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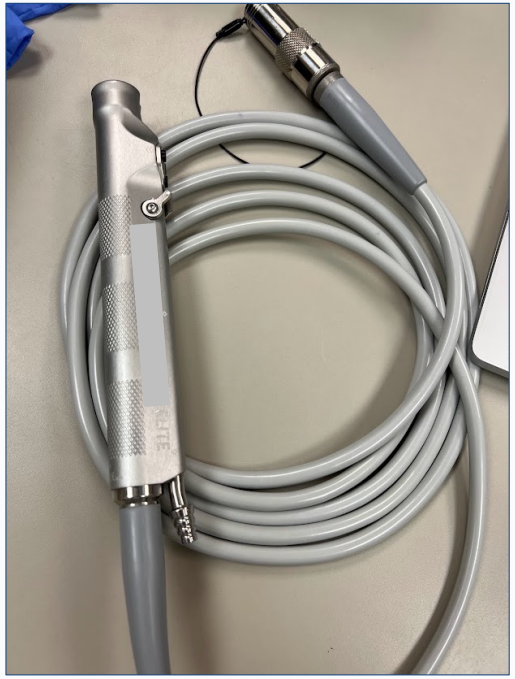
Seeing is Believing: Using Borescope Inspection Results to Transform Shaver Handpiece Reprocessing Practices

Name: Kevin Anderson
Affiliation: Healthmark, A Getinge company

Shaver Handpiece

A brief introduction

- Reusable handpiece
- Power box
- Disposable component
  - Blade
  - Burr
- Arthroscopy
  - Knee, shoulder, hip, small joint





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Shaver Handpiece History

Implicated in surgical site infection outbreak in 2009

- Outpatient arthroscopy cases in TX, United States

INFECTION CONTROL AND HOSPITAL EPIDEMIOLOGY DECEMBER 2011, VOL. 32, NO. 12

ORIGINAL ARTICLE

Outbreak of *Pseudomonas aeruginosa* Surgical Site Infections after Arthroscopic Procedures: Texas, 2009

Pritish K. Tosh, MD;[1,2,a] Maureen Disbot, MS, RN, CCRN;[3] Jonathan M. Duffy, MD, MPH;[1,2] Marc L. Boom, MD, MBA;[3] Gary Heseltine, MD, MPH;[4] Arjun Srinivasan, MD;[2] Carolyn V. Gould, MD, MSCR;[2] Sandra I. Berríos-Torres, MD[2]

SETTING. Seven organ/space surgical site infections (SSIs) that occurred after arthroscopic procedures and were due to *Pseudomonas aeruginosa* of indistinguishable pulsed-field gel electrophoresis (PFGE) patterns occurred at hospital X in Texas from April 22, 2009, through May 7, 2009.

OBJECTIVE. To determine the source of the outbreak and prevent future infections.

DESIGN. Infection control observations and a case-control study.

METHODS. Laboratory records were reviewed for case finding. A case-control study was conducted. A case patient was defined as someone who underwent knee or shoulder arthroscopy at hospital X during the outbreak period and subsequently developed organ/space SSI due to *P. aeruginosa*. Cultures of environmental and surgical equipment samples were performed, and selected isolates were analyzed by PFGE. Surgical instrument reprocessing practices were reviewed, and surgical instrument lumens were inspected with a borescope after reprocessing

Shaver Handpiece History

- FDA Issued Safety Alert (after 2009 SSI report)
- New inspection technology developed (borescope)
- Shaver instructions for use (IFU) were updated to include borescope inspection
- Industry standards updated (AORN)



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Shaver Handpiece IFU Example

V. MANUAL CLEANING

1. After preliminary cleaning is complete, prepare a suitable detergent solution (reference "Detergent Selection" section above).
2. Thoroughly scrub the device with a clean, soft-bristled brush that is dampened with the detergent solution until all visible soil has been removed.
3. Do not immerse the device in water or detergent solution.
4. To clean the cannulated section of the device:
   a. Feed the wire end of a cleaning brush through the cannulation of the device.
   b. Oscillate the brush back and forth from both the front and the rear of the device. Brush all sections of the cannulation.
   c. It is recommended that the cannulation be inspected with an illuminated, magnifying scope to ensure that all debris is removed.

