Infection Control: Syringes used for making Earmold Impressions

A.U. Bankaitis, Ph.D., FAAA
Oaktree Products, Inc.
St. Louis, MO

Background Information:

Infection control refers to the conscious management of the environment for purposes of minimizing or eliminating the potential spread of disease.[1,2] In response to the AIDS epidemic, during the mid to late 1980's, the Centers for Disease Control and Prevention (CDC) issued a number of recommendations and guidelines for minimizing cross-infection of bloodborne diseases to healthcare workers. These guidelines were based on the principle that every patient is assumed to be a potential carrier of and/or susceptible host for an infectious disease. Eventually, these pronouncements were officially formalized into the Universal Blood and Bloodborne Pathogen Precautions. More commonly referred to as universal precautions, the general pronouncements are as follows:

1. Appropriate personal barriers (gloves, masks, eye protection, gowns) must be worn when performing procedures that may expose personnel to infectious agents
2. Hands must be washed before and after every patient contact and after glove removal
3. Touch and splash surfaces must be pre-cleaned and disinfected
4. Critical instruments must be sterilized
5. Infectious waste must be disposed of appropriately

CDC 1987[3]

Differentiation of Terms:

Cleaning refers to procedures in which gross contamination is removed from surfaces or objects without killing germs.[1,2] It does not necessarily involve any level of germ killing but cleaning is an important prerequisite for other processes in which killing germs remains an objective. Cleaning must occur prior to disinfection or sterilization as the effectiveness of these procedures may be compromised without it.

Disinfection refers to a process in which germs are killed.[1,2] The term encompasses a wide range of germ killing. Levels of disinfection vary according to how many and what specific germs are killed. Household disinfectants kill a limited number of germs commonly found in the household. In contrast, hospital-grade disinfectants are much stronger and kill a larger number and variety of germs. As such, hospital-grade disinfectants should be incorporated in infection control protocols implemented in patient care settings, including clinics, hospitals, or private practice facilities where audiology services are provided.

Sterilization involves killing 100% of vegetative microorganisms, including associated endospores.[1,2] When microbes are challenged, they revert to the more resistant life form called a spore.[3] Sterilants, by definition, must neutralize and destroy spores because if the spore is not killed, it may become vegetative again and cause disease. Whereas disinfection may kill some germs, sterilization, by definition, kills all germs and associated endospores each and every time.

Cleaning:	removal of gross contamination
Disinfecting:	killing a percentage of germs
Sterilization:	killing 100% of germs including endospores

Syringes - Infection Control Recommendations:

According to the CDC, critical instruments must be sterilized. Critical instruments refer to those instruments or objects introduced directly into the bloodstream (e.g., needles), non-invasive instruments that come in contact with intact mucous membranes or bodily substances (e.g., blood, saliva, mucous discharge, pus), or instruments that can potentially penetrate the skin from use or misuse. Non-critical

items are those instruments or objects that either do not ordinarily touch the patient or touch only the externally intact skin. ***Since syringes are used to inject earmold impression material into the ear, and earmold impression techniques require the ear canal to be clear of cerumen, it is not anticipated that syringes will come in contact with cerumen. Therefore, syringes should be cleaned and then minimally disinfected prior to reuse.***

Recommended Disinfecting Procedures prior to reusing Syringe, Option 1:

- Prior to inserting syringe into patient's ear, place an extension tip (Item232E) on the end of the syringe
- Inject impression material
- Once impression material injected, remove extension tip from syringe and throw extension ship away
- Once left over impression material removed from syringe, clean entire outer surface of syringe using either paper towel or disinfectant towelette.
- After cleaning, using a fresh disinfectant towelette, wipe entire surface of syringe
- Put syringe in appropriate storage location so it is ready for reuse.

