Controversies in Reprocessing Flexible Endoscopes: High Level Disinfection or Terminal Sterilization????

HONG KONG HOSPITAL AUTHORITY - ADVANCED COURSE FOR INFECTION CONTROL NURSES – NOVEMBER 2017

Learning Objectives

1. Review global trends for MIS procedures and use of endoscopes including recommendations for enhanced reprocessing procedures

2. Contrast lethality and validation methods between high level disinfection and terminal sterilization

3. Identify and contrast quality control approaches of high level disinfection to terminal sterilization in healthcare facilities.

Janet Prust - Disclosure

Employee of 3M Health Care

Infection Prevention Division

Association for Advancement of Medical Instrumentation (AAMI)
Positions held:

AAMI Board of Directors – Director representing industry since 2015

Member:

- AAMI Finance committee
- Sterilization Standards Committee
- WG 61: Chemical sterilants hospital practices – co-chair
- WG 84: Endoscope reprocessing
- WG 40: Steam sterilization hospital practices
- WG 13: Washer disinfectors; TAG to ISO TC 198 WG 13
- WG 93: Cleaning of reusable devices
- Sterilization of endoscopes stakeholders group
- Task group – HVAC conditions in OR

Minimally Invasive Surgery (MIS) – Key Global Trend

MIS is a key advancement with better patient outcomes: faster recovery, reduced infections, less cost

Type	Procedure example	Example devices	Patient Risk	Method per Spaulding Classification
Rigid	Arthroscopy Laparoscopy	Arthroscope Laparoscope	High	Steam sterilization
Flexible	Diagnostic: Colonoscopy Bronchoscopy	Colonoscope Bronchoscope	HIGH?	High level disinfection (HLD) or terminal sterilization
Flexible short	Surgical: kidney biopsy, bladder stone removal	Cystoscope Ureterscope	High	Low temp terminally sterilize
Flexible	ERCP - MIS Colonoscopy with biopsy	Duodenoscope Colonoscope	HIGH	HLD or terminal sterilization ????

Key question: Should all devices used for MIS be sterilized?

Increasing Recognized Outbreaks Related to Endoscopy Procedures

Growing recognition of patient infections from inadequately processed devices or inadequate guidelines

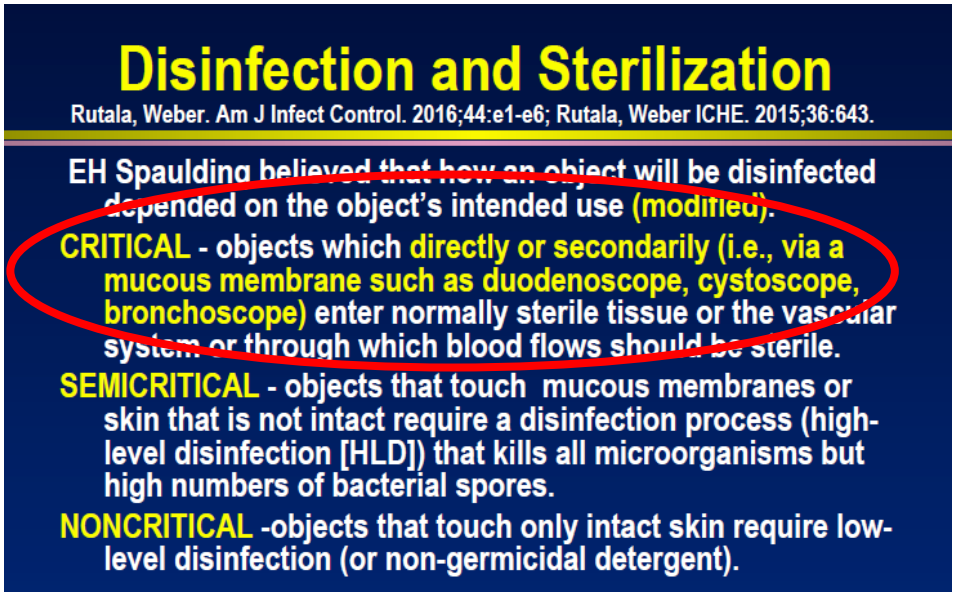
Flexible endoscopes

- Commonly used for surgical procedures with high level disinfection
- Critical device is a higher risk of infection to patient

HLD or Terminal Sterilization? The key question

Is the Spaulding Classification Out of Date?

Proposed of Reclassification of Semi-Critical Devices to Critical Devices (e.g. flexible endoscopes)



Source: Dr. William Rutala, USA APIC 2016, SGNA 2017, AAMI 2017

Do Spaulding Classifications need to be revised?

Proposed of Reclassification of Semi-Critical Devices to Critical Devices (e.g. flexible endoscopes)

Patient Contact	Examples	Device Classification	Minimum Disinfection Level
Intact Skin		Non-Critical	Low Level or Intermediate Level Disinfection
Mucous Membranes or non-intact skin		Semi-Critical	High Level Disinfection
Sterile areas of the body, vascular system		Critical	Sterilization

Source: Healthcare Purchasing News (June 2014)

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 (modified).

CRITICAL - objects which directly or 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).

Source: Dr. William Rutala, USA SGNA 2017
Duodenoscope and Endoscope Reprocessing: A need to shift from disinfection and sterilization

Dr. Spaulding's Risk Classifications

Earle Spaulding of Temple University (Philadelphia, PA) in a 1939 paper on disinfection of surgical instruments *in a chemical solution* proposed "a strategy for sterilization or disinfection of inanimate objects and surfaces based on the degree of risk involved in their use for the medical community".

Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008

More than 30 years ago, Earle H. Spaulding devised a rational approach to disinfection and sterilization of patient-care items and equipment.[14] This classification scheme is so clear and logical that it has been retained, refined, and successfully used by infection control professionals and others when planning methods for disinfection or sterilization.[1, 13, 15, 17, 19, 20] Spaulding believed the nature of disinfection could be understood readily if instruments and items for patient care were categorized as critical, semicritical, and noncritical according to the degree of risk for infection involved in use of the items.

