COOK MEDICAL EUROPE LTD.
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FSN & FSCA Ref: 2026FA0002

Date: 25 February 2026

Urgent Field Safety Notice
Instinct Plus Endoscopic Clipping Device

For Attention of: Chief Executive / Risk Management / Purchasing / Procurement Officer

Contact details of local representative (name, e-mail, telephone, address etc.)
Cook Medical Europe Ltd. O'Halloran Road National Technology Park Limerick, Ireland E-mail: European.FieldAction@CookMedical.com Phone: Please refer to the attached Country Contacts List 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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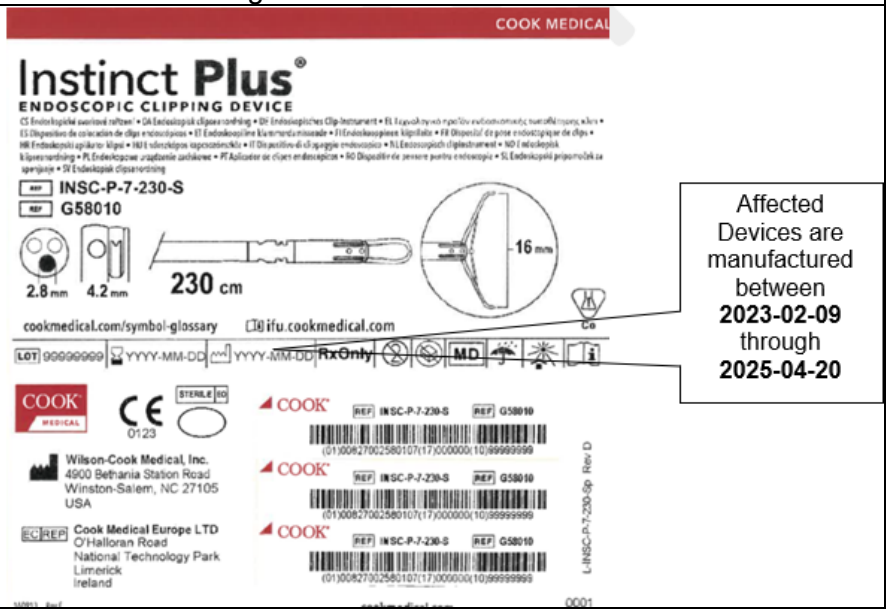
Urgent Field Safety Notice (FSN)
Instinct Plus Endoscopic Clipping Device

Information on Affected Devices	
1.	1. Device Type(s)
	Instinct Plus Endoscopic Clipping Device is a long-term, non-bioabsorbable gastrointestinal endoscopic clip.
1.	2. Commercial name(s)
	Instinct Plus Endoscopic Clipping Device
1.	3. Primary clinical purpose of device(s)
	Instinct Plus Endoscopic Clipping Device is intended for endoscopic clip placement within the gastrointestinal tract for the purpose of: 1. Endoscopic marking, 2. Hemostasis for • Mucosal/submucosal defects less than 3 cm, • Bleeding ulcers, • Arteries less than 2 mm, • Polyps less than 1.5 cm in diameter, • Diverticula in the colon, and • Prophylactic clipping to reduce the risk of delayed bleeding post lesion resection, 3. Anchoring to affix jejunal feeding tubes to the wall of the small bowel, 4. As a supplementary method for closure of GI tract luminal perforations less than 20 mm that can be treated conservatively, 5. Anchoring to affix fully covered esophageal self-expanding metal stents to the wall of the esophagus in patients with fistulas, leaks, perforations, or disunion.
1.	4. Device Model/Catalogue/part number(s)
	INSC-P-7-230-S/G58010
1.	5. Affected serial or lot number range
	This recall is for all INSC-P-7-230-S devices manufactured between 2023-02-09 through 2025-04-20.



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	Reason for Field Safety Corrective Action (FSCA)
2.	1. Description of the product problem
	Cook Medical has received reports of a malfunction that occurs when the user attempts to open the clip jaws by actuating the handle. The malfunction that may occur is the clip housing detaching from the catheter attachment and the clip remaining attached to the drive wire. Please see Figure 1 for a visual representation of the malfunction. The clip will extend from the catheter, but it will remain attached to the internal drive wire instead of opening the clip jaws. The clip cannot be opened if this occurs.  *Figure 1* This malfunction was previously communicated in FSN 2025FA0005; however, Cook is now voluntarily removing certain lot numbers from the field because they were manufactured prior to implementation of updated manufacturing processes, which are intended to reduce occurrences of this device malfunction.
2.	2. Hazard giving rise to the FSCA
	Potential hazardous situations that could occur due to this malfunction are significant delay in procedure, foreign object detachment in the patient, clip not deploying as intended, additional hemostasis treatment, or a sharp object exposed at the patient end of the device. Potential harms to the patient that may occur with the above hazardous situations are bleeding that may or may not require intervention, surgery or interventional radiology, rebleed, perforation, laceration or other injury, mucosal tearing or irritation, hospitalization for observation, endoscopic retrieval of an object, aspiration, intubation, or death. Additionally, the device failure may result in deployment of the clip without being attached to tissue, or the malfunction could be recognizable prior to use and the device would be replaced with an insignificant delay in procedure and the potential for injury is unlikely.
2.	3. Probability of problem arising
	The probability of this incident occurring is occasional.
2.	4. Predicted risk to patient/users
	The current performance supports a risk level of negligible to low with a worst-case potential risk of high.
2.	5. Background on Issue
	In 2025, Cook Endoscopy, as a United States-based manufacturer, brought heightened awareness to Instinct Plus users of the potential malfunction as described above in Section 2.1. The manufacturing processes were updated to reduce the likelihood of this malfunction and all non-expired devices that were manufactured prior to the implementation are being removed from the market.

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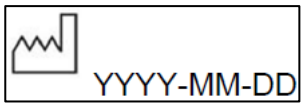
Type of Action to mitigate the risk		
3.	1. Action To Be Taken by the User ☒ Identify Device ☒ Quarantine Device ☒ Return Device To determine if the device is affected, refer to the date of manufacture located on the product label beside the symbol below:  ☒ Complete Reply Form & Return to Cook Please complete the enclosed Reply Form. Where product is indicated as being available for return, our Customer Services department will contact you to organize the return and issue you with the relevant Returns Authorization number. Please include your contact details on the Reply Form. Returned Product should be addressed to: Cook Medical EUDC Robert-Koch-Straße, 2 52499 Baesweiler Germany Credit will be provided for the returned affected products where applicable.	
3.	2. By when should the action be completed?	Within five (5) business days of receipt.
3.	3. Is customer Reply Required? *	Yes, within five (5) business days of receipt.
3.	4. Action Being Taken by the Manufacturer ☒ Product Removal Affected lot numbers of Instinct Plus devices are being removed from the market and should be returned to Cook per the attached directions on the Field Action Reply Form.	
3	5. By when should the action be completed?	Within five (5) business days of receipt.
3.	6. Is the FSN required to be communicated to the patient /lay user?	No

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General Information		
4.	1. FSN Type	New
4.	2. Further advice or information already expected in follow-up FSN?	No
4.	3. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Cook Endoscopy/Wilson-Cook Medical, Inc.
	b. Address	4900 Bethania Station Road, Winston-Salem, NC USA
4.	4. The Competent (Regulatory) Authority of your country has been informed about this communication to customers.	
4.	5. Name/Signature	Blair Younts Team Lead, Regulatory Reporting & Field Actions

	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 potentially 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.