Iowa Association of Ambulatory Surgery Centers

Enhanced Optical Inspection of Medical Devices

"To See or Not to See; That is the Question?"

Presented by:
Healthmark Industries

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Eastern Regional Clinical Support Manager

healthmark™

Disclosure

- I am an employee of Healthmark Industries Fraser, Michigan USA
- I am involved with the manufacture and distribution of medical products to healthcare facilities and healthcare professionals
- No compensation has been received for this presentation or for travel to and from the seminar
- All opinions are those of the presenter

Healthmark Policy

Healthmark's Policy is to provide our customers and the healthcare community with the highest quality, state of the art medical products and support services in a timely and cost effective manner.

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.**

Agenda

- What is Visual Inspection and its purpose
- Defining Enhanced Visual Inspection
- Current Standards and Practices
- Applying Available tools to Recommended Practices
- Thoughts on how to implement Visual Inspection at your facility.

Visual Inspection

- The most basic verification of the performance of a cleaning process is by carefully inspecting the cleanliness of instruments and materials. This is usually performed by the unaided eye.
- All objects should be free of any visible soils, deposits, pitting etc.
- Inspection includes checking pivots, box joints, instrument serrations and for damage or missing parts.

Clean

What is Clean?

- AAMI does not have a definition.

- Definition of clean (from Merriam-Webster)
  - a : free from dirt or pollution
  - b : free from contamination or disease
  - c : free or relatively free from radioactivity

- Clean (klēn) adjective (google search)
  - 1. free from dirt, marks, or stains.
    - synonyms: washed, scrubbed, cleansed, cleaned; spotless, unsoiled, unstained, unsullied, unblemished, immaculate, pristine, dirt-free; hygienic, sanitary, disinfected, sterilized, sterile, aseptic, decontaminated; laundered
    - Informal; squeaky clean, as clean as a whistle
  - 2. morally uncontaminated; pure; innocent.
    - synonyms: virtuous, good, upright, upstanding; More

Cleaning

FDA on Cleaning

- Cleaning: Physical removal of soil and contaminants from an item to the extent necessary for further processing or for the intended use.

Cleaning from AAMI ST:79

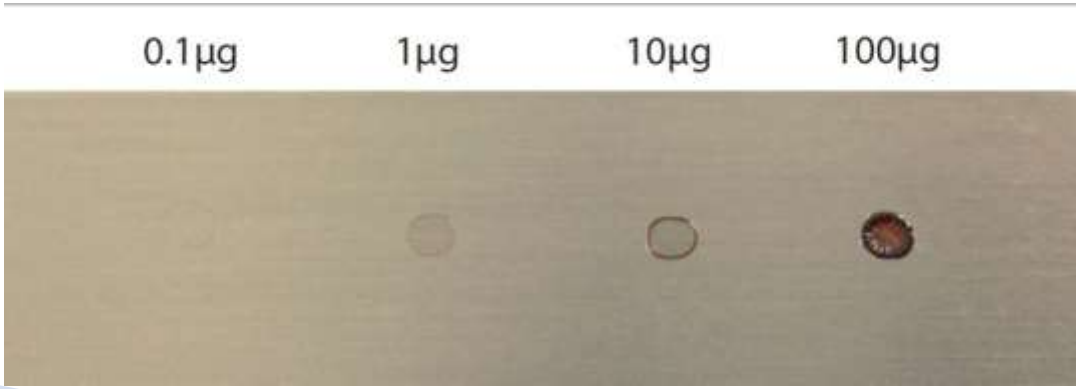
2.18 cleaning: Removal of contamination from an item to the extent necessary for further processing or for the intended use.

NOTE—In health care facilities, cleaning consists of the removal, usually with detergent and water, of adherent organic and inorganic soil (e.g., blood, protein substances, and other debris) from the surfaces, crevices, serrations, joints, and lumens of instruments, devices, and equipment by a manual or mechanical process that prepares the items for safe handling and/or further decontamination.

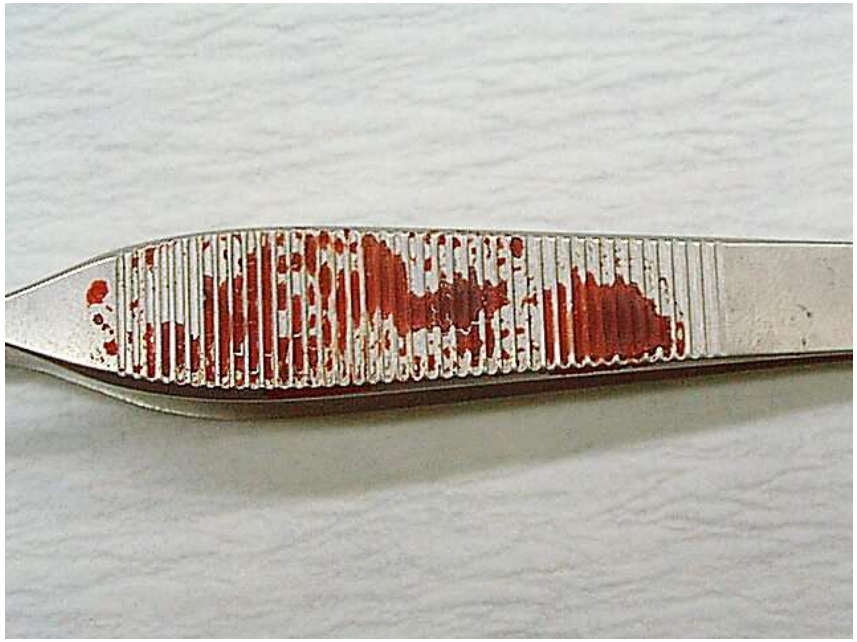
Visual Inspection for Clean

- The Current Standard is: **“Visually Clean”**
- We need to use all available tools to help our “Eyes”
  - Cleaning Verification products like:
    - Cleaning Verification tests for Sonics
    - Cleaning Verification tests for Washer Disinfectors
    - Cleaning Verification tests for Cart Washers
    - Cleaning Verification tests for spot residual soil like Protein or Hemoglobin
    - Cleaning Verification tests for cannulas and lumens (endoscopes, shavers, suctions)

