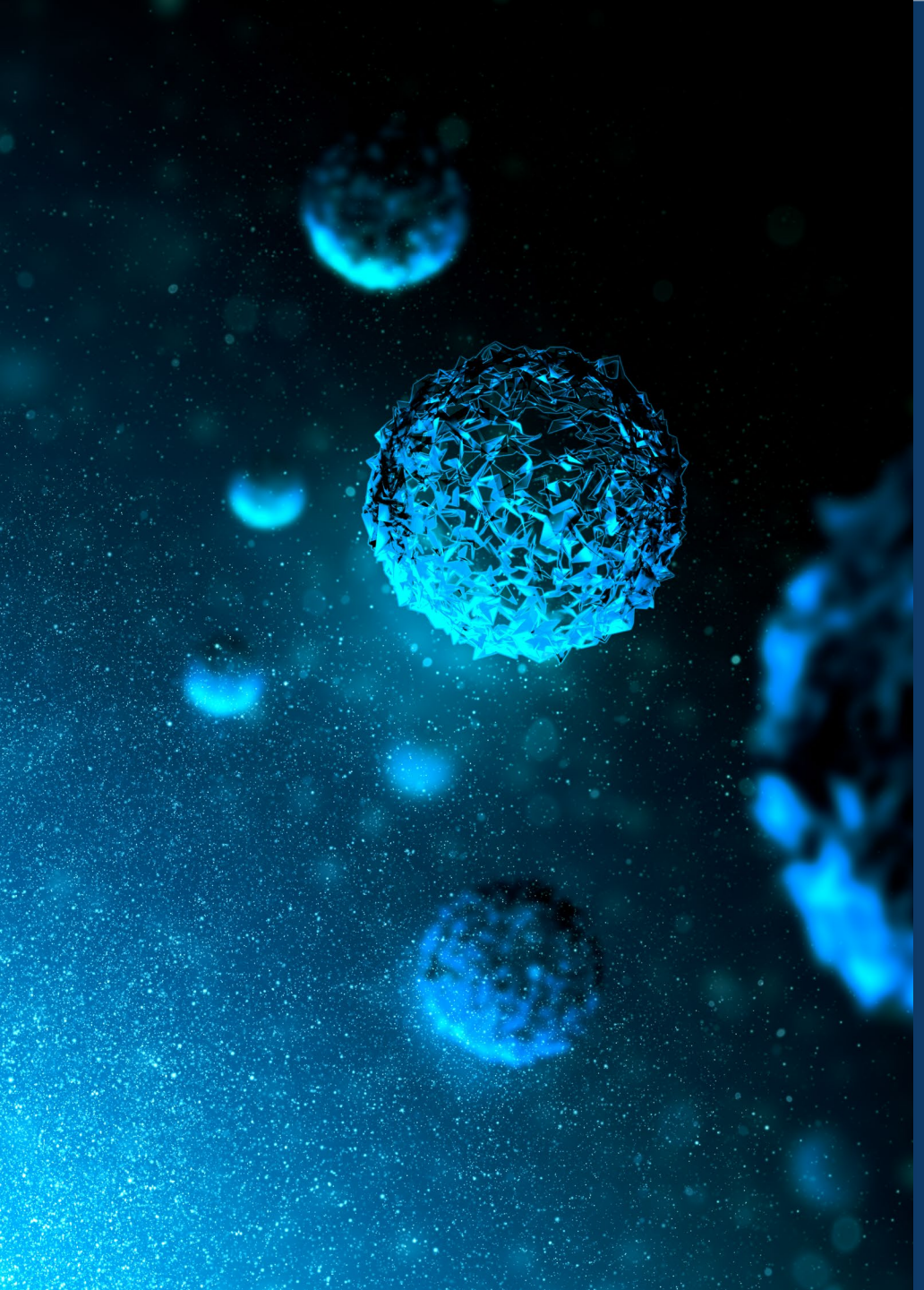


High Level Disinfection Best Practices

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Agenda

- FDA/CDA Guidelines
- Spaulding Classification
  - Percutaneous procedures
- TIR-99
- Sterilization and high-level disinfection modalities
- Hierarchy to standards and guidelines

