



## Ambu<sup>®</sup> aScope<sup>™</sup> Broncho

This document includes published studies on bronchoscope performance, sterility, cost-effectiveness, organizational impact, and COVID-19 implications. The studies support claims related to Ambu aScope Broncho single-use endoscopes.

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**Ambu**

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# PREFACE

Ambu aScope Broncho is a sterile single-use bronchoscope that eliminates patient cross-contamination. aScope Broncho eliminates the need for complex reprocessing, ongoing repairs, and microbiological sampling and culturing.

The design of aScope Broncho is based on the latest conventional bronchoscopes, and the familiar form and function delivers consistent performance.

This dossier provides an overview of the evidence related to aScope Broncho. A systematic literature search was conducted to obtain a balanced and impartial overview of the data. It is comprised of studies published from 2013 to 2020 related to performance, sterility, cost-effectiveness, organizational impact, and reusable bronchoscope COVID-19 implications.



## A history of breakthrough ideas

Ambu has been bringing breakthrough healthcare solutions to life since 1937. Today, millions of patients and healthcare professionals worldwide depend on the efficiency, safety and performance of our single-use endoscopy, anesthesia, and patient monitoring diagnostics solutions. Our efforts have evolved from early innovations like the Ambu Bag™ resuscitator and the Ambu BlueSensor™ electrodes to our newest landmark solutions like aScope Broncho - the world's first single-use bronchoscope. Moreover, we continuously look to the future with a commitment to deliver innovative, high-quality products. Ambu leads by example by offering eco-friendly product disposal, all while remaining cost-effective to the consumer.

Headquartered near Copenhagen, Denmark, Ambu employs approximately 4,200 people in Europe, North America and the Asia-Pacific region.

**For more information**, please visit [ambu.com](https://www.ambu.com)

# SUMMARY OF EVIDENCE

Ambu launched the world's first single-use bronchoscope in 2009. Ambu's single-use bronchoscopes are primarily used in Operating Rooms and Intensive Care Units; they are currently being used in 96% of the top 500 United States hospitals. In the last 12 months, Ambu has increased its market share in the United States as the market continues to transition to single-use bronchoscopy to avoid costly and unnecessary expenses associated with mitigating cross-contamination.

The purpose of this dossier is to provide a comprehensive resource to describe the value of aScope Broncho. The dossier provides a summary of performance, sterility, cost-effectiveness, organizational impact, and COVID-19 implications.

## The studies included in this dossier demonstrate:

- aScope Broncho is equivalent to reusable bronchoscopes in performance in the ICU<sup>7</sup>
- aScope Broncho is often the preferred method for both bronchoscopy and intubation<sup>12</sup>
- Healthcare professionals are more satisfied with aScope than with reusable bronchoscopes<sup>15</sup>
- aScope Broncho can achieve a larger broncho alveolar lavage (BAL) volume yield than reusable bronchoscopes<sup>16</sup>
- Reusable bronchoscopes, even when properly reprocessed, do not guarantee sterility and can lead to infection<sup>11</sup>
- Single-use bronchoscopes have the potential to reduce the risk of COVID-19 transmission by eliminating reprocessing, an aerosol-generating procedure<sup>14</sup>
- aScope Broncho is often the cost-effective option for facilities when compared to reusable bronchoscopes<sup>2</sup>
- Single-use bronchoscopes reduce the number of individuals needed to perform a bronchoscopy<sup>7</sup>
- Single-use bronchoscopes are immediately available which allows procedures to be initiated more quickly than with reusable bronchoscopes<sup>14</sup>



Improved or equivalent performance



Greater physician satisfaction



Sterile



Cost-effective

24/7

Always available

# **SYSTEMATIC LITERATURE REVIEW**

# SUPPORTING EVIDENCE-BASED PRACTICE WITH THE BEST AVAILABLE EVIDENCE

## Quality of the studies



### Low Quality of Evidence

- 5-10 years old
- Commentary
- Weak external validity to the United States
- Small sample size



### Medium Quality of Evidence

- 1-5 years old
- Case control and cohort studies
- Moderate external validity to the United States
- Medium sample size



### High Quality of Evidence

- Published in the last year
- Prospective or randomized studies/models and meta analyses
- Strong external validity to the United States
- Large sample size

## How were the studies in this dossier selected?

Two major scientific online databases, PubMed (MEDLINE) and Embase, were searched for all relevant articles from 2010 to 2020. Articles published in the English language within the areas of infection control, performance and health economics were included.

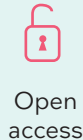


This evidence dossier includes summaries of 16 published studies related to bronchoscopes.



# CLINICAL PERFORMANCE





# TAKE AWAY

The aScope Broncho scored well for ease of use, imaging, and aspiration and had a learning curve score of excellent by the 9th procedure.

# KEY FINDINGS

- Bronchoscopists highlighted its portability, immediacy of use and the possibility of taking and storing images.
- Bronchoscopists were satisfied in 96.6% of the bronchoscopies.
- The cumulative sum (CUSUM) analysis showed average scores > 70/100, or “good”, starting with the first procedure.
- After the 9th procedure, more than 80% of were classified as “excellent”, or a score >80/100.

