**Subject:** Voluntary Medical Device Field Action/Removal for Angiodyn Angiographic Catheter 5F IM
**Affected product:** Angiodyn Angiographic Catheter 5F IM (5011505) with lotnumber 2601-0288
**FSCA-identifier:** FSCA 26-001
**Date:** 2026-04-03
Field Safety Notice

Dear B.Braun 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 Angiodyn Angiographic Catheter 5F IM; these devices are subject to 100% inspection being conducted by PendraCare due to a supplier-related defect in the pouch. This anomaly was noticed during the packaging process of the angiographic catheter.

On March 26st of 2026 an email was sent to B.Braun regarding possible delays for delivery of the devices due to a supplier pouch issue. On March 23rd, it was notified to B.Braun that a shipment with order number **4516697293** containing 36 boxes and **4516809768** containing 13 boxes of item **5011505** with affected lot number was unintentionally sent to B.Braun and requested to hold at B.Braun location and sent it back to PendraCare immediately once received . After several emails to following up to ensure the return, PendraCare was notified only on the 2nd of April 2026 that 28 boxes were already distributed to the market. This is hence triggering a formal field safety corrective action to be able to retrieve the devices and ensure the 100% inspection to disregard any issue found in pouch.

This field action is not related to an adverse event.

## Angiodyn Catheter Affected Lot number:

| Customer Order | UDI | Model/Catalog Description | Lot | Total Qty |
|---|---|---|---|---|
| **4516697293** | Pouch: 08718122047743<br>Box: 38718122047744 | 5011505<br>Angiodyn Angiographic Catheter 5F IM | 2601-0288 | 36 boxes |
| **4516809768** | Pouch: 08718122047743<br>Box: 38718122047744 | 5011505<br>Angiodyn Angiographic Catheter 5F IM | 2601-0288 | 13 boxes |

The root cause is being determined by the supplier, 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 26-001 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