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New Developments in Reprocessing Semicritical Items

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

University of North Carolina (UNC) Health Care System and UNC at Chapel Hill, NC

DISCLOSURES

- Consultation
  - Advanced Sterilization Products, Clorox
- Honoraria (speaking)
  - Advanced Sterilization Products, 3M
- Grants
  - CDC

Reprocessing Semicritical Items

- New Developments in Reprocessing
  - Endoscopes
  - Laryngoscopes
  - Infrared coagulation device
  - Nasopharyngoscopes
  - Endocavitary probe
  - Prostate biopsy probes
  - Tonometers

DISINFECTION AND STERLIZATION

- EH Spaulding believed that how an object will be disinfected depended on the object's intended use
  - CRITICAL - objects which 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

Processing "Semicritical" Patient Care Objects

Classification:	Semicritical objects come in contact with mucous membranes or skin that is not intact.
Object:	Free of all microorganisms except high numbers of bacterial spores.
Level germicidal action:	Kills all microorganisms except high numbers of bacterial spores
Examples:	Respiratory therapy and anesthesia equipment, GI endoscopes, endocavitary probes, etc.
Method:	High-level disinfection

High-Level Disinfection of "Semicritical Objects"

Exposure Time ≥ 8m-45m (US), 20°C

Germicide	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

Semicritical Equipment

- Reprocessing semicritical items has been shown to have a narrow margin of safety
- Generally, the narrow margin of safety attributed to high microbial load and complex instruments with lumens
- Any deviation from the recommended reprocessing protocol can lead to the survival of microorganisms and an increased risk of infection
- Problems encountered with reprocessing semicritical equipment often related to improper cleaning

