

- [Skip to main page content](#)

U.S. Food and Drug Administration (/default.htm)

Search FDA



[Home \(/default.htm\)](#) [Medical Devices \(/MedicalDevices/default.htm\)](#)

[Medical Device Safety \(/MedicalDevices/Safety/default.htm\)](#)

[Medical Device Recalls \(/MedicalDevices/Safety/ListofRecalls/default.htm\)](#)

Baxter Corporation Recalls 50 mm 0.2 Micron Filter Due to the Potential for a Missing Filter Membrane and Possible Particulate Matter Contamination

- [fShare \(https://www.facebook.com/sharer/sharer.php?u=http%3a%2f%2fwww.fda.gov%2fMedicalDevices%2fSafety%2fListofRecalls%2fucm524230.htm\)](https://www.facebook.com/sharer/sharer.php?u=http%3a%2f%2fwww.fda.gov%2fMedicalDevices%2fSafety%2fListofRecalls%2fucm524230.htm)
- [Tweet \(https://twitter.com/intent/tweet/?text=Baxter%20Corporation%20Recalls%2050%20mm%200.2%20Micron%20Filter%20Due%20to%20the%20Potential%20for%20a%20Missing%20Filter%20Membrane%20and%20Possible%20Particulate%20Matter%20Contamination&url=http%3a%2f%2fwww.fda.gov%2fMedicalDevices%2fSafety%2fListofRecalls%2fucm524230.htm\)](https://twitter.com/intent/tweet/?text=Baxter%20Corporation%20Recalls%2050%20mm%200.2%20Micron%20Filter%20Due%20to%20the%20Potential%20for%20a%20Missing%20Filter%20Membrane%20and%20Possible%20Particulate%20Matter%20Contamination&url=http%3a%2f%2fwww.fda.gov%2fMedicalDevices%2fSafety%2fListofRecalls%2fucm524230.htm)
- [+](#)
- [Email \(mailto:?subject=Baxter%20Corporation%20Recalls%2050%20mm%200.2%20Micron%20Filter%20Due%20to%20the%20Potential%20for%20a%20Missing%20Filter%20Membrane%20and%20Possible%20Particulate%20Matter%20Contamination&body=http%3a%2f%2fwww.fda.gov%2fMedicalDevices%2fSafety%2fListofRecalls%2fucm524230.htm\)](mailto:?subject=Baxter%20Corporation%20Recalls%2050%20mm%200.2%20Micron%20Filter%20Due%20to%20the%20Potential%20for%20a%20Missing%20Filter%20Membrane%20and%20Possible%20Particulate%20Matter%20Contamination&body=http%3a%2f%2fwww.fda.gov%2fMedicalDevices%2fSafety%2fListofRecalls%2fucm524230.htm)

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.

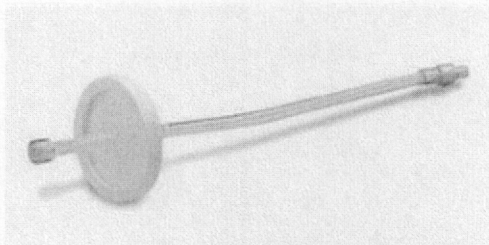


Image of Baxter 50 mm 0.2 Micron Filter

Recalled Product:

- 50 mm 0.2 Micron Filter
- Product code: H93835
- Lot numbers: All unexpired lots
- Manufacturing dates: June 27, 2013 to June 27, 2016
- Distribution dates: August 12, 2013 to June 20, 2016

- Devices recalled in the U.S.: 130,100 units nationwide

Device Use

The 50 mm 0.2 Micron Filter is used in hospital pharmacy settings by pharmacy technicians to filter bacteria and other microscopic matter when preparing water-based solutions used for Intravenous (IV) fluid administration sets. The micron filter is a disposable device that attaches to the standard Baxter Pharmacy Pump tube, a pump that facilitates repeatable fluid drug dosage through the use of IV bags, syringes, infusers, and other drug administration containers.

Reason for Recall

Baxter Corp. is recalling the 50 mm 0.2 Micron Filter after receiving reports about the presence of particulate matter and the potential absence of filter membrane layers in the filter set (depicted in the image above). The absence of a filter membrane layer and/or the presence of particulate matter in the set may contaminate a solution. This could result in bloodstream infections that may cause fever, septic shock, multiple organ dysfunction, and other serious adverse health consequences including death.

Who May be Affected

- Patients receiving IV repeated medication dosage compounded in water-based solutions and filtered with the 50 mm 0.2 Micron Filter
- Pharmacy technicians and other health care professionals using the 50 mm 0.2 Micron Filter to prepare and filter medication dosages in water-based solutions

What to do:

On August 26, 2016, Baxter Corp. sent an "Urgent Product Recall" letter to affected customers and other third party distributors. The letter instructed customers to:

- locate and remove all affected product lots from their facilities
- contact Baxter Healthcare Center for Service to arrange for return and credit
- complete an enclosed Baxter customer reply form and return it to the company
- forward a copy of the communication to any third party customers
- conduct a consumer-level recall if they are dealers, wholesalers, or distributors

Contact Information

Customers can contact the Baxter Healthcare Center by phone at 888-229-0001 between the hours of 7 a.m. and 6 p.m. Central Time, Monday through Friday or by email at:
corporate_product_complaints_round_lake@baxter.com
(mailto:corporate_product_complaints_round_lake@baxter.com)

Date Recall Initiated:

August 24, 2016

Additional Resources:

- Baxter Corp. Press Release (<http://www.baxter.com/news-media/newsroom/press-releases/2016/09-27-16-filters-recall.page>)
(<http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm>)

- FDA MedWatch Safety Alert for this Recall
(/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm523572.htm)

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>) either online, by regular mail or by FAX to 1-800-FDA-0178.

More in Medical Device Recalls

(/MedicalDevices/Safety/ListofRecalls/default.htm)

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

2015 Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/ucm429489.htm)

2014 Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/ucm384921.htm)

Page Last Updated: 10/06/2016

Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players
(/AboutFDA/AboutThisWebsite/WebsitePolicies/ViewingFiles/default.htm).

Accessibility (/AboutFDA/AboutThisWebsite/Accessibility/default.htm)

Website Policies (/AboutFDA/AboutThisWebsite/WebsitePolicies/default.htm)

U.S. Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993
1-888-INFO-FDA (1-888-463-6332)

Contact FDA (<http://www.fda.gov/AboutFDA/ContactFDA/default.htm>)



(/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm)



(https://twitter.com/US_FDA)



(<https://www.facebook.com/FDA>)



(<http://www.youtube.com/user/USFoodandDrugAdmin>)



(<http://www.flickr.com/photos/fdaphotos/>)



Home (/default.htm) Latest Recalls (/Safety/Recalls/default.htm) Report an Adverse Event
(<https://www.accessdata.fda.gov/scripts/medwatch/>)

- MedWatch Safety Alerts (/Safety/MedWatch/default.htm)
- News Releases (/NewsEvents/Newsroom/PressAnnouncements/default.htm)
- Consumer Updates (/ForConsumers/ConsumerUpdates/default.htm)
- About FDA (/AboutFDA/default.htm)
- Contact FDA (/AboutFDA/ContactFDA/default.htm)
- ◀ Browse by Product Area