

 CENTRAL SERVICE ASSOCIATION OF ONTARIO

## The Need for Formal Training & Education of MDR Personnel

45<sup>th</sup> Annual CSAO Conference  
Taking it to the Top: People, Process & Peak Performance  
September 7-9, 2014



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## Presented by SPSmedical


- Largest sterilizer testing Lab in North America and now a part of *Crosstex International*, a Cantel Medical Company
- Develop and market sterility assurance products that offer advanced technologies
- Provide full day sterilization Seminars and on-site Facility sterilization audits
- Corporate member: CSA and AAMI, serving on numerous sterilization working groups





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## Objectives

Upon completion, participants will be able to...

- explain the importance of compliance with best practices,
- identify where reprocessing best practices can be found,
- describe some common errors with reprocessing surgical instruments,
- describe some common errors with reprocessing flexible endoscopes
- Describe some recent improper reprocessing incidents reported in the national news.

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## Training & Education


Healthcare personnel performing medical device reprocessing duties (e.g. decontamination, inspection, preparation, packaging, sterilization, sterile storage and distribution) must be properly trained to execute these critical tasks efficiently and effectively.

Efficiently in order to reprocess instruments sets on time and complete, and effectively to make sure they are indeed sterile. Of course, sterile is most important because a non-sterile instrument in the OR, is like a loaded gun.



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## Training & Education


The Medical Device Reprocessing Department (MDR) plays an important role in infection prevention efforts, particularly in relation to surgery patients.

Failure to follow HLD and/or sterilization "**best practices**" can result in infections, which causes harm to patients and increased costs to healthcare facilities.



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## DID YOU KNOW?

In the United States, it is reported that more than 5,000 patients each day come down with a HAI and over 300 die each day.

In Canada, it is reported that over 250,000 patients each year come down with a HAI and 8-12,000 die each year. 1/9 Canadians admitted to a hospital will acquire an infection, thereby eroding public trust and it is estimated that a severe HAI costs and additional \$12,000 - \$35,000 per patient.

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## Healthcare Associated Infections



While the delivery of *non-sterile* instruments certainly is not the leading cause of surgical site infections, it has been documented as one of the causes.

You and I must do everything possible to reduce HAIs, which means compliance with best practices not some of the time, not most of the time, but all of the time!



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## Best Practices



In the U.S., medical device reprocessing “**best practices**” are detailed in **AAMI Standards**, **AORN Perioperative Standards and Recommended Practices**, along with other documents, such as **SGNA** who’s focus is on flexible gastrointestinal endoscopes.



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## Best Practices



In Canada, medical device reprocessing “**best practices**” are detailed in **CSA** and **ORNAC Standards**, **Provincial Guidelines**, **Health Canada Recommendations**, along with other documents, such as **CSGNA** for flexible gastrointestinal endoscopes.



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## Training & Education



It is critical to have and comply with these important documents for proper facility design, for writing and updating Policies & Procedures, as well as Training & Education of MDR personnel. Compliance with **best practices** ensures **PATIENT SAFETY!**



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## Training & Education



What if your personnel do not know these best practices?  
What if your facility does not have the resources to comply with these best practices? Let’s take a look at some **common errors** with the reprocessing of reusable medical devices.



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## Common errors in the reprocessing of Surgical instruments

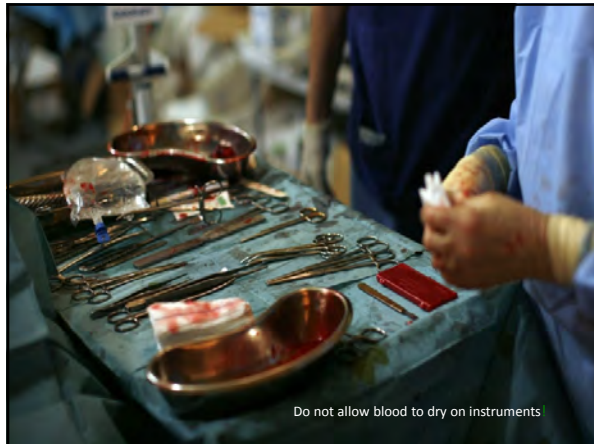


### Point of Use (Surgery)

- Failure to wipe off gross soil from instruments and/or flush lumens with sterile water
- Delays in transporting soiled instruments to the decontamination area
- Failure to spray instruments with pre-clean solution
- Transporting without using a closed container and/or without a biohazard label

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### Common errors in the reprocessing of Surgical instruments

**Reprocessing area (Decontamination)**

- Not wearing proper PPE
- Not having a 3 section sink to “soak-wash-rinse”
- Not having an ultrasonic cleaner
- Not having sinks or an ultrasonic of sufficient size
- Testing some, but not all mechanical cleaners
- Not having MFG’s IFUs
- Not following MFG’s IFUs

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### Did You Know this device requires 25 min exposure time?

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### Pilling®

Do you have them?  
All of them?

