Is contamination of bronchoscopes really a problem?

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What we know

314

More than 314 patients suspected contaminated by bronchoscopes in US from 2016-2017. (1)

215

215 medical device reports to FDA on contaminated bronchoscopes in 2017. (1)

60

More than 60 outbreak articles published on contaminated bronchoscopes. (3)

Top 1 Health Technology Hazard in 2016

Contamination and inadequate cleaning of endoscopes on ECRI annual list for "Top 10 Health Technology Hazards" past 9 years. (2)

More nosocomial infection and pseudo-infection outbreaks have been linked to contaminated endoscopes than to any other medical device. (4)

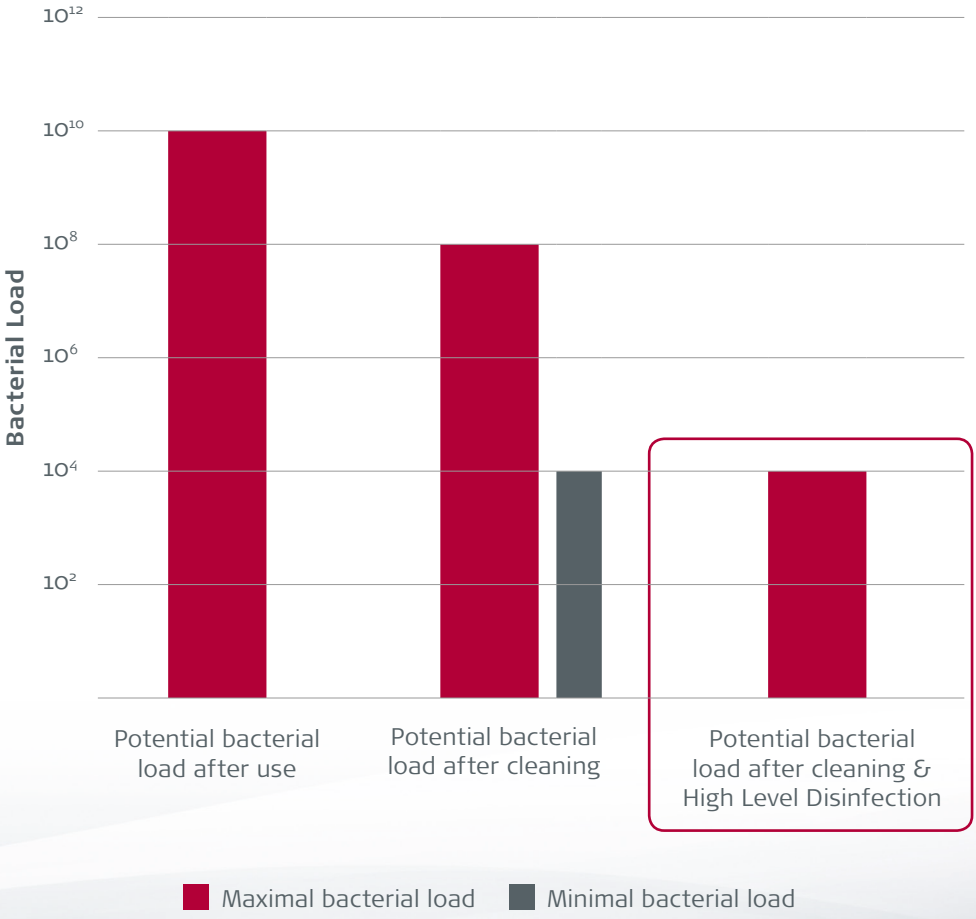
250

Between 2012 and the spring of 2015, endoscopes caused at least 250 life-threatening infections worldwide, including infections with the superbug carbapenem-resistant enterobacteriaceae, according to the results of an investigation conducted by a U.S. Senate committee. (5)

