

# Care of Ear Cleaning Equipment

Note: Terms are defined in the [Definitions](#) section.

If you have any questions or comments contact IPC at [ipcsurvstdadmin@ahs.ca](mailto:ipcsurvstdadmin@ahs.ca).

## Best practice recommendations

### Purpose

- Describe Alberta Health Service's approach, under guidance from IPC Senior Management, for care of **ear cleaning equipment**.
- Minimize the risk of exposure or injury, and to prevent transmission of micro-organisms to patients and personnel.

This Best Practice Recommendation (BPR) categorizes ear syringe nozzles as **semi-critical** and other reusable ear cleaning equipment components as **non-critical** using the [Spaulding](#) medical device **Risk Class** in compliance with the Alberta Health. 2019 standards for the **reprocessing** of reusable medical devices and for the use of **single-use medical devices** in all health care facilities and settings, ([Cleaning, Disinfection and Sterilization Standard](#)).

### Application

This BPR should be followed by all Alberta Health Services (AHS) staff, medical staff, volunteers, students and other persons acting on behalf of AHS.

### IPC Practices

1. [Routine practices](#) are used at all times, e.g., [point-of-risk assessment](#), [hand hygiene](#) and selection of [personal protective equipment](#). Additional precautions requiring personal protective equipment such as masks, gown, and eye protection may be indicated by a point-of-care risk assessment to prevent transmission of specific organisms or infections that may not be fully prevented by routine practices.
  - 1.1. Hand hygiene. See the [AHS Hand Hygiene Policy](#) and [Hand Hygiene Procedure](#) for more details.
  - 1.2. [Point of Care Risk Assessment \(PCRA\)](#) is conducted at the start of each staff and patient interaction to evaluate the likelihood of exposure to blood and body fluids.
  - 1.3. [Personal Protective Equipment \(PPE\)](#) appropriate for the task and to minimize the risk of exposure to infectious agents. For example:
    - Gloves, gown, mask and eye protection as needed to prevent contact with blood and body fluids, excretions, secretions, mucous membranes or non-intact skin.
  - 1.4. Handling patient care items and equipment
    - Discard items labelled as single-use after each use.
    - Reprocess (clean and at minimum low-level disinfect), multi-patient reusable ear cleaning equipment according to validated manufacturer's instructions for use (MIFU) or if validated MIFU unavailable, reprocess according to current accepted methods (outlined in Section 3).
2. Health Canada categorizes ear cleaning equipment as a Class I medical device requiring distributors to have a Health Canada Establishment License and be classified as 'Hospital/HC Facilities-Grade' by Health Canada in the Health Canada Drug Product Database.

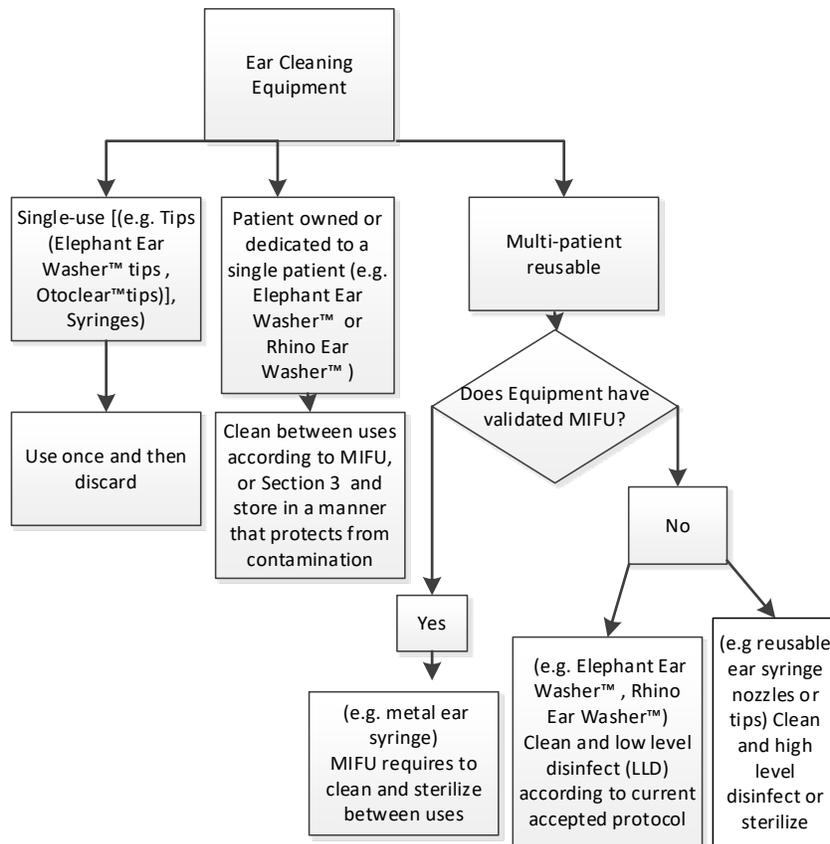
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- Health Canada, Canadian Standards Association (CSA) and Alberta Health standards require reusable **medical equipment** to have validated cleaning and disinfection/sterilization instructions.
- All disinfectants must have a **Drug Identification Number (DIN)** from Health Canada.
- When the MIFU for ear cleaning equipment requires high-level disinfection or sterilization reprocessing should take place in a centralized medical device reprocessing area.

