Surrey-North Delta
Division of Family Practice
A GPSC initiative

MEDICAL DEVICE REPROCESSING TOOLKIT

For Office Reprocessing

Surrey/North Delta Division of Family Practice

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Introduction:

Dear Doctor,

As you may have heard, or have been notified, many offices are undergoing audits to assess their office sterilization process and technique to control the potential for contamination and infections. To help ease the process of preparing for the office assessment, this Medical Device Reprocessing (MDR) Toolkit was created for reference.

Please note that more information for each point of the toolkit can be found by matching the heading number to the corresponding section number in the Physician Office Medical Device Reprocessing Assessment (POMDRA) Tool for steam Sterilization. For ease of access, the 2018 POMDRA from the College of Physicians and Surgeons of British Columbia can be accessed online from the following link: https://www.cpsbc.ca/programs/pomdra/assessment-tool.

If there are any questions regarding this MDR toolkit please contact the Surrey/North Delta Division of Family Practice.

Note: Please be advised, this toolkit is based off of the Sept 2018 edition of POMDRA. Physicians are advised that there may be changes required to keep this toolkit current with each revision of POMDRA. Physicians are advised to visit: https://www.cpsbc.ca/programs/pomdra to check if a newer version of POMDRA has been released. A comparison is advised to check for any differences in requirements.

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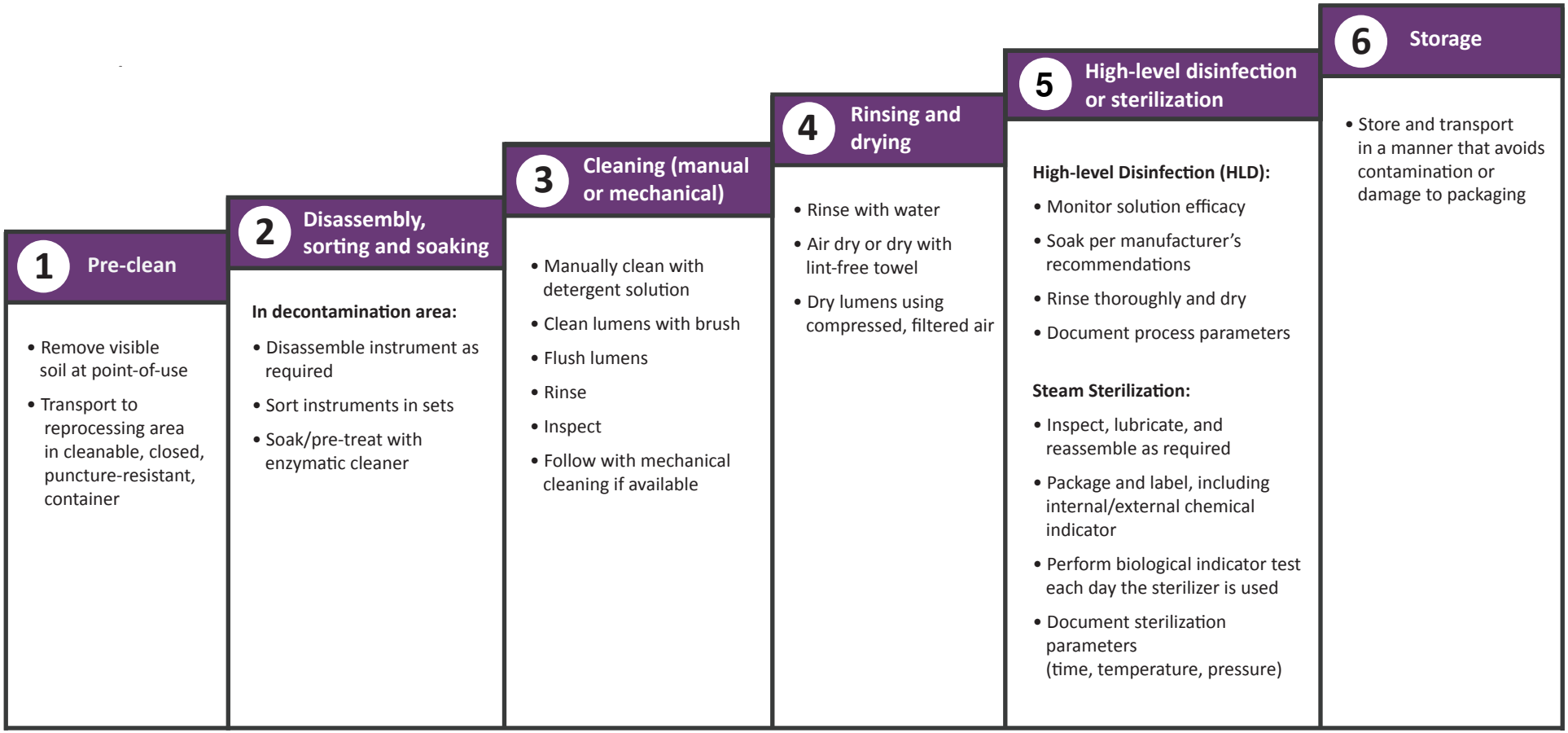
Reprocessing Steps