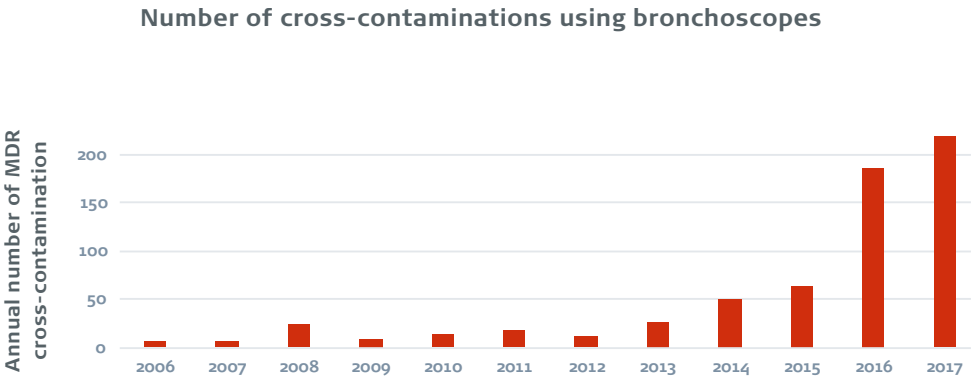
High Level Disinfection does not methodically clean bronchoscopes

Cleaning and High Level Disinfection eliminate somewhere between 6 and 12 logs of microorganisms, but endoscopes can potentially contain 10 log bioburden. Thus even after cleaning and high-level disinfection, **scopes can potentially still have 4 logs left or as many as 10,000 organisms left before essentially next patient use.** (6)

Ofstead et al. 2018 substantiates this as they find 14 (58%) of 24 ready to use bronchoscopes contaminated by a diversity of microbial growth. (7)



Growth in bronchoscope medical device reports to FDA



Number of MDR reports on infection or device contamination associated with reprocessed flexible bronchoscopes. (1)

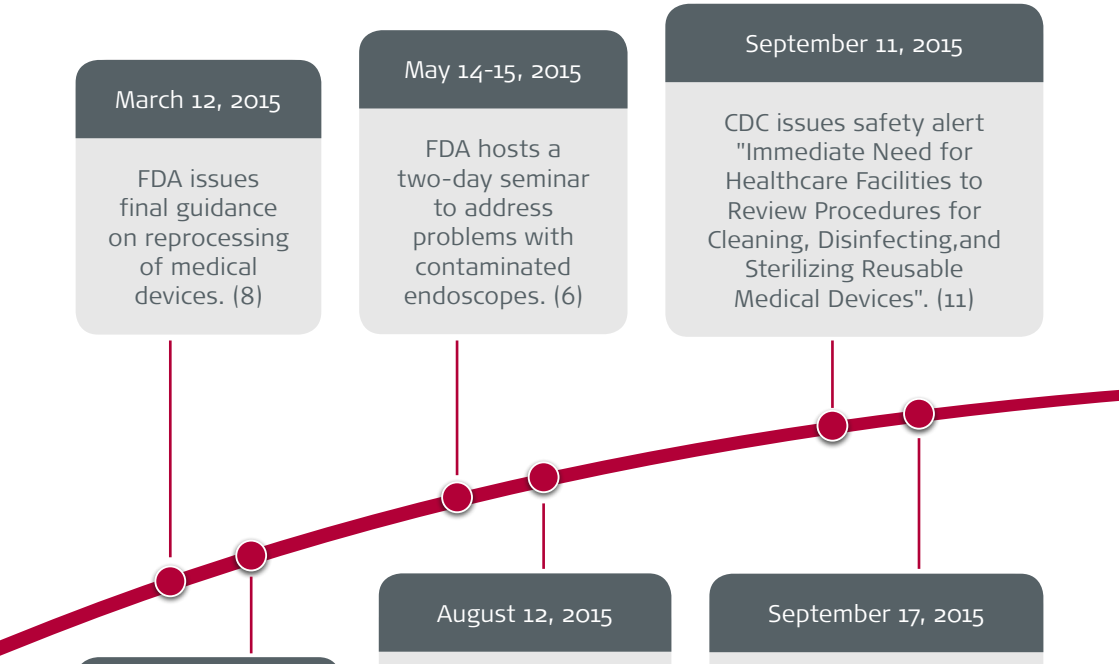
Increased focus on cross-contaminated endoscopes from US authorities over the recent years has led to a high increase in filing of Medical Device Reports (MDR) on bronchoscopes.

