Avid Medical Recalls Medical Convenience Kits for Risk of Fungal Contamination

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

- Adult Chest Tube Tray
- Fistula On-Off Kit
- Fistula (On/Off All in One bag)
- Dialysis Access
    - Part and Lot Numbers: See “Full List of Affected Devices”
    - Distribution Dates: May 9, 2019 to March 19, 2021
    - Devices Recalled in the U.S.: 1,570
    - Date Initiated by Firm: April 2, 2021

Device Use

Avid Medical’s medical convenience kits include a set of devices that are used to complete routine medical and surgical care such as:

- Draining fluid from an adult’s chest
- Surgical repair of an abnormal connection between an artery and a vein (arteriovenous fistula)
- Dressing changes around the surgical site of an arteriovenous fistula
- Creating a dialysis access where a patient is connected to the dialysis machine

Each convenience kit listed above includes a Chloraprep™ 3 mL applicator, which is used to sanitize skin before surgery or catheter procedures. The Chloraprep 3 mL applicator is manufactured by another firm, BD/Carefusion 213.

Reason for Recall

Avid Medical is recalling medical convenience kits that include the BD/Carefusion Chloraprep™ 3mL applicator. The applicator was recalled due to the risk of contamination with a specific type of fungus called Aspergillus penicillioides.

If skin preparation products are contaminated with Aspergillus penicillioides, the fungus can cause serious systemic infection, sepsis, illness, and death to the patient. If the fungus is introduced in the patient's bloodstream during placement of an intravascular catheter, the catheter may need to be removed, requiring additional medical procedures. If the fungus infects a surgical site, the patient may require medical and surgical treatments and require long-term treatment with antifungal drugs.

There have been no deaths, complaints, or reported injuries related to this issue.

Who May be Affected

- Health care providers using Avid Medical convenience kits
- Patients who receive care using Avid Medical convenience kits

What to Do

On April 9, 2021, Avid Medical sent an Urgent Notice of Field Action to all affected customers and provided the following instructions:

- Immediately examine all inventory locations.
- Discontinue use of kits affected by this recall.
- Discard any inventory on hand in accordance with facility standard procedures.
- Report responses received from customers/end-users of the product and quantities destroyed to Quality@owens-minor.com (mailto:Quality@owens-minor.com).

Contact Information

Customers with questions about this recall should email Quality@owens-minor.com.

Full List of Affected Devices

- Adult Chest Tube Tray (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=186860)
    - Part Numbers:
        - LAKC001-04; Package GTIN: 20809160261016; Lot Number: 1404809 (Expiration Date: 08/01/2021) and 1408337 (Expiration Date: 09/01/2021)

        - LAKC001-04; Package GTIN: 20809160293130; Lot Number: 1427628 (Expiration Date: 09/01/2021)
        - LAKC001-04; Package GTIN: 20809160313005; Lot number: 1427629 (Expiration Date: 09/01/2021), 1432814 (Expiration Date: 11/30/2021), and 1436046 (Expiration Date: 11/30/2021)
- Fistula On-Off Kit (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=186862)
    - Part Numbers:
        - MMTN020; Package GTIN: 20809160223489; Lot Number: 1351695 (Expiration Date: 10/31/2021)
        - LAKC001-04; Package GTIN: 20809160293130; Lot Number: 1427628 (Expiration Date: 09/01/2021)
        - LAKC001-04; Package GTIN: 20809160313005; Lot number: 1427629 (Expiration Date: 09/01/2021), 1432814 (Expiration Date: 11/30/2021), and 1436046 (Expiration Date: 11/30/2021)
- Fistula (On/Off All in One bag) (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=186863)
    - Part Numbers:
        - VAMK024-03; Package GTIN: 20809160342500; Lot Number: 1445301 (Expiration Date: 04/30/2022) and 1445302 (Expiration Date: 04/30/2022)
        - LAKC001-04; Package GTIN: 20809160293130; Lot Number: 1427628 (Expiration Date: 09/01/2021)
        - LAKC001-04; Package GTIN: 20809160313005; Lot number: 1427629 (Expiration Date: 09/01/2021), 1432814 (Expiration Date: 11/30/2021), and 1436046 (Expiration Date: 11/30/2021)
- Dialysis Access (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=186864)
    - Part Numbers:
        - VMED004-03; Package GTIN: 20809160238247; Lot Number: 1409970 (Expiration Date: 04/26/2022), 1412734 (Expiration Date: 10/01/2021), 1413146 (Expiration Date: 10/01/2021), and 1413395 (Expiration Date: 04/25/2022)
        - LAKC001-04; Package GTIN: 20809160293130; Lot Number: 1427628 (Expiration Date: 09/01/2021)

- LAKC001-04; Package GTIN: 20809160313005; Lot number: 1427629 (Expiration Date: 09/01/2021), 1432814 (Expiration Date: 11/30/2021), and 1436046 (Expiration Date: 11/30/2021)

Additional Resources:

- FDA advises health care professionals not to use ChloraPrep 3 mL applicators manufactured by BD (Becton, Dickinson and Company) (/drugs/drug-safety-and-availability/fda-advises-health-care-professionals-not-use-chloraprep-3-ml-applicators-manufactured-bd-becton)
- BD Expands Voluntary Recall of ChloraPrep™ 3 mL Applicator Nationwide to Include All U.S. States (Parent firm for this recall) (/safety/recalls-market-withdrawals-safety-alerts/bd-expands-voluntary-recall-chlorapreptm-3-ml-applicator-nationwide-include-all-us-states)

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.