Ultrasound Infection Prevention
Risks, Challenges and Solutions

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Learning objectives

• Review recent research documenting infection risk from ultrasound procedures.

• Determine the reprocessing requirements for ultrasound probes, used in a variety of procedures, by applying the Spaulding classification, CDC and FDA guidelines.

• Discuss the significance of available evidence demonstrating the high frequency of contact between the ultrasound probe and sterile puncture site in a variety of percutaneous interventions.

• Explain the application of the ultrasound IP Toolkit components (‘Locate and Profile’, ‘Algorithm’, ‘Risk Assessment’ and ‘Policy’ tools) to ensuring that patients are safe from infection risk.
What is ultrasound?

• Ultrasound probes are heat sensitive reusable medical devices used to visualise the anatomy in a variety of procedures.

• Ultrasound probes can require LLD, HLD or sterilization depending on the patient contact site. The same probe may require LLD for one procedure, then HLD for another procedure.

• Ultrasound probes come in a variety of shapes and sizes for a variety of procedures.

- **External / Surface Probes**
  - e.g. Doppler, linear, curvilinear, intraoperative probes

- **Endocavitary Probes**
  - e.g. transvaginal, transrectal, transesophageal probes
Risk from ultrasound procedures

2017, USA. Joint Commission. 74% of all immediate threats to life were from improper sterilization or HLD of devices.

2018, USA. Facilities being cited for improper ultrasound probe reprocessing.


Risk from ultrasound procedures

2012, UK. Patient death from hepatitis B infection thought to have been transmitted via endocavitary ultrasound

Probe was not properly disinfected.

MHRA (similar to FDA) released an alert to review all ultrasound disinfection practices in UK.

Risk from ultrasound procedures

2018, Scotland. Study demonstrated epidemiological link between improper endocavitary probe disinfection with LLD and increased infection risk.

- 30 days after a TV scan (results highly significant):
  - Patient is 41% more likely to have positive bacterial cultures
  - Patient is 26% more likely to be prescribed antibiotics

- 30 days after a TR scan (results highly significant):
  - Patient is 3.40x more likely to have positive bacterial cultures
  - Patient is 75% more likely to be prescribed antibiotics

- 30 days after a TOE scan:
  - Patient is 4.92x more likely to have positive bacterial cultures (result highly significant)
  - Patient is 5% more likely to be prescribed antibiotics (not significant)
Outbreaks have occurred in external ultrasound probe guided procedures, linked to contaminated ultrasound gel.

Multiple patients affected across many facilities, following ultrasound guided CVC insertion, nerve blocks, arthrocentesis, amniocentesis, among many more.1-3

Overview of ultrasound probe reprocessing

**Cleaning**
A process which involves physical removal of soil from the surfaces of devices to prepare the items for safe handling and/or further decontamination.

**Disinfection**
Process by which pathogenic microorganisms are destroyed in order to prevent patient to patient transmission.

**Storage**
A process that prevents recontamination of reprocessed devices, ensuring they are available for reuse.

**Traceability**
The ability to verify the history, location, or application of an item by means of documented recorded identification. Semi-critical and critical probes must be traced.

AAMI ST58:2013 - Chemical sterilization and high-level disinfection in health care facilities.
Spaulding classification

**Device Classification**
- **CRITICAL**: Device enters or contacts sterile tissue or the bloodstream
- **SEMI-CRITICAL**: Device contacts mucous membranes or non-intact skin
- **NON-CRITICAL**: Device only contacts intact, healthy skin

**Disinfection Level Required**
- **Low Level Disinfection**: Most vegetative bacteria and viruses destroyed, except bacterial spores, mycobacteria, fungi, or small non-lipid viruses.
- **High Level Disinfection**: All viable microorganisms must be destroyed, except bacterial spores.
- **Sterilization**: All viable microorganisms must be destroyed.
CDC & FDA: Sheaths don’t replace reprocessing

‘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.’ (pg. 89)


‘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.’ (pg. 17)


‘The probe used in a semi-critical application should be cleaned and sterilized or at least receive high level disinfection after use even if a sheath was used. Probes used for critical applications should be cleaned and sterilized after use even if a sterile sheath was used. Sheaths can fail during use and the level of resulting contamination may not be easily visible.’ (pg. 57)
Ultrasound is complex

- People
  - Doctors
  - Nurse Practitioners
  - Physician Assistants
  - Students
  - Technicians
  - Sonographers
  - Radiologists
    - Physical Therapists
    - Allied Health
    - etc.

