

Efficacy of Washer-Disinfector (WD) in Eliminating Healthcare-Associated Pathogens from Surgical Instruments

William A. Rutala, Ph.D., M.P.H., C.I.C

**Director, Statewide Program for Infection Control and Epidemiology
and Professor of Medicine, University of North Carolina at Chapel
Hill, NC, USA**

**Former Director, Hospital Epidemiology, Occupational Health and
Safety, UNC Health Care, Chapel Hill, NC (1979-2017)**

DISCLOSURES

2022-2023

- **Consultations-none related to surgical instrument reprocessing**
- **Consultations**
 - PDI (Professional Disposables International)
- **Honoraria**
 - PDI
- **Other**
 - Kinnos, Ideate Medical

Critical Medical/Surgical Devices

Rutala et al. ICHE 2014;35:883; Rutala et al. ICHE 2014;35:1068; Rutala et al. AJIC 2016;44:e47



- **Critical-enter sterile tissue**
 - Transmission: direct contact
 - Control measure: **sterilization**
 - **Surgical instruments**
 - Enormous margin of safety, 100 quadrillion, 10^{17} , rare outbreaks, if ever
 - ~85% of surgical instruments <100 microbes
 - Washer-disinfector removes or inactivates 10-100 million
 - Sterilization kills 1 trillion spores

Efficacy of Washer-Disinfector

Efficacy of Disinfection/Sterilization

Influencing Factors

Cleaning of the object

Organic and inorganic load present

Type and level of microbial contamination

Concentration of and exposure time to disinfectant/sterilant

Nature of the object

Temperature and relative humidity



Bioburden on Surgical Devices

Surgical Instruments Carry a Low Microbial Load (<100 CFU, 85%)

- Bioburden on instruments used in surgery (Nystrom, J Hosp Infect 1981)
 - 62% contaminated with $<10^1$
 - 82% contaminated with $<10^2$
 - 91% contaminated with $<10^3$
- Bioburden on surgical instruments (Rutala, Am J Infect Control 1997)
 - 72% contained $<10^1$
 - 86% contained $<10^2$
- Bioburden on surgical instruments (50) submitted to CP (Rutala, AJIC 2014)
 - 58% contained <10
 - 20% contained $\leq 10^2$
 - 16% contained $\leq 5 \times 10^2$
 - 6% contained $<10^3$

Efficacy of Washer-Disinfector

Background

- Reusable surgical instruments must be thoroughly cleaned in water with detergents or enzymatic products before sterilization
- Washer-disinfector reduces the microbial load and removes foreign material that interferes with sterilization
- In addition, washer-disinfector decontaminates the instruments and renders them safe to handle
- Although some studies have evaluated the cleaning of endoscopes and measured soil components (eg, protein, hemoglobin, carbohydrate, endotoxins, mo) on endoscopes, very few studies have evaluated the efficacy of a washer-disinfector

Purpose

- Test the efficacy of a washer-disinfector when medical and surgical instruments were contaminated with high numbers of microorganisms (10^7 - 10^8) on exposed and nonexposed surfaces and then subjected to a washer-disinfector process.
- Also disabled the enzymatic and detergent phases of the cycle to determine the effectiveness of the washer-disinfector in eliminating microorganisms in the absence of enzymes and detergents.



Washer-Disinfector

Rutala WA, Gergen MF, Weber DJ. ICHE 2014;35:883-885

- Five Chambers (Reliance 777 automated multichamber washer-disinfector was used). The programmed cycle included 5 phases.
 - **Pre-wash**: water/enzymatic is circulated over the load for 1 min
 - **Wash**: detergent wash solution (150°F) is sprayed over load for 4 min
 - **Ultrasonic cleaning**: basket is lowered into ultrasonic cleaning tank with detergent for 4 min
 - **Thermal and lubricant rinse**: hot water (180-200°F) is sprayed over load for 1 min; instrument milk lubricant is added to the water and is sprayed over the load
 - **Drying**: blower starts for 4 min and temperature in drying chamber at 180-240°F

Test Organisms

- VRE (vancomycin-resistant *Enterococcus*)
- MRSA (methicillin-resistant *S. aureus*)
- *P. aeruginosa*
- *Mycobacterium terrae*
- *Geobacillus stearothermophilus* spores

