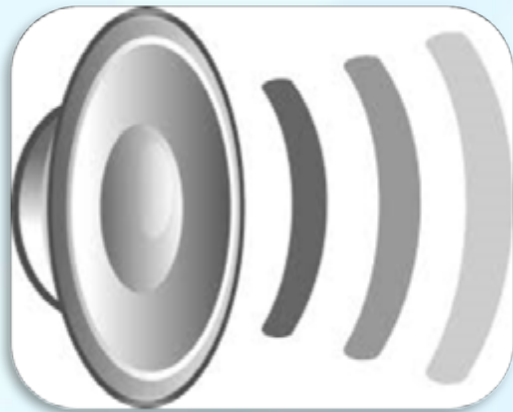
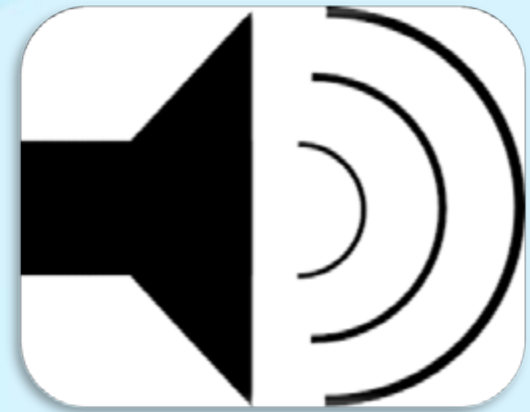


Welcome to
***Empowering Nurses to Protect Themselves and Their Patients:
Device Reprocessing and Sterilization***

The audio for today's conference will be coming through your computer speakers. Please ensure your speakers are turned on and the volume up.



Thank you!



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PROGRAM DESCRIPTION:

Patients and providers always face the risk of the introduction of foreign pathogens that lead to infections during surgical and invasive procedures. The proper disinfection or sterilization of equipment utilized in these environments is essential to minimize the breach of host barriers and reduce the risk of person-to-person transmission of disease pathogens. This webinar will discuss the importance of bedside nurses in device needs reprocessing and sterilization, the current state of device reprocessing and sterilization policies and regulations, the bioburden and importance of assembly/disassembly of tools in decontamination, and evidence-based practices for processing flexible endoscopes.

OBJECTIVES:

- Describe infection control techniques that reduce the risk and spread of healthcare- associated infections (HAI).
- Identify unsafe practices that place patients at risk for HAIs.
- Describe best practices for infection control and prevention in daily practice in healthcare settings.

SPECIFIC OBJECTIVES FOR THIS ACTIVITY:

- Discuss evidence-based practices for processing flexible endoscopes.
- Participant will be able to discuss the importance of device reprocessing and sterilization for the front line nurse (RN).



TUNE IN TO
SAFE HEALTHCARE:
A CDC WEBINAR SERIES



Nursing Infection
Control Education
NETWORK

Empowering Nurses to Protect Themselves and Their Patients: Device Reprocessing and Sterilization

July 12, 2017



Before We Get Started...

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To submit a question:

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- Questions will be addressed at the end of the webinar, as time allows.

To ask for help:

- Please press the "Raise Hand" button, located on the top left-hand side of the screen.

The speakers' slides will be provided to participants in a follow-up email.



Seun Ross DNP, MSN, CRNP-F, NP-C, NEA-BC
Director, Nursing Practice & Work Environment
American Nurses Association

ANA: Who We Are



- Only full-service professional organization representing the nation's 3.6 million registered nurses (RNs)
 - Fosters high standards of nursing practice
 - Promotes general welfare of nurses in the workplace
 - Lobbies on health care issues affecting nurses and the general public
 - Advances policy initiatives pertaining to health care reform
- Most trusted profession 15 years in a row
- Spends the most time with patients and their families

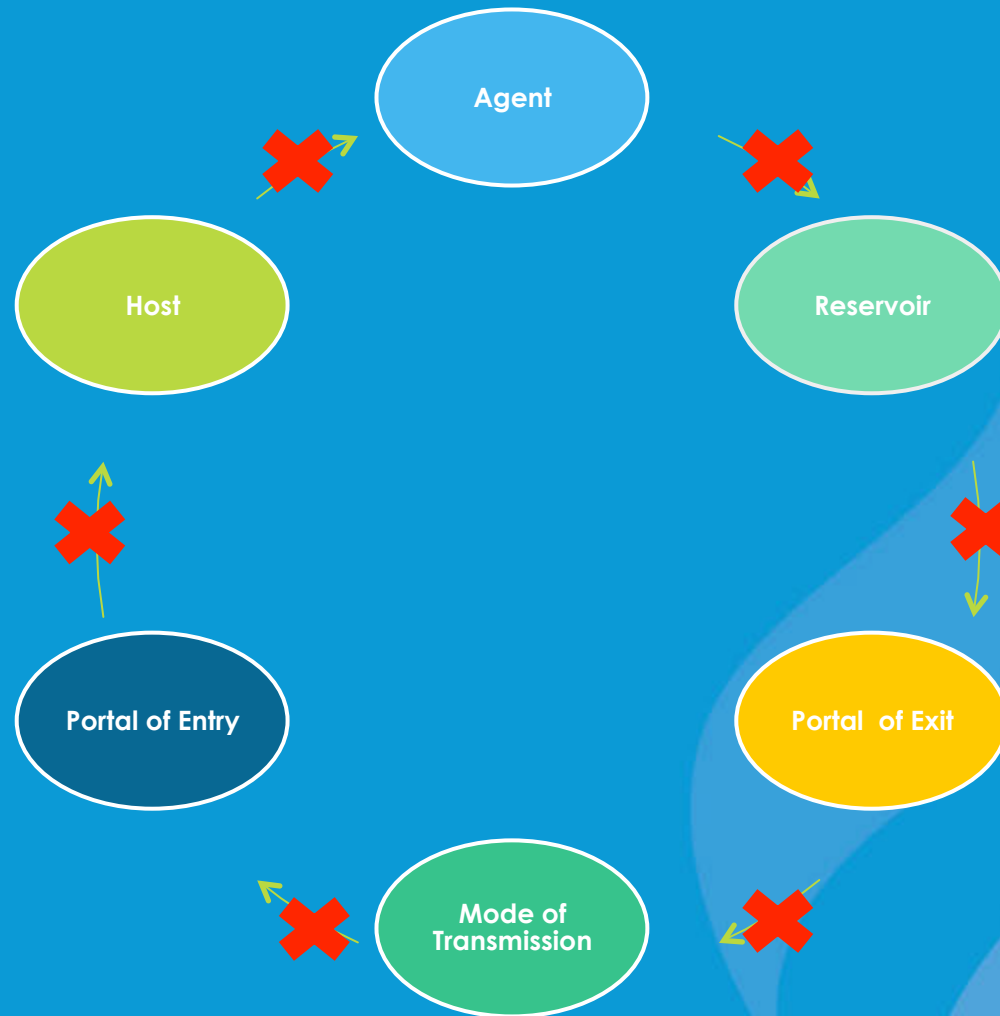
(ANA, n.d.)

