Infection Prevention and Control

IPAC Procedure	Standard Process for Cleaning and High-Level Disinfection (HLD) of Re-Usable Ophthalmic Medical Devices using Tristel™ Duo OPH
Date	September 11, 2024
Reviewed Date	N/A
Revised Date	N/A

Site Applicability

All Vancouver Coastal Health (VCH) sites that process ophthalmic devices at the point-of-care (POC), outside the Medical Device Processing Department (MDRD).

Scope

All staff and medical staff that are directly responsible for cleaning and disinfecting ophthalmic medical devices.

Purpose

To prevent patient-to-patient transmission of pathogens on re-usable ocular devices by:

1. Providing consistent, evidence-based cleaning and HLD of re-usable ocular devices that come into contact with the surface of the eye; and
2. Describing a point-of-care (POC) HLD process using Tristel™ products for implementation in ophthalmology and optometry clinics/settings.

Training and Education Requirements

Training, education and competency for staff will include:

1. Review of IPAC Procedure: Standard Process for Cleaning and HLD of Re-Usable Ophthalmic Medical Devices using Tristel™ Duo OPH.
2. Attend program-based education and training.
3. Complete on-line training by logging onto the provided training platform, Tristel 3T (https://3t.app/) Start by registering on Tristel 3T using the appropriate link for your site:
    a. Downtown Eastside Eye Clinic (DEEC)
    b. Eye Care Centre at Vancouver General Hospital
4. Annual re-certification of competency is required and can be completed by repeating the training provided in the portal.

Workflow

1. Provide a space and process that supports HLD of ophthalmic medical devices at the POC.
2. Provide access to hand hygiene infrastructure, such as Alcohol-Based Hand Rub (ABHR) or a dedicated hand hygiene sink.
3. Provide access to personal protective equipment (PPE), including gloves and facial protection.
4. Create a workflow that supports clear separation between clean and contaminated devices.

5. Create a one-way workflow that supports reprocessing of devices following a dirty to clean workflow.

Required Products

Product	Description	PeopleSoft Item ID
Tristel™ Clean	Ready to use, triple enzymatic foam for cleaning ocular devices.	VCHA # 00146064
Tristel™ Duo Wipes	Ready to use, non-woven, low lint, low-absorbing soft dry wipes designed for compatibility with Tristel™ solutions and ocular device surfaces.	VCHA # 00146065
Tristel™ Duo OPH	Ready to use, chlorine dioxide based HLD foam for use on cleaned, reusable, non-lumened, semi-critical devices used in ophthalmology.	VCHA # 00144003
Tristel™ Rinse Wipes	Read to use, sterile, deionized water wipes to remove excess disinfectant from ocular medical devices.	VCHA # 00146063

Procedure

Tristel™ Duo OPH is a chlorine dioxide based foam designed to provide high-level disinfection of medical devices used in ophthalmology such as diagnostic lenses, tonometer prisms, slit lamps, pachymeters, and A-scan and B-scan biometry probes.

In a uniform contact time of 2 minutes, Tristel™ Duo OPH is mycobacterial, virucidal, fungicidal and bactericidal and is effective against a wide range of common pathogens including Adenovirus, *Acanthamoeba castellanii* and MRSA.

Tristel™ Duo OPH is accompanied by various supporting Tristel™ products to create a complete ophthalmic device decontamination process:

- **Tristel™ Duo Wipes:** When using a dry wipe in your decontamination process, it is essential that the wipe is made of a soft, durable, low-linting material to reduce the risk of leaving scratches and lint build-up on medical devices. Duo Wipes are designed to apply Tristel™ Clean and Tristel™ Duo OPH foam to the medical device with the above requirements in mind, as well as being low absorbing to ensure maximal foam distribution.
- **Tristel™ Clean:** To ensure the success of the high-level disinfection step, blood, other bodily fluids, gels, and lubricants must be thoroughly cleaned from the surfaces of medical devices beforehand. Tristel™ Clean is a triple-enzyme foam designed for the cleaning of medical devices. When using Tristel™ Clean, no intermediate rinsing is required when using Tristel™ Duo OPH for high-level disinfection.
- **Tristel™ Rinse Wipes:** For patient safety, residual disinfectant solution must be removed from the medical device. Tristel™ Rinse Wipes are sterile wipes impregnated with deionized water, designed

specifically to remove excess disinfectant from a medical device. One rinse is required to remove Tristel™ Duo OPH residues unless more rinse cycles are specified by the device manufacturer.

