EDUCATION

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High Level Disinfection and Sterilization Options for Flexible Endoscopes

One Integrated Approach to Healthcare.

STERIS

Continuing Education

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  - **1** contact hour(s) of continuing education credit:

    - **CBRN (**California Board of Registered Nursing);
    - **CBSPD** (Certified Board for Sterile Processing and Distribution); and
    - **IAHCSMM** (International Association of Healthcare Center Service Materiel Management).

  - **1** AEU by **BASC** (provider # 1417)

- Participants must be present for the entire presentation/seminar to achieve successful completion and receive continuing education credit; partial credit will not be given.

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Learning Objectives

Upon completion of this program, you will be able to:

- Review current standards and guidelines regarding flexible endoscopes
- Discuss the advantages and disadvantages of high level disinfection and sterilization methods

Definitions

- Regulations
  - A rule or directive made and maintained by an authority
  - Mandatory
- Standards
  - Provide requirements and specifications that can be used to ensure consistency and fit for purpose
  - National and International (often the same, often not)
  - Voluntary, but can become mandatory
    - Act of legislation – New Jersey adoption of standards published by Association for the Advancement of Medical Instrumentation (AAMI)
    - If you claim compliance

Definitions, continued

- Guidelines, Recommended Practices, Technical Information reports
  - Technical guidance, information or preferred procedures regarding a given topic
    - e.g., AAMI TIRs, AORN Guidelines for Perioperative Practice
  - Voluntary but with interpretation

Regulatory Agencies

Agencies that Provide Accreditation Services

Groups That Provide Standards and Guidelines

Guidelines

- CDC Guideline for Decontamination and Sterilization in Healthcare Facilities

- ASGE/SHEA/SGNA/APIC: Multi-society guideline on reprocessing flexible gastrointestinal endoscopes

- SGNA: Standards of Infection Control in Reprocessing of Flexible Gastrointestinal Endoscopes

- SGNA: Guideline for Use of High Level Disinfectants & Sterilants for Reprocessing Flexible Gastrointestinal Endoscopes

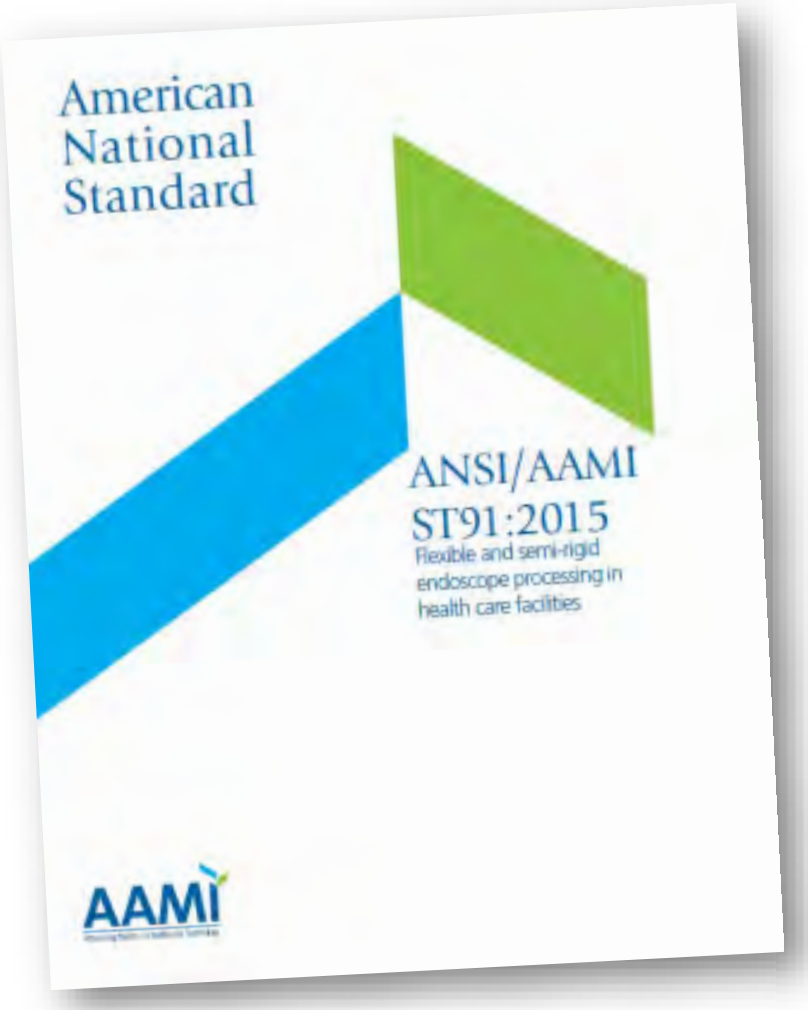
- AORN Guideline for Cleaning and Processing Flexible Endoscopes and Endoscope Accessories

Association for the Advancement of Medical Instrumentation

User Standards

- **ANSI/AAMI ST91 -** Flexible and semi-rigid endoscope processing in health care facilities
- **ANSI/AAMI ST58 -** Chemical sterilization and high-level disinfection in healthcare facilities
- **AAMI/ANSI ST41 -** Ethylene oxide sterilization in healthcare facilities, safety and effectiveness
- **AAMI TIR34 -** Water for reprocessing of medical devices

