



Urgent Medical Device Removal - Immediate Action Required

IntellaTip MiFi™ XP Asymmetric (N4) Curve Temperature Ablation Catheters

November 20, 2015

Dear Materials Manager / Field Action Contact:

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.

This Removal affects all lots of Asymmetric N4 curves of the IntellaTip MiFi XP Temperature Ablation Catheters manufactured to date and listed below. **Further distribution or use of any remaining product affected by this action should cease immediately.**

Affected Product Listing

Product Description	Material Number (UPN)	Lot	Expiration Date Range
IntellaTip MiFi XP Asymmetric (N4) Curve	M004EPM4500N40	16743760, 17135083, 17614450, 18140623, 18162387	2/16/2017 to 7/3/2018
IntellaTip MiFi XP Asymmetric (N4) Curve	M004EPM4790N40	16743398, 17135082	2/16/2017 to 7/22/2017
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	8/15/2016 to 7/2/2018
IntellaTip MiFi XP Asymmetric (N4) Curve	M004PM4790N40	16743269, 16818653, 16818654, 16872007, 16993525, 17511087, 18159904, 18385792	9/1/2016 to 9/20/2018

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

If you are a distributor, please note that the removal depth is to the hospital level and this removal notification should be forwarded to your customers.

We are notifying worldwide regulatory authorities in affected geographies of this Removal as required.

Please read carefully through the enclosed Removal 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 you expect from Boston Scientific.

Sincerely,

Makram Nehme
Regulatory Affairs & Quality Assurance Specialist
Boston Scientific Middle East S.A.L.(Offshore)
Beirut -Lebanon
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Encl: Recall Instructions
Reply Verification Tracking Form

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Removal Instructions

The Account Reply Verification Tracking Form enclosed with this Customer Removal Notice must be completed and returned by **18 December 2015** even if you do not have any of the devices from the affected lot.

1. **Immediately discontinue use of and segregate affected product.**
 - Immediately remove all affected product from your inventory
 - Segregate this product in a secure location for return to Boston Scientific.
2. **Complete and return the Account Reply Verification Tracking Form (RVTF).**
 - Complete the enclosed Account Reply Verification Tracking Form (even if you do not have any product to return), following the directions on this page and the Account Reply Verification Tracking Form.
 - Return the Account Reply Verification Tracking Form:
Email:
makram.nehme@bsci.com
attiehc@bsci.com

Please email or fax your Account Reply Verification Tracking Form(s) immediately. You will be contacted by Boston Scientific and provided a Returned Goods Authorization (RGA) Number after your RVTF is received. When returning the product, place the original form with returned products.

3. **Package/Ship the Affected Product.**
 - Package any product that is being returned in an appropriate shipping box.
 - Affix a shipping label to the outside of the shipping box.
 - Write the **RGA number** in large print on the outside of the box, either on or near the shipping label.
 - Seal the box, and return it to: **[Address]**



RECALL REMOVAL REPLY VERIFICATION TRACKING FORM
PRODUCT NAME: IntellaTip MiFi XP Removal

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: makram.nehme@bsci.com attiehc@bsci.com OR Fax to #:

Account #: 43554	Customer Name: FAROUK MAAMOUN TAMER & CO
Contact Name: FAROUK MAAMOUN TAMER & CO Address: WADI HURAYMELA STR., AL AMMARIYAH City: JEDDAH State: - Province: - Postal Code: 21411 Country: Saudi Arabia	

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
M004EPM4500N40	17135083	2 EA	5/25/2015	FOC FOC 4130-100	
M004EPM4500N40	17614450	5 EA	5/25/2015	FOC FOC 4130-100	

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 #:

Customer Name:

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Date:

Account #: 43554

Field Action #: 91104079