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**«Hospital_Name»**
«Users_Name»- «Department»
«Customer_Address»
«Zip_Code» «City» -«Country_name»

**Reference: 92185477-FA** December 2017

# Field Safety Notice - Urgent Medical Device Recall
# Malecot Nephrostomy Catheter System
# Malecot Nephrostomy Catheter Set
# Re-Entry™ Malecot Nephrostomy Catheter Set
# Percutaneous Access Set

Dear «Users_Name»,

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- **Please immediately discontinue use of the Boston Scientific product reported in the list and remove all of the affected units from your inventory**, regardless of where these units are stored in your facility. Segregate the units in a secure place, pending return to Boston Scientific.

2- **Please complete the attached Verification Form** even if you do not have any product to return.

3- **When completed, please return the Verification Form to your local Boston Scientific office** for the attention of «Customer_Service_Fax_Number» on or before **xx January 2018**.

4- **If you have products to return,** please package them in an appropriate shipping box and **contact** «Customer_Service_Tel» **of your local Boston Scientific office,** to arrange return.

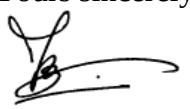
5- Please pass this notice to any healthcare professional from your organization that needs to be aware and to any organization where the potentially affected devices have been transferred (If appropriate). Please provide Boston Scientific with details of any affected devices that have been transferred to other organizations (if appropriate).

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 Barlangua
Quality Department
Boston Scientific International S.A.

Attachment: Verification Form