

Flexible Endoscopes: Guideline Update 2023

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Disclosure Information

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Outcome

Participants will gain knowledge of recent updates to the Guideline for Processing Flexible Endoscopes and strategies for implementation.

Objectives

1. Discuss changes to guideline recommendations.
2. Describe examples of guideline key takeaways in practice.
3. Discuss implementation strategies for guideline updates.

Is this still a problem? Yes!

Far more outbreaks than any other medical or surgical device

>130 outbreaks

- GI endoscopes
- Bronchoscopes

>25 outbreaks of MDROs

- Duodenoscopes

No deficient practices identified in some outbreaks

Rutala et al, 2019

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Why haven't we fixed this?



Purpose

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What scopes are the problem?

colonoscopes
EBUS
duodenoscopes
bronchoscopes
cystoscopes
ureteroscopes
gastrosopes

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FDA: Duodenoscopes

Updated June 30, 2022

Stop using fixed endcap duodenoscopes

- No longer marketed

Transition to fully disposable or disposable endcaps

- Replace with newer models

Significantly less contamination risk

- 522 postmarket surveillance studies

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FDA: Urological Endoscopes

April 2021

- Raising awareness of infection risk
- Cystoscopes, ureteroscopes, cystourethroscopes

Updated April 4, 2022

- Recall from Karl Storz, updating IFUs
 - **Do not use HLD or liquid chemical sterilization**
 - **Sterilize affected endoscopes**
 - **Do not use affected endoscopes if you do not have access to recommended sterilization method**

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FDA: Bronchoscopes

Last updated June 25, 2021

Consider using sterilization instead of HLD when feasible

- Greater margin of safety
- Precleaning, leak testing, cleaning, then sterilization

Consider single-use bronchoscopes

- Increased risk for spreading infection
- No support for immediate processing of the bronchoscope

Should not reprocess or reuse single-use bronchoscopes

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Guideline Revision

- Evidence Review

- Abundance of guidelines, expert opinions, & literature reviews

- Nursing: AORN, GI (SGNA), Urology (SUNA)
- Proceduralists: GI, Urology, Pulmonology
- Sterile Processing: AAMI, HSPA
- Infection Preventionists/Epidemiologists: APIC, SHEA
- FDA, CDC, CMS & Accreditation

- United States focus

- 248 recommendations

- Major editorial revision
- New content, few changes to intent



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What is new?

