

## Information Regarding Reported Black Specks in Certain IV Tubing Set Drip Chambers from ICU Medical

**Date:** 12 May 2026

### **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 on May 8, 2026, concerning reports of small black specks observed on the inner wall of 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 is related to black specks within the drip chamber wall, raising questions about whether they represent biological contamination or could enter the fluid path.

### **Investigation Update**

While ICU Medical has not yet received any samples for investigation, the healthcare provider conducted testing with an independent laboratory, which confirmed the material to be embedded and not loose in the fluid path, which is consistent with the plastic molding process. Based on prior ICU Medical technical evaluations of this visual condition and the information reviewed to date for the reported events provided by the reporting healthcare provider, the observed black specks are consistent with discolored PVC material embedded in the wall of the drip chamber (reference figure 1 below) and not loose in the fluid path. When confirmed to be embedded within the chamber wall, outside the fluid path, this condition is considered cosmetic and is not expected to affect device function or patient safety. In addition, the product is sterilized as part of the validated manufacturing process. At this time, ICU Medical or the reporting healthcare facility have not identified any evidence indicating that the reported condition represents any risk of biological contamination.

## 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



## Conclusion

ICU Medical has reviewed the reported concern, engaged with the Maine Center for Disease Control and Prevention (CDC) and healthcare stakeholders, and assessed the available information against prior investigations and technical understanding of the component and manufacturing process.

Based on the current assessment, ICU Medical is not recommending sequestration or discontinuation of use of the lots identified in the public health alert on the basis of evaluation to date.

Sincerely,

A handwritten signature in black ink, appearing to read "Joseph Canavan".

Joseph Canavan, VP QRA