Oscor Recalls ATAR Reusable and Disposable Extension Cable(s) Due to Risk of Cable Separation from Connector

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)

- Oscor ATAR Reusable Extension Cable; Oscor ATAR Disposable Extension Cable
- Model/Item Numbers: See "**Full List of Affected Devices**"
- Lot Numbers: See "**Full List of Affected Devices**"
- Manufacturing Dates: January 1, 2011 to April 12, 2017
- Distribution Dates: January 11, 2011 to April 12, 2017
- Devices Recalled in the U.S.: 47,706

Device Use

Oscor's ATAR cable is an extension cable intended to connect an electrode/lead from a patient or another cable to a diagnostic machine or an external pacemaker.

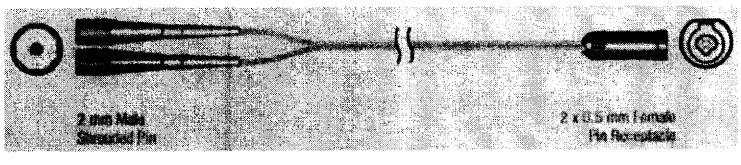

Image of the Oscor ATAR-MDR Extension Cable

Reason for Recall

Oscor Inc. is recalling specific lots of the ATAR Extension Cables due to a risk of the extension cables separating from the connectors during use.

Detachment of the extension cable and connectors can result in a delay and/or failure of cardiac pacing therapy for the patient. As the failure occurs without warning, it is possible that pacing-dependent patients may suddenly be left unpaced without adequate warning to their caregivers to quickly exchange the defective cable. Sudden pacing delay and/or failure may result in immediate and serious adverse health consequences, including death.

Who May be Affected

- Hospitals and health care professionals using Oscor's ATAR Reusable or Disposable Extension Cable.
- Patients and patient care-givers using the ATAR extension cables for cardiac pacing or diagnostic procedures.

What to Do

On June 23, 2017, Oscor sent affected hospitals and health care providers a "Product Recall Letter" informing them of the device's risks, and corrective actions that should be implemented to minimize the risk of patient harm.

The letter directed affected hospitals and health care providers to:

- Use the list provided with the letter to immediately inventory and set-aside all affected product (including unused product that is stored, or in alternate locations).
- Review, complete, sign, and return the acknowledgement form attached in the letter, directly to Oscor, Inc. at the fax number or e-mail on the form for immediate replacement (as applicable).
- Contact Oscor's Customer Service Team for shipment and other relevant instructions if their organization has affected cables to return.

Contact Information

Customers with questions may contact Oscor's Customer Service Group at (727)

-937-2511 or via email at atar@oscor.com (mailto:atar@oscor.com).

Date Recall Initiated

March 31, 2017

Full List of Affected Devices

- ATAR Reusable Extension Cable (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=154469)
- ATAR Disposable Extension Cable (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=156849)

How do I report a problem?

Health care professionals and consumers may report adverse reactions or quality problems they experienced using these devices to MedWatch: The FDA Safety Information and Adverse Event Reporting Program (http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm). Health care professionals employed by facilities that are subject to FDA's user facility reporting requirements (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/default.htm) should follow the reporting procedures established by their facilities.

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

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

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