- Can you see soil/bioburden with your unaided eyes?



Normal Surfaces are not usually a Cleaning Concern

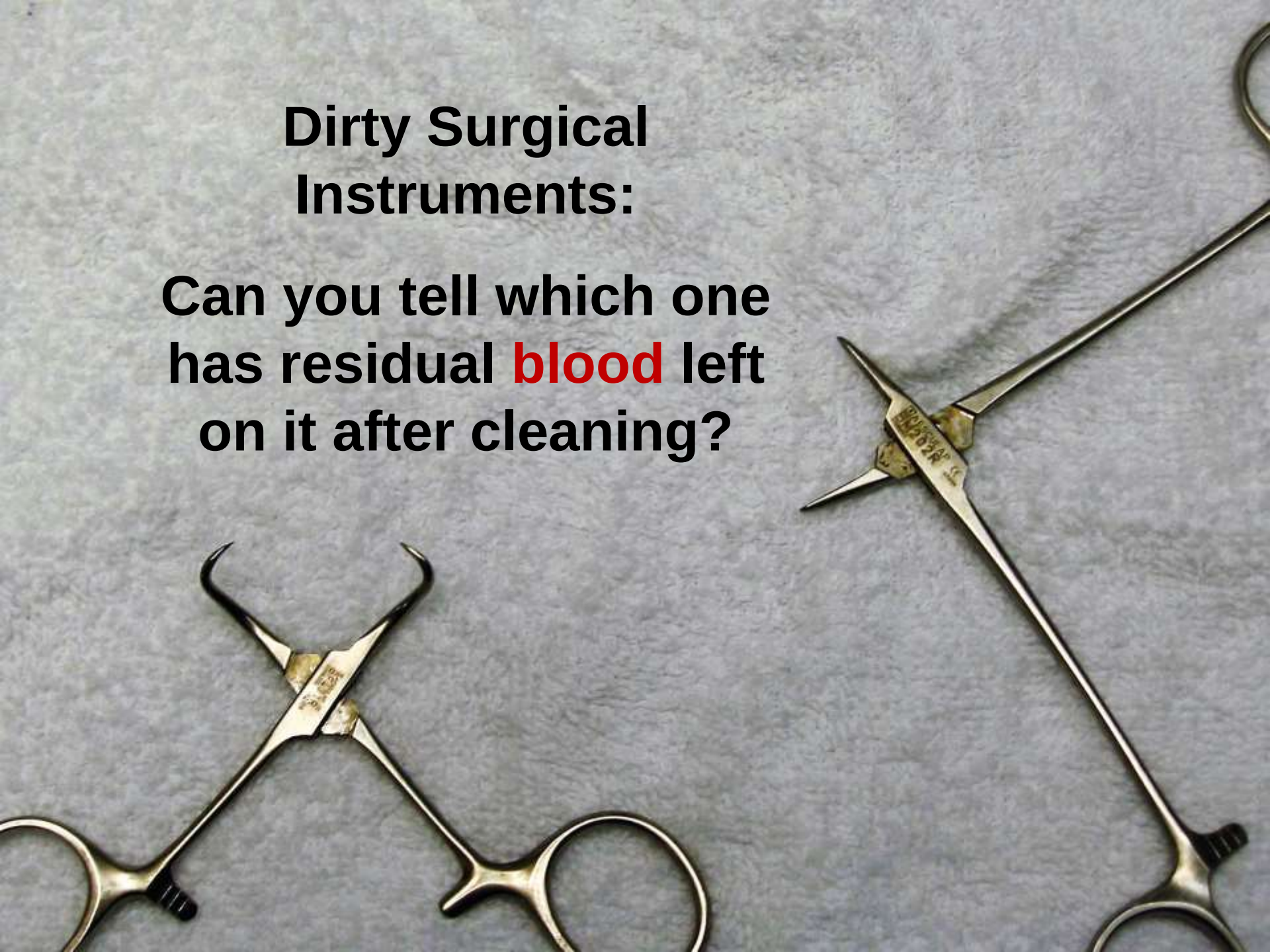


Instruments Provide Physical Challenge to Cleaning

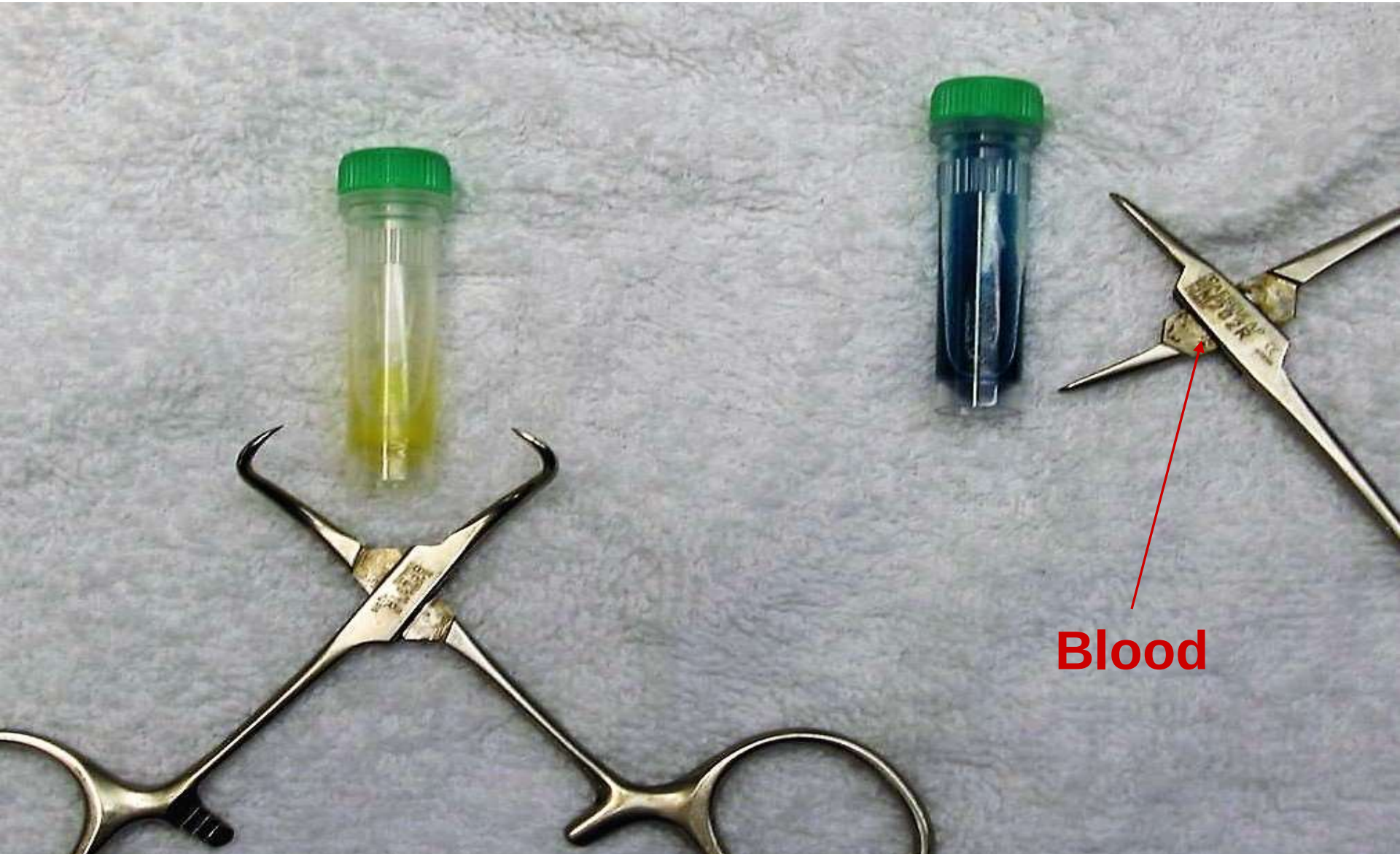
- Nooks and crannies
- Box Locks
- Take apart
- Lumen items
- Rongeurs

Dirty Surgical Instruments:

Can you tell which one has residual blood left on it after cleaning?



Both look visibly soiled. Using a spot residual soil test can help differentiate between blood and rust in this case.



Visual Inspection

Support for using a Magnifying Glass

ST 79

3.2.2.2

3.3.7.2

Annex D

Visual Inspection: Close-up

Visual Inspection Close-up

Unaided eye

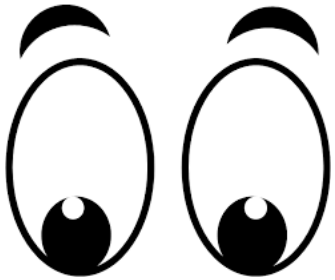
Using a table magnifier

Is the chuck attachment really clean?

Going beyond just using your eyes

First basic step

- Visual Inspection



Second Step

- Magnification

What is third??

- The IFU gives us direction
  - Technology is evolving and allows us to look inside and in places we can not see with an unaided eye.

Enhanced Optical Inspection

- Magnification
  - Handheld
  - Desktop
  - Bench or Table mounted




- Microscope
  - Traditional
  - Electronic


- Borescope
  - Allows visualization of the cannula or lumen
  - Rigid or Flexible
  - Manual or Camera


Enhanced Visibility

- Today's advanced technology enables personnel to examine medical devices in a more thorough and effective way.
- AAMI, AORN and IFU recommend using visual support technology to examine internal and difficult-to-see areas of surgical instruments.
- An investigation of a hospital's endoscope devices by research firm Ofstead & Associates found by using a boroscope to look inside reprocessed endoscopes, 71 percent of endoscopes failed the criteria for a patient-ready device.
- With advanced examination tools, such as flexible boroscopes and USB-enabled microscopes, central processing staff can examine contaminant-prone areas previously inaccessible to the naked eye.