## Flandes et al. 2020

**Bronchoscopist’s perception of the quality of the single-use bronchoscope (Ambu aScope 4™) in selected bronchoscopies. A multicenter study in 21 Spanish pulmonology services**

### STUDY AIM

To evaluate the perception of the bronchoscopist about the quality of the aScope Broncho and the existence of a learning curve during the performance of bronchoscopies.

# 96.6%

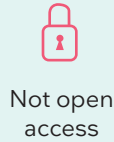
**Physician satisfaction rate with clinical performance of aScope Broncho**



### METHODS

- A prospective, observational, multicenter, cross-sectional study was conducted of an approved single-use bronchoscope
- 21 Spanish pulmonology units were analyzed by utilizing a standardized questionnaire completed by the bronchoscopists at the end of each bronchoscopy.
- Variables were described with absolute and relative frequencies, measures of central tendency and dispersion depending on their nature.
- The existence of learning curves was evaluated by CUSUM analysis.





# TAKE AWAY

aScope Broncho was preferred by physicians over standard methods for both bronchoscopy and intubation.

# KEY FINDINGS

- aScope Broncho was preferred in 86/149 (58%) of cases over standard methods of bronchoscopy
- Higher acceptability of and preference for the aScope Broncho are due to the maneuverability and the optimized visualization of the scope during tracheal intubation or of the bronchial system.
- Advancing the aScope was rated “Easy” or “Very easy” in 87% of cases, versus 60% in standard methods of bronchoscopy”.

## Kriege et al. 2020

**Evaluation of intubation and intensive care use of the new Ambu® aScope™ 4 Broncho and Ambu® aView™ compared to a customary flexible endoscope a multicentre prospective, non-interventional study**

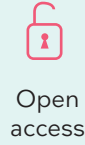
### STUDY AIM

To obtain a broad user perspective on the aScope Broncho, focusing on the device functionalities within regular clinical practice and therapeutic use of flexible endoscopes in the ER, OR, and ICU.



### METHODS

- A prospective multicenter study of the acceptability of and preference for the novel aScope Broncho (with that of the customary flexible endoscope (reusable or single-use) normally used at each of the study centers.
- From September 26th, 2017 to February 28th, 2018, a total of 176 aScope Broncho-aided interventions were evaluated in the OR, ICU or ER at the 8 included study sites.
- Patients 18 years and older eligible for an airway procedure involving a bronchoscopy procedure (tracheal intubation, bronchoalveolar lavage or biopsy) were enrolled.



# TAKE AWAY

Single-use bronchoscopes achieved a larger BAL volume yield than reusable bronchoscopes, with comparable cell yield and viability. This can potentially reduce post-procedure side effects (such as pleuritic chest pain and coughing) and eliminate the risk for infection.

# KEY FINDINGS

- The total volume yield was significantly higher in the aScope 3 regular group: median 152 ml (IQR 141- 166 ml) as compared to conventional 124 ml (110-135 ml).
- The total cell yield and viability were similar in both groups, with no significant differences.
- Single-use bronchoscopes have the potential for use in pharmaceutical preclinical and clinical studies for medicine development.

## Zaidi et al. 2017

Single use and conventional bronchoscopes for broncho alveolar lavage (BAL) in research: a comparative study

### STUDY AIM

To examine single-use bronchoscopes as an alternative to reusable bronchoscopes for BALs.



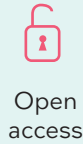
### METHODS

- Observational study of BAL volume, cell count and viability, between 10 procedures utilizing aScope and 50 procedures utilizing conventional multiple-use bronchoscopes in healthy volunteers.
- Broncho alveolar lavage was performed from a sub segmental bronchus within the right middle lobe; a total of 200 ml of warmed normal saline was instilled then aspirated using handheld suction.
- Ten volunteers, (mean age 23 years, six male) participated.

# CONTAMINATION AND INFECTION







# TAKE AWAY

Even the most rigorous reprocessing methods, like ethyl alcohol after each disinfection cycle, cannot guarantee sterile bronchoscopes.

# KEY FINDINGS

- 564 of 620 samples (91.0%) tested negative and 56 samples (9%) tested positive for at least one specimen, of which 3% were pathogenic or potentially pathogenic microorganisms.
- Alcohol treatment reduced the percentage of contamination from 4.1% to 0.6% among the 167 bronchoscopes
- Routine microbiologic monitoring of endoscopes is both time-consuming and expensive but could be saved by implementing a highly efficient decontaminating procedure, such as flushing with 70% ethyl alcohol.