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Note: If using utility water for rinsing, flush all surfaces with critical water to prevent metal discoloration.

7. Check devices for visible soil. Repeat cleaning if soil is visible and re-inspect.
8. After flushing operation is complete, it is recommended that forced air be used through all channels to remove water droplets.

AORN Guidelines

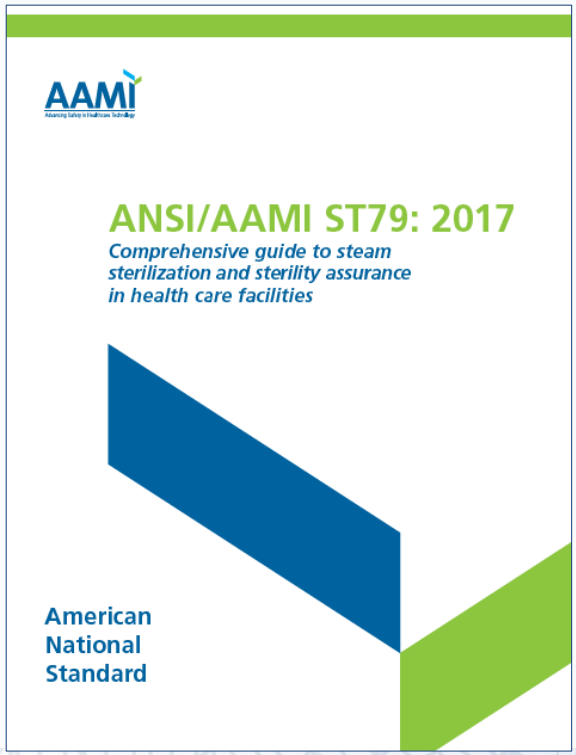
Section 10.3.3 – Inspect the internal channels of reusable **arthroscopic shavers** using an **endoscopic camera or borescope**

AORN™

AAMI Standards – ST79:2017

Section 7.6.1

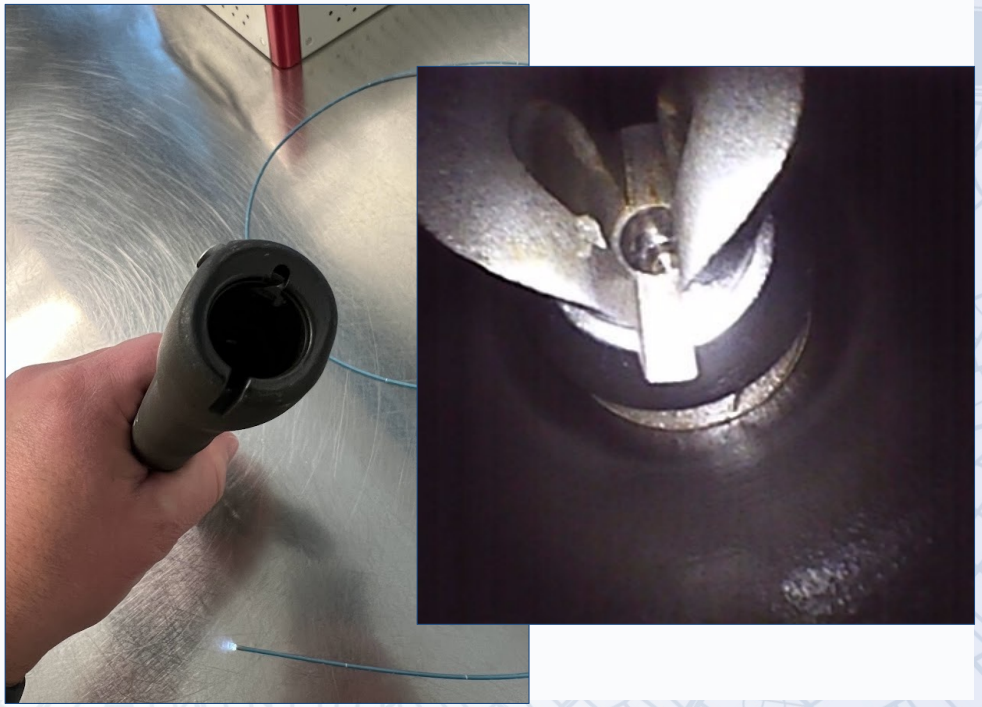
- Devices **should be inspected** for flaws, damage, debris, detergent residue, etc.