Enhanced Visibility

Supporting Documentation

FDA

- H. Visual Inspection
  - All routine cleaning instructions should include instructions for visual inspection, which may include use of magnification and adequate lighting. The instructions should advise the user that if the device is determined not to be visually clean at the end of the cleaning step, the user should either repeat the relevant previous cleaning steps or safely dispose of the device.
  - Additionally, the visual inspection instructions should identify acceptance or failure criteria related to device performance (e.g., unacceptable deterioration such as corrosion, discoloration, pitting, cracked seals), as well as instructions to properly dispose of devices that fail.

Reference: (March 17, 2015, Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling. Guidance for Industry and Food and Drug Administration Staff)

Enhanced Visibility

Supporting Documentation

AAMI ST79

- 7.5.5 Verification of the cleaning process
  - “After completing the cleaning process, personnel should visually inspect each item carefully to detect any visible soil. Inspection using magnification might identify residues more readily than the unaided eye. Visual inspection alone may not be sufficient for assessing the efficacy of cleaning processes;…..”

Enhanced Visibility

Manufacturers Instructions for Use (IFU)

- STRYKER Shaver HandPiece – 1000400638 R-2012/10 *
  - INSPECTION – EN 21
  - Step 9
    - "…Visually inspect the hand piece, including all internal surfaces, for remaining soil. **Use an endoscopic camera and endoscope if necessary to see the inner surface of the lumen.** If soil remains, repeat the manual cleaning procedure, focusing on those areas…"

* www.stryker.com

- Arthrex – Adapteur Power System™ II (APS II) Shaver Hand pieces – DFU-0154r10*
- INSPECTION AND MAINTENANCE
  - Step 4 in the DFU (IFU)
    - "…Check device for visible soil. **It is recommended that the cannulation be inspected with an illuminated, magnifying scope.** Clean the device using the guidelines for manual cleaning if any soil is visible…."

*www.arthrex.com

USB Microscope

- Helps ensure quality control for the CSSD by close visual inspection of reprocessed instruments.
- This particular USB microscope has a 2M pixels LENS and CMOS sensor along with a magnification ratio of 5x-270x.
- The camera function used with the supplied software, allows you to capture still and video images when inspecting the instruments.

Flexible Inspection Scope and USB Camera

- The standard for checking the cleanliness of all instruments is visual inspection. It has been difficult to physically inspect small bore lumens.
- More IFU's detail the use of a borescope to inspect lumens and cannulas.

IFU

Shavers

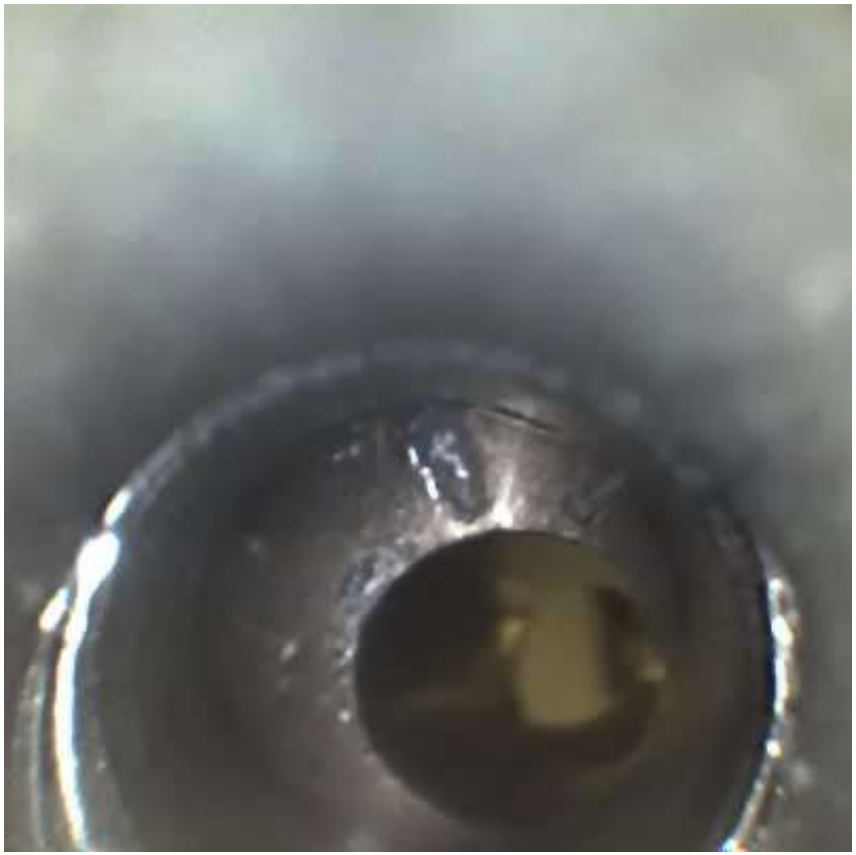
The FDA has become aware of events in which tissue has remained within certain arthroscopic shavers, even after the cleaning process was believed to have been completed according to the manufacturer's instructions (April 2009).

Reports submitted to the FDA suggested that the tissue retained was not evident to the naked eye.