ANSI/AAMI ST91

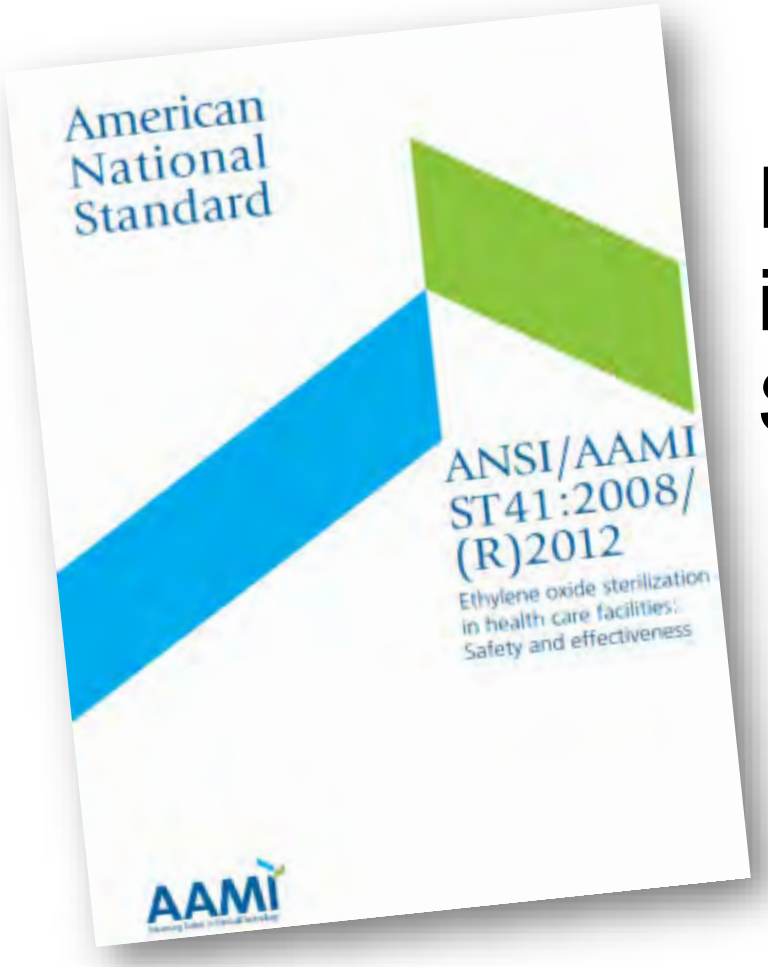


Flexible and semi-rigid endoscope reprocessing in health care facilities

ANSI/AAMI ST58

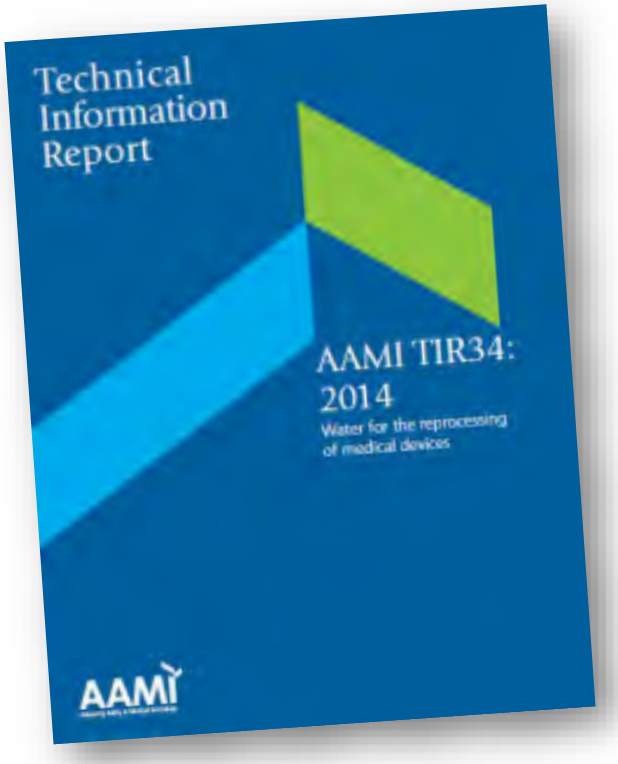
Guidelines for the selection and use of liquid chemical sterilants (LCSs)/high-level disinfectants (HLDs) and gaseous chemical sterilizers for use in hospitals and other health care facilities

ANSI/AAMI ST41



Ethylene oxide sterilization in health care facilities: Safety and effectiveness

AAMI TIR34 - Endoscopy Water



- Utility water:
  - Washing, rinsing soil and cleaning chemistry
  - Meets quality requirements from device and cleaning chemistry manufacturer
- Critical water:
  - Extensively treated for final rinse
- Automated Endoscope Reprocessors (AERs):
  - Incoming water does not contain not contain excessive microbial levels
  - Filtration used for bacteria-free quality
  - Critical water

FDA Guidance

Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling

Guidance for Industry and Food and Drug Administration Staff

Document issued on: March 17, 2015

This document supersedes: "Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: FDA Reviewer Guidance" (available at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM080268.pdf) issued April 1996.

The draft of this document was issued on May 2, 2011.

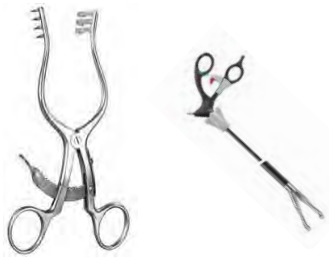
Increased Focus on Reprocessing Validations

- Quality of Reprocessing Instructions
- Attention to Human Factors
- Cleaning Validations

"It is important to note that cleaning, disinfection and sterilization are distinctly different processes." - FDA

* Reprocessing Medical Devices in Healthcare Settings: Validation Methods & Labeling, March 2015, Pg.6

Spaulding Classification

Patient Contact	Examples	Device Classification	Minimum Inactivation Level
Intact skin		Non-Critical	Cleaning and/or Low/Intermediate Level Disinfection
Mucous membranes or non-intact skin		Semi-Critical	Cleaning and Sterilization (or High Level Disinfection)
Sterile areas of the body, including blood contact		Critical	Cleaning and Sterilization

Endoscopes and HAIs

- Endoscopes most commonly linked to health care associated outbreaks and pseudo-outbreaks
- Flexible endoscopes represent high-risk devices
  - High levels of bacterial contamination
    - Mouth - 200+ species
    - Large intestine - 1,000 species
- Complex designs
- Numerous reports of breaches in reprocessing

Clostridium difficile

- $5 billion/year in healthcare costs
- Hospital costs >40% per case
- It's all about 100% spore kill!


