

# Reprocessing ultrasound probes used in percutaneous procedures

## Critical Summary

- Percutaneous procedures are a common and diverse group of medical interventions
- These procedures often utilize ultrasound to guide the needle and increase first attempt success rates
- The level of disinfection required for ultrasound probes used in percutaneous procedures varies depending on the type of tissue that the probe contacts
- A number of factors can increase the risk of contact between the probe and sterile tissue, such as the technique used or anatomy of the patient
- Clinicians performing percutaneous procedures must be aware of these complexities and ensure that ultrasound probes have received the appropriate level of disinfection based on the Spaulding Classification

Percutaneous procedures are those that involve needle puncture of the skin, often under the guidance of ultrasound imaging. There are more than 140 percutaneous procedures performed in a number of different clinical environments, making this a complex area of infection prevention. The risk of contact between the ultrasound probe and sterile tissue during a percutaneous procedure can vary significantly. Clinicians must be aware of the requirements of the Spaulding classification and be able to ensure that probes used in percutaneous procedures have undergone sufficient disinfection or sterilization prior to use.

## The Spaulding Classification for ultrasound probes

The Spaulding Classification is a rational approach to disinfection and sterilization of medical devices that contact the patient. This universally accepted classification scheme has been retained, refined and successfully implemented in clinical settings for over 50 years. It also remains as the foundational guidance and cornerstone of federal and international infection prevention policies. The FDA and other organizations use the Spaulding classification to determine the level of disinfection an ultrasound probe requires, based on the type of tissue that the probe contacts during use.<sup>1-3</sup>

The Spaulding Classification groups devices that contact only intact skin as non-critical devices (Figure 1). Devices that contact non-intact skin or mucous membranes are classified as semi-critical, while those that contact sterile tissue or the bloodstream are classified as critical. Semi-critical and critical devices minimally require high-level disinfection (HLD) and the use of an FDA-approved sterile sheath.<sup>1-3</sup> Surface ultrasound probes used in percutaneous procedures can be classified under any of the three levels of the Spaulding classification. Clinicians must decide in advance whether the probe might contact sterile tissue, broken skin or only intact skin during the procedure.

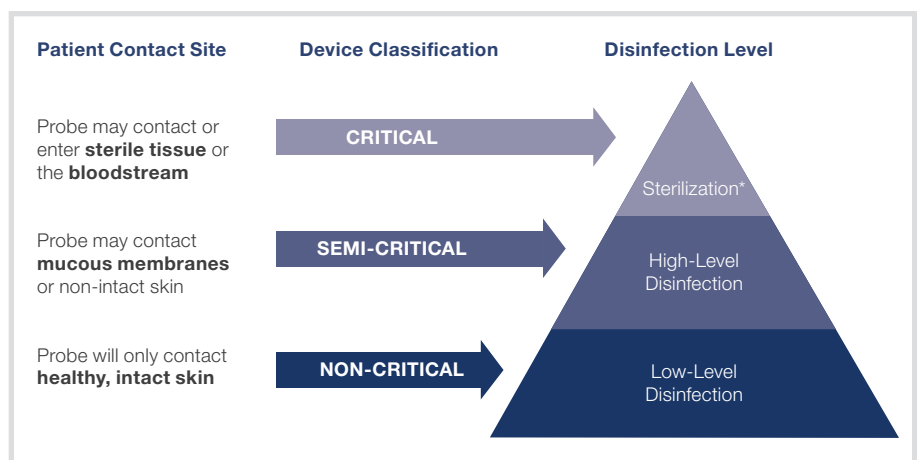


Figure 1. The Spaulding Classification.

\*Or high-level disinfection with a sterile sheath if sterilization is not possible<sup>1,2</sup>


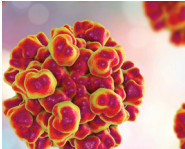
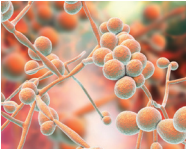

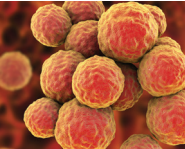
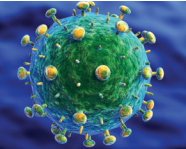
Disinfection Levels	Spores	Non-enveloped viruses	Fungi	Mycobacteria	Bacteria	Enveloped viruses
						
High-level disinfection	Some	✓	✓	✓	✓	✓
Low-level disinfection	X	Some	Some	X	✓	✓

Figure 2. The significant biological and resultant pathological difference between high- and low-level disinfection

## Determining Spaulding for percutaneous procedures

There are more than 140 distinct ultrasound-guided percutaneous procedures, covering at least 9 types of procedural category (Table 1). Common types of percutaneous procedure include biopsies, nerve blocks and vascular access. Some of these procedures will involve no contact between the ultrasound probe and the puncture site, meaning LLD is appropriate for the probe. In some cases, there may be a risk of contact with broken skin during the procedure, meaning the device is semi-critical and requires HLD. Other times, the probe may contact sterile tissue or break the sterile field. In these scenarios, the device is critical and requires sterilization or, if sterilization is not possible, HLD.<sup>1</sup>