## Gavaldà et al. 2015

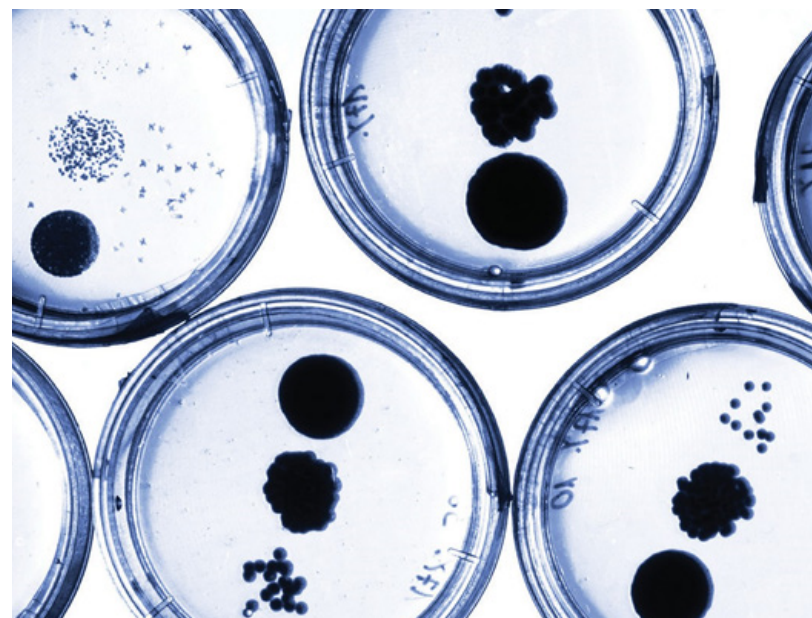
### Microbiological monitoring of flexible bronchoscopes after high-level disinfection and flushing channels with alcohol: results and costs

#### STUDY AIM

To assess whether bronchoscope reprocessing methods achieved an appropriate decontamination level and whether manual flushing with 70% ethyl alcohol at the end of the cycle reduces the risk of microbiological contamination.

#### METHODS

- Direct observation of 18 different bronchoscopes cultured monthly during a four-year period to examine growth of bacteria, fungi, and mycobacteria.
- Additional manual flushing of bronchoscope's channels with 70% ethyl alcohol at the end of each disinfection cycle, was implemented for automatically reprocessed equipment for a two-year period.
- A decision algorithm was designed for interpretation of the relevance of positive culture results, adapted from the Australian guideline for microbiological testing of gastrointestinal and respiratory endoscopes.





Contamination  
and infection



Open  
access

# TAKE AWAY

Contaminated endoscopes have been linked to many outbreaks of device-related nosocomial infections and can cause serious harm and give rise to concerns over these procedures.

# KEY FINDINGS

- Strict adherence to cleaning and disinfection guidelines do not guarantee prevention of biofilm formation during endoscopy.
- The ability of bacteria to form biofilms on the inner channel surfaces can contribute to failure of the decontamination process.
- Implementation of microbiological surveillance of endoscope reprocessing is appropriate to detect early colonization and biofilm formation in the endoscope and to prevent contamination and infection in patients after endoscopic procedures.

## **Kovaleva et al. 2013**

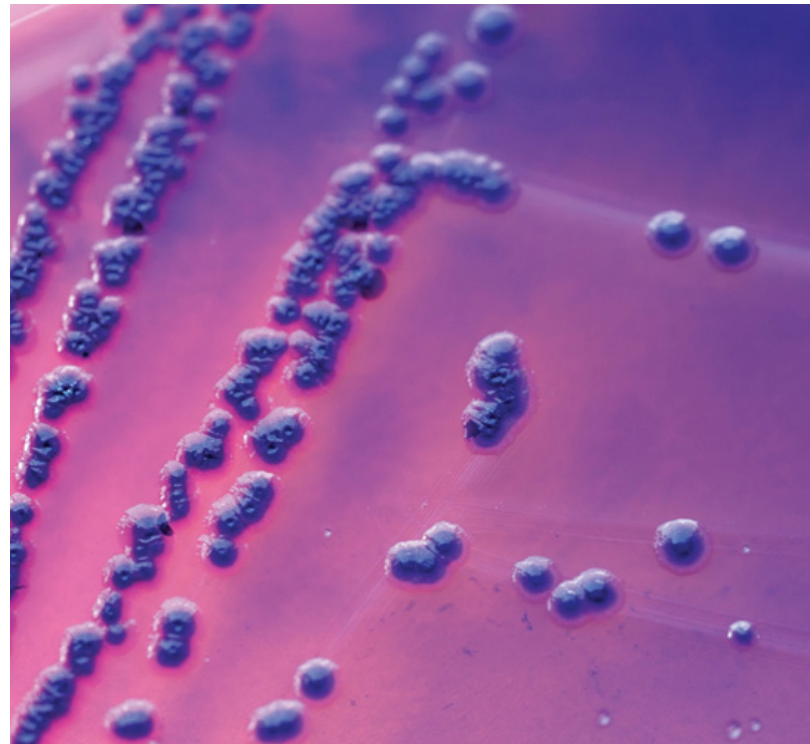
### **Transmission of infection by flexible gastrointestinal endoscopy and bronchoscopy**

#### **STUDY AIM**

To present an overview of the infections and cross-contaminations related to flexible gastrointestinal (GI) endoscopy and bronchoscopy; illustrate the impact of biofilm on endoscope reprocessing and post-endoscopic infection.

#### **METHODS**

- A review of infections and cross-contaminations in flexible gastrointestinal endoscopy and bronchoscopy.





Contamination  
and infection



Not open  
access

## TAKE AWAY

Bronchoscopes may pose an under-recognized potential for transmission of CRE and related MDROs, warranting greater public awareness, enhanced preventive measures, and updated reprocessing guidance.

