



## Urgent Medical Device Correction - Immediate Action Required

### Threader™ Monorail and Threader™ Over the Wire Micro-Dilatation Catheters

XX May, 2016

Dear Materials Manager/Field Action Contact:

Boston Scientific is initiating a voluntary Field Correction related to the above referenced product family. Boston Scientific has determined that certain Threader™ Monorail and Threader™ Over the Wire Micro-Dilatation Catheters were shipped from the Australia distribution center with an international Direction for Use (DFU) rather than an Australian DFU. This action is being conducted following consultation with the Therapeutic Goods Administration.

The below Affected Product Listing provides a list of all products within the scope of this Field Correction. No other products or countries are affected by this Field Correction.

#### Affected Product Listing

Product Description	Material Number (UPN)	Batch Number	Expiration Date
Threader™ Monorail	H7493926912120	18647602	11/30/2017
Threader™ Over the Wire	H7493927012120	18647652	11/30/2017
Threader™ Over the Wire	H7493927012120	18753516	12/31/2017
Threader™ Over the Wire	H7493927012120	18647655	11/30/2017

Enclosed with this notification is a copy of the Australian DFU. We ask that you read the enclosed information carefully and post it in a visible location that is easily accessible to all users of these devices. Please complete any additional requirements that are consistent with your internal policies and procedures. **Please Note: No product is being removed from the market and you are not required to return product to Boston Scientific.**

We also ask that you complete and return the enclosed Customer Acknowledgement Form as per the attached Field Correction Instructions.

**If you are a distributor, please note this Field Correction is to the hospital level and should be forwarded to your customers without delay.**

Affected worldwide regulatory authorities are being notified of this Field Correction as required.

Boston Scientific is committed to continuing to offer products that meet the highest quality standards and we appreciate your understanding as action is taken to ensure customer satisfaction. If you have additional questions regarding this communication please contact your local Boston Scientific Sales Representative.

Sincerely,

Encl: Australia DFU  
Customer Acknowledgement Form  
Field Correction Instructions

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**Field Correction Instructions**

The Acknowledgment Form enclosed with this notification must be completed and returned **even if you no longer have any of the product.**

1. **Immediately post this information in a visible location near the product to ensure this information is easily accessible to all users of the device.**
2. **Complete and return the Acknowledgment Form.**
  - Complete the enclosed Acknowledgment Form (even if you no longer have any of the products), following the directions on this page and on the form.
  - Return the Acknowledgment Form to your FCS or Boston Scientific as soon as possible.