Inoculation of the Test Instruments

- Four instruments were inoculated with the test organisms:
 - Stille-Luer rongeur 
 - Kerrison rongeur 
 - Vaginal speculum 
 - Kocher clamp
- Instruments inoculated with 10µl of the test organisms
- Inocula placed on an exposed surface of the instrument and allowed to air dry in biological safety cabinet
- After drying, each instrument transported to CP and processed in WD

Quantitation of Test Organisms After WD

- After the washer-disinfector cycle was complete, the instruments were aseptically placed in peel packs for transport to the lab
- Each instrument was then immersed in sterile trypticase soy broth (300-400ml) and shaken on a clinical rotator for 1hr at 110rpm.
- After shaking, samples (10^{-1} , 10^{-2} dilutions) were collected for quantification of the test organisms
- The remaining amount of the sample was filtered
- All growth was quantitated and identified

Microbial Contamination of Nonexposed Area

- The second set of experiments were done identically, except that the **inocula were nonexposed** by placing in the hinged area of a surgical device (or the screw threads of the vaginal speculum)
- And then the **hinged instruments were closed** (normally open to allow contact with the detergent solution) or the **thumb screw of the vaginal speculum was tightened**.



Washer-Disinfector

Physical Removal/Thermal Inactivation of Inoculum (Exposed) on Instruments

Rutala WA, Gergen MF, Weber DJ. ICHE 2014;35:883-885

WD Conditions	Organism	Inoculum	Log Reduction	Positives
Routine	MRSA	2.6×10^7	Complete	0/8
Routine	VRE	2.6×10^7	Complete	0/8
Routine	<i>P aeruginosa</i>	2.1×10^7	Complete	0/8
Routine	<i>M terrae</i>	1.4×10^8 (8.1)	7.8	2/8
Routine	GS spores	5.3×10^6 (6.7)	4.8	11/14
No Enz/Det	VRE	2.5×10^7	Complete	0/10
No Enz/Det	GS spores	8.3×10^6 (6.9)	5.5	8/10



Washer-Disinfector

Physical Removal (P)/Thermal Inactivation (T) of Inoculum (Nonexposed) on Instruments
Rutala WA, Gergen MF, Weber DJ. ICHE 2014;35:883-885

WD Conditions	Organism	Inoculum	Log Reduction	Positives
Routine	MRSA	2.6×10^7	Complete (T)	0/8
Routine	VRE	2.9×10^7	Complete (T)	0/8
Routine	<i>P aeruginosa</i>	2.1×10^7	Complete (T)	0/8
Routine	<i>M terrae</i>	1.2×10^8	7.6 (T)	6/8
Routine	GS spores	8.1×10^6	~1 (no P/T)	12/12
No Enz/Det	VRE	2.4×10^7	Complete (T)	0/10
No Enz/Det	GS spores	8.7×10^6	1.6 (no P/T)	10/10

**Washer-disinfector was extremely effective (>7-
log₁₀ reduction) in eliminating contamination with
both exposed and nonexposed test bacteria
(MRSA, VRE, *P. aeruginosa* and *M. terrae*)**

The exposed *G. stearothermophilus* spores were substantially reduced (~5- $\log_{10}$ reduction), but the nonexposed or “hidden” spores were not eliminated.

Washer-disinfector remained effective in eliminating bacteria and spores in the absence of the detergent and enzymatic cleaner

Summary

- Inocula used far exceed the microbial load on used surgical instruments (<100 vs >10,000,000)
- Washer-disinfector extremely effective in eliminating/reducing high numbers of pathogenic bacteria and spores on stainless steel surgical instruments
- Disabling the WD by preventing the introduction of the detergent and enzymatic cleaner did not alter the effectiveness of the WD
- Crevices, hinges and covered surfaces protect the inocula from forced flow of liquids and inhibited elimination of spores

Summary

- *G. stearothermophilus* spores, which are relatively resistant to heat, survived the washer-disinfector process when not removed by fluidics and ultrasonic cleaning
- Thermal inactivation, fluids, and ultrasonic energy were more important than the cleaning agents in eliminating microorganisms, as effective elimination occurred in the absence of detergents and enzymatic cleaners

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THANK YOU!
www.disinfectionandsterilization.org



Cleaning Monitoring

- While cleaning is critical in eliminating microbial contamination from instruments, there are no FDA-cleared commercially available methods for rapid detection of soil components (e.g., protein level $<6.4\mu\text{g}/\text{cm}^2$) that can be used by hospitals to monitor cleaning effectiveness and shown to be clinically significant (e.g., interfere with the effectiveness of sterilization)