Simplifying High-Level Disinfection for Urological Procedures: A Case Study

A novel method for high-level disinfection achieves faster, simpler endocavitary probe processing for busy urology practices

Matthew Allaway, M.D.
Urologist, Urology Associates, Founder and CEO, Perineologic®, Cumberland, MD

EXECUTIVE SUMMARY

In a busy urology practice, numerous bottlenecks can impact workflow. One of the most time-consuming tasks is reprocessing medical devices between procedures. Endocavitary ultrasound probes, which are widely used for screening, diagnosis, and treatment of urological conditions, require high-level disinfection (HLD) after each use to prevent the spread of infection. Traditional methods of HLD use harsh germicidal agents that can damage probes and require complex workflows limiting the number of procedures clinicians can perform during a typical workday.

The Food and Drug Administration (FDA) has recently granted De Novo clearance for a new category of Class II devices with the generic name 'foam or gel chemical sterilant/high-level disinfectant,' as an alternative to such conventional germicidal soaks and gaseous treatments. Marketed in the United States as Tristel™ ULT, the first of these newly cleared disinfectants uses a proprietary foam containing chlorine dioxide, which has been shown to be effective against pathogens ranging from Human papillomavirus (HPV) type 16 and type 18 to *Mycobacterium terrae*.

As a practicing urologist and founder of Perineologic®, I am committed to delivering safe, precise, and efficient care for patients with urological disorders. We developed the PrecisionPoint® transperineal biopsy technology to address infection risk associated with prostate biopsy. More than 260,000 men have been treated with this approach and it is quickly becoming the new standard of care. In early 2024, we added Tristel ULT to our armamentarium. Adopting Tristel ULT has enabled us to better allocate the clinic staff's time to patient care. As a result, we have increased the number of life-saving procedures we can perform during a typical workday. These efficiencies have improved the overall efficiency of our practice and reduced unnecessary costs and waste. Drawing upon our experience, the goal of this case study is to review unmet needs with conventional high-level disinfectants and to illustrate how Tristel ULT can potentially transform endocavitary ultrasound probe reprocessing and maintenance in a typical urology practice.

INTRODUCTION

Medical devices are ubiquitous in today's healthcare settings and proper reprocessing is critical for protecting patients and practitioners against the transmission of infectious diseases. Ultrasound probes are reusable medical devices widely used in the screening, diagnosis, and treatment of urological conditions. Many procedures are performed using transrectal ultrasound (TRUS) guidance,

Tristel ULT

Tristel ULT is approved in more than 35 countries for high-level disinfection of surface and endocavitary ultrasound probes. Chlorine dioxide, the active ingredient in Tristel ULT, is an oxidizing biocide that penetrates the cell wall and inhibits protein synthesis. Chlorine dioxide has been successfully used in Europe for more than 25 years and has demonstrated efficacy against dormant organisms and spores.

Within 2 minutes of application, Tristel ULT has demonstrated efficacy against:

- ***Chlamydia trachomatis***
- ***Neisseria gonorrhoeae***
- **Carbapenem resistant *Klebsiella pneumoniae* (CRKP)**
- **Extended-spectrum beta-lactamase (ESBL) producing Escherichia coli**
- ***Streptococcus agalactiae***
- ***Candida albicans***
- **Human immunodeficiency virus (HIV) type 1**
- **Hepatitis B virus surrogate duck hepatitis B virus**
- **Human papillomavirus type 16 (HPV16) and type 18 (HPV18)**
- **C.difficile**

Unlike conventional germicidal agents, HLD with Tristel ULT does not require specialized equipment, plumbing, or electricity and can be performed at the point of use. Its substantially faster reprocessing time allows for high throughput—more procedures can be performed in less time compared to conventional disinfection methods.

To learn more about Tristel ULT, visit: https://www.parkerlabs.com/products/tristel-ult/

making the TRUS probe one of the most important tools in standard urology practice. For example, TRUS is used to position perirectal spacers which are deposited between the rectal wall and the prostate before radiation therapy to protect the rectum from radiation exposure.[1] TRUS is also used to place fiducial markers which are used to monitor prostate position and volume in patients receiving treatment for prostate cancer.[2] Brachytherapy is another common procedure utilizing TRUS to place radioactive seeds within the prostate to treat the cancer.[3]

Prostate biopsies are another common procedure performed in the urology clinic using TRUS. Ninety-nine percent of prostate biopsies are conducted transrectally.[4] Each year, over 2 million transrectal (TR) biopsies are performed in North America and Europe.[5] With traditional TR biopsy, a TRUS probe is introduced into the rectum to guide the biopsy needle, which is also introduced into the rectum. Despite a patient's bowel preparation, the biopsy needle may come into contact with fecal material that can be passed through the rectum into the prostate, which is a sterile and highly vascular organ. When this occurs, the patient may be exposed to infection and life-threatening sepsis. Current data estimates that 3% to 5% of patients who undergo TR biopsy are readmitted for infection, representing a major public health concern.[6,7]

A re-emerging procedural innovation, transperineal (TP) prostate biopsy also utilizes a TRUS; however, the biopsy needle is inserted through the perineum (see sidebar). The potential for fecal contamination is very low since the biopsy needle is not introduced into the rectum or passed through the rectal wall. Available evidence demonstrates rates of reported post-TP infection and sepsis are significantly reduced, ranging between 0% and 2%.[8–12] Although the potential for infection is reduced by sampling through the perineum rather than the rectum, the TRUS probe needs to be high-level disinfected after each use to prevent transmission of infections.