Spaulding EH. Chemical disinfection of medical and surgical materials. In: Lawrence C, Block SS, eds. Disinfection, sterilization, and preservation. Philadelphia: Lea & Febiger, 1968:517-31.

Photo: Temple University Historical Archives

Table 1: Spaulding's Classification of Medical Devices and Required Level of Processing/Reprocessing

Classification	Definition	Level of Processing/Reprocessing	Examples
Critical Device	Device that enters sterile tissues, including the vascular system	Cleaning followed by Sterilization	▪ Surgical instruments ▪ Biopsy instruments ▪ Foot care equipment ▪ Cystoscopes*
Semi-critical Device	Device that comes in contact with non-intact skin or mucous membranes but do not penetrate them	Cleaning followed by High-Level Disinfection (as a minimum) Sterilization is preferred	▪ Respiratory therapy equipment ▪ Anaesthesia equipment ▪ Tonometer ▪ Cystoscopes*
Noncritical Device	Device that touches only intact skin and not mucous membranes, or does not directly touch the client/patient/resident	Cleaning followed by Low-Level Disinfection (in some cases, cleaning alone is acceptable)	▪ ECG machines ▪ Oximeters ▪ Bedpans, urinals, commodes

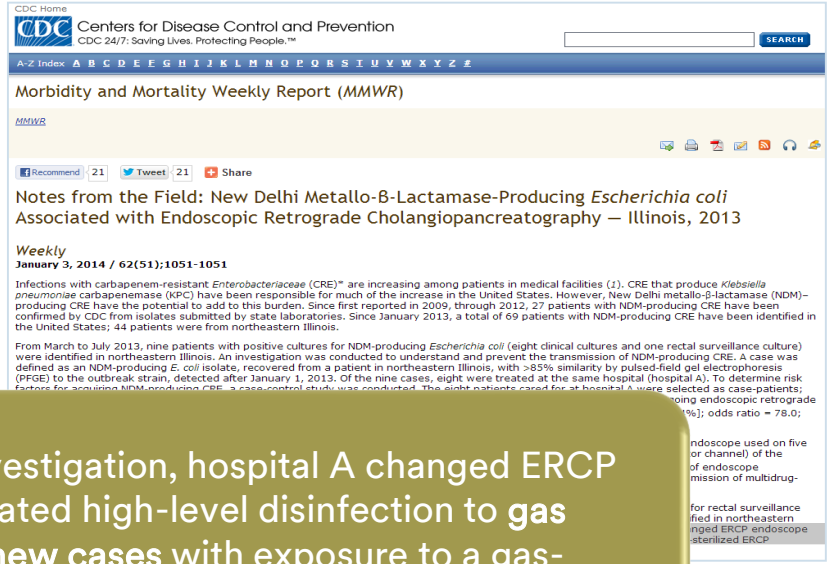
*Cystoscopes – 2012 appear in Critical and Semi-critical classification section. The preferred level of reprocessing is sterilization.

Original paper = Did it actually provide examples of devices?

Source: Berry and Kohn OR Technique 2016

MIS and Outbreaks Renews Need for Terminal Sterilization

- 2012 outbreaks with multi-drug resistant organisms seen
- US CDC published alert



CDC Home

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SEARCH

A-Z Index A B C D E F G H I J K L M N O P Q R S T U V W X Y Z #

Morbidity and Mortality Weekly Report (*MMWR*)

MMWR

Recommend 21 Tweet 21 Share

Notes from the Field: New Delhi Metallo-ß-Lactamase-Producing *Escherichia coli* Associated with Endoscopic Retrograde Cholangiopancreatography — Illinois, 2013

Weekly
January 3, 2014 / 62(51);1051-1051

Infections with carbapenem-resistant *Enterobacteriaceae* (CRE)* are increasing among patients in medical facilities (*1*). CRE that produce *Klebsiella pneumoniae* carbapenemase (KPC) have been responsible for much of the increase in the United States. However, New Delhi metallo-β-lactamase (NDM)–producing CRE have the potential to add to this burden. Since first reported in 2009, through 2012, 27 patients with NDM-producing CRE have been confirmed by CDC from isolates submitted by state laboratories. Since January 2013, a total of 69 patients with NDM-producing CRE have been identified in the United States; 44 patients were from northeastern Illinois.

From March to July 2013, nine patients with positive cultures for NDM-producing *Escherichia coli* (eight clinical cultures and one rectal surveillance culture) were identified in northeastern Illinois. An investigation was conducted to understand and prevent the transmission of NDM-producing CRE. A case was defined as an NDM-producing *E. coli* isolate, recovered from a patient in northeastern Illinois, with >85% similarity by pulsed-field gel electrophoresis (PFGE) to the outbreak strain, detected after January 1, 2013. Of the nine cases, eight were treated at the same hospital (hospital A). To determine risk

In September 2013, as a result of the investigation, hospital A changed ERCP endoscope reprocessing from automated high-level disinfection to **gas sterilization with ethylene oxide**; **no new cases** with exposure to a gas-sterilized ERCP endoscope have been identified.

CRE Outbreak - USA FDA Gastroenterology and Urology Devices Advisory Panel – May 2015

Supplemental Measures to Enhance Duodenoscope Reprocessing: FDA Safety Communication

August 4, 2015

- *"Combined with strict adherence to the duodenoscope manufacturer's reprocessing instructions, the following supplemental measures may further help reduce the risk of infection transmission associated with the use of duodenoscopes."*
- ***"When possible and practical, duodenoscopes should be sterilized due to the greater margin of safety provided by sterilization."***

Supplemental Measures:

Microbiological Culturing

Ethylene Oxide Sterilization

Use of a Liquid Chemical Sterilant Processing System

Repeat High-Level Disinfection

U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

All facilities recommended to take action for reprocessing with more than HLD

Evidence - Ethylene Oxide Sterilization (EO) Resolved Endoscope CRE Outbreaks

1. Epstein et al JAMA 2014; 312:1447-1455 / Northeastern Illinois Hospital with outbreak first reported in CDC MMW Jan 2014; No breach in reprocessing with HLD identified

