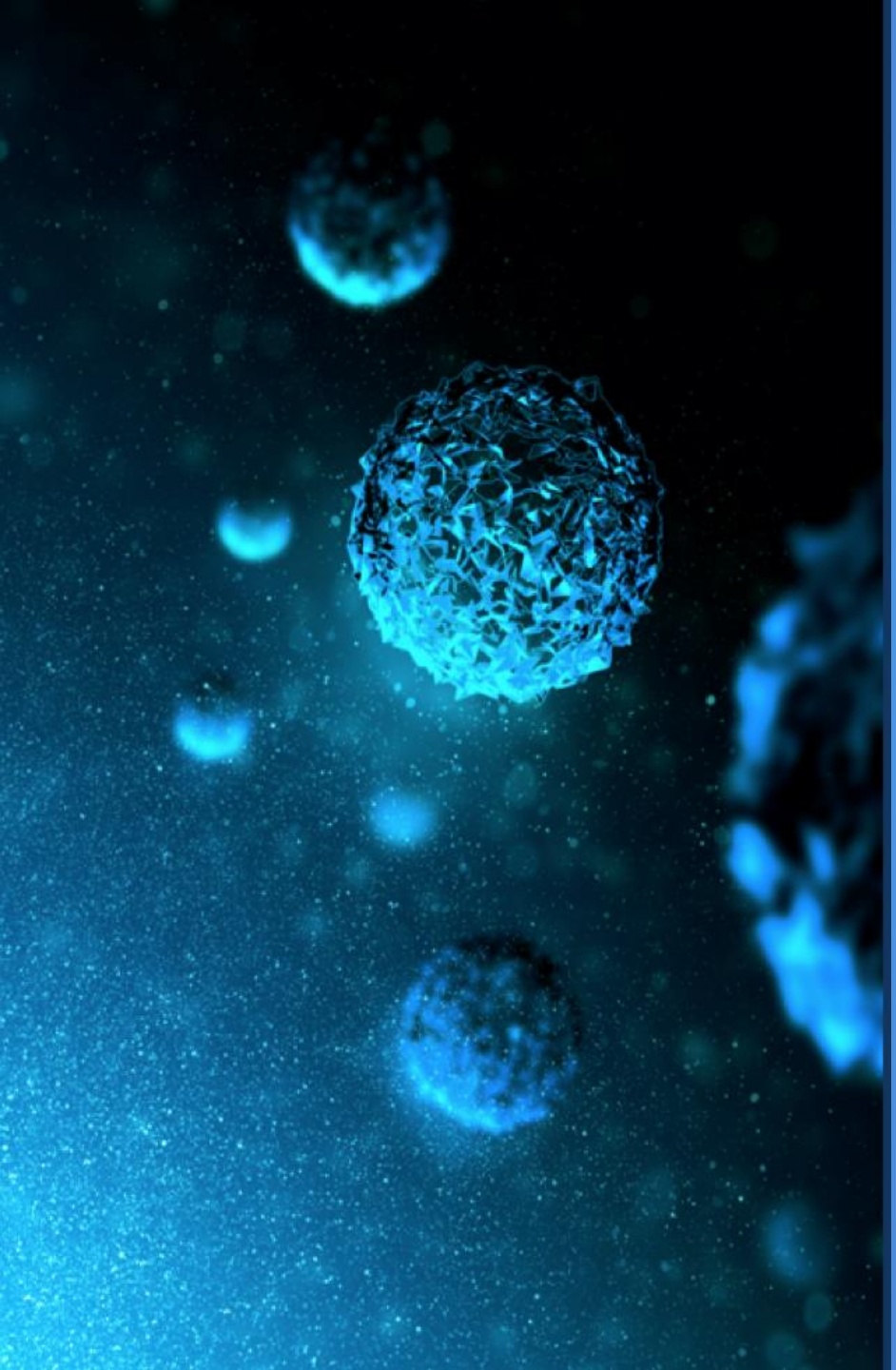

The Future of Ultrasound Transducer Cleaning and Disinfection: Quality and Safety Updates

Maureen Spencer M.Ed, BSN, RN, CIC, FAPIC

Infection Preventionist Consultant

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

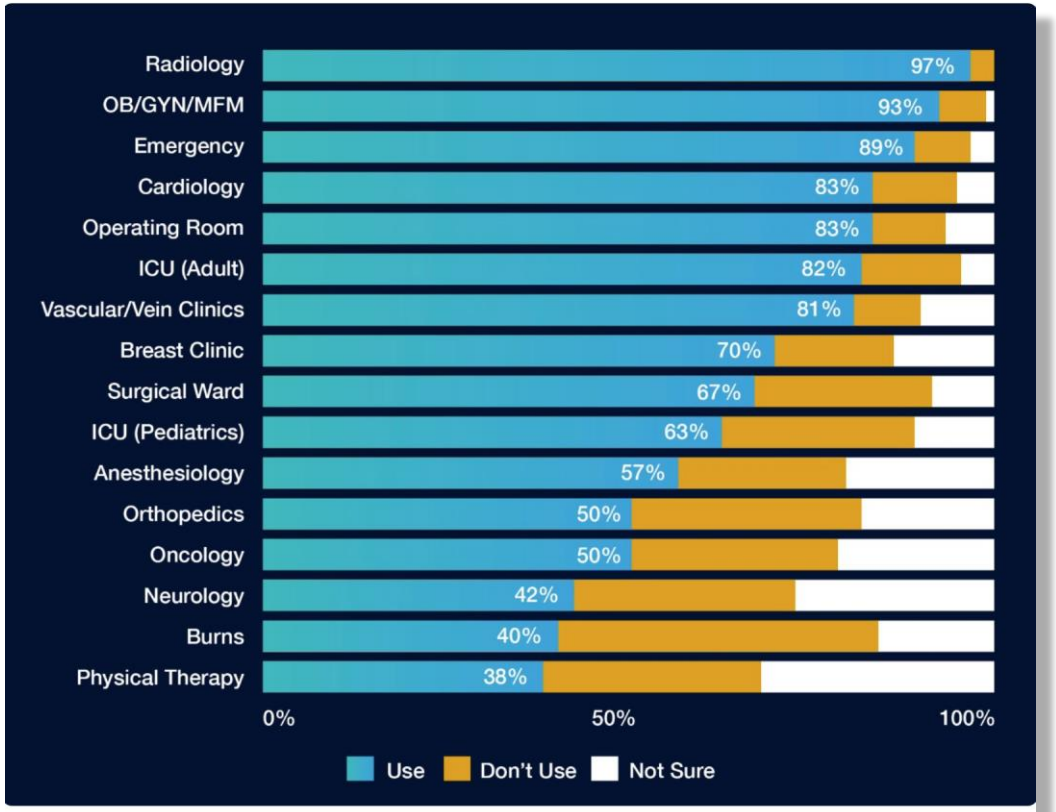

Figure 1. Adapted from Carrico 2018.[1] All departments surveyed recorded use of ultrasound.

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

American Journal of Infection Control 46 (2018) 913-20

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Major Article

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

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Key Words:
Disinfection
Interventional ultrasound
Reprocessing
Probe
Endocavitary
Doppler
Ultrasound gel

Background: Improper infection prevention practice associated with ultrasound probe use has been linked to increased infection risk, outbreaks, and death. Although guidelines for reprocessing and use of probes exist, it is unclear how extensively these have been adopted in practice.

Methods: Infection preventionists from U.S. health care facilities were surveyed (N = 358). The anonymous survey had 31 multiple choice, sliding scale, and text response questions. The survey was developed and deployed and the data were stored in the REDCap system.

Results: A high degree of noncompliance with U.S. guidelines was identified. Surface probes used in invasive procedures were not high-level disinfected or sterilized 15% (intraoperative) to 78% (peripheral line placements) of the time. Of invasive procedures, 5%-47% did not use sterile gel (same procedures, respectively). Of the participants, 20% were aware of instances where an ultrasound probe was used but was not correctly reprocessed. Extensive breaches of infection control guidelines were reported. The rapid expansion in use of ultrasound has brought clinical benefit but may be exposing patients to preventable infection risk.

Conclusions: Infection preventionists are well placed to act as major drivers of change based on their expertise and experience in the management of infection risk across facilities and health systems. They, along with clinicians responsible for probe use and reprocessing, should review practices relating to ultrasound in their facilities. Where practice does not comply with guidelines, policy and training should be updated to ensure patient safety.

- Procedures were not high-level disinfected or sterilized 15% (intraoperative) to 78% (peripheral line placements).
- Of invasive procedures, 5%-47% did not use sterile gel.
- 20% were aware of instances where an ultrasound probe was used but was not correctly reprocessed.
- Extensive breaches of infection control guidelines were reported.
- Conclusions: Infection preventionists are well placed to act as major drivers of change based on their expertise and experience in the management of infection risk across facilities and health systems.

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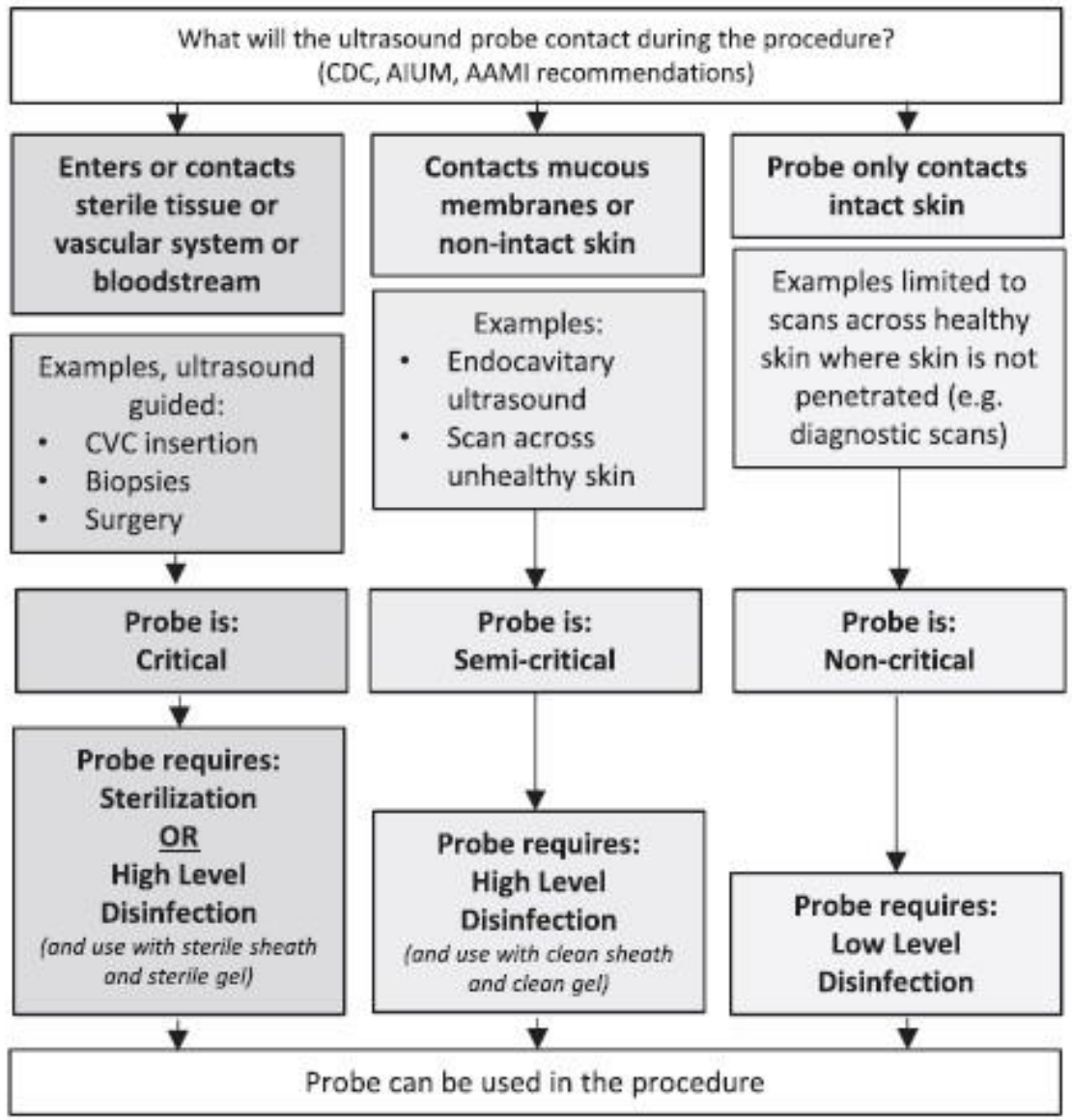
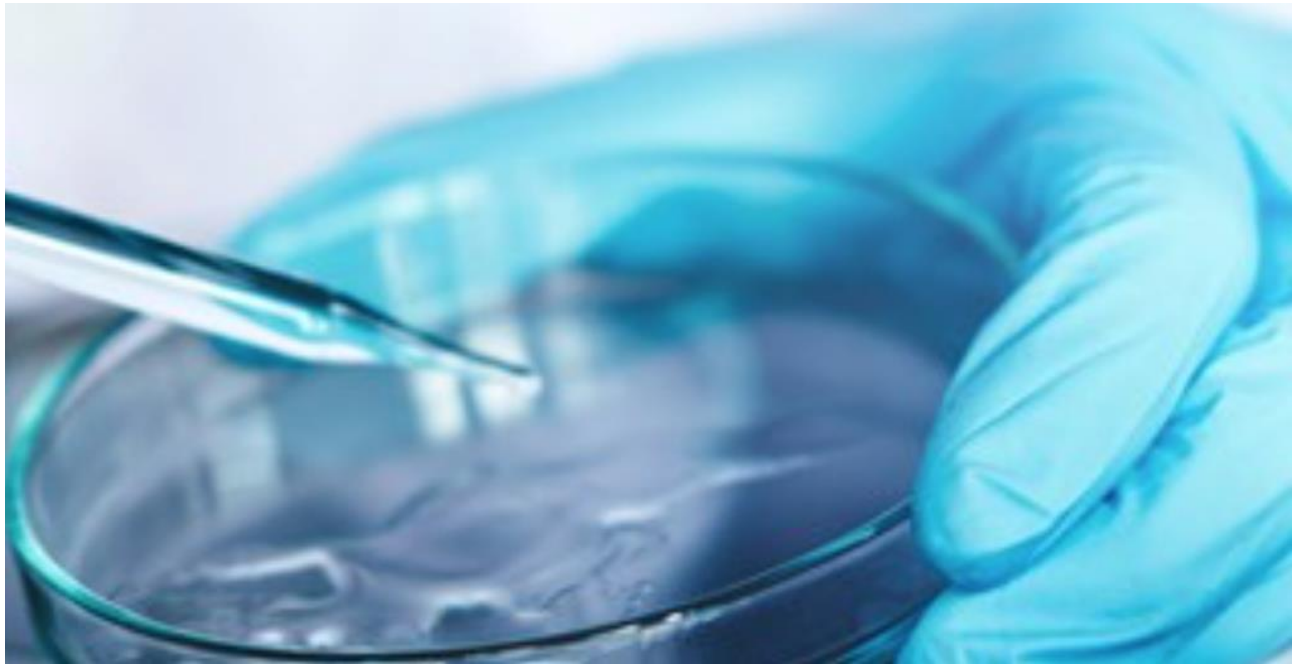