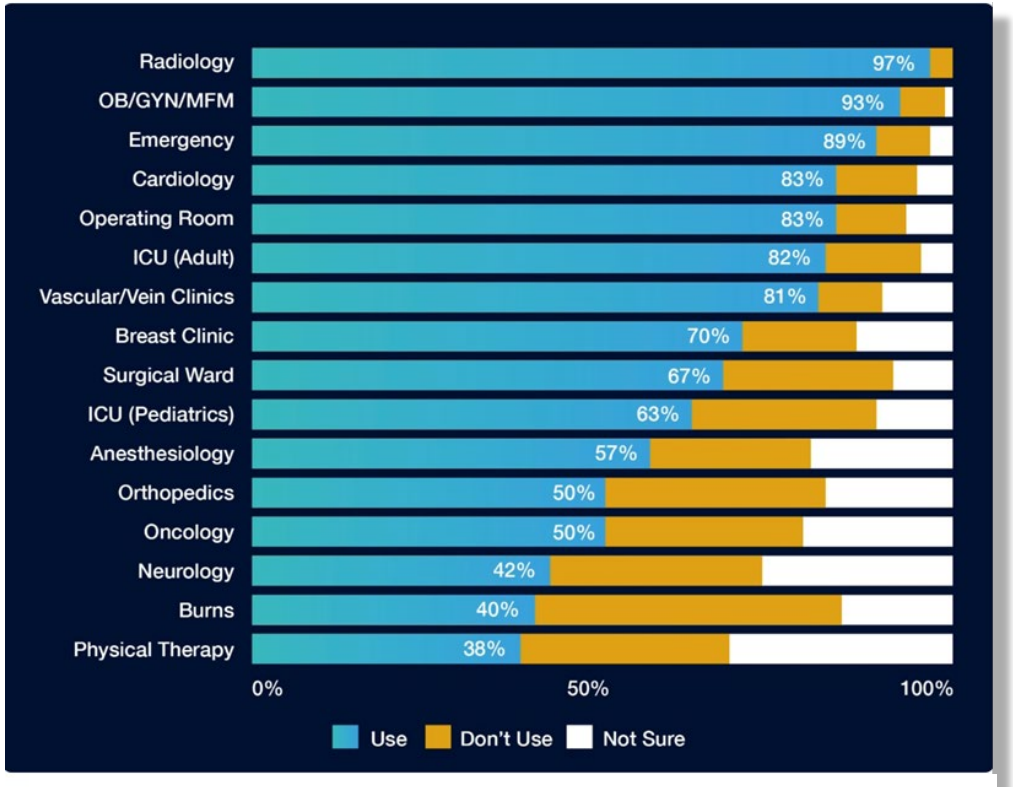
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Proliferation of Medical Applications of Ultrasound

Growth of ultrasound procedures has been considerable. [1]

Ultrasound imaging is now one of the most widely used and rapidly growing global diagnostic tools. Nearly 140 million ultrasound procedures are performed annually in the US.[1]

Diagnostic medical devices, such as ultrasound probes, are often heavily contaminated after use and can harbor serious disease-causing pathogens such as HPV, chlamydia, and MRSA, which may contribute to a HAI. [2-5]



Adapted from Carrico RM, et al. Am J Infect Control. 2018;46(8):913-920[8]

1. Frost & Sullivan: Healthcare Infrastructure and Procedural Volume for Ultrasound Imaging, 2018
2. Buescher DL et al. 2016. Ultrasound Obstet Gynecol 47(5): 646-65
3. Oide S et al. 2019. J Med Ultrason 46(4): 475-479
4. Leroy S, et al. J Hosp Infect 2013;83(2): 99-106
5. M'Zali, F., et al. 2014. PLoS One 9(4): e93368

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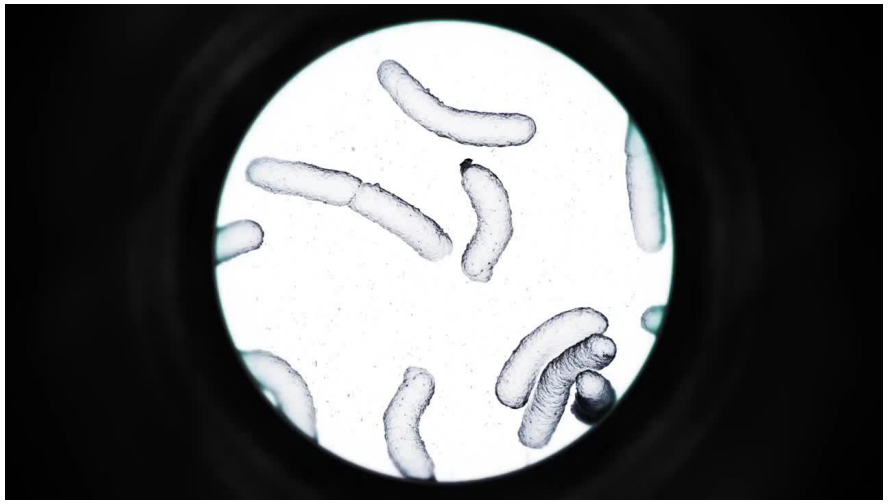
Ultrasound probes can be exposed to a variety of procedures:

