# PART 3: DECONTAMINATION AND REPROCESSING

## A. Definition of Terms

**Decontamination** is a GENERAL TERM used to get rid of contamination; remove soil and pathogenic microorganisms from objects so they are safe to handle, subject to further processing, use or discard. **Reprocessing** are the steps necessary to make a contaminated reusable medical device ready for its next intended use. Equipment that is reused must be decontaminated and reprocessed by cleaning, disinfection and/or sterilization after each patient to prevent transmission of disease and to maintain the integrity of the equipment.

**Three levels of Reprocessing**

1. **Cleaning** is a process that REMOVES microorganisms, dirt, impurities or visible soil (e.g., organic and inorganic material) from objects and surfaces. Cleaning does not kill the microbes but lowers their numbers and the risk of spreading infection. This is normally accomplished manually or mechanically using water with detergents or enzymatic products.

2. **Disinfection** is a process that ELIMINATES MANY or all pathogenic microorganisms, except bacterial spores (i.e. nonsporicidal), on inanimate objects. This refers to the use of chemicals or "disinfectants" to kill microorganisms on surfaces. This process does not necessarily clean dirty surfaces or remove microbes, but by killing the microbes on a surface after cleaning, lowers the risk of spreading infection. Medical equipment and devices must be thoroughly cleaned prior to disinfection. There are two levels of disinfection:

    a. **Low level disinfection** kills most vegetative bacteria and some fungi as well as enveloped (lipid) viruses. Low level disinfectants do not kill mycobacteria or bacterial spores. This is used in non-critical medical equipment/devices or some environmental surfaces. Examples of low level chemical disinfectants are sodium hypochlorite and alcohol. Alcohol does not inactivate bacterial spores and isopropyl alcohol is unable to inactivate hydrophilic viruses (i.e., poliovirus, coxsackie virus).

    b. **High level disinfection** destroys vegetative bacteria, mycobacteria, fungi and enveloped (lipid) and non-enveloped (non-lipid) viruses, but not necessarily bacterial spores. This is used for reprocessing of semi-critical medical equipment/devices. Examples of high-level chemical disinfection are glutaraldehyde, hydrogen peroxide, ortho-phthalaldehyde, peracetic acid with hydrogen peroxide, and chlorine.

3. **Sterilization** is a process that destroys or ELIMINATES ALL forms of microbial life (including bacterial spores) and is carried out in health-care facilities by physical or chemical methods. This level of reprocessing is required when processing critical medical equipment/devices.

    Some commonly used methods of sterilization are the following:
    a. Autoclaving or steam sterilization for 20 minutes at 121°C - 132°C or for 30 minutes if the instruments are in wrapped packs. This form of sterilization inactivates all viruses.
    b. Dry heat or sterilization by hot air for 1-2 hours at 170°C. This is a method used for items that cannot be autoclaved. This is a poor alternative since it is suitable only for metal instruments and a few natural suture materials.

    Boiling instruments is now regarded as an unreliable means of sterilization and is not routinely recommended in hospital practice.

**Germicide,** a term that includes both "antiseptics" and "disinfectants", is an agent that can KILL microorganisms, particularly pathogenic organisms or germs (e.g. bactericide, fungicide, virucide, sporicide)

1. **Antiseptic** is a substance that inhibits the growth or action of microorganisms especially in or on living tissue. This germicide is applied to LIVING TISSUE or SKIN.

2. **Disinfectant** is a chemical that destroys vegetative forms of harmful microorganisms (such as bacteria or fungi) especially on inanimate objects but it may be less effective in destroying spores. This germicide is applied only to INANIMATE OBJECTS or SURFACES.

## B. Common and Locally Available Cleaning and Decontamination Solutions

**Soaps and Detergents.** Even non-medical grade soaps and detergents are effective at disrupting the lipid bilayer envelope of the SARS-CoV-2.

