



Healthmark Academy
EMPOWERING THE HEART OF THE HOSPITAL



Damage is Danger

Protecting Patients Through Visual Inspection of Flexible Endoscopes



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Michael has served as a sterile processing technician and manager prior to his roles as an educator for several vendors. He has collaborated in the development of multiple AAMI-ANSI standards, including ST9 and ST103. Michael is one of the contributing authors of the DNV-GL's Sterile Processing Program Certification. He has also been published in Infection Control Today, Becker's Hospital Review, and Healthcare Purchasing News.

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Relevant Financial Disclosures

- I am an employee of Healthmark, A Getinge company.
- I am involved with the manufacturing and distribution of medical products.
- No compensation has been received for this presentation.
- All opinions are those of the presenter.
- This presentation is not intended to be used as a training guide or promotion. Before using any medical device, always review the manufacturer's instructions for use.

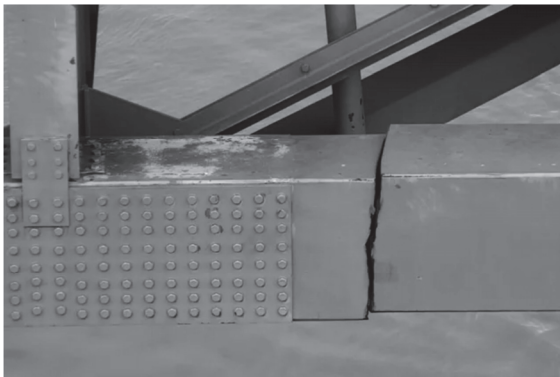




U.S. Standards and guidelines for visual inspection

Recommendations for inspecting endoscopes	SGNA	Multi-society	AORN	AAMI
Perform every time a scope is used	✓	✓	✓	✓
Evaluate endoscope cleanliness	✓	✓	✓	✓
Look for any visible damage or defects	✓	✓	✓	✓
Use good lighting and magnification	✓	✓	✓	✓
Use a borescope for channels & ports			✓	

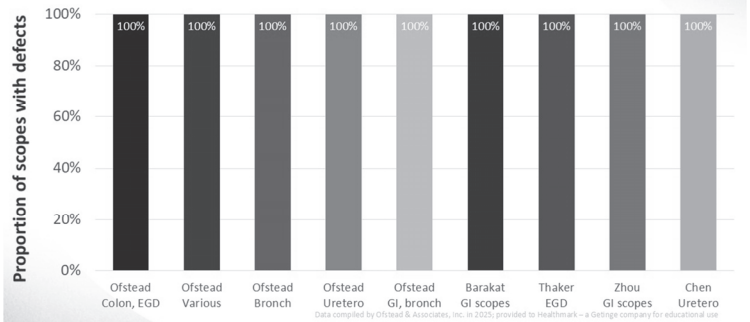
AAMI ST91 7.8.2: "Lighted magnification should be used to inspect endoscopes and accessories for external cleanliness and damage..."



"The way we're supposed to inspect the bridge is you literally go inch by inch along that beam and physically inspect every inch of the beam," said Lorie Tudor, Arkansas Department of Transportation Director said. "That did not happen."



Published evidence from nine studies: Ability of borescopes to detect visible defects



Preventable? YES!

- During a therapeutic procedure, a clip emerged and fell into the patient
 - No clips had been used during this case
 - Clips were used in a previous case that day
- The clip was retrieved without injury
- The manufacturer observed:
 - Instrument channel damage in bending section
 - “crack, worn, and blockage”

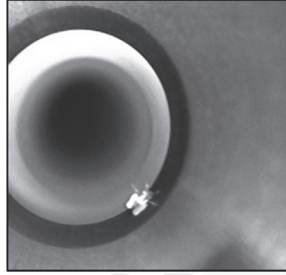
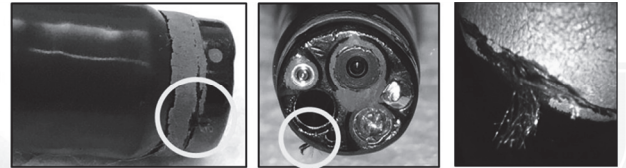


Photo Courtesy Ofsted: Channel with retained fragment of hemostasis

Preventable? YES!