- Non-intact skin
- Rashes/abscesses
- Surgical wounds
- Needle guided procedures
- Drainages
- Central line insertions







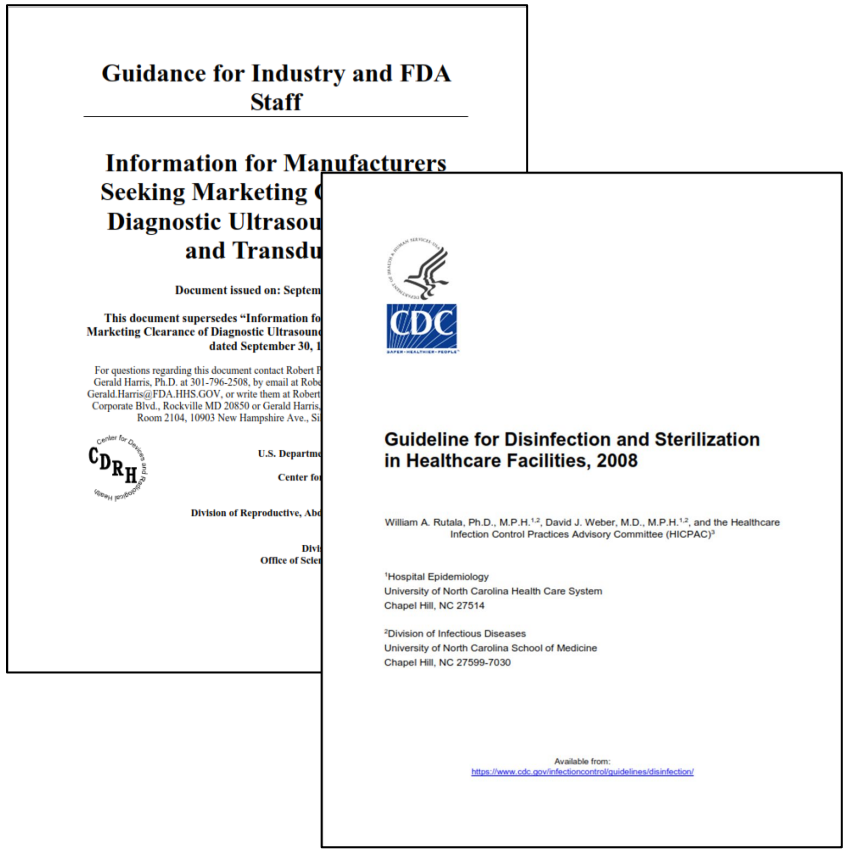






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FDA and CDC use the Spaulding classification



- Devised by E. Spaulding as a **rational approach to disinfection and sterilization** of reusable devices based on infection risk.[1]
- **Federal guidelines (CDC, FDA) use this framework** to define requirements for device disinfection and sterilization in healthcare settings.[2,3]
- Healthcare facilities must correctly apply this framework for reimbursement (e.g., CMS infection control worksheet, TJC standards).[4,5]

1. Spaulding EH. Chemical disinfection of medical and surgical materials. In: Lawrence C, Block SS, editors. Disinfection, sterilization, and preservation. Philadelphia (PA): Lea & Febiger; 1968. p. 517-31.
2. CDC 2008. Guideline for Disinfection and Sterilization in Healthcare Facilities.
3. FDA 2019. Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers.
4. TJC 2019. Comprehensive Accreditation Manual for Hospitals.
5. Centers for Medicare and Medicaid Services (CMS). CMS Hospital Infection Control Worksheet 2015, Sections 3A and 3B. Available here.

