Medical Instrument Reprocessing: Current issues with cleaning and cleaning monitoring



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Objectives:

- ***Surgical instruments***
  - Automated versus manual cleaning
  - Fragile instruments
- ***Flexible Endoscopes***
  - Lumens and role of friction
- ***Monitoring cleaning: quality systems***
- ***Summary***

All Clipart Pictures in this presentation are from Google Images

Surgical Instruments:

Table 1
Contamination levels on devices after surgical procedures

Surgery type (no. of devices)	Total contamination/device (contamination/cm^2)			
	Bacteria (CFU)	TOC (μg)	Protein (μg)	Hemoglobin (μg)
VP shunt (18)	1.0 ± 1.0 (0.03 ± 0.04)	1,626 ± 2,612 (47 ± 111)	4,388 ± 5,440 (107 ± 160)	144 ± 269 (2.9 ± 8.1)
Craniofacial (10)	2.7 ± 3.4 (0.05 ± 0.08)	1,026 ± 946 (23 ± 26)	7,883 ± 13,279 (99 ± 133)	1,138 ± 8.1 (10 ± 30)
Orthopedic (18)	13.0 ± 24.0 (0.23 ± 0.39)	3,813 ± 4,844 (64 ± 101)	50,817 ± 66,941 (942 ± 1471)	1,141 ± 1,733 (20 ± 40)
C-section (26)	88.0 ± 124.0 (0.72 ± 1.0)	7,340 ± 4,850 (63 ± 84)	6,944 ± 12,565 (47 ± 75)	3,802 ± 4,517 (34 ± 74)
Spinal (16)	0.9 ± 1.6 (0.01 ± 0.02)	2,808 ± 2,397 (44 ± 55)	293 ± 291 (4 ± 3)	774 ± 1,298 (9 ± 13)

NOTE. Values are averages ± SD.
C-section, caesarean section; *CFU*, colony forming units; *TOC*, total organic carbon; *VP*, ventriculoperitoneal.

Organic residuals: High
Microbial residuals: Low

Cloutman-Green Biochemical and microbial contamination of surgical devices: A quantitative analysis. American Journal of Infection Control 2015;43:659-61

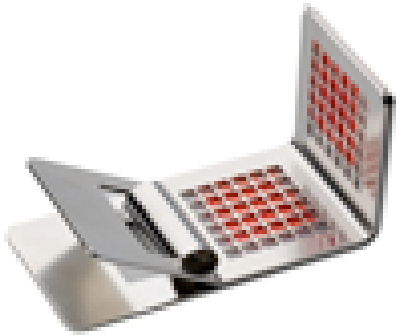
Healthcare Facilities:

Medical devices are cleaned manually & by automated washers

How can you be sure instruments have been properly cleaned?

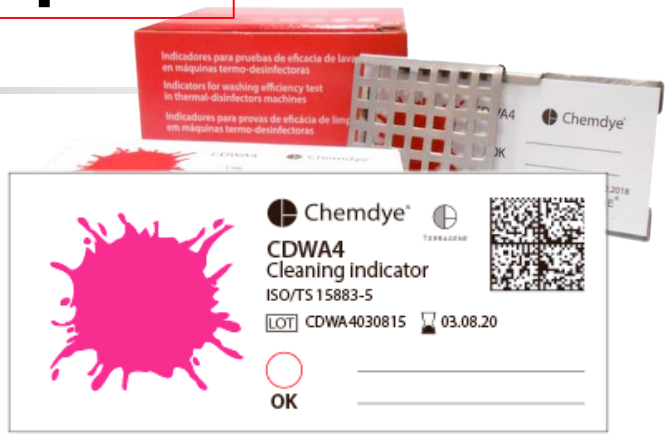
Many commercial WD cleaning indicators

Representative examples



STERIS: Verify All Clean WD indicator

Steritec Wash-Checks



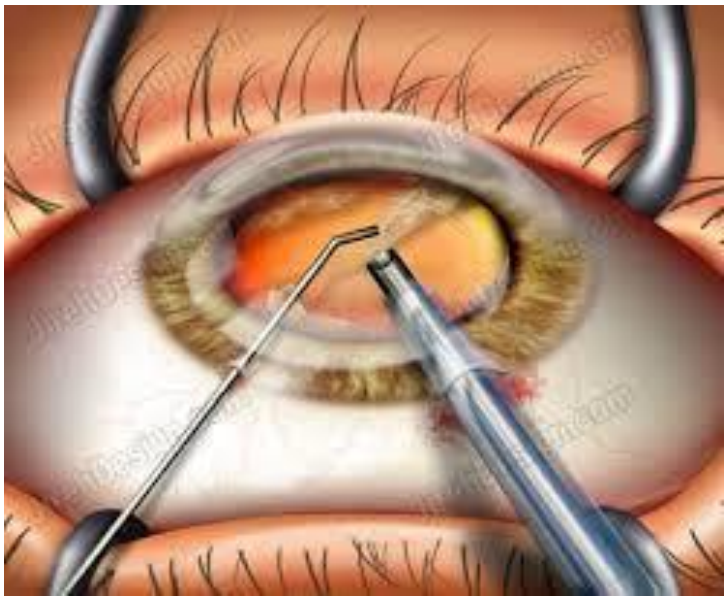
CHEMDYE Splat Test WD indicator

GKE Multilevel WD cleaning indicator

TOSI WD indicator

What about fragile instruments that cannot be cleaned in WD?