AAMI Standards – ST79:2017

Section 7.6.4.5

- After completing the cleaning process, personnel **should visually inspect** each item carefully do detect any visible soil.
  - Visual inspection alone might not be sufficient for assessing the efficacy of cleaning.



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Inspecting Shaver Handpieces & Lumened Devices

Reprocessing inspection guidance outside the United States

CANADA

Names optical device

CSA Z314:23 · Clause 14

Cleanliness and functionality verified by visual inspection, with magnification matched to device complexity. Lumens and hidden internal surfaces inspected with a borescope or similar optical device.

Strongest ex-US citation: names an optical / borescope method for lumens.

AUSTRALIA / NEW ZEALAND

Lumen inspection · method open

AS 5369:2023 (now AS/NZS 5369:2023, Amdt 1 · 2026)

Superseded AS/NZS 4187:2014 in Dec 2023. Inspection for cleanliness and function is a defined step; lumened devices must be verified clean. Method is risk-based and IFU-driven.

Cite AS 5369:2023, not the retired 4187:2014. No borescope-specific wording.

EUROPE / EU

IFU-driven · method open

EN ISO 17664-1 & -2 + EU MDR Annex I, GSPR 11

No pan-European borescope rule for shavers. Inspection is a mandatory step the manufacturer must specify in validated IFUs, with devices designed for safe, verifiable reprocessing under MDR.

Expectation flows through manufacturer IFUs and validation.

CHINA

Lumen inspection · method open

WS 310.2-2016 (National Health Commission)

Cleaning quality checked by visual inspection or lighted magnifier, including lumens. Peer-reviewed CSSD practice increasingly applies borescopes to suction and handpiece lumens.

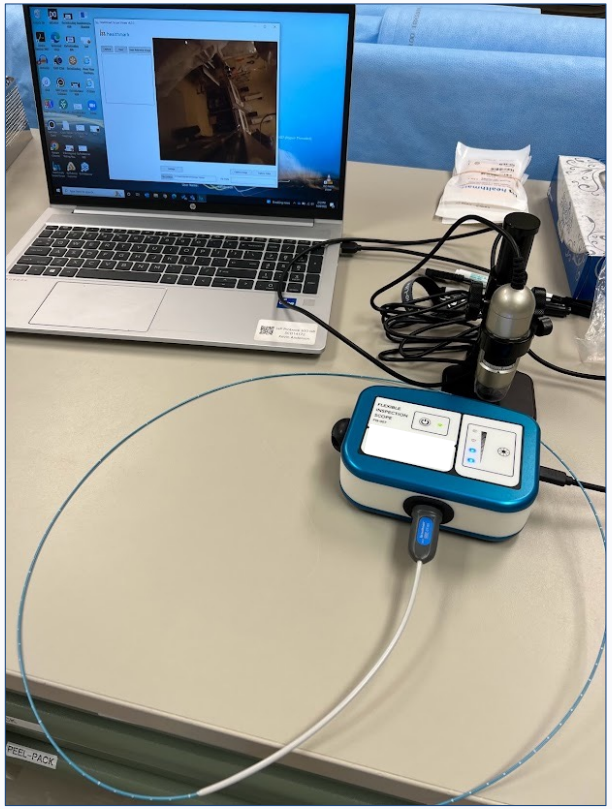
Standard mandates magnified visual inspection; borescope use is emerging.

Bottom line: No ex-US standard names arthroscopic shavers specifically; they fall under general lumened / internal-channel requirements. **Canada (CSA Z314:23) alone prescribes an optical / borescope method.**

Sources: CSA Z314:23; AS 5369:2023 (Standards Australia / ACSQHC); EN ISO 17664-1/-2:2023 & EU MDR 2017/745; WS 310.2-2016 (NHC, China).