Infection by the Numbers

- At any given time, about 1 in every 25 patients has an infection related to their hospital care
- Antibiotic-resistant germs cause more than 2 million illnesses and at least 23,000 deaths annually in the US

(CDC, 2016)

What Can Nurses Do?



Nurses on the Frontlines of Infection Prevention



**Nursing Infection
Control Education
NETWORK**

□ Enhancing Education and Training on Infection Control for U.S. Nurses

- \$1.4 million contract over two years
- ANA in partnership with CDC and 20 nursing specialty organizations

New Jersey State Nurses Association
**Device Reprocessing and Sterilization: What the
Front Line Nurse Needs to Know**




Christine Filippone, DNP, MSN, BSN, ANP, CIC
**Director, Epidemiology/Infection Prevention, Community
Medical Center**

The findings and conclusions in this report are those of the author and do not necessarily represent the official position of the Centers for Disease Control and Prevention.




Device Reprocessing and Sterilization: What the Front Line Nurse Needs to Know

Christine Filippone, PhD (c), DNP, MSN, RN, ANP, C, CIC




Device Reprocessing and Sterilization: What the Front Line Nurse Needs to Know.

- Each year in the United States there are millions of procedures performed in hospitals and out patient centers annually.
- These procedures involve contact by a medical device with a patient's sterile tissue or mucous membrane.




Device Reprocessing and Sterilization: What the Front Line Nurse Needs to Know.

- A major risk of all procedures is the introduction of infectious organism.
- Cleaning is essential before disinfection and sterilization.
- Failure to properly clean, disinfect, or sterilize equipment places patients at risk for infection.
- Cleaning followed by use of effective disinfectants and sterilization practices is essential for ensuring the instruments do not transmit infectious pathogens to patients.
- Nurses need to know what type of reprocessing is required for what type of equipment.



Device Reprocessing and Sterilization: What the Front Line Nurse Needs to Know.


- **Reusable Medical Device** (as defined by the US Food and Drug Administration) are devices that health care providers can reprocess and reuse on multiple patients.



Device Reprocessing and Sterilization: What the Front Line Nurse Needs to Know.

➤ **Reprocessing**


- Cleaning: the removal of all foreign material from objects (must precede disinfection and sterilization)
- Disinfection: a process that eliminates many or all pathogenic microorganisms on inanimate objects with the exception of the bacterial endospore.
- Sterilization-the complete elimination of all forms of microbial life



Device Reprocessing and Sterilization: What the Front Line Nurse Needs to Know.


All reusable medical devices can be grouped into one of three categories according to the degree of risk of infection associated with the use of the device:

- Critical devices: surgical forceps
- Semi-critical devices: endoscopes
- Non-critical devices: stethoscopes



Device Reprocessing and Sterilization: What the Front Line Nurse Needs to Know.


- ▶ **How can we as nurses reduce “risk of exposure”**
 - ▶ By prepping surgical equipment after use before reprocessing or sterilization. This process will reduce the retention of blood, tissue, bio- debris which in turn decreases the survivability of micro-organisms
 - ▶ Prepping can include spray and proper containment.



Device Reprocessing and Sterilization: What the Front Line Nurse Needs to Know.


Overview of reprocessing:

- 1. Point-of-Use Processing: Reprocessing begins with processing at the point of use (i.e., close proximity to the point of use of the device), to facilitate subsequent cleaning steps. This step includes prompt, initial cleaning steps and/or measures to prevent drying of soil and contaminants in and on the device.



Device Reprocessing and Sterilization: What the Front Line Nurse Needs to Know.

- 2. Thorough Cleaning: The device should be thoroughly cleaned after the point-of-use processing. Thorough cleaning is performed in a dedicated cleaning area.
- 3. Disinfection or Sterilization: Depending on the intended use of the device, the device should be disinfected or sterilized.



Device Reprocessing and Sterilization: What the Front Line Nurse Needs to Know.

- Failure to comply with evidence based guidelines have led to numerous outbreaks and have placed patients at risk for infection.
- It is your role to advocate and protect our patients.

