Is contamination of bronchoscopes really a problem?

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What we know

210

More than 210 patients contaminated by bronchoscopes in US from 2014-2016 (1)

183

183 medical device reports to FDA on contaminated bronchoscopes in 2016 (1)

60

More than 60 outbreak articles published on contaminated bronchoscopes (2)

Top 1 Hazard

Contamination and inadequate cleaning of endoscopes on ECRI annual list for "Top 10 Health Technology Hazards" past 8 years (3)

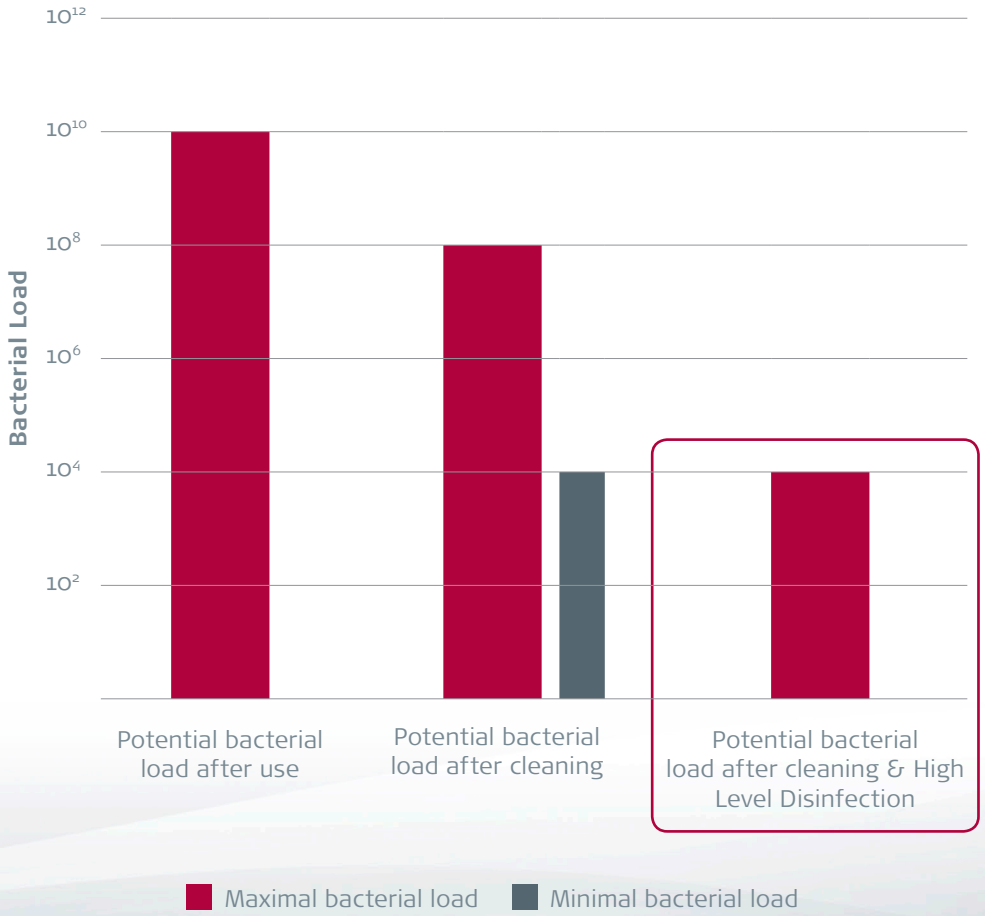
250

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 (4)

