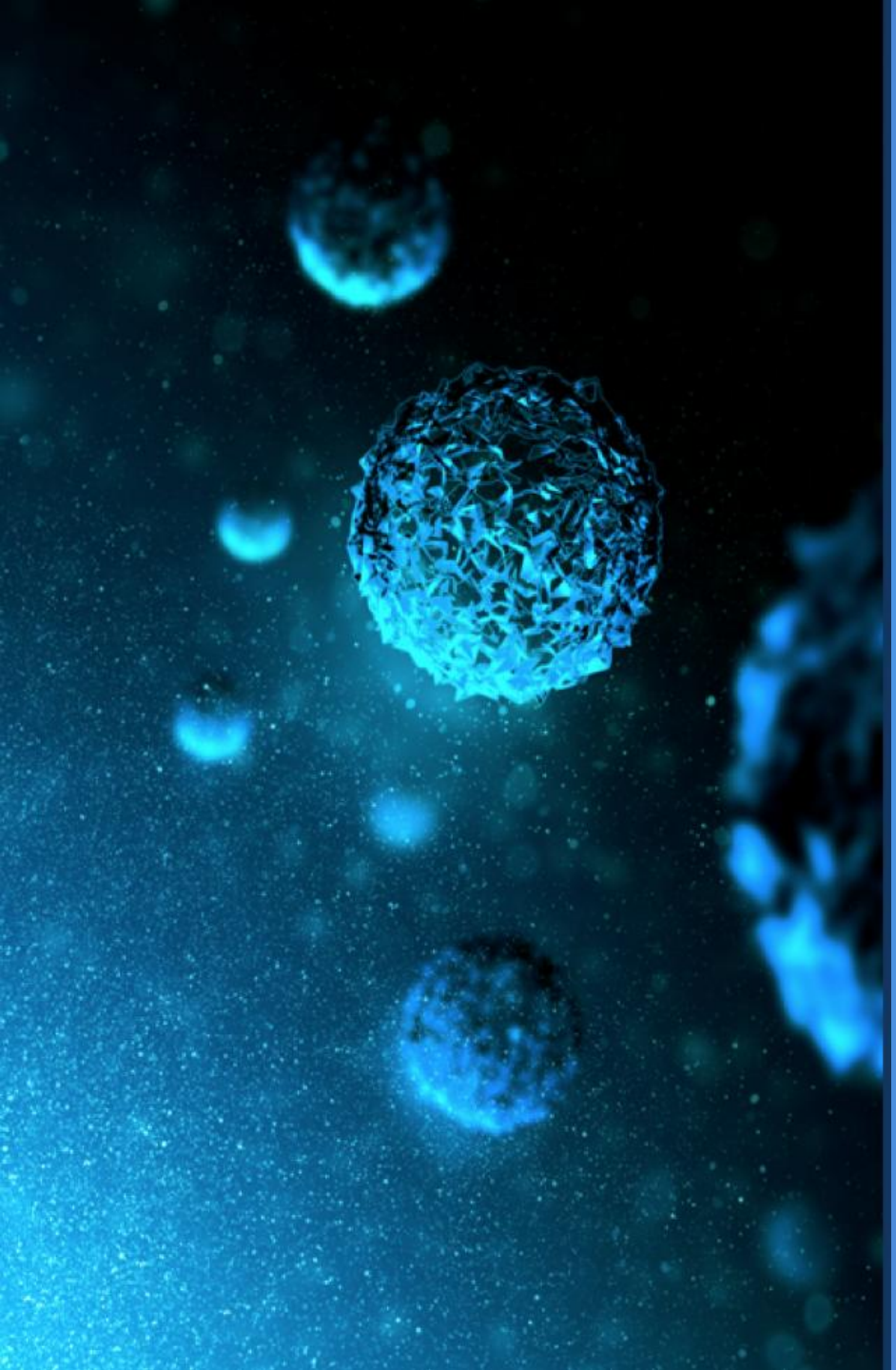

Ultrasound Infection Prevention

Disinfection of Probes Used in Percutaneous Procedures

Maureen Spencer, M.Ed., BSN, RN, CIC, FAPIC
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- Maureen Spencer is a Registered Nurse with a Master's Degree in Education, board certification in infection control, and a Fellow of the Association for Professionals in Infection Control and Epidemiology (FAPIC). She has published 55 peer-reviewed papers and several chapters in infection prevention books. Maureen was elected to the APIC Board – Nominating and Awards Committee in 2025. Currently, she is an Independent Infection Preventionist Consultant.
- Her previous positions included:
  - IP Consultant with ForHealth Consulting Group at UMass Medical School during the COVID pandemic
  - Director, Clinical Implementation and Education at Accelerate Diagnostics, Tucson, AZ
  - Corporate Director, Infection Prevention for Universal Health Services, King of Prussia, PA
  - Infection Control Director, New England Baptist Hospital, Boston, MA
  - Infection Prevention Legal Nurse Consultant
  - Director, Infection Control Unit at Mass General Hospital, Boston, MA,
  - Nurse Epidemiologist, VA Medical Center, West Roxbury, MA
  - Infection Control Nurse, Carney Hospital, Boston, MA
  - Microbiology technician – through high school and nursing school

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 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

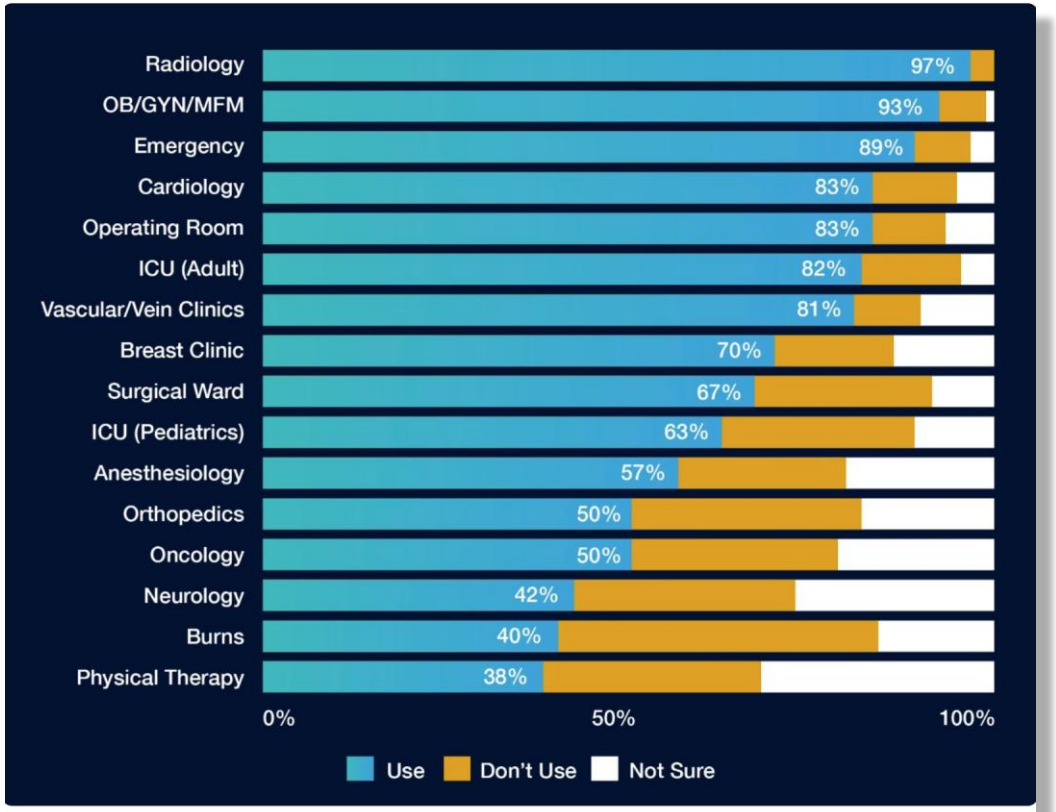
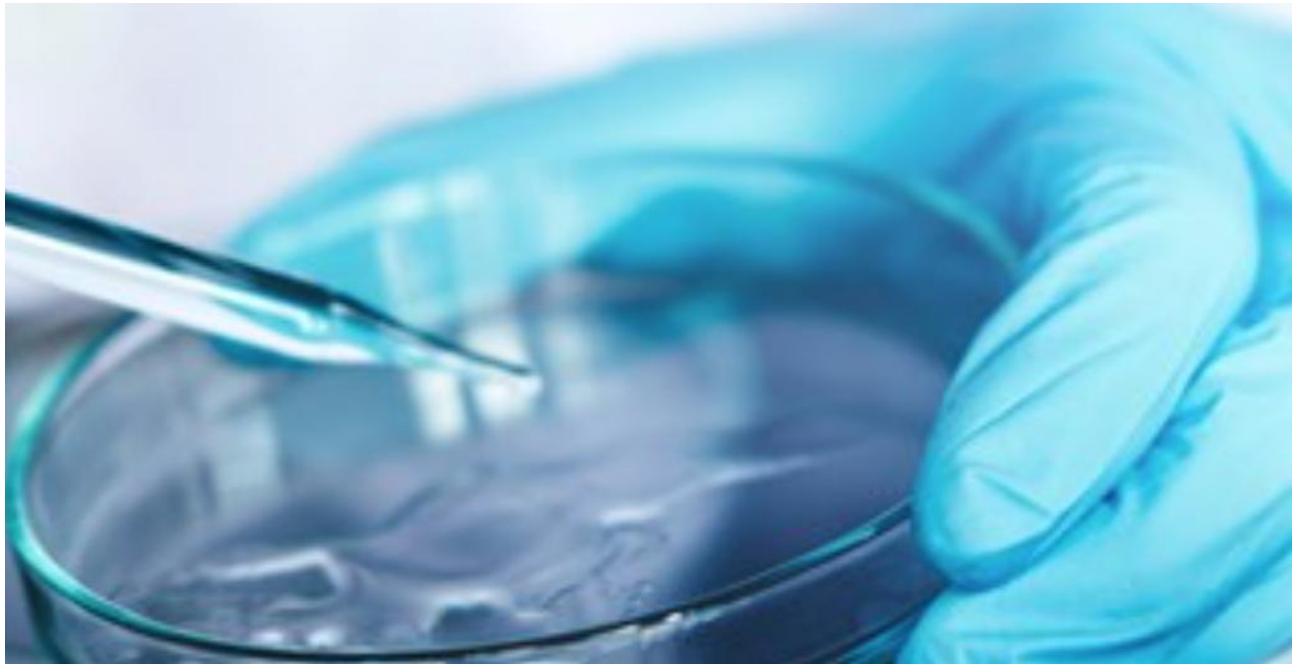


Figure 1. Adapted from Carrico 2018.[1] All departments surveyed recorded use of ultrasound.

- Expansion into medical services with no previous experience in ultrasound guidance
- Expansion into ambulatory settings
- Introduction of wireless probes

- **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]

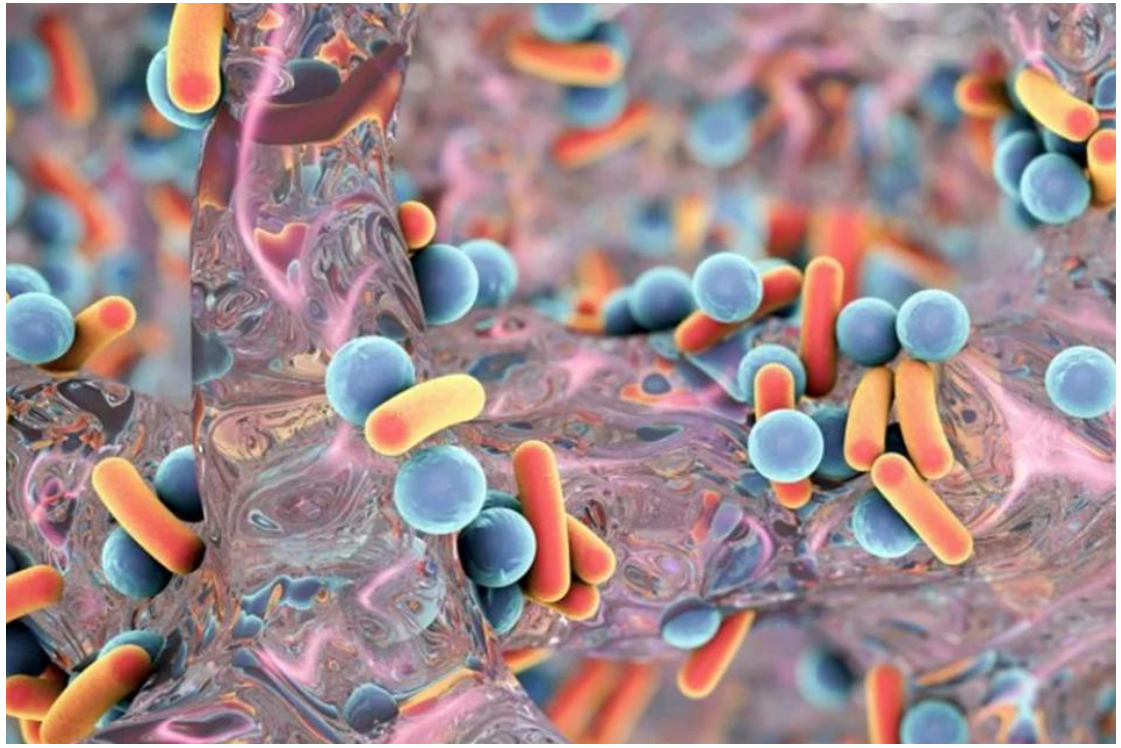


- **More than 80% probe handles** remain contaminated when not disinfected.[3,4]

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.

- 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_0rP-zMKu4. Accessed 2/27/23

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.

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."

MHRA UK 2012. Medical Device Alert: Reusable transoesophageal echocardiography, transvaginal and transrectal ultrasound probes (transducers) (MDA/2012/037).