American Nurses Association\California

Reprocessing and Sterilizing Medical Devices: Regulations, Policies, and Legislations

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Reprocessing and Sterilizing Medical Devices: Regulations, Policies, and Legislations

July 12th, 2017
8:00 a.m. PST

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Organizations that Offer Guidance

Association for the Advancement of the Medical Instrumentation (AAMI)

- ST 79 – steam sterilization and sterility assurance

Centers for Disease Control and Prevention (CDC)

- *Guideline for Sterilization in Healthcare Facilities* (2008)

Joint Commission

International Association Hospital Central Sterile Material Management (IAHCSMM)

Association of periOperative Registered Nurses (AORN)

- *Guidelines for Perioperative Practice* book updated every five years

Food and Drug Administration (FDA)

- Non-binding guidance document to assist manufacturers seeking 510(k) clearance

Goals of the Recommended Practices

- Provide a framework for the safe workflow to reprocess medical instruments
- Set standards for sterility assurance in the healthcare industry
- Offer evidence-based rationale for the practices
- **Prevents** disease transmission or healthcare associated infections
- Receive consistent quality patient care



Single-Use Medical Device Reprocessing



PROS

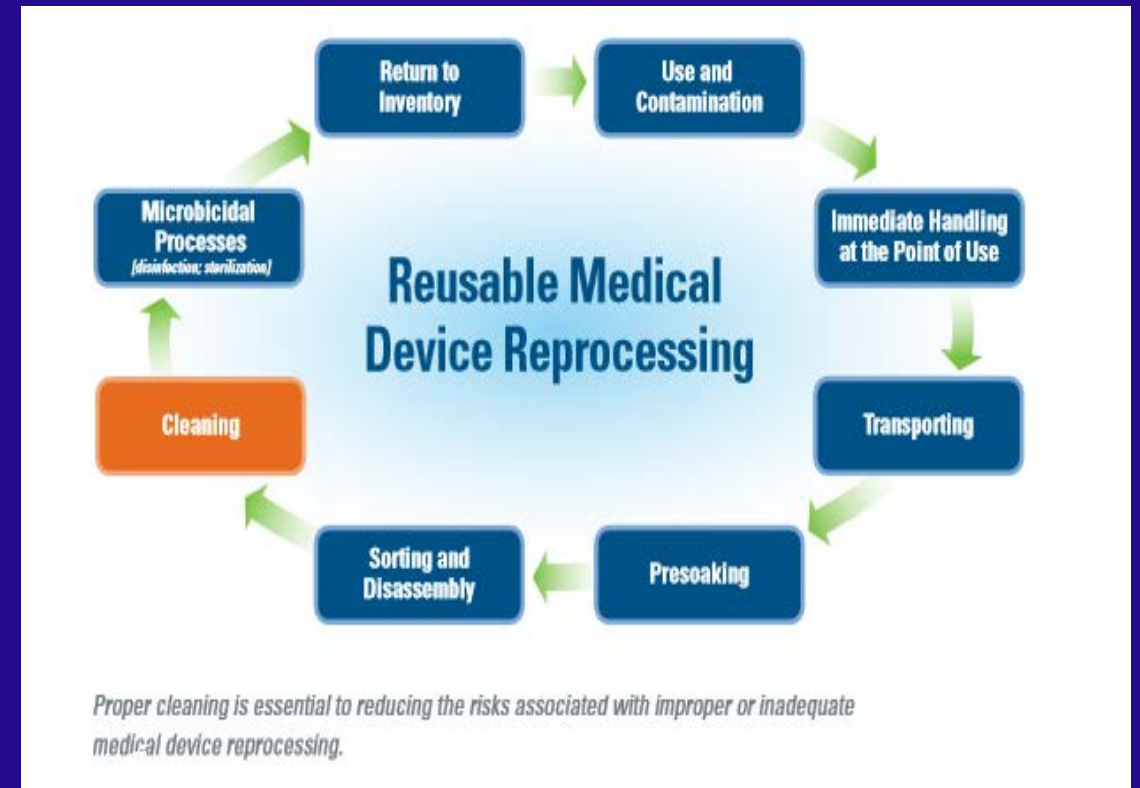
- Produce less medical waste
- Provide cost-effective medical devices
- Have strict control in place by FDA on medical device reprocessors

CONS

- Goes against manufacturer's guidelines for use
- Manufacturer no longer guarantees product after reprocessing
- Providers and frontline staff perceive product of inferior quality

Common Issues with Policies

- Challenges for effective disinfection include
 - Confusion between nursing and environmental services staff over the allocation of cleaning responsibilities
 - Insufficient training
 - Inadequate time to complete cleaning
 - Difficulty ensuring disinfection of mobile equipment
 - Contamination of reusable cleaning supplies with pathogenic bacteria



Shoemake & Stoessel, 2015



Evidence-Based Practice (EBP) and Policy Recommendations

- Use appropriate PPE
- Advise schools to put greater emphasis on infection control in current curriculum
- Develop an institutional infection control policy based on local, state, federal, accrediting agencies, and professional organizations' recommendations.
 - Get PAs, MAs, MDs, and others involved



**Nursing Infection
Control Education**
N E T W O R K

Federal Legislation



Photograph By LYLE STAFFORD, Times Colonist

Baseline

- “Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals”



Current legislation

- H.R. 872 DEVICE Act of 2017

California Legislation



Photo from Assemblymember Tom Daly's page at
<https://a69.asmdc.org/>



S.B. 43 introduced by Senator Jerry Hill

– Establish CA as the **FIRST** state in the nation a system to monitor and track antibiotic-resistant infections and deaths related to those infections

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Bioburden and the Importance of Instrument Assembly and Disassembly

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Bioburden and the Importance of Instrument Assembly and Disassembly

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Background

 **Sterile Processing Issues: Industry Experts Address Persistent Problems**

Contamination of equipment in emergency settings: An exploratory study with a targeted automated intervention

Bacterial contamination of inanimate surfaces and equipment in the intensive care unit

Surgical site infections linked to contaminated surgical instruments

Major article

Microbial contamination of surgical instruments used for laparotomy

Hospital replaces all surgical instruments after contamination

 **Challenging Residual Contamination of Instruments for Robotic Surgery in Japan**

Spaulding Classification

- ▶ **Critical:** instruments that are introduced directly into the human body and enter or come in contact with the bloodstream or normally sterile areas of the body
- ▶ **Semi-critical:** instruments that come in contact with mucous membranes or possibly non-intact skin
- ▶ **Non-critical:** intact skin and environmental surfaces

What is Bioburden?

The number of viable organisms in or on an object or surface **OR** organic material found on a surface/object prior to decontamination and sterilization.

