Urgent Recall for Product Correction

Advantage™ and Advantage Fit™ System, Transvaginal Sling,
Lynx™ System, Suprapubic Sling,
Obtryx™ System, Transobturator Sling (Curved or Halo),
Obtryx II™ System with PrecisionBlue™ Design, Transobturator Sling (Curved or Halo),
Solyx™ SIS System, Single Incision Sling

ARTG # 104326

24th February 2016

Dear Doctor:

The TGA carried out a clinical review of urogynaecological surgical mesh implants which have highlighted the importance of:
- Appropriate patient selection;
- Surgeon experience; and
- The need for fully informed patient consent.

Boston Scientific (BSC) has made important updates to the Directions for Use (DFU) for the below referenced products. These updates are based on BSC's review, as well as input from TGA based on their clinical review. Warnings, precautions and adverse events have been added to present the most comprehensive and up to date information available.

Boston Scientific (BSC) is providing this information update for product Directions For Use of the following Mid-Urethral Sling products:

- Advantage™ and Advantage Fit™ System, Transvaginal Sling
- Lynx™ System, Suprapubic Sling
- Obtryx™ System, (Curved or Halo), Transobturator Sling
- Obtryx™ II System with PrecisionBlue™ Design (Curved or Halo),Transobturator Sling
- Solyx ™ SIS System, Single Incision Sling

BSC has made revisions to the Directions for Use (DFU) for these products

NO product is being recalled and you are NOT required to return product to Boston Scientific.

Note that there is no impact to previously implanted devices.

Action Required

It is very important that you read this entire product correction notice and ensure that all users of the product correction notice (please refer to the affected list of products attached). **You must also complete the enclosed Customer Acknowledgment Form and return it to Boston Scientific, indicating that you have received, read, and understood the important information contained in this notice.**

Updated Directions for Use

The Direction For Use for all Boston Scientifics Mid-Urethral Sling System product lines were reviewed and updated and/or revised to ensure consistency alignment of language across all Mid-Ureteral Sling lines. The updated sections of the DFU are bulleted below and summarized in blue text. Strikethrough text will be text that has been removed.

- Update Rx (USA) Caution statement.
- Update Indication for Use statement, include the word ("Urethral" per K081275) (Clarification)
- Update General Warnings,
- Updated Precautions,
- Updated AE list (new terminology. Adverse Events that were stated in other SLING DFU's were aligned across the slings lines for consistency).
- Update to add (1) Adverse Event " scarring/scar contracture"
- DFU instruction content alignment, where applicable

CAUTION STATEMENT

The Rx Caution Statement has been updated to include language which is specific for physicians trained in the use of surgical mesh for repair of stress urinary incontinence**.**

CAUTION: Federal 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.

INDICATIONS FOR USE STATEMENT

The word "urethral" has been added to the indications for use statement for language consistency across all mid-urethral sling lines.

The mesh implant is intended for use as a suburethral sling for the treatment of stress urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

STEPS TO USE

The statement below has been revised for further clarification.

Make a 1.0 cm to 1.5 cm vertical midline incision on the anterior vaginal wall at the level of the mid-urethra. Dissect bilaterally to the interior portion of the inferior pubic ramus at the 45 angle of the midline crating a pathway for delivery device placement.

GENERAL WARNING SECTION

The statements below have been revised for further clarification.

REVISED

~~Patients with blood coagulation disorder.~~ Careful consideration should be given to performing this procedure for patients with untreated coagulopathies or who are being treated with either anticoagulants or antiplatelet agents.

- Patients with ~~renal insufficiency or upper urinary tract obstruction~~ with hypertonic bladders or vesico ureteral reflux.

REMOVED

- The statements below have been removed from the General Warning Section as these warnings can be supported by the Contraindications Section of the Directions for Use.
- Women planning future pregnancies.
- Overweight women (weight parameters to be determined by the physician).
- Patients with blood coagulation disorder.
- Patients with compromised immune system or any other conditions that would compromise healing.

RELOCATED WARNING to the beginning of DFU

The statement below has been removed from the General Warning Section and relocated to a WARNING at the beginning of the DFU

- This product is intended for use only by clinicians with adequate training and experience in treatment of female stress urinary incontinence (SUI). The physician is advised to consult the medical literature regarding techniques, complications and hazards associated with the intended procedures.

POST PROCEDURAL WARNING

The statement below has been, removed from the Post Procedural Section, revised and relocated to the Precautions Section of the DFU

- Retropubic bleeding can occur. Check carefully before releasing patient from the hospital.

PRECAUTIONS SECTION

Four new Precaution statements have been added. Other statements have been revised for clarification. One statement has been relocated from the Post Procedural Warning Section to the Precautions Section. One statement has been removed from the Precautions section and relocated to the Adverse Event Section.

NEW

- The use of polypropylene mesh in urogynecologic procedures such as the treatment of stress urinary incontinence, regardless of the route of delivery (transvaginal,suprapubic or transobturator), has been associated with cases of erosion. Erosion has been reported in bladder, vagina, urethra, ureter, and bowel. Treatment of the erosion may require surgical removal.