Hospitals to report superbug infections

C. diff germ kills 3 more in Cuyahoga

HARLAN SPECTOR
Plain Dealer Reporter

Hospital infection spreads, toughens

C. diff cases in region grow.


The Washington Post

Stomach Bug Mutates Into Medical Mystery

Technology Hazards

#2 - Inadequate Cleaning of Flexible Endoscopes before Disinfection Can Spread Deadly Pathogens

ERCP Scopes

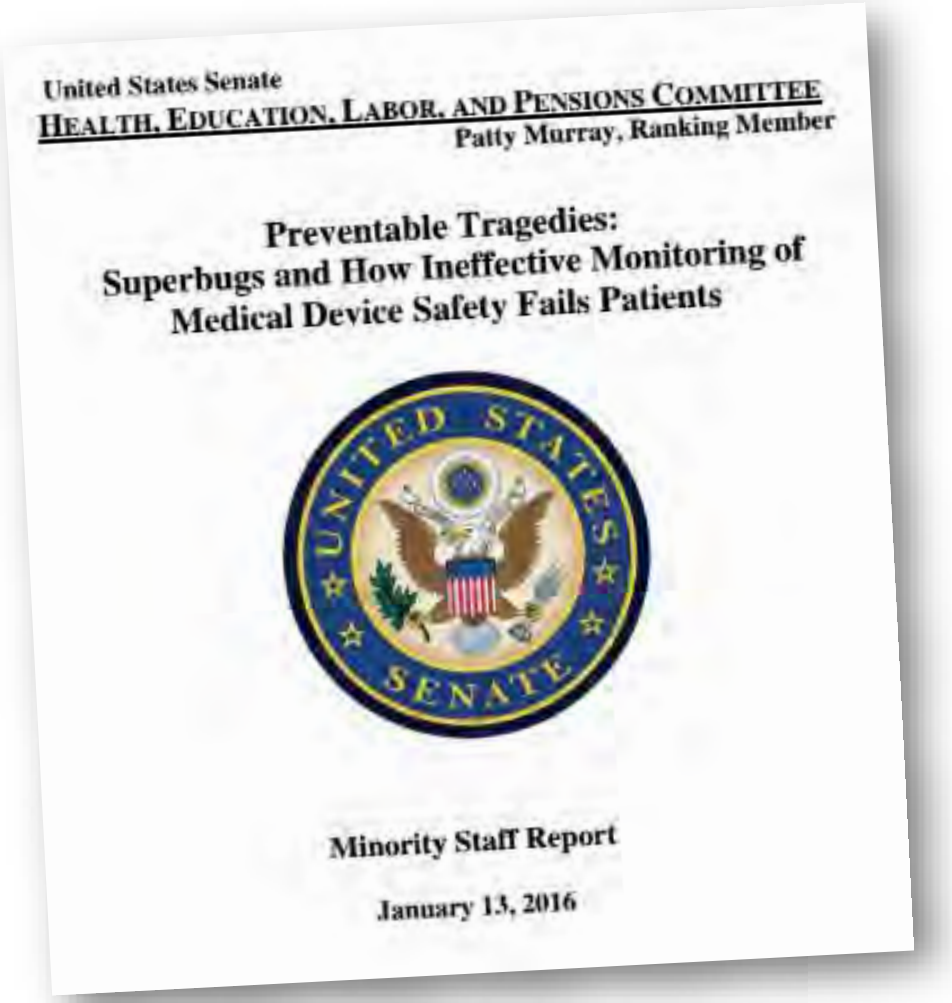
Deadly superbug infected patients at Seattle hospital

'Superbug' linked to 2 deaths

Superbug outbreak extends to hospital, linked to scope

Medical scope now tied to Wisconsin superbug outbreak

Senate Committee on Health, Education, Labor & Pensions



United States Senate

HEALTH, EDUCATION, LABOR, AND PENSIONS COMMITTEE

Patty Murray, Ranking Member

Preventable Tragedies:
Superbugs and How Ineffective Monitoring of Medical Device Safety Fails Patients

Minority Staff Report

January 13, 2016

Senate Committee: Scope Outbreak Worse Than Reported
January 15, 2016

Industry silence, hospital missteps, poor regulation cited

Senate investigations have concluded:

- The global wave of ‘superbug” infections linked to contaminated duodenoscopes was much wider than previously believed and could have been largely avoided
- At least 250 people in 25 outbreaks worldwide were sickened by the tainted instruments between 2012 and 2015
- The FDA, in turn, failed to alert hospitals, health care workers and the public for 17 months after learning of the potential hazard

Evaluation of Residual Contamination

Contents lists available at ScienceDirect

American Journal of Infection Control

journal homepage: www.ajicjournal.org

Brief Report

Assessing residual contamination and damage inside flexible endoscopes over time

Cori L. Ofstead MSPH [a,*], Harry P. Wetzler MD, MSPH [a], John E. Eiland MS, RN [a], Otis L. Heymann BA [a], Sarah B. Held MBA, RN [b], Michael J. Shaw MD [c]

[a] Ofstead & Associates, Inc, St Paul, MN
[b] Fairview Maple Grove Medical Center, Maple Grove, MN
[c] Division of Gastroenterology, Department of Medicine, University of Minnesota Medical School, Minneapolis, MN

Study: Damage and Contamination

Contents lists available at ScienceDirect

American Journal of Infection Control

journal homepage: www.ajicjournal.org

ELSEVIER

AJIC American Journal of Infection Control

Major Article

Longitudinal assessment of reprocessing effectiveness for colonoscopes and gastroscopes: Results of visual inspections, biochemical markers, and microbial cultures

Cori L. Ofstead MSPH [a,*], Harry P. Wetzler MD, MSPH [a], Otis L. Heymann BA [a], Ellen A. Johnson BAS [a], John E. Eiland MS, RN [a], Michael J. Shaw MD [b]

