Medical Devices Reprocessing concerns and Recommendations of the Scientific Advisory Panel on Reprocessing of Medical Devices (SAP-RMD)

Medical devices have become increasingly complex as more sophisticated and less invasive surgical procedures are developed. The manufacturers' validated reprocessing instructions for these devices have not kept pace with the requirements listed in Canadian National Standards (e.g. CSA Z314.3, CSA Z314.8, CSA Z17664, CSA Z314.1, CSA Z314.22) and National or Provincial Guidelines (e.g.. Health Canada Infection Control guidelines, Provincial Infectious Diseases Advisory Committee (PIDAC) Best Practices for Cleaning, Disinfection and Sterilization - published 2006). These reprocessing issues have been compounded because medical device licensing procedures do not require pre-market review of instructions for use of Class I and Class II devices and because surgical instruments that are loaned or leased to hospitals may not be distributed with reprocessing instructions.

Concern regarding the safety of patients receiving healthcare in Canada and recommendations of the Auditor General's report of 2004 prompted Health Canada to strike a Scientific Advisory Panel on Reprocessing of Medical Devices (SAP-RMD) with the mandate of addressing both single-use and reusable medical device reprocessing issues.

The SAP-RMD has developed a series of recommendations regarding the reprocessing and reuse of Single-use Medical Devices in Canada. These recommendations are available on Health Canada's website[1].

In addition, the SAP-RMD has compiled an extensive list of specific reusable medical devices currently being used in Canada that were deemed to have unique reprocessing concerns (i.e. difficult to clean and or sterilize despite compliance with manufacturers' recommended protocols) and has provided recommendations to both Health Canada and the healthcare facilities for addressing these concerns in the attached table **"Reusable Medical Devices: Reprocessing concerns and recommendations of the Scientific Advisory Panel on Reprocessing of Medical Devices**".

It should be noted that the information included in the table is not exhaustive and was current at the time of publication.

[1] Scientific Advisory Panel on Reprocessing of Medical Devices (SAP-RMD) (February 10-11, 2005) - Panel Recommendations: http://hc-sc.gc.ca/dhp-mps/md-im/activit/sci-consult/reproc-retraite/saprmd_gcsrmm_recom_2005-02-10_e.html

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General Recommendations to Health Care Facilities:

1. **Follow manufacturer's instructions for Extended Steam Sterilization Cycles:**
Medical device manufacturers often indicate steam sterilization times that are outside the cycle parameters normally used in North American healthcare facilities. Users need to be aware that the biological indicators (BIs) and chemical indicators (CIs) that are validated for routine steam cycles cannot be used to monitor the extended steam cycles. To ensure adequate steam sterilization, facilities should contact the manufacturer to determine if standard steam cycles can be used. This confirmation should be in writing. If standard cycles are deemed inadequate, ensure the medical device manufacturer's steam sterilization cycles are followed. (For additional details see: Alfa MJ et al *"User Alert: Problems with process monitors for extended steam sterilization cycles"* Canadian Journal of Infection Control, Oct 2006).

2. **Develop facility-specific reprocessing policy and procedures:**
Every healthcare facility that offers patient procedures requiring medical device reprocessing must provide a copy of the device-specific manufacturers' instructions, but in addition there should be site-specific instructions. These should reflect the processes, equipment and products used in that facility. These should include; device handling, cleaning, wrapping, sterilization and/or disinfection instructions with appropriately detailed schematic diagrams or photographs. These need to be updated as changes occur (including site-specific processes, changes in products and equipment, and updates to the device manufacturer's instructions)

3. **Plan for adequate turn-around times for device reprocessing:**
When scheduling patient procedures, adequate time must be allowed for reprocessing device and instrument sets (including loaner instrument sets). Flash sterilization in the surgical suite to compensate for inadequate medical device inventory is unacceptable because the manufacturers' validated reprocessing protocols cannot be accomplished in this environment. Healthcare facilities must comply with the specific information provided in the following documents; CSA Z314.8, CSA Z314.3, CSA Z314.22 and CSA Z314.1. Failure to do so may jeopardize patient safety and expose the facility to legal liability for not exercising due diligence.

4. **Provide formal training to personnel who reprocess medical devices:**
Any staff involved in reprocessing of medical devices shall have formal, documented training (including theoretical and practical components) prior to being allowed independent responsibility for reprocessing of medical devices. Continuing education and regular (preferably annual) competency testing of all staff is required (PIDAC, AAMI ST79).

5. Establish procedures for Medical Device Tracking:

Life-span tracking of limited reuse devices:
Reprocessing of limited reuse medical devices must be tracked to ensure that use of the device does not exceed the manufacturers' specified lifespan, since medical devices used beyond their lifespan may fail, leading to adverse patient events. This requires a unique identifier for each instrument and a method to track use and functionality. If a tracking procedure is not provided by the device manufacturer, the healthcare facility should develop one or consider it disposable. If this is not possible, purchase of alternative devices should be considered.

Tracking to facilitate recall:
It is recommended that facilities implement an instrument tracking process to allow for: recall following sterilization failure, alerts issued by manufacturers, retrospective prion-related instrument recalls, and inventory monitoring. Implementation of a medical device tracking system ensures the ability of the facility to provide specific patient notification related to infection control issues.

6. Establish procedures for life-cycle management of medical devices and reprocessing equipment:
Medical devices and reprocessing equipment are often replaced only when they are beyond repair, long after their design has become obsolete. A plan should be made for replacement of old and obsolete devices and equipment. This should be an integral part of the initial purchase process as well as the capital equipment and medical device replacement plans.

7. Ensure notification of adverse events related to medical devices:
To ensure appropriate action, any adverse event associated with the use of a medical device must be reported to the device manufacturer as well as to Health Canada using the appropriate "Health Products and Food Branch Inspectorate Medical Devices Problem Report Form", or by calling the Inspectorate Hotline number 1-800-267-9675 to reach a Medical Device Inspector in your Region. This form along with a guidance document on Voluntary and Mandatory Problem Reporting are available on Health Canada's website.[2]

Failure to comply with this may result in adverse events occurring across Canada due to lack of communication or device recall. The healthcare facility may also wish to notify the appropriate regional and provincial authorities.

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http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/md_prob_rep-rap_incident_im_e.html
http://hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/rep_md_prob-rap_inc_im_tc-tm_e.html

8 . Monitor lifespan for implantable screws, wires and plates:
Facilities should ask device manufacturers for the validated lifespan of implantable screws, wires and plates (i.e. the number of times the item can be cleaned and re-sterilized without compromising functionality).

9. Ensure device materials are compatible with sterilization process:
Facilities should ensure that their protocols consider compatibility of the medical device materials with the mode of sterilization used. Containers, wraps and devices must be validated by the manufacturer as being compatible with the sterilant to be used.

10. Disseminate and use current protocols to manage risks of Creutzfeld-Jakob Disease (CJD) and prions:
Each healthcare facility needs to ensure they have current policies and procedures relating to CJD and high-risk medical procedures that comply with Health Canada Infection Control Guidelines for Prevention of Transmission of Classic CJD. This includes the ability to track instrumentation used for neuro-surgical, spinal and intra-ocular procedures. At a minimum, the policy should include patient screening and appropriate communication regarding the risk status of patients scheduled for neuro-surgical, spinal, and intra-ocular procedures. In addition the facility should have available surgical instruments that can either be discarded or quarantined after the procedure. A protocol for handling and disposal of high-risk tissue is also recommended.