Considerations and Set Up:

1. HLD of ophthalmic medical devices must be performed in the following situations:
    a. A new re-usable ophthalmic device has been brought into service.
    b. When a re-usable ophthalmic device touches the surface of the eye.
    c. After every client/patient use.
    d. If the device has become contaminated during use.
2. Complete all required sequential steps as outlined in this IPAC Procedure to ensure appropriate cleaning and HLD of devices is achieved.
3. Inspect all devices for signs of damage or defect. If the device is damaged, remove from use immediately. Label the device as contaminated and requiring repair or replacement.
4. Inspect all products associated with the decontamination process. Do not use the product if there is any visible damage.
5. Check the expiry date on each product. If the expiry date has elapsed, do not use the product.
6. Follow these steps when opening a new bottle of Tristel™ Clean:
    a. Perform hand hygiene.
    b. Remove the security cap from the bottle and prime the bottle in preparation for first use. To prime Tristel™ Clean, depress the pump two (2) to four (4) times. Dispensed foam can be flushed with water to drain or contained on a wipe and disposed in regular waste streams.
7. Follow these steps when opening a new bottle of Tristel™ Duo OPH:
    a. Perform hand hygiene and don appropriate PPE.
    b. Remove the security cap from the bottle and depress the pump four (4) times to prime the bottle. Dispensed foam can be flushed with water to drain or contained in a wipe and disposed in regular waste streams.
    c. Record the date the bottle is first used (e.g., opened), and the “Use by Date” in the designated area on the front label of the bottle.
        i. The “Use by Date” is the date 6 months after opening. Check that the “Use by Date” does not extend past the expiration date.
        ii. The “Expiration Date” is printed on the Tristel™ Duo OPH label. If the 6 months from opening extends beyond the expiration date, record the expiration date as the “Use by Date” field on the label.

Setting Up Reprocessing Area:

1. Perform hand hygiene.
2. Clean and disinfect all surfaces where reprocessing will occur, using VCH approved cleaning/disinfecting wipes.
3. Designate and clearly label bins that will house ocular devices:
    a. Bin for soiled/contaminated devices
    b. Bin for storage of cleaned reprocessed devices.

4. Blue pads or paper towel.
5. Have appropriate PPE (e.g., gloves and eye protection) stored near reprocessing area.

Directions for Use:
Cleaning using Tristel™ Clean and Tristel™ Duo Wipes:
1. Perform hand hygiene and don PPE.
2. Clean ocular devices within one hour of use to prevent drying of gross soil.
3. Dispense Tristel™ Clean onto a dry Duo Wipe.
4. Use enough foam to cover the entire surface of the device and wipe until visibly clean. Use additional foam and wipes as needed.
5. Once the device is visibly clean, it is ready for HLD.
6. Place the cleaned ocular device onto designated areas (e.g., blue pad, paper towel) in preparation for the next step.
7. Follow steps 1-6, if processing multiple devices simultaneously.
8. Discard used cleaning wipes into regular waste streams.

HLD of Ophthalmic Devices:
1. Place Tristel™ Duo Wipe in our gloved hand.
2. Place the clean ocular device on top of the wipe in your hand.
3. Dispense 3 aliquots of Tristel™ Duo OPH directly onto the device, regardless of the size of the ophthalmic device.
4. Use the wipe to spread the foam over the surface of the device and ensure all areas are covered.
5. Place the device into the clean bin.
6. Wait 2 minutes to achieve HLD. Use a timer to ensure contact time of 2 minutes is observed.
7. Doff gloves and perform hand hygiene.

Rinsing Ocular Devices:
1. Perform hand hygiene and don new gloves.
2. Place Tristel™ Rinse Wipe in your hand.
3. Wipe the entire surface of the device so all the Tristel™ Duo OPH residue is removed.
4. Place the device into the clean bin and allow to thoroughly air dry (approximately 1 minute).
5. Doff gloves and perform hand hygiene.
6. Doff PPE.
7. Once devices have air dried, use clean hands to transfer all devices to clean, non-porous storage containers.