- Places
  - OBGYN/MFM
  - Interventional radiology
  - Emergency
  - Cardiology
  - Surgery
  - Anesthesiology
  - Gastroenterology
    - Musculoskeletal
    - Nephrology
    - etc.

- Procedures
  - Transvaginal scans
  - Transrectal scans
  - External surface scans
  - Intraoperative scans
  - Biopsies
  - Drainages
  - Aspirations
    - Injections
    - Cannulations
    - etc.

Probes are widely used in invasive procedures and can involve contact with sterile tissue or mucous membranes

**Complex to manage**
Varied practices in ultrasound reprocessing across healthcare

2018, USA. Survey finds ultrasound use is far more widespread than expected.

Ultrasound is used in almost every healthcare department.

Variability in ultrasound probe disinfection practices for the same procedure across the nation.

How do we begin to standardize probe reprocessing policy and practice rationally?
External Ultrasound Probe Reprocessing
External probe reprocessing is more complex than endocavitary probe reprocessing.
Example procedures with external ultrasound probes

Scan across healthy skin
eg routine pregnancy

Scan across unhealthy skin
eg epidermal cyst scan

Percutaneous intervention
eg biopsy

Increasing risk of infection

Probe

Healthy skin

Probe

Non intact skin

Probe

Needle
Sterile tissue
Target

Skin
The Spaulding Classification

• CDC, FDA, AORN guidelines and AAMI standards use this framework to define requirements for device disinfection and sterilization in healthcare settings.¹⁻⁶

• Healthcare facilities must correctly apply this framework for accreditation (covered in CMS infection control worksheet and TJC standards).⁷,⁸

• It is a rational approach to disinfection and sterilization of resuable devices based on risk¹⁻⁹

• Framework is so clear and logical that it has been successfully used since its inception in 1968 by reprocessing experts to determine the appropriate level of disinfection or sterilization.¹

2. FDA 2000. Content and Format of Premarket Notification [510(k)] Submissions for Liquid Chemical Sterilants/High Level Disinfectants.
5. AORN. Guidelines for Perioperative Practice
6. ST58:2013 Chemical sterilization and high-level disinfection in health care facilities.”
The Spaulding classification

- **CRITICAL**: Device enters or contacts sterile tissue or the bloodstream
  - "The first category is that of critical items, so called because the risk is great. They are either introduced beneath the surface of the body or attached to another object which is, i.e., transfer forceps, scalpel blades, cardiac catheters and plastic components of the heart-lung oxygenator."

- **SEMI-CRITICAL**: Device contacts mucous membranes or non-intact skin
  - "Materials in the second category are semicritical items...They make direct contact with mucous membranes, but these tissues are intact and therefore constitute barriers to infection."

- **NON-CRITICAL**: Device only contacts intact, healthy skin
  - "The third category consists of noncritical items which do not make contact with the patient or, if they do, only with unbroken skin."

The Spaulding Classification

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Ultrasound probes used during surgical procedures also can contact sterile body sites. These probes can be covered with a sterile sheath to reduce the level of contamination on the probe and reduce the risk for infection. However, because the sheath does not completely protect the probe, the probes should be sterilized between each patient use as with other critical items. If this is not possible, at a minimum the probe should be high-level disinfected and covered with a sterile probe cover.” (pg. 19)
FDA reprocessing recommendations for probes used in surgery and in biopsies

‘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.’ (pg. 17)

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Other guidelines

• American Institute of Ultrasound in Medicine (AIUM) changed their guidelines in March 2018 from HLD to LLD for percutaneous intervention

• Contradicts FDA, CDC and Spaulding

• AIUM includes a caveat – “If there is reason to believe that the probe cover may become compromised, the probe must be high-level disinfected prior to the procedure”

• A survey found that 25.4% of interventional radiologists had experienced a needle stick injury in the past year; 75.5% of cases were attributed to operator error¹

Application of FDA, CDC and Spaulding to other procedures

Biopsy probe requires minimum HLD with use of sterile sheath according to FDA & CDC.

