Point-of-care High-level Disinfection for Reusable Ocular Devices that Contact the Surface of the Eye

This Best Practice Recommendations (BPR) replaces previous versions which recommended traditional high-level disinfection (HLD) methods (e.g., soaking in chemical solution). **Note:** If you have any questions or comments contact IPC at ipcsurvstdadmin@ahs.ca.

Best practice recommendations

Objectives

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

1. Providing consistent, evidence-based provincial recommendations for cleaning and high-level disinfection (HLD) of reusable ocular devices that contact 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.

Applicability

These recommendations apply to all AHS staff, medical staff, and other persons acting on behalf of AHS.

Background

Point-of-care (POC) HLD describes a process using Tristel™ products approved by Health Canada.

- HLD is required for semi-critical medical devices including re-usable ocular devices that touch the surface of the eye.
- HLD of ocular devices is performed at the bedside to facilitate patient flow through ophthalmology clinics.
- Use POC HLD when the manufacturer's instructions recommend a low-level disinfectant (e.g., alcohol swab).
- Low level disinfection does not meet the Alberta Health requirements for ocular devices that touch the surface of the eye.

Tristel™ Cleaning Wipes

- Intended for cleaning ocular devices.
- Impregnated with a low-foaming surfactant and a triple-enzymatic detergent.
- The device does not have to be dried after cleaning or before HLD step [confirmed by manufacturer].

Tristel Duo OPH™ (each bottle provides product for 100 disinfection events)

- HLD using a chlorine dioxide formulation specifically designed for re-usable ocular devices including (but not limited to) tonometer, ocular ultrasound probes, pachymeter tips, ultrasound shells, Ret-Cam, and contact diagnostic ophthalmic lens (e.g., laser lens, fundus lens, gonioscopy lens).
  Note: Disposable/single-patient use devices (e.g., tonometer tips and tip covers) must be discarded after use.
- Chlorine dioxide (ClO2) is generated when the two precursor solutions meet at the egress point of pump and react chemically.
- The pump dispenses a ready-to-use foam that is used with Tristel Duo Wipes™.
- Tristel Duo OPH™ does not require minimum effective concentration (MEC) testing [confirmed by manufacturer].

Tristel Duo Wipes™

- Non-woven, low-linting, dry wipes made of 100% polypropylene designed for compatibility with the Tristel™ solutions and the ocular device surface.

Tristel Rinse Wipes™

- Intended for rinsing and removing excess disinfectant from ocular devices after HLD with Tristel Duo OPH™.
- Impregnated with de-ionized water.
- One rinse is required to remove Tristel Duo OPH™ residues. More rinse cycles may be specified by the device manufacturer.

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1. Pre-implementation considerations

1.1 Training, education and competency testing for staff should:

- Be specific to POC HLD for eye equipment.
- Use a written standard operating procedure (SOP).
- Include a process for periodic review of competency, e.g., annually.

1.2 Workflow

Set up a space and process that supports:

- hand hygiene;
- use of personal protective equipment;
- clear separation of clean and contaminated devices; and
- one-way workflow where reprocessing moves in a single direction from the dirtiest task to the cleanest task to prevent cross-contamination.

2. Point-of-care (POC) HLD with Tristel™ Products

2.1 General principles

- Perform the POC HLD process if any of the following occur:
  i. a new reusable ocular device is brought into service;
  ii. after each patient use;
  iii. contamination while in use.

2.2 Complete all steps of HLD process in a continuous sequential manner. Once started, follow the process until completion.

2.3 Inspect and verify that the ocular device is in good working order. Device must remain cleanable and free from damage at every step (i.e., cleaning, HLD and rinsing).

2.4 Remove ocular devices found to be defective or damaged from use immediately. Label as contaminated and requiring repair or replace device.

