

Updates on Disinfection and Cleaning of Ultrasound Transducers Exposed to HPV

HPV is the most common sexually transmitted infection in the United States. Active infections of high-risk, cancer-causing strains of HPV infect 23% of the US population,¹ resulting in 30,000 cases of cancer per year.²

New research shows that common methods used to disinfect ultrasound transducers are not effective against HPV, and can leave actively infectious HPV on transducers.^{3,4,5} To reduce the chance of interpatient transmission of HPV and other viruses, current recommendations from the CDC,⁶ AUIM,⁷ FDA,⁸ and Health Canada (HC)⁹ all recommend that ultrasound transducers that come into contact with mucosal membranes (such as for vaginal/rectal/esophageal procedures) use both an ultrasound probe cover and high level disinfection. In keeping with current best practices, FDA and HC regulations explicitly require all vaginal, rectal and esophageal ultrasound systems sold in the United States and Canada to come with instructions recommending both ultrasound probe covers and high-level disinfection.^{6,7}

HPV is unusually resistant to high-level disinfectants,¹⁰ specifically including common high-level disinfectants glutaraldehyde (GUS) and *ortho*-Phthalaldehyde (OPA), both of which can leave actively infectious HPV on ultrasound transducers.^{11,12,13} Even with disinfectants that work well against HPV, such as hypochlorite bleach or high-strength hydrogen peroxide,^{11,13,6} mucus must be removed from the transducer for the disinfectant to be effective.¹⁴ This is why probe covers are recommended. By covering the ultrasound transducer, mucus is collected on the outside of the probe cover, not on the transducer. To remove the mucus, simply remove and discard the used cover after each procedure. To ensure the highest patient safety, we recommend a disinfectant with proven effectiveness against HPV, in combination with our viral barrier ultrasound probe cover.

Sheathing Technologies' viral barrier ultrasound probe covers are proven in FDA-reviewed in vitro testing to provide a viral barrier from viruses 20 nm in diameter or larger while the probe cover remains intact without leakage.¹⁵ (All currently known human pathogens are 20nm or larger, excepting prions.) These viral barrier covers have been tested to be free of gaps and pores prior to usage. However, due to the theoretical possibility of microscopic tears during use, the FDA still recommends that users follow a high-level disinfection process after each patient exam.

Sheathing Technologies' wide range of 3D Viral Barrier ultrasound probe covers are the highest quality product available for your infectious control needs. We are happy to provide you additional information about our products through our [free sample program](#).

Sheathing Technologies, Inc. is proud to be the market leader in product quality and patient safety – we've got you covered!

¹ McQuillan G, Kruszon-Moran D, Markowitz LE, Unger ER., Paulose-Ram R. Prevalence of HPV in adults aged 18–69: United States, 2011–2014. NCHS data brief, no 280. Hyattsville, MD: National Center for Health Statistics. 2017

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- ³ Casalegno JS, Le Bail Carval K, Eibach D. High risk HPV contamination of endocavity vaginal ultrasound probes: an underestimated route of nosocomial infection? PLoS ONE. 7(10):e48137. 2012.
- ⁴ M'Zali F, Bounizra C, Leroy S, Mekki Y, Quentin-Noury C, Kann M. Persistence of Microbial Contamination on Transvaginal Ultrasound Probes despite Low-Level Disinfection Procedure. PLoS ONE. 9(4):e93368-. 2014.
- ⁵ Ma STC, Yeung AC, Chan PKS, Graham CA. Transvaginal ultrasound probe contamination by the human papillomavirus in the emergency department. Emerg Med J. 30(6):472-475. 2013.
- ⁶ Centers for Disease Control and Prevention Guideline for Disinfection and Sterilization in Healthcare Facilities, Page 19. Centers for Disease Control and Prevention website. http://www.cdc.gov/hicpac/pdf/guidelines/Disinfection_Nov_2008.pdf Updated November, 2008. Accessed November 11, 2016.
- ⁷ AIUM practice guideline for ultrasonography in reproductive medicine. Journal of ultrasound in medicine : official journal of the American Institute of Ultrasound in Medicine. 28(1):128-37. 2009.
- ⁸ Guidance for Industry and FDA Staff: Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers, Sections 1.7.4.1, 1.8.1.6, and Appendix D. US Food and Drug Administration website. <http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm070911.pdf>. Updated September 9, 2008. Accessed November 10, 2016.
- ⁹ Guidance for Industry - Device Licence Applications for Ultrasound Diagnostic Systems and Transducers, Section 3.2.1. Health Canada website. http://www.hc-sc.gc.ca/dhp-mps/alt_formats/pdf/md-im/applic-demande/guide-ld/ultrasound_ultrasons-eng.pdf. Updated July 06, 2005. Accessed November 10, 2016.
- ¹⁰ Roden RB, Lowy DR, Schiller JT. Papillomavirus is resistant to desiccation. The Journal of Infectious Diseases. 176(4):1076-9. 1997.
- ¹¹ Ryndock E, Robison R, Meyers C. Susceptibility of HPV16 and 18 to high level disinfectants indicated for semi-critical ultrasound probes. Journal of Medical Virology. 88(6):1076-80. 2016.
- ¹² Merz E. Is Transducer Hygiene sufficient when Vaginal Probes are used in the Clinical Routine? Ultraschall in der Medizin (Stuttgart, Germany : 1980). 37(2):137-9. 2016.
- ¹³ Meyers J, Ryndock E, Conway MJ, Meyers C, Robison R. Susceptibility of high-risk human papillomavirus type 16 to clinical disinfectants. The Journal of Antimicrobial Chemotherapy. 69(6):1546-50. 2014.
- ¹⁴ K103059, 501(k) Summary. US Food and Drug Administration website. https://www.accessdata.fda.gov/cdrh_docs/pdf10/K103059.pdf. Updated February 24, 2011. Accessed November 10, 2016.
- ¹⁵ Viral Barrier Information. Sheathing Technologies, Inc. Website. <http://www.sheathes.com/pdfs/Viral-Barrier-Letter.pdf> Updated March 4, 2016. Accessed March 4, 2016.