



**SOUTH CAROLINA
DEPARTMENT OF
PUBLIC HEALTH**



This is an official DPH Health Alert

On July 1, 2024, the S.C. Department of Health & Environmental Control (DHEC) became two separate agencies: S.C. Department of Environmental Services (SCDES) and S.C. Department of Public Health (DPH).

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Reports of Visible Contamination of ICU Medical IV Tubing - Multiple states, 2026

Summary

The South Carolina Department of Public Health (DPH) has been notified by the Centers for Disease Control and Prevention (CDC) that there is an ongoing investigation of visibly contaminated IV tubing sets from ICU Medical distributed by Medline to health care settings in Maine and Pennsylvania. Additional states might be impacted.

Health care facilities should check to see if IV tubing products are manufactured by ICU Medical, and if so, conduct an inspection to determine if there is any visible contamination and take protective measures.

Background

The contamination is reported as small black particulate matter or specks visible on the internal surfaces of the drip chambers. The manufacturer is aware and working with the Food and Drug Administration (FDA) and CDC in the investigation. It is unknown whether foreign material in the infusion packaging poses a health risk to patients.

No definitive etiology of the black specks has been identified, although ICU Medical [issued a response](#) suggesting that the specks are consistent with the molding

process. No known adverse events have been linked to the impacted product. An investigation is ongoing.

The ICU Medical product types identified as containing visible contaminant include:

- Primary Set Piggyback with Backcheck Valve, 2 CLAVE Y-Sites, Secure Lock, 100 Inch
- Primary PLUM Set CLAVE Port, CLAVE Y-Site, Secure Lock, 103 Inch
- Secondary Set Secure Lock, 34 Inch with IV Set Hanger

Specific lot numbers and images of affected tubing can be found listed in the [Maine CDC Public Health Alert](#).

Recommendations

- Health care facilities should check if IV tubing products are manufactured by ICU Medical, and if so, physically inspect supplies, particularly drip chambers, to assess for any visible contamination as soon as possible.
- If visible contamination is identified, health care facilities should:
 - Sequester and do not use the affected products,
 - File an [FDA MedWatch](#) report,
 - Inform the manufacturer, and
 - Report to DPH at hai_unit@dph.sc.gov.

Additional Information

Maine CDC Public Health Alert

[Ongoing Investigation of Contaminated IV Sets from ICU Medical | Maine Center for Disease Control & Prevention](#)

Response from ICU Medical

[ICU Medical CDC Response to IV Tubing Set Drip Chambers](#)

FDA MedWatch Reporting

<https://www.accessdata.fda.gov/scripts/medwatch/index.cfm>

Categories of Health Alert messages:

Health Alert	Conveys the highest level of importance; warrants immediate action or attention.
Health Advisory	Provides important information for a specific incident or situation; may not require immediate action.
Health Update	Provides updated information regarding an incident or situation; unlikely to require immediate action.
Info Service	Provides general information that is not necessarily considered to be of an emergent nature.