2.5 If the instrument or device has been used on a patient with known or suspected Creutzfeldt-Jakob Disease (CJD), refer to Public Health Agency of Canada (2007) *Infection Control Guidelines: Classic Creutzfeldt-Jakob Disease in Canada Quick Reference Guide* and notify site Infection Prevention and Control.

2.6 See Appendix A *Tristel Duo OPH – High-level Disinfection for Re-usable Ocular Devices that Contact the Surface of the Eye* for a 1-page overview. The 1-page overview links to a step by step YouTube video of the process.

3. Initial opening of a new Tristel™ Duo OPH Foam bottle

3.1 Perform hand hygiene.

3.1 Don gloves.

3.2 Remove the transport locks.

3.3 Depress the pump four times to prime and prepare for use. Contain dispensed foam from

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priming in a wipe and dispose in garbage.

3.4 Record the date the bottle is opened and the “use by” date on the label.

- The “use by” date is either the expiry date on the bottle or 6 months from opening date, whichever comes first.

4. Clinic set-up

4.1 Beginning of each clinic day

4.1.1 Clean and disinfect all reprocessing spaces.

4.1.2 Designate and clearly label spaces or device holders:

i. ocular devices after patient use (dirty/contaminated);
ii. ocular devices during the cleaning process; and
iii. clean ocular devices after the HLD process is complete.

4.1.3 Wear appropriate PPE (eye protection and gloves).

4.1.4 Check expiry dates of all products. Do not use if past expiry.

4.2 End of each clinic day

4.2.1 Clean and disinfect all reprocessing spaces.

5. Cleaning steps using Tristel™ Cleaning Wipes

5.1 Perform hand hygiene and don personal protective equipment required by Tristel™ Safety Data Sheet (eye protection, gloves).

5.2 Clean ocular devices immediately, ideally within one hour after use, to prevent drying of soil.

5.3 Wipe the ocular device with a Tristel™ Cleaning Wipe from clean to dirty until all visible soil is removed (i.e., from cord to lens, or from handpiece to lens if cordless).

5.4 Inspect the device for residual soil.

5.5 Verify it is in good working condition.

5.6 Place the clean ocular device onto the designated prepared clean surface (or in a device holder, if available).

5.7 Discard the wipe into the garbage.

5.8 Remove gloves and discard into garbage. Perform hand hygiene.

5.9 Proceed to step 6.

6. Chemical HLD process

6.1 With clean hands, access and don clean gloves.

6.2 Remove a Tristel™ Duo Wipe from container. Hold in your hand.

6.3 Place the clean ocular device on top of the Tristel™ Duo Wipe in your hand.

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6.4 Pump three aliquots of Tristel™ Duo OPH™ directly onto the ocular device and use the wipe to cover the surface of the instrument.

6.5 Place the clean ocular device onto a clean surface (or in a clean device holder, if available).

6.6 Discard the wipe in the garbage.

6.7 Set a timer and observe that the two-minute contact time is achieved.

6.8 Remove gloves and discard into garbage. Perform hand hygiene.

6.9 Proceed to step 7.

7. Rinse with Tristel™ Rinse Wipes

7.1 With clean hands access and don new gloves.

7.2 Remove the wipe from its sachet and lay it out in the palm of your hand.

7.3 Wipe the entire surface of the device so all Tristel™ Duo OPH residue is removed.

7.4 Place the device on a new clean surface or device holder until completely dry (set timer for one minute) or dry device with a low-linting cloth.

7.5 Discard the wipe in the garbage.

7.6 Remove gloves and discard into garbage. Perform hand hygiene.

7.7 Place the device into a clean container that is labelled as reprocessed. If any concerns about contamination, then repeat HLD process (see 2.1).

8. Storage of ocular devices

8.1 If the reprocessed device will not be re-used immediately:

- **Device attached to a unit**: Store on its stand and cover with a clean, disposable cover, and labelled as reprocessed.
- **Unattached device:** Store in a closed, clean, dry container labelled as reprocessed.

