

**Subject: Urgent Voluntary Medical Device Field Action/Removal for Angiodyn catheters – Lot specific.**

**Affected product:** Angiodyn Catheter 4F and 5F Pigtail 130 cm.

FSCA-identifier: FSCA 19-003

Field Safety Notice

Dear B.Braun,

The purpose of this letter is to notify you that PendraCare International B.V. is conducting a field action/removal for specific lots of the Angiodyn Catheter 4F and 5F Pigtail 130 cm due to non-conformities that have been found during production inspection. This field action is not related to any patient harm or adverse event.

**Angiodyn Catheter Affected Lot numbers:**

PO number	OC number	Item	Description	Boxes	Lot numbers
4510580294	C190408-003	5011596	4F 3DS	10	1905-0674
4510580294	C190408-003	5011500	4F JR4	50	1905-0615
4510580294	C190408-003	5011514	4F JL5	10	1905-0628
4510580294	C190408-003	5011514	4F JL5	20	1906-0371
4510580294	C190408-003	5011514	4F JL5	10	1905-0628
4510657793	C190507-008	5011538	JL4/JR4/PIG	2	1906-0383
4510657793	C190507-008	5011500	4F JR4	92	1906-0357
4510657793	C190507-008	5011514	4F JL5	20	1905-0628
4510657793	C190507-008	5011644	4F JL3.5	14	1906-0408
4510657793	C190507-008	5011514	4F JL5	20	1905-0628
4510769544	C190613-001	5011533	4F IM	2	1907-0291
4510778754	C190614-002	5011533	4F IM	10	1907-0291
4510483035	C190307-010	5011527	5F PIG/130	3	1904-0263
4510580294	C190408-003	5011503	5F PIG145/130	2	1905-0616
4510580294	C190408-003	5011527	5F PIG/130	3	1905-0639

An abnormality in the production process of the above mentioned lots might have caused damages to the inside of the catheters. The root cause has been determined and relevant corrective and preventive actions are being implemented.

Our records indicate that you have received the affected lots distributed

Distribution date	Packing List number
22-08-2019	6492
27-05-2019	6389
3-7-2019	6433

Actions to be taken immediately:

1. Stop shipment:
  - a. Stop distribution of the products of the affected lot 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 filed 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 and return to: PendraCare International B.V. Kamerlingh-Onnesstraat 6 9351 VD Leek, The Netherlands.
  - c. PendraCare will replace all products that are returned

Please use PendraCare TNT account number 181971 to return products as “Fast delivery.”

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.

Sincerely,

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welling<sup>®</sup>  
vascular innovations