Following Spaulding’s rationale, if the probe contacts sterile tissue, then these probes are critical devices.
‘Virtual Observation’ analysis study

• Purpose of this study was to investigate whether contact with puncture site occurred in routine procedures

• Video stills were analysed from educational YouTube content. The first 100 videos from each procedure search were analysed with selection criteria applied (e.g. probe and needle need to be clearly visible and performed on a real patient).

• Following Spaulding’s rationale, if the probe contacts sterile tissue, then these probes are critical use devices. If probe contacts broken sin, probes are semi critical use devices.
Methods – Category definition and assignment

Category A
Clear contact between probe and needle puncture

Category B
Probe and needle in very close proximity (< 10 mm)

Category C
Probe and needle not in very close proximity (> 10 mm)
Results – High risk of contact between probe and puncture in 90% of procedures

<table>
<thead>
<tr>
<th>Ultrasound guided procedure category</th>
<th>Search string</th>
<th>Met inclusion criteria (n)</th>
<th>A:* n (%)</th>
<th>B:† n (%)</th>
<th>C:‡ n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biopsy</td>
<td>Ultrasound guided biopsy</td>
<td>21</td>
<td>9 (43%)</td>
<td>10 (48%)</td>
<td>2 (10%)</td>
</tr>
<tr>
<td>Nerve block (NB)</td>
<td>Ultrasound guided nerve block</td>
<td>29</td>
<td>9 (31%)</td>
<td>12 (41%)</td>
<td>8 (28%)</td>
</tr>
<tr>
<td>Drainage</td>
<td>Ultrasound guided drainage</td>
<td>10</td>
<td>5 (50%)</td>
<td>4 (40%)</td>
<td>1 (10%)</td>
</tr>
<tr>
<td>Central venous catheter insertion (CVC)</td>
<td>Ultrasound guided central venous catheter</td>
<td>18</td>
<td>9 (50%)</td>
<td>8 (44%)</td>
<td>1 (6%)</td>
</tr>
<tr>
<td></td>
<td>Ultrasound guided peripherally inserted central catheter</td>
<td>36</td>
<td>21 (58%)</td>
<td>13 (36%)</td>
<td>2 (6%)</td>
</tr>
<tr>
<td>Peripheral venous access</td>
<td>Ultrasound guided peripheral IV &lt;search 2&gt;</td>
<td>36</td>
<td>21 (58%)</td>
<td>13 (36%)</td>
<td>2 (6%)</td>
</tr>
<tr>
<td><strong>Total, Average: n (%)</strong></td>
<td></td>
<td></td>
<td><strong>53 (50%)</strong></td>
<td><strong>47 (40%)</strong></td>
<td><strong>14 (10%)</strong></td>
</tr>
</tbody>
</table>

* Category A: Clear contact between ultrasound probe and needle or puncture site.
† Category B: Ultrasound probe is in very close proximity (<10mm).
‡ Category C: Ultrasound probe is not in close proximity (>10mm).
Results – Examples of clear contact (Category A)

Internal jugular vein central venous catheter insertion

Central venous catheter insertion
Results – Examples of clear contact (Category A)

Liver abscess drainage  Pericardiocentesis
Results – Examples of clear contact (Category A)

Interscalene block

Thoracentesis
Takeaways from virtual observation

• Analysis shows regular contact between needle and probe

• Important for facilities to review and observe their use of ultrasound to guide procedures and apply Spaulding

• When developing policies, prioritize evidence based guidelines and standards promulgated by standards development agencies recognized by TJC and CMS.

• Where risks to the patient exist, reviews and risk assessments should be conducted to maximise patient safety.
Practicalities of implementation in vascular access

• There are some procedures where routine HLD of probes used in percutaneous interventions would be more difficult

• Example: mobile vascular teams – there is currently no practicable solution for mobile HLD

• Institutions should review what they should do for these procedures

• AVA guidelines recommend LLD + sheath, however include a caveat that recommends HLD:

  “14. In the event ongoing process monitoring identifies cleaning and disinfectant failure(s), adverse patient outcomes that may be attributable to transducer reprocessing methods, or user techniques that demonstrate risk to the use of Low Level Disinfection (e.g., needlestick injuries, damage to transducer/probes, punctures of sheaths during procedures) existing approaches should be re-evaluated with consideration of operational and organizational changes including centralization of cleaning and disinfection, use HLD, or other changes that serve to protect the safety of the patient. “

Practicalities of implementation

• This is a complex issue that needs collaboration between IPs, reprocessing experts, risk management experts, quality experts, patient safety experts, department heads and staff.