**FIBEROPTIC CABLE CARE**

**Recommended:**

- Use Pilling cable care solution
- Use Pilling cable care solution on all cables
- Use Pilling cable care solution on all cables
- Use Pilling cable care solution on all cables

**Not Recommended:**

- Use alcohol
- Use acetone
- Use bleach
- Use hydrogen peroxide
- Use isopropyl alcohol
- Use water
- Use any other cleaning solution

**CLEANING AND STERILIZATION**

**Type of Heat Treatment:**

Heat Treatment	Temperature	Time
Autoclave (gravity displacement)	121°C (250°F)	30 Minutes
Autoclave (pre-vacuum)	132°C (270°F)	30 Minutes
Steam Heat Pressure (pre-vacuum)	132°C (270°F)	30 Minutes
Steam Heat Pressure (gravity displacement)	121°C (250°F)	30 Minutes
Steam Heat Pressure (pre-vacuum)	132°C (270°F)	30 Minutes

**The following sterilant types are recommended for use with cables:**

- Ethylene Oxide
- Hydrogen Peroxide
- Gamma Radiation
- Steam

**Rx ONLY**

**lifeFlex**

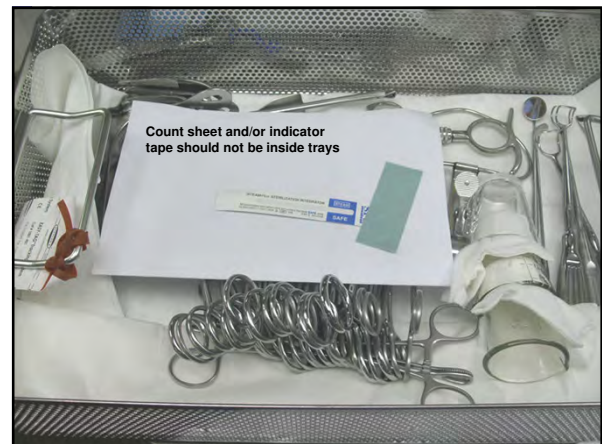
Research Triangle Park, NC 27709 USA  
USA: (919) 246-6999 • International: (919) 246-6999

### Common errors in the reprocessing of Surgical instruments

**Reprocessing area (Prep & Pack)**

- Not inspecting 100% of instruments,
- Not using inspection lamps and/or lens,
- Cleaning instruments and/or rigid containers,
- Assemble hinged instruments in the closed position,
- Using improper materials (i.e. marking pens, tape and/or wrap inside trays, sterilization tape on rigid containers, peel pouches or count sheets inside trays).
- Improper use of lot control labels.

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## Common errors in the reprocessing of Surgical instruments



### Sterilization

- Improper loading of sterilizers,
- Incorrect sterilization mode and/or parameters,
- Not enough dry time for type of load,
- Wet packs,
- Not allowing sterilized packs to cool to room temperature,
- Placing sterilized items to cool near AC vent.

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## Common errors in the reprocessing of Surgical instruments



### Storage

- Placing sterile items in a high traffic area,
- Improper ceiling tiles and/or storage shelves,
- Dust on storage shelves,
- Putting clean items on top of sterile items,
- Exceeding temperature and/or humidity ranges,
- Stacking "wrapped" packs on top of each other.

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## Did You Know

"wrapped" trays should not be stacked?



**Caution:** Do not stack trays. Stacking trays can result in damage of the wrap caused by undue pressure from the weight.



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## How many of you reprocess flexible endoscopes?

Flexible endoscopes are some of the most challenging devices for MDR personnel to reprocess due to their unique design and complex reprocessing steps.

Let's take a look at some **common errors** with the reprocessing of flexible endoscopes.



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## Common errors in the reprocessing of Flexible Endoscopes

### Point of Use (Procedure Room)

- Not wearing proper PPE,
- Not having MFG's IFUs,
- Reprocessing delay (multiple procedures and/or when the procedures are performed at night or on the weekend),
- Failure to clean all channels (even if unused, fluid and debris can enter channels at the distal tip),
- Transporting without using a closed container and/or not labeled with biohazard id.



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## Common errors in the reprocessing of Flexible Endoscopes

### Leak Testing

- Not having the MFG's IFU available,
- Use of damaged water resistant cap,
- Overlooking pressurization prior to immersion,
- Incomplete angulation of the distal tip in all directions during the leak test,
- Not following the MFG's IFUs for reprocessing a damaged endoscope.



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## Common errors in the reprocessing of Flexible Endoscopes

### Manual Cleaning

- Failure to fully submerge the endoscope,
- Failure to submerge for the required length of time,
- Neglecting to dilute the detergent per the MFG's IFU,
- Using worn, damaged or improper brushes,
- Failure to use MFG's validated cleaning adapters,
- Damaged/improperly reprocessed cleaning adapters,
- Failure to thoroughly rinse.



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## Common errors in the reprocessing of Flexible Endoscopes

### Manual HLD

- Using a sink or basin of insufficient dimensions,
- Using a solution after its expiration date,
- Not MRC testing prior to each use.



### AER

- Failure to manually clean and/or rinse before using the AER.

