

Reprocessing Medical Devices

Dr. Michelle Alfa

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SAFE REPROCESSING OF NARROW-LUMEN MEDICAL DEVICES



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Overview

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

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!

Difficult to Clean Medical Devices:

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



“Critical” Devices pose highest risk of infection transmission

Medical Device: Cleaning

Soil: Patient secretions (eg blood, serum, mucous)

Bioburden:

Sterile Surgery; Instruments : $\sim 10^1 - 10^3$ cfu/device
(Chu et al AJIC 27:315, 1999)

Mucosal surface; Endoscope lumens: $\sim 10^4 - 10^9$ cfu/device
(Alfa et al AJIC Oct 1999)

Cleaning removes 3-4 Log_{10} of bioburden

(Note: if bioburden low initially, it is replaced by water organisms during washing)

What you can't see CAN hurt you!

Non-ported Medical Devices

- Sonication often recommended by manufacturer as part of manual cleaning process
- Detergent: enzymatic versus activated H_2O_2
- Rinsing to remove detergent
- Guidelines recommend visual inspection to confirm cleaning

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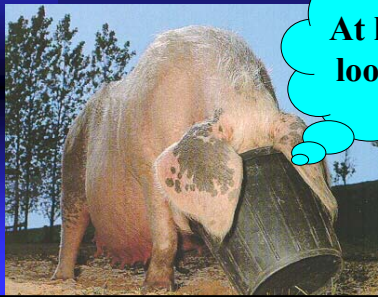
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Visual Inspection of Cleaning?



At least I can look inside!!

Manual Versus Automated Cleaning

- Laparoscopic devices & Sphincterotomes
- Sonication
- Fluid flow access
- Volume of fluid flow

CLEANING NARROW LUMEN DEVICES

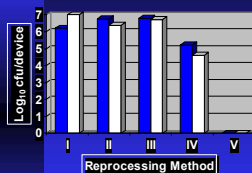
Sonic Irrigator Auto

(Medi-Safe)

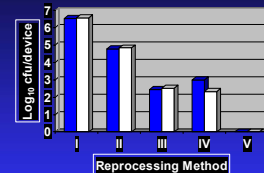


Cleaning of Laparoscopic devices

A) Non-portcd



B) Portcd



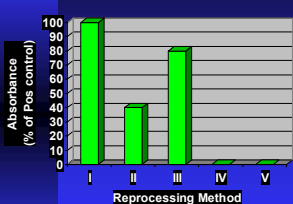
■ E. faecalis □ B. stearothermophilus

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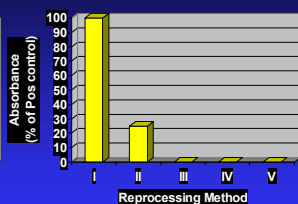
- I: Uncleaned-positive control
- II: Manual cleaning
- III: SI-Auto (ported device connected, non-ported device not connected)
- IV: SI-Auto (Retro-flushed)
- V: Negative control

Protein removal; Laparoscopic devices

A) Non-portcd



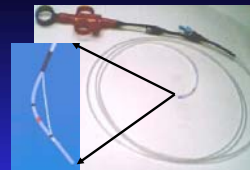
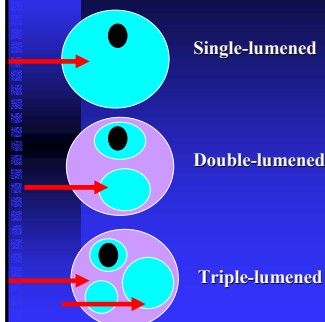
B) Portcd



- I: Uncleaned-positive control
- II: Manual cleaning
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Sphincterotomes: cross-section

(single-use)



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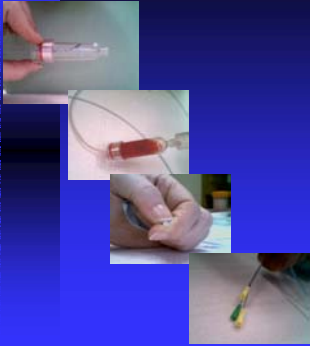
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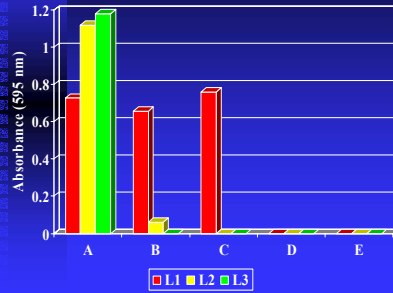
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Sphinctertome Inoculation:



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

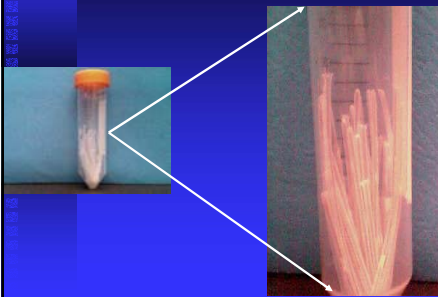
Simulated-use testing: Sphinctertome (Bradford's Assessment of Protein in Lumens)



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

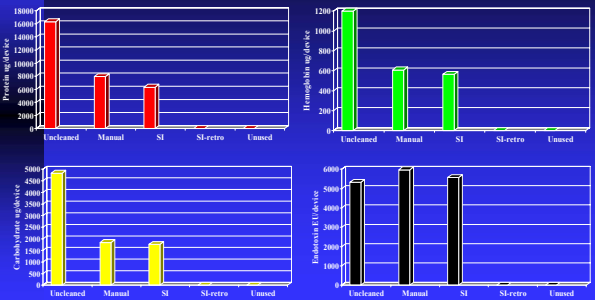


Residual Soil and Bioburden Levels: (Destructive Testing)



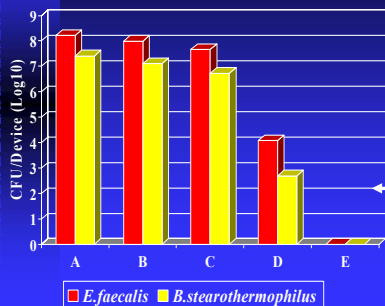
1. 25 mls sterile PBS (submerge cut segments)
2. Vortex
3. Sonicate
4. Centrifuge
5. Vortex
6. Sample

Soil Removal from Sphinctertome



All data represent the average of three replicates

Simulated-use testing: Sphinctertome (Viable Bioburden in Sphinctertomes)



- A: Not cleaned
 - B: Manual cleaning
 - C: SI-Auto
 - D: SI-Auto (retro-flush)
 - E: Unused/uncleaned
- Lower limit of detection (250 cfu/ml)

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

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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 Log_{10} from different steps (e.g. cleaning; 3Log_{10} , disinfection 6Log_{10})
- 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
2. Feigal DW Jr, Hughes JM. FDA and CDC Public Health Advisory: infections from endoscopes inadequately reprocessed by an automated endoscope reprocessing system Sept. 10, 1999. <http://www.fda.gov/cdrh/safety/endoscopereprocss.html>
3. Alvarado, CJ, M Reichelderfer. APIC guideline for infection prevention and control in flexible endoscopy. *AJIC* 200028:138-55.

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