What's Trending in the SPD, Sterilization and High-Level Disinfection World

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DISCLOSURES

2023

- **Consultation, honoraria**
  - PDI (Professional Disposables International)
- **Consultation**
  - Kinnos, Ideate Medical

www.disinfectionandsterilization.org

Sources of Healthcare-Associated Pathogens

Weinstein RA. Am J Med 1991:91 (suppl 3B):179S

- Endogenous flora (SSI, UTI, CLABSI): ~40-60%
- Exogenous: ~20-40% (e.g., cross-infection via contaminated hands [staff, visitors])
- Other (environment): ≤20%
  - Medical devices
  - Contact with environmental surfaces (direct and indirect contact)

SPD, Sterilization and HLD

- Describe the Spaulding classification scheme for disinfection and sterilization of patient care items
- Describe available methods for high-level disinfection and sterilization and types of indicators used to ensure the process was effective
- Understand the current issues and new technologies in sterile processing department, sterilization and high-level disinfection

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CDC Guideline for Disinfection and Sterilization

Rutala, Weber, HICPAC. November 2008. www.cdc.gov; Rutala et al. AJIC 2019;47:A3-A9

Medical/Surgical Devices

WA Rutala, DJ Weber, and HICPAC, www.cdc.gov

EH Spaulding believed that how an object will be disinfected depended on the object's intended use (developed 1968).

CRITICAL-medical/surgical devices which enter normally **sterile tissue** or the vascular system or through which blood flows should be **sterile**.

SEMICRITICAL-medical devices that touch **mucous membranes** or skin that is not intact require a disinfection process (**high-level disinfection** [HLD]) that kills all microorganisms but high numbers of bacterial spores.

NONCRITICAL-medical devices that touch **only intact skin** require **low-level disinfection**.

Critical Medical/Surgical Devices

Rutala et al. ICHE 2014;35:883; Rutala et al. ICHE 2014;35:1068; Rutala et al. AJIC 2019;47:A3-A9

- Critical
  - Transmission: direct contact
  - Control measure: sterilization
  - Surgical instruments
    - Enormous margin of safety, rare outbreaks, if ever
    - ~85% of surgical instruments <100 microbes
    - Washer/disinfector removes or inactivates 10-100 million
    - Sterilization kills 1 trillion spores

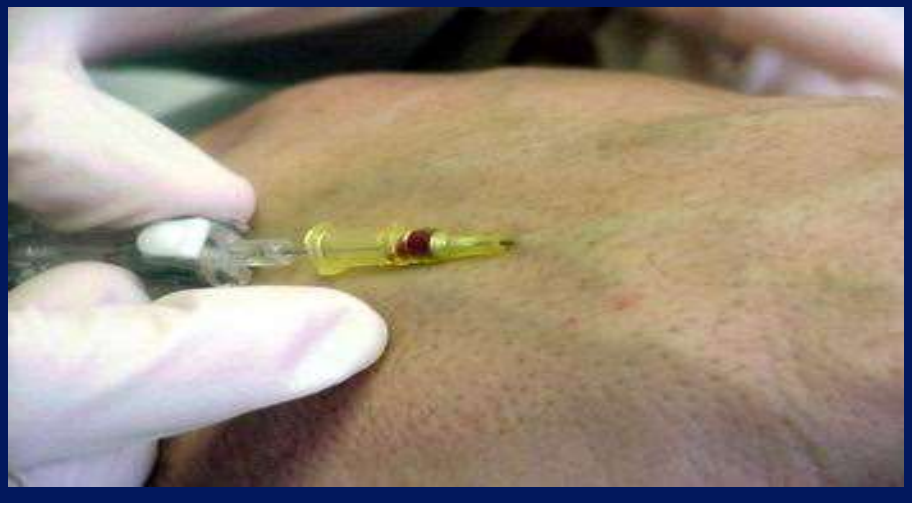
Semicritical Medical Devices

Rutala et al. Am J Infection Control (AJIC) 2019;47:A3-A9

- Semicritical
  - Transmission: direct contact
  - Control measure: high-level disinfection
  - Endoscopes top ECRI list of 10 technology hazards, >150 outbreaks (GI, bronchoscopes)
    - 0 margin of safety
      - Microbial load, 10^7-10^{10}
      - Complexity
      - Biofilm
  - Other semicritical devices, occasional outbreaks
    - ENT scopes, endocavitary probes (prostate, vaginal, TEE), laryngoscopes, cystoscopes
    - Reduced microbial load, less complex

Noncritical Environmental Surfaces and Medical Devices

Rutala et al. AJIC 2019;47:A3-A9; Rutala, Weber. Env Issues NI, Farber 1987



- Noncritical environmental surfaces and medical devices
- Transmission: secondary transmission by contaminating hands/gloves via contact with the environment and transfer to patient
- Control measures: hand hygiene and low-level disinfection
- Noncritical devices (stethoscopes, blood pressure cuffs, wound vacuum), rare outbreaks

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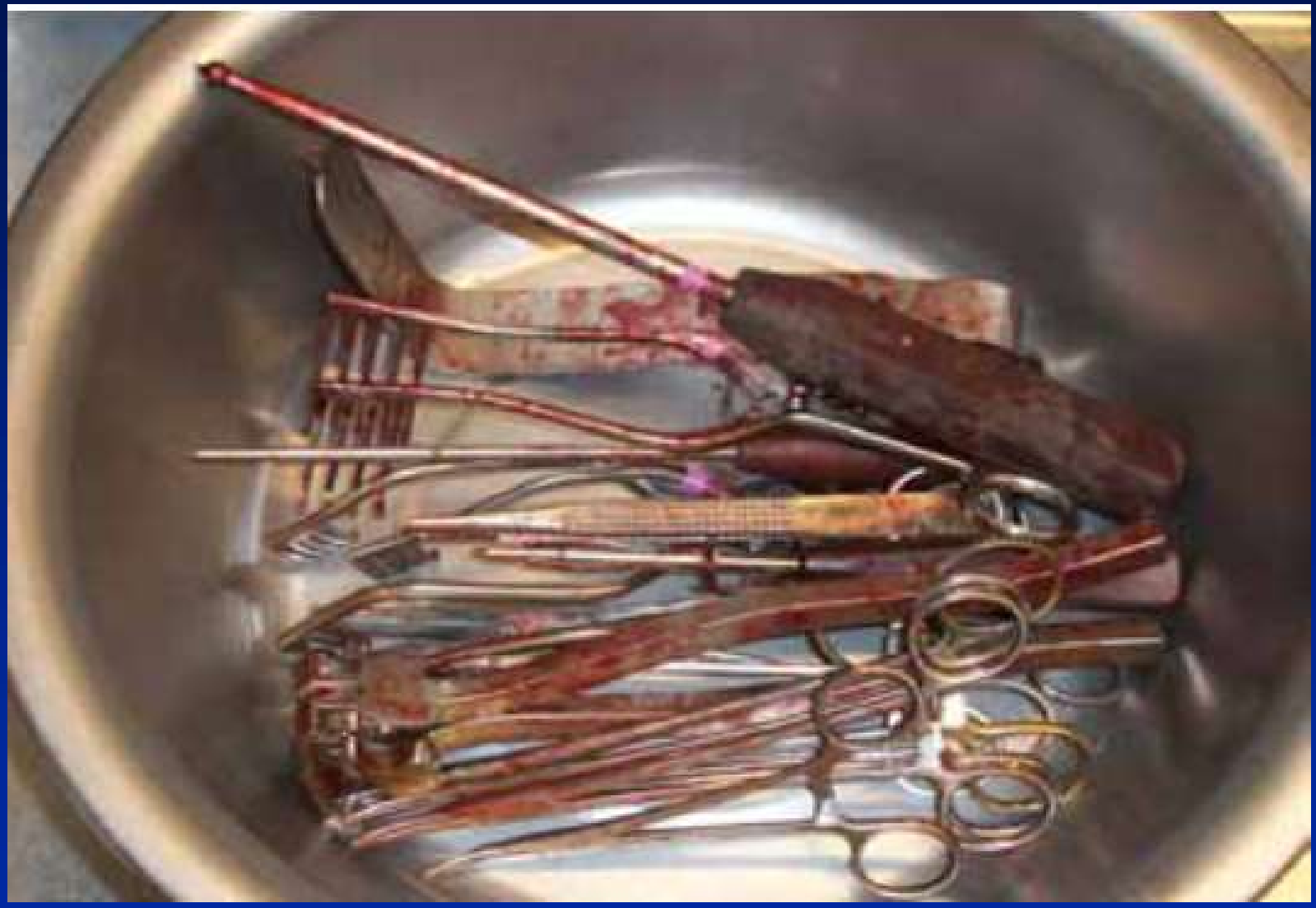
- Describe available methods for high-level disinfection and sterilization and types of indicators used to ensure the process was effective
- Understand the current issues and new technologies in sterile processing department, sterilization and high-level disinfection

Central Processing

- Goal
  - Orderly processing of medical and surgical instruments to protect patients from infections while minimizing risks to staff and preserving the value of the items being reprocessed
  - Ensure consistency of sterilization practices requires a comprehensive program that ensures operator competence and proper methods of cleaning and packaging instruments, loading the sterilizer, operating the sterilizer, and monitoring the entire process

Central Processing
Physical Facilities

- Facility ideally divided into three (or four) areas:
  - Decontamination-reusable items are received, sorted, and decontaminated; negative pressure; 10AC/hr. Personnel wear gloves when handling contaminated instruments; face masks, eye protection, and gowns/aprons when splashing may occur.
  - Packaging-used for inspecting, assembling, and packaging clean, but not sterile, material.
  - Sterilization and storage-limited access area with a controlled temperature and relative humidity.



Pre-Cleaning

- Surgical instruments are pre-cleaned in the OR. Ideally, instruments should arrive in Central Processing free on visible contamination
- To keep instruments wet from OR to CP, many hospitals spray instruments with an enzymatic solution
- Wipe instruments clean and keep lumens flushed throughout surgery. Soiled instruments that will not be reused should be allowed to soak in a basin of sterile water for the remainder of the procedures
- Keep instruments moist (e.g., damp towel) as it prevents hardening

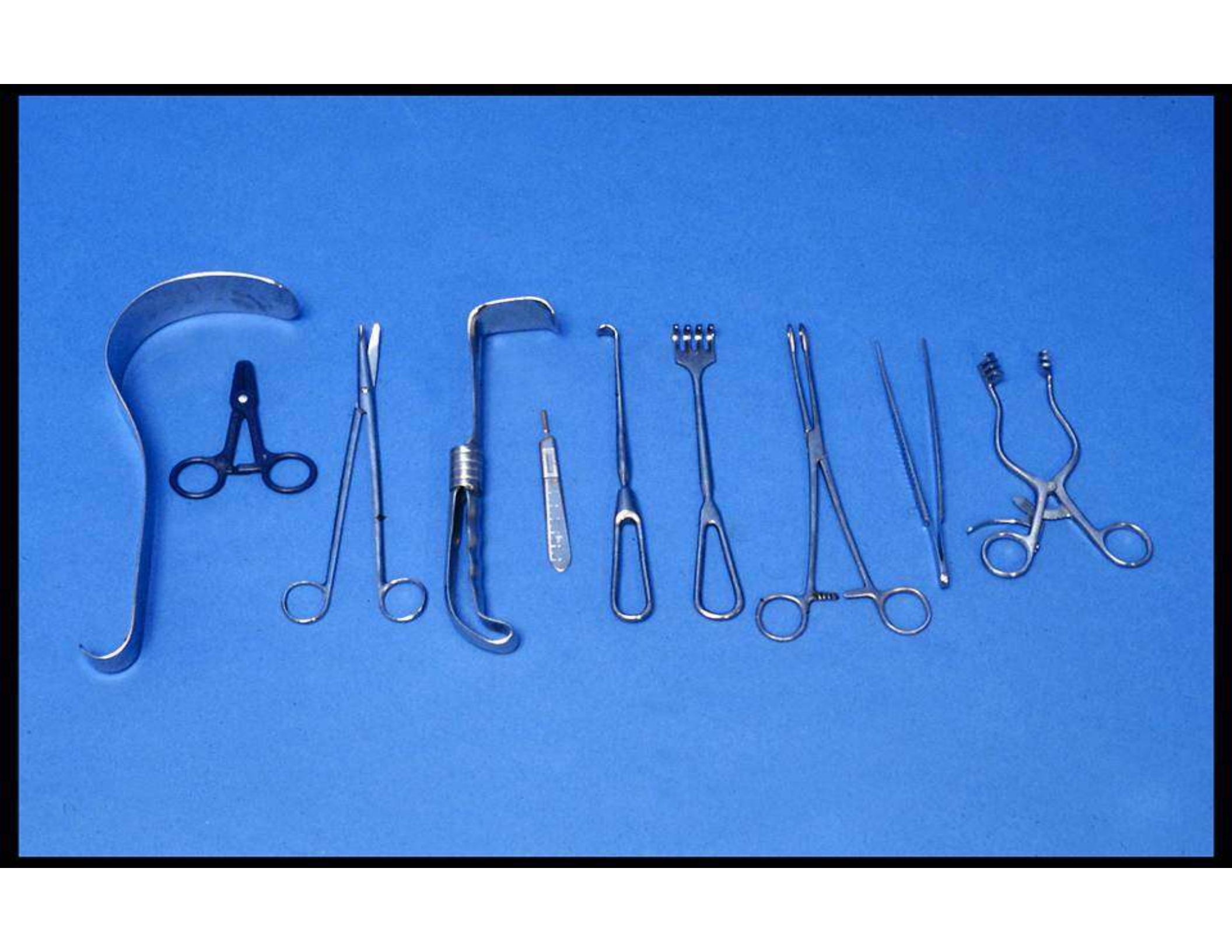
Cleaning

- Items must be cleaned using water with detergents or enzymatic cleaners before processing.
- Cleaning reduces the bioburden and removes foreign material (organic residue and inorganic salts) that interferes with the sterilization process.
- Cleaning and decontamination should be done as soon as possible after the items have been used as soiled materials become dried onto the instruments.