## KEY FINDINGS

- While bronchoscope transmission of multidrug-resistant bacteria is not a new public health risk, bronchoscopes remaining persistently contaminated specifically with CRE or a related MDRO despite being reprocessed according to manufacturer instructions and published guidelines is a relatively newly identified concern.
- Cleaning and high-level disinfection of bronchoscopes performed in accordance with published guidelines and manufacturer instructions may not always be sufficiently effective to eliminate this risk of CRE and MDRO transmission.
- Factors such as damaged and inadequately serviced bronchoscopes and the presence of an inaccessible biofilm were identified as risks for transmission of MDROs.

### **Mehta et al. 2020**

#### **Bronchoscope-related “superbug” infections**

#### **STUDY AIM**

To investigate the risk of bronchoscopes transmitting infections of carbapenem-resistant enterobacteriaceae (CRE) and related multidrug-resistant organisms (MDROs).



#### **METHODS**

- A systematic review of 12 published cases of bronchoscope-transmitted superbug infections.
- The review additionally aimed to assess whether supplemental measures might be advisable to enhance the safety and effectiveness of bronchoscope reprocessing.
- Published literature and the United States Food and Drug Administration’s medical device database of adverse events were searched beginning in 2012, when endoscopy first emerged as a recognized risk factor for transmission of CRE





Contamination and infection



Not open access

# TAKE AWAY

Contaminated and damaged bronchoscopes were used at all sites as a result of ineffective high-level disinfection, even when guidelines were correctly followed.

# KEY FINDINGS

- Microbial growth was found in 14 of 28 fully reprocessed bronchoscopes (58%), including mold, *Stenotrophomonas maltophilia*, and *Escherichia coli/Shigella* species.
- 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.

## Ofstead et al. 2018

### Effectiveness of reprocessing for flexible bronchoscopes and endobronchial ultrasound bronchoscopes

#### STUDY AIM

To evaluate the effectiveness of real-world bronchoscope reprocessing methods.



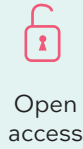
#### METHODS

- Direct observation of reprocessing methods for flexible bronchoscopes, multifaceted evaluations performed after manual cleaning and after high-level disinfection, and assessments of storage conditions.
- Visual inspections of ports and channels were performed using lighted magnification and borescopes.
- Contamination was detected using microbial cultures and tests for protein, hemoglobin, and adenosine triphosphate (ATP).
- ATP tests were used to assess reprocessing practices and storage cabinet cleanliness.

# COVID-19







# TAKE AWAY

Single-use bronchoscopes have the potential to reduce the risk of COVID-19 transmission by eliminating reprocessing, an aerosol-generating procedure.

# KEY FINDINGS

- The single-use bronchoscopes hold several advantages compared to reusable bronchoscopes, including cost, risk of nosocomial infection spread and portability.
- The option for parallel, as opposed to linear, use in the respiratory suite can decrease delays between procedures and increase the number of bronchoscopies that can be performed.
- The immediate availability and the possibility of out-of-hours use is a distinct advantage of single-use bronchoscopes

## **Barron and Kennedy 2020**

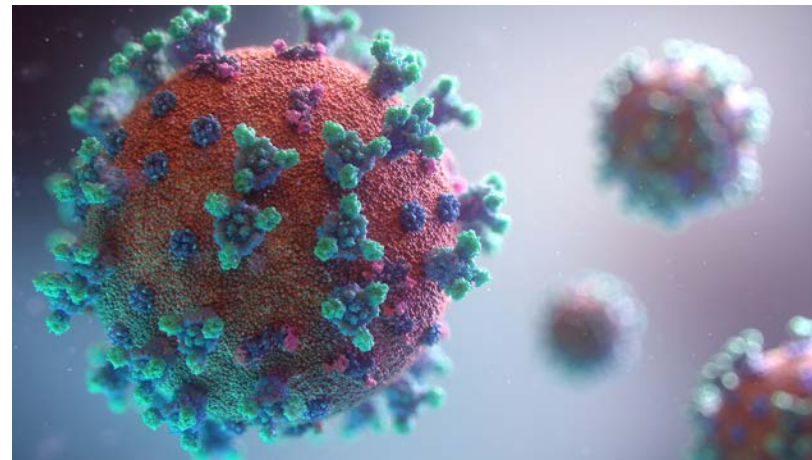
### **Single-use (disposable) flexible bronchoscopes: the future of bronchoscopy?**

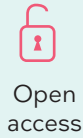
#### **STUDY AIM**

To assess the benefits of single-use bronchoscopes over reusable bronchoscopes during the COVID-19 pandemic.

#### **METHODS**

- A review based on previously conducted studies
- An outline was created for the potential uses of single-use bronchoscopes in a respiratory setting, both during and after the current pandemic.





# TAKE AWAY

Reusable bronchoscopes used in patients with COVID-19 potentially expose patients to contamination leading to a secondary infection and reprocessing staff to COVID-19 droplets during reprocessing. Single-use bronchoscopes will substantially reduce the risk for patients and reprocessing personnel.