### Recommendations

- Ear cleaning equipment must be designed and intended for use on humans.
- Ear cleaning equipment is either single-use, dedicated to a single patient, patient-owned or multi-patient reusable.



### 2.1. Single-use ear cleaning equipment

2.1.1. Ear cleaning equipment labelled as single-use is discarded after each use. Single-use ear cleaning equipment and components are used once and discarded, e.g., disposable ear syringe nozzles or tips. See [Appendix A](#): Examples of Disposable Ear Cleaning Equipment/Components

### 2.2. Dedicated or patient-owned ear cleaning equipment

2.2.1. Dedicated or patient-owned ear cleaning equipment is:

- never used for another individual;
- cleaned between uses according to MIFU;
- inspected before and after each use and replaced if damaged, corroded, e.g., bottle becomes cloudy, or no longer functional;
- labelled and stored in a manner that prevents use by other individuals or contamination, i.e. in a clean designated container that is labelled with personal identifiers such as the patient's name and room number and stored in a closed cupboard in a clean space.

### 2.3. Multi-patient reusable ear cleaning equipment

2.3.1. Heat tolerant multi-patient reusable ear cleaning equipment with validated reprocessing instructions, i.e., metal ear syringe, is cleaned and steam **sterilized** according to the manufacturer's instructions prior to reuse on another patient. See [Appendix B](#): Example of Reusable Ear Cleaning Equipment/Components (multi-patient/reusable) and MIFU for cleaning and disinfection or sterilization

2.3.2. Multi-patient reusable ear cleaning equipment without validated reprocessing instructions, e.g., Elephant Ear Washer™, Rhino Ear Washer™; See [Appendix C](#): Examples of Trigger Spray Ear Irrigation Equipment and MIFU, is cleaned and at minimum, low-level disinfected (LLD) as outlined in Section 3 prior to reuse on another patient.

2.3.3. A sufficient supply of ear cleaning equipment is available to perform **ear cleaning** safely and allow for equipment reprocessing between patients.

### 3. Reprocessing of multi-patient reusable ear cleaning equipment without validated reprocessing instructions, e.g., Elephant Ear Washer™, Rhino Ear Washer™.

#### 3.1. Reprocessing area requirements include:

- Designated space with a decontamination (utility) sink. Patients' rooms/washrooms and sinks used for hand hygiene must not be used for reprocessing.
- Separation of clean and dirty processes. Where physical separation is not possible, spatial separation and a one-directional work flow pattern (moving in one direction from the dirtiest to the cleanest task) must be established to limit cross-contamination.
- The space is cleaned regularly and cleaned and disinfected between reprocessing steps.
- The area is kept free of excess and unrelated devices and supplies.

#### 3.2. Reprocessing steps:

- Dispose of single-use tip.
- Empty ear wash container.

