

It is essential to adequately reprocess ultrasound probes prior to patient use, including external ultrasound probes used in intraoperative and percutaneous procedures.

Reprocessing external ultrasound probes used to guide invasive procedures

Introduction

External ultrasound probes are used in a multitude of procedures including diagnostic wound and trauma scans, invasive procedures (e.g. biopsies, injections and drainages) and in surgery (Figure 1). The expansion of ultrasound has brought immense clinical benefit to patients but has also generated some potential infection prevention challenges which need to be addressed. It is essential to adequately reprocess ultrasound probes prior to patient use, and the framework governing this reprocessing is the universally accepted Spaulding classification system.

The Spaulding Classification System

The Spaulding classification is the framework for medical device reprocessing used by the US Food and Drug Administration (FDA), Centers for Disease Control and Prevention (CDC), Association for the Advancement of Medical Instrumentation (AAMI) and many other organizations.¹⁻⁶ A medical device is assigned a category based on the site of patient contact, and this defines the reprocessing requirements.

If external probes used to guide invasive procedures contact sterile tissue or the bloodstream at the needle insertion site, the probe is critical according to the Spaulding classification (Box 1).¹⁻⁶

Box 1: Definitions of critical devices under the Spaulding classification.

“Critical devices are devices that are introduced directly into the bloodstream or which contact a normally sterile tissue or body-space during use.” – FDA³

“Critical devices are those that are introduced directly into the human body, either into or in contact with the bloodstream or other normally sterile areas of the body.” – AAMI⁴

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1. U/G liver biopsy
2. U/G extra visceral abdominal mass biopsy
3. U/G chest mass biopsy
4. U/G breast biopsy
5. U/G bone tissue/lesion biopsy
6. U/G fine needle aspiration of thyroid nodules
7. U/G superficial lymph node biopsy
8. Intraoperative biopsies
9. Transplant surgeries using ultrasound (e.g., liver, kidney, heart)
10. U/G thrombectomy
11. U/G breast surgery
12. U/G hepatic tumor ablation
13. U/G abscess localization and removal
14. U/G lithotripsy
15. U/G fluid/cyst aspirations
16. U/G foreign body localization/removal
17. Focused assessment with sonography in trauma (FAST)
18. Burn patient assessment (contact with sterile tissue, blood)
19. Deep wound assessment (contact with sterile tissue, blood)
20. Focussed diagnostic echocardiography (e.g., cardiac resuscitation in presence of trauma)
21. U/G percutaneous tracheostomy
22. U/G thoracentesis
23. U/G transbronchial needle aspiration
24. U/G thermal ablation of renal lesion
25. U/G nasogastric intubation
26. U/G endotracheal intubation
27. Intraoperative U/G thermal ablation of liver lesion
28. U/G abdominal paracentesis
29. U/G percutaneous transhepatic biliary drainage
30. U/G cholangiography/biliary stenting
31. U/G percutaneous suprapubic cystostomy
32. U/G percutaneous cholecystectomy
33. U/G intravascular valve replacement
34. U/G intravascular valve repair
35. U/G intravascular thrombus dissolution
36. U/G vascular ablation
37. U/G transvenous pacemaker placement
38. U/G arterial heart ablations
39. U/G direct percutaneous sclerosis of vascular malformation
40. Intraoperative U/G cardiac surgeries
41. U/G pericardiocentesis
42. Evaluation of vessel patency
43. U/G central venous access
44. U/G peripheral IV placement
45. U/G urinary catheterization
46. U/G nerve blocks
47. U/G suprapubic bladder aspirations
48. U/G percutaneous nephrostomy
49. Tumor staging and metastatic surveys
50. Intraoperative U/G resection surgeries
51. Intraoperative U/G metastasectomy
52. Intraoperative U/G ablative surgeries
53. U/G percutaneous peripheral nerve stimulation
54. U/G perineural catheter placement
55. U/G spinal pain procedures
56. Intraoperative ultrasound in neurosurgical procedures
57. U/G tendinous calcium barbotage
58. U/G trigger point needling
59. U/G tendon and articular injections
60. U/G percutaneous needle tenotomy
61. U/G aspiration of juxta-articular collections
62. U/G aspiration of soft tissue collections
63. U/G arthrocentesis
64. U/G foreign body removal
65. U/G general anesthesia
66. U/G neuroaxial and chronic pain procedures
67. U/G airway assessment
68. U/G amniocentesis
69. U/G cordocentesis
70. U/G chorionic villus sampling



1. U/G liver biopsy



43. U/G internal jugular cannulation



46. U/G femoral nerve block

Figure 1 – Non-exhaustive list of procedures involving the use of ultrasound where the probe risks contact with sterile tissue or the bloodstream. These procedures are performed across departments including radiology, OB/GYN/MFM, emergency, cardiology, operating rooms, adult intensive care units and vascular clinics. U/G = ultrasound guided.

Critical ultrasound probes require sterilization.¹⁻⁶ If sterilization is not possible, the CDC offers a concession that the ultrasound probe can undergo high level disinfection and be used with a sterile sheath (Box 2).⁵

Box 2: CDC guideline for disinfection and sterilization in healthcare facilities (2008).

“If [sterilization] is not possible, at a minimum the probe should be high-level disinfected and covered with a sterile probe cover.”⁵

Sheath Use

The use of a protective barrier does not change the classification of the probe and merely acts as another mechanism to reduce infection risk (Box 3).^{5,6}

Box 3: Federal guidelines on sheath use.

“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.”
– CDC⁵

“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.” – FDA⁶

The classification of an ultrasound probe as a non-critical device is limited to use in external scans across healthy, intact, unbroken skin (e.g., routine transabdominal scans).

Conclusion

Facilities should review their ultrasound guided intraoperative and percutaneous procedures in light of the Spaulding classification. Where contact with sterile tissue can occur, the probe should be sterilized or be high level disinfected and used with a sterile sheath according to FDA, CDC guidelines and AAMI standards.

References

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