# KEY FINDINGS

- The presence of gastrointestinal pathogens found in bronchoscopes and broncho alveolar lavage (BAL) samples suggests the possibility of cross-contamination caused by intermingling bronchoscopes and gastrointestinal endoscopes during reprocessing.
- The American Association for Bronchology and Interventional Pulmonology has recommended the use of sterile, single-use bronchoscopes would substantially reduce the risks for patients and reprocessing personnel.
- Using bronchoscopes that have physical defects and harbor viruses, bacteria, or fungi puts vulnerable patients at risk and could have adverse effects on public health.

## **Ofstead et al. 2020**

### **Potential impact of contaminated bronchoscopes on novel coronavirus disease (COVID-19) patients**

#### **STUDY AIM**

To outline the potential impact of contaminated, reusable bronchoscopes and single-use bronchoscopes on COVID-19 patients.

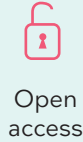


#### **METHODS**

- A review based on previously conducted studies

# COST-EFFECTIVENESS





# TAKE AWAY

aScope is cost-effective, in comparison to reusable bronchoscopes, and is associated with a cost saving £211.12 (\$289.50) and a small gain in quality-adjusted life year (QALYs) (0.0105).

# KEY FINDINGS

- Over a 24-month time horizon, aScope was the cost-effective (dominant) strategy compared to reusable bronchoscopes, with aScope being less costly (£220.00 vs £431.13) or (\$301.70 vs 591.20) and more effective (1.59 vs 1.58 QALYs)
- Implementation of the single-use technology in the intensive care unit is cost-effective in most scenarios.
- Sensitivity analyses demonstrated a net monetary benefit (NMB) of £315.68 at a willingness to pay (WTP) threshold of £10,000/QALY. This is equivalent to \$432.9 at a WTP threshold of \$13,712.3/QALY.
- PSA indicated that aScope had a 100% probability of being cost-effective at a WTP threshold of £10,000/QALY (\$13,712.3/QALY).

## Mærkedahl et al. 2020

### Cost-utility analysis of the Ambu® aScope™ 4 Broncho single-use flexible video bronchoscope compared to reusable flexible video bronchoscopes

## STUDY AIM

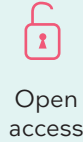
To conduct a cost-utility analysis (CUA) of the aScope vs reusable bronchoscopes from a third-party payer perspective within a 24-month time horizon.

## METHODS

- A decision tree model was developed to estimate the CUA of the aScope vs reusable bronchoscope from a third-party payer perspective within a 24-month time horizon.
- Infection rates, utilities, and model parameters were obtained using targeted literature reviews.
- Scenario and probabilistic sensitivity analyses (PSA) were conducted to explore parametric uncertainties around the base case analysis.
- Procedure-related costs were sourced from literature and unit costs of infections were estimated using United Kingdom National Health Service tariffs







# TAKE AWAY

Single-use bronchoscopes provide a net savings and a reduction in infection when compared to reusable bronchoscopes.

# KEY FINDINGS

- Single-use bronchoscopes have a net savings of £291.00 (\$399.00) per procedure when compared with reusable bronchoscopes.
- The risk for patient contamination (15%) and infection (18%) resulted in a 2.8% risk of patient infection post-bronchoscopy.
- When only United States based studies were examined, the associated risk of infection decreased to 2.4%.
- The micro-costing analysis revealed a mean capital, repair, and reprocessing cost per use of a reusable bronchoscope of £116.40 (\$159.60), £92.90 (\$127.40) and £39.90 (\$54.70), respectively.
- Reusable bronchoscopes were found to have a mean cost per patient of £511.00 (\$700.7) and associated risk of infection of 2.8%.

## Mouritsen et al. 2019

**A systematic review and cost effectiveness analysis of reusable vs. single-use flexible bronchoscopes**

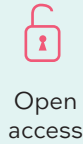
### STUDY AIM

A systematic review and cost effectiveness analysis of reports of cross-contamination or infection following use in any clinical setting.

### METHODS

- A systematic review and cost effectiveness analysis of reports of cross-contamination or infection following reusable bronchoscope use in any clinical setting.
- A micro-costing analysis was performed to quantify the economics of reusable bronchoscopes in the peri-operative setting from a high-throughput tertiary center.
- The risk and incidence of infection was used as a measure of effectiveness and used to determine the cost per patient of treating clinical consequences of bronchoscope-induced infection.





# TAKE AWAY

The cost per procedure for the single-use bronchoscopes is comparable to that for reusable bronchoscopes. The decision process for determining whether to use single-use bronchoscopes or reusable bronchoscopes in an ICU should include the frequency of procedures and the number of bronchoscopes needed.

