Subject: Urgent Voluntary Medical Device Field Action/Removal for **Convey 6F LEFTBU 3.5 catheters – Lot specific.**
Affected product: Convey Catheter 6F LEFTBU 3.5.
FSCA-identifier: FSCA 23-001
Field Safety Notice

Dear Boston Scientific colleagues,

The purpose of this letter is to notify you that PendraCare International B.V. is conducting a voluntary field action/removal for specific lots of the 6F Convey Catheter 6F LEFTBU 3.5 due to braiding wire protruding the side hole. This anomaly was noticed due to customer complaints raised by a BSC customer. This field action is not related to an adverse event.

Convey Catheter Affected Lot numbers:

Source System ID	UPN	Model/Catalog Description	Lot	Total Qty
16235403	H749392647200	6F Convey LeftBU3.5 SH (SIDE HOLES)	22050345	250
16590326	H749392647200	6F Convey LeftBU3.5 SH (SIDE HOLES)	22090049	250
16712350	H749392647200	6F Convey LeftBU3.5 SH (SIDE HOLES)	23030776	300

Four complaints had been received about the braiding protrusion side holes defects on 6F Convey Guiding Catheter lots 2205-0345 (1 complaint), 2209-0049 (1 complaint) and 2303-0776 (2 complaints). The root cause is being determined and relevant corrective and preventive actions are being planned.

Our records indicate that you have received the affected lots distributed.

Actions to be taken immediately:

1. Stop shipment:
    a. Stop distribution of the products of the affected lots by this Field Action/Removal.
    b. Remove the lots mentioned from your inventory and/or notify your customers to return them.
    c. Segregate the affected products for return to PendraCare.
    d. Forward a copy of this Field action/removal notification to all sites to which you have distributed the affected products. Or use your own QMS form for this purpose.
2. Complete and return the "Medical Device Field Action/Removal Acknowledgment Form":
    a. Promptly complete, sign and return the enclosed "Medical Device Field Action/Removal Acknowledgment Form" (even in the case that you don't have any products to return) to the following email: qara@pendracare.com
3. Package and return the affected products:
    a. Pack the boxes of the products into an appropriate box.
    b. Seal the box and return to: PendraCare International B.V. Van der Waalspark 22, 9351 VC Leek, The Netherlands.

Please use UPS account number *W79Y76* for the return of devices.
PendraCare will replace all products that are returned

We sincerely apologize for the inconvenience this may cause and appreciate your understanding as we take action to ensure the quality of our products.
We are committed to continue offering products that meet the highest quality standards that is expected from PendraCare.
We will keep you duly informed regarding any further actions and our findings.
Should you need any additional information, please do not hesitate to contact us.

Director Quality Assurance and Regulatory Affairs

Medical device removal Acknowledgment Form

Urgent Voluntary Medical Device Removal for Convey Catheter 6F LEFTBU 3.5.
Response is Required

Please fill in the following information (Complete, Sign and Return at): qara@pendracare.com
Return Products via UPS account number W79Y76.

Customer Information	
Company	
Person responsible	
Address	
City, State/Province and Zip Code	
Telephone Number	
Reference Number of returned products	
Quantity of boxes and Lot number	

Affected products:

Convey Catheter Affected Lot numbers:

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I acknowledge receipt of the Urgent Voluntary Field Action / Removal for the lots of Convey catheters indicated in the table provided with this letter. Additionally, we have inspected our inventory to check if have the products listed in this field action/removal:

☐ We have segregated the affected Products and have scheduled their return to PendraCare
☐ We have no Convey catheters of the affected lots in our inventories.
☐ We have shipped these products to hospitals. They have been notified and have segregated the products
☐ We have shipped these products to hospitals. They have been notified, products had been used.

I have checked my stock and have quarantined inventory consisting of _____ <units, boxes>.

I have identified and notified my customers to whom the product was shipped to or may have been shipped by (**specify date and method of notification**);

Signature of Receipt _____

Name/Title	
Telephone	
Email address	