COOK MEDICAL EUROPE LTD.
O'HALLORAN ROAD
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LIMERICK, V94 N8X2, IRELAND
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WWW.COOKMEDICAL.EU

FSN and FSCA Ref: 2025FA0004 (2025_CIRL_FA002)

Date: 14-May-2025

Urgent Field Safety Notice

Universa® Soft Ureteral Stent Set
&
Universa® Firm Ureteral Stent Set

For Attention of*:Chief Executive/Risk Management/Purchasing

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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Universa® Soft Ureteral Stent Set
&
Universa® Firm Ureteral Stent Set

Risk addressed by FSN

1. **Information on Affected Devices**	
1.	1. Device Type(s)
	Used for temporary internal drainage from the ureteropelvic junction to the bladder. The set includes a stent, a stent positioner, and a wire guide. Device is supplied sterile
1.	2. Commercial name(s)
	Universa® Soft Ureteral Stent Set and Universa® Firm Ureteral Stent Set
1.	3. Unique Device Identifier(s) (UDI-DI)
	USI: SOFT0827002CIRL202007008009CD UFI: FIRM0827002CIRL202309008036FP
1.	4. Primary clinical purpose of device(s)
	Universa® Soft Ureteral Stent Set and Universa® Firm Ureteral Stent Set are used for temporary internal drainage from the ureteropelvic junction to the bladder. Ureteral stents have been employed to relieve obstruction in a variety of benign, malignant and post-traumatic conditions. These stents may be placed using endoscopic, percutaneous, or open surgical techniques. The multi-length stents will accommodate ureters from approximately 22-32cm in length.
1.	5. Device Model/Catalogue/part number(s)
	See attached customer distribution list
1.	6. Software version
	N/A
1.	7. Affected serial or lot number range
	See attached customer distribution list
1.	8. Associated devices
	N/A

2 **Reason for Field Safety Corrective Action (FSCA)**	
2.	1. Description of the product problem
	The heat sealer used to seal the tyvek lid to the tray for USI/UFI product between the 07 August 2024 and the 03 April 2025, periodically aborted heat seal cycles resulting in heat seal cycle times outside of validated settings. The sterile barrier of all units sealed during

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	this time are potentially impacted which may affect sterility which poses a risk to patient health.
2.	2. Hazard giving rise to the FSCA
	If a contaminated ureteral stent is placed in a patient, the harm will be that an infection could develop from microorganisms residing on the stent. Given that the device is indwelling in a semi-permanent manner increases the likelihood that infection will develop. The severity of the infection will depend on many factors, both from the pathogenic microorganism as well as patient- and procedure-related factors including Urinary tract infections, Kidney infection, sepsis, renal damage, formation of encrustations or stones of encrustations or stones, biofilm formation and/or fistula formation.
2.	3. Probability of problem arising
	It is considered a reasonable probability that the patients could develop the above mentioned health outcomes.
2.	4. Predicted risk to patient/users
	Immediate Health Consequences *Urinary Tract Infection (UTI):* The presence of an infected stent can lead to localized infections in the urinary tract, characterized by symptoms such as burning during urination, urgency, frequency, and cloudy or foul-smelling urine. *Pyelonephritis (Kidney Infection):* Infections can ascend to the kidneys, resulting in pyelonephritis. Symptoms may include fever, chills, flank pain, nausea, and vomiting. This condition requires prompt medical attention to prevent further complications. *Sepsis:* If the infection spreads beyond the urinary tract, it can lead to urosepsis, a life-threatening infection with a systemic inflammatory response. Symptoms include high or low body temperature, rapid heart rate, rapid breathing, confusion, and death. **Long-Term Health Consequences** *Renal Damage:* Persistent infections can lead to kidney damage or scarring, potentially resulting in reduced kidney function or chronic kidney disease. *Formation of Encrustations or Stones:* Long-term exposure to an infected stent can lead to mineral deposits forming around the stent, which may cause additional blockages or require surgical intervention. *Biofilm Formation:* Bacteria can form biofilms on the stent, making the infection more resistant to antibiotics difficult to treat. This can lead to persistent infections and complications over time.

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	Fistula Formation: In rare cases, prolonged infection can lead to abnormal connections between organs (e.g., urinary tract and adjacent structures), requiring surgical repair.
2.	5. Other information relevant to FSCA
	The Heat Sealer is used for 93 RPNs but only 70 of these RPNs were manufactured and sealed between the 07 August 2024 and the 03 April 2025, therefore only RPNs and lot numbers manufactured in this time frame are relevant to the FSCA.

	3. Type of Action to mitigate the risk	
3.	**1. Action To Be Taken by the User** ☒ Identify Device ☒ Quarantine Device ☒ Return Device ☐ Destroy Device ☐ On-site device modification/inspection ☒ Follow patient management recommendations ☐ Take note of amendment/reinforcement of Instructions For Use (IFU) ☒ Other ☐ None Please complete the enclosed Customer / Distributor 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 / Distributor Reply form. Returned Device(s) should be addressed to: Cook Medical EUDC Robert-Koch-Straße, 2 52499 Baesweiler GERMANY Credit will be provided for the returned affected device(s) where applicable	
3.	2. By when should the action be completed?	13-Jun-2025

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3.	3. Particular considerations for: Implantable device Is follow-up of patients or review of patients' previous results recommended? Yes Physicians should follow their institution's protocols/guidelines for the standard of patient care after the procedure for identification and treatment (s) of infection or any complications**.**	
3.	4. Is customer Reply Required? (If yes, form attached specifying deadline for return)	Yes
3.	**5. Action Being Taken by the Manufacturer** ☒ **Product Removal** ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☐ Other ☐ None Provide further details of the action(s) identified: N/A.	
3	6. By when should the action be completed?	13-Jun-2025
3.	7. Is the FSN required to be communicated to the patient /lay user?	No

	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. If follow-up FSN expected, what is the further advice expected to relate to:	
	N/A	

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4	6. Anticipated timescale for follow-up FSN	N/A
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Cook Ireland Ltd
	b. Address	O'Halloran Road, National Technology Park, Limerick, Ireland.
	c. Website address	www.cookmedical.eu
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers.	
4.	9. List of attachments/appendices:	See attached list of affected lots
4.	10. Name/Signature	Annemarie Beglin Annemarie Beglin (May 14, 2025 16:12 GMT+1)
		Annemarie Beglin **Director, Quality Assurance** **Cook**

	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. (As appropriate) Please transfer this notice to other organisations on which this action has an impact. (As appropriate) 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.