# KEY FINDINGS

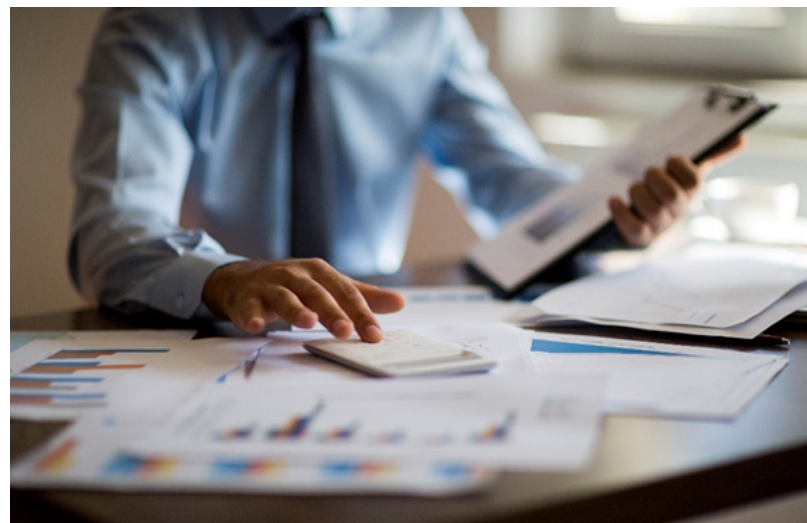
- The costs per PT for reusable bronchoscope 1, reusable bronchoscope 2, and single-use bronchoscopes were € 1613.84 (\$1,958.70), €410.24 (\$497.90), and €204.49 (\$248.20), respectively.
- Reusable bronchoscopes varied significantly in cost depending on the number of procedures performed per year and that cost for purchase and maintenance were most significant. The cost per procedure for the reusable bronchoscopes and single-use bronchoscopes were comparable when there were 55 procedures per year.
- Healthcare professionals were more satisfied with the aScope than with the two reusable bronchoscopes.

## Perbet et al. 2017

### Cost analysis of single-use (Ambu® aScope™) and reusable bronchoscopes in the ICU

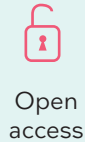
## STUDY AIM

To measure the cost of broncho alveolar lavage (BAL) and percutaneous tracheostomy (PT) using reusable bronchoscopes and single-use bronchoscopes in an ICU of a university hospital. The secondary objective was to compare the satisfaction of healthcare professionals with reusable bronchoscopes and single-use bronchoscopes.



## METHODS

- Cost analysis based on observational data collected between August 2009 and July 2014 in a 16-bed ICU.
- All procedures (BAL and PT) were performed in the ICU by senior physicians.
- A multidisciplinary team, comprising endoscopist physicians, bacteriologists, infection control specialists, biomedical engineers and staff of the endoscope reprocessing unit, coordinated the epidemiological and microbiological investigations.
- Healthcare professional satisfaction with single-use bronchoscopes and reusable bronchoscopes was determined based on eight factors: implementation, anatomic landmarks, device insertion, tracheal positioning, quality of picture, luminosity, kickstand and maneuverability, and global satisfaction.



# TAKE AWAY

Significant savings can be made by using single-use bronchoscopes for percutaneous dilatational tracheostomies (PDTs) instead of reusable bronchoscopes.

# KEY FINDINGS

- Systematic literature search revealed an average acquisition cost of \$135, reprocessing cost of \$123, and repair cost of \$148, resulting in a total average cost of \$406 per PDT procedure for reusable bronchoscopes. single-use bronchoscopes cost an average of \$249 per PDT procedure.
- The estimated savings per use of single-use bronchoscopes compared to reusable bronchoscopes was \$157.

## Sohrt et al. 2019

### Cost comparison of single-use versus reusable bronchoscopes used for percutaneous dilatational tracheostomy

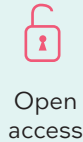
## STUDY AIM

To calculate the cost of using single-use bronchoscopes or reusable bronchoscopes per PDT procedure.

## METHODS

- A systematic literature search was conducted to identify studies comparing the costs of reusable bronchoscopes and single-use bronchoscopes for PDT.
- All costs were estimated in 2016 prices and the calculated costs were presented as means (standard deviations) in USD.
- To gather PDT-specific data, a questionnaire regarding repair rates and the costs of reusable bronchoscopes used for PDT was conducted to supplement the estimation from the literature. Due to scarce resources, western countries were selected. The United States, United Kingdom, and Germany were selected as they represent the biggest markets for single-use bronchoscopes.
- The mean repair cost per bronchoscope use for this study was calculated from questionnaire results and from Perbet et al.<sup>15</sup> weighted by the number of procedures reported.





# TAKE AWAY

Implementation of the single-use technology in the intensive care unit is cost effective in most scenarios.

# KEY FINDINGS

- The CEA showed a savings of \$118 per use and elimination of 0.7% of the risk of infection with single-use technology.
- The current technology is estimated to have an average cost of \$424 per use and 0.7% risk of infection.
- Estimates found current technology has approximately a 3% risk of cross-contamination and a 21% risk of subsequent infection.
- Single-use technology has an average cost of \$305 per use and a 0% risk of infection.
- Pneumonia was estimated to be the most likely manifestation of infection.

## Terjesen et al. 2017

### Early assessment of the likely cost effectiveness of single-use flexible video bronchoscopes

#### STUDY AIM

To conduct an early cost-effectiveness analysis (CEA) of single-use bronchoscope technology compared with the current reusable technology in a US hospital intensive care setting.

#### METHODS

- A CEA was conducted to determine an incremental cost-effectiveness ratio (ICER).
- A decision analytic model based on the best available evidence from a literature search and a Delphi panel was constructed to estimate the short-term costs and benefits of single-use bronchoscopes compared with reusable bronchoscopes
- A literature review was conducted to inform the impact of risk on the model.



