

ICU Medical Issues a Voluntary Nationwide Recall of Certain Lots of Plum and Sapphire Microbore Infusion Sets with Inline Filters

SAN CLEMENTE, California, 7 October 2019 – [ICU Medical, Inc.](http://www.icumedical.com) announced a voluntary recall on 29 July 2019 of certain lots of Plum and Sapphire Microbore Infusion Sets with inline filters due to the potential for small amounts of fluid leaking out of the air vents on the inline filters. To date, ICU Medical is not aware of adverse events related to this matter and is issuing this notification out of an abundance of caution.

Based on complaints the affected product lots, which were distributed nationwide to ICU Medical customers, are listed below:

Item Code	Product Description - PlumSets	Lot #
118790412	High-Pressure Filter PRIMARY I.V. PLUMSET Convertible Pin, 104 Inch with Orange Polyethylene-Lined*/Light Resistant Tubing, Prepierced Injection Site and OPTION-LOK	855505H, 865135H, 918695H, 928085H, 937325H, 3864774, 3935434, 4011065, 4088425
142560488	Primary PLUM Set 0.2 Micron Filter, Prepierced Y-Site, Polyethylene Lined Light Resistant Tubing, Distal Microbore Tubing, Secure Lock, 104 Inch	865455H, 896215H, 897455H, 3864785, 4095291
149530489	Primary PLUM Set Yellow Striped Tubing, Distal Microbore Tubing, 0.2 Micron Filter, Secure Lock, 107 Inch	925155H

Item Code	Product Description - Sapphire Sets	Lot #
163350455	SAPPHIRE Primary 1.2 Micron Filter Set Microbore, 122 Inch	855935H, 855965H, 876145H, 885395H, 896135H, 936605H, 3843263, 3864786
163620455	SAPPHIRE Primary 0.2 Micron Filter Set, Microbore, CLAVE Y-Site, 118 Inch	855645H, 885415H, 896625H, 4008547
163630455	SAPPHIRE Epidural Set Yellow-Striped Microbore, 0.2 Micron Filter 119 Inch	876175H, 885385H, 896995H, 908235H, 925755H, 3843264
163730455	SAPPHIRE Epidural Set Yellow-Striped Microbore, 0.2 Micron Filter, PAV 123 inch	896225H, 916845H, 925825H, 948155H
163830455	SAPPHIRE Primary 0.2 Micron Filter Set Non-Vented, Microbore, PAV, CLAVE Y-Site, 122 Inch	855665H, 865495H, 896195H, 3849197, 4064964
163840455	SAPPHIRE Primary 1.2 Micron Filter Set Non-Vented, Microbore, PAV, 123 Inch	855995H, 865505H, 876185H
240100401	SAPPHIRE Epidural Set with NRFit Connector Yellow-Striped Microbore, 0.2 Micron Filter 119 Inch	897525H, 905915H, 926235H

ICU Medical is asking customers to quarantine all affected product at your facility and return the affected product to Stericycle for credit. For instructions on returning product or additional assistance, call Stericycle at 1-855-311-5437 Monday through Friday, between the hours of 8 a.m. to 5 p.m. Eastern Time.

Customers with questions regarding this recall can call ICU Medical at 1-866-829-9025 option 8, Monday through Friday, between the hours of 8 a.m. and 6 p.m. Central Time.

If the benefits of a filtered microbore infusion set are greater than the potential risks of a filter leak (as described below), please review the [customer notification](#) for additional details regarding actions required by the user.

As of the date of this press release, FDA is actively evaluating the information in an effort to classify this recall. Fluid leakage may potentially cause delay of infusion, medication under-delivery, contamination of the fluid path which is on the patient side of the filter, exposure to hazardous medications, or fluid path air-in-line. Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report **Online**: www.fda.gov/medwatch/report.htm
- **Regular Mail or Fax**: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

Additional information regarding this recall, along with notifications to the customer can be found on ICU Medical's Website [here](#).

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