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# Scoping the Future: Infection Prevention and Control in the Next Era of Flexible Endoscope Reprocessing

IPAC BC Education Day Presentation
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Provincial Health Services Authority
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PROVINCIAL INFECTION CONTROL NETWORK OF BRITISH COLUMBIA
A program of the Provincial Health Services Authority

# Conflicts of Interest

We have no conflicts of interest to declare

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# Objectives

Recognize the Infection Risks

Gain Confidence in the Evidence-Informed Process

Understand the Consensus-Based Development Approach

Support Safer Reprocessing as Infection Prevention and Control (IP&C) Professionals

*Reprocessing of medical devices is the process of cleaning, disinfecting, and sterilizing used medical devices to make them safe for reuse, and therefore crucial for preventing health care-associated infections and ensuring patient safety.*

# What are Flexible Endoscopes?

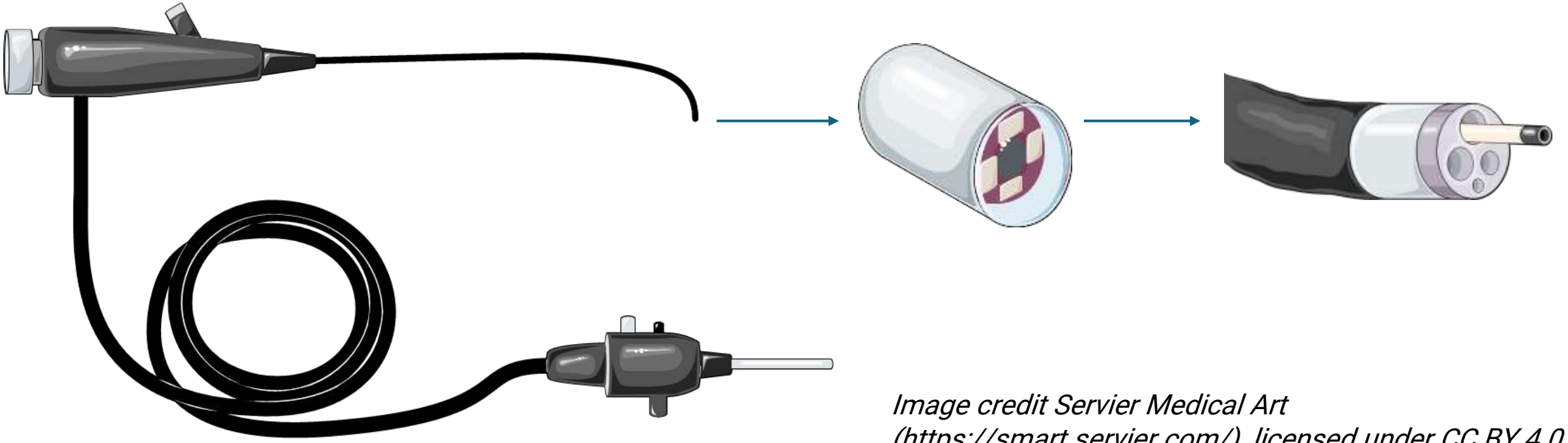


*Image credit Servier Medical Art (https://smart.servier.com/), licensed under CC BY 4.0 (https://creativecommons.org/licenses/by/4.0/)*

- Complex medical devices
- Endoscopy procedures:
  - Bronchoscopy
  - Colonoscopy
  - ERCP (Endoscopic Retrograde Cholangiopancreatography) etc.

# What are Flexible Endoscopes?

- Lumened design
- Integrated systems:
  - Mechanical
  - Optical
  - Electrical
  - Elevator mechanism