Reference:

Ontario Agency for Health Protection and Promotion (Public Health Ontario), Provincial Infectious Diseases Advisory Committee. Best practices for cleaning, disinfection and sterilization in all health care settings. 3rd ed. Toronto, ON: Queen's Printer for Ontario; 2013. Available from: http://www.publichealthontario.ca/en/eRepository/PIDAC_Cleaning_Disinfection_and_Sterilization_2013.pdf

Office reprocessing checklist:

RISK LEGEND:

Legislated requirement: must be compliant
High Risk: Health hazard. Will need to stop practice and correct immediately. May pose risk for infection or injury
Medium Risk: Must be corrected, not an immediate risk.
BOLD WRITING: Key points to be completed

Use and Training (1):

- Ensure written manufacture instructions for use (MIFU) are available for each device; with validated material indicating that steam sterilization is appropriate.
- Written MIFU for the sterilizer are available
- Material safety data sheets are available for all detergents/enzymatic cleaners: risks associated; first aid; and safety requirements.
- Cleaning products/detergents/enzymatic cleaners are labeled and have the manufacturers' expiry date. If products have a drug identification number (DIN) it must be visibly labeled.
- Ensure that staff assigned to reprocessing complete training and education for reprocessing. Reprocessing is done in a timely manner.
- Proper hand hygiene followed during reprocessing: after handling contaminated instruments; prior to putting on personal protective equipment (PPE). – Recommendation: complete provincial module on hand hygiene: SEE APPENDIX

Policies/Procedure (2):

- Written, step by step, procedures on the complete reprocessing process, at the facility, available for staff.
- Written policy/procedure available for the recall of improperly reprocessed equipment.
- Policy in place requiring scheduled preventative maintenance of sterilizer, with written **documentation logging when it occurs**.

Physical Space (3):

- Reprocessing occurs in area solely dedicated to that purpose. IF reprocessing is occurring in dual-purpose area (exam room), patients are not present when reprocessing occurs.
- No food, other contaminates or personal effects storage in reprocessing area.
- All surfaces in reprocessing area can be cleaned and disinfected (countertops, sinks, and floor); with there being sufficient counter space available to handle volume of work.
- Workflow pattern, moving from dirty to clean, present.
- Sink sufficient in size and depth for cleaning and rinsing present in reprocessing area.
- Via alcohol based hand rub or soap and water, the reprocessing area has means for hand hygiene.
- **Documented schedule** in place, along with written instructions, for the cleaning/disinfecting of reprocessing areas; and for storage areas where sterilized packaged devices are kept.
- All cleaning products/detergents/enzymatic cleaners are stored in a way that no damage occurs to containers and they can be accessed safely.

Pre-cleaning (5):

- Prior to cleaning, devices are sorted and disassembled.
- At point of use, pre-cleaning of devices is done immediately to remove gross soil/organic material.
- Any solutions used for pre-cleaning are discarded and not used in cleaning steps
- Instruments transferred from cleaning to sterilization station must be done so using closed, plastic containers.

Cleaning (7):

- Detergents/enzymatic cleaners are medical grade products.
- Detergents/enzymatic cleaners are prepped and used according to MIFU.
- During cleaning medical devices are fully immersed in prepared Detergents/enzymatic cleaners, following MIFU.
- Medical devices/instruments are scrubbed with a cleaning brush/tool to remove any organic matter.