Reprocessing Semicritical Items

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MULTISOCIETY GUIDELINE ON REPROCESSING GI ENDOSCOPES, 2011

Petersen et al. ICHE. 2011;32:527

INFECTION CONTROL AND HOSPITAL EPIDEMIOLOGY JUNE 2011, VOL. 32, NO. 6

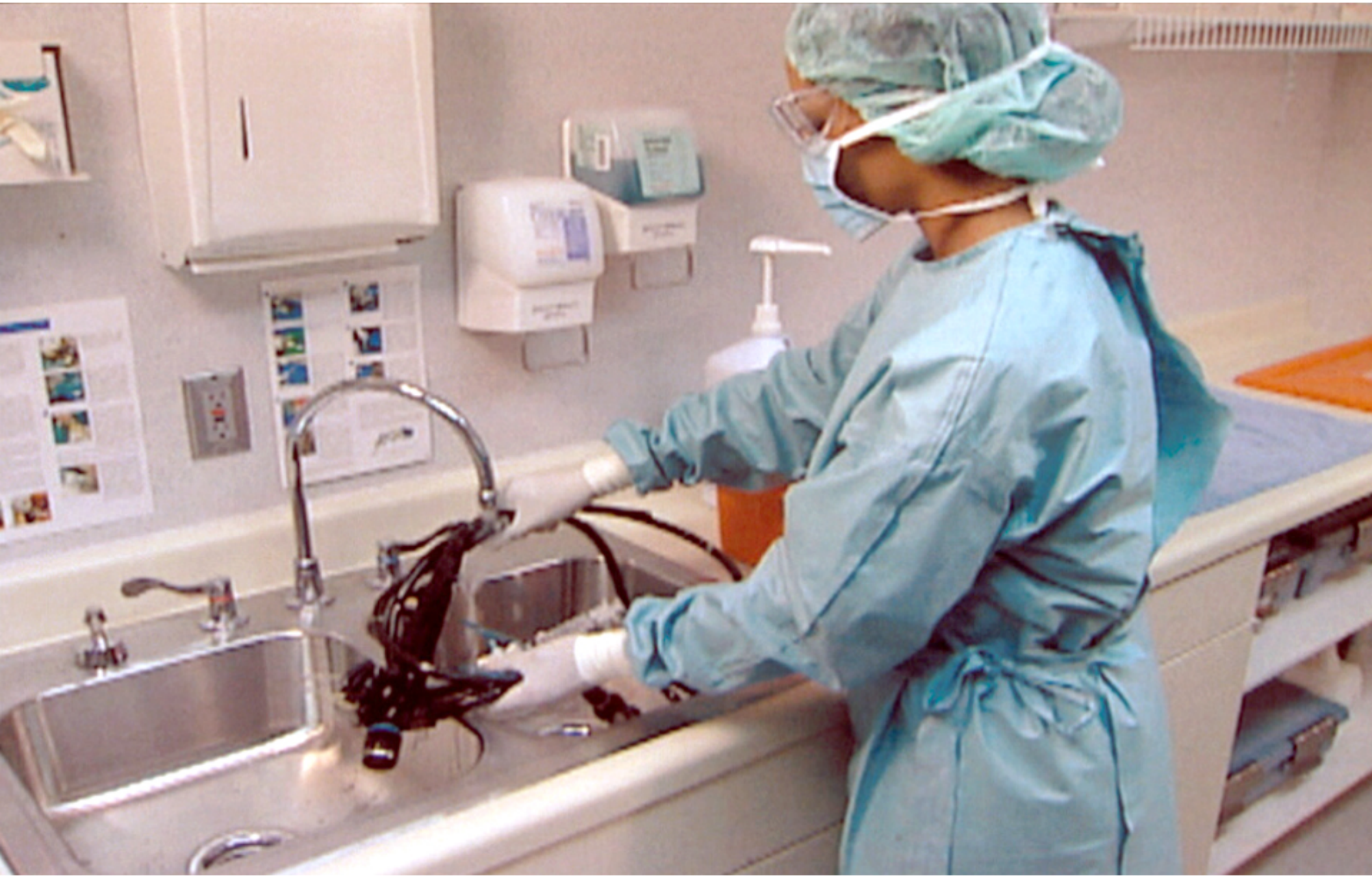
ASGE-SHEA GUIDELINE

Multisociety Guideline on Reprocessing Flexible GI Endoscopes: 2011

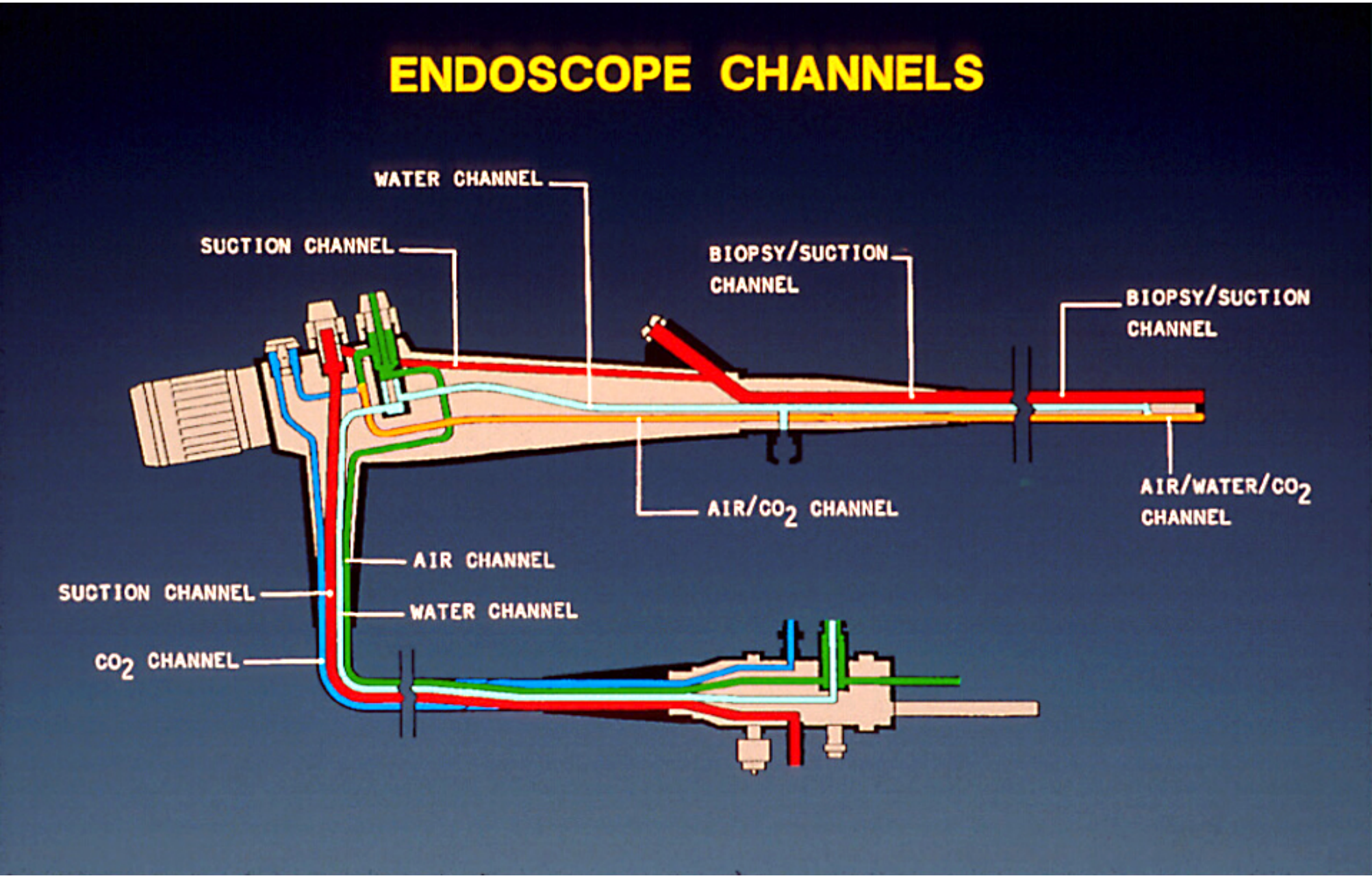
Bret T. Petersen, MD, FASGE; Jennifer Chennat, MD; Jonathan Cohen, MD, FASGE; Peter B. Cotton, MD, FASGE; David A. Greenwald, MD, FASGE; Thomas E. Kowalski, MD; Mary L. Krinsky, DO; Walter G. Park, MD; Irving M. Pike, MD, FASGE; Joseph Romagnuolo, MD, FASGE; for the ASGE Quality Assurance in Endoscopy Committee; and William A. Rutala, PhD, MPH; for the Society for Healthcare Epidemiology of America

