THE IMPORTANCE OF HIGH-LEVEL DISINFECTION ON TRANSVAGINAL ULTRASOUND (TVUS) PROBES

WHAT ARE TVUS PROBES?

TVUS probes are pelvic ultrasound devices that use high-frequency sound waves for the creation of images.[1] TVUS probes enable examinations of female reproductive organs such as the vagina, cervix, uterus, fallopian tubes, and ovaries, helping to identify and diagnose conditions.[1] TVUS examinations are internal and involve inserting the probe into the vaginal canal.[1]

WHY DO TVUS PROBES REQUIRE HIGH-LEVEL DISINFECTION?

1. Infection Control Guideline Endorsement

When recommending methods of disinfection or sterilization, infection control guidelines follow the Spaulding classification.The classification is based on the infection risk to patients taking into account the intended use of the device.[2] When entering the patient, TVUS probes contact the intact mucous membrane of the cervix and vaginal wall. Therefore, regulatory bodies recommend high-level disinfection of TVUS probes after use based on the Spaulding classification (Table 1.).[2]

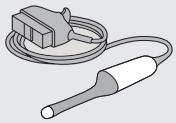
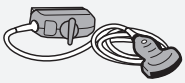
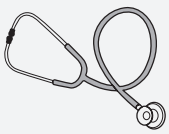
CATEGORY	DEVICE APPLICATION		REQUIRED LEVEL OF DISINFECTION	CAN BE USED ON TVUS PROBES
CRITICAL	Contact with the bloodstream or sterile tissues.	 Surgical instruments, e.g. scalpels, tweezers, scissors, kidney dishes and clamps.	**Sterilization** Eliminates all forms of microbial life.	✗ **Heat/Chemical sterilization removes, kills, or deactivates all microorganisms. However, it should not be used on heat-sensitive devices such as a TVUS probe.**
SEMI-CRITICAL	Contact with mucous membranes or non-intact skin.	 Endoscopes and endocavity ultrasound probes.	**High-Level Disinfection** Destroys all vegetative microorganisms, mycobacteria, enveloped and non-enveloped viruses, fungal spores and some bacterial spores.	✓ **Provides the correct level of disinfection for TVUS probes.**
NON-CRITICAL	Contact with intact skin.	 Abdominal ultrasound probes.  Stethoscopes and blood pressure cuffs.	**Intermediate-Level Disinfection** Destroys mycobacteria, most viruses, most fungi and bacteria. **Low-Level Disinfection** Destroys most bacteria, some viruses and some fungi.	✗ **Does not provide sufficient disinfection for TVUS probes.** ✗ **Does not provide sufficient disinfection for TVUS probes.**

TABLE 1. THE SPAULDING CLASSIFICATION[2]

2. Micro Perforation & Probe Cover Leakage Risks

The use of probe covers is endorsed by global guidelines to minimize contamination when performing TVUS procedures.[3–12] Contamination can still occur from micro perforations, partial and complete breaks of the cover during use, or incorrect placement of the cover on the probe (see Figure 1). **Some commercially produced ultrasound probe covers have unacceptably high leakage rates of up to 81%,** and are not a reliable barrier against infectious agents, particularly viruses.[13]

Contamination can remain even when a TVUS probe is covered and disinfected with an intermediate or low-level disinfectant.[14–17] If a TVUS probe is insufficiently disinfected in between patient use, or the cover was damaged/incorrectly placed (see Figure 1), nosocomial transmission can occur from patient to patient, or from patient to healthcare worker. The use of disinfectants with insufficient efficacy on medical devices will not reduce the contamination to a safe level. **Pathogens can also persist for prolonged periods if a surface or device is not sufficiently disinfected.**[5] For example, Human Papillomavirus (HPV) can survive on surfaces for up to **seven days**.[18]