What will the ultrasound probe contact during the procedure?
(CDC, AIUM, AAMI recommendations)
Enters or contacts sterile tissue or vascular system or bloodstream
Contacts mucous membranes or non-intact skin
Probe only contacts intact skin
Examples, ultrasound guided:
• CVC insertion
• Biopsies
• Surgery
Examples:
• Endocavitary ultrasound
• Scan across unhealthy skin
Examples limited to scans across healthy skin where skin is not penetrated (e.g. diagnostic scans)
Probe is: Critical
Probe is: Semi-critical
Probe is: Non-critical
Probe requires: Sterilization OR High Level Disinfection
(and use with sterile sheath and sterile gel)
Probe requires: High Level Disinfection
(and use with clean sheath and clean gel)
Probe requires: Low Level Disinfection
Probe can be used in the procedure

- **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]

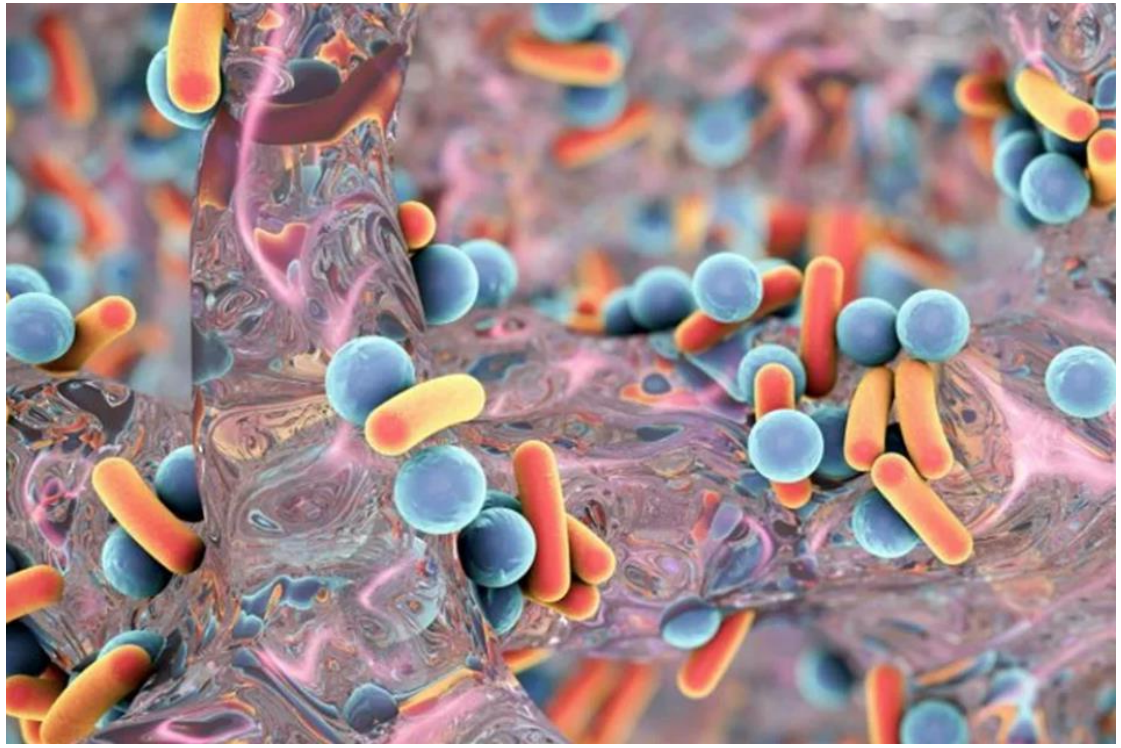


- **More than 80% probe handles** remain contaminated when not disinfected.[3,4]

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).

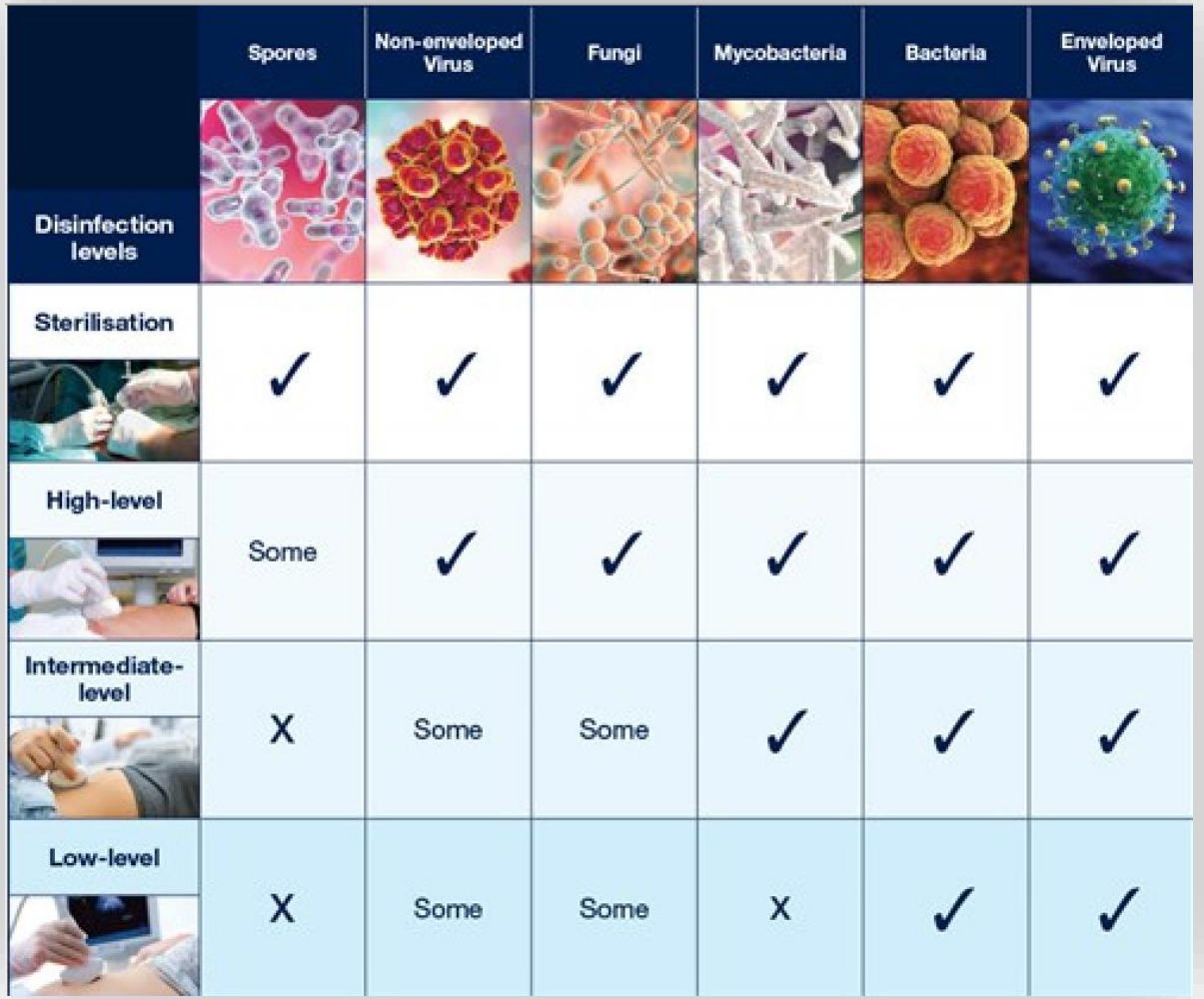
“How many bacteremias that look like present on admission, are from prior ultrasound procedures?”

“ICD 10 coding is not there to track.”

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

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.

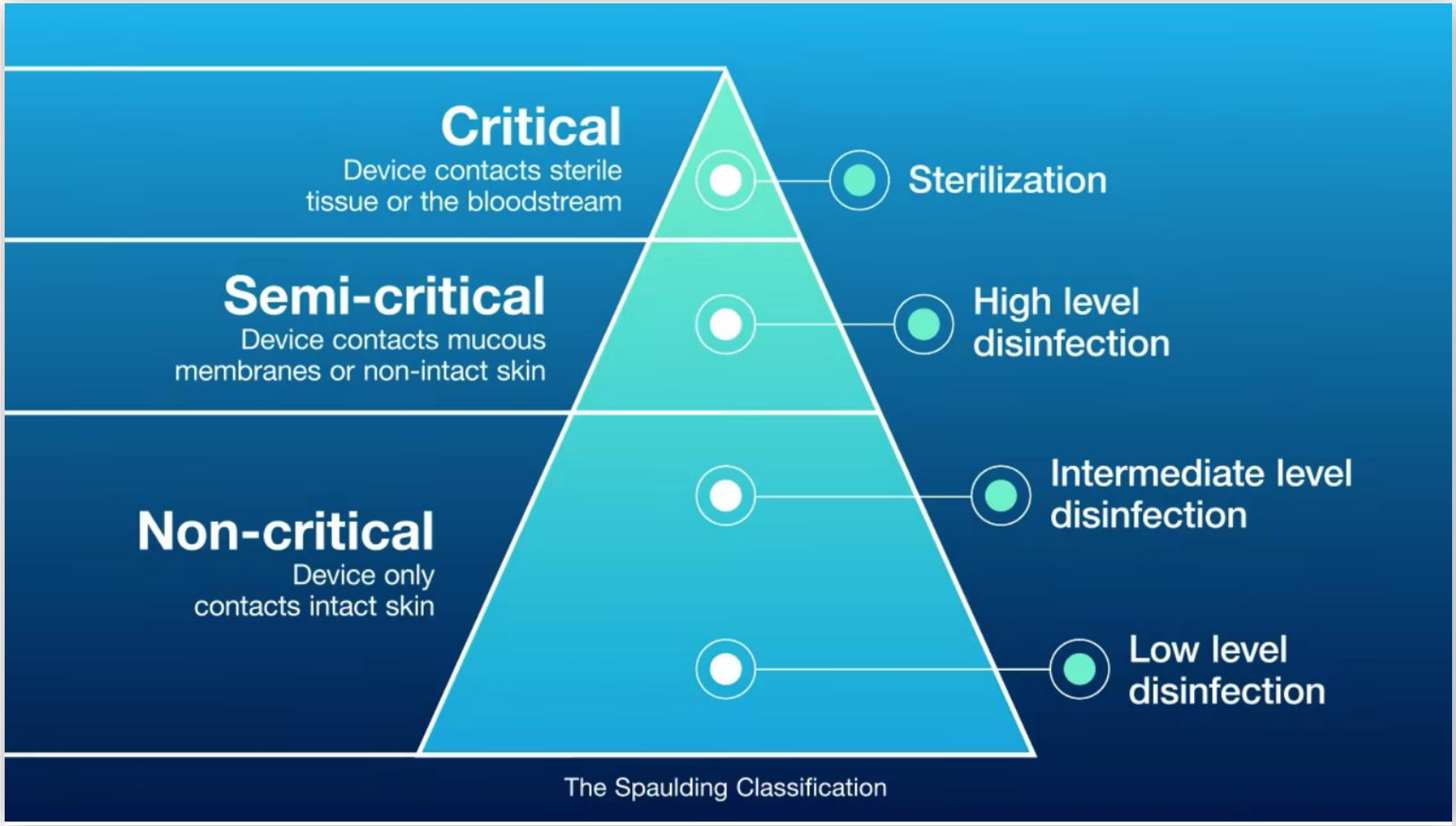
There are many wipes on the market that are EPA registered with varying kill profiles.

- 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.

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*	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)

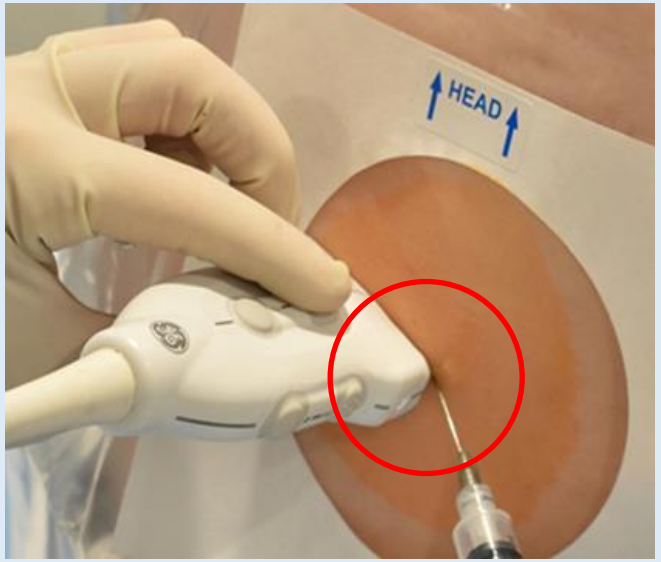
CRITICAL

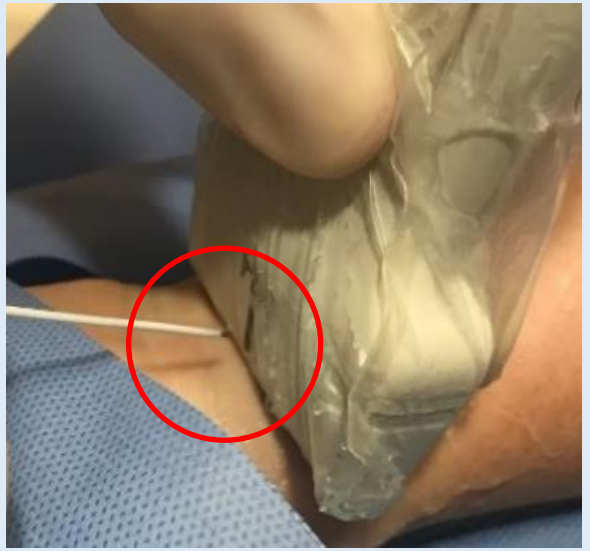
FDA 2019/2023: "*Critical devices should be sterilized and the use of a sterile sheath is recommended for each use.*" [1]

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.