- Medical devices with lumens are flushed with Detergents/enzymatic cleaners and brushed with proper brush/cleaning tool.
- Cleaning tools used to manually clean medical devices are either disposable or sterilized at the end of the day.
- Detergents/enzymatic cleaners are discarded at least daily or when visibly soiled.

Rinsing/Drying Post Cleaning (8):

- Following cleaning process, all devices/instruments must be rinsed with water.
- Following the rinse, the device/instrument is thoroughly dried with a cloth, or air dried, in preparation for packing and sterilization.

Packing and Labeling – Pre-sterilization (9):

- Only packing material designed for sterilization is used.
- An **external** chemical indicator (CI) is visible on the outside of the pouch/packaging. **Pay attention to expiration dates.**
- An **internal** CI is placed in each pouch/pack-wrapped device to be sterilized (unless already part of the pouch/pack wrap)
- All reusable **critical and semi critical** medical devices are packaged prior to sterilization in steam.
- Medical devices are placed in the packaging in **open** and/or **unlocked** position.
- Medical devices are distributed evenly in packages and packaged disassembled **if** indicated in MIFU.
- All medical device packages are labeled with:
    - Sterilization date
    - Initials of individual that packaged device
    - Name or set of device, if device is not visible through packaging
    - If multiple loads performed in a day, label load number
    - If multiple sterilizers used, label sterilizer number

Loading the Sterilizer (10):

- Packaged devices are loaded in the steam sterilizer in a manner that ensures steam contact and penetration.

Steam Sterilization Process (11):

- An appropriate, Canada-licensed table top sterilizer is being used.
- According to the MIFU, appropriate sterilization cycles are being used for the medical devices.
- Flash or immediate use steam sterilization of unwrapped medical devices is not being performed.

Biological Monitoring of Sterilizer (12):

- A Biological Indicator (BI) test is performed at least once each day the sterilizer is used. A control BI test is conducted simultaneously.
- When the sterilization load is complete, the BI test is immediately incubated in the BI incubator.
- BI control and the tested BI should be marked with the same lot number.
- All sterilized devices are not released for use until the final BI test result is available and negative for growth.
- Final readouts of the BI (test and control) are reviewed and **documented by staff.**
- If a BI test indicates spore growth, all medical devices sterilized since the last negative BI test are quarantined and not used.

Chemical Monitoring of Sterilizer (13):

- Once sterilization cycle is complete, inspect the **internal/external chemical indicator (CI)** in each package and **document the results**.
- If failed internal/external CI found, contents of package are not used

Physical Monitoring of Sterilizer (14):

- Physical parameters (time, temperature, pressure) of each cycle are monitored.
- Temperature should reach minimum Temperature required for sterilization, as outline in MIFU. That temperature should be recorded on the kept log along with time duration required for sterilization portion of the cycle based on MIFU.

Record Keeping (15):

- **A written log of all sterilizer tests, loads/cycles and their contents are kept, along with monitoring results.**
- **A written log of preventative maintenance of the sterilizer is kept, along with a schedule for regular cleaning.**

Unloading the Sterilizer (16):

- After the completion of each cycle, all packages, at time of removal, are verified for the absence of moisture and the integrity of the packaging.

Sterilization Failures/Unsuccessful Outcomes (17):

- All sterilizer indicators showing failure are investigated.

Storage of Sterilized Medical Devices (18):

- Devices stored in their sterile packaging until time of use.
- Stored securely in a way that keeps them clean, dry and prevents contamination. **Do not store in corrugated cardboard boxes**.

Personal Protective Equipment (PPI) (19):

- PPI pertinent to the task is available and used when required.
- PPI include, but are not limited to, gloves and gowns.

Reference

"POMDRA Tool for Steam Sterilization." Edited by College of Physicians and Surgeons of British Columbia, *Practice Standards and Professional Guidelines | College of Physicians and Surgeons of British Columbia*, September 2018. Available from: www.cpsbc.ca/programs/pomdra/assessment-tool.

DATE:_____

Sterilization Load Report (up to two loads per report).

Sterilizer Model #:

Sterilizer Serial #:

On completion of each cycle, verify and document parameters.