- Eye surgery instruments

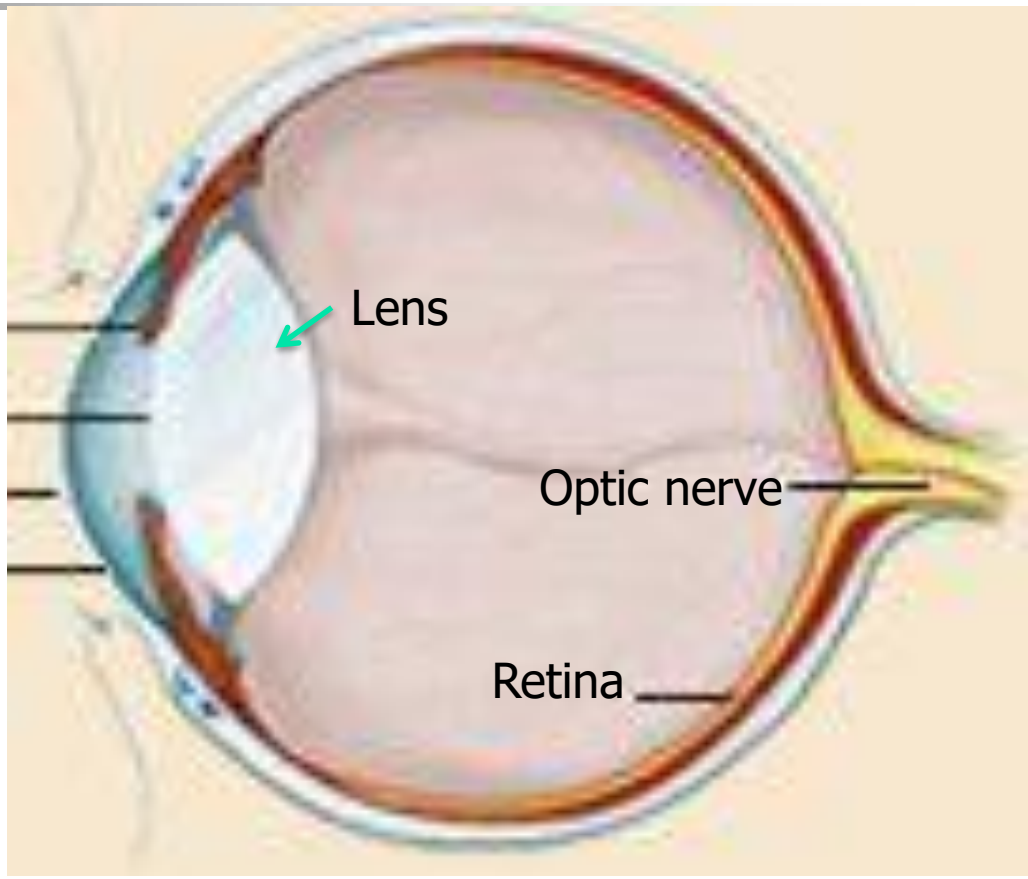


Cataract Surgery

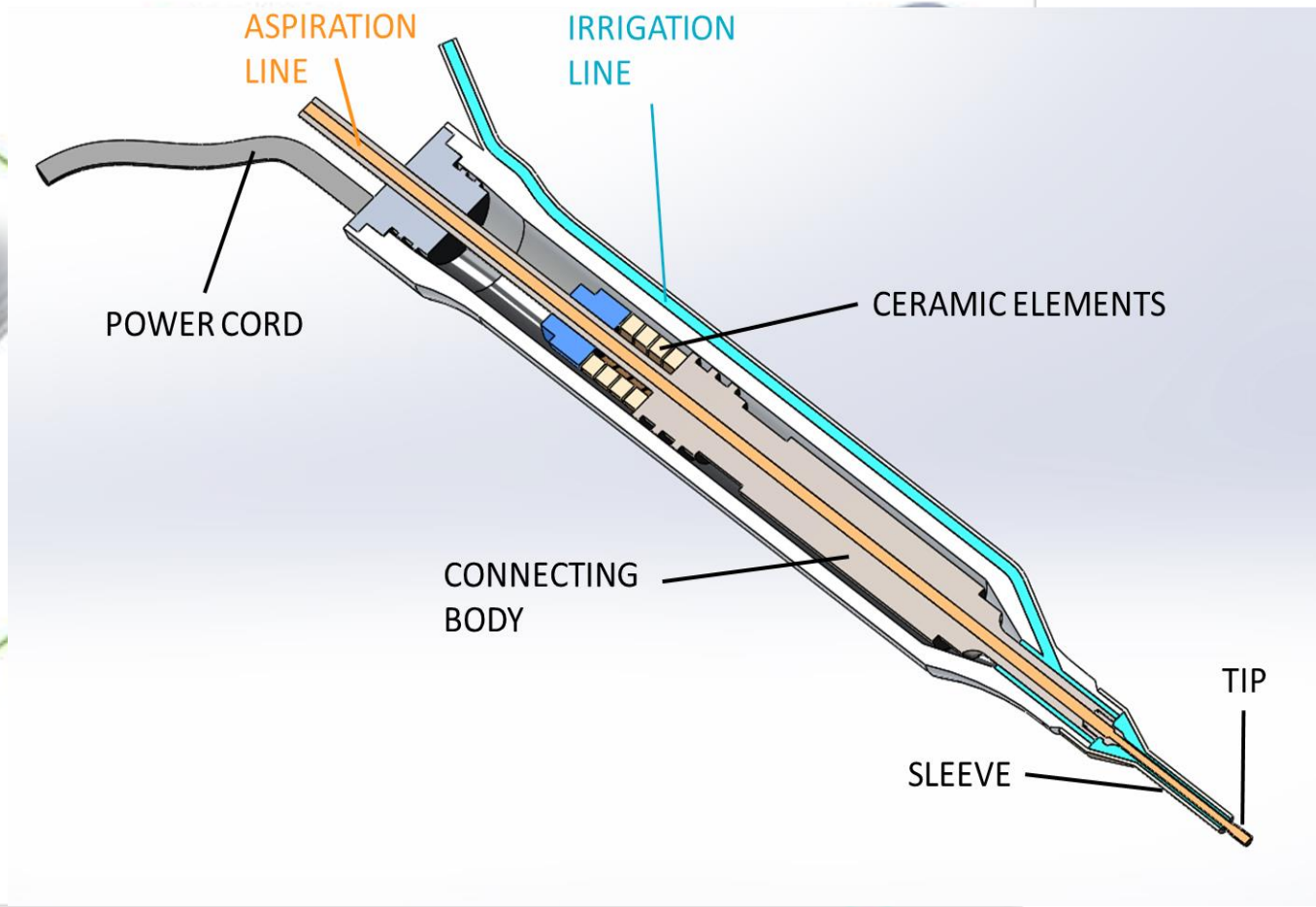
Phaco surgery:

- the natural lens, is broken up by ultrasound, and suctioned out.

- ***An artificial lens*** is implanted



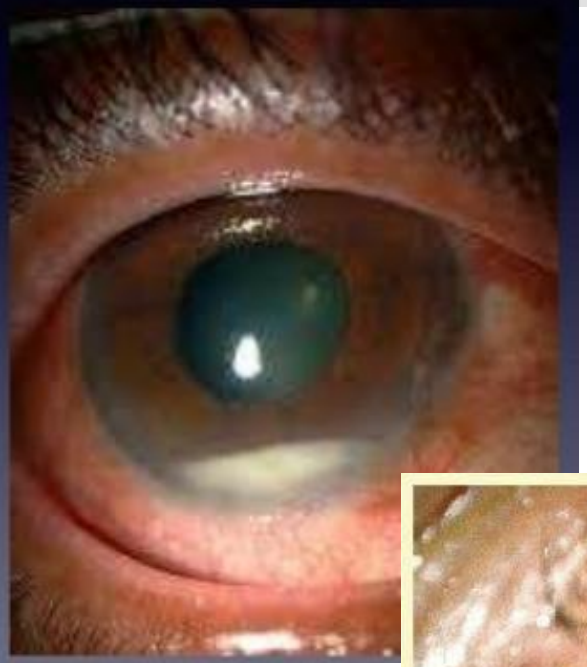
Phaco emulsion handpiece

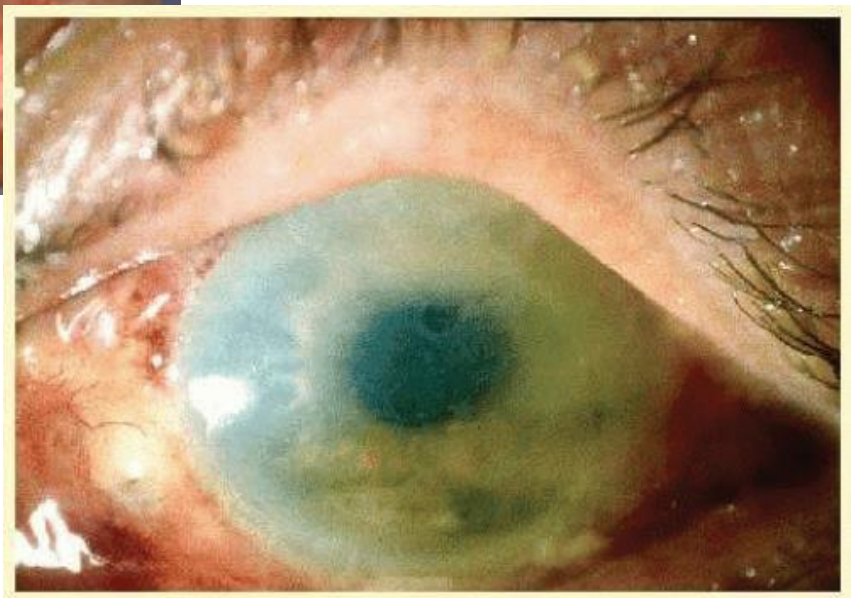


Images from Surgical Design Corporation Website

Toxic Anterior Segment Syndrome (TASS)

- Entry of a non infectious material in the anterior segment
- 12 to 48 hours after surgery
- Limited to anterior segment
- Gram stain and culture negative





Reprocessing of surgical instruments used for cataract surgery

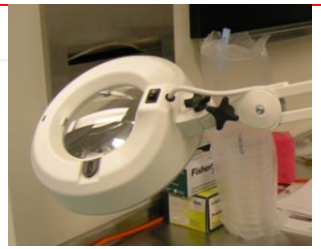
- MIFU indicates no detergent cleaning, only flushing with sterile distilled or RO water
- Automated flushing units or manual flushing
- How to evaluate cleaning adequacy?