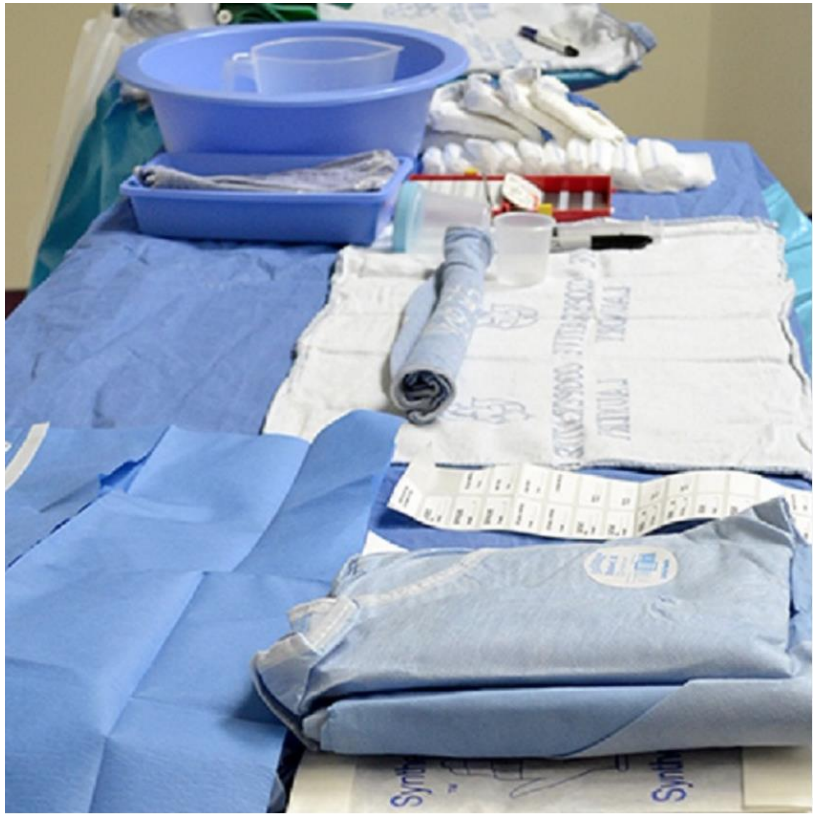
Specialty group	Number of procedures
Nerve block	35
Aspirations	27
Biopsy	18
Drainage	15
Vascular Access	9
Injection	9
Intraoperative	8
Ablation	6
Other	13
Total	140

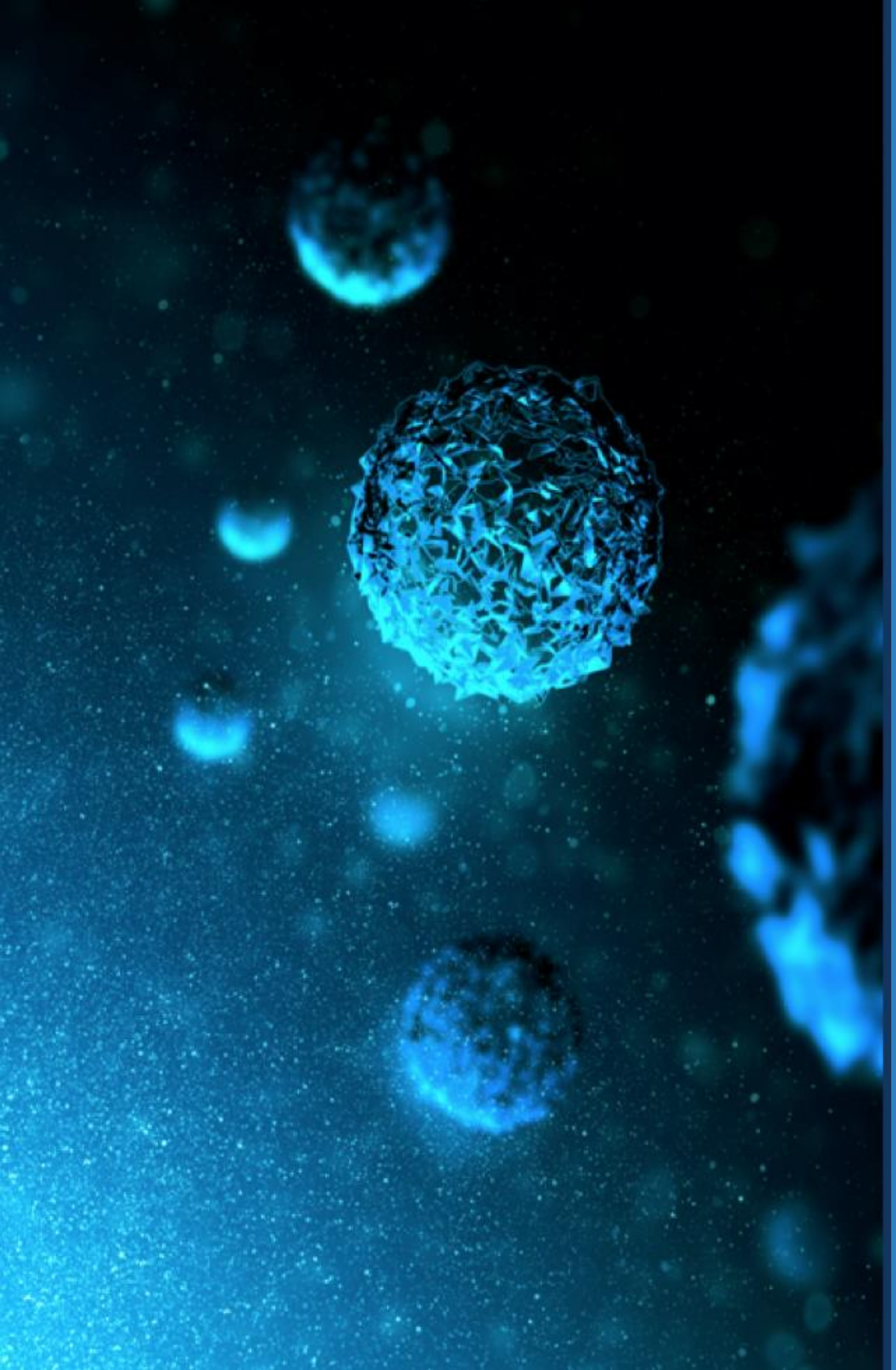
Percutaneous procedure: Entry, by puncture or minor incision, of instrumentation through the skin or mucous membrane and/or any other body layers necessary to reach the site of the procedure.

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

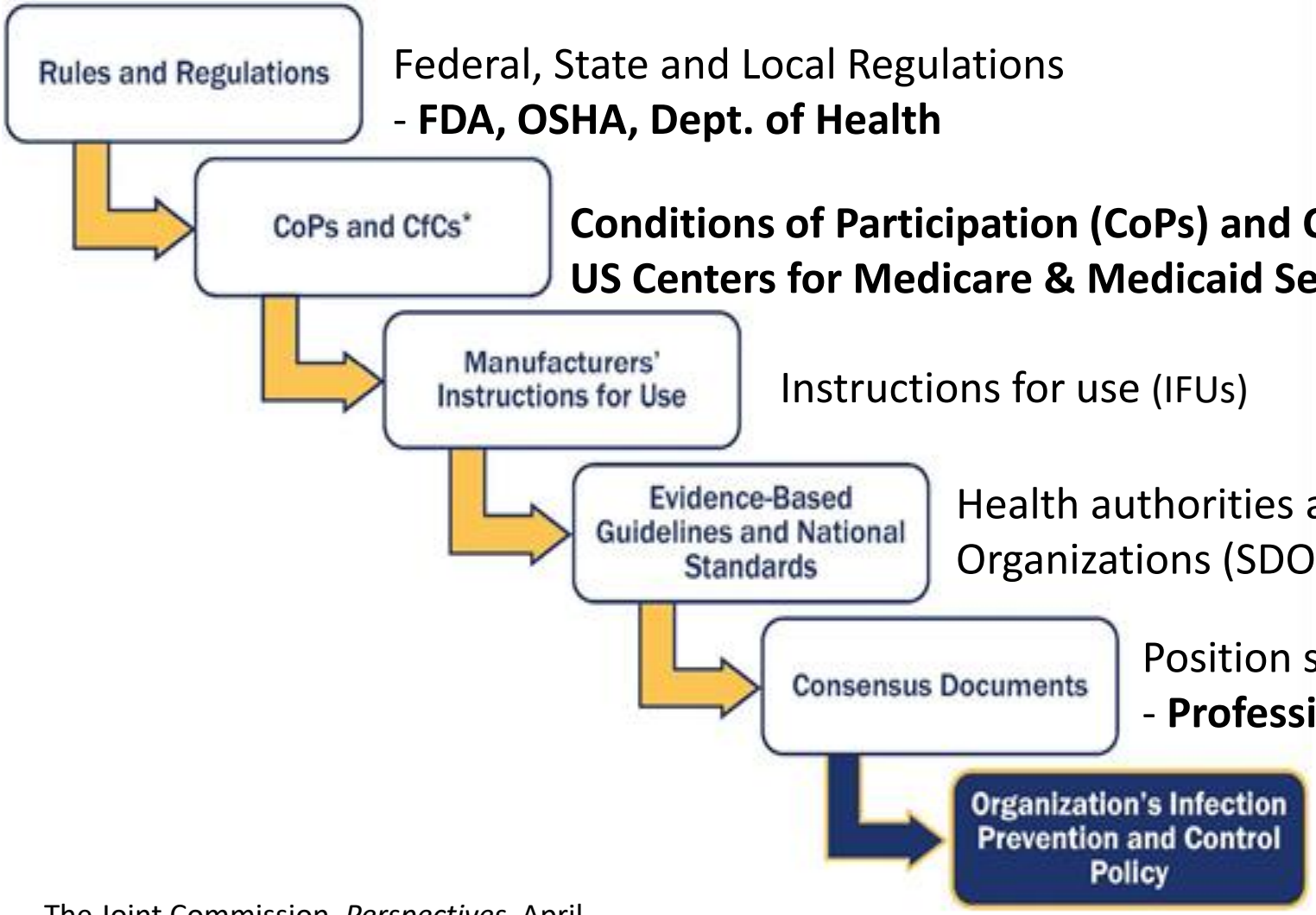
- Includes surfaces, **instruments**, and people.

- 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**

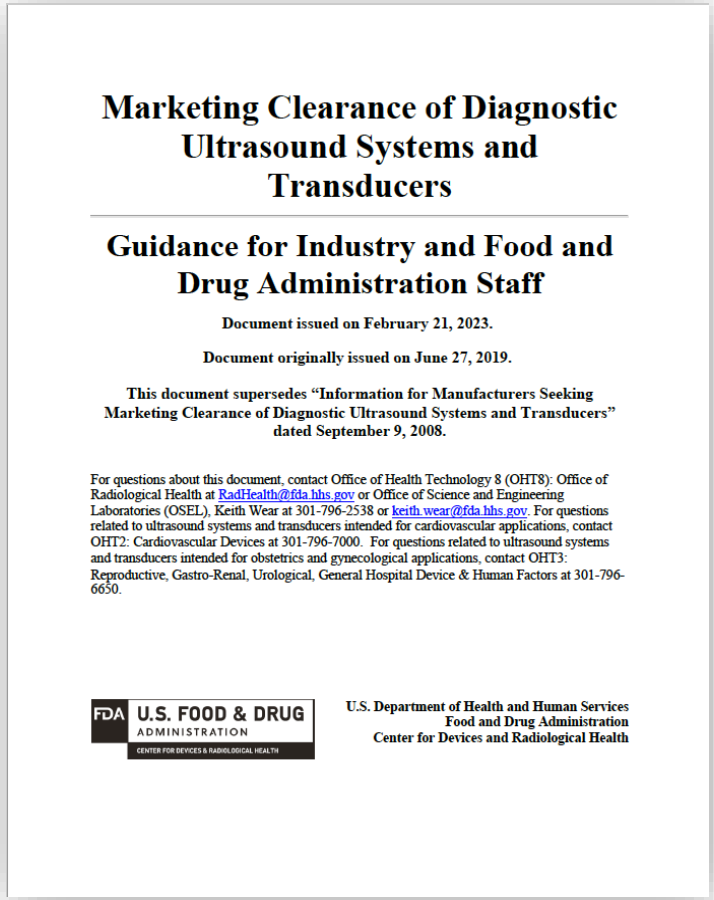
Position statements and other documents
- **Professional & medical societies**

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.

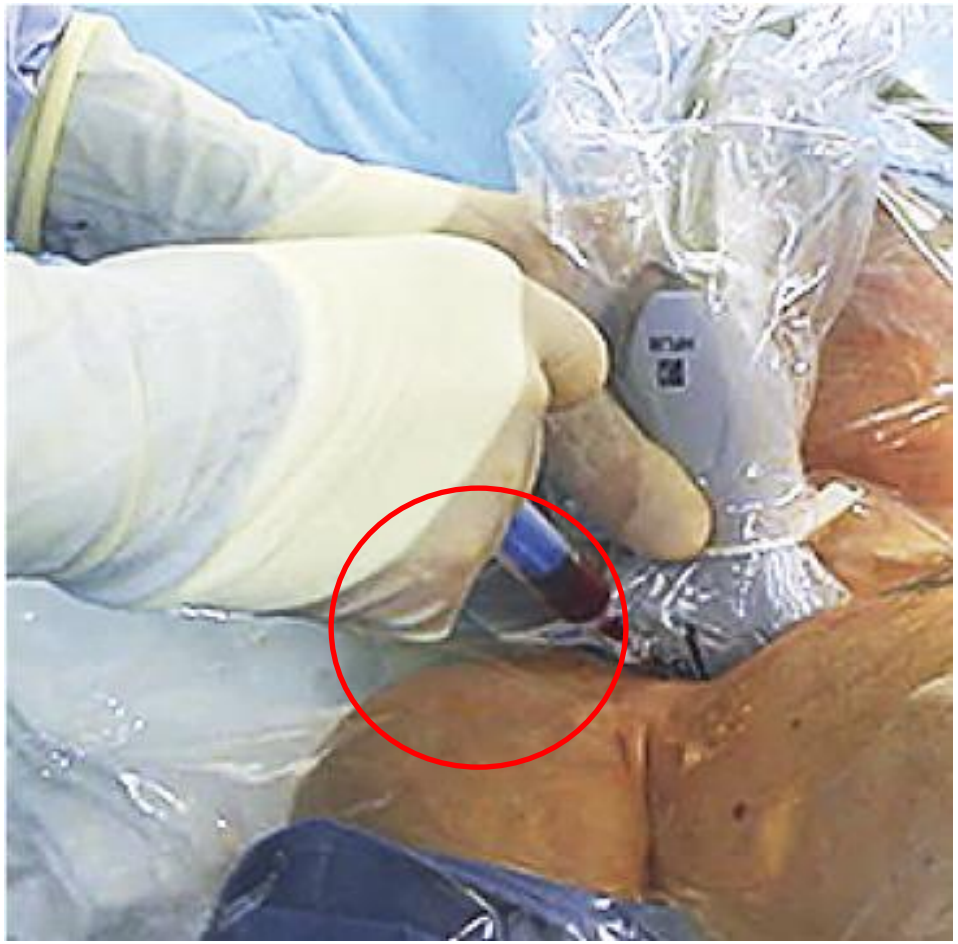
1) **Awareness of procedural risk** is not uniform across disciplines and providers.

