Medical Instrument Reprocessing: Current issues with biofilm, cleaning and cleaning monitoring

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Disclosures:

Consulting services: 3M, Olympus, ASP, Ofstead Associates, KARL STORZ, Novaflux, Kikkoman

Royalties: U of Manitoba: license to Healthmark

Sponsored Speaker: 3M, Ruhof, Ambu, Olympus

I do NOT represent any company and discussion of specific products is not meant as an endorsement.

Objectives:

- ***Reusable medical devices***
  - Contamination levels
- ***Biofilm: Infection transmission***
- ***Monitoring cleaning: quality systems***
- ***Summary***

All Clipart Pictures in this presentation are from Google Images

Contamination levels on surgical instruments vs flexible endoscope after patient-use before cleaning.

Contaminant	Surgical Instruments*	Flexible endoscope**
	Maximum level detected	
Bacteria	1.7 Log_{10} CFU/cm^2	7 Log_{10} CFU/cm^2
Protein	2,413 µg/cm^2	115.5 µg/cm^2
Hemoglobin	108 µg/cm^2	85.5 µg/cm^2

*Cloutman-Green E, et al Am J Infect Control 2015;43: http://dx.doi.org/10.1016/j.ajic.2015.02.017

** Alfa MJ, et al Am J Infect Control 1999;27:392-401

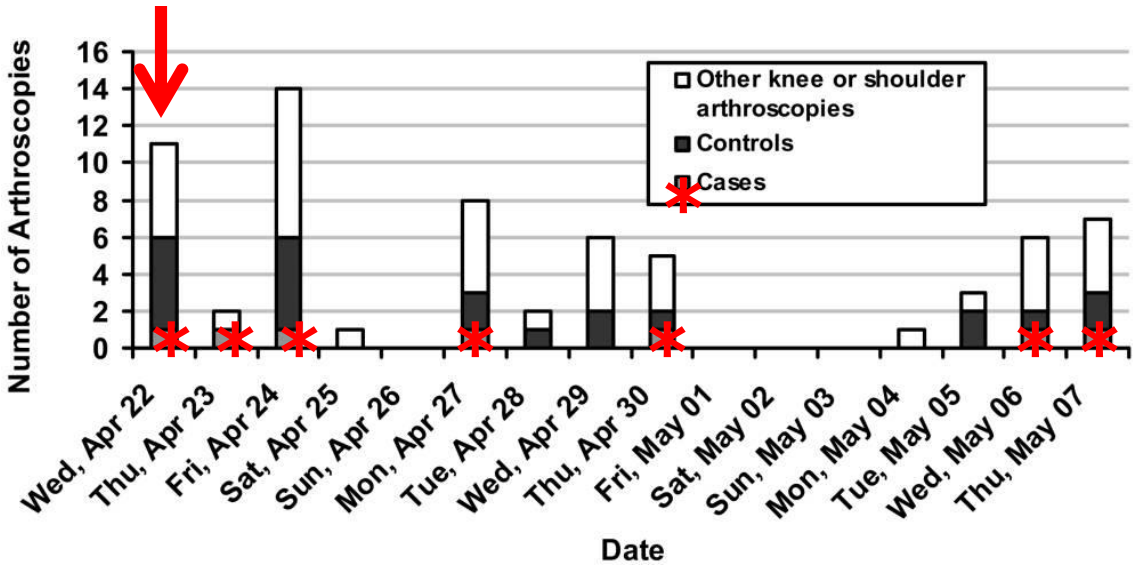
Infection transmission related to Surgical instruments

Year [Ref]	Surgical device	Disinfection/ Sterilization	Pathogen [Infection]	Issue
1999 [Zaluski]	Phacoemulsifier [Eye surgery]	Steam	*P. aeruginosa* [endophthalmitis]	Contamination of internal lines
2011 [Tosh]	Arthroscopic handpieces	Steam sterilization	*P. aeruginosa* [knee infections]	Tissue retained inside handpieces after cleaning
2012 [Dancer]	Orthopedic & Ophthalmologic surgical instruments	Steam: wet-packs & intact packs	Bacillus sp, Coagulase negative *Staphylococci* [deep skin & soft tissue infections]	Instruments in intact wrapped packs contaminated
2017 [Sheitoyan-Pesant]	Ultrasonic surgical aspirator used in craniotomy surgery	Steam	*P. acnes, S. capitis, S. aureus, S. agalactiae, E.faecalis*, [brain abscess, epidural empyema, meningitis]	Inadequate cleaning due to process change.

