cpsa
COLLEGE OF PHYSICIANS
& SURGEONS OF ALBERTA

Medical Device Reprocessing

General standards

Last revised: JULY 2020

DATE: _____ CLINIC NAME: _____

IPAC CLINIC ID: _____ DESIGNATED CONTACT: _____

IPAC ASSESSOR: _____

For assistance or more information on infection prevention & control, contact the CPSA IPAC Program at ipac@cpsa.ab.ca or 780-969-5004.

STANDARDS

M.1. GENERAL		YES	NO	N/A	IF "NO" PLEASE COMMENT
M.1.1	There are current (dated) written policies and procedures on all steps of reprocessing readily available for staff.				
M.1.1.1	storage of dirty instruments				
M.1.1.2	transport of dirty instruments within the office				
M.1.1.3	disassembly				
M.1.1.4	sorting and soaking				
M.1.1.5	physical removal of soil				
M.1.1.6	rinsing (done under the surface of the water)				
M.1.1.7	drying (lint free cloth)				
M.1.1.8	physical inspection				
M.1.1.9	wrapping of sterile packages				
M.1.1.10	HLD				
M.1.1.11	sterilization				
M.1.1.12	storage of sterile packages/instruments				
M.1.1.13	use, cleaning &/or disposal of PPE				
M.1.1.14	use and cleaning of cleaning accessories (Sterilization or High Level Disinfection)				
M.1.1.15	recall process for failed cycle/failed chemical indicator and failed BI				
M.1.2	There is written information from the manufacturer on the safe and appropriate reprocessing of all medical equipment (e.g. forceps scissors, ear syringe), included in the written procedures				
M.1.3	There is a designated reprocessing area that is separate from patient care areas.				
M.1.3.1	• If it is necessary that instrument cleaning, drying and wrapping occurs in a dual-purpose area, then reprocessing does not occur when patients or other personnel are				

	present or when cleaned equipment is not secure from potential recontamination				
M.1.3.2	If a dual-purpose area is used, all surfaces are cleaned and disinfected immediately before and immediately following the decontamination of instruments.				
M.1.3.3	Basins and sinks that are used for cleaning are cleaned and low-level disinfected before and after use.				
M.1.4	Dedicated hand hygiene stations, which are not used for the reprocessing of equipment, are readily available for staff in the reprocessing area. (Either hand washing sinks or alcohol dispensers).				
M.1.5	Appropriate Personal Protective Equipment (PPE) is worn by staff when reprocessing. (Eye protection and mask or face shields, appropriate cover gowns, gloves).				
M.1.5.1	Face protection: eye protection with mask or full face shield				
M.1.5.2	Reusable eye protection is cleaned and disinfected between uses				
M.1.5.3	Disposable Gown: moisture impervious gown				
M.1.5.4	Gloves: tear and chemical resistant				
M.1.5.5	If gloves are reusable, they are cleaned and disinfected at least daily and each staff member has their own pair				
M.1.6	There is a designated staff member responsible for reprocessing.				
M.1.7	There is documented training process for staff performing reprocessing.				
M.1.8	All **critical** medical equipment is **sterilized** between each patient use.				
M.1.9	All **semi-critical** medical equipment receives a **minimum** of high level disinfection between each patient use.				
M.1.10	Single use products are never reprocessed.				

M.2. CLEANING		YES	NO	N/A	IF "NO" PLEASE COMMENT
M.2.1	Cleaning with detergent or enzymatic solutions and clean water always precedes subsequent high-level disinfection or sterilization processes. (Name the cleaner(s) used in comment section)				Cleaner(s):
M.2.2	Detergent or enzymatic cleaning solutions are prepared and used according to manufacturer's directions.				
M.2.3	Manual cleaning using friction is performed using cleaning accessories (brushes or sponges).				
M.2.3.1	All manual cleaning is done under the surface of the water to minimize splashing and aerosolization of contaminated water.				
M.2.4	Cleaning accessories are disposable or are thoroughly cleaned and are high level disinfected or sterilized between uses.				
M.2.5	Ultrasonic washers are used in accordance with the manufacturer's written instructions for installation, operation and preventative maintenance.				
M.2.5.1	Gross soiling is removed from the device before ultrasonic cleaning is performed				
M.2.5.2	Following ultrasonic cleaning, equipment is thoroughly rinsed with clean tap water prior to additional reprocessing steps.				
M.2.5.3	The efficiency of the ultrasonic is checked (weekly) using an aluminum foil ablation test and/or an ultrasonic activity meter and the results are documented.				
M.2.6	Automatic washers are used in accordance with the manufacturer's written instructions for installation, operation and preventative maintenance				
M.2.7	There is documented preventative maintenance of the automatic washer as specified by the manufacturer.				
M.2.8	Cleaning procedures include the following steps prior to high level disinfection or sterilization:				