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

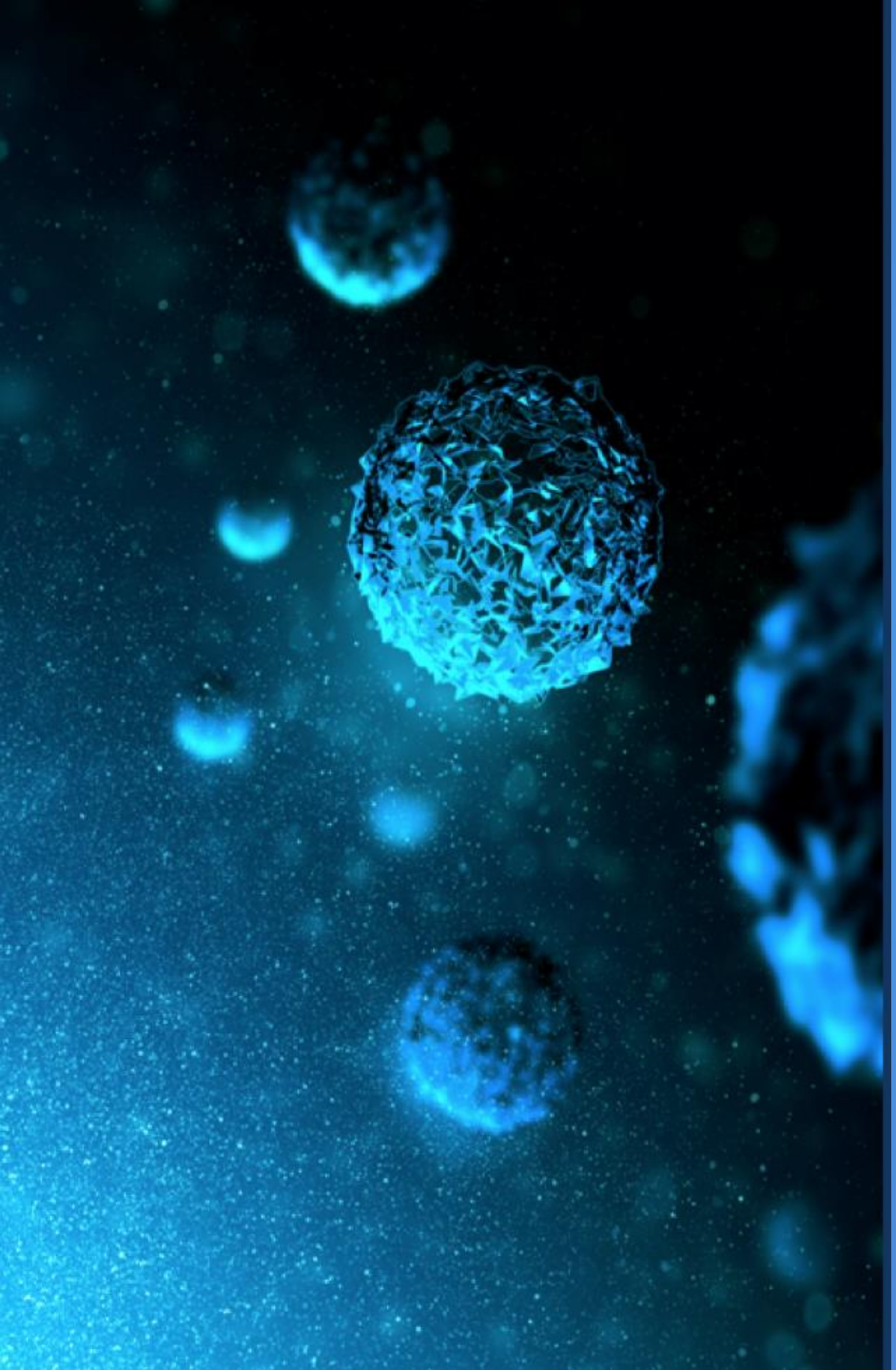
   https://youtu.be/DgQbQSBYeQU

3) **Unique patient anatomy**

4) **Emergent conditions**



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

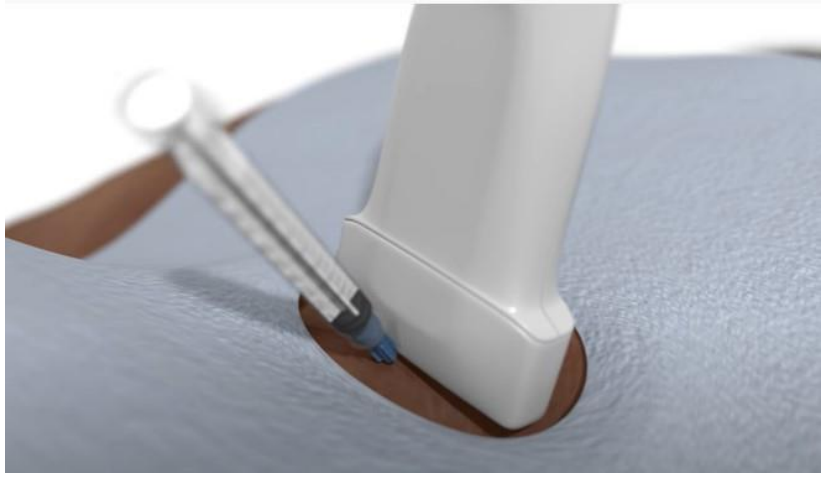


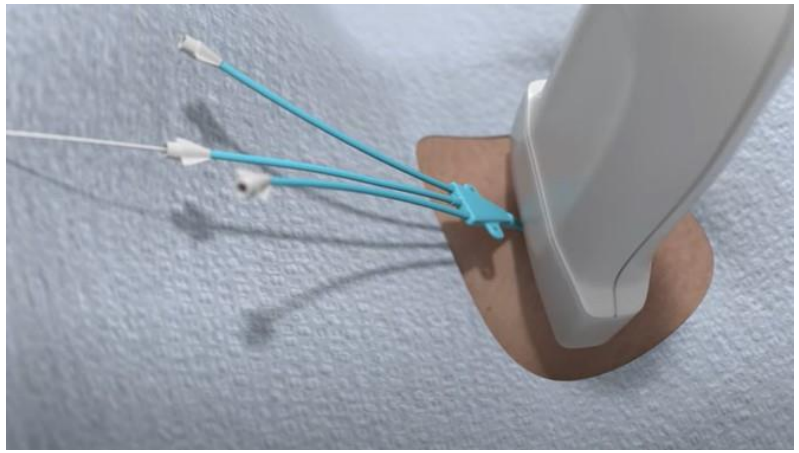
140 Percutaneous Procedures

Observations from the Literature

Ultrasound guided IV Cannulation and Thoracentesis

(Screen capture from training video)





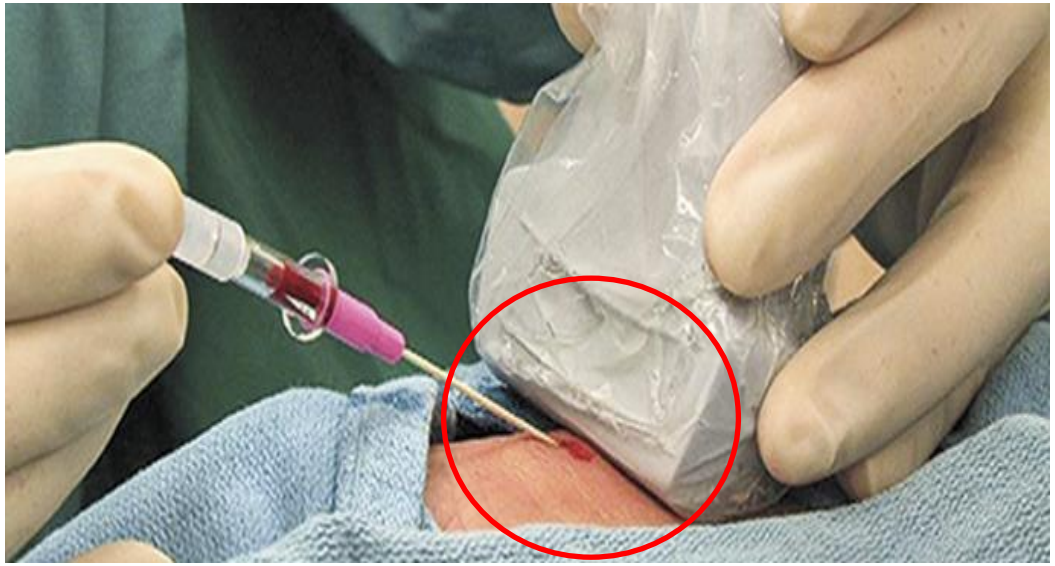
IV Cannulation

Thoracentesis

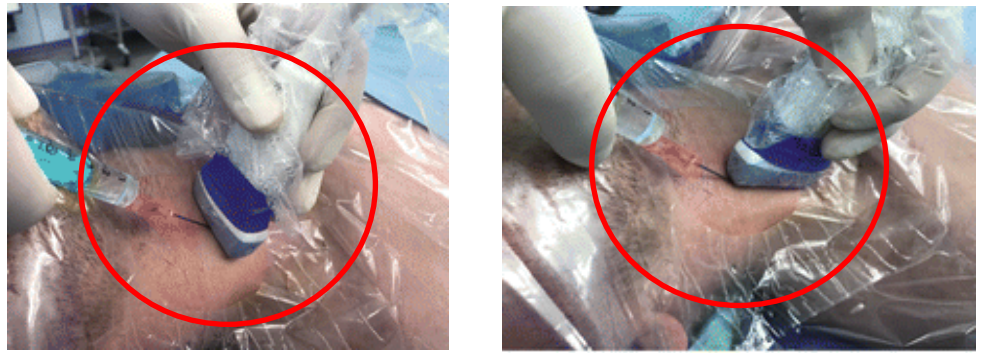
https://youtu.be/buTSag9xK6U

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

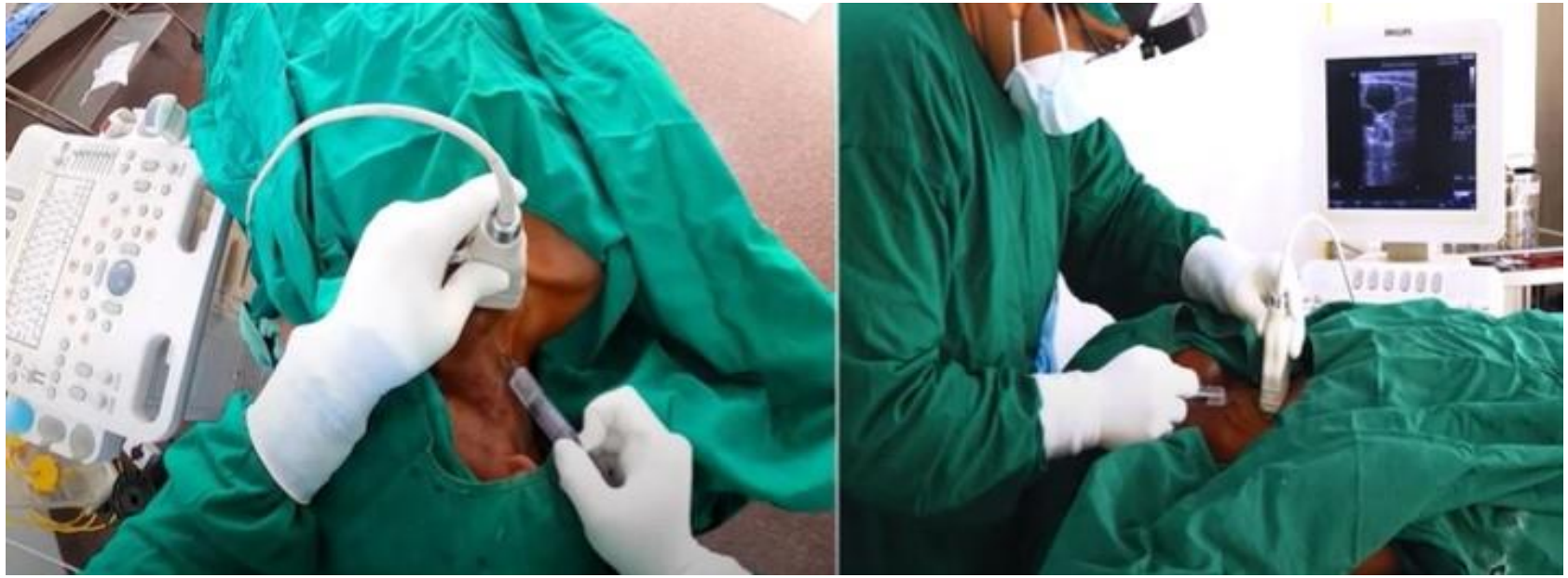
- Intravascular U/G management, large thrombus burden
- U/G arterial access
- U/G cannulation hemodialysis arteriovenous access
- U/G central venous catheter insertion
- U/G hemodialysis cannulation
- U/G percutaneous embolization
- U/G peripheral venous access
- U/G resuscitative endovascular balloon occlusion aorta
- U/G peripherally inserted central venous catheter

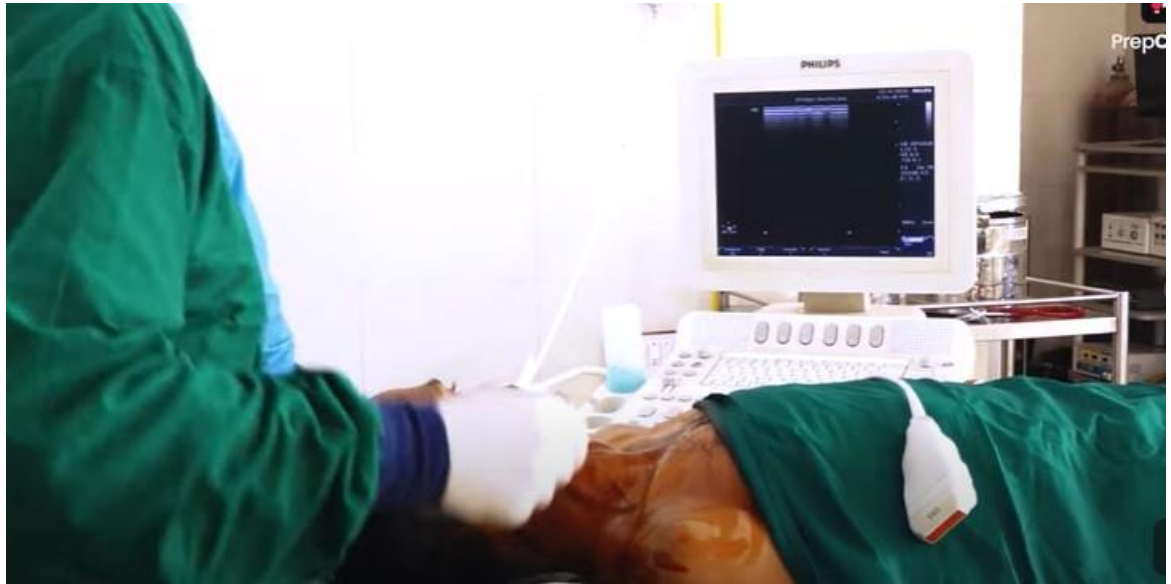


Insertion of Radial Arterial Catheter
N Engl J Med 2014



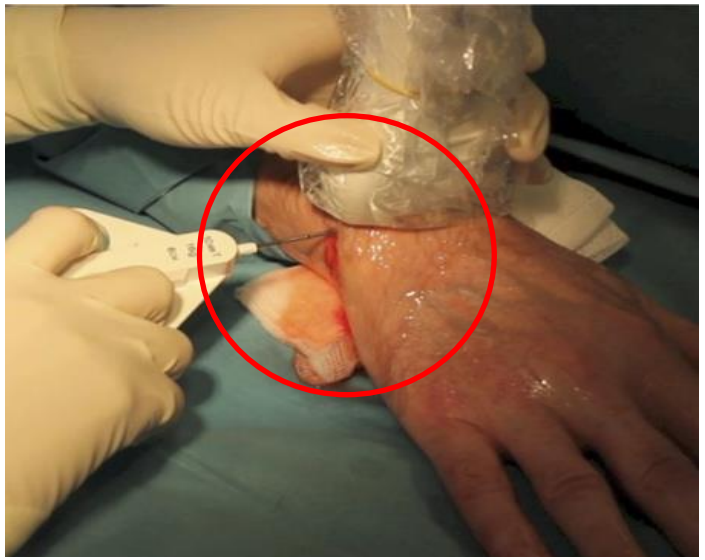
Central venous catheter placement
Critical Care 2017



