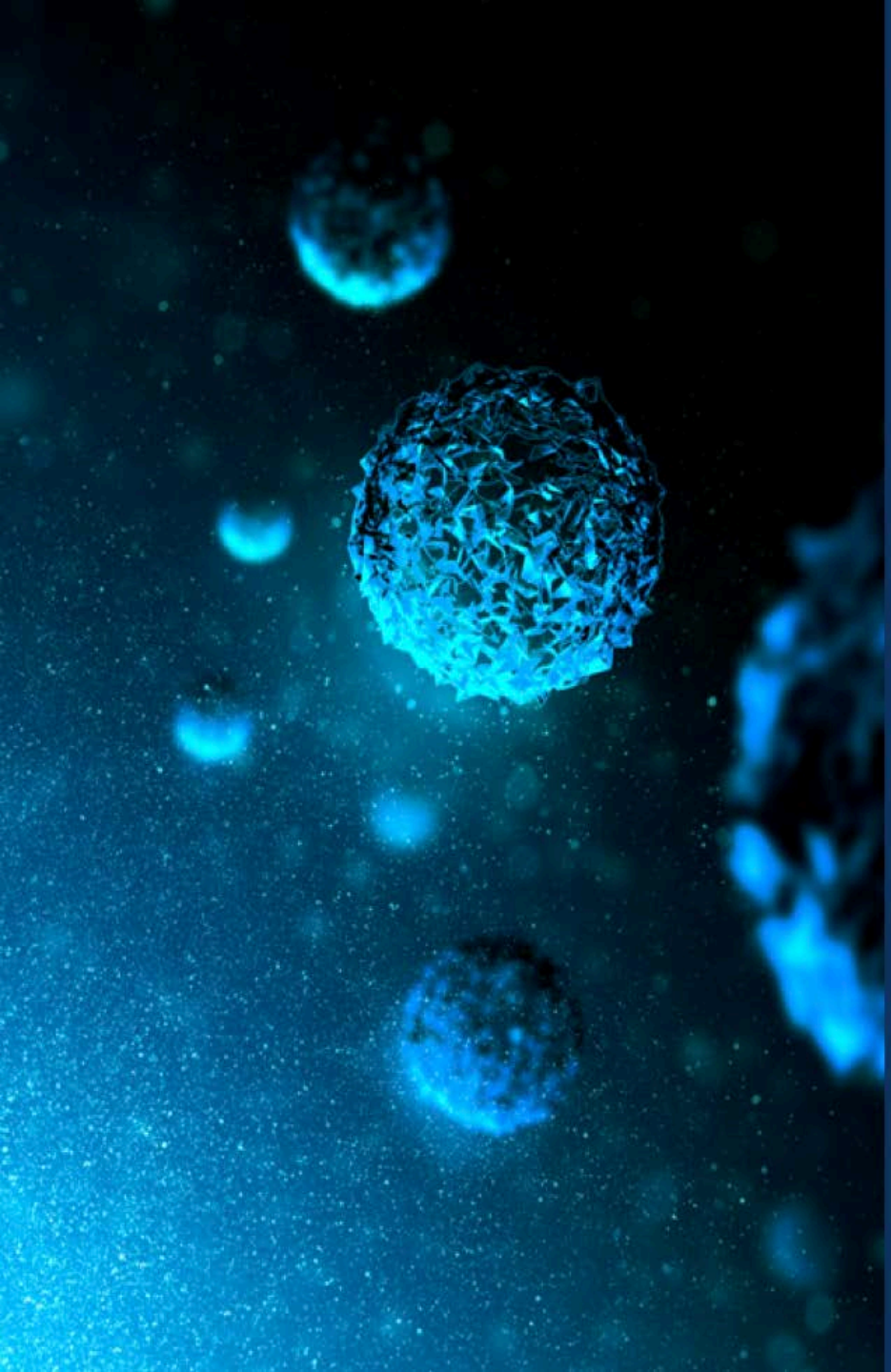




Ultrasound Infection Prevention *Disinfection of Probes Used in Percutaneous Procedures*

Maureen Spencer M.Ed, BSN, RN, CIC, FAPIC
Infection Preventionist Consultant

Learning Objectives

1. Characterize the range of percutaneous procedures.
2. Discuss the implications of available evidence demonstrating contact between the ultrasound probe and sterile needle or puncture site.
3. Explain the significance of risk assessment findings to patient safety.
4. Determine reprocessing requirements for probes, used in a key group of percutaneous procedures, by applying the Spaulding Classification and relevant regulatory requirements, standards and guidelines.

Ultrasound Imaging: A rapidly expanding modality

Ultrasound imaging is currently used for more clinical applications than any other imaging modality.

Real-time results, safety, portability and cost-effectiveness continue to drive growth including:

- Development of new procedures and Point of Care (POCUS) applications
- Expansion into medical services with no previous experience in ultrasound guidance
- Expansion into ambulatory settings
- Introduction of wireless probes

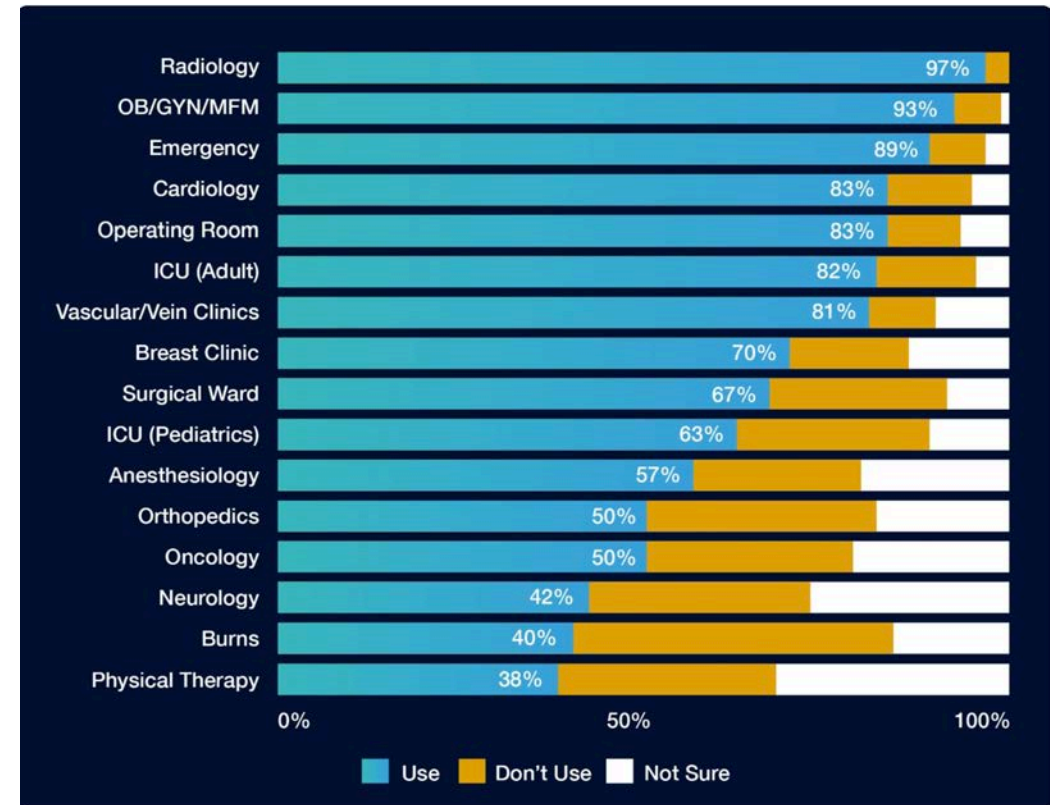


Figure 1. Adapted from Carrico 2018.¹ All departments surveyed recorded use of ultrasound.

Risk of Improper Probe Disinfection

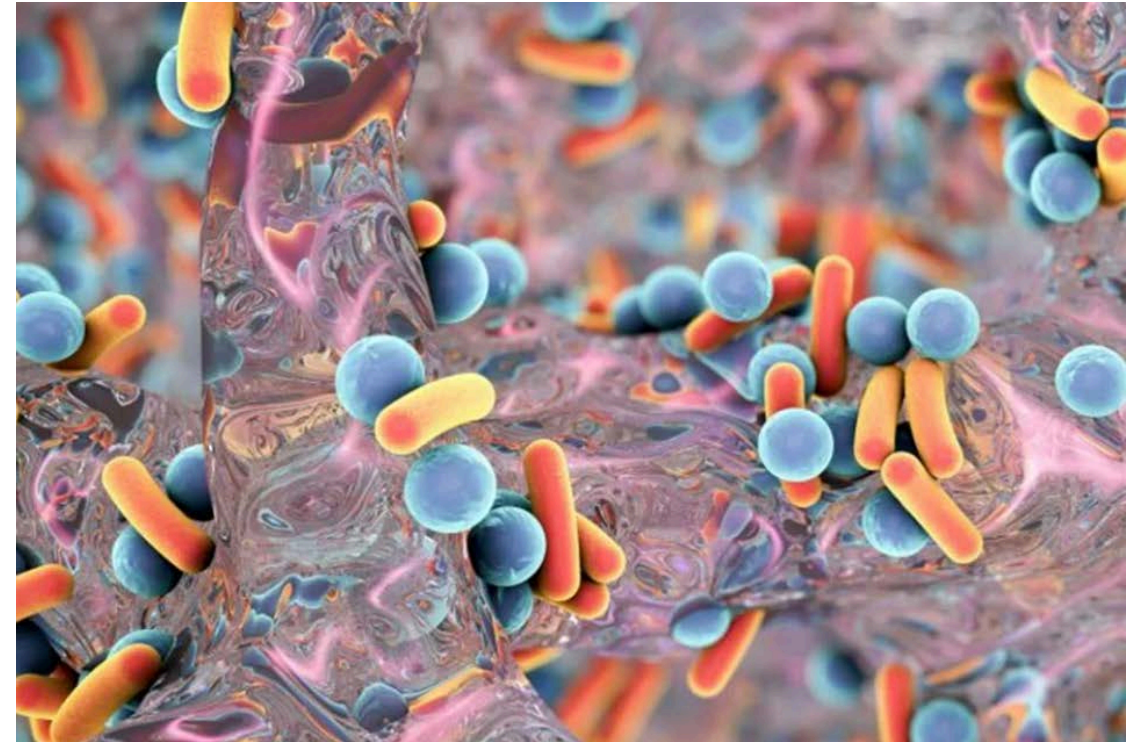
- **More than 45% of probes in 5 EDs and 5 ICUs** had bacterial contamination, over 50% had blood contamination.¹
- **More than 90% of transvaginal probes** contaminated after cleaning with paper towel, more than 50% tested positive for MRSA or other potentially pathogenic bacteria.²
- **More than 80% probe handles** remain contaminated when not disinfected.^{3,4}



1.Keys, M., et al. Crit Care Resusc. 2015;17(1): 43-46.
2.Oide, S., et al. (2019). J Med Ultrason 46(4): 475-479.
3.Buescher DL, et al. Ultrasound Obstet Gynecol 2016;47(5): 646-651.
4.Ngu, A., et al. (2015). Infect Control Hosp Epidemiol 36(5): 1-4.

