

# Instrument Reprocessing:

## A Foot Care Nurse's Guide to Steam Sterilization



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# Introduction

## Purpose of this Guide

This handbook provides information on the requirements to achieve successful sterilization of foot care instruments using a steam autoclave.

Instrument care and reprocessing is an integral part of foot care in clinics, long-term care settings and in the home.

In December 1997, Health Canada published guidelines specifically to foot care. All foot care instruments are considered critical items by Spaulding's Classification (*Table 1*). Therefore, all instruments used in foot care must be sterile before use on a client/patient and all instruments must be sterilized by dry heat, autoclave, or by chemical sterilization.

In April 2006 the Provincial Infectious Diseases Advisory Committee (PIDAC) produced a document entitled Best Practices For Cleaning, Disinfection and Sterilization of Medical Equipment/Devices (April 2006, Reviewed and Revised Feb 2010 and May 2013). The preferred method for decontamination of heat-resistant medical equipment/devices is steam sterilization.

PIDAC was originally established in 2004 in response to the recommendation by the Expert Panel on SARS and Infectious Disease Control (Walker Panel) to provide a standing source of expert advice on infectious diseases in Ontario. Since that time, PIDAC continues to contribute to a significant body of knowledge and advice on matters related to prevention, surveillance and control measures necessary to protect the people of Ontario from infectious disease.

Transmitted infectious disease through non-sterile instruments can be personally devastating and costly. Foot care providers are responsible for ensuring patients/clients under their care are not at risk.

The information in this document does not reflect the opinions or recommendations of any one specific source. All efforts were taken to provide the best available evidence at time of production.

Any reference throughout to specific pharmaceutical, medical supplies or equipment products as examples does not imply endorsement of any of these products.

**This document is not all-inclusive and covers typical or common practices in foot care. It does not replace the recommendation to complete a recognized qualification/certification course in reprocessing practices. A plan must be in place for each person involved in reprocessing to obtain this qualification.**



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Every nurse has basic responsibilities to clients, co-workers and the general public when providing foot care services. Infection prevention and control is one of the most important responsibilities. Acquiring or transmitting an infection is everyone's risk. When providing foot care you will not know if a person has a disease or condition, therefore, good infection control procedures can adequately protect everyone who works or visits your work environment. "Effective reprocessing requires rigorous compliance with recommended protocols" — Public Health Agency of Canada

## Responsibilities to your clients

- Provide care within your scope of practice
- Keep confidential all information and records regarding a client
- Protect your clients from acquiring any disease or infection while in your care
- Provide the highest quality of care or service and all necessary measures to protect clients from infection during treatment
- We are in the age of the internet and litigation - the public are informed and demanding more of healthcare

## Responsibilities to Co-workers

- Protect co-workers and other Health Care Providers (HCP) from disease or infection
- Promote training in Infection Prevention and Control (IP&C) for those who work for/with you
- Ensure you support proper IP&C methods (e.g. handwashing stations)
- Provide Personal Protective Equipment (PPE) that is clean and in good repair

## Education and Training

All staff involved in reprocessing of medical equipment/devices must be supervised and shall be qualified through education in a formally recognized course for sterilization technology, training and experience in the functions they perform<sup>1</sup>. Any individual involved in any aspect of reprocessing obtains education, orientation and training specific to the medical equipment/device to be reprocessed. A process shall be in place to ensure continued competency, including continuing education.

## Guidelines - PIDAC

Best Practices For Cleaning, Disinfection and Sterilization of Medical Equipment/Devices (April 2006, Reviewed and Revised Feb 2010 and May 2013)

Sterilization is used on critical medical equipment/devices

- The preferred method for decontamination of heat-resistant equipment/devices is steam sterilization.
- Best practices in reprocessing must include validation of cleanliness, sterility and function of the reprocessed instrument/device



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<sup>1</sup> Ontario. Ministry of Health and Long-Term Care and the Provincial Infectious Diseases Advisory Committee. Best Practices for Cleaning, Disinfection and Sterilization in All Health Care Settings. May, 2013. Available at: [http://www.publichealthontario.ca/en/BrowseByTopic/InfectiousDiseases/PIDAC/Pages/PIDAC\\_Documents.aspx](http://www.publichealthontario.ca/en/BrowseByTopic/InfectiousDiseases/PIDAC/Pages/PIDAC_Documents.aspx)

- For equipment/devices that cannot withstand heat sterilization, some examples of chemical sterilants include:
  - 6% hydrogen peroxide;
  - 2% glutaraldehyde (> 10 hours);
  - hydrogen peroxide gas plasma;
  - 0.2% peracetic acid;
  - 7% accelerated hydrogen peroxide (6 hours)
  - 100% ethylene oxide.



## CSA Group

CSA is a standards development organization (SDO) accredited both in Canada and the U.S. This accreditation acknowledges that we comply with a specific set of accreditation criteria. As a result, the standards are recognized around the world for their balance, technical superiority, and ability to meet the needs of industry, regulators, manufacturers and consumers.

CSA Group has the largest subject area recognition of the SDOs accredited by the Standards Council of Canada (SCC), an organization that co-ordinates Canada's National Standards System. Accreditation is maintained by developing consensus standards that adhere to the requirements established by the SCC.



## MDRAO (formerly CSAO)

MDRAO (Medical Device Reprocessing Association of Ontario) is a provincial non-profit Medical Device Reprocessing (MDR) Association and Member Organization of the World Forum for Hospital Sterile Supply. Objectives include promoting Membership, providing Educational Opportunities as well as Professional Development and Advocacy.

What MDRAO Offers

- MDR Certification through Classroom and Distance Education
- MDR Recertification
- MDR Textbook and Workbook (Based on Canadian Standards)

## Spaulding's Classification

In 1968 Dr. Earle Spaulding devised a rational approach to disinfection and sterilization based on the patient's risk for infection. This is now referred to as Spaulding's classification and it has been refined and retained over the years because it is so clear and logical. Spaulding believed that instruments and equipment should be cleaned and reprocessed according to the level of risk associated with their intended use. The three categories he described were critical, semicritical and noncritical as in the table below.

<b>Classification</b>	<b>Definition</b>	<b>Level of Processing</b>	<b>Examples</b>
Critical Equipment/ Device	Equipment/device that enters sterile tissues, including the vascular system	Cleaning followed by Steam Sterilization	<ul style="list-style-type: none"> <li>• Surgical instruments</li> <li>• Biopsy instruments</li> <li>• Foot care equipment</li> </ul>
Semicritical Equipment/ Device	Equipment/device that comes in contact with non- intact skin or mucous membranes but do not penetrate them	Cleaning followed by High- Level Disinfection (as a minimum) Sterilization is preferred	<ul style="list-style-type: none"> <li>• Respiratory therapy equipment</li> <li>• Anaesthesia equipment</li> <li>• Tonomoter</li> </ul>
Noncritical Equipment/ Device	Equipment/device that touches only intact skin and not mucous membranes, or does not directly touch the client/ patient/resident	Cleaning followed by Low- Level Disinfection (in some cases, cleaning alone is acceptable)	<ul style="list-style-type: none"> <li>• ECG machines</li> <li>• Oximeters</li> <li>• Bedpans, urinals, commodes</li> </ul>

*Table 1*

**Read and follow all instructions in the documentation for any equipment or products completely and thoroughly before use.**

**This will significantly reduce or prevent equipment and/or reprocessing failures.**

# MAINTAINING INSTRUMENTS



# Types of Materials

## Stainless Steel

- Approximately 20 different grades that make up surgical instruments
- Stainless - not stain-proof
- Chromium imparts the stainless quality
- Stainless steel is an alloy and is man-made



Figure 1

## Chrome Plated Brass

- Brass is softer and used for some products
- Chrome plating to protect against oxidation
- Chrome flakes off

## Tungsten Carbide

- Harder than stainless steel
- Originally used for jaws of needle holders
- TC presence is indicated by gold handles (Figure 1)



Figure 2

## Titanium

- Lighter, stronger, and more tactile than stainless steel
- Non-magnetic
- Blue anodization indicates titanium (Figure 2)
- Very expensive

## Aluminum

- Very light and strong
- Used primarily for sterile containers (Figure 3)



Figure 3

## Passivation

A process called passivation (a nitric acid mix) is used to etch away the surface iron molecules, until the chromium molecules arrive at the surface. This ultra thin layer (1.5 - 2.5 nanometers) of chromium prevents moisture from coming into contact with the iron molecules – prevents surface rusting – this is also why you should not engrave instruments. This would break the passivated layer, therefore causing rusting at the engraving site.