M.2. CLEANING		YES	NO	N/A	IF "NO" PLEASE COMMENT
M.2.8.1	Application of an appropriate product or covering with a moist towel to prevent drying of soil				
M.2.8.2	Covered during transport to the reprocessing area				
M.2.8.3	Disassembly (as required by manufacturer)				
M.2.8.4	Sorting and soaking				
M.2.8.5	Physical removal of soil				
M.2.8.6	Rinsing (done under the surface of the water)				
M.2.8.7	Drying (lint free cloth)				
M.2.8.8	Physical Inspection				
M.2.8.9	Wrapping (required for sterilization)				
M.2.8.10	Sharp tips of instruments in peel pouches are protected				

M.3. HIGH LEVEL DISINFECTION (HLD)		YES	NO	N/A	IF "NO" PLEASE COMMENT
High level disinfectant:		**Exposure time:** **Temperature:**			**Chemical test strip:** **Expiry date:**
M.3.1	The HLD product used has a Drug Identification Number (DIN) from Health Canada. (List the DIN in comment section)				**DIN:**
M.3.1.1	HLD are not used past their expiry date. (List the current lot expiry date in comment section):				**Expiry Date:**
M.3.2	HLDs are prepared according to manufacturer's directions to achieve the manufacturer's recommended minimum effective concentration.				
M.3.3	Equipment is immersed in the HLD solution according to the manufacturer's recommended time of immersion.				

M.3. HIGH LEVEL DISINFECTION (HLD)		YES	NO	N/A	IF "NO" PLEASE COMMENT
M.3.4	When preparing HLD solutions, sources of extrinsic contamination (contaminated containers/preparation areas) are prevented.				
M.3.5	HLD concentration is checked before use, daily when in use, with an appropriate chemical test strip; and is discarded if the concentration is less than the minimum effective concentration. (MEC)				
M.3.6	There is a log kept of concentration check results.				
M.3.7	There is a log kept of dates when HLD is changed.				
M.3.8	Test strips are not used past the expiry date listed on current stock. (List expiry date of current stock in comment section)				**Expiry Date:**
M.3.9	Test strip containers are dated upon opening, and the expiry date is recorded on the container.				
M.3.10	A quality control procedure for checking test strips each time a new bottle is opened is performed according to the manufacturer's recommendation.				
M.3.11	A log is kept of the quality control procedure performed on test strips.				
M.3.12	Rinsing of medical equipment following HLD is always performed with three separate rinses of clean water (under the water surface) that is changed after each use. (It is recommended that sub-micron filtered or sterile water be used.)				
M.3.13	All reprocessed equipment is stored in a manner to keep them clean and dry. (e.g. not under the sink or in cardboard boxes)				

M.4. STERILIZATION		YES	NO	N/A	IF "NO" PLEASE COMMENT
Autoclave make: **Model #:** **Attached printer:**	**Type of sterilizer cycle(s) (wrapped, unwrapped):**				**Cycle exposure time(s) and temperature(s):**
Chemical indicator: **Expiry date:**	**Biological indicator:** **Expiry date:**				**Biological indicator incubator:**
M.4.1	Equipment with lumens or other specialized types of equipment are validated for use in the sterilizer being used.				
M.4.2	All sterilization procedures follow the manufacturer's instructions for installation, operation and preventative maintenance of sterilization equipment.				
M.4.2.1	Independent biomedical or technician services perform regularly scheduled inspection and verification that the sterilizer is working properly				
M.4.3	A log is kept of routine and scheduled preventative maintenance performed on sterilization equipment.				
M.4.4	Critical equipment to be sterilized is wrapped and secured in materials that allow sterilant penetration, are appropriate to the sterilization method and provide a barrier to contamination.				
M.4.5	Instrument wrapping or packaging:				
M.4.5.1	All wrapping material is used according to manufacturer's instructions.				
M.4.5.2	Peel pouch packages are either self sealing or heat sealed.				
M.4.5.3	Peel pouch seals are smooth and air tight.				
M.4.5.4	All hinged instruments are cleaned, wrapped and sterilized in an open position				
M4.5.5	Instruments are placed in packages in a manner that allows for aseptic opening and removal of package contents.				