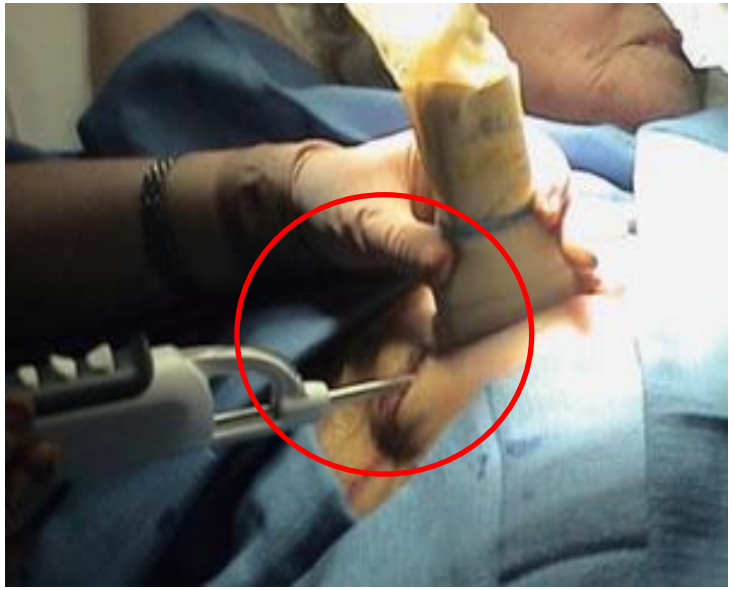

PHILIPS

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

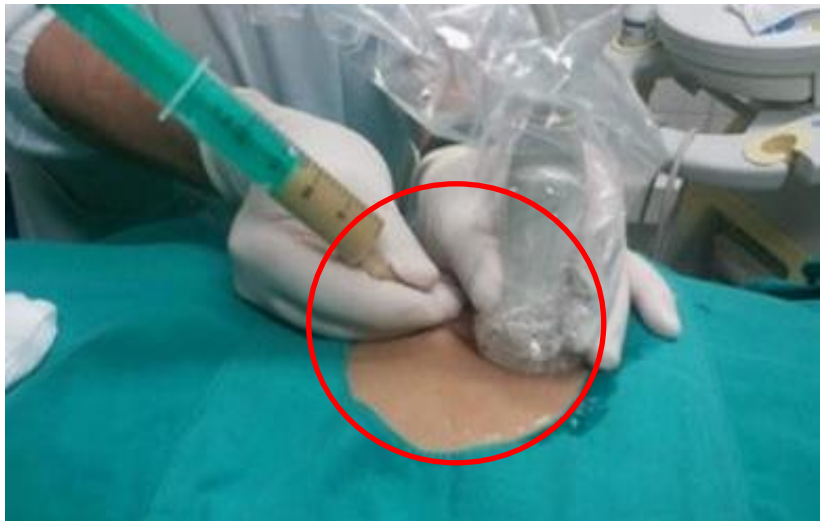


Core biopsy breast

Clin Onc 2016

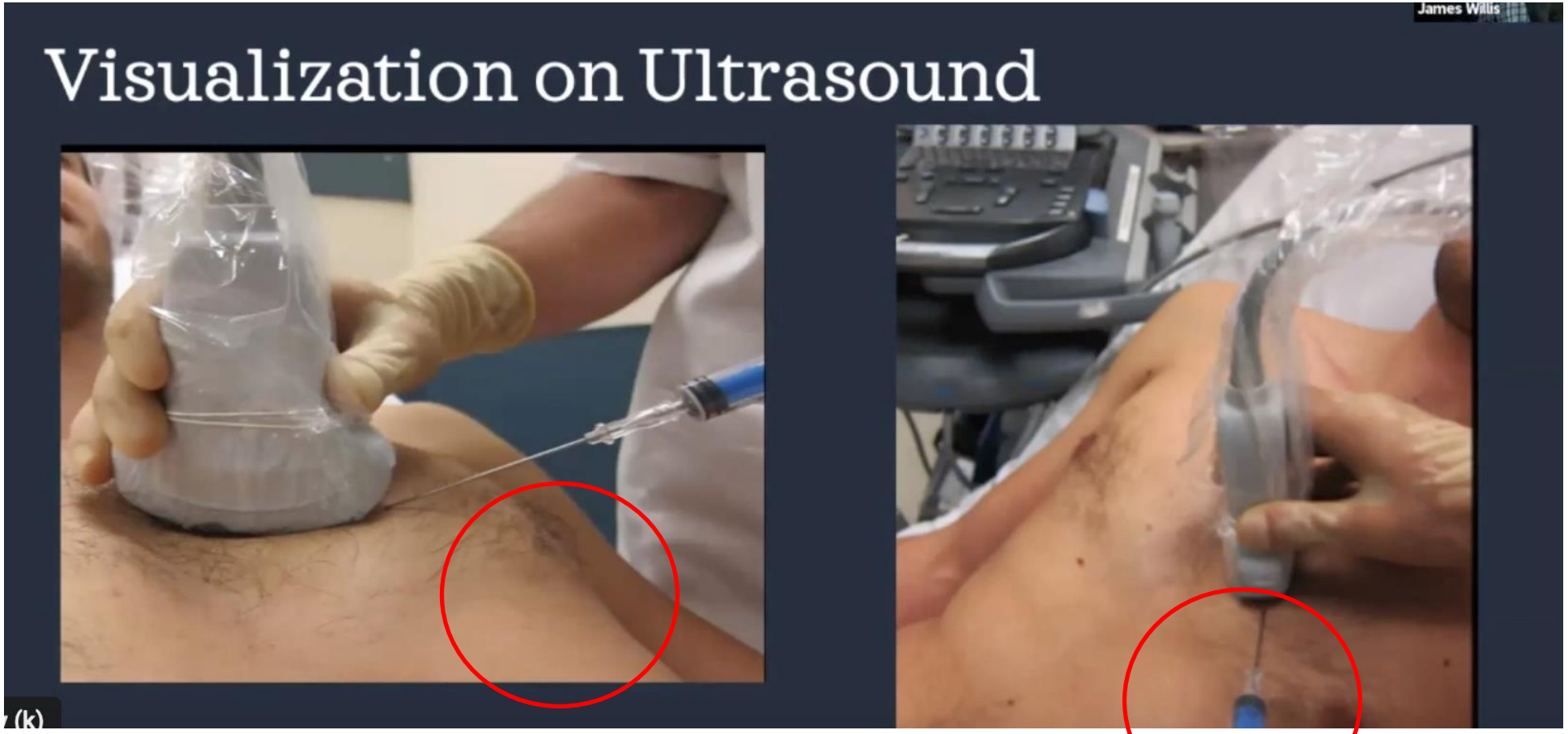
Active retrieval of fluid for diagnostic testing

- 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

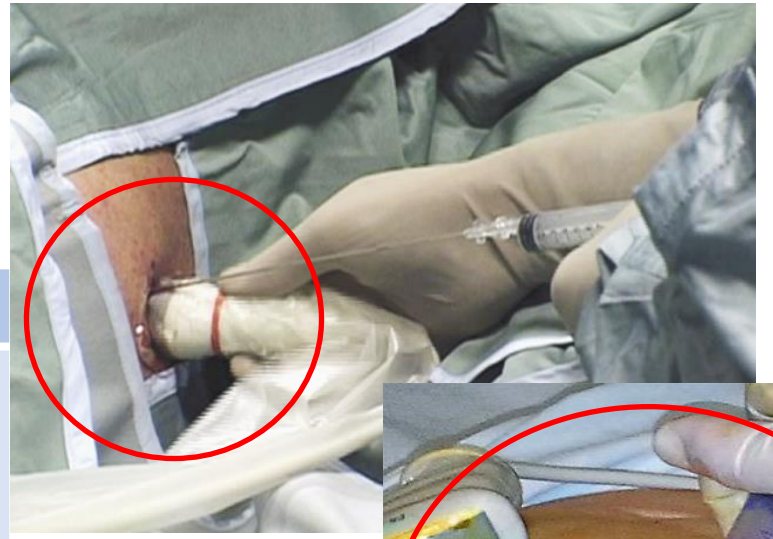


Pericardiocentisis

https://youtu.be/JIr5Mf6c8W4

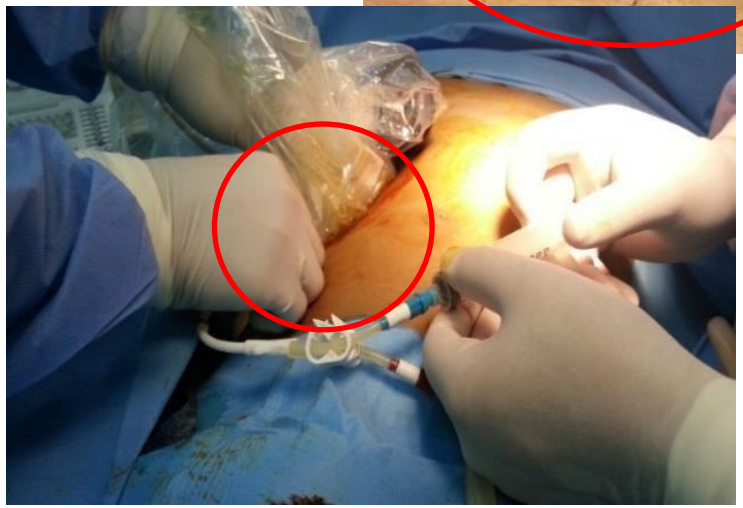
Passive removal of fluid (abscess drainage)

- 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

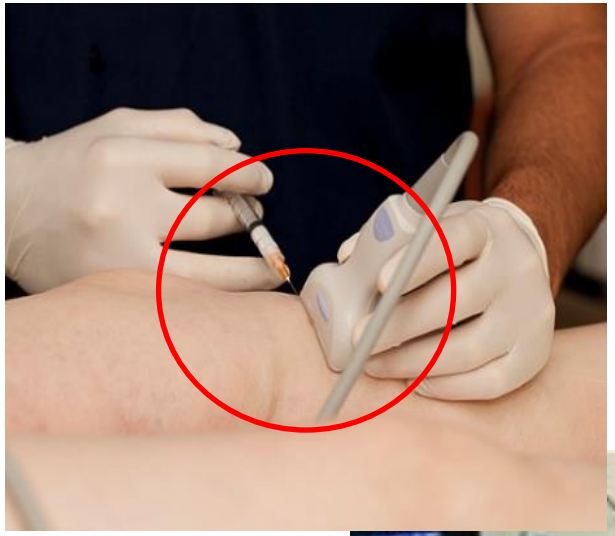
- U/G femoral nerve block
- U/G ankle block
- U/G axillary block
- U/G brachial plexus block
- U/G cervical nerve root block
- U/G celiac plexus neurolysis
- U/G continuous peripheral nerve block
- U/G penile nerve block
- U/G dorsal ramus block
- U/G epidural placement of a thoracic paravertebral catheter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

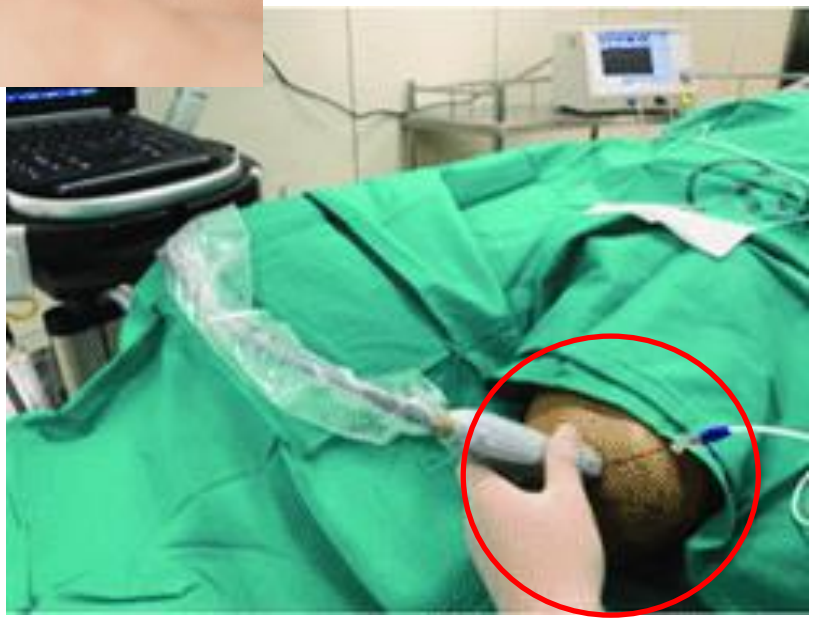
Am Col Emerg Phys 2019

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



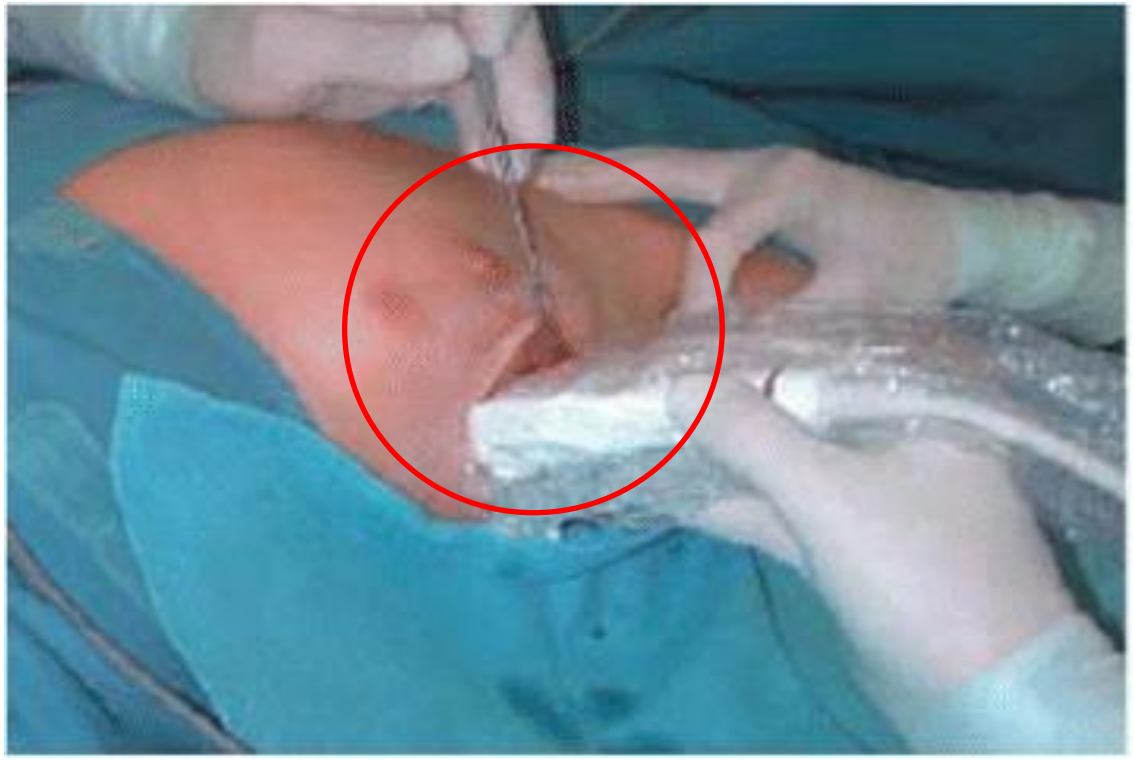
Ultrasound-guided ablation
Vein Health 2022



