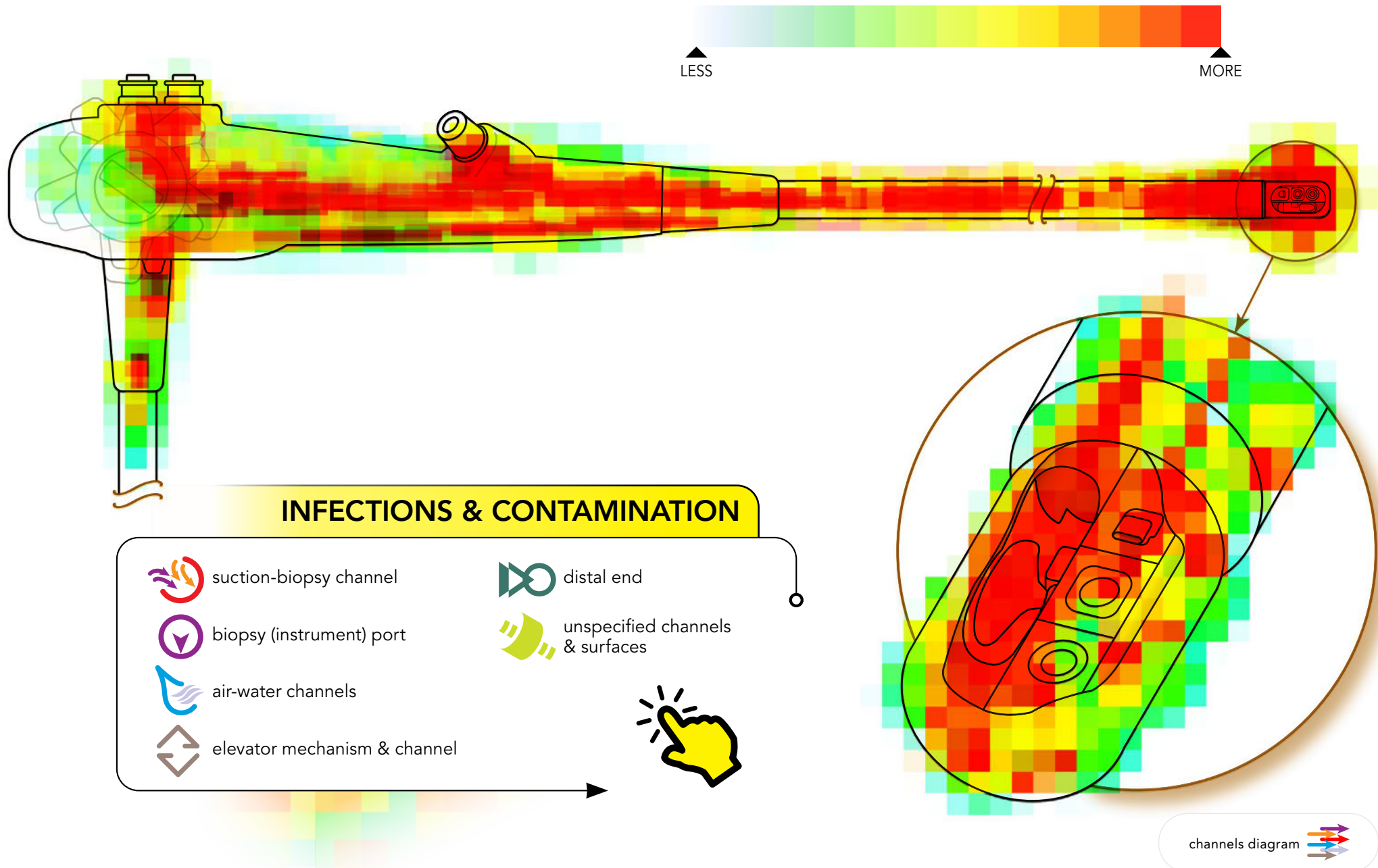
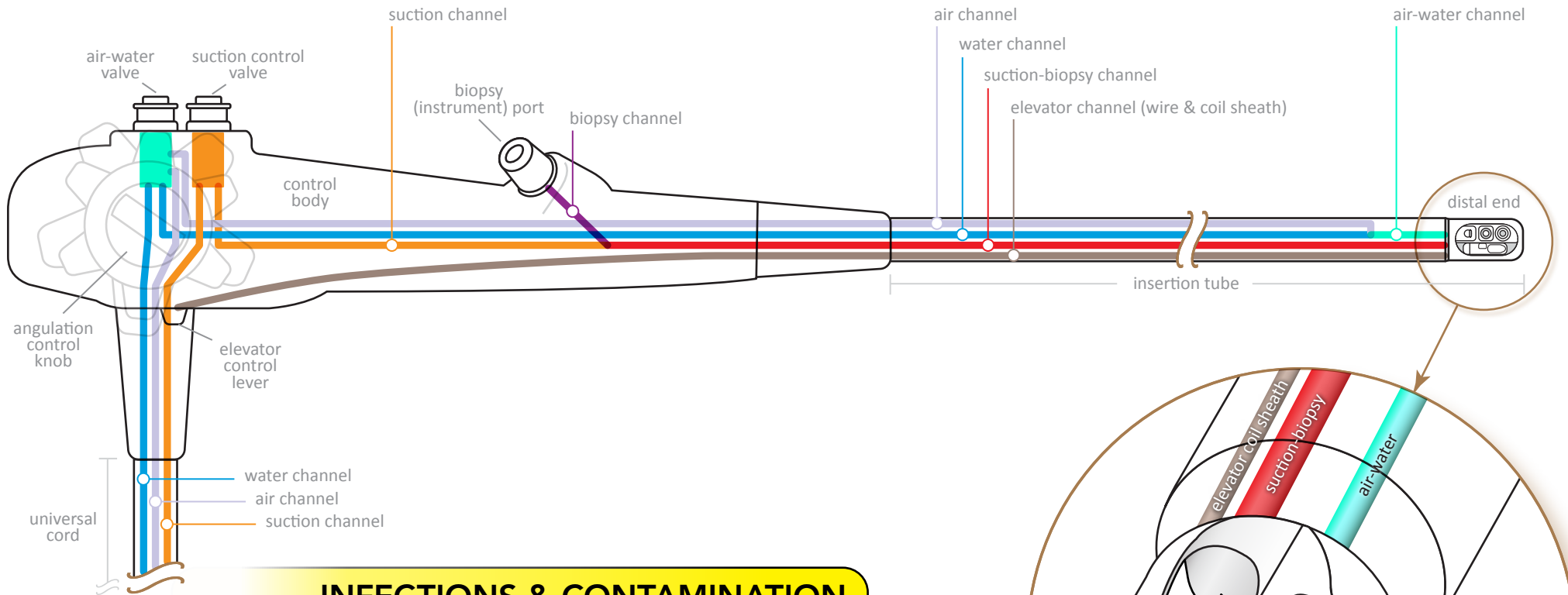