Most surgical instruments are made from 4/20 (four twenty) grade stainless steel, its salient characteristics are its 12% - 14% chromium content which gives it its “stainless” properties. 4/20 is magnetic, due to its iron content which can of course rust. 4/20- steel is also capable of “self-healing”. Where the passivated surface is damaged, rusting occurs until the chromium molecules are exposed. Joints and box locks are more likely to produce rust deposits since the joint action wears away the passivated layers especially if not lubricated. The passivation treatment is also less likely to deeply penetrate the joint crevasses. Polishing is required after passivation to produce a high-polish or satin finish.

## Polishing

- Polishing (*Figure 4*) is the second processing step which reduces corrosion
- Produces a smooth surface where chromium oxide forms
- Satin finished instruments are more prone to surface corrosion than highly polished instruments



Figure 4

## Surgical Instrument Steel

### Surgical Instruments Must:

- Withstand repeated cleaning and sterilizing
- Perform precisely as designed
- Have the ability to do so for a long time without losing their qualities
- Withstand exposure to prepping solutions, blood, saline, and various chemicals

## The “Never Do” List<sup>2</sup>

- Never use any type of abrasives or hard metal brushes to pre-clean instruments
- Never leave disposable sharps among instruments or place cutting items loose on a tray
- Never dump, stack or jam instruments and/or baskets of instruments
- Never use an ultrasonic washer for chrome, mixed metals or other softer metals with weak surfaces that are vulnerable to cavitation
- Never let instrument sets sit with moisture inside
- Never tilt containers or baskets with instruments inside
- Never place heavy instruments on top of delicate instruments
- Never mix lower grade instruments with surgical grade instruments

## Components of Reprocessing with Steam Sterilization

Cleaning is the most important step in reprocessing instruments. This involves soaking then cleaning to remove all visible debris. Cleaning is necessary for any instrument that will be reused. Cleaning must be followed by sterilization. The manufacturer’s recommendations for cleaning instruments must be followed carefully. Dilution of cleaning products varies amongst manufacturers and must be followed as well. The following components of reprocessing are:

- Soaking (followed by rinsing)
- Cleaning (followed by rinsing)
- Inspecting
- Lubricating
- Packaging
- Sterilizing
- Storing
- Transporting

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<sup>2</sup> Source: Cory S. Nestman, Senior Professional Service Consultant, Steritec Inc.

# Soaking

- Disassemble items that have multiple parts
- Dispose of sharps in an approved sharps container
- Soak instruments after use (Figures 5, 6 and 7)
- Soaking softens material making items easier to clean
- Use detergent based products that include enzymes
- Enzymes break down large, hard to remove materials into smaller, easy to remove fragments
- Protease breaks down protein
- High protein content in most body fluids including blood, tissue and mucous



Figure 5



Figure 6



Figure 7

Saline, iodine preparations and blood can damage the surface of instruments and should be placed in a soaking solution before they can dry on the instrument.

## About Detergents

- Usually contains 1 or 2 protease enzymes
- Used for moderate to heavy organic debris
- Dilute 1oz:gallon or less of water (follow manufacturers instructions)
- Non-corrosive to metals
- Low-foaming
- Suitable for manual cleaning and ultrasonic cleaners
- Low residue - rinses easily in water
- Detergents with enzymes dissolve dried soil without mechanical action (figure 8)
- Follow the detergent manufacturer's instructions for concentration and temperature
- Detergent solutions will penetrate dirt (Figure 12) and loosen them from the surface
- Detergent lowers the surface tension of the solution to penetrate, surround and immerse the soil
- Not enough detergent instruments may not be cleaned properly
- Too much detergent instruments may not rinse easily
- A thorough rinse will remove residue (detergent and soil)



Figure 8

It may not always be convenient to have containers for soaking instruments after use. Spray foam (Figure 9) detergents are available with the following benefits:

- Ready to use
- Thick foam reduces splashing and spills
- Covers instruments well
- Ideal for applications where instrument cleaning is not immediately available
- Prevents bio burden from drying onto instruments



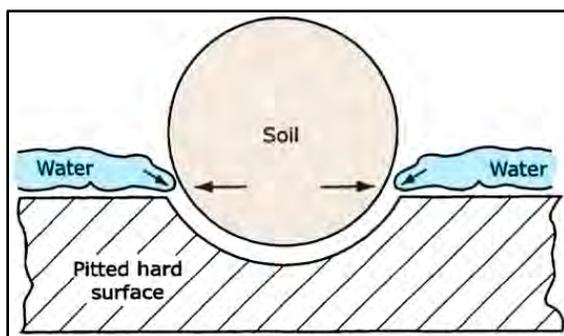
Figure 9

## Cleaning

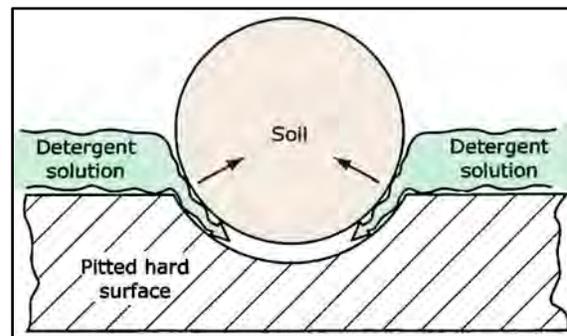
- Cleaning solutions maintain shine, prevent rust and lubricate instruments (Figure 10)
- Don appropriate Personal Protective Equipment (PPE)
- Ensure instruments are rinsed well from the soaking process
- Hot water can set proteins and make instruments difficult to clean - warm water is preferred for most soil and cool water is preferred for blood
- Manually clean instruments with a brush to remove gross soil below the solution level and use an ultrasonic cleaner — this prevents aerosols from being formed
- Rinse an item 3 times
  1. to remove detergent and soil
  2. to ensure complete cleanliness
  3. to prevent spotting
- Dry with a clean towel



Figure 10



Cleaning without detergent Figure 11



Cleaning with detergent Figure 12

# Ultrasonic Cleaners

## Degassing

- Degas fresh solutions
- Fresh solutions contain dissolved gases - usually air
- Degassing increases effective ultrasonic action
- Operate the U/S cleaner without instruments until the solution becomes turbulent (*Figures 13 and 14*)
- Use U/S cleaners with a basket
- Cleaning takes 3-5 minutes
- Follow detergent manufacturer guidelines for water temperature
- Do not mix metals e.g. don't place stainless steel in the same solution as carbon steel



Figure 13



Figure 14

As sound waves from the transducer radiate through the solution, they cause alternating high and low pressures. (*Figure 15*)

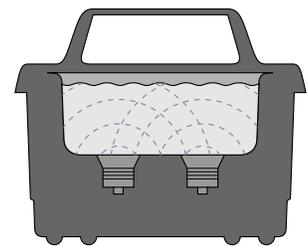


Figure 15

During the low pressure stage, millions of microscopic bubbles form and grow. This process is called cavitation. (*Figure 16*)

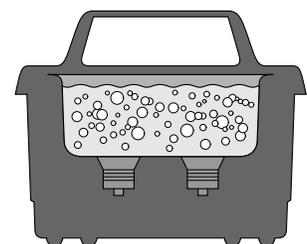


Figure 16

During the high pressure stage the bubbles implode. Implosions act like tiny scrub brushes working in all directions and on all surfaces, recesses and openings. (*Figure 17*)