Radiofrequency ablation
J Pain Res 2020

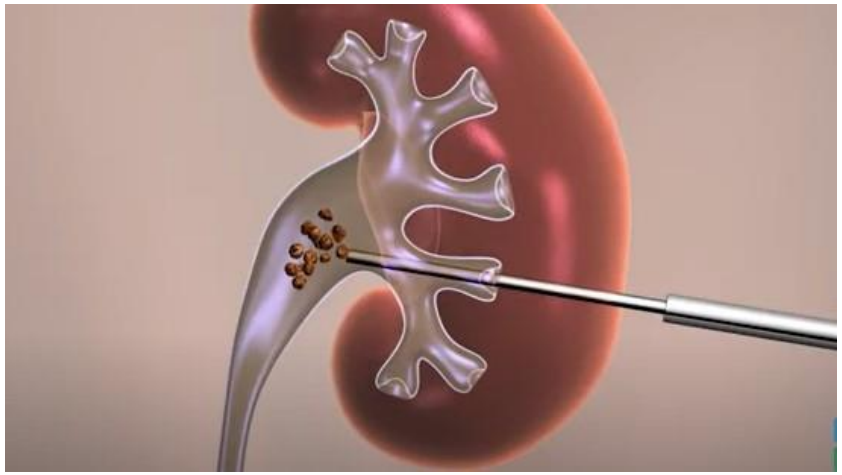
Surgical interventions

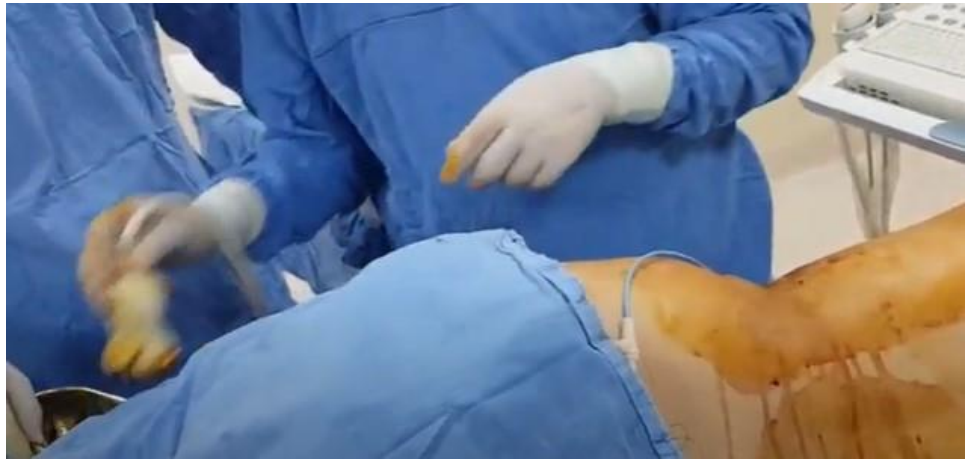
- Excision with U/G needle localization
- Intraoperative U/G percutaneous biopsy of tumor
- Intraoperative U/G tracer injection
- U/G implantation of iodine seeds
- U/G percutaneous renal transplant biopsy
- U/G transplantation of ASCs or placebo to the submandibular glands
- U/G transthoracic punctures
- U/G vacuum-assisted excision

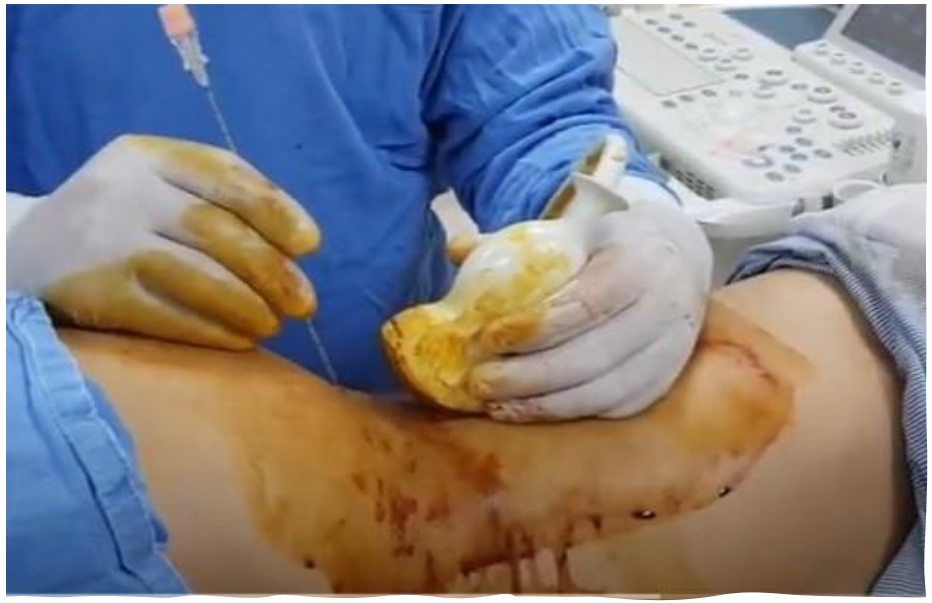


Surgery for palpable breast cancer
World J Surg Onc 2015

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





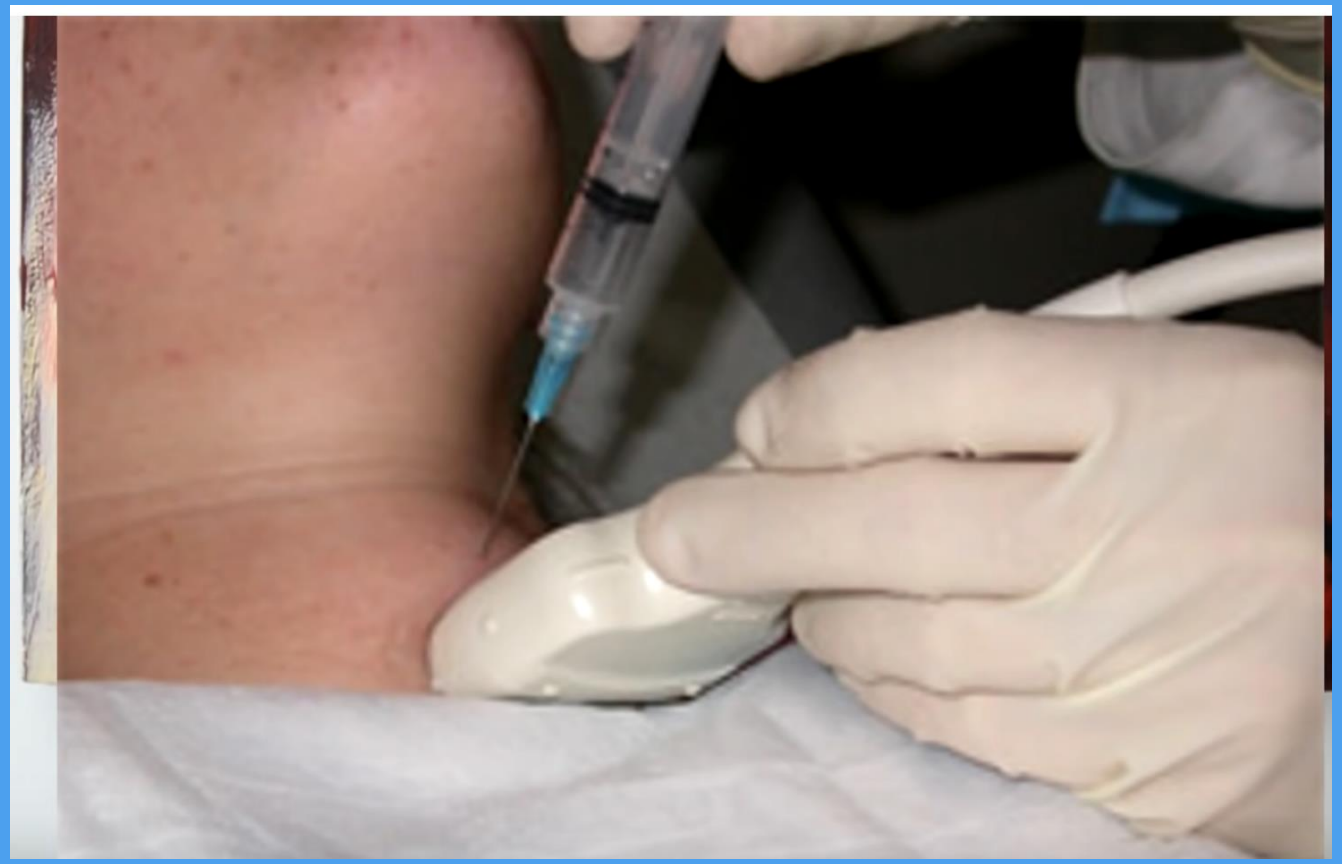


How would you categorize this probe?

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

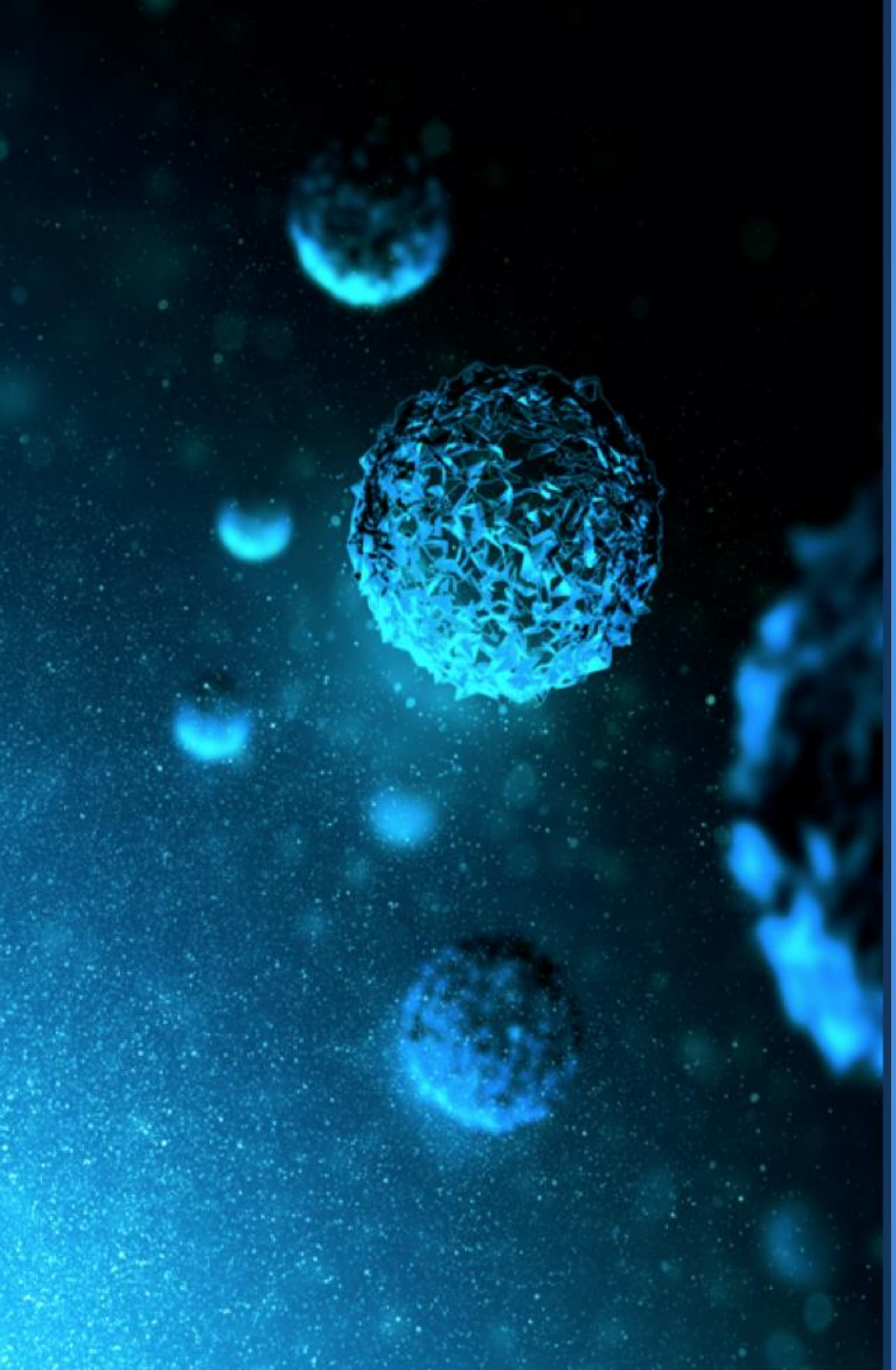
How would you categorize this probe?



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

FINE NEEDLE ASPIRATION OF THE THYROID

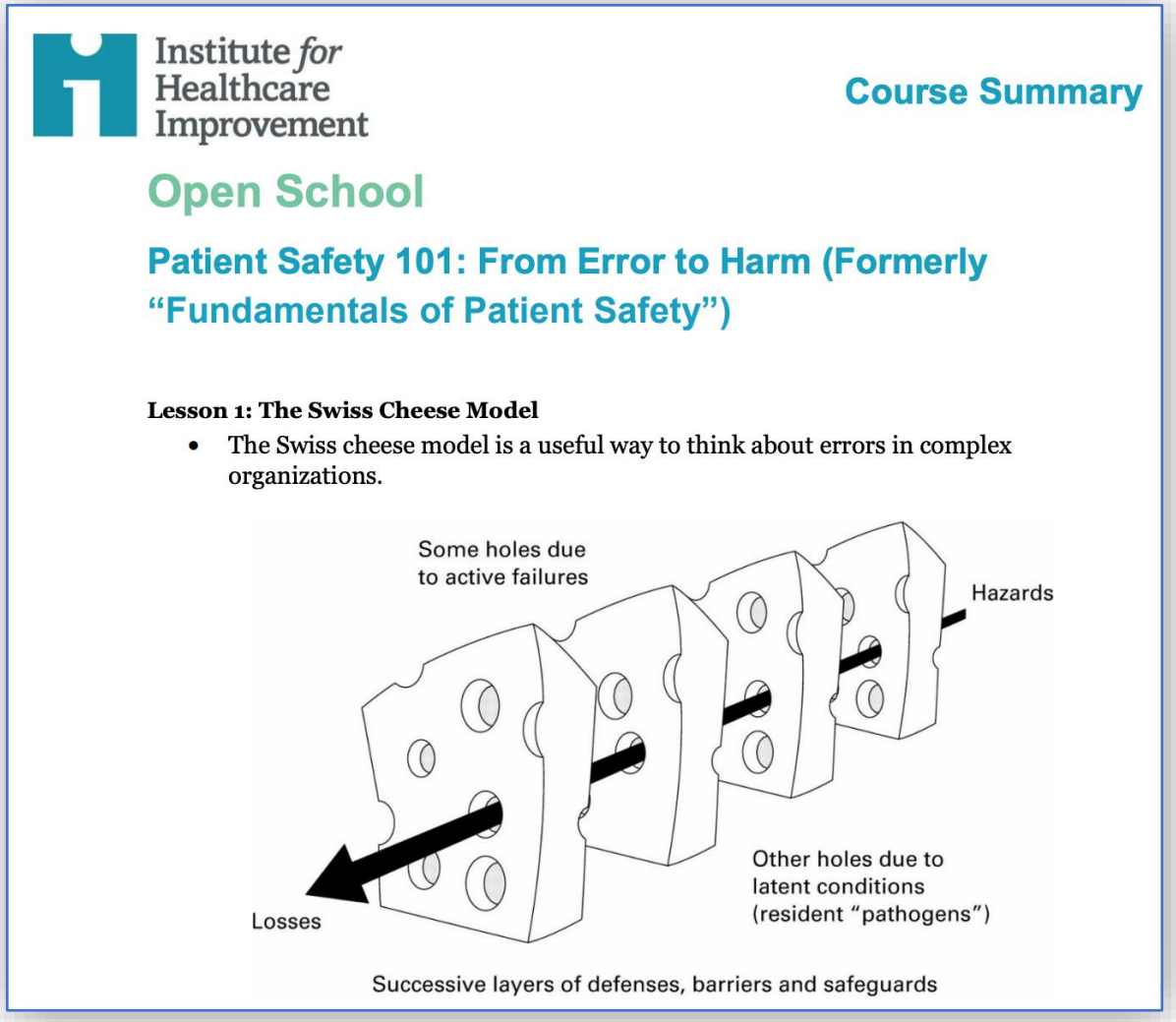
https://www.youtube.com/watch?v=QiS7Xxya_2U