When determining the Spaulding classification of a procedure, there are several variables to consider that may influence the risk of contact between ultrasound probe and puncture site. These variables could include the type of procedure being performed, the technique being utilized, the level of training of the clinician performing the procedure, condition of the patient and tissue at the procedural site, as well as aspects of the clinical environment. If these variables cannot be controlled, the clinician should consider using a higher level of disinfection. For example, the FDA defines biopsies as always semi-critical or critical procedures, requiring HLD or sterilization.<sup>1</sup>

**Non-critical**  
Requires low-level disinfection

Probe only contacts healthy, intact skin. No risk of contact with puncture site.



**Critical**  
Requires sterilization or high-level disinfection with the use of a sterile sheath

Probe contacts sterile puncture site or needle



Figure 3. Percutaneous procedures may be critical or non-critical, depending on the risk of contact between the probe and sterile tissue

Table 1. Diversity of ultrasound-guided percutaneous procedures. Adapted from Ultrasound in Percutaneous Procedures: One Size Does Not Fit All for Reprocessing published in Infection Control Today.<sup>4</sup>

**Vascular access**

Intravascular U/G management of large thrombus burden  
 U/G arterial access  
 U/G cannulation of the hemodialysis arteriovenous access  
 U/G central venous catheter insertion  
 U/G hemodialysis cannulation  
 U/G percutaneous embolization  
 U/G peripheral venous access  
 U/G resuscitative endovascular balloon occlusion of the aorta  
 U/G peripherally inserted central venous catheter

**Biopsy**

U/G biopsy of bone lesion  
 U/G biopsy of breast  
 U/G biopsy of esophagus  
 U/G biopsy of liver  
 U/G biopsy of pancreas  
 U/G biopsy of pleural fluid  
 U/G biopsy of pulmonary lesions  
 U/G biopsy of salivary gland  
 U/G biopsy of sclerosing mesenteritis  
 U/G biopsy of thrombus  
 U/G transcutaneous needle biopsy of the base of the tongue and floor of the mouth  
 U/G biopsy of papilloma  
 U/G percutaneous sural nerve biopsy  
 U/G renal biopsy  
 U/G chest biopsy  
 U/G biopsy of thrombus  
 U/G skeletal muscle biopsy  
 U/G biopsy of tumour

**Aspiration**

U/G aspiration of brain abscess  
 U/G aspiration of cyst  
 U/G aspiration of gall bladder  
 U/G aspiration of head and/or neck lumps  
 U/G aspiration of joints and soft tissues  
 U/G aspiration of kidney  
 U/G aspiration of lesions  
 U/G aspiration of liver  
 U/G aspiration of lung  
 U/G aspiration of lymph node  
 U/G aspiration of omentum  
 U/G aspiration of parathyroid  
 U/G aspiration of parotid gland  
 U/G aspiration of pneumothorax  
 U/G aspiration of rotator cuff calcific tendinopathy  
 U/G aspiration of salivary gland  
 U/G aspiration of sentinel nodes  
 U/G aspiration of spleen  
 U/G aspiration of submandibular glands  
 U/G aspiration of superficial inguinal node  
 U/G aspiration of synovial tissue  
 U/G aspiration of thyroid  
 U/G aspiration of hematoma  
 U/G percutaneous aspiration of hyperreactive luteinosis  
 U/G amniocentesis  
 U/G paracentesis  
 U/G pericardiocentesis

**Drainage**

U/G drainage of pancreatic pseudocyst  
 U/G drainage of walled-off pancreatic necrosis  
 U/G external ventricular drain  
 U/G liver drainage  
 U/G percutaneous appendix drainage  
 U/G percutaneous catheter drainage  
 U/G percutaneous drainage of diverticula  
 U/G percutaneous drainage of iliopsoas abscess  
 U/G percutaneous drainage of splenic abscess  
 U/G percutaneous drainage of muscle hematomas  
 U/G percutaneous drainage of spermatic cord abscess  
 U/G percutaneous drainage psoas abscess  
 U/G percutaneous pericardial effusion drainage  
 U/G percutaneous transhepatic gallbladder drainage  
 U/G puncture and drainage of abdominal and pelvic abscesses