The Spaulding Classification

Device Classification

Disinfection Level

Probe may contact or enter **sterile tissue** or the **bloodstream**

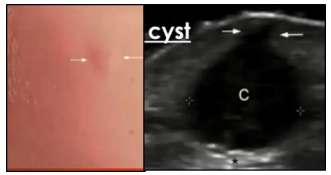


Intraoperative probe

Biopsy probe

CRITICAL

Probe may contact **mucous membranes** or **non-intact skin**

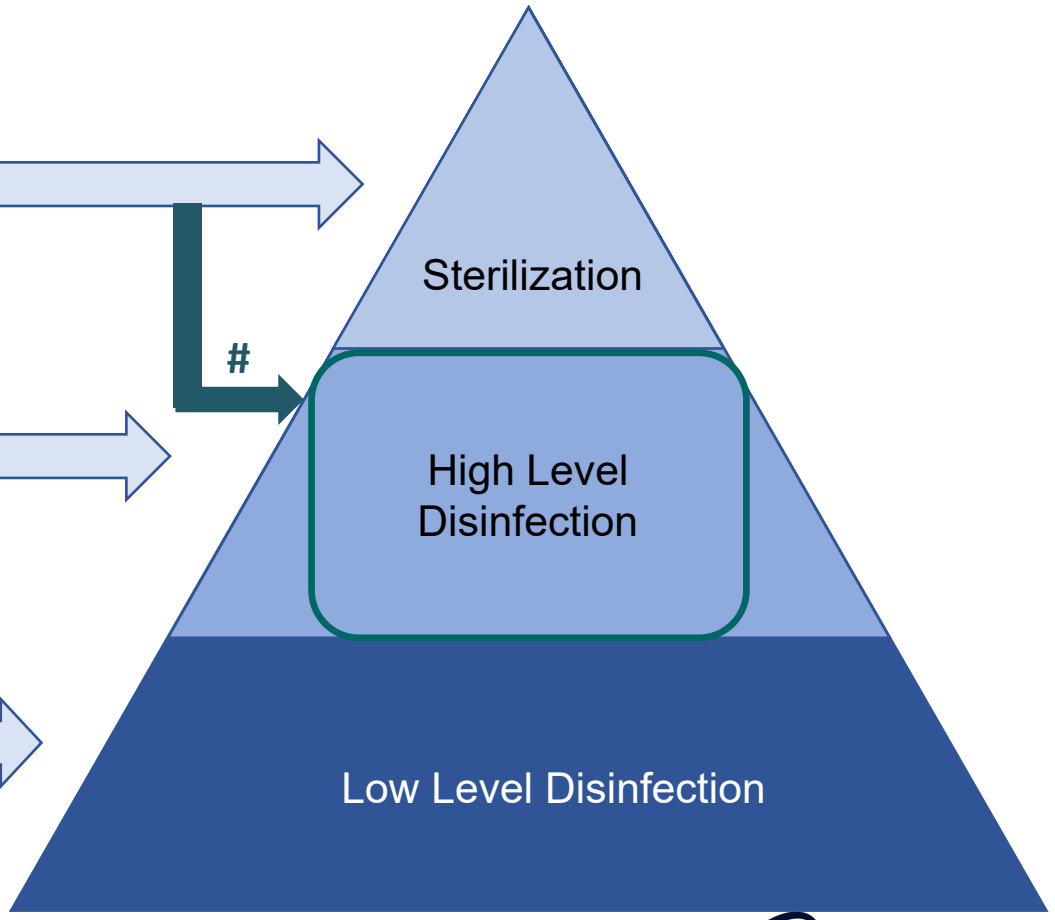


Probe scanning non-intact skin

SEMI-CRITICAL

Probe will only contact **healthy**, **intact skin**

NON-CRITICAL



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Biopsies

Specific guidance for intraoperative and biopsy probes is based on Spaulding:

"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..." [1]

"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." [2]

1. FDA 2019. Marketing Clearance of Diagnostic Ultrasound Systems and Transducers.
2. CDC 2008. Guidelines for Disinfection and Sterilization in Healthcare Facilities.

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Sheaths

- Not a terminal barrier
- Gouge marks evident on ultrasound transducers (likely from a needle strike)
- Suggests that sheaths can be breached during needle guidance
- Condoms used on ultrasound probes can fail up to 13% of the time, while commercial covers fail up to 5% of the time [3]

FDA

"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."** [1]



CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION

"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."** [2]

"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." [2]



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Non-Critical Needle Guided Procedures







Probe is non-critical, requires low-level disinfection

- Probe only contacts healthy, intact skin
- No risk of contact with sterile tissue (puncture site) or sterile intervening devices (needle)

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Critical Needle Guided Procedures