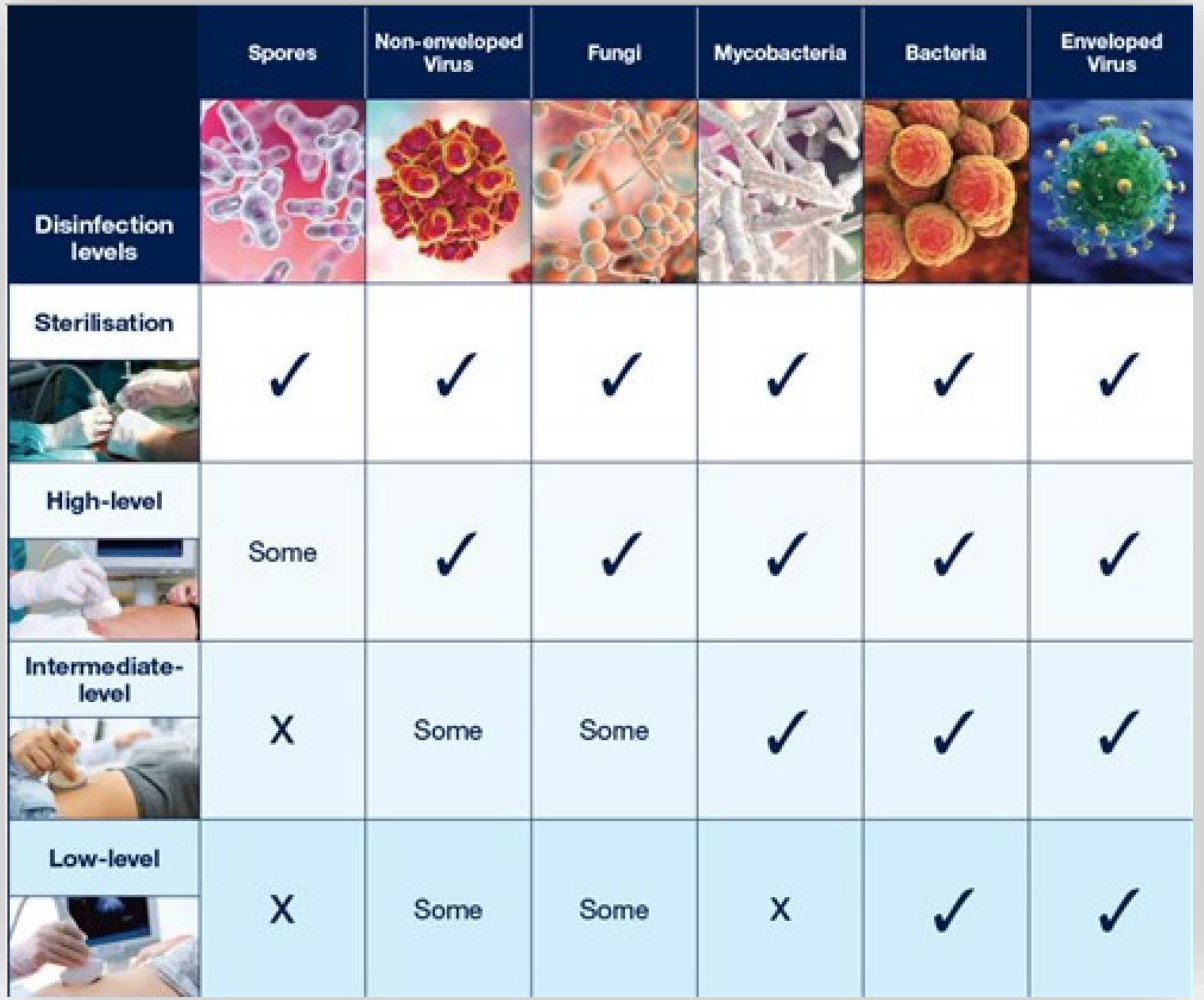
“How many bacteremias that look like present on admission, are from prior ultrasound procedures?”

“ICD 10 coding is not there to track.”

Is evidence of transmission and infection limited, because we’re not looking for it? All HOB reporting may offer new insights into risk.

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* (only difference between LLD and ILD), lipid viruses, some non-lipid viruses, and fungi, but not bacterial spores.



Disinfection levels	Spores	Non-enveloped Virus	Fungi	Mycobacteria	Bacteria	Enveloped Virus
Sterilisation	✓	✓	✓	✓	✓	✓
High-level	Some	✓	✓	✓	✓	✓
Intermediate-level	X	Some	Some	✓	✓	✓
Low-level	X	Some	Some	X	✓	✓

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

There are many wipes on the market that are EPA registered with varying kills profiles.

- Efficacy is dependent on the microbiocidal properties of the chemistry, the mechanical action of wiping and hold-time.
- Applied per IFUs and at specified contact time, depending on the chemistry, wipes can kill bacteria, enveloped viruses, some fungi and some non-enveloped viruses. **Mycobacteria and spores are unaffected**. Remember that LLD/ILD processes do not eliminate all bacteria, viruses and fungi, therefore surfaces disinfected by wiping, can still retain viable pathogens.
- Efficacy of wipes can be affected by coverage, mechanical action and failure to meet required contact time before the next use.

Purpose

- To examine effectiveness of a manual cleaning process using wipes, addressing concerns raised by the Robert Koch Institute regarding the lack of validation for wipe disinfection of semi-critical devices.

Methods

- 2 highly experienced and compliant participants, using wipes to clean probes after guided biopsy procedures.
- Blue dye wipe was applied by users, with glasses that filtered out the blue color, without any time limit until they detetermined the cleaning process complete.

Results

- Wetting gaps identified in all cleanings across 4 probes tested.
- Users observed significant challenges ensuring complete surface wetting, particularly in complex device parts (clip-on areas, fixtures for additional biopsy attachments).
- *"Manual methods alone may not adequately mitigate the risk of infection transmission ." (p* value < 0.0001).

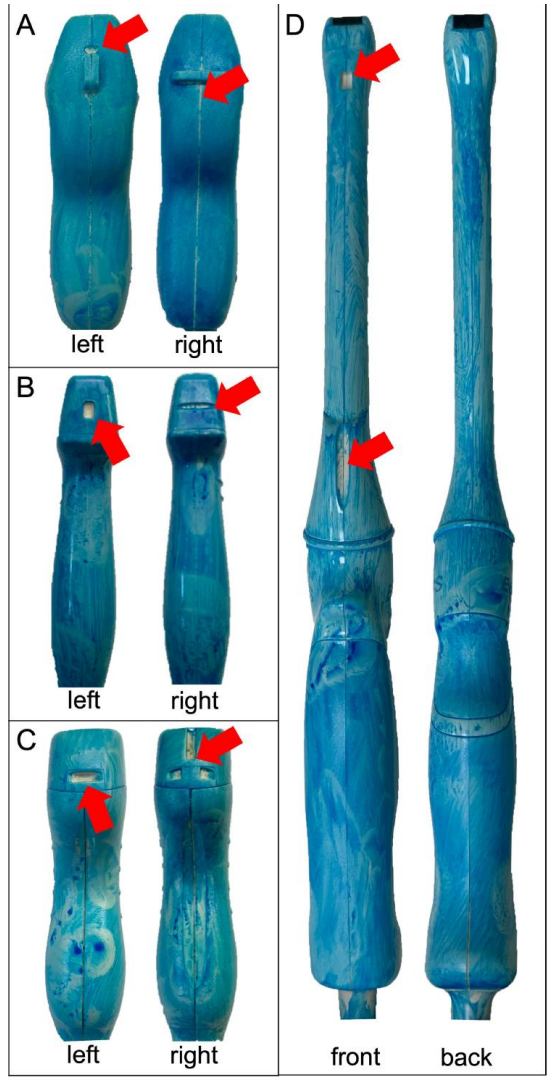


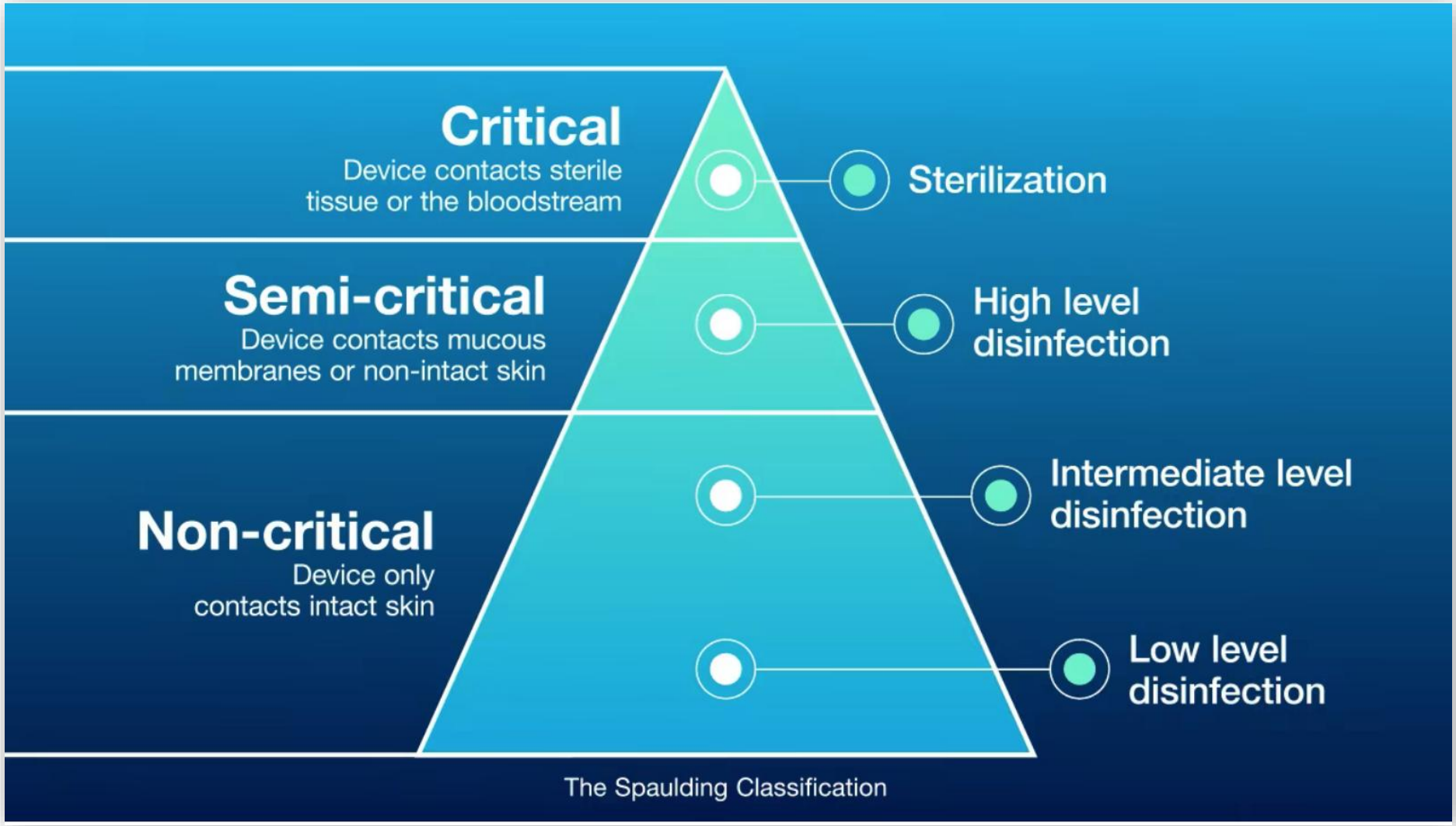
Figure 2. Procedural examples of US probes with identified wetting gaps (red arrows).: linear VF10-5 probe in left and right views with wetting gaps at the attachment grooves and housing seam (**A**), linear X6-16L probe in left and right views with wetting gaps at the attachment grooves (**B**), convex CH5-2 probe in left and right views with wetting gaps at the attachment grooves (**C**), and creenshot ry E8CS probe in front and back views with wetting gaps at the attachment grooves (**D**).

Kühnel C, Gühne F, Visualization of Effectiveness: The Use of a Set of Colored Cleaning Wipes for Visible Disinfection of Ultrasound Probes, Hygiene 2024, 4, 189–196.

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	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 (does not penetrate)*	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.

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.

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)

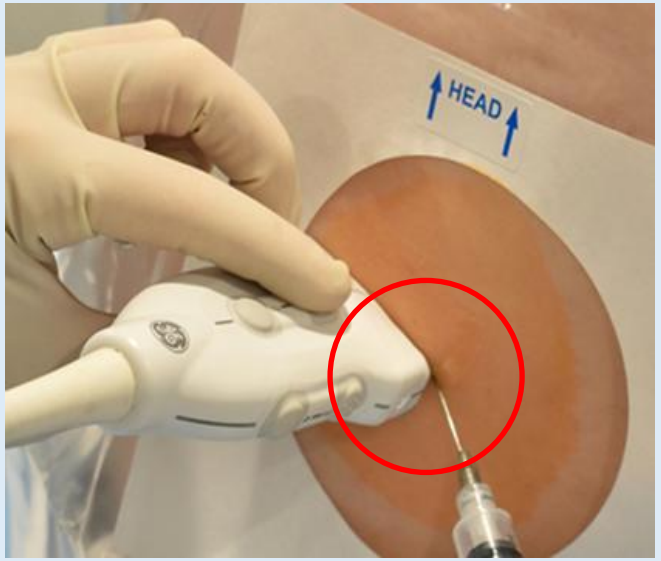
CRITICAL

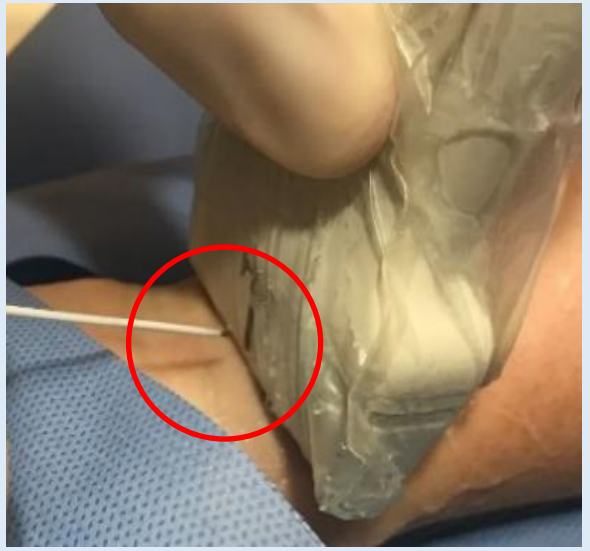
FDA 2019/2023: "*Critical devices should be sterilized and the use of a sterile sheath is recommended for each use.*" [1]

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.

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





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.

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 tendinoapthy
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 nerven 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, licodaine, 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 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.