The beneficial role of GI endoscopy for the prevention, diagnosis, and treatment of many digestive diseases and cancer is well established. Like many sophisticated medical devices, the endoscope is a complex, reusable instrument that requires reprocessing before being used on subsequent patients. The most commonly used methods for reprocessing endoscopes result in high-level disinfection. To date, all published occurrences of pathogen transmission related to GI endoscopy have been associated with failure to follow established cleaning and disinfection/sterilization guidelines or use of defective equipment. Despite the strong published data regarding the safety of endoscope reprocessing, concern over the potential spread gaps in infection prevention practices.[10] Given the ongoing occurrences of endoscopy-associated infections attributed to lapses in infection prevention, an update of the multisociety guideline is warranted.

This document provides an update of the previous guideline, with additional discussion of new or evolving reprocessing issues and updated literature citations, where appropriate. Specific additions or changes include review of expanded details related to critical reprocessing steps (including cleaning and drying), reprocessing issues for various endoscope attachments such as flushing catheters, discussion of risks related to selected periprocedural practices including



ENDOSCOPE CHANNELS



GI ENDOSCOPES AND BRONCHOSCOPES

- Widely used diagnostic and therapeutic procedure
- Endoscope contamination during use (GI 10^9 in/10^5 out)
- Semicritical items require high-level disinfection minimally
- Inappropriate cleaning and disinfection has lead to cross-transmission
- In the inanimate environment, although the incidence remains very low, endoscopes represent a risk of disease transmission

TRANSMISSION OF INFECTION

- Gastrointestinal endoscopy
  - >300 infections transmitted
  - 70% agents *Salmonella sp.* and *P. aeruginosa*
  - Clinical spectrum ranged from colonization to death (~4%)
- Bronchoscopy
  - 90 infections transmitted
  - *M. tuberculosis*, atypical *Mycobacteria*, *P. aeruginosa*

Spach DH et al Ann Intern Med 1993: 118:117-128 and Weber DJ, Rutala WA Gastroint Dis 2002;87

Multi-Society Guideline for Reprocessing Flexible Gastrointestinal Endoscopes, 2011

- Since 2003, changes in
  - High-level disinfectants
  - Automated endoscope reprocessors
  - Endoscopes
  - Endoscopic accessories
- However, efficacy of decontamination and high-level disinfection is unchanged and the principles guiding both remain valid
- Additional outbreaks of infection related to suboptimal infection prevention practices during endoscopy or lapses in endoscope reprocessing (unfamiliarity with endoscope channels, accessories, attachments; gaps in infection prevention at ASC)

Multi-Society Guideline for Reprocessing Flexible Gastrointestinal Endoscopes, 2011

- Transmission categorized as:
  - Non-endoscopic and related to care of intravenous lines and administration of anesthesia or other medications
    - Multidose vials
    - Reuse of needles and syringes
    - Intravenous sedation tubing
  - Endoscopic and related to endoscope and accessories
    - Failure to sterilize biopsy forceps between patients
    - Lapses in reprocessing tubing used in channel irrigation

Multi-Society Guideline for Reprocessing Flexible Gastrointestinal Endoscopes, 2011

- Unresolved Issues
  - Interval of storage after which endoscopes should be reprocessed before use
    - Data suggest that contamination during storage for intervals of 7-14 days is negligible, unassociated with duration, occurs on exterior of instruments and involves only common skin organisms
    - Data are insufficient to proffer a maximal outer duration for use of appropriately cleaned, reprocessed, dried and stored endoscopes
    - Without full data reprocessing within this interval may be advisable for certain situations (endoscope entry to otherwise sterile regions such as biliary tree, pancreas)

Multi-Society Guideline for Reprocessing Flexible Gastrointestinal Endoscopes, 2011