New Sections

Pre-Purchase Evaluation

- Single Use vs Reusable Leadership

Transport to the Point of Use

New Content

Ergonomics & Human Factors

PPE cooling devices

Balloons & Elevators

Simethicone

Hand over

Role-specific education

Strengthened

Sterilization

Cleaning verification testing

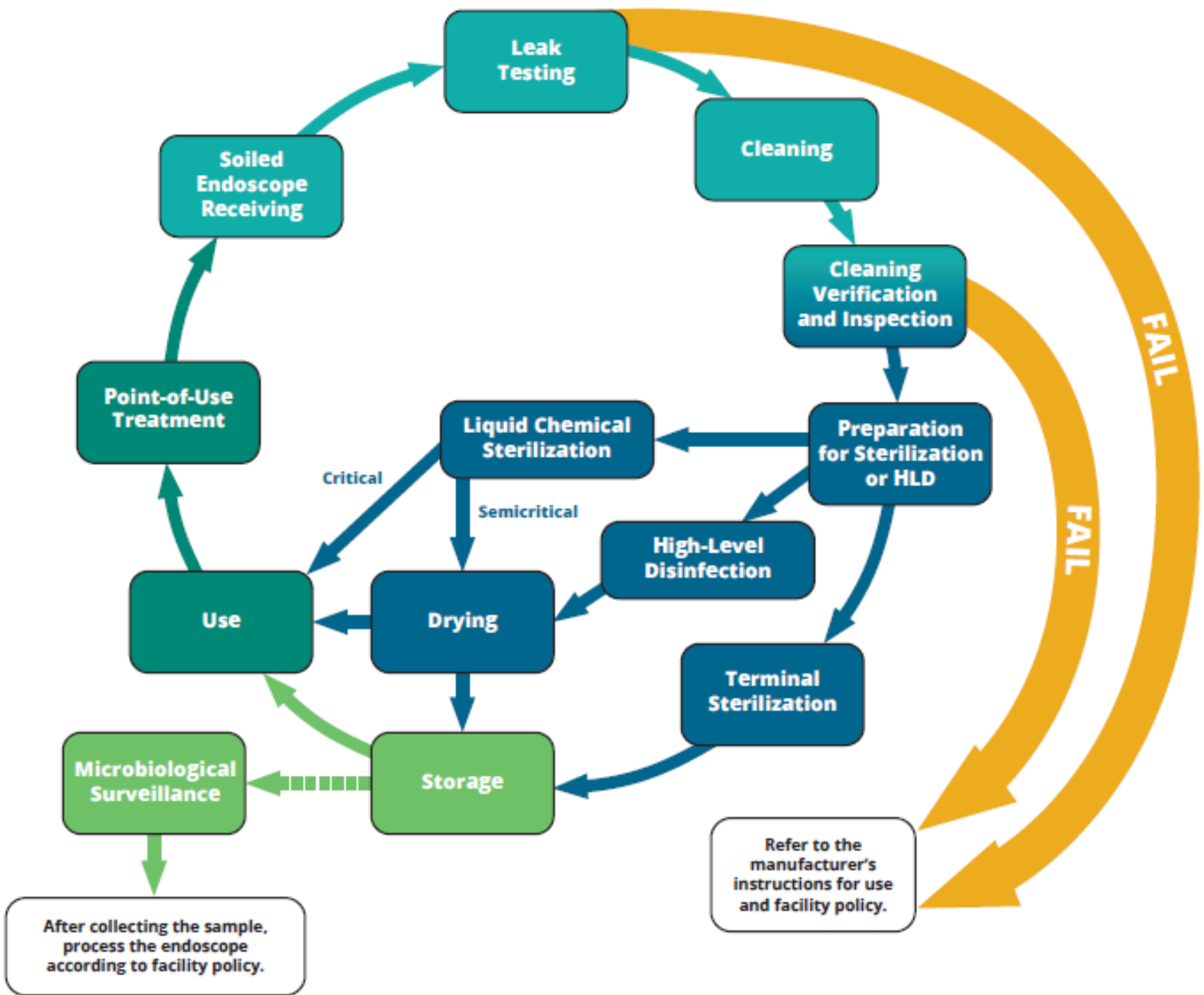
Borescope inspection

Drying

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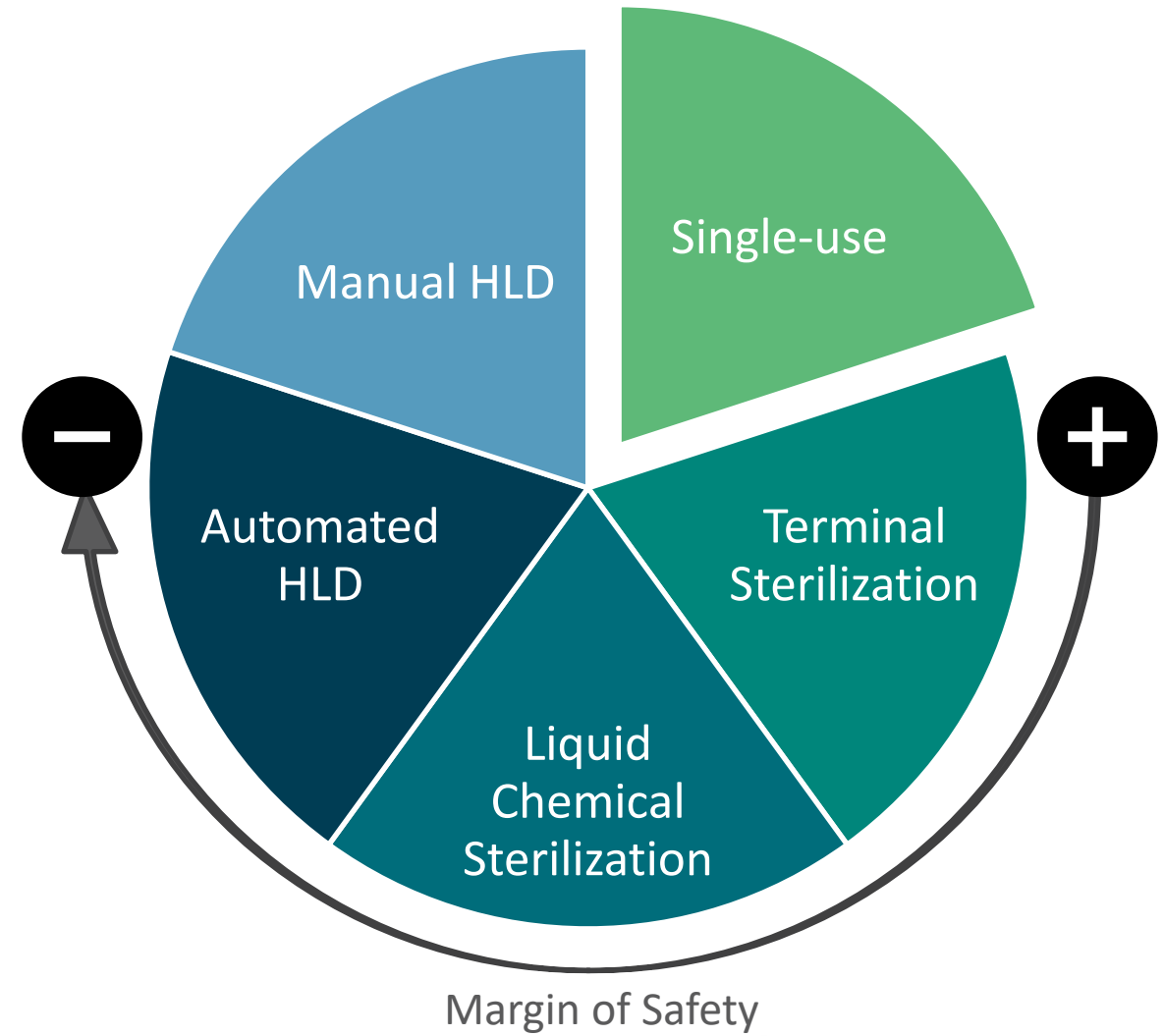
Processing Cycle



