EVIDENCE DOSSIER

Ambu® aScope™ 4 Broncho

Ambu

June 2023, 2nd edition

This document includes published peer-reviewed studies on clinical performance, infection control, contamination, cost-effectiveness and organizational impact related to the Ambu aScope 4 Broncho.

CONTENTS

ABBREVIATIONS

AABIP: The American Association for Bronchology and Interventional Pulmonology

AAMI: The Association for the Advancement of Medical Instrumentation®

BAL: Bronchoalveolar lavage

CDC: Centers for Disease Control and Prevention

ECRI: Emergency Care Research Institute

FDA: U.S. Food & Drug Administration

FOB: Flexible fiber-optic bronchoscope

HICPAC: Healthcare Infection Control Practices Advisory Committee

HLD: High-level disinfection

ICU: Intensive care unit

MDR: Medical device report

MTG: Medical technology guidance

OI: Organizational Impact

SEPAR: Spanish Society of Pneumology and Thoracic Surgery

SPLF: French Language Society of Pneumology

SUFB: Single-use flexible bronchoscope

PREFACE

This dossier will help you get an overview of the clinical landscape related to Ambu® aScope™ 4 Broncho, a single-use bronchoscope. The introduction summarizes the Safety Communications the Food & Drug Administration (FDA) has issued regarding the risks of patient cross-contamination inherent to reusable bronchoscopes and Manufacturer and User Facility Device Experience (MAUDE) reports. The main section is comprised of studies published from 2010 to 2023 related to contamination, infectious outbreaks, clinical performance and health economics aspects of reusable bronchoscopes and single-use bronchoscopes. The last section offers an introduction to the benefits of aScope 4 Broncho.

While each study summary is accurate to the original publication, the original copies can be made available upon request. Should you wish to discuss any publication in this dossier in more detail, do not hesitate to send an inquiry to US-HealthEcon@Ambu.com.

The studies presented have been selected to provide an overview of the most impactful publications regarding aScope 4 Broncho.

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 4 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 attention in subsequent editions.

A HISTORY OF BREAKTHROUGH IDEAS

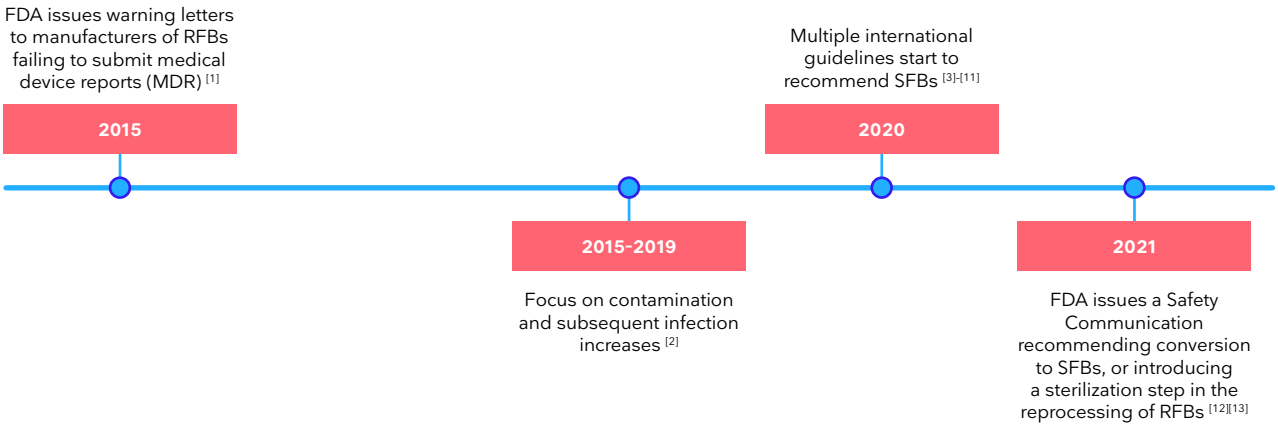
Ambu has been bringing the solutions of the future to life since 1937. Today, millions of patients and healthcare professionals worldwide depend on the efficiency, safety, and performance of our single-use endoscopy, anesthesia, and patient-monitoring diagnostics solutions. The manifestations of our 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 4 Broncho, which have a positive impact on your work. As the world's leading supplier of single-use endoscopes, with more than 1.5 million scopes sold in 2021 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 4,500 people in Europe, North America and the Asia-Pacific region.

For more information, please visit ambuUSA.com

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 JUNE 25, 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

HOW WERE THE STUDIES IN THIS DOSSIER SELECTED?

PubMed (Medline) and Embase, two major scientific outline databases were searched for all relevant articles up to 2023. Articles published in English on infection control, workflow, procedure relocation, and health economics were included. Commentaries, letters to the editor, book chapters, and publications with no clinical or economic relevance were excluded. To provide the reader with the most up-to-date studies, this document only includes studies published after 2013.

This clinical evidence dossier is updated bi-annually and includes summaries of published peer-reviewed studies related to bronchoscopes and bronchoscopy procedures. Stay up to date with the most recently published literature, abstracts and bronchoscopy-related data by scanning the QR code to visit our Supporting Evidence page at ambuUSA.com/supporting-evidence/broncho.

CLINICAL PERFORMANCE

Clinical Performance

Not open access

TAKEAWAY

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[14]

Kriege et al., 2020

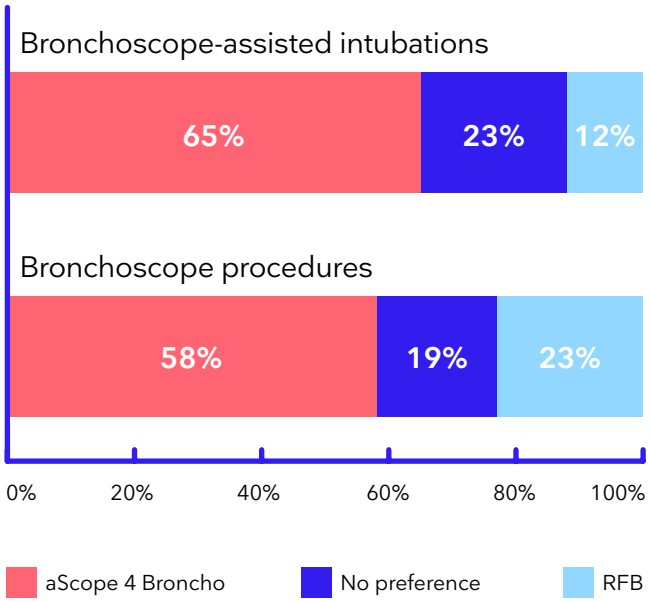
STUDY AIM

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



Clinical Performance

Not open access

TAKEAWAY

Single-use bronchoscopes achieved a larger BAL volume yield than conventional bronchoscopes, with comparable cell yield and viability. Better volume yields can potentially reduce post-procedure side effects such as pleuritic chest pain and cough.

KEY FINDINGS

The median BAL volume yield from the single-use bronchoscopes was 152 mL (IQR 141– 166 mL) as compared to 124 mL (110– 135 mL), $p < 0.01$, from the conventional bronchoscopes. The greater BAL volume return achieved with single-use bronchoscopes could lead to reduced risk of post-procedure side effects such as cough, pleuritic chest pain and fever, which may improve tolerability and patient comfort.

The median total cell yield from single-use bronchoscopes was 7.33×10^{6} (5.13×10^{6}–9.80×10^{6}) compared with 7.0×10^{6} (4.53×10^{6}–1.64×10^{7}) for conventional procedures, $p = 0.61$.

Single use and conventional bronchoscopes for Broncho alveolar lavage (BAL) in research: a comparative study (NCT 02515591)[15]

Zaidi et al., 2017

STUDY AIM

This study aimed to compare the BAL volume yield, total cell yield and viability between samples obtained using single-use and conventional bronchoscopes.

METHODS

- At a hospital in Liverpool, UK, 10 healthy patients underwent bronchoscopy with aScope™ 4 Broncho Regular 5.0/2.2, and 50 healthy patients underwent bronchoscopy with a conventional bronchoscope.
- Warmed 0.9% saline was instilled to the right middle lobe in sequential aliquots (60, 50 and 40 mL), with aspiration into a sterile syringe using gentle manual suction. BAL yields were recorded, and the fluid was transported immediately to the laboratory on melting ice.
- BAL fluid was filtered through double-layered gauze to remove mucus plugs. Cells were pelleted by centrifugation (1500 rpm for 10 min at 39°F) and washed with 50 mL cold RPMI medium (Gibco™ RPMI 1640 Medium) containing antibiotics.
- Primary outcome measures were compared with values from the preceding 50 conventional procedures using the Mann-Whitney U Test.

Clinical Performance

Open access

TAKEAWAY

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 maneuvering 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[16]

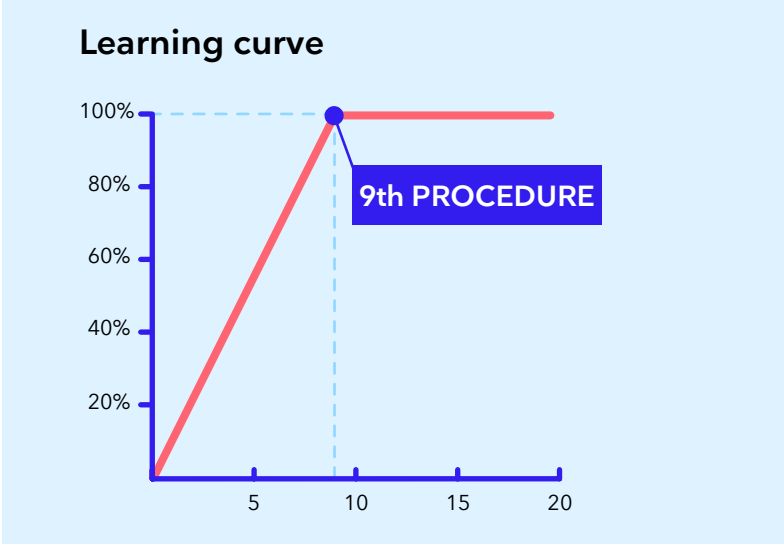
Flandes et al., 2020

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).



CONTAMINATION AND INFECTIONS

Infection Open access

TAKEAWAY

Borescope evaluations and microbial culturing should be conducted frequently to ensure safe endoscopy procedures. In addition, using borescopes allowed researchers to see the structural damage, foreign material, and moisture inside the endoscopes.

KEY FINDINGS

- Sterile processing teams should regularly check endoscopes using a borescope examination and microbial culturing to ensure endoscope safety
- Borescope examinations and microbial culturing highlighted flaws and damages, including channel shredding, filamentous debris, water retention, discoloration, dents, and red particles

Borescope Examination and Microbial Culture Results of Endoscopes In a Tertiary Care Hospital Led to Changes In Storage Protocols to Improve Patient Safety[17]

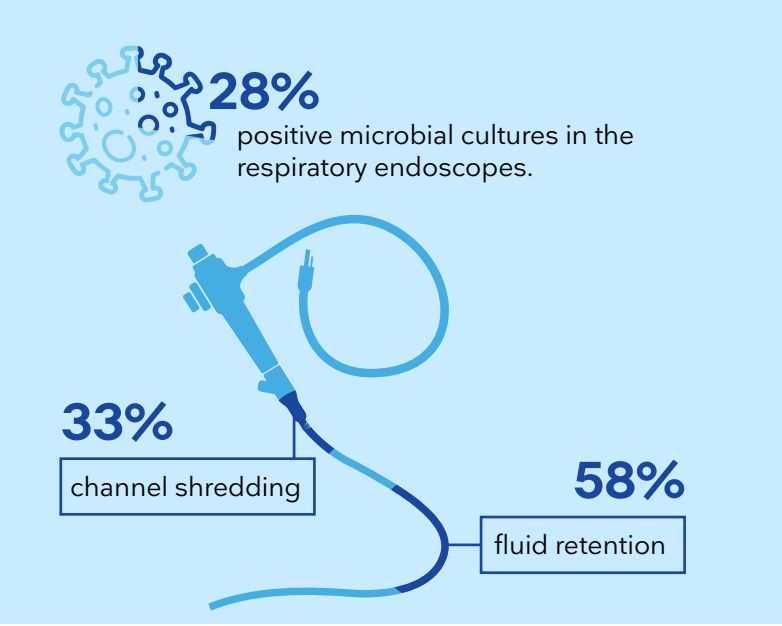
Wallace et al., 2022

STUDY AIM

Conventional visual inspections and close observation of endoscopes in a tertiary care hospital were conducted by performing borescope examinations and microbial sampling on respiratory, gastrointestinal (G.I.), and urological endoscopes.

METHODS

- Forty-two endoscopes were cultured using a flush-brush-and-flush method, and 36 were examined using a borescope that included the use of an antegrade and retrograde approach
- Water was then absorbed through a filter onto a blood agar plate and nurtured



Infection Open access

TAKEAWAY

Cross-contamination is a relevant healthcare issue. Reprocessing methods are flawed, and suggestions for new approaches should be discussed. Single-use endoscopes should be used in place of reusable devices whenever possible.

KEY FINDINGS

- Eight studies were used and met vital criteria requirements
- 8.69 percent of the reusable, flexible bronchoscopes were contaminated with a 95 percent confidence variable
- There is a need for an infection control paradigm shift in which the following are introduced:
    1. Introduction of single-use bronchoscopy where feasible
    2. Including a sterilization step during reprocessing
    3. Mandatory and improved surveillance strategies
    4. Adherence to the Spaulding classification, making all therapeutic bronchoscopes a critical device.

Cross Contamination Rate of Reusable Flexible Bronchoscopes: A Systematic Literature Review and Meta-Analysis[18]

Travis et al., 2023

STUDY AIM

To access the average cross-contamination rate of available reusable, flexible bronchoscopes based on published literature.

METHODS

- Researchers conducted a literature review using both PubMed and Embase (databases consisting of references and abstracts on life sciences and biomedical topics) to access the cross-contamination rates of reusable, flexible bronchoscopes
- Studies detected microorganisms or colony forming units (CFU) levels and a total number of samples > 10.

8.69%

cross-contamination rate of reusable flexible bronchoscopes

Infection Open access

TAKEAWAY

Visual inspection with magnification and borescopes identified actionable defects that could interfere with processing effectiveness in 100% of endoscopes.

Infection preventionists play a vital role in supporting reprocessing personnel now that more stringent guidelines, standards, and manufacturer instructions suggest visually inspecting each endoscope after each use.

KEY FINDINGS

- Sterile processing units discovered that every endoscope that had been processed had a defect during their visual investigation
- The impaired endoscopes had scratches, dents, channel shredding, and adhesive disintegration
- Debris included accessories and white, black, brown, yellow/green, and red residue
- Site personnel discovered that scopes either needed to be reprocessed or repaired.

The Utility of Lighted Magnification and Borescopes For Visual Inspection of Flexible Endoscopes[19]

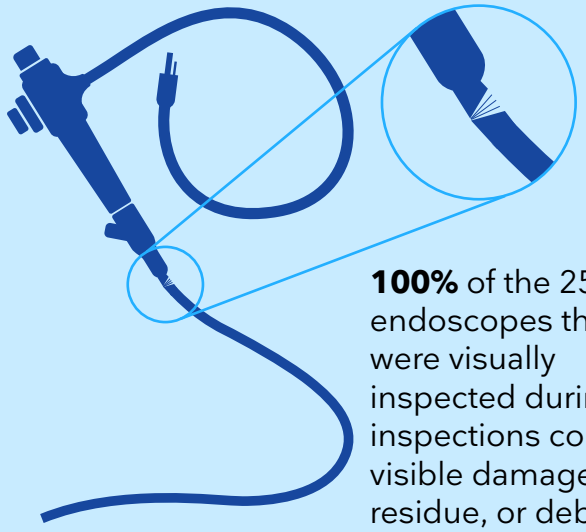
Ofstead et al., 2023

STUDY AIM

To investigate a new visual inspection curriculum using magnification and borescopes in an endoscopy department that had yet to apply these tools

METHODS

- Site members conducted two visual inspections of reprocessed endoscopes over two months after receiving training and visual inspection tools
- Researchers recorded their findings using log sheets, photographs, and videotapes
- Researchers used a risk assessment tool to ascertain whether an endoscope should be reprocessed, repaired, or required some other type of action



100% of the 25 endoscopes that were visually inspected during both inspections contained visible damage, residue, or debris.

Infection Open access

TAKEAWAY

Bronchoscopy-related pseudo-outbreaks occur despite standardized procedures for HLD. New technology that is either high-quality disposable or able to undergo sterilization 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

- 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. 8 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.
- Of the 11 patients who had bronchoscopy with scope A and had adenovirus testing performed during this timeframe, 6 (55%) had molecular evidence of adenovirus infection.
- Of the 24 patients who had bronchoscopy with scope B and had Adenovirus testing performed during this timeframe, 4 (17%) were positive.
- 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[20]

Seidelman et al., 2021

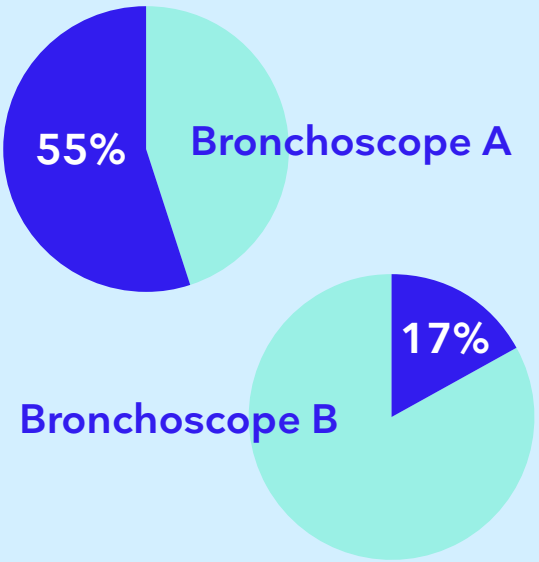
STUDY AIM

The aim of this study is to investigate a pseudo-outbreak of adenovirus from an academic hospital in the southeastern United States, after the discovery of a cluster of adenovirus in a bronchoalveolar 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

TAKEAWAY

Bronchoscopes may pose an underrecognized potential for transmission of CRE and related MDROs.

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.
- 10 out of 12 cases reported that the bronchoscope had been reprocessed, of which, only 5 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[21]

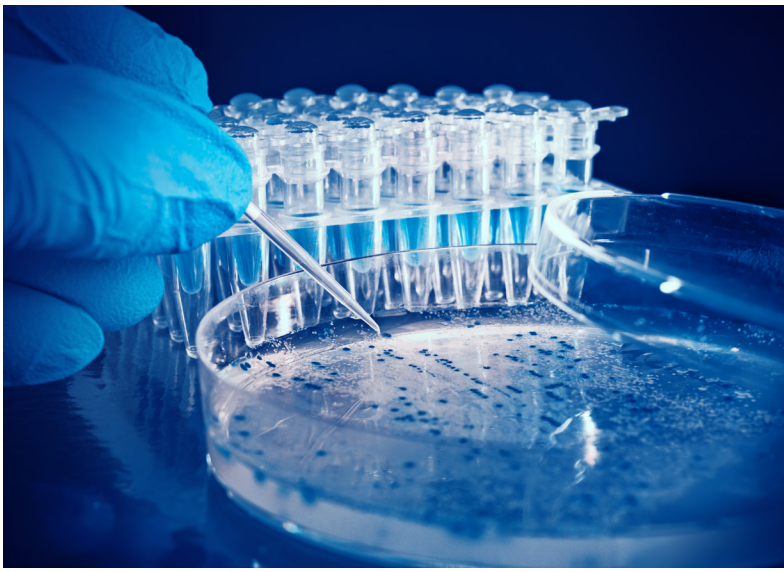
Mehta and Muscarella 2019

STUDY AIM

The primary aims of this review were to investigate the risk of bronchoscopes transmitting infections of CRE and related MDROs, and to assess whether supplemental measures might be advisable to enhance the safety and effectiveness of bronchoscope reprocessing.

METHODS

- They reviewed the available medical literature 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 searched 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 searched 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 a rigid bronchoscope or other types of microorganisms (e.g., mycobacteria and fungi).



Contamination | Not open access

TAKEAWAY

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 Escher- ichia 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[22]

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 82.4° F to 89.6° F for 5 to 7 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.

Infection Open access

TAKEAWAY

In this study, 569 patients are contaminated by a bronchoscope, of whom 115 (20.21%) are showing symptoms of infection. Most of the infections are linked directly to a bronchoscope, which in most cases causes pneumonia.

KEY FINDINGS

Flexible endoscopes for therapeutic procedures (bronchoscopy) and reusable accessories, such as biopsy forceps, are used in sterile body cavities and should be classified as critical devices. They should be sterilized after each procedure.

Inadequate cleaning of flexible endoscopes has been frequently associated with microbial transmission during endoscopic procedures.

The true rate of transmission during endoscopy may go unrecognized because of technically inadequate surveillance, no surveillance at all, low frequency, or the absence of clinical symptoms.

Transmission of Infection by Flexible Gastrointestinal Endoscopy and Bronchoscopy[23]

