



COOK MEDICAL EUROPE LTD.

FSN & FSCA Ref: 2025FA0001

Date: 17 April 2025

**Urgent Field Safety Notice – Medical Device Removal**  
**Check-Flo Performer<sup>®</sup> Introducer**

For Attention of: Chief Executive / Risk Management / Purchasing

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

Cook Medical Europe Ltd.

[Redacted address information]

E-mail:

Phone:

[Redacted contact details]

For any further information or support concerning the information within this FSN, please contact your local Cook Medical Sales Representative or Cook Medical Europe Ltd.



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## **Urgent Field Safety Notice – Medical Device Removal**

### **Check-Flo Performer® Introducer**

#### **Risk Addressed by FSN**

<b>1. Information on Affected Devices</b>	
1.	<p><b>1. Device Type(s)</b></p> <p>Performer introducers are designed to perform as a guiding sheath and/or introducer sheath and come with a Check-Flo® value. Some Performer introducers are available with a radiopaque tip incorporated in the sheath material to identify the location of the sheath's distal tip.</p> <p>RPN RCFW-14.0-38-30-RB products are intended to be supplied with a 14 French introducer sheath.</p>
1.	<p><b>2. Commercial name(s)</b></p> <p>Check-Flo Performer® Introducer</p>
1.	<p><b>3. Unique Device Identifier (UDI-DI)</b></p> <p>(01)00827002089570(17)271210(10)16376242</p>
1.	<p><b>4. Primary clinical purpose of device(s)</b></p> <p>Performer introducers and guiding sheaths are intended to introduce therapeutic or diagnostic devices into the vasculature.</p>
1.	<p><b>5. Device Model/Catalogue/Part Number(s)</b></p> <p>Reference Part Number (RPN): RCFW-14.0-38-30-RB Order Number (GPN): G08957</p>
1.	<p><b>6. Affected serial or lot number range</b></p> <p>16376242</p>



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<b>2. Reason for Field Safety Corrective Action (FSCA)</b>	
2.	<p><b>1. Description of the product problem</b></p> <p>Cook Medical identified that devices from the affected device lot may contain the incorrectly sized introducer sheath.</p> <p>This issue was identified via field complaints; multiple users have reported the introducer sheaths from lots 16376242 to be the incorrect size. Furthermore, inspection of products remaining in-house from these lots revealed they contained the incorrectly sized introducer sheath.</p> <p>You are receiving this letter as Cook Medical records indicate that impacted products were shipped to your facility.</p>
2.	<p><b>2. Hazard giving rise to the FSCA</b></p> <p>If this issue is detected prior to patient contact, the user may experience increased procedural time. If this issue is not detected prior to patient contact, potential adverse events that may occur include increased procedural time, access site injury, and/or vessel injury.</p> <p>To date, Cook Medical has not received any customer complaints related to the adverse patient effects listed above for the affected lots; this issue was detected prior to use in all relevant customer complaints received thus far.</p>
<b>3. Type of Action to Mitigate the Risk</b>	
3.	<p><b>1. Actions To Be Taken by the User</b></p> <p><input checked="" type="checkbox"/> Identify Device(s)  <input checked="" type="checkbox"/> Quarantine Device(s)  <input checked="" type="checkbox"/> Return Device(s) to Cook Medical  <input checked="" type="checkbox"/> Other</p> <p>Please complete the enclosed Customer Reply Form. Where devices are indicated as being returned, our Customer Services department will contact you to organize the return and issue you with the relevant Returns Authorization number. Please include contact details on the Customer Reply form.</p> <p>Returned Device(s) should be addressed to:  Cook Medical EUDC  Robert-Koch-Straße, 2  52499 Baesweiler  GERMANY</p> <p>Credit will be provided for the returned affected device(s) where applicable.</p>
3.	<p><b>2. Is Customer Reply Required?</b>  Form is attached specifying deadline for return.</p> <p style="text-align: right;">Yes</p>
3.	<p><b>3. Action Being Taken by the Manufacturer</b></p> <p><input checked="" type="checkbox"/> Product Removal</p>



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4. General Information		
4.	1. FSN Type	New
4.	2. Further advice or information already expected in follow-up FSN?	No
4.	3. Manufacturer information Refer to page 1 of this FSN for contact details of local representative.	
	a. Company Name	Cook Incorporated
	b. Address	[REDACTED]
4.	4. The Competent (Regulatory) Authority of your country has been informed about this communication to customers.	
4.	5. Name/Signature	[REDACTED]
		[REDACTED]

#### Transmission of this Field Safety Notice

This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the affected devices have been transferred.

Please transfer this notice to other organisations on which this action has an impact.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

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.