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 $\leq 5x10^2$
  - 6% contained $<10^3$

Cleaning

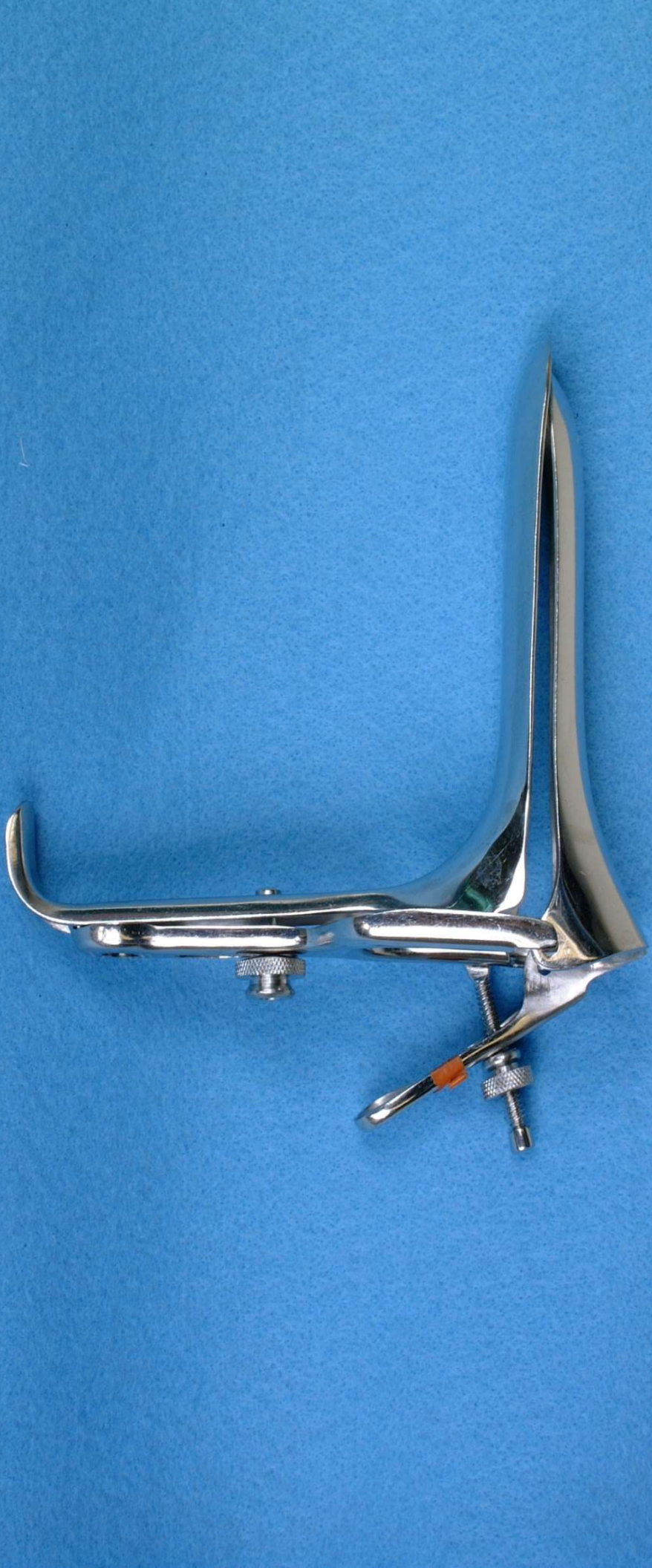
- Mechanical cleaning machines-automated equipment may increase productivity, improve cleaning effectiveness, and decrease worker exposure
  - Utensil washer-sanitizer
  - Ultrasonic cleaner
  - Washer sterilizer
  - Dishwasher
  - Washer disinfector
- Manual

Efficacy of Washer-Disinfector

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



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	$2.6x10^7$	Complete	0/8
Routine	VRE	$2.6x10^7$	Complete	0/8
Routine	*P aeruginosa*	$2.1x10^7$	Complete	0/8
Routine	*M terrae*	$1.4x10^8$ (8.1)	7.8	2/8
Routine	GS spores	$5.3x10^6$ (6.7)	4.8	11/14
No Enz/Det	VRE	$2.5x10^7$	Complete	0/10
No Enz/Det	GS spores	$8.3x10^6$ (6.9)	5.5	8/10

Washer-disinfector was extremely effective (>7-log_{10} reduction) in eliminating contamination with both exposed and nonexposed test bacteria (MRSA, VRE, *P. aeruginosa* and *M. terrae*)

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

Verifying Cleaning Processes

- AAMI recommends incorporating test methods that verify the functionality of the automated washer
- Washer indicators have been in use in Europe and Canada and some US hospitals
- Washer indicators are chemical indicators imprinted with a dried test soil formula and a dye.

Cleaning Indicators for Washer-Disinfectors

- Monitor the automated washer and instrument cleaning chemistry functionality
- Complete soil removal of the dried test soil pattern is a “pass”
- Indicator includes proteins, lipids, and polysaccharides to mimic common challenging test soils

IS THERE A STANDARD TO DEFINE WHEN A DEVICE IS CLEAN?

- There is currently no standard to define when a device is “clean”, cleanliness controlled by visual
- Potential methods: level of detectable bacteria; protein (6µg/cm^2) based on Bradford’s reagent or ninhydrin; endotoxin; ATP; lipid
- This is due in part to the fact that no universally accepted test soils to evaluate cleaning efficiency and no standard procedure for measuring cleaning efficiency
- At a minimum, a cleaning process should: reduce the natural bioburden; remove organic/inorganic contaminants; provide devices that when sterilized have a SAL 10^{-6}

Cleaning Verification Tests
AAMI Summit September 2023

- No cleaning verification products cleared by FDA
- Tests criteria-easy-to-perform (e.g., go-no go color change), rapid, sensitive, accurate, robust, relevant, not damaging
- Options:
  - Protein <6.4µg/cm^2
  - Carbohydrate <1.8µg/cm^2
  - Hemoglobin <2.2µg/cm^2

Critical Items
Sterilization

The complete elimination or destruction of all forms of microbial life and is accomplished in healthcare facilities by either physical or chemical processes

Sterilization of "Critical Objects"

Rutala, Weber, HICPAC. November 2008. www.cdc.gov; Rutala et al. AJIC 2019;47:A3-A9

Heat resistant

- Steam sterilization

Heat sensitive

- Ethylene oxide
- Hydrogen peroxide gas plasma
- Ozone and hydrogen peroxide
- Vaporized hydrogen peroxide

Steam Sterilization

Rutala, Weber AJIC 2019;47:A3-A9

- Advantages
  - Non-toxic
  - Cycle easy to control and monitor
  - Inexpensive
  - Rapidly microbicidal
  - Least affected by organic/inorganic soils
  - Rapid cycle time
  - Penetrates medical packing, device lumens
- Disadvantages
  - Deleterious for heat labile instruments
  - Potential for burns

Minimum Steam Sterilization Times

Time at 132°C in Prevacuum Sterilizer

Rutala, Weber, HICPAC. November 2008. www.cdc.gov

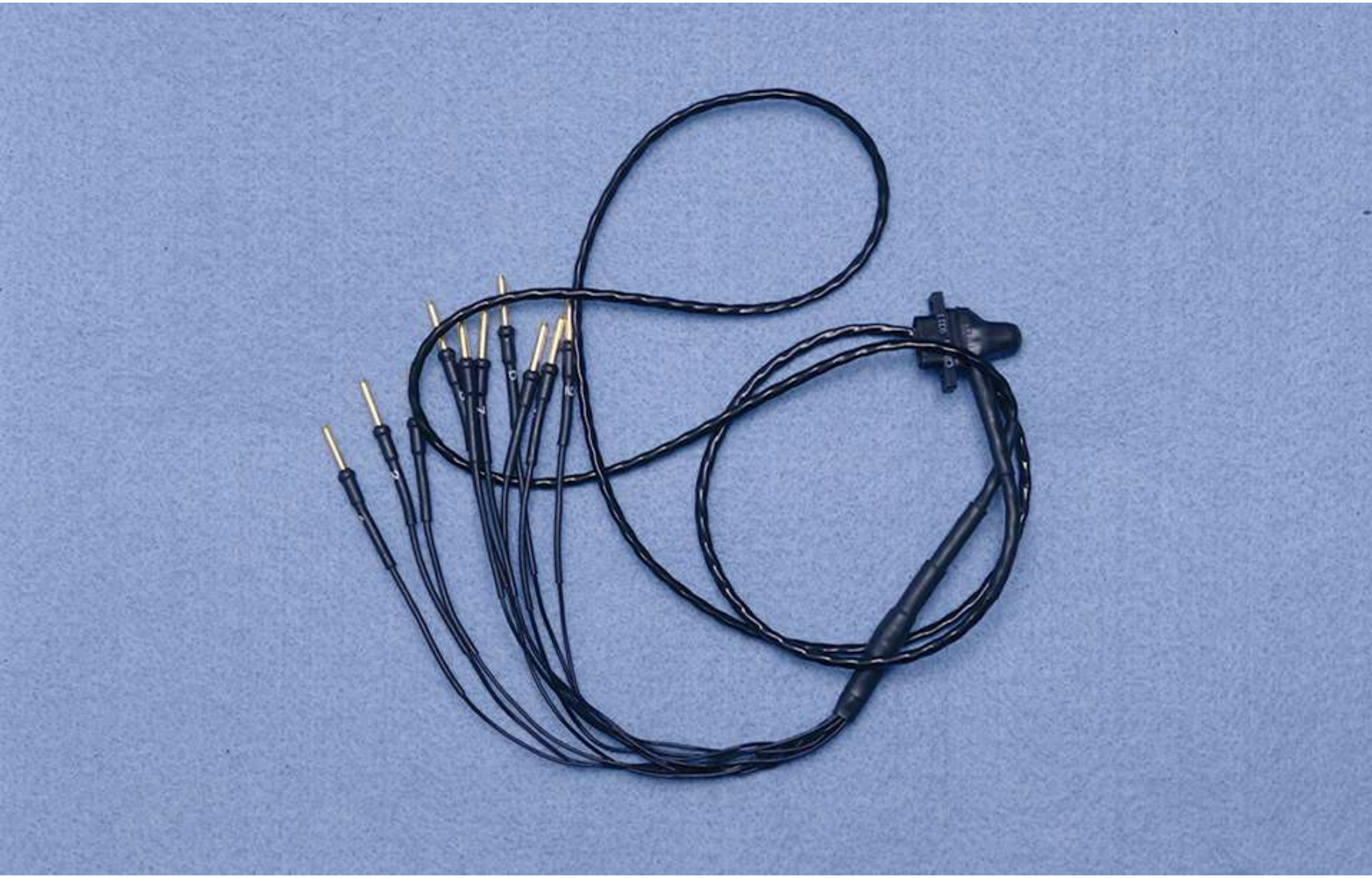
Item	Minimum exposure	Minimum drying time
Wrapped instruments	4 min	30 min
Textile packs	4 min	5 min

Immediate Use Steam Sterilization

- "Flash" originally defined as sterilization of an unwrapped object at 132°C for 3 min at 27-28 lbs pressure in gravity
- "Flash" used for items that must be used immediately and sterilized unpackaged (not sterile once removed from sterilizer)
- "Flash" is an antiquated term and replaced by "immediate use steam sterilization"

Immediate Use Steam Sterilization

- "Immediate Use" is defined as the shortest possible time between a sterilized item's removal from sterilizer and aseptic transfer to sterile field; now same time-temp (132°C, 4min)
- The same critical reprocessing steps (such as cleaning, decontaminating, and transporting) must be followed
- A sterilized item intended for immediate use is not stored for future use.
- Sterilization process monitoring is essential
- Instruments inventories should be adequate to meet surgical volumes and permit the time to complete all critical elements of reprocessing