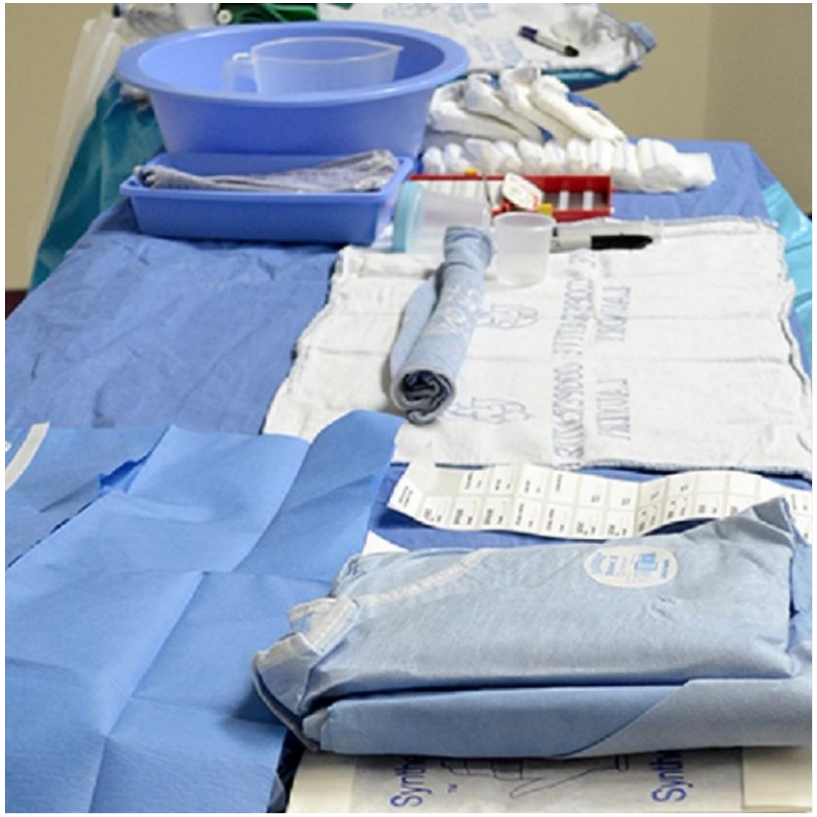
Specialty group	Number of procedures
Nerve block	35
Aspirations	27
Biopsy	18
Drainage	15
Vascular Access	9
Injection	9
Intraoperative	8
Ablation	6
Other	13
Total	140

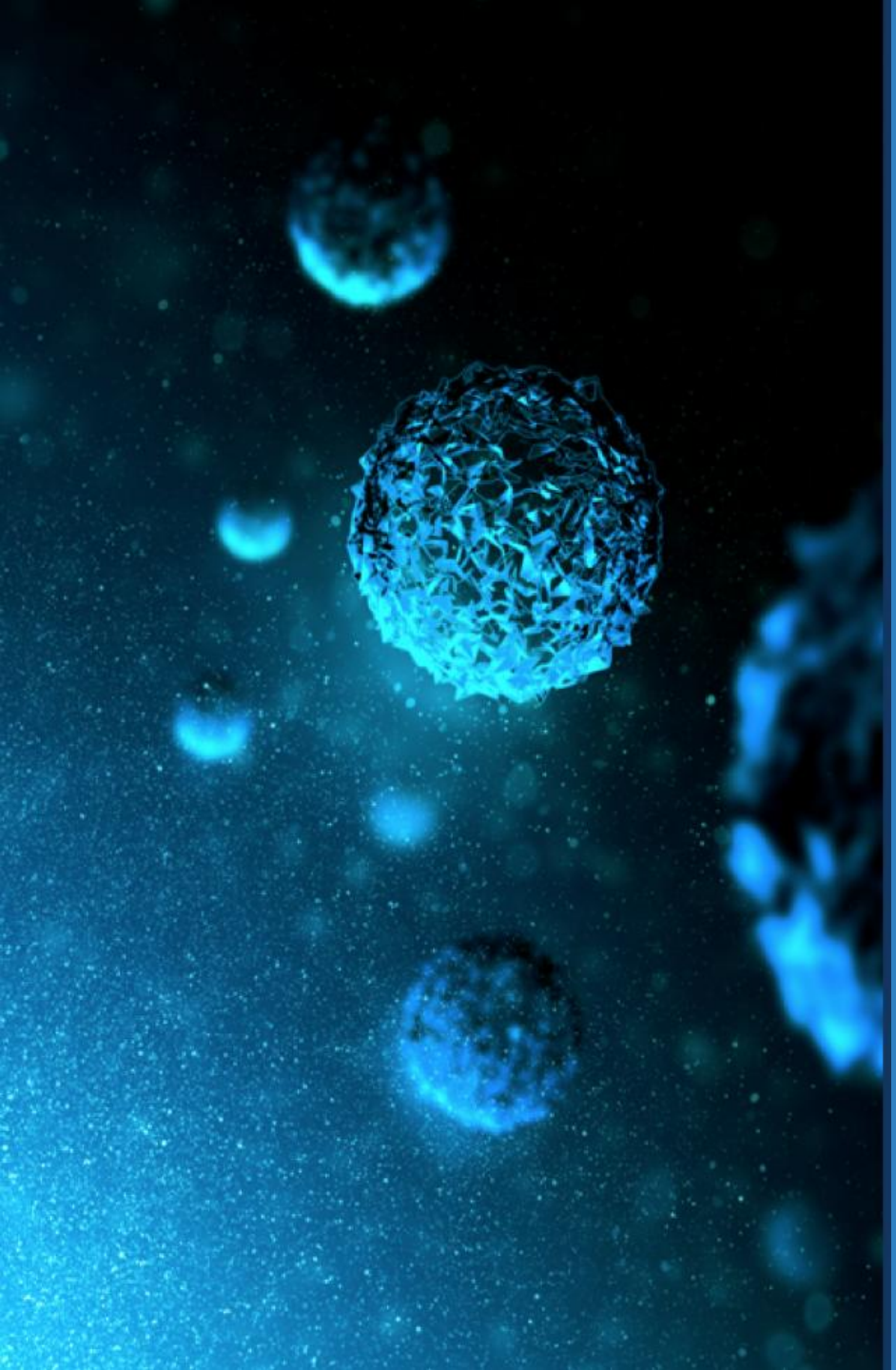
Percutaneous procedure: Entry, by puncture or minor incision, of instrumentation through the skin or mucous membrane and/or any other body layers necessary to reach the site of the procedure.

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

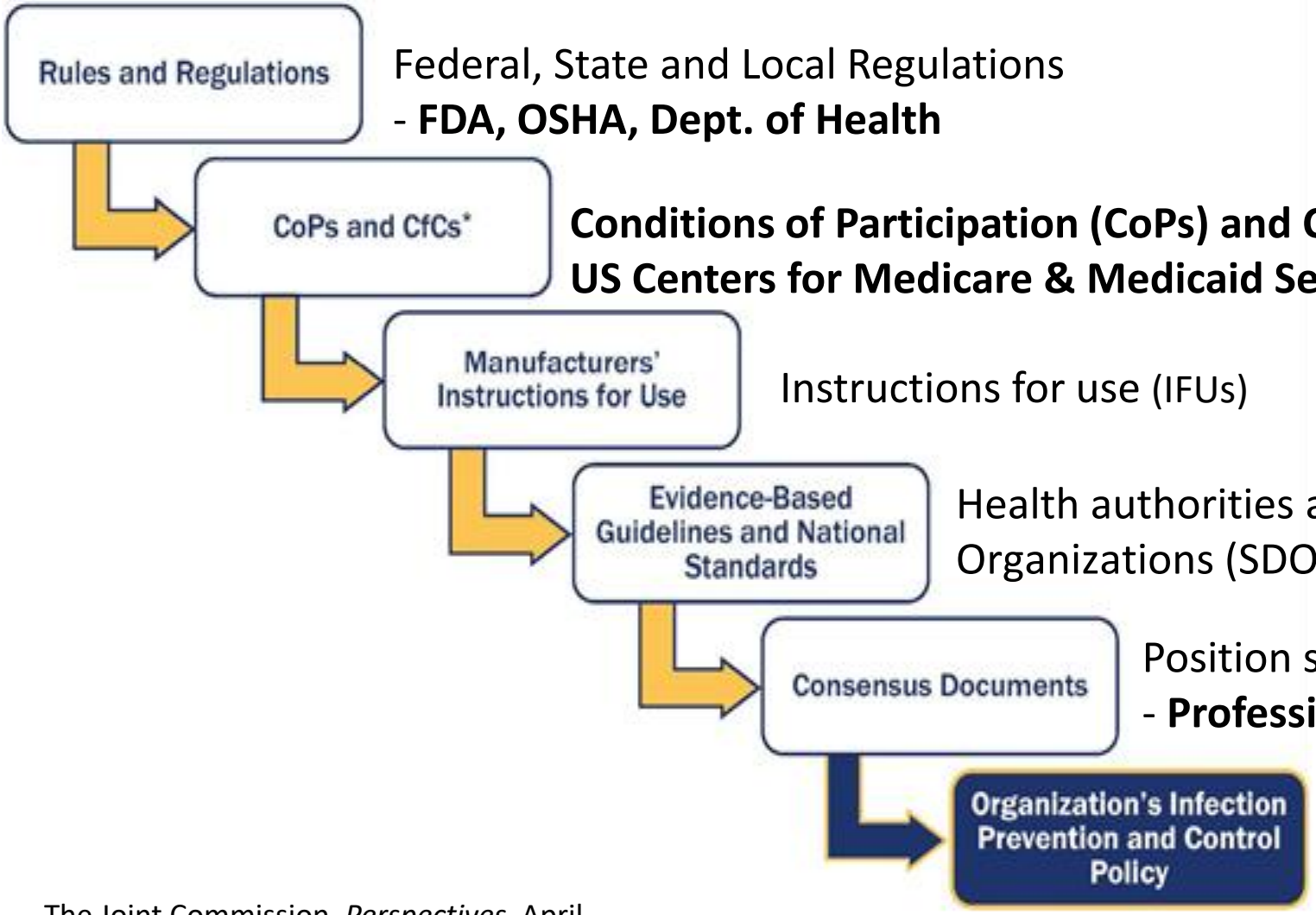
- Includes surfaces, **instruments**, and people.

- Outside of the OR, maintenance of the sterile field is recommended when performing any procedure that could transmit microbes to the patient.





Regulations, Standards, Guidelines and Position Statements



Federal, State and Local Regulations
- **FDA, OSHA, Dept. of Health**

Conditions of Participation (CoPs) and Conditions for Coverage (CfCs)
US Centers for Medicare & Medicaid Services

Instructions for use (IFUs)

Health authorities and recognized Standards Development Organizations (SDOs): **CDC, WHO, TJC, ANSI/AAMI, AORN, HSPA**

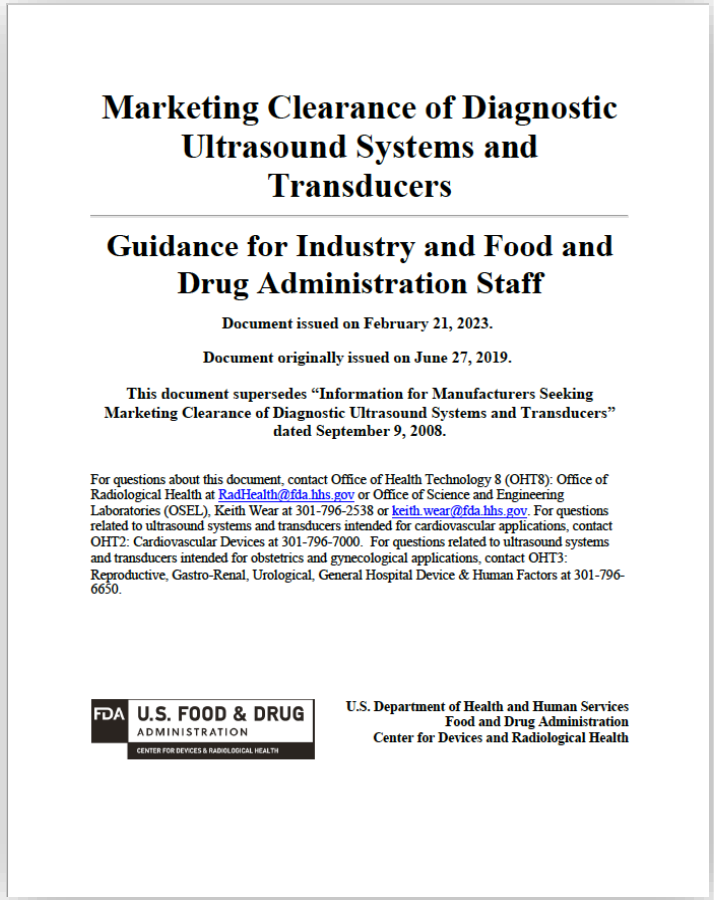
Position statements and other documents
- **Professional & medical societies**

The Joint Commission. *Perspectives.* April 2019:vol 39: Issue 4

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."*



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.

FDA U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DEVICES & RADIOLOGICAL HEALTH

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

*"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."*

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."***

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

	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.

	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 ***inconsistent with Spaulding, FDA and CDC***. Demotion of probes used on **non-intact skin** from Semi-Critical to Non-critical.

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

	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.

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

- Published in April 2025
- *LLD is acceptable* for semi-critical probes on the basis these procedures are *performed on intact skin.*
- *Sterilization or HLD is not required* for ultrasound probes applied to *intact skin* for the intended use of guiding *percutaneous procedures, such as central line placement, amniocentesis, or biopsy.*
- Oxford Learners Dictionary: PERCUTANEOUS - *Made or done through the skin.*

Infection Control & Hospital Epidemiology, April 28, 2025

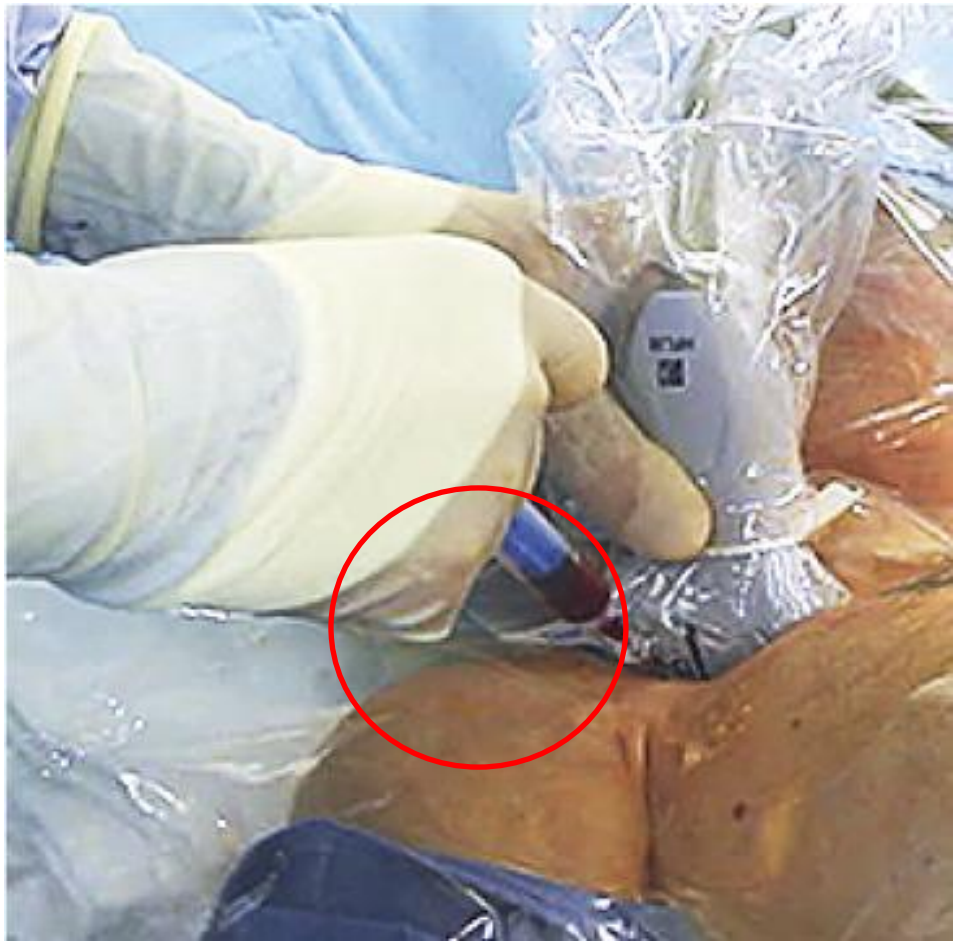
1) **Awareness of procedural risk** is not uniform across disciplines and providers.

2) **Variation in clinical technique,** skill or training among providers.