M.4. STERILIZATION		YES	NO	N/A	IF "NO" PLEASE COMMENT
M.4.5.6	Peel pouch packages are not over-stuffed. e.g. instruments do not touch side seams of pouch.				
M.4.5.7	Loading of the sterilizer ensures that steam is able to circulate freely around each package to allow steam to enter and exit from each package.				
M.4.5.8	If peel pouch packages are placed in the sterilizer on edge, they are positioned so that the paper side is facing the plastic side of the next pack				
M.4.5.9	Packages do not contact the chamber wall of the sterilizer.				
M.4.5.10	Sterilized items are dry prior to any handling.				
M.4.6	Each load is monitored visually or via printout with mechanical or digital indicators (time, temperature and pressure).				
M.4.7	A log is kept indicating that the mechanical or digital parameters were met for each load.				
M.4.8	An external chemical indicator is used on the outside of each wrapped package.				
M.4.9	An internal chemical indicator is placed inside each wrapped package.				
M.4.10	Chemical indicators are not used past their expiry date.				
M.4.11	If mechanical or chemical indicators suggest inadequate processing, the items are not used.				
M.4.12	Sterilizers are monitored with a biological indicator each day the sterilizer is used. (With every load if sterilizing implantable devices)				
M.4.12.1	Biological indicator is run in an appropriate challenge pack.				
M.4.13	Biological indicators are not used past their expiry date.				
M.4.14	If biological monitor is positive, all loads are recalled and the equipment is not used				
M.4.15	A log is kept of biological monitoring results.				

M.4. STERILIZATION		YES	NO	N/A	IF "NO" PLEASE COMMENT
M.4.16	A log is kept of all maintenance and interventions associated with a positive biological monitor.				
M.4.16.1	The biological indicator incubator is appropriate for the BI used.				
M.4.16.2	The BI incubator is used according to manufacturer's instructions.				
M.4.16.3	The BI incubator is monitored for time and temperature after each use according to manufacturer's directions				
M.4.17	A log is kept of each sterilization cycle that includes:				
M.4.17.1	Load number				
M.4.17.2	Load contents				
M.4.14.3	Date				
M.4.18	Wrapped sterilized equipment is labeled with:				
M.4.18.1	Load number				
M.4.18.2	Load contents				
M.4.18.3	Date				
M.4.19	There is a process in place that clearly identifies a non-reprocessed piece of equipment from one that has been reprocessed to prevent use of contaminated equipment on patients.				
M.4.20	The sterile storage area is well-ventilated and protected from dust, moisture, vermin, and temperature (to avoid excessive humidity) extremes.				
M.4.21	Semi-critical equipment sterilized unwrapped is stored in a clean, dry area until use. (e.g. specula)				

LIST OF INSTRUMENTS/DEVICES REPROCESSED			
Sterilization			High level disinfection
Wrapped		Unwrapped	
Peel pouch	Flat wrap		

ADDITIONAL COMMENTS

REFERENCES

1. Canadian Standards Association. 2009. CSA-Z314.8-08. *Decontamination of reusable medical devices*.
2. Canadian Standards Association. 2011. CSA-Z314.3-09. *Effective sterilization in health care facilities by the steam process*.
3. Health Canada. 1998. *Hand Washing, Cleaning, Disinfection and Sterilization in Health Care*. Canada Communicable Disease Report, December 1998.
4. Ontario Agency for Health Protection and Promotion (Public Health Ontario). Provincial Infectious Diseases Advisory Committee. 2013. *Best practices for cleaning, disinfection, and sterilization of medical equipment/devices*. 3rd ed. Toronto, ON: Queen's Printer for Ontario.