Risk of Improper Probe Disinfection

- Meta analysis: **Prevalence of 12.9% for frequently occurring bacteria** and **1% for viruses** on transvaginal & transrectal probes after low level disinfection (LLD) with wipes and sprays.¹
- **More than 20% of probe heads remained contaminated** after low level disinfection with wipes.²
- The Joint Commission found that **74% of all immediate threats to life** were due to improper sterilization or high-level disinfection (HLD) processes.³



1. Leroy S, et al. J Hosp Infect 2013;83(2): 99-106.

2. Buescher DL, et al. Ultrasound Obstet Gynecol 2016;47(5): 646-651

3. TJC Quick Safety 33: Improperly sterilized or HLD equipment – a growing problem https://www.jointcommission.org/resources/news-and-multimedia/newsletters/newsletters/quick-safety/quick-safety-issue-33-improperly-sterilized-or-hld-equipment--a-growing-problem/improperly-sterilized-or-hld-equipment--a-growing-problem/#.Y_OrP-zMKu4. Accessed 2/27/23

Evidence of Transmission

Investigation aimed to evaluate risk of infection associated with 3 semi-invasive procedures across national datasets.

Microbiological reports and antibiotic prescriptions within 30 days of procedure used as proxy measures for infection.

- **Microbiological hazard ratios, higher** after procedures, compared to unexposed cohort (after adjustment for age, co-morbidities, previous hospitalization).
- **Antibiotics hazard ratio higher** for transvaginal and transrectal procedures.

Procedure	Microbiological Reports (HR)	Antibiotic Prescribing (HR)
Transesophageal echocardiography	HR: 4.92; 95% CI: 3.17–7.63),	No change
Transvaginal ultrasound	HR: 1.41; 95% CI: 1.21–1.64	HR: 1.26; 95% CI: 1.20–1.32
Transrectal ultrasound	HR: 3.40; 95% CI: 2.90–3.9	HR: 1.75; 95% CI: 1.66–1.84

Scott D, Fletcher E, Kane H, Malcolm W, Kavanagh K, Banks AL, Rankin A. Risk of infection following semi-invasive ultrasound procedures in Scotland, 2010 to 2016: A retrospective cohort study using linked national datasets. *Ultrasound*. 2018 Aug;26(3):168-177.

Evidence of Transmission



UK Medicines and Healthcare Products Regulatory Agency

Medical Device Alert

“The MHRA is aware of an incident where the death of a patient from hepatitis B infection may have been associated with a failure to appropriately decontaminate a transoesophageal echocardiography probe between each patient use.”

“The MHRA is issuing this alert to advise users to appropriately decontaminate all types of reusable ultrasound probes.”

Limited Evidence of Transmission.....

“How many bacteremias that look like present on admission, are from prior ultrasound procedures?”

“ICD 10 coding is not there to track.”



Is evidence of transmission and infection limited, because we're not looking for it?

Understanding Disinfection Levels

High Level disinfectants: Destroy all microorganisms (small number of bacterial endospores are permitted to remain). Disinfectants are bactericidal, virucidal (both lipid and non-lipid), fungicidal and mycobactericidal.

Intermediate Level disinfectants destroy all vegetative bacteria, including tubercle bacilli, lipid viruses, some non-lipid viruses, and fungi, but not bacterial spores.

Low level disinfectants destroy all vegetative bacteria (except tubercle bacilli), lipid viruses, some non-lipid viruses, and some fungi, but not bacterial spores.

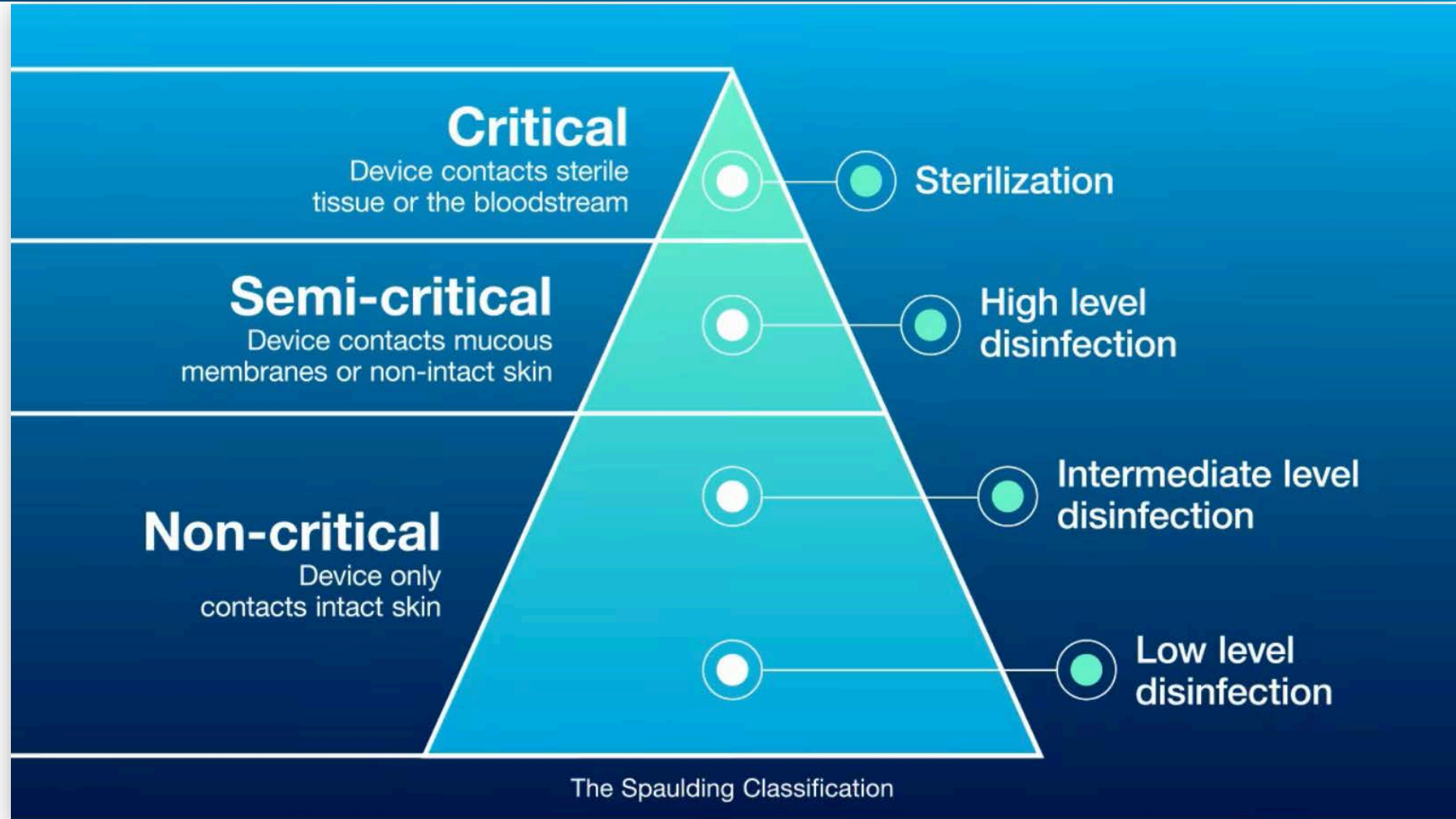


Sterilization and Disinfection: The Spaulding Classification

Framework for disinfection of reusable medical devices ¹

The basis of international device regulations, standards and guidelines:

- FDA ²
(legal/regulatory)
- CDC guidelines ³
- TJC
- AAMI ANSI/AAMI ST79 standard ⁴
- AORN guidelines
- And more.....



1. Spaulding EH (1968). Chemical disinfection of medical and surgical materials. Disinfection, sterilization, and preservation.
2. FDA Jun 19, 2019, Reissued Feb. 21, 2023. Marketing Clearance of Diagnostic Ultrasound Systems and Transducers.
3. CDC 2008. Guideline for Disinfection and Sterilization in Healthcare Facilities.
4. ANSI/AAMI ST79: 2017.

Spaulding Classification: Three levels of disinfection based on risk of procedure

Spaulding Classification	Contact w/ Patient	Risk of Transmission	Disinfection Level
Non-Critical	Intact skin only	Low	Intermediate Level Disinfection (ILD) Low Level Disinfection (LLD)
Semi-Critical	Mucous membranes or non-intact skin*	Medium	High Level Disinfection (HLD)
Critical	Sterile tissue or bloodstream	High	Sterilization**

* CDC nonintact skin: Areas that have been opened by cuts, abrasions, dermatitis or chapped skin.

** FDA: Where sterilization is not possible, probes classified as critical should be high-level disinfected and used with a sterile sheath.

Sterile sheath does not change Spaulding Classification

FDA-approved, single-use, sterile sheaths are also recommended for semi-critical and critical applications.

- **Use of a sheath does not change the level of disinfection required.**^{1,2}
- Condoms used on probes: Failure rate as high as 13%, Commercial covers failure rate of 5%.³
- Probes returned for service have shown gauge marks, indicating the sheath was breached.⁴



Gouge marks on ultrasound probe used for central venous catheter (CVC) placement.⁴

1. FDA 2019. Marketing Clearance of Diagnostic Ultrasound Systems and Transducers.

2. CDC 2008. Guidelines for Disinfection and Sterilization in Healthcare Facilities.

3. Basseal JM, et al. Infection, Disease & Health. 2020; 25(2):77-81.

4. De Cassai A, Tonetti T. Central venous line placement and ultrasound probe damage: a word of caution. J Med Ultrasound 2019;27:110.

