

Reference: 92185477-FA

13 December 2017

Field Safety Notice (for Distributor) - Urgent Medical Device Recall
Malecot Nephrostomy Catheter System
Malecot Nephrostomy Catheter Set
Re-Entry™ Malecot Nephrostomy Catheter Set
Percutaneous Access Set

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.

Our records indicate that your facility received some of the concerned product. The **table below provides a complete list of all affected products**, including Product Description and Material Number (UPN). Please note that **only the devices listed below are affected. No other Boston Scientific product is involved in this Field Safety Notice.**

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

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:

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

INSTRUCTIONS:

- 1- **Check your Inventory for the products affected by this Field safety Notice.**
- 2- **Please segregate and do not distribute any of the affected products found in your inventory.**
- 3- **Please notify all your customers that have received affected product of this Field Safety Notice.** To effectively manage this Field Safety Notice, your accounts are to communicate directly with you, not Boston Scientific. If any of your customers are distributors, please notify them that they must communicate this recall to the medical facility level.
- 4- **Have all affected product returned to your facility** and held in quarantine for reconciliation
- 5- **Please complete the attached Verification Form, even if you do not have any product to return.**
- 6- **When completed, please return the Verification Form to your local Boston Scientific office** for the attention of Nikoletta Fanti - email: fantin@bsci.com on or before **05 January 2018.**
- 7- **If you have products to return,** please package them in an appropriate shipping box and **contact** Export Services mail address: BDCEExportServicesCusSerIC@bsci.com **of your local Boston Scientific office,** to arrange return.

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

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

If you have any questions or would like assistance with this Field Safety Notice, please contact your local Sales Representative.

Yours sincerely,



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

Attachment: Verification Form