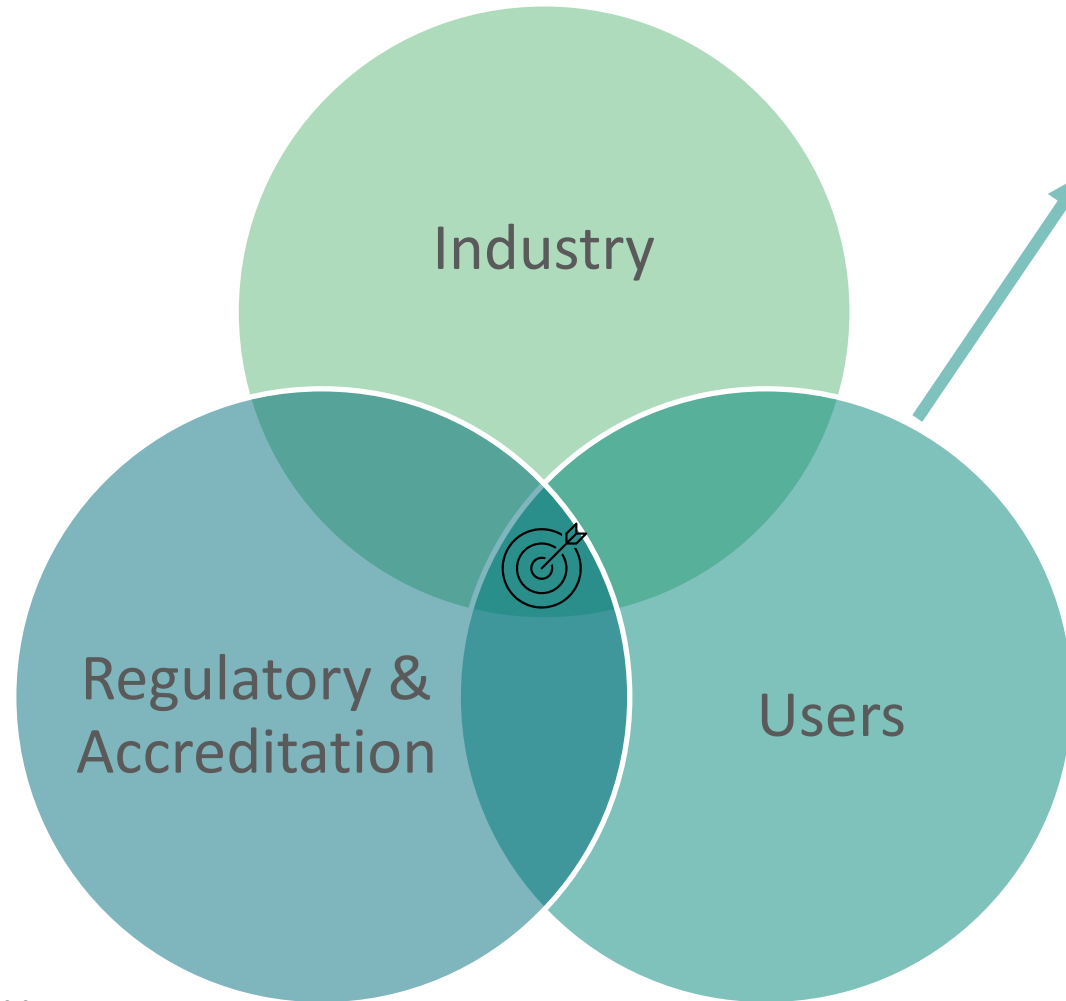
Processing Options

Sterilize reusable flexible endoscopes that are manufacturer validated for sterilization when possible.

[Recommendation]



What is the solution?



Quality Systems Approach

- Patient safety culture
- Oversight
- Access to IFUs and guidelines
- Resources
 - Time, personnel, inventory, space
- Prioritizing worker safety and ergonomics
- Standardizing processes
- Improving traceability
- Monitoring process and outcome measures
 - ***Cleaning!***