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

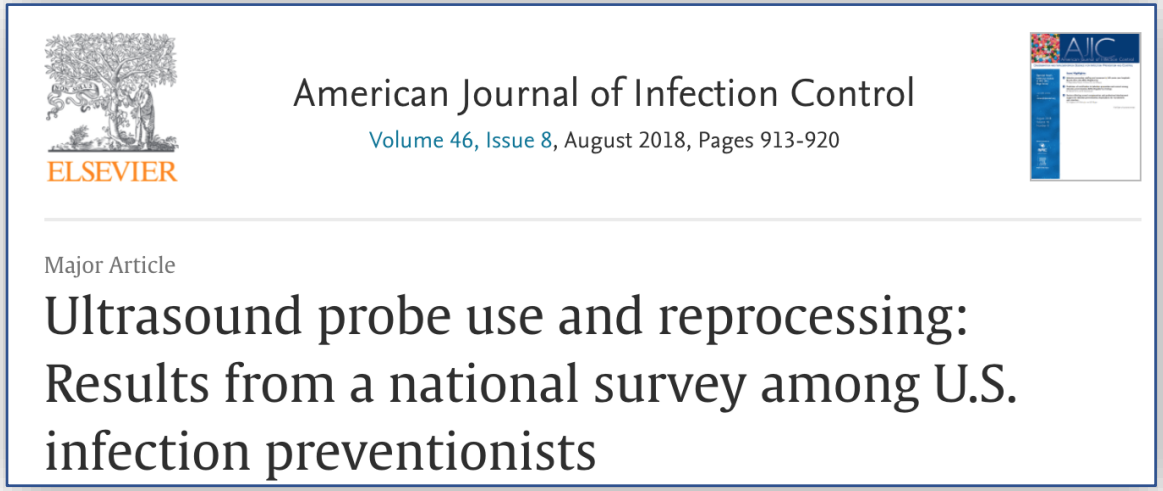
Patient Safety 101: From Error to Harm (Formerly "Fundamentals of Patient Safety")

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

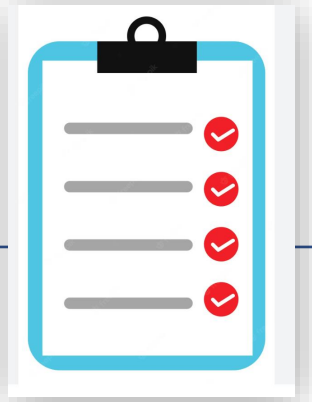
- Harm reduction models recommend that policy should address all possible outcomes resulting from the range of staff performing procedures.
- Standardization of reprocessing procedures may offset risk of varying levels of knowledge, skill and competency and potential for breaks in safe practice.



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

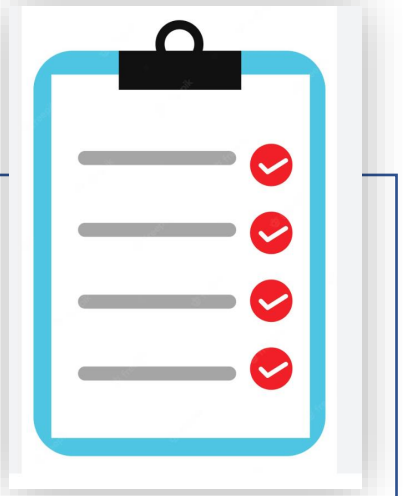
- Surface probes used in invasive procedures were not high-level disinfected or sterilized in 15% of intraoperative procedures.
    - In the same group of invasive procedures, 5%-47% did not use sterile gel.
- Of the participants, 20% were aware of instances where an ultrasound probe was used but was 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. There is clear evidence that _____ (location/department/service) demonstrates **procedures that satisfy**:
   - Current FDA _____ , 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 according to IFUs, 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)**

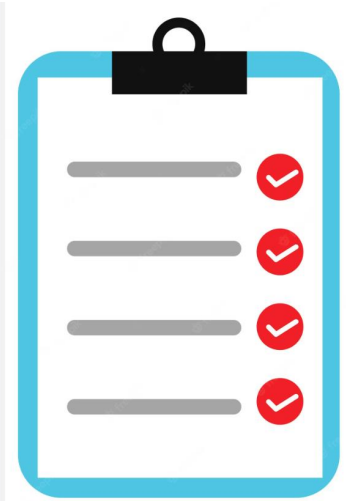


3. There is clear evidence that processes related to the **storage** of ultrasound probes and transducers, to prevent exogenous contamination and ensure safety for the next patient use.

4. Procedures are in place to **monitor the use of high-level disinfectants.**
   - 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 disinfection and preventative maintenance on equipment.



7. There is clear evidence that a process exists to identify non-compliance with reprocessing procedures and a system to re-train staff.

8. A Root Cause Analysis (RCA) is conducted as a mechanism for identifying, responding to, and **reporting sentinel events** that occur in the organization as related to percutaneous ultrasound procedures. Staff re-training may be a strategy that is identified in the RCA Policy.

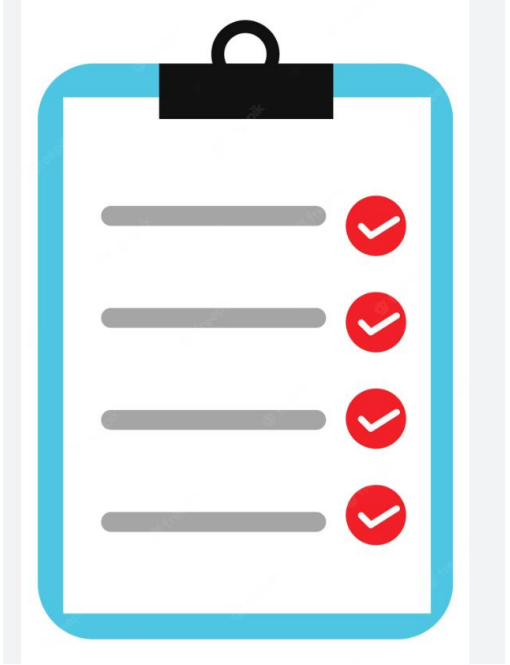
9. There is clear evidence that a process is in place to notify patients of adverse incidents if contamination is discovered and patient exposure is suspected.

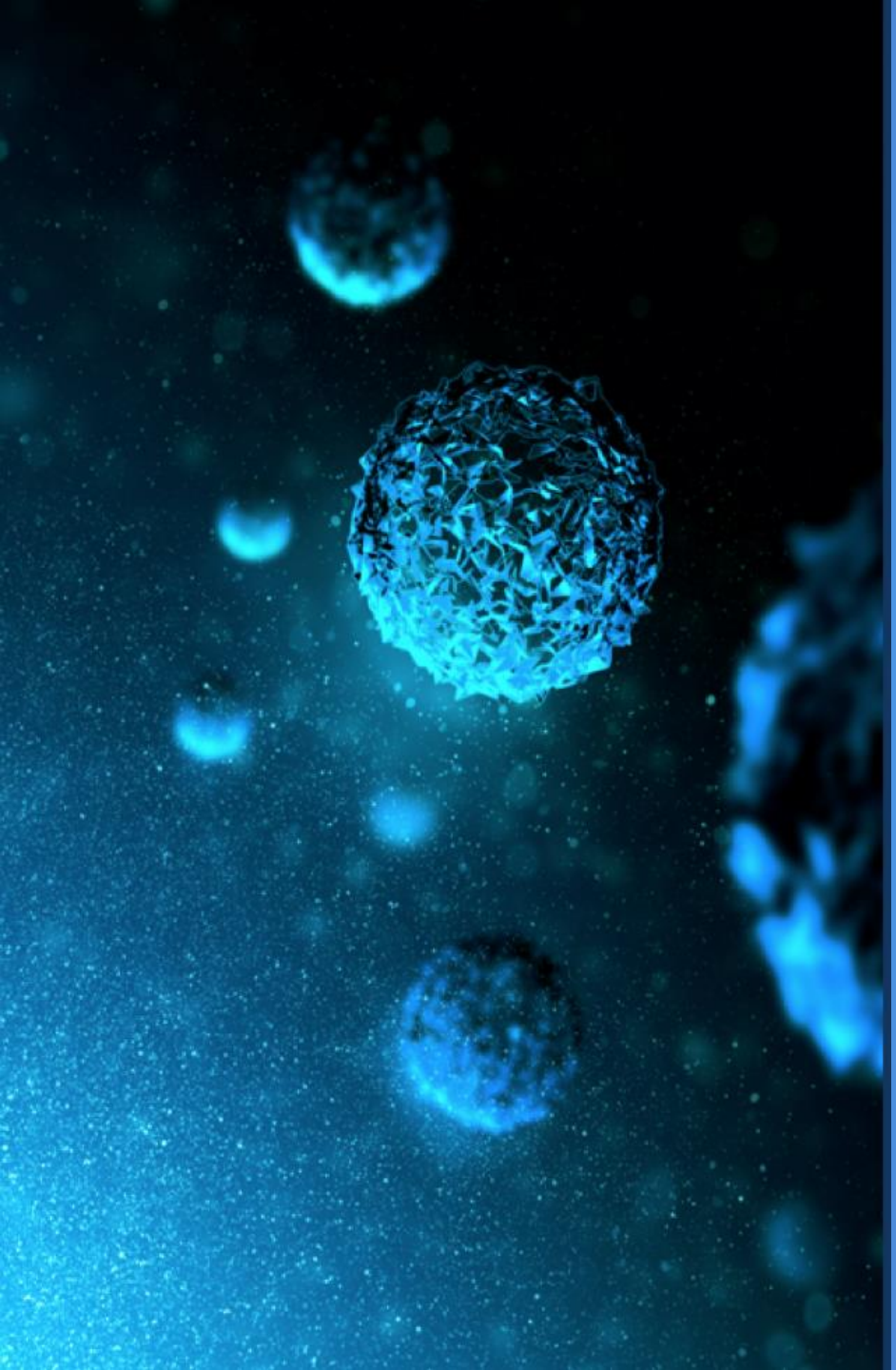
Clinical percutaneous procedures:

- 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





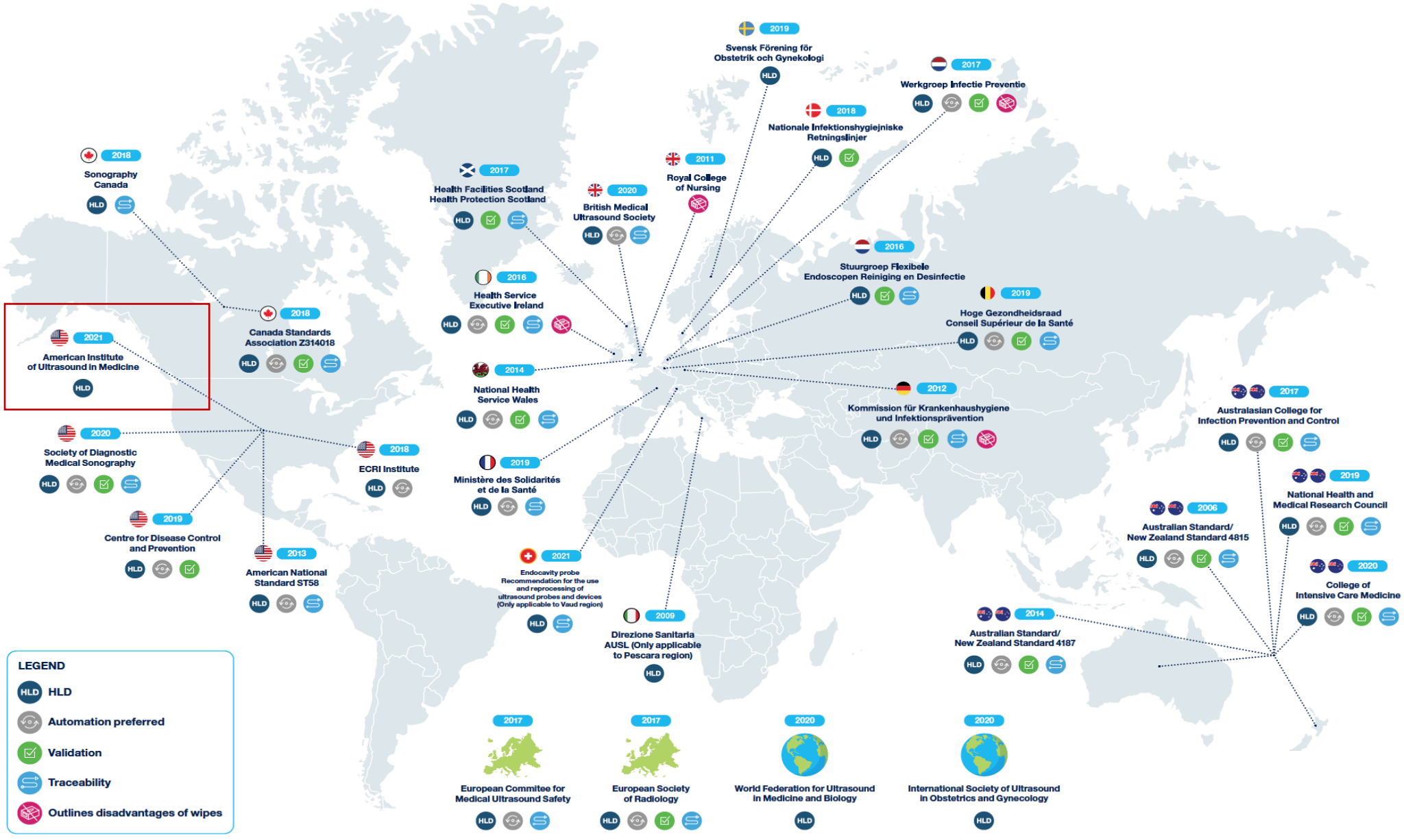
Outside of the U.S.
Guidance from Health Authorities

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.

*With exception for 140 percutaneous procedures



# of Ultrasound Reprocessing by Following Manufacturer's Instructions for Use and the Spaulding Classification

Jenna Rivera, MPH, CPH, CIC; Sheryl Ferriter, MPH, CPH, CIC
Infection Prevention and Control, Moffitt Cancer Center, Tampa, FL

Background

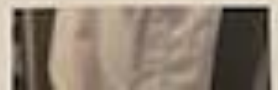
Ultrasound has been implicated in outbreaks involving contaminated multi-use gel and improperly reprocessed transducers. Ultrasound is heavily utilized in healthcare as it is user friendly and portable enough to travel to the bedside for point-of-care (POC) interactions. Ultrasound usage varies from quick surface exams to intraoperative applications, spanning all levels of the Spaulding Classification. Careful attention is needed to ensure the transducer is appropriately reprocessed due to the high volume usage and procedure variability.

Methods

In July 2021, Infection Prevention partnered with a third-party vendor to survey the four Center locations where POC ultrasound is used to assess exam type, volume, current reprocessing, storage, and transportation. The cleaning and disinfection protocol from the manufacturers' instructions for use were reviewed to identify any lapses in current reprocessing and chemical compatibility for all transducers identified. A literature review was also completed for reprocessing requirements and recommendations for transducers used in percutaneous procedures.

Results

The survey identified multiple staff positions that utilized POC ultrasound, including sonographers, nurses, mid-level providers, and physicians throughout eighteen different departments. 88 transducers were identified as non-critical, of which 56 being used in percutaneous procedures. There were 15 semi-critical transducers identified and 23 critical. In a collaboration with the identified stakeholders, a comprehensive policy was created for the management and reprocessing of ultrasound transducers and equipment. We determined that transducers used in percutaneous procedures are intended to contact intact skin, therefore classifying the device as non-critical and can safely be reprocessed via low-level disinfection. Care cards were created for each transducer and attached to the ultrasound system for ease of access to POC users. Information on the card included the Spaulding Classification, level of reprocessing required, and the manufacturer designated compatible disinfectant.