11. Develop validated reprocessing methods for Specialty Equipment:
Specialty equipment, created solely for in-house use, must be reviewed and evaluated by the reprocessing departments, risk management, legal, biomedical engineering, and infection control departments of the healthcare facility. For these devices a process for cleaning, sterilization and functionality testing shall be validated by an external laboratory. The approach outlined above can also be applied when the site decides to continue using a device no longer supported by the manufacturer, if there is no alternative device available.

Reusable Medical Devices: Reprocessing Concerns and Scientific Advisory Panel Recommendations

Item	Medical Device	*SUMD Available	Reprocessing Concerns	Recommendations
General Instruments				
1	**Airway Introducers/ Dilators**	yes	Porous Material • Absorbs liquid chemical disinfectants (LCD). Manufacturers' recommended LCD not appropriate for device reprocessing in healthcare facilities (e.g. povidone iodine, bleach) There is limited use for some devices and no unique identifiers are provided on these devices for tracking purposes. Limited life span with no expiry date to track.	<u>To Health Canada:</u> Health Canada shall require manufacturers to: • Provide instructions that are reflective of current "Best Practice" recommendations regarding disinfectants to be used in health care facilities;[1, 2, 3] • Provide a unique identifier and mechanism (e.g. tracking form) for tracking reuse; • Provide expiry date to track device life span. <u>To Healthcare Facilities:</u> SUMD recommended for those difficult to clean and track.
2	**Esophageal Bougies**	no	Manufacturers' do not provide instructions or validated methods for permeation of the narrow lumens with disinfectant or for rinsing. Porous material absorb liquid chemical disinfectants (LCD). Manufacturers' recommended LCD not appropriate for device reprocessing in healthcare facilities. (e.g. povidone iodine, bleach) Mercury or tungsten gel filled • If autoclaved has been known to rupture;[4] • Use of device beyond expiration date may result in mercury or tungsten leakage; • Mercury is an environmental hazard.	<u>To Health Canada:</u> Health Canada shall require manufacturers to: • Ensure that the manufacturer provides validated method for lumen permeation; • Provide instructions that are reflective of current "Best Practice" recommendations regarding disinfectants to be used in health care facilities.[1, 2, 3] <u>To Healthcare Facilities:</u> Develop a plan to remove from use the first generation devices that pose a risk to the patient. Recommend use of tungsten filled esophageal dilators. If used, do not autoclave mercury-filled esophageal bougies.[4] Expiration date and integrity of device must be reviewed each time reprocessed.

Item	Medical Device	*SUMD Available	Reprocessing Concerns	Recommendations
3	**Electro-surgical cauteries/forceps**	Yes for some	Difficult to clean due to: • Ingress of fluid for some models. There is limited use for some devices and no unique identifiers are provided on these devices for tracking purposes. Sterilization instructions for some devices do not meet typical sterilization cycles used in Canadian health care facilities	<u>To Health Canada:</u> Health Canada shall require manufacturers to: • Provide a unique identifier and mechanism (e.g. tracking form) for tracking reuse for those that are limited use devices with limited use; • Ensure device design does not allow ingress of fluid; • Provide validated instructions that are reflective of typical sterilization cycles used in Canadian health care facilities. <u>To Healthcare Facilities:</u> SUMD recommended for those devices that are difficult to clean. SUMD recommended for limited use devices that have no unique identifier.
4	**Self-retaining retractors**	no	Difficult to clean due to: • Multiple components; • Narrow lumens; • Delicate attachments; • Moving parts that do not disassemble. Sets (packaging + contents) that exceed 25lbs compromise effective sterilization and pose ergonomic risk[6].	<u>To Health Canada:</u> Health Canada shall require manufacturers to: • Provide device specific instructions; • Provide validated instructions that are reflective of typical sterilization cycles used in Canadian health care facilities; • Provide schematics. <u>To Healthcare Facilities:</u> Heavy retractors should be separated into two instrument trays for sterilization.
5	**Laryngeal and silicone resuscitator masks**	Yes for some	Material is porous therefore absorbs detergents and/or liquid chemical disinfectants (LCD) which weakens the products. Materials are thermal labile therefore cannot be subjected to excessive heat (drying or pasteurization). Healthcare facilities often not following complex reprocessing instructions.	<u>To Healthcare Facilities:</u> SUMDs are recommended if the health care facility is unable to follow the detailed instructions. Detailed and documented staff training and written procedures for reprocessing are required.

Item	Medical Device	*SUMD Available	Reprocessing Concerns	Recommendations
6	**Skin Meshers, Dermabrader**	No (Yes, single use blade available for dermabrader)	Reprocessing instructions are: • Inadequate; • Confusing. When following manufacturers' recommendations devices are difficult to clean. Manufacturers advise against dismantling the ratchet handles despite the fact that debris gets trapped inside. Handling during cleaning and attempts to dismantle can cause lacerations and is an occupational health risk Regular servicing by the manufacturers is required, but is often overlooked by users because of confusing manufacturer instructions.	<u>To Health Canada:</u> Health Canada shall require manufacturers to: • Reassess design and provide validated reprocessing instructions; • Device specific instructions need to be correlated with appropriately detailed schematics. <u>To Healthcare Facilities:</u> Ensure preventative maintenance of devices as per manufacturers' directions. Staff training required by manufacturers. Detailed competency testing of staff is required.
7	**ET tubes**	yes	Material is porous therefore absorbs detergents and/or liquid chemical disinfectants (LCD). Cuff is difficult to clean and deterioration from repeated reprocessing may lead to rupture which poses a patient safety issue.	<u>To Healthcare Facilities:</u> SUMD recommended.
8	**Oral airways (e.g. two-piece)**	yes	Difficult to clean due to: • Problems with dismantling. Material is porous therefore absorbs detergents and/or liquid chemical disinfectants (LCD).	<u>To Healthcare Facilities:</u> SUMD recommended.
9	**Aerosol spray tips**	yes	Difficult to clean due to • Narrow lumens. Reprocessing instructions are: • Inadequate. Sterilization instructions do not meet typical sterilization cycles used in Canadian health care facilities	<u>To Health Canada:</u> Health Canada shall require manufacturers to: • Ensure that the manufacturer provides device specific validated method for lumen permeation; • Provide validated instructions that are reflective of typical sterilization cycles used in Canadian health care facilities. <u>To Healthcare Facilities:</u> SUMD recommended.