Common commercially available germicide solutions are effective in inactivating most microbial contaminants, including SARS-CoV-2. Examples of these are the following:

**Antiseptics:**

1. Alcohol (Ethyl & Isopropyl)
    a. Bactericidal, tuberculocidal, fungicidal, and virucidal but nonsporicidal
    b. Optimum bactericidal concentration is 60%–90% solutions in water (volume / volume)
    c. Antimicrobial action of alcohol is the denaturation of proteins. Absolute ethyl alcohol, a dehydrating agent, is less bactericidal than mixtures of alcohol and water because proteins are denatured more quickly in the presence of water.
    d. NOT recommended for sterilizing medical and surgical materials principally because they lack sporicidal action and they cannot penetrate protein-rich materials.
    e. Use of alcohol to decontaminate is due to its antiseptic rather than disinfecting properties.
    f. “Ethyl alcohol, at concentrations of 60%–80%, is a potent VIRUCIDAL agent that inactivates all of the lipophilic viruses (e.g., herpes, vaccinia, and influenza virus) and many hydrophilic viruses (e.g., adenovirus, enterovirus, rhinovirus, and rotaviruses but not hepatitis A virus or poliovirus) . Isopropyl alcohol is not active against the non-lipid enteroviruses but is fully active against the lipid viruses. Studies also have demonstrated the ability of ethyl and isopropyl alcohol to inactivate the hepatitis B virus (HBV) and the herpes virus, and ethyl alcohol to inactivate human immunodeficiency virus (HIV), rotavirus, echovirus, and astrovirus.” (CDC, 2008) The coronaviruses are RNA viruses that have a lipid bilayer.
    g. Recommended wet contact time is 10 minutes.

2. Iodophors / Povidone Iodine
    a. Bactericidal, mycobactericidal, fungicidal and virucidal but require prolonged contact times to kill certain fungi and bacterial spores
    b. Iodophors are used both as antiseptics and disinfectants while pure iodine solutions or tinctures are primarily antiseptics.
    c. Iodophor is a combination of iodine and a solubilizing agent or carrier, which provides a sustained-release reservoir of iodine and releases small amounts of free iodine in aqueous solution. Unlike iodine, iodophors are generally non-staining and relatively free of toxicity and irritancy.
    d. Iodine can penetrate the cell wall of microorganisms quickly, and the lethal effects are believed to result from disruption of protein and nucleic acid structure and synthesis.
    e. Antiseptic iodophors are not suitable for use as hard-surface disinfectants because of concentration differences. Iodophors formulated as antiseptics contain less free iodine than do those formulated as disinfectants.
    f. Recommended wet contact time of iodine in iodophor (50 ppm) is 10 minutes and povidone-iodine (1% iodine) is 1 minute.

**Disinfectants:**

1. Chlorine and Chlorine Compounds (Household Bleach & Chlorine Tablets)
    a. Available as Liquid (e.g., 5.25%–6.15% aqueous sodium hypochlorite or household bleach) or Solid (e.g., calcium hypochlorite or chlorine tablets or powder)
    b. Broad spectrum antimicrobial activity, do not leave toxic residues, are unaffected by water hardness, are inexpensive and fast-acting, remove dried or fixed organisms and biofilms from surfaces, and have a low incidence of serious toxicity
    c. Germicidal activity of chlorine is attributed largely to undissociated hypochlorous acid (HOCl). The dissociation of HOCl to the less microbicidal form (hypochlorite ion $OCl^-$) depends on pH.
    d. The disinfecting efficacy of chlorine decreases with an increase in pH. It should *not* be mixed with ammonia, acids and formaldehyde.
    e. Widely used in healthcare facilities in a variety of settings such as spot-disinfection of countertops and floors and for decontamination of small blood spills.
    f. The DOH recommendation for the use of aqueous sodium hypochlorite solution (i.e. dilute household bleach to be sprayed or wiped on surfaces) uses the following concentration: 1 part bleach mixed with 9 parts clean water to make a 0.5% (5000ppm) disinfectant solution, assuming that the household bleach solution is 5% sodium hypochlorite. For example, 100ml of 5% bleach solution plus 900ml of water will make 1 liter of 0.5% sodium hypochlorite disinfectant solution.
    g. Recommended wet contact time of sodium hypochlorite (0.05 – 0.5%) is 5 minutes, whereas sodium chlorite (0.23%) is 10 minutes.