Ultrasound probes classified as **Critical**

Probes that risk contact with sterile tissue or the bloodstream:

- Surgery
- **Percutaneous interventions where probe may contact sterile puncture site (drainages, injections, biopsies)**
- Scans across open wounds (surgical wounds, skin avulsion, 2nd or 3rd degree wounds, burns, pox)

CRITICAL

FDA 2019/2023: *“Critical devices should be sterilized and the use of a sterile sheath is recommended for each use.”*¹

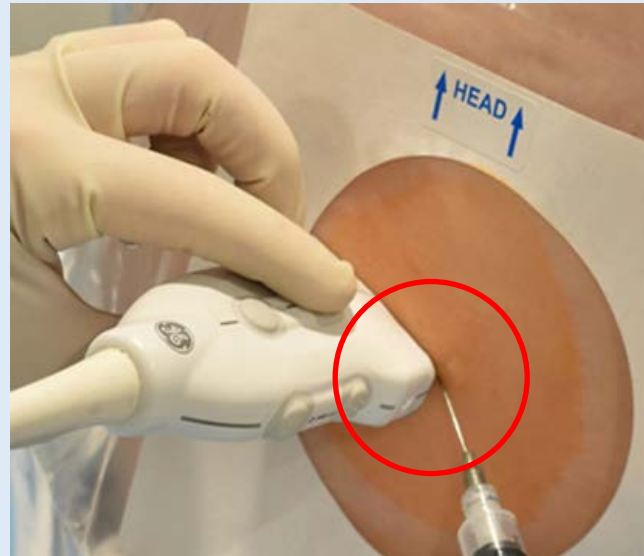
CDC 2008: *“If [sterilization] is not possible, at a minimum the probe should be high-level disinfected and covered with a sterile probe cover.”*²

1. FDA Jun 19, 2019, Reissued Feb. 21, 2023. Marketing Clearance of Diagnostic Ultrasound Systems and Transducers.

2. CDC 2008. Guideline for Disinfection and Sterilization in Healthcare Facilities.

When probe contacts sterile puncture site it is considered Critical

Probe is critical, requires sterilization or HLD with use of a sterile sheath. Probe contacts sterile puncture site and needle.



Ultrasound probes classified as **Semi-Critical**

Probes that risk contact with mucous membranes or non-intact skin:

- Transvaginal scans
- Transrectal scans
- Scans across areas that have been opened by cuts, abrasions, dermatitis, chapped skin or 1st degree burns.

**SEMI-
CRITICAL**

*FDA 2019/2023: "Probes used in semi-critical applications should undergo sterilization between uses whenever feasible, but high-level disinfection is minimally acceptable."*¹

*CDC: While use of the probe cover could be considered as changing the category... because condoms/covers can fail, the probe should be high-level disinfected."*²

1. FDA Jun 19, 2019, Reissued Feb. 21, 2023. Marketing Clearance of Diagnostic Ultrasound Systems and Transducers.

2. CDC 2008. Guideline for Disinfection and Sterilization in Healthcare Facilities.

140 different percutaneous ultrasound guided procedures

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
U/G pharmacomechanical thrombolysis and angioplasty
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
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 hyperreactio luteinalis
U/G amniocentesis
U/G paracentesis
U/G pericardiocentesis
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
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
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
U/G cryoablation
U/G electroporation ablation
U/G ethanol ablation
U/G laser ablation
U/G microwave ablation
U/G radiofrequency ablation
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
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

Percutaneous procedures by specialty group

Percutaneous ultrasound guided procedures are **a large, diverse and complex group of interventions** ranging from injections on healthy, intact skin to breast and liver biopsies.

Some procedures present more risk than others, procedures **span all 3 levels of Spaulding Classification**.

Additional considerations: Technique used, level of training, patient’s medical condition and unique patient anatomy may impact the type of tissue the probe contacts.

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

Percutaneous procedures & the sterile field

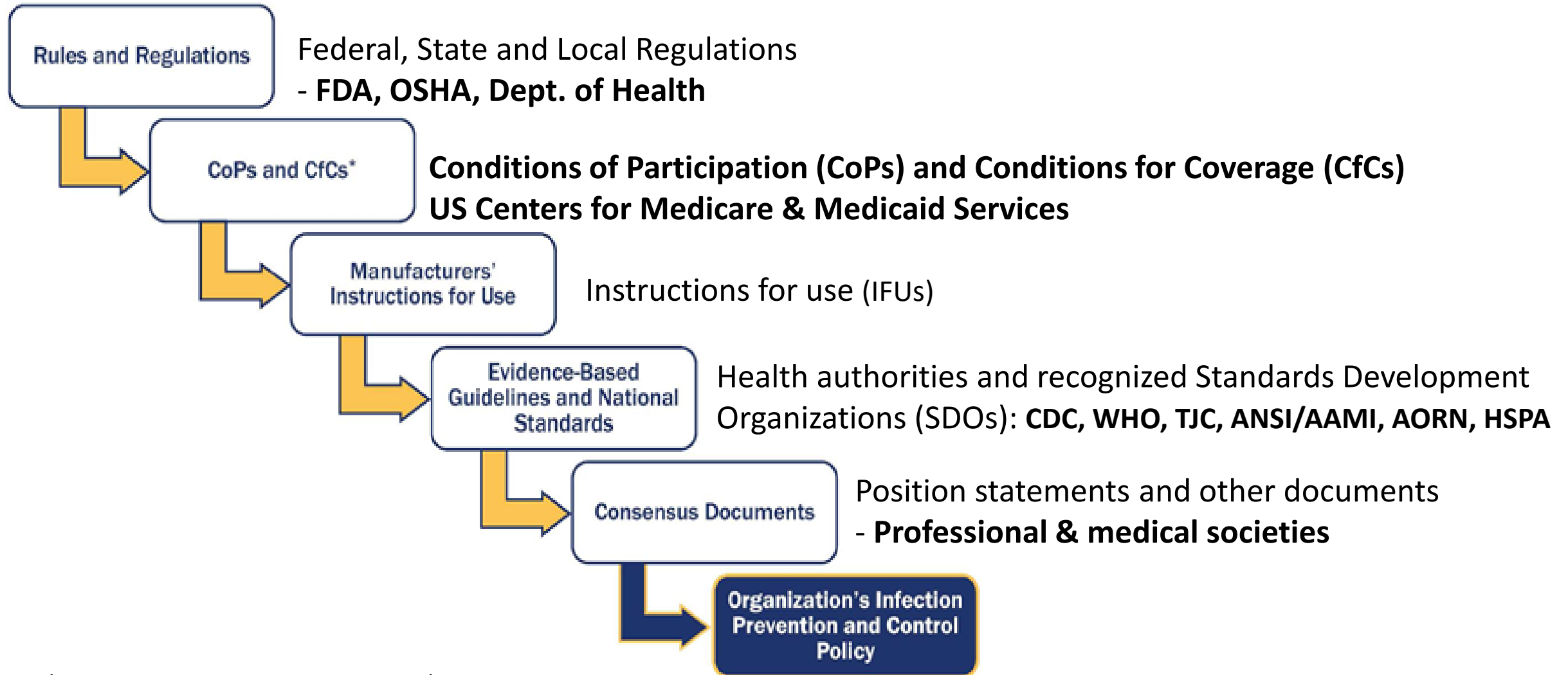
Percutaneous procedure: Entry, by puncture or minor incision, of instrumentation through the skin or mucous membrane and/or any other body layers necessary to reach the site of the procedure.

Sterile field: A designated area, free of microbes and other pathogens that can lead to infection.

- Includes surfaces, **instruments**, and people.
- Outside of the OR, maintenance of the sterile field is recommended when performing any procedure that could transmit microbes to the patient.



The Joint Commission (TJC): Hierarchical Approach to Standards and Guidelines



AIUM Intersociety Position Statement, November 2021

American Institute of Ultrasound in Medicine (AIUM) Mission: To empower and cultivate a global multidisciplinary community engaged in the use of medical ultrasound through raising awareness, education, sharing information, and research.

Position statement on use of ultrasound probes used in percutaneous procedures: In a departure from previous guidance, recommends **recategorization of probes used in all percutaneous procedures** (except those involving internal organs or mucous membranes) **as non-critical. LLD is an adequate level of disinfection.**

- Reprocessing requirements for probes used on non-intact skin, inconsistent with Spaulding (AAMI standards and past AIUM recommendations).
- Rationale for change: *“Recommendations for high-level disinfection (HLD) of sheathed probes used for percutaneous procedures **are not evidence-based and will result in unwarranted and unnecessary use of resources.**”*

AIUM Intersociety Position Statement:¹ 6 key points

	Statement	Additional Considerations
1	Ultrasound-guided percutaneous procedures are imaged transcutaneously, i.e. through intact skin , to monitor procedures done percutaneously in conjunction with a transducer cover and can be safely performed in conjunction with LLD .	Depending on patient, procedure and technique the skin may not be intact .
2	Proper hand washing plus sterile gloves has been safely used for over a century (in surgery). LLD of devices placed inside of sterile covers should be equally safe .	• FDA & CDC: Use of sheath does not change the level of disinfection required.^{1,2} • Condom failure rate: 13% • Commercial cover failure rate: 5%.³

1. Disinfection of Ultrasound Transducers Used for Percutaneous Procedures. J Ultrasound Med, 2021 40: 895-897.

2. FDA Jun 19, 2019, Reissued Feb. 21, 2023. Marketing Clearance of Diagnostic Ultrasound Systems and Transducers.

3. CDC 2008. Guideline for Disinfection and Sterilization in Healthcare Facilities.

4. Basseal JM, et al. Infection, Disease & Health. 2020; 25(2):77-81.

AIUM Intersociety Position Statement: 6 key points

	Statement	Additional Considerations
3	If contamination of covered transcutaneous transducers with blood or other bodily fluids occurs, it can be eliminated with low-level disinfection.	Low level disinfectants do not kill bacterial spores and some non-lipid viruses, and some fungi
4	HLD was meant to clean instruments intended for contact with internal organs or mucous membranes, only.	Reinterpretation of disinfection guidance <i>inconsistent with Spaulding, FDA and CDC.</i> Demotion of probes used on non-intact skin from Semi-Critical to Non-critical.

