

SUBJECT: USE OF ULTRASOUND GEL PRODUCTS	REFERENCE #8140A
DEPARTMENT: REHABILITATION SERVICES	PAGE: 1 OF: 3
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POLICY:

_____ Hospital shall assure patient safety by ensuring the use of uncontaminated ultrasound gel products.

PROCEDURE:

- Prior to using ultrasound gel, the need for sterile or nonsterile gel shall be determined and the proper gel shall be selected.
- Once a container of sterile or nonsterile ultrasound gel is opened, it is no longer sterile and contamination during ongoing use is possible.
- Open containers of ultrasound gel may be used promptly for low-risk procedures on intact skin and for low-risk patients.
- **Sterile Gel:**
 - The only ultrasound gel that is sterile is unopened ultrasound gel containers/packets labeled as sterile. Ultrasound gel products that are labeled as nonsterile or that are not labeled at all with respect to sterility are **NOT** sterile.
 - Sterile gel shall be used for all invasive procedures in which a device is passed through tissue (e.g., needle aspiration, needle localization, tissue biopsy), for all procedures involving a sterile environment or non-intact skin, and for all procedures on neonates.
 - Sterile gel shall be used in patients with immunodeficiencies or on immunosuppressive therapy.
 - Sterile gel shall be used for procedures with mucosal contact where biopsy is not planned but any possible added bioburden would be undesirable or mucosal trauma is likely (e.g., transesophageal echocardiography (TEE) procedures, transvaginal ultrasound procedures without biopsy, transrectal ultrasound procedures without biopsy).
 - Aseptic technique shall be used when using sterile gel.

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- **Nonsterile Gel:**

- Single-use containers shall be used whenever possible when using nonsterile gel.
- Containers of gel shall be labeled with the contents and the date.
- Unused gel shall be discarded after one (1) month.
- If reusable containers are used for nonsterile gel:
 - Empty the containers
 - Wash them in hot, soapy water or hospital-grade disinfectant
 - Rinse them thoroughly
 - Dry them before refilling
- Bottles shall not be "topped-up," and cracked reusable bottles should be discarded.
- When filling a reusable container, ensure that the large bulk container expiration date has not passed.
- Fill bottles by using a dispensing device on the large bulk container, not by inserting the tip of the refillable bottle into the bulk container to aspirate the contents.
- Refill bottles as close as possible to the time of use.
- Ensure that tips of containers or dispensing nozzles do not come in direct contact with patients, staff, instruments or the environment. Dispense gel into a medicine cup or on a clean disposable cloth and then onto the patient's skin.

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- Warming Gel:
 - Only use warmed gel when required.
 - Bottles should be removed from the warmer as soon as possible and dried immediately.
 - Gel warmers shall be cleaned weekly with low-level EPA-approved hospital detergent disinfectant and cleaned immediately if the warmer becomes soiled.
- Storage of Ultrasound and Medical Gel:
 - Product must be stored in areas that are dry and protected from potential sources of contamination, such as dust, moisture, insects or rodents.
 - If evidence of contamination is present, or if package integrity has been breached, product must be discarded.
 - Product should be rotated by date during restocking.

REFERENCES:

- US Food and Drug Administration (FDA), Medical Devices, Medical Device Safety, Alerts and Notices, *FDA Safety Communication: Update on Bacteria Found in Other-Sonic Generic Ultrasound Transmission Gel Poses Risk of Infection*, June 8, 2012, last updated 1/12/2015, <http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm299409.htm?source=govdelivery>
- Centers for Disease Control and Prevention (CDC), *Pseudomonas aeruginosa Respiratory Tract Infections Associated with Contaminated Ultrasound Gel Used for Transesophageal Echocardiography - Michigan, December 2011-January 2012*, MMWR, April 20, 2012, 61(15);262-264, <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6115a3.htm>
- Healthy Canadians, Recalls and Alerts, *Notice to Hospitals - Important Safety Information on Ultrasound and Medical Gels*, 2004, <http://www.healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2004/14289a-eng.php>