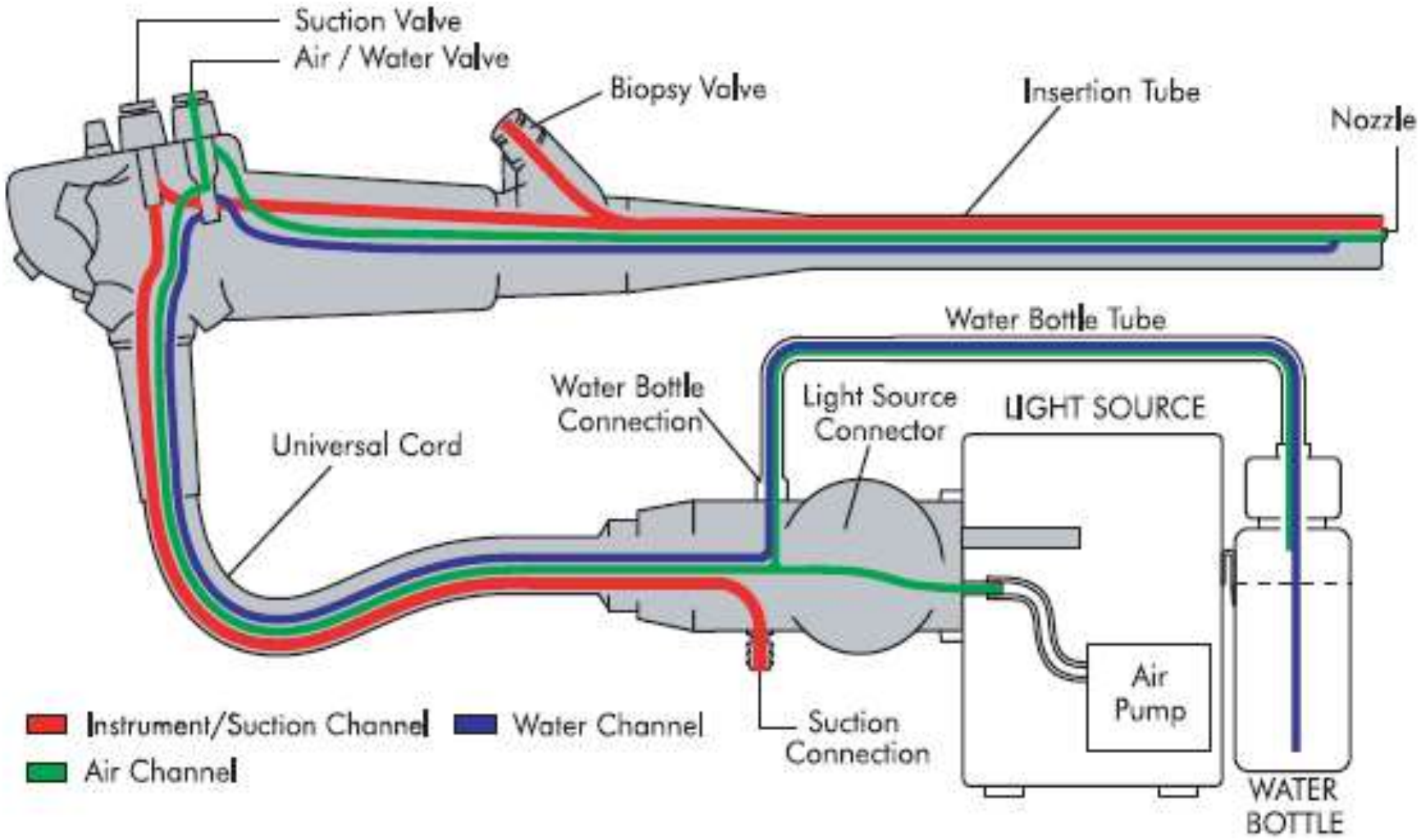
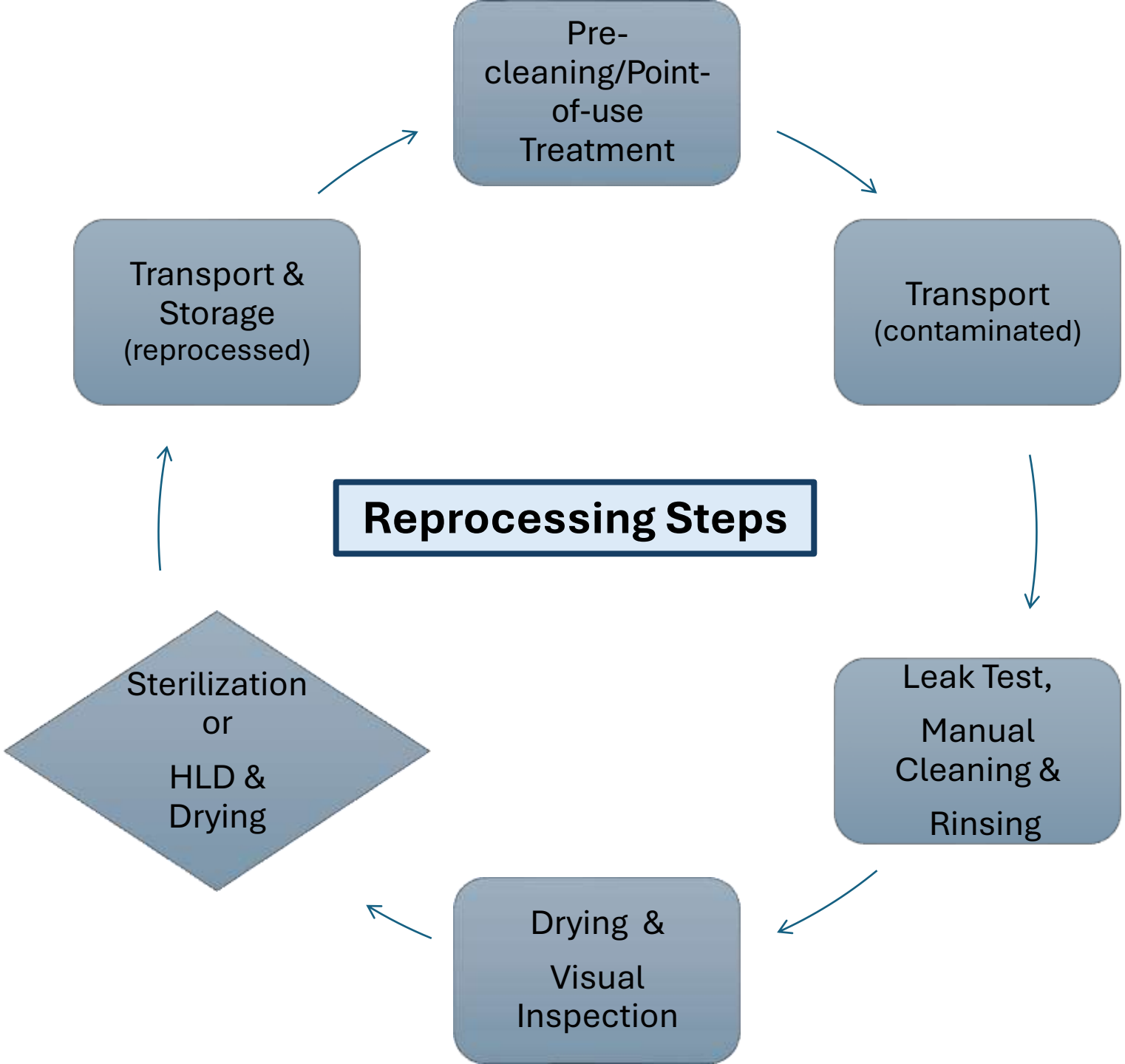
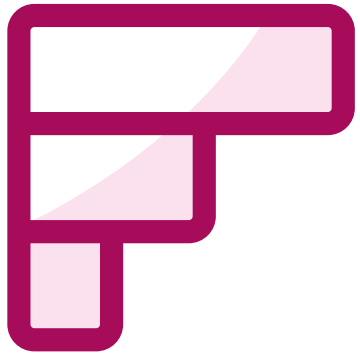



