# EVIDENCE DOSSIER

Ambu® aScope™ 5 Broncho

Ambu

**April 2022, 1st edition**

This document includes published peer-reviewed studies on contamination, infection control, COVID-19, health economics, clinical performance, organisational impact and environmental impact and initiatives related to the Ambu® aScope™ 5 Broncho.

# CONTENTS

# ABBREVIATIONS

**AGP:** Aerosol-generating procedure

**BAL:** Broncho alveolar lavage

**CAPA:** COVID-19 associated pulmonary aspergillosis

**CT:** Computed tomography

**COVID-19:** Severe acute respiratory syndrome coronavirus 2

**CUSUM:** Cumulative checksum analysis

**DNA:** Deoxyribonucleic acid

**ER:** Emergency room

**FDA:** U.S. Food and Drug Administration

**HCW:** Healthcare worker

**HLD:** High-level disinfection

**HRQoL:** Health-related quality of life

**ICU:** Intensive care unit

**MDR:** Medical device report

**MTG:** Medical technology guidance

**NICE:** National Institute for Health and Care Excellence

**NHS:** UK National Health Service

**OR:** Operating room

**PCR:** Polymerase Chain Reaction

**PPE:** Personal protective equipment

**QALY:** Quality-adjusted life years

**RFB:** Reusable flexible bronchoscope

**RNA:** Ribonucleic acid

**SEPAR:** Spanish Society of Pneumology and Thoracic Surgery

**SFB:** Single-use flexible bronchoscope

# PREFACE

This dossier will help you get an overview of the clinical landscape related to Ambu® aScope™ 5 Broncho, a single-use bronchoscope. The introduction summarizes the Safety Communications that the U.S. Food and Drug Administration (FDA) has issued regarding the risks of patient cross-contamination inherent to reusable flexible bronchoscopes (RFBs). The main section is composed of studies published from 2015 to 2021 related to contamination, infectious outbreaks, COVID-19, health economics, clinical performance, organisational impact, and environmental impact. The last section offers environmental initiatives and an introduction to the benefits of Ambu® aScope™ 5 Broncho.

Each study summary is true to the original publication, and a link to the original manuscript can be found in the references. Should you wish to discuss any publication in this dossier in more detail, do not hesitate to send an inquiry to Global Health Economist Helena Travis (hetr@ambu.com).

The study titles are taken from the publications as they appear in their original form, allowing the reader to make an accurate internet search if they wish to find out more.

We hope this evidence dossier provides you with an understanding of the overall evidence landscape concerning aScope 5 Broncho and assists you in your day-to-day evidence-based practice.

While every effort has been made to provide accurate information, we will be pleased to correct any errors or omissions brought to our notice in subsequent editions.

### A HISTORY OF BREAKTHROUGH IDEAS

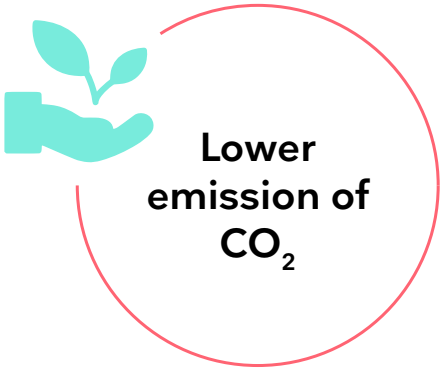
Ambu A/S has been bringing the solutions of the future to life since 1937. Today, millions of patients and healthcare professionals worldwide depend on the efficiency, safety and performance of our single-use endoscopy, anaesthesia, and patient-monitoring diagnostic solutions. The manifestations of our efforts have ranged from early innovations like the Ambu® Bag™ resuscitator and the Ambu® BlueSensor™ electrodes to our newest landmark solutions like Ambu® aScope™ – the world's first single-use flexible endoscope. Moreover, we continuously look to the future with a commitment to delivering innovative quality products, like aScope 5 Broncho, which have a positive impact on your work. As the world's leading supplier of single-use endoscopes, with more than 1 million scopes sold in 2020 alone, Ambu leads by example, offering a service to help you dispose of our bronchoscopes in the most cost-effective, risk-free and eco-friendly way possible. Headquartered near Copenhagen, Denmark, Ambu employs approximately 4,200 people in Europe, North America and the Asia-Pacific region.

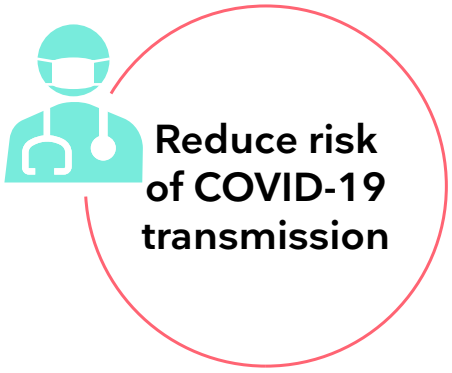
For more information, please visit www.ambu.com

# SUMMARY OF EVIDENCE

The studies included in this dossier demonstrate that:

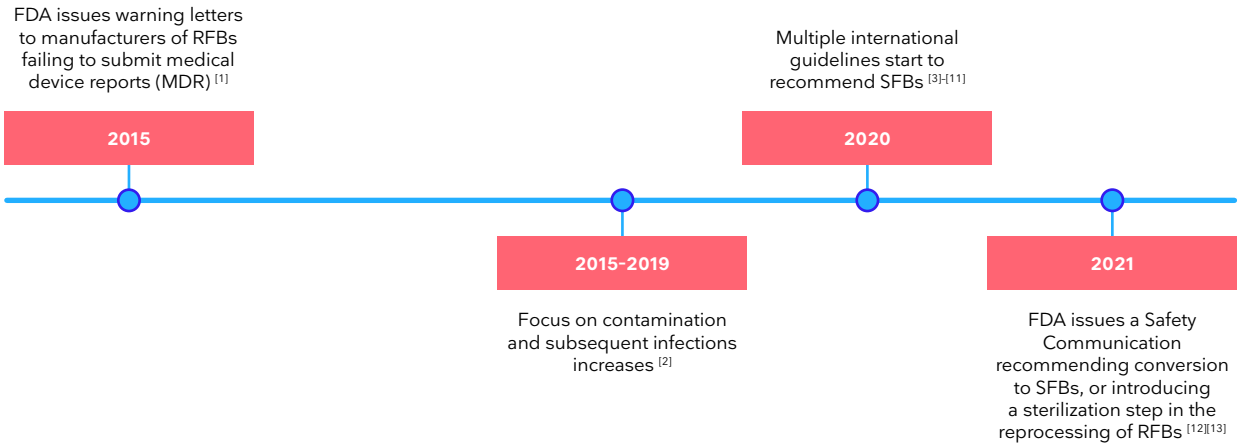
- Even properly reprocessed reusable flexible bronchoscopes (RFBs) cannot guarantee sterility and can lead to patient-to-patient cross-contamination.
- Single-use flexible bronchoscopes (SFBs) have the potential to reduce the risk of COVID-19 transmission by eliminating reprocessing.
- Single-use flexible bronchoscopes are often the cost-effective option for facilities, when compared to RFBs.
- Evidence shows that SFBs have a lower emission of carbon dioxide ($CO_2$) equivalent and energy consumption compared to RFBs.


