Medtronic Recalls MindFrame Capture LP Revascularization Device Due to Wire Material That May Break or Separate During Use

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: The MindFrame Capture LP revascularization device
- Product Lot Numbers: 300010, 300011, 300012, 300013, 300014, 300015, 300016, 300017, 300018
- Distribution Dates: March 18, 2016 to January 17, 2018
- Manufacturing Dates: February 3, 2016 to January 14, 2018
- Devices Recalled in the U.S.: 529 nationwide

Device Use

The MindFrame Capture LP revascularization device is intended to restore blood flow or remove blood clots within a blood vessel in the brain during an acute **ischemic stroke (https://medlineplus.gov/ischemicstroke.html)** in patients who are ineligible for or fail intravenous tissue plasminogen activator (IV t-PA) therapy.

Reason for Recall

Medtronic is recalling the MindFrame Capture LP revascularization device because there is a risk of the delivery wire breaking or separating during use. The clot retriever could be left inside the patient's bloodstream, and this or the attempts made to retrieve the device, can lead to further complications including bleeding, additional blockage of blood vessels, more severe stroke symptoms, or death.

Who May be Affected

- Health care providers using this device during revascularization procedures
- All patient groups undergoing procedures involving the MindFrame Capture LP Revascularization device

What to Do

On February 26, 2018, Medtronic sent an Urgent Medical Device Recall Notice to all affected customers and asked them to remove any affected MindFrame Capture LP Revascularization devices from inventory and quarantine them. The notice also requested customers return the affected products to Medtronic.

On April 4, 2018, Medtronic followed up with their customers with another Urgent Medical Device Recall notice regarding patient management. The notice recommended health care providers to:

- Review the notification and distribute the information to all appropriate personnel
- Follow up with the patient closely and
  - Consider **anti-platelet therapy (https://medlineplus.gov/bloodthinners.html)**
  - Consider repeating imaging on the patient
- Complete and return the acknowledgement and receipt form to Medtronic

Contact Information

Customers with questions may contact Medtronic Quality Assurance by email at **Rs.nvcomplaints@medtronic.com (mailto:Rs.nvcomplaints@medtronic.com)** or by phone at 1(800) 633-8766

Date Recall Initiated

February 26, 2017

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 (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)

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)