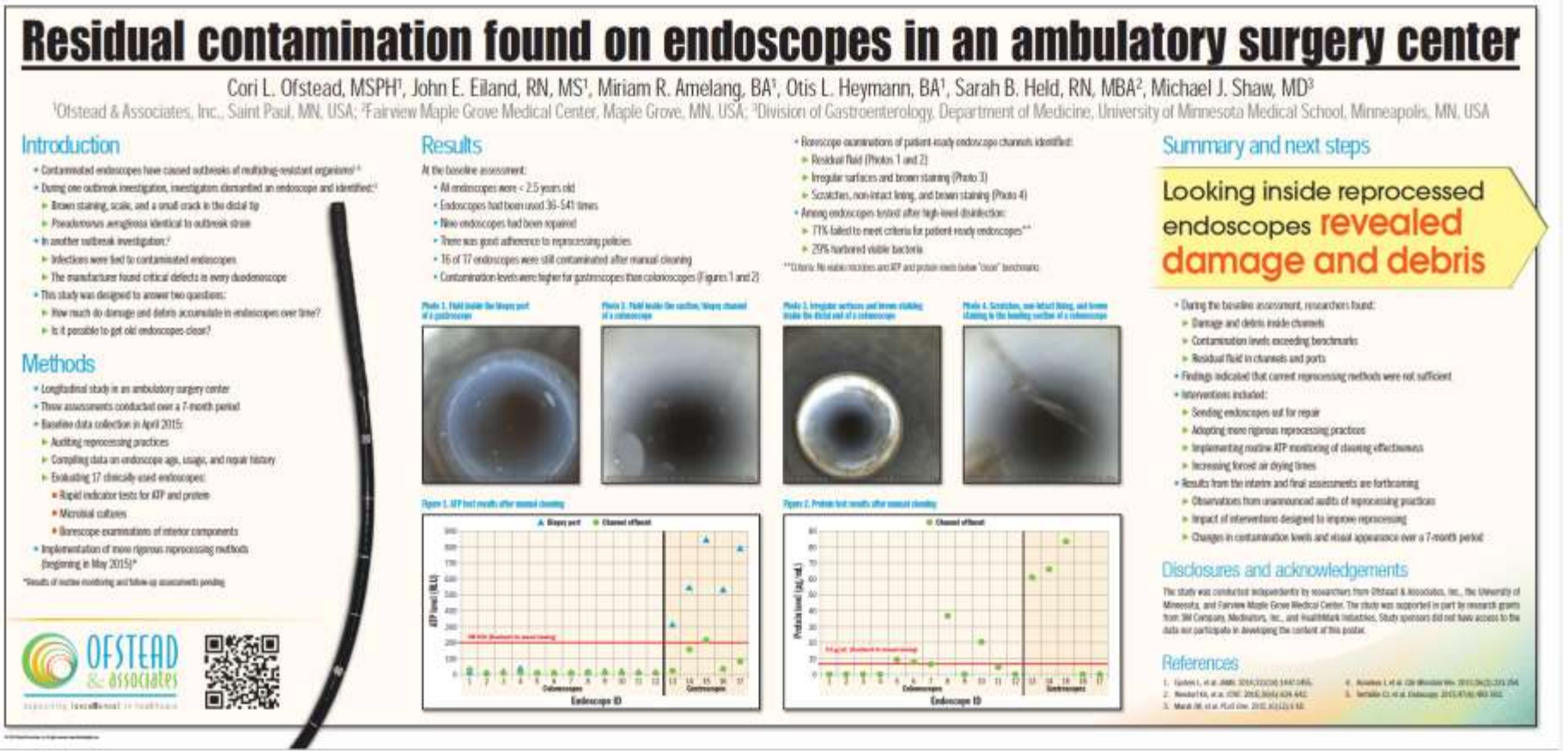
Multiple manufacturers of these devices recently informed their customers of this situation and reiterated the importance of proper cleaning procedures.

True stories

- Shavers
  - Recent Inspections
    - Two hospitals
      - Visually inspected 8 shavers with a FIS
      - All 8 shavers were ready to be sterilized
      - 4 out of the 8 were visually inspected using enhanced visual inspection (FIS) and found bioburden
    - Next hospital 1 out of the 2 were observed having bioburden
    - See the video at the right



Support for using enhanced visual inspection – Poster at AORN 2016



Residual contamination found on endoscopes in an ambulatory surgery center

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Introduction

- Contaminated endoscopes have caused outbreaks of multidrug-resistant organisms[1-4]
- During one outbreak investigation, investigators dismantled an endoscope and identified:[1]
  - Brown staining, scale, and a small crack in the distal tip
  - Pseudomonas aeruginosa identical to outbreak strain
- In another outbreak investigation:[2]
  - Infections were tied to contaminated endoscopes
  - The manufacturer found critical defects in every duodenoscope
- This study was designed to answer two questions:
  - How much do damage and debris 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 7-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:
    - Rapid indicator tests for ATP and protein
    - Microbial cultures
    - Borescope examinations of interior components
- Implementation of more rigorous reprocessing methods (beginning in May 2015)*

*Results of routine monitoring and follow-up assessments pending

Results

At the baseline assessment:

- All endoscopes were < 2.5 years old
- Endoscopes had been used 36–541 times
- Nine endoscopes had been repaired
- There was good adherence to reprocessing policies
- 16 of 17 endoscopes were still contaminated after manual cleaning
- Contamination levels were higher for gastroscopes than colonoscopes (Figures 1 and 2)

- Borescope examinations of patient-ready endoscope channels identified:
  - Residual fluid (Photos 1 and 2)
  - Irregular surfaces and brown staining (Photo 3)
  - Scratches, non-intact lining, and brown staining (Photo 4)
- Among endoscopes tested after high-level disinfection:
  - 71% failed to meet criteria for patient-ready endoscopes**
  - 29% harbored visible bacteria