- During gastroscope withdrawal from patient:
 - Injury caused by exposed metal parts on the bending section
 - Patient experienced bleeding
- The manufacturer:
 - Confirmed bending section rubber was peeling off
 - Found scratches on the insertion tube



Photos illustrate an example of exposed metal wires on distal end

Photos Courtesy Ofsted: Similar damage on a gastroscop

Patient injuries and exposures: Gastrosopes

Endoscope defects observed					Bad outcomes		
Damage to distal end, bending section, or insertion tube	Adhesive issues	Leak test failure (dry, wet, electrical)	Angulation problems	Internal scratches, dents, kinks	Injuries and other harms	Foreign debris fell into patient	Case prolonged
					Exposed metal caused bleeding		7
						Piece of dried tissue	Yes ⁸
						Piece of mucosa	Yes ⁹
						Staple from another procedure	Yes ¹⁰
						Pieces of brush	Yes ¹¹
						“Tissue-like substance”	Yes ¹²

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Preventable? YES!

- A female patient had trouble swallowing after trauma due to a motor vehicle accident (MVA)
- During EGD, the forceps pushed out a piece of tissue from another case
- Attempted tissue retrieval failed
- Borescope exam of the channel discovered severe buckling of the insertion tube near the boot
- Manufacturer stated buckling “could conceivably trap bioburden”
- Patient notification and testing included:
 - The exposed MVA patient
 - The previous patient (presumed tissue source)



Photo courtesy Ofstead: Scope with buckled insertion tube

Patient injuries and exposures: Duodenoscopes

Endoscope defects observed					Bad outcomes		
Damage to distal end, bending section, or insertion tube	Adhesive issues	Leak test failure (dry, wet, electrical)	Angulation problems	Internal scratches, dents, kinks	Injuries and other harms	Foreign debris fell into patient	Case prolonged
					Torn mucosa entire length of esophagus		Yes ¹³
						Stent from another patient	Yes ¹⁴
						Stent from another patient	Yes; 10 min ¹⁵
					2 nd scope required	Blue detergent	Yes ¹⁶

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Preventable? YES!

- During kidney stone removal, the ureteroscope got stuck in the patient's ureter
- The surgeon used a cystoscope to see why it was stuck:
 - Metal was poking out of bending section
 - Removal of the ureteroscope tore out the ureter
 - Ureter was removed from the scope with scissors
 - Surgeon placed a stent and a catheter
- Hospitalization was extended to treat bleeding
- Stent removal planned for 6 weeks later, with a possible need for surgery "to reimplant the ureter"
- Visual inspection after the procedure found damaged bending section cover and a cut in the lining



Photo Courtesy Ofstead; Ureteroscope with damaged bending section

Patient injuries and exposures: Ureteroscopes

Endoscope defects observed					Bad outcomes		
Damage to distal end, bending section, or insertion tube	Adhesive issues	Leak test failure (dry, wet, electrical)	Angulation problems	Internal scratches, dents, kinks	Injuries and other harms	Foreign debris fell into patient	Case prolonged
					Bending section broke, got stuck in kidney		Yes ¹⁷
					Scope stuck, tore out ureter; patient hospitalized		Yes; 30 min, further procedures ¹⁸
					Distal end got stuck and tore ureter		Yes; 45 min ¹⁹
						Plastic from scope tip	Yes; 5 min ²⁰
						Pieces of scope	Yes ²¹
						Distal ring of scope	Yes; surgery ²²

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Patient injuries and exposures: Cystoscopes

Endoscope defects observed					Bad outcomes		
Damage to distal end, bending section, or insertion tube	Adhesive issues	Leak test failure (dry, wet, electrical)	Angulation problems	Internal scratches, dents, kinks	Injuries and other harms	Foreign debris fell into patient	Case prolonged
					Rough, raised bending rubber caused bleeding		Yes ²³
					Exposed metal and damaged bending section caused injury		Yes ²⁴
						Plastic from scope tip	Yes ²⁵
						Insertion tube piece	Yes ²⁶
						3 black pieces	Yes ²⁷
						Black plastic	Yes ²⁸

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Patient injuries and exposures: Bronch/EBUS/Intubation

Endoscope defects observed					Bad outcomes		
Damage to distal end, bending section, or insertion tube	Adhesive issues	Leak test failure (dry, wet, electrical)	Angulation problems	Internal scratches, dents, kinks	Injuries and other harms	Foreign debris fell into patient	Case prolonged
					2 nd scope used	Distal tip	Yes; 30 min ²⁹
						Broken pieces	Yes; 30 min ³⁰
						Broken distal tip	Yes ³¹
					2 nd scope used; Initial retrieval not successful; Retrieved next day	Piece of insertion tube	Yes ³²
						5 cm ² mesh or tissue	Yes ³³
						Casing on scope tip	Yes ³⁴