Item	Medical Device	*SUMD Available	Reprocessing Concerns	Recommendations
10	**Delicate clamps (vascular clamps - bulldogs, suture holders - serafins)**	yes	Difficult to clean and sterilize due to: • Hinged devices that are hard to keep open. Repeated opening decreases tensile strength.	To Healthcare Facilities: SUMD recommended.
11	**Line Access Stopcocks**	yes	Difficult to clean and sterilize due to: • Problems with disassembly.	To Healthcare Facilities: SUMD recommended.
12	**Valvutome Scissors**	no	First generation devices cannot be cleaned due to: • The design that traps bioburden; • The absence of device specific manufacturer reprocessing instructions.	To Health Canada Health Canada shall require manufacturer to: • Provide validated device specific instructions with schematics. To Healthcare Facilities: Remove first generation devices from use. Newer models exist and should be considered to replace first generation devices.
13	**Internal Defibrillator Paddles**	yes	Manufacturer recommends different sterilization methods for the paddle and handles therefore increasing adverse outcomes due to delays in an emergency situation because assembly prior to use is required. Although manufacturers have recommended partial assembly before sterilization there are still difficulties because device is used in emergency situations where time for assembly is not feasible. For limited use devices, no unique identifier is provided on device components for tracking/testing purposes. Limited number of reuses but these devices do not always last as long as manufacturers' recommended number of uses.	To Health Canada: Health Canada shall require manufacturers to: • Provide a unique identifier and mechanism (e.g. tracking form) for tracking reuse for those that are limited use devices with limited use. For medical devices to be used in emergency situations such as cardiac arrest intra-operatively, design should be assessed to ensure that immediate use is possible (i.e. doesn't require assembly at point of use). To Healthcare Facilities: As per manufacturers' instructions: • Ensure limited-use tracking is performed; • Test functionality; • Ensure appropriate cleaning and disinfection for safe handling before sending to bioengineering.

Item	Medical Device	*SUMD Available	Reprocessing Concerns	Recommendations
Gynecological				
14	**Fallopian tube clip applicators**	Yes for some	Some applicators manufactured prior to 1998 can no longer be serviced. Regular servicing/calibration by the manufacturer is required, but is often overlooked by users.	<u>To Health Canada:</u> Health Canada shall require manufacturers to: • Provide updated instructions; • Communicate to the user when servicing support for old devices is no longer provided. <u>To Healthcare Facilities:</u> • Ensure servicing is performed as per manufacturers' instructions; • Remove from use all applicators that can no longer be serviced.
15	**Stress incontinence devices (pessaries)**	(yes sizers/ fitting sets are not available)	Reprocessing instructions are: • Confusing. Sizer devices are often not properly cleaned and sterilized by users due to confusing manufacturers' instructions. Porous material absorbs detergents and liquid chemical disinfectants (LCD). Although pessaries are single patient use, some facilities may be reprocessing these devices.	<u>To Health Canada:</u> Health Canada shall require manufacturers to: • Provide validated reprocessing instructions for sizer devices used for fitting pessaries; • Provide appropriate pessary cleaning instructions for the patient/client. <u>To Healthcare Facilities:</u> • Ensure pessaries are single patient use; • Purchase sizer devices that can be steam autoclaved to prevent problems associated with retention of residual chemicals.
16	**Vaginal speculums**	yes	Unable to get reusable devices clean unless cleaned immediately after procedure. Screws are easily lost and not interchangeable.	<u>To Healthcare Facilities:</u> Recommend SUMDs where possible.

Item	Medical Device	*SUMD Available	Reprocessing Concerns	Recommendations
17	**Laser Vaginal Speculums**	no	This type of insulated device requires special cleaning and inspection that is often overlooked by reprocessing personnel.	<u>To Health Canada:</u> Health Canada shall require manufacturers to • Provide specific functionality testing directions and equipment required. <u>To Healthcare Facilities:</u> Speculums with insulated finish require: • Inspection post-cleaning to ensure no damage (e.g. chipping) as this may lead to arcing that can cause patient burns; • Special cleaning methods to prevent damage to the finish.

Item	Medical Device	*SUMD Available	Reprocessing Concerns	Recommendations
Dental/ENT/Facial Maxillary Instruments				
18	**Punch forceps; Instrument for ethmoid sinus surgery**	no	Difficult to clean due to: • The absence of flushing ports; • Inability to disassemble. Reprocessing instructions are: • Not device specific; • Inadequate.	<u>To Health Canada:</u> Health Canada shall require manufacturers to: • Provide validated device specific reprocessing instructions; • Provide instructions that are reflective of current "Best Practice" recommendations regarding disinfectants to be used in health care facilities;[1, 2, 3] • Provide a unique identifier and mechanism (e.g. tracking form) for tracking reuse; • Provide expiry date to track device life span. <u>To Healthcare Facilities:</u> Detailed and documented staff training and written procedures for reprocessing are required.
19	**Hand pieces (nasal shaver)**	no	First generation devices cannot be cleaned due to: • The design that traps bioburden; • The absence of device specific manufacturer reprocessing instructions.	<u>To Health Canada:</u> Health Canada shall require manufacturers to: • Provide validated device specific reprocessing instructions with schematics; • Provide validated method for lumen permeation; • Provide instructions that are reflective of current "Best Practice" recommendations regarding disinfectants to be used in health care facilities.[1, 2, 3] <u>To Healthcare Facilities:</u> Develop a plan to remove from use the first generation devices that pose a risk to the patient.

Item	Medical Device	*SUMD Available	Reprocessing Concerns	Recommendations
20	**Mouth gag**	no	Difficult to clean due to: • Inability to dismantle; • Many wires, joints, narrow long lumen; • A handle that doesn't disassemble and some handles that break down (made of resin). Reprocessing instructions are: • Not available.	<u>To Health Canada:</u> Health Canada shall require manufacturers to: • Provide a unique identifier and mechanism (e.g. tracking form) for tracking reuse for those that are limited use devices with limited use; • Ensure device design does not allow ingress of fluid; • Provide validated instructions that are reflective of typical sterilization cycles used in Canadian health care facilities. <u>To Healthcare Facilities:</u> Detailed and documented staff training and written procedures for reprocessing are required.
21	**Snares**	No (except wires)	Difficult to clean due to: • Applicator that has long narrow lumen. Reprocessing instructions are: • Not available. Adverse patient events possible if snare wire incorrectly assembled or wrong wire size selected.	<u>To Health Canada:</u> Health Canada shall require manufacturers to: • Provide device specific instructions; • Provide validated instructions that are reflective of typical sterilization cycles used in Canadian health care facilities; • Provide schematics. <u>To Healthcare Facilities:</u> Detailed and documented staff training and written procedures for reprocessing are required. Reprocessing personnel must demonstrate competency in assembly of nasal and tonsil snares.
22	**Endofiles**	No	Difficult to clean due to: • Irregular surface.	<u>To Healthcare Facilities:</u> Detailed and documented staff training and written procedures for reprocessing are required.

Item	Medical Device	*SUMD Available	Reprocessing Concerns	Recommendations
23	**Accessory devices (e.g. biopsy forceps, sphinctertomes baskets, graspers, snares, sheaths, cautery tips)**	yes	Difficult to clean due to • Long narrow lumens; • No cleaning and irrigation ports; • Complex wires. Reprocessing may lead to poor functionality Reprocessing instructions are: • Not specific to the device; • Inadequate and often lead to damage.	<u>To Healthcare Facilities:</u> SUMD recommended.