• Working together to discuss, observe procedures and review or write policy takes time.

• A group of experts have developed some tools to help IPs initiate these processes to work toward the common goal of patient safety.
Introducing the Ultrasound IP Toolkit

• Four free practical tools designed by a group of concerned IPs and device reprocessing experts to help users meet existing evidence-based guidelines and standards.

• Editable to comply with institutional, local, state and regional policies/guidelines.

Contributors

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Accessing the toolkit

www.ultrasoundinfectionprevention.org

Instructional video by Amy Nichols RN MBA CIC presented at APIC 2018 National Conference
Accessing the toolkit

Download all 4 tools as a zip file
Download tools individually
Option to sign up for updates as more tools are posted

www.ultrasoundinfectionprevention.org
### Tool 1 – First locate ultrasound machines

<table>
<thead>
<tr>
<th>Strategy</th>
<th>Rationale</th>
<th>How</th>
<th>Limitations</th>
</tr>
</thead>
</table>
| 1. Locate where ultrasound machines are by searching the organization’s asset register. | Clinical/Biomedical Engineering department maintains an asset register of equipment used throughout the facility. The asset register links the ultrasound machine and associated service contracts to department locations. | Ask the Clinical/Biomedical Engineering department to provide a complete list of ultrasound probes and consoles from their asset register. Identify the department in which they are located. | • Not all ultrasound machines may be listed on the register.  
• Asset registers may be incomplete (e.g., due to mergers/acquisitions, purchases being made by local departments, trial equipment is being used or other reasons). |
| 2. Locate where ultrasound consumables are being used (e.g., gel, probe sheaths/covers). | All ultrasound probes are used with ultrasound gel which is essential for imaging quality. Some ultrasound probes are used with sheaths/covers. Locating ultrasound gel and probes covers will lead to the departments using ultrasound probes. | Approach materials management, purchasing or supply chain management and request they search purchase orders and inventory lists for each department/the facility, and provide a report of material. | • It may be difficult to obtain purchase orders and inventory, particularly if a central system is not in place.  
• Some consumables may be ordered centrally and distributed or may be ordered and purchased locally (e.g., by individual departments or units). |
| 3. Survey departments to identify where ultrasound is used. | End users are the best placed to know where ultrasound is being used. | Approach departments and ask about their ultrasound use. Methods include but are not limited to: departmental/facility wide email, physically visiting or phoning each department and/or patient care unit leadership. | • It may be time consuming to reach all departments.  
• It may be difficult to identify staff with full knowledge of ultrasound use in their department. |
| 4. Identify billable ultrasound procedures in financial records. | Ultrasound procedures should be billed. If ultrasound procedure item codes are obtained, they can then be used to identify which departments or providers are billing for those items. | Identify ultrasonography billing codes; ask finance department for a list of billing records that involve ultrasound procedure item codes and determine which departments are billing for those items. | • Billing may not provide department specific information.  
• The finance system may not be setup to readily perform these searches.  
• It may be difficult to determine which item codes are associated with ultrasound procedures or probes. |

- Example strategies are listed
- Ordered by assumed effectiveness
- All can be used in combination to locate all your machines
Tool 1 – Profile procedure policy and practice

• Checklist guides user through reviewing policy and procedures

• Visit department and read policy

• Record how policy directs user to disinfect and use probe

• Determine if policy complies with guidelines (see Tool 2)
### Tool 1 – Profile procedure policy and practice

<table>
<thead>
<tr>
<th>Reprocessing:</th>
<th>□ Sterilized</th>
<th>□ HLD</th>
<th>□ LLD/ILD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cover use:</td>
<td>□ Sterile</td>
<td>□ Single use non-sterile</td>
<td>□ None</td>
</tr>
<tr>
<td>Gel use:</td>
<td>□ Single use sterile</td>
<td>□ Single use non-sterile</td>
<td>□ Multiuse bottle</td>
</tr>
</tbody>
</table>

4. **Observe Practice.** How is the probe reprocessed and used by the end users for this procedure?

