

Capio™ SLIM

Suture Capturing Device

Boston
Scientific

Product Review for the Purchasing Committee



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Dedicated to Women's Health

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Product Overview



Product Overview: Capiro SLIM Suture Capturing Device

The Capiro SLIM Suture Capturing Device features a reduced profile to minimize the space required within the surgical field, easy suture loading and a funnel shaped catch, designed for consistent ease of use.

Ergonomic Handle
Providing
3 Finger Grip

70% Reduction
in Shaft Diameter

Easy Suture
Dart Loading

New “funnel” suture
dart catch design

36% Reduction in Head Width



Capiro SLIM
Suture Capturing Device



Capiro OPEN ACCESS
Suture Capturing Device

Comprehensive Specs



Comparison to Capio™ Open Access Suture Capturing Device

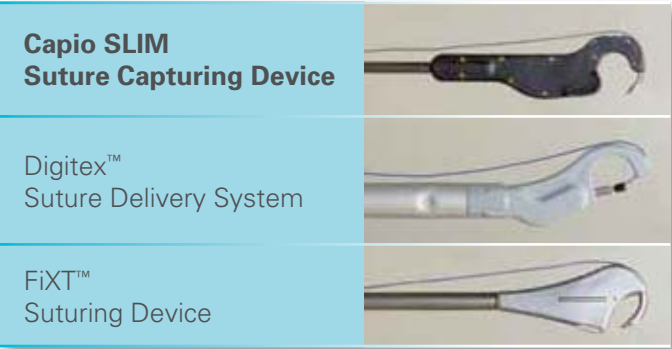
	Shaft Diameter (mm)	Head Width (mm)	Device Weight (g)	Carrier Diameter (mm)
Capio SLIM Suture Capturing Device*	3.0	6.3	38.2	1.2
Capio Suture Capturing Device**	10.1	9.8	45.4	1.2
% Difference	70%	36%	16%	Same

*Measurements were recorded using one (1) of each device. Data on file at Boston Scientific.

**Head width and device weight values are an average of five (5) device measurement recordings. Shaft diameter values are an average of fifteen (15) device measurement recordings. Data on file at Boston Scientific.

Comprehensive Specs (cont.)

Comparison of Device Heads



Building on the history and reducing the profile, the Capio SLIM Suture Capturing Device features one of the smallest device profiles and carrier diameter while keeping the same bite depth as the current Capio Open Access Suturing Device.

Figure 1: Comparison of Device Heads illustrates the difference in carrier diameter amongst these fixation devices. The Capio SLIM Suture Capturing Device carrier diameter is 45% less than the FiXT Suturing Device and 43% less than the Digitex Suture Delivery System.

Fixation Device Comparison

	Shaft Diameter (mm)	Head Width (mm)	Device Weight (g)	Carrier Diameter (mm)
Capio OPEN ACCESS Suture Capturing Device**	10.1	9.8	45.4	1.2
Capio SLIM Suture Capturing Device*	3.0	6.3	38.2	1.2
Digitex Suture Delivery System*	9.5	9.6	133.3	2.1
FiXT Suturing Device*	4.8	6.9	121.1	2.2

Figure 2: Fixation Device Comparison illustrates the device profile differences amongst these fixation devices. The Capio SLIM Suture Capturing Device has the smallest device profile based on the following measurements: shaft diameter, head width and device weight.

*Measurements were recorded using one (1) of each device.
**Head width and device weight values are an average of five (5) device measurement recordings. Shaft diameter values are an average of fifteen (15) device measurement recordings.
Data on file at Boston Scientific.

