DISINFECTION AND STERILIZATION GUIDELINE RECOMMENDATIONS FOR PODIATRIC PHYSICIANS

These guidelines and recommendations are based on current literature and Center for Disease Control (CDC) recommendations. The recommendations here are intended to offer general guidance for podiatric medical offices on infection control. They are not intended to establish a standard of care or industry custom. This document incorporates information from the CDC documents: **"Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008"** by William A. Rutala, Ph.D., M.P.H., David J. Weber, M.D., M.P.H., and the Healthcare Infection Control Practices Advisory Committee (HICPAC), and the **"Guide to Infection Prevention for Outpatient Podiatry Settings,"** developed by The Joint Commission, with funding from the CDC. It is recommended that these documents be consulted for more detailed information.

I. Classification of Instrumentation:

a. Critical Instrumentation:
Critical instruments confer a high risk for infection if they are contaminated with any microorganism. Thus, objects that enter sterile tissue or the vascular system must be sterile because any microbial contamination could transmit disease. This category includes all instrumentation used in surgical procedures. All instruments in this category should be sterilized.

Examples include: Surgical instrumentation including saws, drills, bone cutters, bone curettes, dissecting scissors, etc.

b. Semi-critical Instrumentation:
Semi-critical instruments contact mucous membranes or non-intact skin. These include instruments used in debridement of ulcerations, abscesses or other non-intact skin or subcutaneous tissues. Reusable semi-critical items require, at a minimum, high-level disinfection using chemical disinfectants prior to reuse.

Examples include: Instruments used in debridement of ulcerations or abscesses such as tissue nippers, curettes, dissecting scissors, etc. and instruments used in nail care such as nail cutting instruments and nail burrs.

c. Noncritical Instrumentation:
Noncritical instruments are those that come in contact with intact skin or nails but not non- intact skin or subcutaneous tissue. Intact skin and nails act as an effective barrier to most microorganisms; therefore, the sterility of items coming in contact with intact skin and nails is "not critical." In contrast to critical and some semi-critical items, most noncritical reusable items may be decontaminated where they are used and do not need to be transported to a central processing area. Virtually no risk has been documented for

transmission of infectious agents to patients through noncritical items when they are used as noncritical items and do not contact non-intact skin and/or subcutaneous tissues. Low or intermediate-level disinfectants can be used for noncritical instruments, depending on the nature and degree of contamination.

Examples include: Scalpel handles used for debridement of hyperkeratotic tissue, spatulas for application of topical creams, etc.

II. Sterilization and Disinfection:

Reusable podiatric medical instruments that are heat stable and have the potential to break intact skin during ordinary use (e.g., nippers, forceps, splitters, curettes) should be ideally sterilized using steam rather than chemical disinfectant for the terminal reprocessing step.

a. STERILZATION

Steam sterilization:

Of all the methods available for sterilization, moist heat in the form of saturated steam under pressure is the most widely used and the most dependable. Steam sterilization is nontoxic, inexpensive, rapidly microbicidal, sporicidal, and rapidly heats and penetrates fabrics. Like all sterilization processes, steam sterilization has some deleterious effects on some materials, including corrosion and combustion of lubricants associated with dental handpieces; reduction in ability to transmit light associated with laryngoscopes; and increased hardening time (5.6 fold) with plaster-cast.

The basic principle of steam sterilization, as accomplished in an autoclave, is to expose each item to direct steam contact at the required temperature and pressure for the specified time. Thus, there are four parameters of steam sterilization: steam, pressure, temperature, and time. The ideal steam for sterilization is dry saturated steam and entrained water (dryness fraction $\geq$97%). Pressure serves as a means to obtain the high temperatures necessary to quickly kill microorganisms. Specific temperatures must be obtained to ensure the microbicidal activity. The two common steam-sterilizing temperatures are 121°C (250°F) and 132°C (270°F). These temperatures (and other high temperatures) must be maintained for a minimum time to kill microorganisms. Recognized minimum exposure periods for sterilization of wrapped healthcare supplies are 30 minutes at 121°C (250°F) in a gravity displacement sterilizer.

Steam sterilization should be used whenever possible on all critical and semicritical items that are heat stable and moisture resistant (e.g., steam sterilizable respiratory therapy and anesthesia equipment), even when not essential to prevent pathogen transmission. Steam sterilizers also are used in healthcare facilities to decontaminate microbiological waste and sharps containers but additional exposure time is required

in the gravity displacement sterilizer for these items.

Gas sterilization:

Ethylene oxide (ETO) is a colorless gas that is flammable and explosive. The four essential parameters (operational ranges) are: gas concentration (450 to 1200 mg/l); temperature (37 to 63°C); relative humidity (40 to 80%) (water molecules carry ETO to reactive sites); and exposure time (1 to 6 hours). These influence the effectiveness of ETO sterilization. Within certain limitations, an increase in gas concentration and temperature may shorten the time necessary for achieving sterilization.

The main disadvantages associated with ETO are the lengthy cycle times, the cost, and its potential hazards to patients and staff; the main advantage is that it can sterilize heat- or moisture-sensitive medical equipment without deleterious effects on the material used in the medical devices. Acute exposure to ETO may result in irritation (e.g., to skin, eyes, gastrointestinal or respiratory tracts) and central nervous system depression. Chronic inhalation has been linked to the formation of cataracts, cognitive impairment, neurologic dysfunction, and disabling polyneuropathies. Occupational exposure in healthcare facilities has been linked to hematologic changes and an increased risk of spontaneous abortions and various cancers. ETO should be considered a known human carcinogen.

ETO is used in healthcare facilities to sterilize critical items (and sometimes semi-critical items) that are moisture or heat sensitive and cannot be sterilized by steam sterilization.