Recommended Disinfecting Procedures prior to reusing Syringe, Option 2

- Inject impression material
- Once impression material injected, remove left over impression material from inside of syringe
- Clean entire outer surface of syringe using either paper towel or disinfectant towelette.
- After cleaning, using a fresh disinfectant towelette, wipe entire surface of syringe
- Put syringe in appropriate storage location so it is ready for reuse.

As previously mentioned, it is not essential to sterilize syringes used for making earmold impressions since the ear canal must be relatively clear of cerumen during such procedures and it is not likely that the tip of the syringe will make contact with copious amounts of cerumen. In the event it is clinical policy for these items to be sterilized prior to reuse, please note the following critical points:

Sterilization challenges inherent to Syringes as a function of VA approved sterilants:
The use of heat pressurization via an autoclave may not be used on syringes since the product is a plastic component and will melt during the procedure, rendering the syringe unusable. ***From this perspective, some sterilization centers may erroneously refer to these products as disposable. Syringes are not one-time use products; they are intended to be reused with multiple patients.*** In the event gas sterilization is an available, this option is considered suitable. Typically, this process involves the use of Ephylene Oxide although there may be other alternative gases used.

Alternative Sterilization Procedures:
In the absence of gas sterilization, the only other alternative is to sterilize instruments via cold sterilization. There are only two EPA-approved liquid chemicals that may be used for sterilization. Glutaraldehyde solutions in concentrations of 2% or higher (i.e. brand name products such as Wavicide, Cidex) or 7.5% or higher levels of hydrogen peroxide (H_20_2) (i.e. brand name products such as Sporox) are the only chemicals approved by the EPA for cold sterilization. It is the current understanding of Oaktree Products, Inc. that the V.A. system has not approved the use of glutaraldehyde-based sterilants, permitting the use of only those sterilants containing 7.5% or higher levels of H_20_2. Great care should be taken to limit the exposure of the wax loops to the minimum sterilization cycle as damage may occur to the loops if submerged for longer periods of time. NOTE: using cold sterilants require immersing syringes for 6 to 10 hours, depending on the specific product being used. This will require the clinic to have a large quantity of syringes available as using them during the day will require long enough soaking times that the same syringe will not be available for use until the next day.

Recommended Sterilization Procedures prior to reusing Syringe, Cold Sterilant:

- Inject impression material
- Once impression material injected, remove left over impression material from inside of syringe
- Place contaminated syringe in designated container
- Immediately after the last appointment of the day, designated covered containers holding contaminated syringes are to be brought to the hazard area by designated personnel. Designated personnel must wear gloves while transporting the closed containers.
- While wearing gloves, clean the surfaces of reusable syringes with a paper towel. The same towel or towelette may be used to clean all instruments unless it becomes visibly contaminated.
- Once the instruments are cleaned, with gloved hands carefully place the syringes in the appropriate tray containing cold sterilant, making sure that all instruments are completely submerged in the solution.
- Cover the tray and allow instruments to soak according to manufacturer's directions.
- Remove gloves and wash hands according to designated procedures.

Retrieval of sterilized instruments

- After cold sterilization is complete, put on a fresh pair of gloves.
- Remove syringes from the solution, placing each instrument on a designated tray.
- Rinse instruments in a sink designated as a cleaning sink.
- Allow instruments to air dry.
- Return instruments to their appropriate location(s) for reuse.
- Cold sterilant should be changed according to manufacturer's instructions or sooner if the solution becomes visibly soiled.

For more information, contact A.U. Bankaitis or Robert Kemp of Oaktree Products.

References:

1. Bankaitis, A.U. and Kemp, R.J. (2003). *Infection Control in the Hearing Aid Clinic*. Boulder, CO: Auban.
2. Bankaitis, A.U. & Kemp, R. J. (2005). *Infection Control in the Audiology Clinic* (2nd edition). St. Louis, MO: Auban, Inc.
3. CDC. (1987). Recommendations for prevention of HIV transmission in healthcare settings. *MMWR*, 36(2s).