Item	Medical Device	*SUMD Available	Reprocessing Concerns	Recommendations
24	**Flexible endoscopes**	no	Staff failing to clean all scope channels due to: • Inadequate training; • After-hours staffing; • New scopes introduced without training prior to use. Inappropriate chemistry used on scope without manufacturers' recommendation. Problems associated with Automated Endoscope Reprocessors (AER): • Connectors; incorrect, none, or not approved; • Wrong chemicals used; • Defaults do not meet standard exposure cycles; • Lack of self-decontamination cycles leading to biofilm formation in AER; • Inability to confirm that scope has completed cycle; • Recontamination after High Level Disinfection (HLD) due to contaminated rinse water (e.g. filter integrity compromised but not detected); • Inability to detect lack of fluid flow through scope channels; • Environmental safety issues (e.g. chemical exposure exceeded); • Failure of LCD due to lack of Minimum Effective Concentration (MEC) testing; • Lack of preventative maintenance (e.g. filters, calibration, etc.). Lack of tracking system linking patient, procedure, AER and scope. Lack of appropriate storage of scopes and/or components post-reprocessing.	<u>To Health Canada:</u> Address and take into consideration the issues mentioned when considering new devices for license approval. <u>To Healthcare Facilities:</u> Ensure problems associated with AER are reported to Health Canada. Ensure that all staff (including after-hours staff) assigned to reprocess endoscopes are appropriately trained and ongoing competency is verified for all models and makes of scopes being used. Staffing levels should be adequate to ensure complete reprocessing of endoscopes for after-hours emergency procedures (e.g. scopes not left soaking in detergent or AER for prolonged periods and are dried and put into storage). All sites should have a tracking system that allows linkage between patient, procedure, AER and scope.

Item	Medical Device	*SUMD Available	Reprocessing Concerns	Recommendations
25	**Fiber-optic mammary retractor**	no	Reprocessing instructions are: • Inadequate; • Not specific to the device.	<u>To Health Canada:</u> Health Canada shall require manufacturers to: • Ensure that the manufacturer provides validated method for lumen permeation; • Provide validated instructions that are reflective of typical sterilization cycles used in Canadian health care facilities. <u>To Healthcare Facilities:</u> Detailed and documented staff training and written procedures for reprocessing are required.
26	**Brain retractor**	no	Difficult to clean due to: • Complex assembly (e.g. 29 ball bearings that require disassembly for cleaning). Time for proper cleaning not often factored into the turnaround time.	<u>To Health Canada:</u> Health Canada shall require manufacturers to: • Provide validated, device specific reprocessing instructions. <u>To Healthcare Facilities:</u> Must have detailed staff training (e.g. in-service). Ongoing education needed. Detailed written procedures for reprocessing required. Time for proper cleaning needs to be factored in the turnaround time.
27	**Awl**	No	Difficult to clean due to: • Long narrow cannula. Reprocessing instructions are: • Inadequate.	<u>To Health Canada:</u> Health Canada shall require manufacturers to: • Provide validated, device specific reprocessing instructions.

Item	Medical Device	*SUMD Available	Reprocessing Concerns	Recommendations
28	**External cranio-fixation halo device**	No	Difficult to clean due to: • Multiple moving parts and screws that cannot be cleaned without disassembly; • Manufacturers' instructions state "do not disassemble when reprocessing". This leads to confusion.	<u>To Health Canada:</u> Health Canada shall require manufacturers to: • Reassess design and provide validated reprocessing instructions; • Provide device specific instructions. <u>To Healthcare Facilities:</u> Detailed and documented staff training and written procedures for reprocessing are required.
29	**Rapid flap applier device**	Unknown	Difficult to clean due to: • Moving parts; • Impossibility of complete disassembly; • Cannulations. Reprocessing instructions are: • Unavailable; • Inadequate.	<u>To Health Canada:</u> Health Canada shall require manufacturers to: • Reassess design and provide validated reprocessing instructions; • Provide device specific instructions. <u>To Healthcare Facilities:</u> Detailed and documented staff training and written procedures for reprocessing are required.
30	**Neuro/Spinal sets**	No	Reprocessing instructions are: • Inadequate. Time for proper cleaning not often factored into the turnaround time. Sterilization instructions for some devices do not meet typical sterilization cycles used in Canadian health care facilities.	<u>To Health Canada:</u> Health Canada shall require manufacturers to: • Provide validated, device specific reprocessing instructions. <u>To Healthcare Facilities:</u> Must have detailed staff training (e.g. in-service). Ongoing education needed. Detailed written procedures for reprocessing required. Time for proper cleaning needs to be factored in the turnaround time. Policies and procedures should comply with HC CJD Infection Control Guidelines for reprocessing of devices used on high-risk tissues.[7, 8]

Item	Medical Device	*SUMD Available	Reprocessing Concerns	Recommendations
31	**Aneurysm clips**	yes	Clips are very fine and delicate making it hard to assess which ones are soiled. Each clip must be put into applier and spread to open position to see which is dirty: this can damage the device.	<u>To Healthcare Facilities:</u> Trialed clips to be disposed of at point of use due to contamination and weakening of tensile strength.
32	**Power Handpieces (saws, drills)**	No	Difficult to clean due to: • A device design that traps bioburden. Reprocessing instructions are: • Inadequate; • Confusing. Sterilization instructions do not meet typical sterilization cycles used in Canadian health care facilities. Manufacturers' recommendations for preventative maintenance are unclear and often not followed by users.	<u>To Health Canada:</u> Health Canada shall require manufacturers to: • Reassess design and provide validated reprocessing instructions; • Provide device specific instructions; • Provide validated instructions that are reflective of typical sterilization cycles used in Canadian health care facilities (unless documentation can be provided that this is not possible); • Provide clear preventative maintenance guidelines. <u>To Healthcare Facilities:</u> Ensure that manufacturers' preventative maintenance program is followed. Detailed and documented staff training and written procedures for reprocessing are required.
33	**Handpiece Accessories (bits, burs, blades)**	yes	Users typically are not equipped to adequately assess device damage or cleanliness after reprocessing.	<u>To Healthcare Facilities:</u> SUMD recommended. If users are reprocessing these devices the following should be met: • Appropriate equipment (e.g. appropriate lighting and microscope) needs to be provided to facilitate assessment of damage and cleanliness of device; • Policies and procedures should comply with HC CJD Infection Control Guidelines for reprocessing of devices used on high-risk tissues.[7, 8]

Item	Medical Device	*SUMD Available	Reprocessing Concerns	Recommendations
Minimally Invasive Surgery				
34	**Rigid endoscope sets (includes trocar, stopcocks, etc.)**	No (yes for trocar/ cannula)	Some sites using high-level disinfection (HLD) for critical devices thus risking adverse reactions and infections in patients when tap water used or inadequate rinsing is performed after HLD (e.g. arthroscopes, laparoscopes, cystoscopes, uteroscopes). Manufacturers' reprocessing instructions confusing as disassembly of stopcocks not specified in cleaning and sterilization instructions. Users unable to differentiate between models with stopcocks that can be disassembled vs. those that cannot. Stopcocks that require disassembly (as per manufacturers' instructions) for sterilization create difficulty due to problems associated with assembly on the sterile field at time of use (e.g. loss of small components). Problems (adverse patient effects) encountered due to dulling of trocars with repeated uses. Users have difficulty distinguishing between single-use and limited reuse trocars due to lack of labeling on the trocar. Users have difficulty tracking number of uses for limited reuse trocars due to lack of unique identifier.	<u>To Health Canada:</u> Health Canada shall require manufacturers to: • Include clear instructions for sterilization of all critical devices (i.e. no HLD); • Reassess design for reusables to determine if they can be sterilized when fully assembled; • Provide a unique identifier and recommend a way to track number of uses for each limited reuse device. <u>To Healthcare Facilities:</u> Steam sterilization preferred method over alternative technologies. Staff training required by manufacturers. Detailed competency testing of staff is required. Written procedures are required. Ensure that spare parts are purchased for small components that get lost or damaged. If unable to verify sharpness of trocars: SUMD recommended. A tracking system must be utilized for limited reuse devices.

