhpdssrcoordinator-dpscreicoordinateur.sc@hc-sc.gc.ca)

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<sup>1</sup> <http://www.hc-sc.gc.ca/dhp-mps/medeff/reviews-examens/index-eng.php>

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Please feel free to contact us, should you require further information.

Sincerely,

E-signed by

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**Attachment:**

Summary Safety Review - Standard Synthetic Mid-urethral Sling - Assessing Long-term Safety and Effectiveness

# Summary Safety Review - Standard Synthetic Mid-urethral Sling - Assessing Long-term Safety and Effectiveness

**Product:** Standard synthetic mid-urethral sling (SMUS) made from non-absorbable synthetic material (synthetic vaginal surgical mesh device)

**Potential Safety Issue:** Safety and effectiveness at or beyond 5 years (long-term), including the risk of complications associated with the use of SMUS (infection, pain, bleeding, urinary dysfunction, erosion/migration of mesh, sexual dysfunction, nerve and/or muscle damage, damage to pelvic structures and surrounding tissues or organs, and a need for surgical correction)

## Key Messages

- **Standard synthetic mid-urethral slings are medical devices authorized for sale in Canada to treat stress urinary incontinence (SUI), which is the accidental leaking of urine on effort or exertion, or on sneezing or coughing, in women.**
- **Health Canada reviewed the long-term (at or beyond 5 years) safety and effectiveness of SMUS used for the treatment of SUI.**
- **This review is a follow-up to previously completed post-market safety reviews assessing various complications related to the use of SMUS and similar devices.**
- **Health Canada's review of the available information concluded that there is no new (not previously known) or increased risk of complications associated with the long-term (at or beyond 5 years) use of SMUS, and the risk of developing chronic pain and/or mesh erosion is lower over the longer term (after 5 or more years).**
- **Health Canada will continue to monitor safety information involving synthetic vaginal surgical mesh devices to identify and assess potential new harms.**

## Overview

Health Canada has been evaluating the post-market safety and effectiveness of vaginal surgical mesh devices since 2009 in response to regulatory activities initiated by the [U.S. Food and Drug Administration](#) (FDA) at that time. In 2009, Health Canada completed a safety review evaluating the complications of vaginal surgical mesh devices for the repair of SUI and pelvic organ prolapse (POP). As a result of the review, Health Canada issued a Notice to Hospitals<sup>1</sup> that discussed the complications associated with these devices for the treatment of SUI and POP.

Since 2012, Health Canada has completed post-market safety reviews<sup>2, 3</sup> related to the use of vaginal surgical mesh devices, including, in 2014, a comprehensive assessment of the devices included in the current review. The risk mitigation activities resulting from these assessments include:

- issuing a Notice to Hospitals<sup>4</sup>,
- working with manufacturers to enhance labelling for licensed devices,
- publishing Information Updates<sup>5, 6</sup> and information for Canadians<sup>7</sup>,
- working with manufacturers to remove certain devices from the market, and
- working with healthcare professional associations, Health Canada's Scientific Advisory Committee for Health Products for Women and patients with lived and living experience to better understand clinical complexities associated with SMUS procedures and patients' experiences with these devices.

In 2022 and as a follow-up to previously completed reviews assessing various complications related to the use of SMUS and similar devices, Health Canada completed an assessment of the long-term (at or beyond 5 years) safety and effectiveness of SMUS for SUI in women. This assessment evaluated the risk of complications (infection, pain, bleeding, urinary dysfunction, erosion/migration of mesh, sexual dysfunction, nerve and/or muscle damage, damage to pelvic structures and surrounding tissues or organs, and a need for surgical correction).

## Use in Canada

- In Canada, SMUS are 1 option used to treat SUI in women and are Class III medical devices.
- Standard synthetic mid-urethral slings are made primarily from non-absorbable synthetic materials (e.g., polypropylene) and are intended to be permanently implanted.
- At the time of this safety review, there were 7 active medical device licences in Canada for SMUS for the treatment of SUI:
  - Ethicon SARRL:
    - Tension Free Vaginal Tape (TVT) System (MDL 00059)
  - Boston Scientific Corporation:
    - Advantage System (MDL 63923)
    - Obtryx transobturator mid-urethral sling (MDL 67255)
    - Lynx system-suprapubic mid-urethral sling (MDL 67256)
    - Obtryx II transobturator sling system (MDL 91914)
  - Coloplast A/S:
    - Urethral slings (MDL 80074)
  - A.M.I. Agency for Medical Innovation GMBH:
    - A.M.I. Incontinence sling (MDL 84869)
- Several SMUS devices have been voluntarily withdrawn from the Canadian market, for various reasons. Although the devices no longer have an active license in Canada, they may remain implanted in some women.
- While sales of SMUS have declined in recent years, approximately 20,000 to 25,000 of these devices are sold per year in Canada.

