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If All Else Fails…Read the Directions

The Importance of Medical Device Manufacturer's Instructions

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CHICA Canada Conference, May 2010

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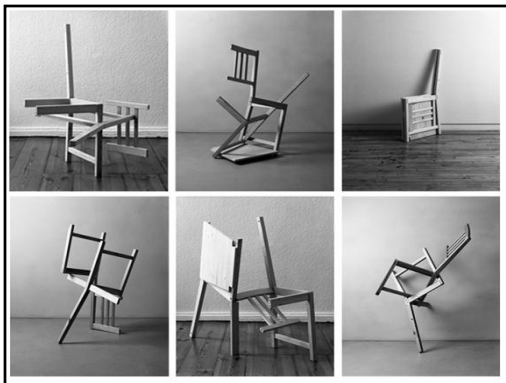
Disclosure

Member of 3M Canada Speakers Bureau:

Received honorarium for speaking at Medical Device Reprocessing Seminars



Manufacturer has received more than 47 reports of cribs being mis-assembled with the mattress platform being used as a side rail, including 27 reports of babies becoming entrapped, resulting in one death.

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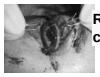
An eyelid retractor made from bending a 3.2-cm paper-clip



Retraction of post-traumatic swollen eyelids with a pair of paper-clips.

"Paper-clip eyelid retractors are simple, cheap, readily available self-made eyelid retractors, and are helpful in opening closed oedematous eyelids in both trauma and postoperative situations. No patients suffered from any undue pressure or complications from the paper-clip eyelid retractors".

Cheng LHH, Kumar P.Ann R Coll Surg Engl. 2008 April; 90(3): 253.

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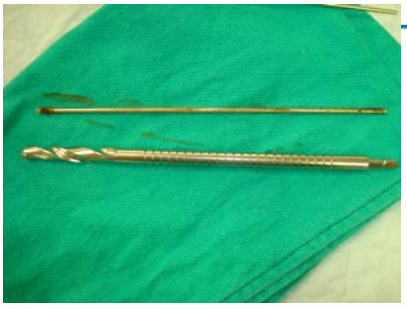

Reamer and guide wire following reprocessing

Objectives:

Following this presentation participants will:

- State the importance of obtaining and following manufacturer's instructions
- Have an awareness of requirements for manufacturer's instructions
- List 3 tools that can be used when requesting and reviewing instructions

Standards, Guidelines and Regulations Requiring Manufacturer's Instructions

- Canadian Standards Association sterilization standards
- Accreditation Canada
- PIDAC guidelines
- Health Canada
- Provincial Departments of Health

Definition: Manufacturer's Instructions

The written directions provided by the manufacturer or distributor of a product that contain the necessary information for the safe and effective use of the product.

CSA Z314.8-08 Decontamination of Reusable Medical Devices

Definition: Validation

Manufacturer's instructions must be validated

Validation: a documented procedure for obtaining, recording and interpreting the results required to establish that a process will consistently yield product complying with predetermined specifications.

CSA Z314.3-09 Effective sterilization in health care facilities by the steam process.

Also Known As:

- IFUs-Instructions for use
- MIFUs-Manufacturer's instructions for use

- DFUs-Directions for use
- MDFUs-Manufacturer's directions for use

Why MIFUs are required

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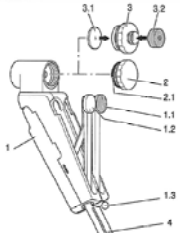
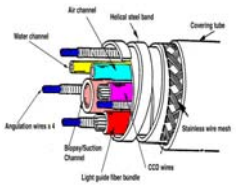
Medical devices have become increasingly complex





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Disinfectants, sterilants and cleaning solutions, if used incorrectly, can damage devices or result in a contaminated device

Cleaning, disinfection and sterilization equipment can malfunction if improperly installed, operated or monitored

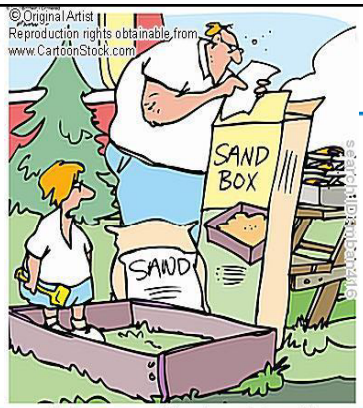
*Bed pan washer-disinfector-Hot and cold water feed lines were reversed and sprayer arms were improperly installed which lead to inefficient cleaning by the equipment.

Ultra-sonic cleaning equipment was installed and assumed to be working correctly. Testing, when done, revealed that 2 of the 4 transducers were not functioning.

