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URGENT MEDICAL DEVICE CORRECTION: Final Update Regarding Reported Discoloration in Certain IV Tubing Set Drip Chambers from ICU Medical

See product families listed below.

Date: July 28, 2026

Final Update: This communication summarizes the findings of the investigation and provides guidance for clinical use related to the previously posted FDA Early Alert on May 27, 2026.

Summary of Investigation Findings

ICU Medical has completed its investigation of reported discoloration observed in certain IV tubing set drip chambers. The investigation confirmed that the observed discoloration is characteristic of the drip chamber material, does not enter the fluid path, and does not affect device safety, performance, or intended use.

Based on these findings, products should continue to be used as intended and per facility protocol.

Background

FDA previously posted an Early Alert on May 27, 2026, based on alignment with ICU Medical regarding reports of discoloration observed in certain IV tubing set drip chambers. To further evaluate the reported observations, ICU Medical conducted an extensive investigation that included evaluation of returned samples, laboratory analysis, simulated-use testing, and inspection of product inventory, and has determined that the reported discoloration is intrinsic to the PVC used to manufacture the drip chamber and remains embedded within the drip chamber wall. The investigation demonstrated that the reported observations represent discoloration of the drip chamber material itself and the discolorations:

- Are not biological contamination
- Are not foreign material
- Do not enter the fluid path
- Do not dislodge under expected use conditions
- Do not affect the structural integrity or performance of the drip chamber

Given these findings, ICU Medical no longer recommends the enhanced inspection activities described in prior communications. Products should continue to be used as intended and per facility protocol.

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Example images of discolorations are shown below.

Pronounced Dark Discoloration

Small Dark Discoloration

White Hazy Discoloration

The investigation confirmed that the reported discoloration does not affect device safety or performance and is a known characteristic associated with PVC injection molding processes used throughout the medical device industry. In alignment with our continuous improvement initiatives, ICU Medical implemented additional process controls and continues to pursue manufacturing enhancements to further reduce the already rare occurrence of discoloration.

Potential Risk

The investigation identified no direct patient risk associated with use of affected products. In some circumstances, a healthcare provider who observes discoloration may elect to replace a product before use, which could result in a delay in therapy. These delays could be clinically significant, especially for time-sensitive, life-saving infusions or when a replacement cannot be readily obtained.

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Products Covered by this Communication

This communication applies to the ICU Medical product families listed below:

- Plum Administration Sets with drip chambers
- IV Non-Dedicated Gravity Administration Sets with drip chambers
- IV Sets with drip chambers
- Oncology Sets with drip chambers

Products manufactured on or before July 4th, 2026 and that are within their expiration date are in the scope of this communication.

Required Actions for Users

The completed investigation supports continued use of products in accordance with their intended use and standard clinical practices.

Healthcare providers should therefore continue using products in accordance with the Instructions for Use and established clinical procedures per facility protocol. No product returns are necessary.

ICU Medical requests that customers:

1. Share this notification with all potential users of the device to ensure they are aware of this notification. If the devices are used or further distributed to another location, please ensure that this communication is delivered there.
2. Complete and return the attached Customer Response Form to MarketAction@mailac.custhelp.com within 10 days of receipt to acknowledge your understanding of this notification.
3. Continue using products as intended and per facility protocol.
4. Report any product quality concerns to ICU Medical Complaint Management using the contact information below.

For further inquiries, please contact ICU Medical using the information provided below:

ICU Medical Contact	Contact Information	Areas of Support
Global Complaint Management	GlobalComplaints@icumed.com 1-866-261-8806	Report on adverse events or product complaints
Customer Service	customerservice@icumed.com 1-800-258-5361	Additional information or technical assistance
Field Action Processing	MarketAction@mailac.custhelp.com	Assistance with customer notifications and response forms

The U.S. Food and Drug Administration (FDA) has been notified of this action. Adverse events 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

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- Regular Mail or Fax: Download the form at www.fda.gov/medwatch 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.

ICU Medical appreciates your partnership throughout this investigation. Based on the completed evaluation, customers should continue to use IV tubing sets with drip chambers as intended and without additional inspection requirements beyond routine clinical practice. We remain committed to delivering safe, reliable products and to communicating transparently with our customers.

Sincerely,

Andrew Mathein

Andrew Mathein
Vice President of Quality and Regulatory

Enclosures:

- Customer Response Form