COOK MEDICAL EUROPE LTD.
O'HALLORAN ROAD
NATIONAL TECHNOLOGY PARK
LIMERICK, V94 N8X2, IRELAND
TEL: +353 61 334440 FAX: +353 61 334441
WWW.COOKMEDICAL.EU

FSN & FSCA Ref: 2023FA0008

Date: 20JUL2023

Urgent Field Safety Notice – Medical Device Recall
Lead Clippers

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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Risk addressed by FSN

1. Information on Affected Devices	
1.	**1. Device Type(s)**
	Lead Clippers are an auxiliary tool indicated for use in patients requiring percutaneous retrieval of cardiac leads.
1.	**2. Commercial name(s)**
	Lead Clippers
1.	**3. Primary clinical purpose of device(s)**
	Lead Clippers are used to separate the connector from pacemaker or defibrillator lead wire.
1.	**4. Device Model/Catalogue/Part Number(s)**
	Reference Part Number (RPN): LR-CLP001 Order Number (GPN): G20003
1.	5. **Affected serial or lot number range**
	N172912, N178633, N178677, N182691, N184187, N184320, N192312, N194720, N187302, N188171, N194884, N172737, N173178, N174134, N174864, N174906, N175201, N175277, N176323, N178518, N179397, N179728, N180115, N181397, N181437, N181629, N182095, N183533, N183826, N183939, N184517, N184881, N185570, N187777, N188290, N188322, N188490, N188741, N189965, N190539, N190720, N191357, N191583, N191973, N192341, N192497, N193021, N193571, N193731, N194362, N194666, N195113, N194084, N174170, N178093, N179534, N187519, N188615, N189751, N192120, N173653, N177898, N177797, N190400, N172875, N173959, N174841, N176830, N180459, N183042, N178609, N179301, N185880, N189099, N195038, N173977, N175964, N177515, N180077, N180953, N184990, N185239, N186318, N187000, N187727, N191791, N191870, N192310, N173691, N174294, N185335, N185615, N186683, N186963, N187107, N187359, N188466, N189666, N189805, N190813, N193490, N195447, N177102, N178814, N183261, N183457, N176716, N187246, N179021, N177239, N186888, N180504, N184518, N193119, N186749, and N189987

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2. Reason for Field Safety Corrective Action (FSCA)	
2.	**1. Description of the product problem** Cook Medical Vandergrift identified that Lead Clippers may experience a complete breach of the chevron seal of the packaging. Therefore, the sterility of affected devices may be compromised.
2.	**2. Hazard giving rise to the FSCA** The affected devices may be non-sterile or contaminated with microorganisms. Potential adverse events that may occur if an affected product is used include infection, potentially being life-threatening and/or requiring medical/surgical intervention. To date, Cook Medical Vandergrift has not received any customer complaints related to the adverse patient effects listed above for the affected lots. However, please be advised that compromised device sterility may go undetected by the user.

3. Type of Action to Mitigate the Risk	
3.	**1. Action To Be Taken by the User** ☒ Identify Device ☒ Quarantine Device ☒ Return Device ☒ Other Please complete the enclosed Customer Reply Form. Where product is 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. 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. Is Customer Reply Required?** Yes. Form is attached specifying deadline for return.
3.	**3. Action Being Taken by the Manufacturer** ☒ Product Removal
3.	**4. Is follow-up of patients or review of patients' previous results recommended?** Physicians should practice standard of care patient monitoring following the procedure for early identification of any complications to mitigate their severity. Cook Medical Vandergrift is not recommending additional patient monitoring as infection would likely present physical signs and symptoms abnormal to post-procedural patient recovery and promptly trigger medical intervention.

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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 For contact details of local representative refer to page 1 of this FSN.	
	a. Company Name	Cook Medical Vandergrift
	b. Address	1186 Montgomery Lane Vandergrift, PA 15690, United States
4.	4. The Competent (Regulatory) Authority of your country has been informed about this communication to customers.	
4.	5. Name/Signature	 Thomas Kardos Vice President, Regulatory Affairs Cook Medical Vandergrift

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.

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Field Action Customer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number	2023FA0008
FSN Date	20Jul2023
Product/Device name	Lead Clippers
Product Code(s)	Reference Part Number (RPN): LR-CLP001 Order Number (GPN): G20003
Batch/Serial Number (s)	N172912, N178633, N178677, N182691, N184187, N184320, N192312, N194720, N187302, N188171, N194884, N172737, N173178, N174134, N174864, N174906, N175201, N175277, N176323, N178518, N179397, N179728, N180115, N181397, N181437, N181629, N182095, N183533, N183826, N183939, N184517, N184881, N185570, N187777, N188290, N188322, N188490, N188741, N189965, N190539, N190720, N191357, N191583, N191973, N192341, N192497, N193021, N193571, N193731, N194362, N194666, N195113, N194084, N174170, N178093, N179534, N187519, N188615, N189751, N192120, N173653, N177898, N177797, N190400, N172875, N173959, N174841, N176830, N180459, N183042, N178609, N179301, N185880, N189099, N195038, N173977, N175964, N177515, N180077, N180953, N184990, N185239, N186318, N187000, N187727, N191791, N191870, N192310, N173691, N174294, N185335, N185615, N186683, N186963, N187107, N187359, N188466, N189666, N189805, N190813, N193490, N195447, N177102, N178814, N183261, N183457, N176716, N187246, N179021, N177239, N186888, N180504, N184518, N193119, N186749, and N189987

2. Customer Details	
Account Number	
Healthcare Organisation Name	
Organisation Address	
Department/Unit	
Contact Name	
Title or Function	
Telephone number	
Email	

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3. Customer action undertaken on behalf of Healthcare Organisation		
☐	I confirm receipt of the Field Safety Notice and that I read and understood its content.	
☐	The information and required actions have been brought to the attention of all relevant users and executed.	
☐	I have affected devices to return - enter Lot number and quantities in table below.	
☐	No affected devices are available for return/ destruction	
Print Name		
Signature		
Date		

4. Return acknowledgement to sender	
Email	European.FieldAction@CookMedical.com
Customer Helpline	Please refer to the attached Country Contacts List
Fax	+ 353 61 239294
Deadline for returning the customer reply form*	Please return this form within 5 business days of receipt, even if you do not have any of the affected product(s).

If you are returning/destroying any affected product, please indicate the part number, lot number and quantity:

Product Part Number	Product Lot Number	Quantity

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It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.