22.1 // Alfa, 2019

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Leadership

Knowledgeable
about sterilization
and HLD

Safe working
conditions

- Ergonomics
- Breaks from PPE

Resources

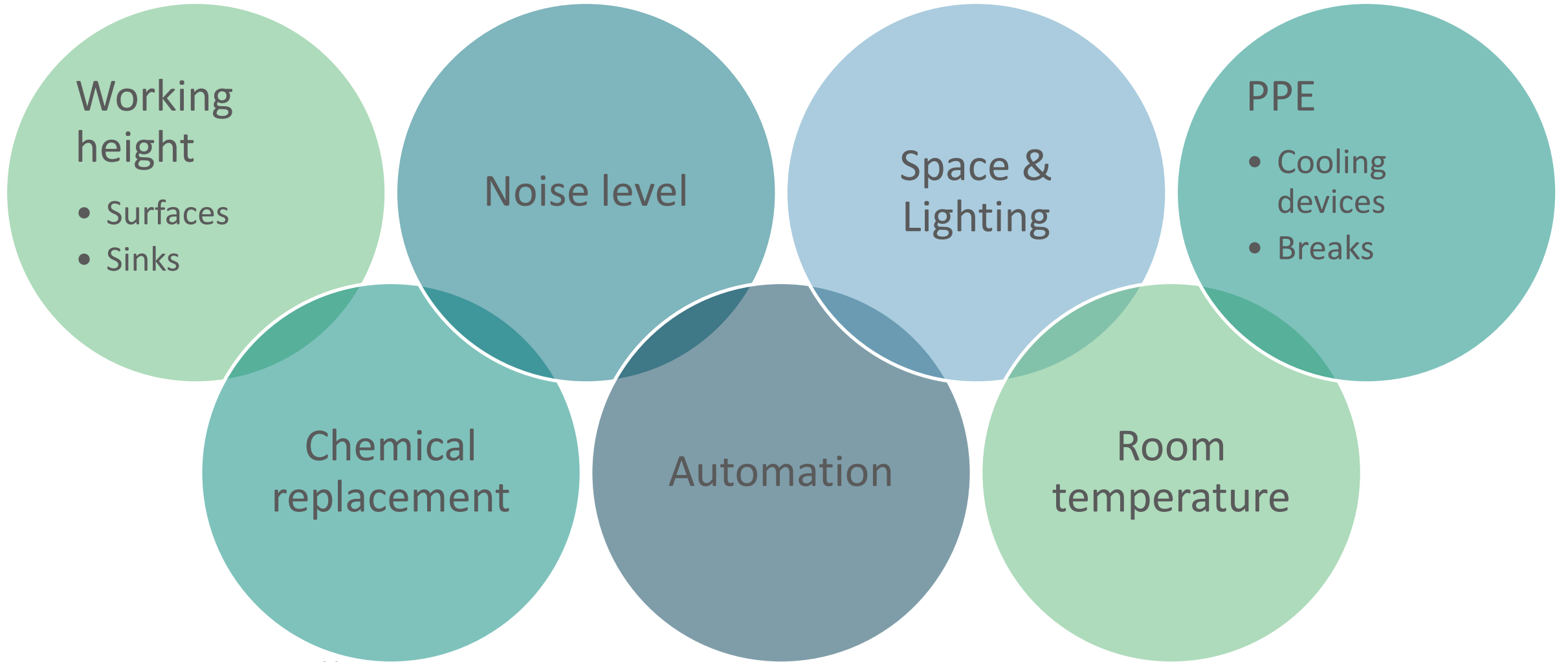
- Time (scheduling)
- Personnel
- Inventory

Access to IFUs

Monitor adherence

Oversee
procurement &
facility design

Ergonomics



1.3.2-3, 3.6, 19.2.1, 22.1 // Sivek et al 2022

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Personal Protective Equipment

Fluid-resistant

Mask

- ASTM F2100 Standard → Levels 1-3

Face Shield or Eye Protection

Gown

- AAMI Level 3 or 4
 - ASTM F1671
- Prefer thumb loops
- Avoid leaning against sink, reinforced area

Gloves

- Utility gloves
- Extended fitted cuffs
- Prefer to elbow
- Optional: exam glove underneath

Shoe covers or Boots

Cooling devices may be worn underneath PPE

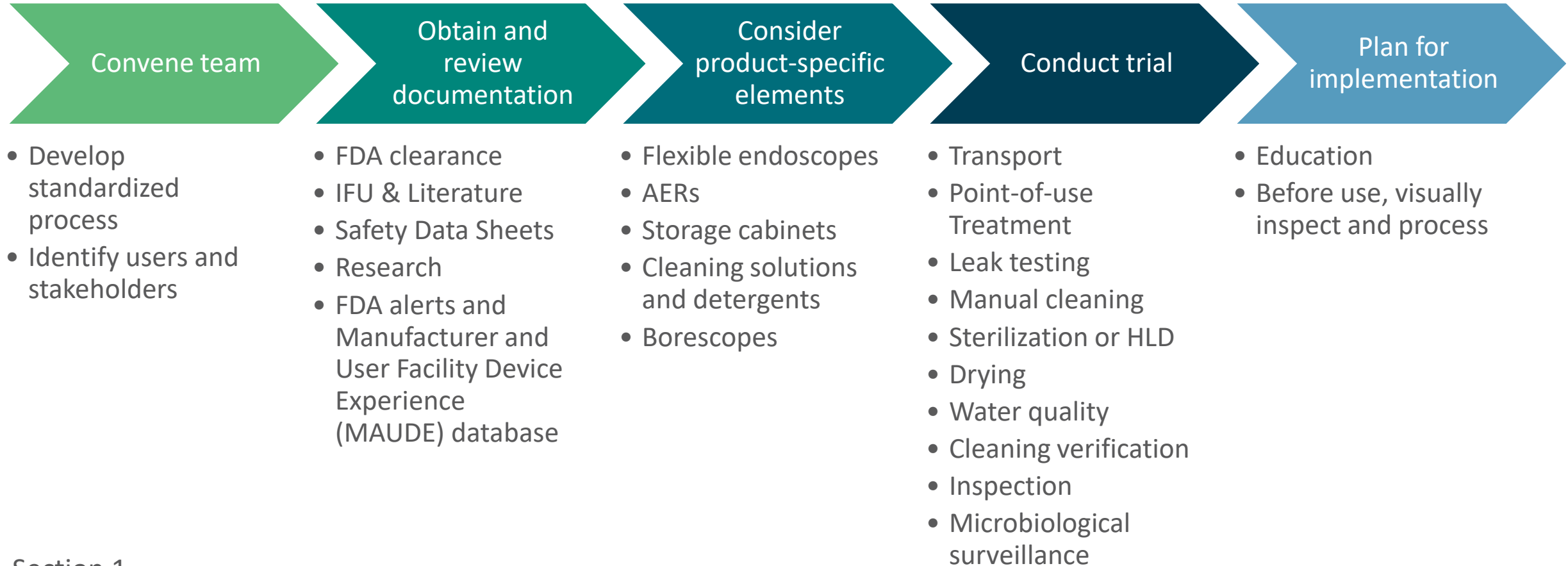
- No fans
- Establish process (cleaning)