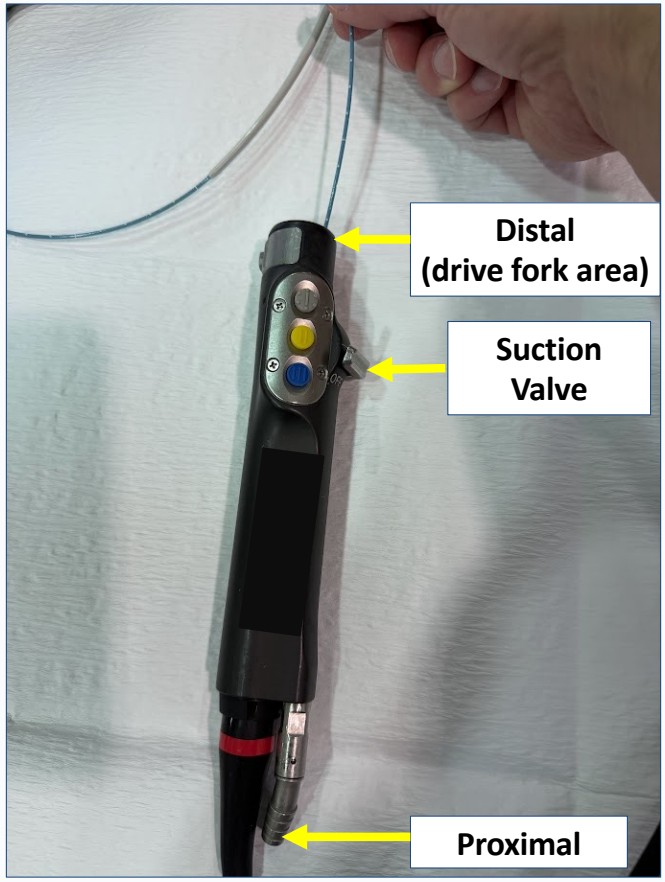
Aim

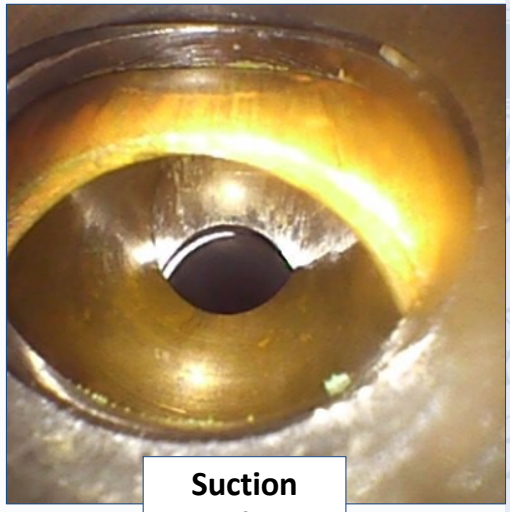
In light of changes in cleaning, inspection, and device IFUs, what is the current state of shaver handpiece processing results?



Methods

- Borescope inspections conducted on shaver handpieces
- Proximal and distal lumens were inspected
- Suction valve was toggled under direct visualization





Methods

- Convenience sampling selection process used
  - Sterile ready for use (37 or 80%)
  - Clean and not yet sterilized (9 or 20%)



