

**Subject:** Voluntary Medical Device Field Action/Removal for Climber Guiding Catheter 6F 3.5EBU shape

**Affected product:** Climber Guiding Catheter with lot number 2402-0087

**FSCA-identifier:** FSCA 26-002

**Date:** 2026-06-26

**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 lot 2402-0087 of the 6F Climber Guiding Catheter 3.5EBU shaped due to a customer complaint for tip detachment.

**Climber Catheter Affected Lot number:**

| Source System ID Complaint | UDI                                            | Model/Catalog Description | Lot       | Total Qty |
|----------------------------|------------------------------------------------|---------------------------|-----------|-----------|
| PPR-26-0502-1              | 08718122024195 (Pouch)<br>38718122024196 (Box) | GC-P6EB350N               | 2402-0087 | 609       |

The root cause is being investigated, and relevant corrective and preventive actions are being planned.

Our records indicate that you have received the affected lots distributed in 19 locations with different amounts per location.

Actions to be taken immediately:

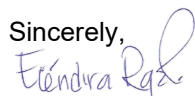
1. Stop shipment:
  - a. Stop distribution of the products of the affected lots by this Field Action/Removal.
  - b. Remove the lots mentioned from your inventory and/or notify your customers to return them.
  - c. Segregate the affected products for return to PendraCare.
  - d. Forward a copy of this 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](mailto: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 26-002 and return to: PendraCare International B.V. Kamerlingh Onnesstraat 6, 9351VD Leek, The Netherlands.

Please use Fedex account number 271488874 for the return of devices.

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

Director Quality Assurance and Regulatory Affairs