Exempt Letter



Urology
Gynecology
100 Boston Scientific Way
Marlborough, MA 01752-1234
www.bostonscientific.com

January 11, 2013

Dear Valued Customer,

Thank you for your inquiry regarding the Capiro™ SLIM Suture Capturing Device. *This information is provided in response to your direct request for regulatory information and may not be used for any other purpose without the expressed written permission of Boston Scientific Corporation.*

The Capiro™ SLIM Suture Capturing Device, Open Access, order number M0068318250 as packaged contains 1 device within an outer box. In addition a multi pack version containing 5 devices within an outer box, order number M0068318261, will be available soon. These devices comply with U.S. FDA Regulation 21 CFR 876.4730, Manual gastroenterology-urology surgical instrument and accessories, and are 510(k) exempt devices. FDA does not require a 510(k) premarket notification for this device type.

The following Capiro™ Sutures are manufactured by Teleflex Medical, Inc and are distributed by Boston Scientific for use with the Capiro SLIM Suture Capturing Devices noted above:

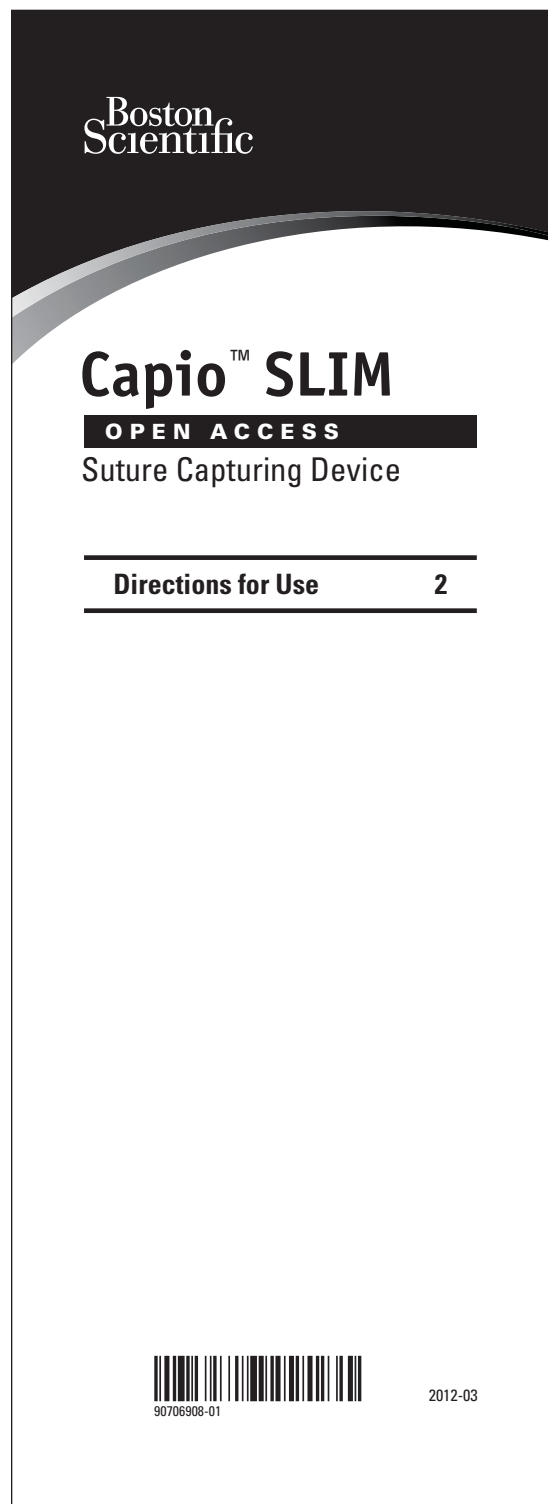
- M0068331131 – Non-absorbable braided polyester suture with 2 tapercut needles
- M0068331141 - Non-absorbable braided polyester suture with 1 tapercut needle & 1 T26mm ½ circle needle
- M0068331231 - Non-absorbable polypropylene monofilament suture with 2 tapercut needles
- M0068331241 - Non-absorbable polypropylene monofilament suture with 1 tapercut needle & 1 T26mm ½ circle needle
- M0068332131 – Absorbable, coated, braided PGA suture with 2 tapercut needles
- M0068331371 - Monodek absorbable, monofilament PDO suture with 1 tapercut needle & 1 T26mm ½ circle needle

Please contact your local sales representative or Boston Scientific directly should you have any additional questions or require additional information.