*Image source: Olympus America Inc., 2007.*
*Image courtesy and permission: Olympus Canada Inc.*

# Why are Flexible Endoscopes Problematic to Reprocess?

- Complex internal design
- Heat sensitive
- Heavy microbial burden
- Manual cleaning requirements
- Damage and wear and tear
- Inconsistent reprocessing practices

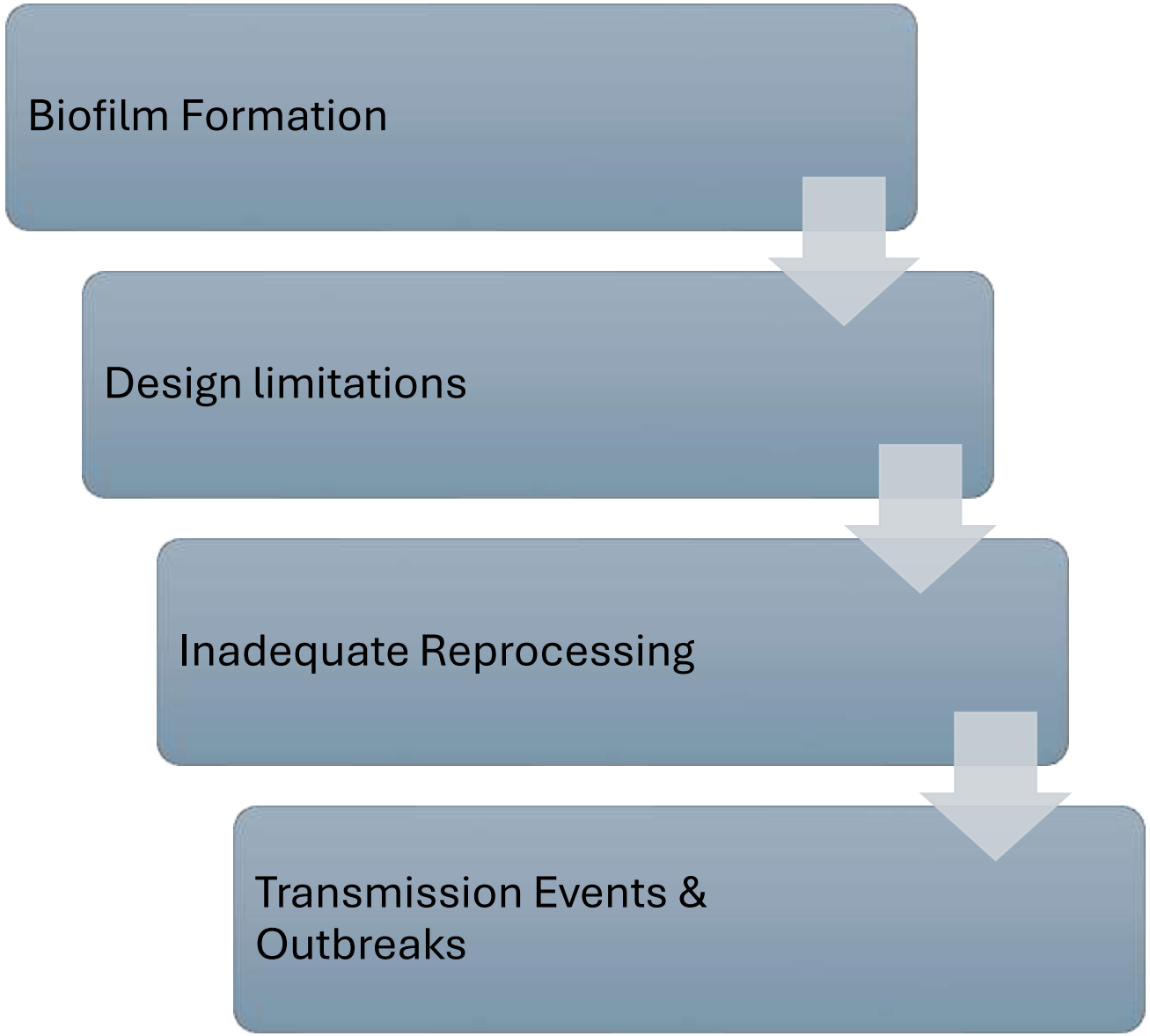

Pre-cleaning/Point-of-use Treatment
Transport (contaminated)
Leak Test, Manual Cleaning & Rinsing
Drying & Visual Inspection
Sterilization or HLD & Drying
Transport & Storage (reprocessed)
Reprocessing Steps



**How confident are you in your organization/facility's current flexible endoscope reprocessing practices?**

# What is the biggest barrier to safe and effective reprocessing in your organization/facility?

# How are Flexible Endoscopes Linked to Infection Transmission in Healthcare?



# Role in Healthcare-Associated Infections

More health care associated infection (HAIs), are associated with contaminated flexible endoscopes than any other medical device.[1]

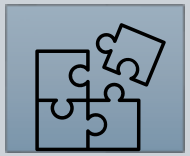
High patient volumes and persistent contamination issues →HAIs, especially Carbapenemase Producing Organisms (CPOs).

1. Rutala WA, Kanamori H, Sickbert-Bennett EE, Weber DJ. 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;47:A62-A66. doi:10.1016/j.ajic.2019.01.017

**Have you accessed the Provincial Best Practice Guidelines for Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (2011) at any point?**

# Provincial Guideline Development

Modular approach to update *Best Practice Guidelines for Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in BC Health Authorities (2011)*.



Flexible endoscope is a component of broader provincial reprocessing guidelines.

Requirements, recommendations and best practices for the reprocessing of flexible endoscopes.

# Status of Reprocessing Guideline Components

- Awaiting Ministry of Health approvals:
  - *Requirements, Recommendations, and Best Practices for Reprocessing of Footcare Devices (final draft)* – August 2023
  - *Requirements, Recommendations, and Best Practices for Reprocessing of Ultrasound Transducer Probes (final draft)* – August 2023
  - ***Requirements, Recommendations, and Best Practices for Reprocessing of Flexible Endoscopes (draft)* – August 2025**
- Under development:
  - General Reprocessing Guidelines

# Acknowledgements: Guideline Contributors

PICNet
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A program of the Provincial Health Services Authority

BC Ministry of Health

PICNet

Provincial Health Services Authority (PHSA) Library Services

Provincial Reprocessing Guideline Task Group

Guideline Reviewers

- Provincial Reprocessing Working Group
- Provincial Infection Prevention and Control Steering Committee
- Occupational Health and Safety Council
- College of Physicians and Surgeons

# **Flexible Endoscopes**: Guideline Development Process

## Guiding Principles

- Rigorous methodology
- Transparency
- Collaboration
- Consensus

## Goals

- Prevent HAIs
- Promote safety
- Standardization
- Evidence-informed

## Objectives

- Evidence review & grading methodology
- Partner engagement:
  - *Consensus*
  - *Enhance credibility & effectiveness*
  - *Promote uptake*