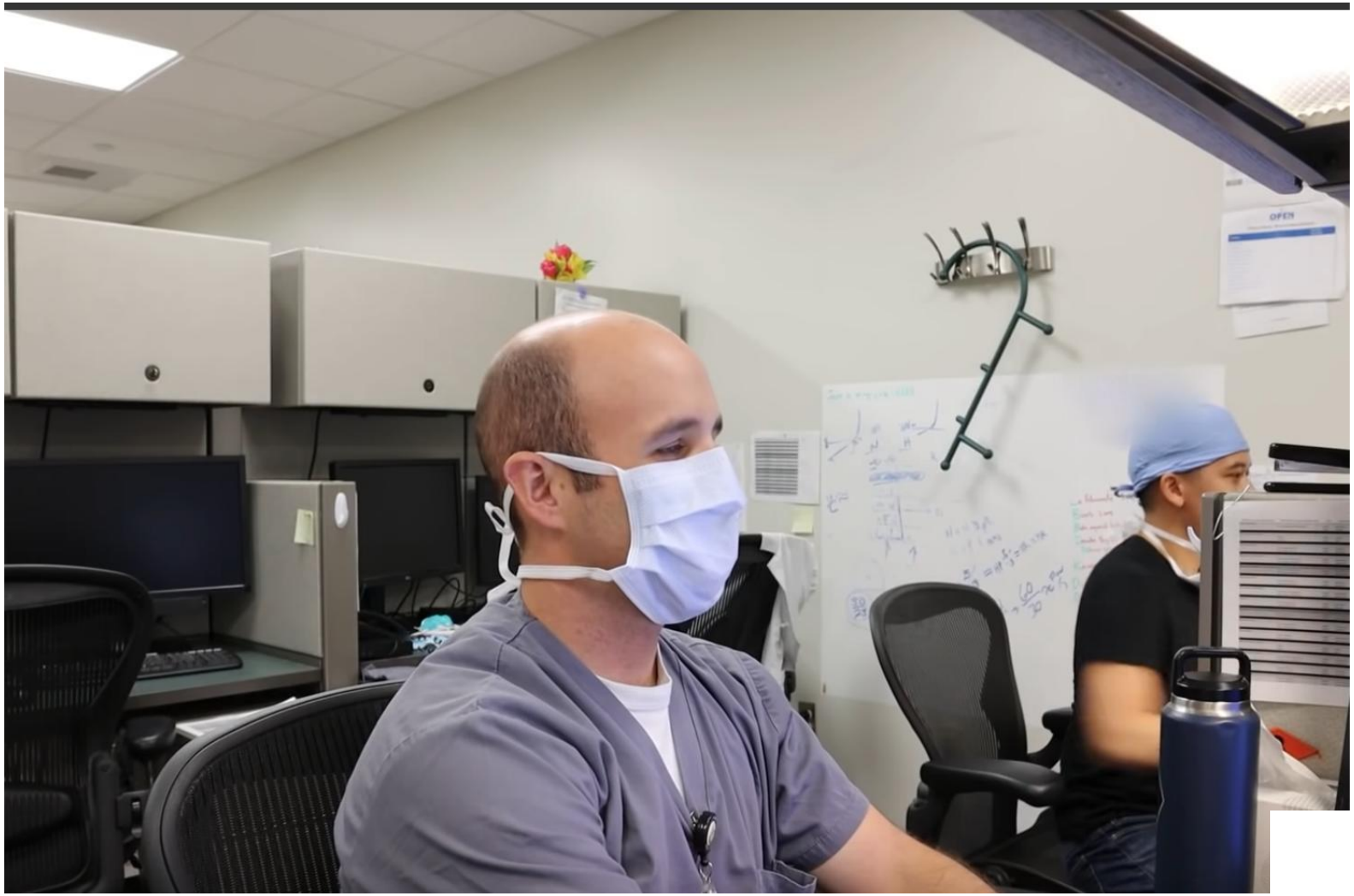
https://youtu.be/DgQbQSBYeQU

3) **Unique patient anatomy**

4) **Emergent conditions**



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



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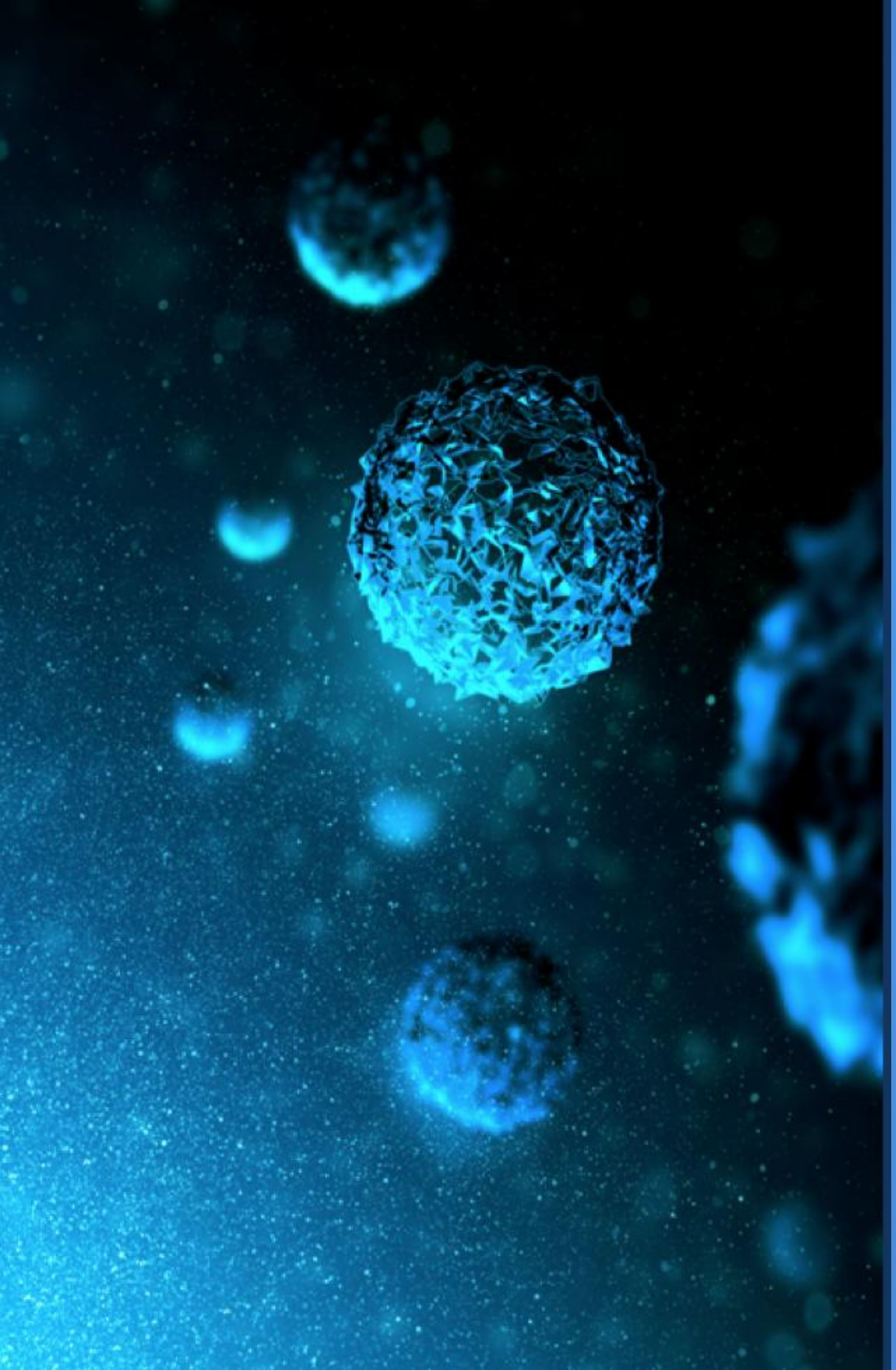
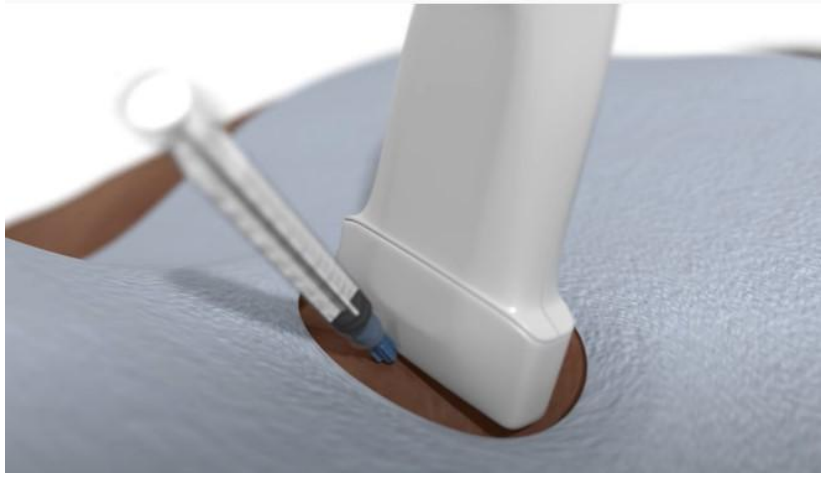


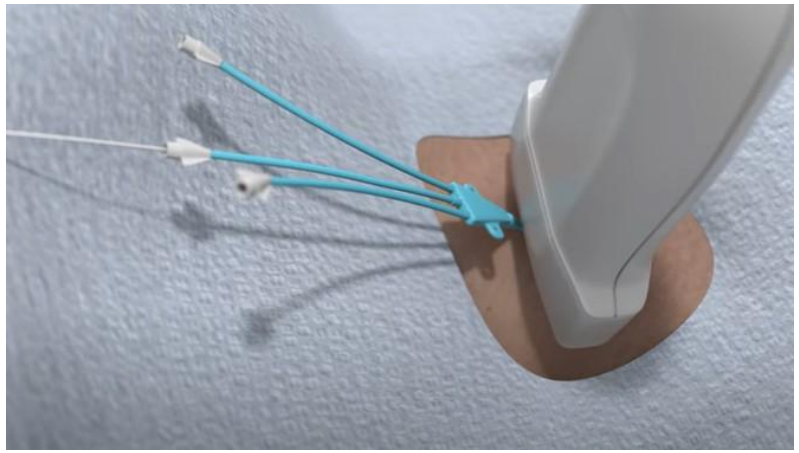
140 Percutaneous Procedures

Observations from the Literature

Ultrasound guided IV Cannulation and Thoracentesis

(Screen capture from training video)





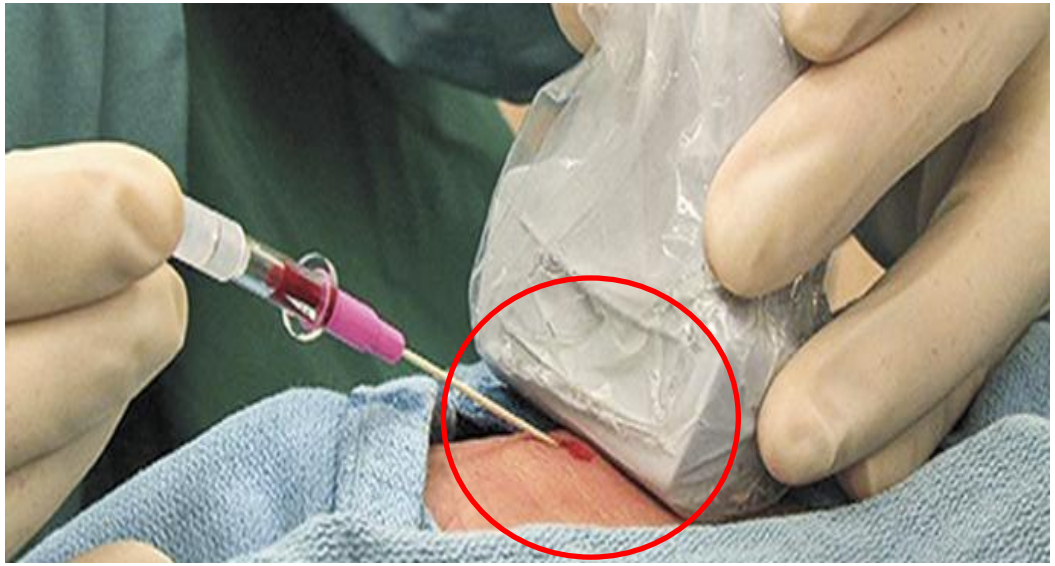
IV Cannulation

Thoracentesis

https://youtu.be/buTSag9xK6U

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

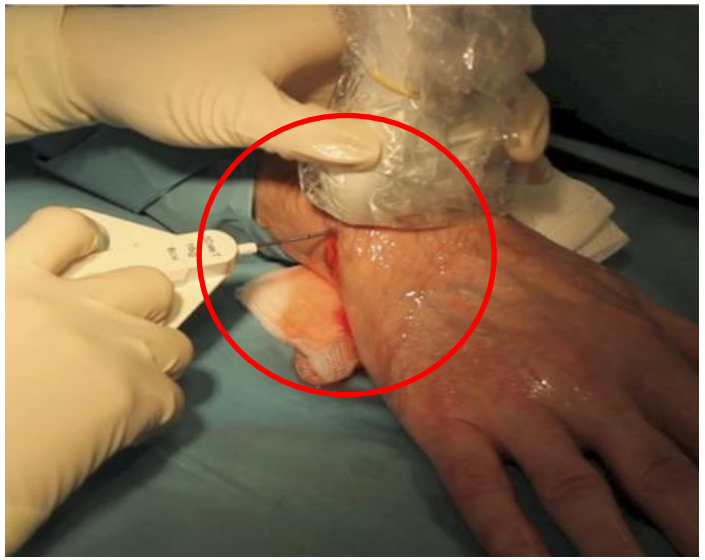


Insertion of Radial Arterial Catheter
N Engl J Med 2014

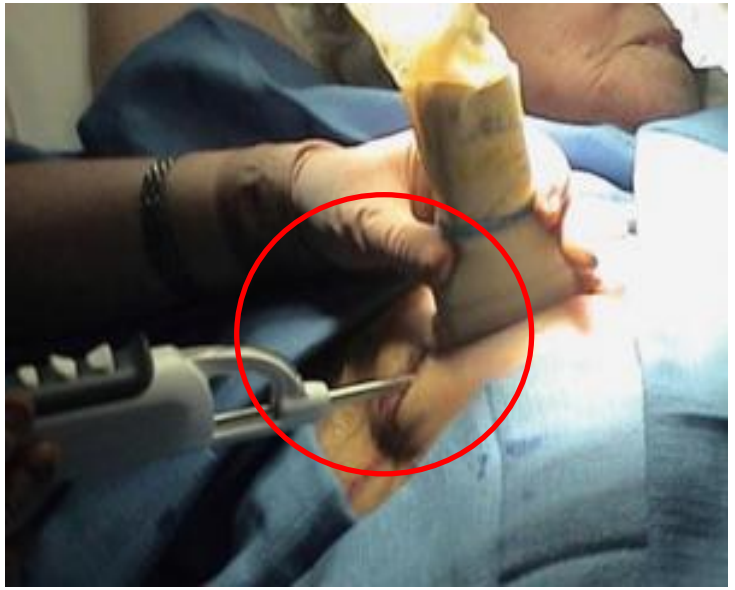
Central venous catheter placement
Critical Care 2017