Item	Medical Device	*SUMD Available	Reprocessing Concerns	Recommendations
35	**Accessory devices for Minimally Invasive Surgery (e.g. L-hook, biopsy forceps, baskets, snares, sheaths, cautery tips, graspers, scissors, robotic instruments)**	yes	Difficult to clean due to: • Inability to dismantle first generation devices. Users are not checking integrity of insulation after every use. Some current designs may allow ingress of patient material which cannot be removed by manufacturers' recommended cleaning process. Complex reassembly instructions may lead to incompatibility or non-functionality of device (e.g. reassembly using components from different manufacturers). Users have difficulty distinguishing between single-use and limited reuse tips due to lack of labeling on the tip (for those designs that have removable tips). Users have difficulty tracking number of uses for limited reuse tips due to lack of unique identifier. Users not using manufacturers' validated sterilization protocol (e.g. placement of devices in plasma sterilization when manufacturer has not validated the process for this specific device, or placing device fully assembled into sterilization process when manufacturers recommendations stipulate disassembly of device for sterilization).	<u>To Health Canada:</u> Health Canada shall require manufacturers to: • Ensure universal symbol for single use is stamped on each device where applicable; • Reassess design and provide validated reprocessing instructions; • Provide device specific instructions; • Provide a unique identifier and recommend a way to track number of uses for each limited reuse device. <u>To Healthcare Facilities:</u> Users must ensure: • Integrity of insulation is checked after every use using manufacturers' recommended protocol; • Detailed staff training and clearly written procedures for reprocessing are provided and followed; • The manufacturers validated sterilization protocol is followed (e.g. do not use plasma when device is only validated for steam sterilization); • A plan is in place to phase out first generation MIS devices that cannot be dismantled and do not have cleaning ports; • Replacement of first generation devices with newer models that have improved validated cleaning processes as they become available; • A tracking system is utilized for limited reuse devices.

Item	Medical Device	*SUMD Available	Reprocessing Concerns	Recommendations
36	**Tissue fragmenters/ aspirators (e.g. liposuction cannulae, cannulated handpieces)**	No (yes for liposuction cannulae)	Difficult to clean due to: • Narrow cannulae that entraps tissue. Reprocessing instructions are: • Inadequate; • Not specific to the device. Users unaware of changes to manufacturers' reprocessing instructions (therefore reusing components such as tubing that have been re-categorized as single use).	<u>To Health Canada:</u> Health Canada shall require manufacturers to: • Provide device specific validated reprocessing instructions; • Automatically inform customers when instructions are updated. <u>To Healthcare Facilities:</u> Staff training and competency testing is required. Written procedures for reprocessing are required. SUMD recommended for cannulated liposuction devices when available. Recommend all tubing be single use.
Item	**Medical Device**	***SUMD Available**	**Reprocessing Concerns**	**Recommendations**
Probes (Critical and Semi-critical)				

Item	Medical Device	*SUMD Available	Reprocessing Concerns	Recommendations
37	**Intra-operative ultrasound probe/transducer (critical device that enters sterile body cavity e.g. liver resection, brain probes, argon probes)**	no	Difficult to clean some devices due to: • Inability to immerse. Reprocessing instructions are: • Inadequate; • Confusing; • Contradictory; • Not followed by users. Users not sterilizing devices due to high demand and lack of inventory (because of cost). Users not reprocessing device because of misconception that sheathing precludes the need to clean and sterilize. Users not doing leak test (where applicable) prior to reprocessing probe as per manufacturers' recommendations. Limited uses therefore this device requires the development of a tracking system.	<u>To Health Canada:</u> Health Canada shall require manufacturers' to: • Reassess design of non-immersible probes; • Provide validated device-specific reprocessing instructions appropriate for intra-operative procedures; • Review current manufacturers' instructions to ensure clarity for users; • Provide a unique identifier and recommend a way to track number of uses for each limited reuse device. <u>To Healthcare Facilities:</u> Sterilization is required for intra-operative probes; a sterile sheath does not eliminate the need to sterilize the device. Leak testing for all probes prior to cleaning as per manufacturers' instructions. Detailed written procedures for cleaning and sterilization based on manufacturers' recommendations. Extensive in-service by the manufacturer. Staff competency testing needs to be on-going. A tracking system must be utilized for limited reuse devices.

Item	Medical Device	*SUMD Available	Reprocessing Concerns	Recommendations
38	**Diagnostic or interventional probes (semi-critical device that contacts intact mucus membrane e.g. ultrasonic imaging probes)**	no	Users are inappropriately rinsing with tap water after HLD.[9, 10] In some cases, users may be performing HLD in inappropriate settings (e.g. Diagnostic Imaging (DI) rooms, lack of ventilation).	<u>To Healthcare Facilities:</u> Staff training required by manufacturers. Detailed competency testing of staff is required. Written procedures are required. HLD is required for diagnostic or interventional probes; a condom or sterile sheath does not eliminate the need to HLD the device. When biopsies are performed a sterile sheath is required. These probes must be rinsed with sterile distilled water after HLD.
39	**Needles**	yes	Reprocessing of needles poses a risk of needle-stick injury to staff. Reprocessing instructions are: • Often unavailable; • Inadequate.	<u>To Health Canada</u> Health Canada shall require manufacturers' to: • Provide device specific validated reprocessing instructions. <u>To Healthcare Facilities:</u> SUMD recommended. If reusable, must have appropriate cleaning materials (e.g. brushes, sharpening stone, water gun).
40	**Ear suctions**	unknown	Size 22-24 lumens are hard to clean.	<u>To Health Canada:</u> Health Canada shall require manufacturers' to: • Provide device specific validated reprocessing instructions. <u>To Healthcare Facilities:</u> Lobby manufacturers to develop SUMD.

Item	Medical Device	*SUMD Available	Reprocessing Concerns	Recommendations
41	**Dental needles**	yes	Reprocessing instructions are: • Often unavailable; • Inadequate. Reprocessing poses the following risk to staff: • Needle-stick injury; • Repetitive stress injury.	<u>To Health Canada:</u> Health Canada shall require manufacturers' to: • Provide device specific validated reprocessing instructions. <u>To Healthcare Facilities:</u> SUMD recommended.

Item	Medical Device	*SUMD Available	Reprocessing Concerns	Recommendations
Ophthalmologic Instruments				
42	**Fine ophthalmology /intra-operative instruments (e.g. Irrigator/ Aspirator (I/A) needles, Phaco tips, needles, tubing, conformers)**	Yes for some	Difficult to clean due to: • Small, fragile and angular design; • Narrow lumens; • Need for microscopic examination. Reprocessing instructions are: • Confusing; • Inadequate. Manufacturers require users to perform validation of sterilization process. Manufacturers do not recommend a cleaning agent. Sterilization instructions do not meet typical sterilization cycles used in Canadian health care facilities. Impossible to track those devices that are limited reuse due to lack of unique identifier. Reprocessing poses the following risk to staff: • Needle-stick injury; • Repetitive stress injury. Improper cleaning/rinsing (i.e. any inorganic or organic residuals left) poses risk of Toxic Anterior Segment Syndrome (TASS). [11] Users that perform manual rinsing are often not providing adequate rinse volume because it is difficult to deliver the copious volumes as recommended by manufacturer. Ultrasonic cleaning (where recommended) is not sufficient alone.	<u>To Health Canada:</u> Health Canada shall require manufacturers to: • Ensure universal symbol for single use is stamped on each device where applicable; • Reassess design and provide validated reprocessing instructions; • Provide device specific instructions; • Provide a unique identifier and recommend a way to track number of uses for each limited reuse device; • Provide validated instructions that are reflective of typical sterilization cycles used in Canadian health care facilities (unless documentation can be provided that this is not possible). <u>To Healthcare Facilities:</u> Recommend users acquire the manufacturer recommended automated rinsing equipment. Lobby manufacturers to develop and provide SUMD. If reusable, must have appropriate cleaning materials, staff training. Written procedures for reprocessing required. SUMD (where available) recommended.