Data compiled by Ofstead & Associates, Inc. in 2025; provided to Healthmark – a Getinge company for educational use

Infections linked to endoscopes with visible defects: Bronchoscopes

Scope/Geography	Pathogen	Patients infected	Visible defects
Bronchoscope (U.S.)	CRE <i>Klebsiella pneumoniae</i> , MDR <i>Pseudomonas aeruginosa</i> (superbugs)	22 (10 deaths)	Instrument channel damage; residual “proteinaceous debris” ³⁶
Bronchoscope (France)	<i>Achromobacter xylosoxidans</i>	7	Crushed, wrinkled, and “striped” insertion tube; “pleated bonding tube” ³⁷

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Preventable? YES!

- During bronchoscopy, part of scope broke off inside the patient
- The piece was retrieved during the procedure
- The manufacturer’s inspection found:
 - Bending section defect with missing adhesive
 - Multiple dents in the insertion tube
 - Chipped boot
 - Detached distal end cover that was chipped
 - Peeling glue on distal cover
 - Insulation failure due to glue defects
 - Electrical continuity test failure
 - Worn labels

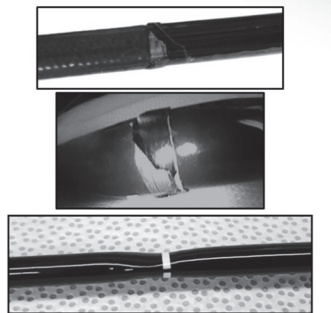


Photo Courtesy Ofstead: Bronchoscope with damaged insertion tube

Infections linked to endoscopes with visible defects: Urology scopes

Scope/Geography	Pathogen	Patients infected	Visible defects
Ureteroscope (U.K.)	MDR <i>Pseudomonas aeruginosa</i> (superbug)	14 (9 urosepsis)	External cuts and puckering; internal laser damage ³⁸
Cystoscope (France)	<i>P. aeruginosa</i>	11	Scratch in channel ³⁹
Cystoscope (N/A)	<i>Salmonella</i>	6	Perforated bending section ⁴⁰
Cystoscope (U.S.)	<i>Escherichia coli</i> , <i>Enterococcus faecalis</i> , <i>Staphylococcus aureus</i> , <i>Serratia marcescens</i>	5	“Foreign bodies” shedding from scope tips ⁴¹⁻⁴³ Scope 1: Dented instrument channel; cracked light guide lens; and cracked, peeling adhesive ⁴⁴ Scope 2: Cracked, scratched; lifted bending rubber ⁴⁵

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Infections linked to endoscopes with visible defects: Gastrosopes and colonoscopes

Scope/Geography	Pathogen	Patients infected	Visible defects
Gastroscope, Colonoscope (Germany)	CRE <i>Klebsiella pneumoniae</i> (superbug)	16* (3 deaths)	"Visible deposits"; scratches and damage in instrument channel; fluid in air/water channel ⁴⁶
Gastroscope, Duodenoscope (U.S.)	NDM+ <i>K. pneumoniae</i> (superbug)	9	Scratches; insertion tube, bending rubber, and instrument channel defects; fluid incursion ⁴⁷
Gastroscope (U.S.)	NDM+ <i>Escherichia coli</i> (superbug)	2	Insertion tube and biopsy channel damage ⁴⁸
Gastroscope (Netherlands)	ESBL+ <i>E. coli</i> (superbug)	4	Distal end damage ⁴⁹
Colonoscope (U.S.)	<i>Salmonella</i>	1 (hospitalized)	Instrument channel stains, scrapes, tear; suction channel kink ⁵⁰

*Additional cases were infected via patient-to-patient transmission (32 total patients involved in the outbreak)

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The 3 T's of Visual Inspection



TOOLS

- External visual inspection tools (e.g. microscope)
- Leak tester(s)
- Internal visual inspection tools (e.g. borescope)



