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Ultrasound in Percutaneous Procedures: One Size Does Not Fit All for Reprocessing

Published on: May 19, 2023

[Lisa Waldowski, DNP, RN, CIC](#), [Maureen Spencer, RN, M.Ed., CIC, FAPIC](#), [Charles E. Edmiston, Jr., PhD, SM \(ASCP\), CIC \(CBIC\), FIDSA, FSHEA, FAPIC](#), [Shawna Paro, MSN, RN, CIC](#)



Accurate device information and proper sterilization or disinfection are crucial to ensure safety during ultrasound procedures.

Patient contact site	Device classification	Disinfection level
Probe contacts or enter sterile tissue or the bloodstream	Critical	Sterilization
Probe contacts mucous membranes or non-intact skin	Semi-critical	High-level disinfection
Probe only contacts healthy, intact skin	Non-critical	Low-level disinfection

Table 1. The Spaulding classification determines the level of disinfection a device requires based on the patient contact site.¹⁻³

(Credit to the authors.)

(To view, left-click on the picture and open in a new tab.)

anatomy also impact the type of tissue the probe contacts, making this a complex area of infection prevention that needs to be assessed carefully. The level of disinfection required for ultrasound probes used in percutaneous procedures varies and transcends all three categories of Spaulding. While many probes will only contact intact skin, others risk contacting broken skin or sterile tissue, such as the needle puncture site.

Clinicians need to be equipped with the right information to correctly classify the ultrasound probes used in these procedures, ensuring that devices have undergone sufficient disinfection or sterilization prior to use.

This article offers an overview of the complexities of percutaneous procedures and the key infection prevention considerations in this area.

The Spaulding Classification determines disinfection requirements

Spaulding Classification is a cornerstone of infection control practice and a foundational aspect of federal and international infection prevention regulations, standards, and guidelines. The FDA and CDC use the Spaulding Classification in official medical device reprocessing guidance, as do the World Health Organization, The Joint Commission (TJC), and the Association for the Advancement of Medical Instrumentation (AAMI), an internationally recognized standards development organization.¹⁻⁶

Under Spaulding, a device is classified as non-critical if it only contacts intact skin (Table 1). Devices that contact non-intact skin or mucus membranes are classified as semi-critical, while those that contact sterile tissue or the bloodstream are classified as critical. Semi-critical and critical devices require high-level disinfection (HLD) and the use of an FDA-approved sterile sheath at a minimum.¹⁻³

Ultrasound-guided percutaneous procedures are a varied and complex group of medical procedures involving needle puncture of the skin under the guidance of ultrasound imaging. The growth of these procedures has been considerable, creating unique challenges for infection prevention.

There are over 140 unique ultrasound-guided percutaneous procedures with different requirements for placement of the probe and needle used to conduct the intervention. Other factors such as the technique used, level of training of the clinician, patient's medical condition and unique patient



Figure 1. Different percutaneous procedures carry different levels of risk of contact between the ultrasound probe and sterile tissue.

(To view, left-click on the picture and open in a new tab.)



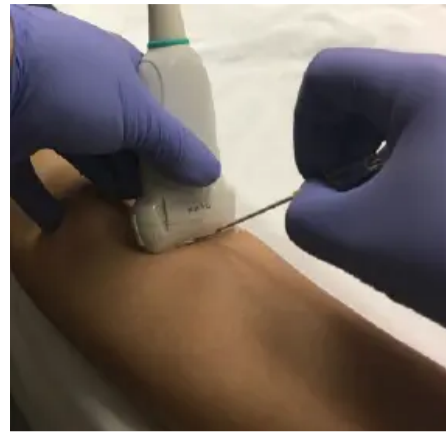


Needle stick injuries also occur at a significant rate during percutaneous procedures, even among experienced interventionalists.¹⁴

Ultrasound-guided central venous catheter placement. Reproduced from Saugel B, et al. *Critical Care* 2017; 21:225.¹⁹

Individual variables can influence the risk of contact

As well as the variation between different types of percutaneous



Ultrasound-guided peripheral intravenous line placement. Reproduced from Gottlieb M. West *J Emerg Med* 2017; 18(6):1047-1054.²⁰

procedures, individual patient or clinician factors may change the level of reprocessing required. These include:

Technique

The “no touch” technique for ultrasound-guided procedures aims to keep the transducer entirely out of the sterile field, away from contact with broken skin, sterile tissue, and sterilized devices. While LLD is acceptable if the no-touch technique is performed without error, the operator's experience level can significantly impact the technique's success. A higher level of disinfection should always be used if the success of the no-touch technique cannot be guaranteed.

Clinical staff

Percutaneous procedures are performed by a range of clinicians with different medical backgrounds and clinical expertise. Infection prevention measures must account for junior staff performing procedures who may have received less formal training. Even with adequate training, multiple attempts are common for percutaneous procedures. Widely used procedures like peripheral intravenous cannula (PIVC) insertion can have first-attempt success rates as low as 65%.¹⁵ Each successive attempt increases the risk of contact between the ultrasound probe and needle, increasing patient infection risk.

Condition of patient

(To view, left-click on the picture and open in a new tab.)



Figure 2. Gouge marks on ultrasound probes indicate contact between the transducer head and needle during percutaneous procedures.

The patient may be immunocompromised or at high mortality risk, requiring a more nuanced consideration of infection risk. There is a general clinical acceptance for heightened awareness for and application of infection prevention practices for those patients in a medically fragile state. There may also be physical characteristics (eg burns, abrasions, wounds, rashes, or pox) that mean the probe is likely to contact with broken skin, therefore requiring HLD or sterilization.

Guidance varies in recommendations for percutaneous procedures.

FDA and CDC guidance states that ultrasound probes must be reprocessed according to the Spaulding classification. That is, probes that come into contact with non-intact skin or sterile tissue must be high-level disinfected at a minimum and should preferably be sterilized. This guidance considers the diversity of percutaneous procedures, allowing for a different level of disinfection depending on the specific clinical procedure and implementation.

In 2021, the American Institute of Ultrasound in Medicine (AIUM) released a position statement on the disinfection of ultrasound probes used for percutaneous procedures, stating that they can safely undergo low-level disinfection (LLD).¹⁶

While guidance is needed in this complex area, this position statement only accounts for a subset of percutaneous procedures—those that contact intact, healthy skin. Some may come in contact with non-intact skin (eg burns, abrasions, wounds, rashes, or pox) and would be semi-critical, minimally requiring HLD. Others will involve contact between the probe and puncture site (sterile tissue), requiring sterilization or HLD with a sterile sheath if sterilization is not possible.

A simplified, universal approach, where all percutaneous procedure probes are considered non-critical, does not account for the reality that some probes have a higher Spaulding classification. Deviation from Spaulding has the potential to create unnecessary risk for patients. To maintain patient safety, clinicians must be aware of the requirements of the Spaulding classification and able to correctly classify probes used in percutaneous procedures as non-critical, semi-critical, or critical.

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