MDRAO – Importance of Bedside & Manual Precleaning

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Medical Device Reprocessing Association of Ontario

MDRAO Conference September 10-12, 2017

MEASURING SUCCESS:

QUALITY ASSURANCE IN MEDICAL DEVICE REPROCESSING

AGENDA

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- Role of MDRD
- Hazards related to reprocessing
- Importance of Adequate Reprocessing
- Standards
  - Bedside PreClean
  - Manual PreClean
- Solutions

Role of MDRD

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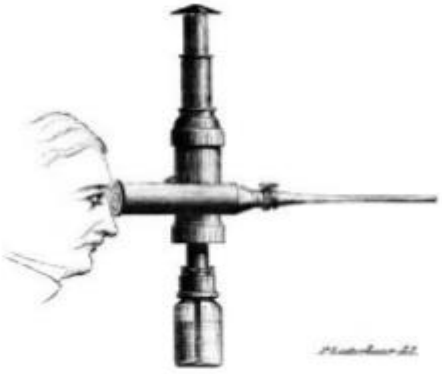
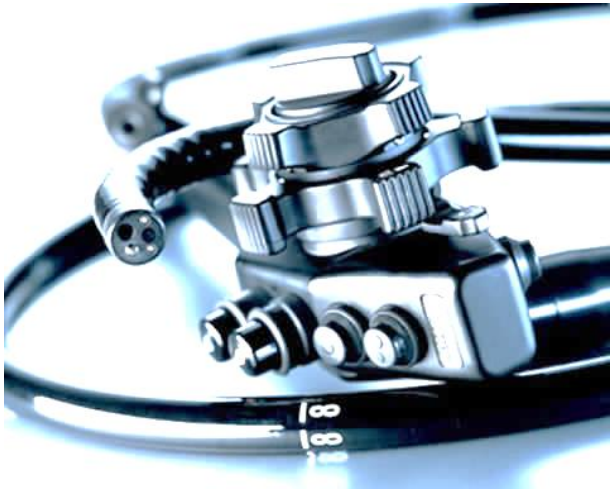
"Medical Devices have become increasingly more complex as more sophisticated and less invasive surgical procedures are developed." [1.]





1. Scientific Advisory Panel on Reprocessing of Medical Devices (SAP-RMD) (February 10-11, 2005) - Panel Recommendations

Top 10 Health Technology Hazards for 2016

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THE LIST FOR 2016

1. Inadequate Cleaning of Flexible Endoscopes before Disinfection Can Spread Deadly Pathogens
2. Missed Alarms Can Have Fatal Consequences
3. Failure to Effectively Monitor Postoperative Patients for Opioid-Induced Respiratory Depression Can Lead to Brain Injury or Death
4. Inadequate Surveillance of Monitored Patients in a Telemetry Setting May Put Patients at Risk
5. Insufficient Training of Clinicians on Operating Room Technologies Puts Patients at Increased Risk of Harm
6. Errors Arise When HIT Configurations and Facility Workflow Do Not Support Each Other
7. Unsafe Injection Practices Expose Patients to Infectious Agents
8. Gamma Camera Mechanical Failures Can Lead to Serious Injury or Death
9. Failure to Appropriately Operate Intensive Care Ventilators Can Result in Preventable Ventilator-Induced Lung Injuries
10. Misuse of USB Ports Can Cause Medical Devices to Malfunction

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Top 10 Health Technology Hazards for 2016

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- “Failure to adequately reprocess contaminated instruments before use can lead to the spread of deadly pathogens.”

- “If precleaning is not carried out effectively, the disinfection or sterilization step may not be effective.”

1

Inadequate Cleaning of Flexible Endoscopes before Disinfection Can Spread Deadly Pathogens

Reprocessing

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- Existing reprocessing methods, when properly and carefully conducted, can and do produce acceptable quality instruments. [1.]
- Rapid turnover of equipment, inadequate training, failure to completely dry the instrument and lack of quality control may contribute to failure of the process [1.]
- Records of reprocessing shall be completed and retained… [2.]

1. Muscarella 2006
2. Decontamination of Reusable Medical Devices. CSA Z314.8-14

Barriers to Infection Control

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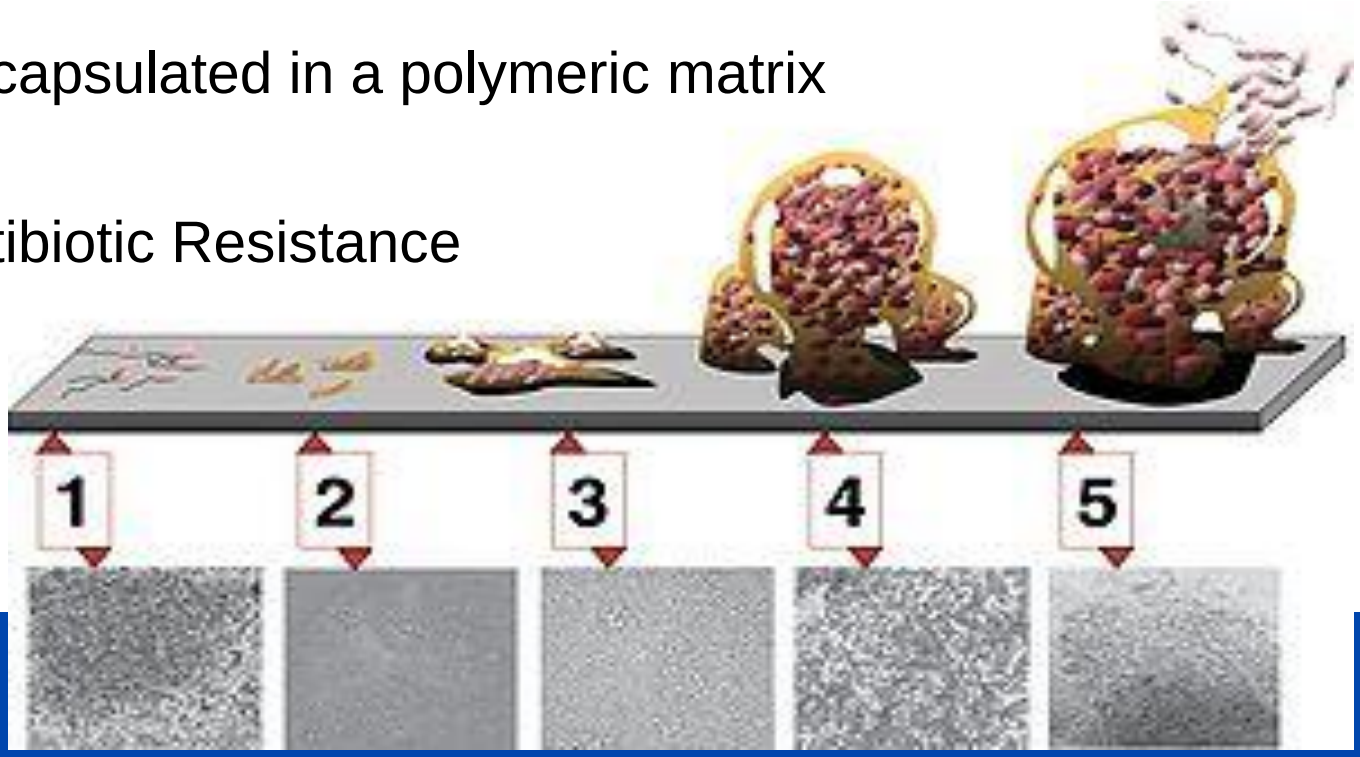
1. **Wet Storage**
    1. Complex equipment + Water
    2. Remember the 24hrs rule
2. **Biofilm formation**
    1. “Cleaning and brushing of endoscope channels as soon as possible after the procedure”
    2. The importance of cleaning and effective brushing
    3. Do NOT soak over overnight*
3. **Equipment complexity and Design flaws**
    1. Reusable accessories
    2. ERCP & Bronchoscopes
4. **Errors in reprocessing**
    1. Lengthy and vauge IFUs

INFECTION PREVENTION AND CONTROL GUIDELINE for **Flexible Gastrointestinal Endoscopy** and **Flexible Bronchoscopy**

Review of Terms: Biofilm

- Matrix of different bacterias and extracellular materials that can tightly adhere to the interior surfaces of endoscopes
- Strong permanent adhesions if not removed immediately
- Encapsulated in a polymeric matrix
- Antibiotic Resistance



Review of Terms: Spaulding Classification

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Level of risk	Application	Process	Examples
Non-critical	In contact with normal and intact skin	Cleaning followed by low-level disinfection (in some case, cleaning alone is acceptable)	BP Cuff, Stethoscope
Semi-critical	In contact with mucous membranes or non intact skin	Cleaning followed by high-level disinfection if sterilization not possible (flexible endoscopes). Sterilization preferred.	Flexible endoscopes, thermometers, endotracheal tubes
Critical	Penetrate sterile tissues (body cavities, vascular system)	Cleaning followed by sterilization	Surgical instrument, intra-uterine devices, vascular catheters

Review of Terms

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- **Personal Protective Equipment:** Gowns, gloves and protective eyewear

Review of Terms

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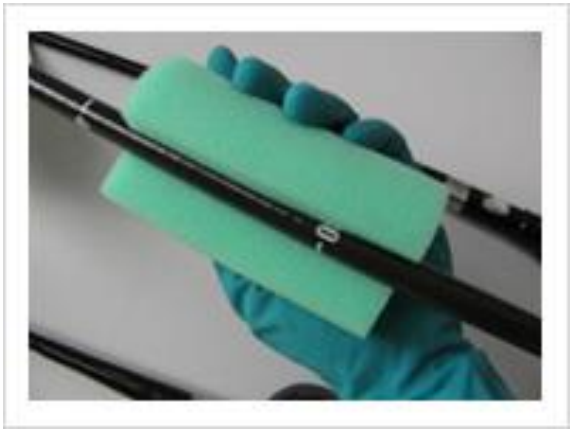
- **Manual Cleaning:** Thorough and meticulous manual cleaning of all instruments must precede HLD or sterilization. [1.]
- Refer to endoscope manufacturers' guidelines for design features unique to a particular instrument



Reprocessing: CSA Guidelines

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- Specific procedures for each scope, consistent with manufacturer's instructions [1.]

a) Beside pre-clean;
b) Transport to reprocessing area;
c) Leak testing, if required;
d) Manual (or automated) flushing, cleaning and rinsing;
e) High-level disinfection or sterilization;
f) Drying;
g) Inspection;
h) Transporting to storage area;
i) storage

1. Decontamination of Reusable Medical Devices. CSA Z314.8-14

CSA Guidelines: Bedside Pre-Clean

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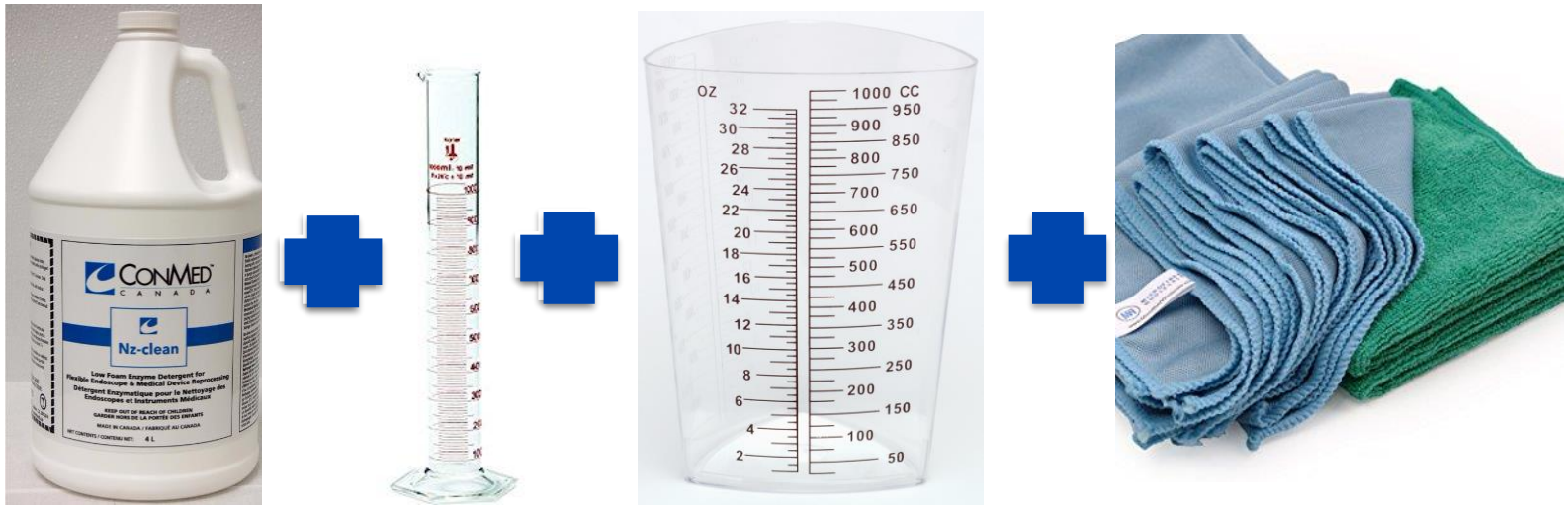
- Immediately after procedure and patient leaves the room
- Solution shall be prepared immediately before use, correctly diluted and used only one.



CSA Guidelines: Bedside Pre-Clean

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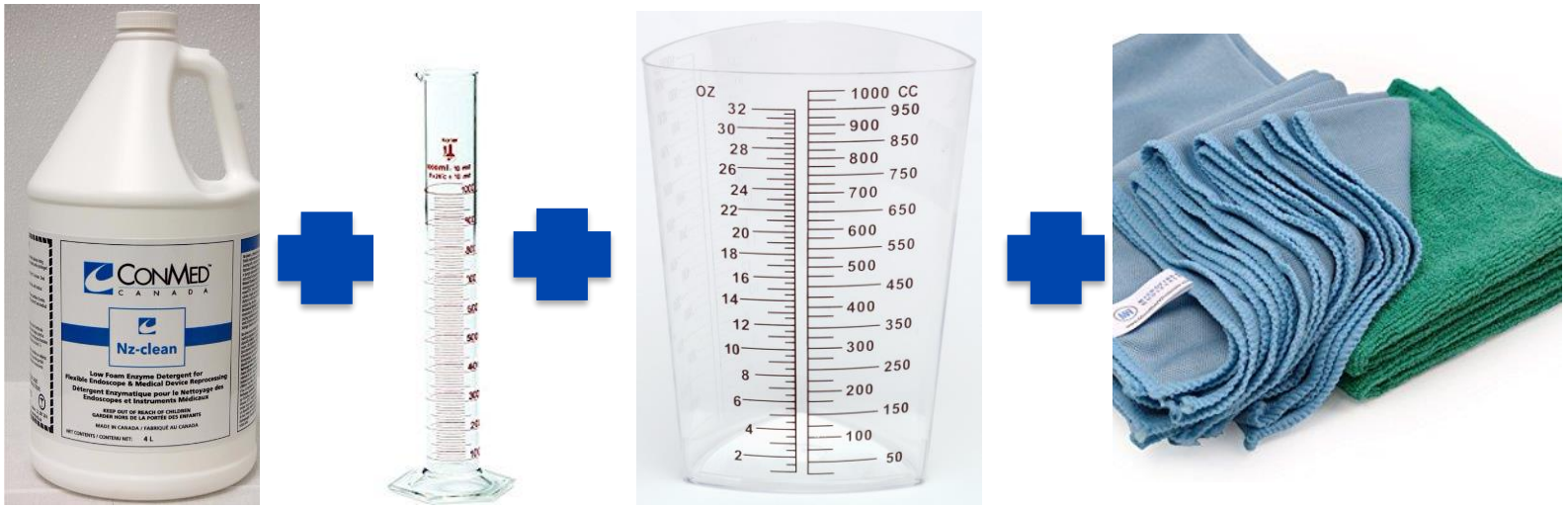
- Wipe insertion tube with enzymatic solation
- Place distal end into enzymatic solution. Alternate suction and flushing.
- Flush or blow out air and water channels in accordance with IFU
- Attach protective video cap



CSA Guidelines: Leak Testing

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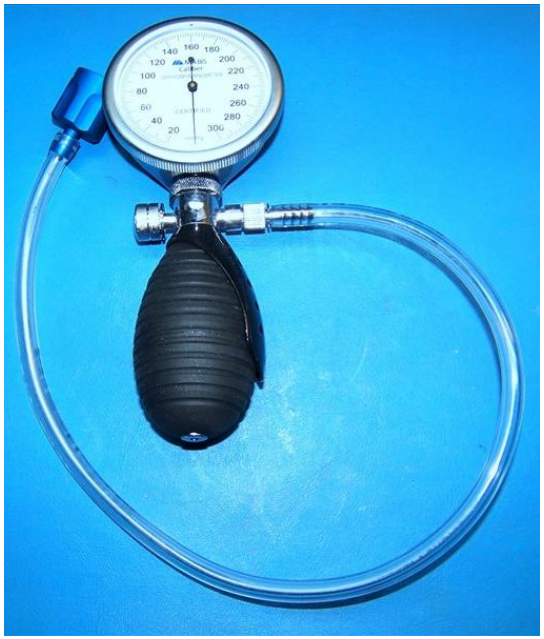
- Ensure the leak tester is working before submersion
- Ensure pressure remains constant
- Leak test for at least 3 minutes
- Pressure must not exceed manufacturers recommendations



CSA Guidelines: Manual Cleaning

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- Fill sink with fresh water and accurately dose with low-foaming detergent
- Immerse scope and clean outer surface
- Brush all channels as per manufacturer's recommendations. After each pass rinse brush in ensymatic
- Flush all channels with enzymatic as per IFU
- Ensure appropriate contact time
- Immerse in clean water and flush channels
- Purge with air

Principle

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Every patient must be considered a potential source of infection and all endoscopes must be decontaminated ***with the same degree of rigor*** following every endoscopic procedure[1]

[1] ***Standards of Infection Control in Reprocessing of Flexible Gastrointestinal Endoscopes,*** *Society of Gastroenterology Nurses and Associates, Inc. (SGNA). First published in 1996, revised 2000, 2005, 2007, 2008.*

Reprocessing Overview

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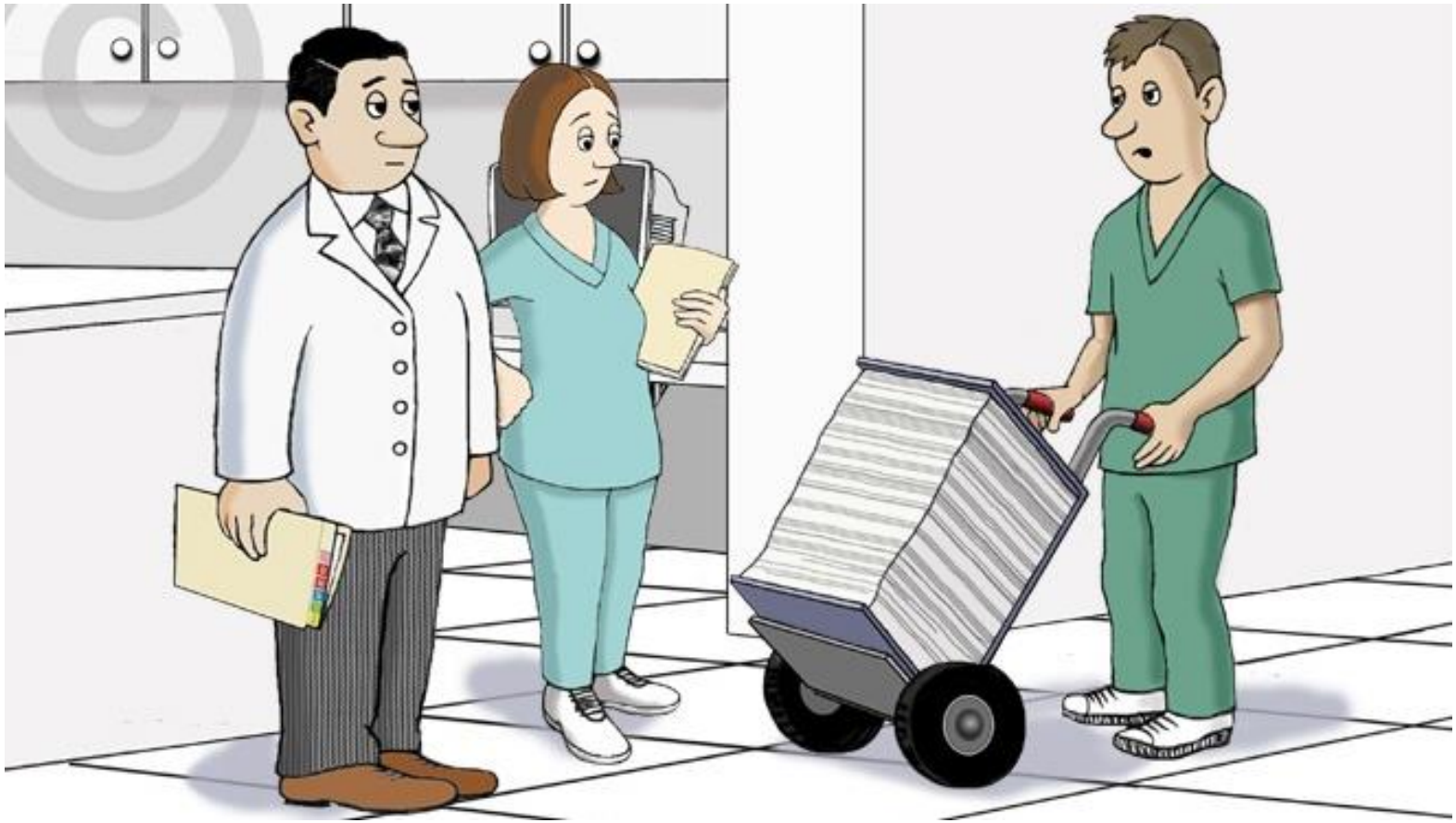

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Solutions: Bedside Pre-Clean

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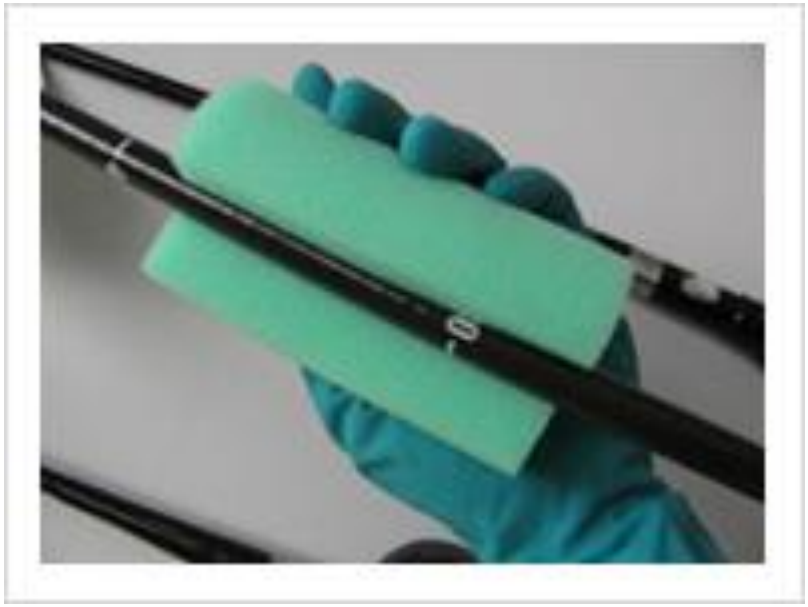

Solutions: Leak Test and Manual PreClean

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- Automated systems ensure consistency with recommended procedures
- Eliminate the human error
- Built in leak tester with pressure monitoring
- Single and dual flush capabilities
- Preset programming to eliminate guess work
- Built in dosing system to meet manufacturers recommendations
- Reporting tool to track each reprocessed scope

Principle

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Hands On Session