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Heat sensitive

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- Hydrogen peroxide gas plasma
- Ozone and hydrogen peroxide
- Vaporized hydrogen peroxide

Ethylene Oxide (ETO)

Rutala, Weber AJIC 2016;44:e1-e6

- Advantages
  - Very effective at killing microorganisms
  - Penetrates medical packaging and many plastics
  - Compatible with most medical materials
  - Cycle easy to control and monitor
- Disadvantages
  - Some states require ETO emission reduction of 90-99.9%
  - Potential hazard to patients and staff
  - Lengthy cycle/aeration time

Vaporized Hydrogen Peroxide

Rutala, Weber AJIC 2016;44:e1-e6; Rutala, Weber AJIC 2019;47:A3-A9

- Advantages
  - Safe for the environment and health care worker; it leaves no toxic residuals
  - Fast - cycle time is 55 min and no aeration necessary
  - Used for heat and moisture sensitive items (metal and nonmetal devices)
- Disadvantages
  - Sterilization chamber is small, about 4.8ft^3
  - Medical devices restrictions based on lumen internal diameter and length-see manufacturer's recommendations, e.g., SS lumen 1mm diameter, 125mm length
  - Not used for liquid, linens, powders, or any cellulose materials
  - Requires synthetic packaging (polypropylene)
  - Limited use and limited comparative microbicidal efficacy data

Hydrogen Peroxide Gas Plasma Sterilization

Rutala, Weber AJIC 2016;44:e1-e6; Rutala, Weber AJIC 2019;47:A3-A9

Advantages

- Safe for the environment and health care worker; it leaves no toxic residuals
- Fast - cycle time is 28-52 min and no aeration necessary
- Used for heat and moisture sensitive items since process temperature 50°C
- Simple to operate, install, and monitor
- Compatible with most medical devices

Hydrogen Peroxide Gas Plasma Sterilization

Rutala, Weber AJIC 2016;44:e1-e6; Rutala, Weber AJIC 2019;47:A3-A9

Disadvantages

- Cellulose (paper), linens and liquids cannot be processed
- Sterilization chamber is small, about 3.5ft^3 to 7.3ft^3
- Endoscopes or medical devices restrictions based on lumen internal diameter and length (see manufacturer's recommendations); expanded claims with NX
- Requires synthetic packaging (polypropylene) and special container tray

Evaluation of Microbicidal Activities of Sterilization Technologies in Salt and Serum (simulate inadequate cleaning)

Rutala et al. Infect Control Hosp Epidemiol 2020 doi:10.1017/ice.2020.2

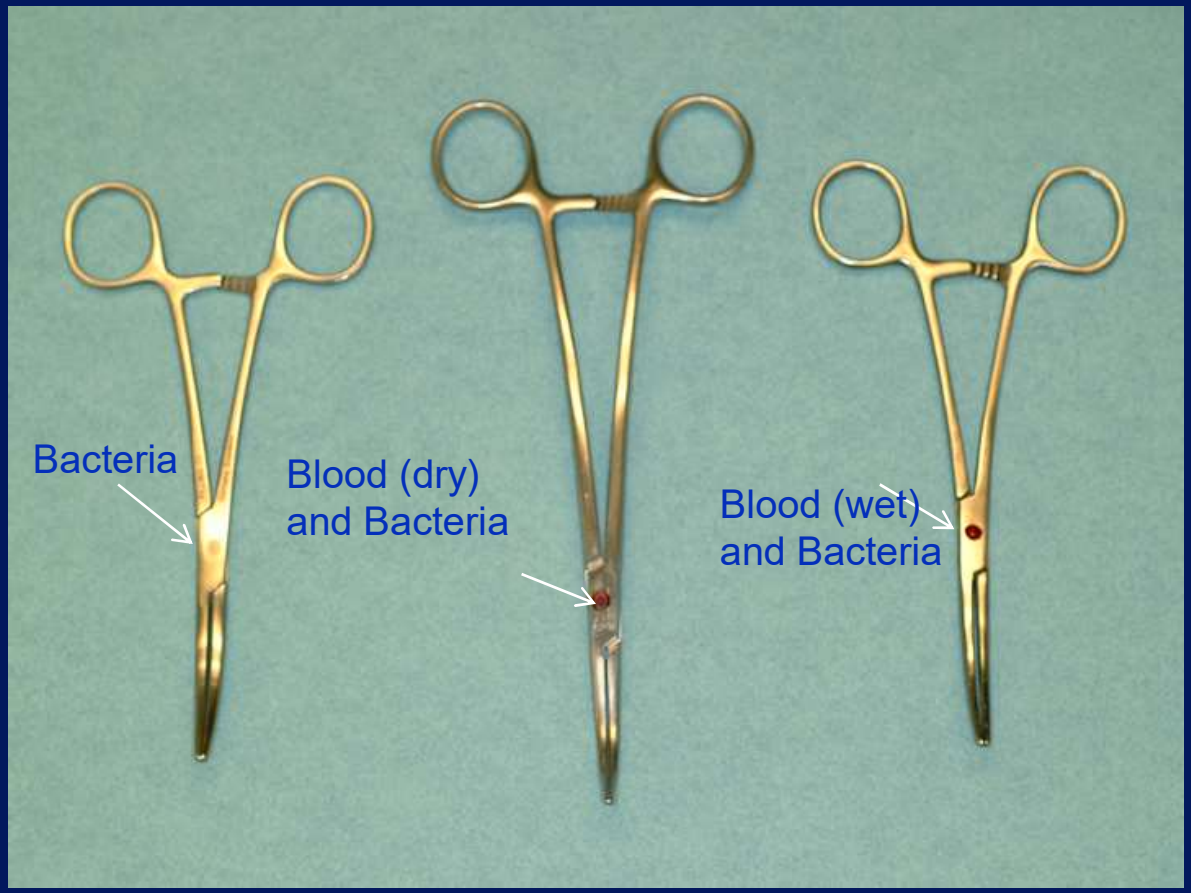
Organism	Mean Inoculating Suspension/mL	Mean Carrier Quantitation (Day of Run)	Mean Carrier Quantitation (24 h ETO)	% Failure (Carriers Positive/Carriers Tested)			
				Steam	ETO	HPGP	VHP
Vegetative cells							
Pseudomonas aeruginosa	8.1×10^8	2.0×10^6	3.5×10^4	0 (0/30)	0 (0/50)	0 (0/40)	13 (5/40)
Escherichia coli	1.1×10^9	3.4×10^6	5.1×10^5	0 (0/30)	4 (2/50)[b]	3 (1/40)[b]	75 (30/40)
Vanomycin-resistant enterococci	5.9×10^8	2.8×10^6	2.8×10^6	0 (0/30)	8 (4/50)[b]	10 (4/40)[b]	93 (37/40)
Staphylococcus aureus	4.8×10^8	2.3×10^6	2.5×10^6	0 (0/30)	0 (0/40)	0 (0/30)	93 (28/30)
Mycobacterium terrae	1.4×10^9	5.2×10^4	3.2×10^5	0 (0/20)	0 (0/30)	0 (0/30)	97 (29/30)
Vegetative cells, total				0 (0/140)	3 (6/220)	3 (5/180)	72 (129/180)
Bacillus atropheaus spores	1.5×10^7	1.2×10^5	1.3×10^5	0 (0/30)	0 (0/30)	0 (0/30)	83 (25/30)
Geobacillus stearothermophilus spores	5.4×10^6	5.1×10^4	6.0×10^4	0 (0/30)	0 (0/30)	0 (0/30)	73 (22/30)
Clostridiodes difficile spores	1.3×10^7	4.4×10^4	4.2×10^4	0 (0/20)	0 (0/30)	0 (0/30)	100 (30/30)
Spore total				0 (0/80)	0 (0/90)	0 (0/90)	86 (77/90)
Overall total				0 (0/220)	2 (6/310)	2 (5/270)	76 (206/270)

Note. ETO, ethylene oxide; HPGP, hydrogen peroxide gas plasma; FCS, fetal calf serum; ND, not done.

[a]To simulate inadequate cleaning, the inoculum for the vegetative bacteria contained 10% FCS and 0.65% salt but 10% FCS and 0.29% salt for the spores *B. atropheaus* and *G. stearothermophilus;* and 10% FCS and 0.52% salt *C. difficile* spores

[b]Runs with ETO and HPGP failure of vegetative bacteria had higher carrier quantitation (day of run) than the mean carrier quantitation for the other runs and that organism (ie, 4.07×10^6 vs 2.54×10^6 for VRE; 8.30×10^6 vs 2.40×10^6 for *E. coli*).

“Dirty” (non-cleaned) Instruments



Steam sterilization is the most effective sterilization technology with the largest margin of safety, followed by ETO and hydrogen peroxide gas plasma.

Table 1. Effectiveness of the Microbicidal Activity of Sterilization Technologies in the Presence of Blood on "Dirty" Instruments[a]

Test Organism	Method of Sterilization	Instruments "Dirty" (Uncleaned) With or Without Blood[b]	Instrument Quantitation (Mean)	No. of Positives/ No. of Runs (% Positive)
Geobacillus stearothermophilus (spores)	Steam Sterilization	Dirty	~ 1.56×10^5	0/10 (0)
		Dirty with blood (spores mixed with blood not sandwich[b])	~1.99×10^5	0/12 (0)
	ETO	Dirty	~1.53×10^5	0/10 (0)
		Dirty with blood	~2.35×10^5	0/11 (0)
	HPGP	Dirty	~1.58×10^5	5/10 (50)
		Dirty with blood	~2.35×10^5	9/15 (60)
Mycobacterium terrae	Steam Sterilization	Dirty	~4.25×10^6	0/10 (0)
P. aeruginosa	HPGP	Dirty	~1.81×106	3/15 (20)
Bacillus atrophaeus (spores)	ETO	Dirty	~ 2.30×10^7	6/10 (60)
		Dirty with blood	~4.08×10^7	9/10 (90)
MRSA	ETO	Dirty	~2.62×10^6	0/10 (0)
		Dirty with blood	~1.72×10^6	0/10 (0)
	HPGP	Dirty	~1.10×10^6	4/10 (40)
		Dirty with blood	~1.27×10^6	4/10 (40)
	Steam sterilization	Dirty	2.56×10^6	0/10 (0)
		Dirty with blood	5.20×10^5	0/10 (0)
VRE	ETO	Dirty	~2.27×10^6	0/10 (0)
		Dirty with blood	~3.59×10^6	0/10 (0)
	HPGP	Dirty	~2.63×10^6	3/10 (30)
		Dirty with blood	~2.34×10^6	9/10 (90)
	Steam sterilization	Dirty	1.90×10^6	0/10 (0)
		Dirty with blood	2.72×10^5	0/10 (0)

Note. ETO, ethylene
[a]Study conditions no
[b]Sandwich consists
experiment was don

rmophilus

Effectiveness of the Microbicidal Activity of Steam Sterilization in the Presence of Blood on "Dirty" Instruments

Rutala et al. Infect Cont Hosp Epidemiol 2021 https://doi.org/10.1017/ice.2021.202

Test Organism	Method of Sterilization	Instruments "dirty" (non-cleaned) with or without blood[2]	Instrument Quantitation (Mean)	% Positive
Geobacillus stearothermophilus (spores)	Steam Sterilization	Dirty	~ 1.56×10^5	0/10 (0)
		Dirty with blood (spores mixed with blood not sandwich[2])	~ 1.99×10^5	0/12 (0)
Mycobacterium terrae	Steam Sterilization	Dirty	~ 4.25×10^6	0/10 (0)

[1]Study conditions not representative of practice or manufacturer's recommendations.

[2]Sandwich consists of "dirty" or non-cleaned instrument, then an inoculum of spores or vegetative bacteria, and lastly overlaid with blood after inoculum dry. One *G. stearothermophilus* experiment was done with the spores mixed with the inoculum and then placed on the dirty instrument.