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



Synovial biopsy
BMJ Annals Rheum Dis 2015

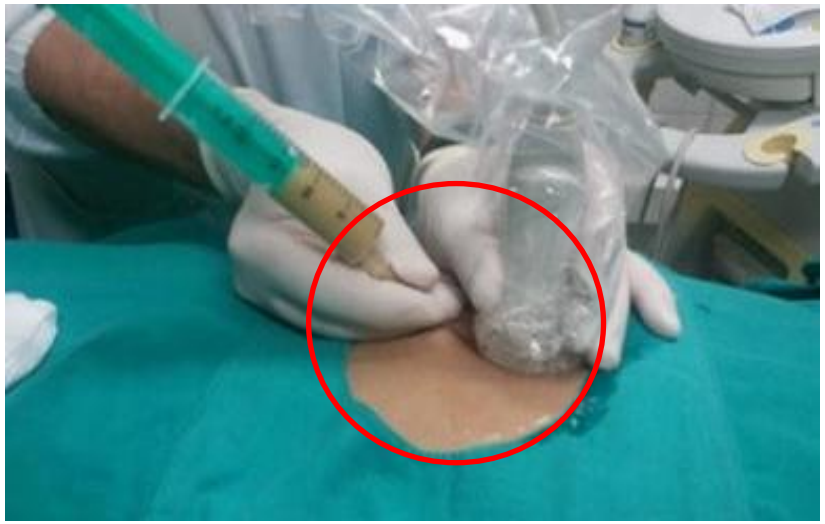


Core biopsy breast

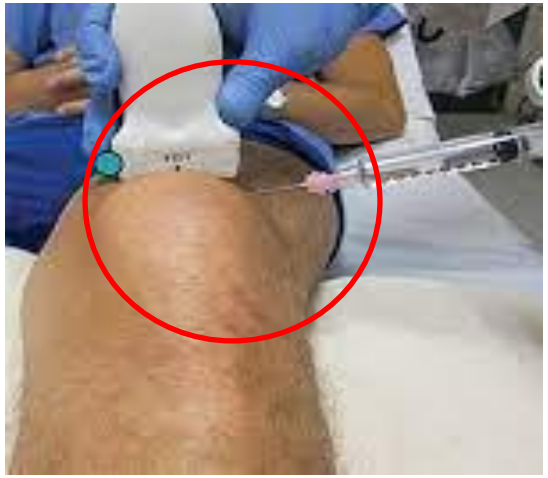
Clin Onc 2016

Active retrieval of fluid for diagnostic testing

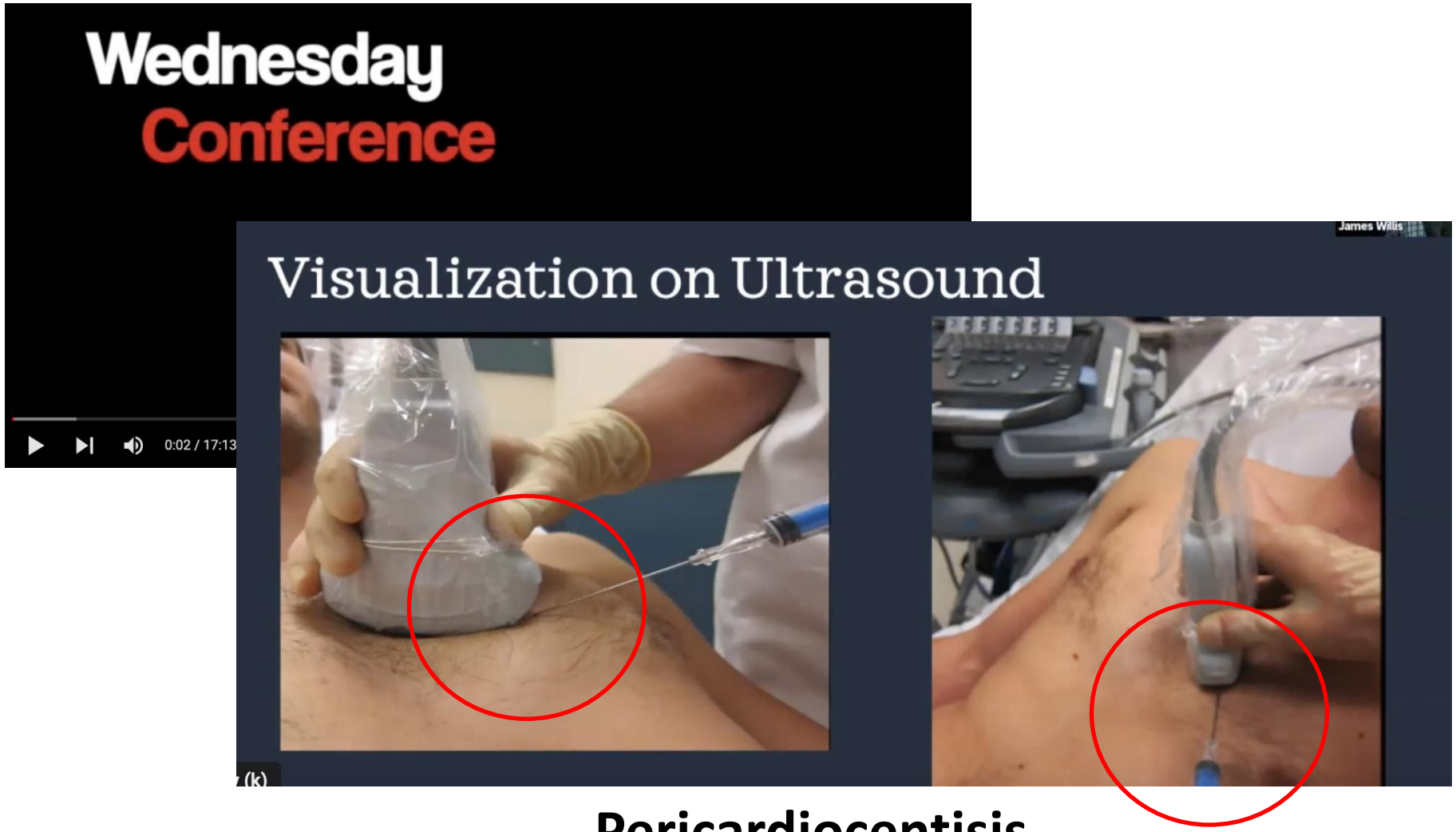
- U/G aspiration brain abscess
- U/G aspiration cyst
- U/G aspiration gall bladder
- U/G aspiration head, neck lumps
- U/G aspiration joints, soft tissues
- U/G aspiration kidney
- U/G aspiration lesions
- U/G aspiration liver
- U/G aspiration lung
- U/G aspiration lymph node
- U/G aspiration omentum
- U/G aspiration parathyroid
- U/G aspiration parotid gland
- U/G aspiration neumothorax
- U/G aspiration rotator cuff calcific tendinoapthy
- 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

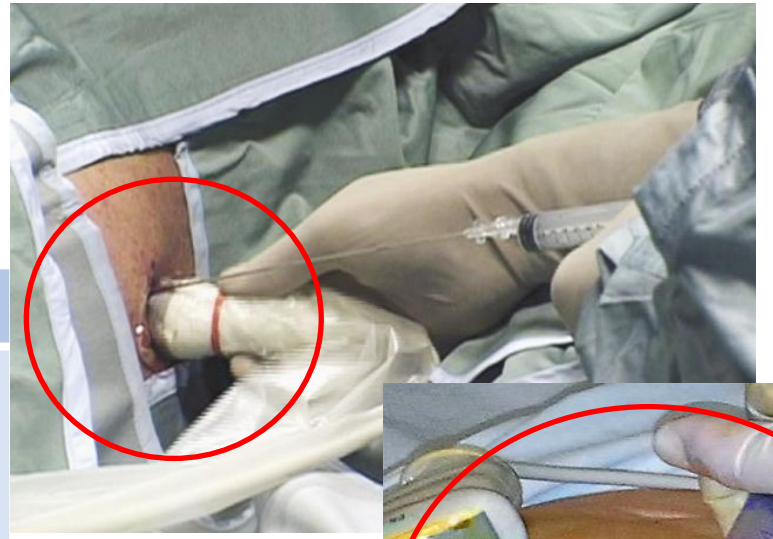


Pericardiocentisis

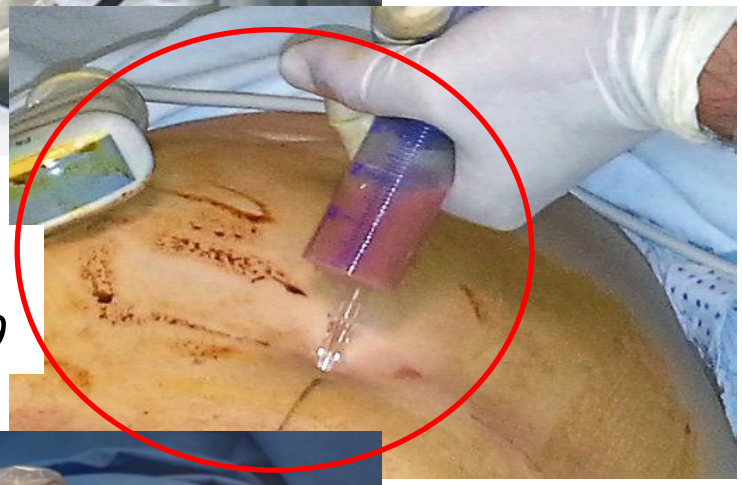
https://youtu.be/JIr5Mf6c8W4

Passive removal of fluid (abscess drainage)

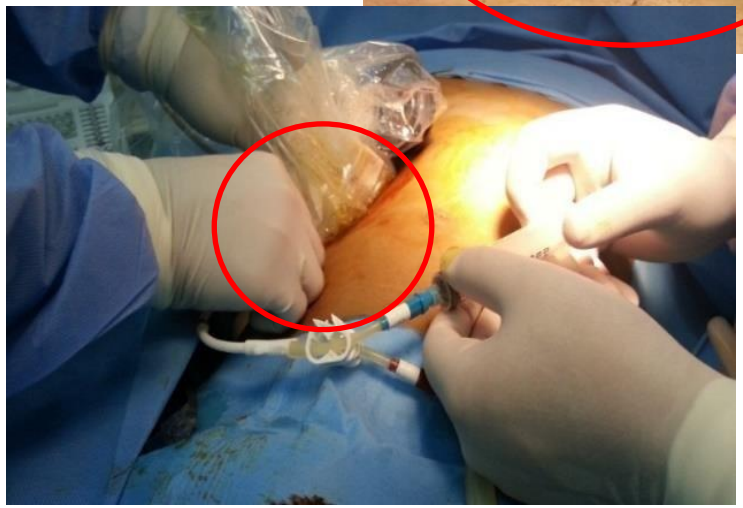
- U/G drainage pancreatic pseudocyst
- U/G drainage walled-off pancreatic necrosis
- U/G external ventricular drain
- U/G liver drainage
- U/G percutaneous appendix drainage
- U/G percutaneous catheter drainage
- U/G percutaneous drainage diverticula
- U/G percutaneous drainage iliopsoas abscess
- U/G 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

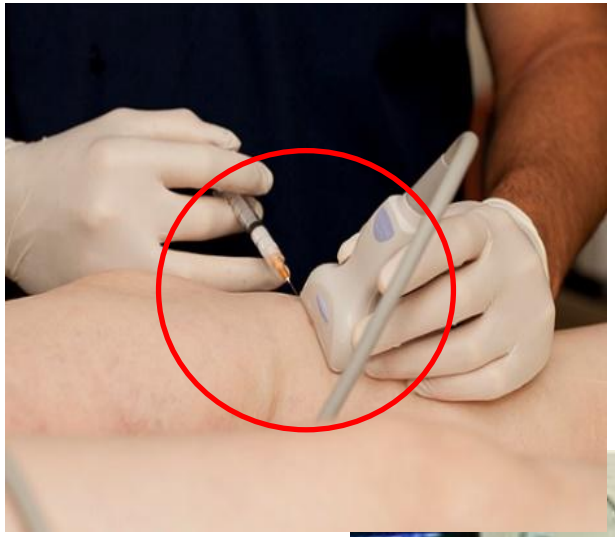
- U/G femoral nerve block
- U/G ankle block
- U/G axillary block
- U/G brachial plexus block
- U/G cervical nerve root block
- U/G celiac plexus neurolysis
- U/G continuous peripheral nerve block
- U/G penile nerve block
- U/G dorsal ramus block
- U/G epidural placement of a thoracic paravertebral catheter
- 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

TAP Block

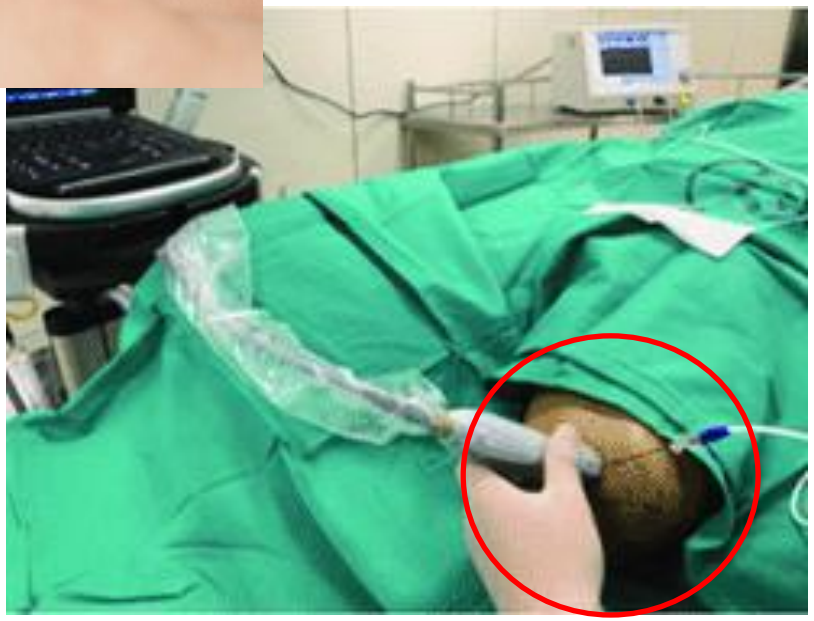
Am Col Emerg Phys 2019

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



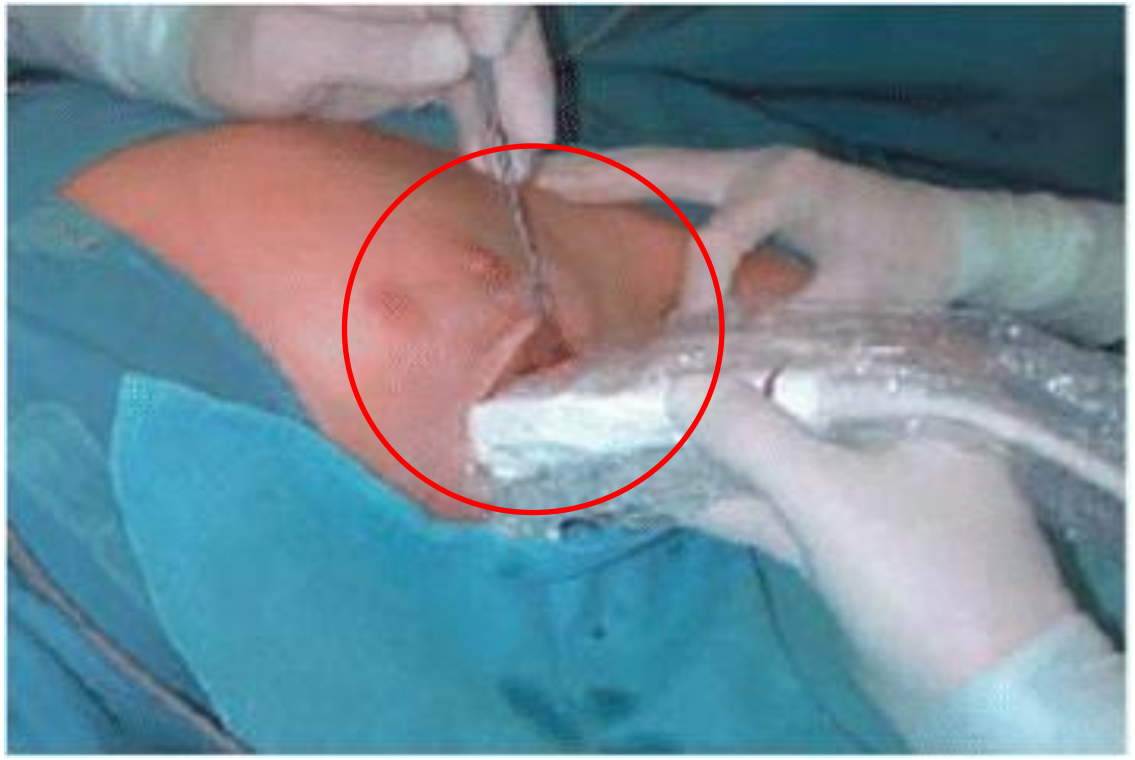
Ultrasound-guided ablation
Vein Health 2022