AIUM Intersociety Position Statement: 6 key points

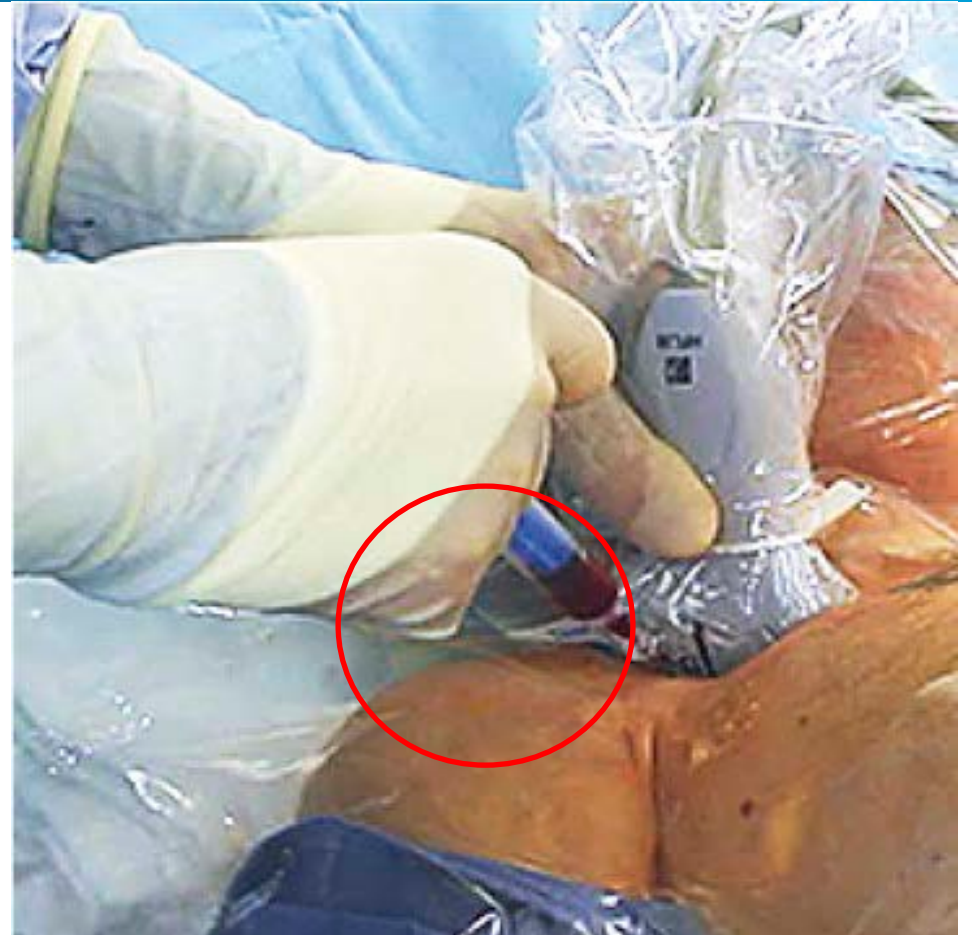
	Statement	Additional Considerations
5	Evidence of infection from transducers relates to contaminated gel and improper cleaning of internal transducers.	Rate of infection from contaminated probes is unknown . No tracking.
6	We recommend cleaning and disinfection for the reprocessing of transducers used for percutaneous procedures on the basis of the scientific and safety information available .	Rate of infection from contaminated probes is unknown . No tracking.

Additional considerations in determining reprocessing level

- 1) **Awareness of procedural risk** is not uniform across disciplines and providers.
- 2) **Variation in clinical technique**, skill or training among providers.

<https://youtu.be/DgQbQSBYeQU>

- 3) **Unique patient anatomy**
- 4) **Emergent conditions**

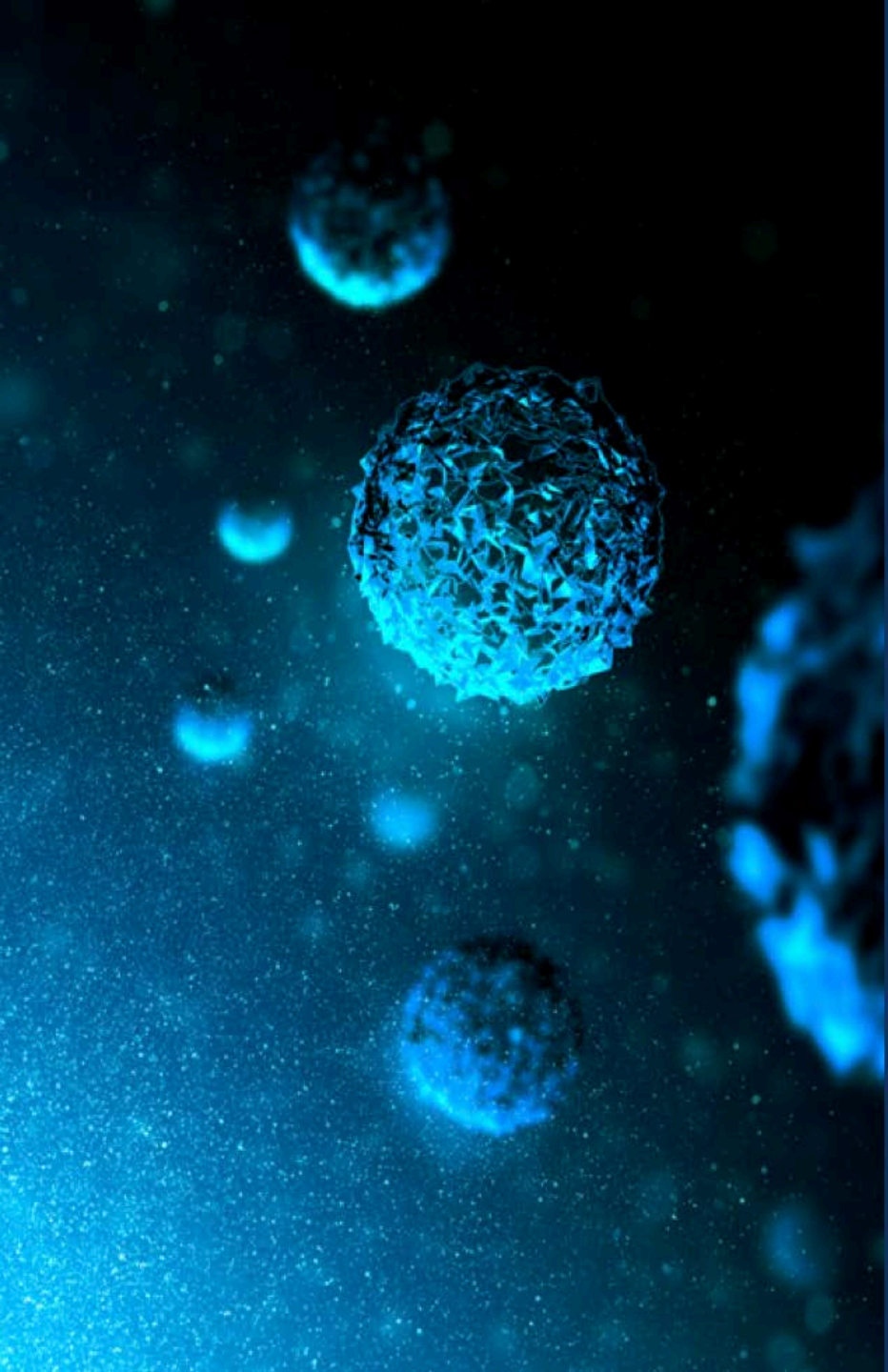


Ultrasound-Guided Cannulation of the Subclavian Vein. *N Engl J Med* 2018.

Additional considerations.....



[e.com/clip/Ugkx_uquAC_Tg_p6QpImxrFB_QITNM2OEGjB](https://www.facebook.com/clip/Ugkx_uquAC_Tg_p6QpImxrFB_QITNM2OEGjB)