TRAINING

- Policies & procedures
- IFU's
- Competencies
- Auditing and feedback



TIME

- Adequate stock
- Administrative & Clinical Support

Infections linked to endoscopes with visible defects: Duodenoscopes

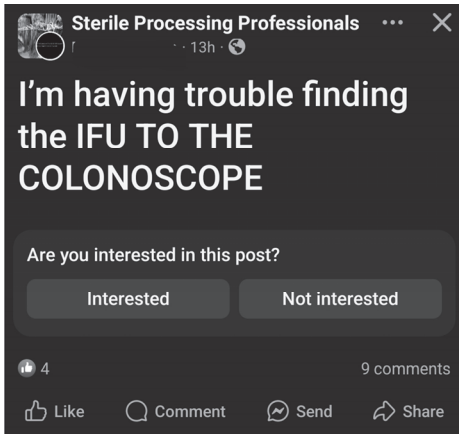
Scope/Geography	Pathogen	Patients infected	Visible defects
Duodenoscope (Netherlands)	MDR <i>Klebsiella pneumoniae</i> (superbug)	27	Cracked biopsy channel; multiple components with brown stains; white oxidation stains; adhesive defects ⁵¹
Duodenoscope (Netherlands)	ESBL+ <i>Citrobacter freundii</i> ESBL + <i>K. pneumoniae</i> (superbugs)	6	"Major" instrument channel damage; visible biofilm ⁵²
Duodenoscope (Israel)	NDM+ <i>Escherichia coli</i> (superbug)	4 (1 sepsis)	Cracks on distal endcap ⁵³
Duodenoscope (France)	NDM+ <i>Pseudomonas aeruginosa</i> (superbug)	10 (2 deaths)	Buckled channel ⁵⁴
Duodenoscope (U.S.)	CRE <i>E. coli</i> , <i>K. pneumoniae</i> (superbugs)	4 (1 death)	Torn channel ⁵⁵
Duodenoscope (U.S.)	<i>Enterobacter</i>	2	Cracked and peeling adhesive; instrument channel leak; angulation issues ^{56,57}

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3 T's of Visual Inspection: Training



- Policies and Procedures – Defined steps required for every scope
- IFU's – Techs must have access and be trained on the steps required
- Competency –
 - Facility specific, model specific.
 - Visually verified
 - Required prior to solo-work.
 - Renewed at least annually.
 - Continuing Education
- Auditing with feedback
 - Checklist
 - Report on compliance KPI's and educate, retrain as needed

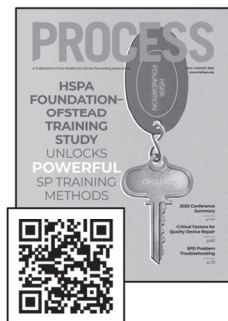
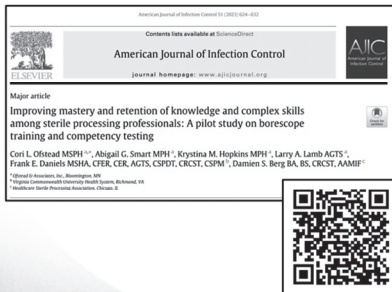


3 T's of Visual Inspection: Time

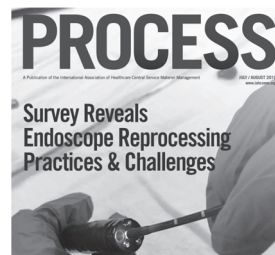


- Adequate Stock
 - Enough time between procedures to clean according to IFU's
 - Allow time for a thorough visual inspection
 - Allow for equipment to be sent out for repair
 - Allow for equipment to be sent out for regular maintenance
- Administrative/Clinical Support
 - No pressure to skip steps
 - Empowered to stop the line

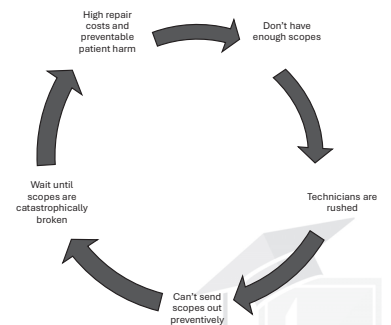
It is Possible!



Under Pressure



"Most of the members who responded (70%) felt pressure to work quickly when reprocessing endoscopes"



You can't afford it? You can't afford not to!



• Biomed Instrum Technol. 2024;58(4):88-98. doi: [10.2345/0899-8205-58.4.88](https://doi.org/10.2345/0899-8205-58.4.88)

Impact of Borescope Inspections on Endoscope Repair Frequency and Costs

• Cori L Ofstead ^{*✉}, Abigail G Smart [†], Larry A Lamb [‡], Frank E Daniels [§]

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PMCID: PMC11584169

Key Findings:

- Overall cost of repairs reduced from \$1.2 million to \$724k (40%)
- Average cost per repair reduced from \$4.4k to \$2.3K (48%)
- Mean Repair Turnaround Time (TAT) reduced from 24 days to 15 days

Questions?