Item	Medical Device	*SUMD Available	Reprocessing Concerns	Recommendations
43	**Phaco handpieces**	no	Difficult to clean due to: • Narrow lumens; • Non immersible. Reprocessing instructions are: • Confusing; • Inadequate. Manufacturers require users to perform validation of sterilization process. Manufacturers do not recommend a cleaning agent. Sterilization instructions do not meet typical sterilization cycles used in Canadian health care facilities. Reprocessing poses the following risk to staff due to repetitive stress injury. Improper cleaning/rinsing (i.e. any inorganic or organic residuals left) poses risk of Toxic Anterior Segment Syndrome (TASS).[11] Users that perform manual rinsing are often not providing adequate rinse volume because it is difficult to deliver the copious volumes as recommended by manufacturer.	<u>To Health Canada:</u> Health Canada shall require manufacturers to: • Reassess design and provide validated reprocessing instructions; • Provide device specific instructions; • Provide validated instructions that are reflective of typical sterilization cycles used in Canadian health care facilities (unless documentation can be provided that this is not possible). <u>To Healthcare Facilities:</u> Recommend users acquire the manufacturer recommended automated rinsing equipment. Lobby manufacturers to develop and provide a reusable device for which manufacturers have validated the cleaning and sterilization protocols. If reusable, must have appropriate cleaning materials and staff training. Written procedures for reprocessing required.
44	**Diamond knives**	no	Extremely fragile (frequently damaged during transport) and expensive, typically owned by surgeons. Not routinely cleaned because it is not part of hospital inventory or inventory levels are inadequate for volume of cases scheduled. Users frequently flash sterilize without prior cleaning (using manufacturers validated instructions) due to lack of inventory, unwillingness to transport to reprocessing department and surgeon-owned instruments not available until just prior to surgery.	<u>To Healthcare Facilities:</u> Work with surgeons to provide appropriate reprocessing that complies with national standards. Ensure devices are reprocessed using manufacturers' recommended reprocessing protocol. Ensure adequate inventory for volumes of cases scheduled. Flash sterilization does not comply with national guidelines when used for elective surgery (i.e. not an emergency situation). Recommend acquiring dedicated protective containers for transport and sterilization of device.

Item	Medical Device	*SUMD Available	Reprocessing Concerns	Recommendations
45	**Ophthalmology Foreign Body Magnet**	no	Difficult to clean due to: • Narrow lumens; • Ingress of patient material. Reprocessing instructions are: • Inadequate. Improper cleaning/rinsing (i.e. any inorganic or organic residuals left) poses risk of Toxic Anterior Segment Syndrome (TASS).[11] Users that perform manual rinsing are often not providing adequate rinse volume because it is difficult to deliver the copious volumes as recommended by manufacturer.	<u>To Health Canada:</u> Health Canada shall require manufacturers to reassess design and provide validated reprocessing instructions. <u>To Healthcare Facilities:</u> Users must properly inspect reprocessed devices to ensure no ingress of patient material. Users must ensure adequate volume of sterile distilled water is used for rinsing.
46	**Lenses**	no	Reprocessing instructions are: • Inadequate; • Confusing (e.g. use of alcohol on its own, no sterilization time given). Sterilization instructions do not meet typical sterilization cycles used in Canadian health care facilities. Due to no company identifier on the device, users are often confused as to what company's reprocessing instructions to follow.	<u>To Health Canada:</u> Health Canada shall require manufacturers to: • Provide validated instructions that are reflective of typical sterilization cycles used in Canadian health care facilities (unless documentation can be provided that this is not possible); • Provide validated device specific reprocessing instructions; • Provide a unique identifier to recognize manufacturer. <u>To Healthcare Facilities:</u> Staff training specific to the device. Written procedures are required.

Item	Medical Device	*SUMD Available	Reprocessing Concerns	Recommendations
Orthopaedic, Spinal Instruments				
47	**Handpieces/ Drills/Saws (chucks, adapters, cordless, oscillating, reciprocating, saggital, jacobs, reamer attachment, trauma drill, shavers)**	no	Difficult to clean due to: • A device design that traps bioburden (e.g. cannulations, chucks and adapters cannot be disassembled). Reprocessing instructions are: • Generic; • Not specific to the device(e.g. pull-back collar on chuck); • Confusing. Sterilization instructions do not meet typical sterilization cycles used in Canadian health care facilities. Manufacturers recommendations for preventative maintenance are unclear and often not followed by users.	<u>To Health Canada:</u> Health Canada shall require manufacturers to: • Reassess design and provide validated reprocessing instructions; • Provide device specific instructions; • Provide validated instructions that are reflective of typical sterilization cycles used in Canadian health care facilities (unless documentation can be provided that this is not possible); • Provide clear preventative maintenance guidelines. <u>To Healthcare Facilities:</u> Ensure that manufacturers' preventative maintenance program is followed. Detailed written procedures for cleaning and sterilization based on manufacturers' recommendations. Extensive in-service by the manufacturer. On-going internal competency testing.
48	**Handpiece Accessories (bits, burs, blades, saws)**	yes	Users, typically, are not equipped to adequately assess device damage or cleanliness after reprocessing.	<u>To Healthcare Facilities:</u> SUMD recommended. If users are reprocessing these devices the following should be met: • Appropriate equipment (e.g. appropriate lighting and microscope) needs to be provided to facilitate assessment of damage and cleanliness of device.

Item	Medical Device	*SUMD Available	Reprocessing Concerns	Recommendations
49	**Batteries**	no	Manufacturers' instructions for flash sterilization create problems with maintenance of the sterile technique. Some manufacturers recommend recharging battery immediately prior to surgery therefore potentially delaying surgery.	<u>To Health Canada:</u> Health Canada shall require manufacturers to: • Provide validated device specific reprocessing instructions; • Provide validated instructions that are reflective of typical sterilization cycles used in Canadian health care facilities (unless documentation can be provided that this is not possible); • Provide clear preventative maintenance guidelines. <u>To Healthcare Facilities:</u> Ensure that manufacturers' preventative maintenance program is followed. Detailed written procedures for cleaning and sterilization based on manufacturers' recommendations. Recommend utilization of batteries that can be sterilized by traditional methods. (wrapped)
50	**Acetabular reamers**	no	Difficult to clean due to: • Inherently complex design; • Lack of schematics showing disassembly.[12] Time for proper cleaning not often factored into the turnaround time. Instructions for frequency of sharpening not provided for cutting instruments.	<u>To Health Canada:</u> Health Canada shall require manufacturers to: • Provide validated device specific reprocessing instructions correlated with appropriate detailed schematics. <u>To Healthcare Facilities:</u> Recommend that reamers are sharpened by qualified instrument technicians. Detailed written procedures for cleaning and sterilization based on manufacturers' recommendations.