**Criteria: No visible residues and ATP and protein levels below "clean" benchmarks

Photo 1. Fluid inside the biopsy port of a gastroscope

Photo 2. Fluid inside the suction/biopsy channel of a colonoscope

Photo 3. Irregular surfaces and brown staining inside the distal end of a colonoscope

Photo 4. Scratches, non-intact lining, and brown staining in the bending section of a colonoscope

Figure 1. ATP test results after manual cleaning

Figure 2. Protein test results after manual cleaning

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 not sufficient
- Interventions included:
  - Sending endoscopes out for repair
  - Adopting more rigorous reprocessing practices
  - Implementing routine ATP monitoring of cleaning effectiveness
  - Increasing forced air drying times
- Results from the interim and final assessments are forthcoming
  - Observations from unannounced audits of reprocessing practices
  - Impact of interventions designed to improve reprocessing
  - Changes in contamination levels and visual appearance over a 7-month period

Disclosures and acknowledgements

This 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, Medivators, Inc., and HealthMark Industries. Study sponsors did not have access to the data nor participate in developing the content of this poster.

References

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3. Marsh JW, et al. PLoS One. 2015;10(12):e0145104.
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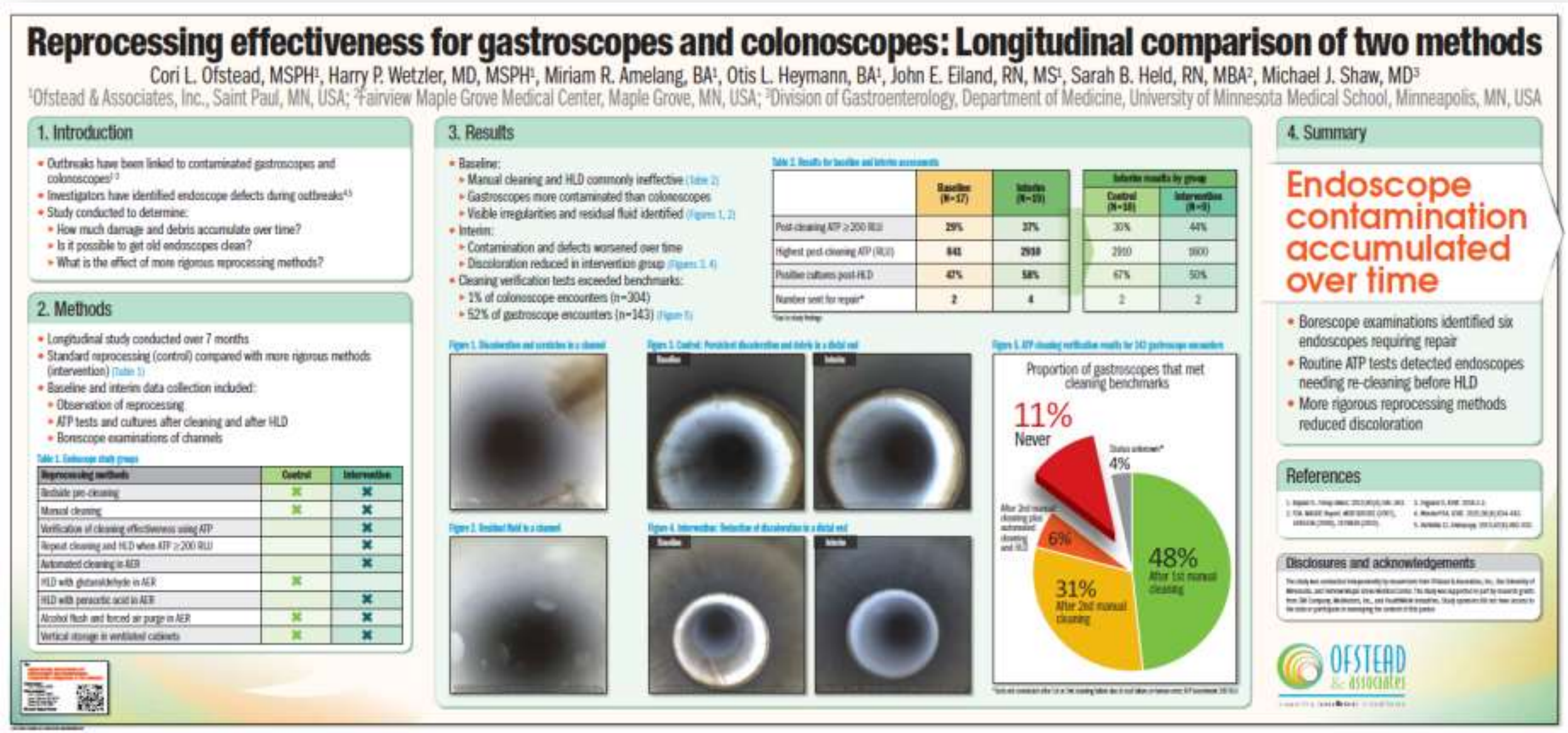
http://www.ofsteadinsights.com/?p=2303

Support for using enhanced visual inspection – Poster at SGNA 2016



http://www.ofsteadinsights.com//wp-content/uploads/Ofstead_SGNA_Poster_Board_2016_SENT.pdf

Support for using enhanced visual inspection

A 

B 

C 

- Fluid and Simethicone residual identified in a scope after processing in 19 of 20 scopes inspected
  - Reference: Ofstead and associates, AJIC 2016, article in press