5. **Assess Practice.** Is the observed practice compliant with your policy?
   - □ Yes
   - □ No
   - □ No policy in place

6. **Were any shaded options selected?**
   - □ Yes. **Go to Q7.**
     - □ No. Congratulations, your policy and practice are compliant. No further action needed. File this form, ensure ongoing training for all users.

7. **Action Plan Required.** Your policy needs updating or users are not trained according to your policy/procedure. Note action and effectiveness review date below for each shaded option.

Effectiveness Review Date: ___/___/____

- Observe how users reprocess and use probe in practice
- If shaded boxes selected, action plan required due to discrepancies between policy, practice and guidelines
Tool 2 - Algorithm

- Organized by department
- Provides a range of typical procedures for that department.
- Probe use and reprocessing requirements are presented as a decision making algorithm based on CDC, FDA guidelines and AAMI standards.

Use this tool:
- As a printed quick reference guide in the department’s procedure room
- To guide assessment of practice/policy in Tool 1
- With Tool 4 – Policy Development Framework, to help build your facility/department policy
Available for the following departments:

1. Anesthesiology
2. Emergency
3. Cardiology
4. Gastroenterology
5. Musculoskeletal
6. Nephrology
7. Neurology
8. OB/GYN/MFM
9. Oncology
10. Pulmonology
11. Radiology and Interventional Radiology
12. Urology
13. Vascular
Tool 3 – Example risk assessment

- Designed to assess potential hazards that may be encountered during the use and reprocessing of ultrasound probes
- Use to assess safety of existing processes and processes under consideration
- Consider new products/processes if mitigations cannot be reduced to low
- Not all rows in example may be relevant to your specific situation – those rows can be deleted and other rows can be added
- 4 templates: cleaning, disinfection, storage and use
Tool 3 – Example risk assessment

• An example risk matrix is provided
• Facility may have standard risk matrix which can be used

<table>
<thead>
<tr>
<th>Likelihood × Severity</th>
<th>Negligible</th>
<th>Minor</th>
<th>Moderate</th>
<th>Significant</th>
<th>Critical</th>
</tr>
</thead>
<tbody>
<tr>
<td>Almost certain</td>
<td>Medium</td>
<td>High</td>
<td>High</td>
<td>Extreme</td>
<td>Extreme</td>
</tr>
<tr>
<td>Likely</td>
<td>Low</td>
<td>Medium</td>
<td>High</td>
<td>High</td>
<td>Extreme</td>
</tr>
<tr>
<td>Possible</td>
<td>Low</td>
<td>Medium</td>
<td>Medium</td>
<td>High</td>
<td>High</td>
</tr>
<tr>
<td>Unlikely</td>
<td>Low</td>
<td>Low</td>
<td>Medium</td>
<td>High</td>
<td>High</td>
</tr>
<tr>
<td>Highly unlikely</td>
<td>Low</td>
<td>Low</td>
<td>Low</td>
<td>Medium</td>
<td>High</td>
</tr>
</tbody>
</table>

**Likelihood** = the chance that the hazard will occur and result in harm

**Severity** = seriousness of harm

**Likelihood × Severity = Risk**
## Tool 3 – Example risk assessment

**Table 1: Risk matrix for determining risk ratings.**

<table>
<thead>
<tr>
<th>Likelihood</th>
<th>Negligible</th>
<th>Minor</th>
<th>Moderate</th>
<th>Significant</th>
<th>Critical</th>
</tr>
</thead>
<tbody>
<tr>
<td>Almost certain</td>
<td>Medium</td>
<td>High</td>
<td>High</td>
<td>Extreme</td>
<td>Extreme</td>
</tr>
<tr>
<td>Likely</td>
<td>Low</td>
<td>Medium</td>
<td>High</td>
<td>High</td>
<td>Extreme</td>
</tr>
<tr>
<td>Possible</td>
<td>Low</td>
<td>Medium</td>
<td>Medium</td>
<td>High</td>
<td>High</td>
</tr>
<tr>
<td>Unlikely</td>
<td>Low</td>
<td>Low</td>
<td>Medium</td>
<td>High</td>
<td>High</td>
</tr>
<tr>
<td>Highly unlikely</td>
<td>Low</td>
<td>Low</td>
<td>Low</td>
<td>Medium</td>
<td>High</td>
</tr>
</tbody>
</table>

### Does this hazard and harm apply?
- **Chemical/Physical**
  - Disinfection/sterilization process not deemed compatible by ultrasound equipment manufacturer leading to damage to ultrasound equipment.
  - Damaged equipment could lead to compromised image quality and misdiagnosis or injury to patients.