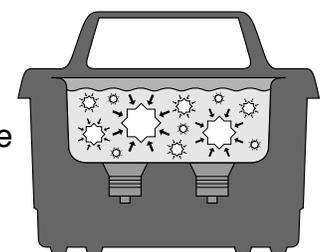


Figure 17

## Inspecting

- Inspect instruments after drying (Figure 18)
- The use of a magnification light is helpful
- Inspect instruments for:
  - Cracks/scratches that can harbour soil
  - Worn spots that can corrode
  - Malfunction
  - Retained soil
  - Misalignment
  - Roughness or dullness of edges
  - Worn or loose box screws
  - Staining
  - Inappropriate sharp edges that can damage tissue or tear gloves



Figure 18

## Instrument Stains (Table 2)

Colour	Cause	What to do
Orange-Brown to Reddish stain (looks like rust)	Do eraser test, if stain rubs off and no pitting exists, problem is most likely from: <ul style="list-style-type: none"> <li>• Detergent residue on towels or high alkaline &gt;8 pH detergent is being used leaving a phosphate surface deposit</li> <li>• Dried blood, iodine or Betadine residue</li> </ul>	<ul style="list-style-type: none"> <li>• Change to Neutral pH detergent.</li> <li>• Rinse the instruments in warm water for at least 30 seconds</li> <li>• Use a stain remover on both the instruments and autoclaves</li> <li>• If problem persists, consider changing to distilled or demineralized water.</li> </ul>
Black, Brown & Pitting	Subjected to an Acidic Low <6 pH substance such as: <ul style="list-style-type: none"> <li>• Low pH detergent residues on instrument surface or from towels</li> <li>• Exposed to other chemical compounds from “cold soaking”</li> <li>• Exposure to bleach</li> </ul>	<ul style="list-style-type: none"> <li>• Change to neutral pH detergent.</li> <li>• Eliminate exposure to chemicals or bleach</li> <li>• Rinse thoroughly and consider using distilled or demineralized water.</li> <li>• Eliminate any use of bleach.</li> </ul>
Rust	<ul style="list-style-type: none"> <li>• Sterilizing instruments of dissimilar metals in the same cycle.</li> <li>• Chemicals in detergents or excess amounts of Iron or other minerals from local water supply.</li> <li>• New instruments may be slightly magnetized during the manufacturing process. After several autoclaving sequences, the instruments lose their magnetic property</li> </ul>	<ul style="list-style-type: none"> <li>• Separate instruments by metal types prior to sterilization.</li> <li>• Use neutral pH detergents and change to distilled or demineralized water.</li> <li>• Wipe off as much residue leaving shiny metal underneath.</li> <li>• Use a stain remover on both the instruments and autoclaves.</li> </ul>

Colour	Cause	What to do
Spotting - Light or Dark coloured	<ul style="list-style-type: none"> <li>• Slow evaporation of water drops with mineral content</li> <li>• Instrument wraps &amp; towels may contain detergent residue.</li> </ul>	<ul style="list-style-type: none"> <li>• Eliminate water droplets and moisture by adhering to autoclave manufacturer's operating instructions.</li> <li>• Change to distilled or demineralized water. Particularly if local water supply is known to contain Iron or other minerals.</li> <li>• Thoroughly wash &amp; rinse wraps &amp; towels with a neutral pH detergent.</li> </ul>
Bluish-Green / Bluish-Black	<ul style="list-style-type: none"> <li>• Cross contamination between dissimilar metals</li> </ul>	<ul style="list-style-type: none"> <li>• Separate instruments by type before cleaning or autoclaving</li> </ul>
Rainbow or Multi-Colour	<ul style="list-style-type: none"> <li>• Heat compromised, tensile strength is compromised</li> </ul>	<ul style="list-style-type: none"> <li>• Check the autoclave for proper temperature</li> </ul>
Bluish-Gray (w/possible pitting)	<ul style="list-style-type: none"> <li>• Improper preparation of cold sterilization solutions</li> </ul>	<ul style="list-style-type: none"> <li>• Follow solution manufacturer's directions closely, particularly temp. &amp; soak times.</li> <li>• Use distilled or demineralized water</li> <li>• Change solution per mfg's instructions</li> </ul>

Table 2

To minimize staining, it is important that the autoclave runs perfectly, and that it has a well-functioning drying cycle. The instruments should come out completely dry, whether in wrappers or loose on a tray. If any moisture is left in the pack, or on the instruments, it will result in tiny water droplets on the instrument surface, which will leave a circular stain after drying. If the drying cycle works perfectly, however, there is a much less chance for deposits to form on the surface of the instrument.

Stains due to metal deposits or plating stains are always near the most magnetic parts of the instrument. New instruments are often highly magnetic in the locks, the serrations and ratchets. This happens because the carbon steel tools used to work on the instruments during production are very magnetic themselves. This magnetism wears off gradually during handling and sterilization. This is the reason why newer instruments tend to stain more visibly.

## Lubricating

- Cleaning may remove lubricant from instruments
- Instruments become stiff or liable to seize up
- Lubricants must be steam penetrable and water soluble (Figure 19)
- Check manufacturer guidelines
- Lubrication reduces instrument wear and replacement costs
- Proper lubrication helps instruments stay clean by preventing build-up of protein and mineral deposits which allows a more effective detergent cleaning



Figure 19

- Not suitable in chemical sterilization
- All instruments benefit from lubrication as it inhibits rust and corrosion and retains sharpness of instruments for longer periods of time
- Lubricant baths (Figures 20 and 21) are suitable for large instrument loads
- 30 sec bath in lubricant
- No wiping required
- Reusable for 14 days
- Lubricants have some antimicrobial properties



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Figure 20

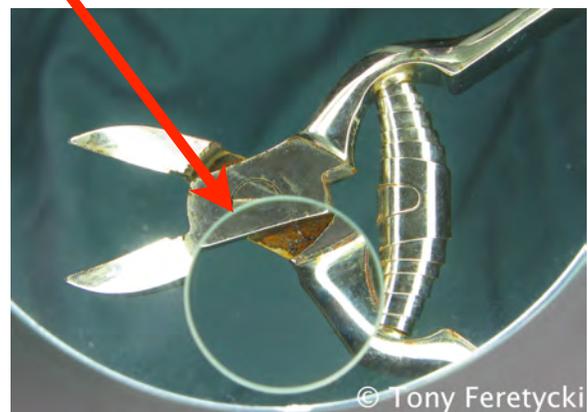
## Instrument Wear

- Chemical or mechanical destruction of the natural passive coating of the high quality steel due to lack of sufficient lubrication



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Figure 21



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## Packaging

- Organize the packaging area (Figure 22)
- Paper-plastic sterilization pouches most common (Figure 23)
- Adhesive strip for self-sealing
- Free of residue and lint
- For small, lightweight, low-profile items
- Should be adequate to contain the instrument
- Barrier to micro-organisms, dust, moisture, insects



Figure 22

## Chemical Indicators (CIs)

### External Indicators

- CIs may be tape, strips or marking pens
- External CIs are on the outside of the package (Figure 24)
- Used to differentiate sterile/unsterile items
- Does not indicate whether the sterilant has penetrated the package



Figure 23

### Internal Indicators

- Internal CIs demonstrate whether or not sterilization conditions were achieved
- Helps identify:
  - improper packaging
  - problems with sterilizer loading
  - equipment malfunctions
- Internal CIs are read when the package is opened and before the instrument is used
- Internal CIs are included in every pack, pouch or tray to be sterilized (Figure 25)
- After processing, the CI will be as dark or darker than the colour match block on the indicator strip (Figure 26)
- Must be placed in an area of the package least accessible to steam

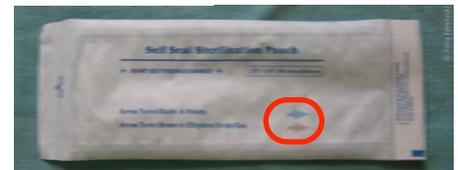


Figure 24



Figure 25

External indicator

Internal indicator



Colour match indicator block

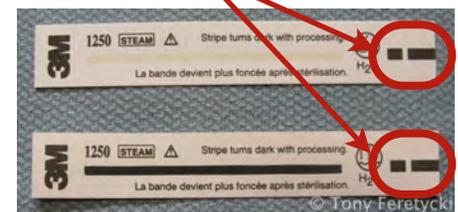


Figure 26

- Instruments must be sterilized in an open position
- Do not seal with pins, paper clips, or staples; these create holes in the material
- Do not write on the paper side of the pouch
  - the ink may leak through
  - the pen may weaken or puncture the paper
- Instrument protectors are ideal for keeping instruments in the open position (Figures 27 and Figure 28)



