Medtronic Vascular Recalls Angiographic Guidewire Component Due to Being Non-sterile

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

- Angiographic Guidewire Component
- Model Numbers:
  - WIRE ANGIO 107042 PNS .035X145 3MMJ PTFE; Part No: 107042
  - WIRE ANGIO 107044 PNS .038X145 3MMJ PTFE; Part No: 107044
  - WIRE ANGIO 107447 PNS .035X145 3MMJ PTFE; Part No: 107447
  - WIRE ANGIO 110003 PNS .035C145 3MMJ PTFE; Part No: 110003
  - WIRE ANGIO 110004 PNS.038X145 3MMJ LTPTF; Part No: 110004
- Distribution Dates: November 23, 2007 to March 29, 2021
- Devices Recalled in the U.S.: 54,997
- Date Initiated by Firm: May 4, 2021

Device Use

Medtronic Vascular's Angiographic Guidewire Component is a guidewire used during angiography (https://medlineplus.gov/ency/article/003876.htm) or other interventional procedures to help place catheters into the vasculature.

Reason for Recall

Medtronic Vascular is recalling the Angiographic Guidewire Component because devices were not sterilized before being shipped directly to hospitals. If patients are exposed to the non-sterile device, serious adverse events could occur such as infection, sepsis (https://medlineplus.gov/sepsis.html), and death.

There have been two complaints, and no reported injuries or deaths related to this issue. However, there is potential for underreporting as physicians may not have been aware that devices were non-sterile.

Who May be Affected

- Health care providers using the Medtronic Vascular Angiographic Guidewire Component
- Patients who receive care using the Medtronic Vascular Angiographic Guidewire Component

What to Do

On May 4th, 2021, Medtronic Vascular sent an Urgent Medical Device Recall letter to affected customers. The letter provided the following instructions:

- Identify and quarantine all unused affected Angiographic Guidewire components as listed in Table 1 of the Urgent Medical Device Recall letter and the enclosed Customer Detail Report.
- Return or exchange all unused affected components in your inventory to Medtronic.
    - Contact Medtronic Customer Service at 1-800-716-6700 to initiate a component return/exchange. Your local Medtronic Representative can assist you in the return of this component.
    - Refer to Table 2 in the Urgent Medical Device Recall letter for applicable part numbers to facilitate reordering.
- Complete the enclosed Customer Confirmation Form and email to rs.cfqfca@medtronic.com (mailto:rs.cfqfca@medtronic.com).
    - Continue to monitor these patients in accordance with your medical facilities standard care protocols.

On June 3, 2021, Medtronic Vascular sent an "Amended Urgent: Medical Device Recall" letter to customers with the following additional instructions:

- Report adverse reactions or quality problems experienced with this component to the FDA and Medtronic. Medtronic will notify all applicable regulatory agencies about this matter:
    - Online at http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm (http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm) (form available to fax or mail), or
    - By phone by to the FDA at (800) FDA-1088
    - By phone by to Medtronic at 800-551-5544
- Utilize standard hospital practice and policies to notify patients who were treated with the recalled components

- Share the notice with all those who need to be aware within your organization and with any organization where the potentially affected devices have been transferred.

Contact Information

Customers with questions about this recall should call Medtronic Patient Services at (800) 551-5544.

Additional Resources:

• Recall Database Entry (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRes/res.cfm?ID=187503)

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.