Subject: Voluntary Medical Device Field Action/Removal for Climber Guiding Catheter 5F EBU 3.5.
Affected product: Climber Guiding Catheter 5F EBU 3.5.
FSCA-identifier: FSCA 25-001
Field Safety Notice

Dear Terumo 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 5F Climber Guiding Catheter 5F EBU 3.5.due to an inadequacy label in labeling of the pouch, the wrong French size is printed on the pouch label (6F). This anomaly was noticed due to customer complaints raised by a Terumo customer. This field action is not related to an adverse event.

Climber Catheter Affected Lot number:

Source System ID Complaint	Serial Number	Model/Catalog Description	Lot	Total Qty
PPR-24-2073-1 PPR-24-2074-1 PPR-24-2075-1	08718122023518	GC-P5EB350N EXTRA BACK UP, EBU3.5	2409-0012	380

Three complaints were received about a mismatch of the French size on the box label compared to the Pouch label (purchased item). 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: gara@pendracare.com
3. Package and return the affected products:
    a. Pack the boxes of the products into an appropriate box.
    b. Seal the box, identify it with number FSCA 25-001 and return to: PendraCare International B.V.Kamerlingh Onnesstraat 6, 9351VD Leek, The Netherlands.

Please use Fedex account number *241488874* 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 continuing to offer 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.

Sincerely,

_____

Eréndira Rodríguez
2025-02-20

Director Quality Assurance and Regulatory Affairs

Medical device removal Acknowledgment Form

Urgent Voluntary Medical Device Stop Shipment for Climber Guiding Catheter 5F EBU 3.5.

Response is Required

Please fill in the following information (Complete, Sign and Return at): qara@pendracare.com
Return Products via Fedex account number 241488874.

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:

Climber Catheter Affected Lot number:

Source System ID Complaint	Serial Number	Model/Catalog Description	Lot	Total Qty
PPR-24-2073-1 PPR-24-2074-1 PPR-24-2075-1	08718122023518	GC-P5EB350N EXTRA BACK UP, EBU3.5	2409-0012	380

I acknowledge receipt of the Urgent Voluntary Field Action / Removal for the lot of Terumo 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 Climber catheters of the affected lot 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	