2. Hydrogen Peroxide (Agua Oxigenada) - 3% is the usual concentration sold over the counter
    a. Has bactericidal, virucidal, sporicidal, and fungicidal properties. Commercially available 3% hydrogen peroxide is a stable and effective disinfectant when used on inanimate surfaces.
    b. Produces destructive hydroxyl free radicals that can attack membrane lipids, DNA, and other essential cell components.
    c. The higher the concentration, the more sporicidal it becomes against aerobic organisms and facultative anaerobes. Concentrations of 6% to 25% show promise as chemical sterilants.
    d. Synergistic sporicidal effects were observed when spores were exposed to a combination of hydrogen peroxide (5.9%–23.6%) and peracetic acid.
    e. Hydrogen peroxide (7.5%) used for 20 minutes at $20^{O}C$ is said to provide a high level of disinfection according to CDC.
    f. Recommended wet contact time for 0.5% accelerated hydrogen peroxide (AHP) is 1 minute.

**Other Commercial Solutions/Preparations:**

1. Chlorhexidine - available in antiseptic and/or disinfectant formulations
2. Quaternary Ammonium Compounds - are widely used as antiseptic and disinfectant solutions (e.g. Benzalkonium Chloride or alkyl dimethyl benzyl ammonium chloride)
3. Glutaraldehyde - an effective disinfectant against wide range of microorganisms, including spores
4. Superoxidized Water or Superoxidized Solution - a new disinfectant solution with neutral pH with similar bactericidal activity to 80% ethanol, but superior to 0.1% chlorhexidine and 0.02% povidone iodine

**NOTE**: Chemical disinfectants could be hazardous to healthcare workers if they are not properly handled. Combining different disinfectants is not recommended and everyone is encouraged to establish a chemical safety program suitable for each working environment, health facility, and institution.

**Spaulding's classification**

A rational approach to disinfection and sterilization of patient-care items and equipment has been devised by Earle H. Spaulding that was later on named, Spaulding's Classification. The classification categorizes instruments and equipments as critical, semicritical, and noncritical according to the degree of risk for infection involved in use of the items and offers specific options for decontamination

**Table 1.** Spaulding's Classification of Some Commonly Used ENT-HNS Out-Patient Instruments/Equipment and Required Level of Reprocessing

| Risk Category | Level of Microbicidal Action | Example of Procedures | Example of medical device* | Method of decontamination |
|---|---|---|---|---|
| **High or Critical**<br><br>with break in the skin or mucous membrane or entering a sterile body cavity | Kills all microorganisms | Nasopharyngeal biopsy,<br><br>Minor surgeries | Blakesley,<br><br>Surgical instruments | Sterilization<br><br>(usually heat if heat-stable or chemical if heat-sensitive) |
| **Intermediate or Semi-critical**<br><br>in contact with mucous membranes or non-intact skin | Kills all microorganisms, except high numbers of bacterial spores | Nasal Endoscopy,<br><br>Laryngoscopy,<br><br>Anterior rhinoscopy,<br><br>Otoscopy in a perforated TM | Rigid scope,<br><br>Flexible scope,<br><br>Nasal speculum,<br><br>Aural speculum | High-level disinfection** by heat or chemicals<br><br>(under controlled conditions with minimum toxicity for humans) |
| **Low or Non-Critical**<br><br>in contact with intact skin | Kills vegetative bacteria, fungi and lipid viruses | Ear Examination<br><br>Otoscopy in an intact TM | Otoscope,<br><br>Aural speculum | Low level disinfection**<br><br>(cleaning) |

*The manufacturer's directions for disinfection and sterilization of instruments and equipment must be followed.
**The manufacturer's instructions for use of disinfectant must be followed

**NOTE:** When implementing the Spaulding's classification scheme, always consider the various factors that may affect the efficacy of disinfection and sterilization relative to the material/s of the instruments or equipment. Inactivating certain types of infectious agents should always be considered when reprocessing complicated medical equipment (e.g., endoscopes, microscopes) that are often heat-sensitive. It is highly advised to verify the manufacturer's recommended method of sterilization and decontamination. Moreover, always make sure that the appropriate PPE is used during the decontamination process.

## C. Decontamination and Reprocessing Instruments & Equipments

Instruments and equipment used during the examination and procedure should be cleaned and washed immediately after use with water and soap or any enzymatic solution. Reprocessing of instruments and equipment should follow the Spaulding's classification with appropriate reprocessing procedures. Full PPE (surgical mask, eye protection such as goggles or face shield, fluid resistant gown, and gloves) should be worn throughout the decontamination process. The reprocessing personnel may consider wearing a fluid resistant apron over the PPE to optimize PPE supply. Some important points to consider on decontaminating instruments include the following:

1. It is ideal to prepare multiple sets of instruments to decrease turnover time. If this is not possible, decontamination of instruments and equipment should follow the Spaulding's classification with appropriate reprocessing procedures (see Table 1)

2. Washable devices such as metal and plastic instruments should be wiped clear of gross soil and may be soaked for a maximum of 30 minutes in clean water, or a dilute solution of detergent before cleaning. Prolonged soaking of devices should be avoided.

3. Follow the reprocessing cycle in designated areas only: Cleaning → Disinfection → Drying → (Sterilization) → Storage

4. Critical devices are sterilized by an approved sterilization process. Ultraviolet light is an unacceptable sterilization method for these devices.

5. It is recommended that endoscopes be reprocessed using cleaning and high-level disinfection.

6. Disinfectant solutions have varying degrees of effectiveness, recommended dilutions, and contact times. To ensure effective disinfection, follow the manufacturer's instructions or any other specific guidelines that have been given.

7. Mixing of cleaners or disinfectants with other chemicals should be avoided as this may either lead to a more hazardous chemical mixture, or a less effective product due to changed or altered properties.

For a comprehensive guide on decontamination and reprocessing, you may also refer to the following:

1. WHO manual Decontamination and Reprocessing of Medical Devices for Health-care Facilities https://www.who.int/infection-prevention/publications/decontamination/en/

2. CDC Guideline for Disinfection and Sterilization in Healthcare Facilities https://www.cdc.gov/infectioncontrol/guidelines/disinfection/

For a detailed list of disinfectants against SARS-CoV-2, you may refer to the following:

1. List of EPA registered disinfectants for use against SARS-CoV2 https://www.epa.gov/pesticide-registration/list-n-disinfectants-use-against-sars-cov-2

2. Information from European Chemicals Agency (ECHA) on Biocidal products having virucidal activity and authorized under the BPR as efficacious against SARS-CoV-2 coronavirus https://echa.europa.eu/information-on-chemicals

3. National Environment Agency of Singapore Interim List of Household Products and Active Ingredients for Disinfection of the COVID-19 VirusRevised May 5, 2020. https://www.nea.gov.sg/our-services/public-cleanliness/environmental-cleaning-guidelines/guidelines/interim-list-of-household-products-and-active-ingredients-for-disinfection-of-covid-19

## D. Decontamination of the Clinic Facility In Between Patients

1. After performing an AGP, leave the room closed for 35 minutes to achieve greater than 99.9% efficiency of air particulate removal in a room with a closed ventilation circuit equipped with a HEPA filtering unit for recycling air at 12 ACH.

2. Staff engaged in cleaning should wear PPE. It is critical that all horizontal and high touch surfaces are thoroughly wiped (e.g. procedure table, countertop, chair, equipment, etc.) with approved low level disinfectant. The manufacturer's instructions for use must be followed (e.g. contact/wet times). Low level disinfectants such as 0.5% chlorine solution or 70% alcohol are also effective and sufficient for cleaning surfaces.