Quality System: Cleaning of Instruments

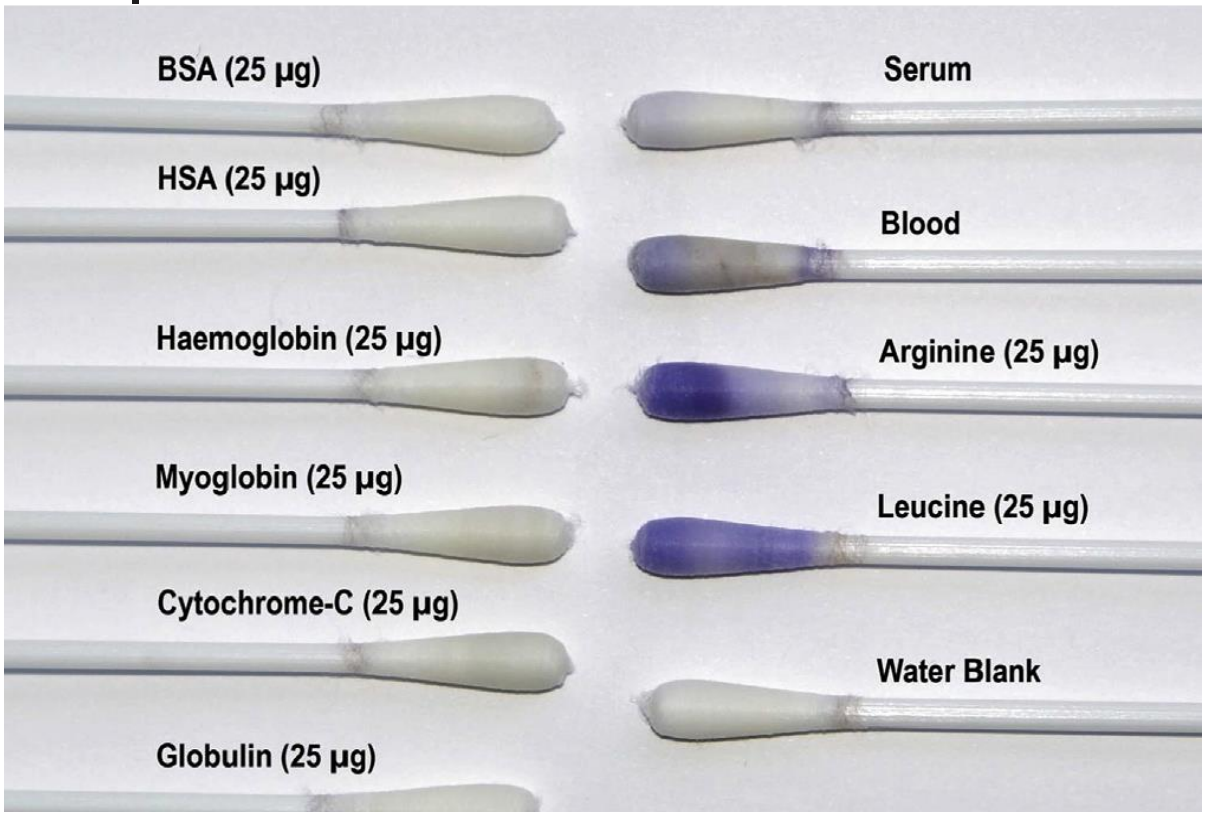
1. Follow validated manufacturer's instructions
2. Ensure adequate cleaning equipment and utilities available on site (water quality)
3. Ensure staff training and ongoing competency assessment**
4. Monitor cleaning adequacy
   - test cleaned instruments
   - test washers

Medical Instruments: Monitoring adequacy cleaning

- Visual inspection: magnifier lamp
- Rapid swab tests
  - swabs to detect protein, hemoglobin
  - ATP
- Automated "ProReveal"
  - spray stain (OPA/NAC) on instrument
  - reprocess instruments analyzed



Ninhydrin testing for residual Protein on surgical instruments



1) Does not detect all proteins

2) Many false negative tests

Nayuni NK et al Critical evaluation of ninhydrin for monitoring surgical instrument decontamnation. J Hosp Infect 2013;84:97-102