- Unresolved Issues
  - Optimal frequencies for replacement of: clean water bottles and tubing for insufflation of air and lens wash water, and waste vacuum canisters and suction tubing
    - Concern related to potential for backflow from a soiled endoscope against the direction of forced fluid and air passage into clean air/water source or from tubing/canister against a vacuum into clean instruments
  - Microbiologic surveillance testing after reprocessing
    - Detection of non-environmental pathogens indicator of faulty reprocessing equipment, inadequate solution, or failed human process

Endoscope Reprocessing, Worldwide

- Worldwide, endoscopy reprocessing varies greatly
  - India, of 133 endoscopy centers, only 1/3 performed even a minimum disinfection (1% glut for 2 min)
  - Brazil, “a high standard …occur only exceptionally”
  - Western Europe, ≥30% did not adequately disinfect
  - Japan, found “exceedingly poor” disinfection protocols
  - US, 25% of endoscopes revealed >100,000 bacteria

Schembre DB. Gastroint Endoscopy 2000;10:215

ENDOSCOPE DISINFECTION

- CLEAN-mechanically cleaned with water and enzymatic cleaner
- HLD/STERILIZE-immerse scope and perfuse HLD/sterilant through all channels for at least 12 min
- RINSE-scope and channels rinsed with sterile water, filtered water, or tap water followed by alcohol
- DRY-use forced air to dry insertion tube and channels
- STORE-prevent recontamination

Reprocessing Semicritical Items

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Reprocessing of Rigid Laryngoscopes

JHI 2008, 68:101; ICHE 2007, 28:504; AJIC 2007, 35: 536

- Limited guidelines for reprocessing laryngoscope's blades and handles
- Many hospitals consider blade as semicritical (HLD) and handle as noncritical (LLD)
- Blades linked to HAIs; handles not directly linked to HAIs but contamination with blood/OPIM suggest its potential and blade and handle function together
- Ideally, clean then HLD/sterilize blades and handles (UNCHC-blades wrapped in a tray-Sterrad; handle wrapped in tray [without batteries]-steam); the blades and handles placed together in a Ziploc bag. Blades and handles checked for function prior to packaging.

Contamination of Laryngoscope Handles

J Hosp Infect 2010;74:123

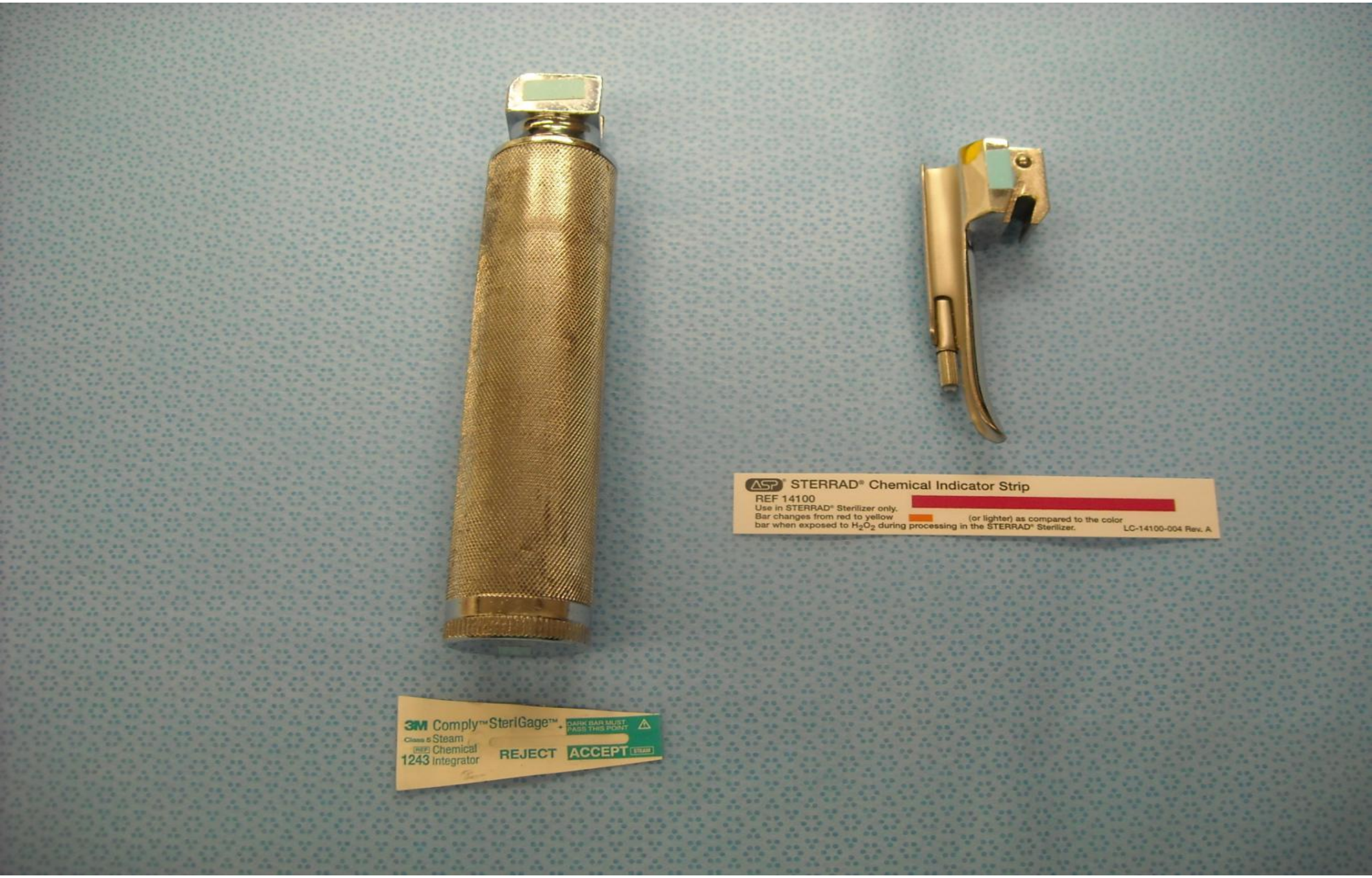
- 55/64 (86%) of the handles deemed “ready for patient use” positive for *S. aureus*, enterococci, *Klebsiella*, *Acinetobacter*