DUODENOSCOPE HOT SPOTS



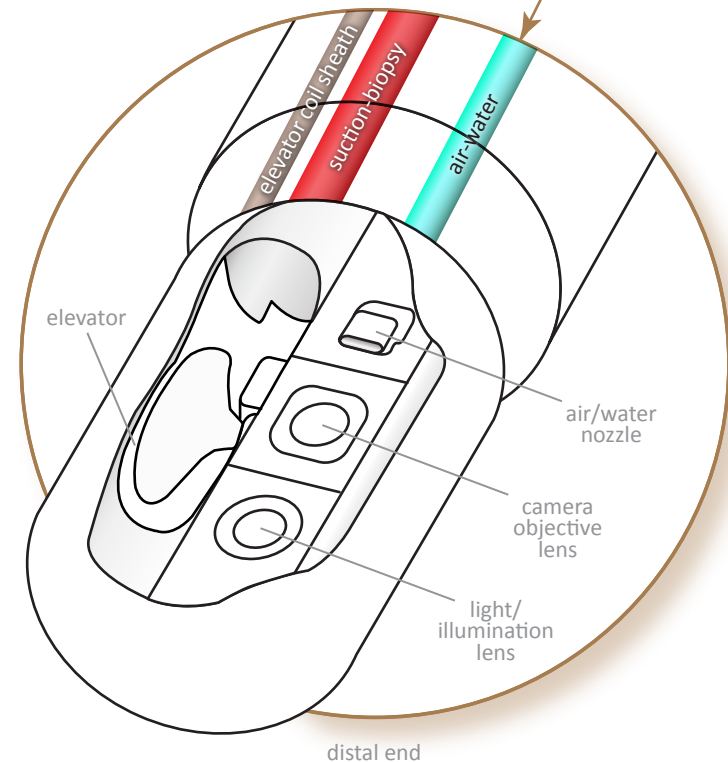
DUODENOSCOPE CHANNELS

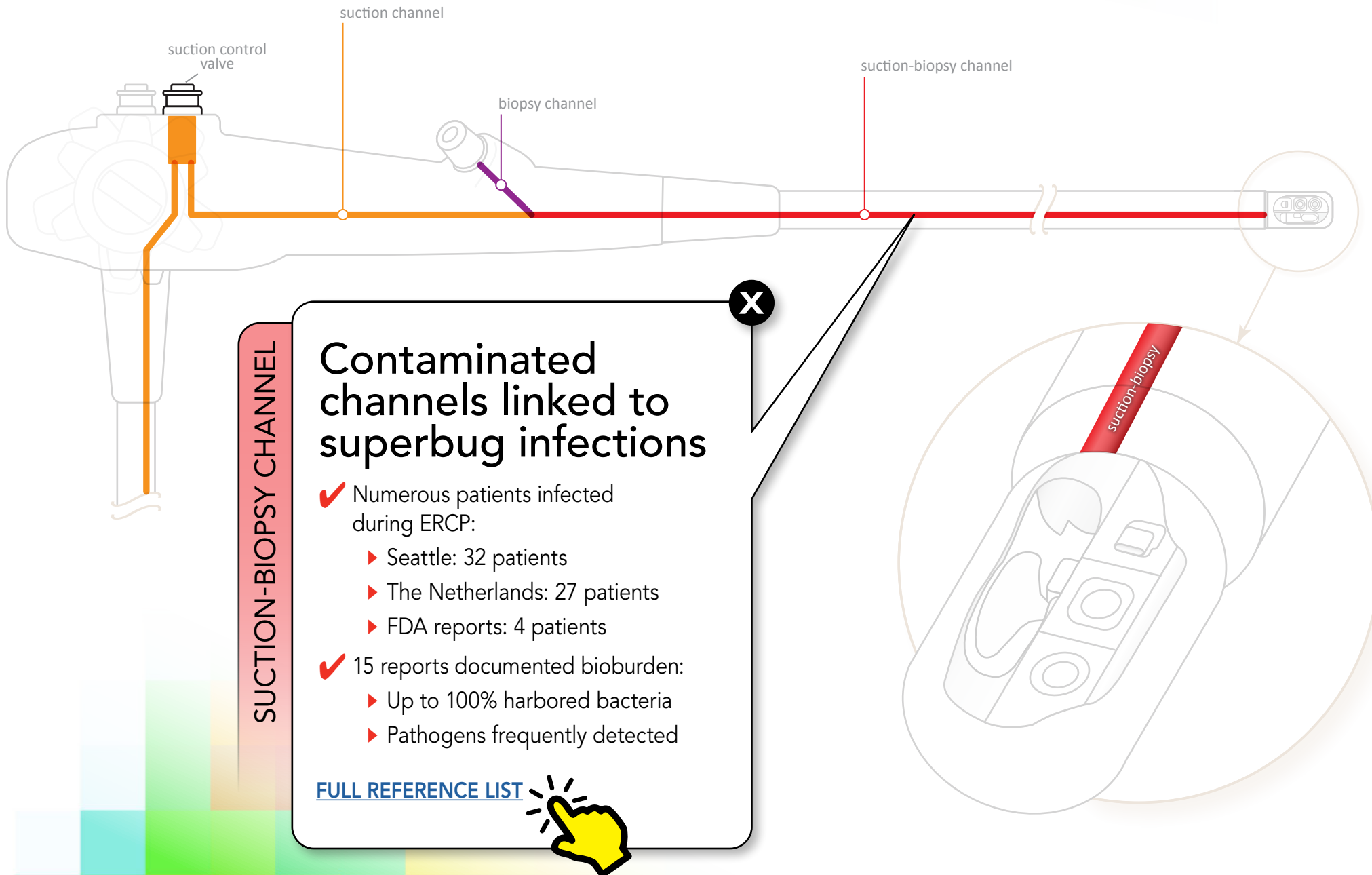


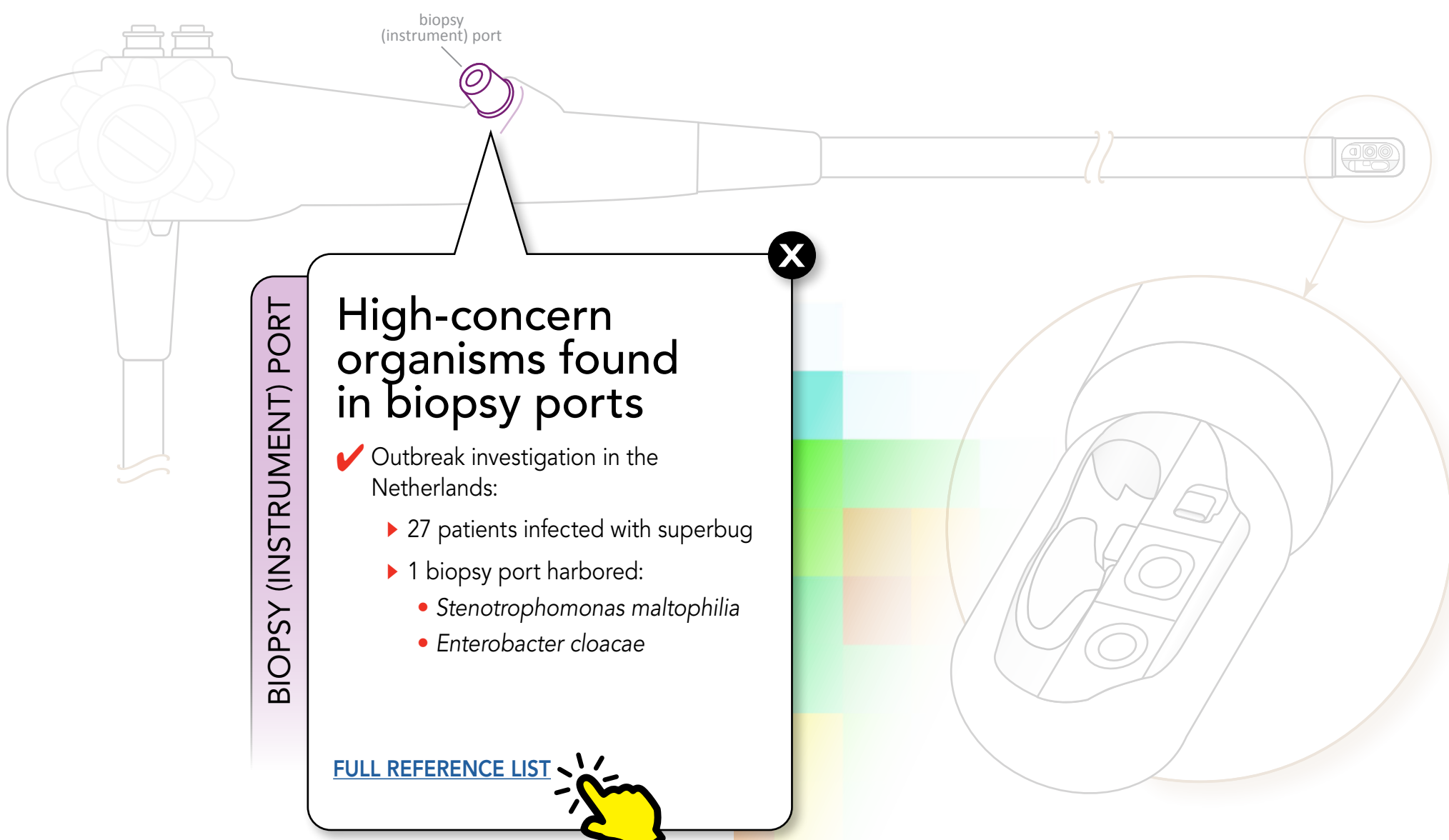
INFECTIONS & CONTAMINATION

-  suction-biopsy channel
-  biopsy (instrument) port
-  air-water channels
-  elevator mechanism & channel

-  distal end
-  unspecified channels & surfaces







biopsy
(instrument) port

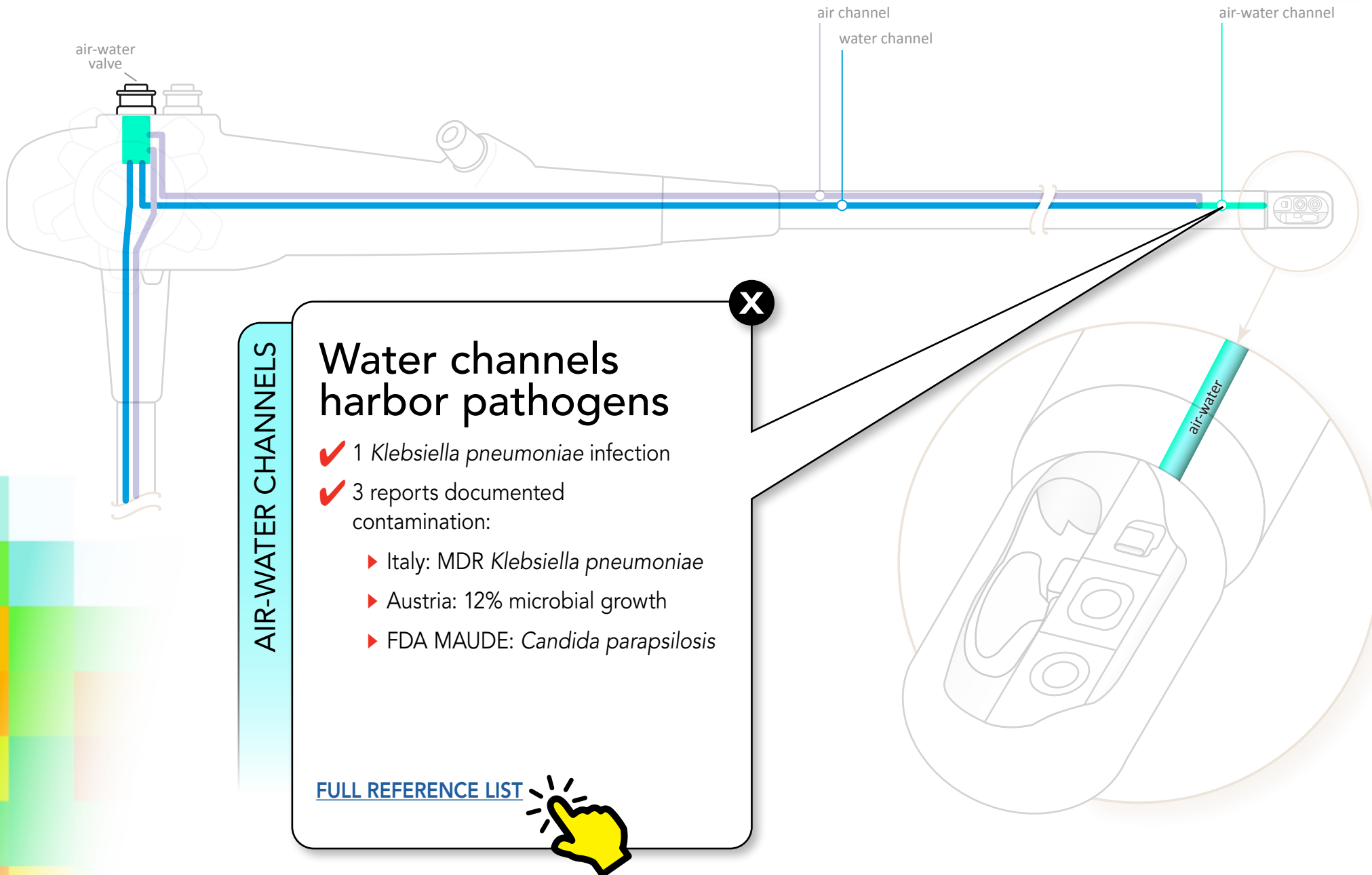
BIOPSY (INSTRUMENT) PORT

High-concern organisms found in biopsy ports

- ✓ Outbreak investigation in the Netherlands:
 - ▶ 27 patients infected with superbug
 - ▶ 1 biopsy port harbored:
 - *Stenotrophomonas maltophilia*
 - *Enterobacter cloacae*

[FULL REFERENCE LIST](#)





ELEVATOR MECHANISM & CHANNEL

Superbug outbreaks linked to contaminated elevator mechanisms

- ✓ Dozens of patients infected:
 - Chicago 35 patients • Seattle 32 patients • The Netherlands 22 patients • Tampa 10 patients
- ✓ 18 reports documented bioburden:
 - ▶ Up to 100% harbored bacteria
 - ▶ Pathogens frequently detected
 - ▶ Double HLD and ETO were not effective

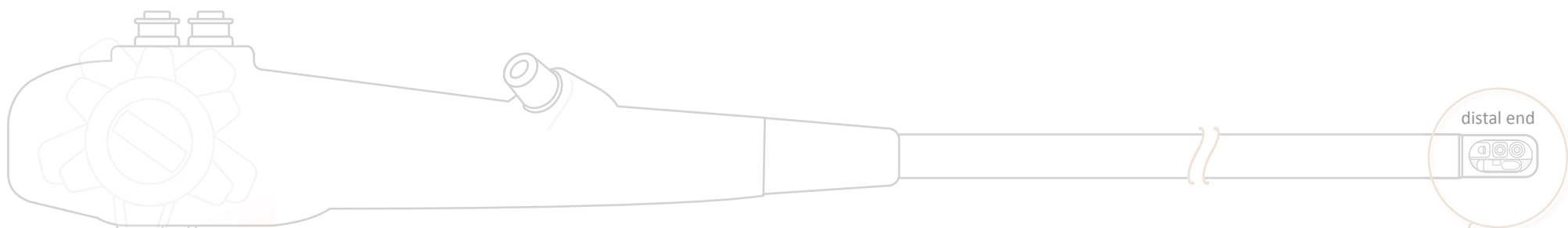
[FULL REFERENCE LIST](#)



elevator channel (wire & coil sheath)