ATP Test for Cleaning

Cleaned instruments:
Manual or automated

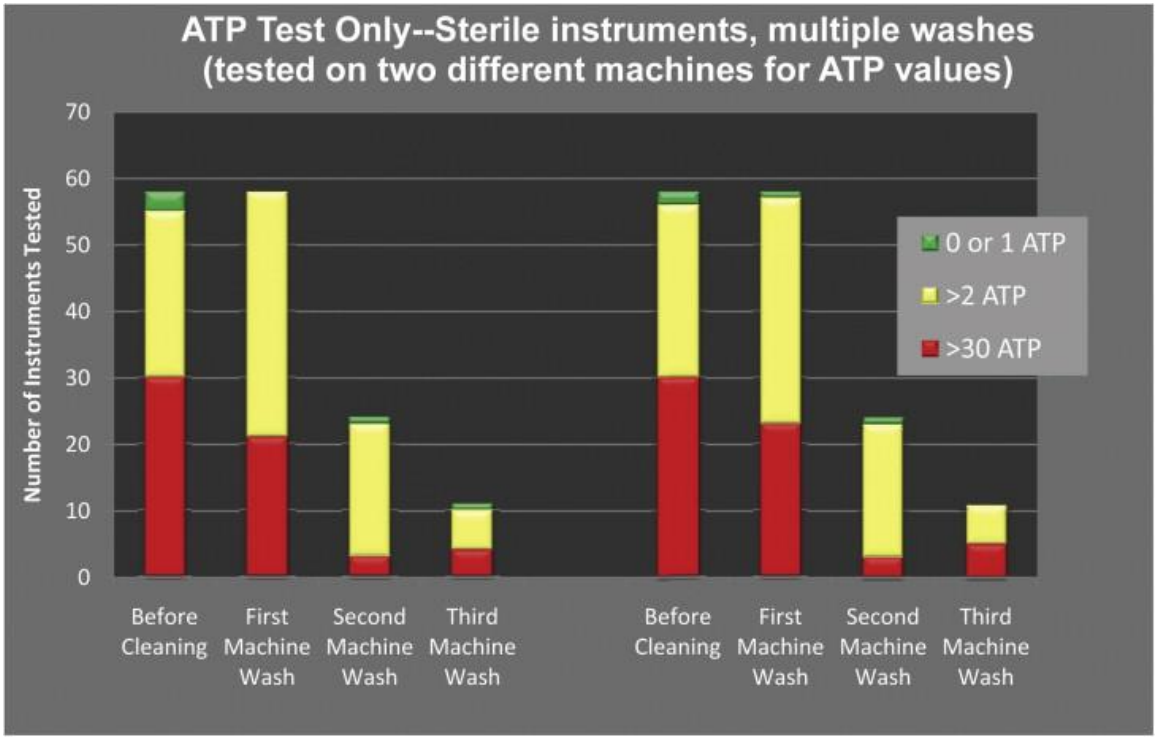
ATP sample:
Swab defined sites

ATP test:
Level of residual ATP indicates if cleaning adequate or not

ATP: high levels in human secretions, low levels in microbes

ATP testing: Cutoff for adequate cleaning?

- Endoscope cleaning; cutoffs published
- Surgical Instruments; needs more data



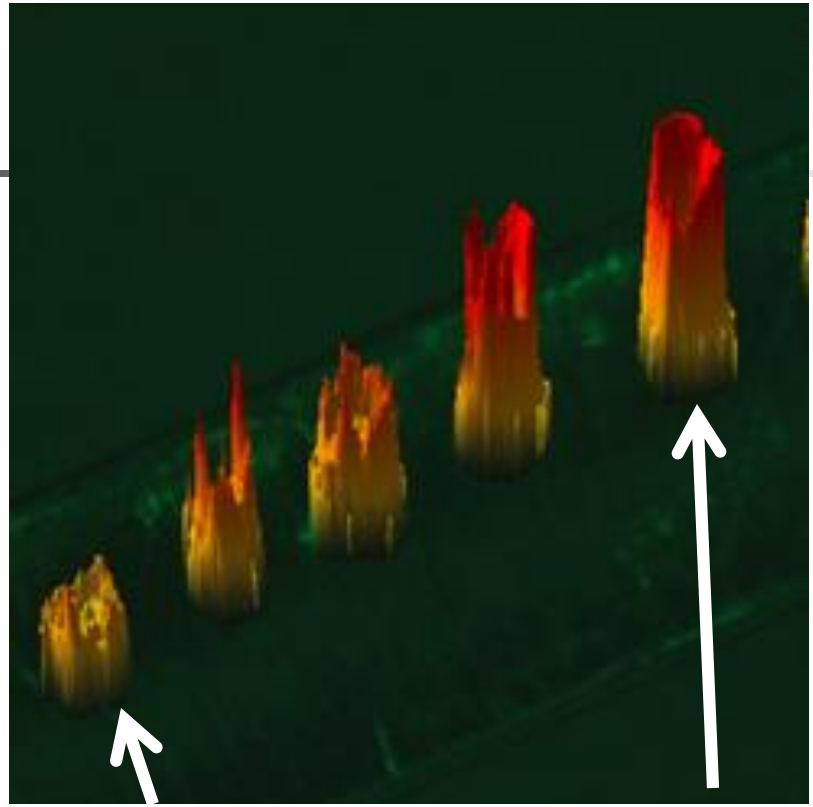
Azzizi J et al AORN Journal 2012 doi: 10.1016/J.aorn.2012.03.018

Pro-Reveal: Assess cleaned instruments for residual protein

1. Spray instrument with flourescent stain solution
2. Place instrument in Pro-Reveal tray
3. Pro-Reveal evaluates for flourescent stained residual protein