Sincerely,

Regulatory Affairs

DFU: Capio SLIM Suture Capturing Device



Catio™ SLIM

OPEN ACCESS

Suture Capturing Device

Rx ONLY

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

WARNING

Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, call your Boston Scientific representative.

For single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

DEVICE DESCRIPTION

The Catio SLIM Suture Capturing Device was designed to be used by the physician to facilitate the consistent placement of sutures in difficult to access locations during open surgical procedures. The Catio SLIM Device was designed to throw, catch and retrieve sutures in one step. The device consists of a one-hand-activated plunger at the proximal end, a tubular shaft and a curved needle driver at the distal end. Depressing the plunger actuates the carrier and drives the suture/dart through the tissue. The needle is automatically caught by the device's needle catch mechanism for easy suture tying, or the device may be re-loaded for additional suture throws.

Sutures sold separately.

Contents

(1) Catio SLIM Suture Capturing Device

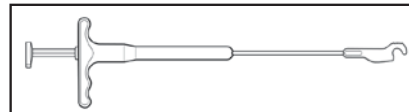


Figure 1 Catio SLIM Suture Capturing Device

INTENDED USE/INDICATIONS FOR USE

The Catio SLIM Suture Capturing Device is intended for use in general suturing applications during open surgery to assist in the placement of suture material in tissues at the operative site. The Catio SLIM Suture Capturing Device is to be used with sensory and/or direct visual control.

WARNINGS

- Punctures or lacerations of vessels, nerves, bladder, urethra or bowel may occur during placement and may require surgical repair.
- Once the suturing action has begun, do not turn, rotate or torque the Catio SLIM Device. To do so, may result in injury.

CONTRAINDICATIONS

The use of the Capiro™ SLIM Suture Capturing Device is contraindicated as follows:

- For placing sutures into or through bone.

ADVERSE EVENTS

Potential complications associated with the use of the Capiro SLIM Device include, but are not limited to:

- bleeding
- dyspareunia
- infection
- inflammatory reaction
- injury to internal organs/tissue including perforation and occlusion
- injury to vessels and nerves
- pain

PRECAUTIONS

- Use only size 0 Capiro Sutures with the Capiro SLIM Suture Capturing Device.
- The physician is advised to consult the medical literature regarding techniques, complications and hazards associated with the intended procedures.
- The Capiro SLIM Suture Capturing Device is not intended to be used to manipulate tissue, organ or bone.
- Do not bend or alter the device as this may result in mechanical damage to the device.

DIRECTIONS FOR USE**Directions for Open Surgical Procedure**

Refer to Technique Tips section for added assistance.

1. Place the suture dart into the carrier at the distal end of the Capiro SLIM Suture Capturing Device. Engage the suture dart into the carrier by gently pulling down on the suture, ensuring that the dart is pulled completely into the carrier. (Refer to Figure 2.)

Note: When loading a dart into the device, verify that the dart is properly positioned in the carrier. The tip of the dart should not protrude from the Capiro Device tip.

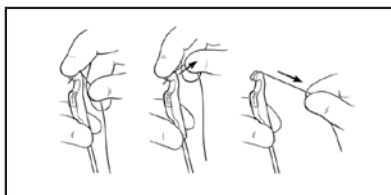
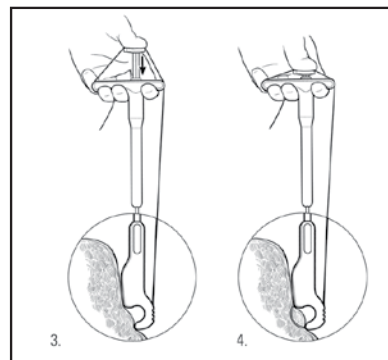


Figure 2.

