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: 2022FA0002

Date: DD:MMM:YYYY.

Urgent Field Safety Notice – Medical Device Recall
Roadrunner® PC Hydrophilic Wire Guide
Roadrunner® UniGlide® Hydrophilic Wire Guide

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.

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: 2022FA0002

Urgent Field Safety Notice (FSN) – Medical Device Recall
Roadrunner® PC Hydrophilic Wire Guide
Roadrunner® UniGlide® Hydrophilic Wire Guide

Risk addressed by FSN

1. Information on Affected Devices		
	1. Device Type(s)	
1.	The Roadrunner PC Wire Guide is coated with AQ (a biocompatible hydrophilic coating), which when activated becomes lubricious. The wire guide is made of a nitinol core with a distal platinum inner spring coil tip, which is completely covered by a bismuth-impregnated polymer jacket. Utilizing proprietary processes, the Roadrunner UniGlide Hydrophilic Wire Guide is constructed from a steerable, metallic core with a polymer coating. A hydrophilic coating is applied over the radiopaque polymer jacket. Wire guide Length, Diameter, Coating, Tip, and Core configurations are indicated on the product label.	
	2. Commercial name(s)	**3. Primary clinical purpose of device(s)**
1.	Roadrunner® PC Hydrophilic Wire Guide	The Roadrunner PC Wire Guide is used for catheter positioning and exchange in diagnostic and interventional procedures, exclusive of the coronary arteries.
	Roadrunner® UniGlide® Hydrophilic Wire Guide	The Roadrunner UniGlide Hydrophilic Wire Guide is intended for use in facilitating the delivery of percutaneous catheters into the peripheral vasculature.

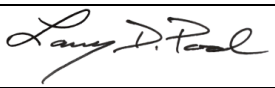
Please refer to Page 5 of this FSN for affected Part Numbers and Lots.

2. Reason for Field Safety Corrective Action (FSCA)	
	1. Description of the product problem
2.	Cook Medical identified that samples from the affected device lots did not meet the acceptance criteria for packaging testing, which included 3-year age acceleration testing. This failure was traced to material that is supplied to Cook Medical from an external supplier.
	2. Hazard giving rise to the FSCA
2.	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 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.

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: 2022FA0002

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 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.

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 Incorporated
	b. Address	750 Daniels Way Bloomington, IN 47402, United States
4.	4. The Competent (Regulatory) Authority of your country has been informed about this communication to customers.	
4.	5. Name/Signature	 Larry D. Pool Director, Post Market Cook Incorporated

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: 2022FA0002

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.

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: 2022FA0002

Product Information

REFERENCE PART NUMBER (RPN)	ORDER NUMBER (GPN)	LOT NUMBERS
HPW-35-150	G56149	14070921, 14108915, 14108916, 14129152, 14141997, 14170230
HPWA-18-150	G56161	14095646, 14174879
HPWA-18-80	G56162	14070920, 14174878
HPWA-35-150	G56173	14070910, 14070913, 14070914, 14070915, 14070916, 14070917, 14080810, 14104898, 14104899, 14104902, 14106628, 14106629, 14120473, 14120474, 14120475, 14122089, 14122091, 14122093, 14122095, 14122322, 14129155, 14129156, 14129157, 14129158, 14129161, 14129162, 14129163, 14131012, 14131013, 14131014, 14134680, 14134681, 14134683, 14134684, 14139356, 14142001, 14142004, 14142005, 14142007, 14147337, 14147338, 14147339, 14148371, 14160531, 14160533, 14160534, NS14095649, NS14122100, NS14122327, NS14129168, NS14131010, NS14131011, NS14131015, NS14133505, NS14142008, NS14147334, NS14147335, NS14147336, NS14147336X, NS14153793, NS14176970
HPWA-35-80	G56172	14156569
HPWAS-35-150	G56176	14112845, NS14062106, NS14080814, NS14089120, NS14118843, NS14139358, NS14142006, NS14144747, NS14148490, NS14149799, NS14153797, NS14172915
HPWAS-35-80	G56175	14174876, 14174880, NS14104906, NS14173970, NS14173971
HPWS-35-150	G56152	14118842
HPWS-35-80	G56151	14156572
RFPC-35-180	G07937	14145420, 14145424, 14156909, 14156912, 14156916, 14164348, 14173577
RFSPC-35-180	G09608	14071906, 14091204, 14134663, 14134667, 14134669, 14134670, 14134673, 14134676, 14143872, 14143873, 14160997, 14184102, NS14143735, NS14152903
RLPC-35-180	G07516	14103953, 14103956, 14143728, 14145412, 14145419, 14153927, 14156907, 14156908, 14156914, 14160996
RPC-35-180	G07518	14063361, 14087089, 14087092, 14117033, 14120926, 14120928, 14151216, 14151218, 14153159, 14158614, 14159695, 14159696