



FSN Ref: QC 2025-029 FSN

FSCA Ref: QC 2025-029 FSCA

Date: 16/01/2026

Urgent Field Safety Notice

Paediatric arterial cannula, reinforced, without connector, with vent plug; Flex Line Venous Catheter, reinforced, with metal tip

For Attention of: Identify either by name or role who needs to be aware of the hazard and/or take action. If this is multiple recipients then include full list.

Contact details of local representative (name, e-mail, telephone, address etc.)

This could be a distributor or local branch of the manufacturer. To be added at the appropriate stage in the different local languages

Urgent Field Safety Notice (FSN)**Paediatric arterial cannula, reinforced, without connector, with vent plug; Flex Line Venous Catheter, reinforced, with metal tip
Detachment of tip****Recall**

1. Information on Affected Devices*	
1	1. Device Type(s)
.	The cannulas consists of soft PVC tubing with encapsulated steel wire reinforcement, terminating in a 90° curved metal tip on the distal end. It is supplied sterile.
1	2. Commercial name(s)
.	Paediatric arterial cannula, reinforced, without connector, with vent plug; Flex Line Venous Catheter, reinforced, with metal tip
1	3. Unique Device Identifier(s) (UDI-DI)
.	5420053414268; 5420053414275; 5420053414282; 5420053414299; 5420053414305; 5420053414312; 5420053414091; 5420053414107; 5420053414114; 5420053414121; 5420053414138; 5420053414145
1	4. Primary clinical purpose of device(s)
.	The paediatric arterial cannula is intended for use in perfusion of the ascending aorta during cardiopulmonary bypass. This device is intended to be used by a cardiovascular surgeon and is intended to be used on patients undergoing cardiopulmonary bypass surgery. The Flex Line Venous Catheter, reinforced, with metal tip is intended for cannula drainage from the superior and inferior vena cava during cardiopulmonary bypass surgery up to six hours or less.
1	5. Device Model/Catalogue/part number(s)
.	AP04519V; AP06019V; AP07519V; AP09019V; AP10519V; AP12019V; 01V101L7; 01V121L7; 01V141L7; 01V161L7; 01V181L7; 01V201L7
1	6. Affected serial or lot number range
.	Affected lot numbers: 24-09-0043, 24-09-0044, 24-09-0045, 24-09-0077, 24-09-0078, 24-09-0100, 24-09-0101, 24-09-0102, 24-09-0136, 24-10-0049, 24-10-0050, 24-10-0051, 24-10-0052, 24-11-0100, 24-11-0101, 24-11-0102, 24-11-0104, 24-11-0105, 25-05-0085, 25-05-0086, 25-05-0087, 25-05-0088, 25-05-0089, 25-05-0090, 25-06-0016, 25-06-0017, 25-06-0018, 25-10-0081

2 Reason for Field Safety Corrective Action (FSCA)	
2	1. Description of the product problem
.	Detachment of the metal tip from the body of the device.
2	2. Hazard giving rise to the FSCA
.	The hazard to the patient is an interruption of the blood flow during cardiopulmonary bypass due to detachment of the tip. The likelihood of occurrence of the defect is remote, however it cannot be excluded with certainty that the same production defect has affected individual units of other lots of the device family which have been manufactured under the same production process and have subsequently been placed on the market. If detachment of the tip occurs during cardiopulmonary bypass, the severity of the harm could be catastrophic (resulting in death), critical (resulting in permanent impairment or irreversible injury) or serious/major (resulting in injury or impairment requiring medical or surgical intervention). The detectability of the defect

	before use of the device is considered to be low. There is no impact towards patients which have been previously treated with the affected devices
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3. Type of Action to mitigate the risk			
3.	<p>1. Action To Be Taken by the User</p> <p> <input checked="" type="checkbox"/> Identify Device <input checked="" type="checkbox"/> Quarantine Device <input checked="" type="checkbox"/> Return Device <input type="checkbox"/> Destroy Device </p> <p> <input type="checkbox"/> On-site device modification/inspection </p> <p> <input type="checkbox"/> Follow patient management recommendations </p> <p> <input type="checkbox"/> Take note of amendment/reinforcement of Instructions For Use (IFU) </p> <p> <input type="checkbox"/> Other <input type="checkbox"/> None </p> <p>Distributors are requested to:</p> <ul style="list-style-type: none"> - check their stock of the affected devices - identify customers (i.e., hospitals) that received or may have received the affected devices - inform their customers of the FSN - return the unused, affected devices in their inventory and the inventory of their customers to the manufacturer. 		
3.	<table border="1" style="width: 100%;"> <tr> <td style="width: 40%;">2. By when should the action be completed?</td> <td style="text-align: center;">16/02/2026</td> </tr> </table>	2. By when should the action be completed?	16/02/2026
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4. General Information	
4.	1. FSN Type New
4.	2. For updated FSN, reference number and date of previous FSN N/A
4.	3. For Updated FSN, key new information as follows: N/A
4.	4. Further advice or information already expected in follow-up FSN? No
4.	5. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)
	a. Company Name Andocor NV
	b. Address Kruisblok 9, 2320 Hoogstraten, Belgium
	c. Website address www.andocor.com
4.	6. The Competent (Regulatory) Authority of your country has been informed about this communication to customers.
4.	7. List of attachments/appendices: Field Safety Notice Distributor/Importer Reply Form; Field Safety Notice Customer Reply Form
4.	8. Name/Signature Insert Name and Title here and signature below

Transmission of this Field Safety Notice	
	<p>This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate)</p> <p>Please transfer this notice to other organisations on which this action has an impact. (As appropriate)</p> <p>Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.</p> <p>Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.</p>