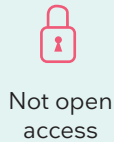


# ORGANIZATIONAL IMPACT





Organizational impact



Not open access

# TAKE AWAY

Single-use bronchoscopes offer many organizational advantages when compared to using reusable bronchoscopes.

# KEY FINDINGS

- Process maps highlighted the complexity of the reusable device process when compared with the single-use device process.
- Among the 12 types of organizational impacts, the single-use bronchoscope scored better than the reusable bronchoscope process in 75% of cases.
- With 15 reusable bronchoscopes available in the institution, using single-use bronchoscopes would represent an extra cost of €154 (\$186.80) per procedure.
- A breakeven analysis found that single-use and reusable devices would have the same cost of €232 (\$281.60) per procedure with an annual procedure volume of 328 bronchoscopies, which is much lower than the current activity (1644 procedures per year).

## Châteauvieux et al. 2018

Single-use flexible bronchoscopes compared with reusable bronchoscopes: positive organizational impact but a costly solution

### STUDY AIM

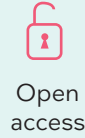
To assess, at a hospital level, the organizational and economic impacts of the introduction of a new medical device, specifically single-use bronchoscopes.

### METHODS

- Process maps were created for both devices (reusable and single-use).
- Interviews with all stakeholders were conducted to examine their organizational and economic impacts.
- Micro-costing analysis was conducted to determine the most economical balance in use of the 2 technologies.







# TAKE AWAY

Single-use bronchoscopes are equivalent in performance and may confer clinical, economic, and logistical advantages over reusable bronchoscopes in the ICU.

# KEY FINDINGS

- Single-use bronchoscopes are an effective alternative to reusable bronchoscopes in the ICU for intubation, bronchial toilet, suction of mucus plug, and airway inspection.
- Single-use bronchoscope microbiological yield was similar to the yield with reusable bronchoscopes, and the reported yield in the literature, with low requirement for a subsequent conventional bronchoscopy.
- The median interval between identification of the need-to-start of the procedure was shorter with single-use bronchoscopes (10 min) versus reusable bronchoscopes (66 min,  $P=0.01$ ).
- 3 personnel (1 intensivist, 1 ICU staff nurse, and 1 respiratory therapist) were needed to perform bronchoscopy with single-use bronchoscopes versus 5 personnel (1 intensivist, 2 endoscopy nurses, 1 ICU staff nurse, and 1 respiratory therapist) with reusable bronchoscopes, with additional resource sparing effect in terms of nursing personnel having to wheel the reusable bronchoscopes equipment to ICU.
- The single-use bronchoscope had a resource-sparing effect with respect to time and personnel as compared to the reusable bronchoscopes.

## Marshall et al. 2017

Experience with the use of single-use disposable bronchoscope in the ICU in a tertiary referral center of Singapore

### STUDY AIM

To compare the utility of single-use bronchoscopes and reusable bronchoscope in the ICU.



### METHODS

- A retrospective review of medical records of 93 patients undergoing flexible bronchoscopy in the ICUs in the year 2015.
- Data were collected retrospectively from patient records and includes patient demographics, indications for procedure, and procedure outcomes.
- The current study was part of an audit as a quality-of-care initiative performed on ICU patients to assess the utility of newly introduced single-use bronchoscopes.

# TECHNICAL SPECIFICATIONS

# Ambu aScope Broncho

aScope Broncho is a sterile single-use bronchoscope that eliminates patient cross-contamination. aScope Broncho eliminates the need for complex reprocessing, ongoing repair, and microbiological sampling and culturing.

The design of aScope Broncho is based on the latest conventional bronchoscopes, and the familiar form and function delivers consistent performance.

## Innovative

aScope Broncho is about enhancing patient safety and workflow. It is always available and sterile straight from the pack. It helps you save time and work smarter by eliminating time-consuming steps required to use, maintain, and handle a reusable scope. It is the ideal solution for a wide range of bronchoscopic procedures.

## Simple set-up

The aScope Broncho solution consists of a single-use bronchoscope and aView2™ HD Monitor unit. Remove aScope Broncho from its packaging, connect it to a View2 HD Monitor, and the system is ready. The system has an integrated rinsing function, and there is no need for an additional light source.

## Familiar control and design

The aScope Broncho Regular has control wheels designed to ensure precise angulation and locking of the endoscope bending section (Up: 180°, Down: 180°). It provides high-definition imaging with the 85°-degree field of view and 6-50mm depth of field ensure optimal visibility of the near and distal bronchial segments. The working channel is designed to enable precise navigation of all segments of the lung as well as the ideal solution for a wide range of bronchoscopic procedures: from intubation to bedside bronchoscopy including BAL & PDT procedures.