- Wash reusable components (spray pump, attached tubing, container) by submerging in a sink of water and detergent or enzymatic cleaner (diluted per MIFU) and suitable for use on ear cleaning equipment (household products are not suitable). Manual cleaning is performed below the surface of the water to minimize splashing and generation of aerosols.
- Pump cleaning solution (diluted per MIFU) through the trigger spray system.
- Discard disposable cleaning accessories, e.g., brushes and sponges. Clean reusable cleaning accessories according to MIFU between uses and store in a clean, dry location.
- Empty, clean and disinfect sink with disinfectant wipes.
- Thoroughly rinse the reusable components by submerging in fresh, clean water. Pump rinse water through the trigger spray system to ensure all cleaning products are removed.
- Empty, clean and disinfect sink with disinfectant wipes.
- Dry the outside of the reusable components with a clean, lint-free, soft absorbent towel. Pump rinse water out of the trigger spray system.
- Inspect the ear cleaning equipment to ensure components are clean and in good working condition.
- Disinfect the reusable components using an AHS approved low-level or **intermediate-level disinfectant**, e.g., 0.5% accelerated hydrogen peroxide, according to MIFU. Pump disinfectant solution through the trigger spray system (pump and tubing included) to achieve the manufacturer's recommended **contact time**. A disinfectant with a short contact time is preferred, e.g., 1 minute.
- Thoroughly rinse the reusable components by submerging in fresh, clean water. Pump rinse water through the trigger spray system to ensure all disinfectant product is removed.
- Empty, clean and disinfect sink with disinfectant wipes.
- Dry the reusable components using a clean lint free towel. Tubing must be completely drained, e.g., by positioning on a clean lint free towel, and allowing to thoroughly dry. Store tubing in a manner that facilitates drying between uses, e.g., by storing vertically.
- Once dry, label ear cleaning equipment as clean/disinfected and store in a clean, dry, protected area until use, e.g., clean utility room.

### 3.3. Before purchasing and using reusable ear cleaning equipment consider:

- Through cleaning and disinfection of ear cleaning equipment is difficult, time consuming and can be performed incorrectly due to:
  - a lack of validated MIFU;
  - the trigger spray housing cannot be disassembled;
  - the narrow tubing that delivers fluid to the trigger spray is hard to clean; and
  - the potential for re-contamination or cross contamination.
- Supply costs, e.g., detergent or enzymatic cleaner and cleaning accessories. Required PPE may include:
  - gloves;
  - mask;
  - face shield; and

- fluid impervious gown.
  - Space with a suitable sink is required for cleaning, e.g., physically separate from patient treatment and clean storage areas.
  - Adequate space is required for storage.
  - Reusable ear cleaning equipment is discarded if it can no longer be cleaned effectively or if functioning is reduced.
- 3.4. A facility/unit procedure is developed for reusable ear equipment that covers all the reprocessing steps.
- 3.5. Manufacturer's Instructions
- Staff who reprocess ear cleaning equipment have access to MIFU in printed (binders, manuals or product labels) or electronic format.
  - Follow MIFU to determine:
    - the [Risk Class](#) (critical, semi-critical or non-critical) assigned to the equipment;
    - if the equipment or component is intended for reuse or is single-use;
    - cleaning, and/or disinfection/sterilization instructions for reusable components.
- 3.6. Consider alternative options to disinfecting/sterilizing ear cleaning equipment on-site including:
- using single-use ear cleaning equipment and discard after use;
  - dedicating ear cleaning equipment to a single-patient. Equipment is cleaned, dried and stored safely (according to MIFU), between uses on that patient; and
  - transporting reusable ear cleaning equipment in a closed, leak-proof container to a centralized reprocessing area for reprocessing.
- 3.7. For information on reprocessing requirements for medical equipment see the [AHS MDR resource page or the Canadian Standards Association \(CSA\) standard Z314-18, Canadian medical device reprocessing](#).
- 3.8. High-level disinfection or sterilization requires:
- an area clearly separated from the patient and other staff areas or a one-way workflow to limit cross-contamination. Designated spaces are used for soiled receiving, cleaning, disinfecting, sterilizing, cooling and storage;
  - process steps, quality assurance parameters, equipment considerations, and other essential reprocessing elements that are consistently carried out to ensure the integrity of the ear cleaning equipment; and
  - cleaning, high-level disinfection, or sterilization and packaging to ensure the equipment can safely be reused on multiple patients.