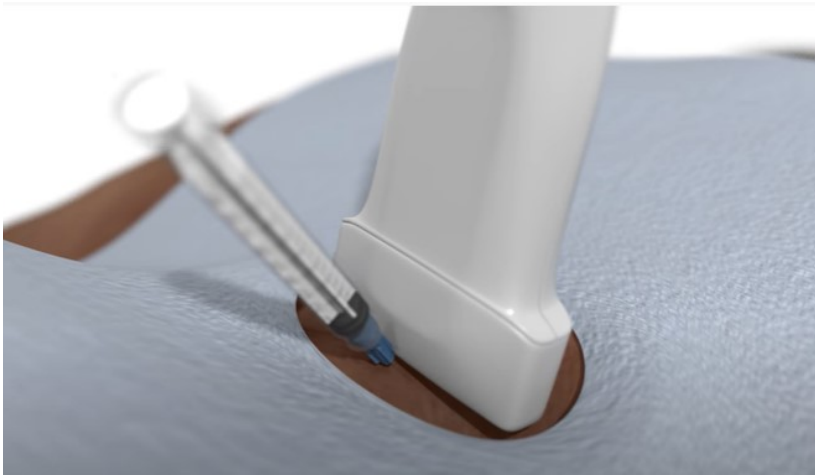
140 Percutaneous Procedures

Observations from the
Literature

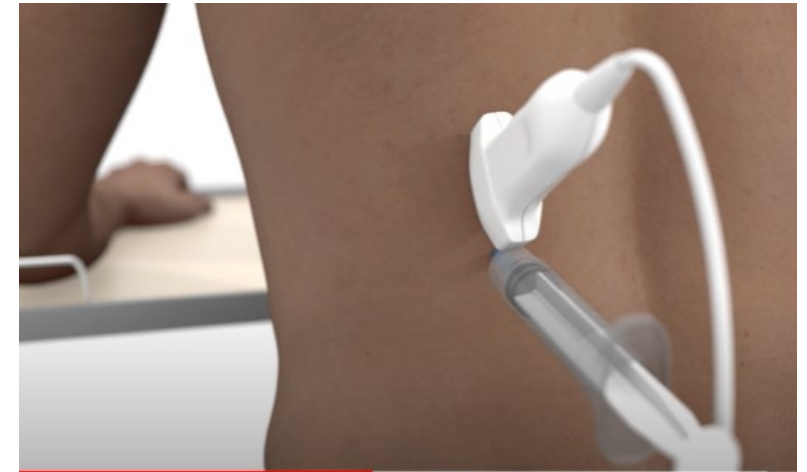
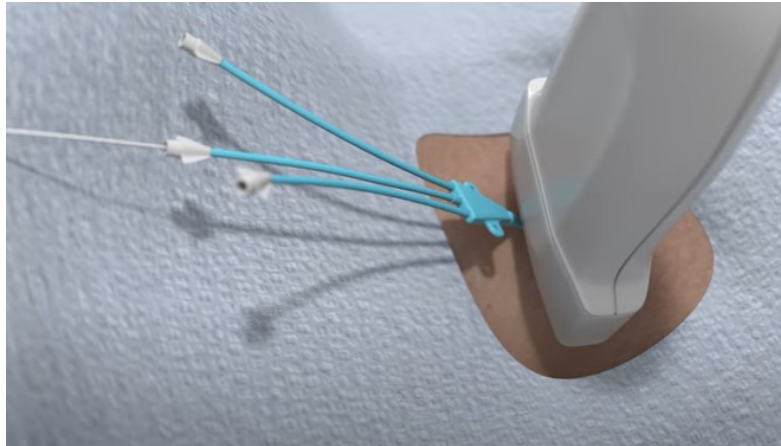
US Academic Medical Center Training Video

Ultrasound guided IV Cannulation and Thoracentesis

(Screen capture from training video)



IV Cannulation



Thoracentesis

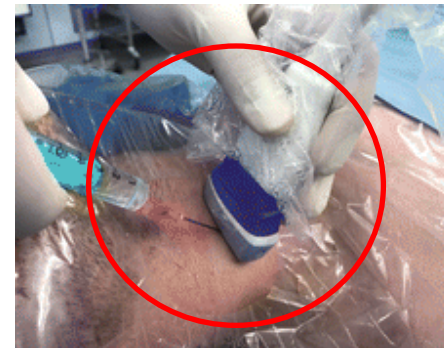
Vascular Access

Placement of a catheter into vasculature for delivery of medication or blood withdrawal

- Intravascular U/G management, large thrombus burden
- U/G arterial access
- U/G cannulation 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 aorta
- U/G peripherally inserted central venous catheter



Insertion of Radial Arterial Catheter
N Engl J Med 2014

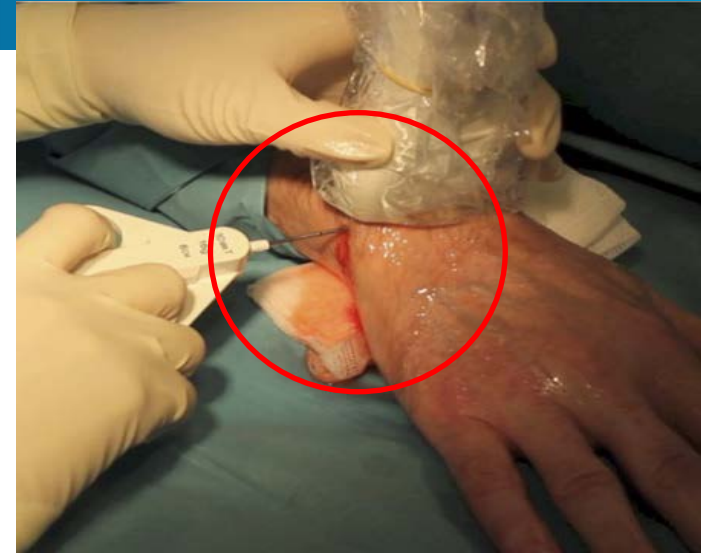


Central venous catheter placement
Critical Care 2017

Active retrieval of tissue for diagnostic testing

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

Biopsy



Synovial biopsy
BMJ Annals
Rheum Dis 2015



Core biopsy
breast
Clin Onc 2016

Aspirations

Active retrieval of fluid for diagnostic testing

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



Aspiration of liver
J Med Ultrasonics 2017



Arthrocentesis. *Am Col Emerg Phys 2015*

Level I Trauma Center, NYC: Emergency Dept. case review

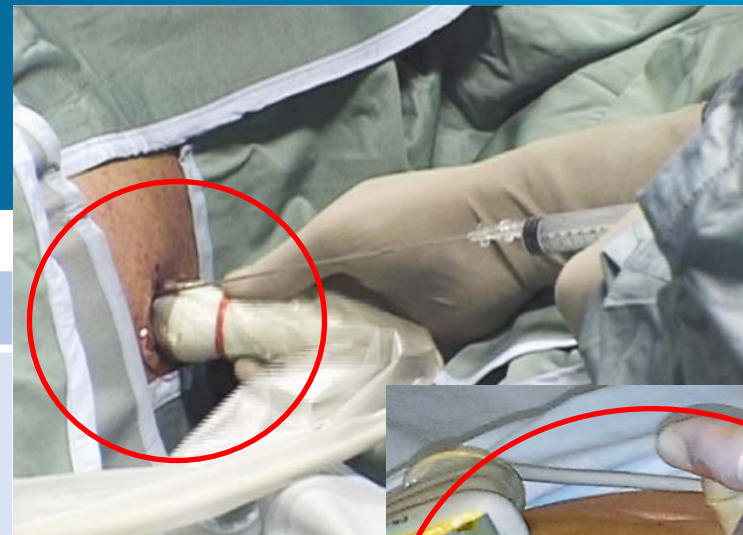


Pericardiocentesis

Drainage

Passive removal of fluid (abscess drainage)

- U/G drainage pancreatic pseudocyst
- U/G drainage 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 diverticula
- U/G percutaneous drainage iliopsoas abscess
- U/G percutaneous drainage splenic abscess
- U/G percutaneous drainage muscle hematomas
- U/G percutaneous drainage 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 abdominal/pelvic abscess



Pleural Catheter
N Engl J Med 2018

Drainage of abscess
Port Jour Gastro 2019



Drainage peritoneal
hydatid disease
J Med Surg Res 2018

Injection of Anesthetic into Nerve for Analgesia

- 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, stellate ganglion b
- 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 nerven block
- U/G thoracic paravertebral block
- U/G thoracolumbar interfascial plane block
- U/G transversus abdominis plane block
- U/G trigeminal nerve block

Nerve Block

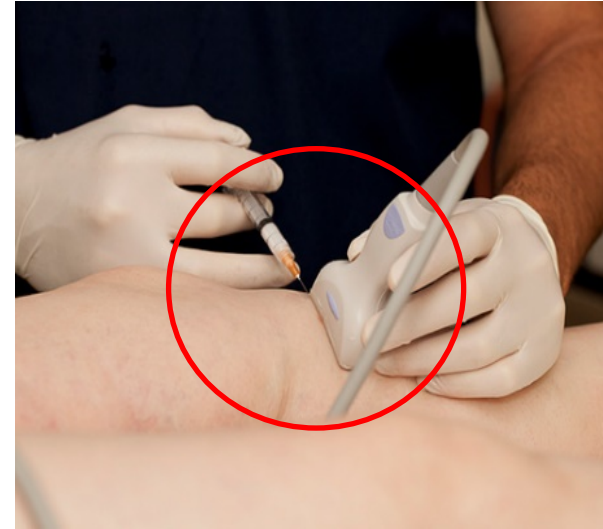


TAP Block
Am Col Emerg Phys 2019

Ablation

Destroying tumor cells or other cells by high energy radiowaves, microwaves, ethanol or cold gases

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



Ultrasound-guided
ablation
Vein Health 2022



Radiofrequency
ablation
J Pain Res 2020

Surgical Interventions

Surgical interventions

- 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



Surgery for palpable breast cancer
World J Surg Onc 2015

Additional ultrasound guided percutaneous interventions

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

FDA reaffirms guidance, February 21, 2023

Appendix E: Cleaning, disinfection and sterilization

FDA reissues requirements with no change to reprocessing guidance:

*“The probe used in a **semi-critical application** should be cleaned and **undergo sterilization or at least receive high level disinfection** after use even if a sheath was used.”*

*“Endoscopic, rectal, and transvaginal probes should be used with a single-use sterile sheath. If these probes are used to assist biopsy procedures, all biopsy accessories should be sterile for the procedure and any reusable biopsy accessories should be reprocessed after each use. If the transducer probe itself has a built-in channel for the needle guide, that channel could create a risk for contamination of the biopsy needle during use unless the channel is thoroughly cleaned and the **probe is sterilized** before use on another patient.”*

Marketing Clearance of Diagnostic Ultrasound Systems and Transducers

Guidance for Industry and Food and Drug Administration Staff

Document issued on February 21, 2023.

Document originally issued on June 27, 2019.

This document supersedes “Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers” dated September 9, 2008.

For questions about this document, contact Office of Health Technology 8 (OHT8): Office of Radiological Health at RadHealth@fda.hhs.gov or Office of Science and Engineering Laboratories (OSEL), Keith Wear at 301-796-2538 or keith.wear@fda.hhs.gov. For questions related to ultrasound systems and transducers intended for cardiovascular applications, contact OHT2: Cardiovascular Devices at 301-796-7000. For questions related to ultrasound systems and transducers intended for obstetrics and gynecological applications, contact OHT3: Reproductive, Gastro-Renal, Urological, General Hospital Device & Human Factors at 301-796-6650.



U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

How would you categorize this probe?