Anesth Analg 2009;109:479

- 30/40 (75%) samples from handles positive (CONS, *Bacillus*, *Streptococcus*, *S. aureus*, Enterococcus) after cleaning

AANA J 1997;65:241

- 26/65 (40%) of the handles and 13/65 (20%) of the blades were positive for occult blood. These blades and handles were identified as ready for patient use.


ASP STERRAD® Chemical Indicator Strip
REF 14100
Use in STERRAD® Sterilizer only.
Bar changes from red to yellow (or lighter) as compared to the color bar when exposed to H_2O_2 during processing in the STERRAD® Sterilizer.
LC-14100-004 Rev. A
3M Comply™ SteriGage™
Class 5 Steam
REF Chemical
1243 Integrator
DARK BAR MUST PASS THIS POINT
REJECT
ACCEPT


ADULT
LARYNGOSCOPE SET
DO NOT DISCARD REUSABLE
PLACE ALL CONTENTS OF BAG
IN GREEN TUBS IN DIRTY
UTILITY ROOM

Laryngoscopes Blades

The Joint Commission, FAQ, October 24, 2011

- How should we process and store laryngoscope blades?
  - Processed via sterilization or HLD
  - Packaged in some way
  - Stored in a way that prevents recontamination. Examples of compliant storage include, but are not limited to, a peel pack post steam sterilization (long-term) or wrapping in a sterile towel (short term)
  - Should not place unwrapped blades in an anesthesia drawer

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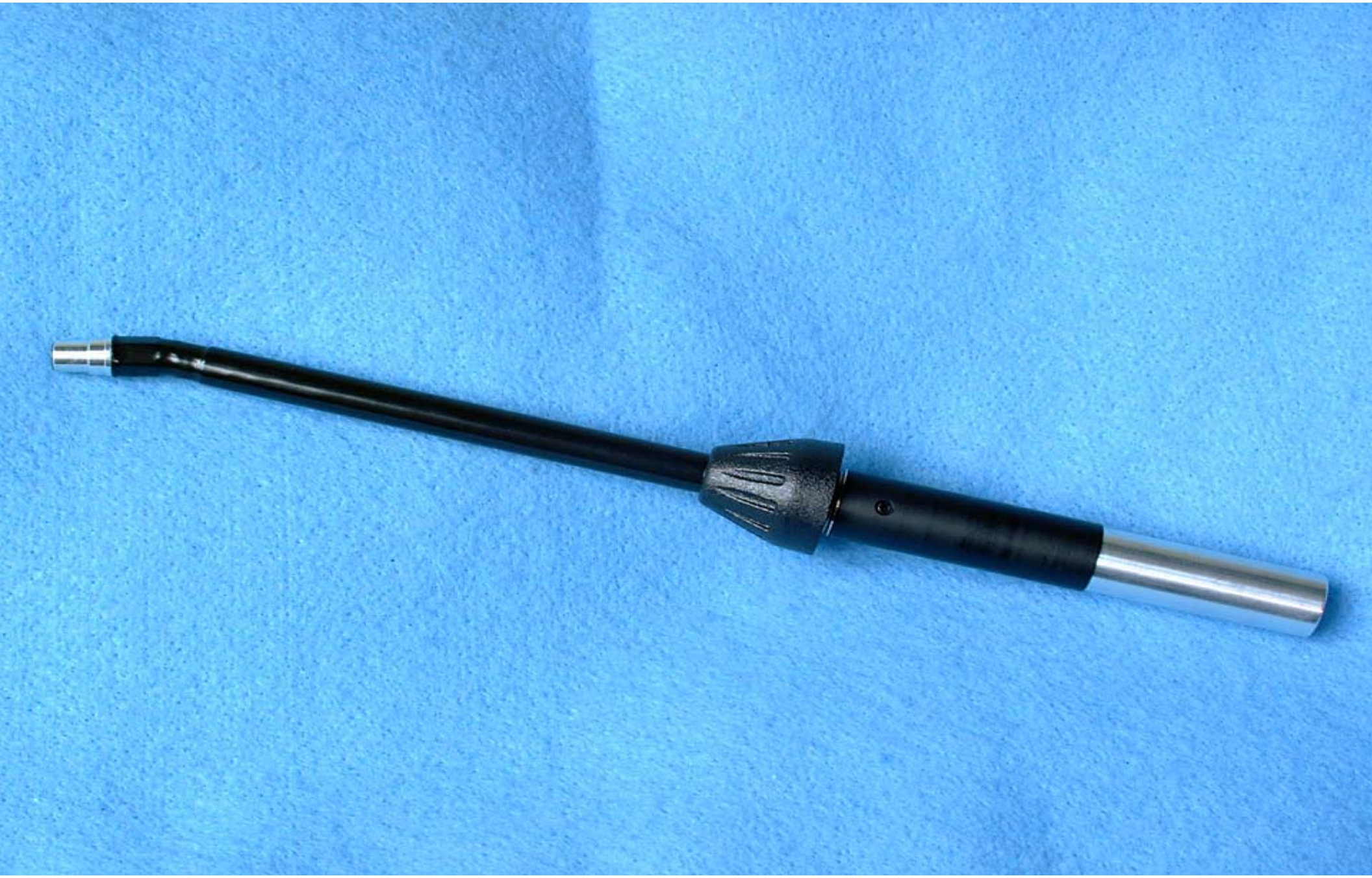