## KEY FEATURES

- Sterile straight from the pack, eliminating the risk of patient cross-contamination
- There is no need for reprocessing or repair, which streamlines your daily workflow and reduces associated costs
- Familiar design that ensures a seamless transition from conventional bronchoscopes
- Performs consistently with compatible endoscopic accessories
- Offers cost transparency - one bronchoscope, one price. No long-term service contracts or leasing agreements
- Offers a cost-effective single-use solution

# The Ambu aScope™ 4 Broncho family



## Ambu aScope 4 Broncho Slim

- Insertion cord diameter: 3.8 mm
- Distal end diameter: 4.2 mm
- Channel average inner diameter: 1.2 mm
- Minimum instrument channel width: 1.2 mm



## Ambu aScope 4 Broncho Regular

- Insertion cord diameter: 5.0 mm
- Distal end diameter: 5.4 mm
- Channel average inner diameter: 2.2 mm
- Minimum instrument channel width: 2.0 mm



## Ambu aScope 4 Broncho Large

- Insertion cord diameter: 5.8 mm
- Distal end diameter: 6.2 mm
- Channel average inner diameter: 2.8 mm
- Minimum instrument channel width: 2.6 mm



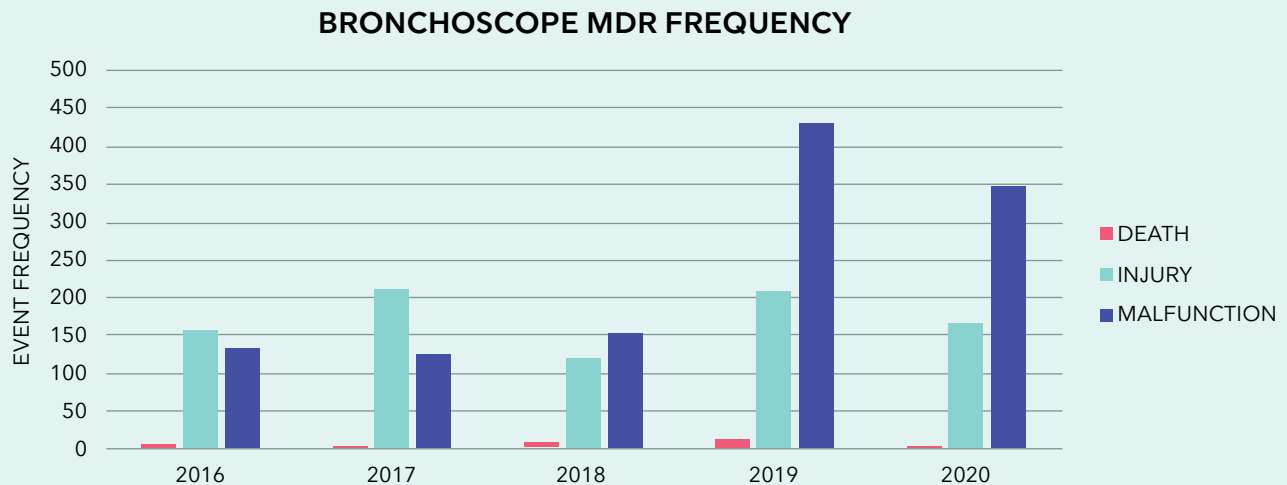
## Ambu aScope 4 Broncho Sampler

- Specifically designed for use with aScope™ 4 Broncho
- Allows user to obtain a sample without having to switch between suction and sampling
- Sterile, closed-loop system supports high-quality sampling by securing and protecting the sample from start to finish

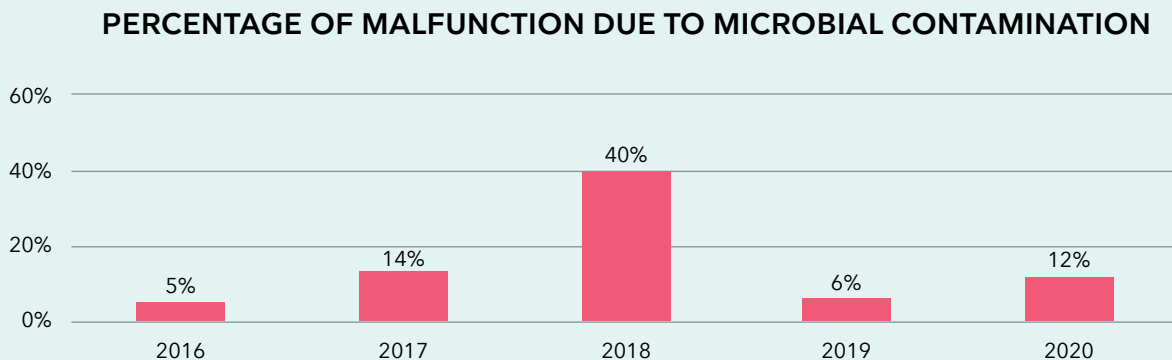
# MANUFACTURER AND USER FACILITY DEVICE EXPERIENCE (MAUDE) REPORT

Each year, the FDA receives several hundred thousand medical device reports (MDRs) of suspected device-associated deaths, serious injuries, and malfunctions. The FDA uses MDRs to monitor device performance, detect potential device-related safety issues, and contribute to benefit-risk assessments of these products. The MAUDE database houses MDRs submitted to the FDA by mandatory reporters (manufacturers, importers, and device user facilities) and voluntary reporters such as health care professionals, patients, and consumers.

The graph below outlines the number of bronchoscope MDRs for death, injury, and malfunction for the years 2016-2020:



The graph below outlines the breakdown, by percentage, of bronchoscope malfunctions due to microbial contamination for the years 2016-2020:



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