Arthroscopic Surgery:

Case Patients:
2 patients: ACL reconstruction
4 patients: Knee debridement [e.g.meniscectomy]
1 patient: shoulder rotator cuff repair

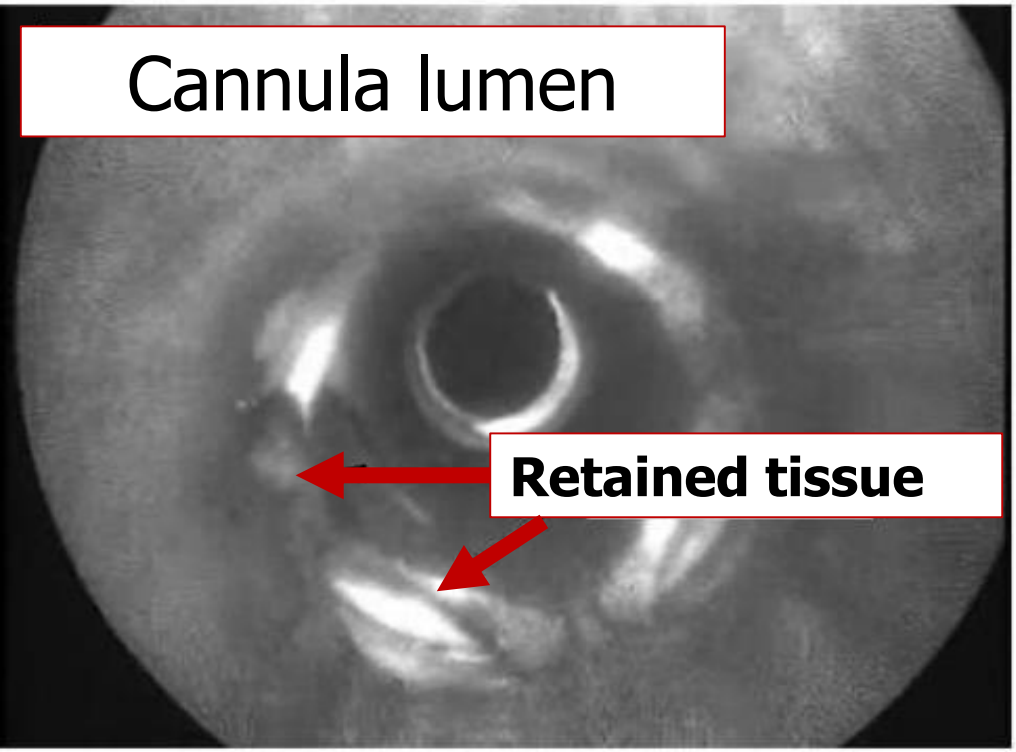
Arthroscopic surgery:
- *P.aeruginosa* infection in 7 patients over ~ 2 weeks
- Identical *P.aeruginosa* strains detected in water and suction canister [not detected in shavers]
-Shaver handpieces **autoclaved**

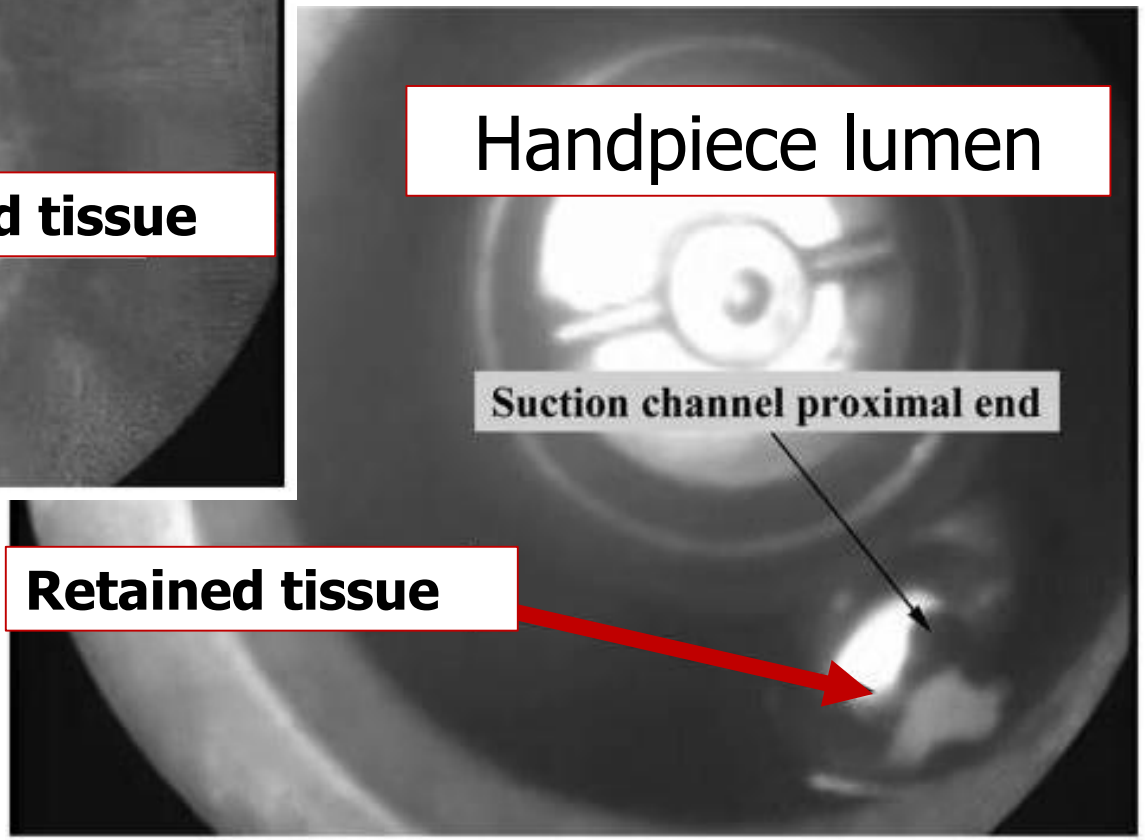


Infections detected 4 – 19 days post surgery

Tosh PG et al Outbreak of *P.aeruginosa* surgical site infections after arthroscopic procedures. ICHE 2011;32:1179-86.