**Nerve block**

U/G femoral nerve block  
 U/G ankle block  
 U/G axillary block  
 U/G brachial plexus block  
 U/G cervical nerve root block  
 U/G celiac plexus neurolysis  
 U/G continuous peripheral nerve block  
 U/G penile nerve block  
 U/G dorsal ramus block  
 U/G epidural placement of a thoracic paravertebral catheter  
 U/G genicular nerve block  
 U/G palatine nerve block  
 U/G infraorbital nerve block  
 U/G intercostal nerve and stellate ganglion blocks  
 U/G laryngeal nerve block  
 U/G lumbar plexus block  
 U/G nerve stimulation  
 U/G neuraxial block  
 U/G ophthalmic regional anesthesia  
 U/G paravertebral block  
 U/G pectoral nerve blocks  
 U/G percutaneous cryoneurolysis  
 U/G percutaneous peripheral nerve stimulation  
 U/G phrenic nerve block  
 U/G pudendal nerve block  
 U/G quadratus lumborum nerve block  
 U/G rectus sheath block  
 U/G regional blockade for lipoma excision  
 U/G sciatic nerve block  
 U/G ophthalmic regional anesthesia  
 U/G mandibular nerve block  
 U/G thoracic paravertebral block  
 U/G thoracolumbar interfascial plane block  
 U/G transversus abdominis plane block  
 U/G trigeminal nerve block

**Injection**

U/G autologous tenocyte injection  
 U/G dry needling with percutaneous paratenon decompression  
 U/G injection of Botulinum type A toxin

U/G joint injection (steroids, lidocaine, hyaluronic acid)  
 U/G lumbar puncture  
 U/G percutaneous ethanol injection  
 U/G percutaneous injection of methylene blue  
 U/G perineural injection for nerve blockade  
 U/G thrombin injection

**Ablation**

U/G cryoablation  
 U/G electroporation ablation  
 U/G ethanol ablation  
 U/G laser ablation  
 U/G microwave ablation  
 U/G radiofrequency ablation

**Intraoperative**

Excision with U/G needle localization  
 Intraoperative U/G percutaneous biopsy of tumor  
 Intraoperative U/G tracer injection  
 U/G implantation of iodine seeds  
 U/G percutaneous renal transplant biopsy  
 U/G transplantation of ASCs or placebo to the submandibular glands  
 U/G transthoracic punctures  
 U/G vacuum-assisted excision

**Other**

U/G assisted interventions in abdominal treatment  
 U/G foam sclerotherapy  
 U/G hydrodissection of the sural nerve  
 U/G percutaneous irrigation of calcific tendinopathy  
 U/G percutaneous nephrolithotomy  
 U/G percutaneous nephrostomy  
 U/G subacromial bursography  
 U/G retrograde pedal access  
 U/G liposuction for hidden arteriovenous fistulas  
 U/G pharmacomechanical thrombolysis and angioplasty  
 U/G cryoanalgesia of peripheral nerve lesions  
 U/G needle lavage  
 U/G dry needling

Specialty group	Number of procedures
Nerve block	35
Aspiration	27
Biopsy	18
Drainage	15
Vascular Access	9
Injection	9
Intraoperative	8
Ablation	6
Other	13
<b>Total</b>	<b>140</b>

# Guidelines require HLD for semi-critical and critical uses of ultrasound probes

Surface ultrasound probes used in semi-critical and critical applications should be sterilized between uses whenever feasible, but high-level disinfection (HLD) is minimally acceptable.<sup>1,2</sup>

Single use, sterile sheaths are recommended for semi-critical and critical applications. However, the use of a sheath does not change the level of disinfection required. Gouge marks on ultrasound probes demonstrate that the needle can penetrate the sheath during percutaneous procedures.<sup>5</sup> This means that biological material present on the sheath and transducer head could come into contact with sterile tissue, increasing the risk of infection.



Figure 4. Gouge marks on ultrasound probes, indicating contact between the transducer head and needle during percutaneous procedures

## Federal guidelines on sheath use

“If [sterilization] is not possible, at a minimum the probe should be high-level disinfected and covered with a sterile probe cover.” –**CDC**<sup>2</sup>

“Do not use a lower category of disinfection or cease to follow the appropriate disinfectant recommendations when using probe covers because these sheaths and condoms can fail.” –**CDC**<sup>2</sup>

“For clinical applications of a semi-critical or critical nature (e.g. intraoperative, transrectal, transvaginal, transesophageal, or biopsy procedures), labeling should recommend, when appropriate, the use of sterile, legally marketed probe sheaths. Note that the use of sheaths does not change the type of reprocessing that is recommended after each use.” –**FDA**<sup>1</sup>

Contact us today to discuss your specific needs on when to HLD at your facility.



**References:** 1. FDA 2019. Marketing Clearance of Diagnostic Ultrasound Systems and Transducers. 2. CDC 2008. Guidelines for Disinfection and Sterilization in Healthcare Facilities. 3. Spaulding EG 1968. Chemical disinfection of medical and surgical materials. Disinfection, sterilization and preservation 4. Waldowski L, Spencer M, Edmiston C, Paro S. Ultrasound in Percutaneous Procedures: One Size Does Not Fit All for Reprocessing. Available at: <https://www.infectioncontroltoday.com/view/ultrasound-percutaneous-procedures-one-size-does-not-fit-all-reprocessing> 5. De Cassai A, Tonetti T. Central venous line placement and ultrasound probe damage: a word of caution. J Med Ultrasound 2019;27:110.

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