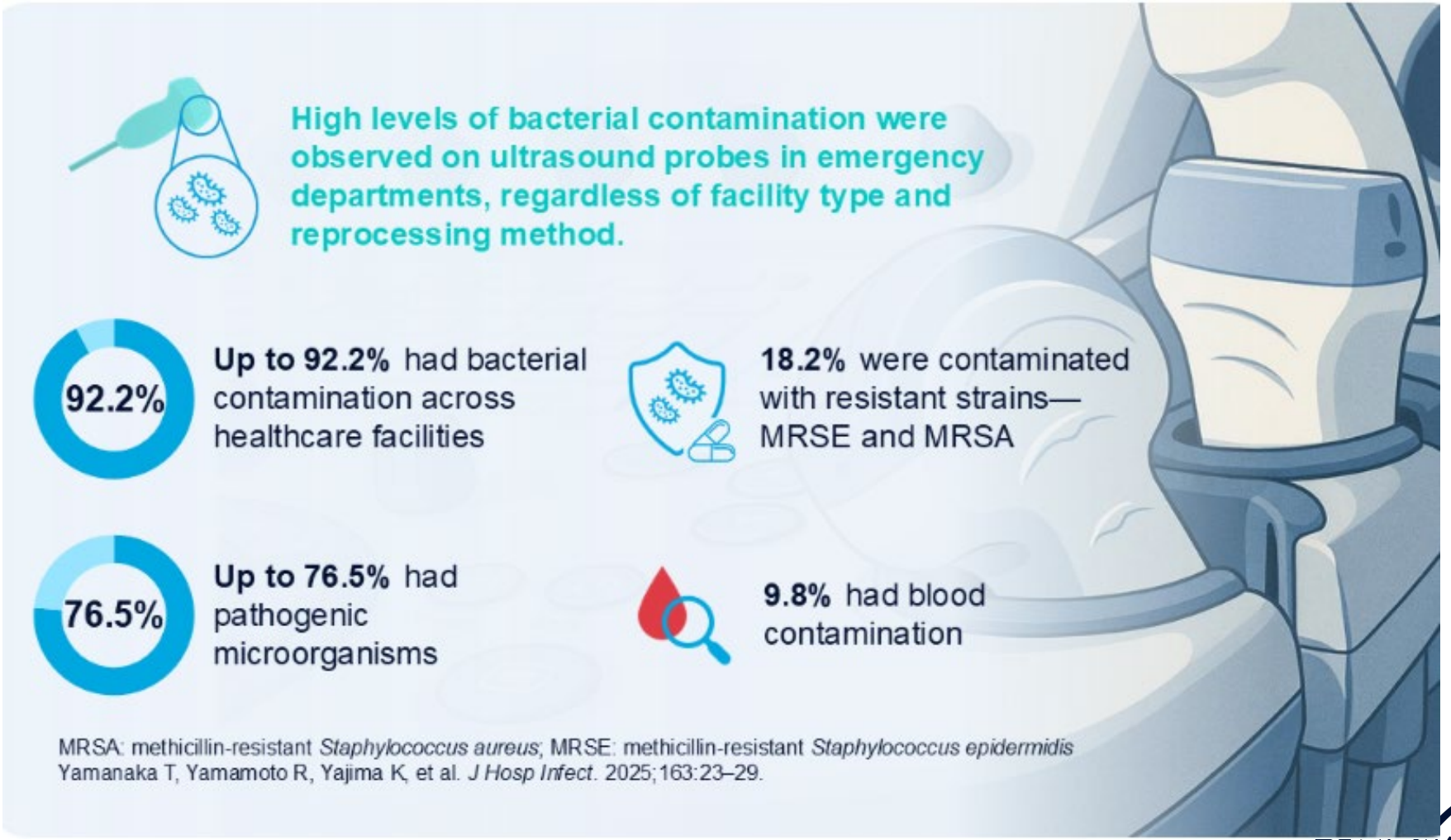


Probe is critical, requires sterilization or HLD with the use of a sterile sheath

- Probe contacts sterile tissue (puncture site)
- Probe contacts sterile intervening device (needle)

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Contamination: Surface Ultrasound Probes



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TIR–99

- First AAMI guidance to specifically address ultrasound probes
- Provides guidance for the proper processing of dilators and ultrasound probes
- Intends to provide clear and comprehensive information and direction for health care personnel regarding the processing of these devices and accessories
- Discussion and guidance on: (note: *processing* not clinical application)

- IFU's
- Spaulding Classification
- Use of probe covers
- Use of ultrasound gel
- Processing area design
- Medical device processing personnel qualifications
- Transportation
- Cleaning and decontamination
- Disinfection
- Sterilization
- Storage
- Quality Control & Improvement
- Automation

TIR99 5.2: Spaulding Risk Assessment

Insights

Before using a device on a patient, the user should perform a risk assessment to determine its Spaulding classification and consult the manufacturer's written Instructions for Use (IFU).

Key considerations for the risk assessment include, but are not limited to:

- The proximity of the device to mucous membranes, non-intact skin, or sterile tissue.
- The manufacturer's IFU for the specific device, including guidance on cleaning, disinfection, and sterilization.
- The technique being employed (e.g., no-touch method, contact of the device with a sterile needle).
- The patient's anatomy and condition.
- The use of additional supplies, such as gels, disposable materials, or sheaths.