# FDA SAFETY COMMUNICATIONS

In recent years, the FDA has continually posted Safety Communications and Warning Letters related to reusable flexible endoscopes that potentially compromised patient safety.




## UPDATED SAFETY COMMUNICATION, 25 JUNE 2021

On June 25, 2021, the FDA published a safety communication substantiating bronchoscope-associated cross-infection. To alleviate the cross-infection risk, FDA recommends introducing a sterilization step during the reprocessing of RFBs, and further that SFBs should be considered when there is an increased risk of spreading infection. The FDA gives five scenarios where there is an increased risk of spreading infection, and where SFBs should be considered [12]:

1. Multidrug resistant organisms (MDROs)
2. Immunocompromised patients
3. Patients with prion diseases
4. When there is limited support for reprocessing
5. When treating patients with the severe acute respiratory syndrome coronavirus 2 (COVID-19)

Read the full communication here

> **Consider using a single-use bronchoscope in situations where there is increased risk of spreading infection or when there is no support for immediate reprocessing of the bronchoscope**
>
> *U.S. Food and Drug Administration*

# SUPPORTING EVIDENCE-BASED PRACTICE WITH BEST AVAILABLE EVIDENCE

Evidence-based decision-making is key when purchasing new devices. The core principle of evidence-based practice is the hierarchy of evidence, which identifies the best available evidence for a given clinical question. This document will not go into depth with the different levels of evidence, but instead provide an easy overview that indicates the quality of the respective studies based on the system below. Studies rated as "low quality of evidence" typically cover conference abstracts, editorials, expert opinions, commentaries, and case reports. Studies rated as "medium quality of evidence" include descriptive studies, cohort studies, case-controls, and meta-analyses based on non-RCT studies. Lastly, studies rated as "high quality of evidence" include RCT studies and meta-analyses based on RCT studies.

LOW QUALITY OF EVIDENCE

MEDIUM QUALITY OF EVIDENCE

HIGH QUALITY OF EVIDENCE

### HOW WERE THE STUDIES IN THIS DOSSIER SELECTED?

Two major scientific online databases, PubMed (MEDLINE) and Embase, were searched for all relevant articles up to September 2021. This document only includes studies published after 2015, in order to provide the reader with the most up-to-date evidence.

This evidence dossier includes summaries of 12 published peer-reviewed studies related to bronchoscopes and bronchoscopy procedures.

# CONTAMINATION AND INFECTIONS

★★☆ Infection Open access

# TAKE AWAY

Bronchoscopy-related pseudo-outbreaks occur despite standardised procedures for HLD. New technology that is high-quality disposable or able to undergo sterilisation is needed. Of a total of 35 patients who had a bronchoscopy with a RFB, 10 (28.6%) tested positive for adenovirus infection.

# KEY FINDINGS

**Setting, and first positive Adenovirus PCR results**

- All inpatient bronchoscopies were performed in a single bronchoscopy suite.
- A total of 10 inpatients had positive Adenovirus Polymerase Chain Reaction (PCR) results by multiplex PCR during the investigation period. Eight out of 10 patients had bronchoscopies with one of two bronchoscopes (scope A or scope B) out of the fleet of eight bronchoscopes in this suite.
- The patient with the earliest Adenovirus-positive BAL specimen had evidence of clinical disease, and the subsequent seven patients were asymptomatic.

**Positive adenovirus samples**

- Of a total of 11 patients who had bronchoscopy with scope A and had Adenovirus testing performed during this timeframe, six (55%) had molecular evidence of Adenovirus infection.
- Of a total of 24 patients who had bronchoscopy with scope B and had Adenovirus testing performed during this timeframe, four (17%) were positive.

**Reprocessing setup**

- In-depth review of reprocessing, endoscope handling and storage, and general cleanliness of the bronchoscope-reprocessing area and clinic environment did not yield any deficiencies.

## Pseudo-Outbreak of Adenovirus in Bronchoscopy Suite[14]

Seidelman et al., 2021

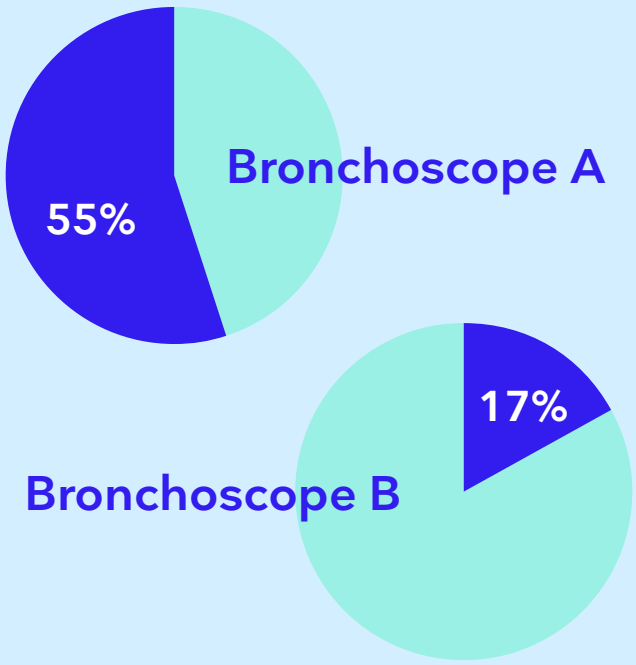
### STUDY AIM

The aim of this study is to investigate a pseudo-outbreak of adenovirus from an academic hospital in the south-eastern United States, after they found a cluster of adenovirus in a broncho alveolar lavage (BAL) sample.

### METHODS

- An epidemiologic investigation was conducted. Medical charts were reviewed to determine symptom status at the time of positive BAL. Procedure logs were reviewed to identify scopes in common among patients and to identify additional patients exposed to implicated scopes.
- Direct observations were made of high-level disinfection (HLD) practices and logs, endoscope storage, and general cleanliness of the bronchoscope-reprocessing area and clinic environment.

**Molecular evidence of Adenovirus infection in patients who were tested:**



★★☆ Infection Not open access

# TAKE AWAY

Reusable flexible bronchoscopes may pose an underrecognized potential risk for transmission of CRE and related MDROs. Cases suggest that high-level disinfection of bronchoscopes performed in accordance with guidelines may not be effective in eliminating the risk of CRE transmission from one patient to another. Damaged RFBs increase this risk.

