

Guidelines for Use and Care of Ultrasound Gel

I. PURPOSE:

Minimize the risk of healthcare-acquired infections from the use of ultrasound gels.
Provide guidance on the shelf-life, storage requirements, and the use of appropriate gel type based on procedures performed.

II. REFERENCES:

Clinician Outreach and Communication Activity (COCA): Safety Communication: Bacteria Found in Other-Sonic Generic Ultrasound Transmission Gel Poses Risk of Infection". Center for Disease Control and Prevention, April 2012

Infection Control and Hospital Epidemiology. Sustained Endemicity of *Burkholderia cepacia* in a Pediatric Institution, Associated with Contaminated Ultrasound Gel. Vol 27-4. April 2006.

Infection Control and Hospital Epidemiology. An Outbreak of Pyodermas among Neonates Caused by Ultrasound Gel Contaminated with Methicillin-Susceptible *Staphylococcus aureus*. Vol 21-12. December 2000.

Health Canada: Notice to Hospitals- Serious Risk of Infection from Ultrasound and Medical Gels. December 2004

American Institutes of Ultrasound in Medicine: Guidelines for Cleaning and Preparing External- and Internal-Use Ultrasound Transducers Between Patients, Safe Handling, and Use of Ultrasound Coupling Gel, last approved March 2021

Parker Labs memo (Gel Warmer (2)) dated August 24, 2020

Tunstall, T. (2010), Infection Control in the Sonography Department, Journal of Diagnostic Medical Sonography, vol. 26, 4: pp. 190-197.

SOCIETY OF DIAGNOSTIC MEDICAL SONOGRAPHY Guidelines for Infection Prevention and Control in Sonography: Reprocessing the Ultrasound Transducer. Revised May 20, 2020

III. DEFINITIONS:

- A. **Point-of-Care Ultrasound:** portable ultrasound machines used at the bedside for diagnostic or therapeutic applications
- B. **US:** Ultrasound
- C. **Intact Skin:** Skin is not broken; no wounds, punctured skin, or tissue
- D. **Non-Intact Skin:** Skin is broken or punctured; there is contact with mucous membranes
- E. **Bacteriostatic:** Capable of inhibiting the growth or reproduction of bacteria

IV. POLICY:

- A. Under section 201(h) of the Federal Food, Drug, and Cosmetic Act, Ultrasonic Transmission Gel is considered a medical device as it is intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, or intended to affect the structure or function of the body.
- B. The guidelines outlined in this policy will be followed when using ultrasound gel during a patient procedure (e.g., cardiac, general, vascular, and Point-of-Care US).
- C. This policy applies to all UCSF locations, including inpatient and outpatient services that use, handle, and/or store ultrasound gel.
- D. Sterile gel is used in procedures that may come into contact with sterile tissue and may enter the vascular system.
- E. Whenever possible, single-use sterile ultrasound gel is preferred and recommended regardless of use on sterile or non-sterile tissue.
 - 1. Non-sterile single ultrasound gel packets are preferred and recommended over multi-use gel containers over Intact Skin.
 - 2. Multi-use ultrasound gel is not recommended; but can be used only over clean, Intact Skin.

V. PROCEDURES

- A. **Sterile Ultrasound Gel (Single Use Only)**
 - 1. Contains a Bacteriostatic agent and is labeled as “sterile.”
 - 2. Sterile gel is no longer considered sterile once it is opened.
 - 3. Discard any unused gel to prevent accidental reuse.
 - 4. Procedures indicated for sterile gel use include:
 - i. All ultrasound examinations or procedures performed on infant and pediatric department patients.
 - ii. All invasive procedures in which a device is passed through tissue, such as needle aspiration, needle biopsy, tissue biopsy or transesophageal echocardiogram.
 - iii. All ultrasound exams or procedures performed on Non-Intact Skin or near fresh surgical sites.
 - iv. Any invasive procedures using ultrasound gel involving sterile body site, such as guided biopsy and Non-Intact Skin (e.g., open chest, limb, cranium, or neck).
 - v. Insertion of PICC and central catheter lines.
 - 5. Sterile or Bacteriostatic gel should be considered for endocavitary examinations performed on intact mucous membranes (e.g., esophageal, gastric, rectal, and vaginal).
- B. **Non-Sterile US Gel (Single use gel packets or Multi-use Containers)**
 - 1. Does not contain a Bacteriostatic agent and is labeled as “non-sterile.”
 - 2. If multi-use containers of ultrasound gel are used, care should be taken to:
 - i. Only be used for low-risk procedures on low-risk patients, over Intact Skin.
 - ii. Discard and replace multidose containers when empty or if integrity of the bottle is compromised (e.g., cracked, broken cap).
 - iii. Containers shall not be refilled or combined with other bottles of gel.
 - iv. Multi-use gel shall be discarded after 28 days from opening or the printed