- As with all surgical procedures, certain risk factors are known to impact patient outcomes in the pelvic floor which include, but are not limited to, impaired vascularity (e.g. diabetes, smoking status, estrogen status, pelvic floor radiation exposure, etc.), age, pelvic floor myalgia, impaired wound healing (e.g. diabetes, steroid usage, etc.), or active infection in or near the surgical site. The above pathophysiologic conditions must be considered when determining whether the patient is an appropriate candidate for mesh implantation, either by Transvaginal, suprapubic or transobturator route.

- Mesh is considered a permanent implant. Removal of mesh or correction of mesh related complication may involve multiple surgeries.

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

REVISED

- Physician should determine when it is suitable for each patient to return to normal activities.
- Patients should be counseled when to resume vigorous activities ~~to refrain from~~ (heavy lifting, exercise), and intercourse after the procedure. ~~for a minimum of four weeks~~.

REVISED and RELOCATED TO PRECAUTIONS FROM POST PROCEDURAL SECTION

- ~~Retropubic~~ Bleeding can occur. Check carefully before releasing patient from the hospital.
- Removal of the word “Retropubic” only applicable to Obtryx, Obtryx II and Solyx System DFU’s.

REVISED and RELOCATED TO ADVERSE EVENT SECTION from Precautions Section

The statement below has been, removed from the Precautions section. The statement was revised and relocated to the Adverse Events section.

- ~~The procedure should be performed with very careful attention to avoid~~ Perforation or laceration of ~~any~~ vessels, nerves, bladder, urethra or ~~and~~ bowel may occur during placement.

ADVERSE EVENTS SECTION

The list of Adverse Events (AE) included in the Boston Scientific Mid-Urethral Sling DFU"s were compared across all product families for consistency. This section of the DFU was revised for clarity and updated terminology used by physicians. Below is the revised listing of AE's that will appear in all Mid-Urethral Sling Directions For Use.

The following adverse events have been reported due to suburethral sling placement, but are not limited to:

As with all implants, local irritation at the wound site and/or a foreign body response may occur.
Tissue responses to the mesh implant could include:

- Erosion/exposure/extrusion of the mesh through the vaginal or urethral mucosa, bladder wall or other surrounding tissue,
- Scarring/scar contracture
- Device migration
- Fistula formation and inflammation.

The occurrence of these events may require surgical intervention and possible removal of the entire mesh.

- Like all foreign bodies, the mesh may potentiate an existing infection.
- Excess tension may cause temporary or permanent lower urinary tract obstruction and retention.
- Allergic reaction has been reported
- Known risks of surgical procedures for the treatment of incontinence include:
  - Ongoing Pain, Pain (pelvic, vaginal, groin/thigh, dyspareunia),
  - Infection,
  - Detrusor instability
  - Complete failure of the procedure
  - Voiding dysfunction (incontinence, mild to moderate incontinence due to incomplete urethral support or due to overactive bladder),
  - 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 occurrence of these events may require surgical intervention. In some instances the response to these events may persist as a permanent condition after the intervention.

Affected Product Information

Our records indicate that your facility has received one or more of the affected products. The table below provides a complete list of all affected products including Product Description and Material Number (UPN). Please note that only the products listed in the table below is affected by this recall for product correction.

No other Boston Scientific product is involved with this Field Correction.

Affected Product Listing

Product Description	**UPN**
Advantage ™ System	M0068502000
Advantage ™ System, 5-Pack	M006850200051
Advantage Fit™ System	M0068502110
Advantage FitTM System, 5-Pack	M0068502111
Lynx™ System	M0068503000
Lynx™ System, 5-Pack	M0068503001
Obtryx™ System, Curved	M0068504000
Obtryx™ System, Curved 5-Pack	M0068504001
Obtryx™ System, Halo	M0068505000
Obtryx™ System, Halo 5-Pack	M0068505001
Obtryx™ II System with PrecisionBlue™ Design, Curved	M0068504110
Obtryx™ II System with PrecisionBlue™ Design, Curved 5-Pack	M0068504111
Obtryx™ II System with PrecisionBlue™ Design, Halo	M0068505110
Obtryx™ II System with PrecisionBlue™ Design, Halo 5-Pack	M0068505111
Solyx™ SIS System	M0068507000
Solyx™ SIS System, 5-Pack	M0068507001

This action is being conducted following consultation with the Therapeutic Goods Administration

Please read carefully through the enclosed instructions. Your local Sales Representative can answer any questions that you may have regarding this action.

We appreciate your understanding as we take action to ensure customer satisfaction. We are committed to continuing to offer products that meet the highest quality standards that you expect from Boston Scientific.

Sincerely,

[Contact]
[Title]
[Phone]
[Email]

Encl: Informational Update Instructions
Customer Acknowledgement Form

Informational Update - Immediate Action Required

The Customer Acknowledgment Form enclosed with this notice must be completed and returned by 24h March, 2016, **even if you no longer have any affected product**.

1. **Complete and return the Customer Acknowledgment Form.**
   - Complete the enclosed Customer Acknowledgment Form (even if you no longer have any of the products), following the directions on this page and on the form.
   - Return the Customer Acknowledgment Form:

     Email: anz_incident_report@bsci.com

     or

     Fax to: **(02) 9330 1406**

Please email or fax your Customer Acknowledgment Form immediately upon completing the steps above.