Conclusions

- All sterilization processes effective in killing spores
- Cleaning removes salts and proteins and must precede sterilization
- Failure to clean or ensure exposure of microorganisms to sterilant (e.g. connectors) could affect effectiveness of sterilization process

Sterilization Practices

Sterilization Monitoring

Rutala, Weber, CDC Guideline 2008. www.cdc.gov

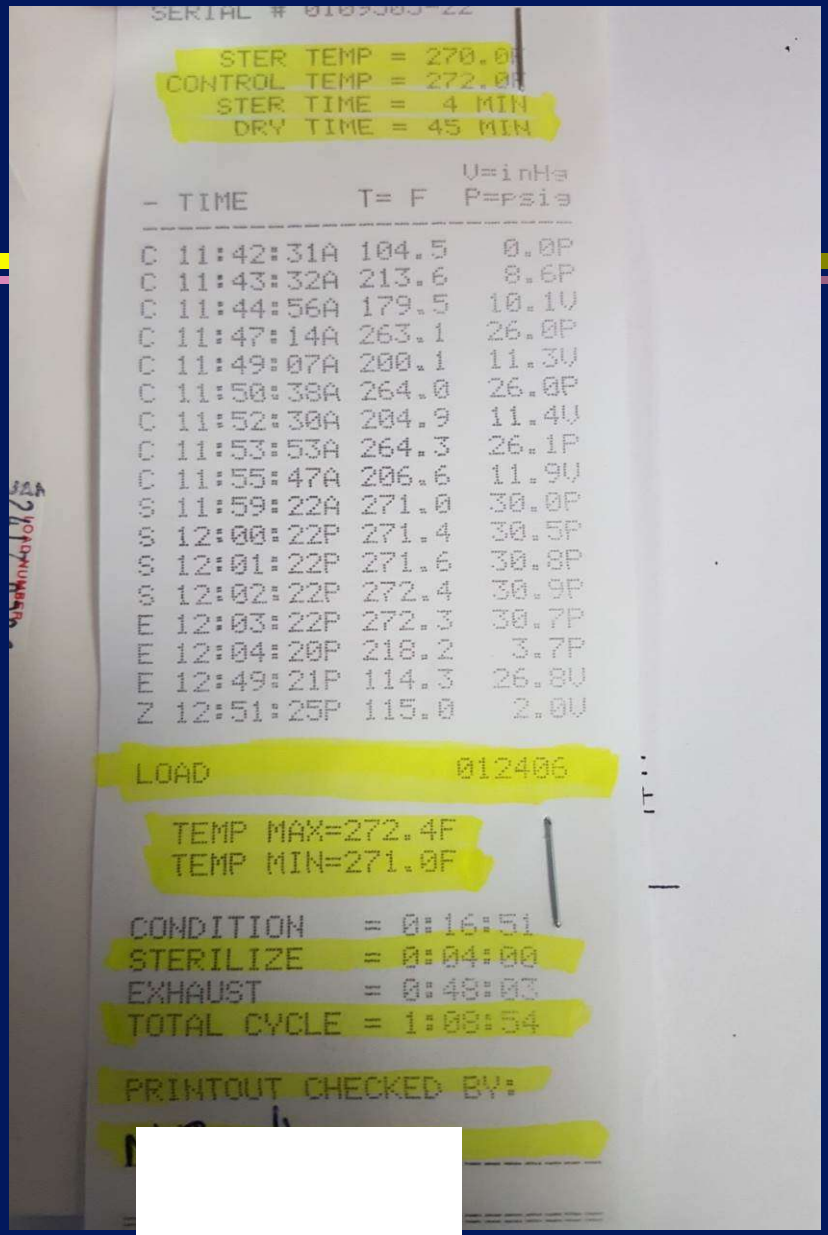
Sterilization monitored routinely by combination of physical, chemical, and biological parameters

- Physical - cycle time, temperature, pressure
- Chemical - heat or chemical sensitive inks that change color when germicidal-related parameters present
- Biological - *Bacillus* spores that directly measure sterilization

Objectives of Monitoring the Sterilization Process

- Assures probability of absence of all living organisms on medical devices being processed
- Detect failures as soon as possible
- Removes medical device involved in failures before patient use

Sterilizer Receipt



SERIAL # 0109383-22

STER TEMP = 270.0F
CONTROL TEMP = 272.0F
STER TIME = 4 MIN
DRY TIME = 45 MIN

-	TIME	T= F	V=inHg P=psig
C	11:42:31A	104.5	0.0P
C	11:43:32A	213.6	8.6P
C	11:44:56A	179.5	10.1V
C	11:47:14A	263.1	26.0P
C	11:49:07A	200.1	11.3V
C	11:50:38A	264.0	26.0P
C	11:52:30A	204.9	11.4V
C	11:53:53A	264.3	26.1P
C	11:55:47A	206.6	11.9V
S	11:59:22A	271.0	30.0P
S	12:00:22P	271.4	30.5P
S	12:01:22P	271.6	30.8P
S	12:02:22P	272.4	30.9P
E	12:03:22P	272.3	30.7P
E	12:04:20P	218.2	3.7P
E	12:49:21P	114.3	26.8V
Z	12:51:25P	115.0	2.0V

LOAD 012406

TEMP MAX=272.4F
TEMP MIN=271.0F

CONDITION = 0:16:51
STERILIZE = 0:04:00
EXHAUST = 0:48:03
TOTAL CYCLE = 1:08:54

PRINTOUT CHECKED BY:

Six Classes of Indicators Are Recognized by International Organization of Standards (ISO)

Table 2. Chemical Indicator Classifications

Class I Process indicators	Process indicators are attached to or printed on the outside of all packs to discern which packages have been processed from those that have not been processed in a sterilizer.
Class 2 Bowie-Dick test	The Bowie-Dick test is used to reveal the pass/fail rate in dynamic air removal steam sterilizers. This Class 2 chemical indicator should be used in an empty chamber daily, preferably before any loads are processed at the beginning of the day.
Class 3 Single parameter indicator	The single parameter chemical indicator is placed inside each package and provides data on time or temperature, revealing if one of these sterilization parameters has been met during a cycle.
Class 4 Multi-parameter indicators	Multiparameter indicators react to two or more sterilization parameters, such as time and temperature or time and pressure.
Class 5 Integrating indicators	React to all critical parameters of sterilization cycle over a range of temperatures; performance must equal that of the biological indicators.
Class 6 Emulating indicators	Cycle specific; react to all critical parameters for a specified sterilization level; used at the pack/tray level.

Dimensions of Dental Hygiene, March 2009

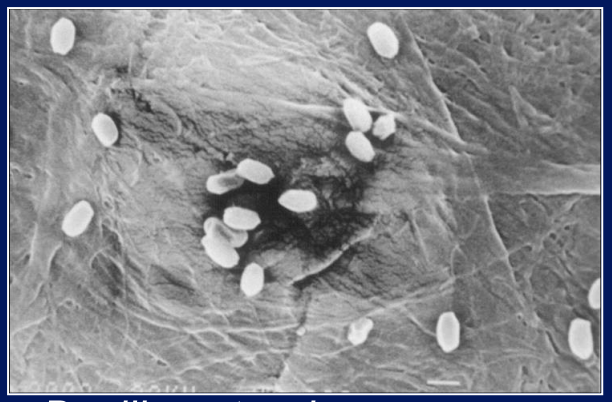
Sterilility Indicators Table

	Before Exposure (Do not use)	After Exposure (Sterile) (Ok if package is intact)
Steam Autoclave		
Tape		
Strip		
Peel Pack		
Ethylene Oxide (ETO. gas)		
Tape		


OCT 0411 0101
LOAD NUMBER
STERILIZED ST
INDEFINITE SHELF LIFE UNLESS DAMAGED OR OPENED
Date
Ster. No.:
Init.:
PREVAC
START AT 12:00:33A
ON 10/04/11
COUNT 10513
STERILIZER VAC 01
SERIAL # 0322706-07
STER TEMP = 270.0F
CONTROL TEMP = 272.0F
STER TIME = 4 MIN
DRY TIME = 1 MIN
V=inHg
TIME T= F P=psig
C 12:00:55A 126.5 1.1P
C 12:02:26A 240.2 17.2P
C 12:03:53A 173.7 13.9V
C 12:04:40A 270.9 26.1P
C 12:06:14A 164.5 17.4V
C 12:07:18A 269.1 26.3P
C 12:08:52A 164.8 18.6V
C 12:09:58A 269.4 26.1P
C 12:11:30A 186.2 18.1V
S 12:20:51A 270.0 29.9P
S 12:21:51A 271.9 31.0P
S 12:22:51A 273.0 31.5P
S 12:23:51A 272.8 31.1P
S 12:24:51A 272.4 30.9P
E 12:25:29A 219.2 3.5P
E 12:26:30A 164.9 17.8V
Z 12:27:52A 160.6 2.0V
LOAD 100401
TEMP MAX=273.2F
TEMP MIN=270.0F
CONDITION =19:56
STERILIZE = 4:00
EXHAUST = 3:01
TOTAL CYCLE =26:57
PRINTOUT CHECKED BY:

Biological Indicators

- **Select BIs that contain spores of *Bacillus atrophaeus***
  - Rationale: BIs are the only sterilization process monitoring device that provides a direct measure of the lethality of the process



Bacillus atrophaeus

Biological Monitors

Rutala, Weber, CDC Guideline 2008. www.cdc.gov

- Steam - *Geobacillus stearothermophilus*
- Dry heat - *B. atrophaeus (formerly B. subtilis)*
- ETO - *B. atrophaeus*
- New low temperature sterilization technologies
  - HP gas plasma - *G. stearothermophilus*
  - HP/Ozone -*G. stearothermophilus*
  - VHP- *G. stearothermophilus*

Rapid Readout BIs for Steam Now Require a 1-3h Readout Compared to 24-48h

Rutala, Jones, Weber ICHE 1996. 17:423

Vol. 17 No. 7 INFECTION CONTROL AND HOSPITAL EPIDEMIOLOGY 423

COMPARISON OF A RAPID READOUT BIOLOGICAL INDICATOR FOR STEAM STERILIZATION WITH FOUR CONVENTIONAL BIOLOGICAL INDICATORS AND FIVE CHEMICAL INDICATORS

William A. Rutala, PhD, MPH; Suzanne M. Jones, MPH; David J. Weber, MD, MPH

Super Rapid Readout Biological Indicators

Commercially available

1491 BI (blue cap)

- Monitors 270°F and 275°F gravity –displacement steam sterilization cycles
- 24-minute result

1492V BI (brown cap)

- Monitors 270°F and 275°F dynamic-air-removal (pre-vacuum, SFPP-steam flush pressure pulse) steam sterilization cycles
- 24-minute result

Rapid (or Super Rapid) Readout Biological Indicator for Steam (20m-24m), ETO (4hr) and HP Sterilizers (variable)

Vaporized Hydrogen Peroxide (VHP) Biological Indicator Options (*all G. stearothermophilus*)

Refer to BI manufacturer's IFU for cycles the BI is cleared for

VHP read out time	Number of cleared biological indicators
2 hours	1
30 minutes	2
24 minutes	1
20 minutes	1
15 minutes	1

Recommendations
Monitoring of Sterilizers
Rutala, Weber, CDC Guideline 2008. www.cdc.gov

- Monitor each load with physical and chemical (internal and external) indicators.
- Use biological indicators to monitor effectiveness of sterilizers at least weekly with spores intended for the type of sterilizer.
- Use biological indicators for every load containing implantable items

Recommendations
Monitoring of Sterilizers
Rutala, Weber, CDC Guideline 2008. www.cdc.gov

- Following a single positive biological indicator used with a method other than steam, treat as non-sterile all items that have been processed in that sterilizer, dating back to last negative biological indicator.
- Following a positive biological indicator with steam sterilization, objects, other than implantable objects, do not need to be recalled because of a single positive spore test unless the sterilizer or procedure is defective or inappropriate cycle settings. If additional spore tests remain positive, consider the items nonsterile and recall and reprocess the items from the suspect load.

Recommendations
Methods of Sterilization
Rutala, Weber, CDC Guideline 2008. www.cdc.gov

- Steam is preferred for critical items not damaged by heat
- Follow the operating parameters recommended by the manufacturer
- Use low temperature sterilization technologies for reprocessing critical items damaged by heat
- Use immediately critical items that have been sterilized by peracetic acid immersion process (no long term storage)

Sterilization and Disinfection

- Describe the Spaulding classification scheme for disinfection and sterilization of patient care items
- Describe available methods for high-level disinfection and sterilization and types of indicators used to ensure the process was effective
- Understand the current issues and new technologies in sterile processing department, sterilization and high-level disinfection

Semicritical Medical Devices

Rutala et al. AJIC 2019;47:A3-A9

- Semicritical
  - Transmission: direct contact
  - Control measure: high-level disinfection
  - Endoscopes top ECRI list of 10 technology hazards, >150 outbreaks (GI, bronchoscopes)
    - 0 margin of safety
      - Microbial load, 10^7-10^{10}
      - Complexity
      - Biofilm
  - Other semicritical devices, rare outbreaks
    - ENT scopes, endocavitary probes (prostate, vaginal, TEE), laryngoscopes, cystoscopes
    - Reduced microbial load, less complex

High-Level Disinfection of "Semicritical Objects"

Rutala, Weber. AJIC 2019;47:A3-A9

Germicide	Exposure Time ≥ 8m-45m (US), 20°C Concentration
Glutaraldehyde	≥ 2.0%
Ortho-phthalaldehyde	0.55%
Hydrogen peroxide*	7.5%
Hydrogen peroxide and peracetic acid*	1.0%/0.08%
Hydrogen peroxide and peracetic acid*	7.5%/0.23%
Hypochlorite (free chlorine)*	650-675 ppm
Accelerated hydrogen peroxide	2.0%
Peracetic acid	0.2%
Glut and isopropanol	3.4%/26%
Glut and phenol/phenate**	1.21%/1.93%