- manufacturer's expiration date, whichever comes first.
- v. Multi-use gel containers must be labeled with open date and 28-day discard date or manufacturer's expiration date, whichever comes first.
 - vi. Appropriately seal the container when not in use
 - vii. Avoid direct contact between the gel container tip and any persons or instrumentation, including the ultrasound transducer, as this can contaminate the contents of the bottle. If the tip of the container is contaminated, discard the container.
 - viii. In between patients, wipe the multi-use container tip with alcohol swab and wipe down the outside of the containers with a hospital approved disinfectant.
3. Use a single-use packet(s) of US gel for any patient in Transmission-Based Isolation (i.e., contact, enteric contact, airborne, droplet, or novel respiratory isolation).
 4. Single-use gel packets are preferred and strongly recommended for procedures when feasible and available.

C. Ultrasound Gel Warmers

1. Warm ultrasound gel may provide patient comfort, but it can also be an ideal temperature to promote the growth of bacteria.
2. Warm the ultrasound gel only when required using approved gel warmers.
3. Multi-use gel containers should not be kept upside down in the warmers to prevent cross-contamination.
4. Use only dry heat to warm gel.
5. Gel warmers should be cleaned and disinfected regularly according to the manufacturer's instructions and infection control policy requirements.

D. Storing Ultrasound Gel

1. Store bulk packages of pre-filled US gel bottles in a clean, dry area, and protect from potential sources of contamination (e.g., dust, moisture, insects, rodents).
2. Remove bottles or packets from corrugated cardboard boxes and store in appropriate designated areas. Discard bottles if integrity is in doubt.
3. Discard if noted expiration date has been met or if opened and missing discard date (28-days or manufacturer's expiration date, whichever comes first).

VI. RESPONSIBILITY

Questions about the implementation of this policy should be directed to the Director of Radiology, Hospital Epidemiology, and Infection Prevention.

VII. HISTORY OF POLICY

Original Date: June 2013
Revision Date: March 2022

VIII. APPENDIX

A. [Ultrasound Gel Use Tip Sheet](#)

APPENDIX A: ULTRASOUND GEL USE TIP SHEET

Ultrasound Gel Use

Critical Probes (touches sterile tissue)	Semi-Critical Probes (touches mucous membrane)	Non-Critical Probes (touches intact skin)
<ul style="list-style-type: none"> Single sterile use gel 	<ul style="list-style-type: none"> Non-sterile "bacteriostatic" single use gel (<i>at a minimum</i>) Sterile single use gel (<i>preferred</i>) 	<ul style="list-style-type: none"> Multi-use gel (<i>non-refillable</i>) Non-sterile "bacteriostatic" or Sterile single use gel (<i>preferred</i>)
Considerations	Considerations	Considerations
<ul style="list-style-type: none"> Use aseptic "clean" technique when handling No other gel may be used 	<ul style="list-style-type: none"> Use aseptic "clean" technique when handling 	<ul style="list-style-type: none"> Avoid multi-use gel when possible Do not touch the patient or probe with the tip of the multi-use bottle Label bottle with opened date and discard date: <ul style="list-style-type: none"> Gel expires 28 days after opening or the printed manufacturer's expiration date, whichever comes first.