The filed reports mention infection or device contamination associated with reprocessed flexible bronchoscopes.

Flexible endoscopes continuously on ECRI Top 10 Health Technology Hazards list

ECRI top 10 health technology hazards year 2010-2017 (2)	
2018	**2. Endoscope Reprocessing Failures Continue to Expose Patients to Infection Risk** **5. Improper Cleaning May Cause Device Malfunctions, Equipment Failures, and Potential for Patient Injury**
2017	**2.** Inadequate Cleaning of Complex Reusable instruments Can Lead to Infections **10.** Device Failures Caused by Cleaning Products and Practices
2016	**1. Inadequate Cleaning of Flexible Endoscopes before Disinfection Can Spread Deadly Pathogens**
2015	**4.** Inadequate Reprocessing of Endoscopes and Surgical Instruments
2014	**6.** Inadequate Reprocessing of Endoscopes and Surgical Instruments
2013	**8.** Inadequate Reprocessing of Endoscopes and Surgical Instruments
2012	**4.** Cross-contamination from Flexible Endoscopes
2011	**3.** Cross-Contamination from Flexible Endoscopes
2010	**1.** Cross-Contamination from Flexible Endoscopes

Since 2015 US authorities have increased cross-contamination considerably



March 12, 2015

FDA issues final guidance on reprocessing of medical devices. (8)

April 29, 2015

AAMI Releases 'Must-Have' Guide for Endoscope Reprocessing – due to public concern about the cleanliness and decontamination of reusable endoscopes. (9)

May 14-15, 2015

FDA hosts a two-day seminar to address problems with contaminated endoscopes. (6)

August 12, 2015

FDA issues warning letters to Olympus, Pentax and Fujifilm for failing to report MDRs to FDA on reusable scopes. (10)

September 11, 2015

CDC issues safety alert "Immediate Need for Healthcare Facilities to Review Procedures for Cleaning, Disinfecting,and Sterilizing Reusable Medical Devices". (11)

September 17, 2015

FDA issues safety communication on bronchoscopes addressing all hospitals and patients. If the reprocessing process is not followed meticulously bronchoscopes can remain contaminated, potentially resulting in infection transmission from one patient to the next. (10)

their focus on endoscope

Ambu
Ideas that work for life

November 9, 2015

Inadequate Cleaning of Flexible Endoscopes Before Disinfection Can Spread Deadly Pathogens becomes number 1 on ECRI Top 10 Health Technology Hazards for 2016. (2)

November 3, 2016

MDR: two patients died due to a contaminated bronchoscope in a US facility. (1)

January 1, 2018

MDR on contaminated bronchoscopes breaks a new record with 215 MDRs reported to FDA in 2017 - 182 reported infections. (1)

November 13, 2015

FDA issues safety communication on Custom Ultrasonics AERs. (13)