It's Necessary and Possible, But Is It Easy?

Major I-40 Bridge in Southeast Closed Indefinitely

May 18, 2021 | Staff | 2-min. read



- Inspector called 911
- All traffic immediately stopped and diverted
- River traffic stopped
- 8 min drive increased to 84 minutes
- Daily cost to the trucking industry estimated at \$2.4 million
- Closed from May 11 to July 31



3 T's Survey and Action Plan Generator

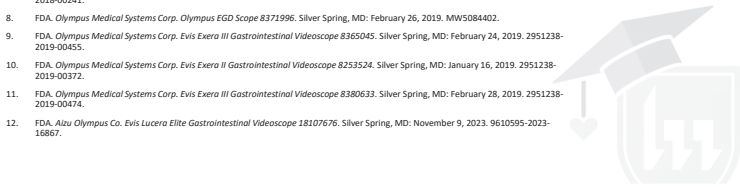


References



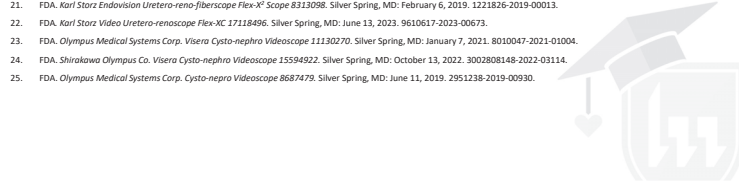
References

1. FDA. *Olympus Medical Systems Corp. Evis Exera III Colonovideoscope 9699365*. Silver Spring, MD: February 12, 2020. 2951238-2020-00337
2. FDA. *Olympus Medical Systems Corp. Evis Exera III Colonovideoscope 8438810*. Silver Spring, MD: March 20, 2019. 2951238-2019-00562
3. FDA. *Olympus Medical Systems Corp. Evis Exera II Colonovideoscope 14565895*. Silver Spring, MD: June 1, 2022. 8010047-2022-09183
4. FDA. *Olympus Medical Systems Corp. Evis Exera III Colonovideoscope 7930729*. Silver Spring, MD: October 3, 2018. 2951238-2018-00597
5. FDA. *Olympus Medical Systems Corp. Evis Exera II Colonovideoscope 8082066*. Silver Spring, MD: November 17, 2018. 2951238-2018-00705
6. FDA. *Olympus Medical Systems Corp. Evis Lucera Elite Colonovideoscope 8007877*. Silver Spring, MD: October 26, 2018. 8010047-2018-02055
7. FDA. *Olympus Medical Systems Corp. Evis Lucera Elite Gastrointestinal Videoscope 7281564*. Silver Spring, MD: January 25, 2018. 8010047-2018-00241
8. FDA. *Olympus Medical Systems Corp. Olympus EGD Scope 8371996*. Silver Spring, MD: February 26, 2019. MW5084402
9. FDA. *Olympus Medical Systems Corp. Evis Exera III Gastrointestinal Videoscope 8365045*. Silver Spring, MD: February 24, 2019. 2951238-2019-00455
10. FDA. *Olympus Medical Systems Corp. Evis Exera II Gastrointestinal Videoscope 8253524*. Silver Spring, MD: January 16, 2019. 2951238-2019-00372
11. FDA. *Olympus Medical Systems Corp. Evis Exera III Gastrointestinal Videoscope 8380633*. Silver Spring, MD: February 28, 2019. 2951238-2019-00474
12. FDA. *Alzu Olympus Co. Evis Lucera Elite Gastrointestinal Videoscope 18107676*. Silver Spring, MD: November 9, 2023. 9610595-2023-16867