- Ultrasound-guided procedures performed percutaneously are varied and diverse, with the probe often used to provide imaging to monitor the procedure. During these procedures, the probe may come into contact with the puncture site, depending on factors such as the specific procedure, techniques employed, and the patient's unique anatomy.
- Interventional devices, such as needles, may penetrate the probe sheath, and gouge marks have been observed on probes used clinically. Probe sheaths do not alter the Spaulding classification, as they may leak or become compromised during a procedure.
- To ensure compliance with the Spaulding classification and enhance patient safety, facilities should standardize their reprocessing protocols. This approach should account for practice variability and align with current scientific evidence and safety standards.
- Facilities should also evaluate contributing factors, including infection rates within the facility, adherence to cleaning and disinfection protocols, and procedure-specific variables, to establish acceptable and safe practices.

Text taken or adapted from AAMI TIR-99 (2024)

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Sterilization & High-Level Disinfection Modalities

FDA Approved



Soaking chemistries

Aldehydes
- Glutaraldehyde (GTA)
- Ortho-phthaldehyde (OPA)

Oxidative
- Peracetic acid (PAA)
- Hyperchlorite (HCl)
- Hydrogen peroxide (H2O2) – liquid
- Hydrogen peroxide (H2O2) – mist

**additional combination chemistries*



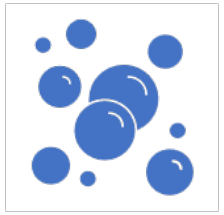
Gaseous

Water vapor (H20) – high temperature

Ethylene oxide (EO)

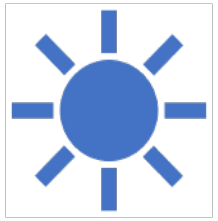
Vapor hydrogen peroxide (VH202)

Chlorine dioxide (ClO2)