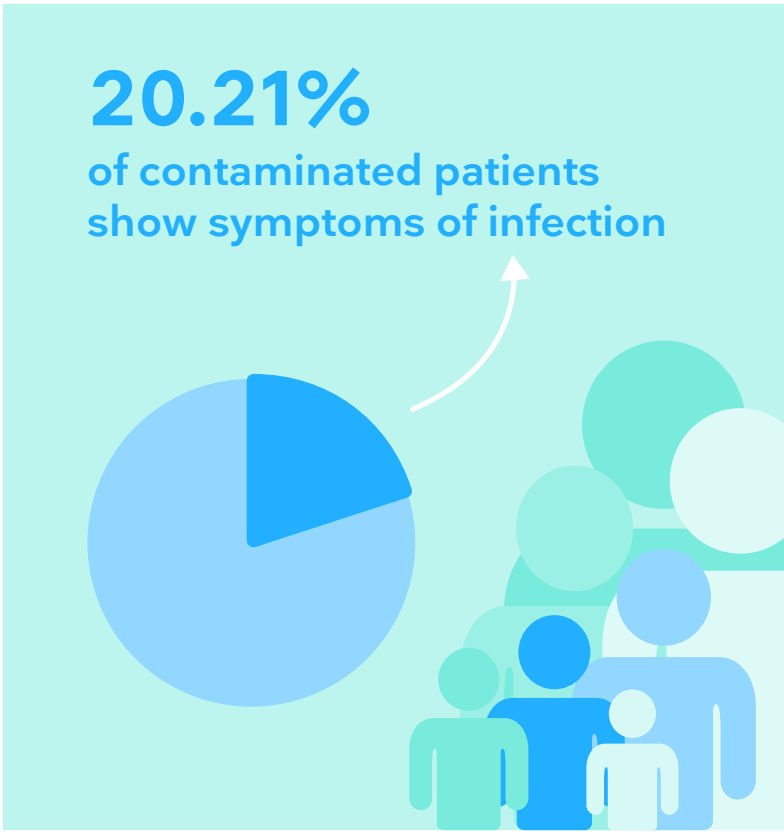
Kovaleva et al. 2013

STUDY AIM

The aim is to present an overview of the infections and cross-contaminations related to flexible bronchoscopy, and to illustrate the impact of biofilm on endoscope reprocessing and post-endoscopic infection.

METHODS

This review was conducted to create an overview of what has been published over time, in order to inform about contamination, infection, microorganisms, reprocessing methods, and reprocessing guidelines.



HEALTH ECONOMICS

Infection Open access

TAKEAWAY

There is no significant difference between the cost of use for reusable and single-use bronchoscopes.

KEY FINDINGS

- The average cost per procedure with a reusable bronchoscope is $266, including repairs, capital investments, and reprocessing costs.
- The average cost for a single-use bronchoscope for use procedure is $289.
- Reusable bronchoscopes may be more economically affordable than their single-use counterparts based on the number of procedures performed at each site.

The Cost of Flexible Bronchoscopes: A Systematic Review and Meta-Analysis[24]

Andersen, C.O., Travis, H., et al., 2022

STUDY AIM

To gather published evidence that is current and that can be used to analyze the different single-use and reusable bronchoscope cost scenarios.

METHODS

- Researchers used information gathered between 2009 and 2020 from publications such as PubMed, Embase, and Google Scholar to compare the differences in total cost between single-use and reusable bronchoscopes. 25 studies were included in the final review.
- Data was cited for relevant outcomes and reviewed using RStudio® 4.0.3 as the regulated mean difference and standard error of the mean in a mixed-effects model.
- The risk of bias was analyzed based on the quality of the information.

Reusable, flexible bronchoscope costs per procedure:

$91	capital investments
$92	repair costs
$83	reprocessing costs

Cost-effectiveness Open access

TAKEAWAY

The findings from this study suggest benefits of single-use flexible bronchoscopes in terms of cost-effectiveness, cross-contamination and resource utilization.

KEY FINDINGS

- The results of a micro-costing analysis revealed a mean (S.E.) capital cost per use of reusable, flexible endoscope at $149.40 ($37.35). In addition, researchers estimated the repair and reprocessing cost per use of a reusable flexible bronchoscope at $119.23 ($29.78) and $50.44 ($12.84), respectively, equaling a total cost per use of a reusable flexible bronchoscope of $319.84
- The average (S.E.) cost per patient with disposable flexible bronchoscopes was projected at $282.36 ($27.98) and a 0% risk of infection
- In cost-effective analysis, they found reusable, flexible bronchoscopes to have an average (S.E.) cost per patient of $655.85) sterling ($76.50) with an associated risk of 2.8 percent

A systematic review and cost effectiveness analysis of reusable vs. single-use flexible bronchoscopes[25]

Mouritsen et al. 2019

STUDY AIM

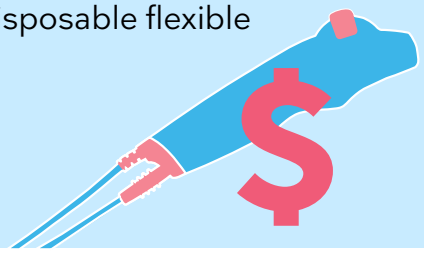
This study aimed to determine the cost per use and cross-contamination risk of reusable flexible bronchoscopes, and to ascertain the cost-effectiveness of single-use flexible bronchoscopes compared with reusable flexible bronchoscopes in various clinical settings.