- ▶ Also referred to as the microbial load or bioload
- ▶ Measured in colony-forming units (CFUs)
- ▶ Elimination of live microbe shown as “Log reduction”



Cleaning, Disinfection, and Sterilization

- **Cleaning:** mechanical removal of dirt or foreign materials
- **Disinfection:** elimination or destruction of almost everything on a surface or item (high, intermediate, low)
- **Sterilization:** Elimination or destruction of all living organisms on a surface or item

Sterile Processing Overview

Cleaning, decontamination and rinsing are critical and users must follow and complete all required processing steps regardless of the sterilizer exposure parameters being used. The device MFG's written instructions for use (IFU) must be followed.



Manufacturer's Instructions

The device manufacturer's written instructions on cycle type, exposure times, temperature settings, and dry times are available and followed.

To follow these sterilization instructions we must first clean and decontaminate instruments in the proper method.

Decontamination

Items are disassembled and thoroughly cleaned with detergent and water to remove soil, blood, body fats and other substances.



This requires a properly designed decontamination area with approved detergents, cleaning brushes and personal protective equipment (PPE) for staff. With the exception of power equipment, instruments should be washed below the water surface to reduce aerosols when manually cleaned.

Decontamination Area: Facility Considerations

Should be separate from other areas with floors, walls, ceiling and work surfaces made of nonporous materials to withstand frequent cleanings and wet conditions.

Decontamination area should have a minimum of 10 air exchanges, negative air flow and be exhausted outdoors without re-circulation. Temperature should be maintained between 60-65°F.

Personal Protective Equipment in the Decontamination Area

- ▶ Hair covering (disposable)
- ▶ Face mask (w/plastic eye shield)
- ▶ Liquid resistant covering
- ▶ Gloves (utility)
- ▶ Scrubs
- ▶ Shoe covers



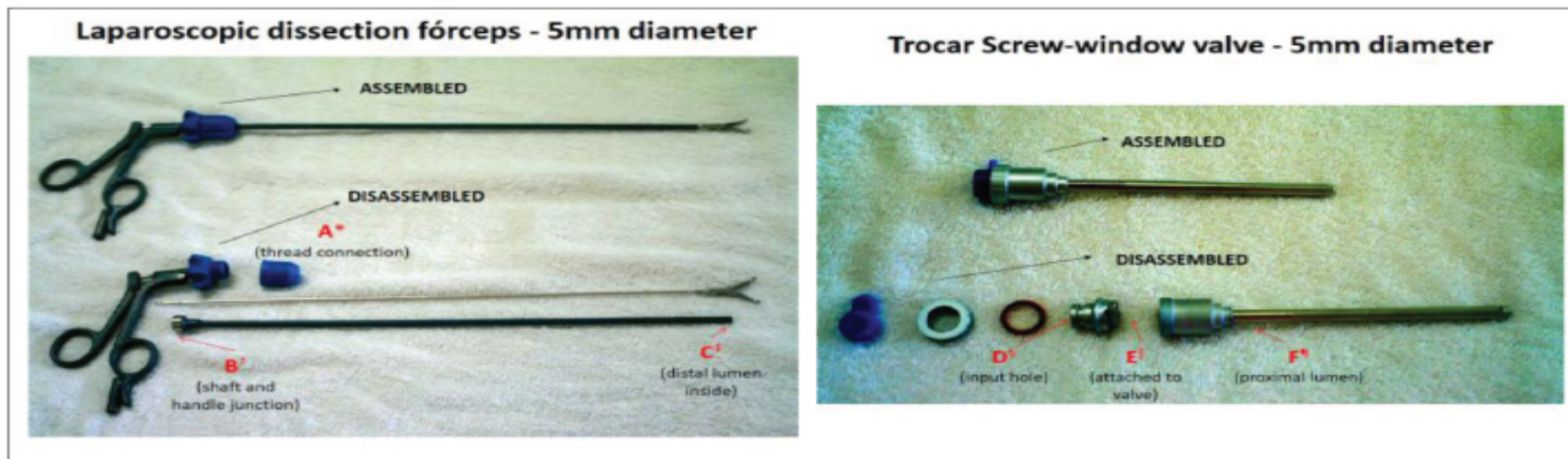
Special Consideration: Lumens

Lumens are brushed and flushed under water with a cleaning solution and rinsed thoroughly.

Lumens are particularly difficult to clean and also difficult to sterilize. It is important to consult with the device manufacturer for information regarding the proper detergent, brush type, brush size, and rinse procedures (treated versus untreated water).

Instructions for Use (IFUs)

Many IFU's require instruments to be taken apart to thoroughly clean the instrument. If this is not followed, bioburden and gross contaminants will remain on the instrument; possibly causing a transfer of these contaminants to a patient.



On a financial note: Not cleaning the instrument properly will shorten the life of the instrument.

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Association of periOperative Registered Nurses