Documentation and Traceability:
Use the VCH Point-of-Care HLD Tracking Sheet (Appendix A) to document the process and traceability information including:
1. Lot Number.
2. In-Use Expiry Date.

3. ID of person who re-processed the device(s).

Associated Documents

Tristel™ Duo OPH Compatibility Chart
Tristel™ Duo OPH HLD Foam for Ophthalmic Medical Devices - Brochure
Tristel™ Clean – User Guide
Tristel™ Duo OPH HLD Foam for Semi-Critical Medical Devices use in Ophthalmology – User Guide
Tristel™ Rinse Wipe – User Guide
Tristel™ Duo OPH HLD Foam for Reusable Tonometer Prisms – Wall Poster
Tristel™ Duo OPH HLD Foam for Reusable Diagnostic Contact Lenses – Wall Poster
Tristel™ Duo OPH HLD Foam for Ophthalmic Ultrasound Probes – Wall Poster

Definitions

Cleaning: The physical removal of foreign material (e.g., dust, soil) and organic material (e.g. blood, secretions, excretions, microorganisms). Cleaning physically removes rather than kills microorganisms. It is accomplished with water, detergents, and mechanical action. Cleaning must be performed before high level disinfection or sterilization.

Disinfectant: A chemical agent that kills most disease-producing microorganism, but not necessarily bacterial spores. Disinfectants are applied only to inanimate objects. Some products combine a cleaner with a disinfectant.

Enzymatic Cleaner: A cleaning agent that contains enzymes with break down proteins such as blood, body fluids, secretion and excretions from surfaces and equipment. Most enzymatic cleaners also contain a detergent. Enzymatic cleaners are used to loosen and dissolve organic substances.

High-Level Disinfection (HLD): A process capable of killing vegetative bacteria, mycobacteria including Mycobacterium tuberculosis, fungi, and lipid and non-lipid viruses, as well as some, but not necessarily high numbers of bacterial spores. High-level disinfection is the minimum level of disinfection required for semi-critical medical devices. Medical devices shall be thoroughly cleaned prior to high-level disinfection.

Manufacturer's Instructions for use (MIFU): The written directions provided by the manufacturer or distributor of a product that contain the necessary information of the safe and effective use of the product.

Medical Device: Any instrument, apparatus, appliance, material, or other article, whether used alone or in combination, intended by the manufacturer to be used for human beings for the purpose of diagnosis, prevention, monitoring, treatment or alleviation of disease, injury, handicap, investigation, replacement, or modification of the anatomy or of a physiological process, or control of conception.

One-Way Workflow: The practice of ensuring that reprocessing work flows in one direction from the dirtiest to the cleanest to prevent contamination.

Personal Protective Equipment (PPE): Special clothing or equipment worn by staff for protection against hazards.

Reprocessing: The steps performed to prepared used medical devices for reuse (e.g. cleaning, disinfection, sterilization).

Reusable: A term given the manufacturer of medical devices that allows it, through the selection of materials and/or components, to be re-used.

Semi-Critical Medical Devices: Medical device(s) that come in contact with non-intact skin or mucous membranes but ordinarily does not penetrate them (e.g., respiratory equipment, transrectal probes, specula). Reprocessing semi-critical devices involves meticulous cleaning followed by, at a minimum, high-level disinfection.

References

1. Alberta Health Services Best Practice Recommendation (2023). Point-of-care High-Level Disinfection for Reusable Ocular Devices that Contact the Surface of the Eye.

2. BC Ministry of Health (2011). Best Practice Guidelines for Cleaning, Disinfection and Sterilization of Critical and Semi-Critical Medical Devices.

3. Health Canada (2018). Guidance Document: Safety and Effectiveness Requirement for High-Level Disinfectants and Sterilants for use on Reusable Semi-Critical and Critical Medical Devices.

Appendix A

Point-of-Care High-Level Disinfection Tracking Sheet						
Clinic Name:						
Date:	**Equipment:**	**Tristel™ Duo OPH Lot Number:**	**Tristel™ Duo OPH Bottle Expiry:**	**Tristel™ Duo OPH "Use By" Expiry Date:**	**Confirm 2-Minute Wet Contact Time:**	**Device Reprocessed By:**