Resolution: **Ethylene oxide *'…(gas) sterilization contributed to controlling this outbreak….'***

2. Zachary L. Smith, et al. GASTROINTESTINAL ENDOSCOPY Volume 81, No. 4 : 2015/ Milwaukee, Wisconsin; Review of the procedure revealed that all standard recommendations and guidelines were followed

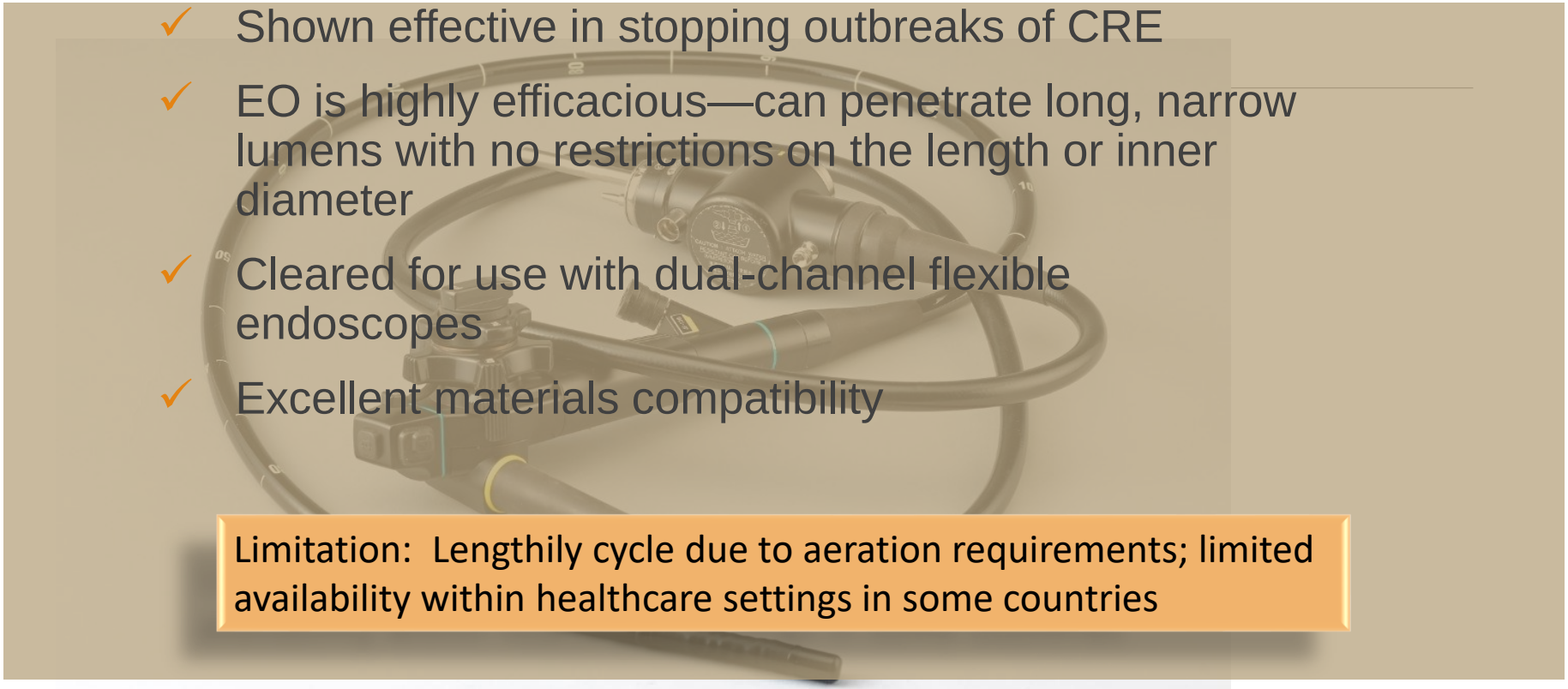
Resolution: ***"After EtO sterilization of all duodenoscopes, no additional cases of CRE infection were diagnosed".***

3. Sheila McCool et al. Abstract. ID Week. Presented Oct. 7–11, 2014. University of Pittsburgh Medical Center; No breach in reprocessing with HLD identified

Resolution: ***"No additional healthcare-associated infections have been noted since ERCP/EUS scope reprocessing included ETO "***

Terminal sterilization with ethylene oxide effectively stopped the outbreaks

Why is Ethylene Oxide able to sterilize flexible GI endoscopes?

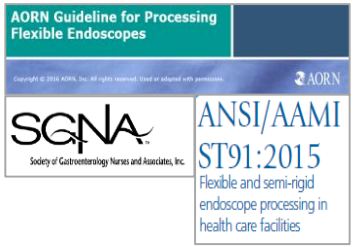


- ✓ Shown effective in stopping outbreaks of CRE
- ✓ EO is highly efficacious—can penetrate long, narrow lumens with no restrictions on the length or inner diameter
- ✓ Cleared for use with dual-channel flexible endoscopes
- ✓ Excellent materials compatibility

Limitation: Lengthily cycle due to aeration requirements; limited availability within healthcare settings in some countries

Public, Regulatory, Professional Attention to the Outbreaks

1. Special US governmental committee stakeholder meetings
2. US Senate sub-committee investigation
3. On-going media reports
4. New or update guidelines
5. Recommendations for independent expert review of processes
6. Revalidated endoscope manufacturers instructions for use
7. New training programs and competency assessment
8. New certification programs
9. **Louder recommendations to revise or clarify Spaulding's classification**



Where these the right questions and right actions?