Load Number:	**Load Number:**
Cycle selected (if applicable): Sterilization exposure time: Sterilization exposure temperature: Items in load: Load started by: Unloaded by: Internal chemical indicator change: ○ Yes ○ No External chemical indicator change: ○ Yes ○ No	Cycle selected (if applicable): Sterilization exposure time: Sterilization exposure temperature: Items in load: Load started by: Unloaded by: Internal chemical indicator change: ○ Yes ○ No External chemical indicator change: ○ Yes ○ No

Daily Biological Indicator Testing

Test BI lot #: _____ Expiry date: _____

Control BI lot #: _____ Expiry date: _____

Growth is read after _____ hours

Time placed in incubator:

BI test: _____ Control: _____ Initial: _____

Time out of incubator:

BI test: ○ positive ○ negative Control: ○ positive ○ negative Initial: _____

Sterilizer cleaning and maintenance due date:_____

Sterilizer Preventative Maintenance

Sterilizer Model #:_____

Sterilizer Serial #:_____

Regular Scheduled Maintenance every:_____

Company	Date	Technician Name	Signature

Sterilizer Cleaning Schedule

Sterilizer Model #:_____

Sterilizer Serial #:_____

Regular Scheduled Cleaning:_____

Name of Individual Cleaning	Date	Initials

Cleaning Schedule

Regular Scheduled Cleaning for Reprocessing Area:_____

Regular Scheduled Cleaning for Storage Area:_____

- **R = Reprocessing area**
- **S= Storage area**

Name	Date	Area Cleaned	Signature

APPENDIX:

Sterilizer Types: Advantages/Disadvantages

Process Option	Advantages	Disadvantages
Steam: **Prevacuum sterilizers** **Gravity displacement sterilizers** **Small table-top sterilizers**	Inexpensive Fast Effective, with a wide margin of safety Nontoxic Readily available Sterilizers are available in many sizes for many applications	Unsuitable for anhydrous materials (e.g., oils and powders), wood, and heat- and moisture-sensitive materials. Some tabletop sterilizers lack a drying cycle and/or printers (for physical monitoring of each cycle). Safe use of steam sterilizers requires a sound knowledge of their requirements. Not all facilities have this expertise.
The following options are not recommended for use in PSEs. They are listed to show the disadvantages.		
Glutaraldehyde (GTA) (2.4%-3.5%)	No notable advantages The use of glutaraldehyde as a sterilant is strongly discouraged	In-use life may be limited (e.g., 14 days, 28 days). Biological and chemical indicators not available. Devices must be used immediately because sterility cannot be maintained during storage. Handling provides opportunities for contamination. Toxic, sensitizing irritant. Needs proper ventilation and closed containers. Lengthy process (6-12 hours). Disposal may require special handling.
Hydrogen Peroxide, Accelerated (7% and 2 %)	No notable advantages. The use of liquid chemicals as a sterilant is strongly discouraged.	In-use life is limited to 21 days or failure of the minimum effective concentration (MEC) test, whichever comes first. Strong oxidizer. Depending on the concentration, it can be corrosive to some materials e.g.,

		copper, brass, carbon-tipped devices and aluminum. May cause irritation and chemical burns to eyes or to mouth and throat if swallowed. May cause slight irritation to skin. Requires copious rinsing with sterile water to maintain sterility. Must be stored in cool place, protected from light. Biological and chemical indicators not available. Devices must be used immediately because sterility cannot be maintained during storage. Frequent handling of devices provides opportunities for contamination. Lengthy process (e.g., 6 hours)
Dry Heat **Gravity convection** **Mechanical convection** **Ref: ISO 20857**	Noncorrosive. Reaches internal parts that cannot be disassembled for direct sterilant contact (via heat conduction). Inexpensive	Lengthy cycle due to slow heat-conduction process. Temperature can be variable especially in gravity convection ovens. High temperatures can damage some materials.
Ethylene Oxide (EtO) Gas Not likely found in a PSE; however, often used to sterilize items purchased prepackaged and sterile.	Noncorrosive Some ability to penetrate some synthetic materials.	Toxic /carcinogenic to humans. Lengthy cycle due to aeration requirements. Requires monitoring of the work areas. Requires control and monitoring of discharge into the environment. Flammable and explosive. Reactive with other chemicals. Expensive compared to steam. Incompatible with some materials, e.g., silicone.