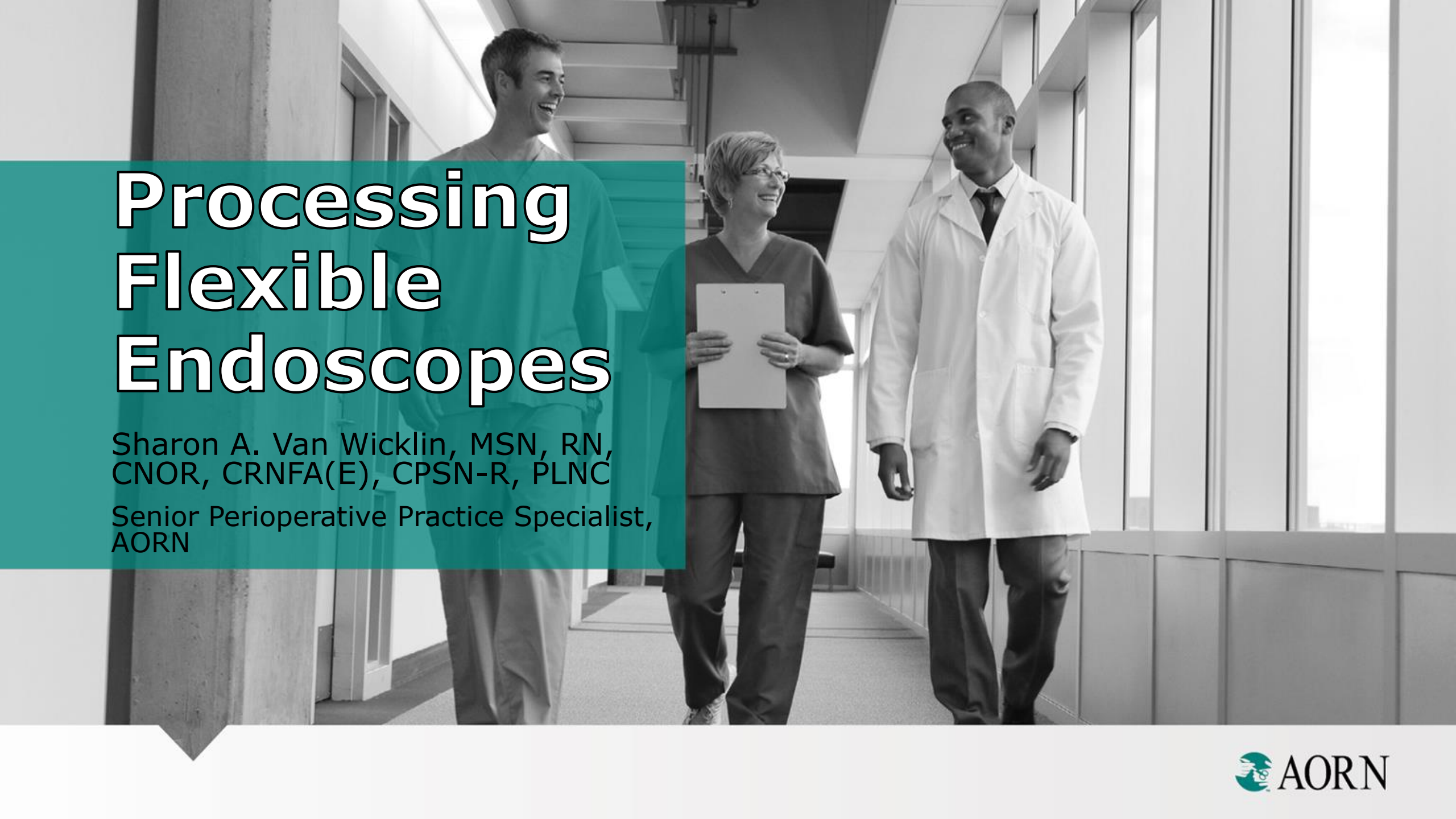
Processing Flexible Endoscopes



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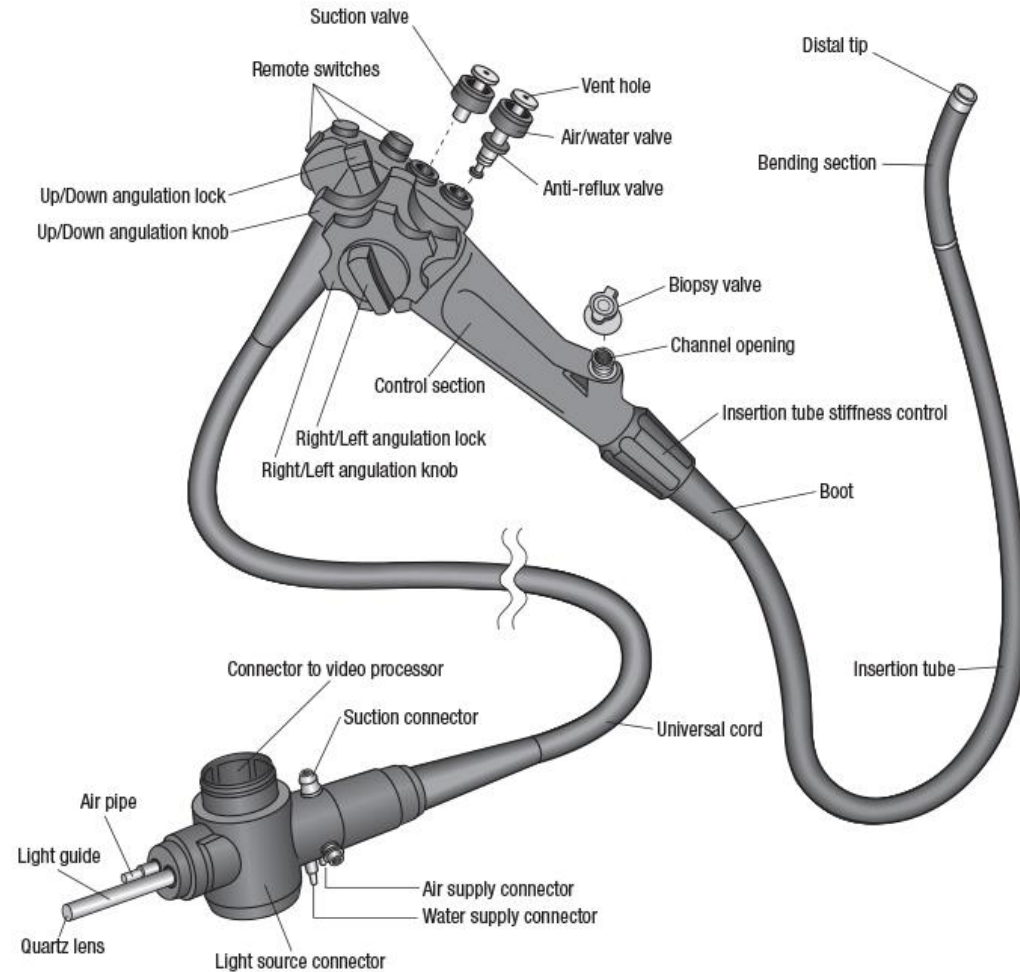
Processing Flexible Endoscopes