[a] Ofstead & Associates, Inc, Saint Paul, MN
[b] Division of Gastroenterology, Department of Medicine, University of Minnesota Medical School, Minneapolis, MN

- Rigorous reprocessing not consistently effective
- Incubation encouraged slow growing microbes
- Need routine visual inspection, and cleaning verification testing

Infections and Outbreaks

Stages of Processing

Contaminated

Cleaned

High- Level Disinfection

Sterilization

Understanding Processing Options

- High-level disinfectant
  - Kills all microorganisms except large number of bacterial spores
  - Use according to label
- Liquid chemical sterilant
  - Product validated to provide microbial kill adequate to obtain FDA clearance for a sterilization label claim (often at longer exposure times)
- Sterilization
  - Validated process to provide free from viable microorganisms

Hierarchy of Resistance

Bacterial Spores
Clostridium difficile
Clostridium perfringens
Clostridium botulinum – food poisoning

Sterilization

Mycobacteria
Mycobacterium tuberculosis
Mycobacterium chelonae

High Level Disinfection

Non-Enveloped Viruses
Poliovirus
Rhinovirus

Intermediate Level Disinfection

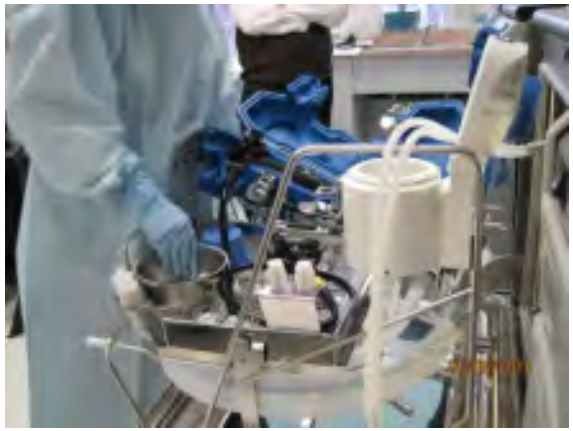
Fungi
Candida albicans – thrush
Trichophyton spp.

Low Level Disinfection

Vegetative Bacteria
Salmonella, ssp.
Staphylococcus, ssp.
E. coli, VRE, MRSA

Enveloped Viruses
Hepatitis A, B & C
Herpes Simplex
HIV, Ebola

Manual vs. Automated



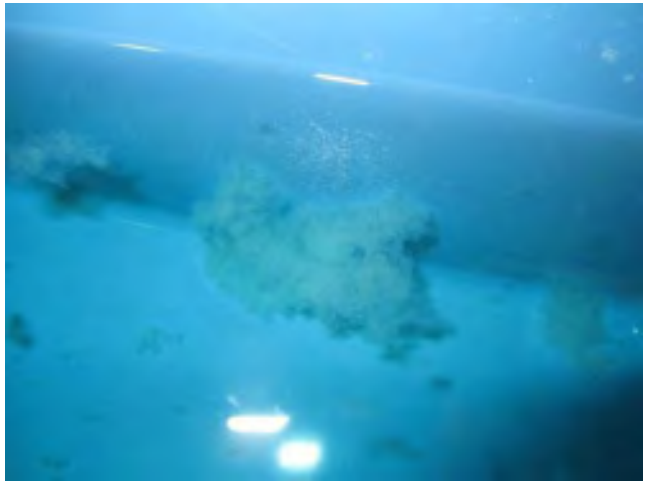
lanual

Automated

Automation

- Automate and standardize processing steps
- Reduced chemical exposure
- Specific design-dependant
- Pre-cleaning still required

Disinfection: Key Points



- Label claims vary
- Single use or multiple use
  - **Note:** Multiple use disinfectants: All surfaces of device in contact

High Level Disinfectant/Sterilants

Chemicals	Sterilant	High Level Disinfection	Notes
3.4% glutaraldehyde 20.1% isopropanol	8 hours at 20oC	10 mins at 20oC	Requires activation 3 rinses following exposure
2% hydrogen peroxide	6 hours at 20oC	8 mins at 20oC	No activation 1 rinse
0.575% OPA	No claim (passes sporicidal test at 32 hours at 20oC)	10 mins at 20oC	No activation 3 rinses
2.4% glutaraldehyde	10 hours at 25oC	45 mins at 25oC	Requires activation 3 rinses following exposure
3.4% glutaraldehyde	10 hours at 25oC	90 mins at 25oC	Requires activation 'Thoroughly' rinse following exposure

High Level Disinfectants

Aldehydes

- Glutaraldehyde
- Orthophthaladehyde (OPA)