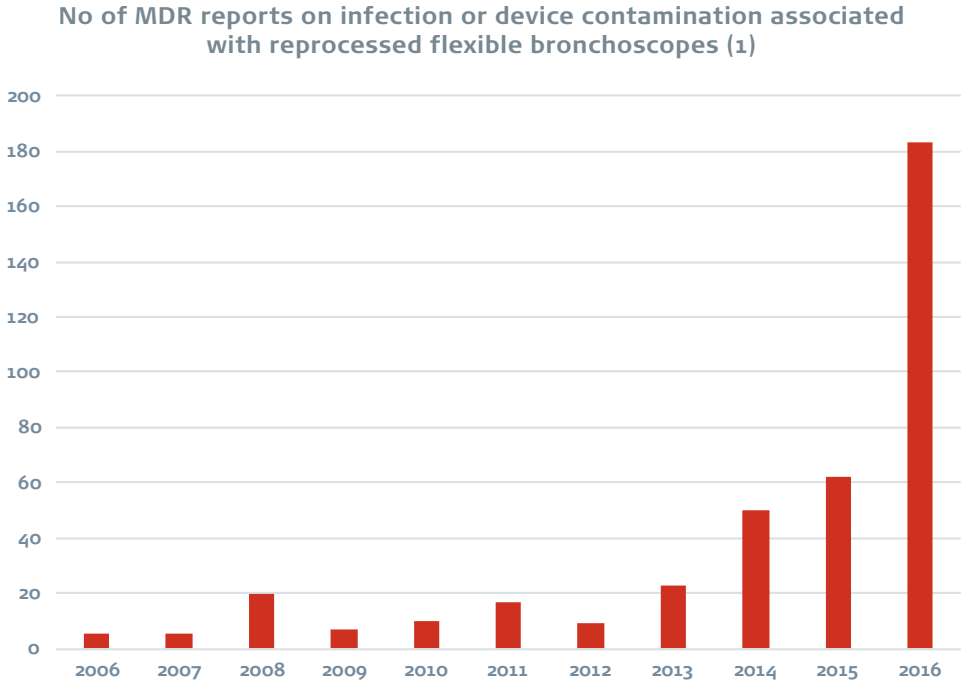
More nosocomial infection and pseudo-infection outbreaks have been linked to contaminated endoscopes than to any other medical device. (5)

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 highlevel disinfection, scopes can potentially still have 4 logs left or as many as 10,000 organisms left before essentially next patient use. (6)



High increase of bronchoscope medical device reports to FDA



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.

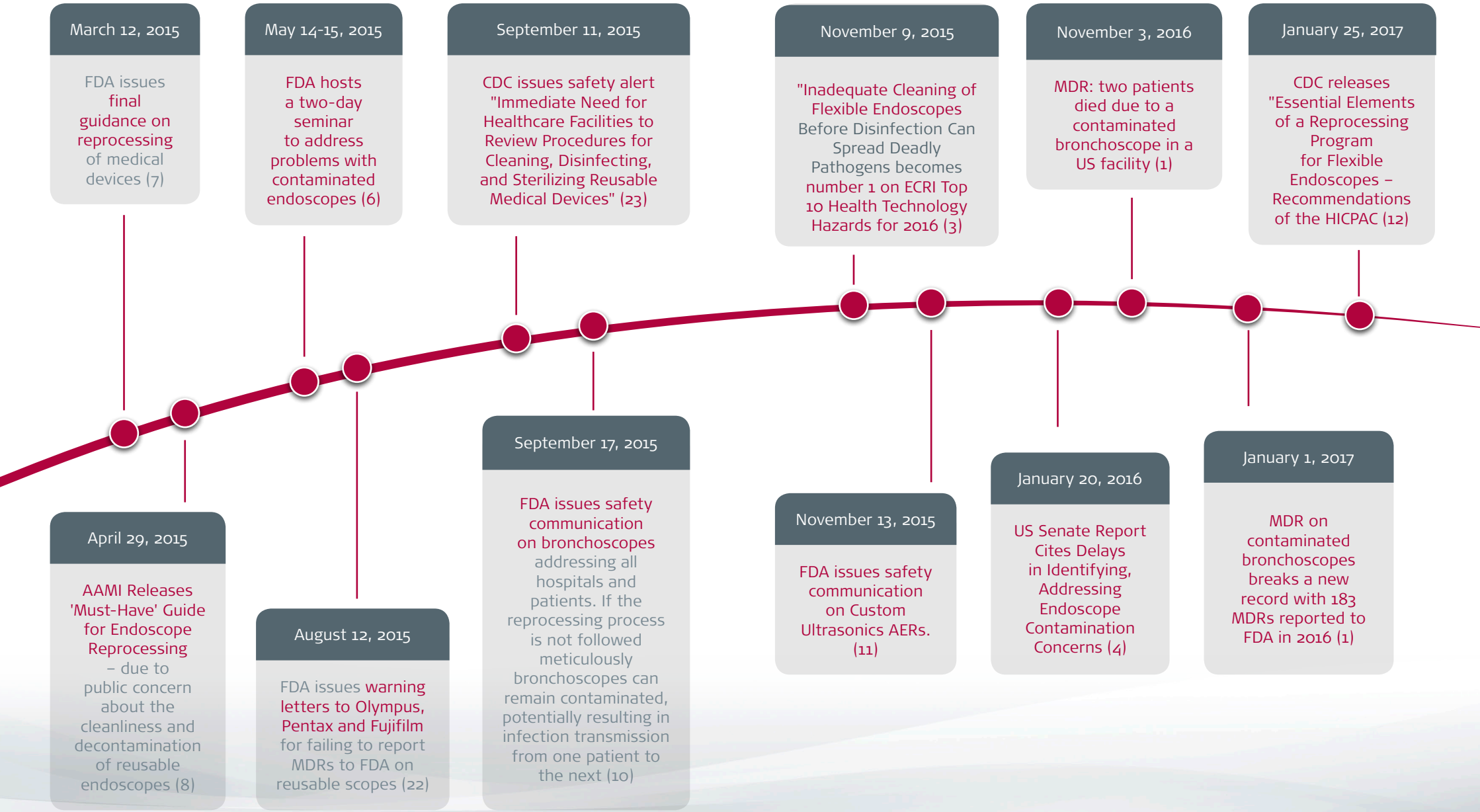
Flexible endoscopes continuously on ECRI Top 10 Health Technology Hazards list