*May cause cosmetic and functional damage; **efficacy not verified

Microbiological Disinfectant Hierarchy

Rutala WA, Weber DJ, HICPAC. www.cdc.gov

Most Resistant

Spores (*C. difficile*)

Mycobacteria (*M. tuberculosis*)

Non-Enveloped Viruses (norovirus, HAV, polio)

Fungi (Candida, *Trichophyton*)

Bacteria (MRSA, VRE, *Acinetobacter*)

Enveloped Viruses (HIV, HSV, Flu)

Most Susceptible

HLD

Comparison of Glutaraldehyde and OPA

Rutala, Weber. AJIC 2019;47:A3-A9

>2.0% Glutaraldehyde

- HLD: 45 min at 25°C
- Needs activator
- 14-day use life, 2-year shelf life
- ACGIH ceiling limit, 0.05ppm
- Strong odor
- MEC, 1.5%
- Cost - $10/gallon
- Disadv-slow mycobactericidal acttivity

0.55% Ortho-phthalaldehyde

- HLD: 12 min at 20°C
- No activator needed
- 14-day use life, 2-year shelf life
- No ACGIH or OSHA limit
- Weak odor
- MEC, 0.3%
- Cost - $30/gallon
- Disadv-Anaphylactic rxn w/ repeated exposure through cysto

Improved Hydrogen Peroxide

Rutala, Weber. AJIC 2019;47:A3-A9

- Advantages
  - No activation required
  - Enhanced removal of organisms
  - No disposal issues
  - No odor or irritation issues
  - No special venting requirements
  - Does not coagulate blood or fix tissues to surfaces
  - Use studies published
  - 8-min at 20^{o}C HLD claim
- Disadvantages
  - Material compatibility concerns for brass, zinc, copper, and nickel/silver plating (cosmetic and functional damage)
  - Eye damage with contact

Peracetic Acid

Rutala, Weber. AJIC 2019;47:A3-A9

- Advantages
  - Enhanced removal of organisms
  - Single-use system eliminates need for concentration testing
  - Compatible with many materials and instruments
  - Does not coagulate blood or fix tissues to surfaces
  - Rapidly sporicidal
- Disadvantages
  - Used for immersible instruments only
  - More expensive than many HLD
  - Eye damage with contact
  - Potential material incompatibility (e.g., aluminum anodized coating becomes dull)

Infections/Outbreaks Associated with Semicritical Medical Devices

Rutala, Weber. Am J Infect Control. Rutala WA, Weber DJ. Am J Infect Control. 2019 Jun;47S:A79-A89.

- HBV and HCV transmission during endoscopy and use of semicritical medical devices can occur, but it is rare (3)
- No articles related to possible transmission of HIV via medical device
- Greatest evidence of transmission associated with GI endoscopes/bronchoscopes(~130 outbreaks) likely due to microbial load and complexity.
- Several other semicritical medical devices are associated with infections related to inadequate reprocessing

Table 2
Infections and outbreaks associated with semicritical medical devices*

Instruments	# Outbreaks/ Infections	# Outbreaks/ Infections with bloodborne pathogens
Vaginal probes	0**	0
Nasal endoscopes	0	0
Hysteroscopes	0	0
Laryngoscopes	2[43-45]	0
Urologic instrumentation (eg, cystoscopes, ureteroscopes)	8[46-53]	0
Transrectal-ultrasound guided prostate probes	1[40]	0
Transesophageal echocardiogram	5[31,54-57]	0
Applanation tonometers	2[41,42]	
GI endoscopes/bronchoscopes	~130[7,8]	3 HBV[34]; HCV[35,38]

GI, gastrointestinal; *HBV*, hepatitis B virus; *HCV*, hepatitis C virus.
*These infections/outbreaks were found in the peer-review literature through PubMed and Google.
**Does not include outbreaks associated with contaminated ultrasound gel used with vaginal probes or transmission via health care personnel.

Transition from HLD to Sterilization

High-Level Disinfection
No Margin of Safety

0 margin of safety

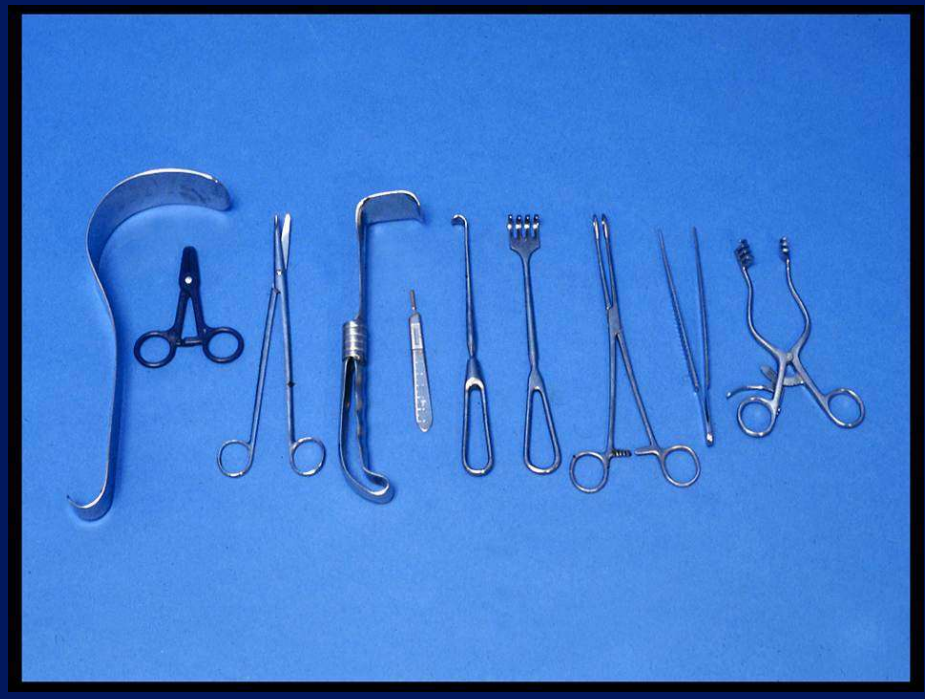
Microbial contamination 10^7-10^{10}: compliant with reprocessing guidelines 10,000 microbes after reprocessing:

maximum contamination, minimal cleaning (10^2)/HLD (10^4)

ENDOSCOPE REPROCESSING: CHALLENGES

Complex [elevator channel]-10^{7-10} bacteria/endoscope

Surgical instruments-$<10^{2}$ bacteria



What Is the Public Health Benefit?
No ERCP-Related Infections

Margin of Safety-currently nonexistent; sterilization will provide a safety margin (~6 $\log_{10}$). To prevent infections, all duodenoscopes should be devoid of microbial contamination.

HLD (≥6 $\log_{10}$ reduction bacteria)

vs

Sterilization (12 $\log_{10}$ reduction spores=SAL 10^{-6})

Reason for Endoscope-Related Outbreaks

Rutala WA, Weber DJ. Infect Control Hosp Epidemiol 2015;36:643-648

- Margin of safety with endoscope reprocessing minimal or non-existent
- Microbial load
  - GI endoscopes contain 7-10 $\log_{10}$ ($10^{7\text{-}10}$)
  - Cleaning results in 2-6 $\log_{10}$ reduction
  - High-level disinfection results in 4-6 $\log_{10}$ reduction
  - Results in a total 6-12 $\log_{10}$ reduction of microbes
  - Level of contamination after processing: 4 $\log_{10}$ (maximum contamination, minimal cleaning/HLD)
- Complexity of endoscope and endoscope reprocessing
- Biofilms-may contribute to failure of endoscope reprocessing

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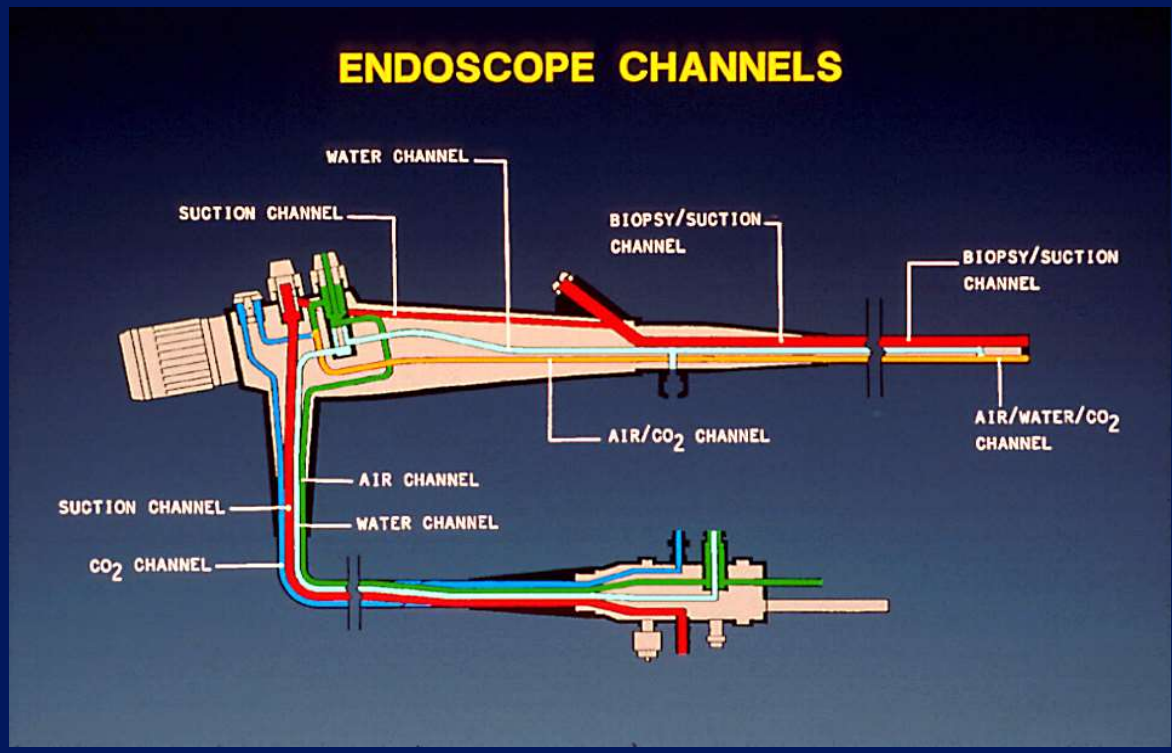
  - Level of contamination after processing: $4\log_{10}$ (maximum contamination, minimal cleaning/HLD)
- Complexity of endoscope and endoscope reprocessing
- Biofilms-may contribute to failure of endoscope reprocessing

FEATURES OF ENDOSCOPES THAT PREDISPOSE TO DISINFECTION FAILURES

Rutala WA, Weber DJ. Infect Control Hosp Epidemiol 2015;36:643-648

- Heat labile
- Long, narrow lumens (3.5ft, 1-3mm)
- Right angle bends
- Rough or pitted surfaces
- Springs and valves
- Damaged channels may impede microbial exposure to HLD
- Heavily contaminated with pathogens, $10^{7\text{-}10}$
- Cleaning (2-6 $\log_{10}$ reduction) and HLD (4-6 $\log_{10}$ reduction) essential for patient safe instrument