AT A GLANCE

Disinfectant Tables

This document is an excerpt from the Guide to Infection Prevention and Control in Personal Service Settings. It helps to classify equipment/instruments and determine the level of reprocessing required based on the intended and actual use of the equipment/instruments. For more information, please consult the full Guide, visit the IPAC in Personal Service Settings webpage or email ipac@oahpp.ca.

Level of Disinfection: High

Destroys or irreversibly inactivates all microbial pathogens (bacteria, fungi, and viruses), but not necessarily large numbers of bacterial spores.

When to Use: Use on semi-critical items and items that hold, manipulate, or contact critical items.

Disinfectant Active Ingredients	Contact Times (Approximately)	Advantages	Disadvantages
1:10 chlorine bleach solution‡ (1 part bleach and 9 parts water); 5,000 parts per million	10 minutes	Inexpensive, fast-acting	Extremely corrosive to metal; may destroy adhesives with prolonged soaking; solution is to be made daily; inactivated by organic material
≥6% hydrogen peroxide (enhanced action formulation)	20 – 30 minutes (follow manufacturer's instructions)	Inexpensive, fast-acting, environmentally friendly, no residue	Is to be stored in a cool place; protect from light; oxidizing properties may be destructive to some equipment (brass, zinc, copper and nickel/silver)
2% hydrogen peroxide (enhanced action formulation)	5 – 8 minutes (follow manufacturer's instructions)	Inexpensive, fast-acting, environmentally friendly, non-toxic, active in the presence of organic materials	May be destructive to some equipment (copper, brass, carbon-tipped devices, anodized aluminum)
0.55% ortho-phthalaldehyde	10 minutes (follow manufacturer's instructions)	Fast-acting, no mixing needed, active in the presence of organic materials	Stains proteins

‡Based on regular household bleach solution of 5.25% sodium hypochlorite solution (50,000 parts per million available chlorine).

Level of Disinfection: Intermediate

Destroys vegetative bacteria, mycobacteria, most viruses, and most fungi but not bacterial spores.

When to Use: Use on non-critical items that require intermediate-level disinfection.

Disinfectant Active Ingredients	Contact Times (Approximately)	Advantages	Disadvantages
1:50 chlorine bleach solution‡ (1 part bleach and 49 parts water); 1,000 parts per million	10 minutes	Inexpensive; fast-acting	Corrodes metal; may destroy adhesives with prolonged soaking; solution is to be made daily; inactivated by organic material
70 – 90% ethyl or isopropyl alcohol	10 minutes	Fast-acting; leaves no residue	Can damage rubber and plastics; flammable; evaporates quickly
0.5% hydrogen peroxide (enhanced action formulation) with efficacy claims against tuberculosis (TB) or mycobacteria	3 – 5 minutes (follow manufacturer's instructions)	Inexpensive; fast-acting; environmentally friendly; non-toxic; active in the presence of organic materials; available in a wipe; cleans and disinfects	May be destructive to some equipment (copper, brass, carbon-tipped devices, anodized aluminum)

‡Based on regular household bleach solution of 5.25% sodium hypochlorite solution (50,000 parts per million available chlorine).

Level of Disinfection: Low

Destroys vegetative bacteria and some fungi and viruses but not mycobacteria or spores.

When to Use: Use on non-critical items that require low-level disinfection and environmental surfaces.

Disinfectant Active Ingredients	Contact Times (Approximately)	Advantages	Disadvantages
1:500 chlorine bleach solution‡ (1 part bleach and 499 parts water); 100 parts per million	10 minutes	Inexpensive; fast-acting	Corrodes metal; may destroy adhesives with prolonged soaking; solution is to be made daily
Quaternary ammonium	10 minutes (follow manufacturer's instructions)	Good cleaning agent for environmental surfaces	Limited use as disinfectant because of narrow microbiocidal spectrum; not recommended as an antiseptic
3% hydrogen peroxide	10 minutes	Inexpensive; fast-acting; environmentally friendly	Oxidizing properties may be destructive to some equipment (brass, zinc, copper and nickel/silver)
0.5% hydrogen peroxide (enhanced action formulation)	Follow manufacturer's instructions	Inexpensive; fast-acting; environmentally friendly; non-toxic; active in the presence of organic materials; available in a wipe; cleans and disinfects	May be destructive to some equipment (copper, brass, carbon-tipped devices and anodized aluminum)
Phenols	Follow manufacturer's instructions	Easy to obtain; cleans and disinfects	Residual phenols on porous materials may cause tissue irritation even when thoroughly rinsed; for environmental surfaces only

‡Based on regular household bleach solution of 5.25% sodium hypochlorite solution (50,000 parts per million available chlorine).