Radiofrequency ablation
J Pain Res 2020

Surgical interventions

- 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

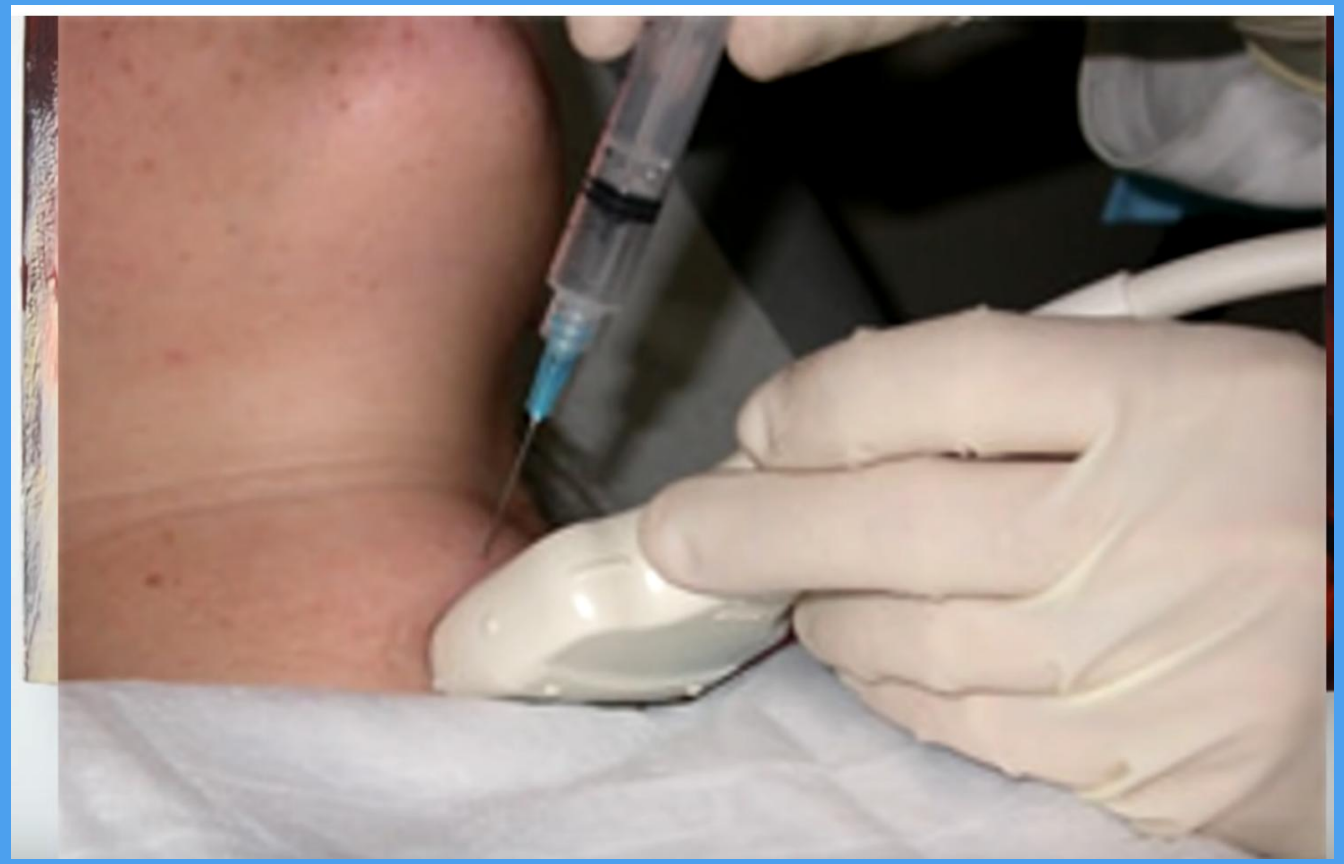
U/G assisted interventions in abdominal treatment
U/G foam sclerotherapy
U/G hydrodissection of the sural nerve
U/G percutaneous irrigation of calcific tendinopathy
U/G percutaneous nephrolithotomy
U/G percutaneous nephrostomy
U/G subacromial bursography
U/G retrograde pedal access
U/G liposuction for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

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

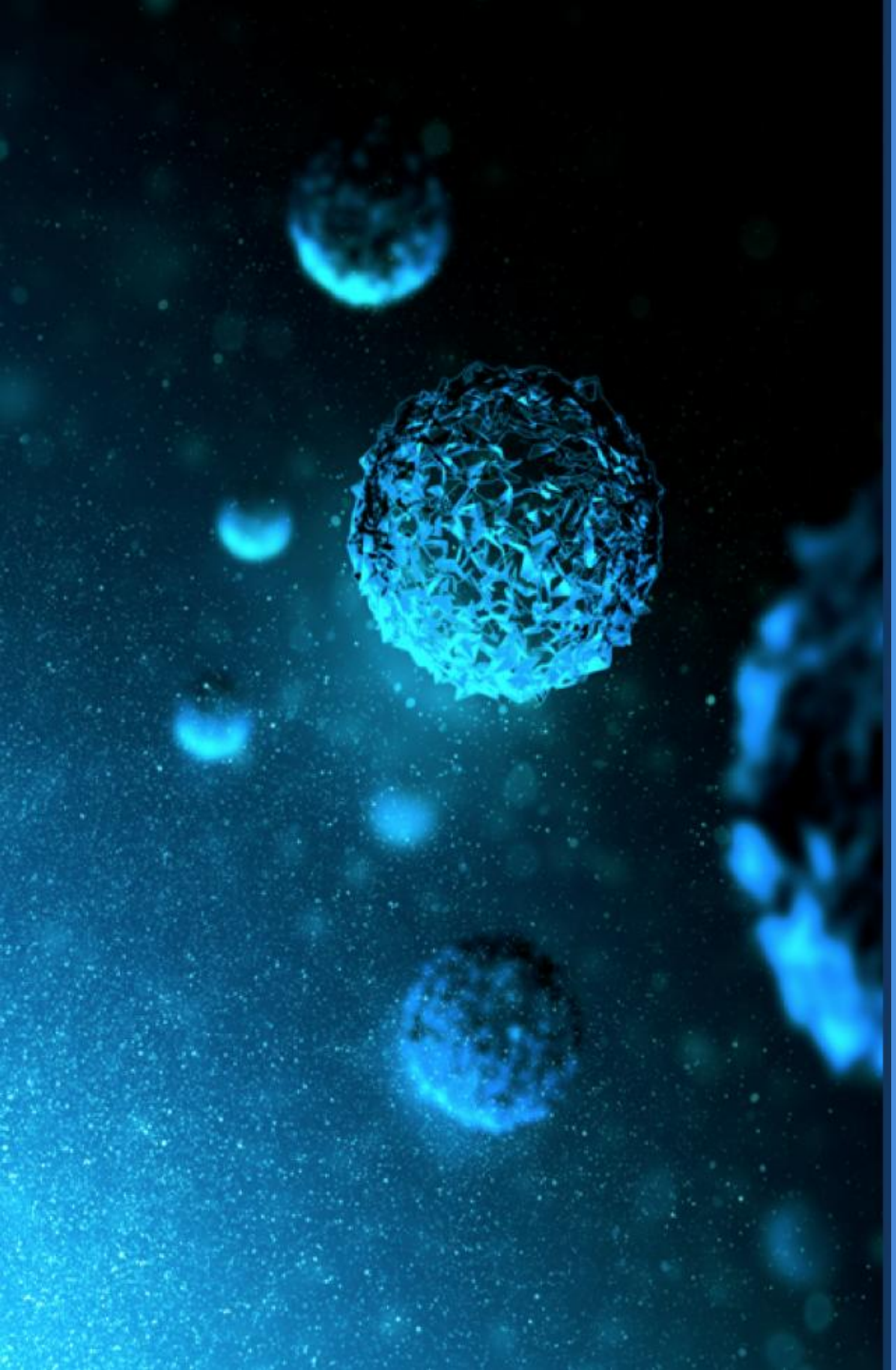
How would you categorize this probe?



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

FINE NEEDLE ASPIRATION OF THE THYROID

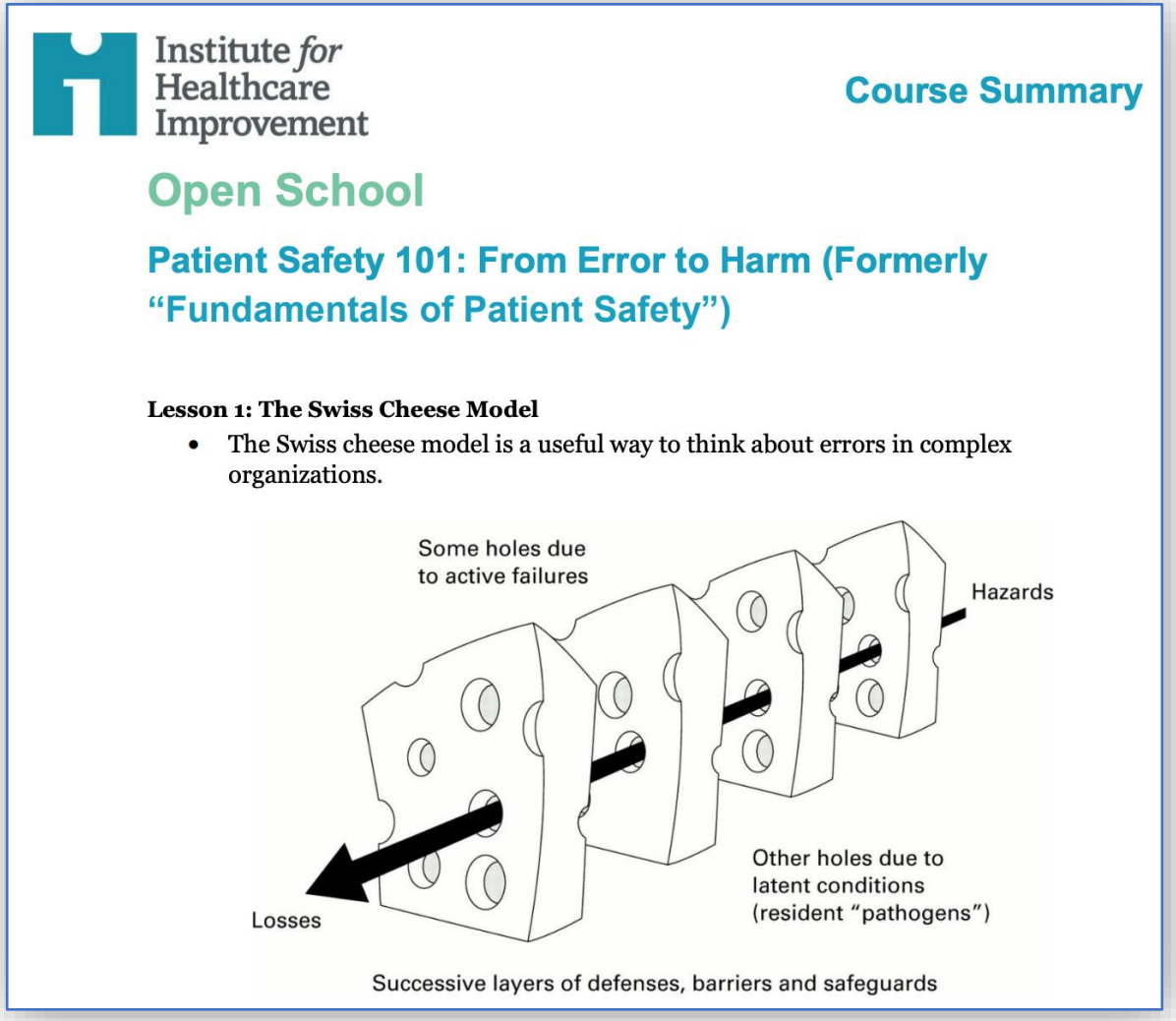
https://www.youtube.com/watch?v=QiS7Xxya_2U



Conducting a Risk Assessment

- 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.