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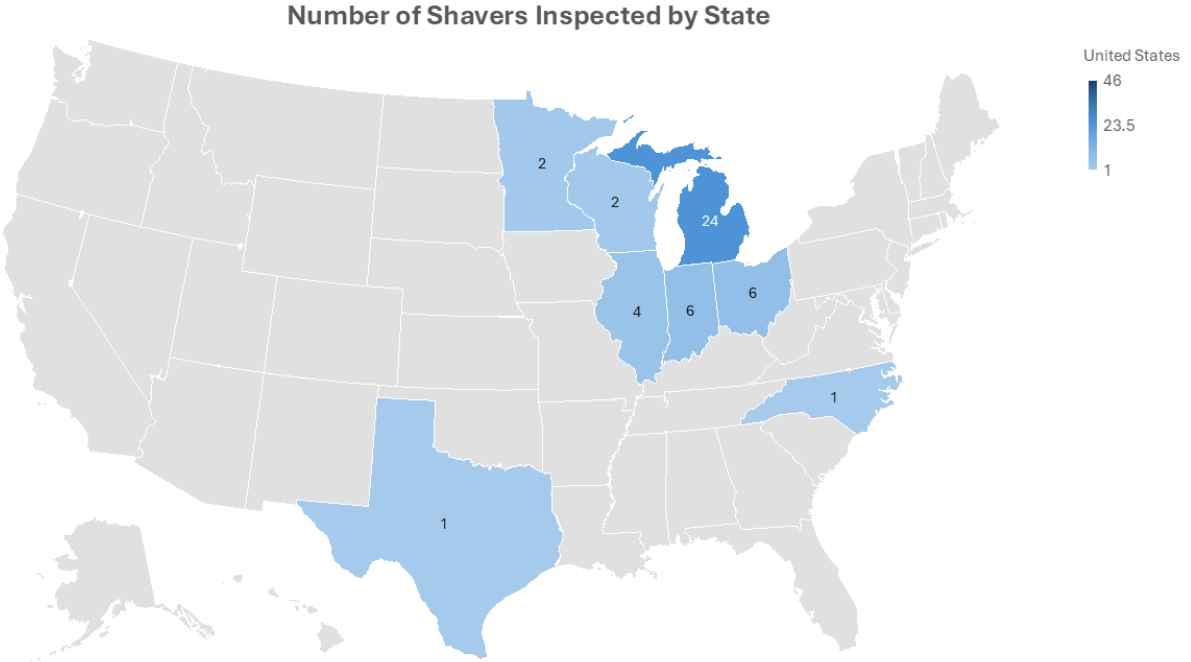
Demographics

- Number of departments: 32
- Number of shavers inspected: 46
- Timeline February 2022 and February 2024



Data - Shaver brands inspected

Brand	Quantity
Stryker	17
Arthrex	14
S & N Dyonics	14
Conmed	1

Results

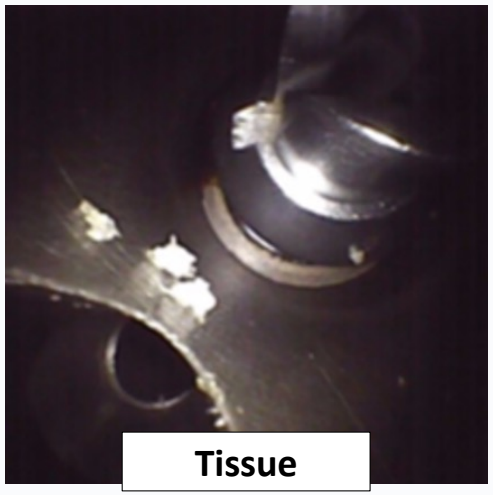
Types of defects observed:

- Scratches (damage) – **11%**
- Foreign object – **6%**
- Residue – **23%**
- Tissue (biological debris) – **60%**









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Results

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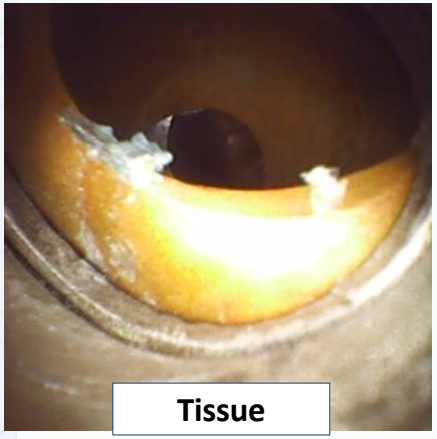
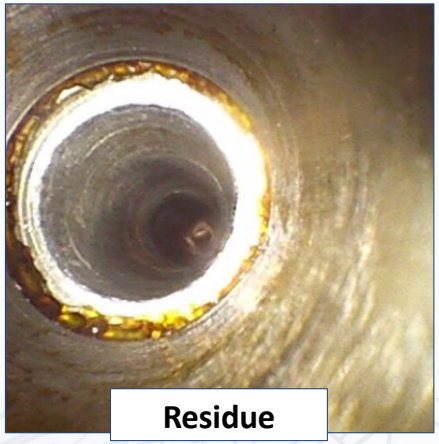
How many shavers had visible defects?