Improper Cleaning: Handpiece lumen & Cannula lumen





Tosh PG et al Outbreak of *P.aeruginosa* surgical site infections after arthroscopic procedures. ICHE 2011;32:1179-86.

Recommendations:

- Meticulous cleaning
- Visualization of interior of lumens and handpieces to ensure no retained biological residues (e.g. borescope)

Pesant et al AJIC 2017;45:433-5

http://dx.doi.org/10.1016/j.ajic.2016.11.020

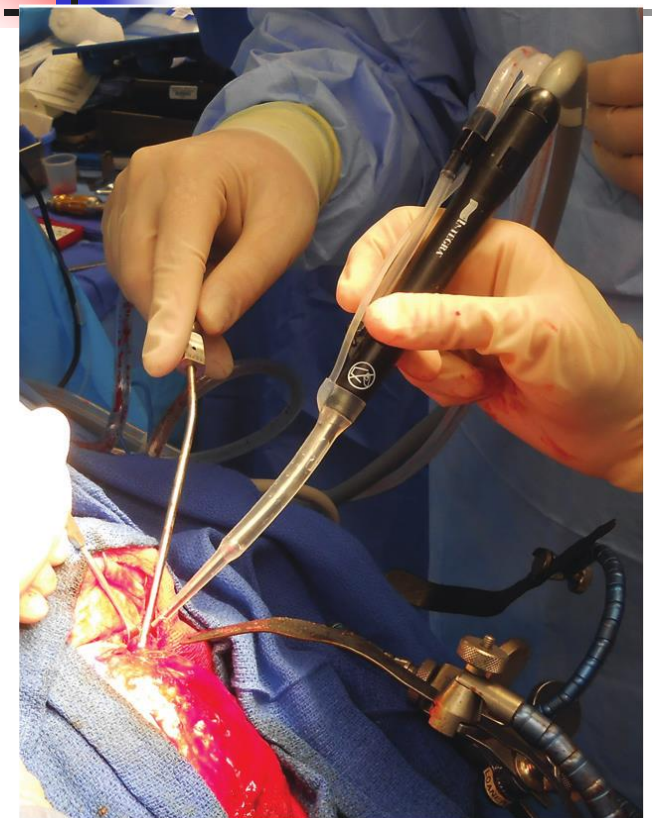


Image from: Wladis E et al Orbit, 2014; 33(3): 234–235

Cavitron Ultrasonic Surgical Aspirator (CUSA) a surgical power tool for tumor resection

Change:

- CUSA sent from OR to CPD for cleaning,
- CUSA sent back to OR for assembly
- CUSA sent to CPD for sterilization

Conclusions:

- Biological fluid dried in complex device → inadequate cleaning
- Suboptimal sterilization

Summary:

- **Multiple rounds of:**
  - Improper cleaning
  - Retained tissue & organic material
  - Biofilm or Buildup Biofilm formation