elevator

elevator coil sheath

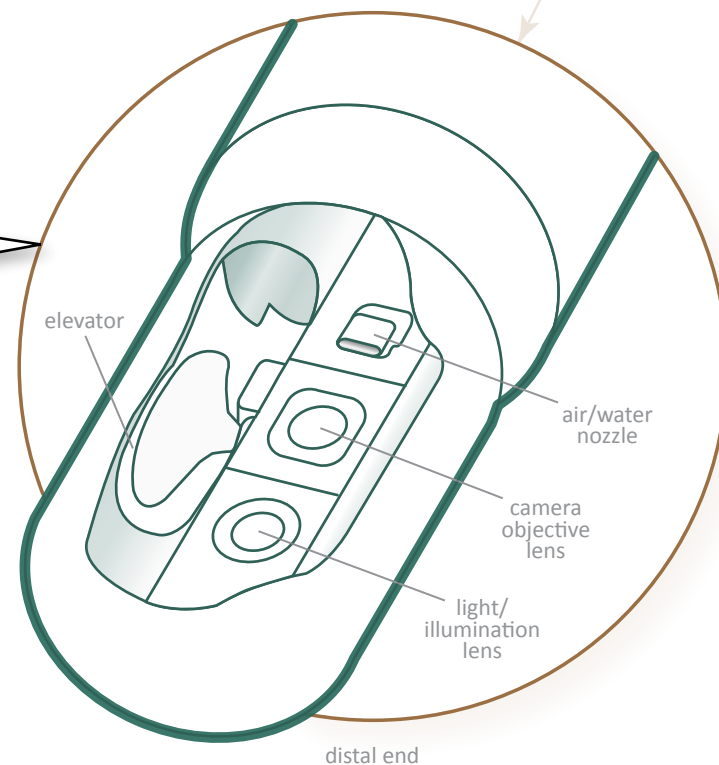


DISTAL END

Three studies found contaminated distal ends

- ✓ Potential pathogens and other microbes were found:
- ▶ Madison, WI: *E. coli*, *Staphylococcus aureus*, and *Sphingomonas*
 - ▶ The Netherlands: High colony counts, pathogens, and GI/oral microbes
 - ▶ US multisite study: *Micrococcus luteus*

[FULL REFERENCE LIST](#)



UNSPECIFIED CHANNELS & SURFACES

Severe infections linked to contaminated channels

- ✓ Superbug infections:
 - ▶ The Netherlands: 27 patients
 - ▶ France: 16 patients
 - ▶ France: 13 patients
 - ▶ China: 3 patients
- ✓ Superbugs were found in unspecified channels
- ✓ One study found bacteria on 22.2% of surfaces

[FULL REFERENCE LIST](#)

throughout unspecified channels or along the external surface of the scope

THE EVIDENCE



SUCTION-BIOPSY CHANNEL INFECTIONS

- ✓ Ross AS, Baliga C, Verma P, Duchin J, Gluck M. A quarantine process for the resolution of duodenoscope-associated transmission of multidrug-resistant *Escherichia coli*. *GIE*. 2015;82(3):477-483.
 - Seattle, WA
 - Virginia Mason Medical Center
 - 32 patients infected with a superbug (16 died)
 - Outbreak pathogen: MDR *Escherichia coli*
 - Suction/biopsy channel harbored MDR *Escherichia coli*
- ✓ Rauwers AW, Troelstra A, Fluit AC, Wissink C, Loeve AJ, Vleggaar FP, Bruno MJ, Vos MC, Bode LG, Monkelbaan JF. Independent root cause analysis of contributing factors, including dismantling of 2 duodenoscopes, to an outbreak of multidrug-resistant *Klebsiella pneumoniae*. *GIE*. 2019;90(5):793-804.
 - Utrecht, the Netherlands
 - University Medical Center Utrecht
 - 27 patients infected with a superbug (attack rate: 29%)
 - Outbreak pathogen: MDR *Klebsiella pneumoniae*
 - Duodenoscope A: Suction/biopsy channel harbored:
 - MDR *Klebsiella pneumoniae* (>200 CFU)
 - *Stenotrophomonas maltophilia* (>200 CFU)
 - *Enterobacter cloacae* (>200 CFU)
 - *Pseudomonas aeruginosa* (>200 CFU)
 - *Klebsiella oxytoca* (>200 CFU)

- Duodenoscope B: Suction/biopsy channel harbored:
 - MDR *Klebsiella pneumoniae* (28 CFU)
 - *Escherichia coli* (3 CFU)
 - *Enterococcus faecium* (1 CFU)
 - MDR *Klebsiella pneumoniae* persisted in both duodenoscopes after repeated reprocessing cycles
 - Duodenoscope C harbored *Acinetobacter pittii* in suction/biopsy channels (not implicated in outbreak)
- ✓ FDA. Olympus Medical Systems Corp. *Evis Exera II Duodenovideoscope* 8201861. Silver Spring, MD: December 27, 2018. 8010047-2018-02598.
- 4 patients infected, including:
 - *Escherichia coli*
 - *Enterococcus faecium*
 - Carbapenem-resistant *Enterobacteriaceae*
 - Biopsy channel harbored carbapenem-resistant *Enterobacteriaceae*
- ✓ Shenoy ES, Pierce VM, Walters MS, Moulton-Meissner H, Lawsin A, Lonsway D, Shugart A, McAllister G, Halpin AL, Zambrano-Gonzalez A, Ryan EE, Suslak D, DeJesus A, Barton K, Madoff LC, McHale E, DeMaria A, Hooper DC. Transmission of Mobile Colistin Resistance (*mcr-1*) by Duodenoscope. *Clin Infect Dis*. 2018;68(8):1327-1334.
- Boston, MA; Massachusetts General Hospital
 - 1 patient infected with a superbug
 - Outbreak pathogen: colistin-resistant *Klebsiella pneumoniae*
 - Suction/biopsy channel harbored:
 - Colistin-sensitive *Klebsiella pneumoniae*
 - *Escherichia coli*



suction-biopsy

biopsy port

air-water

elevator

distal end

unspecified



THE EVIDENCE



SUCTION-BIOPSY CHANNEL CONTAMINATION

Studies in the United States

- ✓ Brock AS, Steed LL, Freeman J, Garry B, Malpas P, Cotton P. Endoscope storage time: assessment of microbial colonization up to 21 days after reprocessing. *GIE*. 2014;81(5):1150-1154.
 - Charleston, SC
 - Medical University of South Carolina
 - Study included 4 duodenoscopes
 - 100% of suction/biopsy channels harbored microbes
 - Microbes found included *Candida parapsilosis* (1 CFU/mL)
- ✓ 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. *AJIC*. 2018;46(6):689-696.
 - USA
 - Study included 5 duodenoscopes
 - Overall, 80% of duodenoscopes were contaminated
 - 80% of suction/biopsy channels harbored microbes, including:
 - *Sphingomonas phyllosphaerae* (TNTC)
 - Gram+ cocci (TNTC)
 - *Bacillus licheniformis* (TNTC)
 - *Micrococcus luteus* (2 CFU/mL)
 - *Paenibacillus lactis* (2 CFU/mL)
- ✓ Visrodia K, Hanada Y, Pennington KM, Tosh PK, Topazian MD, Petersen BT. Duodenoscope reprocessing surveillance with adenosine triphosphate testing and terminal cultures: a clinical pilot study. *GIE*. 2017;86(1):180-186.