Conclusion

As ultrasound utilization continues to grow, it is essential to analyze each usage for the level of reprocessing required. Infection preventionists should seek out where ultrasound is used in their facility to be familiar with how these transducers are used. Involvement of Infection Prevention is also essential before purchase to assure that the facility can be compliant with manufacturer cleaning and disinfection protocols.

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nanosonics
Infection Prevention. For Life.

Methods

In July 2021, Infection Prevention partnered with a third-party vendor to survey the four Center locations where POC ultrasound is used to assess exam type, volume, current reprocessing, storage, and transportation. The cleaning and disinfection protocol from the manufacturers' instructions for use were reviewed to identify any lapses in current reprocessing and chemical compatibility for all transducers identified. A literature review was also completed for reprocessing requirements and recommendations for transducers used in percutaneous procedures.

Improperly precleaned transducer. Gel leftover from procedure.

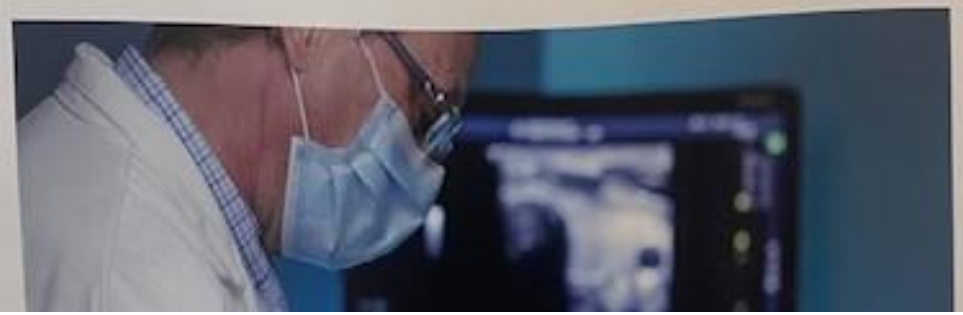
Nicks or other damage to the lens provide barriers to reprocessing.

Storage of endocavitary transducers should maintain the level of reprocessing.

Impl

Conclusion

As ultrasound utilization continues to grow, it is essential to analyze each usage for the level of reprocessing required. Infection preventionists should seek out where ultrasound is used in their facility to be familiar with how these transducers are used. Involvement of Infection Prevention is also essential before purchase to assure that the facility can be compliant with manufacturer cleaning and disinfection protocols.



Disinfection Options

Low-level Disinfection

- **Applicable Probes**
  Convex, linear, phased array, etc.
- **Applicable Scene**
  Probes contact intact skin
- **Classification**
  Non-critical
- **Frequency**
  Every time after use

High-level Disinfection

- **Applicable Probes**

  Endocavity – transvaginal, transrectal, transesophageal

- **Applicable Scene**

  Probes contact mucous membrane

- **Classification**

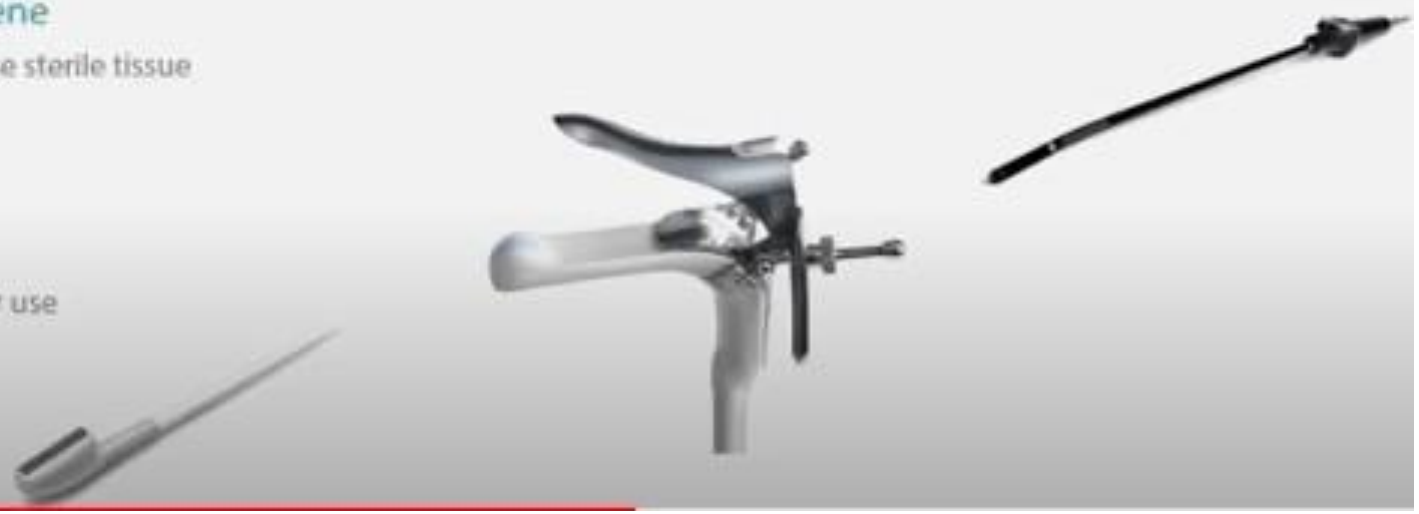
  Semi-critical

- **Frequency**

  Every time before and after use

Sterilization (Transducer)

- **Applicable Probes**
  Intraoperative
- **Applicable Scene**
  Enters otherwise sterile tissue
- **Classification**
  Critical
- **Frequency**
  Every time after use



- Automatic process with Hydrogen Peroxide
- Automatic process with Hydrogen Peroxide and Paracetic Acid
- UV-C Photons Disinfection
- Foam wipes with proprietary chlorine dioxide chemistry

Ultrasound Gel Contamination Outbreaks

Multistate Outbreak of Burkholderia cepacia Infections Associated with Contaminated Ultrasound Gel — Last Updated: Aug 2021
https://www.cdc.gov/hai/outbreaks/b-cepacia-ultrasound-gel/index.html
Additional laboratory testing of isolates or specimens from patients with reported Bcc infections and of additional lots of MediChoice® M500812 **ultrasound gel** is currently underway. The manufacturer of MediChoice®M500812...
Related: Outbreak of Burkholderia stabilis In...

Outbreak of Burkholderia stabilis Infections Associated with Contaminated Nonsterile, Multiuse Ultrasound Gel — 10 States, May–September 2021 — Last Updated: Dec 2022
https://www.cdc.gov/mmwr/volumes/71/wr/mm7148a3.htm
This practice could have allowed introduction of contaminated **ultrasound gel** into sterile body sites when **gel** and associated viable bacteria were not completely removed from skin, leading to invasive infections....
Related: CDC Library: COVID-19 Science Update... | Science Clips - Volume 12, Issue, 3 ... | Science Clips - Volume 14, Issue 50,...

Pseudomonas aeruginosa Respiratory Tract Infections Associated with Contaminated Ultrasound Gel Used for Transesophageal Echocardiography — Michigan, December 2011–January... — Last Updated: Oct 2014
https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6115a3.htm
The Oakland County Health Department, the Michigan Department of Community Health, and the Food and Drug Administration (FDA) were notified of the findings. On January 23, all implicated **ultrasound gel** in multiuse bottles...

[PDF] Outbreak of Burkholderia stabilis Infections Associated with Contaminated Nonsterile, Multiuse Ultrasound Gel — 10 States, May–September 2021 — Last Updated: Dec 2022
https://www.cdc.gov/mmwr/volumes/71/wr/pdfs/mm7148a3-H.pdf
This practice could have allowed introduction of contaminated **ultrasound gel** into sterile body sites when **gel** and associated viable bacteria were not completely removed from skin, leading to invasive infections....

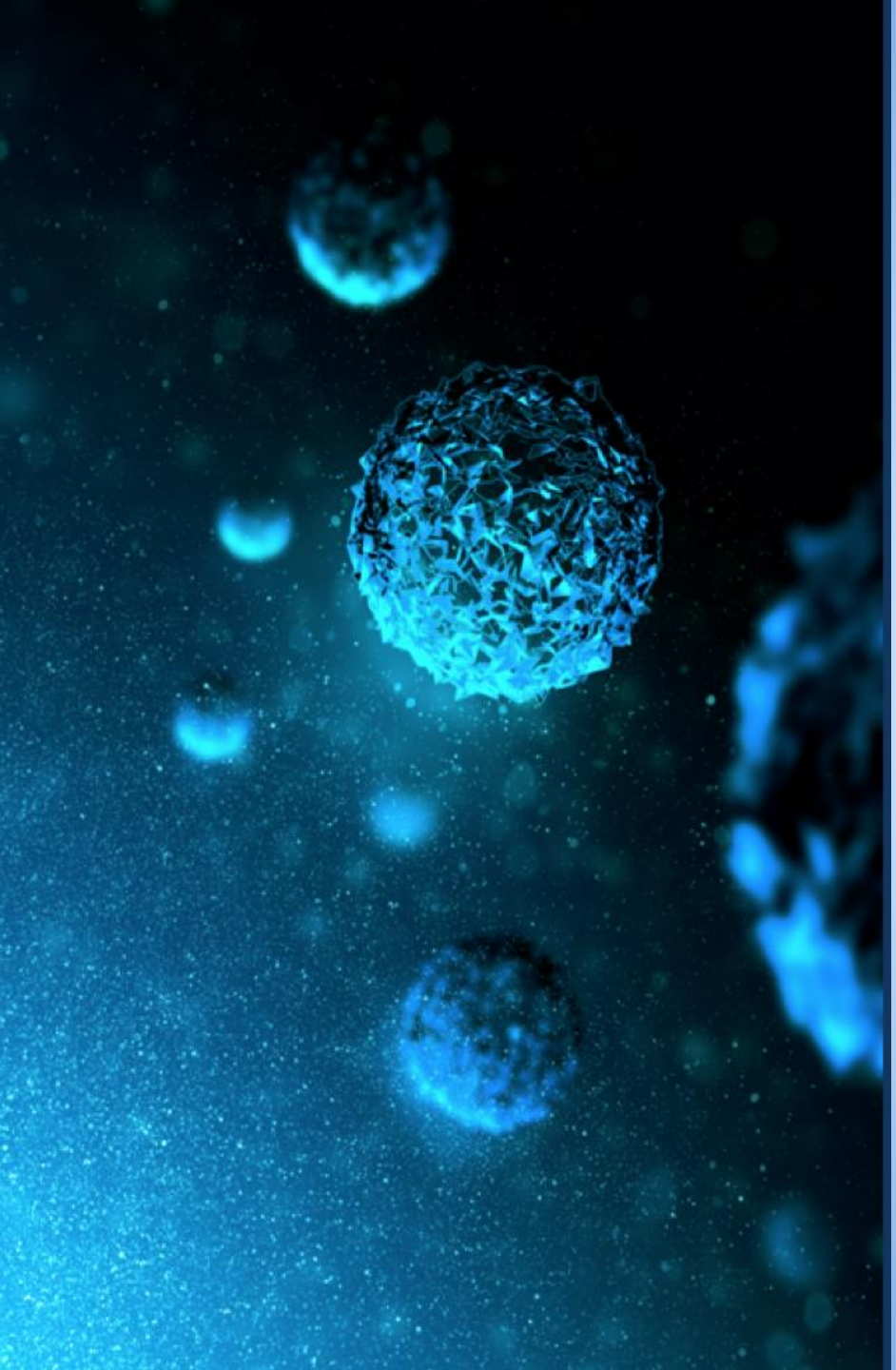
Outbreak of Achromobacter xylosoxidans and Ochrobactrum anthropi Infections after Prostate Biopsies, France, 2014 - Volume 22, Number 8—August 2016 - Emerging Infectious... — Last Updated: Jul 2016
https://wwwnc.cdc.gov/eid/article/22/8/15-1423_article

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.



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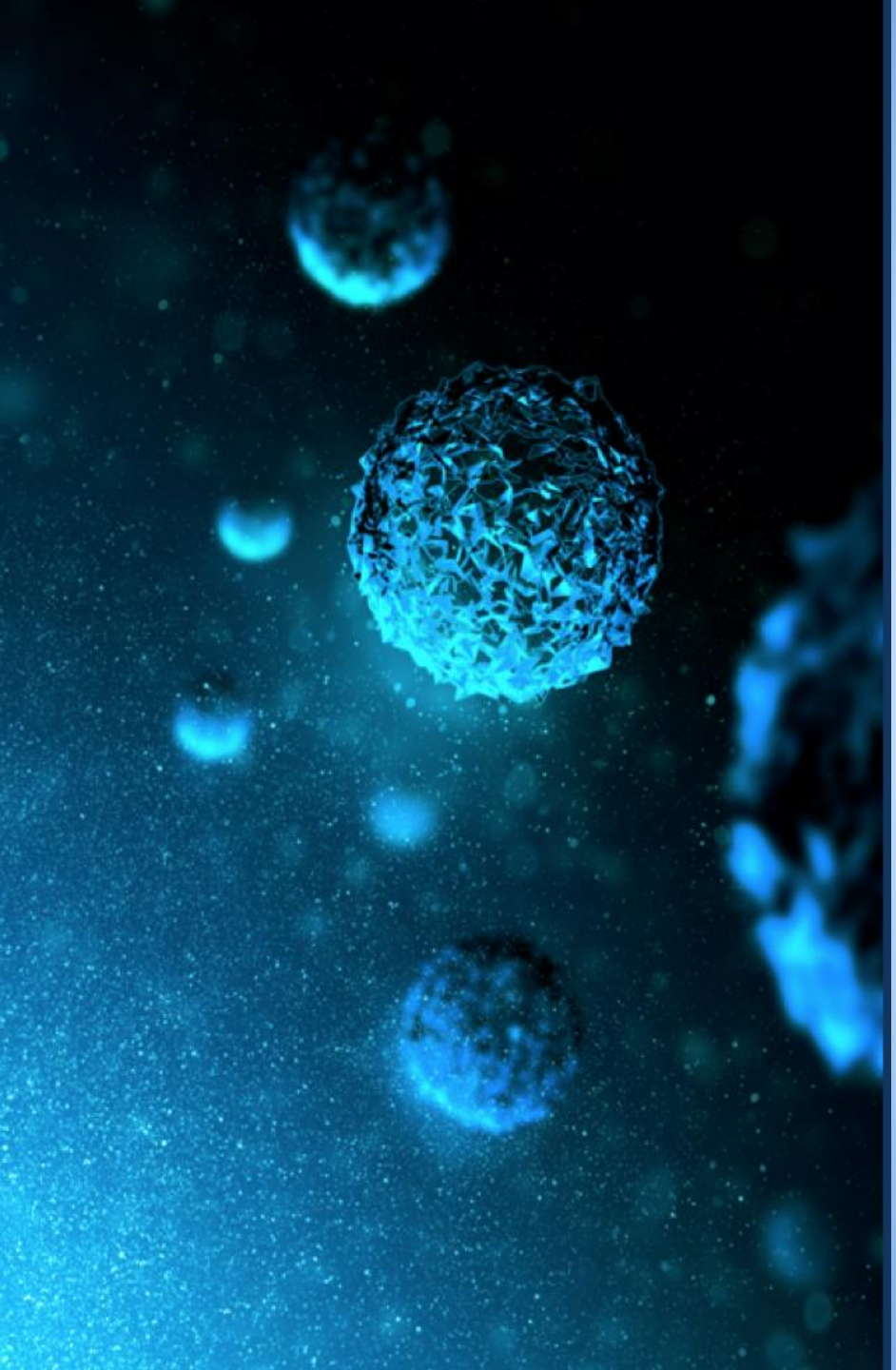
Questions



Thank you!

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