

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

Reference: 91104079-FA

Date

Urgent Field Safety Notice - Medical Device Removal IntellaTip MiFi™ XP Asymmetric (N4) Curve Temperature Ablation Catheters

Dear «Users_Name»,

Boston Scientific is implementing a Medical Device Removal for all N4 curves of the IntellaTip MiFi XP Temperature Ablation Catheters. Boston Scientific has received reports of bent distal tips, and in four cases, this situation resulted in exposed internal wires in the asymmetric curve models (known as N4) of IntellaTip MiFi XP. The most common clinical observation is prolongation of the procedure to exchange a bent catheter with a new device. Though no serious patient harms have been reported, a bent catheter tip or exposed internal wire could result in tissue damage to blood vessels and cardiac structures.

Our records indicate that your facility received some of the concerned product. **Table below provides a complete list of all affected products**, including Product Description, Material Number (UPN) and Lot/Batch numbers and expiry date. Please note that **only the material listed below is affected. No other Boston Scientific product is involved by this Field Safety Notice.** **Further distribution or use of any remaining product affected by this action should cease immediately.**

Product Description	Material Number (UPN)	Lot	Expiration Date Range
IntellaTip MiFi XP Asymmetric (N4) Curve	M004EPM4500N40	16743760, 17135083, 17614450, 18140623, 18162387	16 Feb 2017 to 3 Jul 2018
IntellaTip MiFi XP Asymmetric (N4) Curve	M004EPM4790N40	16743398, 17135082	16 Feb 2017 to 22 Jul 2017
IntellaTip MiFi XP Asymmetric (N4) Curve	M004PM4500N40	16309584, 16615976, 16623754, 16623755, 16722434, 16736927, 16739588, 16743271, 16872124, 16999075, 17118111, 17157418, 17201805, 17222051, 17222052, 17370483, 17376573, 17376574, 17436562, 17436563, 17436565, 17451802, 17478950, 17499145, 17499152, 17590503, 17611785, 17625992, 17768306, 17791420, 17925492, 17925493, 18012208, 18161715	15 Aug 2016 to 2 Jul 2018
IntellaTip MiFi XP Asymmetric (N4) Curve	M004PM4790N40	16743269, 16818653, 16818654, 16872007, 16993525, 17511087, 18159904, 18385792	1 Sept 2016 to 20 Sept 2018

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**, irregardless 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** to the attention of «Customer_Service_Fax_Number» on or before **xx December 2015**.
- 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 health professional of your organization that need 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 take action 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,


Quality Department
Boston Scientific International S.A.

Attachment: Verification Form