3. The use of single-use disposable cleaning equipment (e.g. disposable towels) is recommended. If disposable cleaning equipment is not available, the cleaning material (cloth, sponge etc.) should be placed in a disinfectant solution effective against viruses or 0.5% chlorine solution. If neither solution is available, the material should be discarded.

**E. Clinic Facility Decontamination at the End of Clinic (after all patients are seen)**

1. **Proper PPE** doffing should be done in designated areas, with the non-reusable PPE discarded in the infectious waste bin, and with strict observance of hand hygiene.

2. **Surgical masks** and equivalent face masks are *not recommended to be reused* for the ORL-HNS workplace. These face masks are intended for single use only.

3. **N95 respirators** are originally intended to be disposed of after initial use. However, reusing N95 respirators after proper reprocessing is an option due to limited supply and overstretched resources during this COVID-19 pandemic. Before reprocessing these respirators, carefully inspect for physical contamination and wash with soap and water. The following are options to decontaminate N95 and its equivalent respirators:
    a. Hydrogen peroxide vaporization (HPV) - This is an effective way to decontaminate N95 respirators and results in an acceptable preservation of function. However, this can only be used on N95 models that do not contain cellulose. The Sterrad sterilization system, which is readily available in most hospitals, creates synergism between peroxide and low temperature gas plasma (an excited or ionized gas) to rapidly destroy microorganisms. This system can be used for non-cellulose and non-paper N95 respirators for up to 2 cycles of decontamination.
    b. Ultraviolet germicidal irradiation (UVGI) - With the standard dosing protocols and full surface area illumination, this method can be used to inactivate viral particles with minimal mask degradation. (Please see PSO-HNS C-19A Appendix D Part 2). Although this process does not have a significant effect on particle penetration, ability to filter or air flow resistance of the respirator, UVGI may decrease the strength of the respirator materials with repeated disinfection cycles.
    c. Moist Heat and Dry Heat - This method of decontamination has been implemented by some hospital systems in the United States and has been used in several hospitals in Taiwan to conserve PPE resources. Moist heat at 60-70°C with 80-85% relative humidity and dry heat at 70°C for 30 minutes were used to disinfect masks and respirators. However, this procedure is not yet supported by well conducted trials and may compromise the integrity of the materials and the respirator fit.
    d. Mask Rotation - Since COVID-19 is believed to lose viability after 72 hours, rotating the use of reprocessed masks for a minimum of 4 days is recommended regardless of which decontamination procedure is employed. CDC also suggests that N95 masks can be reused up to 5 times but reserve these masks for low risk areas in the workplace. For areas with limited resources, new or unused masks may be reserved for aerosol generating procedures or surgeries, or for high risk areas. Between use, each respirator and mask must be individually stored in a clean paper bag and properly labeled (e.g. with the user name, day decontaminated, number of times reprocessed). Moreover, these items must not be shared even if they have been reprocessed.

4. **Elastomeric respirators** with some safety modifications, particularly on the exhalation valves, have been widely used for comfort, effective seal, and due to the limited supply of medical grade masks and respirators. Since these respirators have a wide range of designs and materials, it is important to check the manufacturer's label for the appropriate sterilization process and specific protocol for each respirator model. Generally, it is recommended that respirators be cleaned and disinfected immediately after doffing. If this is not possible, place them immediately in a sealed plastic bag and perform the decontamination in a safe cleaning

area and with the necessary PPE. In general, the basic steps to clean and disinfect a respirator are the following:

a. Remove filters, cartridge, & metal attachment
b. Clean respirators with soap and water, then rinse with water
c. Disinfect with recommended germicidal solutions. Submerging the respirator in 0.5% or 5,000 ppm bleach solution for a minimum of 10 minutes works for most models.
d. Rinse thoroughly with water and air dry
e. Inspect and repair or replace parts if necessary
f. Store in a clean bag or sealed storage container for succeeding use

**Note**: With a wide variety of filter cartridges, it is important to review the model specification, capability, and proper disposal.