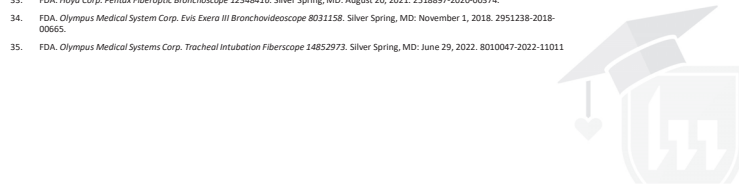
References

13. FDA. *Olympus Medical Systems Corp. Single Use Distal Cover 13518299*. Silver Spring, MD: February 11, 2022. 2951238-2022-00318
14. FDA. *Alzu Olympus Co. Evis Lucera Duodenovideoscope 18321844*. Silver Spring, MD: December 13, 2023. 9610595-2023-19502
15. FDA. *Olympus Medical Systems Corp. Evis Lucera Duodenovideoscope 14465148*. Silver Spring, MD: May 21, 2022. 8010047-2022-08676
16. FDA. *Alzu Olympus Co. Evis Exera III Duodenovideoscope 16508665*. Silver Spring, MD: March 8, 2023. 9610595-2023-03983
17. FDA. *Olympus Medical Systems Corp. Uretero-reno Videoscope 8525485*. Silver Spring, MD: April 17, 2019. 2951238-2019-00746
18. FDA. *Alzu Olympus Co. Uretero-reno Videoscope 20174539*. Silver Spring, MD: September 9, 2024. 9610595-2024-17988
19. FDA. *Olympus Medical Systems Corp. Urtero-reno Fiberscope 7982334*. Silver Spring, MD: October 18, 2018. 2951238-2018-00631
20. FDA. *Richard Wolf GmbH Cobra Vision Sensor-Ureterorenoscope 15523744*. Silver Spring, MD: October 1, 2022. 1418479-2022-00026
21. FDA. *Karl Storz Endovision Uretero-reno-fiberscope Flex-X² Scope 8313098*. Silver Spring, MD: February 6, 2019. 1221826-2019-00013
22. FDA. *Karl Storz Video Uretero-rensoscope Flex-XC 17118496*. Silver Spring, MD: June 13, 2023. 9610617-2023-00673
23. FDA. *Olympus Medical Systems Corp. Visera Cysto-nephro Videoscope 11130270*. Silver Spring, MD: January 7, 2021. 8010047-2021-01004
24. FDA. *Shirakawa Olympus Co. Visera Cysto-nephro Videoscope 15594922*. Silver Spring, MD: October 13, 2022. 3002808148-2022-03114
25. FDA. *Olympus Medical Systems Corp. Cysto-nephro Videoscope 8687479*. Silver Spring, MD: June 11, 2019. 2951238-2019-00990



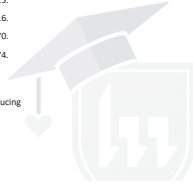
References

26. FDA. *Hoya Corporation Pentax Video Cystoscope 11515805*. Silver Spring, MD: March 18, 2021. 9610877-2021-00057
27. FDA. *Shirakawa Olympus Co. Cysto-Nephro Videoscope 16542448*. Silver Spring, MD: March 14, 2023. 3002808148-2023-02490
28. FDA. *Olympus Medical Systems Corp. Evis Cystovideoscope 8389204*. Silver Spring, MD: March 5, 2019. 8010047-2019-01183
29. FDA. *Olympus Medical Systems Corp. Evis Exera II Ultrasonic Bronchofibervideoscope 10196601*. Silver Spring, MD: June 25, 2020. 8010047-2020-03637
30. FDA. *Alzu Olympus Co. Evis Exera II Bronchovideoscope 17378754*. Silver Spring, MD: July 24, 2023. 9610595-2023-10472
31. FDA. *Alzu Olympus Co. Evis Exera III Bronchovideoscope 18637189*. Silver Spring, MD: February 3, 2024. 9610595-2024-02375
32. FDA. *Alzu Olympus Co. Evis Exera III Bronchovideoscope 17685602*. Silver Spring, MD: September 5, 2023. 9610595-2023-12727
33. FDA. *Hoya Corp. Pentax Fiberoptic Bronchoscope 12348416*. Silver Spring, MD: August 20, 2021. 2518897-2020-00374
34. FDA. *Olympus Medical System Corp. Evis Exera III Bronchovideoscope 8031158*. Silver Spring, MD: November 1, 2018. 2951238-2018-00665
35. FDA. *Olympus Medical Systems Corp. Tracheal Intubation Fiberscope 14852973*. Silver Spring, MD: June 29, 2022. 8010047-2022-11011