ECRI top 10 health technology hazards year 2010-2017 (3)	
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

For the past 8 years cross-contamination of endoscopes has been recognized as a major patient safety issue by the ECRI organization.

ECRI Institute is a nonprofit US organization focusing on improving patient safety.

Since 2015 US authorities have increased their focus on endoscope cross-contamination considerably



March 12, 2015

FDA issues final guidance on reprocessing of medical devices (7)

April 29, 2015

AAMI Releases 'Must-Have' Guide for Endoscope Reprocessing – due to public concern about the cleanliness and decontamination of reusable endoscopes (8)

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 (22)

September 11, 2015

CDC issues safety alert "Immediate Need for Healthcare Facilities to Review Procedures for Cleaning, Disinfecting, and Sterilizing Reusable Medical Devices" (23)

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)

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 (3)

November 13, 2015

FDA issues safety communication on Custom Ultrasonics AERs. (11)

November 3, 2016

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

January 20, 2016

US Senate Report Cites Delays in Identifying, Addressing Endoscope Contamination Concerns (4)

January 25, 2017

CDC releases "Essential Elements of a Reprocessing Program for Flexible Endoscopes – Recommendations of the HICPAC (12)

January 1, 2017

MDR on contaminated bronchoscopes breaks a new record with 183 MDRs reported to FDA in 2016 (1)

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

Flexible bronchoscopes are difficult to clean and disinfect due to the long and narrow channel. More healthcare–associated outbreaks have been linked to contaminated endoscopes than to any other medical device. (5,12)

