SOUTH CAROLINA DEPARTMENT OF PUBLIC HEALTH

SCHAN South Carolina Health Alert Network

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DPH Health Advisory

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 *Paraburkholderia fungorum* Associated with Non-sterile Ultrasound Gel — Multiple States, 2024–2025

Summary

The CDC is assisting with an ongoing multistate investigation involving the use of non-sterile ultrasound gel for ultrasound-guided percutaneous procedures (procedures that involve puncturing the skin).

As of May 8, 2025, the CDC is aware of 40 isolates of *Paraburkholderia fungorum* (an environmental bacterium formerly known as *Burkholderia fungorum*) primarily isolated from patient blood cultures. These isolates are linked by whole-genome sequencing and are from patients in four states within the U.S. and two other countries. Product testing has isolated *P. fungorum* from two non-sterile ultrasound gel products, MediChoice® and ClearImage®, both 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 blood culture collection. The CDC, along with state and local health departments, continues to investigate this issue in collaboration with the U.S. Food and Drug Administration (FDA).

Healthcare providers should use only sterile, single-use ultrasound gel for percutaneous procedures. 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.

Please visit https://www.cdc.gov/healthcare-associated-infections/bulletins/outbreak-ultrasound-gel.html for further information about this outbreak, as well as specific considerations for healthcare providers regarding the use of ultrasound gel. Healthcare facilities should report any adverse events or quality problems experienced with the use of ultrasound gel products to the product manufacturer and the FDA's MedWatch Adverse Event Reporting program.

Background

Multiple prior healthcare outbreaks have been reported in association with the use of contaminated, non-sterile ultrasound gel for ultrasound-guided percutaneous procedures. Percutaneous procedures involve the puncture of skin or tissue, including but not limited to the placement of central and peripheral

intravenous catheters, amniocentesis, paracentesis, tissue biopsy, and surgical procedures. There have been previous outbreaks of *Burkholderia cepacia* complex related to the use of non-sterile ultrasound gel for ultrasound-guided percutaneous procedures.

The use of non-sterile ultrasound gel for percutaneous procedures can result in patient harm. Microorganisms that may be present in non-sterile ultrasound gel can spread to sterile body sites (like the bloodstream) through procedures involving skin or tissue puncture, which can cause serious infections. Even for microorganisms that do not usually cause infection, they could also contaminate test (culture) specimens during collection, which could lead to unnecessary antimicrobial treatment and diversion of healthcare and laboratory resources. Either of these risks are not limited to scenarios where there is known product contamination, since microorganisms may be present in non-sterile products.

Additional Resources

- CDC Morbidity and Mortality Weekly Report (MMWR) related to an outbreak of *Burkholderia stabilis* infections associated with the use of non-sterile ultrasound gel in healthcare facilities.
- Reporting Serious Problems to the FDA using MedWatch.

DPH contact information for reportable diseases and reporting requirements

Reporting ***Paraburkholderia fungorum*** is consistent with South Carolina Law requiring the reporting of diseases and conditions to your state or local public health department. (State Law # 44-29-10 and Regulation # 61-20) as per the DPH 2025 List of Reportable Conditions.

Federal HIPAA legislation allows disclosure of protected health information, without consent of the individual, to public health authorities to collect and receive such information for the purpose of preventing or controlling disease. (HIPAA 45 CFR §164.512).

Regional Public Health Offices – 2025

Mail or call reports to the Epidemiology Office in each Public Health Region

MAIL TO:

Lowcountry	Midlands	Pee Dee	Upstate
3685 Rivers Avenue, Suite 201 N. Charleston, SC 29405 Fax: (843) 953-0051	2000 Hampton Street Columbia, SC 29204 Fax: (803) 251-3170	1931 Industrial Park Road Conway, SC 29526 Fax: (843) 915-6506	352 Halton Road Greenville, SC 29607 Fax: (864) 282-4373

CALL TO:

Lowcountry	Midlands	Pee Dee	Upstate
Allendale, Bamberg, Beaufort, Berkeley, Calhoun, Charleston, Colleton, Dorchester, Hampton, Jasper, Orangeburg Office: (843) 441-1091 Nights/Weekends: (843) 441-1091	**Aiken, Barnwell, Chester, Edgefield, Fairfield, Kershaw, Lancaster, Lexington, Newberry, Richland, Saluda, York** Office: (888) 801-1046 Nights/Weekends: (888) 801-1046	**Clarendon, Chesterfield, Darlington, Dillon, Florence, Georgetown, Horry, Lee, Marion, Marlboro, Sumter, Williamsburg** Office: (843) 915-8886 Nights/Weekends: (843) 409-0695	**Abbeville, Anderson, Cherokee, Greenville, Greenwood, Laurens, McCormick, Oconee, Pickens, Spartanburg, Union** Office: (864) 372-3133 Nights/Weekends: (864) 423-6648

For information on reportable conditions, see
dph.sc.gov/professionals/health-professionals/sc-list-reportable-conditions

DPH Bureau of Communicable Disease Prevention & Control
Communicable Disease Epidemiology Section
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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.