



November 08, 2019

URGENT: MEDICAL DEVICE RECALL
CrossCath® Support Catheter

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

Cook Medical considers the safety and satisfaction of our customers a top priority. We appreciate your time and attention in reading this important notice.

Purpose of this Letter

The purpose of this letter is to advise you that Cook Medical is voluntarily recalling specific lots of the CrossCath® Support Catheter. Refer to the Product Information section below for the list of affected products.

The CrossCath® Support Catheter is intended for use in small vessel or superselective anatomy for diagnostic and interventional procedures, including peripheral use.

Reason for Voluntary Recall

Cook Medical has identified that an error occurred during manufacturing which may cause the radiopaque marker bands to be too loose on certain CXC3.0 CrossCath® Support Catheters (compatible with 0.014” wire guides) and too tight on certain CXC3.4 CrossCath® Support Catheters (compatible with 0.018” wire guides).

Risk to Health

If radiopaque marker bands are too loose, they can potentially dislodge from their original position. Potential adverse events that may occur if an affected product is used include increased procedural time to obtain a replacement, additional intervention to remove separated marker band(s), and embolism.

If radiopaque marker bands are too tight, they may be deformed, crack, and/or separate. In addition to the potential adverse events listed above, there is the potential for increased procedural time due to difficult advancement of the catheter through a lesion and additional intervention to remove a catheter that becomes stuck within a lesion.

Product Information

PRODUCT BRAND NAME	CATHETER SIZE (PROXIMAL / DISTAL FR)	WIRE GUIDE COMPATIBILITY	REFERENCE PART NUMBER (RPN)	ORDER NUMBER	LOT NUMBER
CrossCath® Support Catheter	3.0 / 1.9 FR	0.014”	CXC3.0-1.9-14-90-P-NS-0	G51572	9945302
			CXC3.4-2.2-18-90-P-NS-0	G51575	9945303
	3.4 / 2.2 FR	0.018”	CXC3.4-2.2-18-135-P-NS-0	G51583	9953512
					9945301
			CXC3.4-2.2-18-150-P-NS-0	G51577	9950878
					9953506



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 distribution and use of this product.
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.

Note: Unaffected products that are returned will not be credited.

3. Please complete the Acknowledgement and Receipt Form within **5 business** days of receiving this letter. **Even if you do not have affected product(s) on hand**, you must still complete the Acknowledgement and Receipt Form and return via fax (812.339.7316) or email (FieldActionsNA@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. Immediately report adverse events to Cook Medical Customer Relations by phone at 800.457.4500 or 812.339.2235, Monday through Friday between 7:30am and 5:00pm (Eastern Time), or by email to: CustomerRelationsNA@CookMedical.com.

Action being Taken by Cook Medical

Cook Medical is removing impacted devices from the market while the root cause of the issue is fully investigated. Once the root cause is determined, corrective actions to prevent future recurrence will be implemented.

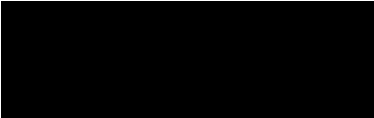
Other Information

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

Adverse events or quality problems experienced with the use of this product may also be reported to the FDA:

- Visit <http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm> to obtain a form to fax or mail.
- Call the FDA at 800.FDA.1088.

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 contact Cook Medical Customer Relations at 800.457.4500 or 812.339.2235. We look forward to your response.



Larry D. Pool
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Cook Incorporated