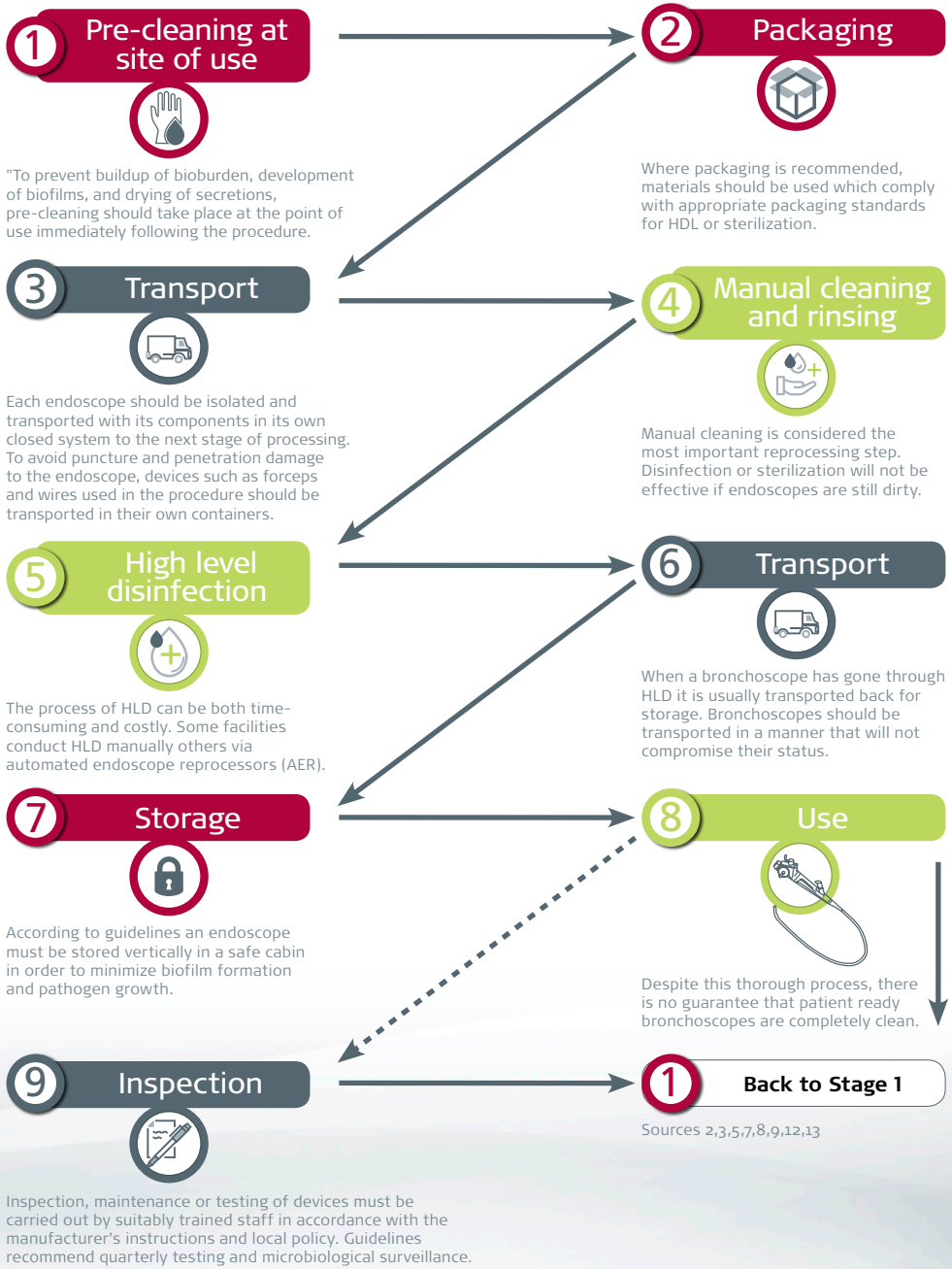
Failure in compliance with scientifically-based reprocessing guidelines has led to numerous outbreaks. However, the persistence of contamination on endoscopes, even after adequate reprocessing, is well documented. (8, 5,13,14)

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. (15)

With more the than 100 steps for reprocessing each endoscope after use, adherence to new complex guidelines (AAMI/ARON/SGNA) is both costly, time-consuming, and occupying various resources. Cost associated with the reprocessing of endoscopes is estimated to be between 50-153 USD per cycle. (13)

The comprehensive reprocessing process is demonstrated in a simplified overview on page 9.

Comprehensive reprocessing is complex, time consuming, and costly



Sources 2,3,5,7,8,9,12,13

Recent cases and articles demonstrate a cross-contamination risk from 0.6 to 4.6%

T.D. Waite et al. 2016 article. UK case (16)

"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. France case (17)

"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 (2)

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%.**

C.J. Terjesen J. Kovaleva L. Ehlers 2017 (18)

"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.**

Cori L. Ofstead al. 2013 article. North America investigation (19)

"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.

Gavalda et al. 2015 article. Spain and Australia investigation (20)

"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 et al. 2016 article. US case (21)

"Practical toolkit for monitoring endoscope reprocessing effectiveness: Identification of viable bacteria on gastroscopes, colonoscopes, and bronchoscopes"
Result: 4 out of 5 patient ready bronchoscopes tested positive for pathogen growth.

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