Guidelines have been updated….. *still issues*

The Joint Commission reports 74% of ITL are reprocessing related (2017) …… *continuing to increase*

Doubled down on competency assessment …. *still not sure it is effective*

IFUs updated …… *nearly impossible to reliably follow*

Periodic culturing implemented……*no reliable method* …….*false sense of security?*

New evidence showing post HLD or sterilization residual contamination with other types of endoscopes including bronchoscopes, colonoscopes, gastroscopes, cystoscopes ……

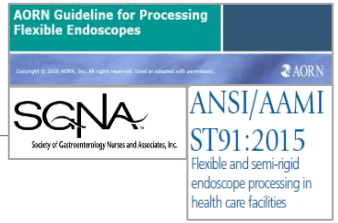


Image sources: AORN, SGNA, AAMI, TJC, Olympus

Strong Evidence for Sterilization of Endoscopes Presented at Stakeholder Meeting

Posted September 13, 2017

Evidence indicating that sterilization is a superior method to high-level disinfection (HLD) for the reprocessing of endoscopes was reported during a meeting held on Sept. 11 at AAMI headquarters in Arlington, VA. In addition to not reducing microbial contamination as effectively as sterilization, reprocessing endoscopes using HLD is overly complex and involves far greater risks to patient safety.

More than 40 stakeholders representing healthcare professional organizations, manufacturers, testing labs, independent research groups, academia, patient and clinical end user interests, the Food and Drug Administration (FDA) Center for Devices and Radiological Health, and the Centers for Disease Control and Prevention, among others, attended the meeting in person or by teleconference.

William Rutala, MS, MPH, PhD, director of the statewide program for infection

Related

Study Shows Endoscope Processing Practices Often Insufficient

FDA Releases Recommendations to Combat Cross-Contamination from Endoscopes

FDA Releases Recommendations for Duodenoscope Reprocessing

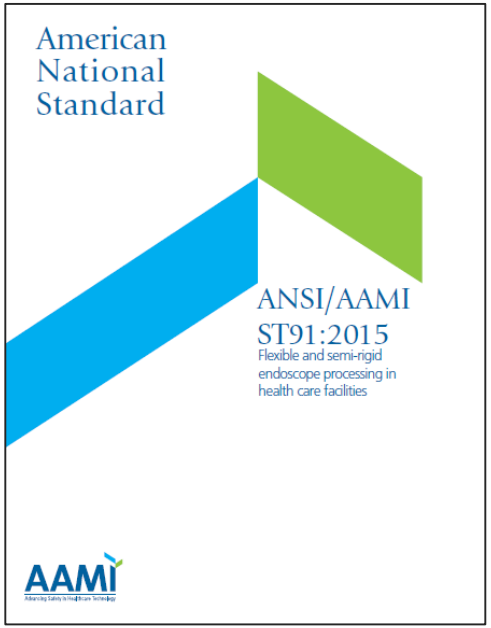
Source: www.aami.org

http://www.aami.org/newsviews/newsdetail.aspx?ItemNumber=5243&utm_source=Email&utm_medium=Web&utm_campaign=Conv

September 11, 2017 – AAMI Stakeholders Meeting

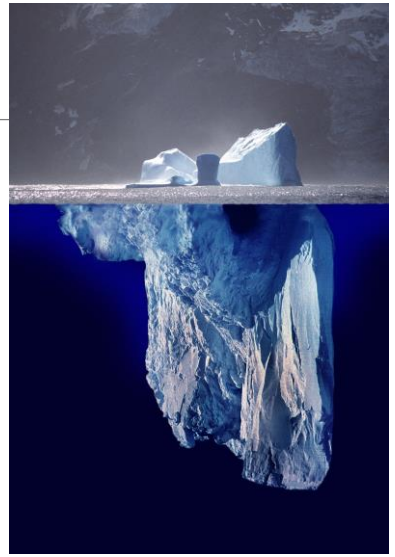
Dr. William Rutala, Cori Ofstead, MPH, Dr. Michelle Alfa invited presenters

- Significant evidence shows that current flexible endoscope reprocessing methods are ineffective
- Contaminated endoscopes have contributed to numerous outbreaks
- Risk is related to all types of flexible endoscopes
- Key challenges:
  - high contamination on endoscopes
  - non-existent margin of safety
  - very complex reprocessing procedures that cannot be consistently achieved
  - complex design of the devices
  - potential biofilm formation



Contributing Factors for Concern

- Inadequate surveillance of outpatient procedures for healthcare-associated infections
- Long lag time between colonization and infection
- Low frequency of infection
- Pathogens “usual” enteric flora
- Risk of some procedures might be lower than others (colonoscopy versus ERCP where normally sterile areas are entered)



Are the known outbreaks the tip of the iceberg?

Source: AAMI presentation - Dr. Rutala Sept 17

Factors that Contribute to Endoscope Disinfection Failures

- Heat labile devices – can not be steam sterilized
- Long, narrow lumens (3.5ft, 1-3mm) in GI endoscopes
- 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

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

AAMI Stakeholders Meeting: Key recommendations to AAMI WG 84

- Assess endoscope reprocessing procedures
- Implement quality control tools including cleaning verification
- Implement lighted, magnification inspection and use of borescope to assess integrity/damage
- Use cleaning device with friction to help reduce/remove biofilm
- Automate manual processes when possible
- Redefine/clarify Spaulding's Classification for critical endoscopes to require terminal sterilization
- Update guidelines and regulations to require sterilization for flexible endoscopes because they are high patient risk items

Strong user recommendation for sterilization of ALL flexible endoscopes at WG 84 meeting in October.

Latest Proposed Definition

Endoscope Reprocessing: A Need to Shift from Disinfection to Sterilization

Rutala, Weber. 2017. Manuscript in preparation.

CRITICAL - objects which directly or 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.

- Duodenoscopes
- Bronchoscopes
- Cystoscopes
- Other GI scopes such as colonoscopes and gastroscopes
  - many patients need a biopsy, which by definition enters sterile tissue
  - many patients will have disruptive or non-intact mucous membranes (e.g., gastric ulcers, other erosions)

Source: sterilizationanddisinfection.org – Dr. Rutala Ohio 2017

Understand Basic Definitions

Cleaning

- Removal of organic soil
- Microbes and soil can still be present
- Device can still be infectious

High-Level Disinfection (HLD)/ Liquid Chemical Sterilization

- Microbial kill under defined conditions
- Spores are not killed HLD
- Spores killed with LCS / device is not sterile/ must be reprocessed if not used immediately
- Effectiveness dependent on meticulous cleaning

Terminal Sterilization

- Kills all living organisms including spores
- Effectiveness dependent on meticulous cleaning
- Dry, packaged, sterile device
- Overkill processes with large margin of safety

Low-Temperature Sterilization Processes

Terminal sterilization processes use chemical gases or vapors at lower temperatures to process heat- and moisture-sensitive instruments.