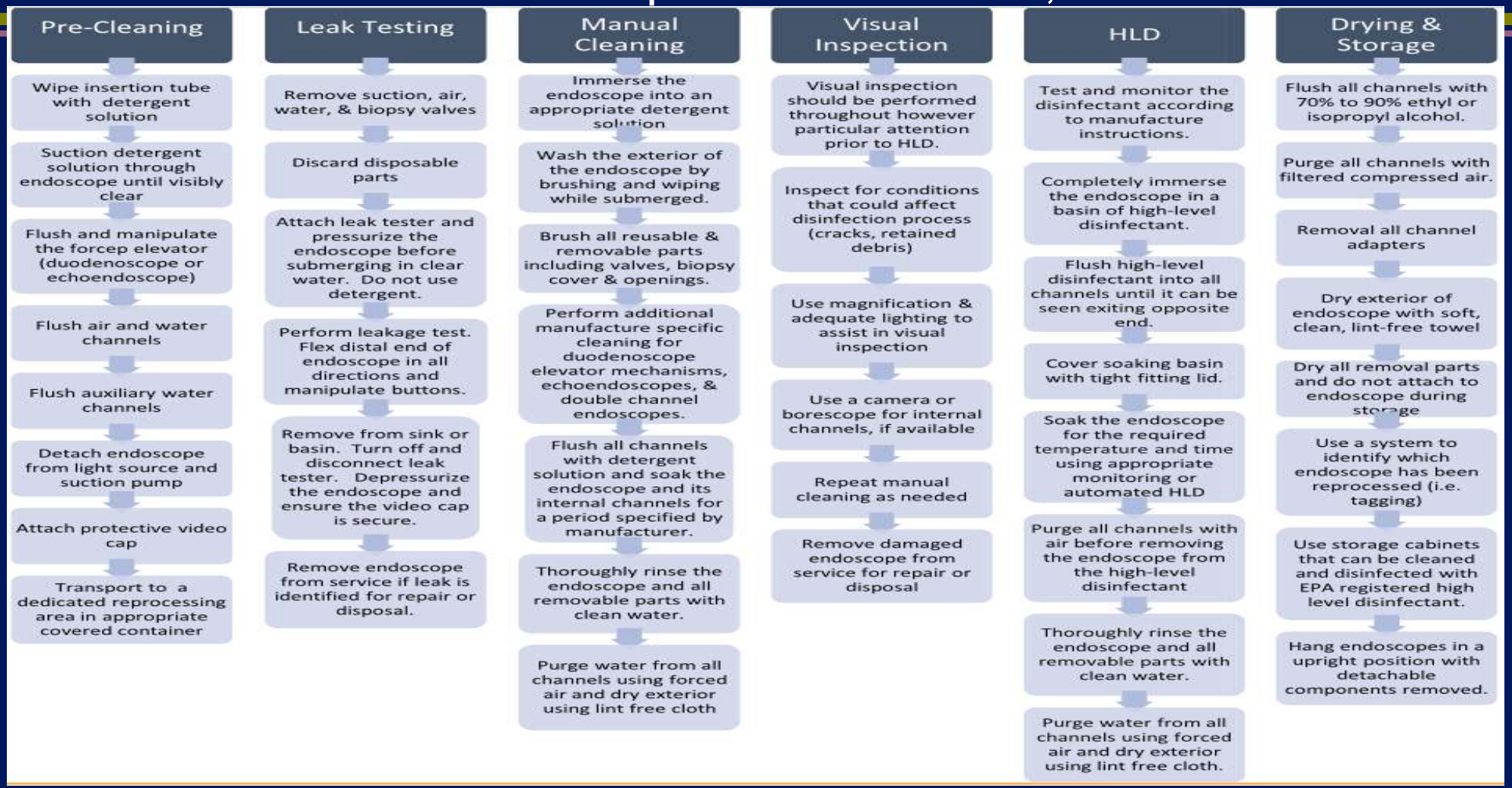
ENDOSCOPE REPROCESSING

CDC 2008: Multi-Society Guideline on Endoscope Reprocessing, 2021

- **PRECLEAN**-point-of-use (bedside) remove debris by wiping exterior and aspiration of detergent through air/water and biopsy channels; leak test
- **CLEAN-mechanically cleaned with water and enzymatic cleaner**
- **HLD/STERILIZE-immerse scope and perfuse HLD/sterilant through all channels for exposure time (>2% glut at 20m at 20°C).** If AER used, review model-specific reprocessing protocols from both the endoscope and AER manufacturer
- **RINSE-scope and channels rinsed with sterile water, filtered water, or tap water.** Flush channels with alcohol and dry
- **DRY-use forced air to dry insertion tube and channels**
- **STORE**-hang in vertical position to facilitate drying; stored in a manner to protect from contamination

Complexity of Endoscope Reprocessing

Chua et al. Techniq Innov Gastro Endo 2021;23:190



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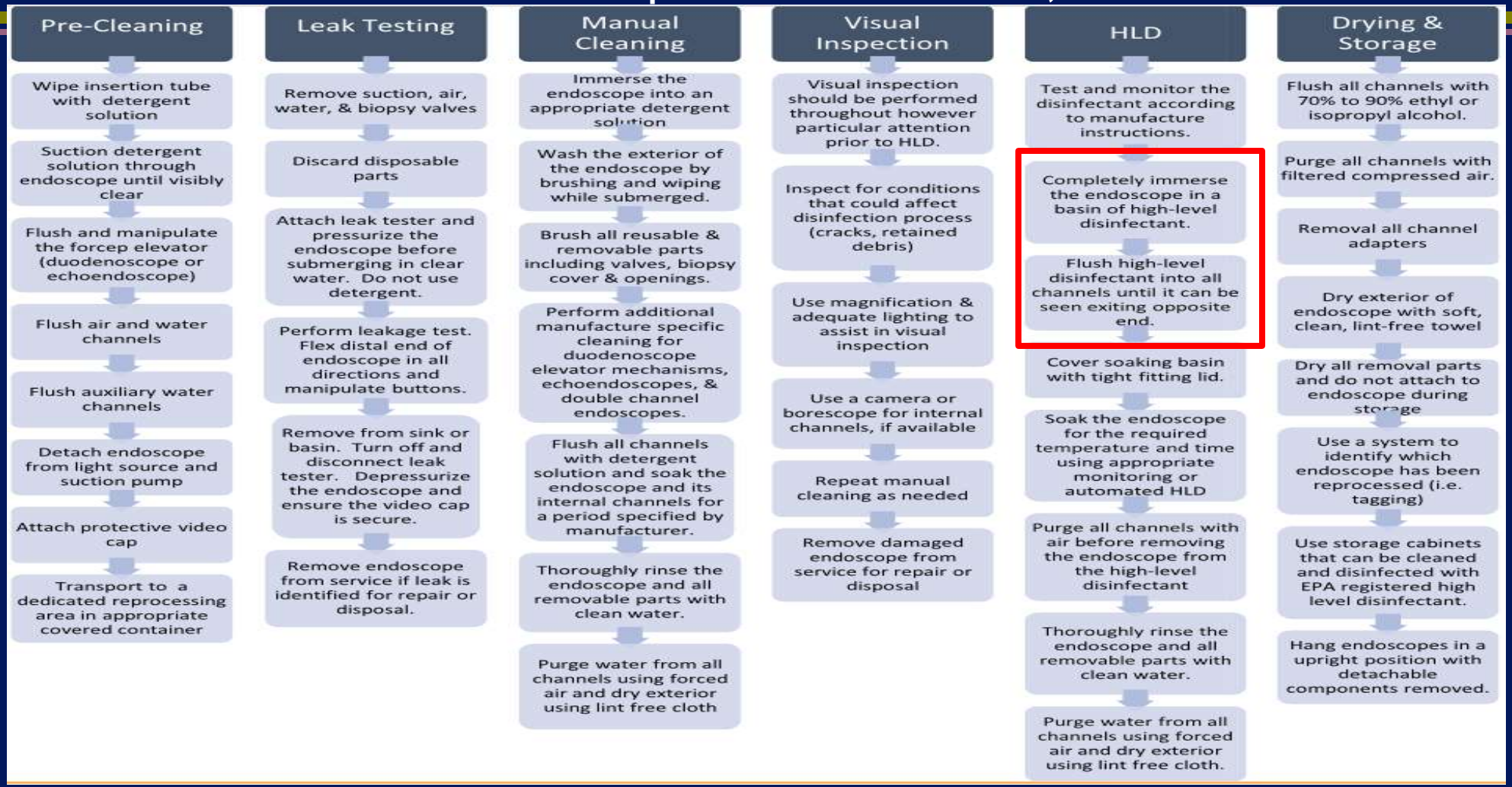
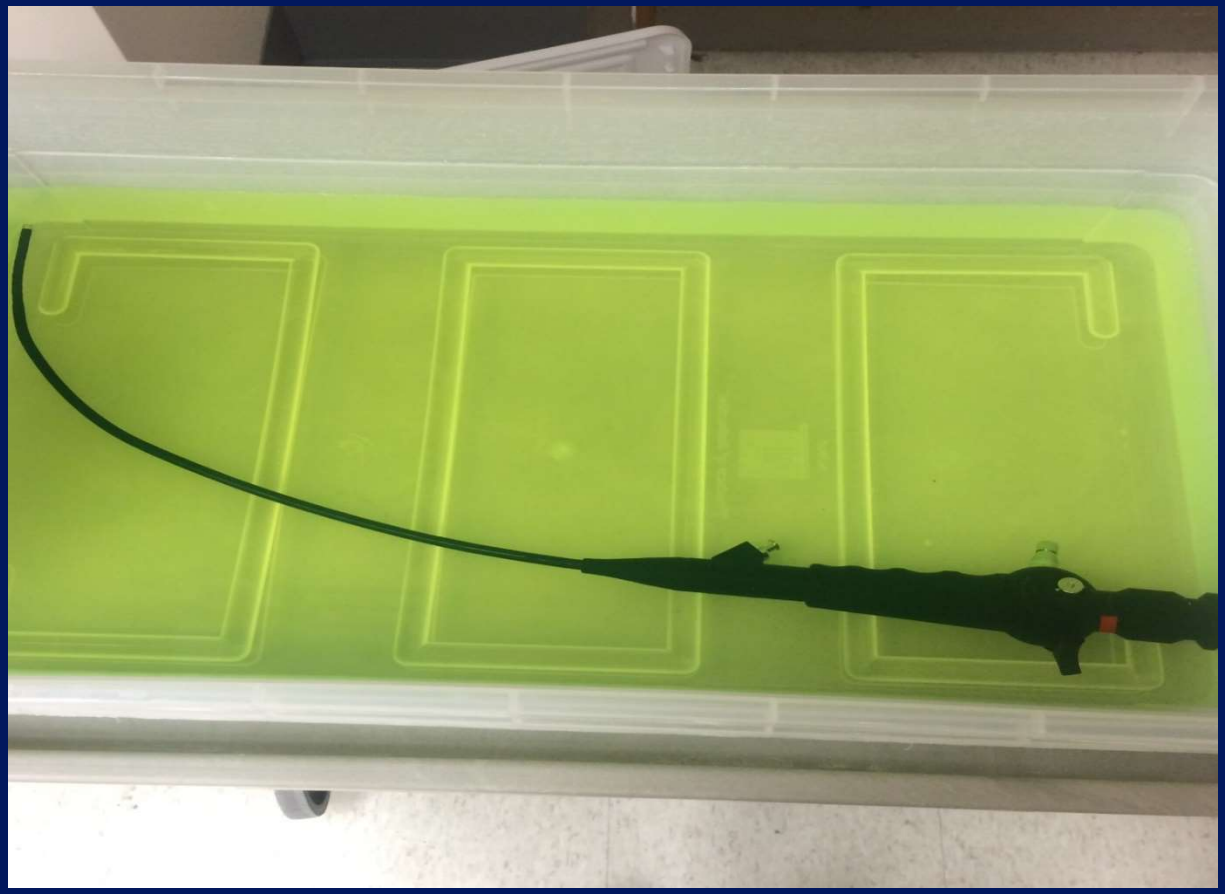


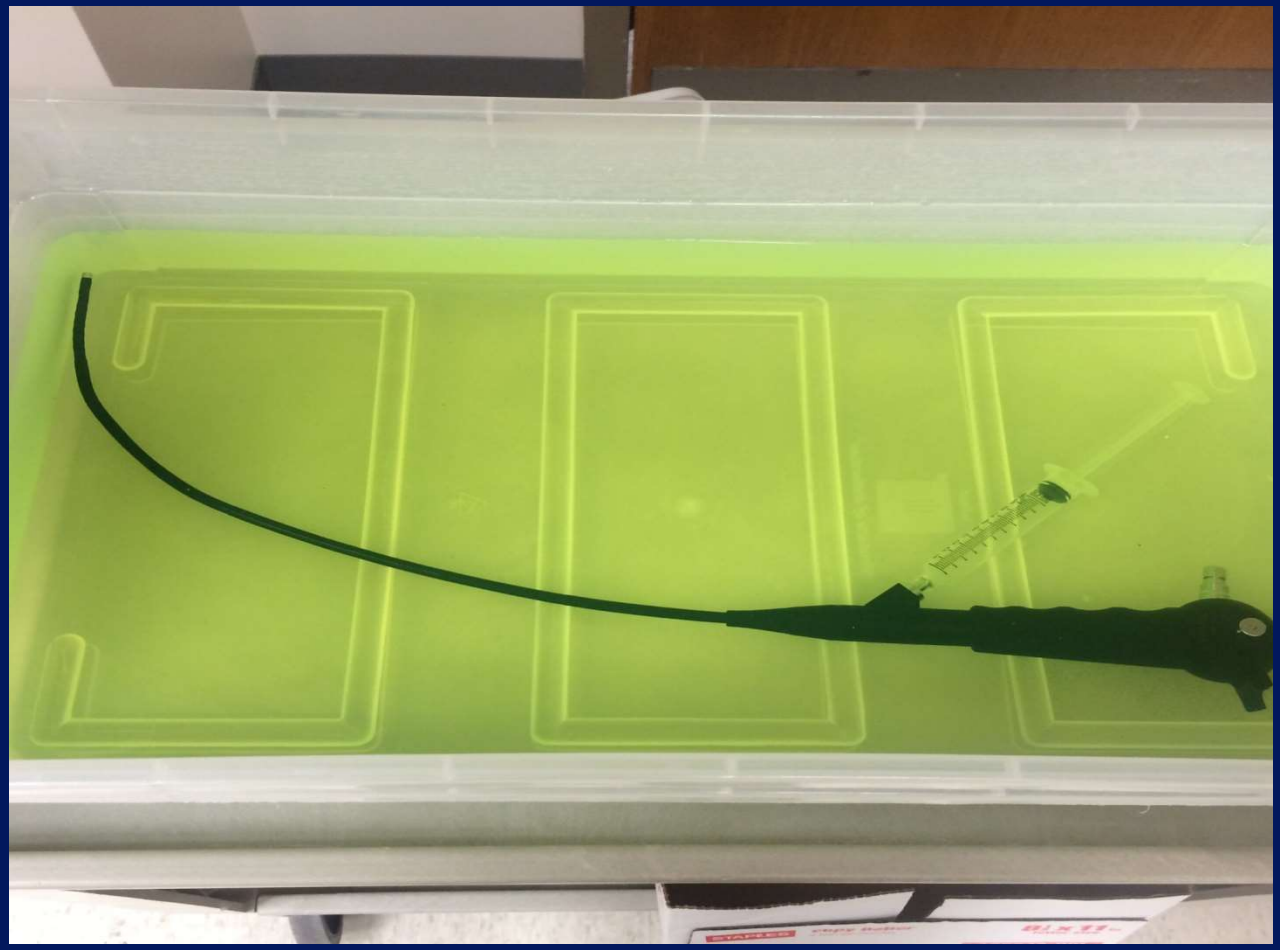
Reprocessing Channeled Endoscopes

Cystoscope- “completely immerse” in HLD (J Urology 2008.180:588)