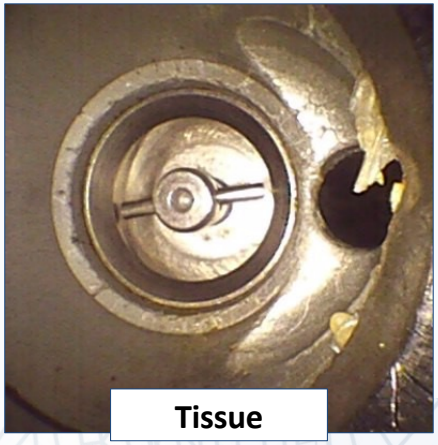
100%



Tissue



Residue



Tissue

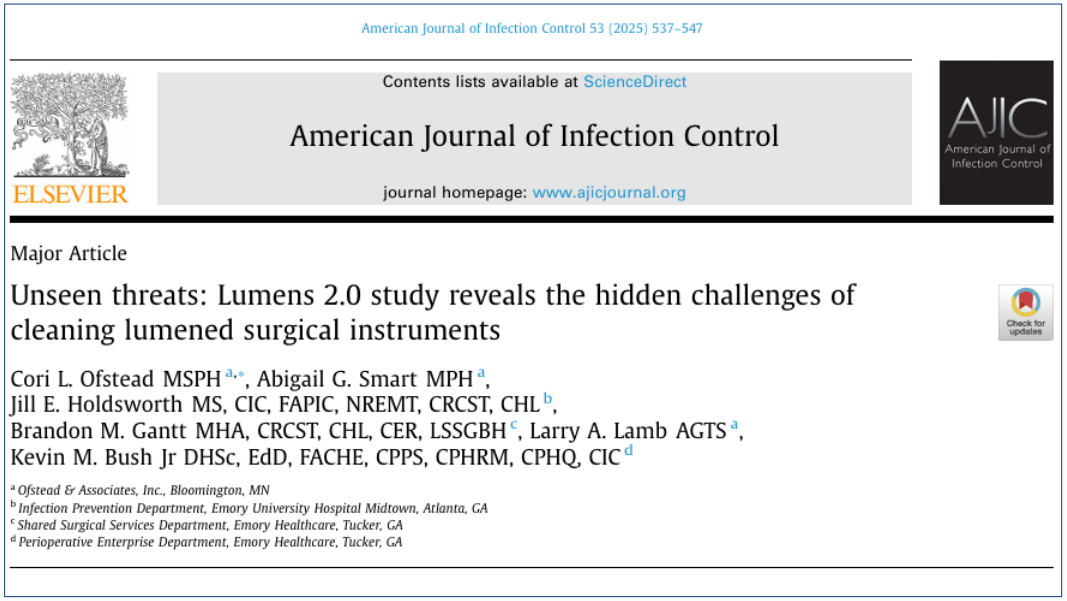


Tissue

Discussion

Results are consistent with other studies like Unseen threats: Lumens 2.0 published in AJIC

- **100% of 40 instruments inspected** internally with a borescope **had visible defects**



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Major Article

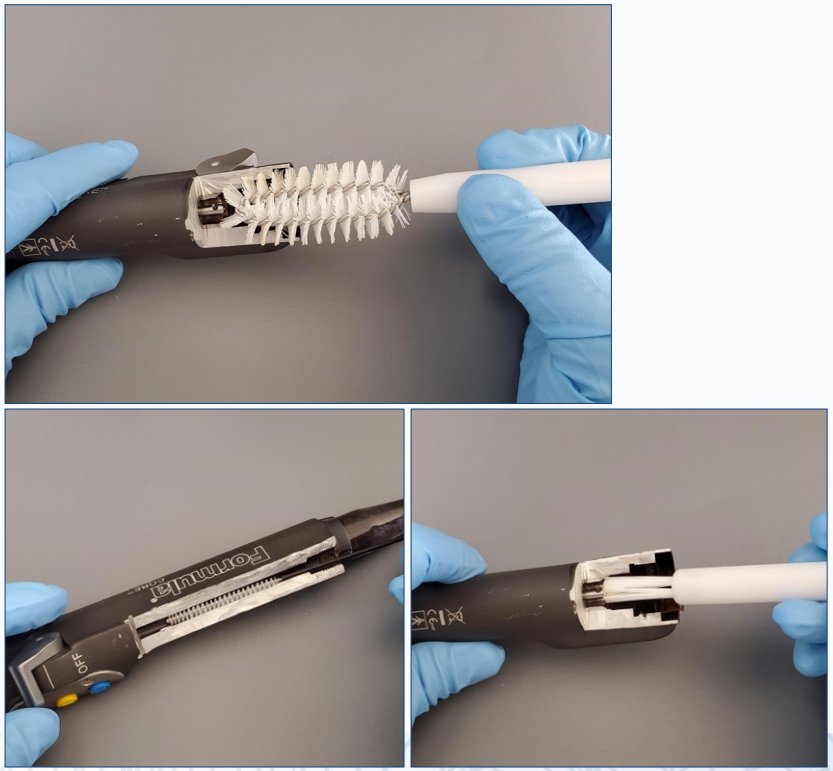
Unseen threats: Lumens 2.0 study reveals the hidden challenges of cleaning lumened surgical instruments