1. Critical
2. Semi-critical
3. Non-critical

Placing Arterial Lines Like a Pro (radial and femoral) | Behind the Knife - Bedside Procedures Ep 3
Behind the Knife: The Surgery Podcast
<https://www.youtube.com/watch?v=nyZeuMrwBH8>

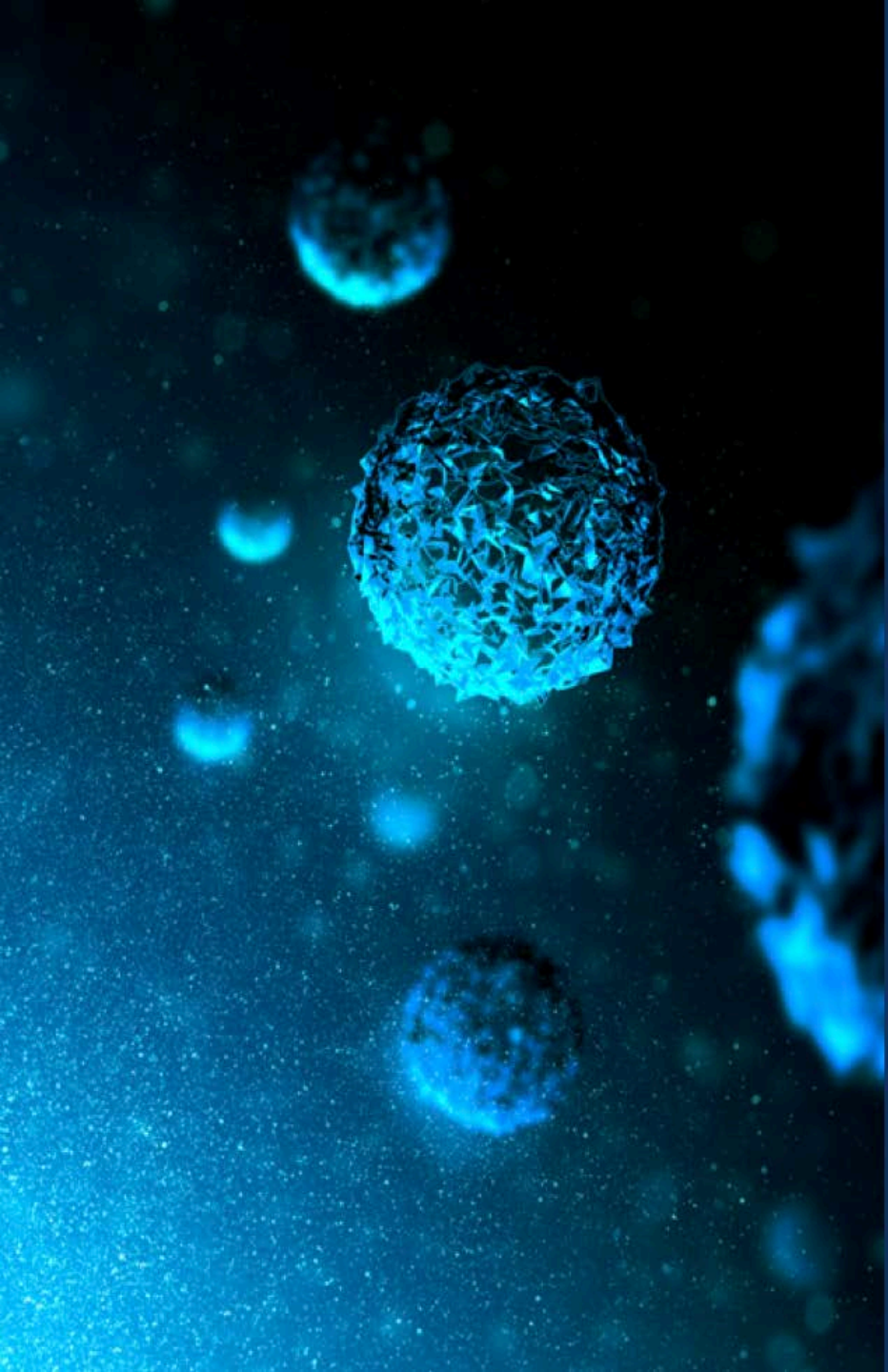
How would you categorize this probe?



1. Critical
2. Semi-critical
3. Non-critical

FINE NEEDLE ASPIRATION OF THE THYROID

https://www.youtube.com/watch?v=QiS7Xxya_2U



Conducting a Risk Assessment

Considerations

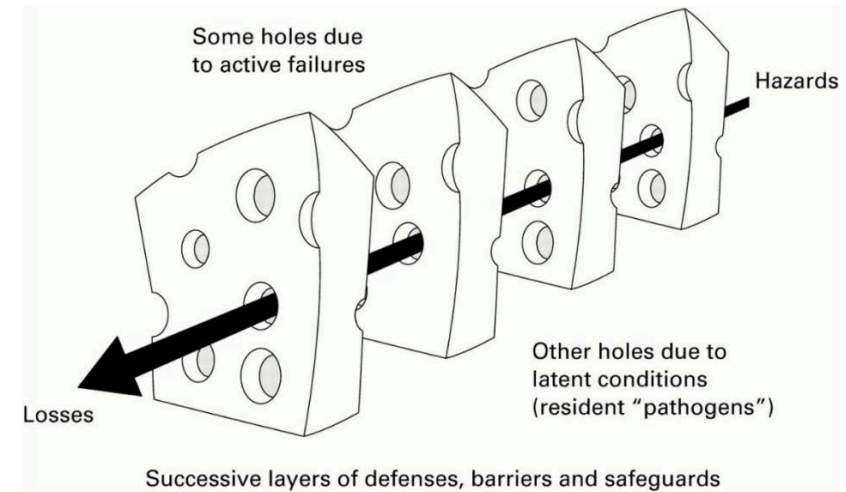
- There is no substitute for observation of medical procedure. First-hand observation of clinical providers' knowledge, skill and technique can provide valuable insights to inform reprocessing policy.
- Many ambulatory settings do not have a dedicated IP to ensure safe practice.
- Harm reduction models recommend that policy should address all possible outcomes resulting from the range of staff performing procedures.
- Standardization of reprocessing procedures may offset risk of varying levels of knowledge, skill and competency and potential for breaks in safe practice.

Open School

Patient Safety 101: From Error to Harm (Formerly "Fundamentals of Patient Safety")

Lesson 1: The Swiss Cheese Model

- The Swiss cheese model is a useful way to think about errors in complex organizations.



Considerations

Responses from 358 infection preventionists to a 2018 survey of ultrasound probe use and reprocessing practice indicated:

- Surface probes used in invasive procedures were not high-level disinfected or sterilized in 15% of intraoperative procedures.
 - In the same group of invasive procedures, 5%-47% did not use sterile gel.
- Of the participants, 20% were aware of instances where an ultrasound probe was used but was not correctly reprocessed.
- Of respondents, 2.5% were aware of situations where an ultrasound probe may have been implicated or involved in an infection. These included cases of dermal infections, infections from ultrasound-guided breast biopsy, vascular infection and pelvic inflammation.



American Journal of Infection Control

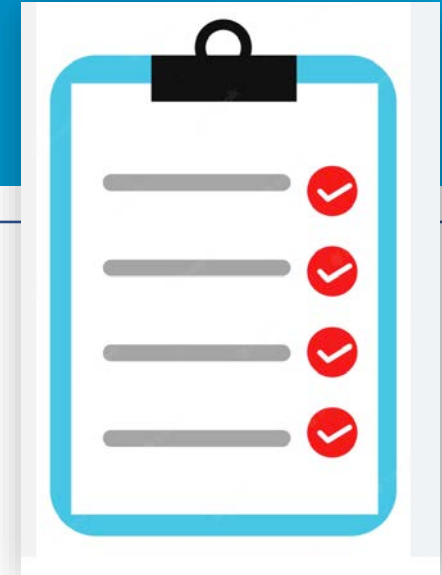
Volume 46, Issue 8, August 2018, Pages 913-920



Major Article

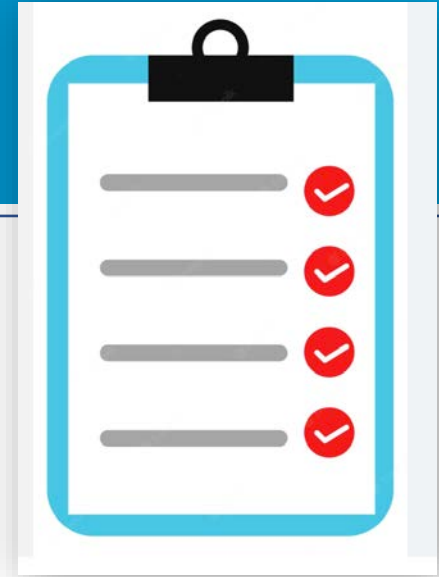
Ultrasound probe use and reprocessing: Results from a national survey among U.S. infection preventionists

Key Components of a Probe/Transducer Disinfection Risk Assessment



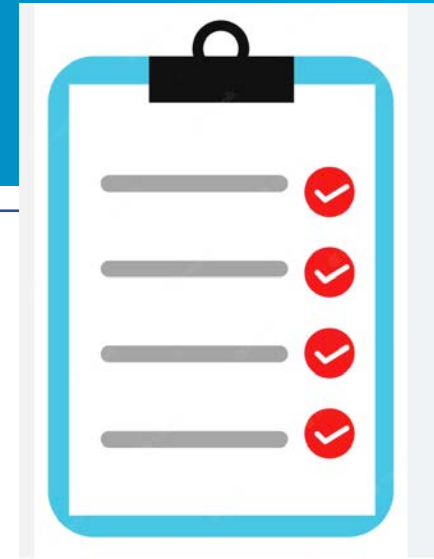
1. There is clear evidence that _____ (location/department/service) demonstrates **procedures that satisfy**:
 - Current AAMI Sterilization and Disinfection Standard (ST79), CDC/HICPAC and AORN guidelines
 - Manufacturer's Instructions for Use (IFUs)
2. Staff in the ultrasound department demonstrated **proper disinfection** of probes as follows:
 - Pre-cleaning in the exam room using an approved wipe/detergent
 - Reprocessing using disinfectant products approved for the required level of disinfection as follows:
 - **Use was on Intact Skin only - Intermediate (ILD) or Low-Level Disinfection (LLD)**
 - **Probe came into contact with Mucous Membranes or Non-Intact Skin - High Level Disinfection (HLD)**
 - **Probe came into contact with Sterile tissue or Bloodstream – Sterilization or High-Level Disinfection (HLD)**

Key components of a probe/transducer Disinfection Risk Assessment



3. There is clear evidence that processes related to the **storage** of ultrasound probes and transducers ensure safety for the next patient use.
4. Procedures are in place to **monitor the use of all disposables and level disinfectants**, as well as steps to take for a failed HLD test.
 - Efficacy against the targeted microorganisms
 - Concentration of disinfectant
 - Contact time
 - Shelf life/Stability: Once prepared diluted disinfectant should be dated with “use by” or “expiry dates” as per manufacturer’s instructions.
5. Procedures are in place to address a failed HLD test.
6. A schedule and log is maintained for **preventive maintenance** on equipment.