Reprocessing Channeled Endoscopes Manually

Cystoscope-HLD perfused through lumen with syringe (luer locks onto port and syringe and lumen filled with HLD)



Reprocessing Channeled Endoscopes

Rutala, Gergen, Bringhurst, Weber. ICHE. 2016;37:228-231

Exposure Method	CRE (*K. pneumoniae*) Inoculum before HLD (glutaraldehyde)	CRE (K. pneumoniae) Contamination after HLD
Passive HLD (immersed, not perfused)	$3.2x10^8$ $1.9x10^9$ $4.1x10^8$	$3.1x10^8$ $4.6x10^8$ $1.0x10^8$
Active HLD (perfused HLD into channel with syringe)	$3.0x10^8$ $9.2x10^8$ $8.4x10^8$	0 0 0

- Pathogens must have exposure to HLD for inactivation
- Immerse channeled flexible scope into HLD will not inactivate channel pathogens
- Completely immerse the endoscope in HLD and ensure all channels (e.g., hysteroscopes, cystoscopes) are perfused
- Air pressure in channel stronger than fluid pressure at fluid-air interface

What Should We Do Now?

GI Endoscopes: Shift from Disinfection to Sterilization

Rutala, Weber. JAMA 2014. 312:1405-1406

EDITORIAL

Editorials represent the opinions of the authors and *JAMA* and not those of the American Medical Association.

Gastrointestinal Endoscopes
A Need to Shift From Disinfection to Sterilization?

William A. Rutala, PhD, MPH; David J. Weber, MD, MPH

More than 10 million gastrointestinal endoscopic procedures are performed annually in the United States for diagnostic purposes, therapeutic interventions, or both.[1] Because gastrointestinal endoscopes contact mucosal surfaces, use of a contaminated endoscope may lead to patient-to-patient transmission of potential pathogens with a subsequent risk of infection.[1]

In this issue of *JAMA*, Epstein and colleagues[2] report findings from their investigation of a cluster of New Delhi metallo-β-lactamase (NDM)-producing *Escherichia coli* associated with gastrointestinal endoscopy that occurred from March 2013 to July 2013 in a single hospital in northeastern Illinois. During the 5-month period, 9 pa-

Related article page 1447

First, endoscopes are semicritical devices, which contact mucous membranes or nonintact skin, and require at least high-level disinfection.[3,4] High-level disinfection achieves complete elimination of all microorganisms, except for small numbers of bacterial spores. Because flexible gastrointestinal endoscopic instruments are heat labile, only high-level disinfection with chemical agents or low-temperature sterilization technologies are possible.[3] However, no low-temperature sterilization technology is US Food and Drug Administration (FDA)-cleared for gastrointestinal endoscopes such as duodenoscopes.

Second, more health care-associated outbreaks and clusters of infection have been linked to contaminated endoscopes than to any other medical device.[3,5] However, until now,

Disinfection and Sterilization

Rutala, Weber. Am J Infect Control. 2016;44:e1-e6; Rutala, Weber ICHE. 2015;36:643.

EH Spaulding believed that how an object will be disinfected depended on the object's intended use (proposed clarification).

CRITICAL - objects which directly or indirectly/secondarily (i.e., via a mucous membrane such as duodenoscope, cystoscope, bronchoscope) enter normally sterile tissue or the vascular system or through which blood flows should be sterile.

SEMICRITICAL - objects that touch mucous membranes or skin that is not intact require a disinfection process (high-level disinfection [HLD]) that kills all microorganisms but high numbers of bacterial spores.

NONCRITICAL -objects that touch only intact skin require low-level disinfection (or non-germicidal detergent).

Future Approaches to Endoscope Reprocessing to Improve Patient Safety

Rutala et al. AJIC 2019:47:A62; Chua et al. Techniq Innov Gastro Endo 2021;23:190

- Optimize current LTST (ETO, VHP, HP plus ozone) or new LTST proving SAL 10^{-6} achieved
- Disposable endoscopes (device innovations)
  - Partially-endcaps, decrease bacterial contamination after HLD
  - Fully-GI and bronchoscopes; cost, scope performance
- Steam sterilization for GI and other endoscopes
- Use of non-endoscopic methods to diagnose or treat disease
- Stop HLD for affected Storz urological endoscopes, transition to sterilization

NEW STERILIZATION TECHNOLOGY

- Hydrogen Peroxide Gas Plasma sterilizer designed specifically for the terminal sterilization of flexible endoscopes
- Incorporates a proprietary vapor diffusion technology to direct Vaporized Hydrogen Peroxide (VHP) into the internal lumen channels of an endoscope
  - Utilizes a pressure differential in each internal endoscope channel to rapidly diffuse VHP to sterilize all endoscope channels
  - Achieves the required VHP efficacy concentration in all internal endoscope channels (up to 4 meters) in < 20 secs
  - Uses lower overall concentration of H_2O_2 with shorter exposure times, thereby eliminating potential damage to the endoscope
- Incorporates a proprietary sterilization container that interfaces with the sterilizer during the sterilization process and facilitates sterile storage (6 months) of the endoscope after processing
- Incorporates a proprietary pre-sterile single-use channel connector that is pressure activated. It seals during VHP transfer and then releases to allow sterilization of the mated connector interface
- Based on initial testing, we were able to sterilize an Olympus duodenoscope (TJF-Q160F) 125 times with no damage to the device

Future Approaches to Endoscope Reprocessing to Improve Patient Safety

Rutala et al. AJIC 2019:47:A62; Chua et al. Techniq Innov Gastro Endo 2021;23:190

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The FDA is Recommending Transition to Duodenoscopes with Innovative Designs to Enhance Safety: FDA Safety Communication

Update as of April 4, 2022: The FDA provided new information supporting the transition to fully disposable duodenoscopes and those with disposable components as well as new information on completed postmarket surveillance studies (also known as 522 studies).

Transition to Innovative Duodenoscope Designs-Disposable Endcaps or Fully Disposable Duodenoscopes

Use Duodenoscopes with Innovative Designs to Enhance Safety: FDA Safety Communication

Share | Tweet | Linkedin | Email | Print

Date Issued: April 5, 2022

The U.S. Food and Drug Administration (FDA) is updating the April 2020 Safety Communication to provide new information supporting the transition to fully disposable duodenoscopes and those with disposable components as well as new information on completed postmarket surveillance studies (also known as 522 studies).

Given the cleaning concerns and contamination data with fixed endcap duodenoscopes and the increasing availability of duodenoscope models that facilitate or eliminate the need for reprocessing, hospitals and endoscopy facilities should complete transition to innovative duodenoscope designs that include disposable components such as disposable endcaps, or to fully disposable duodenoscopes. The use of a removable component to facilitate cleaning leads to significantly less contamination; interim results from one

FDA Cleared at least 6 Duodenoscopes with Disposable Components or Fully Disposable

Fully Disposable:

- Ambu Innovation GmbH, Duodenoscope model aScope Duodeno (fully disposable duodenoscope cleared under K201098)
- Boston Scientific Corporation, EXALT Model D Single-Use Duodenoscope (fully disposable duodenoscope cleared under K193202)

Disposable Components:

- Fujifilm Corporation, Duodenoscope model ED-580XT (disposable endcap duodenoscope cleared under K181745)
- Olympus Medical Systems, Evis Exera III Duodenovideoscope Olympus TJF-Q190V (disposable endcap duodenoscope cleared under K193182)
- Pentax Medical, Duodenoscope model ED34-i10T2 (disposable elevator duodenoscope cleared under K192245 and K210710)
- Pentax Medical, Duodenoscope model ED32-i10 (disposable elevator duodenoscope cleared under K202365)

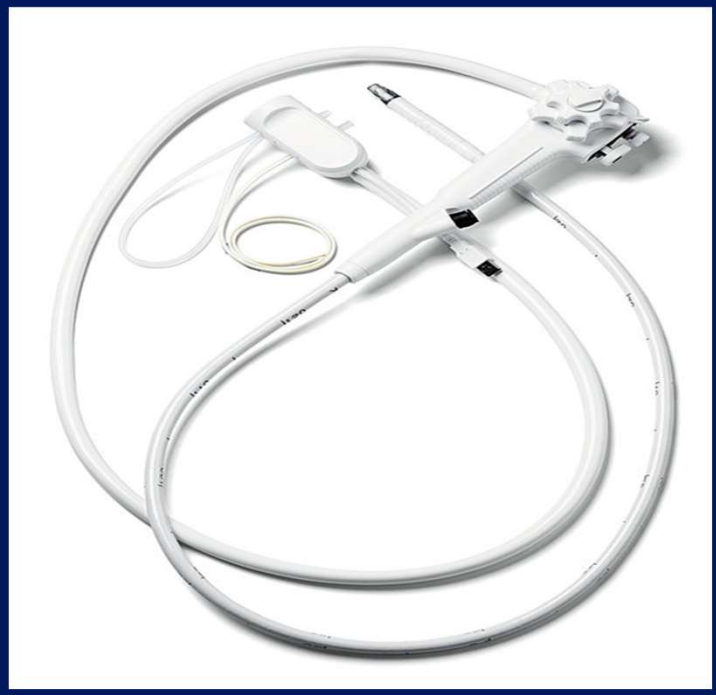
No Longer Marketed:

- Pentax Medical, Duodenoscope model ED34-i10T (disposable endcap duodenoscope cleared under K163614 and K181522)

Transition to Innovative Duodenoscope Designs-Disposable Endcaps or Fully Disposable Duodenoscopes

Duodenoscopes with disposable endcap

Sterile, single-use duodenoscope for ERCP



Transition to Innovative Duodenoscope Designs-Disposable Endcaps or Fully Disposable Duodenoscopes: Why?

www.fda.gov

- Best solution to reducing the risk of disease transmission by duodenoscopes is through innovative device design that make reprocessing easier, more effective, or unnecessary.
- Postmarket surveillance studies on fixed endcap design indicate that as high as 6.6% (56/850) of samples tested positive with high concern organisms (e.g., *E. coli*, *Pa*). Interim results with removable components show 0.5% (2/417) tested positive with high concern organisms
- As a result, Pentax and Olympus are withdrawing their fixed endcap duodenoscopes from the market, and Fujifilm has completed withdrawal

Effect of Disposable Elevator Cap Duodenoscopes on Microbial Contamination

Forber et al. JAMA IM 2023;183:191-200

Microbial contamination detected in 11.2% of standard duodenoscopes and 3.8% of disposable elevator cap duodenoscopes without affecting technical performance and safety of ERCP

Table 2. Primary and Secondary Study Outcomes

Outcome	Disposable elevator cap duodenoscope			Standard duodenoscope			*P* value
	No. (%)	Scope ID	Occurrences/ cases performed	No. (%)	Scope ID	Occurrences/ cases performed	
Microbiology outcomes							
No.	208	NA	NA	214	NA	NA	NA
Persistent microbial contamination[a]							
Yes	8 (3.8)	NA	NA	24 (11.2)	NA	NA	.004
No	200 (96.2)	NA	NA	190 (88.8)	NA	NA	

Sterilize Karl Storz Urological Endoscopes

www.fda.gov

UPDATE: Change in Reprocessing Methods with Certain Karl Storz Urological Endoscopes – Letter to Health Care Providers

April 4, 2022

As the U.S. Food and Drug Administration (FDA) continues to evaluate the risk of patient infections and contamination issues associated with reprocessed urological endoscopes, the FDA is aware that the current reprocessing instructions for certain urological endoscopes manufactured by Karl Storz are inadequate and are being changed updated by Karl Storz. The affected urological endoscopes include cystoscopes, ureteroscopes, cystourethroscopes and ureterorenoscopes, used for viewing and accessing the urinary tract.