# KEY FINDINGS

- The review identified 12 cases reported associating a bronchoscope with infections of CRE or a related MDRO, or with bacteria suspected to be one of these two types.
- Ten out of 12 cases reported that the bronchoscope had been reprocessed, five of them according to manufacturer instructions or published guidelines.
- Although the transmission by bronchoscopes 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's instructions and published guidelines is a relatively newly identified concern.

## Bronchoscope-related "superbug" infections[15]

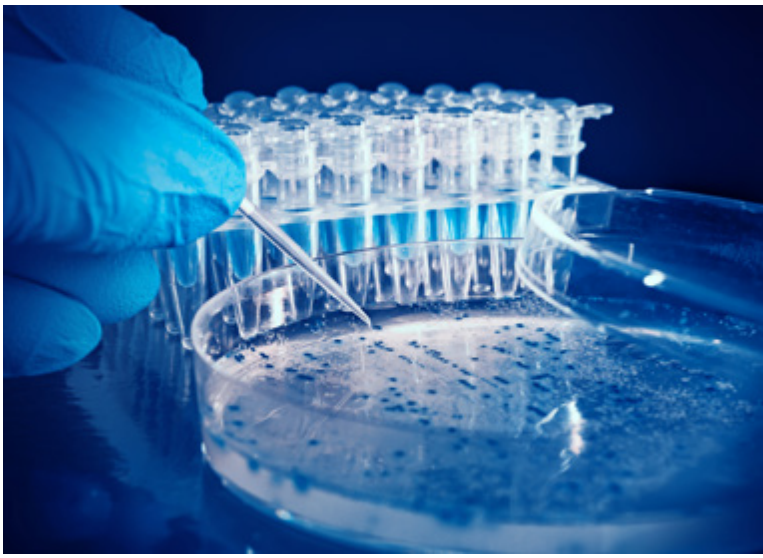
Mehta and Muscarella, 2019

### STUDY AIM

The primary aims of this review were to investigate the risk of bronchoscopes transmitting infections of Carbapenem-resistant Enterobacteriaceae (CRE) and related multi-drug resistant organisms (MDROs), and to assess whether supplemental measures might be advisable to enhance the safety and effectiveness of bronchoscope reprocessing.

### METHODS

- Available medical literature was reviewed by searching the MEDLINE/PubMed database beginning in 2012, when endoscopy first emerged as a recognized risk factor for transmission of CRE.
- The FDA's Manufacturer and User Facility Device Experience Database (MAUDE) was similarly queried to identify these same types of infections by using the product codes "EOQ" and "PSV", which the FDA uses to refer to bronchoscopes. The FDA's device recall database was also queried to determine whether any bronchoscope models associated with an infection of CRE or a related MDRO had been recently recalled due to a potential reprocessing or infection concern.
- The review focuses on "true" infections associated with flexible bronchoscopy, and excludes cases involving rigid bronchoscopes or other types of microorganisms (e.g., mycobacteria and fungi).



★★☆ Contamination Not open access

# TAKE AWAY

Researchers examined 24 clinically used bronchoscopes. After manual cleaning, 100% of bronchoscopes had residual contamination. Microbial growth was found in 14 fully reprocessed bronchoscopes (58%), including mold, Stenotrophomonas maltophilia, and Escherichia coli/Shigella species.

# KEY FINDINGS

- Researchers examined 24 clinically used bronchoscopes (nine therapeutic, nine pediatric, and six EBUS) and two newly acquired therapeutic bronchoscopes that had not been used or reprocessed. Protein was detected in samples from 100% of bronchoscopes after manual cleaning. Microbial growth was found in 14 fully reprocessed bronchoscopes.
- Species identified post-HLD included environmental bacteria and normal flora (e.g., Bacillus spp., Staphylococcus epidermidis), as well as recognized pathogens (e.g., Stenotrophomonas maltophilia, Escherichia coli/Shigella spp.) and mold (Lecanicillium lecanii/Verticillium dahliae).
- Researchers observed irregularities on all clinically used bronchoscopes. Internal examinations identified fluid, discoloration, scratches, filamentous debris, and dented channels. There did not appear to be an association between bronchoscope age, study site, and irregularities.

## Effectiveness of Reprocessing for Flexible Bronchoscopes and Endobronchial Ultrasound Bronchoscopes[16]

Ofstead et al. 2018

### STUDY AIM

To evaluate the effectiveness of real-world bronchoscope-reprocessing methods, using a systematic approach.

### METHODS

- This prospective study was conducted in three large, tertiary-care hospitals in the United States in 2017.
- Site personnel performed reprocessing in accordance with their institutional practices. Researchers maintained strict aseptic technique while obtaining samples after manual cleaning and post-HLD. Tests performed before and after HLD allowed evaluation of changes in organic residue levels after disinfection.
- Microbial culture samples were harvested from ports and distal ends, using sterile swabs moistened with sterile, deionized water that were placed into transport medium (480/482C ESwabs; COPAN Diagnostics). Channel effluent was obtained using the flush-brush-flush technique, and channel swabs and effluent were placed into Dey-Engley neutralizing broth (Hardy Diagnostics). Samples were processed at FDA-registered, International Organization for Standardization-certified microbiology laboratories and incubated at 28° C to 32° C for five to seven days. Species identification was performed for molds and gram-negative bacteria.
- To confirm the validity of sampling and testing methods, clinically used gastroscopes were sampled for use as positive control subjects. Sterile materials were used as negative control subjects.

★★☆ Contamination Open access

# TAKE AWAY

A total of 620 samples were obtained from RFBs: 56 samples (9%) tested positive for at least one specimen. Of the 56 positive samples, 37 (6.0%) corresponded to alert level 1, 10 (1.6%) corresponded to alert level 2 and 9 (1.4%) corresponded to alert level 3.

# KEY FINDINGS

- Microbiology-culture tests were obtained from 18 different bronchoscopes in a total of 620 samples. Of the 620 samples, 564 (91%) were negative for bacteria, mycobacteria and fungi, and 56 (9%) were positive for at least one specimen, of which 37 (6%) corresponded to alert level 1, 10 (1.6%) corresponded to alert level 2 and 9 (1.4%) corresponded to alert level 3.
- The mean annual cost of the surveillance program was estimated at €23,035 for sampling processing.