Institute *for* Healthcare Improvement

Course Summary

Open School

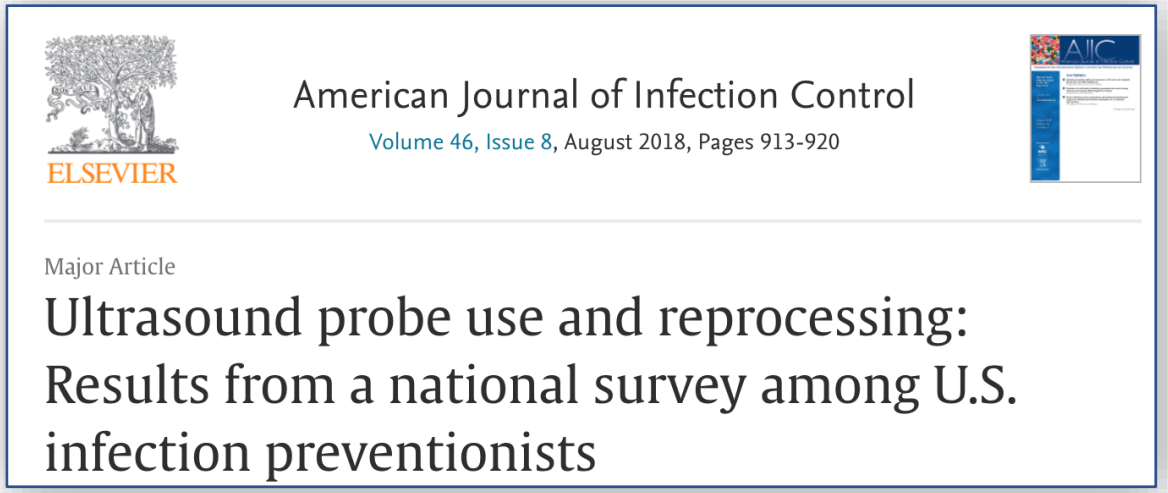
Patient Safety 101: From Error to Harm (Formerly "Fundamentals of Patient Safety")

Lesson 1: The Swiss Cheese Model

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

Successive layers of defenses, barriers and safeguards

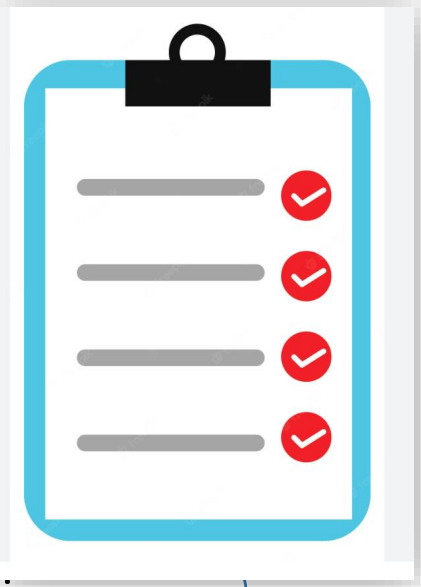
- Harm reduction models recommend that policy should address all possible outcomes resulting from the range of staff performing procedures.
- Standardization of reprocessing procedures may offset risk of varying levels of knowledge, skill and competency and potential for breaks in safe practice.



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.

Carrico RM, et al. Ultrasound probe use and reprocessing: Results from a national survey among U.S. infection preventionists, Am J Infect Cont. Vol (46),8. 2018,



1. Create tracking sheet(s) to keep all your information
2. TRACER: Find all your ultrasound machines and probes
3. Separate the ultrasound probe utilization into the 3 Spaulding Classification Groups
4. Gather an interdisciplinary team to prioritize and guide goal setting and strategy development
5. Semi-Critical and Critical Probe(s): High Level Disinfection/Sterilization
6. Ultrasound Needs to meet Spaulding Classification
7. Quotes to purchase

1

Ultrasound Utilization and Risk Group Identification (Inpatient and Outpatient)

Location and contact person	Dept	Machine (Manufacturer and model)	Probe types	Utilization (procedures being performed)	Spaulding Classification	Point of use cleaning product	Trans and Storage	Follow IFU for Cleaning/ Disinfection (Yes/No)

2

Find all your ultrasound machines and probes

Strategy 1
1. Locate where ultrasound machines are by searching the organization's asset register.
2. Locate where ultrasound consumables are being used (e.g., gel, probe sheaths/covers).
3. Survey departments to identify where ultrasound is used.
4. Identify billable ultrasound procedures in financial records.

Visit all locations, watch procedures and take pictures

- Are there different products/machines/probes?
- Who performs the ultrasound? What procedures/exams are performed
- Do they follow a standardized practice/process?
  - Do they have the IFU for the machine(s) and probe(s)
  - Which standards/guidelines are followed?
- Point of use cleaning: What product(s) are used?
- How are machines and probes stored?
- Who provides education?
- Is HLD or sterilization already being performed?
- Is there a transportation process?

1-Ultrasound Infection Prevention Tool-kit(Tool 1 – Locate and Profile
https://www.ultrasoundinfectionprevention.org/media/c3khempd/ultrasound-iinfection-prevention-toolkit-tool-1.pdf

2

Tracer template

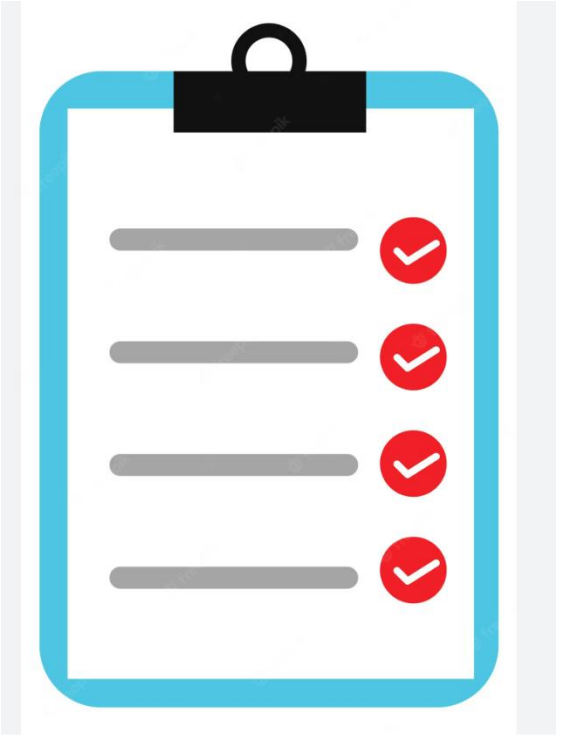
Competency/Performance	Notes
Transport Probe locations (ICU, ED, Anesthesia, IV Therapy to CMS. If CMS is closed, the probe will need to be brought to another area for HDL)	
Does this unit have HLD?	
What brand ultrasound machine/model is being used?	
What ultrasound transducer probe is being used?	
What wipes are approved for cleaning and disinfecting?	Ultrasound machine- Transducer Probe-
How many wipes were used to clean the transducer probe?	
Was it wiped appropriately from clean to dirty?	
How are the probes used?	Critical Semi Critical Non Critical
Are all the probes no matter how used HLD?	Yes No: Are the staff able to describe the difference between when to HLD and when not How is a probe identified as a clean/HLD probe
Storage of probes: must be stored on ultrasound machine (hanging) or hanging in a hook/rack	When do they use the HLD bag? All the time or only when HLD? Are staff able to speak about when a sticker is on the bag, what it means? ASK
Transportation if applicable	Cleaned at point of use with a disinfecting wipe (how cleaned: from cord up to top of transducer to remove gel, visible soil and a second wipe to disinfect, dry the probe) 1. What wipe 2. What is the contact time of the wipe Placed in transport bin (open faced) (Bin to be stored in clean utility room) Using clean a scope bags Patient sticker sent with bin
What disinfection wipes to you use? What is the contact time? Is the machine tagged with a sticker for which wipe is approved? If not – it needs one	
Training for HLD	Required for HLD: Upon hire: Annual:
Lint free wipe (2)	Ensure probe is dry prior to going into the HLD Wipe the probe with a drying wipe (lint free) before storing probe in bag. When cycle completed ensure
Review documentation of HLD	Is log easy to read? Anything apparent missing? Are the lot numbers on the stickers, the same as the products being used? How do you know when you need to change the solutions? When you change the box of indicators, what do you need to do?
PM of machine? Do the staff know when it was last PM? Is there a PM sticker on the machine?	
HLD Locations	CMS, Ultrasound, IR, Vascular Ultrasound Pain Management, Ultrasound

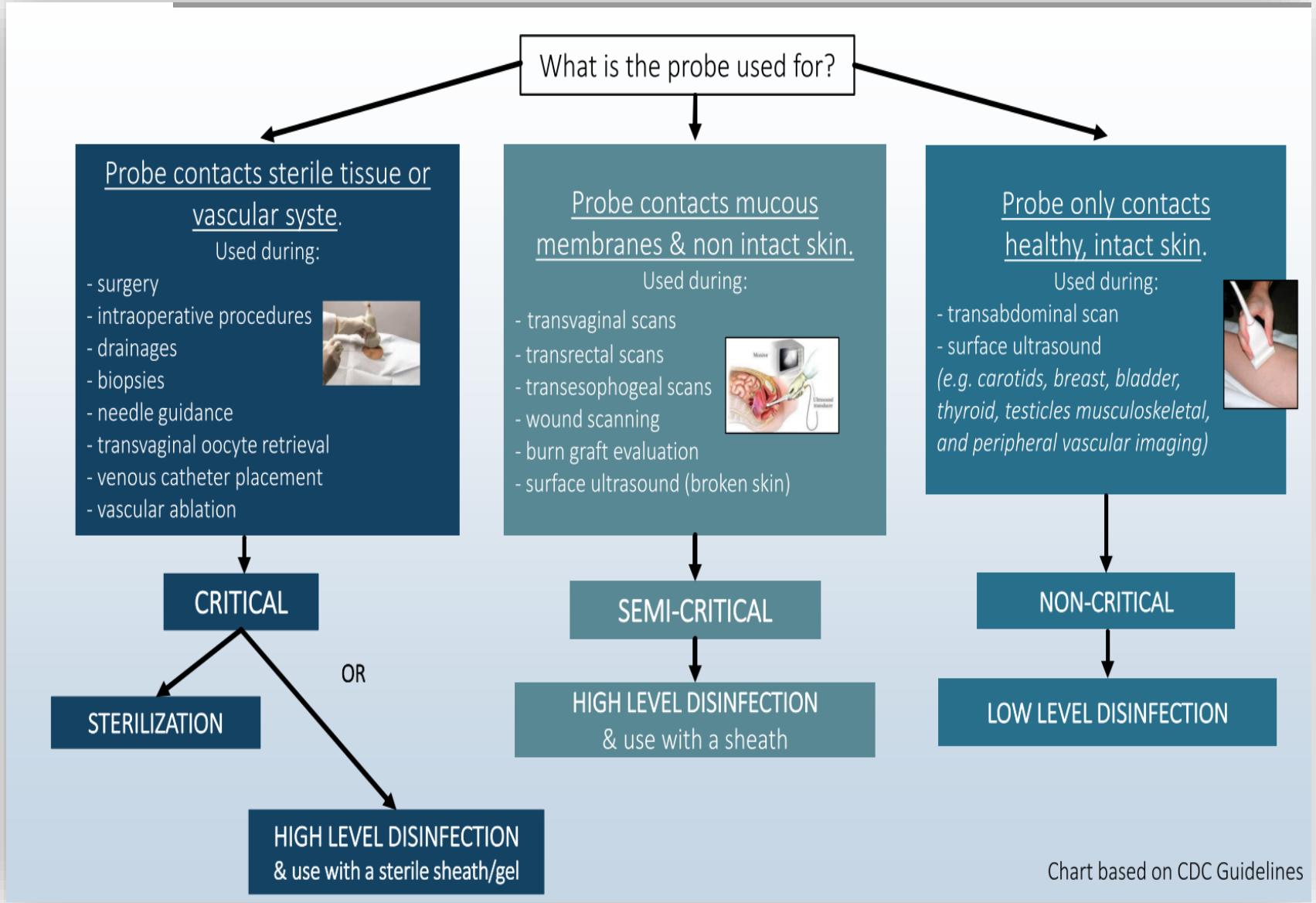
Clinical percutaneous procedures

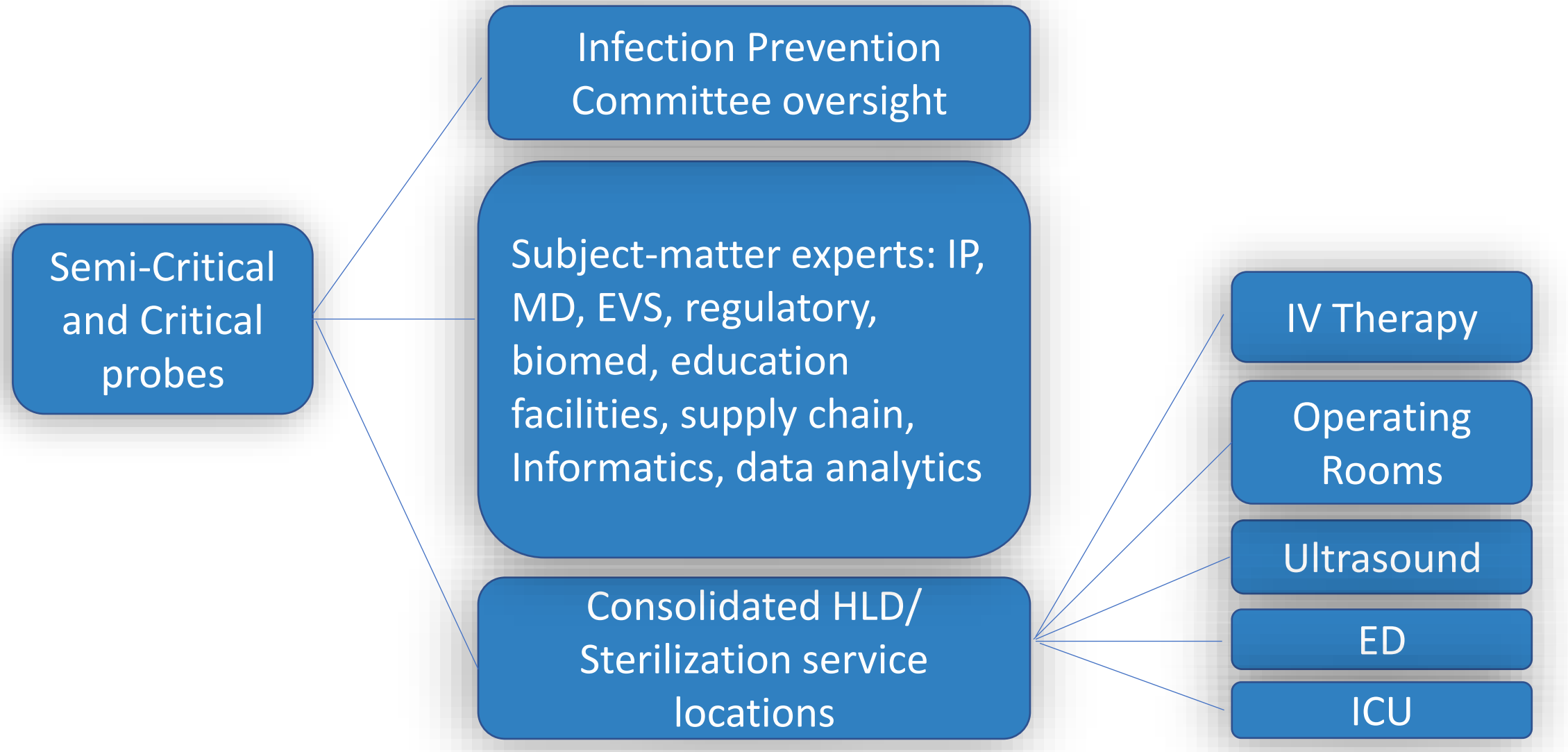
- Central line placement with probe on the insertion site
- Bloody procedures with contact with an LLD probe
- Inserting probe in breast tissue without HLD

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




What is the probe used for?
Probe contacts sterile tissue or vascular syste.
Used during:
- surgery
- intraoperative procedures
- drainages
- biopsies
- needle guidance
- transvaginal oocyte retrieval
- venous catheter placement
- vascular ablation
CRITICAL
STERILIZATION
OR
HIGH LEVEL DISINFECTION
& use with a sterile sheath/gel
Probe contacts mucous membranes & non intact skin.
Used during:
- transvaginal scans
- transrectal scans
- transesophogeal scans
- wound scanning
- burn graft evaluation
- surface ultrasound (broken skin)
SEMI-CRITICAL
HIGH LEVEL DISINFECTION
& use with a sheath
Probe only contacts healthy, intact skin.
Used during:
- transabdominal scan
- surface ultrasound
(e.g. carotids, breast, bladder, thyroid, testicles musculoskeletal, and peripheral vascular imaging)
NON-CRITICAL
LOW LEVEL DISINFECTION
Chart based on CDC Guidelines


Semi-Critical and Critical probes
Infection Prevention Committee oversight
Subject-matter experts: IP, MD, EVS, regulatory, biomed, education facilities, supply chain, Informatics, data analytics
Consolidated HLD/ Sterilization service locations
IV Therapy
Operating Rooms
Ultrasound
ED
ICU

5

Can probes undergo HLD or sterilization?