In April 2021, the FDA communicated about reported patient infections and possible contamination issues with reprocessed urological endoscopes. At the FDA's request, Karl Storz conducted reprocessing validation testing on a sample of flexible urological endoscopes and identified reprocessing failures following high-level disinfection. Inadequate reprocessing of urological endoscopes may increase the risk of patient infection.

Sterilize Karl Storz Urological Endoscopes

www.fda.gov

- At FDA request, Karl Storz conducted reprocessing validation testing on a sample of flexible urological endoscopes and identified reprocessing failures following HLD.
- Do not use HLD methods or liquid chemical sterilization to reprocess affected urological endoscopes (HLD not achieved for affected products)
- Sterilize affected urological endoscopes after each use by using sterilization methods recommended in MIFU
- Do not use affected urological endoscopes if you do not have access to an appropriate sterilization method

Sterilize Karl Storz Urological Endoscopes

https://www.karlstorz.com/cps/rde/xbcr/karlstorz_assets/ASSETS/3680244.pdf

ENDOSCOPES FOR MEDICINE AND TECHNICAL SCIENCE
INSTRUMENTS FOR OTO-RHINO-LARYNGOLOGY

KARL STORZ — ENDOSKOPE

Rev 1: April 2022

FSN Ref: 22-0002

Date: April 1, 2022

Urgent Medical Device Recall Notice
Certain KARL STORZ Flexible Endoscopes for Urological Use

For Attention of: Representatives for medical product safety, users, operators, importers, distributors

Commercial name(s):	See Appendix
Device Model/Catalogue/part numbers :	See Appendix
Affected serial numbers:	All serial numbers of devices listed
FSN Type:	New FSN, Ref.: 22-0002

Sterilize Karl Storz Urological Endoscopes

https://www.karlstorz.com/cps/rde/xbcr/karlstorz_assets/ASSETS/3680244.pdf

KARL STORZ—ENDOSKOPE

APPENDIX
Affected Endoscopes and Reprocessing Methods

X = Method Not Acceptable and ✓ = Method Acceptable

Scope Base Part Number	Scope Kit Number	Product Description	Current IFU	Affected Reprocessing Methods	
				All High-Level Disinfection	Liquid Chemical Sterilization (STERIS System 1E)
11272C1	N/A	Flexible Cysto-Urethroscope Fiberscope	Z18449US-BD (08-2018)	X	X
11272C2	11272CK2	Flexible Cystoscope	Z18449US-BD (08-2018)	X	X
11272CU1	11272CUK1	Flexible Cystoscope	Z18449US-BD (08-2018)	X	X
11272V	N/A	Flexible CMOS Video Cysto Urethroscope	Z18446US-BE (01/2020)	X	X
11272VA	11272VAK	Flexible CMOS Video Cysto Urethroscope	Z18446US-BE (01/2020)	X	X
11272VH-TL	11272VHK-TL	HD-VIEW Flexible HD Cysto-Urethroscope	Z23875US-BC (10-2021)	X	X
11272VHU-TL	11272VHUK-TL	HD-VIEW Flexible HD Cysto-Urethroscope	Z23875US-BC (10-2021)	X	X
11272VN	11272VNK	Flexible Video Urethro Cystoscope	Z18442US-BD (08/2018)	X	X
11272VNU	11272VNUK	Flexible Video Urethro Cystoscope	Z18442US-BD (08/2018)	X	X
11272VU	11272VUK	Flexible CMOS Video Cysto Urethroscope	Z18446US-BE (01/2020)	X	X
11272VUA	11272VUAK	Flexible CMOS Video Cysto Urethroscope	Z18446US-BE (01/2020)	X	X
11272VUE	11272VUEK	Flexible Video Cysto-Urethroscope	96136031USCA V1.1 (04/2021)	X	X

Did supplemental measures work?

Supplemental Measures to Reduce Infection Risk

Rutala WA, Weber DJ. ICHE 2015;36:643-648; Rutala et al. AJIC 2019:47:A62

Hospitals performing ERCPs should do one of the following; FDA adopted these recommendations

- **Ethylene oxide sterilization** after high level disinfection with periodic microbiologic surveillance
- **Double high-level disinfection** with periodic microbiologic surveillance
- High-level disinfection with scope quarantine until negative culture
- **Liquid chemical sterilant** processing system using peracetic acid (rinsed with extensively treated potable water) with periodic microbiologic surveillance
- High-level disinfection with periodic microbiologic surveillance

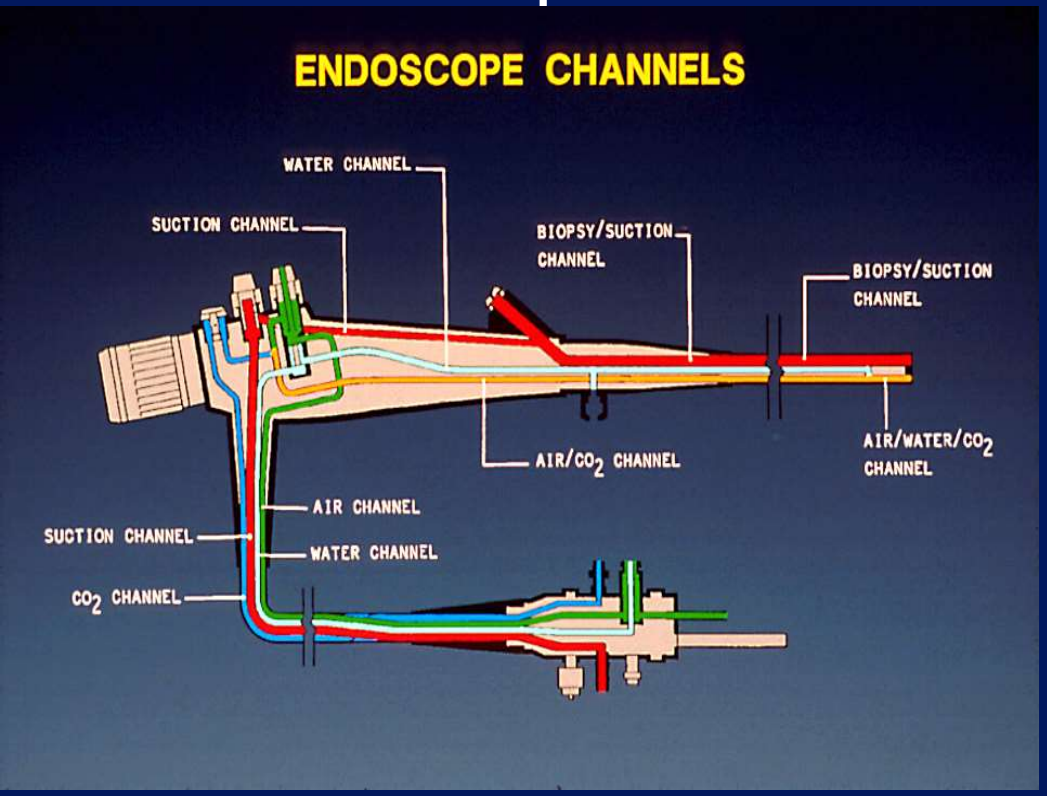
Supplemental Measures for Endoscope Reprocessing

Day et al. Gastro Endosc 2021;93:11-35; Gromski et al. Gastro Endosc 2021;93:927; Synder et al. Gastroenterology 2017;153:1018; Bartles et al Gastro Endos 2018;88:306

- In a nonoutbreak setting, repeat HLD has no significant benefit compared with single HLD in reducing bacterial contamination rates for duodenoscopes (16.1% v 9.2%)
- In nonoutbreak setting, limited data suggest that ETO sterilization does not reduce bacterial contamination rates in duodenoscopes compared with single HLD
- No significant difference of positive cultures when comparing double HLD (8) with duodenoscopes undergoing liquid chemical sterilant (9).
- The use of ETO sterilization on duodenoscopes during infectious outbreaks has been associated with terminating these outbreaks and such a modality should be considered in selected settings and patient populations
- However, many barriers to widespread use of ETO including cost, only 20% hospital use ETO (availability), possible damage to scopes, exposure of staff to ETO, exposure/turnaround time

Endoscope Reprocessing

Microbial Load/Complex Instruments



New Guidelines

- Multi-society guideline-2021
- AAMI, ST91-2021
- SGNA-2021
- AORN-2021
- Must educate/comply but confident will not prevent all infections and patient exposures due to microbial load and instrument complexity

Efficacy of Microbiologic Surveillance in Detecting Bacterial Contamination in Processed Endoscopes

Day et al. Gastro Endosc 2021;93:11-35; Olafsdottir et al. AJIC 2018;46:697-705

- Microbiologic testing not advised per US standards
- Surveillance as a QA measure advised by some international organizations
- ATP proposed as alternative but not widely applied
- ATP testing does not correlate well with microbiological cultures after HLD of duodenoscopes and should not be recommended as a surrogate for terminal cultures
- ATP testing might have a role as a quality assurance test after the manual cleaning stage and for training endoscope reprocessing staff

INFECTION CONTROL AND HOSPITAL EPIDEMIOLOGY FEBRUARY 2007, VOL. 28, NO. 2

ORIGINAL ARTICLE

How to Assess Risk of Disease Transmission to Patients When There Is a Failure to Follow Recommended Disinfection and Sterilization Guidelines

William A. Rutala, PhD, MPH; David J. Weber, MD, MPH

BACKGROUND. Disinfection and sterilization are critical components of infection control. Unfortunately, breaches of disinfection and sterilization guidelines are not uncommon.

OBJECTIVE. To describe a method for evaluating a potential breach of guidelines for high-level disinfection and sterilization of medical devices.

METHODS. The appropriate scientific literature was reviewed to determine the frequency of failures of compliance. A risk assessment model was constructed.

RESULTS. A 14-step protocol was constructed to aid infection control professionals in the evaluation of potential disinfection and sterilization failures. In addition, a model is presented for aiding in determining how patients should be notified of the potential adverse event. Sample statements and letters are provided for communicating with the public and individual patients.

CONCLUSION. Use of a protocol can guide an institution in managing potential disinfection and sterilization failures.

Infect Control Hosp Epidemiol 2007; 28:146-155

In the United States in 1996, there were approximately 46,500,000 surgical procedures and a much larger number of

infection failure on record involved the distribution of an inactive lot of glutaraldehyde disinfectant solution that had

Semicritical/Critical Reprocessing Failures

- Examples of failures
  - Use Quat/Alcohol wipe rather than HLD (ENT, vaginal probes)
  - Failure to monitor concentration of HLD
  - Staff did not flush and brush all channels
  - Channels not perfused with HLD (cystoscopes)
  - Time and/or temperature on AER was wrong
  - Steam cycle at 0 minutes rather than 4 minutes (132^{o}C)

1. Confirm disinfection or sterilization reprocessing failure
2. Impound any improperly disinfected/sterilized items
3. Do not use the questionable disinfection/sterilization unit (e.g., sterilizer, automated endoscope reprocessor) until proper functioning can be assured
4. Inform key stakeholders
5. Conduct a complete and thorough evaluation of the cause of the disinfection/sterilization failure
6. Prepare a line listing of potentially exposed patients
7. Assess whether disinfection/sterilization failure increases patient risk for infection
8. Inform expanded list of stakeholders of the reprocessing issue
9. Develop a hypothesis for the disinfection/sterilization failure and initiate corrective action
10. Develop a method to assess potential adverse patient events
11. Consider notification of state and federal authorities
12. Consider patient notification
13. Develop long-term follow-up plan
14. Perform after-action report

FIGURE 1. Protocol for exposure investigation after a failure of disinfection and sterilization procedures

Failure to Follow Disinfection and Sterilization Principles

Rutala, Weber. ICHE 2007;28:146-155; Weber, Rutala, AJIC 2013;41:S67-71

- What do you do?
  - Follow the 14 steps at website www.disinfectionandsterilization.org (confirm failure, embargo improperly D/S items, investigate the cause, etc)
  - The steps provide a general outline, but each event is unique and you must be flexible and adaptable
  - Communication among key stakeholders is very important
  - Ethical to notify patients if there is a risk-should be upfront and factual
  - Train staff and access processes/practices to minimize recurrence
  - These are stressful events (patients and staff) but the goal is to assess failure and protect patients rather than assessing blame

SPD, Sterilization and HLD

- Describe the Spaulding classification scheme for disinfection and sterilization of patient care items
- Describe available methods for high-level disinfection and sterilization and types of indicators used to ensure the process was effective
- Understand the current issues and new technologies in sterile processing department, sterilization and high-level disinfection

SPD, Sterilization and HLD
Summary

- Disinfection and sterilization technologies and practices (e.g., monitoring cleaning) must be followed to prevent exposure to pathogens that may lead to infection.
- Endoscope represent a nosocomial hazard. Urgent need to understand the gaps in endoscope reprocessing. Reprocessing guidelines must be followed to prevent exposure to pathogens that may lead to infection. Endoscopes have narrow margin of safety and manufacturers should be encouraged to develop practical sterilization technology.

THANK YOU!

www.disinfectionandsterilization.org