Boston Scientific

Urgent Medical Device Product Removal - Immediate Action Required

Malecot Nephrostomy Catheter System
Malecot Nephrostomy Catheter Set
Re-Entry™ Malecot Nephrostomy Catheter Set
Percutaneous Access Set

12-Dec-2017

Dear Doctors/ Materials Manager

Boston Scientific (BSC) is initiating a removal of certain Malecot Nephrostomy Catheters due to reports of some catheters breaking at the mid-shaft bond during use. The bond is located where the renal end of the Malecot catheter is bonded to the catheter shaft. BSC has received seventeen (17) complaints for this issue since December 1, 2013.

If the catheter bond breaks while inside the patient, the most common adverse health consequence would be additional intervention for endoscopic retrieval of the detached fragment. The most severe consequence that is reasonably expected to occur due to this issue is an additional open or laproscopic procedure to remove the detached fragment.

This removal affects all batches of the UPNs listed in the table below.

Since affected products may be used in different areas of your institution, we have listed the use(s) of the affected UPNs to facilitate your locating the affected products:

Affected Product Listing

Product Description	Use(s)	Material Number (UPN)
Malecot Nephrostomy Catheter System	Interventional Radiology or Oncology	M001224110
Malecot Nephrostomy Catheter Set	Urology	M0064101000
		M0064101010
Re-Entry™ Malecot Nephrostomy Catheter Set		M0064101040
		M0064101050
Percutaneous Access Set		M0064201150

If you identify any product from the affected batches within your inventory, please segregate the affected product immediately and return it to Boston Scientific in accordance with the enclosed instructions. You will receive credit for all removed product returned to Boston Scientific.

Boston Scientific is notifying worldwide regulatory authorities of this removal as required.

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

We regret any inconvenience that this action may cause, and we appreciate your understanding as we take action to ensure patient safety and customer satisfaction. We are committed to continuing to offer products that meet the highest quality standards that you expect from Boston Scientific.

Sincerely,

[redacted]

Brendan Smith
Boston Scientific Quality Systems
763-494-1133
BSCFieldActionCenter@bsci.com

Encl: Removal Instructions
Reply Form

Copy: Chairman Medical Board and relevant Head of Departments

Urgent Medical Device Removal - Instructions

The Reply Verification Tracking Form enclosed with this Notice must be completed and returned **even if you do not have any remaining removed units**.

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

2. **Complete and return the Reply Verification Tracking Form (RVTF).**
   - Complete the enclosed Reply Verification Tracking Form even if you do not have any product to return, following the directions on this page and on the Reply Verification Tracking Form.
   - Verify by product batch/lot number in product table to determine if the batch within your inventory is affected. If so, indicate on your Verification Form the quantity of units from each batch that you will be returning.
   - Return the Reply Verification Tracking Form to Boston Scientific Sales Representative.

RECALL REMOVAL REPLY VERIFICATION TRACKING FORM

PRODUCT NAME: 92185477-FA – Malecot Bond Break Removal 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 #: