Boston Scientific Corporation Recalls Imager II Angiographic Catheters Due to Tip Detachment

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

Boston Scientific Corporation IMAGER II 5F Angiographic Catheters

- See lot numbers below under Full List of Affected Devices
- Distribution Dates: July 16, 2018 to November 26, 2019
- Devices Recalled in the U.S.: 6,130
- Date Initiated by Firm: February 11, 2020

Device Use

The Boston Scientific Corporation IMAGER II 5F Angiographic Catheters are used to provide a pathway to deliver contrast agents to blood vessels including carotid arteries.

Reason for Recall

Boston Scientific Corporation is recalling IMAGER II 5F Angiographic Catheters because there is a potential for the catheter tip to become detached during a patient procedure or during procedure preparation.

Use of the affected product may lead to additional surgical intervention to remove the catheter tip in the patient's blood vessel and increased time in the hospital. There is also the potential for serious adverse events including obstruction of blood flow (embolism), stroke, or death.

There are nine reported injuries.

Who May be Affected

- Health care providers using the Boston Scientific IMAGER II 5F Angiographic Catheters
- Patients receiving cardiac surgery with the Boston Scientific IMAGER II 5F Angiographic Catheters

What to Do

On February 11, 2020, Boston Scientific Corporation sent a letter to customers informing them of the affected lot numbers and provided the following instructions:

- Remove any affected lots in the hospital inventory
- Stop using any product with the affected lot number
- Complete the Verification Form and include the quantity of units from each affected lot
- Return the affected lots to Boston Scientific Corporation

Contact Information

Customers who have questions about the notification should contact their local sales representative or BSCFieldActionCenter@bsci.com (mailto:BSCFieldActionCenter@bsci.com).

Full List of Affected Devices

Product Description	Outer Package UPN #	Inner Package UPN #	GTIN	Lot/Batch #	Expiration Date
Imager™ II Angiographic Catheter	M001314051	M001314050	08714729354871	134092	23-Aug-2020
	M001314051	M001314050	08714729354871	134600	12-Sep-2020
	M001314061	M001314060	08714729354888	134011	20-Aug-2020
	M001314141	M001314140	08714729354963	133737	10-Aug-2020
	M001314341	M001314340	08714729355168	139512	12-Mar-2021
	M001314581	M001314580	08714729355403	134631	13-Sep-2020
	M001314591	M001314590	08714729355410	132447	13-Jun-2020
	M001314661	M001314660	08714729355489	132355	8-Jun-2020
	M001315151	M001315150	08714729355892	132823	26-Jun-2020
	M001315151	M001315150	08714729355892	133447	13-Jul-2020
	M001315151	M001315150	08714729355892	133448	16-Jul-2020
	M001315151	M001315150	08714729355892	134946	25-Sep-2020

Additional Resources:

- Medical Device Recall Database Entry (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=179611)

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 either online, by regular mail or by FAX.