Figure 27

- 1 external process indicator (Figures 29 and Figure 30)
  - located outside the instrument area
  - indicates direct exposure to sterilization process
  - distinguishes between processed and unprocessed instruments
- 2 internal multi-variable indicator
  - located inside the instrument area
  - responds to time, temp, saturated steam
  - eliminates the extra step of adding a separate CI to each pouch

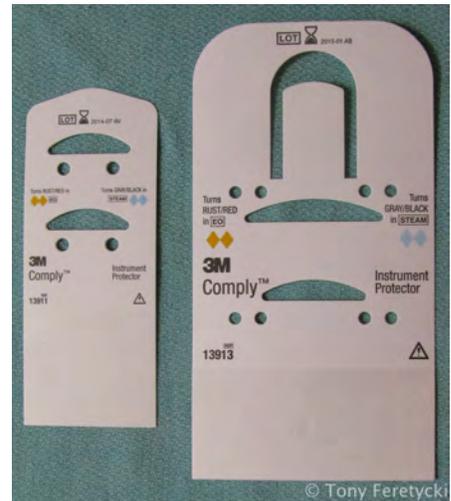


Figure 28



Figure 29



Figure 30

## Class 5 Integrators

- For use in all steam cycles (Figure 31)
- Responds to all physical conditions in the sterilizer
  - presence of saturated steam
  - temperature
  - time of exposure
- Distinct pass/fail criteria
- High level of sterility assurance
- Does not replace the routine use of a biological indicator
- Used with every sterilization cycle



Figure 31

## Biological Indicators (BIs)

- Impregnated with *geobacillus stearothermophilus* spores (Figure 32)
- Requires an incubator from the BI manufacturer (Figure 33)
- BIs are inserted into a package with the load
- Test with a BI in the first load of the day
- Results available in 24 hours
- Instruments should not be released until the results of the BI are known
- Placed in the lower portion of the sterilizer nearest the chamber drain opening
- Absence of microbial growth is a clear indication of sterilizer effectiveness
- Presence of growth indicates sterilization was inadequate
  - Corrective action must be taken
  - Instruments must be reprocessed
- Ensure an unsterilized BI is incubated as a control for the viability of the lot of indicators you are using



Figure 32



Figure 33



Unprocessed  
Control (Failed)  
Processed (Passed)

Figure 34

- All instrument packs must have a load control label (Figures 35 and 36)
- Identity of the person who assembled the package (if different from the operator)
- Sterilizer number (if more than 1 sterilizer)
- Load number of the sterilizer
- Sterilization date
- A BI and Class 5 Integrator are used to test the first sterilizer load each day the sterilizer is used or if load parameters change (i.e. changing from a wrapped cycle to on unwrapped cycle)
- Place in a sterilization pouch to challenge the indicators
- Place the pouch in the most challenging area of the sterilizer (e.g. near the drain)
- Items in the processed load should not be released until the results of the BI are known - usually in 24 hours



Figure 35

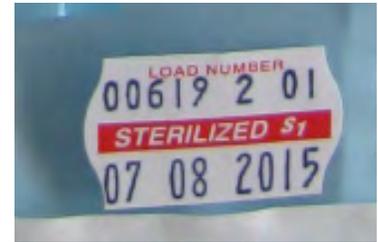
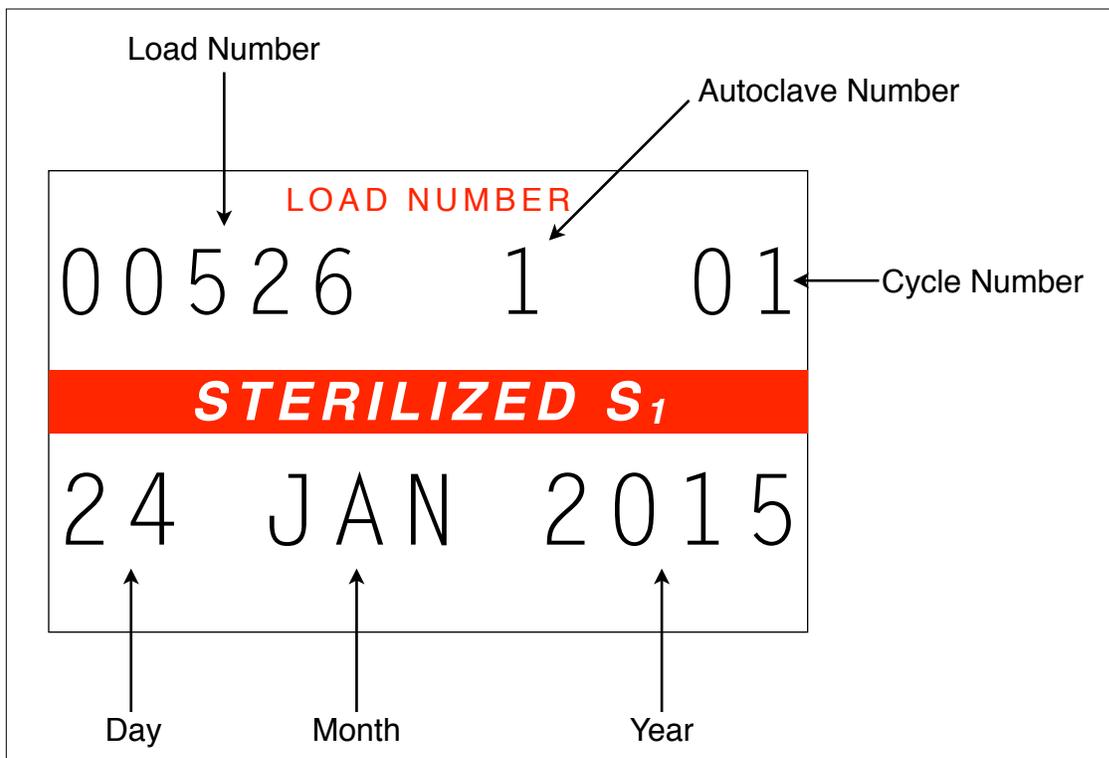


Figure 36

## Load Control Label



# Sterilizing

## Types of Sterilizers

- Table-top (Figure 37)
  - for wrapped instruments
  - standards state there must be a printer or data logger
  - can process larger instrument loads than cassette-type
- Cassette-type (Figure 38)
  - for wrapped instruments
  - fast sterilizing cycle
  - optional printer
  - **does not meet the standard if the printer is not installed**
- Pot-style (Figure 39)
  - unwrapped instruments only
  - no printer option
  - **no longer meets the standard**



Figure 37



Figure 38

## Sterilization

- Validated process used to render a product free of all forms of viable microorganisms
- The sterility of instruments processed in unwrapped cycles cannot be maintained if exposed to a non-sterile environment
- In a sterilization process, the nature of microbial death is described by an exponential function. Therefore, the presence of microorganisms on any individual item can be expressed in terms of probability. While this probability can be reduced to a very low number, it can never be reduced to zero.<sup>3</sup>



Figure 39

<sup>3</sup> ANSI/AAMI ST46:2002 (American National Standards Institute/Association for the Advancement of Medical Instrumentation) Steam sterilization and sterility assurance in health care facilities

Important factors in steam sterilization:

- temperature
- time
- sterilization agent-steam
- Steam (moist heat) contains 3600 times more heat energy than dry air at the same temperature
- Moist heat kills microorganisms by coagulating their proteins
- Autoclaves are
  - safe
  - accurate
  - reproducible
  - validatable

Typical Load Parameters for Steam Autoclaves			
Load	Temp	Time	Pressure
Wrapped instruments	134°C 274°F	7-8 min	30 psi

Table 3

- Vacuum autoclave: used for large volumes of wrapped instruments
- Gravity displacement autoclave: used for individual wrapped/unwrapped instruments (Figure 40)