Training. The Alberta Health [Reusable & single-use medical devices standards](#) requires all personnel involved in the reprocessing of critical and semi-critical medical devices to be appropriately educated and trained for the reprocessing duties/tasks that they perform..

## Definitions

**Contact time** means the length of time a disinfectant drug must be in contact with a target surface or device to achieve the desired efficacy result.

**Drug Identification Number (DIN)** means a number assigned by Health Canada to a drug product which uniquely identifies the product and must appear on the marketed product label.

**Ear cleaning** means removing ear wax (cerumen) from the external auditory ear canal, e.g., irrigation. Ear wax removal is indicated when cerumen or a foreign body blocks the ear canal and causes hearing loss, pain or infection.

**Ear cleaning equipment** means any equipment used to irrigate, flush and remove ear wax.

**Ear wax (cerumen) removal** means the process used to remove cerumen or foreign material blocking the external auditory canal resulting in hearing loss, pain or infection.

**Intermediate-level disinfectant** means a substance, or mixture of substances capable of destroying or irreversibly inactivating all microbial pathogens, including mycobacteria but not bacterial spores.

**Low-level disinfectant** means a substance, or mixture of substances capable of destroying or irreversibly inactivating, at a minimum, vegetative bacteria.

**Manufacturer** means a person (including a partnership, firm or association) who sells a medical device under their own name, or under a trade-mark, design, trade name or other name or mark owned or controlled by the person, and with respect to the medical device, is responsible for:

- designing;
- manufacturing;
- assembling;
- processing;
- labelling;
- packaging;
- refurbishing;
- modifying; or
- assigning the medical equipment an intended purpose, whether those tasks are performed by that person or on their behalf.

**Medical equipment** means any instrument, apparatus, appliance, material, or other article, whether used alone or in combination, including the software necessary for its proper application, intended by the Manufacturer to be used for a human being for any of the following purposes:

- diagnosis, prevention, monitoring, treatment, or alleviation of disease;
- diagnosis, monitoring, treatment or alleviation of, or compensation for an injury or handicap;
- investigation, replacement or modification of the anatomy or of a physiologic process; or control of conception;

and that does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but that can be assisted in its function by such means.

**Non-critical** means a medical device which either touches only intact skin but not mucous membranes or does not directly touch the patient.

**Reprocessing** means the steps performed to prepare a used medical device for reuse, e.g., cleaning, and disinfection or sterilization.

**Risk Class** means the Spaulding classification based on the risk of infection involved with the use of the medical device on a patient. The three risk classes are:

- Critical medical devices;
- Semi-critical medical devices; or

- Non-critical medical devices

**Semi-critical** means a medical device that comes into contact with mucous membranes or non-intact skin, but ordinarily does not penetrate them.

**Single patient-use** means a critical or semi-critical medical device that is designated by its manufacturer for use and reuse on a single patient, but may not be reused on another patient.

**Single-use medical device** means a critical or semi-critical medical device designated by the manufacturer for single-use only and may be indicated by, but not limited to, the following terms used for labelling by the manufacturer:

- disposable;
- consumable;
- not for reuse or do not reuse;
- discard after Single-use;
- do not use twice; or
- a symbol such as: 

**Sterilization/Sterilized** means the validated process used to render a product free from viable microorganisms.

**Validated** means a documented procedure for obtaining, recording, and interpreting the results required to establish that a process for cleaning, disinfection or sterilization of a medical device will consistently yield safe products complying with the CSA Standard Z17664.

### Sources/References

Appendix A: Examples of disposable ear cleaning equipment/components

Appendix B: Examples of reusable ear cleaning equipment/components

Appendix C: Examples of trigger spray ear irrigation equipment and MIFU

Alberta Health. 2019. Reusable & single-use medical devices standards: standards for the reprocessing of reusable medical devices and for the use of single-use medical devices in all health care facilities and settings. Retrieved from <https://open.alberta.ca/publications/9781460145470>

Canadian Standards Association (CSA). 2018. Standard CSA Z314-18. Canadian medical device reprocessing.