4.2-3 // Ofstead et al 2022

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Pre-Purchase Evaluation



Section 1

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Single-Use vs Reusable

Reusable

- Ability to clean and dry
- Availability of processing method in IFU
- Time
- Complexity & human factors
- Competency
- Maintenance & repair

Useful life

Financial impact

Intended use

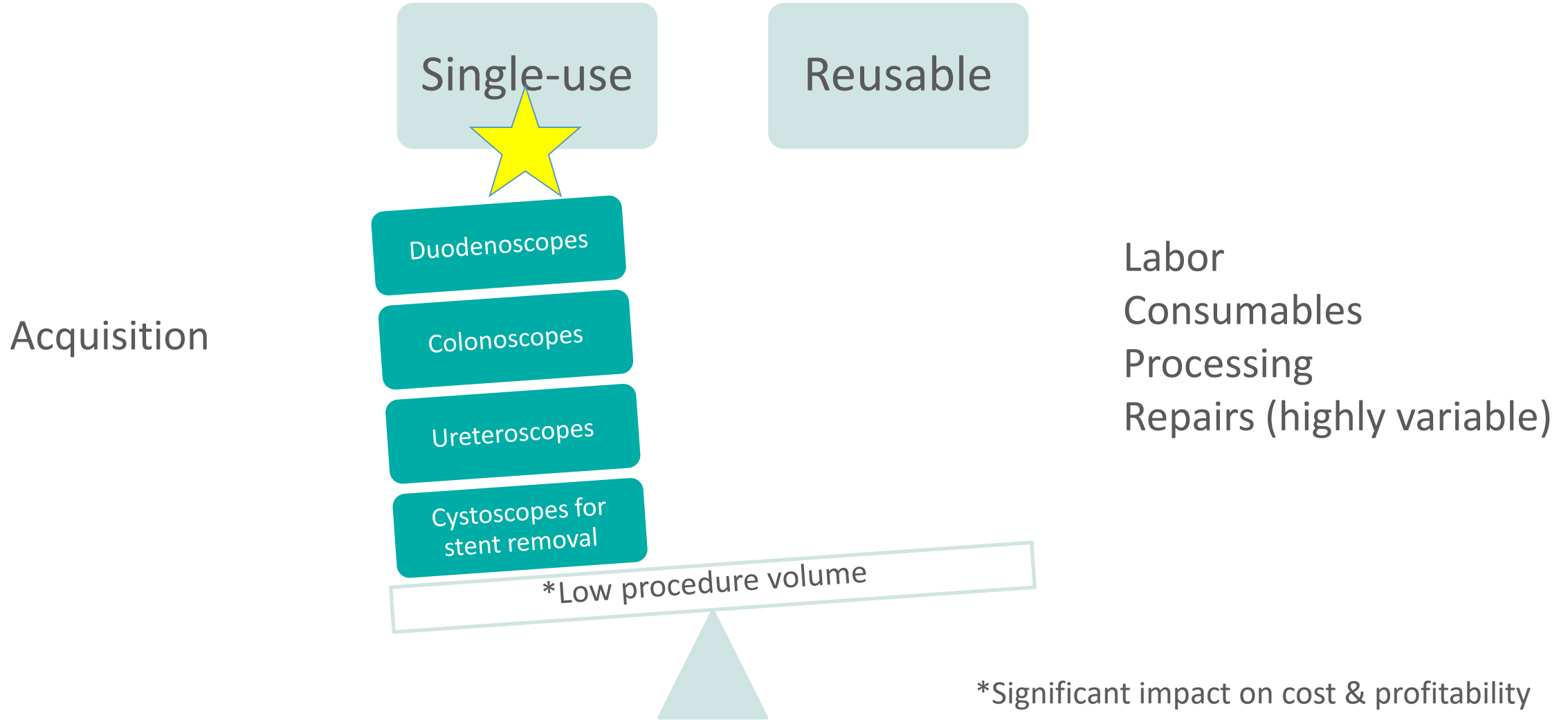
Inventory

Storage requirements

Single-Use

- Disposal requirements and cost
- Reducing risk of infection (MDRO)
- No access to immediate processing (equipment, support)
- Immediate access