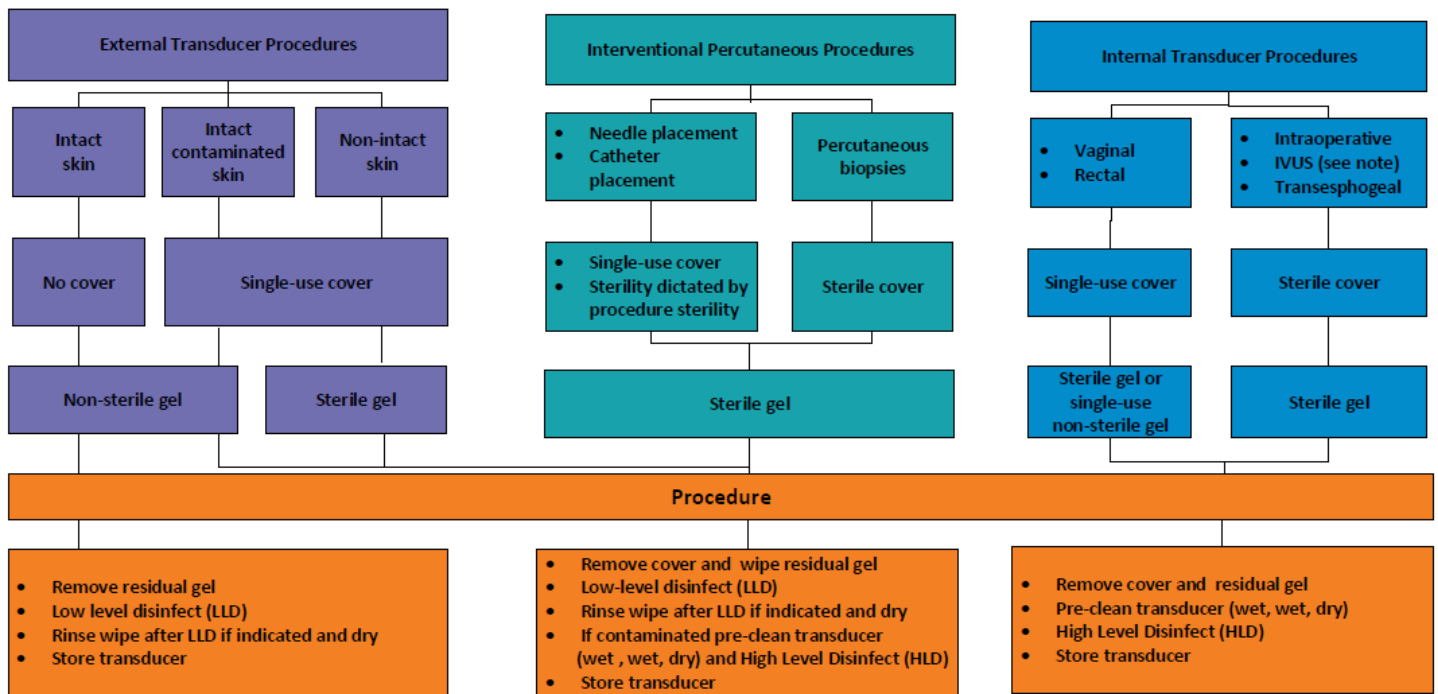
General Considerations (all gel)

- Ensure gel is only used within its shelf life
- Warming the gel promotes the growth of bacteria.
- Expiration / discard dates are based on the manufacturer's IFUs but must be discarded if:
 - Multi-use gel (discard date is limited to 28 days from opening)
 - Integrity of container is compromised (e.g., cracked/broken, missing cap, etc.)
 - Evidence of contamination
- Check before use for evidence of contamination and discard if present
- Store gel protected from sources of contamination (e.g., dust, moisture)
- Use appropriate gel type based on exam or procedure and skin tissue
- Refer to UCSF Medical Center Administrative Policy: Ultrasound Gel

APPENDIX B: PROBE TRANSDUCER PREPARATION AND CLEANING

Probe Transducer Preparation and Cleaning

Select your procedure section:



Key Definitions

- LLD: Hospital approved disinfectant wipe & manufacturer approved
- HLD: Trophon or endoscopy reprocessing (manufacturer approved method)
- Pre-clean (wet, wet, dry):
 - Low-level disinfect (wet)
 - Rinse wipe (wet)
 - Wipe using lint-free dry cloth (dry)

Note:
IVUS catheters are single use, therefore no cleaning is required, follow manufacturer procedure instructions