References

36. Galdys AL, Marsh JW, Delgado E, Pasculle AW, Pacey M, Ayres AM, et al. Bronchoscope-associated clusters of multidrug-resistant *Pseudomonas aeruginosa* and carbapenem-resistant *Klebsiella pneumoniae*. *Infect Control Hosp Epidemiol*. 2019;40:40-6.
37. FDA. *Hoya Corp. Pentax Fiberoptic Bronchoscope 13447528*. Silver Spring, MD: February 3, 2022. 9610877-2022-00227.
38. Kumarage J, Khonyongwa K, Khan A, Desai N, Hoffman P, Taori SK. Transmission of MDR *Pseudomonas aeruginosa* between two flexible ureteroscopes and an outbreak of urinary tract infection: The fragility of endoscope decontamination. *J Hosp Infect*. 2019;102:89-94.
39. Sorbets E, Ervevin M, Juma-Bilak E, et al. An outbreak of *Pseudomonas aeruginosa* urinary tract infections following outpatient flexible cystoscopy. *Am J Infect Control*. 2019;47:1510-2.
40. FDA. *Olympus Medical Systems Corp. Cysto-Nephro Videoscope 8701602*. Silver Spring, MD: June 14, 2019. 2951138-2019-00939.
41. FDA. *Olympus Medical Systems Corp. Cysto-Nephro Videoscope 13471296*. Silver Spring, MD: February 7, 2022. 2951238-2022-00314.
42. FDA. *Olympus Medical Systems Corp. Cysto-Nephro Videoscope 13471448*. Silver Spring, MD: February 7, 2022. 2951238-2022-00315.
43. FDA. *Olympus Medical Systems Corp. Cysto-Nephro Videoscope 13471719*. Silver Spring, MD: February 7, 2022. 2951238-2022-00316.
44. FDA. *Olympus Medical Systems Corp. Cysto-Nephro Videoscope 13470902*. Silver Spring, MD: February 7, 2022. 8010047-2022-02470.
45. FDA. *Olympus Medical Systems Corp. Cysto-Nephro Videoscope 13470989*. Silver Spring, MD: February 7, 2022. 8010047-2022-02474.
46. Haak J, Klempien I, Hans JB, Schaefer S, et al. Endoscope-associated outbreak of OXA-181-carbapenemase-producing *Klebsiella pneumoniae* and its implications for hygiene management. *J Hosp Infect*. 2025.
47. Yang AF, Sherman A, Nazarian E, Haas W, Mehr J, Pedrani M, et al. Evidence of transmission of New Delhi metallo- β -lactamase-producing *Klebsiella pneumoniae* through a gastrointestinal endoscope without an elevator channel. *Infect Control Hosp Epidemiol*. 2024:1-6.



References: Guidelines and FDA Communications

- AAMI, ANSI, ANSI/AAMI ST91: 2021 Flexible and semi-rigid endoscope processing in health care facilities. Arlington, VA: Association for the Advancement of Medical Instrumentation; 2021. p. 1-190.
- Association of periOperative Registered Nurses (AORN). Guidelines for Perioperative Practice: 2023 Edition. Guideline for Processing Flexible Endoscopes. Denver, CO: 2023. p. 213-266.
- Society of Gastroenterology Nurses and Associates (SGNA). Standards of infection prevention in reprocessing flexible gastrointestinal endoscopes. Chicago, IL: 2023. p. 1-31.
- Day LW, Muthusamy VR, Collins I, Kushnir VM, Sawhney MS, Thosani NC, et al. Multisociety guideline on reprocessing flexible GI endoscopes and accessories. *Gastrointest Endosc*. 2021;93:11-33.e6.
- FDA. *Infections associated with reprocessed urological endoscopes—Letter to health care providers*. Silver Spring, MD: April 1, 2021.
- FDA. *Flexible bronchoscopes and updated recommendations for reprocessing: FDA safety communication*. Silver Spring, MD: June 25, 2021.



References

48. Codman J, Berriel-Cass D, Nguyen C, Marcinek D, Bachman B, Gallogly B. DS 39 Transmission of New Delhi Metallo- β -lactamase producing *Escherichia coli* through a gastroscop from an esophagogastroduodenoscopy procedure. *Am J Infect Control*. 2024;52.
49. FDA. *Aizu Olympus Co. Evis Exera III Gastrointestinal Videoscope 17044116*. Silver Spring, MD: June 1, 2023. 9610595-2023-08305.
50. FDA. *Olympus Medical Systems Corp. Evis Exera III Colonovideoscope 12288277*. Silver Spring, MD: August 6, 2021. 8010047-2021-09912.
51. Rauwers AW, Troelstra A, Fluit AC, Wissink C, Loeve AJ, Vleggaar FP, et al. Independent root cause analysis of contributing factors, including dismantling of 2 duodenoscopes, to an outbreak of multidrug-resistant *Klebsiella pneumoniae*. *Gastrointest Endosc*. 2019;90:793-804.
52. Cimen C, Bathoorn E, Loeve AJ, Flijs M, Berends MS, Nagegast WB, et al. Uncovering the spread of drug-resistant bacteria through next-generation sequencing based surveillance: Transmission of extended-spectrum β -lactamase-producing *Enterobacteriales* by a contaminated duodenoscope. *Antimicrob Resist Infect Control*. 2024;13:1.
53. Dabaja-Younis HK, Schechner V, Firan I, Khamaysi I, Levi GD, Lurie-Weinberger MN, et al. Identification and control of two outbreaks of unrelated New Delhi metallo- β -lactamase-producing carbapenem-resistant *Escherichia coli* traced to the same endoscope defect. *Infect Control Hosp Epidemiol*. 2023;44:1673-5.
54. FDA. *Hoya Corporation Pentax Video Duodenoscope 20461509*. Silver Spring, MD: October 16, 2024. 2518897-2024-00064.
55. FDA. *Olympus America Medical ERCP Duodenoscope 20156426*. Silver Spring, MD: September 5, 2024. 20156426.
56. FDA. *Aizu Olympus Co. Evis Exera III Duodenovideoscope 18021564*. Silver Spring, MD: October 27, 2023. 9610595-2023-15989.
57. FDA. *Aizu Olympus Co. Evis Exera III Duodenovideoscope 18021776*. Silver Spring, MD: October 27, 2023. 2429304-2023-00338.