- **Steam sterilization infective**

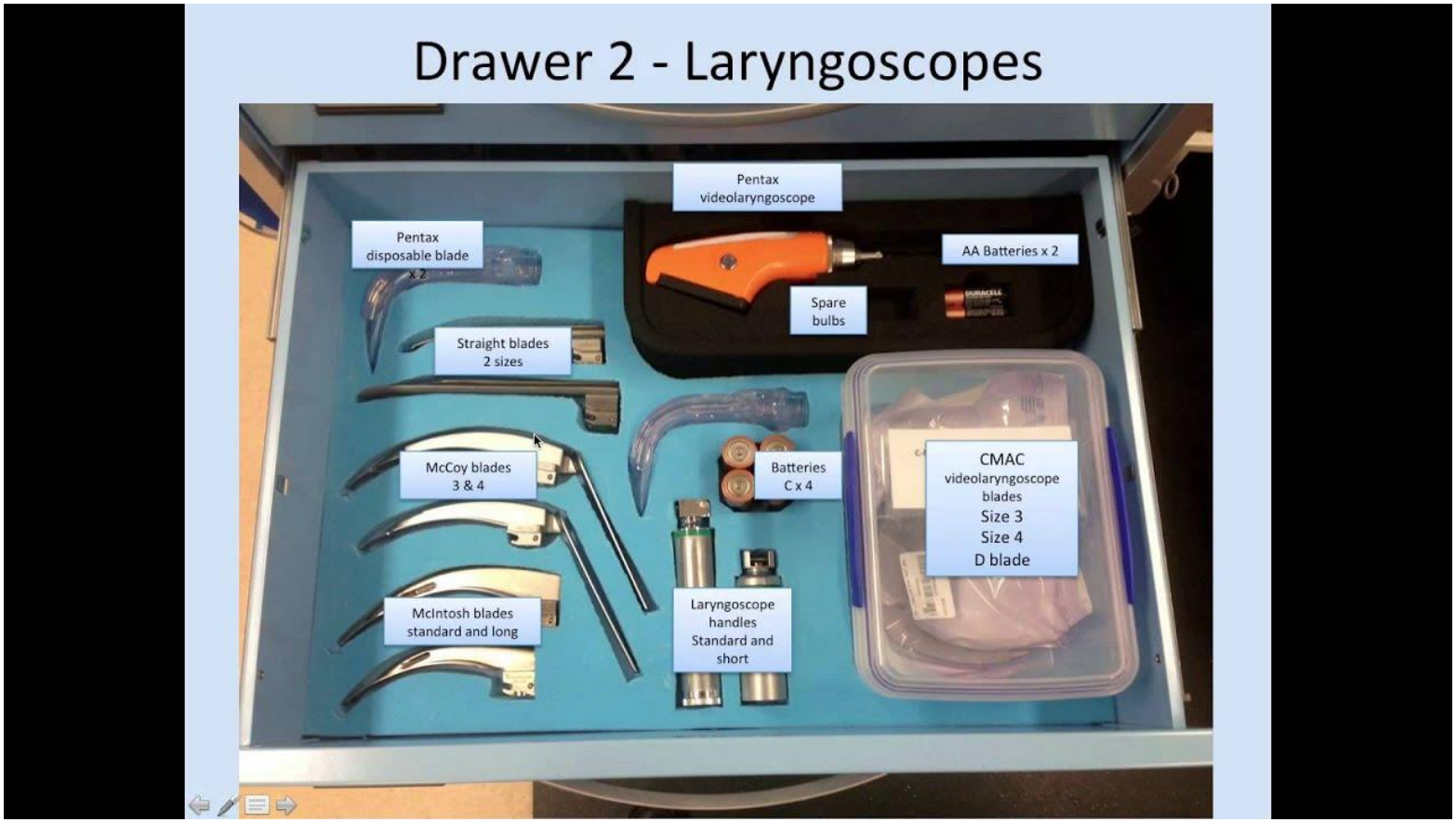
Infection Transmission Due to Contaminated Surgical Instruments

- **Data from USA:**
  - 1.6 million endoscope procedures/year
  - 51.4 million surgical procedures/year
- Risk of infection from reusable surgical instruments is lower than for reusable flexible endoscopes

Southworth P.M. Infections and exposures: reported incidents associated with unsuccessful decontamination of reusable surgical instruments. J Hosp Infect 2014;88:127-131

Emergency: Crash cart

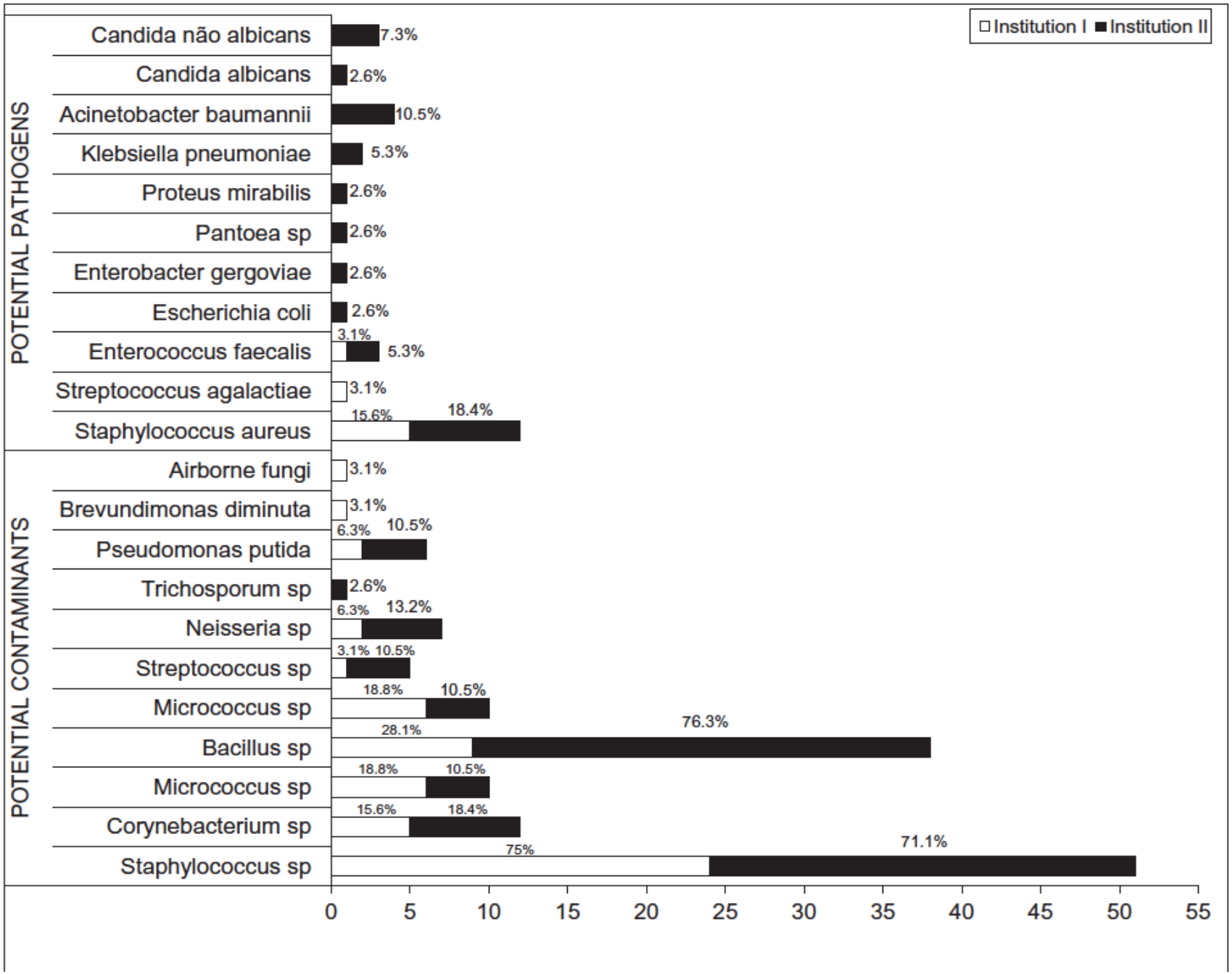
Historically; Airway devices stored unwrapped in Crash cart