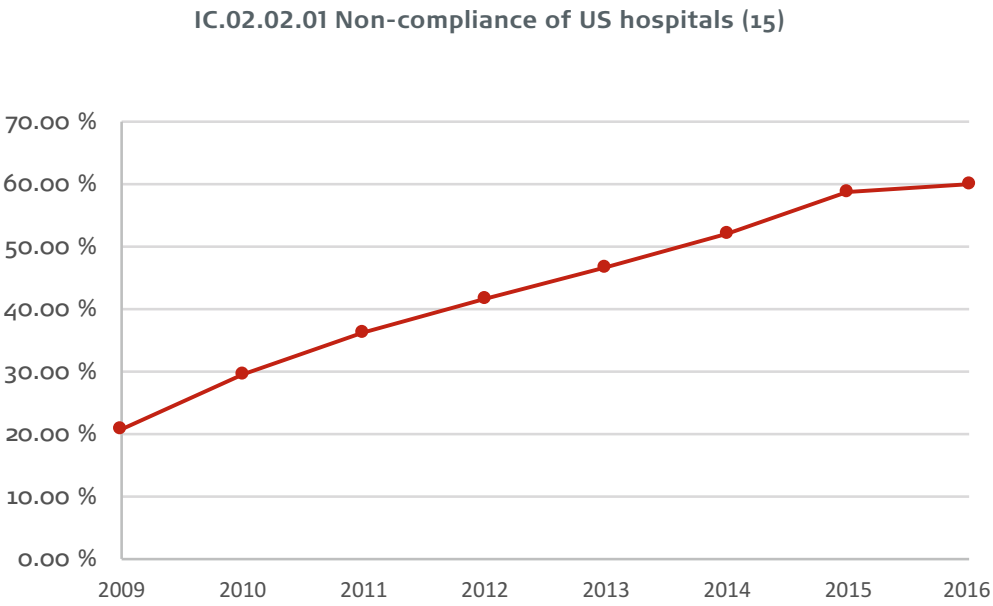
January 20, 2016

US Senate Report Cites Delays in Identifying, Addressing Endoscope Contamination Concerns. (5)

January 25, 2017

CDC releases "Essential Elements of a Reprocessing Program for Flexible Endoscopes – Recommendations of the HICPAC. (14)

Continuous increase in **non-compliance** with an infection control standard



Standard IC.02.02.01: Requires organizations to reduce the risk of infections associated with medical equipment, devices and supplies. Since 2009, there has been a continuous increase in non-compliance with IC.02.02.01 as equipment is improperly high level disinfected (HLD) and sterilized.

The Joint Commission accredits and certifies nearly 21,000 health care organizations and programs in the United States.

"To this point, The Joint Commission has found that from 2013-2016, immediate threat to life (ITL) declarations directly related to improperly sterilized or HLD equipment increased significantly. In 2016, 74 percent of all ITLs were related to improperly sterilized or HLD equipment." (15)

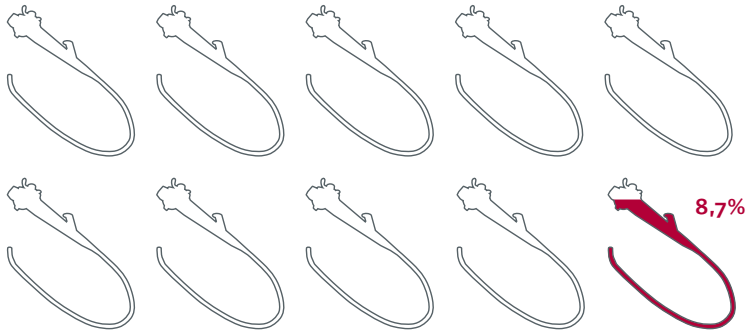
High prevalence of contaminated bronchoscopes

- **A quantification of a systematic literature search revealed an overall 8.7% contamination of bronchoscopes (16-28)**

Mean contaminated scopes ± SEM	8.7% ± 0.7%
Number of samples	1664
Studies included	13
Number of countries	8

- **Studies performed in: Brazil, France, Israel, Italy, Japan, Spain, UK and US**

Contaminated reusable bronchoscopes

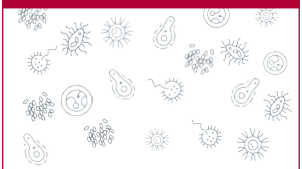


Contaminated reusable bronchoscopes

Search query: "Endoscope contamination" in PubMed.
- Inclusion criterion: published in or after 2008; have conducted tests for microbiological growth on bronchoscopes; the papers state the amount of positive or negative samples or bronchoscopes included.