Health Canada. 2014. Guidance document – Disinfectant drugs. Retrieved from [http://www.hc-sc.gc.ca/dhp-mpps/prodpharma/applic-demande/guide-ld/disinfect-desinfect/disin\\_desin-eng.php](http://www.hc-sc.gc.ca/dhp-mpps/prodpharma/applic-demande/guide-ld/disinfect-desinfect/disin_desin-eng.php).

AHS training materials for staff include:

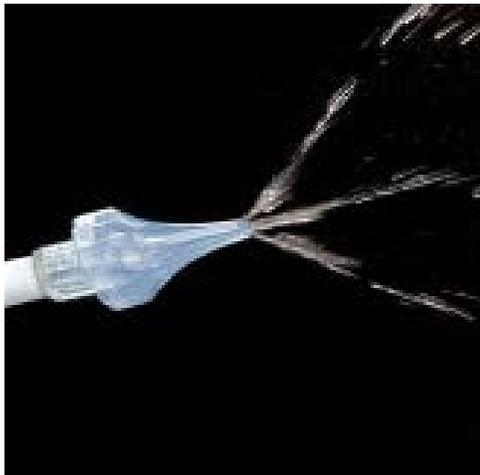
- Annual Continuing Education Infection Prevention and Control module accessible on AHS Insite
- MDR Training Videos available on AHS IPC External Website: Medical Device Training Videos

**Appendix A:** Examples of single-use disposable ear cleaning equipment/components (single-use/disposable)

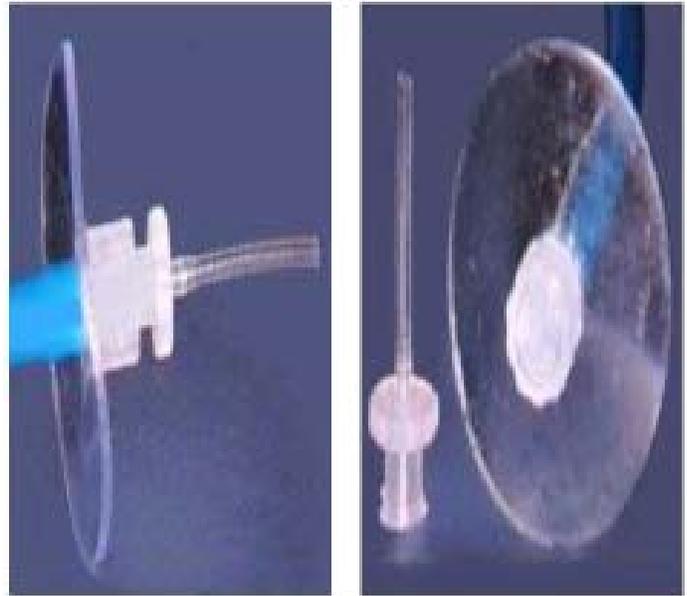
OtoClean™ irrigator tip (single-use, disposable)

[http://www.bionixmed.com/MED\\_PDFs/Sellsheet\\_OtoClear.pdf](http://www.bionixmed.com/MED_PDFs/Sellsheet_OtoClear.pdf)

Can be used with a disposable leur lock syringe



Tip Elephant Ear Washer™



Leur lock syringe (20- 50 ml) can be used with an OtoClear™ irrigator tip



2 or 3 oz ear/ulcer sterile disposable syringe



**Appendix B:** Example of reusable ear cleaning equipment/components (multi-patient/reusable) and MIFU for cleaning and disinfection or sterilization

Metal ear syringes



V. Mueller metal ear syringe instructions for use:

<https://catalog1.bd.com/vmueller/all-metal-ear-syringes-au5456.html>

**Appendix C:** Examples of trigger spray ear irrigation equipment without validated MIFU

**Note:** The Elephant Ear Washer™ and Rhino Ear Washer™ tips are single-use and discarded after use.

Elephant Ear Washer™



Rhino Ear Washer™