**The Importance of Air Removal**

- Air and steam do not mix
- Air inhibits steam contact
- Air is 1.6 times more dense than steam

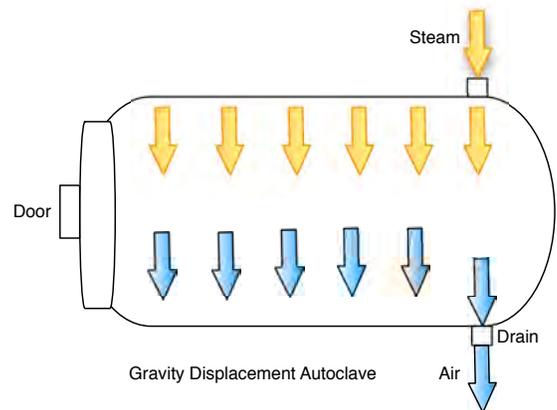


Figure 40

Indicators necessary for validation of the steam sterilization process		
Internal/External Chemical Indicators — most paper/plastic pouches have this feature integrated into the pouch	Every pack	 
Class 5 Steam Integrators	Every load	
Biological Indicators	First load of the day and any change in parameters (time or temperature)	

Table 4

Place packages in the sterilizer in a manner that:

- facilitates air removal
- steam penetration
- steam evacuation for drying

Wrapped items must not contact the interior surface of the sterilizer chamber

- contact can damage the wrapper
- packages must not be compressed
- vertical orientation (*Figure 41*) facilitates air removal, steam contact, and drainage of condensate
- Air and steam pass through only the paper side of paper-plastic pouches
- Paper side up for horizontal loading (*Figure 42*)

A wrapper containing a Class 5 Steam Integrator and a Biological Indicator (*Figure 43*) must be included in the first load of the day and any time the sterilizing parameters change. An example would be when changing from a wrapped instrument cycle to an unwrapped instrument cycle.



Figure 41



Figure 42

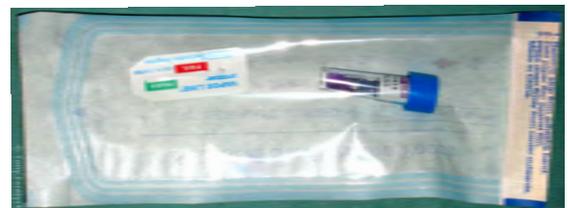


Figure 43

# Physical Monitors

Physical parameters:

- time
- temperature
- pressure
- Verified by examination of the sterilizer printout (Figure 44)
- Done on completion of each cycle before the load is released
- Failure to inspect sterilization charts and indicators constitutes negligence

# Records

National Standards of Canada requires that sterilization records include:

- Date and time
  - Temperature
  - Total length of cycle
  - Lot/load number of items
  - Operator initials
- } (Figure 45)

Keep permanent records of every sterilization cycle. Keep written records of all testing and maintenance carried out on every sterilizer. The records should be kept in a logbook. (Figures 46 and 47)

# Unloading the Sterilizer

- Remove instrument packs from the sterilizer
- Packs shall be inspected for:
  - package integrity
  - dryness
  - intact seal
  - correct change in external CIs
- Packages that don't meet inspection criteria shall be repackaged and reprocessed
- Items that have been dropped on the floor, compressed, torn or wet are considered contaminated and shall be repackaged and reprocessed



Figure 44

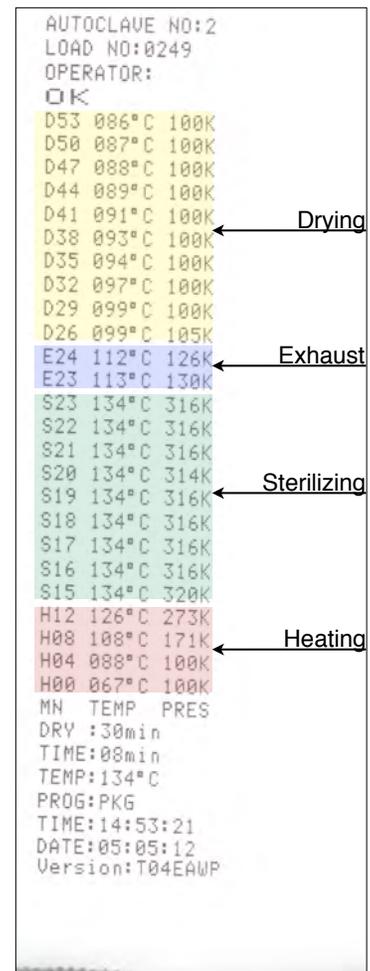


Figure 45

```

AUTOCLAVE NO:2
LOAD NO:0249
OPERATOR:
CHK
D35 086°C 100K
D50 087°C 100K
D47 088°C 100K
D44 089°C 100K
D41 091°C 100K
D38 092°C 100K
D35 094°C 100K
D32 097°C 100K
D29 099°C 100K
D26 099°C 100K
E24 112°C 126K
E23 113°C 126K
S23 134°C 316K
S22 134°C 316K
S21 134°C 316K
S20 134°C 316K
S19 134°C 316K
S18 134°C 316K
S17 134°C 316K
S16 134°C 316K
S15 134°C 320K
H12 126°C 273K
H08 108°C 171K
H04 089°C 100K
H00 067°C 100K
MN TEMP PRES
DRY : 120min
TIME:08:00
TEMP:134°C
PROG:PVG
TIME:14:53:21
DATE:05:05:12
Version:104EAPP
  
```

CI Lot: _____	<input type="checkbox"/> Pass
Loc: _____	<input type="checkbox"/> Fail
BI Lot: _____	<input type="checkbox"/> Pass
Loc: _____	<input type="checkbox"/> Fail
Control - Incubation Date	
Lot: _____	<input type="checkbox"/> Pass
In: _____	<input type="checkbox"/> Fail
Out: _____	
Nipper	Credo
Nipper set	Adson
Black's file	Mosquito
Rasp	Bur
#3 handle	Nail splitter
Gouge handle	Scissors
Probe	Tissue nipper
File	

Figure 46

CI Lot: <u>271</u>	<input checked="" type="checkbox"/> Pass
Loc: <u>Bottom Back</u>	<input type="checkbox"/> Fail
BI Lot: <u>120215</u>	<input checked="" type="checkbox"/> Pass
Loc: <u>Bottom Back</u>	<input type="checkbox"/> Fail
Control - Incubation Date	
Lot: <u>120215</u>	<input type="checkbox"/> Pass
In: <u>14/03/2012</u>	<input checked="" type="checkbox"/> Fail
Out: <u>15/03/2012</u>	
6 Nipper	2 Credo
6 Nipper set	Adson
2 Black's file	Mosquito
Rasp	2 Bur
#3 handle	Nail splitter
3 Gouge handle	Scissors
Probe	Tissue nipper
File	

Figure 47

## Disadvantages of Steam Sterilization

- Unsuitable for anhydrous materials (oils, powders), wood, heat and moisture sensitive materials
- Some sterilizers lack a drying cycle and/or printer for physical monitoring of each cycle
- Safe use of steam sterilizers requires sound knowledge of their requirements. Not all settings or practices have this expertise.