Cost of infections per bronchoscopy dependents on the risk of cross-contamination

Cost of infection per bronchoscopy

Low risk of cross-contamination	Medium risk of cross-contamination	High risk of cross-contamination
		
0.03*0.2021*15,000 = **£91**	0.08*0.2021*15,000 = **£243**	0.58*0.2021*15,000 = **£1758**
Risk of cross-infection: 3% (29) times risk of subsequent infection: 20.21% (3) times the cost of VAP: £15,000 (30)	Risk of cross-infection: 8% times risk of subsequent infection: 0.21% (3) times the cost of VAP: £15,000 (30)	Risk of cross-infection: 58% times risk of subsequent infection: 0.21% (3) times the cost of VAP: £15,000 (30)

Three different risks of cross-contamination:
- Delphi panel estimates risk of cross-contamination: 3.4% rounded to 3% (29)
- Systematic literature review: 8.7% rounded to 8%
- Ofstead et al 2018 found 58% - 14 out of 24 reusable bronchoscopes contaminated (7)

Reprocessing of an endoscope is highly complex with more than 100 steps

More healthcare–associated outbreaks have been linked to contaminated endoscopes than to any other medical device.

Failure in compliance with scientifically-based reprocessing guidelines has led to numerous outbreaks. (4,14,31)

However, the persistence of contamination on endoscopes, even after adequate reprocessing, is well documented. (4,7,9,18,32,33,)

Experts widely demand a switch from HDL to sterilization or single-use products. (3,7,34,35)

Cori Ofsteads presentation APIC 2018 ***"Patients undergoing bronchoscopy are at high risk for infection. Bronchoscopes are critical instruments that should be sterile. Move towards the use of sterilized or single-use bronchoscopes."*** (31)

CDC Guideline 2008.Disinfection and Sterilization in Healthcare Facilities ***"Unfortunately, audits have shown that personnel do not consistently adhere to guidelines on reprocessing"*** (4)

AAMI 2015 reprocessing guideline ***"In nearly all of these cases, failure to comply with manufacturer's written instructions for use (IFU) or established guidelines or malfunctioning equipment that was undetected has led to numerous outbreaks of infection due to improperly processed flexible and semi-rigid endoscopes."*** (35)

Cori Ofsteads presentation APIC 2018 ***"Patients undergoing bronchoscopy are at high risk for infection. Bronchoscopes are critical instruments that should be sterile. Move towards the use of sterilized or single-use bronchoscopes."*** (31)

In the March 2015 reprocessing guideline, FDA identifies bronchoscopes as being part of a subset of devices that poses a greater likelihood of microbial transmission and represents a high risk of infection if not adequately reprocessed. (8)

With more the than 100 steps for reprocessing each endoscope after use, adherence to new complex guidelines (AAMI/ARON/SGNA) is both **costly** and **time-consuming. (32)**

Cost associated with the reprocessing of endoscopes is estimated to be between **£42-£129 per cycle. (32)**

Comprehensive reprocessing is complex, time consuming, and costly

1 Pre-cleaning at site of use

"To prevent buildup of bioburden, development of biofilms, and drying of secretions, pre-cleaning should take place at the point of use immediately following the procedure.

2 Packaging

Where packaging is recommended, materials should be used which comply with appropriate packaging standards for HDL or sterilization.

3 Transport

Each endoscope should be isolated and transported with its components in its own closed system to the next stage of processing. To avoid puncture and penetration damage to the endoscope, devices such as forceps and wires used in the procedure should be transported in their own containers.

4 Manual cleaning and rinsing

Manual cleaning is considered the most important reprocessing step. Disinfection or sterilization will not be effective if endoscopes are still dirty.

5 Leak testing & High lever disinfection

The process of HLD can be both time-consuming and costly. Some facilities conduct HLD manually others via automated endoscope reprocessors (AER).

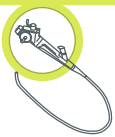
6 Transport

When a bronchoscope has gone through HLD it is usually transported back for storage. Bronchoscopes should be transported in a manner that will not compromise their status.

7 Drying & Storage

According to guidelines an endoscope must be stored vertically in a safe cabin in order to minimize biofilm formation and pathogen growth.

8 Use



Despite this thorough process, there is no guarantee that patient ready bronchoscopes are completely clean.