Cost Effectiveness



1.4

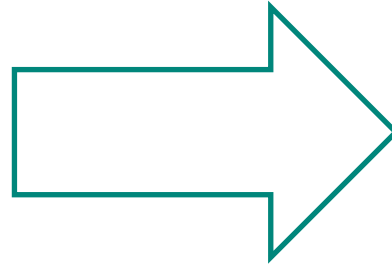
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Point-of-Use Treatment

Immediately
after use

Keep moist



Time frame for cleaning

- Manufacturer/Facility
- 60 minutes
- Clock starts when point-of-use treatment is performed

Delayed processing

- Extended soaking

Section 5, 6.2, 8.2

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Balloons & Elevators

More focused cleaning

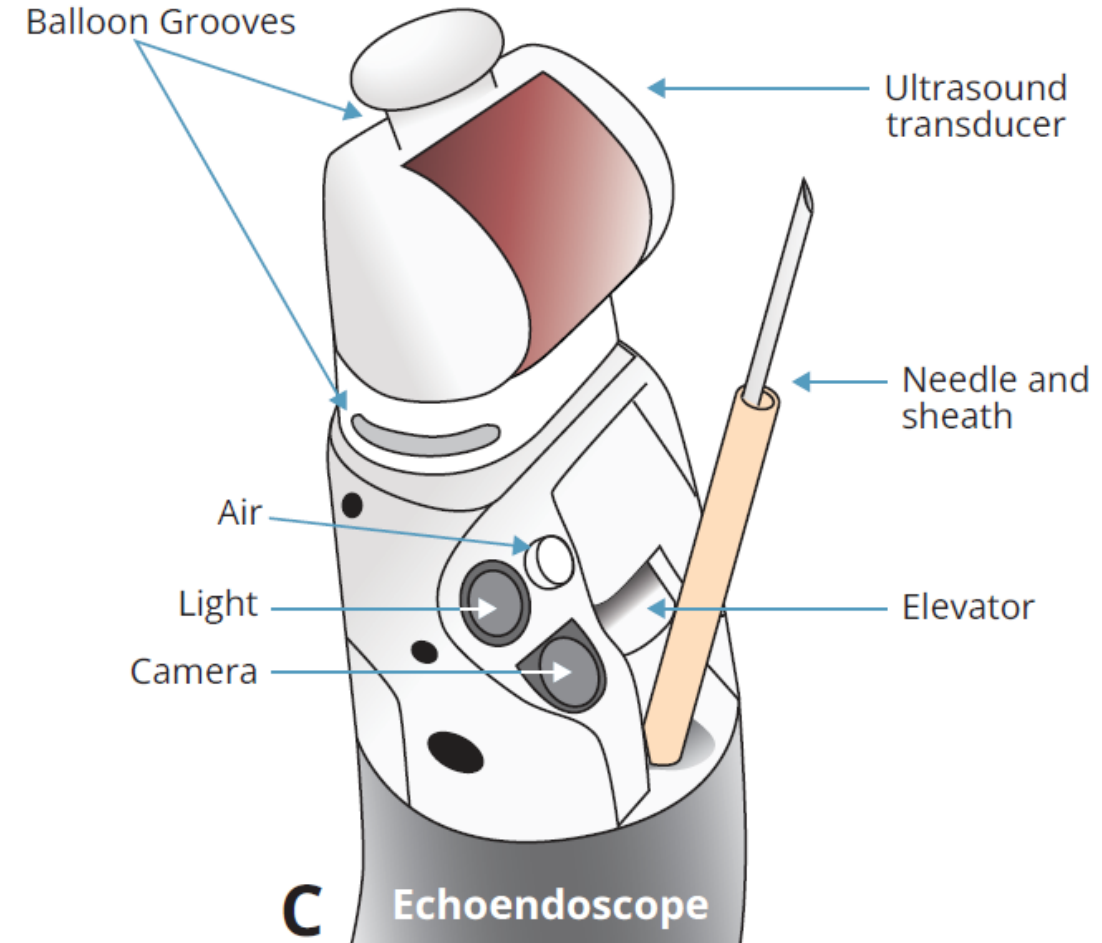
Discard single-use balloons

Raise & lower elevator during cleaning and leak testing

Test point for cleaning verification

Replacing manual cleaning in AER with FDA-cleared cleaning cycle → risk assessment, no elevator mechanism

5.2, 7.3.3, 8.6.2-3, 8.7.1, 8.15, 9.5.3



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Cleaning Verification Testing

Use before sterilization or HLD, do not use after

Determine frequency (eg, after each use, daily)

- After each use for high-risk endoscopes (determined by facility)
 - Duodenoscopes, Bronchoscopes, Urology endoscopes

Test

- Which test to use
 - ATP, Protein, Carbohydrate, Hemoglobin
- Collection test points
- Establish benchmarks