Infrared Coagulation (IRC)

- IRC is a widely used method for treating hemorrhoids. The procedure involves applying infrared light to compress and seal hemorrhoid veins.
- The manufacture sells a sterile disposable sheath and states removing and soaking lightguides between procedures is no longer required.
- The manufacturer also states that the lightguide is damaged by immersion in a disinfectant (as the lightguide is not sealed at the end and disinfectant gets between the quartz glass and the covering)

Infrared Coagulation (IRC)

- CDC guideline recommends immersion for reprocessing endocavitary probes with covers because integrity of the cover is compromised
- Since the lightguide cannot be immersed we investigated an alternative procedure
  - Wipe the probe for 2 minutes with 1:10 bleach (5000 ppm)
  - Wipe probe with sterile water for 1 minute and let air dry

DISINFECTION OF INFRARED COAGULATION DEVICE

Rutala et al. AJIC; 2012:78

This method, which removed or inactivated >6$\log_{10}$ of myco-bacteria, should eliminate all contaminating pathogens

Table 1

Efficacy of hypochlorite disinfection of contaminated IRC device*

Test organism	Average $\log_{10}$ reduction†	Total positive plates
M terrae	6.89*	1/5‡
P aeruginosa	7.47*	0/5
E faecalis	7.29*	0/5

*Five replicates per test organism.

†Average $\log_{10}$ inoculum was identical to the log reduction.

‡1 CFU was recovered on the filter of 7H11 plate.

Wiping the non-immersible IRC probe for 2 min with 5000 ppm chlorine was effective in removing/inactivating microorganisms from the instruments

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Sterile Endoscopic Sheaths to Replace High-Level Disinfection

Fig 1. Commercial sterile, disposable, polyurethane endoscopic sheath (Slide-on EndoSheath System, Medtronic ENT, Jacksonville, FL) studied in 100 nasopharyngoscopic procedures.

Sterile Endoscopic Sheaths to Replace High-Level Disinfection

Sterile Endoscopic Sheaths to Replace High-Level Disinfection

Alvarado, Anderson, Maki. AJIC. 2009;37:408.

Use of a high-quality sheath, combined with detergent cleaning and disinfection with 70% alcohol can provide decontaminated instrument

Table 1. Results of bacterial cultures of 100 nasopharyngoscopes used in a clinical examination at 3 sampling times: baseline, preprocedure, with a cleaned and high-level disinfected scope ready to use; immediately postprocedure, after removing the sheath but before reprocessing; and after cleaning, disinfection with 70 % ethanol and drying

	Baseline, preprocedure (range cfu)	Immediately postprocedure, after sheath removal, before reprocessing (range cfu)	After cleaning, 70% ethanol disinfection and drying (range cfu)
No. nasopharyngoscopes studied	100	100	100
No. positive cultures of head (cfu)	16 (2-100)	13 (2-32)	0 (. . .)
Coagulase-negative *Staphylococcus*	6 (2-100)	8 (4-32)	0 (. . .)
Staphylococcus aureus	1 (12)	0 (. . .)	0 (. . .)
Corynebacterium spp	2 (2-10)	0 (. . .)	0 (. . .)
Bacillus spp	10 (2-92)	5 (2-10)	0 (…)
No. positive cultures of shaft (cfu)	8 (1-10)	1 (10)	0 (. . .)
Coagulase-negative *Staphylococcus*	3 (2-10)	1 (10)	0 (. . .)
Staphylococcus aureus	0 (…)	0 (. . .)	0 (. . .)
Corynebacterium spp	1 (6)	0 (. . .)	0 (. . .)
Bacillus spp	6 (1-8)	0 (. . .)	0 (. . .)

cfu, Colony-forming units.