- Ethylene Oxide – no lumen or materials restrictions
- Vaporized Hydrogen Peroxide – restrictions – require booster
- Steam Formaldehyde – restrictions on lumen, high temp and humidity
- Liquid chemical sterilant system
  - Device not packaged
  - Non sterile water used to rinse
  - Not terminal or over-kill process

Sterilization of Flexible Endoscopes

Steam	Hydrogen Peroxide	Hydrogen Peroxide / Ozone	Liquid Chemical Sterilization	Ethylene Oxide
Damage from high temperature Limitations on channel length and inner diameter	Designed with a sterility assurance level (SAL) of 10^{-6} Limitations on channel length and inner diameter - * outside of US booster may be available Highly oxidative chemistry	Designed with a sterility assurance level (SAL) of 10^{-6} Limitations on channel length and inner diameter Highly oxidative chemistry No history of clinical use and limited availability to date	Not a terminal sterilization process using sterilizer JIT reprocessor Not designed with a sterility assurance level (SAL) of 10^{-6}	Designed with a sterility assurance level (SAL) of 10^{-6} No limitations on channel length and inner diameter Long history of safe use for flexible endoscopes

H_2O_2 Processes

- Lumen limitations with conventional H2O2 process
- May require use of extra H2O2 in form of ‘booster’
- Not available for all types of sterilizers
- Proper use critical
  - Damage to device
  - Inadequate sterilization
  - Manufacturers instructions provide compatibility info

Image source: Google images

Comparison of methods for reprocessing:

High level disinfection

Low temperature terminal sterilization

Endoscope Reprocessing Basic Theory:

HOW IT SHOULD WORK

- Endoscopes are highly contaminated with use
- Cleaning removes most of the debris and microbes
- HLD takes care of almost everything else
- Sterilization is not required (yet), but it should kill everything

HOW IT ACTUALLY DOESN'T WORK

- GI endoscopes are contaminated with 10-14 logs of microbes post procedures
- **Manual cleaning 2-6 log reduction in microbes**
- HLD 4-6 log reduction in microbes
- Sterilization 12+ log reduction in microbes / over kill process with large margin of safety

RUTALA & WEBER, ICHE 2015; RUTALA & WEBER, JAMA 2014; RUTALA 2015 FDA PANEL PRESENTATION

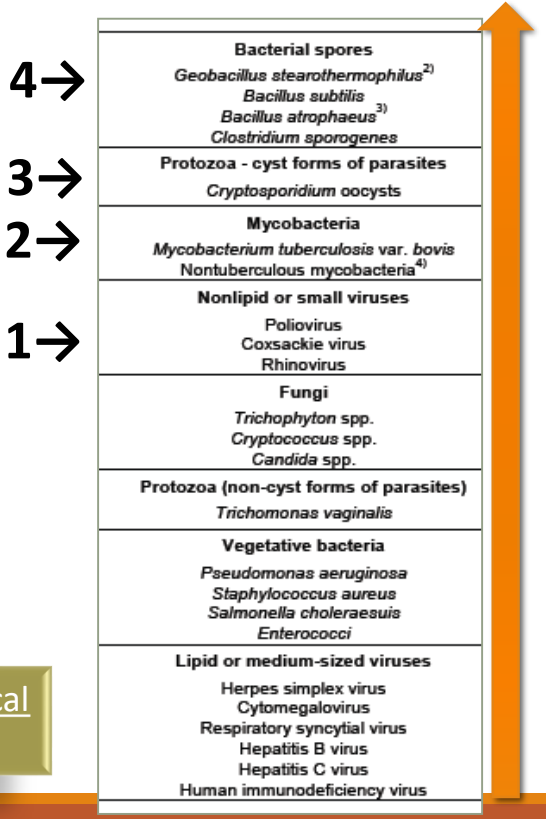
What is a Disinfectant or Liquid Chemical Sterilant?

An agent that destroys pathogenic or other microorganisms by chemical or physical means.

Three types of disinfectants:

1. Low level – no tuberculocidal claim
   - Non-critical devices and environmental surfaces, e.g. hospital bed rails, touch screens
   - Quaternary ammonium formulations, iodophors, alcohols, phenols, chlorinated compounds, oxidizers
2. Intermediate level – tuberculocidal claim
   - Non-critical devices , e.g.. stethoscopes, oximeters
   - Quaternary ammonium, phenols, chlorinated compounds, oxidizers
3. High level – capable of killing bacterial spores <u>in low numbers</u>
   - Semi-critical devices, e.g.. tonometers, speculums, non-invasive endoscopes
   - Glutaraldehyde, OPA, 2% H_2O_2, peracetic acid formulations
4. Liquid chemical sterilant – capable of killing spores

Sterilization or disinfection claims are based <u>on formulations, contact time or critical parameters and the validation method</u> – not the chemical



Source: Centers for Disease Control and Prevention. Guideline for disinfection and sterilization in healthcare facilities. 2008. CDC

What is a Chemical Sterilant?

Three categories of chemical sterilants:

Liquid Chemical Sterilant

Chemical agent that provides microbial kill adequate to obtain sterilization label claim

High Level Disinfectant

Liquid chemical sterilant with a shorter contact time and achieves microbial kill except for large numbers of spores.