# Storage

## Shelf Life

- Shelf life of sterilized packages is event-related
- Based on the concept of:
  - correct cleaning
  - wrapping
  - sterilization
  - storage and handling
- Sterility can be maintained almost indefinitely
- If the integrity of the package has been compromised or is questionable, the package is considered non-sterile

(Figure 48)



Figure 48

## Basic Principles

- Pick an area with limited traffic - a room with a door
- Store sterile items by themselves away from dirty items
- Storage area should be clean, well-lit, dry, dust/lint free
- Store items 10" from the floor, 18" from the ceiling and 2" from the walls
- Protect sterile items from tearing, crushing, puncturing, and compression
- Use the first-in, first-out (FIFO) system of inventory control
- Avoid potential hazards: rodents, insects, moisture
- Avoid areas with sinks, electrical panels, printers and copiers
- Keep windows and doors closed in the storage area
- Never store sterile items on window sills or on the floor

# Transport

## Guidelines for Handling

- Wash hands before handling sterile items
- Keep sterile items away from sources of contamination
- Hold sterile items away from your body during transport
- Do not drop, throw, or mishandle sterile supplies
- Do not crush packages containing sterile instruments
- Visually inspect all packaging for punctures, tears and water damage
- Transport instruments to clinics in plastic containers
- Transport bins should be clean and be covered during transport
- Vehicles should be routinely cleaned and maintained

## Instruction for Reprocessing Reusable Instruments

<p>Instructions</p>	<ul style="list-style-type: none"> <li>• Follow instructions and warnings as issued by the manufacturers of any decontaminants, disinfectants and cleaning agents. Wherever possible avoid use of mineral acids and harsh, abrasive agents.</li> <li>• No part of the process shall exceed 140°C.</li> <li>• Some sensitive materials (e.g. Aluminium) are damaged by high alkaline solutions (pH&gt;10).</li> <li>• Devices with long, narrow cannula, hinges and blind holes require particular attention during cleaning.</li> </ul> <p><i>Note: When reprocessing medical devices, always handle with care, wearing protective clothing, gloves and eyewear in accordance with local Health &amp; Safety procedures.</i></p>
<p>Reprocessing Limitations</p>	<ul style="list-style-type: none"> <li>• Repeated processing has minimal effect on these instruments.</li> <li>• End of life is normally determined by wear and damage in use.</li> <li>• Any specific limitations on the number of reprocessing cycles shall be made available with the instrument.</li> </ul>
<p>Point of Use</p>	<ul style="list-style-type: none"> <li>• Wherever possible, do not allow blood, debris or bodily fluids to dry on instruments.</li> <li>• For best results and to prolong the life of the medical device reprocess immediately after use.</li> <li>• If they cannot be reprocessed immediately, use an enzymatic foam spray cleaner or an instrument soak to help prevent soil from drying.</li> </ul>
<p>Automated Cleaning</p>	<ul style="list-style-type: none"> <li>• Reprocess all instruments as soon as it is reasonably practical following use.</li> <li>• Disassemble only where intended, without the use of tools unless specifically provided by the manufacturer. Where instructions for disassembly are required, these are available with the device.</li> <li>• Use only low foaming, non-ionising cleaning agents and detergents following the manufacturer's instructions for use, warnings, concentrations and recommended cycles.</li> <li>• Load instruments carefully, with any box joints and hinges open and so that any fenestrations in instruments can drain.</li> <li>• Place heavy instruments with care in the bottom of containers, taking care not to overload wash baskets.</li> <li>• Place instruments with concave surfaces facing down to prevent pooling of water.</li> </ul>

Manual Cleaning	<ul style="list-style-type: none"> <li>• Reprocess all instruments as soon as it is reasonably practical following use.</li> <li>• Disassemble only where intended, without the use of tools unless specifically provided by the manufacturer. Where instructions for disassembly are required, these are available with the device.</li> <li>• Manual cleaning is not advised if an ultrasonic cleaner is available. If the equipment is not available, use the following process: <ul style="list-style-type: none"> <li>● Use a double sink system (wash/rinse) dedicated for instrument cleaning (not used for hand washing). Ensure that the water temperature does not exceed 35°C.</li> <li>● In the first sink, keeping the instrument submerged, with an autoclavable brush, apply cleaning solution to all surfaces until all soil has been removed. Pay particular attention to serrations, teeth, ratchets and hinges, always brushing away from the body and avoiding splashing. Ensure hinged instruments are thoroughly cleaned in both open and closed positions.</li> <li>● In the second sink, rinse instruments thoroughly with soft, high purity water so that the water reaches all parts of the instrument, then carefully hand dry or use a drying cabinet.</li> </ul> </li> <li>• Note: <i>Manual cleaning is NOT a disinfection process: When manual cleaning is used it may not be possible to disinfect the device prior to further handling.</i></li> </ul>
Inspection	<ul style="list-style-type: none"> <li>• After cleaning, visually inspect all surfaces, cannulations, ratchets, joints, holes and lumens for complete removal of soil and fluids. If ANY soil or fluid is still visible, return the instrument for repeat reprocessing.</li> <li>• Visually inspect and check:- all instruments for damage and wear; cutting edges are free from nicks and present a continuous edge; jaws and teeth align correctly; all articulated instruments have a smooth movement without excess play; locking mechanisms (such as ratchets) fasten securely and close easily; long, slender instruments are not distorted; any component parts fit and assemble correctly with mating components.</li> <li>• Remove for repair or replacement any blunt, worn out, flaking, fractured or damaged instruments.</li> </ul> <p><i>Note: If an instrument is returned to the manufacturer / supplier, the instrument <b>must</b> be decontaminated and sterilized and be accompanied with the relevant documented evidence.</i></p>
Lubrication	<p>Apply surgical grade lubricant that is water soluble to hinges, joints and moving parts as per the lubricant manufacturers instructions.</p>

Packaging	Single-use paper/plastic pouches are used most often for sterile packaging. Ensure the pouch is large enough for the instrument. If the pouch is too small, it cannot be sealed adequately. CSR autoclave wraps are not suitable for foot care instrument packaging. CSR autoclave wraps are better suited for large instrument sets in trays, bowls and basins, etc.
Sterilization	<ul style="list-style-type: none"> <li>• Autoclaves should comply with the requirements of, and be validated and maintained in accordance with ANSI/AAMI ST79</li> <li>• Moist heat sterilization operating at temperature 134°C for wrapped instruments for a holding time of 8 minutes – always following the instructions of the machine manufacturer.</li> <li>• When sterilizing multiple instruments in one autoclave cycle, ensure that the sterilizer manufacturers stated maximum load is not exceeded.</li> <li>• Ensure instruments are dry before sterilization.</li> </ul>
Storage	<ul style="list-style-type: none"> <li>• Ensure instruments are dry before storage, and stored in dry, clean conditions at an ambient room temperature.</li> </ul>

## **Purchasing a Steam Sterilizer**

### **Steam sterilization is the “gold standard” of sterilization methods**

It kills microorganisms rapidly without the use of toxic chemicals. Unfortunately, it can only be used for reusable devices that tolerate high temperatures.

### **Types of Table-top Steam Sterilizers**

When purchasing a sterilizer, insist on written information from the vendor or manufacturer demonstrating that the sterilizer is capable of sterilizing the devices and packaging used in your office. Ensure that it has a printer or data logger.

### **Prior to Purchasing**

Consider whether steam sterilization is cost-effective for your practice. Consider capital outlay, equipment maintenance, staff training and staff time, sterilizer packaging materials and quality control supplies.

Consider also whether the space in your office or home can accommodate reprocessing. It must allow for the required separation of soiled and clean devices and the steps in the cleaning process.

What to consider when choosing to reprocess reusable medical devices in your office or clinic:

- The purchase price of the sterilizer
- Time and cost required for daily testing and maintenance
- Cost of preventive maintenance and periodic testing
- Operational costs (electricity, distilled water, detergents, cleaners, insurance, etc.)
- Cost of additional instruments to accommodate prolonged cycle times
- Cost of training staff
- Cost of packaging
- Cost of Biological Indicator monitoring and other quality controls required by the manufacturer
- Cost of personal protective equipment (PPE) required for staff that reprocess.
- Time to document each load and results of monitoring
- Availability of adequate space to locate the sterilizer within the designated “clean” area where reprocessing will take place in your office or home. Prior to purchase, obtain dimensions (e.g. height, width and depth) of sterilizer to ensure that it will fit.

When seeking quotes from suppliers, it is important to specify the type of load and instruments you intend to reprocess. The manufacturer should state clearly the type of load and instruments for which the sterilizer is suitable. Purchase only the type of sterilizer that is suitable for the types of loads you intend to process. Ensure the sterilizer has a Health Canada medical device license.