## Microbiological monitoring of flexible bronchoscopes after high-level disinfection and flushing channels with alcohol: Results and costs[17]

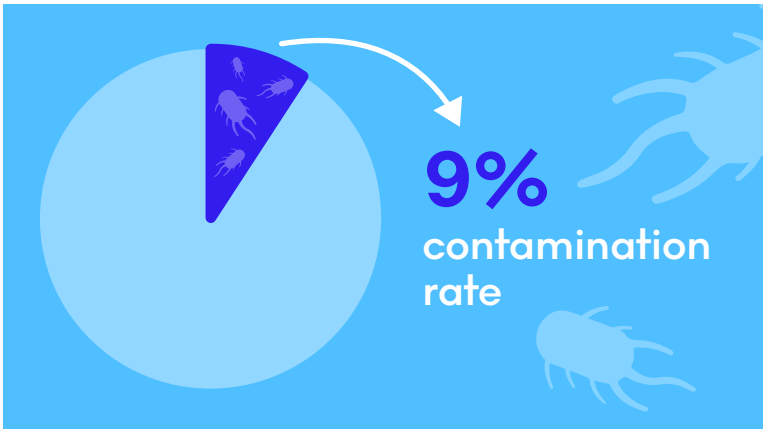
Gavaldà et al., 2015

### STUDY AIM

The study aims to assess whether bronchoscope-reprocessing methods achieved an appropriate decontamination level, and whether manual flushing of 70% ethyl alcohol at the end of the cycle reduces the risk of microbiological contamination.

### METHODS

- During the study period all bronchoscopes were cultured monthly. The cultures were obtained according to the recommendations of the Spanish Society of Pneumology and Thoracic Surgery (SEPAR).
- All samples were handled by an infection control nurse and a technician under an aseptic process. The samples were obtained by a retrograde method, flushing 20 mL of sterile physiological saline through the working channel, and waiting for 5 minutes before collecting the flow-through in three sterile containers to examine the growth of bacteria, fungi, and Mycobacterium species, respectively.
- When bronchoscope contamination with a relevant microorganism was reported by the Microbiology Department, the bronchoscope was taken out of use in patients, and a second sample was obtained. Bronchoscopes shown to be contaminated with the same microorganism in two consecutive cultures were kept out of clinical use and underwent exhaustive revision and sterilization by the manufacturer.



# SINGLE-USE BRONCHOSCOPY IN THE ERA OF COVID-19

COVID-19 Open access

# TAKE AWAY

Bronchoscopy is associated with an increased risk of the spread of COVID-19, not only due to it being an aerosol-generating procedure (AGP) but also because of the requirement of cleaning the RFBs. Although no case of patient-to-patient spread of COVID-19 due to bronchoscopy has been reported, RFBs are associated with contamination by human protein, deoxyribonucleic acid (DNA), and harbour infection even after standard cleaning.

# KEY FINDINGS

- In the hospital environment, certain high-risk procedures have the potential to cause transmission of the virus to healthcare workers (HCWs) and nosocomial transmission to patients through different mechanisms, including the generation of aerosols and fomite formation via contamination of medical devices.
- As bronchoscopes reduce in size, with progression toward the peripheral lung nodule, and evolve further capabilities such as ultrasound and tracking, trickier surfaces for cleaning arise with more crevices for speculative pathogens. As a result, single-use devices should be used where possible, and changing to SFB has been advised by respiratory societies internationally.
- Single-use bronchoscopes have many advantages, including portability, mobility, and availability, thus allowing bronchoscopy out of the bronchoscopy unit and into the intensive care unit (ICU) and emergency room (ER).
- The question of whether RFBs could spread COVID-19 between patients has not been answered, but, if a case arises, it may spell the end of the RFB era in many situations.

## Can single-use bronchoscopes help prevent nosocomial COVID-19 infections?[18]

Barron and Kennedy, 2021

### STUDY AIM

In this review, the authors outline the rationale for transition to SFBs. Further, they have analysed the evidence related to the reduction in COVID-19 transmission arising from a switch to these single-use devices, and the potential impact that this switch may have on the quality of pulmonology services.

### METHODS

This review was conducted to create an overview of the published literature related to reduction of COVID-19 transmission to health-care workers and nosocomial transmission to patients through different mechanisms, including the generation of aerosols and fomite formation via contamination of medical devices.

**Bronchoscopy is associated with an increased risk of the spread of COVID-19**

★☆☆ COVID-19 Open access

# TAKE AWAY

The management of patients with COVID-19 is complex, and bronchoscopy may be helpful under some circumstances, such as tracheobronchial obstruction by secretions and the diagnosis of CAPA. Further, multiple recommendations covering this field have been published, with all of them including protective equipment, disinfection, and to use disposable bronchoscopes when available.

# KEY FINDINGS

**Bronchoscopy in the management of COVID-19**

The management of patients with COVID-19 is complex, and bronchoscopy may be helpful in some circumstances, such as tracheo bronchial obstruction by secretions. Another emergent role of bronchoscopy in COVID-19 patients is for the diagnosis of COVID-19 associated pulmonary aspergillosis (CAPA). An increasing number of reports documenting CAPA cases have raised concerns about this superinfection as an additional contributing factor to mortality.

**Bronchoscopy - how to perform**

At the time of scheduling, patients should be asked about contacts and symptoms. If the patient has risk factors, signs or symptoms of a viral infection, the procedure should be possibly delayed. There are 17 recommendations, including personal protective equipment (PPE), disinfection, and other safety measures such as avoiding rigid bronchoscopy and limiting the number of staff in the room. Further, bullet no. 4 states: *"Use disposable bronchoscopes when available"*.

## Interventional pulmonology during COVID-19 pandemic: current evidence and future perspectives[19]

Piro et al., 2021

### STUDY AIM

In this review, the authors summarize the knowledge and the principal statements about endoscopic activity in the COVID-19 period, for both diagnosis of COVID-19 and management of patients. How to safely perform both bronchoscopy and pleural-related procedures is described, with the aim of helping the staff to decide when and how to perform a procedure. They also highlight how interventional pulmonology could help in the case of complications related to COVID-19.

### METHODS

This review was conducted to create an overview of the published literature on how to tackle bronchoscopy procedures in the era of the COVID-19 pandemic.

# CLINICAL PERFORMANCE

★☆☆ Contami-nation | Infection | Cost | Open access

# TAKE AWAY

Most of the studies on SFBs' efficacy and cost-effectiveness have been in an anaesthetic setting. They outline the benefits of SFBs during the COVID-19 pandemic and provide a rationale for their more frequent use in the pulmonology suite. Single-use bronchoscopy allows for parallel as opposed to linear use in the respiratory suite, which can decrease delays between procedures and increase the number of bronchoscopies that can be performed.

# KEY FINDINGS

- Single-use bronchoscopy allows for parallel as opposed to linear use in the respiratory suite, which can decrease delays between procedures and increase the number of bronchoscopies that can be performed.
- Bronchoscopy is an AGP associated with a high risk of viral transmission during the COVID-19 pandemic.
- Single-use flexible bronchoscopes can reduce the number of healthcare personnel exposed to COVID-19. SFBs have many advantages over their reusable counterparts.
- Most of the studies on SFB efficacy and cost-effectiveness have been in an anaesthetic setting.
- The benefits of SFBs during the COVID-19 pandemic are outlined, and these provide a rationale for their more frequent use in the pulmonology suite.