Item	Medical Device	*SUMD Available	Reprocessing Concerns	Recommendations
***51**	**Flexible-coiled and cannulated devices (e.g. reamers, drill guides and bits**	(Yes for reamers and drill bits)	Difficult to clean due to: • Inherently complex design.	To Health Canada: Health Canada shall require manufacturers to: • Reassess inherently complex design and provide validated reprocessing instructions; • Provide validated device specific reprocessing instructions. To Healthcare Facilities: SUMD recommended when available. Develop a plan to remove from use the first generation devices that pose a risk to the patient. Recommend flexible solid shaft reamers. If reusable, must have documented in-service training from the manufacturers and appropriate cleaning materials. Detailed written procedures for cleaning and sterilization based on manufacturers' recommendations. Flexible coiled reamers and guides should be placed into detergent and/or water solution immediately after use (in Operating Room).
52	**Bone rasps**	no	Difficult to clean due to: • Uneven surface; • Generic cleaning instructions.	To Health Canada: Health Canada shall require manufacturers to: • Provide validated device specific reprocessing instructions.
53	**Cement bowls**	yes	Difficult to clean due to: • Cement residue that hardens.	To Healthcare Facilities: SUMD recommended
54	**Kerrisons, rongeurs and punches**	No	Difficult to clean due to: • Tissue/bone gets trapped in the shaft, cutter teeth or other sites. Reprocessing instructions are: • Generic for older generation devices.	To Healthcare Facilities: Develop a plan to remove from use the first generation devices that pose a risk to the patient and replace with new generation that disassemble for cleaning. Detailed written procedures for cleaning and sterilization based on manufacturers' recommendations.

Item	Medical Device	*SUMD Available	Reprocessing Concerns	Recommendations
55	**Vice grips**	No	Difficult to clean due to: • Moving parts and springs; • Tissue gets trapped. Reprocessing instructions are: • Generic. Hardware store vice-grips are not acceptable. They are not a validated/licensed medical device.	<u>To Health Canada:</u> Health Canada shall require manufacturers to: • Provide validated device specific reprocessing instructions; • Reassess design and provide validated reprocessing instructions. <u>To Healthcare Facilities:</u> Detailed written procedures for cleaning and sterilization based on manufacturers' recommendations.
56	**External fixation components**	Some fixator pins and locking bolts are disposable	Impossible to track those devices that are limited reuse due to lack of unique identifier. Users cannot easily identify fixator pins that are SUMD and have been exposed to secretions/tissue and reprocessed.	<u>To Health Canada:</u> Health Canada shall require manufacturers to: • Ensure universal symbol for single use is stamped on each device where applicable. <u>To Healthcare Facilities:</u> Discard all SUMDs and/or implanted devices that are exposed to or trialed on a patient at time of procedure. Discard all SUMDs and/or implanted components at the time of removal from a patient (e.g. In O.R. or clinic setting).

Item	Medical Device	*SUMD Available	Reprocessing Concerns	Recommendations
57	**Intra-medullary nailing system**	No (Yes for flexible reamer)	Difficult to clean due to: • Poor design; • Lack of adequate cleaning instructions (disassembly or not); • Generic instructions; • Articulations and moving parts that don't come apart; • Multiple long angled cannulations. Old design impossible to clean, new design available yet manufacturers have not replaced these items (or notified users) in currently used instrument sets. Sterilization instructions do not meet typical sterilization cycles used in Canadian health care facilities. Inability to assess the extent of disassembly required for multiple parts. Possible metal fatigue due to multiple reprocessing. Unable to track implant to patient. Instructions for frequency of sharpening not provided for cutting instruments.	<u>To Health Canada:</u> Health Canada shall require manufacturers to: • Reassess design and provide validated reprocessing instructions; • Provide device specific instructions; • Provide validated instructions that are reflective of typical sterilization cycles used in Canadian health care facilities (unless documentation can be provided that this is not possible); • Validate the life span for re-sterilization (i.e. extent of metal fatigue, build up of organic and inorganic residuals) of implants (e.g. plates and screws); • Provide a unique identifier and recommend a way to track each implantable device to the patient; • Send a notice out when there is a design change or process change; • Provide sterile implants individually packaged. If not, a tracking system for re-sterilized implants is required. <u>To Healthcare Facilities:</u> Staff training by manufacturers is required. Detailed written procedures including: • Including pictures detailing disassembly; • Cleaning and sterilization are required; • Extensive in-service and competency testing. Time for proper cleaning needs to be factored in the turnaround time. Reusable components should be placed into detergent and/or water immediately after use (in OR).
58	**Spinal Systems (e.g. Cable grip systems)**	No	Difficult to clean due to: • Multiple cannulations; • Multiple moving parts. Reprocessing instructions are: • Inadequate; • Inappropriate (e.g. "using established hospital methods", "certain instruments may require dismantling before cleaning"). Users may not be aware of specific disassembly requirements (e.g. plate holders separate into 4 pieces).	<u>To Health Canada:</u> Health Canada shall require manufacturers to: • Provide validated device specific reprocessing instructions correlated with appropriate detailed schematics. <u>To Healthcare Facilities:</u> Must have detailed staff training (e.g. in-service). Ongoing education needed. Detailed written procedures for reprocessing required.

Item	Medical Device	*SUMD Available	Reprocessing Concerns	Recommendations
59	**Modular fixation systems**	no	Difficult to clean due to: • Poor design; • Lack of adequate cleaning instructions (disassembly or not); • Generic instructions; • Articulations and moving parts that don't come apart. Sterilization instructions do not meet typical sterilization cycles used in Canadian health care facilities. Inability to assess the extent of disassembly required for reprocessing for depth gauges and drill guides. End of life due to metal fatigue is unknown. Instructions for frequency of sharpening not provided for cutting instruments. Unable to track implant to patient.	<u>To Health Canada:</u> Health Canada shall require manufacturers to: • Reassess design and provide validated reprocessing instructions; • Provide device specific instructions; • Provide validated instructions that are reflective of typical sterilization cycles used in Canadian health care facilities (unless documentation can be provided that this is not possible); • Validate the life span for re-sterilization (i.e. extent of metal fatigue, build up of organic and inorganic residuals) of implants (e.g. plates and screws); • Provide a unique identifier and recommend a way to track each implantable device to the patient; • Send a notice out when a design changes or process changes (find in earlier table); • Provide sterile implants individually packaged. If not, a tracking system for re-sterilized implants is required. <u>To Healthcare Facilities:</u> Detailed written procedures for cleaning and sterilization are required with extensive in-service and competency testing. Staff training by manufacturers required. Detailed written procedures including: • Including pictures detailing disassembly; • Cleaning and sterilization are required; • Extensive in-service and competency testing. Time for proper cleaning needs to be factored in the turnaround time. Discard all implantables that have been in contact with patient secretions/tissue or trialed on patient at time of procedure.