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## Common errors in the reprocessing of Flexible Endoscopes

### Storage

- Oversight in removing all valves and water resistant cap when storing the endoscope,
- Neglecting to ensure that scopes are hung with all locks in the free position,
- Crowded and unsecured scope storage areas,
- Storing in original shipment cases.

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We believe  
all of these common reprocessing errors  
can be eliminated with formal training  
and education of healthcare personnel to  
comply with “**best practices**”  
all of the time.

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## Medical device reprocessing has become very complex!

No healthcare facility wants to find themselves in the national news or in a lawsuit due to **errors** in device reprocessing. But it does happen...

**January, 2014** - Hospital exposes 18 patients to risk of "mad cow" disease because surgical tools were not sterilized properly.

**November, 2013** - A class-action lawsuit has been launched against a New Brunswick hospital over the use of unsterilized biopsy forceps at a clinic over a 14-year period.

**April, 2013** - Maryland Casualty Co. urged a Pennsylvania federal judge to declare that it doesn't have to defend a Pittsburgh medical center against claims it used unsterilized endoscopes on scores of patients.

**August, 2012** - A woman from Two Hills has launched a \$15-million class-action lawsuit against the East Central Health region, alleging the health authority acted "recklessly, carelessly and recklessly" in failing to ensure that tools used on thousands of patients at St. Joseph's General Hospital were properly sterilized.

**May, 2012** - The University of Pittsburgh's School of Dental Medicine is accused in a lawsuit of being negligent and using dirty tools to treat a patient.



Feb 24, 2012  
Today Show - NBC  
Dirty surgical instruments

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## CRE outbreak

The Chicago Sun-Times reported on January 6, 2014 that the largest outbreak of a superbug – “CRE” in U.S. history has been confirmed at a hospital outside of Chicago, IL.

The hospital – Advocate Lutheran General – linked these critical patient infections of CRE (carbapenem-resistant Enterobacteriaceae) to an **endoscopy procedure** that uses fluoroscopy and an ERCP endoscope (or, duodenoscope).

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## CRE outbreak

Between January and September of 2013, **243** patients who had undergone **ERCP** were notified by the hospital of their increased risk of CRE infection. Of the 114 patients who were tested, **38** were either infected or colonized with CRE, with 28 not displaying symptoms of infection. Unfortunately, 10 patients infected, some them critically, has infections of the blood, urine or in wounds.

This outbreak involving 38 patients (16% of the total that underwent **ERCP**) is especially concerning because CRE has a mortality rate as high as 50%.

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## CRE outbreak

The CDC reported that a likely contributing factor to this superbug outbreak was the improper automated cleaning and/or disinfection of the implicated **ERCP** endoscopes.

The CDC reported that previous studies have shown an association between **ERCP** endoscopes and transmission of multidrug-resistant bacteria; the design of the **ERCP** endoscopes might pose a particular challenge for cleaning and disinfection.



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## January 24, 2014

SEATTLE -- A breakdown in training left instruments dirty and opened the doors to dangerous infections for more than 100 patients at Seattle Children's Hospital.

In November, a technician found a poorly cleaned **colonoscope**. Another turned up a few days later. The endoscope's manufacturer spells out multi-step cleaning instructions to avoid cross contaminating patients. Dr. Zerr says hospital procedures came up short on those requirements. So far nobody has gotten sick, but the errors launched a State Health Department investigation.

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## MDR Personnel



**Need a tremendous amount of training and education...**  
Especially when reprocessing "complex" medical devices, such as orthopedic instruments, spine instruments, neuro instruments, ophthalmic instruments and flexible endoscopes.



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## Conclusion



The formal training and education of MDR personnel is a critical aspect of infection prevention because the future of healthcare is the use of more and more complex instruments.

And, while thousands of instruments are reprocessed each and every day at your facility, you must never forget...that behind every instrument is a **PATIENT!**

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## THANK YOU!



**SPS**medical Supply Corp.  
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[www.SPSmedical.com](http://www.SPSmedical.com)

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## References & Resources



**Association for the Advancement of Medical Instrumentation (AAMI)**  
1110 North Glebe Road, Suite 220 · Arlington, VA 22201-4795  
[www.aami.org](http://www.aami.org)

**Association of periOperative Registered Nurses (AORN)**  
2170 South Parker Road, Suite 300 · Denver, CO 80231-5711  
[www.aorn.org](http://www.aorn.org)

**Society of Gastroenterology Nurses and Associates, Inc. (SGNA)**  
330 N. Wabash Ave. Suite 2000 Chicago, IL 60611-5165 [www.sgna.org](http://www.sgna.org)

**Canadian Standards Association (CSA)**  
178 Rexdale Blvd. Toronto, OH Canada M9W 1R3 [www.csagroup.org](http://www.csagroup.org)

**Provincial Infectious Diseases Advisory Committee. (PIDAC)**  
480 University Ave. Suite 300 Toronto, ON Canada M5G 1V2  
[www.publichealthontario.ca](http://www.publichealthontario.ca)

**Operating Room Nurses Association of Canada (ORNAC)**  
66 Leopolds Dr. Ottawa, OH Canada K1V 7E3 [www.ornac.ca](http://www.ornac.ca)

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