Key components of a probe/transducer Disinfection Risk Assessment



7. There is clear evidence that a process exists to identify and address **re-training of staff** if non-adherence to disinfection procedure or contamination of sterile/semi-critical/non-critical items is suspected or discovered.
8. A Root Cause Analysis (RCA) is conducted as a mechanism for identifying, responding to, and **reporting sentinel events** that occur in the organization. Staff re-training may be a strategy that is identified in the RCA Policy.
9. There is clear evidence that a process is in place to **notify patients of adverse incidents** if contamination is discovered and patient exposure is suspected.
 - In the event an adverse event the department will follow Policy #_____ (Disclosure of Unanticipated Outcomes).

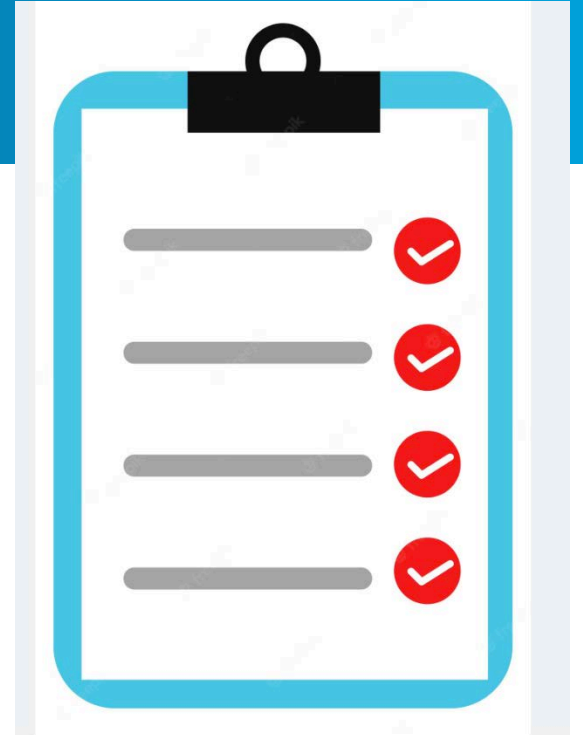
Frequent Risk Assessment Findings

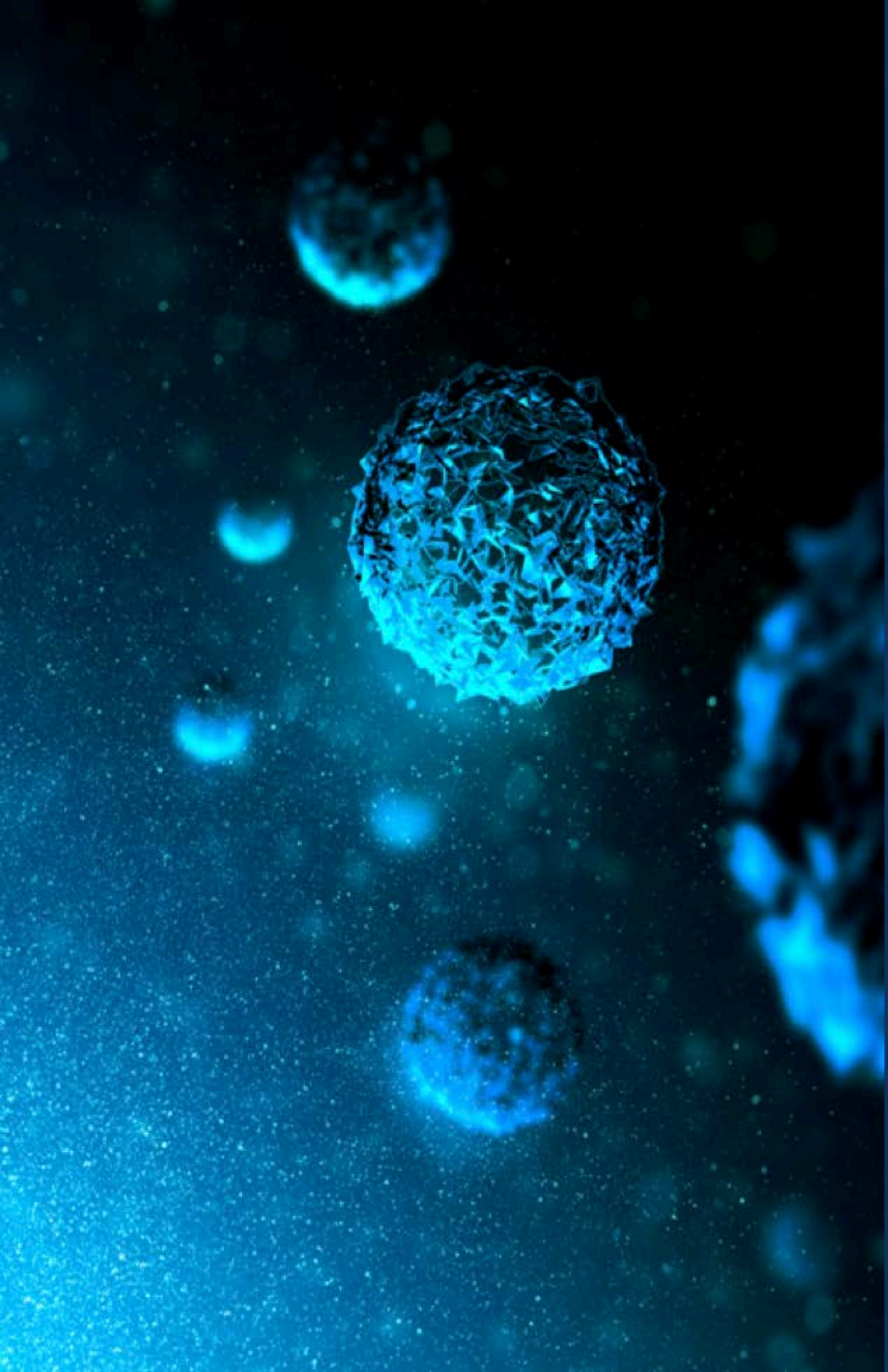
Clinical percutaneous procedures:

- Central line placement with probe on the insertion site
- Bloody procedures/probes
- Inserting probe in breast tissue without HLD

Reprocessing:

- Mis-use of wipes, wipes that damage probes
- Non-compliance with wipe contact and/or drying time
- Expired strips and biological indicators
- Non-compliance with MIFUs
- Non-compliance with Spaulding as dictated by MIFUs





Outside of the U.S.
*Guidance from Health
Authorities*

Outside of the US



UK, Australia, Europe -- movement toward ultrasound-specific guidelines, recommendations are consistent FDA, CDC and Spaulding Classification

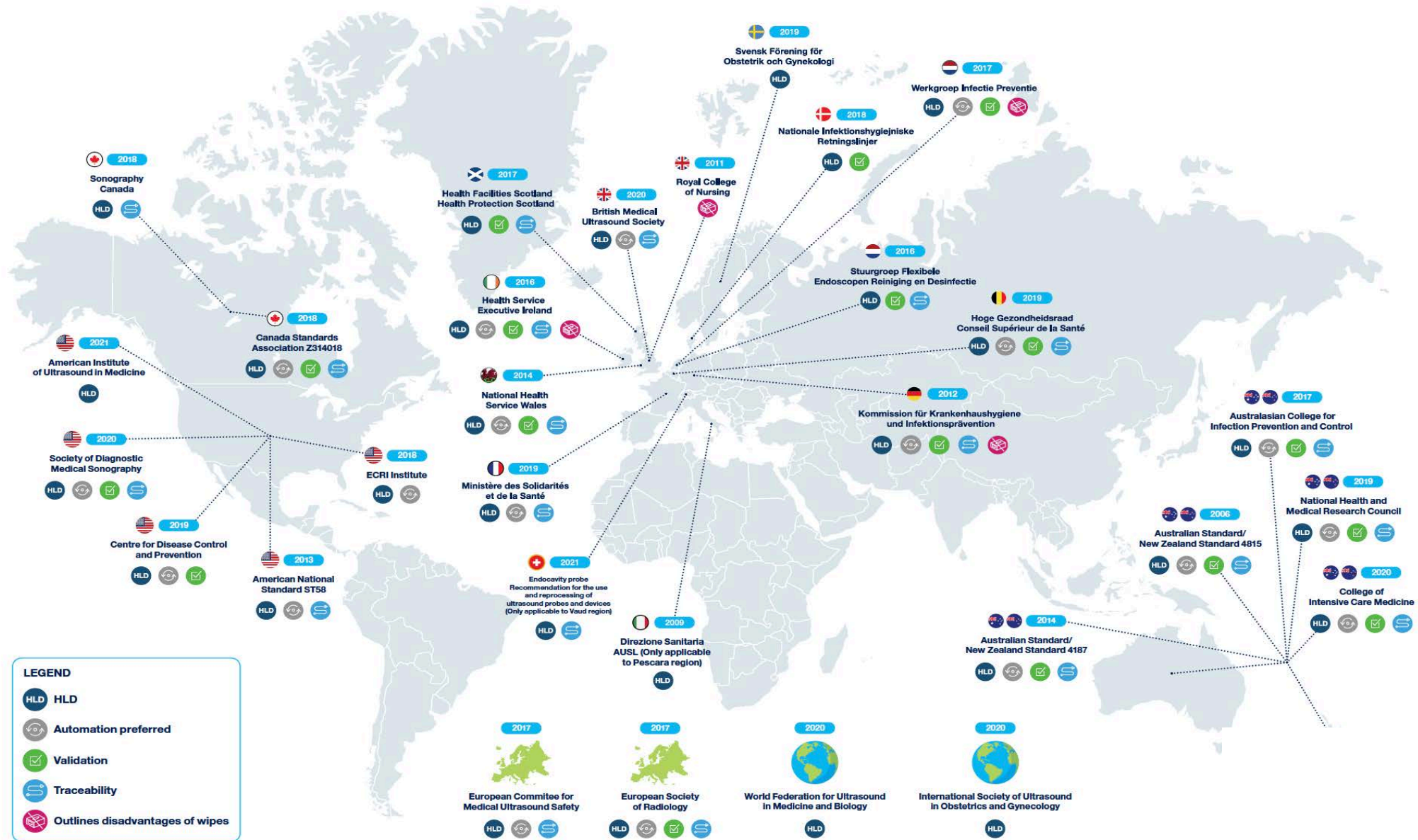
- NHS Scotland¹
- Joint Guidance Australasian Society for Ultrasound in Medicine and Australasian College for Infection Prevention and Control²
- European Society of Radiology Ultrasound Working Group: Guidance in 2017,³ in response to results from a practice survey:
 - Interventional ultrasound (biopsies, injections, procedures where skin is breached) recommend minimum of high-level disinfection (HLD) and use of a sterile sheath.
 - For endocavitary procedures, strongly recommend use of sterile gel inside and outside the cover.