Cori L. Ofstead MSPH [a,*], Abigail G. Smart MPH [a],
Jill E. Holdsworth MS, CIC, FAPIC, NREMT, CRCST, CHL [b],
Brandon M. Gantt MHA, CRCST, CHL, CER, LSSGBH [c], Larry A. Lamb AGTS [a],
Kevin M. Bush Jr DHSc, EdD, FACHE, CPPS, CPHRM, CPHQ, CIC [d]

[a] Ofstead & Associates, Inc., Bloomington, MN
[b] Infection Prevention Department, Emory University Hospital Midtown, Atlanta, GA
[c] Shared Surgical Services Department, Emory Healthcare, Tucker, GA
[d] Perioperative Enterprise Department, Emory Healthcare, Tucker, GA

Contributing Factors

- **56%** of facilities **did not have the requisite borescope equipment**
- Number and dimensions of brushes were only specified in the IFU of one shaver manufacturer
- 56% of facilities had shavers that didn't specify the number and dimensions of brushes
- **No facilities had all the necessary brushes**

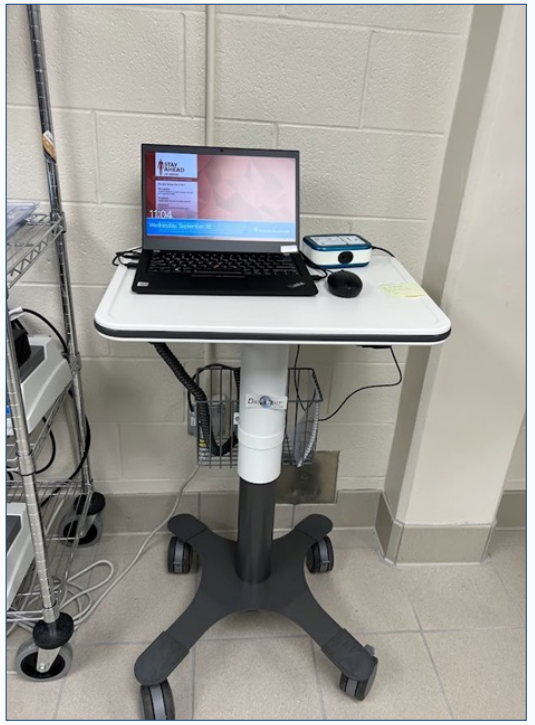


Contributing Factors

What about the 44% that did have at least one borescope?

- Training/education deficit
- Equipment maintenance is an issue
  - Some borescope equipment was broken
- Process design problems





Conclusions

- Shavers **failed inspection 100%** of the time
- **Over half** facilities **didn't have proper inspection equipment**
- **No facilities had all the brushes** necessary for proper cleaning
- Gaps in proper equipment, brushes, and adherence to IFUs **may lead to increased risk for patients**
- Significant investment in equipment, training, and process monitoring is needed

Suggestion for Further Investigation

- When proper training, equipment, and strict adherence to IFUs is being practiced – will we see a better result in cleaning outcomes
- Gaps in proper equipment, brushes, and adherence to IFUs may lead to increased risk for patients – efforts to survey/audit outpatient arthroscopy adverse events should be considered

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Thank you!

Time for questions?