9 Inspection

Inspection, maintenance or testing of devices must be carried out by suitably trained staff in accordance with the manufacturer's instructions and local policy. Guidelines recommend quarterly testing and microbiological surveillance.

1 Back to Stage 1

Sources 2,3,4,8,9,12,14,32

Recent cases and articles demonstrate a cross-contamination risk from 0.6 to 58%

T.D. Waite et al. 2016 article. UK case (28)

"Pseudo-outbreaks of Stenotrophomonas maltophilia on an intensive care unit in England"
Two pseudo-outbreaks occurred due to contaminated reusable bronchoscopes, affecting a total of 18 patients.
Conclusion
"most notably the change to single-use bronchoscopes, have negated the false-positive reporting of S. maltophilia. In turn, this has reduced the risk of inappropriate antibiotic use and isolation of patients, and has increased patient safety."

M. Guy et al. 2016 article. French case (16)

"Outbreak of pulmonary Pseudomonas aeruginosa and Stenotrophomonas maltophilia infections related to contaminated bronchoscope suction valves, Lyon, France, 2014"
A total of 157 patients exposed to 216 bronchoscopic procedures from 1. December 2013 to 17. June 2014 were analysed. 10 cases of cross-contamination were linked directly to two bronchoscope suction valves, resulting in an **overall contamination risk of 4,6%.**

J. Kovaleva et al. 2013 (3)

Review *"Transmission of Infection by Flexible Gastrointestinal endoscopy and Bronchoscopy"*
Result: Out of a total patient population of 569 the same contaminant was found in the patent as well as in the bronchoscope in 115 cases resulting in **an infection risk of approx. 20%.**

Wang et al. 2018 article. US rates (37)

Significant higher infection rates after bronchoscopy than after colonoscopy and osophagogastroduodenoscopy.
Result: 15,6 out of 1000 (1.56%) patient experienced a post bronchoscopy infection

C.J. Terjesen J. Kovaleva L. Ehlers 2017 (29)

"Early Assessment of the Likely Cost Effectiveness of Single-Use Flexible Video Bronchoscopes"
Overall conclusions

- Using the current technology **(reusable bronchoscopes) is estimated to have an average cost of $US424 and to hold a 0.7% risk of infection.** The newer technology (Single-Use) has an average cost per use of $US305 and a 0% risk of infection.
- **Results show a possible saving of $US118.56 per procedure and the elimination of a 0.7% risk of infection if the single-use option is adopted instead of the current technology.**

Gavalda et al. 2015 article. Spain and Australia investigation (22)

"Microbiological monitoring of flexible bronchoscopes after high-level disinfection and flushing channels with alcohol: Results and costs."
Result: A total of **620 samples** were obtained. 56 samples (9%) tested positive for at least one specimen, of whom 3% were pathogenic or potentially pathogenic microorganisms. **Risk of contamination was 4,1%** without flushing channels with alcohol and **0,6%** when scope channels were flushed.

Cori L. Ofstead al. 2013 article. North America investigation (38)

"Transmission of multidrug-resistant organisms and other pathogens via contaminated endoscopes: Can buildup biofilm be eliminated by routine cleaning and high-level disinfection?"
Result: 251 bronchoscopes tested and in **4% of the bronchoscopes** organic debris remains after cleaning was found.

Cori L. Ofstead al. 2018. Study performed in three large US hospitals (7)

"Microbial growth was found in 14 (58%) fully- reprocessed bronchoscopes, including mold, Stenotrophomonas maltophilia, and Escherichia coli/Shigella spp."
"Visible irregularities were observed in 100% of bronchoscopes, including retained fluid; brown, red, or oily residue; scratches; damaged insertion tubes and distal ends; and filamentous debris in channels. Reprocessing practices were substandard at two of three sites."

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Ambu Ltd.
Burrel Road
St. Ives Cambridgeshire PE27 3LE
Phone +44 1480 498 403
Fax +44 1480 498 405
Language ambu.co.uk

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