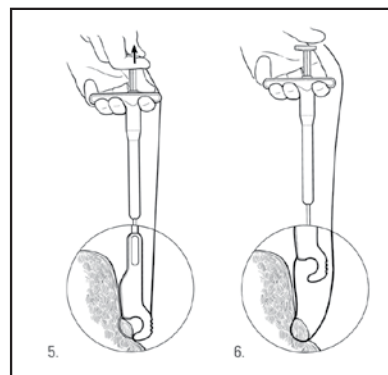
2. Position the device with the distal tip in the desired location against the tissue to be sutured as shown in Figure 3 and hold firmly in place.
3. Fully depress the plunger in one continuous motion, as shown in Figures 3 and 4, to pass the suture through the tissue.

Note: Once the suturing action has been initiated, completely depress the plunger. Do not stop in mid-stitch and allow the dart to reverse direction. It is important to maintain pressure against the tissue with the device to ensure that the dart penetrates the tissue and latches into the catch.



Figures 3 and 4.

4. Unplunge. Release plunger and verify it is back in its original position. This allows the carrier to retract into the housing, leaving the dart in the catch and the suture through the tissue as shown in Figure 5 and 6.



Figures 5 and 6.

5. Remove the Capiro™ SLIM Suture Capturing Device (Figure 6) from the incision.
6. Remove the dart from the catch by holding onto the suture and sliding the dart up toward the handle to the key hole slot. If additional suturing is required, the surgeon may repeat Steps 1 through 6.
7. Complete surgical procedure as desired. Ensure darts are properly discarded.

TECHNIQUE TIPS

Read and understand the following technique tips for the Capiro SLIM Suture Capturing Device.

- During use, secure suture with thumb to maintain adequate dart tension in carrier. To facilitate suture capture during use, hold the proximal end of the device in one hand with thumb securing suture in the slot on the driver button and suture grasped under the thumb. (Refer to Figure 7.) Position the distal head of the device against the tissue to be sutured as described in detail in the prior section.

DFU: Capio SLIM Suture Capturing Device (cont.)

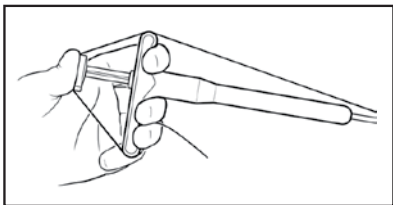


Figure 7.

- Between each throw, rinse/soak the head of device in sterile saline while plunging and unplunging the driver button to help clear the distal tip of tissue and blood.

Steps to Remove a Device Fragment

- In the event the device breaks and a fragment is in the patient, assess to determine if it can be located and removed without damage to the surrounding anatomy. Use caution not to disturb the operative site until it is located to avoid pushing it further from view.
- If the fragment is in direct view it should be grasped with a fine needle driver or forceps and returned to the manufacturer along with the device for investigation.
- If the fragment is not in direct view, use of x-ray studies may help to localize its location. Radiologic assistance should be utilized to guide dissection and retrieve the fragment, minimizing injury to surrounding tissue.

HOW SUPPLIED

Handling and Storage

Store in a cool, dry, dark place. Do not use if package is opened or damaged. Use the device prior to the "Use by" date noted on the product label. Do not use if labeling is incomplete or illegible.

WARRANTY

Boston Scientific Corporation (BSC) warrants that reasonable care has been used in the design and manufacture of this instrument. **This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose.** Handling, storage, cleaning and sterilization of this instrument as well as other factors relating to the patient, diagnosis, treatment, surgical procedures and other matters beyond BSC's control directly affect the instrument and the results obtained from its use. BSC's obligation under this warranty is limited to the repair or replacement of this instrument and BSC shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this instrument. BSC neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument. **BSC assumes no liability with respect to instruments reused, reprocessed or resterilized and makes no warranties, express or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such instruments.**



Catalog Number
Número de catálogo
Numéro de catalogue
Bestell-Nr.
Numero di catalogo
Catalogusnummer
Referência



Consult instructions for use.
Consultar las instrucciones de uso.
Consulter le mode d'emploi.
Gebrauchsanweisung beachten.
Consultare le istruzioni per l'uso.
Raadpleeg instructies voor gebruik.
Consulte as Instruções de Utilização



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Conteúdo



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Lot
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Lot
Charge
Lotto
Partij
Lote



Product Number
Número del producto
Référence
Produktnummer
Codice prodotto
Productnummer
Número do Produto



Recyclable Package
Envasé reciclable
Emballage recyclable
Wiederverwertbare Verpackung
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Recyclebare verpakking
Embalagem Reciclável



Use By
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Date limite d'utilisation
Verwendbar bis
Usare entro
Uiterste gebruiksdatum
Validade



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Dirección del patrocinador australiano
Adresse du promoteur australien
Adresse des australischen Sponsors
Indirizzo sponsor australiano
Adres Australische sponsor
Endereço do Patrocinador Australiano



For single use only. Do not reuse.
Para un solo uso. No reutilizar.
À usage unique. Ne pas réutiliser.
Für den einmaligen Gebrauch. Nicht wieder verwenden.
Esclusivamente monouso. Non riutilizzare.
Uitsluitend bestemd voor eenmalig gebruik. Niet opnieuw gebruiken.
Apenas para uma única utilização. Não reutilize.



Do Not Resterilize
No reesterilizar
Ne pas restériliser
Nicht erneut sterilisieren
Non risterilizzare
Niet opnieuw steriliseren
Não reesterilize



Do not use if package is damaged.
No usar si el envase está dañado.
Ne pas utiliser si l'emballage est endommagé.
Bei beschädigter Verpackung nicht verwenden.
Non usare il prodotto se la confezione è danneggiata.
Niet gebruiken als de verpakking is beschadigd.
Não utilize se a embalagem estiver danificada.



Sterilized using ethylene oxide.
Esterilizado por óxido de etileno.
Stérilisé à l'oxyde d'éthylène.
Mit Ethylenoxid sterilisiert.
Sterilizzato con ossido di etilene.
Gesteriliseerd met ethylenoxide.
Esterilizado por óxido de etileno.



**EU Authorized
Representative**

Boston Scientific International S.A.
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92729 NANTERRE CEDEX
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Free Fax 1800 836 666



**Legal
Manufacturer**

Boston Scientific Corporation
One Boston Scientific Place
Natick, MA 01760-1537
USA
USA Customer Service 888-272-1001



**Do not use if package
is damaged.**



**Recyclable
Package**

C € 0197

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Reimbursement Guide: Capio SLIM Suture Capturing Device

Reimbursement



Is this product reimbursable by insurance?

The procedures for which it is used are reimbursable. Billing guides with respective coding and estimated Medicare reimbursement for relevant pelvic floor reconstruction procedures are available online at www.bostonscientific.com/reimbursement. For additional coding and reimbursement information, contact your local Territory Manager or the Women's Health Reimbursement Help Desk at UroWH.reimb@bsci.com OR (508) 683-4022.

What is the Medicare Pass-Through Code (aka C-code or HCPCS)?

This Medicare Pass-Through Code for this product is C2631 (*repair device, urinary, incontinence, without sling graft*).

Is this a patient-chargeable product?

Yes. The appropriate Revenue Code for Capio SLIM is 272 – Medical/Surgical Supplies and Devices-Sterile Supply. Medicare does not dictate a provider's charge structure or how it itemizes those charges. Section 2202.8 of the Medicare Provider Reimbursement Manual dealing with Ancillary Services (e.g. operating room) does not specifically address which items are part of the basic "routine" charge and which are charged in addition to the basic charge. Medicare is on record that it is up to the individual hospital to determine whether to and how to itemize the charge for a specific supply. However, Medicare does require that charges billed on the CMS-1450 form (aka UB-04) be aggregated under the appropriate Revenue Code.

