

HEALTH ALERT

JB Pritzker, Governor

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Non-sterile Ultrasound Gel Associated with Multistate Outbreak of *Paraburkholderia fungorum -* May 19, 2025

Summary and Action Items

- The Centers for Disease Control and Prevention (CDC) has received reports of Paraburkholderia fungorum (an environmental bacterium) associated with the use of ultrasound gel from multiple states from 2024–2025.
- Use only single-use sterile ultrasound gel for percutaneous procedures (procedures that involve puncturing the skin).
- Review protocols for percutaneous procedures and ensure non-sterile ultrasound gel products are excluded, including the products currently associated with the outbreak.
- Ensure providers who perform percutaneous procedures are trained in the appropriate use of ultrasound gel products.
- Clinical labs should conduct a one year lab lookback to identify cases of *Paraburkholderia* fungorum from sterile sources (e.g. blood cultures).

Background

The use of contaminated, **non-sterile ultrasound gel** has previously been associated with healthcare outbreaks when used for ultrasound-guided percutaneous procedures. Percutaneous procedures involve skin or tissue puncture, including but not limited to, the **placement of central and peripheral intravenous catheters**, **amniocentesis**, **paracentesis**, **tissue biopsy**, **and surgical procedures**.

The CDC is investigating a multistate cluster of *Paraburkholderia fungorum*, an environmental pathogen rarely associated with human illness. To date, 40 cases of blood infection (bacteremia) caused by *P. fungorum* have been identified, at least some of whom had undergone prior ultrasound-guided percutaneous procedures. *P. fungorum*, identified in at least two non-sterile ultrasound gel products, is genetically linked to the clinical cases.

Product testing has isolated *P. fungorum* from at least two **non-sterile ultrasound gel products:**

- MediChoice® (lots: 240302; 240306)
- ClearImage® (lots: 230221, 230256, 240227, 240230)

Both products were manufactured by NEXT Medical Products Company (Branchburg, NJ); these product isolates are also genetically related to the *P. fungorum* patient isolates. Further investigation by healthcare facilities confirmed that some of these patients had undergone ultrasound-guided percutaneous procedures prior to culture collection.

Recommendations

- Healthcare facilities and clinicians should report cases of clinical infection with Paraburkholderia fungorum to their local health department.
- Adverse events or quality issues associated with ultrasound gel products should be reported to the manufacturer and the FDA's MedWatch Adverse Event Reporting program.

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- Use only single-use sterile ultrasound gel for all percutaneous procedures (procedures that
 involve puncturing the skin). An ultrasound gel product label's claim of "bacteriostatic" or
 "preservative" without a specific indication of sterility should be considered non-sterile for
 clinical purposes.
- Healthcare facilities should ensure that infection preventionists, interventional radiology departments, and other departments and clinicians who perform ultrasound-guided percutaneous procedures review protocols for percutaneous procedures and ensure non-sterile ultrasound gel products are excluded, including the products currently associated with the outbreak (i.e., sterile ultrasound gel products (MediChoice® [lots: 240302; 240306] and ClearImage® [lots: 230221, 230256, 240227, 240230]), both manufactured by NEXT Medical Products Company [Branchburg, NJ]).
- Ensure providers who perform percutaneous procedures are trained in sterile technique and the appropriate use of ultrasound gel products.
- Clinical labs should conduct a one year lab lookback to identify cases of Paraburkholderia fungorum from sterile sources (e.g. blood cultures). Report cases to the local health department.

Contact

IDPH Regional Infection Prevention Program at DPH.IP@Illinois.gov.

Target Audience

Local Health Departments, Hospital Infection Preventionists, Infectious Disease Physicians, Interventional Radiologists, Emergency Medicine Physicians, Hospital Administrators, and Regional Health Offices.

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Resources

- 1. Alert: Use Only Sterile Ultrasound Gel for Percutaneous Procedures: https://www.cdc.gov/healthcare-associated-infections/bulletins/outbreak-ultrasound-gel.html
- 2. Outbreak of Burkholderia stabilis Infections Associated with Contaminated Nonsterile, Multiuse Ultrasound Gel 10 States, May–September 2021 | MMWR: https://www.cdc.gov/mmwr/volumes/71/wr/mm7148a3.htm#B1_down