### Rate likelihood, severity and risk

### Can mitigation be applied or low risk after mitigation?
- Ensure the disinfection/sterilization process is deemed suitable by the manufacturer and follow the manufacturer’s IFU regarding disinfection or sterilization.
- Following the manufacturer’s instructions for use with respect to disinfection/sterilization protocol.
- Using a validated, automated disinfection/sterilization method that is also deemed compatible with the equipment.

### Risk After Mitigation
- Low
Tool 4 – Policy development framework

This tool provides the framework to help develop an ultrasound infection prevention policy.

Comprehensive document covering all aspects of probe reprocessing, probe use and staff training.

Completely editable document to address different departments and facilities.

Developed based on major evidence based guidelines, standards and scientific literature.
Tool 4 – Policy development framework

4. Overview of ultrasound probe reprocessing and use

The steps in ultrasound probe reprocessing and use are summarized in Figure 1. The steps are probe cleaning, disinfection/sterilization, transport/storage, gift selection, cover selection and patient use. The information in these steps need to be linked (traceability) and responsibilities throughout this process must be clearly defined.

The requirements in this policy relating to ultrasound reprocessing and use have been developed based on the reusable medical device reprocessing requirements in the ANSI/AAMI Standard ST38:2013 Chemical Sterilization and High-Level Disinfection in Health Care Facilities (AAMI Standard) and specific ultrasound use and reprocessing requirements in the CDC 2008 Guideline for Disinfection and Sterilization in Healthcare Facilities (CDC Guidelines).1,5 Where elements relate to facility accreditation, reference is made to the Centers for Medicare and Medicaid Services (CMS) Infection Control WorkSheets.1,5,6 This policy also follows recommendations from the MIFUs of chemical sterilants, high level disinfectants, reprocessing equipment and ultrasound probes used at this facility to ensure compatibility with probe materials.

This policy complies with the following local and state regulation/policies [list relevant regulations].

Update this overview to specify relevant regulations.

5. Ultrasound probe reprocessing

5.1 Cleaning

Cleaning is the essential first step in reprocessing. Improper cleaning could result in subsequent failure or activation defective. The CDC Guidelines define cleaning as “...the removal of visible soil (e.g., organic and inorganic material) from objects and surfaces.” This is generally accomplished manually or mechanically and may include a rinsing step (See “Rinsing and Drying”).1,5

Extra care should be taken when cleaning probes that have indentations or complex surfaces. The probe MIFU should always be consulted for cleaning instructions and lists of compatible products. Typical cleaning solutions indicated for use with ultrasound probes include detergent-based cleaning wipes, detergent in combination with running water and enzymatic cleaning agents. The cleaning method should be indicated for use on ultrasound probes, be effective, be compatible with the probe and be safe for the user. Ensure appropriate PPE is available for staff to undertake the cleaning process. Perform rinsing if required by the MIFU of the cleaning product. After the conclusion of the cleaning process, the probe should be dried to prevent interference in subsequent steps.

According to AAMI Standards and CDC Guidelines cleaning should be confirmed by visual inspection before the device is disinfected or sterilized.1,5

Note the cleaning process used in your department/facility and reference or specify the standard operating procedure (SOP) here.

5.2 Disinfection and Sterilization

5.2.1 Assigning the Spaulding Classification of the Probe

Each ultrasound probe should be classified according to the Spaulding criteria based on its intended use. Medical devices can be classified into three categories based on the patient tissues they contact and associated infection transmission risk. The Spaulding classification system dictates the level of disinfection/sterilization required for the ultrasound probe.1,5

Referenced

Blue instructional boxes to help you edit and customize for your facility or department
6.3 Gel Use

Ultrasound coupling gel is necessary to allow passage of the ultrasound energy into patient tissues and is required for a good quality image. It is used in almost all ultrasound procedures. As such, policy describing safe handling and use is paramount to reducing and preventing cross infection. Numerous outbreaks from contaminated ultrasound gel have been reported in the literature. In some cases, these infections have been associated with invasive procedures such as ultrasound-guided central venous catheter placement, pericardiocentesis, amniocentesis and surgeries. Gel is typically available in single-use sachets (sterile and non-sterile) as well as in non-sterile multi-use gel bottles. Careful selection of the correct type of gel is important for preventing infections. A rationale for sterility requirements for gel use can be derived from the Spaulding classification. For critical items, sterile gel should be used, for semi-critical, a minimum of single-use clean room manufactured gel should be used, for non-critical a minimum of multi-use gel can be used (Table 2).