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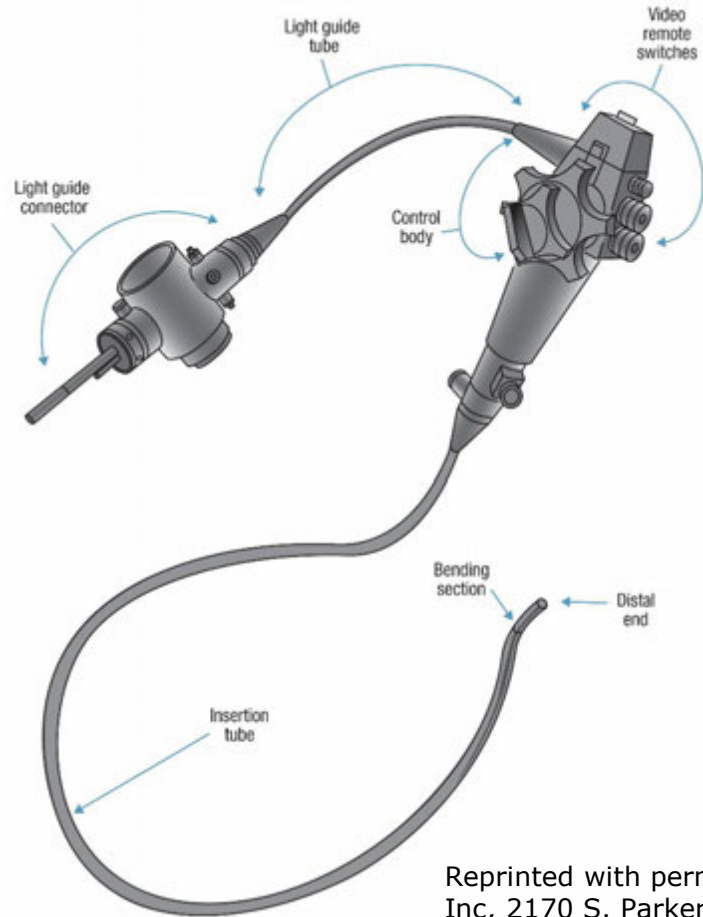
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Objective

1. Discuss evidence-based practices for processing flexible endoscopes



Precleaning



- Preclean as soon as possible after use

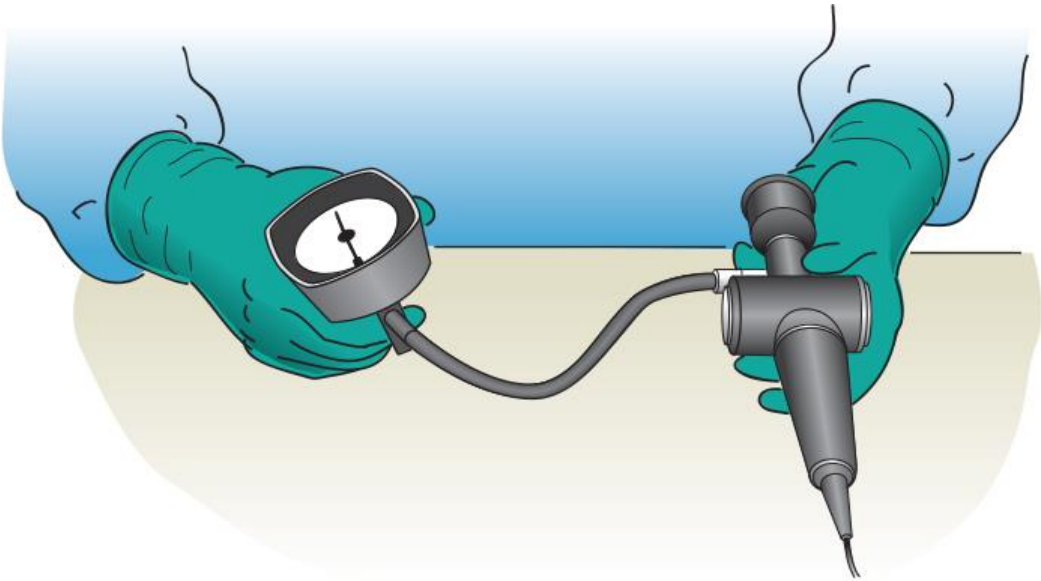
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Transporting

- Transport in a closed container or transport cart that is
 - leak proof
 - puncture resistant
 - large enough to contain all contents
 - labeled with a biohazard legend
- Begin processing as soon as possible
 - If processing is delayed, follow manufacturer's IFU for delayed processing



Leak Testing



- Perform leak testing before
 - manual cleaning
 - placing the endoscope into cleaning solutions

Manual Cleaning

- Begin manual cleaning as soon as possible after leak testing

Cleaning is the most important step in processing flexible endoscopes!