Laryngoscopes

The use and reprocessing for ***non-channeled, less-complex endoscopes (eg, laryngoscopes, nasal endoscopes)*** *also pose risk. Any incomplete cleaning and/or disinfection, as well as scope damage, can result in transmission of infection.*

Pynnonen M et al. Reprocessing Flexible Endoscopes in the Otolaryngology Clinic. Otolaryngol Clin N Am 2019;52:391–402



De Sousa et al AJIC 2016;44:294-8

CSA Group

CAN/CSA-Z314-18
National Standard of Canada

Canadian medical device reprocessing

CSA Z314-18 Recommends:

Reusable

single-use

Laryngoscope Blades:

- Sterilized if they can be safely sterilized
- If sterilization is not possible; use HLD

CSA Z314-18 Recommends:

- During storage, laryngoscopes shall be kept free from contamination until time of use.
- The individual blade shall be contained in a plastic bag, placed in a clean storage location. If sterilized, a peel pack may be used.

Nielsen SW et al Mandated wrapping of airway cart instruments: Limited access without the intended safety benefits. Laryngoscope 2019;129:715-719

- **Study results (N = 100 for each group):**
  - longer layout time for wrapped instruments
  - no difference in infections or complications
- **Conclusions:**
  - Sterile airway sets for routine cases (meets Joint commission requirements)
  - Emergency air-way cart instruments unwrapped

Healthcare Facilities:

Medical devices are cleaned manually & by automated washers

How can you be sure instruments have been properly cleaned?

CAN/CSA-Z314-18
Canadian Medical Device Reprocessing

Clause 11:

Decontamination of reusable medical devices

KEY PERFORMANCE INDICATORS (KPIs)

- Automated washer-disinfector cycle monitoring
- Automated cart washer cycle monitoring
- Washer-disinfector cleaning efficacy testing [***Each day of use***]
- Ultrasonic cleaning efficacy testing [***minimally-weekly, preferably daily***]
- Water quality (hardness, bacteria-free, etc.)

Characteristics common to washer-disinfector effective cleaning performance

- Proper **Loading**
- Unobstructed spray arms or nozzles & clean drain screens (Spray **Pressure**)
- **Concentration** of cleaning chemistries
- **Time** of exposure to mechanical washing action
- Prescribed wash water **Temperature**

CAN/CSA-Z314-18 Canadian Medical Device Reprocessing

Ideal WD Cleaning Monitor

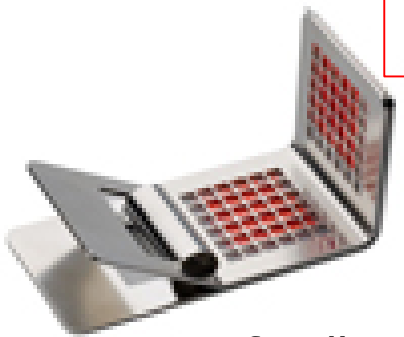
Validated by manufacturer for parameters in label claim:

- detergent
- time
- temperature
- water impingement pressure
- cavitation (ultra-sonic units)