Item	Medical Device	*SUMD Available	Reprocessing Concerns	Recommendations
60	**Shoulder repair, replacement sets**	No (Yes for drill bits)	Difficult to clean due to: • Poor design; • Lack of adequate cleaning instructions (disassembly or not); • Generic instructions; • Articulations, moving parts that don't come apart; • Angled cannulated awl; • Serrated cable grips. Sterilization instructions do not meet typical sterilization cycles used in Canadian health care facilities. Inability to assess the extent of disassembly required for reprocessing for depth gauges and drill guides. The end of life for the medical device due to repeated reprocessing has not been determined. Instructions for frequency of sharpening (awl and drill bits) not provided. Unable to track implant to patient.	<u>To Health Canada:</u> Health Canada shall require manufacturers to: • Reassess design and provide validated reprocessing instructions; • Provide device specific instructions; • Provide validated instructions that are reflective of typical sterilization cycles used in Canadian health care facilities (unless documentation can be provided that this is not possible); • Validate the life span for re-sterilization (i.e. extent of metal fatigue, build up of organic and inorganic residuals) of implants (e.g. wires); • Send a notice out when a design changes or process changes (find in earlier table); • Provide sterile implants individually packaged. If not, a tracking system for re-sterilized implants is required. <u>To Healthcare Facilities:</u> Detailed written procedures for cleaning and sterilization are required with extensive in-service and competency testing. Staff training by manufacturers required. Detailed written procedures including: • Including pictures detailing disassembly; • Cleaning and sterilization are required; • Extensive in-service and competency testing. Time for proper cleaning needs to be factored in the turnaround time.

Item	Medical Device	*SUMD Available	Reprocessing Concerns	Recommendations
61	**Total hip repair or replacement sets**	No (Yes for guide pins and depth gauges)	Difficult to clean due to: • Poor design (reamer and acetabular);[12] • Cement remains on instrument; • Lack of adequate cleaning instructions (disassembly or not); • Font for instructions to small to read; • Generic instructions not specific to device; o Articulations, moving parts that don't come apart; o Long angled cannulations (broaches, T Bars); o Loaded with shafts + catches bioburden; o Trial handles that are spring loaded; o Impactor requires end to be unscrewed, etc.; o T-Handle has pull-back collet. Sterilization instructions do not meet typical sterilization cycles used in Canadian health care facilities. Inability to assess the extent of disassembly required for reprocessing (depth gauges, drill guides, flexible reamer, impactor, slap hammer). Handling during cleaning and attempts to dismantle can cause lacerations and is an occupational health risk. Instructions for frequency of sharpening (broaches and graters) not provided. End of life due to metal fatigue unknown. Unable to track implant (hip pinning) to patient.	<u>To Health Canada:</u> Health Canada shall require manufacturers to: • Reassess design and provide validated reprocessing instructions; • Provide device specific instructions; • Provide validated instructions that are reflective of typical sterilization cycles used in Canadian health care facilities (unless documentation can be provided that this is not possible); • Validate the life span for re-sterilization (i.e. extent of metal fatigue, build up of organic and inorganic residuals) of implants (e.g. hip pinning); • Send a notice out when a design changes or process changes (find in earlier table); • Provide sterile implants individually packaged. If not, a tracking system for re-sterilized implants is required. <u>To Healthcare Facilities:</u> Detailed written procedures for cleaning and sterilization are required with extensive in-service and competency testing. Staff training by manufacturers required. Detailed written procedures including: • Including pictures detailing disassembly; • Cleaning and sterilization are required; • Extensive in-service and competency testing. Time for proper cleaning needs to be factored in the turnaround time. To ensure adequate turnaround times (includes disassembly, cleaning, assembly, functionality testing, sterilization, and all other steps required for total reprocessing), it is critical to ensure that inventory of devices is adequate. See general recommendations. Reusable components should be placed into detergent and/or water immediately after use (in OR).

Item	Medical Device	*SUMD Available	Reprocessing Concerns	Recommendations
62	**Total knee repair or replacement sets**	No	Difficult to clean due to: • Poor design (reamer and cutting blocks); • Lack of adequate cleaning instructions (disassembly or not); • Cement remains on instrument; • Generic instructions; • Font for instructions to small to read; • Generic instructions not specific to device; o Articulations, moving parts that don't come apart; o Rasps – sharp edges catches bioburden; o Spring loaded parts; o Cutting blocks have sharp edges and multiple cannulations; o Impactor (multiple pieces); o T-Handle has pull-back collet; o Trials are made of porous materials thus stain and crack from repeated sterilizations and uses; o Cutting blocks have guide slots that are not identified in the instructions. Sterilization instructions do not meet typical sterilization cycles used in Canadian health care facilities. Instructions for frequency of sharpening (cutting block pins) not provided for cutting instruments.	<u>To Health Canada:</u> Health Canada shall require manufacturers to: • Reassess design and provide validated reprocessing instructions; • Provide device specific instructions; • Provide validated instructions that are reflective of typical sterilization cycles used in Canadian health care facilities (unless documentation can be provided that this is not possible); • Validate the life span for re-sterilization of trials; • Send a notice out when a design changes or process changes (find in earlier table). <u>To Healthcare Facilities:</u> Staff training by manufacturers required. Detailed written procedures including: • Pictures detailing disassembly; • Cleaning and sterilization are required; • Extensive in-service and competency testing. To ensure adequate turnaround times (includes disassembly, cleaning, assembly, functionality testing, sterilization, and all other steps required for total reprocessing), it is critical to ensure that inventory of devices is adequate. See general comments. Reusable components should be placed into detergent and/or water immediately after use (in OR).

Item	Medical Device	*SUMD Available	Reprocessing Concerns	Recommendations
Suction and Related Equipment				
63	**Suctions in general**	Some	Difficult to clean due to: • Poor design; • Lumens (micro-needle suctions (#22 & 24 gauge IMPOSSIBLE to clean); • Curved needle ear suctions should be disposed of ; • Long narrow angulated lumens (bronchoscopy). Reprocessing instructions are non-existent. Tips can be lost inside patient (Yankauer).	<u>To Health Canada:</u> Health Canada shall require manufacturers to: • Provide instructions that are reflective of current "Best Practice" recommendations regarding reprocessing to be used in health care facilities; • Provide validated sterilization documentation; • Correlation between metric and imperial sizing. <u>To Healthcare Facilities:</u> SUMD recommended for those difficult to clean. Lobby the manufacturers for disposables esp. for microsurgery. Ongoing competency testing required. Written detailed reprocessing procedures required. #22 & 24 gauge ear suctions, single use recommended. Reusable components should be placed into detergent and/or water immediately after use (in OR).
64	**Tubing (e.g. Silicone, and latex)**	Yes	Narrow lumen tubing is impossible to clean. Manufacturers instructions are: • Inadequate (e.g. sterilization instructions need to be appropriate/validated for tubing composition). Difficult to visually inspect.	<u>To Health Canada:</u> Health Canada shall require manufacturers to: • Provide validated instructions that are reflective of typical sterilization cycles used in Canadian health care facilities (unless documentation can be provided that this is not possible). <u>To Healthcare Facilities:</u> SUMD recommended.

Item	Medical Device	*SUMD Available	Reprocessing Concerns	Recommendations
Implantables				
65	**Marlex Mesh**	Yes	Impossible to clean. Instructions confusing: • Resterilization instructions listed but not validated.	<u>To Healthcare Facilities:</u> This is a SUMD that should be purchased sterile and should not be reused.
66	**Aortic and Vascular grafts**	Yes	Limited use for some devices with no unique identifier on device for tracking purposes. Lack of manufacturers' validated instructions on sterilization parameters.	<u>To Healthcare Facilities:</u> SUMD recommended. If grafts are in contact with patient secretions/tissue, should be discarded.

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