CHALLENGES IN UROLOGICAL PROBE DISINFECTION

Current guidelines for reprocessing ultrasound probes, such as TRUS probes, require high-level disinfection (HLD) after each use to prevent the spread of infection.[13,14] By definition, HLD eliminates all microorganisms, except a large number of bacterial endospores. Repeated use of harsh disinfectants can result in significant damage to ultrasound probes, shortening their lifespan.[15,16] While efficacy and compatibility with devices are key considerations when selecting the most appropriate method for HLD, the cost, safety for the user, time, additional equipment requirements (e.g., air extraction, plumbing) and labor required for disinfection are also important considerations.

In the past, FDA has cleared several chemical agents for performing HLD. These include glutaraldehyde, hydrogen peroxide, hypochlorite and hypochlorous acid, ortho-phthaldehyde, and peracetic acid (see Table 1).[15] HLD using these conventional methods can be time-consuming and costly because of long contact times for disinfection, extensive protocols for concentration testing and rinsing, transportation to and from a centralized reprocessing room, and the need to inspect the device for leaks before each disinfection.[14]

Most high-level disinfectants require specialized equipment and annual preventative maintenance, which can be expensive. Automated probe reprocessors have been shown to consistently achieve HLD with a low degree of variability.[17] Although these closed-system chambers are expensive and can be damaging, many urology practices had to opt for automated HLD methods because of the lack of an alternative. However, due to their size, some TRUS probes will not fit inside the automated chamber and are not compatible with the existing automated reprocessor, forcing the clinic to work with open soak HLD options. Such solutions require specific health and safety assessments and procedures for fume extraction, waste management and operator personal protection.

The contact time for these conventional HLDs can be several minutes to an hour, which is not conducive for busy clinics. It limits the number of procedures that can be performed or requires a prohibitive level of investment in numerous ultrasound probes.

Active Ingredients/Range of Available Concentrations	High-Level Disinfectant Contact Conditions		
	Contact time range (min)	Required temperature range (°C)	Method
Glutaraldehyde (2.4%–3.4%)	5–90	20–37.8	Manual or automated soak
Glutaraldehyde (3.4%), isopropanol (20.1–26%)	5–10	25	
Glutaraldehyde (1.12%), phenol/phenate (1.93%)	20	25	
Hydrogen peroxide (2.0–7.5%)	8–30	20	
Hydrogen peroxide (1.0%–7.35%), peracetic acid (0.08%–0.23%)	15–25	20	
Hypochlorite and hypochlorous acid (400–675 ppm active free chlorine)	10	25–30	
Ortho-phthalaldehyde (0.55%–5.75%)	5–12	5–25	
Peracetic acid (3100–3800 ppm)	5–7	20–25	
Included in the November 30, 2023 update:			
Chlorine dioxide (320 ppm)	2	20	Manual application using proprietary wipes

Table 1. FDA-cleared high-level disinfectants.[15]

DISCOVERING TRISTEL ULT HIGH-LEVEL DISINFECTANT

Tristel ULT is a novel high-level disinfectant for surface and endocavitary ultrasound probes (see sidebar). Recently cleared for use in the United States and Canada, chlorine dioxide, the active ingredient in Tristel ULT, has been available in various formulations for more than 25 years in Europe.

My first encounter with Tristel ULT was in 2017 when I was visiting a large group of urologists in the United Kingdom who use the PrecisionPoint Transperineal Access System (see sidebar) and used Tristel ULT to HLD transrectal ultrasound probes. Unlike the harsh, time-consuming germicidal soaks used to disinfect TRUS probes, Tristel ULT is an effective, ready-to-use foam compatible with commercially available ultrasound probes and can be used at the site of care. Immediately, I saw how incorporating Tristel ULT could transform ultrasound probe reprocessing in our practice.

INTEGRATION OF TRISTEL ULT INTO PRACTICE

Nearly a decade after being introduced to Tristel ULT, it was approved for use in the United States. Shortly after, our clinics switched from manual aldehyde soaks to using Tristel ULT for HLD of our ultrasound probes. The most notable benefits of adopting Tristel ULT for us are:

A simplified workflow. HLD with Tristel ULT is less labor-intensive for the staff and does not require specialized training. As an additional benefit, Tristel provides access to a free training portal with educational videos on how to use the foam disinfectant. Tristel ULT is portable and is used without water or electricity, permitting disinfection at the site of care. This reduces the time the staff spends transporting the probe and eliminates the risk of dropping or damaging the ultrasound probe during transport to the reprocessing room.