1. Health Service Executive (HSE) Quality Improvement Division—Decontamination Safety Programme. HSE guidance for decontamination of semi-critical ultrasound probes; semi-invasive and non-invasive ultrasound probes. Document: QPSD- GL-028-1. 2017.

2 Australasian Society for Ultrasound in Medicine (ASUM), Basseal, J ,et al. Guidelines for Reprocessing Ultrasound Transducers. *Australasian Journal of Ultrasound in Medicine*. 2017.

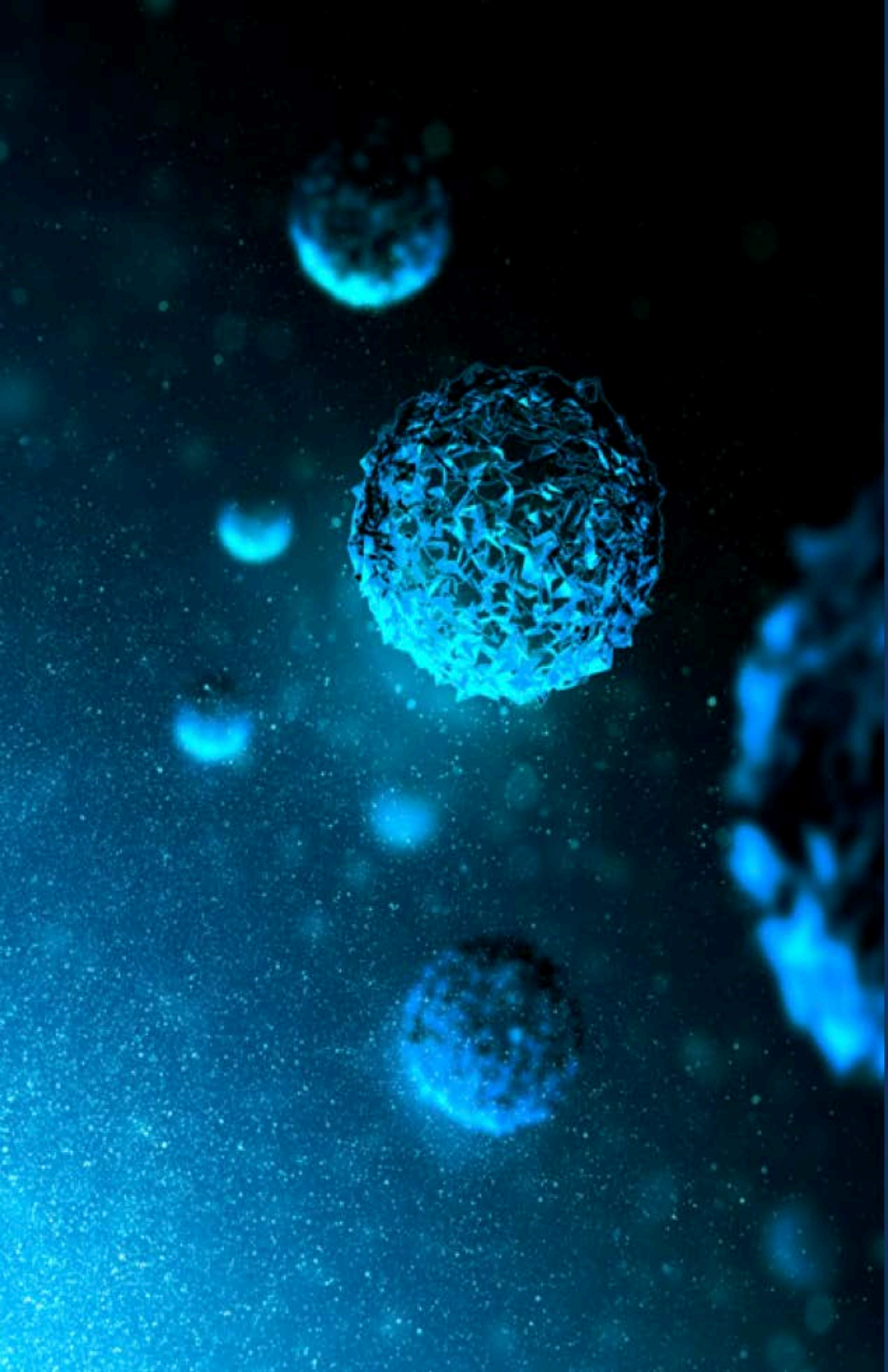
3. European Committee for Medical Ultrasound Safety (ECMUS). Best practice recommendations for cleaning and disinfection of ultrasound maintaining transducer integrity. 2017.

International guidelines on semi-critical ultrasound probe disinfection

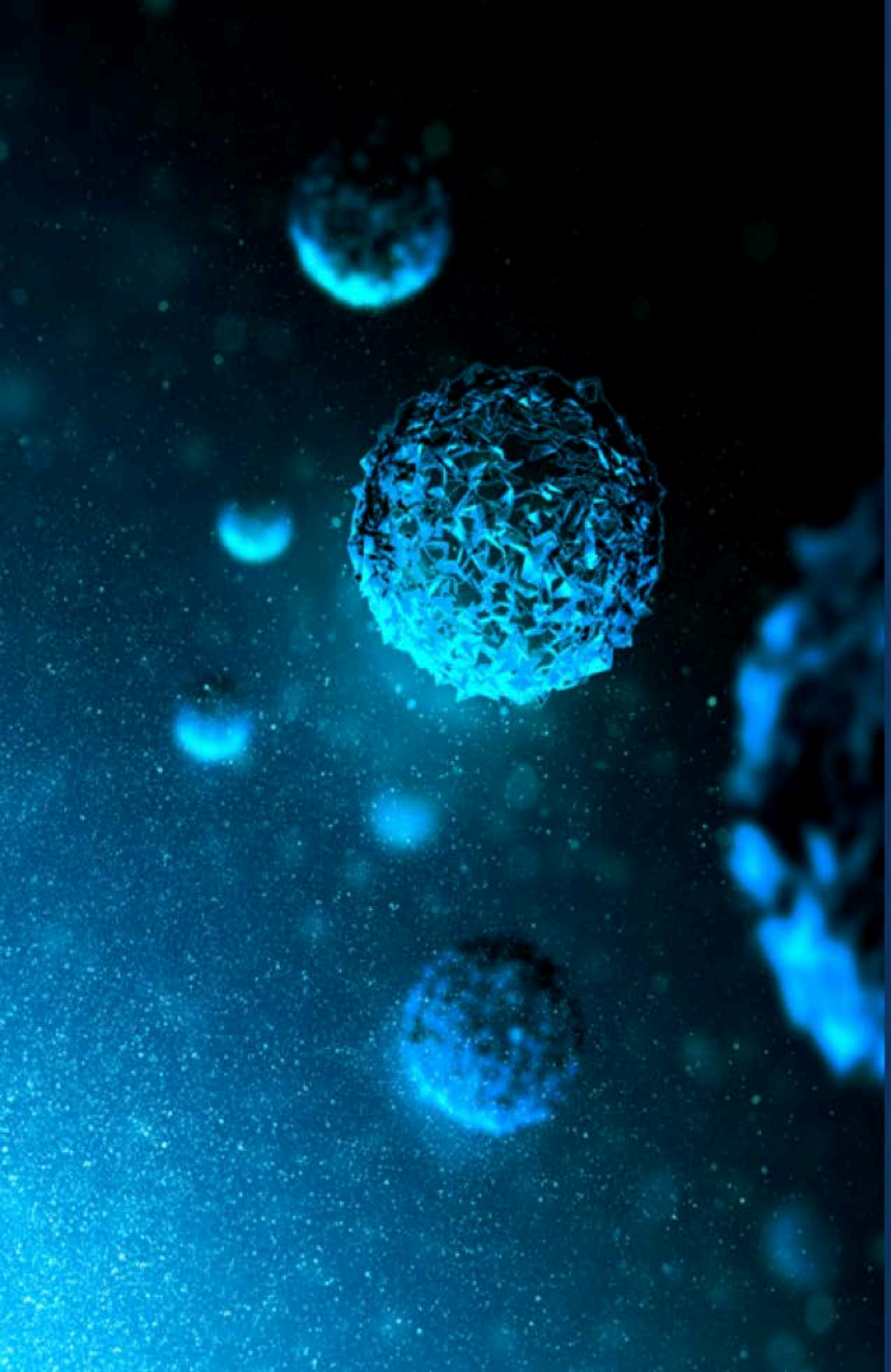


What we covered

1. The range, complexity and diversity of ultrasound-guided percutaneous procedures.
2. Determination of critical, semi-critical and non-critical uses and corresponding level of reprocessing using the Spaulding Classification framework, FDA and CDC requirements and guidelines.
3. The potential for contact between the probe and sterile needle or puncture site, along with examples from the literature and implications for patient safety.
4. Findings from system-wide risk assessments of probe reprocessing practice and implications for policy.



Questions

A vertical strip on the left side of the slide shows a microscopic view of cells. The cells are spherical and have a textured, bumpy surface. They are set against a dark background with some blue and green highlights, suggesting a fluorescent or electron micrograph.

Thank you!

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