After completion of the procedure, the probe should be immediately cleaned and all visible gel and bioburden removed before subjecting the probe subsequent reprocessing steps. Relevant staff should be educated regarding the use of probe covers and ultrasound coupling gel and competency regularly checked.

<table>
<thead>
<tr>
<th>Critical probes</th>
<th>Semi-critical probes</th>
<th>Non-critical probes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sterile single use gel</td>
<td>Non-sterile single-use gel as a minimum</td>
<td>Multistate, non-refillable gel</td>
</tr>
<tr>
<td>Sterile single use gel preferred</td>
<td>Multiuse, non-refillable gel</td>
<td>Acceptable</td>
</tr>
</tbody>
</table>

Table 2: Ultrasound gel use during ultrasound guided procedures

- **Considerations**
  - Use aseptic technique when handling
  - Sterile single use gel is the minimum requirement for invasive procedures where there is risk of the probe and gel contacting sterile tissue and blood
  - Use aseptic technique when handling

- **Considerations**
  - Avoid multisite gel where possible, single use gel preferred
  - Refillable bottles should be avoided due to established risk of bacterial growth
  - Generally gel warmers should not be used due to the risk of pathogen growth
  - Discard multisite bottles based on facility policy and MFSU
  - Care should be taken not to touch the patient or probe with the tip of the multi-use gel bottle

**General considerations (all gel)**
- Ensure gel is only used within its shelf life
- Store gel protected from sources of contamination (e.g., dust, moisture)
- Check before use for evidence of contamination

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**Figures and tables summarizing considerations**

**Critical ultrasound probes**
- Contact or enter sterile body cavities, sterile tissue or the vascular system.
- Confer high risk for infection transmission if they are contaminated with any microorganism.
- Require sterilization to be free from all viable microorganisms.

In general, critical ultrasound probes include those used in surgical procedures and some ultrasound guided interventions (e.g., percutaneous procedures where the probe can contact the puncture site). These invasive procedures require a sterile field and sterile instrumentation as they access sterile body sites.

- The CDC guidelines state specifically for critical ultrasound probes, if sterilization of the probe is not possible, the probe can undergo HLD and be used with a sterile sheath.

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**Critical ultrasound probes decision tree**

- **Yes/Unsure**
  - Can the probe be sterilized?
    - **Yes**
      - Probe requires: Sterilization
    - **No**
      - Semi-critical: Contact serum membrane or mucous membrane (e.g., lips, mouth, nasopharynx, eyes, skin, rectum, anus, umbilicus) or skin, mucous membrane, blood, body fluids or sterile tissue.
        - **Yes**
          - Probe requires: High level disinfection
            - New or used with sterile sheath (critical probe or if unsure) or used with strong disinfectant
          - **No**
        - **No**
          - Non-critical: Will only contact skin.
            - **Yes**
              - Use with sterile sheath (critical probe or if unsure) or used with strong disinfectant
            - **No**

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**Tool 4 – Policy development framework**

Provides background info on ultrasound reprocessing topic

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**Figure 2. A flowchart decision tree to determine the level of reprocessing and sheath type required before use of an ultrasound probe on a patient.**

Apply the above rationale to the procedures used in your department/facility. List the procedures performed and assign the Spaulding classification of the probe and sheath and reference or specify the SOP here. For peripheral IVs, mid-lines and PICCs, multiple attempts
Summary

• There is risk from ultrasound procedures

• Risk is compounded from the complexity of ultrasound – variety of departments, procedures and end users

• Follow federal guidelines and national standards and apply the Spaulding classification to standardize your disinfection practices

• Download and use the toolkit to help assess, evaluate and create your facility policy

www.ultrasoundinfectionprevention.org