ISO Working group 13: defining standardized parameters for Cleaning

Many commercial WD cleaning indicators

Representative examples only



STERIS: Verify All Clean WD indicator

Steritec Wash-Checks

CHEMDYE Splat Test WD indicator

GKE Multilevel WD cleaning indicator

WD-Chex™ Washer-Disinfector Monitor

Getinge Assured WD Monitor

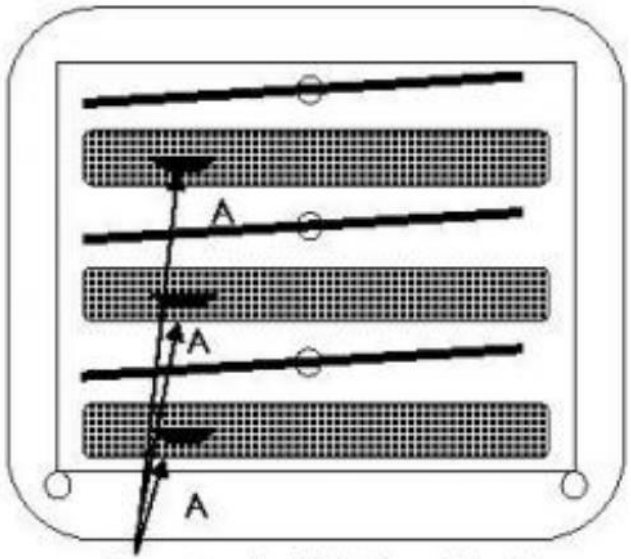
TOSI WD indicator

Images from manufacturer's website

Placement of cleaning monitors in WD

Cleaning monitor on each level of WD with multi-level racks

TOSI® PLACEMENT



Location A - Multi-Level Rack
Place one (1) TOSI® on each level. Arrange so that TOSI® is in the center of the radius of the spinner arm.

Images & information from manufacturer's website

Monitoring tests for Washer-disinfector Cleaning

Rapid washer-disinfector cleaning test (manufacturer)	Description	Endpoint assessment	Washer-disinfector defects detected	Published data*
VERIFY All Clean Test (STERIS Corporation; Mentor, OH)	Bright red test soil contains protein, lipids, and endotoxin. Mesh design of holder mimics difficult-to-clean surfaces.	Visual decision is based on residual red color, as per MIFU.	Detergent concentration Wash cycle time Temperature Water pressure Overloading	None available
Wash-Checks (Getinge Group; Rochester, NY)	Red test soil mimics the removal of blood and tissue from surgical instruments. Design of holder mimics surgical instrument joint.	Visual decision is based on residual red color, as per MIFU.	Detergent concentration Wash cycle time Temperature Water pressure	None available
Chemdye 'SPLAT' test (Gallay Medical & Scientific; Mulgrave, Victoria, Australia)	Organic components are red colored. Design of holder creates cleaning challenge.	Visual decision is based on residual red color, as per MIFU.	Detergent concentration Wash cycle time Temperature Water pressure Overloading	None available
gke Clean-Record (gke GmbH; Waldems-Esch, Germany)	Colored synthetic test soil is on plastic carriers. Different colored indicators assess various cleaning challenges. Design of holder does not create a cleaning challenge.	Visual decision is based on residual color for each type of indicator, as per MIFU.	Detergent concentration and type Wash cycle time Temperature Water pressure Overloading	None available
TOSI (Getinge; Gothenburg, Sweden)	Blood-based red test soil contains hemoglobin, albumin, and fibrin. Design of holder creates a challenge by mimicking uneven surfaces of surgical instruments.	Visual decision is based on residual red color, as per MIFU.	Protolytic detergent concentration Wash cycle time Temperature Water pressure Overloading	Alfa et al;[39] Fruh and Pfeifer[40]
PINNACLE (Serim Research Corporation; Elkart, IN)	Test substrate is dyed protein (orange-pink color). Design of holder does not create a cleaning challenge.	Visual decision is based on lighter color of indicator color pad compared to color of internal control standard pad, as per MIFU.	Enzymatic detergent concentration and activity Wash cycle time Temperature Water pressure	Alfa et al[39]

Scientific Data: Very few peer reviewed published studies!

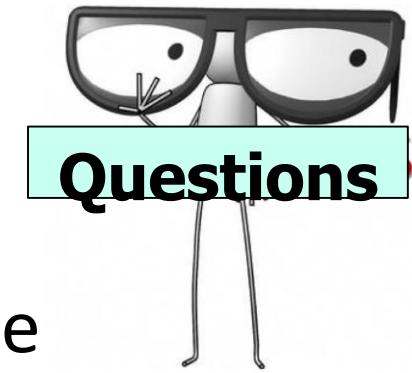
Alfa MJ Medical instrument reprocessing: current issues with cleaning and cleaning monitoring. AJIC 2019;47:A10–A16.

