Boston Scientific Corporation
Building 1, Level 6, Connect Corporate Centre
191 O'Riordan Street
Mascot NSW 2020

www.bostonscientific.com

URGENT - Medical Device Recall

Uphold™ Lite ARTG # 150342; and

Solyx™ SIS ARTG # 104326

TGA Ref: RC-2017-RN-01508-1

December 2017

Dear Chief Executive Officer,

On Tuesday, November 28 2017, the Therapeutic Goods Administration (TGA) notified Boston Scientific of TGA's decision to remove two transvaginally implanted Boston Scientific mesh products from the Australian Register of Therapeutic Goods (ARTG), effective January 4, 2018:

- The Uphold LITE with Capio SLIM, whose sole use is the treatment of pelvic organ prolapse; and

- The Solyx Single Incision Sling System, which is used for the treatment of stress urinary incontinence.

The TGA believes there is currently a lack of adequate scientific evidence for it to be satisfied that the risks to patients are outweighed by the benefits of these devices.

Further information can be found on the TGA website:

https://www.tga.gov.au/alert/tga-actions-after-review-urogynaecological-surgical-mesh-implants

Following this direction from TGA, Boston Scientific is recalling all Uphold LITE with Capio SLIM and Solyx Single Incision Sling System products from the Australian market.

No other Boston Scientific devices are affected by this recall.

The following Catalog (UPN) Numbers are impacted by this recall:

Product Name	Catalog (UPN) Number
Uphold LITE with Capio SLIM	M0068318170
Solyx Single Incision Sling System	M0068507000

Please Note: This does not impact the Boston Scientific Capio SLIM device (UPN: M0068318250 and M0068318261).

We are contacting you as product has been supplied to your organisation.

Further distribution or use of any remaining product affected by this recall should cease immediately.

Please read carefully through the removal instructions included with this notification and direct any questions that you may have regarding this notification to your local Sales Representative. Or, contact Boston Scientific Customer Service on 1800 676 133 for further information.

This action is being taken in consultation with the Therapeutic Goods Administration.

Sincerely,

[redacted]

Paul Braico
Managing Director
Boston Scientific Pty Ltd
Australia & New Zealand

Encl: Recall Instructions; and
Reply Verification Tracking Form

Recall Instructions

The Reply Verification Tracking Form enclosed with this letter must be completed and returned **even if you do not have any recalled product**.

1. **Immediately discontinue use of and segregate recalled product.**
   - Immediately remove all affected recalled product from your inventory.
   - Segregate this product in a secure location prior to return to Boston Scientific.

2. **Complete and return the Reply Verification Tracking Form.**
   - Complete the enclosed Reply Verification Tracking Form (even if you do not have any product to return), following the directions on this page and the Reply Verification Tracking Form.
   - Report all inventory to be returned and report in single-unit quantity(ies), not boxes.
   - Return the Reply Verification Tracking Form as described below:

     Email: ANZ_Incident_Report@bsci.com
     or
     Fax to: (02) 9330 1406

   Please email or fax your Account Reply Verification Tracking Form(s) immediately. You will be contacted by Boston Scientific and provided a Returned Goods Authorization (RGA) Number after your RVTF is received. When returning the product, place the original form with returned products.

   Credits will be issued for all recalled product that is properly returned to Boston Scientific.

3. **Package/Ship the Recalled Product.**
   - Please contact Boston Scientific Customer Service on 1800 676 133 to arrange return of Recalled Product.
   - Seal the box, and return to:

     Boston Scientific Warehouse
     Door 2, 1 Milner Avenue
     Horsley Park NSW 2175.

Boston Scientific

RECALL REMOVAL REPLY VERIFICATION TRACKING FORM

PRODUCT NAME: "TGA Solyx and Uphold Removal (92199841-FA)" Field Action

Instructions: This form must be completed and returned in all cases even if you do not have any affected product.

Immediately complete form and Scan/e-mail to: **OR** **Fax to #:**

Account #:	**Customer Name:**

Contact Name:
Address:
City: **State:** **Province:** **Postal Code:**
Country:

Our records indicate you have received the following affected product:

UPN/Material Number	Lot/Batch/Serial Number	Quantity Shipped	Shipment Date	P.O. Number	Quantity Single Units to be Returned

Section to be filled out by Customer:

1. Please Indicate:

☐ We have checked all areas where affected product could be located and have determined we do not have any affected product.

OR

☐ We have found affected product and have quarantined as instructed in this Recall Notification. Please indicate the quantity to be returned (in single units) in the above table. To return affected product, follow the instructions provided within this notification or from your (country) local office.

Please also indicate:

Are you a Distributor? ☐ Yes, and we have notified all customers that have been shipped/sold affected product
☐ No

2. Sign and Date to acknowledge this Field Action Notification (must be completed):

Print Name:_____ Signature:_____ Date:_____

Phone:_____ Fax:_____ E-mail:_____

BSC OFFICE USE ONLY:

RGA Number: **RGA# Issued By:** **Date:**

Replacement Order # (if applicable):

Date:

Field Action #: