Boston Scientific International S.A.
ZAC Paris Nord II/Bât Emerson - 33 rue des Vanesses – 93420 Villepinte
Siège social : Parc du Val Saint Quentin – 2 rue René Caudron
78960 Voisins le Bretonneux – France

Tel 33 (0)1 48 17 47 00
Fax 33 (0)1 48 17 47 01
www.bostonscientific.com

«Hospital_Name»
«Users_Name»- «Department»
«Customer_Address»
«Zip_Code» «City» - «Country_name»

Reference: 91130383-FA

6th June 2016

Field Safety Notice - Urgent Medical Device Product Advisory

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

Dear «Users_Name»,

This notification is being sent to inform you of updates that Boston Scientific has made to the Directions for Use (DFU's) for our Stress Urinary Incontinence products listed in this notice.

In order to enhance patient and physician information regarding the use of our devices and to provide you with comprehensive information based on published literature and post-market data, we have made revisions to the Directions for Use (DFU) for the products referenced below. These updates include changes to ensure consistency across all product lines, which may include revisions to current statements and/or relocation of information to another section within the DFU. In addition two Warnings, and two Precautions, have been added.

The following is not a comprehensive list of all changes. It highlights the new Warnings and Precautions that have been added. Please refer to this advisory in addition to the Directions for Use provided with the products to ensure that you have the latest information for the following products:

Mid-Urethral Sling Systems

- 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.

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 off the midline creating a pathway for delivery device placement.

GENERAL WARNING SECTION
Two new warning statements have been added. Other statements have been revised for clarification.

NEW

- 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
~~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.

PRECAUTIONS SECTION
Two 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.

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 mid-urethral slings systems for female stress urinary incontinence. Please note that only the products listed in the table below are the subject of this product advisory.

Affected Product Listing

Product Description	**UPN**
Advantage™ System	M0068502000
Advantage™ System, 5-Pack	M006850200051
Advantage Fit™ System	M0068502110
Advantage Fit™ 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

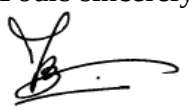
INSTRUCTIONS:

1. **Please complete the attached Acknowledgement Form**
2. **When completed, please return the Acknowledgement Form to your local Boston Scientific office** to the attention of «Customer_Service_Fax_Number» on or before **xx xx 2016.**

Your local Sales Representative can answer any questions that you may have regarding this product advisory.

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.

Yours sincerely,



Marie Pierre Barlangua
Quality Department
Boston Scientific International S.A.

Attachment: Acknowledgement Form

Please complete the form & send it to Your Local Office:
«Customer_Service_Fax_Number»

«Sold_to» - «Hospital_Name» - «City» - «Country_name»

Acknowledgement Form – Important Medical Device Information

Advantage™ and Advantage Fit™ System, Transvaginal Sling
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Solyx™ SIS System, Single Incision Sling

91130383-FA

I acknowledge receipt of the Boston Scientific Field Safety Notice

dated 6th June 2016

and took action as required in the "Instructions" of the letter.

NAME*_____Title _____

Telephone _____ Department _____

Customer' **SIGNATURE***_____**DATE***_____
* Required field DD/MM/YYYY