Reprocessing Medical Devices
Dr. Michelle Alfa
Sponsored by JohnsonDiversey www.johnsondiversey.com

Overview
- Cleaning; basic considerations
- Manual versus automated cleaning
- Infection transmission associated with improper reprocessing
- Critical evaluation of published information

SAFE REPROCESSING OF NARROW-LUMEN MEDICAL DEVICES
Michelle J. Alfa, Ph.D., FCCM
St. Boniface Hospital, Winnipeg, MB

Device Reprocessing: Spaulding Classification

Device

I. Cleaned; manually or automated
   (may also be decontaminated, e.g. washer/disinfector)

II. Packaged
    for Terminal Sterilization
    Sterilized: Steam*
    Sterilized: ETO gas
     or Plasma

III. High level disinfected:
    Liquid e.g.; 2% Glutaraldehyde

IV. Point of use Sterilization:
    Liquid e.g.; peracetic acid (STERIS)

IF IT ISN'T CLEAN – IT CAN’T BE PROPERLY STERILIZED!

Medical Device: Cleaning

Stall: Patient secretions (eg blood, serum, mucus)

Bioburden:
Sterile Surgery: Instruments : ~ 10^1 - 10^3 cfu/device
   (Chu et al AJIC 27:315, 1999)
Mucosal surface: Endoscope lumens: ~ 10^4 - 10^6 cfu/device
   (Alfa et al AJIC Oct 1999)
Cleaning removes 3-4 Log's of bioburden
   (Note: if bioburden low initially, it is replaced by water organisms during washing)

What you can’t see CAN hurt you!

Difficult to Clean Medical Devices:

- Narrow lumened (Flexible endoscopes, GI accessory devices; sphinctertomes)
- Hinged/serrated edges (Laparoscopic devices)
- Non-ported (GI biopsy forceps)

“Critical” Devices pose highest risk of infection transmission

Non-ported Medical Devices

- Sonication often recommended by manufacturer as part of manual cleaning process
- Detergent: enzymatic versus activated H2O2
- Rinsing to remove detergent
- Guidelines recommend visual inspection to confirm cleaning

A Webber Training Teleclass
Hosted by Paul Webber paul@webbertraining.com
Reprocessing Medical Devices
Dr. Michelle Alfa
Sponsored by JohnsonDiversey www.johnsondiversey.com

Visual Inspection of Cleaning?
At least I can look inside!!

Manual Versus Automated Cleaning
- Laparoscopic devices & Sphinctertomes
- Sonication
- Fluid flow access
- Volume of fluid flow

CLEANING NARROW LUMEN DEVICES
Sonic Irrigator Auto
(Medi-Safe)

Cleaning of Laparoscopic devices
A) Non-ported
B) Ported

Protein removal; Laparoscopic devices
A) Non-ported
B) Ported

Sphincterotomes: cross-section
(single-use)
- Single-lumened
- Double-lumened
- Triple-lumened

A Webber Training Teleclass
Hosted by Paul Webber paul@webbertraining.com
Reprocessing Medical Devices
Dr. Michelle Alfa
Sponsored by JohnsonDiversey www.johnsondiversey.com

A Webber Training Teleclass
Hosted by Paul Webber paul@webbertraining.com

Sphinctertome Inoculation:

1. Soil with ATS in “retro-flush” direction
2. Hold RT for 1 Hr, flush out excess ATS via ports
3. Process by cleaning method
4. Access L1, L2, L3 using needles
5. Flush out excess fluid
6. Instill Bradford’s Reagent (detects protein)
7. Incubate RT; 20 minutes
8. Read Absorbance to determine if protein remains in L1, L2, L3 AFTER CLEANING.