PrecisionPoint Transperineal Access System

Transperineal (TP) biopsy has been used since the 1920s for the detection of prostate cancer. Since its inception, TP biopsy has been shown to have high detection accuracy and a low potential for infection. However, earlier versions of the technique were invasive and required general anesthesia and hospitalization.[5]

In the early 1980s, transrectal ultrasound (TRUS)-guided TP biopsy techniques were introduced, improving tissue sampling and cancer detection. While TRUS became the gold standard for prostate biopsy imaging, TP biopsy became nearly obsolete with the advent of TRUS-guided TR (TRUS-TR) biopsy in 1989. Compared to the TP biopsy techniques available at the time, TRUS-TR allowed for more systematic tissue sampling, higher diagnostic accuracy, and greater convenience.[5]

The resurgence of TP biopsy in recent years has been driven by the goal of reducing the potential for life-threatening infection and sepsis commonly associated with TRUS-TR biopsy. The free-hand technique is at the forefront of modern advances in TP biopsy and allows for more complete tissue collection without the need for a brachytherapy grid.

The PrecisionPoint Transperineal Access System is an FDA-cleared device used in conjunction with all cylindrical TRUS transducer probes for free-handed TP biopsy of the prostate. The PrecisionPoint system maximizes the cancer detection rate because it allows for sampling in all regions of the prostate, including difficult-to-access sites, through a single puncture of the skin under local anesthesia. Since the PrecisionPoint apparatus samples tissue through the perineum, the patient is not required to do a bowel prep or premedicated with antibiotics.

To learn more about the PrecisionPoint Transperineal Access System, visit: https://perineologic.com/precisionpoint/

Higher patient throughput. After cleaning the probe according to the manufacturer's instructions, the staff simply apply the Tristel foam disinfectant to a proprietary dry wipe and wipe the surface of the probe. HLD is achieved within 2 minutes of application and the probe is ready for use after a final wipe to remove any residue foam. Unlike traditional HLD methods, no additional rinsing or special equipment is required. The increased time efficiency afforded by substantially quicker reprocessing times means the care team can perform more procedures during a typical workday. Since implementing Tristel ULT, we perform 15 procedures per day with one ultrasound probe whereas previously we only managed 10.

Lower procedure costs. The highly advanced TRUS probes recommended for prostate biopsy cost between $15,000 to $36,000 per probe. Compared to conventional germicidal soaks, Tristel ULT provides effective HLD without harsh chemicals that can compromise the integrity of the probe. Maximizing the lifespan of expensive ultrasound probes results in less waste and more opportunities for use in life-saving procedures. At a cost per HLD procedure of $3.15, together with the simplified workflow and staff time saving, we have assessed Tristel ULT to be more cost-effective than our previous HLD method of manual soaking. In the three months of use we have saved $$$ and we expect the savings to be even higher over time.

A CHOICE OF MANUAL VS. AUTOMATED HIGH-LEVEL DISINFECTION

When choosing between manual and automated HLD options, there is often concern manual disinfection is less effective, highly variable, and inherently more prone to human error. However, no studies have demonstrated manual application of Tristel ULT is less effective than automated systems. FDA clearance indicates the Tristel ULT is considered safe and effective for achieving HLD of ultrasound probes, eliminating this concern.

DOCUMENTATION AND COMPLIANCE

Current guidelines recommend written documentation of ultrasound probe HLD after every use.[18] Maintaining an HLD log ensures procedures for HLD have been met, and establishes traceability and accountability in the event of a reprocessing failure. It is best practice to have a single standardized method to collect such records. Tristel's 3T Track and Trace app makes it easier to establish traceability and accountability when using Tristel ULT for HLD of endocavitary ultrasound probes. The Tristel 3T is free of charge and easy to implement.

CONCLUSION AND RECOMMENDATIONS

Ultrasound-guided technology is an indispensable tool used to screen, diagnose, and treat urological conditions. To achieve the highest level of quality imaging, which is critical for life-saving procedures such as prostate biopsy, the integrity of the ultrasound probe must be protected. The wear and tear that currently exists with conventional HLD techniques diminishes the lifespan of the ultrasound probe and results in unnecessary costs and waste. Lengthy reprocessing times reduce the availability of an ultrasound probe and limit patient throughput.

Tristel ULT is a novel manual high-level disinfectant with the potential to transform ultrasound probe reprocessing. Integrating this ready-to-use foam provides effective HLD while substantially reducing reprocessing time and maximizing the lifespan of the probe. Protecting your investment—the ultrasound probe—and increasing time efficiency enables clinicians to perform more procedures to improve patient outcomes.

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