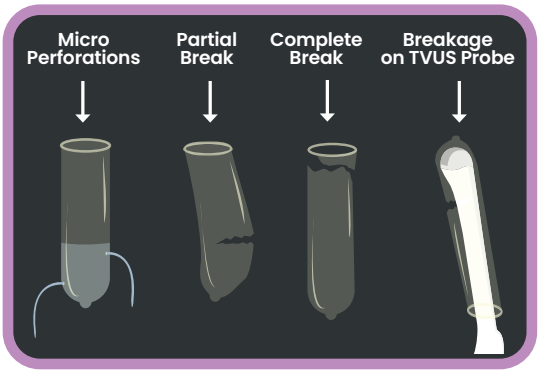


FIGURE 1. MICRO PERFORATION & PROBE COVER LEAKAGE

3. TVUS Probe Cable and Plug Contamination

TVUS probe components (Figure 2) at risk of blood and microbial contamination include:

- the insertion shaft, which enters the patient[20,21]
- the handle of the device[20,21]
- the probe holder

High-level disinfection will prevent the spread of harmful pathogens from one patient to another while also safeguarding healthcare professionals during procedures. Some automated disinfection units are only capable of disinfecting the insertion shaft and handle of the TVUS probe. Tristel ULT offers high-level disinfection for the TVUS probe.

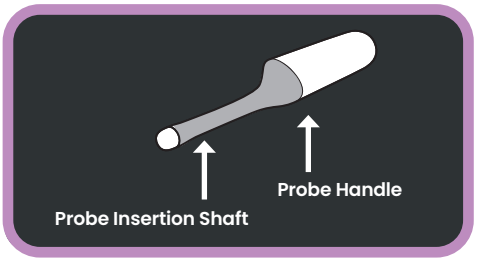


FIGURE 2. COMPONENTS OF A STANDARD TVUS PROBE

4. Risk of Bacterial Spores from the Environment

Bacterial spores such as *Bacillus subtilis* are common environmental contaminants.[22] TVUS probes are not required to be stored or decontaminated in a sterile area, which could cause the devices to become recontaminated. Bacterial spores are considered the most resistant microorganisms to disinfectants (Figure 3) and sterilization is needed to destroy high levels of spores. The high temperatures and harsh chemicals used during sterilization can cause damage to the probe, therefore an alternative method of high-level disinfection should be used.

MOST RESISTANT TO DISINFECTANTS

BACTERIAL SPORES	***Bacillus subtilis, Clostridioides difficile***
PROTOZOAN CYSTS	***Coccidia***
MYCOBACTERIA	*Mycobaterium tuberculosis*
NON-ENVELOPED VIRUSES	**Poliovirus, Norovirus**
FUNGI	***Candida* spp., *Aspergillus* spp.,**
VEGITATIVE BACTERIA	***Pseudomonas aeruginosa***
ENVELOPED VIRUSES	**Coronavirus**

LEAST RESISTANT TO DISINFECTANTS

FIGURE 3. RESISTANCE OF MICROORGANISMS TO DISINFECTANTS. ADAPTED FROM CENTERS FOR DISEASE CONTROL AND PREVENTION (2008)[2]

CLINICAL COMPLIANCE AND INFECTION PREVENTION FOR TRANSVAGINAL ULTRASOUND (TVUS) REPROCESSING

Evolving Standards & Regulatory Alignment

In alignment with evolving standards, **chlorine dioxide** has been incorporated into the American National Standard for chemical sterilization and high-level disinfection in healthcare facilities **(ANSI/AAMI ST58:2024)**, supporting its use within regulated reprocessing workflows.[24] According to AAMI, adopting and implementing ST58 will be critical for preventing healthcare-associated infections (HAIs).