Citation

Ontario Agency for Health Protection and Promotion (Public Health Ontario). Guide to infection prevention and control in personal service settings. 3rd ed. Toronto, ON: Queen's Printer for Ontario; 2018. At a glance, Disinfectant tables.

Disclaimer

This document was developed by Public Health Ontario (PHO). PHO provides scientific and technical advice to Ontario's government, public health organizations and health care providers. PHO's work is guided by the current best available evidence at the time of publication.

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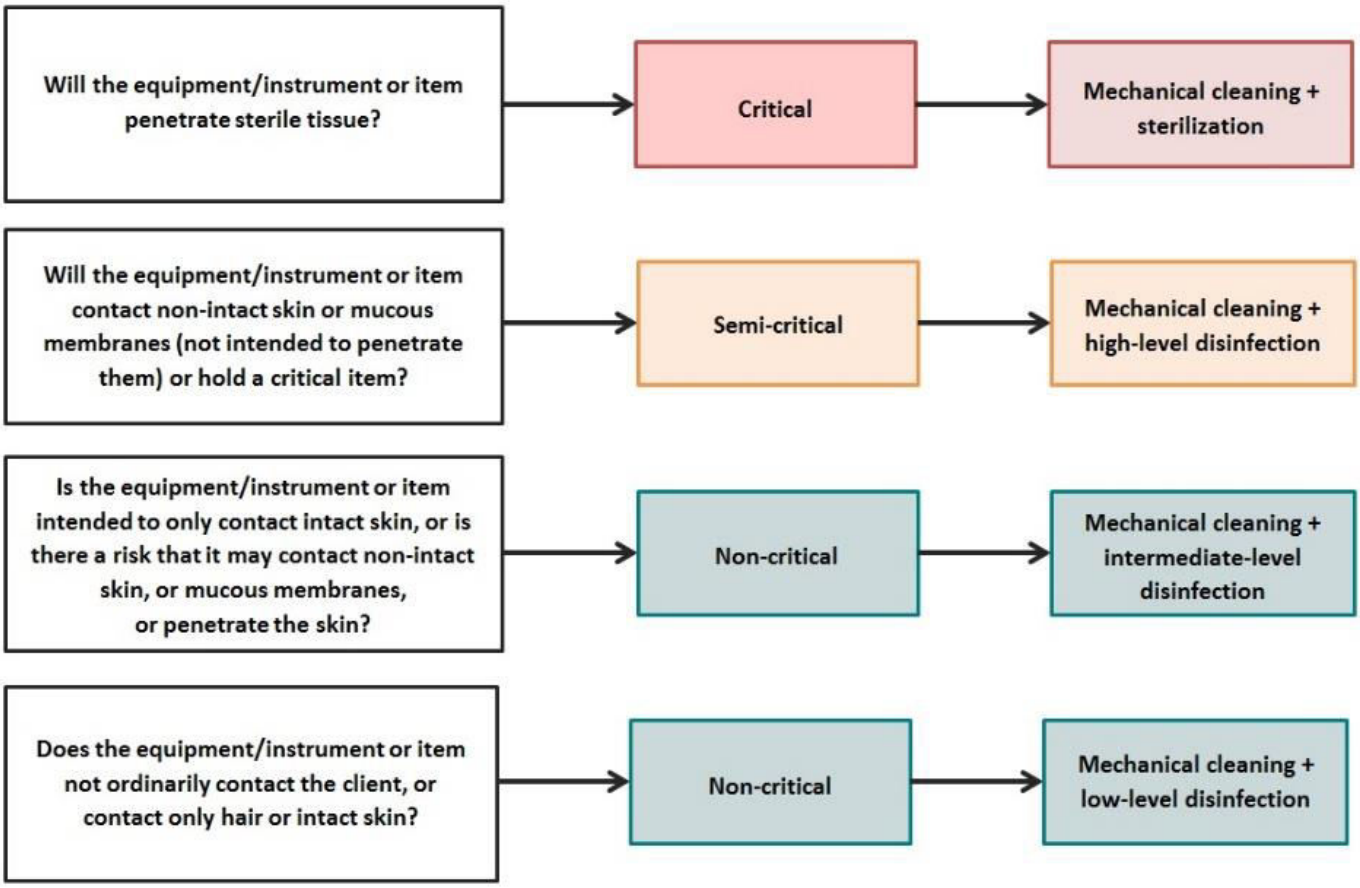
AT A GLANCE