**Outbreak of surgical complications (TASS) caused by a steam sterilizer that was improperly maintained according to MIFU.

*Alfa MJ, Olson N, Buelow-Smith L. Simulated-use testing of bedpan and urinal washer disinfectors: Evaluation of Clostridium difficile spore survival and cleaning efficacy. AJIC, Feb. 2008, Vol. 36, No.1: 5-11.

**Hellinger WC, Hasan SA, Bacalis LP et al. Outbreak of toxic anterior segment syndrome following cataract surgery associated with impurities with autoclave steam moisture. ICHE. March 2006, Vol. 27, No. 3: 294-298.



"Let me guess: Step two, add sand."

Health Canada Notice

Hospitals shall have in place:

- Procedures to ensure that reusable devices are cleaned, disinfected and sterilized according to manufacturer's instructions.
- A mechanism to regularly review these procedures and ensure that they are being followed.
- A requirement, at the time of purchase, that manufacturers include complete instructions and, where necessary, adequate training for the cleaning disinfecting and sterilizing of reusable devices.
- A procedure to report to Health Canada any cases in which the manufacturer does not provide adequate instructions.

Health Canada Health Products and Food Branch. Notice to Hospitals: Inadequate cleaning/sterilization of EZ clean monobloc acetabular reamers a reuseable medical device , April 21, 2004

Important for:

- Reusable medical devices
- Products used to reprocess medical devices (e.g. cleaning and disinfectant products)
- Equipment used to reprocess medical devices
- Products used for disinfectant or sterilization monitoring
- Packaging for medical devices (e.g. wrappers, pouches, containers)

Format for MIFUs

- Product Labels
- Product Inserts
- User manuals
- Electronic or printed material
- Official updates to original instructions (e.g. responses to product alerts, ongoing validation studies)

MIFUs for Reusable Medical Devices:

- Device-specific, legible and understandable
- Clearly indicate which parts need to be disassembled
- Can be achieved within the facility's resources
- In accordance with intended use of the device
- State if device is immersible
- Specify sterilization cycles (method, time,temperature)
- Specify if there is a limit to # of times a device can be reprocessed or if reprocessing will degrade the device.

CSA Z414.3 Effective Sterilization in Health Care Facilities by the Steam Process, 2009

Reusable Medical Device Instructions

Validated cleaning methods and reprocessing instructions
- Soaking
- Manual or Automated Cleaning (rinsing, drying)
- Lubrication
- Assembly/wrapping
- Schematic drawings

Provision of in-service to staff reprocessing the device

Routine maintenance schedules

Disinfectant Products

- Require a Drug Identification Number (DIN) or Natural Product Number (NPN) from Health Canada

Disinfectant Label Information

Precaution for use of product

Storage

Vapour control

PPE

Disposal

Accidental exposure spill F/U

Microbicidal claims: list of organisms killed

Manufacturer
Product X
Manufacturer contact information

List of active ingredients

Expiration Date___
Mixing or Opening Date_____

DIN/NPN

Directions for use:

Preparation: dilution or activation or RTU

Limitations of use (e.g. only in specific AER)

Compatible materials

Level of disinfection provided

Concentration, temperature, contact time, activation, efficacy testing

Rinsing: volume & type of water

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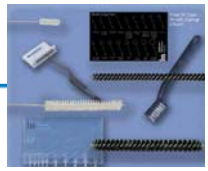
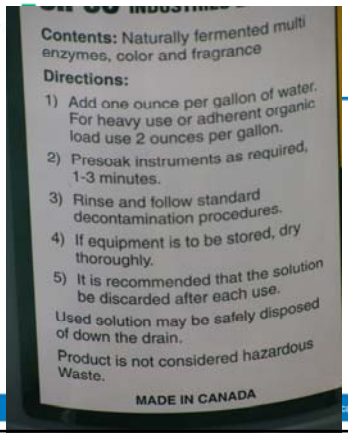
Cleaning Products



- Instrument detergents
- Enzymatic cleaning agents
- Cleaning accessories e.g. brushes, sponges, etc.