- Rochester, MN
- Mayo Clinic
- Study included 20 duodenoscopes and 74 samples
- Overall, 60% of duodenoscopes were contaminated after HLD:
 - *Stenotrophomonas maltophilia*
 - *Pseudomonas aeruginosa*
 - *Klebsiella pneumoniae*
 - *Enterococcus faecalis*
 - *Cellulosimicrobium*
 - Yeast and fungi
- 55% of suction/biopsy channels harbored microbes

- ✓ Mark J, Underberg K, Kramer R. Results of duodenoscope culture and quarantine after manufacturer-recommended cleaning process. *GIE*. 2020.
 - Aurora, CO
 - Children's Hospital Colorado
 - Study included 280 samples of duodenoscopes
 - Overall, 12.5% of 280 were contaminated, including 1 with *Pseudomonas aeruginosa*
 - 14.5% of 117 suction/biopsy channels harbored >10 CFU
- ✓ Heroux R, Sheppard M, Wright SB, Sawhney M, Hirsch EB, Kalaidjian R, Snyder GM. Duodenoscope hang time does not correlate with risk of bacterial contamination. *AJIC*. 2017;45(4):360-364.
 - Boston, MA
 - Beth Israel Deaconess Medical Center
 - Study included 18 duodenoscopes and 465 samples
 - Overall, 22.2% harbored microbes
 - 1.6% of suction/biopsy channel samples harbored microbes (max CFU: 4,512)

suction-biopsy

biopsy port

air-water

elevator

distal end

unspecified



THE EVIDENCE



✓ Bartles RL, Leggett JE, Hove S, Kashork CD, Wang L, Oethinger M, Baxter L, Brandabur JJ. A randomized trial of single versus double high-level disinfection of duodenoscopes and linear echoendoscopes using standard automated reprocessing. *GIE*. 2018;88:306-313.

- Renton, WA
- Providence St. Joseph Health
- Study included 45 duodenoscopes (2,925 encounters)
- Overall, 7.7% were contaminated
- 2.9% of suction/biopsy channels harbored microbes

✓ Snyder GM, Wright SB, Smithey A, Mizrahi M, Sheppard M, Hirsch EB, Chuttani R, Heroux R, Yassa DS, Olafsdottir LB, Davis RB, Anastasiou J, Bapat V, Bidari K, Pleskow DK, Leffler D, Lane B, Chen A, Gold HS, Bartley A, King AD, Sawhney MS. Randomized comparison of 3 high-level disinfection and sterilization procedures for duodenoscopes. *Gastroenterology*. 2017;153(4):1018-1025.

- Boston, MA
- Beth Israel Deaconess Medical Center
- Study included 18 duodenoscopes and 516 samples
- Overall, 18.3% of samples were contaminated:
 - 16.1% had growth after HLD
 - 16% had growth after double-HLD
 - 22.5% had growth after HLD plus ETO gas sterilization
- 1.7% of suction/biopsy channels harbored ≥ 10 CFU

✓ De Wolfe TJ, Safdar N, Meller M, et al. A prospective, randomized comparison of duodenoscope reprocessing surveillance methods. *Can J Gastroenterol Hepatol*. 2019.

- Madison, WI
- University of Wisconsin Hospitals and Clinics, Gastrointestinal Ambulatory Procedure Center
- Study included 7 duodenoscopes and 248 samples

• Overall, 11.7% of samples were contaminated, and high-concern organisms were found:

- *Staphylococcus aureus*
- *Escherichia coli*
- *Sphingomonas*

• 1.6% of suction/biopsy channels harbored microbes

Studies outside of the United States

✓ Ciccozzi M, Cella E, Lai A, De Florio L, Antonelli F, Fogolari M, Di Matteo FM, Pizzicannella M, Colombo B, Dicuonzo G, Angeletti S. Phylogenetic analysis of multi-drug resistant *Klebsiella pneumoniae* strains from duodenoscope biofilm: microbiological surveillance and reprocessing improvements for infection prevention. *Front Public Health*. 2019;7(219).

- Rome, Italy
- University Hospital Campus Bio-Medico
- Study included 5 duodenoscopes and 3 EUS
- Overall, 87.5% of endoscopes harbored *Klebsiella pneumoniae* in one or more channel
- 50% of suction and biopsy channels harbored *Klebsiella pneumoniae* (including MDR strains)

✓ Rauwers AW, Voor In't Holt AF, Buijs JG, de Groot W, Hansen BE, Bruno MJ, Vos MC. High prevalence rate of digestive tract bacteria in duodenoscopes: a nationwide study. *Gut*. 2018;67(9):1637-1645.

- the Netherlands
- Nationwide study of 150 duodenoscopes in 67 ERCP centers
- Overall, 22% of 150 duodenoscopes were contaminated
- 139 duodenoscope suction/biopsy channels were sampled:
 - 12% had microbial growth ≥ 20 CFU
 - 10% harbored GI/oral microbes



suction-biopsy

biopsy port

air-water

elevator

distal end

unspecified



THE EVIDENCE



- 146 duodenoscope biopsy channels were sampled:
 - 3% had microbial growth ≥ 20 CFU
 - 4% harbored GI/oral microbes
- 137 duodenoscope suction channels were sampled:
 - 3% had microbial growth ≥ 20 CFU
 - 4% harbored GI/oral microbes
- ✓ Paula H, Presterl E, Tribl B, Diab-El Schahawi M. Microbiologic surveillance of duodenoscope reprocessing at the Vienna University Hospital from November 2004 through March 2015. *ICHE*. 2015;36(10):1233-1235.
 - Vienna, Austria
 - Vienna General Hospital
 - Study included 8 duodenoscopes and 412 samples
 - Overall, 11% of samples were contaminated
 - 9.3% of 108 suction/biopsy channel samples harbored microbes
- ✓ Cristina ML, Sartini M, Schinca E, Ottria G, Dupont C, Bova P, Coccia G, Casini B, Spagnolo AM. Is post-reprocessing microbiological surveillance of duodenoscopes effective in reducing the potential risk in transmitting pathogens? *Int J Environ Res Public Health*. 2019;17(140).
 - Italy
 - Hospital not specified
 - Study included 4 duodenoscopes
 - Overall, 75% of duodenoscopes were highly contaminated
 - Suction/biopsy channels harbored:
 - *Pseudomonas aeruginosa* (2500 CFU/scope); including 40% MDR
 - *Klebsiella pneumoniae* (2580 CFU/scope); including 17% ESBL+
 - *Enterobacter*
 - *Stenotrophomonas maltophilia*
 - *Acinetobacter baumannii* (2600 CFU/scope)
 - *Pseudomonas luteola* (450 CFU/scope)

FDA reports

- ✓ FDA. Olympus Medical Systems Corp. *Evis Exera Duodenovideoscope* 8665084. Silver Spring, MD: June 4, 2019. 8010047-2019-02084.
 - During routine surveillance, contamination found in:
 - Biopsy channel:
 - *Stenotrophomonas maltophilia* (100 CFU/100 mL)
 - *Klebsiella oxytoca* (100 CFU/100 mL)
 - *Acinetobacter denitrificans* (40 CFU/100 mL)
 - *Pseudomonas aeruginosa* (5 CFU/100 mL)
 - Suction channel:
 - *Pseudomonas putida* (100 CFU/100 mL)
 - *Stenotrophomonas maltophilia* (5 CFU/100 mL)
 - *Ochrobactrum anthropi* (5 CFU/100 mL)
- ✓ FDA. Olympus Medical Systems Corp. *Evis Exera II Duodenovideoscope* 6510507. Silver Spring, MD: April 21, 2017. 8010047-2017-00484.
 - During routine surveillance, contamination found in:
 - Biopsy channel: *Sphingomonas* spp (>100 CFU/20 mL)
 - Suction channel: *Sphingomonas* and *Ochrobactrum anthropi* (>100 CFU/20 mL)
- ✓ FDA. Hoya Corp. *Pentax Video Duodenoscope* 4944874. Silver Spring, MD: July 24, 2015. 2518897-2015-00026.
 - *Pseudomonas aeruginosa* found in biopsy channel during routine surveillance



suction-biopsy

biopsy port

air-water

elevator

distal end

unspecified



THE EVIDENCE



BIOPSY (INSTRUMENT) PORT CONTAMINATION

- ✓ Rauwers AW, Troelstra A, Fluit AC, Wissink C, Loeve AJ, Vleggaar FP, Bruno MJ, Vos MC, Bode LG, Monkelbaan JF. Independent root cause analysis of contributing factors, including dismantling of 2 duodenoscopes, to an outbreak of multidrug-resistant *Klebsiella pneumoniae*. *GIE*. 2019;90(5):793-804.