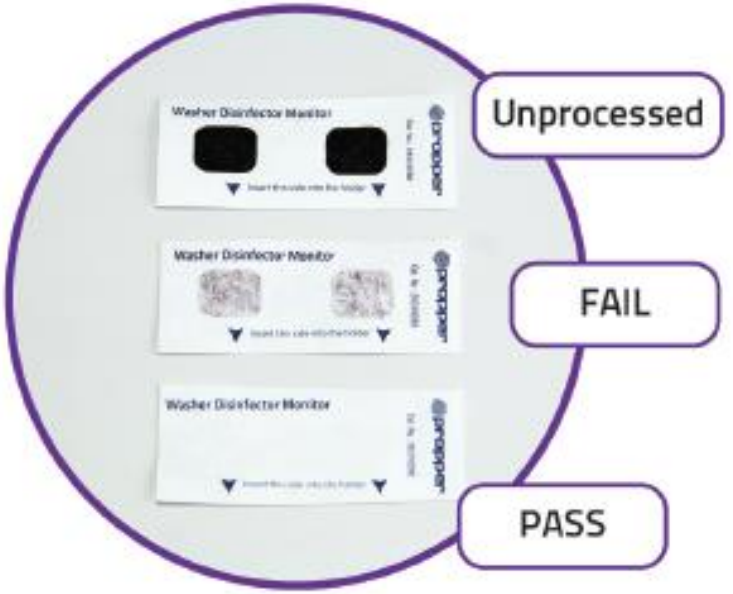
How can you make a choice?

- ***Validation of WD cleaning monitoring tests by manufacturer:***
  - No standardization of requirements
  - Cannot equate one WD cleaning monitoring test to another one
  - Cleaning is multi-factorial
  - Cavitation testing needed for ultrasonic cleaner

Selection of WD Cleaning Monitor: ASK QUESTIONS!

- Ask vendors to provide data on how time, temp, detergent and water impingement pressure affect their WD cleaning monitor
- Ask vendors of WD cleaning monitors for recommendations and tools for implementation
- Compare WD Cleaning monitors In-House





WD-Chex
WD Monitor

Images & information from manufacturer's website

WD Wash-Check

Result	Description	Possible Reasons for Result
Pass (Optimum Result)	Red test soil is completely removed and no residuals are left. The result indicates sufficient cleaning achieved at the place of positioning of the Cleaning Monitor.	Optimal Result
Fail (Moderate Results)	Most of the test soil is being removed however some residuals of the red spot are detected primarily in the areas protected by the Cleaning Monitor Holder.	• Incorrect positioning for Washer-Disinfector Monitor i.e. positioning some of the instruments in the load prevents direct access of cleaning solutions to the Cleaning Monitor (shadowing) • Cleaning time too short • Cleaning temperature does not match recommendation for solutions • Dosage of the cleaning solutions too low • Clogged or loose spray arms
Fail (Insufficient Results)	Major portion of the red test soil is being removed however residuals are clearly visible.	• Incorrect positioning for Washer-Disinfector Monitor i.e. positioning some of the instruments in the load prevents direct access of cleaning solutions to the Cleaning Monitor (shadowing) • Overloading or incorrect loading • Cleaning time too short • Cleaning temperature does not match recommendation for solutions • Dosage of the cleaning solutions is too low • No uniform distribution of detergent • Clogged or loose spray arms • Insufficient water pressure • Residuals from pre-cleaning
Fail (Critical/Poor Results)	Red test soil is largely or completely unaffected.	• Incorrect positioning of Washer-Disinfector Monitor i.e. positioning some of the instruments in the load prevents direct access of cleaning solutions to the Cleaning Monitor (shadowing) • Overloading or incorrect loading • Cleaning time too short • Cleaning temperature does not match recommendation for solutions • Dosage of the cleaning solutions too low • No uniform distribution of detergent • Clogged or loose spray arms • Insufficient water pressure • Residuals from pre-cleaning • Incorrect temperature for solutions • No cold pre-rinsing step in place or pre-rinsing too hot • Complete breakdown of the washing machine or the detergent

Images & information from manufacturer's website

https://www.gke.eu/en/washer-disinfectors.html

No.	Failure cause	Failure consequence
1	Detergent damaged by storage	Enzymes, especially in solution with high pH-values, decompose at higher temperature and longer storage time and lose their cleaning efficacy.
2	Blocked spray nozzle	Spray nozzle is deflected or blocked by dirt. (Is only discovered if the indicator is positioned in the spray area.)
3	Wrong programming of the WD	Dosing of detergent and/or changing of water quality at wrong time or detergent is added after the cleaning process step.
4	Failure in central dosing from barrels	Magnetic valves of the dosing system are defect or wrongly programmed (often all WDs are affected).
5	Connection of the spray arm is leaking or cart not locked correctly	Connection of the spray arm is leaking because of worn out seals or incorrect insertion of the cart, therefore less spray strength is observed.
6	Detergent canister mixed up by mistake	Detergent and neutralizer or 2-component detergent have been mixed up or one of the components is used twice.
7	Tube from pump to chamber is not fixed or leaking	Dosage in the chamber is too low or not present at all.
8	Suction tube kinked, injection lance faulty or tube not correctly inserted in the canister	Dosing does not take place or dosage is too low.
	Air in tube and/or	