## Single-Use (Disposable) Flexible Bronchoscopes: The Future of Bronchoscopy?[20]

Barron and Kennedy, 2020

### STUDY AIM

This study aims to outline the potential uses of the SFB in a respiratory setting, during and after the COVID-19 pandemic.

### METHODS

This review was conducted to inform about the situation around a pandemic, and how pulmonologists could translate their new workflow into their everyday work setting.

★★☆ Clinical Performance Open access

# TAKE AWAY

In more than 90% of 300 cases involving aScope 4 Broncho, all the pulmonary segments could be reached, and all the planned techniques could be performed. This gave a general level of satisfaction with the device of 86% and a recommendation for its use in similar cases. The SFB scored well for ease of use, imaging, and aspiration. Further, they found a learning curve with excellent scores from the ninth procedure. Bronchoscopists additionally highlighted its portability, immediacy of use, and the possibility of taking and storing images.

# KEY FINDINGS

- In more than 90% of the cases, all the pulmonary segments could be reached, and all the planned techniques could be performed. This gave a general level of satisfaction with the device of 86% and a recommendation for its use in similar cases.
- Three hundred procedures were performed in total, of which 282 bronchoscopies were satisfactorily performed with aScope 4 Broncho. In 6% of the procedures, the specialists had to change the aScope for their usual bronchoscope.
- The specialists rated the ease of intubation and manoeuvring in the tracheobronchial tree as “very easy” (average score 8/10), and the image and aspiration quality as “optimal” (average score 8/10).
- The learning curve showed excellent results from the ninth procedure.

## Bronchoscopist’s perception of the quality of the single-use bronchoscope (Ambu® aScope™ 4) in selected bronchoscopies: a multicentre study in 21 Spanish pulmonology services[21]

Flandes et al., 2020

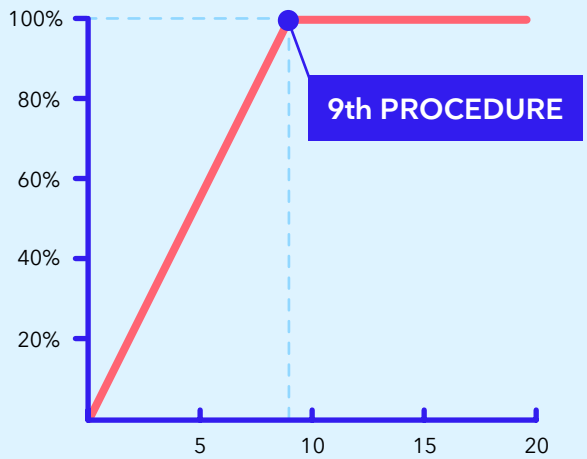
### STUDY AIM

The purpose of the study is to assess the quality of aScope 4 Broncho based on 300 bronchoscopies in 21 Spanish hospitals.

### METHODS

- Bronchoscopists evaluated the quality of the aScope 4 Broncho by setting up a prospective, observational, multicenter, cross-sectional study in 21 Spanish pulmonology services.
- They used a standardized questionnaire completed by the bronchoscopists at the end of each bronchoscopy. The 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 using the cumulative checksum analysis (CUSUM).
- All statistical methods were assessed via Microsoft Excel 2016 (Microsoft Corporation, Redmond, WA, USA) and STATA version 14.0 (StataCorp, Texas, USA).

**Learning curve**



★★☆ Clinical Performance  Not open access

# TAKE AWAY

Physicians prefer aScope 4 Broncho to their conventional RFB, both for intubation and bronchoscopy. In total, 175 procedures were performed, with 26 of them being bronchoscope-assisted intubations and the rest conventional bronchoscopy procedures. One hundred and three (59%) preferred aScope 4 Broncho; 35 (20%) had no preference; and 37 (21%) preferred their conventional RFB. All cases were statistically significant.

# KEY FINDINGS

Overall, physicians had the following preference after conducting 175 intubations and bronchoscopy procedures: 103 (59%) preferred aScope 4 Broncho; 35 (20%) had no preference; and 37 (21%) preferred their conventional RFB. All cases were statistically significant.

- 149 were bronchoscopy procedures
  - 86 (58%) of doctors preferred aScope 4 Broncho
  - 29 (19%) had no preference
  - 34 (23%) preferred their conventional RFB
- 26 were bronchoscope-assisted intubations
  - 17 (65%) preferred aScope 4 Broncho
  - 6 (23%) had no preference
  - 3 (12%) preferred their conventional RFB

## 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[22]

Kriege et al., 2020

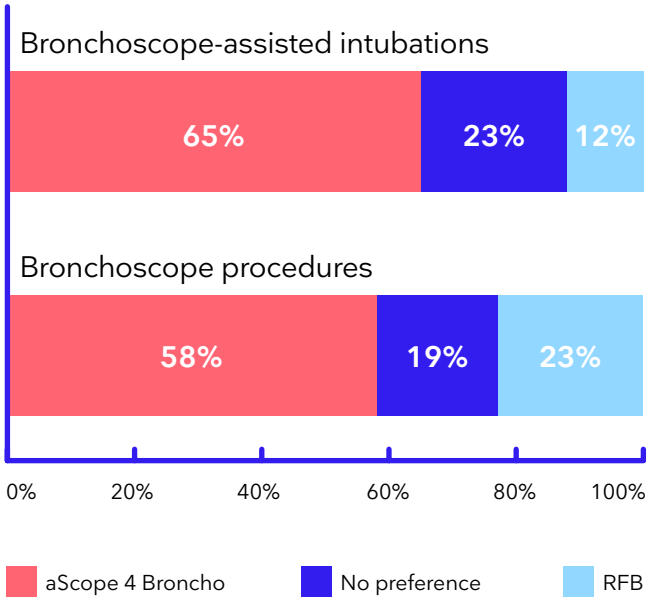
### STUDY AIM

This study aims to compare the utility between the novel aScope 4 Broncho and the standard bronchoscope in a non-interventional study.

### METHODS

- The study is an international, multicenter non-interventional study, investigating the user perspective on aScope 4 Broncho.
- During normal clinical procedures within the operating room (OR), ICU, and ER, where a bronchoscopy was requested, the physician decided which bronchoscope they would use for the procedure.
- After the procedure, the physician filled out the case report form to evaluate the bronchoscope.