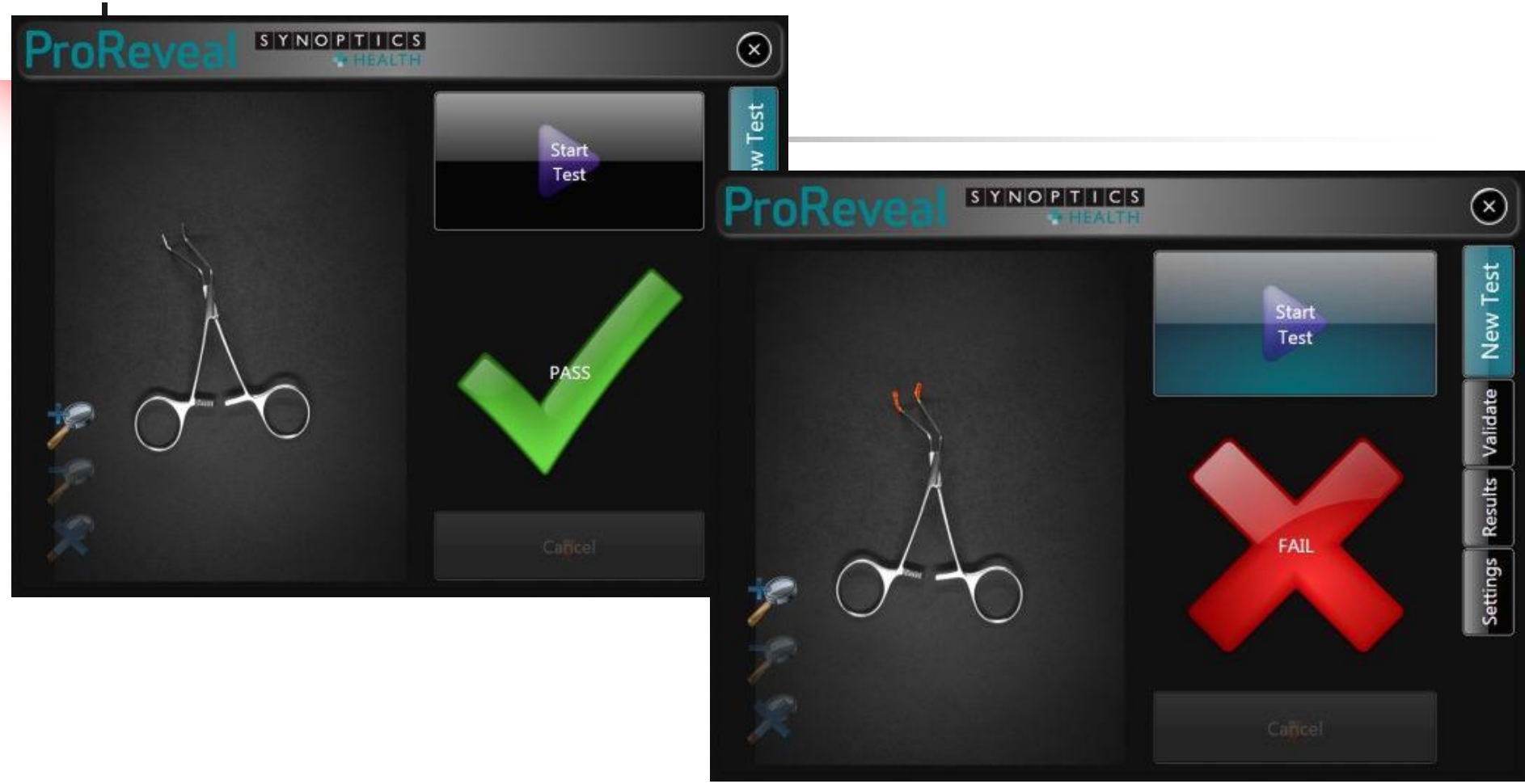
http://www.synopticshealth.com/proreveal-test/

Pro-Reveal detection of bovine serum albumin (BSA) spotted onto stainless steel surface



Perrett D et al *The in-situ detection of residual protein on surgical instruments: Development of the Pro-Reveal System.* Medical Device Decontamination 2014: vol 18

Results: Image and Interpretation

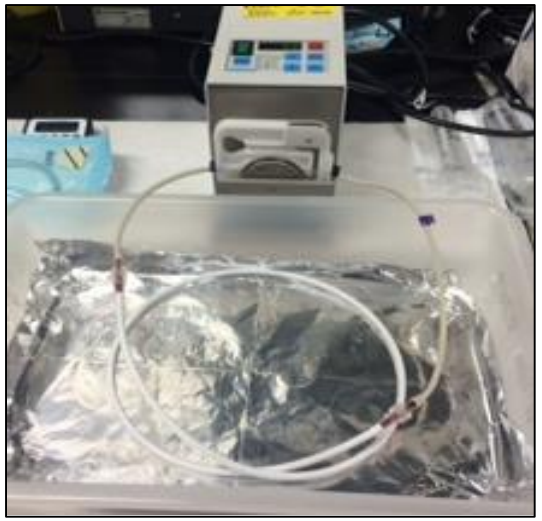


Cannot assess adequacy of cleaning inside lumens

http://www.synopticshealth.com/proreveal-test/

Can current duodenoscope MIFU reprocessing eliminate traditional biofilm?