DAILY INSPECTION LOG SHEET EXAMPLE:

ProFormance™ Log Sheet: 3 Level Rack (WTK-3L)

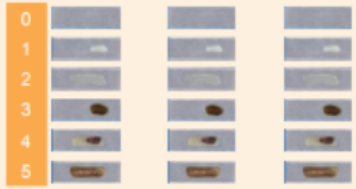
Date:	Facility:	Washer:	Rack No:	Name:

	Chamber				Racks				Comments
	Bottom		Top		Bottom		Top		
	yes	no	yes	no	yes	no	yes	no	
Spray nozzles/arms are free of debris									
Nozzles(holes) properly aligned at target surface (up & down)									
All spray arms are present									
Spray arm spin freely									

	yes	no	
Debris screen (in bottom of chamber) is clear of debris			
Instrument rack coupling with manifold properly			
No staining/scaling from detergent, hardwater, etc.			
Detergent/enzyme at sufficient level in container			

Proformance

Record Result (circle result)



Comments

WTK-3L/01/10

Images & information from manufacturer's website

Ultrasonic Cleaners

11.6.6.6
Ultrasonic cleaners shall be tested for sonication performance (e.g., commercial methods or the foil test) at least weekly, or preferably each day it is used. The test results shall be documented. The test and ultrasonic MIFUs shall be followed for appropriate testing protocols.

Lid closed during use

Change detergent solution:
- daily or;
- if visibly soiled or;
- as per Sonicator or detergent MIFU (e.g. every cycle)

CAN/CSA-Z314-18 Canadian Medical Device Reprocessing

Ultrasonic Monitors

Cleaning monitors

Steritec; Wash check
Ultrasonic monitor

OK-Sonic, Propper
Manuf Co.

Getinge; Assured
Ultrasonic monitor

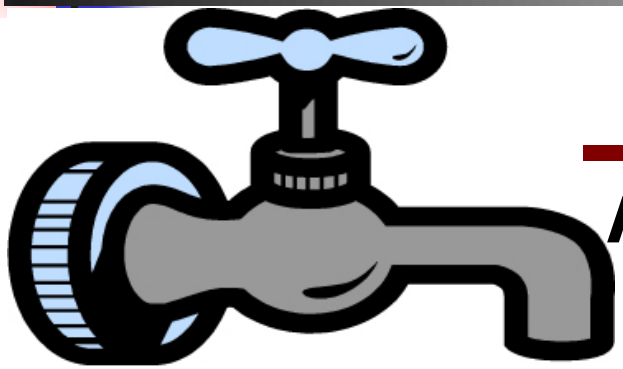
Cavitation monitor

Healthmark; Sonocheck
Ultrasonic monitor

Quality System: Cleaning of Instruments

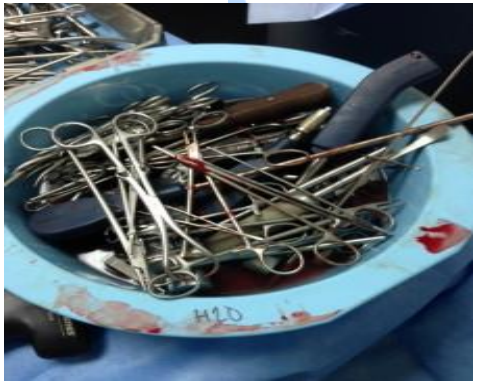
1. Follow validated manufacturer's instructions
2. Ensure adequate cleaning equipment and utilities available on site
3. Ensure staff training and ongoing competency assessment**
4. Monitor:
   - Cleaning adequacy of WDs
   - Sonication of Ultra-sonics

Paradigm Shift:
Medical Device Cleaning….



Rub-a-dub-dub

300 instruments in the TUB!



Paradigm Shift

Quality System Process:

1. Validated Manufacturer's cleaning instructions
2. Staff training & appropriate cleaning equipment
3. Cleaning monitoring
4. HLD and Sterilization monitoring

- Zaluski S, Clayman HM, Karsenti G, Bourzeix S, Tournemire A, Faliu B, et al. Pseudomonas aeruginosa endophthalmitis caused by contamination of the internal fluid pathways of a phacoemulsifier. J Cataract Refract Surg 1999;25:540-5.
- Gillespie JL, Arnold KE, Noble-Wang J, Jensen B, Arduino M, Hageman J, et al Outbreak of Pseudomonas aeruginosa Infections After Transrectal Ultrasound-Guided Prostate Biopsy Urology 2007;69: 912–914.
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- Sheitoyan-Pesant C, Alarie I, Iorio-Morin C, Mathieu D, Carignan A. An outbreak of surgical site infections following craniotomy procedures associated with a change in the ultrasonic surgical aspirator decontamination process 2017;45:433-5.
- Deshpande A, Smith GWG, Smith AJ. Biofouling of surgical power tools during routine use. J Hosp Infect 2015;90:179-85 doi:10.1016/j.jhin.2015.03.006.