Inspecting

- Use lighted magnification to inspect for cleanliness and damage
 - Use a borescope* to inspect internal channels



**Borescope: A device used to inspect the inside of an instrument through a small opening or lumen of the instrument*

Cleaning Verification

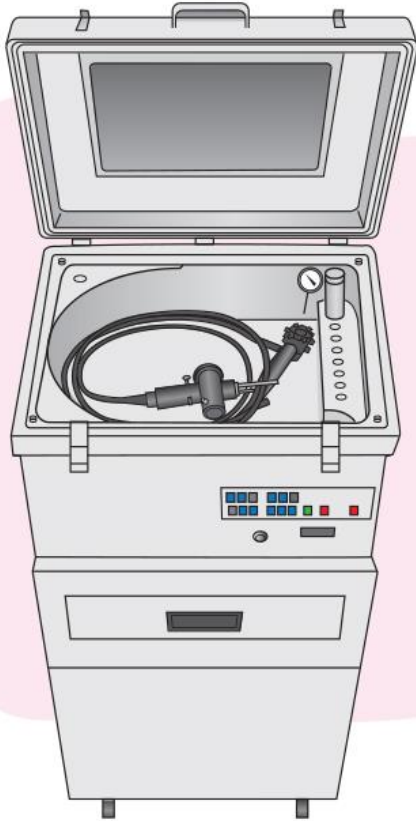
- Verify manual cleaning of flexible endoscopes using cleaning verification tests at established intervals



Cleaning Verification

- Cleaning verification tests include
 - Adenosine triphosphate (ATP)
 - Protein
 - Carbohydrate
- Cleaning verification tests may help reduce errors in manual cleaning and improve cleaning effectiveness

Mechanical Processing



- Mechanically clean and process or mechanically clean and sterilize flexible endoscopes
- Mechanically rinse and flush the endoscope and endoscope channels with critical* or sterile water

**Critical water: Water that is extensively treated to remove microorganisms and other materials*

Alcohol Flush

- Conduct a risk assessment to determine whether endoscope lumens should be flushed with 70% to 90% ethyl or isopropyl alcohol



Drying

- Dry exterior surfaces of the endoscope with a soft, lint-free cloth or sponge
- Dry endoscope channels by purging with instrument air* or with a mechanical processor drying system until bone dry*

**Instrument air: A medical gas that is not respired, is filtered to 0.01 micron, free of liquids and hydrocarbon vapors, and dry to a dew point of -40° F (-40° C)*

**Bone dry: Completely dry. Derived from an allusion to the dryness of bone after being left in the sun to dry*



Storage

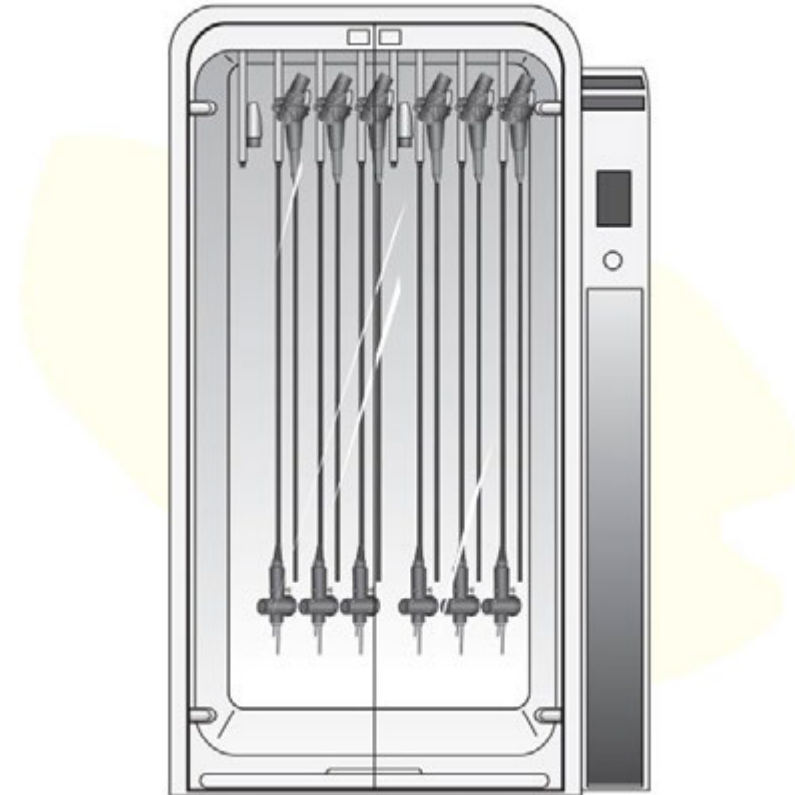
- Store flexible endoscopes in a drying cabinet*

**Drying cabinet: A medical device designed for storage of flexible endoscopes that circulates continuous HEPA-filtered air through each endoscope channel and within the cabinet*



Storage

- If a drying cabinet is not available, store flexible endoscopes in a closed cabinet with HEPA-filtered air that provides positive pressure and allows air circulation



Storage

Professional Organization Recommendations

- 3 hours to 1 month

Studies

- 48 hours to 56 days

Facility Variables

- Type of endoscopes
- Processing effectiveness
- Compliance with IFU
- Storage conditions
- Frequency of use
- Patient population

Storage

- Establish a policy to determine the maximum safe storage time for processed flexible endoscopes

FLEXIBLE ENDOSCOPES-PROCESSING
(Insert facility name or a header)

ADMINISTRATIVE APPROVAL

Date Created: _____
Last Date Reviewed: _____
Next Date Reviewed: _____
Date of Next Review: _____

Approval signature(s) with title and date of signature:

Signature _____	Title _____	Date _____
Signature _____	Title _____	Date _____
Signature _____	Title _____	Date _____

Purpose

To provide guidance to perioperative, endoscopy, and sterile processing personnel for processing all types of reusable flexible endoscopes and accessories. The expected outcome is that the patient will be free from signs and symptoms of infection.

Policy

It is the policy of **[insert name of facility]** that:

- Flexible endoscopes and accessories will be pre-cleaned at the point of use.
- Flexible endoscopes designed to be leak tested will be leak tested after each use, after any event that may have damaged the endoscope, and before use of a newly purchased, repaired, or loaned endoscope.
- After leak testing and before high-level disinfection (HLD) or sterilization, flexible endoscopes will be manually cleaned.
- Flexible endoscopes, accessories, and associated equipment will be visually inspected for cleanliness, integrity, and function before use, during the procedure, after the procedure, after cleaning, and before disinfection or sterilization.
- Following manual cleaning and when compatible with the endoscope manufacturer's instructions for use (IFU), flexible endoscopes and accessories will be either mechanically cleaned and mechanically processed by exposure to a high-level disinfectant or liquid chemical sterilant or will be mechanically cleaned and sterilized.
 - Chemicals and solutions used for cleaning and processing flexible endoscopes and endoscope accessories will be handled in accordance with local, state, and federal regulations and the manufacturer's IFU.
- Flexible endoscopes and accessories will be stored in a manner that minimizes contamination and protects the device or item from damage.
- Records of flexible endoscope processing and procedures that enable traceability in the event of a processing failure will be completed and maintained.
 - Records will be maintained for **[facility-specific time period]**.