- **Manual or automated system used under defined conditions ; rinsed with water**

Gaseous Chemical Sterilants

- Chemical agent that achieves terminal sterilization and is used in a sterilizer.
- Validated process with defined cycle conditions and achieves Sterility Assurance Level (SAL) of 10^{-6}

Disinfection or sterilization claims are based on formulations, contact time or critical parameters and the validation method – not the chemical

Source: ANSI/AAMI ST58 2013 - Chemical sterilization and high-level disinfection in health care facilities

Chemical Germicidal Agents Comparison

Liquid chemical sterilants/ high-level disinfectants

- 2% hydrogen peroxide
- Glutaraldehyde formulations
- OPA formulations
- Peracetic acid (hydrogen peroxide) formulations

Gaseous sterilization methods

- Ethylene Oxide gas
- Hydrogen peroxide vapor with plasma (50+%)
- Hydrogen peroxide vapor without plasma
- Formaldehyde vapor

"Processes that use LCSs/HLDs and gaseous chemical sterilization processes are validated by different methods and they do not provide the same level of sterility assurance.
Medical devices undergoing gaseous chemical sterilization can be packaged to maintain product sterility indefinitely. However, devices processed with LCSs/HLDs are not packaged." AAMI ST 58

Terminal Sterilization – designed for higher margin of safety

- Definition of terminal sterilization: Demonstrate ability to kill 12+ Logs of spores validated with a Sterilization Assurance Level (SAL 10^{-6})

- HLD/LCS = 6 Logs

1,000,000 = 10x10x10x10x10x10 = 10^6

"Disinfection processes do not ensure the margin of safety associated with sterilization processes"

- Sterilization = 12+ Logs

1,000,000,000,000 = 10x10x10x10x10x10x10x10x10x10x10x10 = 10^{12}

"The level of assurance in the margin of safety for sterilization is exponential of HLD"

Double HLD = 2,000,000

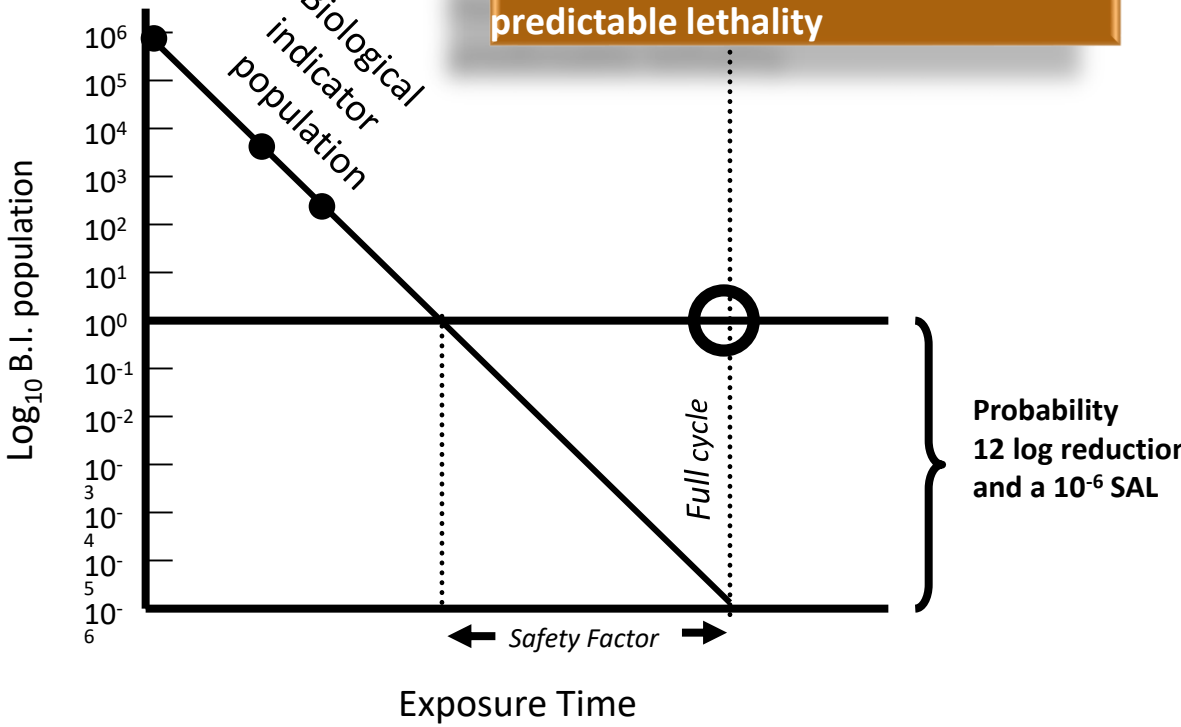
Terminal sterilization process validated to SAL and has a high margin of safety

Terminal Sterilization Validation Requirement

- Validated process to render a product free from viable microorganisms.
- Measured by kill of BI of most resistant organism to process
- Process achieves an SAL of 10^{-6} SAL – a one in a million chance a single organism can survive
- 12 logs of bacterial spore kill

ANSI/AAMI ST58; 2013

Demonstrates log linear kill kinetics = predictable lethality



Sterilization cycles designed with twice as much exposure time needed to kill BI

Terminal Sterilization Margin of Safety

- Margin of Safety refers to overkill factor in sterilization processes
- Provides successful process with:
  - Variation in sterilizer performance
  - Some variation in cleaning process
  - Variation in instrumentation (traditional processes)
- Possible because of linear kill kinetics and prediction of probability of surviving organism - SAL

Exercise: Calculate Remaining Logs

14 log bioburden -2 log removed by cleaning - 4 log killed by HLD =
8 log remaining Worst case w/HLD

14 log bioburden – 6 log removed by cleaning – 6 log killed by HLD =
2 log remaining with perfect process and heavy contamination scope

10 log bioburden – 6 removed by cleaning - 6 log killed by HLD =
0 log (2 log extra) perfect HLD world and low contamination

14 log bioburden – 2 removed by cleaning -12 log kill by sterilization =
0 log (heavy contamination, marginal cleaning = Overkill Sterilization

Materials Compatibility for Sterilization See Instructions for Use (IFU)

OLYMPUS

3.7 Ethylene oxide gas sterilization

The endoscope and accessories listed as compatible with ethylene oxide gas sterilization in Table 3.1 can be sterilized by ethylene oxide gas and aerated within the parameters given in Tables 3.2 and 3.3. When performing ethylene oxide gas sterilization, follow all national, professional, and institutional reprocessing protocols as well as the instructions provided by the manufacturer of your sterilization equipment.

