92201802-FA - Capio Suture Management Technique Advisory Field Action

Boston Scientific
Advancing science for life™

12-Feb-2018

Important Medical Device Information

Capio™ Suture Capturing Devices (SLIM, Standard, Open Access, RP)
Uphold™ Vaginal Support System
Uphold LITE with Capio™ SLIM Vaginal Support System
Pinnacle™ Anterior Pelvic Floor Repair Kit
Pinnacle™ Posterior Pelvic Floor Repair Kit
Pinnacle LITE Posterior with Capio SLIM Pelvic Floor Repair Kit

No product is being recalled and you are not required to return product to Boston Scientific.

There is no impact to previously implanted mesh devices.

Dear Doctor,

Boston Scientific (BSC) is committed to providing high quality products and is dedicated to patient safety. We have observed a gradual increasing trend in reports regarding the Capio suture breakage and/or detachment of the Capio suture darts from both the Capio suture and the pelvic floor kit mesh assembly (Uphold™ Vaginal Support System, Uphold LITE Vaginal Support System, Pinnacle™ Anterior Pelvic Floor Repair Kit, Pinnacle™ Posterior Pelvic Floor Repair Kit, Pinnacle™ LITE Posterior with Capio SLIM Pelvic Floor Repair Kit). The mesh assembly refers to the portion of the pelvic floor delivery system which is removed from the patient following implantation of the mesh. As a result, BSC is voluntarily initiating a Field Safety Notice to the technique for use of the Capio Suture Capturing Devices (SLIM, Standard, Open Access, RP) and the Uphold™ LITE with Capio™ SLIM Vaginal Support System, and Pinnacle™ LITE Posterior with Capio SLIM Pelvic Floor Repair Kits. UPNs are listed in the table below.

Capio suture breakage and/or detachment of the Capio suture darts occurs when higher amounts of counter-traction (tension) are placed on the Capio suture or pelvic floor kit mesh assembly during deployment. The most common reported injury has been a prolonged procedure beyond anticipated/expected duration. In some cases BSC has received reports of suture breaks resulting in un-retrievable device fragments. Although the risk-benefit assessment of further intervention varies from case to case, extensive dissection to attempt removal of retained fragments is typically not recommended.

The Capio and pelvic floor kit products continue to perform within our Risk Management expectations but as BSC continuously strives to ensure the highest level of product quality and clinical performance, our Quality and Research and Development teams have conducted extensive testing to determine the root cause of the Capio suture damage.

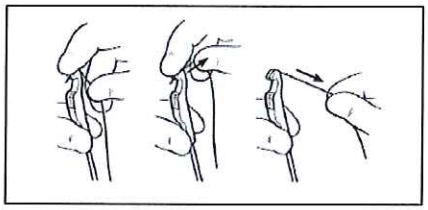
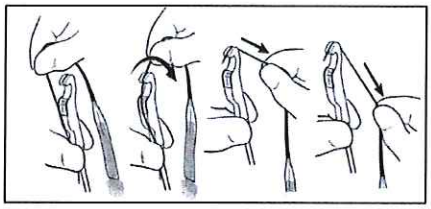
Root Cause Investigation:
If the Capio suture or pelvic floor kit mesh assembly is placed under excessive counter-traction during deployment, it can result in an interaction between the suture and the Capio carrier that could potentially damage the suture and may cause the dart to detach. The testing confirmed that higher amounts of counter-traction (tension) placed on the Capio

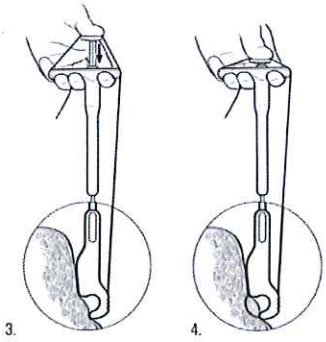
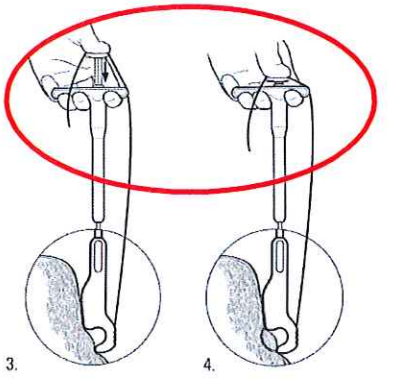
suture or pelvic floor kit mesh assembly during deployment contributes to an increased likelihood of damage to the Capio suture and potential Capio dart detachment.

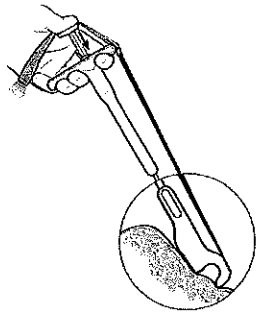
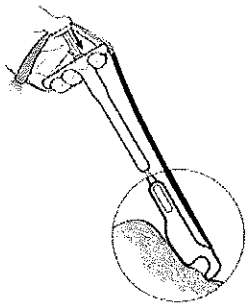
Our Quality and Research and Development team is continuing their investigation to determine if potential design changes will help mitigate this risk. In the interim, BSC recommends the following technique for Capio use.