8.2 Porous packaging (e.g., foam or wood) is not cleanable and is not suitable for device storage.

9. Document and perform traceability

9.1 Use the Tristel 3T™ system to document the process and traceability information (preferred method); or

9.2 Manually document the Tristel™ HLD process including:

i. lot number
ii. in-use expiry date
iii. identification of person responsible for reprocessing the device.

9.3 See Appendix B *Point-of-care High-level Disinfection Tracking Sheet* for tracking sheet template.

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References

1. CSA Standard. 2018. Z314-18 Canadian medical device reprocessing,
2. Health Canada. 2018. Guidance document - Safety and effectiveness requirements for high-level disinfectants and sterilants for use on reusable semi-critical and critical medical devices (2018)
3. Public Health Agency of Canada. 2007. Infection Control Guidelines: Classic Creutzfeldt - Jakob Disease in Canada Quick Reference Guide. Retrieved from: https://www.canada.ca/content/dam/phac-aspc/migration/phac-aspc/nois-sinp/pdf/cjd-eng.pdf
4. Tristel, Pre-Clean Wipe User Guide. Retrieved from: PRE-089-4-Pre-Clean-Wipe-User-Guide-EN-DE-FR-IT-DA- RU.pdf (tristel.com)
5. Tristel, Rinse Wipe User Guide. Retrieved from: RIN-098-4-Rinse-Wipe-User-Guide-EN-DE-FR-IT-DA-RU.pdf (tristel.com).

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Appendix A

Tristel™ Duo OPH High-level Disinfection for Reusable Ocular Devices that Contact the Surface of the Eye

Reusable equipment that touches the surface of the eye such as lenses, ultrasound shells, probes, pachymeters, applanation tonometer tips, etc. are required to be reprocessed between use on different patients by first cleaning to remove physical matter followed by high-level disinfection (HLD). AHS is implementing the Tristel Duo OPH system to ensure standardized, evidence-informed reprocessing of this equipment across the province to prevent patient-to-patient transmission of pathogens on reusable ocular devices.

What is Tristel Duo OPH?

Tristel Duo OPH is a point-of-care system approved by Health Canada in 2021 to achieve efficient reprocessing of this equipment in the clinical setting. Tristel Duo OPH's rapid kill time and compatibility with most ophthalmic devices can improve clinical efficiency and workflows. The Tristel Duo OPH system consists of three products: Tristel Clean (a triple-enzyme foam used for cleaning), Tristel Duo OPH (a chlorine dioxide (ClO_2) foam used for HLD) and Tristel Rinse Wipes (impregnated with deionized water designed specifically to remove excess Tristel Duo OPH).

How to use Tristel Duo OPH: Please refer to YouTube video of the process.

STEP 1: CLEAN/ PREPARE FOR DISINFECTION

Hand Hygiene Eye Protection & Don Gloves	Pump Tristel Clean onto Duo Wipe *or* Use Tristel Clean Wipes to remove all physical matter from device - no rinse required	Remove Gloves & Clean Hands

STEP 2: HIGH LEVEL DISINFECTION

Hand hygiene & don clean gloves	Pump Tristel Duo OPH 3x onto Duo Wipe Lather on surface	Start timer 2 mins	Remove gloves and clean hands

STEP 3: RINSE

Hand Hygiene & don clean gloves	Use Tristel Rinse wipes to wipe equipment and remove excess disinfectant - no dry time required	Remove gloves & clean hands eye protection

STEP 4: TRACKING/ DOCUMENTATION
After every reprocessing event, log the following:

Date (MM/DD/YYYY)	Equipment	Tristel ™ Duo OPH lot number	Tristel ™ Duo OPH bottle expiry	Tristel ™ Duo OPH In-Use expiry date	Confirm two-minute contact	Device reprocessed by