- Utrecht, the Netherlands
- University Medical Center Utrecht
- Superbug outbreak investigation involving 27 patients and four duodenoscopes
- Biopsy port of 1 duodenoscope harbored high-concern organisms (but no superbugs):
 - *Stenotrophomonas maltophilia* (10 CFU/100 mL)
 - *Enterobacter cloacae* (10 CFU/100 mL)

AIR-WATER CHANNELS INFECTIONS

- ✓ FDA. Olympus Medical Systems Corp. EVIS EXERA II Duodenovideoscope 7745807. Silver Spring, MD: August 2, 2018. 8010047-2018-01509.
 - 1 patient infection with a superbug
 - Pathogen: Carbapenem-resistant *Klebsiella pneumoniae*
 - A/W channel harbored microbes (1 CFU/mL)

AIR-WATER CHANNELS CONTAMINATION

- ✓ Ciccocozzi M, Cella E, Lai A, De Florio L, Antonelli F, Fogolari M, Di Matteo FM, Pizzicannella M, Colombo B, Dicuonzo G, Angeletti S. Phylogenetic analysis of multi-drug resistant *Klebsiella pneumoniae* strains from duodenoscope biofilm: microbiological surveillance and reprocessing improvements for infection prevention. *Front Public Health*. 2019;7(219).

- Rome, Italy
- University Hospital Campus Bio-Medico
- Study included 8 endoscopes (duodenoscope/EUS)
- Overall, 87.5% of endoscopes harbored *Klebsiella pneumoniae* in one or more channel
- 37.5% of A/W channels harbored MDR *Klebsiella pneumoniae*
- 37.5% of auxiliary water channels harbored *Klebsiella pneumoniae* (including MDR strains)

- ✓ Paula H, Presterl E, Tribl B, Diab-El Schahawi M. Microbiologic surveillance of duodenoscope reprocessing at the Vienna University Hospital from November 2004 through March 2015. *ICHE*. 2015;36(10):1233-1235.

- Vienna, Austria
- Vienna University Hospital
- Study included 8 duodenoscopes and 412 samples
- Overall, 11% of 412 samples were contaminated
- 12% of 108 A/W channel samples harbored microbes

- ✓ FDA. Olympus Medical Systems Corp. Evis Exera II Duodenovideoscope 8201799. Silver Spring, MD: December 27, 2018. 8010047-2018-02584.

- A/W channel harbored *Candida parapsilosis*
- 1 patient infection with *Enterobacter cloacae*:
 - Facility denied patient sepsis and death were linked to contaminated endoscope

THE EVIDENCE



ELEVATOR MECHANISM & CHANNEL INFECTIONS

✓ Epstein L, Hunter JC, Arwady MA, Tsai V, Stein L, Gribogiannis M, Frias M, Guh AY, Laufer AS, Black S, Pacilli M, Moulton-Meissner H, Rasheed JK, Avillan JJ, Kitchel B, Limbago BM, MacCannell D, Lonsway D, Noble-Wang J, Conway J, Conover C, Vernon M, Kallen AJ. New Delhi Metallo- β -Lactamase-producing carbapenem-resistant *Escherichia coli* associated with exposure to duodenoscopes. *JAMA*. 2014;312(14):1447-1455.

- Park Ridge, IL
- Advocate Lutheran General Hospital
- 35 ERCP patients infected with superbug
- Outbreak pathogen: New Delhi metallo- β -lactamase-producing (NDM+) *Escherichia coli*
- Elevator harbored:
 - NDM+ *Escherichia coli*
 - *Klebsiella pneumoniae*

✓ Ross AS, Baliga C, Verma P, Duchin J, Gluck M. A quarantine process for the resolution of duodenoscope-associated transmission of multidrug-resistant *Escherichia coli*. *GIE*. 2015;82(3):477-483.

- Seattle, WA
- Virginia Mason Medical Center
- 32 patients infected with a superbug (16 died)
- Outbreak pathogen: MDR *Escherichia coli*
- 50% (4/8) of elevators harbored MDR *Escherichia coli*

✓ Verfaillie CJ, Bruno MJ, Voor In't Holt AF, Buijs JG, Poley JW, Loeve AJ, Severin JA, Abel LF, Smit BJ, de Goeij I, Vos MC. Withdrawal of a novel-design duodenoscope ends outbreak of a VIM-2-producing *Pseudomonas aeruginosa*. *Endoscopy*. 2015;47(6):493-502.

- Rotterdam, the Netherlands
- Erasmus Medical Center
- 22 ERCP patients infected with a superbug
- Outbreak pathogen: VIM-2 *Pseudomonas aeruginosa*
- Crack in elevator recess harbored:
 - VIM-2 *Pseudomonas aeruginosa*
 - *Enterococcus faecium*

✓ Alrabaa SF, Nguyen P, Sanderson R, Baluch A, Sandin RL, Kelker D, Karlapalem C, Thompson P, Sams K, Martin S, Montero J, Greene JN. Early identification and control of carbapenemase-producing *Klebsiella pneumoniae*, originating from contaminated endoscopic equipment. *AJIC*. 2013;41(6):562-564.

- Tampa, FL
- Hospital A and B (not specified)
- 10 patients infected with a superbug
- Outbreak pathogen: MDR *Klebsiella pneumoniae*
- Elevator harbored:
 - Carbapenem-resistant *Klebsiella pneumoniae*
 - Carbapenem-resistant *Escherichia coli*

✓ Shenoy ES, Pierce VM, Walters MS, Moulton-Meissner H, Lawsin A, Lonsway D, Shugart A, McAllister G, Halpin AL, Zambrano-Gonzalez A, Ryan EE, Suslak D, DeJesus A, Barton K, Madoff LC, McHale E, DeMaria A, Hooper DC. Transmission of Mobile Colistin Resistance (mcr-1) by Duodenoscope. *Clin Infect Dis*. 2018;68(8):1327-1334.

- Boston, MA
- Massachusetts General Hospital
- 1 patient infected with a superbug from another patient with pre-existing infection
- Pathogen: Colistin-resistant *Klebsiella pneumoniae*

suction-biopsy
biopsy port

air-water

elevator

distal end

unspecified



THE EVIDENCE



- Elevator harbored:
 - Colistin-sensitive, MDR *Klebsiella pneumoniae*
 - *Escherichia coli*
 - *Micrococcus luteus*
 - *Staphylococcus epidermidis*
 - *Bacillus* spp.