STORZ
KARL STORZ—ENDOSKOPE

FUJIFILM

PENTAX MEDICAL

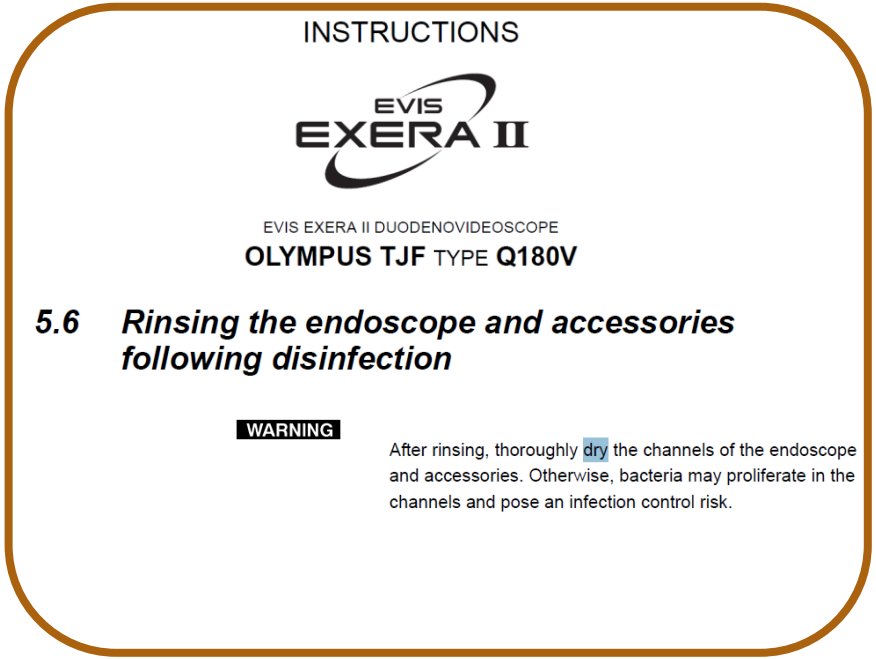
A) Ethylene Oxide Gas Sterilization (Recommended)

Ethylene Oxide (ETO) Gas Sterilization can be performed on these endoscopes, provided the following special instructions, which may differ from other endoscopes, are followed to ensure the proper performance of the instrument. Adhere to the sterilization manufacturer's instructions and always use a biological indicator.

Device manufacturers provide instruction for EO processing in addition to HLD method
H2O2 processes for some types of endoscopes include statement re: damage

Drying and Sterilization of Endoscopes

- Similar to HLD – drying is critical for sterilization
- Device is dried PRIOR to packaging
- No solid data on appropriate drying method or time
  - “Unresolved issue”
  - Limited direction provided in IFU
- New concern on use of alcohol as a drying agent
  - Similar to aldehydes – alcohol is shown to be a potential fixative agent of bioburden


INSTRUCTIONS

EVIS EXERA II

EVIS EXERA II DUODENOVIDEOSCOPE

OLYMPUS TJF TYPE Q180V

5.6 Rinsing the endoscope and accessories following disinfection

WARNING

After rinsing, thoroughly dry the channels of the endoscope and accessories. Otherwise, bacteria may proliferate in the channels and pose an infection control risk.

Guidelines for Drying Endoscopes

New evidence confirming residual moisture remain in endoscopes; Key focus of newer guidelines

AORN

- "Instrument air should be provided in the endoscopy processing room. Compressed air facilitates flushing and drying of channels and lumens."
- "Clean, filtered air is required for drying lumens and small channels without introducing contaminants into the clean device."
- "Use a drying cabinet or a cabinet with HEPA-filtered air and positive pressure with air circulating around the endoscopes."

SGNA

- "All channels and the surface of the endoscope must be thoroughly dried **before storage**."
- "Drying is as important to the prevention of disease transmission and nosocomial infection as cleaning and HLD."
- **"An endoscope that is not dry must be reprocessed *before use*."**

Terminal Sterilization Performance Monitoring and Routine Load Release

Performance Monitoring and Routine Load Release

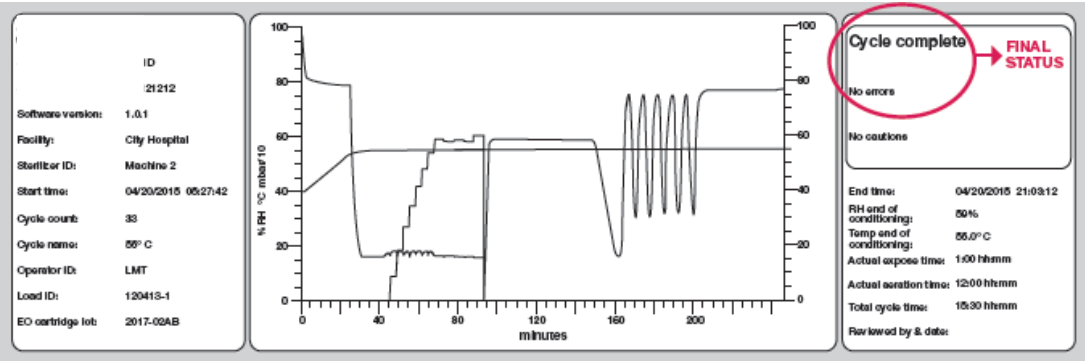
- **Three Types Sterilizer Efficacy Monitoring**
  1. Physical monitoring of cycle (sterilizer cycle printout)
  2. External and internal chemical indicator monitoring of packages
  3. Monitoring of every load with a Process Challenge Device (routine test pack) with a biological and a chemical indicator

- **Routine Load Release**
  1. Verify all indicator provide an acceptable result
  2. Quarantine implants until BI results are known

Quality Control – Physical monitoring of critical cycle parameters

Physical monitoring of critical cycle parameters

- Cycle Temperature
- Cycle Time
- Sterilant concentration (and humidity for EO)
- Pressure (for H2O2)