# Research Question Development

Needs assessment survey

Review jurisdictional guidelines

Develop research questions

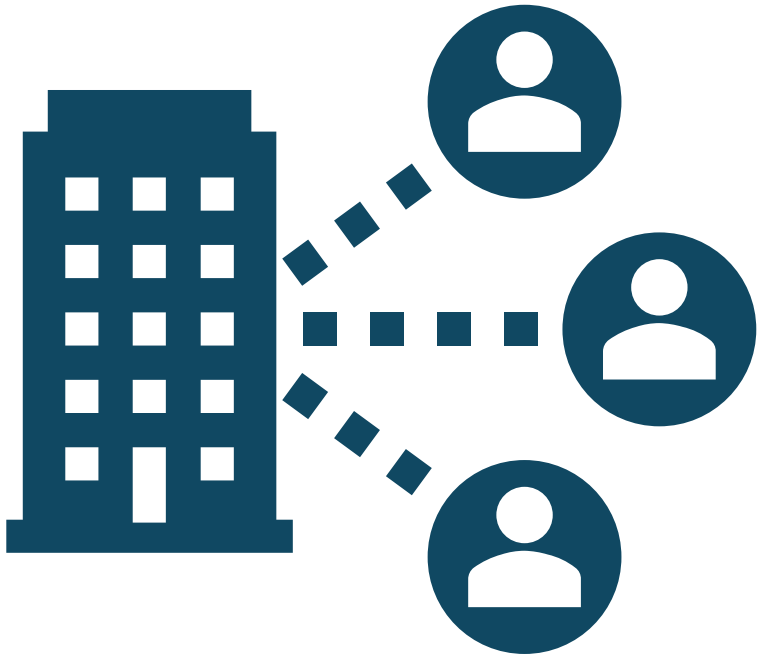
Consultation with Clinical Librarians

# Engagement

Collaboration and consultation with subject matter experts and end users.

1. Established a Reprocessing Guideline Task Group(RGTG)
   - Multi-disciplinary subject matter experts
   - Consultation and iterative reviews of evidence syntheses and guideline content drafts.

2. Review by other partners



# Timeline


**May 2023**
Needs Assessment: knowledge gaps and practice challenges
**May 2023 – Aug. 2024**
Library search strategy & literature search
**May 2024 – May 2025**
Develop guidelines and recommendations
**June–Aug. 2025**
External review and approval submission
Develop research questions (*N=30*)
**Mar.–Aug. 2023**
Systematic literature review, synthesis and critical appraisal
**June 2023 – Dec. 2024**
Reprocessing Guidelines Task Group
**July 2024 – May 2025**

# Evidence Review and Grading

Evidence reviewed and graded using the Public Health Agency of Canada's Infection Prevention and Control Guidelines: Critical Appraisal Toolkit.

# PHAC Critical Appraisal Toolkit Evidence Rating Scale

| Grade of Evidence | | |
|---|---|---|
| **Strength of Evidence** | Grades | |
| **Strong** | AI | • Direct evidence from meta-analysis or multiple strong design studies of high quality, with consistency of results. |
| | AII | • Direct evidence from multiple strong design studies of medium quality with consistency of results; OR<br>• At least one strong design study with support from multiple moderate design studies of high quality, with consistency of results; OR<br>• At least one strong design study of medium quality with support from extrapolation from multiple strong-design studies of high quality, with consistency of results. |
| **Moderate** | BI | • Direct evidence from multiple moderate design studies of high quality with consistency of results; OR<br>• Extrapolation from multiple strong design studies of high quality, with consistency of results. |
| | BII | • Direct evidence from any combination of strong or moderate design studies of high/medium quality, with a clear trend but some inconsistency of results; OR<br>• Extrapolation from multiple strong design studies of medium quality or moderate design studies of high/medium quality, with consistency of results; OR<br>• One strong design study with support from multiple weak design studies of high/medium quality with consistency of results. |
| **Weak** | CI | • Direct evidence from multiple weak design studies of high/medium quality, with consistency of results; OR<br>• Extrapolation from any combination of strong/moderate design studies of high/medium quality, with inconsistency of results. |
| | CII | • Studies of low quality regardless of study design; OR<br>• Contradictory results regardless of study design; OR<br>• Case series/case reports; OR<br>• Expert opinion. |

# Good Practice Statements (GPS)

## Guideline recommendations

- Well-known, accepted, and established best practices.
- Consensus & consistency across jurisdictional guidelines.
- Endorsed by the RGTG.

# Recommendation Categories

## Shall

Mandatory **requirements**

- Legislated requirements
- National/provincial policies
- Established best practices
- Strong evidence

## Should

Practice **recommendations**

- Advised but **not mandatory**
- Facilities are encouraged to work towards this goal.

# Flexible Endoscopes Guideline

Content

# Guideline Purpose and Scope

## Purpose

- Evidence-informed recommendations for the **reprocessing of lumened flexible endoscopes** to prevent **HAIs**.

## Scope

- Health care workers and health care settings
- In conjunction with:
  - Manufacturer's Instructions for Use (MIFU)
  - Relevant standards (e.g., Accreditation)
  - Provincial and local policies and procedures
- Support development of internal standard operating procedures (SOPs)

**Out of scope**:

- Endoscopy clinical procedures
- Non-lumened scopes/rigid scopes

# Facilitators to Safe and Effective Reprocessing

**IP&C Program**

Policies, training, and practices

PPE, hand hygiene cleaning and disinfection supplies, amenities, and resources.

**Education and Training**

Training, competency, and adherence assessments

SOPs

Qualified staff

**Procurement**

Clinical and MDR consultation.

Sufficient inventory

MIFUs reviewed

**Reprocessing Area Workflow**

Separate reprocessing areas.