Support for using enhanced visual inspection

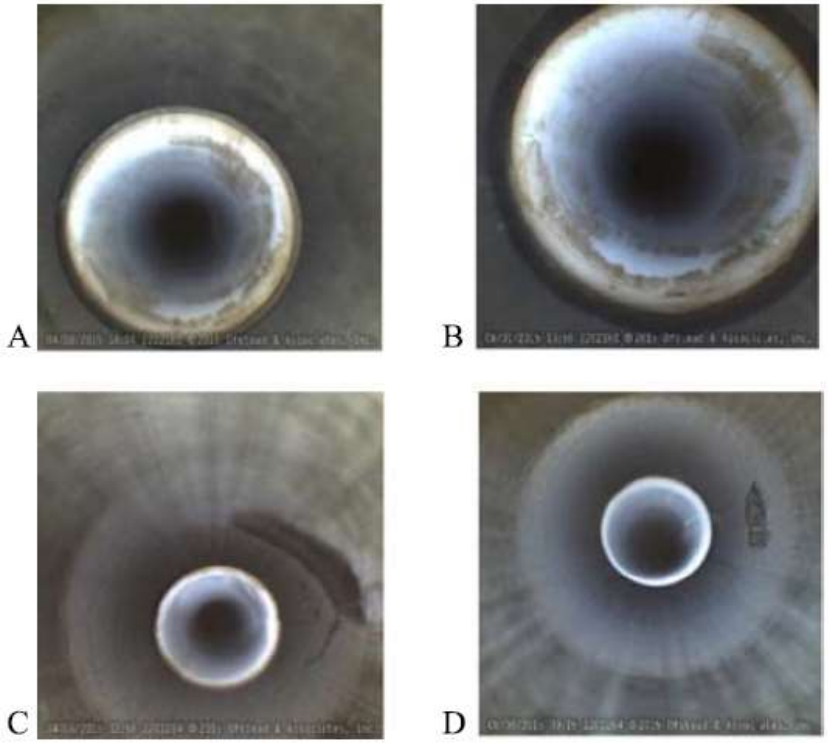
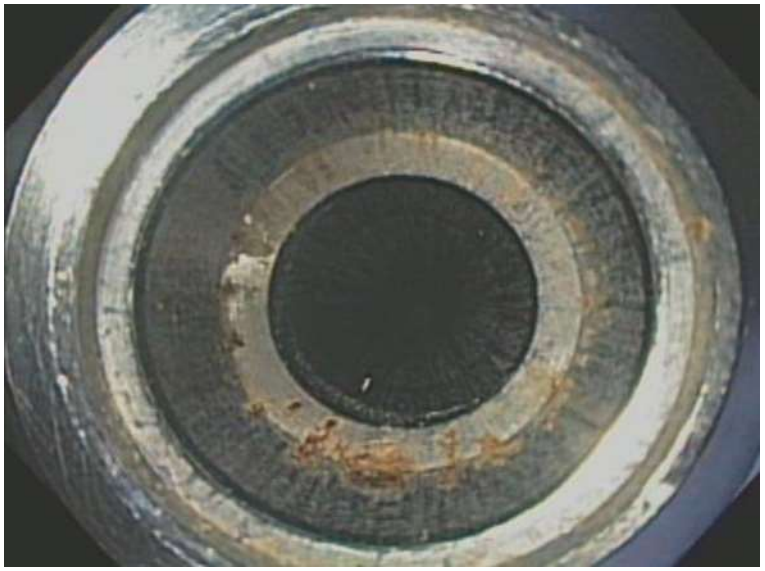


Fig 2. Discoloration and scratches observed. (A) In a control group colonoscope at baseline. (B) In the same control group colonoscope at 2-month assessment. (C) In an intervention colonoscope at baseline. (D) In the same intervention colonoscope at 2-month assessment.

- Borescope inspection identified scratches, discoloration, debris, & fluid
- These changed over time
- Allowed damaged and contaminated scopes to be identified and reprocessed and sent for repair
- When went for repair, manufacturer determined there were critical defects

- Reference; Ofstead and associates, AJIC 2016. Article in press.

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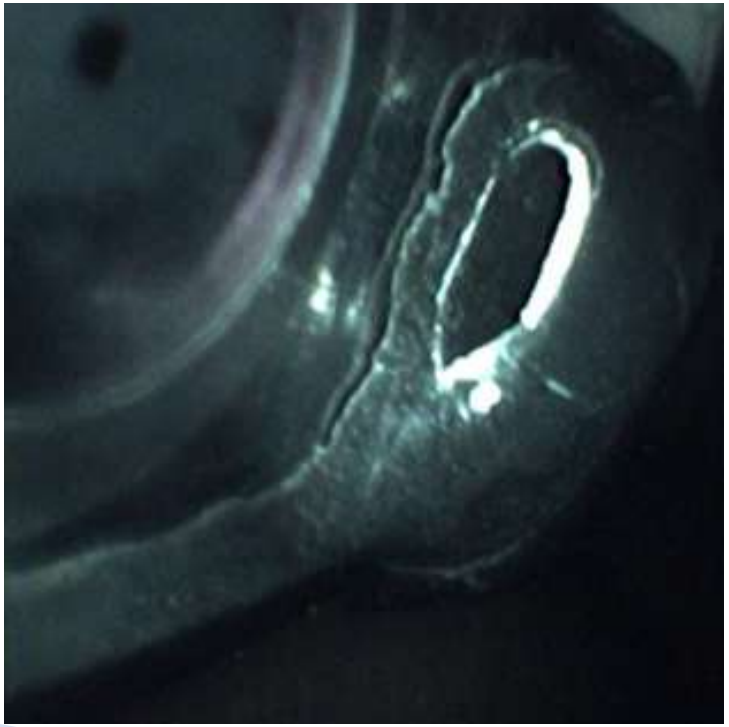