References: Published evidence on borescope inspections

- Ofstead CL, Wetzler HP, Heymann OL, Johnson EA, Eiland JE, Shaw MJ. Longitudinal assessment of reprocessing effectiveness for colonoscopes and gastroscopes: Results of visual inspections, biochemical markers, and microbial cultures. *Am J Infect Control*. 2017;45:e26-e33.
- Ofstead CL, Heymann OL, Quick MR, Eiland JE, Wetzler HP. Residual moisture and waterborne pathogens inside flexible endoscopes: Evidence from a multisite study of endoscope drying effectiveness. *Am J Infect Control*. 2018;46:689-96.
- Ofstead CL, Quick MR, Wetzler HP, Eiland JE, Heymann OL, Sonetti DA, et al. Effectiveness of reprocessing for flexible bronchoscopes and endobronchial ultrasound bronchoscopes. *Chest*. 2018;154:1024-34.
- Ofstead CL, Heymann OL, Quick MR, Johnson EA, Eiland JE, Wetzler HP. The effectiveness of sterilization for flexible ureteroscopes: A real-world study. *Am J Infect Control*. 2017;45:888-95.
- Ofstead CL, Smart AG, Hopkins KM, Wetzler HP. The utility of lighted magnification and borescopes for visual inspection of flexible endoscopes. *Am J Infect Control*. 2023;51:2-10.
- Barakat MT, Girotra M, Huang RJ, Banerjee S. Scoping the scope: Endoscopic evaluation of endoscope working channels with a new high-resolution inspection endoscope (with video). *Gastrointest Endosc*. 2018;88:501-11.
- Thaker AM, Kim S, Sedarat A, Watson RR, Muthusamy VR. Inspection of endoscope instrument channels after reprocessing using a prototype borescope. *Gastrointest Endosc*. 2018;88:612-9.
- Zhou M, Huang X, Liu LL, He RP, Hu L, Xun Z, et al. Investigation of the internal conditions of 213 reprocessed endoscopic channels. *Surg Laparosc Endosc Percutan Tech*. 2023;33:4-11.
- Chen TT, Nguyen MV, Cerrato C, Berger JH, Vartanian KB, Gerrity JJ, et al. Clinical evaluation of miniature flexible scope for diagnosis of ureteroscope working channel defects. *J Endourol*. 2023;37:628-33.



References

- Associated Press. Inspector who failed to catch Mississippi River bridge crack is fired. *NBC News*; May 18, 2021: <https://www.nbcnews.com/news/us-news/inspector-who-failed-catch-mississippi-river-bridge-crack-fired-n1267723>
- Lombardo, Jessica. I-40 Bridge Closure Puts the Cost of Doing Nothing to Repair Infrastructure on Display. *For Construction Pros.com*; May 20, 2021: <https://www.forconstructionpros.com/infrastructure/news/21440197/i40-bridge-closure-puts-the-cost-of-doing-nothing-to-repair-infrastructure-on-display>
- Sadlock, Joshua. Crisis Averted as Bridge Inspectors Discover Fracture in Hernando de Soto Bridge in Arkansas. *Engineering.com*; May 19, 2021: <https://www.engineering.com/crisis-averted-as-bridge-inspectors-discover-fracture-in-hermano-de-soto-bridge-in-arkansas/>



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