Simulated-use testing: Sphinctertome
(Bradford’s Assessment of Protein in Lumens)

Residual Soil and Bioburden Levels:
(Destructive Testing)

1. 25 mls sterile PBS (submerge cut segments)
2. Vortex
3. Sonicate
4. Centrifuge
5. Vortex
6. Sample

Soil Removal from Sphinctertome

Summary:

- Manual cleaning: no impact on non-ported channel
- Automated cleaning: no impact on non-ported channel
- Bacteria most difficult to remove from lumen
- Retro-flushing using automated cleaning: optimal for non-ported accessory devices
- Approximately 1L fluid flows through device (automated)

Issues are the same for biopsy forceps because they are Non-ported

A: Not cleaned
B: Manual cleaning
C: Sonic Irrigator-Auto
D: Sonic Irrigator-Auto (retro-flush)
E: Unused/uncleaned

All data represent the average of three replicates

E. faecalis E. stearothermophilus

<table>
<thead>
<tr>
<th>Method</th>
<th>Soil Removal A</th>
<th>Soil Removal B</th>
<th>Soil Removal C</th>
<th>Soil Removal D</th>
<th>Soil Removal E</th>
</tr>
</thead>
<tbody>
<tr>
<td>Uncleaned</td>
<td>500</td>
<td>1000</td>
<td>1500</td>
<td>2000</td>
<td>2500</td>
</tr>
<tr>
<td>Manual SI</td>
<td>200</td>
<td>400</td>
<td>600</td>
<td>800</td>
<td>1000</td>
</tr>
<tr>
<td>Auto SI</td>
<td>100</td>
<td>200</td>
<td>300</td>
<td>400</td>
<td>500</td>
</tr>
<tr>
<td>Auto SI-retro</td>
<td>50</td>
<td>100</td>
<td>150</td>
<td>200</td>
<td>250</td>
</tr>
<tr>
<td>Unused</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

All data represent the average of three replicates

CFU/Device (Log10)

A: Not cleaned
B: Manual cleaning
C: SI-Auto
D: SI-Auto (retro-flush)
E: Unused/uncleaned

Lower limit of detection (250 cfu/ml)

<table>
<thead>
<tr>
<th>Method</th>
<th>Viable Bioburden A</th>
<th>Viable Bioburden B</th>
<th>Viable Bioburden C</th>
<th>Viable Bioburden D</th>
<th>Viable Bioburden E</th>
</tr>
</thead>
<tbody>
<tr>
<td>Uncleaned</td>
<td>5000</td>
<td>10000</td>
<td>15000</td>
<td>20000</td>
<td>25000</td>
</tr>
<tr>
<td>Manual SI</td>
<td>2000</td>
<td>4000</td>
<td>6000</td>
<td>8000</td>
<td>10000</td>
</tr>
<tr>
<td>Auto SI</td>
<td>1000</td>
<td>2000</td>
<td>3000</td>
<td>4000</td>
<td>5000</td>
</tr>
<tr>
<td>Auto SI-retro</td>
<td>500</td>
<td>1000</td>
<td>1500</td>
<td>2000</td>
<td>2500</td>
</tr>
<tr>
<td>Unused</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

All data represent the average of three replicates

Summary:

- Manual cleaning: no impact on non-ported channel
- Automated cleaning: no impact on non-ported channel
- Bacteria most difficult to remove from lumen
- Retro-flushing using automated cleaning: optimal for non-ported accessory devices
- Approximately 1L fluid flows through device (automated)

Issues are the same for biopsy forceps because they are Non-ported
Reprocessing Medical Devices  
Dr. Michelle Alfa  
Sponsored by JohnsonDiversey  www.johnsondiversey.com

Infection Transmission:
- Laparoscopic devices: rare
  - autoclave can fail if lumen too heavily soiled
- Sphinctertome: ??unknown
  - if manual cleaning done for single-use
    sphinctertomes; cautery wire channel an issue
- Olympus Recall: bronchoscopes;  
  P.aeruginosa & M.tuberculosis
- Colonoscopy: Hepatitis C

Critical Publication Evaluation:
- Design of device; are channels accessible?
- Positive & Negative Controls
- Does method used destructive and/or in-situ testing?
- Cannot add Log₁₀ from different steps
  (e.g., cleaning: 3Log₁₀, disinfection 6 Log₁₀)
- Spores or organisms alone are NOT a good indicator for cleaning efficacy

Reprocessing of Narrow-lumen Medical Devices
- See no evil
- Hear no evil
- Speak no evil

References:
1. Decontamination of Reusable Medical Devices  
  CSA International document Z314.8-00, March 2000
  http://www.fda.gov/cdrh/safety/endoscopereproce ss.html