Note: Cleaning products do not require a Drug Identification Number (DIN)



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Equipment Used in Reprocessing

- Ultrasonic cleaners
- Automated lumen cleaners
- Packaging heat sealers
- Washer-disinfectors
- Automated endoscope reprocessors (AERs)
- Automated drying equipment/cabinets
- Sterilizers

Equipment requirements/instructions

- **Medical Device License from Health Canada for Class II and higher**
- **Establishment License for Class 1 Devices**
- **If the equipment (e.g. sterilizer, AER) requires a chemical product, the chemical must have a DIN**

- **Installation instructions**
- **What types of devices the equipment has been validated to process (e.g. lumened, porous devices)**
- **Methods to test that equipment is operating according to its specifications**
- **Schedule and details of preventive maintenance program**

Sterilization Packaging:

- Single use or reusable textile wraps
- Sterilization pouches
- Rigid instrument container or container system

Packaging Requirements and MIFUs

Evidence of:
Medical Device License

- **Compatibility with sterilization method and devices to be sterilized**
  - Heat/chemical resistant
  - Allows for sterilant penetration
- **Instructions for closure or sealing**
- **Ability to aseptically dispense package contents**
  - Sealing, flexibility
- **Prevents contamination during storage/handling**
  - Intact seal, strength, shelf life data
- **Lint-free and particulate-free**
- **Non toxic/non leaching**
  - Dyes and labels
- **Reprocessing & Maintenance for reusable containers or wraps**

Disinfectant/Sterilization Monitoring

- Test Strips to measure efficacy of disinfectants
- Biological Indicators
- Chemical Indicators

Disinfectant Test Strips

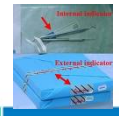
- Specific to the disinfectant and the minimum effective concentration of the disinfectant
- Quality assurance procedure to ensure each batch of strips will perform effectively
- Clear criteria for determining pass/fail of disinfectant concentration

Biological Indicators:

- Appropriate for the method of sterilization e.g. steam: *Geobacillus stearothermophilus*, ETO: *Bacillus atrophaeus*
- Clear directions for placement in sterilizer
- Detailed instructions for handling
- Method of incubation
- Clear criteria for indication of positive or negative result

Chemical Indicators

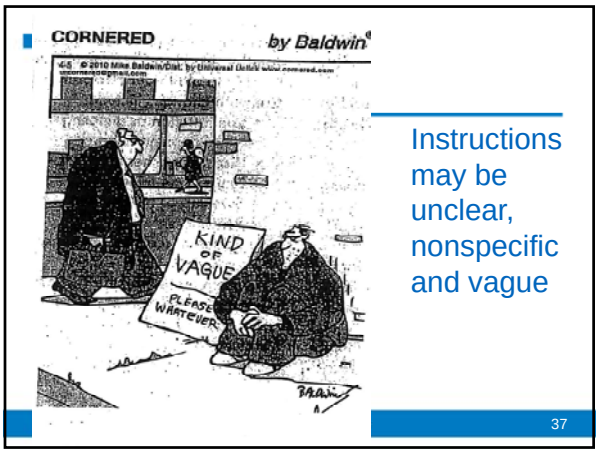
- Appropriate for the method of sterilization
- Class of indicator (1-6)
- What variables does the indicator measure e.g. steam: time, temperature, pressure?
- What are the stated values or endpoints measured?
- Clear criteria for pass/fail result (ease of reading)




How to Obtain MIFUs

- Ensure it is a requirement prior to purchase of any instrument, equipment, reprocessing product or device
- Request from distributor, vendor or manufacturer
- Subscribe to a commercially available medical device manufacturer's instruction data base
- Ensure your organization has a process to review or receive manufacturer's alerts, cautions, revisions or recalls of product and that you are on the distribution list

Problems with Manufacturer's Instructions



Instructions may be unclear, nonspecific and vague

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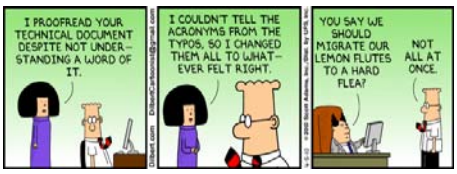
Instructions may be unclear due to poor or inaccurate translation from another language OR applicable to standards in another country

Instructions may be generic and not specific to the device, equipment or product.

One size does not fit all…



Instructions may be written in technical jargon or terms not well understood by users

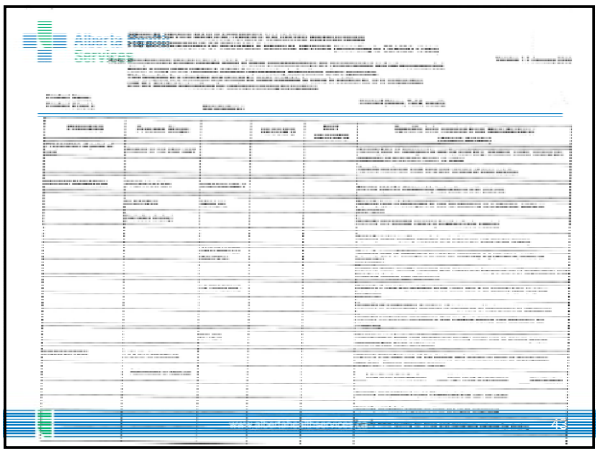
Tools to Assist You

- CSA/ISO 17664 **Sterilization of Medical Devices - Information to be Provided by the Manufacturer for the Processing of Resterilizable Medical Devices**
- **Health Canada DRAFT GUIDANCE DOCUMENT: Information to Be Provided by Manufacturers for the Reprocessing and Sterilization of Reusable Medical Devices, December 2006**

http://www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-ld/md_dgd_manrep_im_eld_fabret-eng.php