Foam

ClO2



Radiation

Ionizing Radiation
- X-ray
- Gamma
- Electron Beam

Non-Ionizing Radiation
- Infra-red
- UV-C

High-Level Disinfection: Solutions

manual and automated







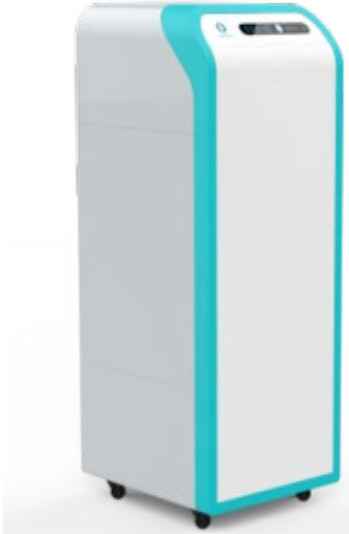












GTA / OPA Soak

- Manual process
- Open system

GUS Station

- Manual process
- Covered system

Astra

- Automatic process
- Covered system

trophon

- Automatic process
- Closed system

Ethos

- Automatic process
- Covered system

Ult

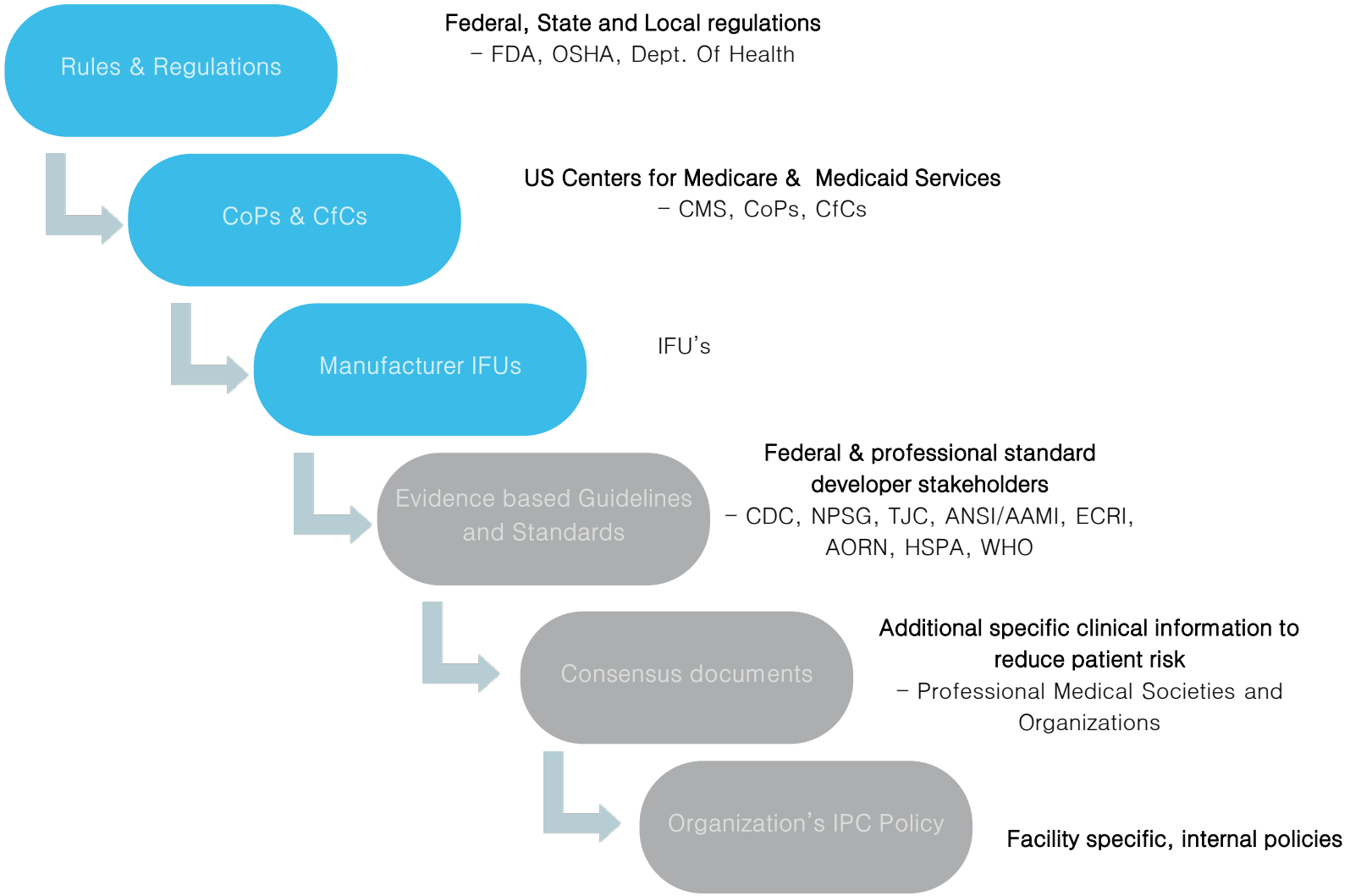
- Manual process
- Open system

Chronos

- Automatic process
- Closed system

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Hierarchal Approach to Standards and Guidelines



- Adopted and used by the CMS and TJC
- Provides a visual, structured pathway of Standard and Guidance organization, depicting a hierarchy of importance of information
- Provides a tool of guidance conflict resolution, through selection and prioritization of the superior source of information

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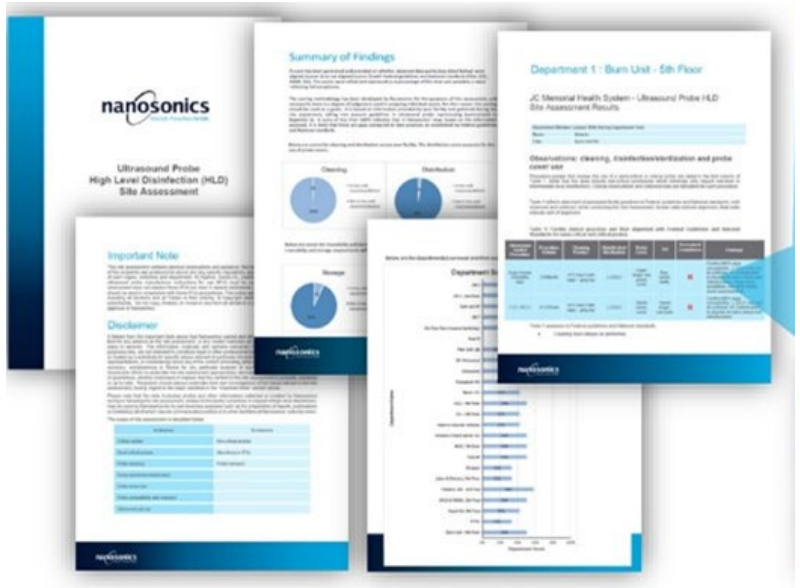
What can our Clinical Team help you with?

- Clinical Offerings:
  - Ultrasound Risk Assessment: In-person Assessment of your Ultrasound Environment with Report
  - In-service Trainings: In-person or Virtual
  - Provide Educational Documents
    - Competency
    - Workflow
    - Policy
    - IFU's
    - Safety Data Sheets
    - CIN's – Customer Information Notices on popular questions from auditors

  - CME Presentation: Best Practice Reprocessing for Ultrasound Probes
    - Can present at ICC Meetings / Skill Fairs / Local APIC Chapters