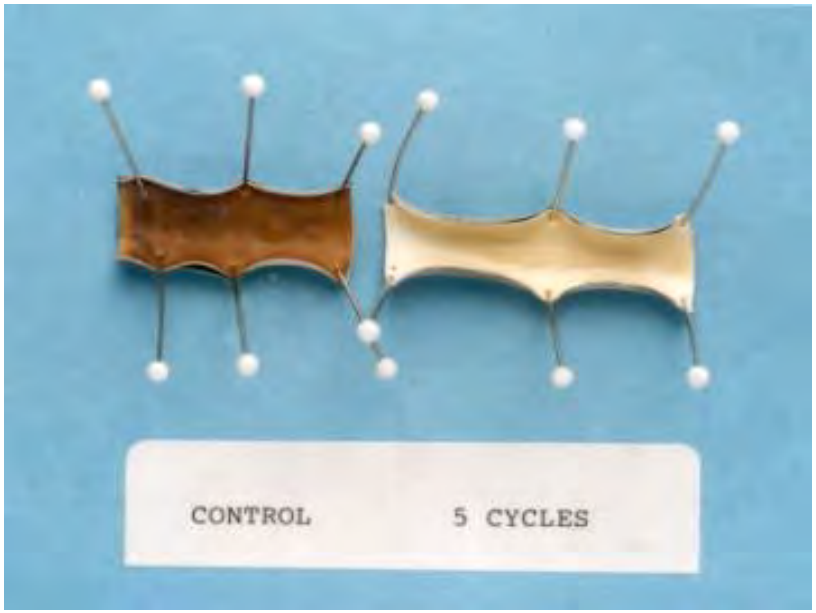
Oxidizing agents

- Hydrogen peroxide
- Peracetic acid

Each Product is Unique

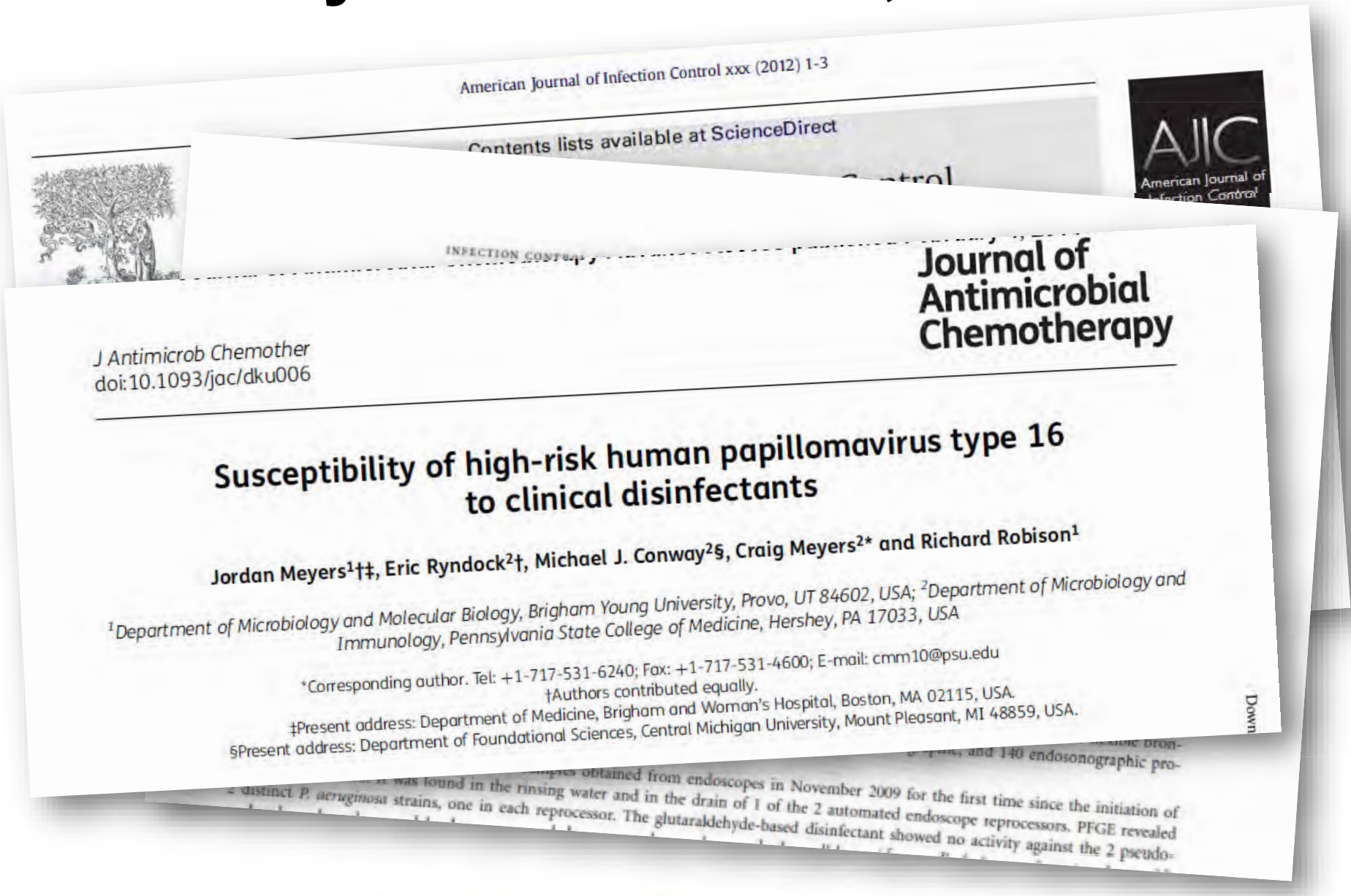
Aldehydes Concerns

- Safety
- Protein binder
- Reduction in use
  - Country-specific regulations
- Development of resistance
- Biofilms



Before & After 5 Cycles of Peracetic Acid, after long term use of Aldehydes.

Aldehydes Concerns, continued



American Journal of Infection Control xxx (2012) 1-3

Contents lists available at ScienceDirect

AJIC
American Journal of Infection Control

Journal of Antimicrobial Chemotherapy

J Antimicrob Chemother
doi:10.1093/jac/dku006

Susceptibility of high-risk human papillomavirus type 16 to clinical disinfectants

Jordan Meyers[1]†‡, Eric Ryndock[2]†, Michael J. Conway[2]§, Craig Meyers[2]* and Richard Robison[1]

[1]*Department of Microbiology and Molecular Biology, Brigham Young University, Provo, UT 84602, USA;* [2]*Department of Microbiology and Immunology, Pennsylvania State College of Medicine, Hershey, PA 17033, USA*

*Corresponding author. Tel: +1-717-531-6240; Fax: +1-717-531-4600; E-mail: cmm10@psu.edu

†Authors contributed equally.

‡Present address: Department of Medicine, Brigham and Woman's Hospital, Boston, MA 02115, USA.

§Present address: Department of Foundational Sciences, Central Michigan University, Mount Pleasant, MI 48859, USA.