### Bronchoscope evaluation



# HEALTH ECONOMICS

★★☆ Cost-effectiveness Open access

# TAKE AWAY

This cost-utility analysis demonstrates that SFBs are cost-effective in comparison with reusable flexible bronchoscopes. They are associated with a cost saving of £211.12 and a small gain in quality-adjusted life years (0.0105).

# KEY FINDINGS

- In the base-case analysis, the total cost and QALYs gained (discounted) regarding aScope 4 Broncho and RFBs were estimated to be £220.00 and 1.59 QALYs, and £431.13 and 1.58 QALYs, respectively.
- This resulted in an incremental cost of -£211.12 (i.e., a saving) and an incremental QALY gain of 0.105 QALYs for the aScope 4 Broncho, indicating that the aScope 4 Broncho was dominant in the base-case analysis.
- The probabilistic sensitivity analysis scatterplot demonstrates that the aScope 4 Broncho was dominant in all iterations. The incremental costs ranged from -£22 up to -£424 per bronchoscopy procedure (i.e., the aScope 4 Broncho procedure was less costly than the RFB procedure).

## Cost-Utility Analysis of the Ambu® aScope™ 4 Broncho Single-Use Flexible Video Bronchoscope Compared to Reusable Flexible Video Bronchoscopes[23]

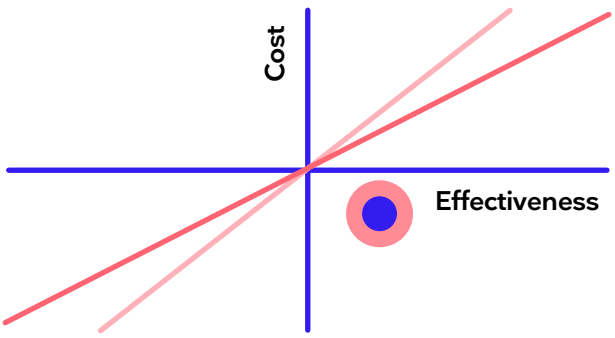
Mærkedahl et al., 2020

### STUDY AIM

This study aims to evaluate the cost-utility of the aScope 4 Broncho compared to RFBs from a UK National Health Service (NHS) perspective.

### METHODS

- A simple decision-tree model estimates the cost-utility of aScope 4 Broncho vs. RFB for bronchoscopy procedures in ICUs for elective care patients.
- The model included costs from a UK third-party payer perspective within a 24-month time horizon.
- The model provided estimates of costs (e.g., acquisition, repair, reprocessing and infections) and quality-adjusted life years (QALYs). All costs and QALYs beyond the first year were discounted at 3.5%, in line with the National Institute for Health and Care Excellence (NICE) reference case.
- The model evaluated aScope 4 Broncho vs. RFB in two separate arms. Each arm had four possible and mutually exclusive outcomes: (1) no infection, (2) sepsis, (3) pneumonia, and (4) tuberculosis. The probability of no infection was set as 1 minus the total probability of the three infection outcomes.
- As aScope 4 Broncho has demonstrated equal performance to RFBs for bronchoscopy procedures, both cohort pathways were assumed to be identical, with the only differences being the costs associated with the use of each device, the cost of infections, the risk of infections, and the associated utility scores, based on health-related quality of life (HRQoL) scores.



# ORGANISATIONAL IMPACT

★★☆ Organisational impact Open access

# TAKE AWAY

**Organisational impact should be considered when assessing medical devices. This study shows that, from an organisational viewpoint, there are many advantages in using SFBs, including working conditions and safety, patient pathways, logistics, training requirements, etc.**

# KEY FINDINGS

- **Among the 12 types of organisational impacts, the SFB process scored better than the RFB process in 75% of cases and was on par in the last 25%.**
- **With the "fleet" of 15 RFBs available in the institution, using SFBs would represent an extra cost of €154 per procedure.**
- **Single-use and reusable devices would in theory have the same cost (€232 per procedure) with an annual activity of 328 bronchoscopies, which is much lower than their current activity of 1,644 procedures per year.**

## Single-use flexible bronchoscopes compared with reusable bronchoscopes: Positive Organisational impact but a costly solution[24]

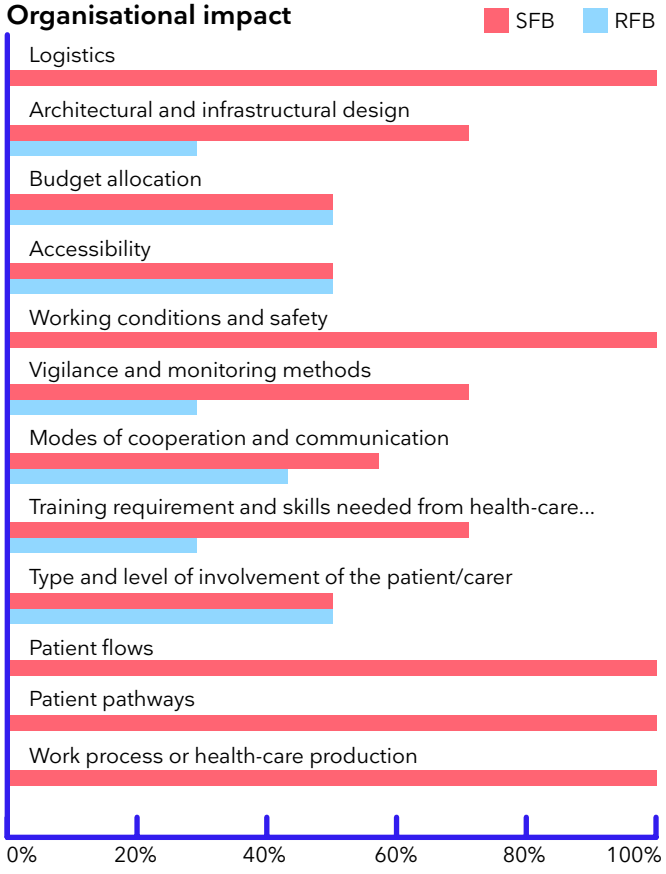
Châteauvieux et al., 2018

### STUDY AIM

The aim of this study was to assess, at a hospital level, the Organisational and economic impacts of the introduction of a new medical device, specifically the SFB.

### METHODS

- Both the organisational and economic impacts of the SFB were evaluated in comparison with the RFB.
- Based on the 12 types of organisational impacts defined by Roussel et al., interviews were conducted with all stakeholders, and the positive and negative aspects of the reusable and single-use processes were analysed.
- Micro-costing analysis was conducted to determine the most economical balance in the use of the two technologies.