The updated standard mirrors a 2024 update of guidelines from the **World Federation for Ultrasound in Medicine** and Biology, which included chlorine dioxide in its instructions for the cleaning and disinfection of endocavitary ultrasound probes.[26]

In 2025, The **American Institute for Ultrasound in Medicine (AIUM)** revised its guidelines to reaffirm transvaginal ultrasound **(TVUS) probes require high-level disinfection (HLD) after every patient use**. This requirement applies regardless of the use of single-use probe covers, as TVUS probes are classified as **semi-critical devices** due to their contact with mucous membranes. Routine HLD is therefore required to mitigate the risk of cross-contamination and HAIs. The 2025 AIUM update further recognizes chlorine dioxide–based systems as an acceptable point-of-care HLD method for ultrasound probe reprocessing.[27]

Evidence-Based Risk Considerations: HPV and Disinfection Efficacy

Common high-risk human papillomavirus (HPV) types include HPV 16 and HPV 18, which are responsible for approximately 70% of cervical cancer cases.[14] These strains have demonstrated resistance to several FDA-cleared high-level disinfectants, including glutaraldehyde and ortho-phthalaldehyde.[i-iii]

Supporting these concerns, Casalegno et al[15] stated that a considerable number of endocavitary transducers are infected with high-risk HPV despite low-level disinfection (LLD) and recommend that endocavitary transducers should be high-level disinfected (2.5% of transducers showed high-risk HPV after use and 1.8% before use; n = 198).

The **Society for Maternal-Fetal Medicine (SMFM)** in 2020 published patient safety guideline aimed at reducing the risk infection transmission during TVUS examinations. The recommendations include:

- The application of single-use sterile probe covers for every TVUS examination.[13]
- The use of sterile single-use ultrasound gel packets.[13]
- Cleaning, i.e. the removal of gross contamination like gel and debris which can reduce disinfectant efficacy, on TVUS probes after each examination.[13]
- **High-level disinfection using an agent with proven efficacy against HPV.[13]**

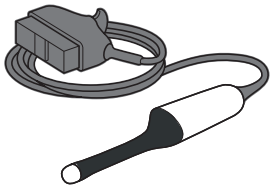
Evidence for Chlorine Dioxide–Based HLD

Tristel ULT is a high-level, FDA-cleared disinfectant that has been tested for efficacy **against mycobacteria, viruses, fungi, and bacteria** with a **2-minute contact time**. Tristel ULT has demonstrated efficacy against **HPV types 16 and 18** and is effective against a broad spectrum of clinically relevant pathogens,[28] including:

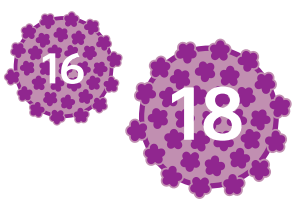
- *Chlamydia trachomatis*
- *Neisseria gonorrhoeae*
- Carbapenem-resistant *Klebsiella pneumoniae (CRKP)*
- ESBL-producing *Escherichia coli*
- *Streptococcus agalactiae*
- *Candida albicans*
- Duck Hepatitis B Virus (DHBV)
- Human Immunodeficiency Virus (HIV)

In addition, Tristel ULT has demonstrated the ability to **inactivate bacterial spores** (*Bacillus subtilis, Clostridium sporogenes*) in accordance with FDA requirements and in alignment with AOAC 966.04[28] test standards. For a full summary of testing and Microbiological Efficacy, scan QR code.

Tested On Probes Without Probe Covers



Tested On HPV Types 16 And 18, The Cause Of 70 Of Cervical Cancers[14]



Proven Effective In 2-Minute Contact Time

Scan here to download a full summary of Microbiological Efficacy for Tristel ULT.

Tristel ULT™

In North America chlorine dioxide–based HLD technology is available under the brand name Tristel ULT™, manufactured and distributed by Parker Laboratories through an exclusive partnership with UK-based Tristel. Tristel ULT has been approved for use in more than 40 countries since 2008 and is currently the only FDA-cleared chlorine dioxide foam disinfectant for ultrasound probes.

Tristel ULT is the product name in North America for Tristel chlorine dioxide high-level disinfectant foam for ultrasound probes. Outside of North America, Tristel chlorine dioxide high-level disinfectant foam for ultrasound probes is marketed under the brand names Tristel Duo for Ultrasound or Tristel Duo ULT. The products are chemically identical, and the listing on OEM documents for Tristel Duo ULT is applicable to Tristel ULT.

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