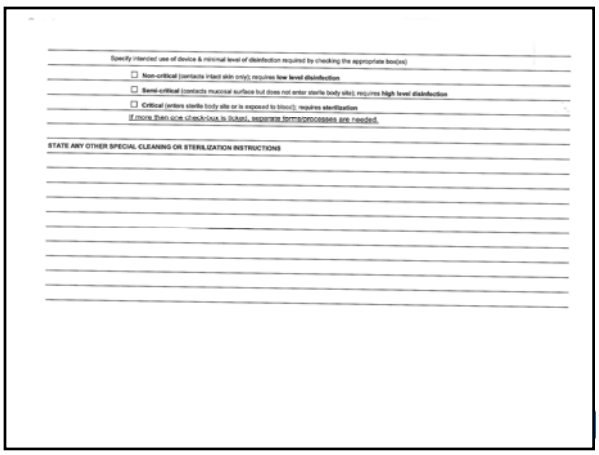
Tools:

- MEDEC Checklist for “Medical Device Manufacturer’s Validated Instructions for Reprocessing of Reusable Medical Devices, January 2010



PROCESS	Process Stage:		RECOM'D	NOT RECOM'D	Specific Info needed from Manufacturer
DISINFECTION	THERMAL				Specify maximum thermal conditions that medical device can tolerate (e.g. time and temperature)
					Specify water quality
DRYING					Specify how device should be dried (e.g. air gun, max pressure, manual, heat, etc)
					Specify maximum temperature the medical device can withstand
PREP and PACK	REASSEMBLY				Device specific reassembly instructions with pictures
					Specify if device is not to be reassembled (or only partially reassembled) prior to sterilization
MAINTENANCE					Specify any medical device requirements for ensuring functionality e.g. sharpening, lubrication, testing function, etc
STERILIZATION					
	Dynamic Air Removal				Specify time and temperature that medical device has been validated for
	CAN/BSO 11140-3* (Bowie-Dick Test (Prevac))				Ensure that commonly used North American Healthcare cycles are considered (See CAN/ISO 17665-2* Annex B)
					If medical device requires exposure times longer than the commonly available North American Healthcare cycles recommended by CAN/BSO 17665, harmonize to 132 – 135°C for 10 or 20 mins
	GRAVITY DISPLACEMENT				Specify time and temperature that medical device has been validated for
					Ensure that commonly used North American Healthcare cycles are considered (See CAN/ISO 17665-2* Annex B)
					If medical device requires exposure times longer than the commonly available North American Healthcare cycles recommended by CAN/BSO 17665, harmonize to 121°C for 45 or 50 mins
	ETO				Specify aeration conditions (including time) that has been validated for
	OTHER APPROVED STERILIZATION PROCESSES				Specify sterilization process including cycle and conditions that instrument has been validated for
	INSTRUMENT CONTAINERS (if provided)				Provide attestation that validation of the recommended sterilization process has been performed in the dedicated containment system.

* = Cited standards are to be used in their most recent version.



Specify intended use of device & minimal level of disinfection required by checking the appropriate box(es)

☐ **Non-critical** (contacts intact skin only); requires **low level disinfection**

☐ **Semi-critical** (contacts mucosal surface but does not enter sterile body site); requires **high level disinfection**

☐ **Critical** (enters sterile body site or is exposed to blood); requires **sterilization**

If more than one check-box is ticked, separate terminal processes are needed.

STATE ANY OTHER SPECIAL CLEANING OR STERILIZATION INSTRUCTIONS

If Problems Encountered

- Notify responsible/affected departments in your organization
- Notify the manufacturer
- Notify Health Canada Medical Devices

http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/rep_md_prob-rap_inc_im_tc-tm-eng.php

Take Home Message

- MIFUs are essential to effective and safe reprocessing of reusable medical devices
- MIFUs are not always readily available but can be obtained
- Make no assumptions:

Know and communicate specifically to the manufacturer what is required

Thank You