PTFE Biofilm Model
(ISO 15883-2005 Annex F)

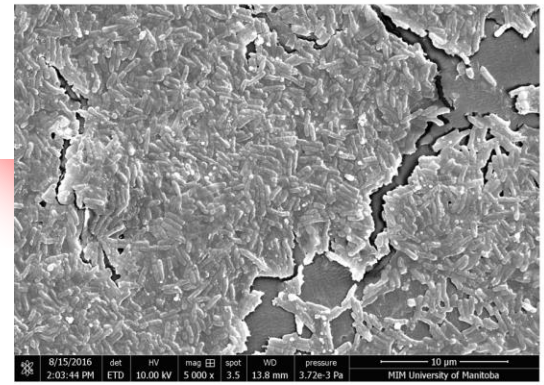


- Biofilm allowed to form overnight in PTFE channel
- MIFU pump-assisted cleaning combined with LCS performed
- Process repeated for 5 times (i.e. 5 consecutive days)
- Culture (concentration)and SEM to assess biofilm removal

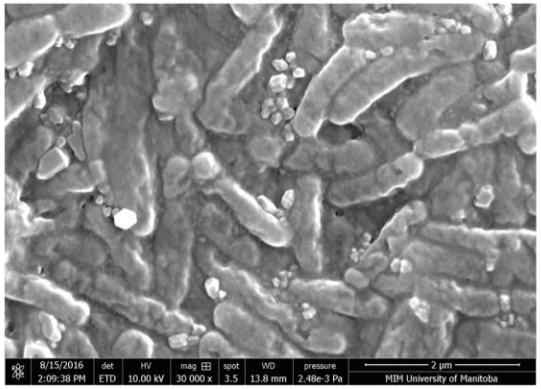
Five Repeated Rounds of Reprocessing

Test Condition	*E.faecalis* Log_{10} CFU/cm^2	*P.aeruginosa* Log_{10} CFU/cm^2	Protein ug/cm^2	ATP Log_{10} RLUs
1. **Positive control** No cleaning No AER	7.72 (0.09)	9.10 (0.09)	172.31 (13.30)	5.35 (0.04)

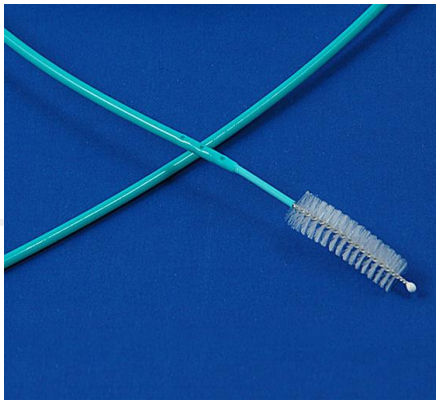
Alfa et al 2017 ICHE



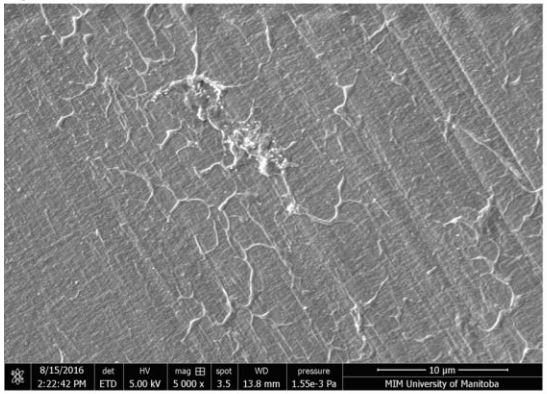
A) Positive control



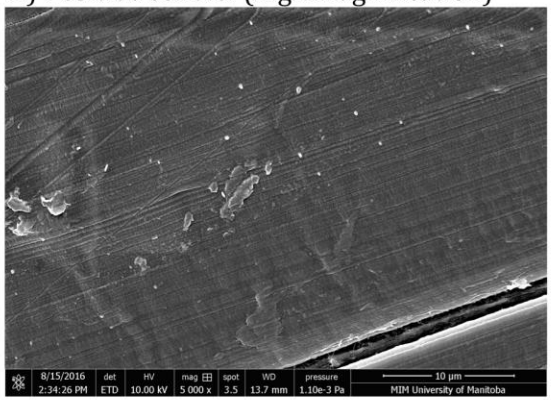
B) Positive control (high magnification)