Consider the following:

- Clarity of instructions for use and for maintenance (daily, monthly, annually)
- The number of instruments that will be reprocessed per load and per day

- Whether the devices are solid (e.g. nippers, files) or porous or lumened (e.g. textiles, suction tips, dental hand-pieces)
- For lumened devices, the limitations of the sterilizer with respect to length and diameter of lumens.
- The type of wrapping required and manufacturer's instructions for use of wrap.
- The presence or absence of a printer or electronic log for documenting each sterilizer cycle. It is the standard that this capability be present on the sterilizer at the time of purchase to facilitate the requirement to log physical parameters of each cycle.

Ensure that you have documentation which:

- Specifies who is responsible for installation and for performing tests to ensure the sterilizer will perform to specifications.
- Specifies the qualifications of technical service providers
- Indicates that the sterilizer can sterilize the medical devices you will be using
- Indicates how to load the sterilizer (e.g. lumened instruments, hollow instruments, textiles, power tools, dental hand pieces, wrapped sets of instruments)
- Indicates if there are any unique requirements for operating the sterilizer. This might include operational constraints specific to altitude and water supply (e.g. reservoir, potable, treated water).
- Defines recommended sterility assurance monitoring:
  - Appropriate biological and chemical indicators
  - Appropriate Class II (Bowie-Dick) chemical indicator for dynamic air removal sterilizers.

### **Service and Maintenance**

Ask the vendor if they:

- provide a sterilizer for a trial period prior to committing to a purchase
  - provide onsite training for the use of the sterilizer
  - provide a service contract
  - provide periodic testing
  - provide evidence that the test person is qualified
  - have the necessary calibrated test equipment
  - have loaner equipment in case of shutdown for repairs and guarantee a response time
  - place restrictions on the provision of loaners
- IF NOT, then ask whether the vendor recommends a particular servicing agent.

### **After Your Purchase**

A sterilizer must be tested after installation and before it is put into service. Successful testing includes no growth of organisms ("negative" tests) after the placements of appropriate biological indicators in the empty chamber for at least 3 sterilizer cycles, and then again with a full test load of devices.

Dynamic air removal sterilizers must also be tested three times with an air detection test pack (a Bowie-Dick test) in an empty chamber.

A sterilizer that fails these tests must not be put into service until the cause is found and corrected and repeat testing confirms effective operation.

The same pre-use testing requirements apply after the following circumstances:

- a) major repairs to a sterilizer
- b) relocation of the sterilizer to another office
- c) unexplained sterilization failures

# Purchasing Instruments

Medical device manufacturers are required to provide information on the processing of medical devices claimed to be re-sterilizable and medical devices intended to be sterilized by the processor.

The processing requirements consist of some or all of the following activities:

- preparation at the point of use
- preparation, cleaning and disinfection
- drying
- inspection, maintenance and testing
- packaging
- sterilization
- storage

Some processing procedures may be generic and well known and will use equipment and consumables conforming to recognized standards. For those medical devices where instructions for use are not required to accompany the device, other means of communicating the information can be used, e.g. wall charts, user manuals or symbols supplied separately.

# Personal Protective Equipment (PPE) for Processing Foot Care Instruments

All reusable medical equipment/devices must be reprocessed using procedures that are effective against all human pathogens, including bloodborne pathogens. Special procedures, including labelling, for specific microorganisms (e.g., MRSA, VRE) are not required. The exception is equipment/devices potentially exposed to CJD. PPE worn for cleaning and handling contaminated equipment/devices includes gloves appropriate to the task, face protection (i.e., full face shield OR fluid-impervious face mask and protective eyewear) and impermeable gown or waterproof apron

<b>Donning PPE</b>		
<b>1</b>	Perform Hand Hygiene	
<b>2</b>	Put on Gown — Standards recommend a fluid impervious full-length gown that covers the forearms as there is a risk of splashes or sprays of blood, body fluids, secretions, or excretions	
<b>3</b>	Put on Mask or N95 Respirator to protect mucous membranes of the nose and mouth	

<p><b>4</b></p>	<p>Put on Eye Protection/Face Shield to protect from exposure of splashes or sprays of blood, body fluids, secretions or excretions</p>	
<p><b>5</b></p>	<p>Put on Gloves — gloves must be long enough to cover the wrists and forearms, be of sufficient weight to be highly tear resistant, and allow adequate dexterity of the fingers</p>	
<p><b>Removing PPE</b></p>		
<p><b>1</b></p>	<p>Remove Gloves — outside of gloves are contaminated (1) grasp outside of glove with opposite hand; peel off (2) hold removed glove in gloved hand (3) slide fingers of ungloved hand under remaining glove at wrist (4) peel glove off over first glove (5) discard gloves</p>	
<p><b>2</b></p>	<p>Remove Gown — gown front and sleeves are contaminated, (1) pull away from neck and shoulders, touching inside of gown only, (2) turn gown inside out (3) fold or roll into a bundle and discard</p>	

<p><b>3</b></p>	<p>Perform Hand Hygiene</p>	 <p>© Tony Feretycki</p>
<p><b>4</b></p>	<p>Remove Eye Protection — outside of eye protection is contaminated (1) remove by headband or earpieces (2) place in a designated receptacle for reprocessing or discard</p>	 <p>© Tony Feretycki</p>
<p><b>5</b></p>	<p>Remove Mask or N95 Respirator — front of mask or respirator is contaminated (1) grasp bottom, then top ties or elastics and remove (2) discard</p>	
<p><b>6</b></p>	<p>Perform Hand Hygiene</p>	 <p>© Tony Feretycki</p>

## Glossary of Terms

**Alcohol-Based Hand Rub (ABHR):** A liquid, gel or foam formulation of alcohol (e.g., ethanol, isopropanol) which is used to reduce the number of microorganisms on hands in clinical situations when the hands are not visibly soiled. ABHRs contain emollients to reduce skin irritation and are less time-consuming to use than washing with soap and water.

**Antimicrobial:** Any agent that kills or suppresses the growth of microorganisms.

**Bactericidal:** Lethal to bacteria.

**Bacteriostatic:** Growth-inhibiting, but not lethal to bacteria.

**Bioburden:** The number and types of viable microorganisms that contaminate the equipment/device, component, product or package.

**Biological Indicator (BI):** A test system containing viable microorganisms providing a defined resistance to a specified sterilization process.

**Chemical Indicator (CI):** A system that reveals a change in one or more predefined process variables based on a chemical or physical change resulting from exposure to the process.

**Cleaning:** The physical removal of foreign material (e.g., dust, soil) and organic material (e.g., blood, secretions, excretions, microorganisms). Cleaning physically removes rather than kills microorganisms. It is accomplished with water, detergents and mechanical action.

**Corrosion:** The process of gradual destruction of metal or an alloy through oxidation or chemical action.

**Critical Medical Equipment/Devices:** Medical equipment/devices that enter sterile tissues, including the vascular system (e.g., biopsy forceps, foot care equipment, dental hand pieces, etc.). Critical medical equipment/devices present a high risk of infection if the equipment/device is contaminated with any microorganism, including bacterial spores. Reprocessing critical equipment/devices involves meticulous cleaning followed by sterilization.

**Decontamination:** The process of cleaning, followed by the inactivation of microorganisms, in order to render an object safe for handling.

**Degassing:** The removal of unwanted gas from a cleaning solution in an ultrasonic cleaner.

**Detergent:** A synthetic cleansing agent that can emulsify oil and suspend soil. A detergent contains surfactants that do not precipitate in hard water and may also contain protease enzymes (see Enzymatic Cleaner) and whitening agents.

**Disinfection:** The inactivation of disease-producing microorganisms. Disinfection does not destroy bacterial spores. Medical equipment/devices must be cleaned thoroughly before effective disinfection can take place.

**Drug Identification Number (DIN):** In Canada, disinfectants are regulated as drugs under the Food and Drugs Act and Regulations. Disinfectant manufacturers must obtain a drug identification number (DIN) from Health Canada prior to marketing, which ensures that labelling and supporting data have been provided and that it has undergone and passed a review of its formulation, labelling and instructions for use.

**Enzymatic Cleaner:** A pre-cleaning agent that contains protease enzymes that break down proteins such as blood, body fluids, secretions and excretions from surfaces and equipment. Most enzymatic cleaners also contain a detergent. Enzymatic cleaners are used to loosen and dissolve organic substances prior to cleaning.