Algorithm for Level of Reprocessing for Equipment and Instruments

This document is an excerpt from the Guide to Infection Prevention and Control in Personal Service Settings. It helps to classify equipment/instruments and determine the level of reprocessing required based on the intended and actual use of the equipment/instruments. For more information, please consult the full Guide, visit the IPAC in Personal Service Settings webpage or email ipac@oahpp.ca.



Adapted from British Columbia Ministry of Health, Health Protection Branch document *Guidelines for Personal Service Establishments*.[87]

Examples of levels of reprocessing required based on classification of equipment and instruments:

Tattoo, piercing, or electrolysis needles. Because these needles are designed to penetrate the skin, they are classified as **critical** and are to be **sterilized**. It is recommended these items be purchased as pre-sterilized, single use and disposable.

- Tweezers used to expose and remove ingrown hairs. Because these tweezers are in contact with non-intact skin, they are classified as **semi-critical** and require cleaning followed by **high-level disinfection.**
- Nail clippers or nippers. Because these items are designed to trim nails and cuticles but may accidently penetrate the skin, they are classified as **non-critical, (intermediate-level disinfection)**, and require cleaning followed by **intermediate-level disinfection**.
- Hair-cutting scissors. Because these items are designed to only contact hair and sometimes intact skin, they are classified as **non-critical (low-level disinfection)**, and require cleaning followed by **low-level disinfection**. Although the instrument is non-critical, if the scissors come into contact with non-intact skin, mucous membranes, or penetrate the skin, the instrument becomes **non-critical** (**intermediate-level disinfection**), requiring cleaning followed by **intermediate-level disinfection**.

Citation

- British Columbia. Ministry of Health. Health Protection Branch. Guidelines for personal service establishments [Internet]. Victoria, BC: Province of British Columbia; 2017 [cited 2018 May 18]. Available from: www2.gov.bc.ca/assets/gov/health/keeping-bc-healthy-safe/pses/pse_guidelines_final_nov_2017.pdf

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Reference:

Ontario Agency for Health Protection and Promotion (Public Health Ontario). Guide to infection prevention and control in personal service settings. 3rd ed. Toronto, ON: Queen's Printer for Ontario; 2018. At a glance, Algorithm for level of reprocessing for equipment and instruments.

Reprocessing Level:

Class	Use	Minimal Level Reprocessing	Examples
Critical	Enters sterile body site, including the vascular system	Cleaning followed by sterilization	• Surgical instruments • Uterine sounds • Tenaculum • Forcepts • Biopsy Instruments
Semi-Critical	Comes in contact with non-intact skin or mucous membranes but does not penetrate them	Cleaning followed by high-level disinfection. Sterilization is preferred	• Vaginal Specula • Endoscopes • Biopsy instruments • Anesthesia equipment • Tonometer
Non-Critical	Touches only intact skin and non-mucous membranes, or does not directly touch patient	Cleaning followed by low-level disinfection (in some cases, cleaning alone is acceptable)	• ECG machine • Oximeters • Stethoscope • BP cuffs

EDUCATION REGARDING REPROCESSING:

For Sterilization – online education:

1) Public Health Ontario medical device reprocessing course: https://www.publichealthontario.ca/en/LearningAndDevelopment/OnlineLearning/InfectiousDiseases/Reprocessing/Pages/Course.aspx

2) CSA course – Medical device reprocessing in a community setting: http://shop.csa.ca/en/canada/medical-device-reprocessing-in-community-healthcare-settings/invt/2703582

For Hand Hygiene- module:

3) Online course : https://learninghub.phsa.ca/Courses/5360/provincial-hand-hygiene-basics-picnet

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Our acknowledgements to Harminder Gakhal, M.D., for creating the Medical Device Reprocessing (MDR) Toolkit under the purview of the Surrey/North Delta Division of Family Practice.