Radiation sterilization:

Sterilization by ionizing radiation, primarily by cobalt 60 gamma rays or electron accelerators, is a low-temperature sterilization method that has been used for a number of medical products (e.g., tissue for transplantation, pharmaceuticals, and medical devices). There are no FDA-cleared ionizing radiation sterilization processes for use in healthcare facilities. Because of high sterilization costs, this method is an unfavorable alternative to ETO and plasma sterilization in healthcare facilities but is suitable for large-scale sterilization. Some deleterious effects on patient-care equipment associated with gamma radiation include induced oxidation in polyethylene and delamination and cracking in polyethylene knee bearings. Several reviews dealing with the sources, effects, and application of ionizing radiation may be referred to for more detail.

Glass Bead Sterilizers:

Glass bead “sterilization” uses small glass beads (1.2-1.5 mm diameter) and high temperature (217°C -232°C) for brief exposure times (e.g., 45 seconds) to inactivate

microorganisms. These devices have been used for several years in the dental profession.

It should be noted that glass bead sterilizers are not approved by the FDA and are no longer acceptable for instrument sterilization; this equipment should be replaced, preferably with steam sterilizer.

b. DISINFECTION

Properties of an ideal disinfectant:

- Broad spectrum: should have a wide antimicrobial spectrum
- Fast acting: should produce a rapid kill
- Not affected by environmental factors: should be active in the presence of organic matter (e.g., blood, sputum, feces) and compatible with soaps, detergents, and other chemicals encountered in use
- Nontoxic: should not be harmful to the user or patient
- Surface compatibility: should not corrode instruments and metallic surfaces and should not cause the deterioration of cloth, rubber, plastics, and other materials
- Residual effect on treated surfaces: should leave an antimicrobial film on the treated surface
- Easy to use with clear label directions
- Odorless: should have a pleasant odor or no odor to facilitate its routine use
- Economical: should not be prohibitively high in cost
- Solubility: should be soluble in water
- Stability: should be stable in concentrate and use-dilution

High-level disinfection:

High-level disinfection traditionally is defined as complete elimination of all microorganisms in or on an instrument, except for small numbers of bacterial spores. The FDA definition of high-level disinfection is a sterilant used for a shorter contact time to achieve a 6-$\log_{10}$ kill of an appropriate *Mycobacterium* species. Cleaning followed by high- level disinfection should eliminate enough pathogens to prevent transmission of infection.

Glutaraldehyde, hydrogen peroxide, *ortho*-phthalaldehyde, and peracetic acid with hydrogen peroxide are cleared by the Food and Drug Administration (FDA) and are dependable high- level disinfectants provided the factors influencing germicidal procedures are met. When a disinfectant is selected for use with certain patient-care items, the chemical compatibility after extended use with the items to be disinfected also must be considered. Some items that may come in contact with intact skin for a brief period of time (i.e., hydrotherapy tanks, bed side rails) are usually considered noncritical surfaces and are disinfected with intermediate-level

disinfectants (i.e., phenolic, iodophor, alcohol, chlorine). Since hydrotherapy tanks have been associated with spread of infection, some facilities have chosen to disinfect them with recommended levels of chlorine.

Intermediate-level disinfection:

Intermediate-level agents destroy all vegetative bacteria, including tubercle bacilli, lipid and some non-lipid viruses, and fungi, but not bacterial spores.

Examples include phenolic, iodophor, alcohol, chlorine.

Low-level disinfection:

Low-level agents destroy all vegetative bacteria (except tubercle bacilli), lipid viruses, some non-lipid viruses, and some fungi, but not bacterial spores.

III. **Debridement:** This section involves debridement of nails and hyperkeratotic lesions.

a. Manual debridement. Nail nippers used in manual debridement are considered semi-critical instrumentation and should, minimally, be cleaned with high-level disinfectants. Reusable podiatric medical instruments that are heat stable and have the potential to break intact skin during ordinary use (e.g., nippers, forceps, splitters, curettes) should be ideally sterilized using steam rather than chemical disinfectant for the terminal reprocessing step. Scalpel blades should not be reused. Scalpel handles can be treated with intermediate-level disinfectants as noncritical instrumentation.

b. Mechanical debridement. Burrs used in mechanical debridement of nails or hyperkeratotic lesions can be treated with high-level disinfectants as semi-critical instrumentation. Burrs should be thoroughly cleaned prior to disinfection.

c. Dust exposure precautions. A dust extraction system or other safeguards should be employed during mechanical debridement to minimize hazardous exposure.

IV. Cleaning:

a. Cleaning is the removal of foreign material (e.g., soil, and organic material) from objects and is normally accomplished using water with detergents or enzymatic products. Thorough cleaning is required before high-level disinfection and sterilization because inorganic and organic materials that remain on the surfaces of instruments interfere with the effectiveness of these processes. Also, if soiled materials dry or bake onto the instruments, the removal process becomes more difficult and the disinfection or sterilization process less effective or ineffective.

Surgical instruments should be presoaked or rinsed to prevent drying of blood and to soften or remove blood from the instruments.

Cleaning is done manually in use areas without mechanical units (e.g., ultrasonic cleaners or washer-disinfectors) or for fragile or difficult-to-clean instruments. With manual cleaning, the two essential components are friction and fluidics. Friction (e.g., rubbing/scrubbing the soiled area with a brush) is an old and dependable method. Fluidics (i.e., fluids under pressure) is used to remove soil and debris from internal channels after brushing and when the design does not allow passage of a brush through a channel. When a washer-disinfector is used, care should be taken in loading instruments: hinged instruments should be opened fully to allow adequate contact with the detergent solution; stacking of instruments in washers should be avoided; and instruments should be disassembled as much as possible.

At a minimum, all instruments should be individually inspected and be visibly clean prior to any level of disinfection or sterilization.