**Hand Hygiene:** A general term referring to any action of hand cleaning. Hand hygiene relates to the removal of visible soil and removal or killing of transient microorganisms from the hands. Hand hygiene may be accomplished using soap and running water or an alcohol-based hand rub. Hand hygiene includes surgical hand antisepsis.

**High-Level Disinfectant:** A chemical agent that achieves high-level disinfection when applied to surfaces or items in the environment.

**Indicator:** A system that reveals a change in one or more of the sterilization process parameters. Indicators do not verify sterility, but they do allow the detection of potential sterilization failures due to factors such as incorrect packaging, incorrect loading of the sterilizer, or equipment malfunction. See also, Biological Indicator and Chemical Indicator.

**Low-Level Disinfection (LLD):** Level of disinfection required when processing non-invasive medical equipment (i.e., non-critical equipment) and some environmental surfaces. Equipment and surfaces must be thoroughly cleaned prior to low-level disinfection.

**Lubricant:** A solution that helps keep instruments in good working order by immersing in instrument lubricant, also known as instrument milk.

**Manufacturer:** Any person, partnership or incorporated association that manufactures and sells medical equipment/devices under its own name or under a trade mark, design, trade name or other name or mark owned or controlled by it.

**Medical Equipment/Device:** Any instrument, apparatus, appliance, material, or other article, whether used alone or in combination, intended by the manufacturer to be used for human beings for the purpose of diagnosis, prevention, monitoring, treatment or alleviation of disease, injury or handicap; investigation, replacement, or modification of the anatomy or of a physiological process; or control of conception.

**Noncritical Medical Equipment/Device:** Equipment/device that either touches only intact skin (but not mucous membranes) or does not directly touch the client/patient/resident. Reprocessing of noncritical equipment/devices involves cleaning and may also require low-level disinfection (e.g., blood pressure cuffs, stethoscopes).

**Passivation:** A two-step process that removes impurities and applies an anticorrosion coating to instruments.

**Personal Protective Equipment (PPE):** Clothing or equipment worn for protection against hazards.

**Physical Monitor:** A device that monitors the physical parameters of a sterilizer, such as time, temperature and pressure.

**Process Challenge Device (PCD):** A test device intended to provide a challenge to the sterilization process that is equal to, or greater than, the challenge posed by the most difficult item routinely processed. Examples include BI test packs which also contain a chemical indicator, or CI test packs which contain a Class 5 integrating indicator or an enzyme-only indicator.

**Reprocessing:** The steps performed to prepare used medical equipment/devices for use (e.g., cleaning, disinfection, sterilization).

**Reusable:** A term given by the manufacturer of medical equipment/devices that allows it, through the selection of materials and/or components, to be re-used.

**Semicritical Medical Equipment/Device:** Medical equipment/device that comes in contact with non intact skin or mucous membranes but ordinarily does not penetrate them (e.g., respiratory therapy equipment, transrectal probes, specula). Reprocessing semicritical equipment/devices involves meticulous cleaning followed by, at a minimum, high-level disinfection.

**Sharps:** Objects capable of causing punctures or cuts (e.g., needles, syringes, blades, clinical glass).

**Single Patient Use:** A term given to medical equipment/devices that may be used on a single client/patient/resident and may be re-used on the same client/patient/resident, but may not be used on other clients/patients/residents.

**Single-use/Disposable:** A term given to medical equipment/devices designated by the manufacturer for single-use only. Single-use equipment/devices must not be reprocessed.

**Spaulding's Classification:** A strategy developed by Dr. Earle H. Spaulding (1968) for reprocessing contaminated medical devices. It classifies devices as critical, semi-critical, or noncritical based on the risk of contamination from a device to a patient.

**Staff:** Anyone conducting activities in settings where health care is provided, including but not limited to, health care providers.

**Sterilant:** A chemical used on medical equipment/devices which results in sterilization of the equipment/device.

**Sterilization:** The level of reprocessing required when processing critical medical equipment/devices. Sterilization results in the destruction of all forms of microbial life including bacteria, viruses, spores and fungi. Equipment/devices must be cleaned thoroughly before effective sterilization can take place.

**Ultrasonic Washer:** A machine that cleans medical equipment/devices by the cavitation produced by ultrasound waves.

**Workplace Hazardous Materials Information System (WHMIS):** The Workplace Hazardous Materials Information System (WHMIS) is Canada's national hazard communication standard. The key elements of the system are cautionary labelling of containers of WHMIS 'controlled products', the provision of Material Safety Data Sheets (MSDSs) and staff education and training programs.

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Guide to the selection and use of sterilization indicators

Canada Communicable Disease Report - Supplement

Volume: 23S8, December 1997, INFECTION CONTROL GUIDELINES, Foot Care by Health Care Providers

Central Supply Association of Ontario, Medical Device Reprocessing Manual, Third Edition, 2015

Provincial Infectious Diseases Advisory Committee (PIDAC), Best Practices for Cleaning, Disinfection and Sterilization in All Health Care Settings. November, 2013.

Provincial Infectious Diseases Advisory Committee (PIDAC), Best Practices for Hand Hygiene, April 2014

Provincial Infectious Diseases Advisory Committee (PIDAC), Infection Prevention and Control for Clinical Office Practice, April 2015.

Provincial Infectious Diseases Advisory Committee (PIDAC), Routine Practices and Additional Precautions In All Health Care Settings, 3<sup>rd</sup> edition, November 2012

## **Manufacturers Instructions for Use (MIFU)**

3M™ Comply™ 1250 Chemical Indicator for Steam

Midmark® Installation and Operation Manual, Models M150, M250, M550, Soniclean® Ultrasonic Cleaner

Professional's Choice, Self Sealing Sterilization Pouches with Internal Process Indicators

SPS Medical, Sporview® Self-Contained BI for Steam Sterilization

SPS Medical, SteamPlus™ Class 5 Steam Sterilization Integrator

Steris®, Verify™ Dual Species Self-Contained Biological Indicator for Installation Testing and Routine Monitoring of Steam and EO Sterilization Processes

Steris®, Verify™ Operating and Servicing Instructions for 6-well E.O. And Steam Incubators

Tuttnauer EZ10 Autoclave, Operation and Maintenance Manual

# Resources

Accreditation Canada, <https://accreditation.ca>

Alberta Health Services, <http://www.albertahealthservices.ca>

CAMDR, Canadian Association of Medical Device Reprocessing, [www.camdr.ca](http://www.camdr.ca)

CSA Group, Canadian Standards Association, <http://www.csagroup.org>

## CSA Standards:

- Z314.0-13 Medical device reprocessing - General requirements
- Z314.3-14 Effective sterilization in health care facilities by the steam process
- Z314.8-14 Decontamination of reusable medical devices
- Z314.10.1-15 Selection and use of gowns and drapes
- Z314.10.2-15 Laundering, maintenance, and preparation of reusable gowns, drapes, and wrappers
- Z314.14-15 Selection and use of packaging (sterile barrier systems) in healthcare settings
- Z314.15-15 Storage, transportation, and distribution of single use and reusable medical devices
- Z314.23-12 Chemical sterilization of reusable medical devices in health care facilities
- Z8000-11 Canadian Health Care Facilities
- SPE 1112-14 User Handbook for Medical Device Reprocessing in Community Health Care Settings

Infection and Prevention Control Canada (IPAC), <http://ipac-canada.org>

Medical Device Reprocessing Association of Ontario (MDRAO), <http://mdrao.ca>

Provincial Infectious Diseases Advisory Committee (PIDAC), <http://www.publichealthontario.ca/en/BrowseByTopic/InfectiousDiseases/PIDAC/Pages/PIDAC.aspx>

## PIDAC Documents:

- The Best Practices for Hand Hygiene, 4th Edition (April 2014)
- Infection Prevention and Control for Clinical Office Practice (June 2013)
- Cleaning, Disinfection and Sterilization of Medical Equipment/Devices (May 2013)
- Routine Practices and Additional Precautions / Annexes A, B & C (November 2012)

Steris University, <http://university.steris.com>