# ENVIRONMENTAL IMPACT

★★☆ Environmental impact Open access

# TAKE AWAY

**Using one set of PPE per reprocessing, along with the materials for cleaning and disinfection, determines that RFBs have comparable or higher material and energy consumption, as well as higher emissions of $CO_2$ equivalents.**

# KEY FINDINGS

- **The materials used for the cleaning operations of the RFBs are a key factor affecting the assessed aspects: energy consumption and emission of $CO_2$ equivalent.**
- **Using one set of PPE per reprocessing, and the materials for cleaning and disinfection, determines that reusable scopes have comparable or higher material and energy consumption, as well as higher emissions of $CO_2$ equivalents.**
- **The three assessed parameters are highly dependent on the cleaning procedure and the use of PPE.**

## Comparative Study on Environmental Impacts of Reusable and Single-Use Bronchoscopes[25]

Sørensen et al., 2018

### STUDY AIM

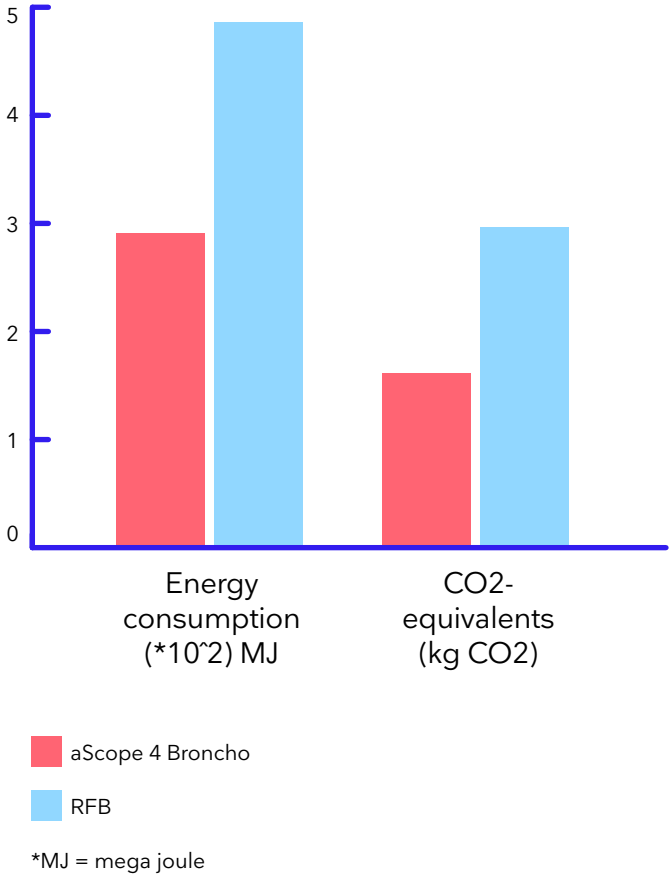
This study aims to compare $CO_2$ equivalent emissions and energy consumption from a SFB (Ambu® aScope™ 4 Broncho) with an RFB.

### METHODS

- The comparison is made using a simplified life-cycle-assessment methodology.
- The assessment compares:

  The use and disposal of one aScope 4 Broncho with the cleaning and sterilisation of one conventional RFB, including PPE.

### Resource consumption




*MJ = mega joule

# ENVIRONMENTAL INITIATIVES

### TAKING A STAND ON THE ENVIRONMENT

As the world's largest supplier of single-use endoscopes, Ambu want to act responsibly. Current regulations prevent Ambu and the end user from recycling the materials used in endoscopes due to the possibility of cross-contamination. The hazardous waste must be burned or sterilized before being disposed of in a landfill. That is why we work towards materials that enable the recycling of our products, and thus contribute to a circular economy. These actions include targets, like recyclable secondary packaging, goals we've already achieved, like phthalate-free products, and other sustainability projects like our partnership with Plastic Bank®.

## 100% **recyclable, reusable or compostable** packaging by 2025*

*if solutions and/or technology exist

Mapping our existing packaging material down to the specific type and following our circular design principles enables us to develop the best possible packaging solution.

## Our products are **100% phthalate-free**

This achievement is the result of many years of dedicated work, collaboration and the prioritisation of safety for patients and healthcare professionals.


**Ambu and Plastic Bank®**

Our partnership with Plastic Bank, is one example of how we contribute to the circular economy. Plastic Bank is an organisation that builds ethical recycling ecosystems and reprocesses the materials for reintroduction into the global manufacturing supply chain.

## A plastic-neutral partnership

Our partnership with Plastic Bank ensures that Ambu® aScope™ endoscopes are plastic neutral in EMEA and Latin America.

- Collectors gather plastic waste that otherwise would have ended up in the ocean in exchange for a premium.
- The plastic is reprocessed for reintroduction into the global manufacturing supply chain.
- The quantity of plastic collected corresponds to the amount of plastic used in all of the Ambu single-use aScope products in EMEA and Latin America throughout the year.

Read about all our Environmental Initiatives here:
www.ambu.com/sustainability

# Ambu® aScope™ 5 Broncho

## SINGLE-USE BRONCHOSCOPY LIKE YOU'VE NEVER SEEN IT BEFORE

Ambu® aScope™ 5 Broncho takes single-use bronchoscopy to a whole new level. It combines the manoeuvrability and high-quality imaging of reusable bronchoscopes with the sterility and efficiency of the single-use concept. The result? You always have access to a sterile single-use bronchoscope with the level of performance needed for a broad range of procedures in the bronchoscopy suite and across the hospital.

**Ambu® aScope™ 5 Broncho HD 5.0/2.2**

**Ambu® aScope™ 5 Broncho HD 5.6/2.8**

**Ambu® aBox™ 2**

aScope 5 Broncho is a family of single-use sterile bronchoscopes that addresses the needs of the bronchoscopy suite. It works with the Ambu® aBox™ 2 display and processing unit with built-in touchscreen.

### A NEW ERA FOR SINGLE-USE BRONCHOSCOPY

aScope 5 Broncho delivers excellent manoeuvrability and imaging. Unlike with traditional bronchoscopes – there is no wear and tear decreasing the quality of the bending performance and imaging because each scope is brand new and only used once.

### GREATER FLEXIBILITY FOR AN OPTIMIZED WORKFLOW

With aScope 5 Broncho, it's easier to plan and manage your schedule because you're not limited by the number of available scopes (as is often the case with reusable bronchoscopes). You have a variety of sizes available in storage whenever you need them. This can save you from the inefficiency and bother of cancellations and rescheduling.

### STERILE AND READY WHEN NEEDED

With the aScope 5 Broncho solution, you can rest assured that you are getting a brand-new, sterile bronchoscope straight from the pack every time, and in this way, eliminating the risk of patient-to-patient contamination. This could be especially relevant in reducing the risk of infection transmission among immunosuppressed pulmonary patient populations.