ELEVATOR MECHANISM & CHANNEL CONTAMINATION

Studies in the United States

- ✓ Brock AS, Steed LL, Freeman J, Garry B, Malpas P, Cotton P. Endoscope storage time: assessment of microbial colonization up to 21 days after reprocessing. *GIE*. 2014;81(5):1150-1154.
 - Charleston, SC
 - Medical University of South Carolina
 - Study included 4 duodenoscopes
 - 100% of elevators harbored microbes, including:
 - *Micrococcus luteus* (49 CFU/mL)
 - Coagulase-negative *Staphylococcus aureus*
- ✓ Visrodia K, Hanada Y, Pennington KM, Tosh PK, Topazian MD, Petersen BT. Duodenoscope reprocessing surveillance with adenosine triphosphate testing and terminal cultures: a clinical pilot study. *GIE*. 2017;86(1):180-186.
 - Rochester, MN
 - Mayo Clinic
 - Study included 20 duodenoscopes and 74 samples
 - Overall, 60% of duodenoscopes were contaminated after HLD:
 - *Stenotrophomonas maltophilia*
 - *Pseudomonas aeruginosa*

- *Klebsiella pneumoniae*
- *Enterococcus faecalis*
- *Cellulosimicrobium*
- Yeast and fungi
- 30% of elevators harbored microbes

- ✓ Mark J, Underberg K, Kramer R. Results of duodenoscope culture and quarantine after manufacturer-recommended cleaning process. *GIE*. 2020.
 - Aurora, CO
 - Children's Hospital Colorado
 - Study included 280 samples of duodenoscopes
 - Overall, 12.5% of 280 were contaminated, including 1 with *Pseudomonas aeruginosa*
 - 17% of 117 elevators harbored >10 CFU
- ✓ Heroux R, Sheppard M, Wright SB, Sawhney M, Hirsch EB, Kalaidjian R, Snyder GM. Duodenoscope hang time does not correlate with risk of bacterial contamination. *AJIC*. 2017;45(4):360-364.
 - Boston, MA
 - Beth Israel Deaconess Medical Center
 - Study included 18 duodenoscopes and 465 samples
 - Overall, 22.2% of samples were contaminated
 - 9.7% of elevators harbored microbes (max CFU: 7,352)
- ✓ De Wolfe TJ, Safdar N, Meller M, Marx Jr. J, Pfau PR, Nelsen EM, Benson ME, Soni A, Reichelderfer M, Duster M, Gopal DV. A prospective, randomized comparison of duodenoscope reprocessing surveillance methods. *Can J Gastroenterol Hepatol*. 2019.
 - Madison, WI
 - University of Wisconsin Hospitals and Clinics, Gastrointestinal Ambulatory Procedure Center



suction-biopsy

biopsy port

air-water

elevator

distal end

unspecified



THE EVIDENCE



- Study included 7 duodenoscopes and 248 samples
 - Overall, 11.7% of samples were contaminated, and high-concern organisms were found:
 - *Staphylococcus aureus*
 - *Escherichia coli*
 - *Sphingomonas*
 - 8.5% of elevators harbored microbes
- ✓ Rex DK, Sieber M, Lehman GA, Webb D, Schmitt B, Kressel AB, Bang JY, Easler J, McHenry L, El-Hajj I, Fogel E, Watkins J, Sherman S. A double-reprocessing high-level disinfection protocol does not eliminate positive cultures from the elevators of duodenoscopes. *Endoscopy*. 2017;50(6): 588-596.
- Indianapolis, IN
 - Indiana University Hospital
 - Study included 56 duodenoscopes and 1,830 samples
 - 6.4% of elevators harbored microbes following double-HLD
 - 0.4% had high-concern organisms, including:
 - *Candida glabrata*
 - *Zygomycete* spp.
 - *Enterococcus* spp.
- ✓ Bartles RL, Leggett JE, Hove S, Kashork CD, Wang L, Oethinger M, Baxter L, Brandabur JJ. A randomized trial of single versus double high-level disinfection of duodenoscopes and linear echoendoscopes using standard automated reprocessing. *GIE*. 2018;88:306-313.
- Renton, WA
 - Providence St. Joseph Health
 - Study included 45 duodenoscopes and 2,925 encounters
 - Overall, 7.7% had contamination

- 5.2% of elevators harbored microbes, including pathogens:
 - *Enterococcus faecalis*
 - *Enterobacter cloacae*
 - *Aeromonas*
 - ESBL ± *Escherichia coli*

- ✓ Snyder GM, Wright SB, Smithey A, Mizrahi M, Sheppard M, Hirsch EB, Chuttani R, Heroux R, Yassa DS, Olafsdottir LB, Davis RB, Anastasiou J, Bapat V, Bidari K, Pleskow DK, Leffler D, Lane B, Chen A, Gold HS, Bartley A, King AD, Sawhney MS. Randomized comparison of 3 high-level disinfection and sterilization procedures for duodenoscopes. *Gastroenterology*. 2017;153(4):1018-1025.

- Boston, MA
- Beth Israel Deaconess Medical Center
- Study included 18 duodenoscopes and 516 samples
- Overall, 18.3% of samples were contaminated:
 - 16.1% had growth after HLD
 - 16% had growth after double-HLD
 - 22.5% had growth after HLD plus ETO gas sterilization
- 2.3% of elevators harbored ≥10 CFU

- ✓ Naryzhny I, Silas D, Chi K. Impact of ethylene oxide gas sterilization of duodenoscopes after a carbapenem-resistant *Enterobacteriaceae* outbreak. *GIE*. 2016;84(2):259-262.

- Park Ridge, IL
- Advocate Lutheran General Hospital
- Study included 6 duodenoscopes
- 1 elevator harbored carbapenemase-resistant *Klebsiella pneumoniae* after HLD+ETO sterilization

suction-biopsy

biopsy port

air-water

elevator

distal end

unspecified



THE EVIDENCE



Studies outside of the United States

- ✓ Azimirad M, Alebouyeh M, Sadeghi A, Khodamoradi E, Aghdaei HA, Mohammad Alizadeh AH, Zali MR. Bioburden and transmission of pathogenic bacteria through elevator channel during endoscopic retrograde cholangiopancreatography: application of multiple-locus variable-number tandem-repeat analysis for characterization of clonal strains. *Expert Rev Med Devices*. 2019;16(5):413-420.
 - Tehran, Iran
 - Shahid Beheshti University of Medical Sciences
 - Study included 68 samples of duodenoscope elevator channels
 - 38.2% of elevators harbored MDR *Pseudomonas aeruginosa*
 - Elevator channels also harbored:
 - *Staphylococcus aureus*
 - *Escherichia coli*
 - *Enterobacter*
 - *Enterococcus*
 - *Clostridium perfringens*
 - *Staphylococcus epidermidis*
- ✓ Ciccozzi M, Cella E, Lai A, De Florio L, Antonelli F, Fogolari M, Di Matteo FM, Pizzicannella M, Colombo B, Dicuonzo G, Angeletti S. Phylogenetic analysis of multi-drug resistant *Klebsiella pneumoniae* strains from duodenoscope biofilm: microbiological surveillance and reprocessing improvements for infection prevention. *Front Public Health*. 2019;7(219):
 - Rome, Italy
 - University Hospital Campus Bio-Medico
 - Study included 5 duodenoscopes and 3 EUS
 - Overall, 87.5% of endoscopes harbored *Klebsiella pneumoniae* in one or more channel
 - 25% of elevator channels harbored *Klebsiella pneumoniae* (including MDR strains)

- ✓ Rauwers AW, Voor In't Holt AF, Buijs JG, de Groot W, Hansen BE, Bruno MJ, Vos MC. High prevalence rate of digestive tract bacteria in duodenoscopes: a nationwide study. *Gut*. 2018;67(9):1637-1645.
 - The Netherlands
 - Nationwide study of 150 duodenoscopes in 67 ERCP centers
 - Overall, 22% of 150 duodenoscopes were contaminated
 - 10% of 148 elevators had microbial growth ≥ 20 CFU
 - 5% of elevators harbored GI/oral microbes (including high-concern organisms)
- ✓ Cristina ML, Sartini M, Schinca E, Ottria G, Dupont C, Bova P, Coccia G, Casini B, Spagnolo AM. Is post-reprocessing microbiological surveillance of duodenoscopes effective in reducing the potential risk in transmitting pathogens? *Int J Environ Res Public Health*. 2019;17(140).
 - Italy
 - Hospital not specified
 - Study included 4 duodenoscopes
 - Overall, 75% of duodenoscopes were highly contaminated
 - Elevators harbored:
 - *Pseudomonas aeruginosa* (2500 CFU/scope); including 60% MDR
 - *Klebsiella pneumoniae*; including 40% ESBL+
 - *Klebsiella oxytoca*
 - *Stenotrophomonas maltophilia*
 - *Acinetobacter baumannii* (2600 CFU/scope)
 - *Escherichia coli*
 - *Citrobacter freundii*