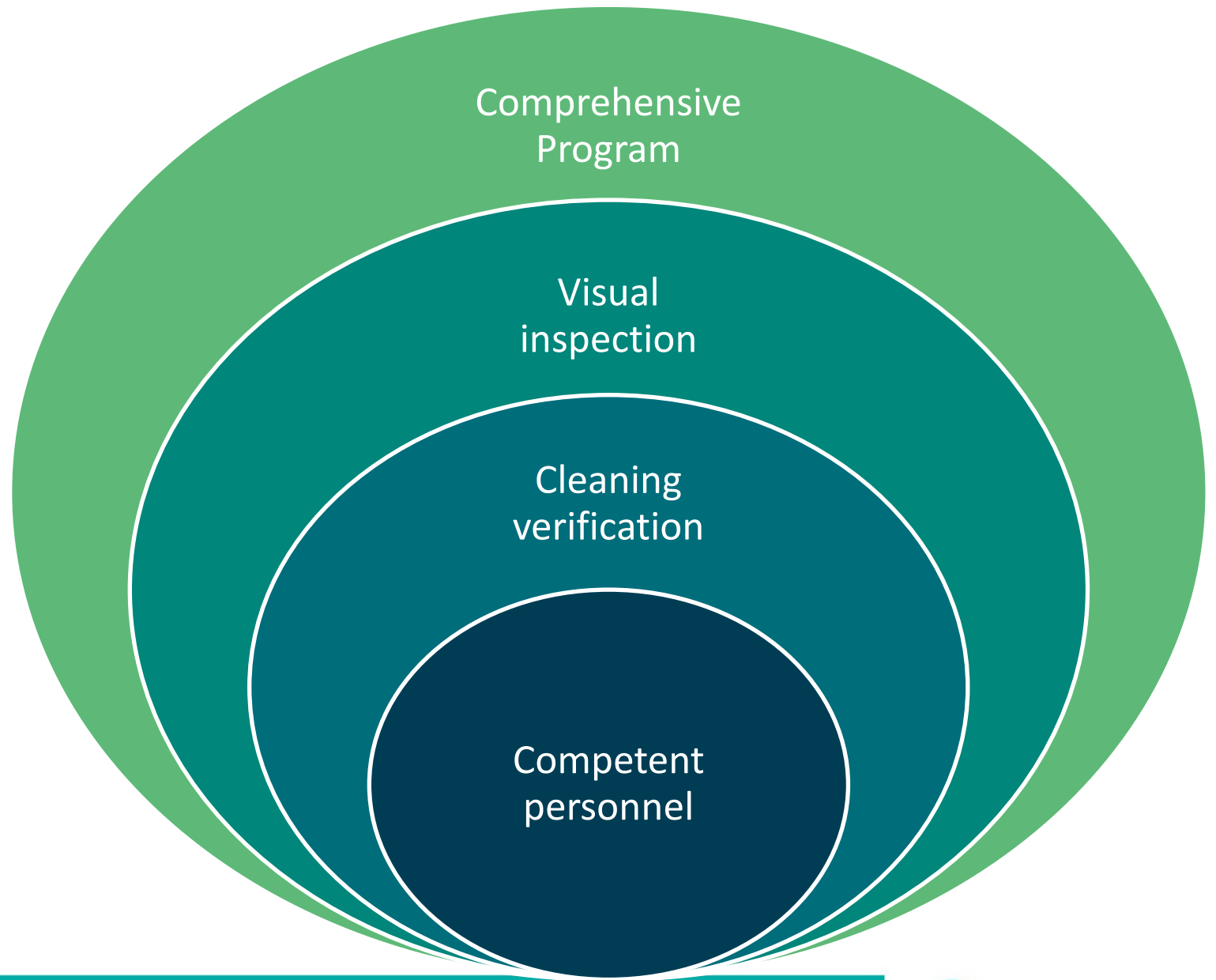
Education!

9.5, 18.3, 20.2.2, 20.5.1, 21.2

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Borescope Inspection



9.4, 12.6, 18.4, 20.2.3, 21.3

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Use a clean borescope to visually inspect accessible channels of flexible endoscopes before sterilization or HLD.

[Recommendation]

9.4, 12.6, 18.3, 20.2.3, 21.3

Before sterilization or HLD

- If used after for verifying dryness, reprocess endoscope

Clean borescope after each use

- Type and size to be used for each type of endoscope

Policies and Procedures

- Baseline assessment of all endoscopes
- Expectations for normal and abnormal findings
- Actions to be taken for abnormal findings

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Simethicone

Found on borescope inspections

Difficult to remove

May require additional cleaning

May impair drying

Do not add to water or irrigation bottle

8.10.1, 6.7, 12.1, 15.2.2 // Barakat et al 2019

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Hand Over

Point-of-use treatment

Began immediately?

- If not, when did the use end and was it kept moist?