Sterile Endoscopic Sheaths to Replace High-Level Disinfection

Elackattu et al. Laryngoscope. 2010;

Microbial counts on insertion shafts for sheath and HLD group were similar, with 1/50 and 0/50.

TABLE I.
Microbial Results.

	IPDSS Group	Traditional Group	*P* Value (CI)
Baseline FNPL handles	3/50 grew organisms: coagulase negative *Staphylococcus* (1), Gram-positive *Bacillus* (1), *Streptococcus* not group D (1), diphteroids (1)	1/50 grew organisms: coagulase-negative *Staphylococcus* (1)	
Baseline FNPL shafts	4/50 grew organisms: coagulase negative *Staphylococcus* (3), Gram-positive *Bacillus* (1)	4/50 grew organisms: coagulase-negative *Staphylococcus* (4)	
Post-use FNPL handles	2/50 grew organisms: coagulase-negative *Staphylococcus* (2)	N/A	
Post-use FNPL shafts	2/50 grew organisms: coagulase negative Staphylococcus (1), fungus (1)	N/A	
Results after disinfection for both study arms (Klenzyme + ETOH for the IPDSS group vs. Klenzyme + Cidex OPA + ETOH for the traditional group)			
FNPL handles postdisinfection	1/50: *Streptococcus* not group D (1)	4/50 grew organisms: Coagulase-negative Staphylococcus (4)	0.36 (−0.149 to 0.03)
FNPL shaft postdisinfection	1/50: *Streptococcus* not group D (1)	No growth	1 (−0.025 to 0.094)

IPDSS = individually packaged disposable sterile sheath; CI = confidence interval; FNPL = Flexible nasopharyngolaryngoscopes; N/A = not applicable; ETOH = ethyl alcohol; OPA = ortho-phthalaldehyde.

Sheath on Nasopharyngoscope

- Two peer-reviewed studies have shown that a sterile, disposable sheath on a nasopharyngoscope during a clinical examination, combined with enzymatic detergent cleaning and disinfection with 70% ethanol can provide a reliably decontaminated, patient ready instrument that eliminates the need for HLD of nasopharyngoscopes (with this specific sheath and this device)
- Thus, this practice (this sheath plus cleaning plus alcohol) may be an option to high-level disinfection

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Endocavitary Probes

- Probes-Transesophageal echocardiography probes, vaginal/rectal probes used in sonographic scanning
- Probes with contact with mucous membranes are semicritical
- Guideline recommends that a new condom/probe cover should be used to cover the probe for each patient and since covers may fail (1-80%), HLD (semicritical probes) should be performed

Endocavitary Probe Covers

- Sterile transvaginal probe covers had a very high rate pf perforations before use (0%, 25%, 65% perforations from three suppliers)
- A very high rate of perforations in used endovaginal probe covers was found after oocyte retrieval use (75% and 81% from two suppliers) but other investigators found a lower rate of perforations after use of condoms (0.9-2.0%)
- Condoms superior to probe covers for ultrasound probe (1.7% condom, 8.3% leakage for probe covers)

Trophon EPR
(uses VHP to achieve HLD in 7m-no independent efficacy data)

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Prostate Biopsy Probe

- Evaluated effectiveness of HLD when assembled (needle biopsy holder in probe) and unassembled.
- Inoculated (10^6-10^7 *P.aeruginosa*): internal lumen/outside surface of needle biopsy holder; internal lumen of probe with and without needle biopsy holder in place
- Conclusion: HLD achieved when unassembled but not when assembled


TYPE 8551
7 MHz

Disinfection of Prostate Probe

Rutala, Gergen, Weber. ICHE. 2007;28:916

Needle guide must be removed from the probe for disinfection

TABLE 1. Effectiveness of Glutaraldehyde Disinfection of Various Components of a Probe Used in Ultrasound-Guided Prostate Biopsy

Inoculation site and status	Experiment set	Size of *P. aeruginosa* inoculum, cfu	No. of positive results/no. of experiments	*P. aeruginosa* yield on culture, mean cfu
Internal lumen of needle guide in probe	A	1.56×10^7	0/5	No growth
Outside surface of needle guide in probe	B	1.21×10^7	6/6	1.2×10^6
Internal lumen of probe				
Needle guide not removed from probe	C	1.69×10^7	6/6	2.82×10^6
Needle guide removed from probe	D	1.81×10^7	0/5	No growth
Inside and outside of needle guide removed from the probe	E	1.81×10^7	0/5	No growth

NOTE. CFU, colony forming units; *P. aeruginosa*, *Pseudomonas aeruginosa*.

