Cook Medical Inc. Recalls Transseptal Needle Due to Risk of Detached Plastic Fragments

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(s): Transseptal needle
- Lot Number: 8833687
- Model: TSNC-18-71.0
- Manufacturing Date: April 23, 2018
- Distribution Dates: May 30, 2018 to November 5, 2018
- Devices Recalled in the U.S.: 97

Device Use

The **Transseptal Needle (https://www.cookmedical.com/products/di_tsnc_webds/)** is used by surgeons to access the left side of a patient's heart during cardiac procedures. Fluoroscopy medical imaging and a guide catheter help the surgeon place the needle in the heart.

Reason for Recall

Cook Medical is recalling one lot of the Transseptal Needle due to a manufacturing error that resulted in some needle tips missing the back bevel that creates a sharp tip. Without a back bevel, the needle tip could damage the inside of the introducer sheath during insertion of the needle resulting in detached plastic fragments. These fragments could potentially enter the patient's bloodstream and result in serious adverse health consequences such as a longer procedure to retrieve the plastic pieces, injury to blood vessel walls, embolism, stroke, or death.

Who is affected?

- Health care providers using this needle during cardiac procedures
- Patients undergoing cardiac procedures with the use of these needles

What to Do

On February 1, 2019, Cook Inc. sent an Urgent Medical Device Recall notification letter to affected customers. The notice asked customers to:

- Share notice with appropriate staff
- Identify and remove any affected transseptal needles and quarantine affected needles

- Immediately stop all distribution and use of affected products
- Return any affected product(s) to Cook Inc. Medical with a copy of the Acknowledgement and Receipt Form to receive a product credit
- Complete and return the Acknowledgement and Receipt Form by fax at 812.339.7316 or email at FieldActionsNA@CookMedical.com (mailto:FieldActionsNA@CookMedical.com)

Contact Information

Health care professionals and distributors with questions are instructed to contact Cook Medical Customer Relations by phone at 800-457-4500 or 812-339-2235, Monday through Friday between 7:30 A.M. and 5:00 P.M. (Eastern Time) or by email to CustomerRelationsNA@CookMedical.com (mailto:CustomerRelationsNA@CookMedical.com).

Date Recall Initiated

February 1, 2019

How do I report a problem?

Health care professionals and consumers may report adverse reactions or quality problems they experience using these devices to MedWatch: The FDA Safety Information and Adverse Event Reporting Program (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home) either online, by regular mail or by FAX to 1-800-FDA-0178.

More in Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/default.htm)

2019 Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/ucm629347.htm)

2018 Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/ucm590900.htm)

2017 Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/ucm535289.htm)

2016 Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/ucm480134.htm)