### KEY FEATURES:

- **Bending angle of 195°/195°**
- **Rotation function with 120° left/right rotation**
- **Compatible with most common endotherapy instruments including active tools**
- **High-resolution camera with 2 LEDs**
- **3-100 mm DoF**
- **120° FoV**
- **Full HD aBox 2 displaying and processing unit**
- **2 endoscope buttons with 4 functionalities**
- **Single-use and sterile: A new scope for every patient**

# REFERENCES


1. The U.S. Food and Drug Administration (FDA), "Safety Communications - Infections Associated with Reprocessed Flexible Bronchoscopes: FDA Safety Communication," 2015, Accessed: Aug. 16, 2021. [Online]. Available: http://wayback.archive-it.org/7993/20170722213119/https:/www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm462949.htm.

2. "MAUDE - Manufacturer and User Facility Device Experience." https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm (accessed Aug. 16, 2021).

3. M. Sorbello et al., "The Italian coronavirus disease 2019 outbreak: recommendations from clinical practice," Anaesthesia, vol. 75, no. 6, pp. 724–732, Jun. 2020, doi: 10.1111/ANAE.15049.

4. Ambu aScope4 Broncho for use in unexpected difficult airways Medical technologies guidance," 2013, Accessed: Aug. 16, 2021. [Online]. Available: www.nice.org.uk/guidance/mtg14.

5. Manual 38. Seguridad en endoscopia respiratoria | separ." https://www.separ.es/node/973 (accessed Aug. 16, 2021).

6. C. Diaz-Agero Pérez, A. Figuerola Tejerina, V. Monge Jodra, and A. Rincón Carlavilla, "Guía para la prevención y control de infecciones en endoscopia flexible," Soc. Madrilena Med. Prev., 2020, Accessed: Aug. 16, 2021. [Online]. Available: https://www.smmp.es/wp-content/uploads/2020/06/Guía-para-la-Prevención-y-Control-de-Infecciones-en-Endoscopia-Flexible.pdf

7. C. R. Bailey et al., "Infection prevention and control 2020," Accessed: Aug. 16, 2021. [Online]. Available: www.anaesthetists.org.

8. 2020 AABIP Statement on COVID-19 Infections; March 19th Updates | AABIP." https://aabronchology.org/2020/03/12/2020-aabip-statement-on-bronchoscopy-covid-19-infection/ (accessed Aug. 16, 2021).

9. COVID-19: infection prevention and control (IPC) - GOV.UK." https://www.gov.uk/government/publications/wuhan-novel-coronavirus-infection-prevention-and-control (accessed Aug. 16, 2021).

10. COVID-19 | Associazione Nazionale Infermieri di Area Critica." https://www.aniarti.it/covid-19/ (accessed Aug. 16, 2021).

11. Précautions particulières pour la réalisation d'une endoscopie bronchique durant la phase épidémique COVID-19. Recommandations de la Société de pneumologie de langue Française (SPLF)."

12. Ambu White Paper, "Flexible Bronchoscopes and Updated Recommendations for Reprocessing: FDA Safety Communication," pp. 12–14, 2021, [Online]. Available: https://www.fda.gov/medical-devices/safety-communications/flexible-bronchoscopes-and-updated-recommendations-reprocessing-fda-safety-communication?utm_medium=email&utm_source=govdelivery.

13. The U.S. Food and Drug Administration (FDA), "Flexible Bronchoscopes and Updated Recommendations for Reprocessing: FDA Safety Communication | FDA," 2021. https://www.fda.gov/medical-devices/safety-communications/flexible-bronchoscopes-and-updated-recommendations-reprocessing-fda-safety-communication?utm_medium=email&utm_source=govdelivery (accessed Jun. 29, 2021).

14. J. Seidelman et al., "Pseudo-Outbreak of Adenovirus in Bronchoscopy Suite," Infect. Control Hosp. Epidemiol., pp. 1–5, Apr. 2021, doi: 10.1017/ice.2021.129.

15. A. C. Mehta and L. F. Muscarella, "Bronchoscope-Related 'Superbug' Infections," Chest, vol. 157, no. 2, pp. 454–469, 2020, doi: 10.1016/j.chest.2019.08.003.

16. C. L. Ofstead et al., “Effectiveness of Reprocessing for Flexible Bronchoscopes and Endobronchial Ultrasound Bronchoscopes,” Chest, vol. 154, no. 5, pp. 1024–1034, 2018, doi: 10.1016/j.chest.2018.04.045.

17. Gavaldà, L., Olmo, A. R., Hernández, R., Domínguez, M. A., Salamonsen, M. R., Ayats, J., et al. (2015). Microbiological monitoring of flexible bronchoscopes after high-level disinfection and flushing channels with alcohol: Results and costs. Respiratory Medicine, 109(8), 1079–1085. https://doi.org/10.1016/j.rmed.2015.04.015

18. S. Barron and M. P. Kennedy, “Can single-use bronchoscopes help prevent nosocomial COVID-19 infections?,” Expert Rev. Med. Devices, vol. 00, no. 00, pp. 1–5, 2021, doi: 10.1080/17434440.2021.1920924.

19. R. Piro et al., “Interventional pulmonology during COVID-19 pandemic: Current evidence and future perspectives,” J. Thorac. Dis., vol. 13, no. 4, pp. 2495–2509, 2021, doi: 10.21037/jtd-20-2192.

20. S. P. Barron and M. P. Kennedy, “Single-Use (Disposable) Flexible Bronchoscopes: The Future of Bronchoscopy?,” Adv. Ther., 2020, doi: 10.1007/s12325-020-01495-8.

21. A. Mærkedahl, A. Lindvig, A. Pagh, and R. Russel, “Cost-Utility Analysis of the Ambu® aScope™ 4 Broncho Single- Use Flexible Video Bronchoscope Compared to Reusable Flexible Video Bronchoscopes,” pp. 1–6, 2020.

22. J. Flandes et al., “Bronchoscopist’s perception of the quality of the single-use bronchoscope (Ambu aScope4™) in selected bronchoscopies: a multicenter study in 21 Spanish pulmonology services.,” Respir. Res., vol. 21, no. 1, p. 320, 2020, doi: 10.1186/s12931-020-01576-w.

23. M. Kriege et al., “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,” Trends Anaesth. Crit. Care, vol. 31, pp. 35–41, Apr. 2020, doi: 10.1016/j.tacc.2020.02.001.

24. C. Châteauvieux et al., “Single-use flexible bronchoscopes compared with reusable bronchoscopes: Positive Organisational impact but a costly solution,” J. Eval. Clin. Pract., vol. 24, no. 3, pp. 528–535, 2018, doi: 10.1111/jep.12904.

25. B. Lilholt Sørensen and H. Grüttner, “Comparative Study on Environmental Impacts of Reusable and Single-Use Bronchoscopes,” Am. J. Environ. Prot., vol. 7, no. 4, p. 8, 2018, doi: 10.11648/j.ajep.20180704.11.