Bristle brush



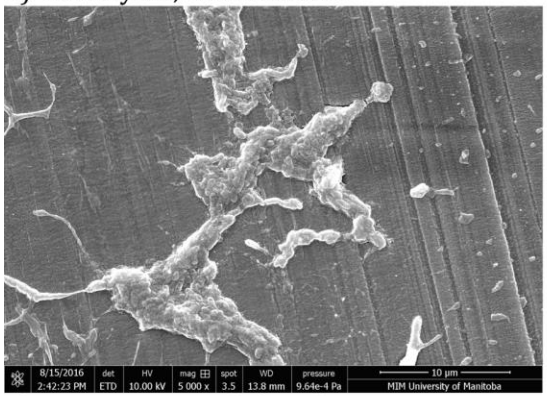
C) Renuzyme; Bristle brush



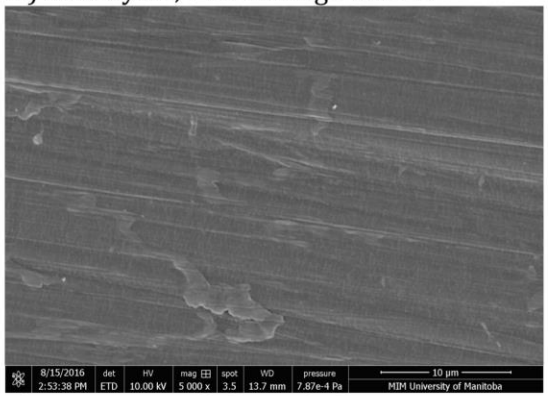
D) Renuzyme; Pull-through cleaner

Enzymatic detergent

Pull-through cleaner



E) Intercept: Bristle brush



F) Intercept: Pull-through cleaner

Non-Enzymatic detergent

Alfa et al 2017 ICHE

ATP Monitoring of Cleaning: flexible endoscopes

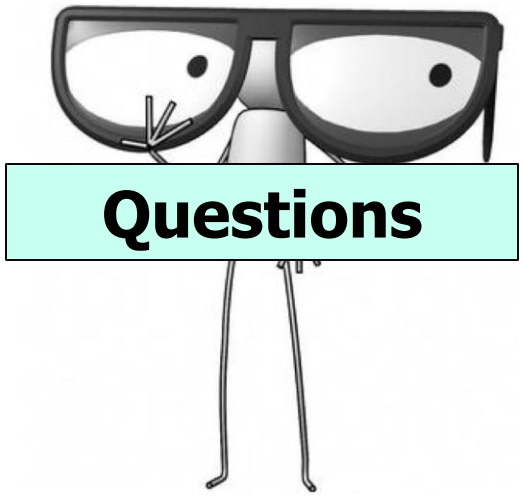
Stage of ATP Testing	RLU (Mean)	Number Tested
After bedside flush	19437	180
Post Manual Cleaning	667	176
Post-AER	227	180
Sterile water	7.8	173

The big advantage of the method is that it is done fast and results are obtained on-site so that instant conclusions can be drawn

Pharol N et al. Monitoring of endoscope reprocessing with an adenosine triphosphate (ATP) bioluminescence method. GMS Hygiene and Infection Control 2017, Vol. 12, ISSN 2196-5226

Quality Systems: Monitoring medical device cleaning

- What is the "benchmark" for "Clean"?
- What monitoring test to use?
- What is the best frequency of testing?
- How does it fit into busy work hospital work-flow?
- Is it sensitive enough?



Frequency of Monitoring??

Quality Assurance Program:
ANSI/AAMI ST79 & CSA Z314.8 recommend <u>weekly (preferably daily) monitoring</u> of mechanical washer cleaning efficacy

- ***Site implementation:***
  - Establish site baseline: initial daily testing of fragile instruments for a short period of time
  - Ongoing each testing minimally 1/week
- ***Published data needed:***
  - Comparisons of various cleaning monitors
  - Impact of monitoring on improving detection of inadequate manual cleaning

Stop Dirty Medical Devices at the Cleaning stage!!

- Once disinfected or sterilized residues are fixed → hard to extract and analyze.
- Fragile instruments: No validated rapid cleaning monitoring methods
- Needs more research

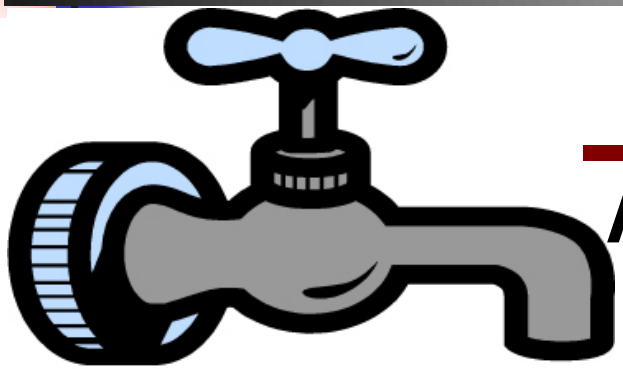
Monitoring tests need to be validated

- 2016 Bill in USA House of Representatives:
  - Cleaning monitoring tests will be regulated along with medical devices
- - Manufacturers need to validate cleaning monitoring tests

Is Monitoring Cleaning worthwhile???

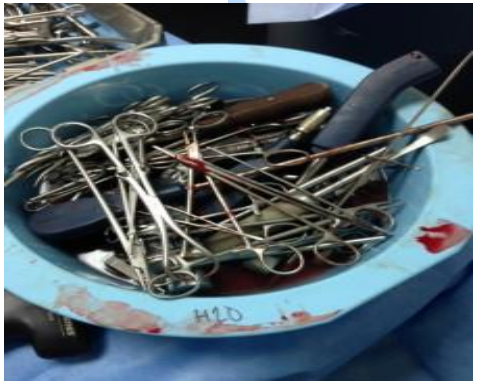
Monitoring of:	Methods:	Pros	Cons	Guidelines
Medical instruments	- ATP test - Organic residual - Pro-Reveal	- Ensures cleaning done properly - Good audit & training tool	- Cost - Staff time - Frequency of testing?	- Guidelines: variable

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

Immediate Need for Healthcare Facilities to Review Procedures for Cleaning, Disinfecting, and Sterilizing Reusable Medical Devices

This is an official CDC HEALTH ADVISORY
Distributed via the CDC Health Alert Network September 11, 2015, 12:15 EDT (12:15 PM EDT) CDCHAN-00382

Recommendations:

- Quality Systems approach
- Training & ongoing competency assessment of staff**
- Audit & Feedback
- Infection Control Policies and Procedures

Remember…. Protect yourself from the RISK!!