Technique:

Based on our research and testing, the following products' Directions for Use will be updated to reflect the following technique:

Prior To Deployment	
Capio Family of Products	**Pelvic Floor Kits**
	
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 Capio Device tip.	**Note:** When loading a dart of the leg assembly into the device, verify that the dart is properly positioned in the carrier. The tip of the dart should not protrude from the Capio Device tip.

Capio Family of Products Deployment Technique Tips	
Existing *Capio Family Directions For Use*	***Updated*** *Capio Family Directions For Use*
	
Existing DFU Technique Tip: "During use, secure suture with thumb to maintain adequate (dart) tension in the carrier."	**Updated DFU Technique Tip:** Use slight counter-traction on the suture while positioning the Capio tip, in order to maintain the position of the dart

	in the carrier. Avoid excessive counter-traction on the suture as this has the potential to damage the suture during deployment. **Note:** The technique of maintaining slight counter-traction on the suture is best described as placing just enough tension on the suture to keep the dart in the carrier. Excessive counter-traction is best described as preventing free movement of the suture during deployment.
Pelvic Floor Kit Deployment Technique Tips	
Existing *Pelvic Floor Kit* *Directions For Use*	***Updated*** *Pelvic Floor Kits* *Directions For Use*
	 Avoid excessive counter-traction that would prevent free movement of the mesh assembly during deployment
No Existing DFU Technique Tip	**Updated DFU Technique Tip:** Use slight counter-traction on the mesh assembly while positioning the Capio tip, in order to maintain the position of the dart in the carrier. Avoid excessive counter-traction on the mesh assembly as this has the potential to damage the suture during deployment. **Note:** The technique of maintaining slight counter-traction on the mesh assembly is best described as placing just enough tension on the suture to keep the dart in the carrier. Excessive counter-traction is best described as preventing free movement of the mesh assembly during deployment.

Affected Device List

Product Description	UPN
Capio™ SLIM Open Access Suture Capturing Device	M0068318250
Capio SLIM Open Access Suture Capturing Device (Box 5)	M0068318261
Capio Open Access Suture Capturing Device (Box 4)	M0068311251
Capio Standard Suture Capturing Device (Box 4)	M0068312321
Capio RP Suture Capturing Device	M0068321010
Uphold™ Vaginal Support System	M0068317080
Uphold LITE with Capio™ SLIM Vaginal Support System	M0068318170
Pinnacle™ Anterior Pelvic Floor Repair Kit	M0068317050
Pinnacle Posterior Pelvic Floor Repair Kit	M0068317100
Pinnacle LITE Posterior with Capio SLIM Pelvic Floor Repair Kit	M0068318150

Your Competent Authority is being notified of this Field Safety Notice.

Please read this letter carefully and immediately post this information in a visible location near the product to ensure this information is easily accessible to all users of the device. Please pass on this notice to any health professional of your organization that need to be aware and to any organization where the potentially affected devices have been transferred (if appropriate).

We regret any inconvenience that this action may cause, and we appreciate your understanding as we act to ensure patient safety and customer satisfaction.

We value your support of BSC and our products. If you have any further questions, please contact your local BSC Representative.

Sincerely,

[redacted]

Ms Yan Yun
Market Development Manager
Urology/Pelvic Health & Surgical Solutions
Boston Scientific Asia Pacific Pte Ltd

Copy: Chairman Medical Board and relevant Head of Departments

Boston Scientific

ACKNOWLEDGEMENT FORM

PRODUCT NAME: 92201802-FA – Capio Suture Management Technique Advisory 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: Boston Scientific Sales Rep OR Fax to #: 64188899

Account #:	**Healthcare Professional Name:**		
Contact Name:			
Address:			
City:	**State:**	**Province:**	**Postal Code:**
Country:			

PLEASE COMPLETE, SIGN AND RETURN THIS FORM AS A CONFIRMATION THAT YOU RECEIVED THIS LETTER FROM BOSTON SCIENTIFIC (even if you do not have any of the referenced product on the enclosed product listing in your current inventory).

My signature below acknowledges receipt of '92201802-FA - Capio Suture Management Technique Advisory Field Action'.

Section to be filled out by Healthcare Professional:

1. **Sign and Date to acknowledge this letter(must be completed):**

Print Name:_____ Signature:_____ Date:_____

Phone:_____ Fax: _____ E-mail: _____

THESE DOCUMENTS ARE THE PROPERTY OF BOSTON SCIENTIFIC CORPORATION AND SHALL NOT BE REPRODUCED, DISTRIBUTED, DISCLOSED OR USED FOR MANUFACTURE OR SALE OF APPARATUS WITHOUT THE EXPRESS WRITTEN CONSENT OF BOSTON SCIENTIFIC CORPORATION.