Company Announcement

When a company announces a recall, market withdrawal, or safety alert, the FDA posts the company's announcement as a public service. FDA does not endorse either the product or the company.

Cook Medical Issues Global Recall of Roadrunner® UniGlide® Hydrophilic Wire Guides due to raw materials issue

SHARE TWEET LINKEDIN PIN IT EMAIL PRINT

For Immediate Release

August 15, 2016

Contact

Consumers

Cook Medical Customer Relations

CustomerRelationsNA@cookmedical.com

1-800-457-4500 or 1-812-339-2235

Media

Marsha Lovejoy, Global Manager, Corporate Content Strategy

marsha.lovejoy@cookmedical.com

1-812-339-2235 ext. 2750

Announcement

DSM Biomedical B.V., the Netherlands, Cook Medical's supplier of hydrophilic coating for the Roadrunner® Uniglide® Hydrophilic Wire Guide, recalled certain lots of material due to concerns about a potential contamination by glass particles ranging in size of approximately 4 to 280 µm. Cook received one lot of the affected recalled

coating. This prompted Cook Medical to initiate a recall of 8,750 units of the Roadrunner UniGlide Hydrophilic Wire Guides on June 24, 2016. Cook is taking this action as a precautionary measure, because it cannot exclude the possibility that glass particles passed through during processing and could be present in the coating of the recalled wire guide units.

Potential adverse events that may occur as a result of this contamination could include vessel damage, bleeding and embolic particulate in the circulatory system. Cook Medical has not received any reports of adverse events of these types to date.

The Roadrunner UniGlide Hydrophilic Wire Guide is intended for use in the delivery of percutaneous catheters into the peripheral vasculature.

A full list of affected products and lot numbers is attached. Products can be identified by the part number and lot number on the outer label of the package. Products in this recall were distributed globally.

Cook Medical has notified its customers and distributors by recall notification letters. The letters requested that all customers and distributors quarantine and discontinue use of all recalled units and return the affected products to Cook as soon as possible for credit.

The FDA and other regulatory agencies around the world have been notified of this action.

Consumers with medical questions or concerns should contact Cook Medical Customer Relations at 1-800-457-4500 or 1-812-339-2235, Monday through Friday, between 7:30 a.m. and 5:00 p.m. Eastern time. For information regarding the recall, please contact *Stericycle Expert Solutions* at 1-866-912-9552.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax. Complete and submit the report online at www.fda.gov/medwatch/report.htm or via regular mail or fax. Download the form at www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, and then complete and return to the address on the preaddressed form, or submit by fax to 1-800-FDA-0178.

Adverse events may also be reported to Cook Medical Customer Relations at 1-800-457-4500 or 1-812-339-2235, Monday through Friday, between 7:30 a.m. and 5:00 p.m. Eastern time or by email at CustomerRelationsNA@cookmedical.com.

RPN	GPN	Affected Lot Numbers
HPW-35-150	G56149	6911533, 6911535, 6935851, 6968779, 6981351, 6986897, 6986898, 7000733
HPW-	G56150	6981026, 6981346

35-180		
HPWA-18-180	G56160	7000727, 7000730, 7000735, NS6999761
HPWA-18-260	G30489	6935843, 6935846, 6948858, 6965469, 6981347, NS6948859
HPWA-18-320	G30490	6911545, 6981349, 7015899
HPWA-25-260	G30491	7015857, 7019022, 7019027
HPWA-35-150	G56173	6911529, 6911530, 6948854, 6948855, 6948855X, 6948856, 6955232, 6955233, 6955234, 6955234X, 6955235, 6961754, 6961756, 6961757, 6961758, 6965625, 6965626, 6968777, 6975365, 6981022, 6995077, 6995078, 6995080, 7012528, 7012529, NS6975369, NS6981025, NS6995079, NS7000728
HPWA-35-180	G56174	6911522, 6911523, 6911524, 6911526, 6911527, 6911528, 6935844, 6955228, 6955229, 6955230, 6955231, 6965235, 6965236, 6965237, 6965238, 6975367, 6975368, 6988487, 6988488, 7015853, 7015854, 7016252, 7016253, 7019017, 7019018, 7019491, 7019492, 7019493, 7019494, 7021223, 7021225, 7021226, 7021227, NS6911520, NS6935845, NS6935847, NS7019495
HPWA-35-260	G30492	6948857, 6961759, 6965240, 6986896, 7000724, 7000725, 7000726, 7012840, 7019019, 7019020, NS6965239, NS6968778, NS6999757, NS6999758, NS7012841, NS7019023, NS7019024
HPWA-35-80	G56172	6948860
HPWAS-35-150	G56176	6919676, 6919680, 6935853, 6935855, 6961761, 6995082, 6995083, 7022591, NS6935854
HPWAS-35-180	G56177	6961752, 6961753, 7012526, 7012527, 7015855, 7015856, 7021222, 7021224
HPWAS-35-260	G30506	6911549, 6911551, 6911552, 6919678, 6935848, 6935849, 6935850, 6935852, 6948861, 6948862, 6955236, 6955237, 6997860, 7000732, 7015897, 7015898, 7019025
HPWS-35-150	G56152	6961755, 6961760, 6999760
HPWS-35-180	G56153	6992197, 6992198, 6999759, 7012530

###

Follow FDA

- Follow @US_FDA
- Follow FDA
- Follow @FDArecalls
- Recent Recalled Product Photos on FDA's Flickr Photostream

Page Last Updated: 08/15/2016
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
1-888-INFO-FDA (1-888-463-6332)

Contact FDA