

Voluntary Medical Device Field Safety Corrective Action/Removal

Field Safety Notice

Device: Climber Guiding Catheter 6F 3.5EBU shape with lot number 2402-0087
Reference: PENDRACARE - FSCA 26-002
Date: 2026-06-26
Action: Removal

Background information

The purpose of this letter is to notify you that **PendraCare International B.V.** is conducting a voluntary field safety corrective action/removal for specific lot 2402-0087 of the 6F Climber Guiding Catheter 3.5EBU shape due to a customer complaint for tip detachment. This field action is not related to an adverse event.

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

Our records indicate that you have received units of the affected lot.

Details on affected devices

Product code	Lot number
GC-P6EB350N	2402-0087

Correction

Terumo Europe is alerting its involved customers about the issue and is asking to identify and segregate the remaining affected units in their inventory prior to return to Terumo Europe.

Customer instructions

- 1) Review this Field Safety Notice and assure that all users are aware of it.
- 2) Identify and segregate the units of the suspected device population.
- 3) If applicable: stop distribution of the products of the lot affected by this removal. Forward a copy of this removal notification to all sites to which you have distributed the affected products.
- 4) Complete and return the CUSTOMER REPLY FORM duly signed. Return this form as quickly as possible to the e-mail address indicated on the form.
If applicable: collect the forms from all sites to which you have distributed the affected products.
- 5) The company representative will contact you to organize pick-up to Terumo Europe and to provide compensation.

We encourage you to contact your local Terumo representative with any questions or concerns.

We confirm that this Field Safety Notice has also been notified to your national Competent Authority by **PendraCare International B.V.**

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.

Eréndira Rodríguez
Director Quality Assurance and Regulatory Affairs
PendraCare International B.V.

Nathalie Gérard, PhD
Complaints & Vigilance Manager
Terumo Europe N.V.

Field Safety Notice - CUSTOMER REPLY FORM

Device: Climber Guiding Catheter 6F 3.5EBU shape with lot number 2402-0087

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Please complete, sign and e-mail this form back:

To:

E-mail:

Hospital/Customer Name		
City		
Country		
<p>Our records indicate that you have received devices from the involved device population.</p>		
<p>By completion and return of this form, I am confirming receipt, reading and acting on this Field Safety Notice:</p>		
<p><input type="checkbox"/> The devices are no longer in stock.</p>		
<p><input type="checkbox"/> We have the following affected unit(s) blocked and ready to return:</p>		
Product code	Lot number	Number of units ready to return
GC-P6EB350N	2402-0087	
Person Responding [Please Print]		
Title		
Phone Number		
Signature		
Date		

FSCA 26-002 [EN]