



ANNOUNCEMENT:

As of March 4th, 2016, Sheathing Technologies has received clearance from the US FDA for **the world's only FDA-cleared Viral Barrier Ultrasound Probe Cover**: 510(k) K153212. (See FDA-Cleared Labeling, below.)

Sheathing Technologies's 3D seamless custom-blended polyurethane probe covers were extensively tested with the world's smallest testable virus, Minute Mouse Virus, which is a spherical virus 20nm in diameter. Based on this testing, our probe covers are FDA cleared as providing a barrier to *all bacteria* and to *all currently known human viruses*, including:

- HPV (Human Papillomavirus): 40nm in diameter
- HIV (Human Immunodeficiency Virus): 120nm in diameter
- Hepatitis A, B, C, D, E, F and G: 27nm – 100nm in diameter
- Norovirus: 23nm – 40nm in diameter
- All other currently known human viruses and bacteria.

The viral barrier test, which the FDA helped Sheathing Technologies develop, is a significant improvement over the viral barrier tests used by other devices (including condoms), which are tested using the significantly less expensive bacteriophage phi-X 174. Phi-X 174 is 27 nanometers in diameter, and tests using this virus provide no guarantee against known human viruses which are smaller than this.

Sheathing Technologies products have a lower average defect rate (< 0.4 %) than our competitors in the ultrasound probe cover market, which have been tested in independent studies as having an average leakage rate varying from 2.3% to 65% (see References). Our requirement for a low defect rate means that we were already meeting the same leakage standard required of latex condoms—one of the most heavily regulated and extensively tested medical devices sold in the United States. With our new 3D seamless product, we have a first-in-class Viral Barrier that *exceeds* even the barrier standards for condoms.

Sheathing Technologies 3D Ultrasound Probe Covers are the best and safest product available for your Infectious Control needs. Here at Sheathing Technologies, we are proud to be the market leader in product quality and patient safety.

Our Viral Barrier probe covers are available in all of our product lines, including Vaginal, Abdominal, Extended Field, and Small Parts.

Lawrence Polayes
CEO
Sheathing Technologies, Inc.

FDA-Cleared Labeling:

Viral Barrier* 3D Seamless Polyurethane Ultrasound Probe Covers

*In vitro testing shows that the probe cover provides a viral barrier from viruses 20 nm in diameter or larger while the probe cover remains intact without leakage.

References:

Casalegno J, Le Bail Carval K, et al. (2012). "High Risk HPV Contamination of Endocavity Vaginal Ultrasound Probes: An Underestimated Route of Nosocomial Infection?" PLoS One 7(10): e48137.

Hignett M, Claman P. (1995). "High Rates of Perforation Are Found in Endovaginal Ultrasound Probe Covers Before and After Oocyte Retrieval for in Vitro Fertilization- Embryo Transfer" J Assist Reprod Genet. Oct; 12(9): 606-609.

Kac G, Podglajen I, et al. (2010). "Evaluation of Ultraviolet C for Disinfection of Endocavitary Ultrasound Transducers Persistently Contaminated despite Probe Covers" Infect Control Hosp Epidemiol 31: 165-170.

Rooks V, Yancey M, et al. (1996). "Comparison of Probe Sheaths for Endovaginal Sonography" Obstet Gynecol 87: 27-9.

SHEATHING TECHNOLOGIES, INC.
18431 TECHNOLOGY DRIVE, MORGAN HILL, CA 95037, USA
PHONE: 800-873-3776 FAX: 877-244-5048
WEBSITE: <http://www.sheathes.com> E-MAIL: info@sheathes.com