Down

...obtained from endoscopes in November 2009 for the first time since the initiation of ... was found in the rinsing water and in the drain of 1 of the 2 automated endoscope reprocessors. PFGE revealed ... distinct *P. aeruginosa* strains, one in each reprocessor. The glutaraldehyde-based disinfectant showed no activity against the 2 pseudo-

...and 140 endosonographic pro-

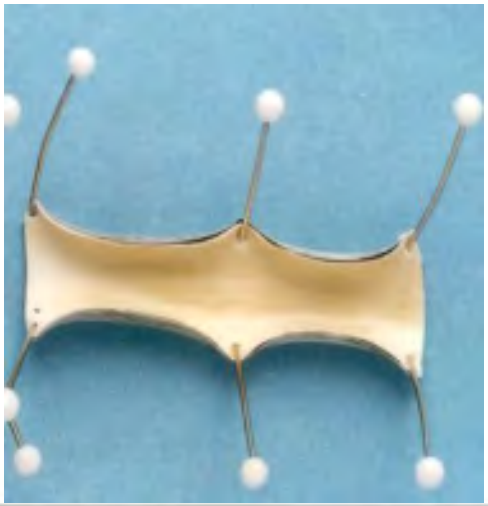
Shift to Oxidative Agents

1 Concern: Safety

- Safe for scopes, patients, staff, environment
- Toxicity of aldehydes
- Efficacy
- Employee health
- Aldehyde resistant organisms
- Efficiency

Oxidizing Chemistries

- Antimicrobial activity, fast cycle times
- Activity can vary on product formulation (e.g., temperature requirements)
- Low toxicity risks
- Effective in aiding the removal of organic matter

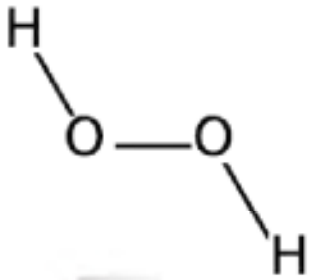


Oxidizing Chemistries, continued

- High level disinfection/sterilization
- Formulation dependent (liquid, gas, plasma)
- Reduce
  - Risk of cross-contamination
  - Risk of infection with resistant bacteria
- Effectiveness against
  - Aldehyde resistant bacteria

Hydrogen Peroxide (H_2O_2)

- Liquid or gas
- Formulation dependent
- HLD/sterilant
  - Environmentally friendly
  - Efficacy & surface compatibility



Hydrogen Peroxide (H_2O_2)

Applications

- Antisepsis
- Cleaning/Surface disinfection
- Disinfection
  - Buildings
  - Vehicles
  - Hospital rooms
  - Laboratories

Peracetic Acid (PAA)

- Effective biocide
- High potency
- Effective in presence of organic soil
- No toxic residues
- Combines with proper buffers and anti-corrosives to safely disinfect or sterilize endoscopes and other heat sensitive devise

Gaseous & Liquid Chemical Sterilization Options

Sterilization Essentials

- Sterilization is dependent on adequate cleaning, rinsing and device preparation
- Process claims are product specific
- Correct equipment installation, maintenance, use and periodic monitoring required for all systems
- Correct handling (including storage) required after the process

Ethylene Oxide

- Ensure devices are clean and dry
- Low pressure (vacuum) systems
- Sterilization parameters should be validated by endoscope manufacturer
- Post-sterilization aeration is essential
- Endoscopes may have a limited number of cycles before requiring extensive repair