suction-biopsy

biopsy port

air-water

elevator

distal end

unspecified



THE EVIDENCE



- ✓ Paula H, Tribl B, Presterl E, Diab-El Schahawi M. Prospective microbiologic evaluation of the forceps elevator in closed-channel duodenoscopes after reprocessing. *AJIC*. 2017;45(2):121-125.
 - Vienna, Austria
 - Vienna General Hospital
 - Study included 6 duodenoscopes (237 samples)
 - 2% of elevators harbored microbes
- ✓ Rauwers AW, Troelstra A, Fluit AC, Wissink C, Loeve AJ, Vleggaar FP, Bruno MJ, Vos MC, Bode LG, Monkelbaan JF. Independent root cause analysis of contributing factors, including dismantling of 2 duodenoscopes, to an outbreak of multidrug-resistant *Klebsiella pneumoniae*. *GIE*. 2019;90(5):793-804.
 - Utrecht, the Netherlands
 - University Medical Center Utrecht
 - Superbug outbreak investigation involving 27 patients and four duodenoscopes
 - 1 elevator channel harbored:
 - *Acinetobacter pittii* (26 CFU)
 - *Stenotrophomonas maltophilia* (6 CFU)
- ✓ Decristoforo P, Kaltseis J, Fritz A, Edlinger M, Posch W, Wilflingseder D, Lass-Flörl C, Orth-Holler D. High-quality endoscope reprocessing decreases endoscope contamination. *Clin Microbiol Infect*. 2018;24(10).
 - Innsbruck, Austria
 - Medical University Innsbruck
 - Study included 16 duodenoscopes
 - 1 elevator harbored *Staphylococcus aureus*

FDA reports

- ✓ FDA. Olympus Medical Systems Corp. *EVIS EXERA II Duodenovideoscope* 7575724. Silver Spring, MD: June 6, 2018. 2951238-2018-00336.
 - 1 elevator harbored:
 - *Escherichia coli*
 - Coagulase-negative *Staphylococcus*
 - *Bacillus*
- ✓ FDA. Olympus Medical Systems Corp. *Evis Exera II Duodenovideoscope* 8201799. Silver Spring, MD: December 27, 2018. 8010047-2018-02584.
 - *Pseudomonas aeruginosa* found in elevator
 - 1 patient infection with *Enterobacter cloacae*
 - Facility denied patient sepsis and death were linked to contaminated endoscope

DISTAL END CONTAMINATION

- ✓ De Wolfe TJ, Safdar N, Meller M, Marx J Jr, Pfau PR, Nelsen EM, Benson ME, Soni A, Reichelderfer M, Duster M, Gopal DV. A prospective, randomized comparison of duodenoscope reprocessing surveillance methods. *Can J Gastroenterol Hepatol*. 2019.
 - Madison, WI
 - University of Wisconsin Hospitals and Clinics, Gastrointestinal Ambulatory Procedure Center
 - Study included 7 duodenoscopes and 248 samples
 - Overall, 11.7% of samples were contaminated, and high-concern organisms were found:
 - *Staphylococcus aureus*
 - *Escherichia coli*
 - *Sphingomonas*
 - 5.8% of 119 distal end samples harbored microbes

suction-biopsy

biopsy port

air-water

elevator

distal end

unspecified



THE EVIDENCE



- ✓ Rauwers AW, Voor In't Holt AF, Buijs JG, de Groot W, Hansen BE, Bruno MJ, Vos MC. High prevalence rate of digestive tract bacteria in duodenoscopes: a nationwide study. *Gut*. 2018;67(9):1637-1645.
 - The Netherlands
 - Nationwide study of duodenoscopes in 67 ERCP centers
 - Overall, 22% of 150 duodenoscopes were contaminated
 - 56 distal end protective caps were sampled:
 - 11% had microbial growth >20 CFU
 - 5% harbored GI/oral microbes (including high-concern organisms)
- ✓ 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. *AJIC*. 2018;46(6):689-696.
 - USA
 - Study included 5 duodenoscopes
 - Overall, 4 (80%) duodenoscopes were contaminated
 - 1 distal end harbored microbes including *Micrococcus luteus* (4 CFU/swab)

UNSPECIFIED CHANNELS & SURFACES INFECTIONS

- ✓ Aumeran C, Poincloux L, Souweine B, Robin F, Laurichesse H, Baud O, Bommelaer G, Traore O. Multidrug-resistant *Klebsiella pneumoniae* outbreak after endoscopic retrograde cholangiopancreatography. *Endoscopy*. 2010;42(11):895-899.
 - Clermont-Ferrand, France
 - CHU Clermont-Ferrand
 - 16 patients infected with a superbug
 - Outbreak pathogen: ESBL+ *Klebsiella pneumoniae*

- Channels harbored multiple pathogens:
 - ESBL+ *Klebsiella pneumoniae*
 - MDR *Pseudomonas aeruginosa*
 - MDR *Morganella morganii*
- ✓ Carbonne A, Thiolet JM, Fournier S, Fortineau N, Kassis-Chikhani N, Boytchev I, Aggoune M, Segulier JC, Senechal H, Tavolacci MP, Coignard B, Astagneau P, Jarlier V. Control of a multi-hospital outbreak of KPC-producing *Klebsiella pneumoniae* type 2 in France, September to October 2009. *Euro Surveill*. 2010;15(48):1-6.
 - Paris, France
 - Assistance Publique-Hôpitaux de Paris
 - 13 patients infected with a superbug (attack rate: 41%)
 - Outbreak pathogen: Carbapenem-resistant *Klebsiella pneumoniae*
 - Channels harbored multiple pathogens:
 - *Klebsiella pneumoniae*
 - *Enterobacteriaceae*
 - *Enterococcus*
- ✓ Qiu L, Zhou Z, Liu Q, Ni Y, Zhao F, Cheng H. Investigating the failure of repeated standard cleaning and disinfection of a *Pseudomonas aeruginosa*-infected pancreatic and biliary endoscope. *AJIC*. 2015;43(8):e43-46.
 - China
 - 3 consecutive ERCP patients infected, including:
 - 2 patients with:
 - *Pseudomonas aeruginosa*
 - *Klebsiella pneumoniae*
 - *Escherichia coli*
 - 1 patient with *Pseudomonas aeruginosa*
 - Channels (unspecified) harbored *Pseudomonas aeruginosa* that persisted through five reprocessing cycles
 - Suction-biopsy and elevator channels harbored high levels of bacteria

suction-biopsy

biopsy port

air-water

elevator

distal end

unspecified



THE EVIDENCE



UNSPECIFIED CHANNELS & SURFACES CONTAMINATION

- ✓ Paula H, Prestler E, Tribl B, Diab-El Schahawi M. Microbiologic surveillance of duodenoscope reprocessing at the Vienna University Hospital from November 2004 through March 2015. *ICHE*. 2015;36(10):1233-1235.
 - Vienna, Austria
 - Vienna General Hospital
 - Study included 8 duodenoscopes and 412 samples
 - Overall, 11% of samples were contaminated
 - 22.2% of surface samples harbored microbes, including:
 - 1 surface with >100 CFU/10 cm² aerobic spore-forming bacilli
- ✓ FDA. *Olympus Medical Systems Corp. Evis Exera II Duodenovideoscope* 8712959. Silver Spring, MD: June 19, 2019. 2951238-2019-00960.
 - Positive cultures post-ETO detected:
 - *Staphylococcus cohnii* spp *urealyticum*
 - *Staphylococcus*



suction-biopsy

biopsy port

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unspecified