One-way workflow

Ventilation, spaces, and resources.

Separation of reprocessed vs. dirty devices.

# Classification & Level of Reprocessing: Considerations

## Reprocessing Principals

- **Cleaning** before disinfection or sterilization
- Spaulding's criteria: reprocessing level based on **anticipated/intended** use
- Sterilization provides highest safety margin – but not always feasible

## Considerations

- **Heat labile**
- Availability of validated sterilization systems

## Challenges to Spaulding's Classification

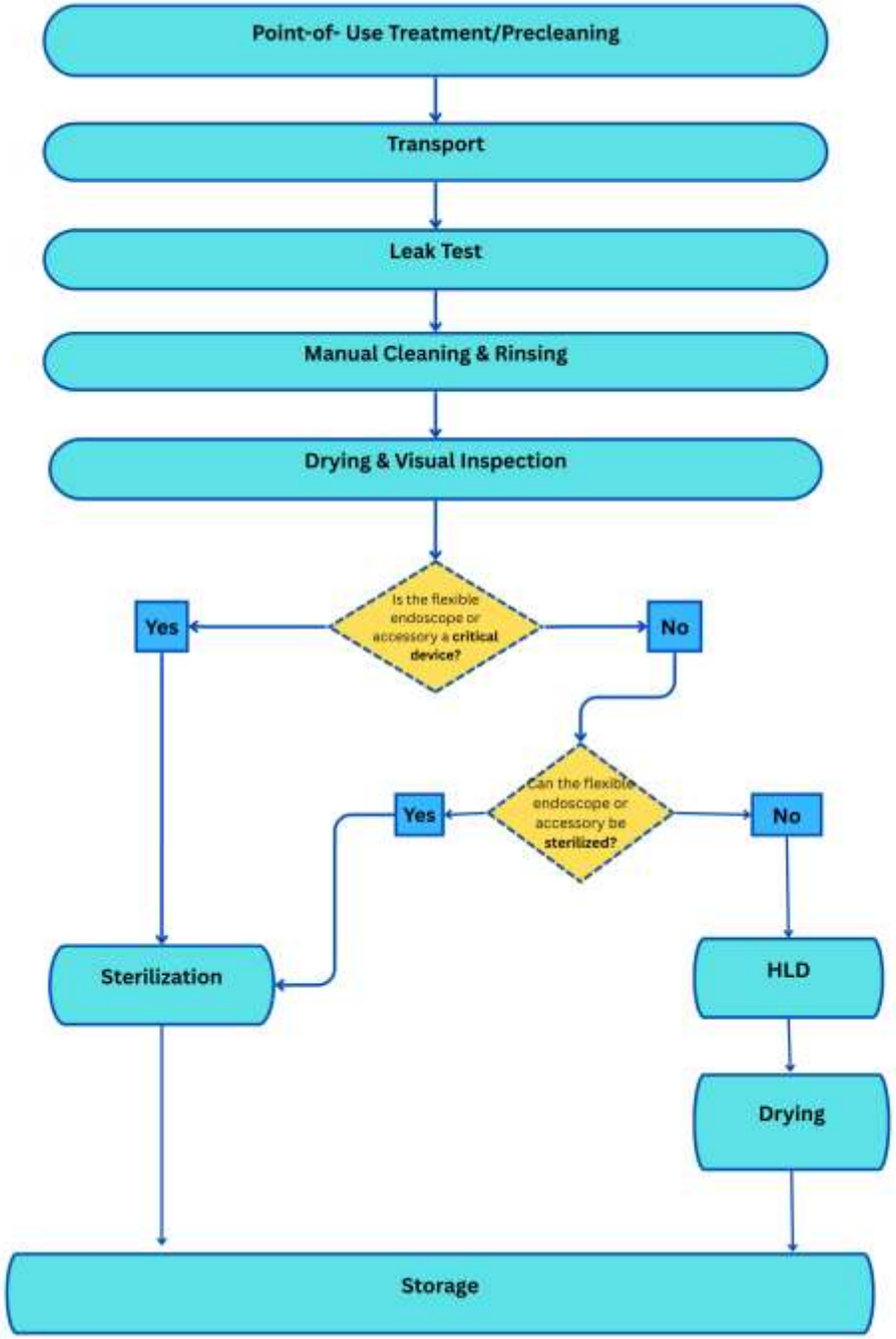
- Some flexible endoscopes enter sterile or invasive body cavities via microbially colonized sites.
- Risk of contamination from endogenous flora.

