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Maine Health Alert Network (HAN) System

PUBLIC HEALTH ALERT

To: Health Care Providers
From: Dr. Isaac Benowitz, State Epidemiologist
Subject: Ongoing Investigation of Contaminated IV Sets from ICU Medical
Date / Time: Friday, May 8, 2026, at 4:36PM
Priority: **High**
Pages: 3
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UPDATE (Wednesday, May 20, 2026): Since the original publication of this alert, the Maine CDC has received additional information from the manufacturer regarding the reports of findings related to IV tubing kits. Please refer to the [manufacturer's letter](#) and the recommendations below.

Recommendations

- 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 866-216-8806 to report the event and to arrange the return of the product for investigation.
- If users visually identify anomalies of free-floating particulate matter within the drip chamber or any other concerns not consistent with the findings described the manufacturer's letter, please report these to the Maine CDC (mecdc.hai@maine.gov) in addition to reporting to the manufacturer and MedWatch.
- Entire lots do not need to be sequestered.

No changes to the original message below have been made.

Ongoing Investigation of Contaminated IV Sets from ICU Medical

The Maine Department of Health and Human Services' Center for Disease Control and Prevention (Maine CDC) is investigating reports of contaminated IV tubing sets from a single

manufacturer with national distribution and alerting Maine health care facilities to inspect their supplies. The contamination is reported as small black dots on the internal walls of the drip chambers and has been reported in numerous lots across three product types from **ICU Medical**. 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. Preliminary reports of similar findings in one other state suggest this may be a widespread issue with one or more nationally-distributed product lines.

The presence of foreign material in infusion material may pose a health risk to patients. It is unknown whether the particulates contain biological material. No information is available at this time about the dates when these lots were shipped to Maine or used. No adverse events have been linked to the contaminated products. The manufacturer, the U.S Food and Drug Administration (FDA), and the U.S. CDC have been notified and are investigating.

As of Friday afternoon May 8, 2026, neither ICU Medical, nor the FDA have issued a recall or any removal actions. The Maine CDC is alerting all health care facilities out of an abundance of caution.

The Maine CDC recommends several interim actions in response to this evolving investigation:

- **Inspect all ICU Medical IV infusion sets, particularly the drip chambers**, for any visual contamination. Attached 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, a small black dot appears in the plastic wall.
- **If any visible contamination is identified, sequester the entire lot** if possible and contact Maine CDC for further instructions (mecdc.hai@maine.gov).
- **Identify any lots** in your facility that are from the list of affected lots (see below).

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

Photos of contaminated drip chambers:

