Enhanced Visual Inspection of Medical Devices

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Disclosure

- All opinions are those of the presenter.
- This sponsored presentation is not intended to be used as a training guide or promotion.
- Before using any medical device, review all instructions for use.
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This goal is supported by a staff committed to individual accountability, professionalism, mutual respect, collaboration and service excellence. This presentation is part of that commitment, educating our customers.
Objectives

- Define Optical inspection
- Review the benefits of optical inspection of medical devices
- Review various methods for optical inspection
- Demonstrate examples of inferior cleaning exposed with the use of optical inspection
Definition: Optical Inspection

Optical inspection is defined as the process of using the unaided eye, alone or in conjunction with various aids, as the sensing mechanism from which judgments may be made about the condition of any medical device to be inspected.
FDA on Visual Inspection

• All routine cleaning instructions should include:
  • Instructions for visual inspection, which may include use of magnification.
  • May include use of magnification and adequate lighting.
  • Visual inspection instructions should identify acceptance or failure criteria.

* Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling Guidance for Industry and Food and Drug Administration Staff Document issued on: March 17, 2015 Appendix E of this guidance was updated on June 9, 2017; page 17; section H
Inspection is Really Important

• The word inspect/inspection:
  • Appears over 80 times in ANSI/AAMI ST 79.
  • Appears in over 900 IFUs.
Visual inspection in IFUs

- daVinci Xi
  - “While brushing, intermittently move the instrument through its full range of motion.
  - Pay particular attention to the instrument tip.
  - Inspect for visible soil; including the tip and all surfaces with fenestrations with 4X magnification.

*Intuitive Surgical, Inc. Reprocessing Instructions Cleaning, disinfection, and sterilization information for reusable instruments, accessories and endoscopes used with da Vinci Xi System. PN 551490-08 Rev. B
Visual inspection in IFUs

• **Stryker Micro Electric:**
  • “**Inspect** the handpiece to make sure there is no visible soil, damage, signs of wear, and/or corrosion.”

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Visual inspection in IFUs

• **Medtronic Microdebriders M4 & M5**
  • **Inspect** components for any damage before and after each use.
  • If damage is **observed** do not use the instrument until it is repaired.

**NOTE**: What is damage? If it is not defined in the IFU, then the facility must decide.

*Reprocessing Instructions Microdebriders  StraightShot M5, StraightShot M4, StraightShot Magnum II, StraightShot III or Midas Rex Spine Shaver*
Enhanced Visual Inspection in IFUs

- Stryker Shaver IFU:
  - Visually inspect the hand piece, including all internal surfaces, for remaining soil.
  - Use an endoscopic camera to see the inner surface of the lumen.
  - If soil remains, repeat the manual cleaning procedure.
Two more deaths reported 5/6/16

- Olympus was informed that following endoscopic retrograde cholangiopancreatography (ERCP) procedures, six patients were infected with E. Coli, and two of the six patients have expired.
  - Scope sent to OEM for inspection
  - A borescope was used to inspect the biopsy and suction channels.
  - Brown stains and scrape marks were found on the biopsy channel interior at 5.5 cm from the distal end.
  - The suction channel had similar brown stains at various locations.
  - Both channels had interior signs of damage which appear to be due to scrapes.

Immediately remove from service for assessment and repair any duodenoscope that shows visible signs of damage. Examples of damage may include:

- Loose parts.
- Damaged channel walls.
- Kinks or holes.
- Cracks and gaps in the adhesive that seals distal cap.
- Other signs of wear or damage.

*1/17/2017 – Posted ED-3490TK Video Duodenoscope by Pentax: FDA Safety Communication - UPDATE - Follow Pentax Validated Reprocessing Instructions
Before you go down that rabbit hole on enhanced visual inspection ask yourself...

- What device must I examine with enhanced visual inspection?
  - E.g. Flexible Endoscope, Orthopedic shaver
  - FDA alert
  - IFU
- Where do I look on any specific device?
  - External
  - Internal
Why use enhanced visual inspection technology

- Various Standards and guidelines support the use:
  - ST 79
  - ST 91
  - AORN
  - SGNA
  - APIC
  - FDA
- You must follow the IFU.
- Publications both peer and non peer review support this practice.
- Medical devices with, (or without), may appear clean with unaided eye.
- Patient safety.
Risk Analysis

• A risk analysis should be completed for all aspects of steam sterilization.
  • Identify any risk that could occur to personnel or patients.
  • Define and quantify the risk.
  • Identify actions that can be taken to resolve or prevent the risk.
  • should be monitored to ensure that the risk has been corrected or prevented.

— ST 79
Example of Enhanced Visual Inspection:
USB Microscope

Document what you see
Borescope Inspection
Borescope Inspection
Borescope Inspection
Visual Inspection: Unaided Eye Versus Magnified
Instrument Inspection
Basics
Instrument Inspection Basics

• Before assembly inspect instruments for:
  • Pitting, cracks, bent tips, misalignment, corrosion, burs, cleanliness, etc.
  • Working parts move freely.
Instrument Inspection Basics

- Inspection points:
  - Box locks
  - Shanks
  - Ring handles
  - Scissor blades
  - Hinges and hinge pin
  - Tungsten carbide inserts
  - Ratchets
  - Weld joints (Bookwalter)
Visual Inspection

- At each workstation on the clean side
- At each workstation in the decontamination area
- Should take place at each stage of process.
Surface Optical Inspection Tools
Internal Optical Inspection Tools
Borescope Inspection – Enhanced Visual Inspection

• Borescopes penetrate device lumens and allow for enhanced visual inspection
• It started with the shaver
From January 2015 to April 2018 these questions were asked to attendees at educational programs given by Healthmark.
Do you process arthroscopic shavers in your facility?

76% - YES
Do you use enhanced visual inspection?

Responses

76% Yes

59% No
Example:
Found inside a Shaver
Examples of Debris Found in Shavers
Standards and Guidelines
Support Borescope Inspection

• AORN
  • Tools such as video borescopes of an appropriate dimension (length and diameter) may be used to visually inspect the internal channels.
  • Internal channels of endoscopes may be inspected using a borescope.

Standards and Guidelines Support Borescope Inspection

• AAMI ST91
  • Tools such as video borescopes of an appropriate dimension (length and diameter) may be used to visually inspect the internal channels of some medical devices.

Standards and Guidelines Support Borescope Inspection

• AAMI ST 79
  • Inspection using enhanced visualization tools such as lighted magnification and video borescopes might identify residues not observable by the unaided eye.

* © 2017 Association for the Advancement of Medical Instrumentation ■ ANSI/AAMI ST79:2017
Standards and Guidelines Support Enhanced Inspection

• SGNA
  • Visual inspection alone is insufficient to determine cleaning adequacy.
  • Use magnification and adequate lighting.
  • Time out for visual inspection.
Standards and Guidelines
Support Enhanced Inspection

• APIC
  • The IP will evaluate human factors, including ensuring that the cleaning area is set up with a bright light and magnification so all sections of the scope being cleaned can be well visualized.
Regulatory Support for Enhanced Visual Inspection

• CDC
  • Consideration should be given to use of a magnifying glass (e.g., 10x) to improve detection of residual debris around the elevator mechanism.
Published Articles that Support Enhanced Visual Inspection

THE FANTASTIC VOYAGE OF ENHANCED VISUAL INSPECTION

BACKGROUND

In the recent update of AORN’s EPW, this statement appears: “Inspection using enhanced visualization tools such as light magnification and colored bioscopes may identify defects not observable in the usual view.”

As medical device is usually dry, and one can see it from the top, you want it to be easy to inspect. It’s a very simple procedure, since all medical devices are inserted and not only to patients, but to staff involved in device that are easily viewable during the inspection process. Staff should select the appropriate tool for the device being inspected. The tool should be selected based on the type of device being inspected and the latest inspection data. Specific tools are used for different devices.

This poster will outline the development of a new technology, Enhanced Visual Inspection of medical devices (EVIDENCE). EVIDENCE is a flexible inspection technique that provides a more complete and efficient inspection of medical devices.

The manufacturer of the device changes their instructions for use (IU), requiring the use of a new tool baseline of flexible inspection scope to inspect the inner workings or the device. Enhanced Visual Inspection tools are the cutting-edge technology that advances the inspection tools for medical devices.

This new technology has been developed by using existing inspection tools modified by the manufacturer. The development of this new technology has allowed for an improved method of inspection that provides a more comprehensive and efficient inspection of medical devices.

METHOD

A highly published outcome at Methodist hospital in Houston, Texas, was presented by Dr. S. Kovach, MD, in a poster session. The results showed that examining the device using the enhanced visual tool improved the ability to identify defects not observable in the usual view. The tool was designed to provide a more comprehensive examination of medical devices.

The enhanced visual tool is a flexible scope that can be used to inspect the inner workings of medical devices. The tool allows for a more thorough inspection of the device, providing a more comprehensive examination of the device.

DISCUSSION

Since 2016, the FDA has added the ability to enhance the visual tool to examine orthopedic devices with some type of enhanced visual inspection tool. Based on this technology, the device/inspecting tool for examining orthopedic devices is currently being developed by the manufacturer. The enhanced visual tool was developed by an American-based company to examine other professional tools to look inside the orthopedic device.

This new technology has been used in many major research papers and has been approved by the FDA.
Residual contamination found on endoscopes in an ambulatory surgery center

Introduction
- Contaminated endoscopes have caused outbreaks of多重耐药株 resistant organisms.
- During one outbreak investigation, investigators discovered an endoscope and identified:
  - Brown staining, scale, and a small crack in the distal tip
  - Pseudomonas aeruginosa identical to outbreak strain
- In another outbreak investigation:
  - Infections were linked to contaminated endoscopes
- The manufacturer found critical defects in every endoscope
- The study was designed to answer two questions:
  - How much do contamination and damage accumulate in endoscopes over time?
  - Is it possible to get old endoscopes clean?

Methods
- Longitudinal study in an ambulatory surgery center
- Three assessments conducted over a 3-month period
- Baseline data collection in April 2015:
  - Auditing reprocessing practices
  - Compiling data on endoscope age, usage, and repair history
  - Evaluating 17 clinically used endoscopes:
  - Non-standardized reprocessing
  - Rapid indicator tests for ATPI and proteins
  - Microbial cultures
  - Biopsy examination of interior components
  - Implementation of more rigorous reprocessing methods (beginning in May 2015)
- Results of routine monitoring and endoscope inspections

Results
- At baseline assessment:
  - 14 endoscopes were used 2-3 years old
  - Endoscopes had been used 16-49 times
  - New endoscopes had been cleaned
  - There was a high adherence to reprocessing policies
  - 10 of the 17 endoscopes were still contaminated after manual cleaning
  - Contamination levels were higher for gastroenterology than for urology (Figures 1 and 2)
- Biopsy examination of patient-ready endoscope channels identified:
  - Residual fluid (Figures 1 and 2)
  - Polyglactin 910, and brown staining (Figure 3)
  - Scrapes, scratch marks, and brown staining (Figure 4)
  - Among endoscopes tested after 7-day incubation:
    - 37% failed to meet criteria for patient-ready endoscopes
    - 20% harbored stable bacteria
- Criteria for viable endoscopy and ATPI and protein values below "clear" levels

Summary and next steps
Looking inside reprocessed endoscopes revealed damage and debris

- During the baseline assessment, researchers found:
  - Damage and debris inside channels
  - Contamination levels exceeding benchmarks
  - Residual fluid in channels and ports
- Findings indicated that current reprocessing methods were insufficient
- Interventions included:
  - Sending endoscopes out for repair
  - Adopting more rigorous reprocessing practices
  - Implementing routine ATPI monitoring of reprocessing effectiveness
  - Increasing bench and air drying times
  - Results from the interim and final assessments are forthcoming

Disclosures and acknowledgments
The study was conducted independently by researchers from Ofstead & Associates, Inc., the University of Minnesota, and Fairview Maple Grove Medical Center. The study was supported in part by research grants from 3M Company, Medtronic, Inc., and HealthPartners Institute. Study sponsors did not have access to the data until the study participants were involved in the development of the poster.

References
External Inspection
Points of an Endoscope

- Instrument/suction channel
- Valve openings
- Biopsy
- Distal tip
- Connection points within scope
- Forceps elevator
- Accessories
Examples of Endoscope Channels
Examples of Endoscope Channels
Examples of Endoscope Channels
Internal / External Damage of Endoscopes
Bacteria in the Gouges - Microscopy Images (source: US FDA OSEL)
Documentation of your inspection

• “In court, the medical record is the care rendered,” they say. “Jurors view good record keeping as an indicator of good care — poor documentation can create an aura of poor care and damage the credibility of the healthcare providers.”

• Thus, if it wasn't documented, it wasn't done.
• Record your findings of your inspection.
• Not all inspection scopes allow you to do this.
• Protect yourself.

In Conclusion

• Build Quality into instrument reprocessing by incorporating enhanced Visual Inspection.
• Evaluate Products available to ensure best utilization in all inspection scenarios.
• Determine Guidelines for all facilities on what devices will be inspected, the frequency of inspection and how to evaluate/interpret devices seen as not clean or damaged.
• Provide Education and training to all technicians.
• Develop a Standardized Policy and implementation plan.
Thank you!