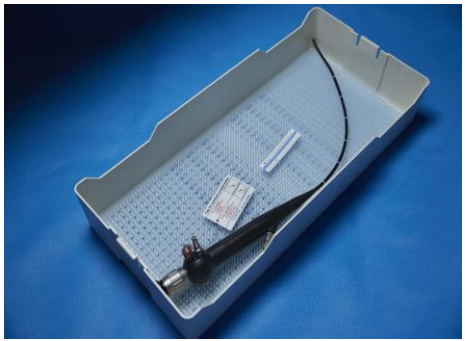


Performance Monitoring and Routine Load Release

Chemical Indicators

- Internal chemical indicators detect equipment malfunctions & assist certain procedural errors

- External chemical indicators distinguish between processed and unprocessed items



Performance Monitoring and Routine Load Release

Biological Indicators for H2O2

- BIs contain spores of *Bacillus stearothermopolis*
  - Only sterilization monitor that provides a proof of lethality of the process
- BIs should comply with ANSI/AAMI/ISO 11138-1, 2016

BI Process Challenge Device (PCD) – if applicable

- PCD may be:
  - User-assembled test pack
  - Commercial preassembled test pack

Quality Control Comparison Terminal Sterilization to HLD/LCS

Quality Control Measure	Terminal Sterilization	HLD or LCS
Packaged for Terminal Sterilization	YES	NO
Critical Physical Parameters in Cycle Report	YES	Manual – No AER – Yes (if w/ printout)
External Chemical Indicators on Device Package	YES	NO
Internal Chemical Indicators inside Device Package	YES	NO
Biological Indicator Designed per International Standards	YES	NO
Process Challenge Device Representing Worst Case Device	YES	NO

Quality Control Comparison

Quality Control Measure	Terminal Sterilization	HLD or LCS
Minimum Effectiveness Concentration of HLD	N/A	YES (solution test strip)
Spore Test Strip HLD	N/A	For one system only
Allows for Recognized Method Product Testing	YES	NO
Acceptable Method for Implants	YES	NO
Endoscope is Dry for Storage after Processing ?	YES	NO
Endoscope is Packaged in Sterile Packaging ?	YES	NO

Summary Points

- Patient-ready endoscopes are contaminated
- Endoscopes are heavily contaminated after the procedure – much more so than surgical instruments
- High level disinfection has zero margin of safety and isn't working to provide safe endoscopes
- Terminal sterilization has a built in margin of safety and robust quality control monitoring requirement
- Key stakeholders are calling for a clarification of Spaulding's classification to move endoscopes to critical medical device category

Thank you

References

1. APSIC Guidelines for Disinfection and Sterilization of Instruments in Healthcare Facilities. Asia Pacific Infection Control Society. Jan 2017
2. ANSI/AAMI ST91:2015. Flexible and semi-rigid endoscope processing in healthcare facilities.
3. ANSI/AAMI ST58:2013. Chemical sterilization and high level disinfection in healthcare facilities.
4. ANSI/AAMI ST41: 2008(R2012). Ethylene oxide sterilization in healthcare facilities: Safe and effective use
5. Epstein L, Hunter J, et. Al. **New Delhi Metallo β-Lactamase-producing carbapenem-resistant *Escherichia coli* associated with exposure to duodenoscopes**. JAMA 2014. (312:1447-55
6. O'Horo, J. C., Farrell, A., Sohail, M. R., *et al.* (2016). Carbapenem-resistant Enterobacteriaceae and endoscopy: An evolving threat. *Am J Infect Control* **44**, 9: 1032-6.
7. William A. Rutala and David J. Weber **(2015). ERCP Scopes: What Can We Do to Prevent Infections?. Infection Control & Hospital Epidemiology, 36, pp 643-648**
8. Chang CL, Su LH, Lu CM, Tai FT, Huang YC, Chang KK. Outbreak of ertapenem-resistant *Enterobacter cloacae* urinary tract infections due to a contaminated ureteroscope. Journal of Hospital Infection. 2013 Oct 31;85(2):118-24.
9. Naryzhny I, Silas D, Chi K. Impact of ethylene oxide gas sterilization of duodenoscopes after a carbapenem-resistant Enterobacteriaceae outbreak. Gastrointestinal endoscopy. 2016 Aug 31;84(2):259-62
10. Rutala, Weber. Am J Infect Control. 2016;44:e1-e6; Rutala, Weber ICHE. 2015;36:643.

References

Naryzhny I, Silas D, Chi K. Impact of Ethylene Oxide Gas Sterilization of Duodenoscopes after a Carbapenem-Resistant Enterobacteriaceae Outbreak. Gastrointestinal Endoscopy. In press January **2016**. **US**

UCLA statement on notification of patients regarding endoscopic procedures. UCLA Health Web site. https://www.uclahealth.org/news/ucla-statement-on-notification-of-patients-regarding-endoscopic-procedures Updated February 19, **2015**. Accessed August 25, 2015. **US**

FDA Safety Communication. Supplemental measures to enhance duodenoscope reprocessing. August **2015**. **US**

Rutala WA. ERCP Scope: A Need to Shift from Disinfection to Sterilization? Presented at: Meeting of the U.S. FDA Medical Devices Advisory Committee Gastroenterology-Urology Devices Panel; May 14-15, **2015**; Washington, D.C. **US**

McCool S, Muto CA, Querry A, et al. High Epstein L, Hunter JC, Arwady MA, et al. New Delhi Metallo-β-Lactamase–Producing Carbapenem-Resistant Escherichia coli Associated with Exposure to Duodenoscopes. JAMA. **2014**; Vol. 312(14):1447-1455. **US**

Smith ZL, Oh YS, Saeian K, et al. Transmission of carbapenem-resistant Enterobacteriaceae during ERCP: time to revisit the current reprocessing guidelines. Gastrointestinal Endoscopy. **2014**;81(4):1041-1045. **US**

Level Disinfection (HLD) Failure in Gastrointestinal Scopes with Elevator Channels – Is it Time to Switch to Ethylene Oxide (ETO) Sterilization? Poster presented at: IDWeek; October 8-12, **2014**; Philadelphia, PA. **US**

Chang, CL, Su LH, Lu CM, et al. Outbreak of ertapenem-resistance Enterobacter cloacae urinary tract infections due to a contaminated ureteroscope. Journal of Hospital Infection. **2013**. Vol 85: 118-124. **Taiwan**.