Infection Prevention & Control MANUAL
Policy & Procedure

Title: Flexible Endoscopes and accessories - Cleaning and Disinfection

NUMBER: IC 07-023

Effective Date: May 2013

Applies To: All CDHA Departments that use, clean and disinfect/sterilize flexible endoscopes and accessories

TABLE OF CONTENTS

Policy ................................................................. 2
Definitions ........................................................... 2
Procedure
  1. Education, training and certification ........................................ 3
  2. Cleaning and disinfection/sterilization instructions ................. 4
  3. Personal Protective Equipment (PPE) ........................................ 4
  4. Enzymatic detergent dilution .................................................. 4
  5. Manual cleaning of flexible endoscopes ................................... 5
  6. Automatic Endoscope Reprocessor cycles ............................... 5
  7. Reprocessing accessory items ............................................... 5
  8. Water Bottle .................................................................... 5
  9. Suction tubing and canisters ................................................. 5
 10. Weekly cleaning of flexible endoscopes ................................ 6
 11. Storage of flexible endoscopes ............................................ 6
 12. New, “on loan” and trial flexible endoscopes and reusable accessories ......................................................... 6
 13. Cleaning brushes .......................................................... 6
 14. Emergency and after hours cleaning ..................................... 7
 15. Transporting flexible endoscopes ......................................... 7
 16. Documentation .................................................................. 7

References ...................................................................... 8

Related Documents ...................................................... 8

This is a CONTROLLED document for internal use only. Any documents appearing in paper form are not controlled and should be checked against the electronic file version prior to use.
POLICY

1. The Infection Prevention and Control (IPAC) Department is responsible for developing and providing an approved endoscope reprocessing policy and procedure for each area that does endoscope reprocessing.

2. The endoscope unit physician and manager co-leads are responsible for ensuring that the approved policy and procedure for endoscope reprocessing is carried out as written.

3. All staff members responsible for any stage of flexible endoscope reprocessing must have the appropriate education and hands on training provided before carrying out reprocessing. (Refer to Appendix A)

   3.1. All endoscope reprocessing staff members must be certified by an Infection Control Practitioner (ICP) prior to completing the task independently.

   3.2. All endoscope reprocessing staff members are to be recertified at least annually and more often as required.

4. All staff members involved with endoscope reprocessing are to adhere to the procedures as outlined.

5. Staff members who reprocess flexible endoscopes and reusable accessories are responsible to ensure all steps of the cleaning and disinfection instructions are followed as written and all flexible endoscope equipment and reusable accessories have received appropriate cleaning prior to disinfection.

6. Staff members who reprocess flexible endoscopes and reusable accessories are responsible to ensure that disinfection cycles are complete and validated for all equipment and documentation is accurately completed as per policy. (See CDHA policy IC 07-025).

DEFINITIONS

Automatic Endoscope Reprocessor (AER): A machine designed to assist with the disinfection/sterilization of flexible endoscopes.

Cleaning: The physical removal of all visible dust, soil and foreign material. Cleaning removes but does not kill microorganisms. It is accomplished with water, detergents, and mechanical action. Thorough and meticulous cleaning is required before any equipment/device may be decontaminated, disinfected and/or sterilized.

Disinf ectant: A product that is used on medical equipment/devices, which results in disinfection of the equipment/device. Disinfectants are applied only to inanimate objects. Some products combine a cleaner with a disinfectant.

Disinfection: A process that kills most disease-producing microorganisms; does not kill bacterial spores.
High Level Disinfection: The process of using a chemical to kill all vegetative “live” bacteria, fungi, mycobacterium, and viruses. This does not necessarily kill bacterial spores.

Low Level Disinfection: Using a chemical to kill most vegetative “live” bacteria and some fungi as well as enveloped viruses. This does not kill mycobacteria or bacterial spores.

Manual Clean: Cleaning of the flexible endoscope by wiping, brushing and flushing the scope and channels using an enzymatic detergent to remove debris. This process must be completed prior to high level disinfection.

Personal Protective Equipment (PPE): Specialized clothing or equipment worn by staff for protection against exposure to body fluids and chemicals.

Pre-Clean: Completed immediately following the endoscope procedure at the bedside. The flexible endoscope is to be flushed and wiped using an enzymatic detergent.

Reprocessing: The steps performed to prepare reusable used medical equipment/devices for re-use (e.g., cleaning, disinfection, and sterilization).

Sterilization: The complete elimination or destruction of all forms of microbial life. Accomplished by either physical or chemical processes.

GUIDING PRINCIPLES AND VALUES

1. Contaminated flexible endoscopes and reusable accessory items are considered potential sources of transmission of infection for both patients and staff. Careful attention must be given to using infection prevention standards when reprocessing this equipment.

2. Competent staff members who maintain consistent excellence in practice are crucial to proper cleaning and disinfection of endoscopes. (Public Health Agency of Canada, 2010)

PROCEDURE

1. Education, training and certification:

   1.1. Health Service Managers (HSMs) contact the Infection Prevention and Control (IPAC) department to arrange an orientation education session and competency testing for staff who have a role in endoscopy reprocessing. Refer to Appendix A for specific information.

   1.2. The Endoscopy department provides hands-on practical training for all types and models of equipment requiring reprocessing prior to competency testing for certification.
1.3. An Infection Control Practitioner (ICP) completes the minimum annual review of staff members’ competency.

2. Cleaning and disinfection/sterilization instructions:

2.1. Complete pre-cleaning immediately following the procedure while at the bedside.

2.2. Complete manual clean immediately following the completion of the procedure and pre-clean.

2.2.1. Failure to clean the flexible endoscope soon after the procedure will allow the formation of biofilm and drying in the channel, making cleaning of the flexible scope difficult.

2.3. Endoscopy Departments:

2.3.1. Ensure there are written reprocessing instructions readily available for all types and models of flexible endoscopes used in the department.

2.3.2. Ensure that all flexible endoscopes and their components are compatible with the automatic endoscope reprocessor (AER) used by that department.

2.3.2.1. Obtain written confirmation of compatibility from the endoscope or AER manufacturer.

2.3.3 Post manufacturer recommended written instructions for all AER machines in the room where the AER is located.

2.3.3. Ensure staff members who use detergents and disinfectants/liquid sterilants are familiar with the WHMIS and MSDS information available for the products in use. Refer to policy CH 80-020 Workplace Hazardous Materials Information System (WHMIS)

2.4. Complete quality assurance procedures for Steris System 1 (Diagnostic cycle and Biological Indicator testing) as recommended by the manufacturer. Document results as per Flexible Endoscope Reprocessing – Documentation Requirements (IC 07-025).

2.5. If flexible endoscopes are sterilized by a Sterile Processing Department (SPD), SPD obtains and retains written confirmation of compatibility and validation of this sterilization method (e.g. ethylene oxide (ETO), peracetic acid, steam etc.) from the manufacturer.

3. Personal Protective Equipment (PPE):

3.1. For all steps of cleaning and disinfection of flexible endoscopes and accessories, wear PPE as recommended by the endoscope and chemical manufacturer.

Note: PPE includes, but is not limited to, full face protection, long sleeved fluid resistant gown and chemical resistant gloves.

4. Enzymatic detergent dilution:

4.1. Prepare enzymatic detergent as per manufacturer instructions with regard to dilution, temperature and time.

4.2. Use potable tap water for dilution unless otherwise specified by the manufacturer.

4.3. Be familiar with the WHMIS and MSDS information for the products in use.
5. Manual cleaning of flexible endoscopes:

5.1. Follow written procedures (refer to Procedure # 2) for the manual clean of flexible endoscopes and complete all steps.

5.2. Refer to Appendix B for a guide for flexible endoscope cleaning.

6. Automatic Endoscope Reprocessor (AER) cycles:

6.1. Ensure that all flexible endoscopes disinfected or sterilized in an AER have a complete cycle with validated printout prior to re-use.

6.2. If a cycle is interrupted, aborted or incomplete, repeat the cycle and insert/write the appropriate information on the Flexible Endoscope Cleaning and High Level Disinfection documentation form. (Refer to Flexible Endoscope Reprocessing – Documentation Requirements (IC 07-025)

6.3. Refer to Flexible Endoscope Reprocessing – Documentation Requirements (IC 07-025) for requirements and additional information.

7. Accessory Items


7.2. Reprocessing Reusable Accessory Items:

7.2.1. Endoscopy and Sterile Processing Departments (SPD) obtain written manufacturer recommended instructions for all accessory items reprocessed.

7.2.2. Clean and disinfect/sterilize all reusable accessory items used in conjunction with flexible endoscopes according to manufacturer recommendations.

7.2.3. Use the Spaulding Classification System (Appendix C) as a reference to ensure all items are receiving appropriate disinfection and/or sterilization.

8. Water bottle:

8.1. For flexible endoscopes with an air/water channel, use the water bottle for the day unless the water bottle becomes contaminated.

Exception – For Endoscopic Retrograde Cholangiopancreatography (ERCP) procedures and Operating Room (OR) settings, use the water bottle only for one procedure and send for reprocessing following that one use.

8.2. Use only sterile water.

8.3. Send the water bottle to SPD at the end of the day/after single use for cleaning and sterilization according to manufacturer’s instructions.

9. Suction tubing and canisters:

9.1. Discard the suction tubing attached to the flexible endoscope following a single patient use.

9.2. Use suction canisters and liners for multiple procedures; change when full.

Exception – For bronchoscope procedures and OR settings, change the suction tubing and canister/liner for each patient.

9.2.1. Assess the fullness of the canister/liner prior to the start of each procedure and document on the health record.
10. Weekly cleaning of flexible endoscopes:

   **Note:** The Endoscopy Department monitors use of all flexible endoscopes to ensure the weekly cleaning is completed.

10.1. If a flexible endoscope is not used during a seven day period, manually clean and high-level disinfect or sterilize.


11. Storage of flexible endoscopes:

11.1. Store vertically in a well ventilated storage cabinet/cupboard.

11.2. Store with no valves, buttons or covers attached.

11.3. Ensure that the endoscope storage cabinet is made of washable material and free from damage.

11.4. Clean the inside of the cabinet at minimum once per week using an approved low-level surface disinfectant.


   **Note:** The department retains this documentation with the Endoscope Cleaning and Disinfection records.

12. New, loaned, and trial flexible endoscopes and reusable accessories:

12.1. To allow for adequate time for assessment of reprocessing instructions and confirmation of the ability to complete the reprocessing in Capital Health facilities, the Endoscopy Departments ensures that all reusable equipment has proper manufacturer recommended cleaning instructions available a minimum of three weeks prior to the planned use of the equipment.

12.2. The Endoscopy Department arranges for reprocessing staff to have the required “expert” training of reprocessing by the manufacturer or vendor prior to the use of the item.

12.3. Obtain written compatibility and validation of disinfection/sterilization of new or loaner flexible endoscopes in the endoscopy departments AER from the endoscope and AER manufacturer prior to use in the department.

   **Note:** This validation must be in writing and retained by the endoscopy and IPAC departments.

13. Cleaning brushes:

13.1. Ensure that all cleaning brushes used in the reprocessing of flexible endoscopes are manufacturer recommended and the appropriate size for the endoscope channels.

   **Note:** Single use disposable brushes are recommended.

13.2. Inspect the brushes prior to each use. Ensure that the bristles are pristine in appearance with no damage or missing bristles on the circumference of the brush.
14. Emergency and after hours cleaning:

14.1. Complete pre-cleaning immediately following the procedure while at the bedside.

14.2. Complete manual clean immediately following the completion of the procedure and pre-clean.

14.2.1. Failure to clean the flexible endoscope soon after the procedure will allow the formation of biofilm and drying in the channel, making cleaning of the flexible scope difficult.

14.3. If disinfection/sterilization knowledgeable staff members are not immediately available, disinfection/sterilization may be postponed until the next morning.

14.4. If disinfection is delayed, repeat the manual clean immediately prior to disinfection/sterilization.

14.4.1. If necessary to delay disinfection of the flexible endoscope, store the endoscope securely in a basin with the insertion tube and universal cord loosely coiled until manual cleaning is repeated and disinfection occurs the next morning.

15. Transporting of flexible endoscopes:

15.1. If transport of a flexible endoscope between departments is required, transport in a container with a lid; do not leave unattended at any time.

Exception: Specified travel carts must have a protective edge on the top shelf of the cart to ensure the flexible endoscope is secure. The endoscope must be completely covered.

15.2. Ensure that the transport container measures no less than 40 cm x 40 cm and is deep enough to ensure the endoscope is secure.

Note: The size of the container is to prevent the excessive coiling of the endoscope which can cause damage.

15.3. When flexible endoscopes are transported in the manufacturer provided hard shell case intended for shipping, consider the endoscope contaminated; clean and disinfect/sterilize prior to use for a procedure.

16. Documentation

16.1. In addition to previously stated documentation requirements:

16.1.1. Document all flexible endoscope reprocessing steps; the Endoscopy Department retains these documents for a minimum of 7 years.

16.1.2. The Endoscopy Departments Health Service Manager (HSM) or delegate verifies reprocessing documentation. Refer to Flexible Endoscope Reprocessing – Documentation Requirements IC 07-025 for details.
REFERENCES


RELATED DOCUMENTS

Policies:
IC 07-025 Flexible Endoscope Reprocessing – Documentation Requirements

Appendices
Appendix A – Certification requirements for CDHA staff responsible for reprocessing flexible endoscopes

Appendix B – Flexible Endoscope reprocessing Summary Chart

Appendix C – Spaulding Classification System

***
Appendix A

Cleaning of Flexible Endoscopes
Process for Manual Scope Cleaning Certification

In the interest of patient safety, when a staff member is assigned manual cleaning of flexible endoscopes:

1. The staff member must attend “Orientation to Flexible Endoscope Cleaning” provided by the Infection Prevention and Control delegate.
   - Contact the IPAC department to arrange for attendance at a session

2. The Manager/Supervisor is responsible to arrange practice time in the decontamination area. This practice time is to be supervised by another staff member who is experienced, competent and certified in manual flexible endoscope cleaning.

When it is determined that the staff member has had adequate practice and is comfortable with the manual scope cleaning procedure, the practical test by the IPAC practitioner will be arranged by the endoscopy department manager or designate.

3. If the staff member is not successful in passing the practical test, further practice and retesting will be required. The endoscopy department manager or designate will arrange for further supervised practice time. Once the additional supervised practice time is complete, the manager or delegate will contact IPAC to arrange for a retesting time.

4. Only staff who successfully pass the certification process can be responsible for manual flexible endoscope reprocessing.

5. A minimum of two weeks’ notice is required by IPAC department staff to arrange education sessions and testing.

6. Records of staff who have been certified in the flexible scope cleaning process will be maintained by the HSM or delegate. A copy will be retained by the IPAC department.

If there are any questions, please contact the CDHA Infection Prevention and Control department at 473-2659.
Appendix B
Flexible Endoscope Reprocessing Summary Chart

End of procedure, endoscope withdrawal

Pre-clean at bedside immediately following procedure

Leak test

Manual clean immediately following procedure

High-level disinfection or Sterilization

Rinse after high-level disinfection (may be part of AER cycle)

Alcohol flush after high-level disinfection, followed by air flush

Proper storage of the endoscope
Appendix C
Spaulding Classification

Instruments and items for patient care have been divided into three categories based on the degree of risk of infection involved in the use of these items.

<table>
<thead>
<tr>
<th>Classification</th>
<th>Definition</th>
<th>Level of Reprocessing</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Semi-critical Equipment/Device</td>
<td>Equipment/device that comes in contact with nonintact skin or mucous membranes but do not penetrate them.</td>
<td>Cleaning followed by High-Level Disinfection (as a minimum).</td>
<td>Respiratory therapy equipment. Anaesthesia equipment. Tonometers.</td>
</tr>
<tr>
<td>Noncritical Equipment/Device</td>
<td>Equipment/device that touches only intact skin and not mucous membranes, or does not directly touch the patient.</td>
<td>Cleaning followed by Low-Level Disinfection</td>
<td>ECG machines. Oximeters. Bedpans, urinals, &amp; Commodes.</td>
</tr>
</tbody>
</table>

Adapted from: Ministry of Health and Long-Term Care/Public Health division/provincial Infectious Diseases Advisory Committee (February, 2010). Best Practices for Cleaning, Disinfection and Sterilization in all Health Care Settings.