Relevant Reimbursement Codes:

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.

Procedure Name	APC Code	CPT® Code	ICD-9-CM Procedure Code	ICD-9-CM Diagnosis Code	Possible MS-DRG Assignment
Level VI Female Reproductive Procedures	0195	57240 - Anterior colporrhaphy, repair of cystocele with or without repair of urethrocele	70.50 - Repair of cystocele and rectocele	618.00- Unspecified prolapse of vaginal walls	748 – Female reproductive system reconstructive procedures
		57250 – Posterior colporrhaphy, repair of rectocele with or without perineorrhaphy	70.51- Repair of cystocele	618.01- Cystocele, midline	662 – Minor bladder procedures with major complication or comorbidity (MCC ¹)
		57260 – Combined anteroposterior colporrhaphy	70.52- Repair of rectocele	618.02- Cystocele, lateral	663 – Minor bladder procedures with complication or comorbidity (CC ¹)
		57267 – Insertion of mesh or other prosthesis for repair of pelvic floor defect, each site, (anterior, posterior compartment), vaginal approach (List separately in addition to code for primary procedure)	70.53- Repair of cystocele and rectocele with graft or prosthesis	618.04- Rectocele	664 – Minor bladder procedures without CC/MCC
			70.54- Repair of cystocele with graft or prosthesis (Anterior colporrhaphy)	618.09- Other prolapse of vaginal walls without mention of uterine prolapse	
			70.55- Repair of rectocele with graft or prosthesis (Posterior colporrhaphy)	618.81 - Incompetence or weakening of pubocervical tissue	
				618.82 - Incompetence or weakening of rectovaginal tissue	

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¹The patient's medical record must support the existence and treatment of the complication or comorbidity.

For additional coding and reimbursement questions please contact our Women's Health Reimbursement Help Desk at UroWH.reimb@bsci.com OR (508) 683-4022.

Ordering Information

Capio™ Slim Suture Capturing Device

Order Number	Description	Unit
M0068318250	Capio SLIM Suture Capturing Device	bx 1
M0068318261	Capio SLIM Suture Capturing Device	bx 5

Capio Sutures

Order Number	Description	Size	Unit
M0068331131	Non-absorbable, coated braided polyester, double armed with TC tapercut needle (dart), 48"	0	bx 12
M0068331231	Non-absorbable, polypropylene monofilament, double armed with TC tapercut needle (dart), 48"	0	bx 12
M0068332131	Absorbable, coated braided PGA, double armed with TC tapercut needle (dart), 48"	0	bx 12
M0068331141	Non-absorbable, coated braided polyester, double armed with TC tapercut needle (dart) and a T 26mm 1/2 circle taper needle, 36"	0	bx 12
M0068331241	Non-absorbable, polypropylene monofilament, double armed with TC tapercut needle (dart) and a T 26mm 1/2 circle taper needle, 36"	0	bx 12
M0068331371	Monodek™ Absorbable, monofilament PDO, double armed with TC tapercut needle (dart) and a T 26mm 1/2 circle taper needle, 48"	0	bx 12



Notes

This image shows a single sheet of white paper with horizontal ruling lines. The lines are evenly spaced and run across the width of the page. There are no margins, text, or other markings on the paper.



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All other trademarks are property of their respective owners.

Caution: Federal Law (USA) restricts these devices to sale by or on the order of a physician. Refer to package insert provided with these products for complete Indications for Use, Contraindications, Warnings, Precautions, Adverse Events, and Instructions prior to using these products.

Data on file. Bench test results may not necessarily be indicative of clinical performance.

Boston Scientific Corporation
One Boston Scientific Place
Natick, MA 01760-1537
www.bostonscientific.com/gynecology

Ordering Information
1.888.272.1001

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WH-138501-AA XM 1/13