Team Name: Regional PCH Program Team Team Lead: Director - Personal Care Homes Approved by: Regional Lead – Community & Continuing Care	Reference Number: CLI.6410.PL.008 Program Area: Personal Care Home Policy Section: General
Issue Date: May 15, 2017 Review Date: Revision Date: March 22, 2022	Subject: Ear Cleaning Equipment

Use of pre-printed documents: Users are to refer to the electronic version of this document located on the Southern Health-Santé Sud Health Provider Site to ensure the most current document is consulted.

POLICY SUBJECT:

Ear Cleaning Equipment

PURPOSE:

To minimize the risk of exposure or injury, and to prevent transmission of micro-organisms to clients and staff during use of instruments and devices used in the cleaning of ears.

BOARD POLICY REFERENCE:

Executive Limitation (EL-01) Global Executive Restraint and Risk Management
Executive Limitation (EL-02) Treatment of Clients

POLICY:

Ear cleaning equipment is single-use and discarded after use. The use of single-client or multi-client reusable equipment is not recommended in Southern Health-Santé Sud.

DEFINITIONS:

Client: Means the individual recipient of health services in any care setting, including hospital, personal care homes, primary care or a person's home.

Ear Cleaning or Ear Wax (Cerumen) Removal: Means the process used to remove ear wax (cerumen) or foreign material from the external auditory 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.

Intended Purpose: Means the use for which medical equipment is intended according to the information supplied by the manufacturer on the labelling, in the instructions and/or promotional materials for the medical equipment.

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 the following:

- 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.

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

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: 

IMPORTANT POINTS TO CONSIDER:

- Routine Practices are used at all times. In addition to Routine Practices, Additional Precautions may be required as indicated by the point of care risk assessment to prevent transmission of specific organisms or infections that may not be fully prevented by Routine Practices.
- 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.
- Ear cleaning equipment must be designed and intended for use on humans.
- Single-use, disposable systems do not require cleaning and reprocessing and are therefore recommended for ear irrigation in Southern Health-Santé Sud
- Nurses must be aware of their scope of practice under legislation to perform ear cleaning.

PROCEDURE:

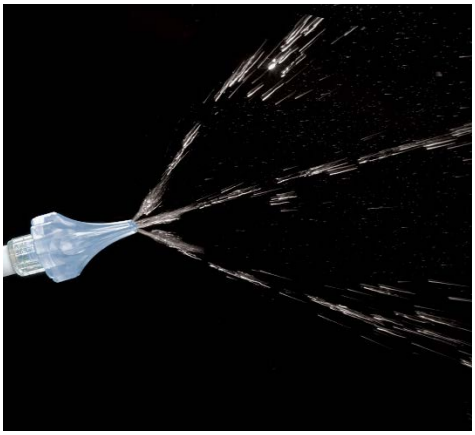
- **Single-Use Ear Cleaning Equipment**
  - Prepare equipment and perform procedure as per Elsevier Clinical Skills – Cerumen Removal
  - Single-use ear cleaning equipment and components are used once and discarded e.g. disposable ear syringe tip used with disposable syringe. See Equipment: Single-Use/Disposable Ear Cleaning Equipment.
  - Following ear cleaning procedure, dispose of single-use tip and single use syringe.

EQUIPMENT/SUPPLIES:

Elsevier Clinical Skills – Website, Cerumen Removal

Single-Use Ear Cleaning Equipment

- OtoClear™ irrigator tip (single-use, disposable)
  https://bionix.com/otoclear-ear-irrigation.html
- Luer lock syringe (20-50 ml) (single-use disposable)



REFERENCES:

Elsevier. (2017, January) Elsevier Clinical Skills: *Product Overview.* Author