# Classification & Level of Reprocessing: Application

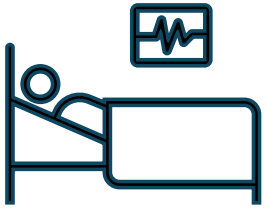
| Classification | Definition | Level of Reprocessing | Examples |
|---|---|---|---|
| Critical & high-risk semi-critical flexible endoscopes | Contact sterile or invasive body cavities (via microbially colonized sites) | • Sterilization, where possible<br>• HLD at minimum | • Bronchoscopes<br>• Cystoscopes<br>• Ureteroscopes<br>• Duodenoscopes (ERCP procedures) |
| Semi-critical flexible endoscopes | Contact with mucous membranes | • HLD at minimum<br>• Sterilization where possible and supported by MIFU | • GI endoscopes |

*Where feasible, use single-use accessories for items that are difficult to clean/reprocess (e.g., biopsy forceps).*

# Flexible Endoscope Reprocessing Flow Chart



# Point-of-Use Treatment/Pre-cleaning



## Purpose

- Removes gross soil and biological residues
- Prevents drying and hardening

## Timing

- Immediately after the procedure
- At point of use

## Process

- Apply fresh cleaning solution to exterior surfaces and aspirated/flushed through accessible interior channels.

# Transport of Used/Contaminated Devices

## Purpose

- Prevent damage and exposure during transport

## Time

- Timely transport
- Enable manual cleaning within 1-hour

## Process

- Use enclosed containers of appropriate size
- Keep device moist
- Clearly identify and separate contaminated devices from reprocessed ones
- Clean and disinfect transport containers

# Leak Test

## Purpose

- Verifies integrity of internal and external surfaces
- Detects leaks or openings

## Process

- Follow MIFU

# Manual Cleaning

## Purpose

- Critical to reprocessing!
- Removes residual biological material
- Prevents biofilm formation
- Essential for effective HLD or sterilization

## Timing

- Begin **within 1-hour** of pre-cleaning

## Process

- Follow MIFU
- Apply fresh cleaning solution (correct concentration, temp, contact time)
- Flush internal channels
- Brush with correct type/size for full contact
- Allow sufficient time
- Focused cleaning of elevator mechanisms
- *Note: AER cleaning does not replace manual cleaning*

# Simethicone Considerations

- Water in-soluble substance – enhances endoscopy visualization
- Difficult to remove during cleaning
- Residue can promote biofilm development
- Use lowest concentration possible
- Identify scopes exposed to simethicone
- Avoid delivery of simethicone via water bottles/irrigation channels during endoscopy procedure.
- **Repeat brushing** to remove residue

# Cleaning Verification Quality Assurance Program

- Assess cleaning effectiveness
- Use rapid tests (e.g., ATP)
- Test at organization-defined frequencies
- Support staff training and competency assessments
- Prioritize high-risk scopes
- Delayed reprocessing

Image credit: examples of a rapid cleaning verification assay, courtesy of Fraser Health

# Drying & Visual Inspection

## Drying

### Purpose

- Removes moisture to enable effective of sterilization or HLD

### Process

- Dry:
  - *External surfaces*
  - *Internal channels & opening*

## Visual Inspection

### Purpose

- Assess for cleanliness, functionality, & damage

### Process

- Inspect external surfaces & distal ends
- Remove if dirty or damaged

# Sterilization or High-level Disinfection

## Sterilization

### Purpose

- Kills microorganisms, including bacterial spores

### Process

- Ensure active Health Canada issued medical device license
- Ensure validated for the device
- Follow MIFU
- Ensure process parameters are documented and met

## HLD, Rinsing & Drying

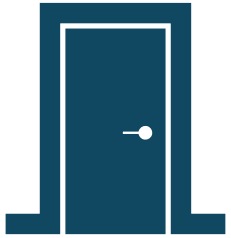
### Purpose

- Kills most microorganisms
- Rinsing removes disinfectant residue
- Drying removes residual fluid, prevents microbial growth and biofilms

### Process

- Use AER (preferred)
- Health Canada medical device license
- Validated for the device
- Follow MIFU
- Document and validate process
- Rinse with critical/sterile water
- Dry external surfaces and internal channels – **min. 10 mins!**
- ⚠️ alcohol flushes – may prolong drying times

# Storage



## Purpose

- Maintains level of reprocessing
- Protect from moisture, contamination, and damage

## Process

- Accessories  detached from the scope
- Sterilized scopes stored in:
  - *Sterile barrier system*
  - *Controlled environment*
- High-level disinfected scopes stored in:
  - *Channel purge drying cabinets (preferred)*
  - *Ventilated HEPA filtered cabinets. Reprocess after >7 days*.
- Follow a regular cabinet cleaning schedule

# Transport of Reprocessed Scopes

## Purpose

- Maintain level of reprocessing
- Prevent damage
- Prevent contamination

## Process

- Transport in enclosed containers. Do not store in in container for prolonged periods of time.
- Clean and low-level disinfect after each use.

