

Concern for Gross Contamination of Intravenous (IV) Tubing Sets from ICU Medical - May 12, 2026

Summary and Action Items

- Healthcare facilities utilizing ICU Medical IV infusion products should inspect all infusion sets, particularly drip chambers, for any signs of visible contamination.
- If contamination is identified, discontinue use immediately, notify [ICU Medical](#) and the [Illinois Department of Public Health](#) (IDPH), and submit a report through [FDA MedWatch](#).

Background

The Centers for Disease Control and Prevention (CDC) was notified by the health departments of Maine and Pennsylvania that multiple healthcare facilities in both states have identified visible contamination in IV tubing sets. Multiple lots have been identified, all from a single manufacturer, [ICU Medical](#). The contamination appears as small black dots on the internal walls of the drip chamber (see picture below). In some products, particulate matter appears in the lumen or chamber of the tubing. In most, particulate matter appears embedded in the plastic material but not within the lumen or chamber.

To date, at least 15 different lot numbers from the same manufacturer have been identified in healthcare facilities in Maine. The ICU Medical product types 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

At this time, CDC has not received any reports of patient infections or adverse events associated with the contaminated products. The manufacturer and the FDA have been notified; a product recall has not been issued at this time.

Recommendations

- Healthcare facilities should identify if ICU Medical IV infusion products are used in their facilities
- Inspect all ICU Medical IV infusion sets, particularly the drip chambers, for any visual contamination. Shown below are two example photos from the contaminated IV infusion sets.
 - The first photo shows a scenario where a saline bag had been connected and particulate matter is visible in the chamber.
 - In the second photo, a small black dot appears in the plastic wall.
- If contamination is identified:

Illinois Department of Public Health

- Stop using and safely sequester the affected products.
- Notify [ICU Medical](#) immediately
- File a report through [FDA MedWatch](#)
- Notify IDPH: dph.haiarprogram@illinois.gov
- Identify any lots in your facility that are from the list of lots identified as affected to date (see below).

Photos of contaminated drip chambers:



Image courtesy of Maine Department of Health and Human Services

The following lot numbers have been implicated to date:

