ICU Medical, Inc.
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UPDATE: Information Regarding Reported Black Specks in Certain IV Tubing Set Drip Chambers from ICU Medical

Date: 15 May 2026

Update: This communication provides an update on our investigation and clear guidance for clinical use based on all information available to date.

Background

ICU Medical is issuing this communication in response to the Public Health Alert issued by the Maine Department of Health and Human Services' Center for Disease Control and Prevention ("Maine CDC") on May 8, 2026, concerning reports of small black specks and discoloration observed on the inner wall of drip chambers, as well as particulate matter found within the drip chambers in certain IV tubing sets. ICU Medical has been in communication with Maine CDC and the reporting healthcare facility to better understand the concern and review the information available to date. Based on the information currently available, the concern involves black specks and particulate matter within the drip chamber wall, raising questions about whether these findings represent biological contamination or could enter the fluid path and pose a risk to patients.

Investigation Update

While ICU Medical is actively conducting an investigation, preliminary testing by the reporting healthcare provider suggests that in most cases the black specks appear to be embedded within the chamber wall, consistent with the plastic molding process. However, the presence of discoloration and particulate matter in the fluid path has not been ruled out. Based on ICU Medical's preliminary investigation and the information reviewed to date for the reported events provided by the reporting healthcare provider, ICU Medical considers the observed black specks, when embedded in the wall of the drip chamber (see Figure 1 below), to be consistent with discolored PVC material. At this time, neither ICU Medical nor the reporting healthcare facility have identified evidence indicating that the reported condition represents a risk of biological contamination; however, this has not been ruled out. ICU Medical is continuing the investigation and will provide updates as appropriate.

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Manufacturing Process Overview

The drip chamber is manufactured in an ICU Medical facility from polyvinyl chloride (PVC) using an injection molding process. During this process, PVC resin is melted and injected into a mold to form the drip chamber. Localized thermal discoloration of the PVC resin can occasionally occur due to heat sensitivity, resulting in small dark spots being incorporated into the molded component. This type of condition is associated with the material and manufacturing process rather than the introduction of external matter.

Figure 1: Embedded black speck in the wall of the drip chamber from healthcare provider

Actions for Users

To help ensure continuity of safe infusion therapy during this active investigation,

- Users should inspect all devices prior to use for any evidence of compromise, including but not limited to marks or black specks on the chamber walls, particulate matter within the drip chamber or fluid path, and condensation within the device.
- If users visually identify any anomalies , they should segregate the individual item, complete a MedWatch complaint per the hospital facility process and contact ICU Medical to return the product sample for investigation.
- Contact ICU Medical at productcomplaintsPP@icumed.com or online at https://icumed.custhelp.com/app/complaint or by calling 1-(866)-216-8806 to report the event and to arrange the return of the product for investigation.

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- To file a MedWatch report, please contact FDA at www.fda.gov/medwatch or 1-(888)-INFO-FDA.

ICU Medical is continuing our active investigation and monitoring in collaboration with healthcare providers and regulatory agencies and will provide an update when new information becomes available.

We recognize that any unexpected visual observation in a medical device can be concerning. ICU Medical remains committed to transparency, patient safety, and maintaining your confidence in our products.