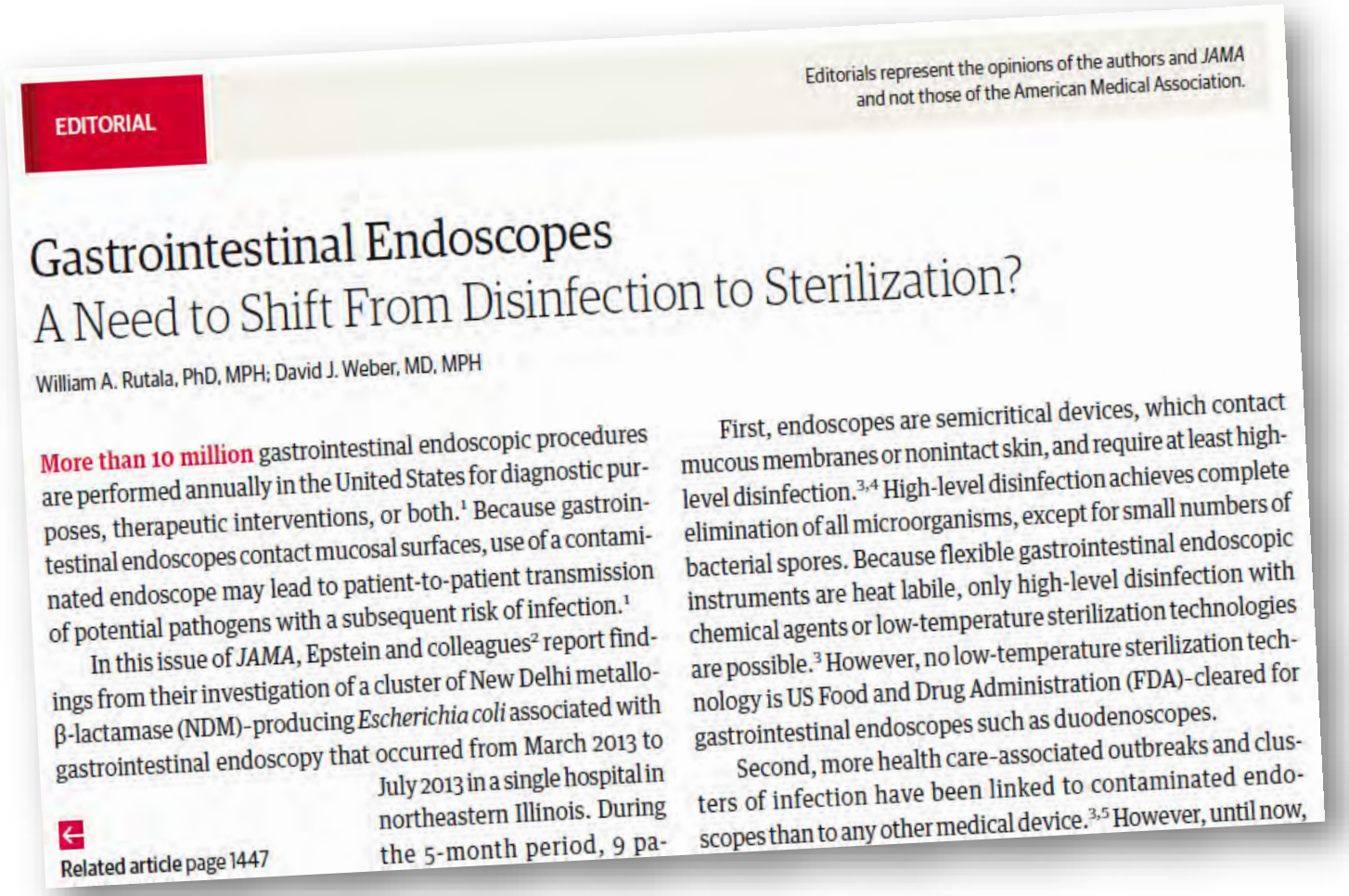
Hydrogen Peroxide Gas

- Processes with and without ‘plasma’
- Vacuum processes require device venting
- Claims (lumen length and diameter restrictions) are product specific
- Generally critical flexible endoscopes
- Ensure devices are clean and dry before sterilization

Liquid Chemical Sterilization

- One system cleared as a liquid chemical sterilant processing system by the FDA
  - Liquid chemical sterilization with peracetic acid sterilant
  - Rinsing with extensively treated water
  - Removal of bacteria, viruses, protozoa and fungi
  - Controlled rinsing (non-toxic)
- Cycle time (23 minutes)
- Validated flexible endoscope models including ERCP scopes
  - Includes specially designed connectors

GI Endoscopes:
Shift from Disinfection to Sterilization



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-

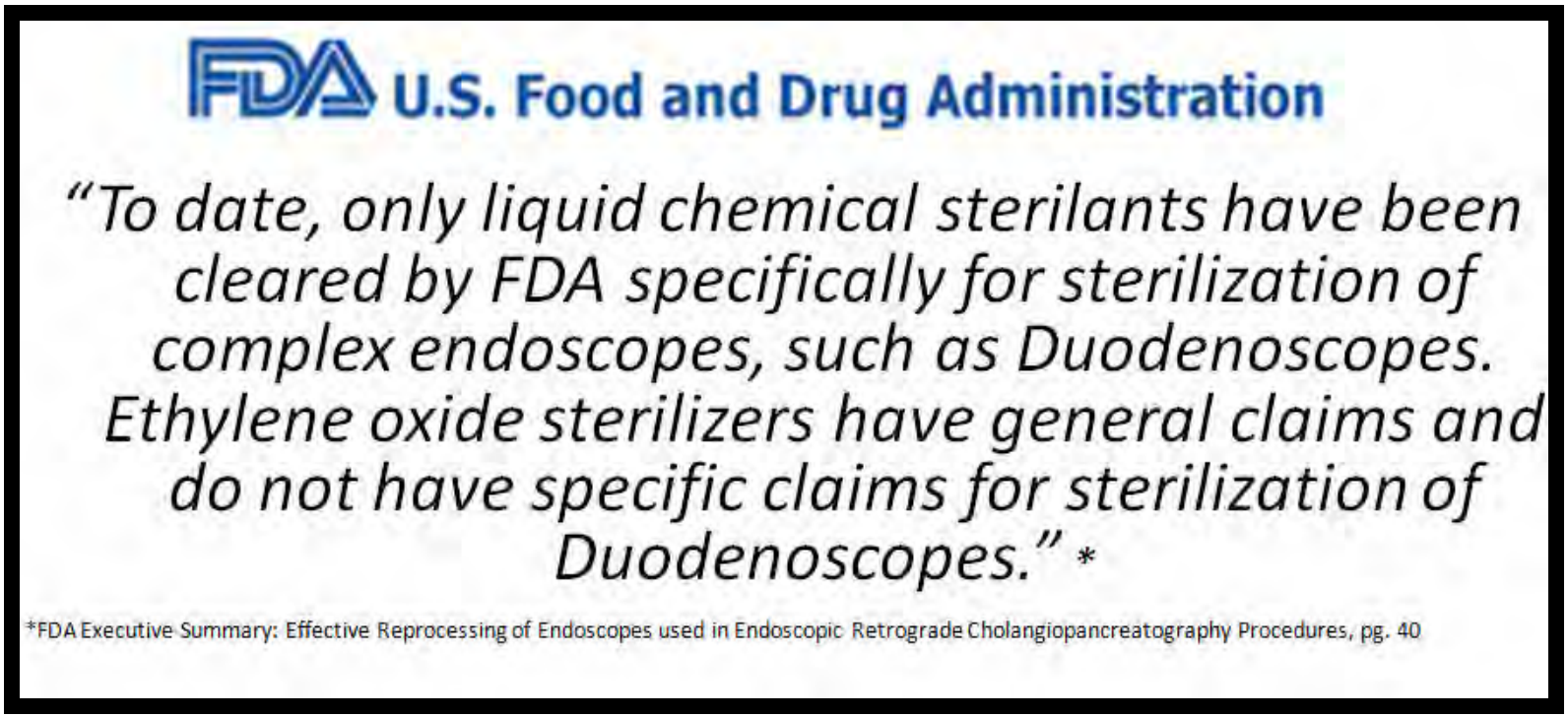
Related article page 1447

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,

Rutala, Weber. The Journal of the American Medical Association (2014). 312(14):1405-1406.