Optical Inspection Tools Recap

Product Review

Flexible Inspection Scope

USB Microscope

Visual Inspection Review

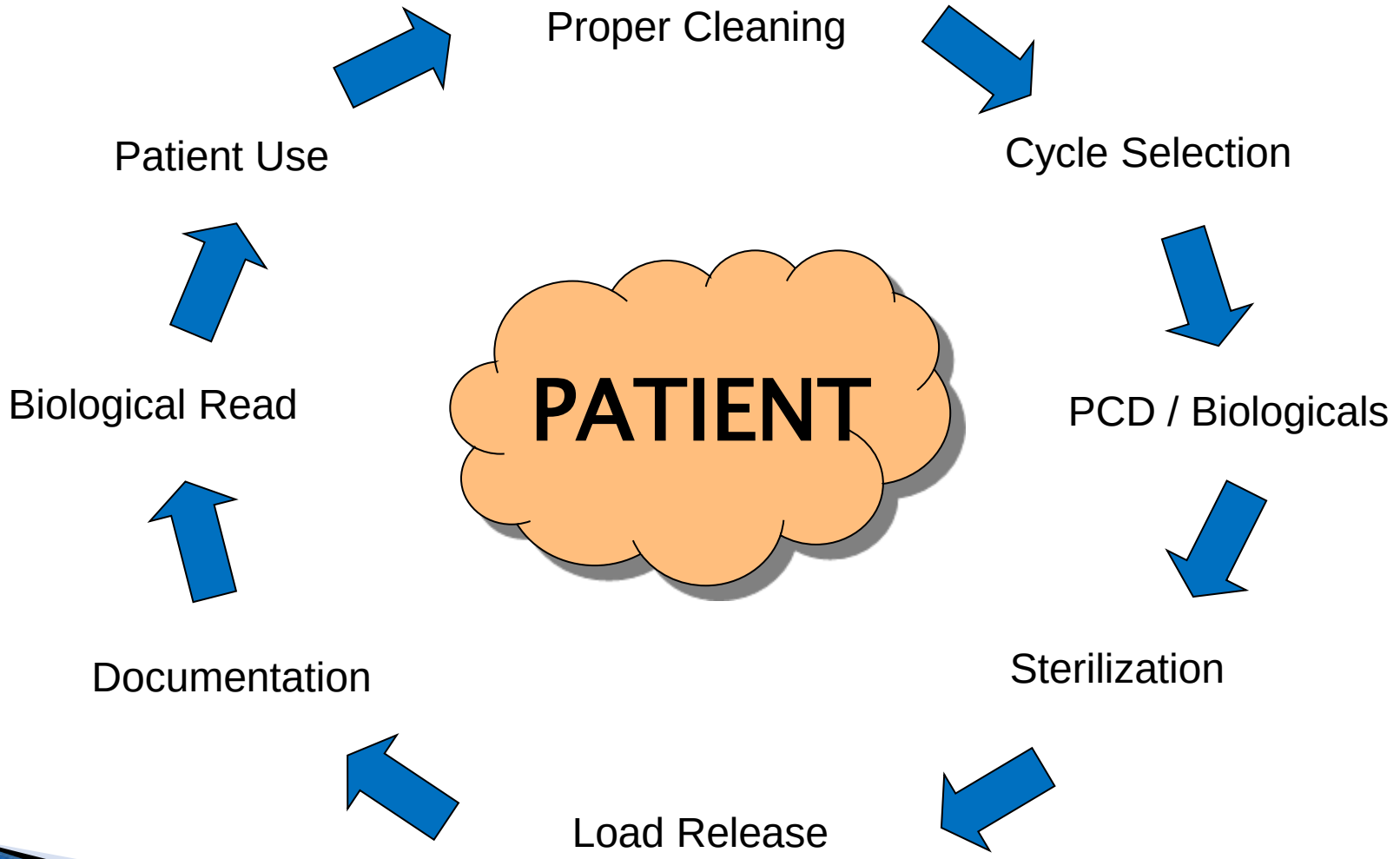
- Takes place every time you touch an instrument
- The current standard is “Visibly Clean”
- Thus first and foremost if it is visual dirty, re-clean it.
- Manufactures Instructions for Use are now requiring visual inspection of the cannulas and lumens of many medical devices.
  - Orthopedic shaver
- Standards, Guidelines and IFU’s state you need various forms of magnification products in your CSSD
- Visual Inspection is a crucial part of the quality process

Enhanced Optical Inspection Review

- Many methods to inspect and enhance the visual inspection process within an CPD/SPD area
  - Your natural eye sight
  - Lamp magnifier
  - Hand held magnifier
  - Digital Microscope
  - Flexible Inspection Scope
- QA Tray Quality – Post Production
- Document your results
- Visual inspection is a way to help verify that you are doing it right each and every time!
- Remember:

"Sterile will never be Sterile unless Clean is Clean first!"

The circle of life



Thank You!

Questions?

On behalf of Healthmark, I would like to thank you all for the opportunity to be here today.

THANK YOU!