# Quality Assurance

## Purpose

- Ensures consistent and safe reprocessing by identifying and correcting errors in the workflow

## Process

- Ensure documentation and verification of:
  - *Procedures and parameters*
  - *Staff training and competency*
  - *Equipment maintenance*
  - *Breaches and corrective actions*

# Traceability

## Purpose

- Links device to:
  - *Patient*
  - *Endoscopy procedure*
  - *Reprocessing activities*
- Enables retrospective investigations

## Process

- Ensure:
  - *Device tracking - automated or semi-automated tracking preferred*
  - *Documentation*
- Keep device and accessories together

# Transmission Events & Outbreaks

- Recall, quarantine and traceability procedures
- Investigation and assessment
- Notification and communication
- Corrective actions

# What is the primary reason flexible endoscopes cannot be steam sterilized?

# Why are flexible endoscopes linked to HAI transmission?

# Flexible endoscopes are the most common source of device-related HAIs

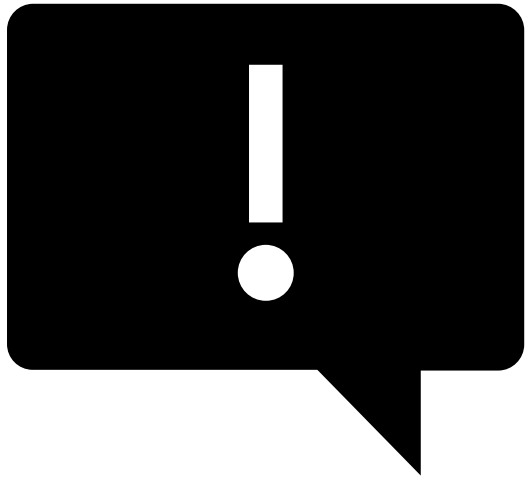
# Which step in the reprocessing workflow do you think is the most inconsistent or rushed?

# How soon should manual cleaning begin after pre-cleaning?

**The 3-minute drying in an automated endoscope reprocessor (AER) is sufficient drying time after high-level disinfection.**

# Select the correct statement related to drying of flexible endoscopes?

# Key Takeaways for Reprocessing of Flexible Endoscopes

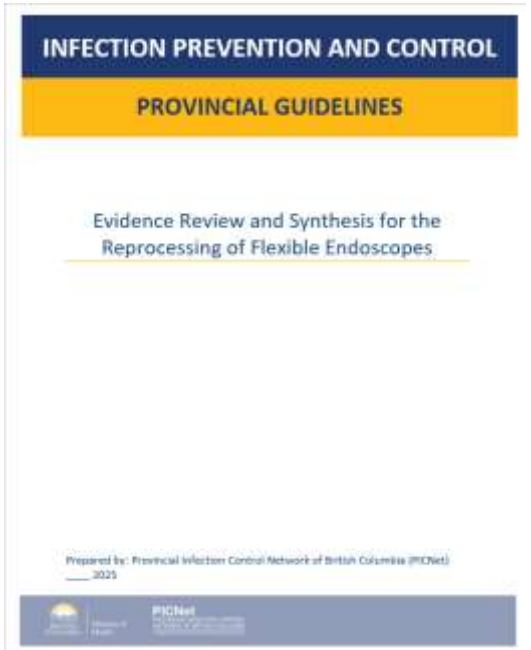


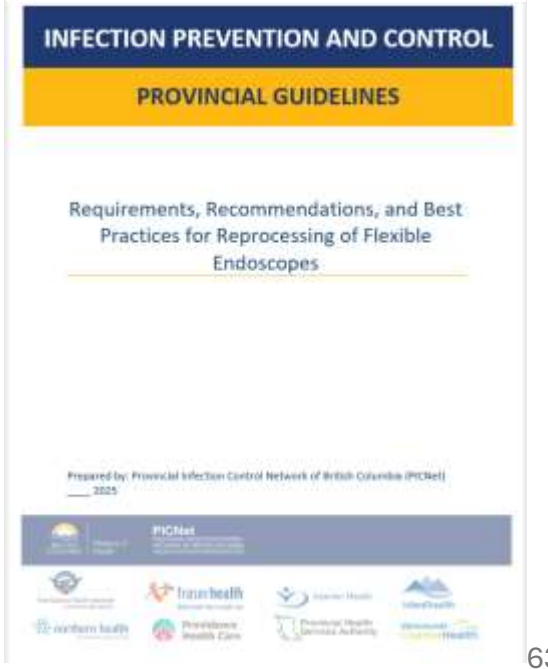
- High risk of transmission
- Complex process requiring consistent adherence
- Provincial guideline enables and supports safe, evidence-informed practice
- **Cleaning and drying are mission critical!**
- Sterilization offers a higher margin of safety

# References


1. Provincial Infection Control Network of BC (PICNet), August 2025, *Evidence Review and Synthesis for the Reprocessing of Flexible Endoscopes*

2. Provincial Infection Control Network of BC (PICNet), August 2025, *Requirements, Recommendations, and Best Practices for Reprocessing of Flexible Endoscopes*

# Thank you

- Please refer to the comprehensive guideline for additional information
- Questions and Answers
- Contact: picnet@phsa.ca