| tubing Type | Manufacturer Number | Lot Number |
|--|---------------------|------------|
| Primary PLUM Set CLAVE Port, CLAVE Y-Site, Secure Lock, 103 Inch | 14687-28 | 13928505 |
| Primary PLUM Set CLAVE Port, CLAVE Y-Site, Secure Lock, 103 Inch | 14687-28 | 14299486 |
| Primary PLUM Set CLAVE Port, CLAVE Y-Site, Secure Lock, 103 Inch | 14687-28 | 14303977 |
| Primary PLUM Set CLAVE Port, CLAVE Y-Site, Secure Lock, 103 Inch | 14687-28 | 14444765 |
| Primary PLUM Set CLAVE Port, CLAVE Y-Site, Secure Lock, 103 Inch | 14687-28 | 14444800 |
| Primary PLUM Set CLAVE Port, CLAVE Y-Site, Secure Lock, 103 Inch | 14687-28 | 14445438 |
| Primary PLUM Set CLAVE Port, CLAVE Y-Site, Secure Lock, 103 Inch | 14687-28 | 14569242 |
| Primary PLUM Set CLAVE Port, CLAVE Y-Site, Secure Lock, 103 Inch | 14687-28 | 14585387 |
| Primary PLUM Set CLAVE Port, CLAVE Y-Site, Secure Lock, 103 Inch | 14687-28 | 14590240 |
| Primary PLUM Set CLAVE Port, CLAVE Y-Site, Secure Lock, 103 Inch | 14687-28 | 14800330 |
| Primary PLUM Set CLAVE Port, CLAVE Y-Site, Secure Lock, 103 Inch | 14687-28 | 14800331 |
| Primary PLUM Set CLAVE Port, CLAVE Y-Site, Secure Lock, 103 Inch | 14687-28 | 14804603 |
| Primary PLUM Set CLAVE Port, CLAVE Y-Site, Secure Lock, 103 Inch | 14687-28 | 14804605 |
| Primary PLUM Set CLAVE Port, CLAVE Y-Site, Secure Lock, 103 Inch | 14687-28 | 14804606 |
| Primary PLUM Set CLAVE Port, CLAVE Y-Site, Secure Lock, 103 Inch | 14687-28 | 14848440 |
| Primary PLUM Set CLAVE Port, CLAVE Y-Site, Secure Lock, 103 Inch | 14687-28 | 14444753 |
| TUBING INTRAVENOUS PRIMARY PLUMSET, CLAVE | 14687-28 | 14304464 |
| Primary Set Piggyback with Backcheck Valve, 2 CLAVE Y-Sites, Secure Lock, 100 Inch | 12662-28 | 13605252 |
| Primary Set Piggyback with Backcheck Valve, 2 CLAVE Y-Sites, Secure Lock, 100 Inch | 12662-28 | 14219155 |
| Primary Set Piggyback with Backcheck Valve, 2 CLAVE Y-Sites, Secure Lock, 100 Inch | 12662-28 | 14301497 |
| Primary Set Piggyback with Backcheck Valve, 2 CLAVE Y-Sites, Secure Lock, 100 Inch | 12662-28 | 14444799 |
| Primary Set Piggyback with Backcheck Valve, 2 CLAVE Y-Sites, Secure Lock, 100 Inch | 12662-28 | 14444920 |
| Primary Set Piggyback with Backcheck Valve, 2 CLAVE Y-Sites, Secure Lock, 100 Inch | 12662-28 | 14555809 |
| Primary Set Piggyback with Backcheck Valve, 2 CLAVE Y-Sites, Secure Lock, 100 Inch | 12662-28 | 14610290 |
| Primary Set Piggyback with Backcheck Valve, 2 CLAVE Y-Sites, Secure Lock, 100 Inch | 12662-28 | 14802329 |
| Primary Set Piggyback with Backcheck Valve, 2 CLAVE Y-Sites, Secure Lock, 100 Inch | 14687-28 | 14822772 |
| Primary Set Piggyback with Backcheck Valve, 2 CLAVE Y-Sites, Secure Lock, 100 Inch | 12662-28 | 14860187 |
| Primary Set Piggyback with Backcheck Valve, 2 CLAVE Y-Sites, Secure Lock, 100 Inch | 12662-28 | 14860190 |
| Secondary Set Secure Lock, 34 Inch with IV Set Hanger | 14229-28 | 13875598 |
| Secondary Set Secure Lock, 34 Inch with IV Set Hanger | 14230-28 | 14444807 |
| Secondary Set Secure Lock, 34 Inch with IV Set Hanger | 14229-28 | 14449267 |
| Secondary Set Secure Lock, 34 Inch with IV Set Hanger | 14230-28 | 14482729 |
| Secondary Set Secure Lock, 34 Inch with IV Set Hanger | 14230-28 | 14482731 |
| Secondary Set Secure Lock, 34 Inch with IV Set Hanger | 14229-28 | 14524260 |
| Secondary Set Secure Lock, 34 Inch with IV Set Hanger | 14229-28 | 14555815 |
| Secondary Set Secure Lock, 34 Inch with IV Set Hanger | 14229-28 | 14573126 |
| Secondary Set Secure Lock, 34 Inch with IV Set Hanger | 14229-28 | 14573129 |
| Secondary Set Secure Lock, 34 Inch with IV Set Hanger | 14230-28 | 14585398 |
| Secondary Set Secure Lock, 34 Inch with IV Set Hanger | 14229-28 | 14623286 |
| Secondary Set Secure Lock, 34 Inch with IV Set Hanger | 14229-28 | 14802338 |
| Secondary Set Secure Lock, 34 Inch with IV Set Hanger | 14229-28 | 14860291 |

Contact: IDPH HAI/AR program dph.haiarprogram@illinois.gov

Target Audience: Local Health Departments, Infection Preventionists, Infectious Disease Physicians, Hospital Administrators, Long-term Care Facilities, and Regional Health Offices.

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