5. **Goggles and face shields** have different materials and compositions. It is important to determine the material used for each equipment and review the manufacturer's disinfection protocols. This is very important specially for the clear plastic material because each has their own compatibility with acids and alkali. (Please see PSO-HNS C-19 A Appendix D - Part 2)
    a. Clear plastic goggles and face shields are usually made from polycarbonate, propionate, acetate, acrylic, and other materials that have different properties and tolerance to disinfecting solutions. Others are derived from a combination of materials with different proportions, hence it is important to verify the exact material used for each equipment to determine the appropriate disinfecting solution.
    b. The most common material for clear box barrier models is acrylic which can be safely disinfected with 0.05% bleach solution but not with alcohol. Some clear plastic materials on the other hand are not compatible either with acid, alkali, 60% or greater concentration of alcohol solution, and may not be suitable for multiple reprocessing.
    c. Once the acid and/or alkali compatibility is confirmed, goggles and face shields should be washed thoroughly in a safe designated area. Make sure that all parts are cleaned using a scratch-free cloth with detergent solution and rinsed with water. Air dry and then wipe the surfaces with the recommended solution or the ideal EPA-registered disinfectant solution.
    d. Wipe the external clear viewing portion with clean water or alcohol to remove residue and maintain clarity.
    e. Inspect and repair or replace parts if necessary
    f. Store in a clean bag or sealed storage container for succeeding use

6. **Gowns or coveralls** that are labeled "disposable" should not be reused because the ties and fasteners may break during doffing. Reusable or washable gowns are typically made of polyester or polyester-cotton fabrics that can be safely laundered according to routine procedures.
    a. Reusable gowns and coveralls must be immediately removed and stored in a properly identified resealable storage container or plastic bag in the doffing area.
    b. Cleaning them individually is ideal, or at the very least, do not mix gowns and coveralls used for a different procedure.
    c. Wash as usual with soap and water
    d. Chlorine bleach of 50–150 ppm (5 ml-120 ml 5% household bleach in 1 Gal of water) concentration can be used to ensure proper disinfection but consider the gown material and need for decontamination.
    e. Rinsing with water effectively removes residual alkali from fabrics and reduces the risk of skin reactions
    f. Press, fold, and pack for storage to ensure cleanliness until its next use.

7. **Surgical gloves** must be disposed properly. Reprocessing gloves is not recommended for better infection control and health-care worker safety,

8. **All textiles** (e.g. towels, linens, etc.) used in the clinic or workplace should be washed based on the specification of each material. Delicate materials that cannot withstand strict

decontamination procedures should not be used.

a. Washing linen with a hot-water cycle (90°C) and regular laundry detergent may be sufficient
b. If a hot-water cycle cannot be used due to the characteristics of the material, chlorine solution for decontamination of textiles needs to be added to the wash cycle

9. **Other surfaces** in the clinic or workplace should be disinfected after clinic hours.
   a. Depending on the material (e.g. table, chairs, trays, etc.), surfaces may be disinfected with either 70% alcohol or a freshly prepared 0.5% or 5,000 ppm bleach solution with a minimum of 10-minute wet contact time before wiping dry. When using bleach for surface disinfection, use only freshly prepared solutions and replace every 24 hours. The scent of the bleach does not equate to the actual disinfecting property of the bleach.
   b. Ultraviolet germicidal irradiation (UVGI) for room surface disinfection at the end of each clinic is ideally performed. The capacity of the UV unit and its irradiance should be compatible with the size and configuration of the room and the materials of each surface, while taking into consideration the duration of exposure and presence of shadowing. Strict safety precautions should also be applied. (Please see PSO-HNS C-19A Appendix D - Part 1)
   c. In the event of shortage of cleaning equipment, the cleaning process should start from the cleanest areas then move onto the dirtiest areas (e.g. an area where an AGP has been performed).

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