Location	Ultrasound Manufacturer & Probe Model	Probe(s) compatible w/ HLD or sterilization (Yes/No) (IFU)	Probe and machine compatible w/ Point of Use cleaning agent (IFU)

6

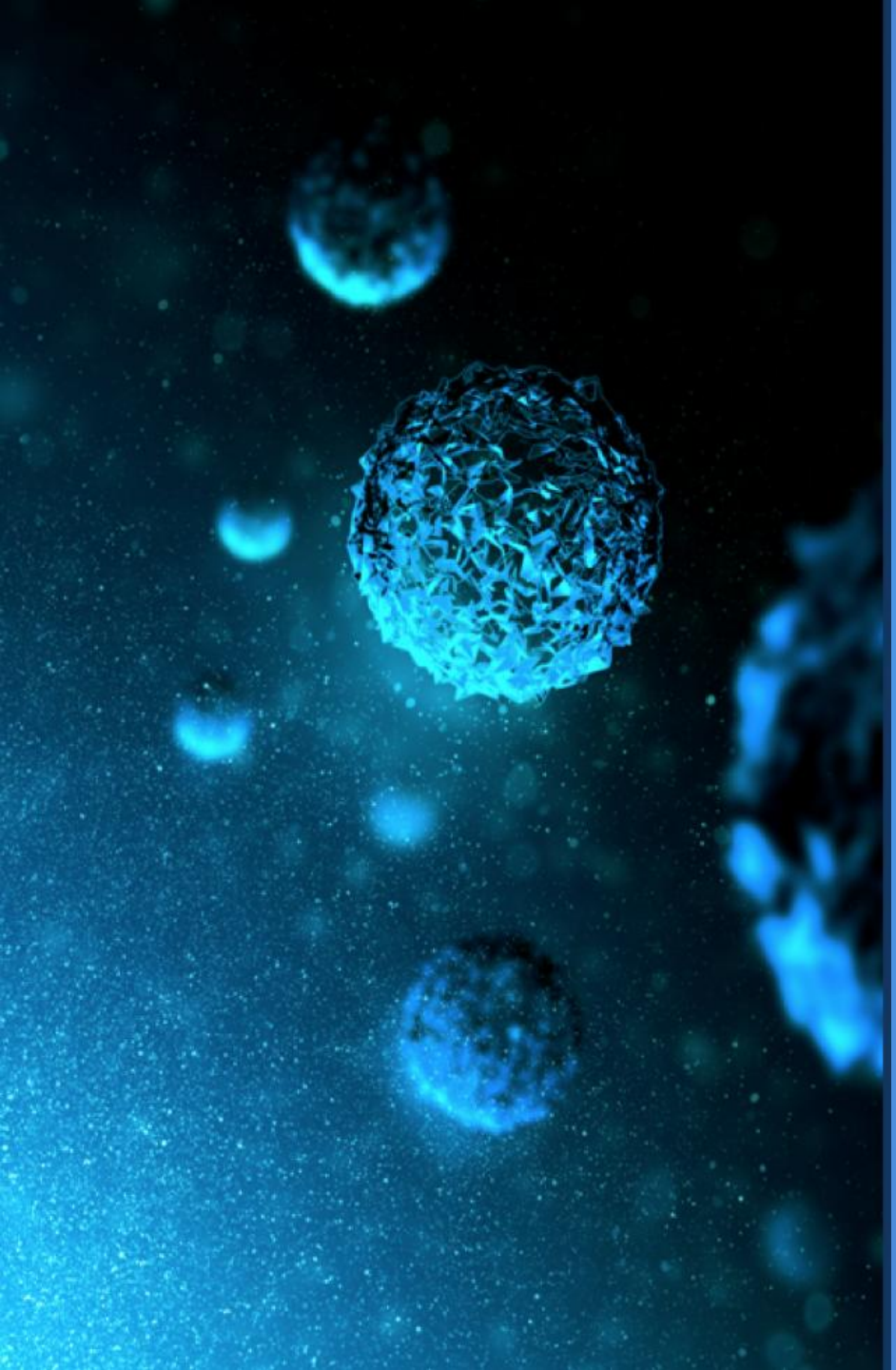
Location	HLD/Sterilization present? Or is it needed?	Consolidated HLD/Sterilization location: Transportation process (Yes/No)	HLD/Sterilization initial training repeated yearly	Utilization of probe(s): How many additional probes are needed?

Consider consolidating reprocessing locations

- HLD/sterilization requires annual training and strict adherence to IFU practice and documentation.
- Standardize locations when able.

7

Location	Can probes undergo HLD/Sterilization?	HLD/Sterilization Equipment -Do you already have HLD? -If yes, which product? -Do you need more, how many?	Transportation process -Purchase bins, BBP labels	HLD initial training Repeated yearly	Utilization of Probes -How many add'l. probes are needed?	Quotes: See below HLD/Sterilization total cost: Transportation total cost: Additional Probe(s): Ultrasound Machines:

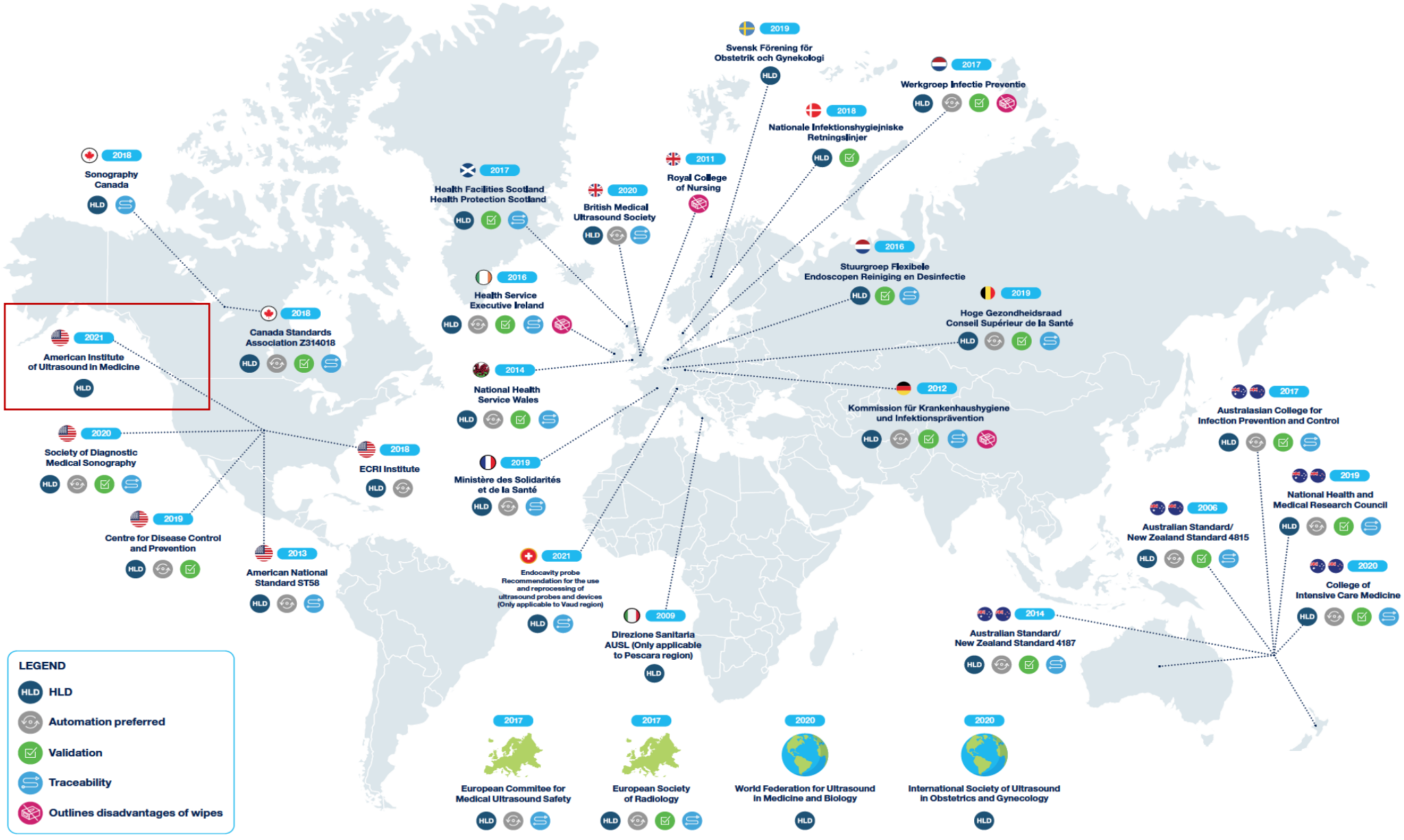


Outside of the U.S.
Guidance from Health Authorities

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

- NHS Scotland[1]
- Joint Guidance Australasian Society for Ultrasound in Medicine and Australasian College for Infection Prevention and Control[2]
- 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.

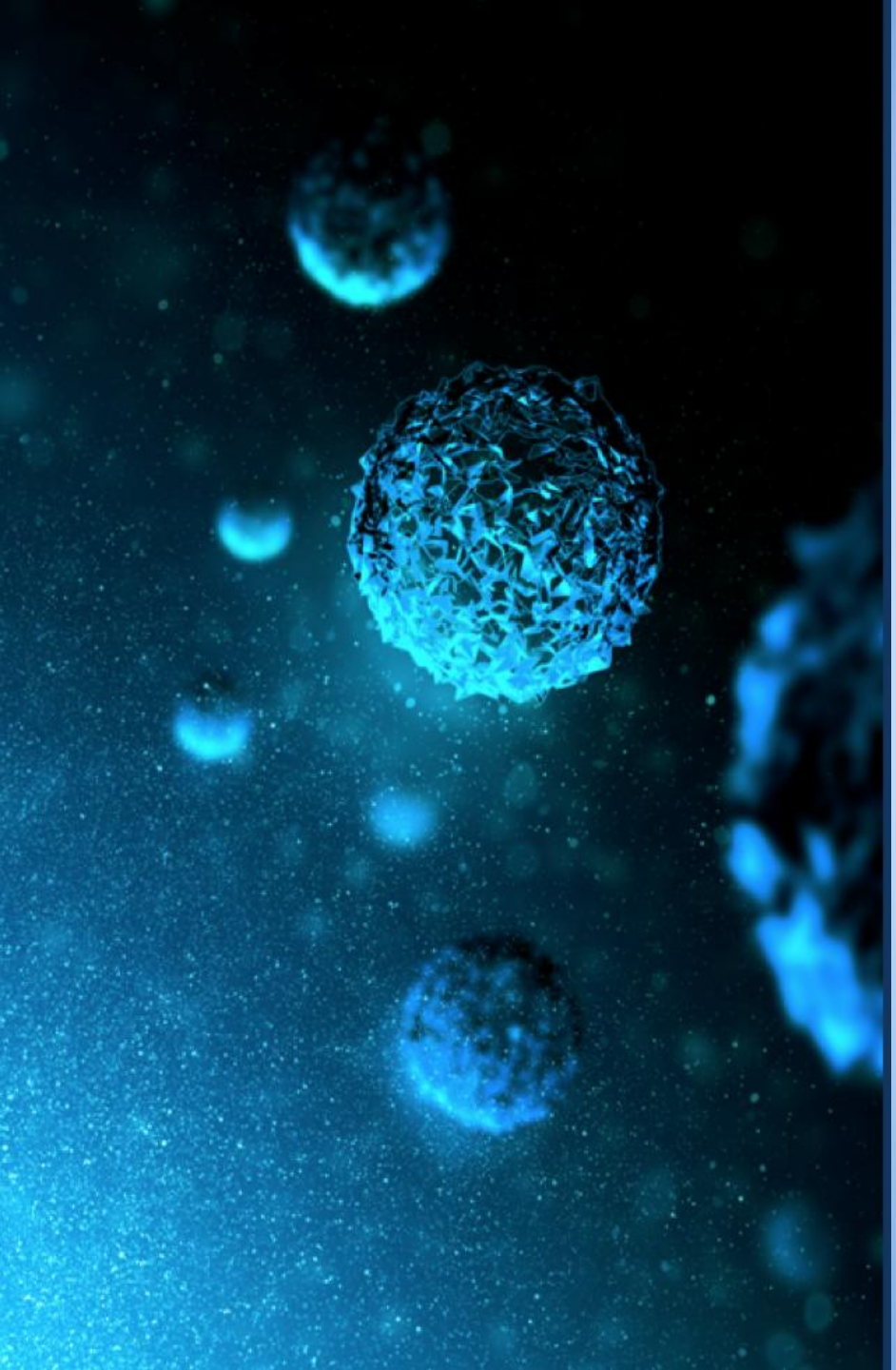

2019
Svensk Förening för Obstetrik och Gynekologi
HLD
2017
Werkgroep Infectie Preventie
HLD
2018
Nationale Infektionshygiejniske Retningslinjer
HLD
2011
Royal College of Nursing
2018
Sonography Canada
HLD
2017
Health Facilities Scotland Health Protection Scotland
HLD
2020
British Medical Ultrasound Society
HLD
2016
Stuurgroep Flexibele Endoscopen Reiniging en Desinfectie
HLD
2019
Hoge Gezondheidsraad Conseil Supérieur de la Santé
HLD
2016
Health Service Executive Ireland
HLD
2018
Canada Standards Association Z314018
HLD
2021
American Institute of Ultrasound in Medicine
HLD
2014
National Health Service Wales
HLD
2012
Kommission für Krankenhaushygiene und Infektionsprävention
HLD
2017
Australasian College for Infection Prevention and Control
HLD
2020
Society of Diagnostic Medical Sonography
HLD
2018
ECRI Institute
HLD
2019
Ministère des Solidarités et de la Santé
HLD
2019
National Health and Medical Research Council
HLD
2006
Australian Standard/ New Zealand Standard 4815
HLD
2019
Centre for Disease Control and Prevention
HLD
2013
American National Standard ST58
HLD
2021
Endocavity probe Recommendation for the use and reprocessing of ultrasound probes and devices (Only applicable to Vaud region)
HLD
2020
College of Intensive Care Medicine
HLD
2009
Direzione Sanitaria AUSL (Only applicable to Pescara region)
HLD
2014
Australian Standard/ New Zealand Standard 4187
HLD
2017
European Commitee for Medical Ultrasound Safety
HLD
2017
European Society of Radiology
HLD
2020
World Federation for Ultrasound in Medicine and Biology
HLD
2020
International Society of Ultrasound in Obstetrics and Gynecology
HLD
LEGEND
HLD
HLD
Automation preferred
Validation
Traceability
Outlines disadvantages of wipes

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.



Thank you!

SCAN ME