Disinfection of Prostate Probe

Rutala, Gergen, Weber. ICHE; 2007;28:916

TABLE 2. Recommendations for Reprocessing Probes Used in Transrectal Ultrasound–Guided Prostate Biopsy

Cleaning
Clean immediately after use
Disassemble the transducer (ie, remove needle guide from the probe)
Brush clean (if possible) or flush each lumen and thoroughly clean all surfaces of reusable components with enzymatic or nonenzymatic detergent
Rinse with tap water
Dry with disposable cloth and/or towel or air dry
Perform visual inspection to ensure the device is clean
High-level disinfection or sterilization
Steam sterilize all heat stable reusable components
Alternatively, perform high-level disinfection of the probe and the needle guide separately following disassembly
Perform high-level disinfection for all heat-sensitive components to ensure that the disinfectant reaches all areas inside the lumens and that the minimum effective concentration of the high-level disinfectant is used
Rinse with sterile water, filtered water, or tap water (the US Food and Drug Administration specifies use of sterile water for rinsing)
If filtered water or tap water is used, follow with an alcohol rinse (not immersion of the probe in alcohol) to enhance drying and ensure that no residual water is left for microbial growth
Dry
Store appropriately to ensure the device is not recontaminated

NOTE. Users should be familiar with the manufacturer's recommendations for use and disinfection of the specific device used by the facility.

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120
180

Adenovirus 8

A Common Cause of Epidemic Keratoconjunctivitis

Adenovirus 8

- Adenovirus is extremely hardy when deposited on environmental surfaces and may be recovered from plastic and metal surfaces for more than 30 days
- Elimination of adenovirus from inanimate surfaces and ophthalmic instruments is essential in preventing outbreaks of epidemic keratoconjunctivitis
- Unfortunately, no reports that validate CDC recommendations for disinfecting tonometer tips.

CDC. MMWR 1985; 34:533.

CDC, 1985

- Applanation tonometers-Soap and water cleaning and then disinfected by soaking them for 5 to 10 minutes in a solution containing either:
  - 5,000 chlorine (~1:10 household bleach)
  - 3% hydrogen peroxide
  - 70% ethyl alcohol
  - 70% isopropyl alcohol

Disinfectants and Antiseptics

Adeno 8 at 1 and 5 min, Rutala et al. AAC, April 2006

- Ineffective <2 $\log_{10}$ reduction
  - Bactoshield (4% CHG)
  - Vesphene (phenolic)
  - 70% isopropyl alcohol
  - 3% hydrogen peroxide
  - TBQ (0.06% QUAT)
  - Novaplus (10% povidone iodine)
  - Soft ‘N Sure (0.5% triclosan)
  - Acute-Kare (1% chloroxylenol)
  - Sterilox (218 and 695 ppm chlorine)
  - Dettol (4.8% chloroxylenol)
  - Accel TB (0.5% accelerated hydrogen peroxide)
  - Microcyn (~80 ppm chlorine)

Disinfectants and Antiseptics

Adeno 8 at 1 and 5 min, Rutala et al. AAC, April 2006

- ~4 $\log_{10}$ reduction
  - Clorox, 1:10, ~6,000 ppm chlorine (but not 1:50)
  - Clorox Clean-up, ~1,910 ppm chlorine
  - Clorox disinfecting spray (65% ethanol, 0.6% Quat)
  - Steris 20 sterilant, 0.35% peracetic acid
  - Ethanol, 70%
  - Lysol disinfecting spray (79.6% ethanol, 0.1% Quat)
  - Cidex, 2.4% glutaraldehyde
  - Cidex-OPA, 0.55% OPA
  - Wavicide, 2.65% glutaraldehyde

CDC Guidelines

- CDC, 1985. Applanation tonometers-soap and water cleaning and then disinfected by soaking them for 5 to 10 minutes in a solution containing either:
  - 5,000 chlorine
  - 3% hydrogen peroxide
  - 70% ethyl alcohol
  - 70% isopropyl alcohol
- CDC, 2008. Wipe clean tonometer tips and then disinfect them by immersing for 5-10 minutes in either 5000 ppm chlorine or 70% ethyl alcohol. Category II.
- These results emphasize the proper selection of disinfectants for use in disinfecting semicritical items (e.g., applanation tonometers)

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Summary

D/S guidelines must be followed to prevent exposure to pathogens that may lead to infection

THANK YOU!

disinfectionandsterilization.org