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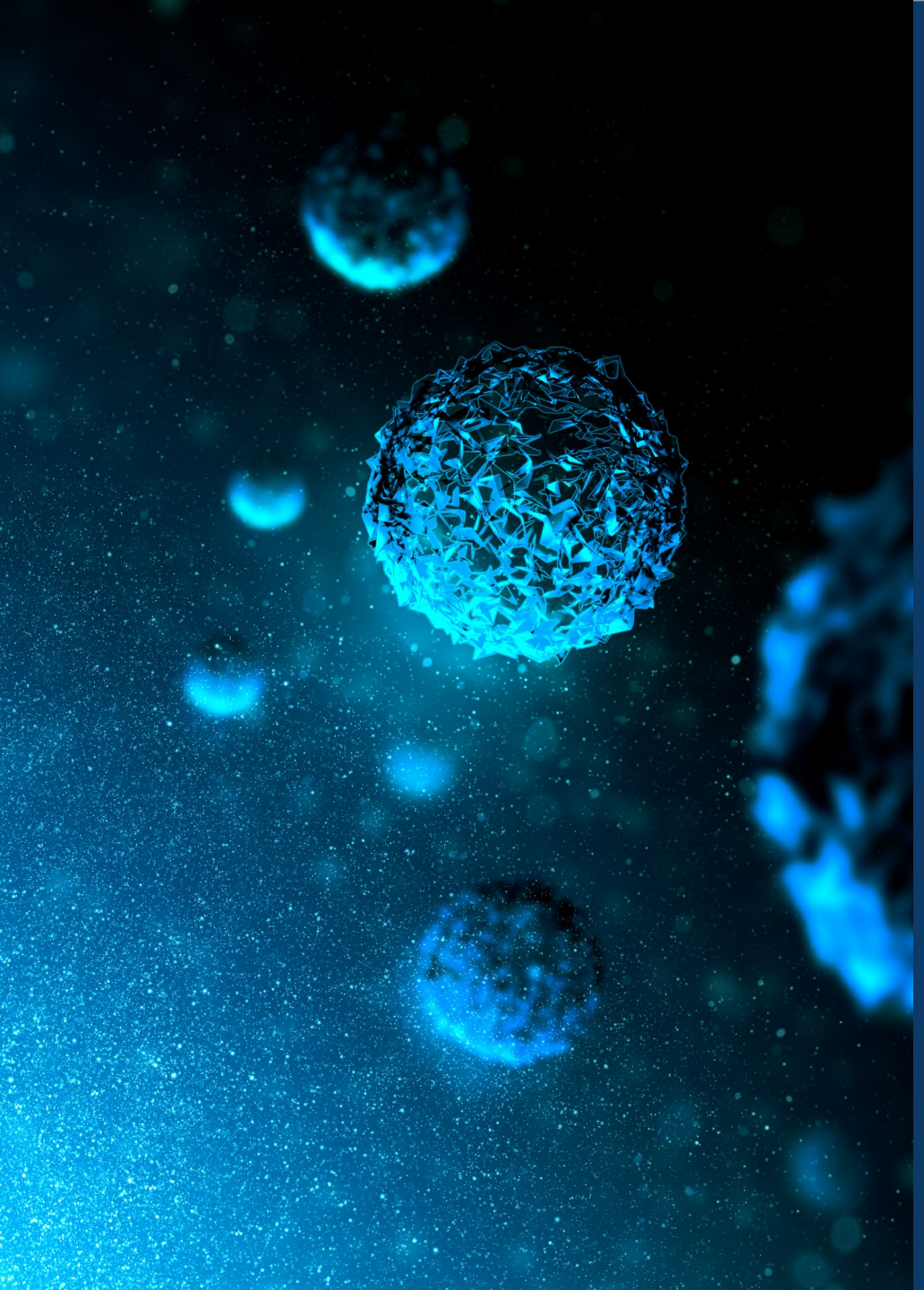
Ultrasound Risk Assessment



Ultrasound Guided Procedure	Procedure Volume	Cleaning Product	Disinfection/ Sterilization	Probe Cover	Gel	Procedural Compliance	Findings
Transvaginal	50.0/Week	Cloth	HLD	Clean single use probe cover	Non-sterile single-use pack	✔	Confirm MIFU wipe compatibility. Clean cover acceptable, but sterile probe cover recommended. Non-sterile bottles should not be used. Non-sterile single-use packet acceptable, but sterile single-use pack recommended.
Biopsy	10.0/Week	CaviWipes	LLD/ILD	Sterile probe cover	Sterile single-use pack	✖	Confirm MIFU wipe compatibility. LLD/ILD may not be sufficient. HLD/sterilization is required for semi-critical and critical probes.
Drainage or Aspiration	10.0/Week	CaviWipes	LLD/ILD	Sterile probe cover	Sterile single-use pack	✖	Confirm MIFU wipe compatibility. LLD/ILD may not be sufficient. HLD/sterilization is required for semi-critical and



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