Procedure Interventions

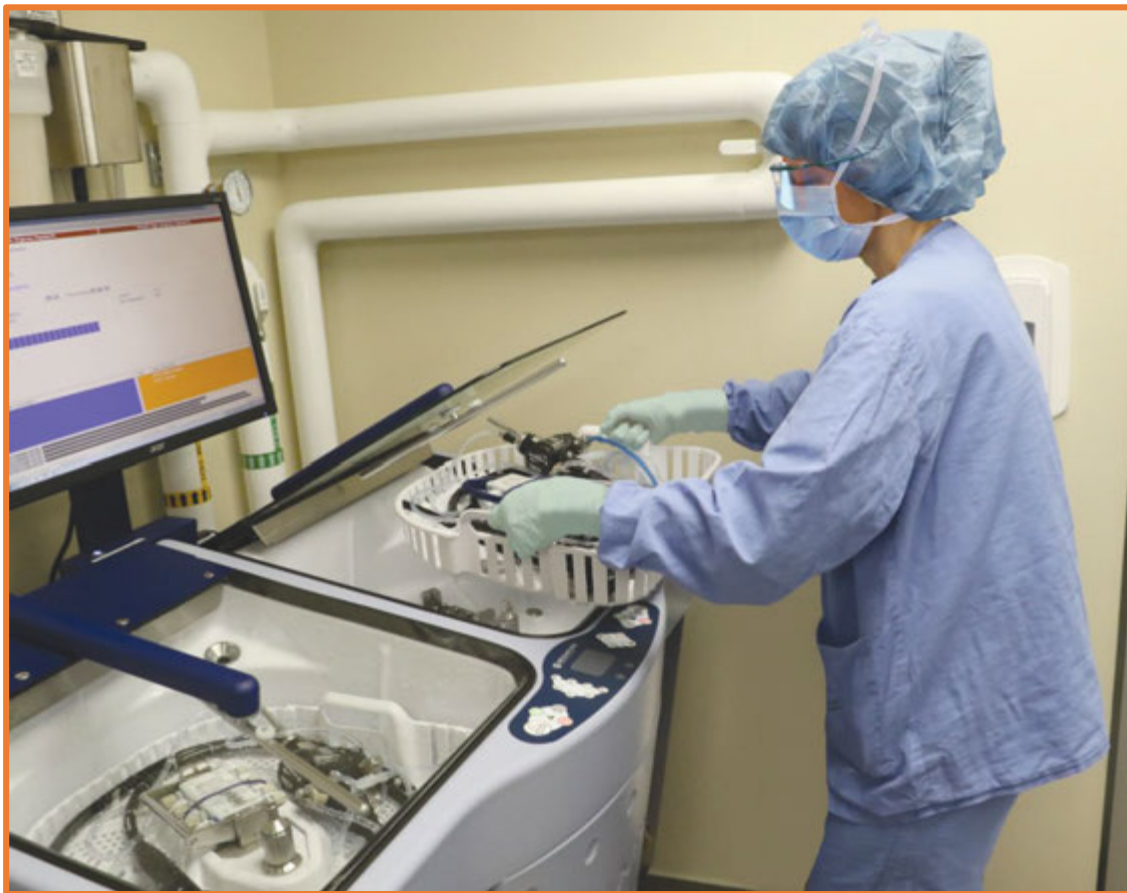
Precleaning

- Preclean flexible endoscopes and accessories at the point of use as soon as possible after the endoscope is removed from the patient (or the procedure is completed) and before organic material has dried on the surface or in the channels of the endoscope.

Page 1 of 7

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Thank you!

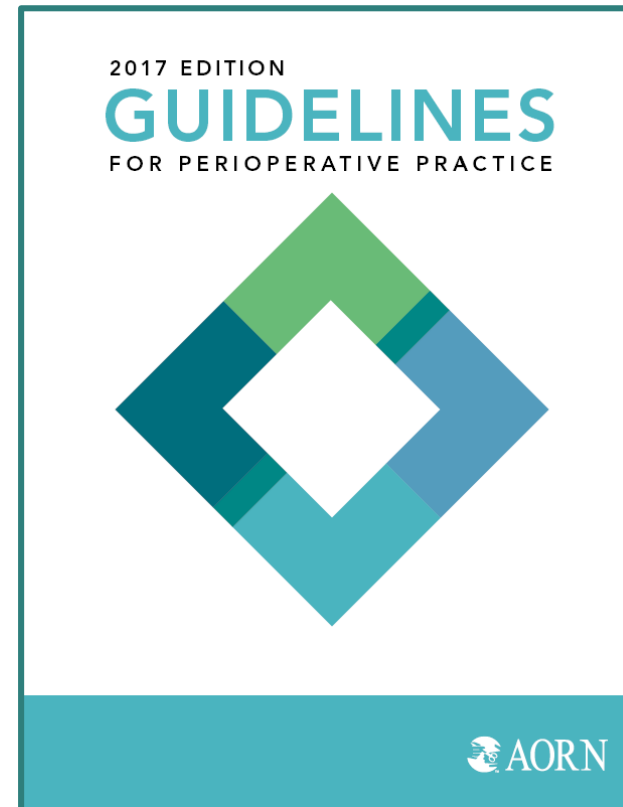


Photograph courtesy of North Kansas City Hospital, North Kansas City, MO.

References

1. Guideline for positioning the patient. In: *Guidelines for Perioperative Practice*. Denver, CO: AORN; 2017.

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