Time point-of-use treatment was completed

Delayed Processing

Reusable accessories

Accompanying endoscope

Traceability

Patient identification

Per facility policy

Traceability

Endoscope exposure during the procedure to

simethicone

a radiographic medium

lubricants

tissue adhesives

poor bowel preparation

increased blood loss

Additional Cleaning

6.7 // Ofstead 2019

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Drying



Retained moisture

Patient infections

Biofilm growth

Microbial contamination

Increased ATP



Widespread problem, underrecognized & overlooked

New Drying Recommendations

Dry after HLD in accordance with IFU

- Regardless of air purge cycle in AER

Clean workspace designated for drying processed endoscopes

Pressure-regulated instrument air or HEPA-filtered air

- Minimum 10 minutes or until no visible moisture
- May use automated drying system

May verify dryness with moisture detection test or borescope

Storage Cabinets



Recommended

- Drying Storage Cabinets
- Ventilated Storage Cabinets, if drying cabinets are not available



Not Recommended

- Standard Storage Cabinets
- Cabinets without vents

13.5.1-4, Glossary

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Storage Times

Risk assessment to determine maximum time

Most studies 7 days

Some studies 21 to 56 days, depends on conditions

- **Optimal processing, drying, storage**
- **HLD vs liquid chemical sterilization**

Factors to consider

Type of endoscopes

Frequency of use

Patient population

Compliance and effectiveness of protocols for processing & drying

Type of cabinet

Storage conditions

Handling and transport practices

IFU & research evidence

References

- AORN Guideline for Processing Flexible Endoscopes
- Alfa (2019) Medical instrument reprocessing: current issues with cleaning and cleaning monitoring. *Am J Infect Control*. 2019;47S:A10-A16.
- Barakat et al (2019) Simethicone is retained in endoscopes despite reprocessing: impact of its use on working channel fluid retention and adenosine triphosphate bioluminescence values. *Gastrointest Endosc*. 2019;89(1):115-123.
- Ofstead et al (2022) Droplet dispersal in decontamination areas of instrument reprocessing suites. *Am J Infect Control*. 2022;50(2):126-132.
- Ofstead et al (2019) Widespread clinical use of simethicone, insoluble lubricants, and tissue glue during endoscopy: A call to action for infection preventionists. *Am J Infect Control*. 2019;47(6):666-670.
- Rutala et al (2019) What's new in reprocessing endoscopes: Are we going to ensure "the needs of the patient come first" by shifting from disinfection to sterilization? *Am J Infect Control*. 2019;47S:A62-A66.
- Sivek et al (2022) Healthcare worker feedback on duodenoscope reprocessing workflow and ergonomics. *Am J Infect Control*. 2022; Epub ahead of print. PMID: 35108583.

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Other Key Resources

Manufacturer's Instructions for Use

ANSI/AAMI ST91:2021 Guideline

HSPA Endoscope Manual, 2nd Ed

SGNA Standards & Position Statements

ASGE Multisociety Guideline

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FDA Safety Communications

Duodenoscopes
June 30, 2022

- <https://www.fda.gov/medical-devices/reprocessing-reusable-medical-devices/infections-associated-reprocessed-duodenoscopes>

Urological Endoscopes
April 4, 2022

- https://www.fda.gov/medical-devices/letters-health-care-providers/infections-associated-reprocessed-urological-endoscopes-letter-health-care-providers?utm_medium=email&utm_source=govdelivery

Bronchoscopes
June 25, 2021

- https://www.fda.gov/medical-devices/safety-communications/flexible-bronchoscopes-and-updated-recommendations-reprocessing-fda-safety-communication?utm_medium=email&utm_source=govdelivery

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AORN Links

Evidence Model & Appraisal Tools

- <https://aorn.org/guidelines/about-aorn-guidelines/evidence-rating>

Evidence Tables

- <https://www.aorn.org/guidelines/about-aorn-guidelines/evidence-tables>

Guidelines

- <https://aorn.org/guidelines/about-aorn-guidelines>

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Guideline Essentials

Implementation Tools

QUICK VIEW (HOW-TO INSTRUCTIONS)

Includes photos, illustrations, videos, and an overview of the Guideline.

CASE STUDIES & FAQs

Learn best practices from your perioperative peers and get the answers you need.

KEY TAKEAWAYS

Retain guideline practices by regularly consulting the key takeaways.

GAP ANALYSIS TOOLS

Understand your team's educational gaps and be a step ahead of surveyors.

CUSTOMIZABLE TEMPLATES

Save time with customizable policies, competency verification tools, and PowerPoint presentations.

IMPLEMENTATION ROAD MAP

Develop a strategic guideline implementation plan with a detailed infographic.

<https://www.aorn.org/essentials>

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Questions?

FAQs

AORN Nurse Consult Line

ORNL “Ask the Clinical Nurses at AORN”

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Wear gloves to handle processed scope?

Clean examination gloves

- “not made with natural rubber latex”

Sterile gloves

- May be used, but not necessary unless the endoscope is intended to be used as a critical item

<https://www.aorn.org/guidelines/clinical-resources/clinical-faqs/flexible-endoscopes>

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Can you use a bag for transport?

Bag is designed for containment and transport of soiled flexible endoscopes

Biohazard label

On a cart

Items are not sharp

<https://www.aorn.org/guidelines/clinical-resources/clinical-faqs/flexible-endoscopes>

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Alcohol flush?



<https://www.aorn.org/guidelines/clinical-resources/clinical-faqs/flexible-endoscopes>

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A close-up photograph of a person's hands holding a bright red heart. The heart is the central focus, and the words "Thank You!" are printed in white, sans-serif font across its middle. The person's hands are visible, with fingers gently cupping the heart. The background is a soft-focus, light-colored fabric, likely a shirt, which adds to the gentle and appreciative atmosphere of the image.

Thank You!