FDA Executive Summary, May 2015



American Journal of Infection Control

American Journal of Infection Control

journal homepage: www.ajicjournal.org

Major article

Effectiveness of the SYSTEM 1E Liquid Chemical Sterilant Processing System for reprocessing duodenoscopes

Gerald McDonnell PhD, Michele Ehrman BS *, Sara Kiess BS

In recent years a troubling number of health care–acquired infection outbreaks and transmission events, some involving highly resistant microbial pathogens and resulting in serious patient outcomes, have been traced to reusable, high-level disinfected duodenoscopes in the United States.

One Liquid Chemical Sterilant Processing System that was successfully tested with Duodenoscopes at extreme worst case conditions using G. *stearothermophilus.*

Joint Commission HLD/Sterilization Assessment Tool – *High Risk*

- No gross cleaning – soil allowed to dry
- HLD manufacturer's IFUs not followed
- Vaginal/rectal/TEE probes not subject to HLD
- No initial of ongoing staff competency
- Lack of leadership oversight of sterilization/ HLD processes

Joint Commission HLD/Sterilization Assessment Tool – *Moderate Risk*

- Gross cleaning not completed at point of use
- HLD/sterilization logs inconsistently completed
- Instruments allowed to dry before cleaning
- Single-use brushes reused
- Multi-use brushes not cleaned between uses

Quality Control Plan

- Verification points
  - Specific for each product/process
- Standards Recommendations
- Cleaning
- Disinfection
- Sterilization
- Documentation

Quality Control

- Knowledge of standards and guidelines
- Risk analysis
  - Where are your risks/hazards?
  - What have you done to reduce these?
  - Continuous improvement
- Reprocessing policy
  - Facility/Department
  - Healthcare organizations should maintain records with traceability back to the patient
- Staff training and demonstrated competency

Action Plan

- Consider the benefits of sterilization versus high level disinfection when making decisions for reprocessing flexible endoscopes.
  - Identify the advantages and disadvantages of aldehyde and oxidative chemistries
- Develop and implement a quality control plan

Questions

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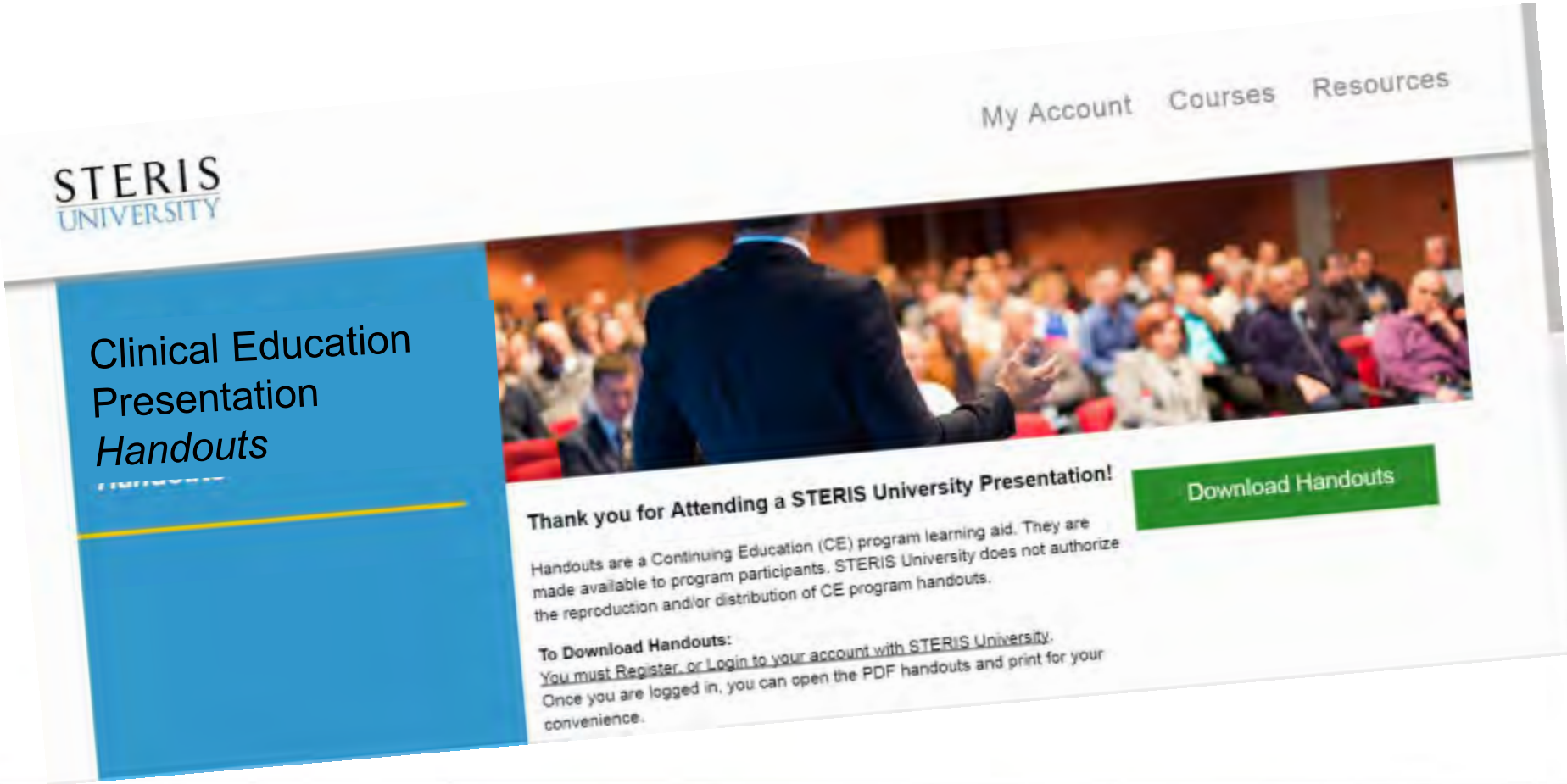
Handouts

To access the handouts for this presentation, go to: university.steris.com/85.



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