# Cook Medical Recalls CrossCath® Support Catheters Due to a Manufacturing Error Which May Cause the Marker Bands to Dislodge or Cause Buckling

*The FDA has identified this as a Class I recall, the most serious type of recall. Use of these devices may cause serious injuries or death.*

**Recalled Product** (Include the following information)

- CrossCath® Support Catheter
- Lot Numbers: 9945302, 9945303, 9953512, 9945301, 9950878, 9953506
- Model Numbers: CXC3.0-1.9-14-90-P-NS-0, CXC3.4-2.2-18-90-P-NS-0, CXC3.4-2.2-18-135-P-NS-0, CXC3.4-2.2-18-150-P-NS-0
- Manufacturing Dates: August 13, 2019 to August 16, 2019
- Distribution Dates: September 03, 2019 to September 19, 2019
- Devices Recalled in the U.S.: 117
- Date Initiated by Firm: November 8, 2019

**Device Use**
The CrossCath® Support Catheters are designed to support a wire guide during access of blood vessels, allow for exchange of wire guides, and provide a pathway for the delivery of saline solutions or diagnostic contrast agents. The catheters have three radiopaque markers spaced equally along the catheter to aid in estimating lengths within the blood vessels (vascular system).

**Reason for 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). Marker bands that are too loose can dislodge from their original position and marker bands that are too tight can cause buckling.

Use of the affected product can cause increased procedural time to obtain a replacement, increased procedural time due to difficult advancement of the catheter through a lesion, additional intervention to remove a catheter that becomes stuck within a lesion, additional intervention to remove separated marker band(s). There is also the potential that the separated

marker band cannot be retrieved, and it can cause permanent impairment like loss of limb; or the fragment can obstruct blood flow (embolize), resulting in life-threatening harm (e.g., stroke), or death.

**Who May be Affected**

- Interventional cardiologists, interventional radiologists, and surgeons who use the CrossCath® Support Catheter.
- Patients receiving cardiac surgery during which the CrossCath® Support Catheter is used.

**What to Do**

On November 8, 2019, Cook Medical issued an Urgent Medical Device Recall to customers, advising them of the product issue and provided the following instructions:

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. Complete the Acknowledgement and Receipt Form and return it to Cook Medical. **Even if you do not have affected product(s) on hand**, you must still complete the Acknowledgement and Receipt Form.
4. Share this notice with appropriate personnel, including 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 (mailto:CustomerRelationsNA@CookMedical.com).

**Contact Information**

Customers with questions or concerns can contact Cook Medical Customer Relations at 1-800-457-4500 or 1-812-339-2235, Monday through Friday between 7:30am and 5:00pm (Eastern Time).

Additional Resources:

- Class 1 Device Recall Cook Medical CrossCath Support Catheter, RPN CXC3.0-1.9-14-90-P-NS-0 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=177688)

- Class 1 Device Recall Cook Medical CrossCath Support Catheter, RPN CXC3.4-2.2-18-90-P-NS-0 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=177691)
- Class 1 Device Recall Cook Medical CrossCath Support Catheter, RPN CXC3.4-2.2-18-135-P-NS-0 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=177692)
- Class 1 Device Recall Cook Medical CrossCath Support Catheter, RPN CXC3.4-2.2-18-150-P-NS-0 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=177693)

**How do I report a problem?**

Health care professionals and consumers may report adverse reactions or quality problems (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home) they experienced using these devices to MedWatch: The FDA Safety Information and Adverse Event Reporting Program using an online form, regular mail, or FAX.