Records retained for 5 years

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Resources

1. Evaluation of Tristel's solutions for the decontamination of ophthalmic medical devices, 2022 Presentation to AHS/User guides www.tristel.com
2. Tristel, Pre-Clean Wipe User Guide. Retrieved from: PRE-089-4-Pre-Clean-Wipe-User-Guide-EN-DE-FR-IT-DA- RU.pdf (tristel.com)
3. Tristel, Rinse Wipe User Guide. Retrieved from: RIN-098-4-Rinse-Wipe-User-Guide-EN-DE-FR-IT-DA-RU.pdf (tristel.com).
4. Health Canada. 2018. Guidance document - Safety and effectiveness requirements for high-level disinfectants and sterilants for use on reusable semi-critical and critical medical devices (2018)
5. Public Health Agency of Canada. 2007. Infection Control Guidelines: Classic Creutzfeldt - Jakob Disease in Canada Quick Reference Guide. Retrieved from: https://www.canada.ca/content/dam/phac-aspc/migration/phac- aspc/nois-sinp/pdf/cjd-eng.pdf

More Information

1. List of ophthalmic devices approved to use Tristel. Tristel Duo OPH Device Compatibility EN - INNOVA Medical Ophthalmics (mediafly.com)

   https://assets.mediafly.com/l/G7GTaaH7KFRn?viewerUrl=https%3A%2F%2Fviewer.mediafly.com

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Appendix B
Point-of-care high-level disinfection tracking sheet

Location ☐ RAH Eye Clinic, Edmonton ☐ RGH Eye Clinic, Calgary

Date (MM/DD/YYYY)	Equipment	Tristel ™ Duo OPH lot number	Tristel ™ Duo OPH bottle expiry	Tristel ™ Duo OPH In-Use expiry date	Confirm two-minute contact	Device reprocessed by

Steps:

1. Hand Hygiene, don PPE, clean ocular device & holder after use with Tristel™ Cleaning Wipe
2. Hand Hygiene, don PPE, use HLD Tristel™ Duo OPH with Tristel™ Duo Wipe – set timer 2 mins
3. Hand Hygiene, don PPE, user Tristel™ Rinse Wipes to clean
4. Hand hygiene, doff PPE
5. When device is dry, it is ready for use or for storage.
6. Complete tracking sheet each time HLD is performed on ophthalmic equipment.
7. Records kept for 5 years

Please refer to YouTube video of the process.

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Note: Equipment = Ocular devices requiring HLD

RAH Eye Clinic

Equipment name	Description
E-A	A Scan Probe labelled E-A and shell
E-B	B Scan Probe labelled E-B
E-S	Standardized A Scan Probe labelled E-S
F-A	A Scan Probe labelled F-A and shell
F-B	B Scan Probe labelled F-B
G-A	A Scan Probe labelled G-A and shell
G-B	B Scan Probe labelled G-B
S1-B	B Scan probe labelled S1-B
S2-B	B Scan probe labelled S2-B
Sonomed B	B Scan probe on Sonomed
UBM shell	UBM shell

RGH Eye Clinic

Equipment name	Description
Ultrasound Room 1 AS	Ultrasound Room 1 A scan standardized
Ultrasound Room 1 B	Ultrasound Room 1 B scan probe
Ultrasound Room 1 Bio	Ultrasound Room 1 Biometry probe and shell
Ultrasound Room 1 20	Ultrasound Room 1 20 Mhz probe
Ultrasound Room 2 A	Ultrasound Room 2 A scan standardized
Ultrasound Room 2 B	Ultrasound Room 2 B scan probe
Ultrasound Room 2 Bio	Ultrasound Room 2 Biometry probe and shell
Ultrasound Room 2 20	Ultrasound Room 2 20 Mhz probe
YAG Cap	YAG Cap laser lens
YAG SLT	YAG SLT laser lens
YAG PI	YAG PI laser lens
Retinal lens	Retinal lens
Pachymeter SN11	Black Pachymeter SN 11
Pachymeter SN85	White Pachymeter SN85
Gonio lens	Gonio lens

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