



20 Jul 2022

URGENT: MEDICAL DEVICE RECALL
Roadrunner® PC Hydrophilic Wire Guide
Roadrunner® UniGlide® Hydrophilic Wire Guide

ATTENTION:
 Risk Management/Recall Administration
Our records indicate that you have received affected products.

Patient safety and customer satisfaction are Cook Medical's highest priorities. We appreciate your time and attention in reading this important notice.

Purpose of this Letter

The purpose of this letter is to inform you that Cook Medical is voluntarily recalling specific lots of Roadrunner® PC Hydrophilic Wire Guide and Roadrunner® UniGlide® Hydrophilic Wire Guide.

Reason for Voluntary Recall

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. Therefore, the sterility of affected devices may be compromised. This failure was traced to material that is supplied to Cook Medical from an external supplier.

Product Information

PRODUCT BRAND NAME	INTENDED USE
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.

See Page 3 for a complete list of affected products and lots.

Market Impact

This recall is strictly specific to lots listed on Page 3. Unaffected devices will continue to be accessible on the market for purchase based on availability.



Risk to Health

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 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.

Actions to be Taken by the Customer

1. Examine inventory immediately to determine if you have affected product(s) and quarantine any affected product that remains unused. Immediately cease all further distribution and use of the affected products.
2. Return the affected product(s) to Cook Medical with a copy of the Acknowledgement and Receipt Form to receive a product credit. Refer to the Acknowledgement and Receipt Form for return instructions.
3. Please complete the Acknowledgement and Receipt Form within **5 business** days of receiving this letter regardless of whether you have affected product(s) on hand. You may return the Form to your local Cook Medical Sales Representative or email to Cook Medical Quality Assurance department (MLY-QA@cookmedical.com).
4. This notice must be shared with appropriate personnel, including down to the user level, within your organization or with any organization where the potentially affected devices have been transferred.
5. Please immediately report adverse events to Cook Medical Quality Assurance department (Email to: MLY-QA@cookmedical.com).

Action being Taken by Cook Medical

Cook Medical is removing potentially affected products from the market. Additionally, a supplier investigation has been opened to determine the appropriate corrective action(s) to prevent reoccurrence of a similar issue.

Other Information

This action is being taken with the knowledge of the Food and Drug Administration.

We recognize that this situation is a potential disruption to your normal operations, and we sincerely apologize. Thank you for your immediate assistance in this matter. If you have any questions or concerns, please email to Cook Medical Quality Assurance department.

Sincerely,

 20 Jul 2022

Jason Poh
Quality Assurance Manager
Cook Asia (Malaysia) Sdn Bhd



Product Information

REFERENCE PART NUMBER (RPN)	ORDER NUMBER (GPN)	DEVICE IDENTIFIER (DI)	LOT NUMBERS
HPW-35-150	G56149	(01)00827002561496-	14070921, 14108915, 14108916, 14129152, 14141997, 14170230
HPWA-18-150	G56161	(01)00827002561618-	14095646, 14174879
HPWA-18-80	G56162	(01)00827002561625-	14070920, 14174878
HPWA-35-150	G56173	(01)00827002561731-	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	(01)00827002561724-	14156569
HPWAS-35-150	G56176	(01)00827002561762-	14112845, NS14062106, NS14080814, NS14089120, NS14118843, NS14139358, NS14142006, NS14144747, NS14148490, NS14149799, NS14153797, NS14172915
HPWAS-35-80	G56175	(01)00827002561755-	14174876, 14174880, NS14104906, NS14173970, NS14173971
HPWS-35-150	G56152	(01)00827002561526-	14118842
HPWS-35-80	G56151	(01)00827002561519-	14156572
RFPC-35-180	G07937	(01)00827002079373-	14145420, 14145424, 14156909, 14156912, 14156916, 14164348, 14173577
RFSPC-35-180	G09608	(01)00827002096080-	14071906, 14091204, 14134663, 14134667, 14134669, 14134670, 14134673, 14134676, 14143872, 14143873, 14160997, 14184102, NS14143735, NS14152903
RLPC-35-180	G07516	(01)00827002075160-	14103953, 14103956, 14143728, 14145412, 14145419, 14153927, 14156907, 14156908, 14156914, 14160996
RPC-35-180	G07518	(01)00827002075184-	14063361, 14087089, 14087092, 14117033, 14120926, 14120928, 14151216, 14151218, 14153159, 14158614, 14159695, 14159696