## Safety Review Findings

- Health Canada reviewed information provided by the manufacturers, as well as information from Canadian<sup>8</sup> and American<sup>9</sup> incident reporting databases, Canadian health professional associations, international regulatory agencies, as well as medical and scientific literature.
- Since Health Canada's comprehensive assessment in 2014, Health Canada has not received reports that describe new (not previously known) risks of complications associated with the use of SMUS for treatment of SUI. Some incidents reported to the Department since 2014 continue to describe serious and permanent issues known to be associated with synthetic vaginal surgical mesh devices, including infection, pain, bleeding, urinary dysfunction, mesh erosion/migration, sexual dysfunction, nerve and/or muscle damage leading to mobility issues, damage to pelvic structures and surrounding tissues, and the need for surgical correction.
- Rates of adverse events and causal links between SMUS and various atypical complications reported to Health Canada could not be confirmed due to a lack of necessary details documented in incident reports, such as potential medical co-morbidities (the existence of more than 1 disease or medical condition at the same time) and/or a lack of medical assessments.
- Health Canada's literature review, which relied on systematic reviews, randomized controlled-trials and meta-analyses that included long-term clinical data on the safety and effectiveness of SMUS, supports that:
  - the long-term (at or beyond 5 years) safety and effectiveness of SMUS, when used for the treatment of SUI, is equivalent to surgical alternatives that do not use vaginal surgical mesh,
  - there are no newly identified risks of complications associated with the long-term (at or beyond 5 years) use of SMUS,
  - effectiveness and patient satisfaction over the long-term (at or beyond 5 years) are relatively high in most patients,
  - the risk of developing chronic pain and/or mesh erosion is lower over the longer term (after 5 or more years), and
  - there is currently no clear causal association in the literature between SMUS and the development of systemic issues such as allergy, immune system dysfunction, rheumatic pain, fibromyalgia and/or fatigue.
- Health Canada assessed the publically available position papers<sup>10, 11, 12</sup> developed by national health care professional associations about the use of SMUS for SUI. Generally, these associations support the use of SMUS for SUI when certain criteria have been met, including clear informed consent and consideration for conservative treatment options, such as perineal rehabilitation (pelvic floor physiotherapy) and incontinence pessary.
- Following a review of the regulatory actions taken in other countries, such as the United States, Australia, Singapore, Switzerland and the United Kingdom, Health Canada determined that the actions taken by the Department are consistent with what is taking place in those countries. Standard synthetic mid-urethral slings indicated for the treatment of SUI continue to be available in Canada and internationally.

## Conclusions and Actions

- Health Canada's review of the available information did not identify new (not previously known) or increased risks of complications associated with the long-term (at or beyond 5 years) use of SMUS compared to Health Canada's previous reviews.
- Health Canada's review also identified that the risk of developing chronic pain and/or mesh erosion is lower over the longer term (after 5 or more years).
- Health Canada will continue to monitor safety information involving vaginal surgical mesh devices, as it does for all health products on the Canadian market, to identify and assess potential harms. Health Canada will take appropriate and timely action should new health risks be identified.
- Health Canada will enhance its existing communications products with more patient-focused information and continue to work with stakeholders to support women in their decision-making.
- For timely and relevant up-to-date information on vaginal surgical mesh devices, Canadians can [subscribe](#) to receive Health Canada updates on these products, including:
  - general information;
  - safety or recall information;
  - risk communications; and
  - updates to the website<sup>7</sup>.

## Additional Information

The analysis that contributed to this safety review included scientific and medical literature, Canadian and international clinical guidelines, incident and regulatory information, as well as consultations with Canadian medical societies and women with lived and living experiences.

For additional information, contact the [Medical Devices Directorate](#).

## References

1. Health Professional Risk Communication - [Surgical Mesh - Complications Associated with Transvaginal Implantation of Surgical Mesh for the Treatment of Stress Urinary Incontinence and Pelvic Organ Prolapse](#). Health Canada. Issued: 2010-02-05
2. Summary Safety Review - [Surgical mesh products made from non-absorbable synthetic \(polypropylene\) material that are used for the transvaginal repair of pelvic organ prolapse \(POP\)](#). Health Canada. Issued: 2019-07-26
3. Summary Safety Review - [Single incision mini-sling \(SIMS\) made from non-absorbable synthetic material \(polypropylene\)](#). Health Canada. Issued: 2020-09-18
4. Health Professional Risk Communication - [Surgical Mesh - Complications Associated with Transvaginal Implantation for the Treatment of Stress Urinary Incontinence and Pelvic Organ Prolapse - Notice to Hospitals](#). Health Canada. Issued: 2014-05-13
5. Information Update - [Information Regarding the Transvaginal Implantation of Surgical Mesh Devices for the Treatment of Pelvic Organ Prolapse and Stress Urinary Incontinence](#). Health Canada. Issued: 2014-05-13
6. Information Update - [Status of non-absorbable synthetic surgical mesh for the transvaginal repair of pelvic organ prolapse in Canada](#). Health Canada. Issued: 2019-07-26
7. [Vaginal surgical mesh](#). Health Canada
8. [Medical Devices incident reporting database](#). Health Canada
9. [MAUDE - Manufacturer and User Facility Device Experience](#). U.S. Food and Drug Administration
10. [SOGC statement in response to College des Médecins in Quebec's report on urethral slings](#). The Society of Obstetricians and Gynaecologists of Canada (SOGC)
11. Welk, B., Carlson, K. V., Baverstock, R. J., Steele, S. S., Bailly, G. G., & Hickling, D. R. (2017). [Canadian Urological Association position statement on the use of transvaginal mesh](#). *Canadian Urological Association Journal*, 11(6S2), S105-7.
12. Walter, J.E., Brennand, E.A., Lemos, N., Cundiff, G.W. (2021). [Letter: Canadian Society of Pelvic Medicine Response to the Collège des Médecins du Québec Rapport d'Enquête](#). *Journal of Obstetrics and Gynaecology Canada*, 43 (3), 298-299.