METHODS

- The preferred reporting items for systematic reviews and meta-analyses (PRISMA) guidance was adhered to in the conduct of the systematic review. Given an evident risk of patient cross-contamination and infection with reusable flexible bronchoscopes.
- In the event of incomplete data on the number of bronchoscopic procedures and number of patients included, a simple regression method was applied to predict missing data.
- The effect measure was the risk of infection. The time horizon of the cost-effectiveness analysis was within 1 year. The micro-costing analysis was conducted at Guy's and St Thomas' NHS Foundation Trust Department of Anaesthesia.
- The modelling approach was based on principles of good practice for decision-analytic modelling in healthcare analyses and constructed using TreeAge (2016 version, TreeAge Software, MA, USA).
- Sensitivity analyses were undertaken to capture uncertainty within parameters and to provide sufficient insight for decision-makers.

$319.84, the total cost per use of a reusable flexible bronchoscope.

$282.36, the projected cost per patient with disposable flexible bronchoscopes.



Infection | Open access

TAKEAWAY

Single-use bronchoscopes result in significant cost savings when used to guide a percutaneous dilatational tracheostomy (PDT) and are preferred to their reusable counterparts.

KEY FINDINGS

- Ninety-nine recipients responded to a questionnaire from 31 hospitals that said they used reusable bronchoscopes at their hospital to perform a PDT.
- Research indicates that the average cost per PDT procedure using a reusable bronchoscope was $406 (acquisition cost of $135, reprocessing costs of $123, and repair cost of $148).
- The average cost per PDT procedure using a single-use bronchoscope was $249.
- The incremental cost difference per use between the two bronchoscopes was $157.

Cost Comparison of Single-Use Versus Reusable Bronchoscopes Used For Percutaneous Dilatational Tracheostomy[26]

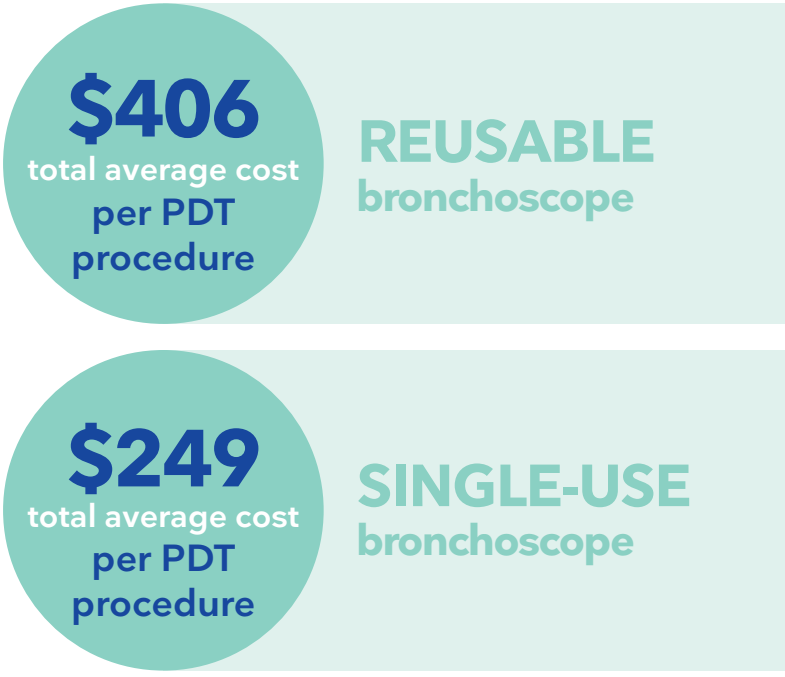
Sohrt, A., Ehlers, L., et al., 2019

STUDY AIM

To compute the cost of using single-use or reusable bronchoscopes per percutaneous dilatational tracheostomy (PDT) procedure.

METHODS

- An overview of the research was completed comparing the cost of both reusable and single-use bronchoscopes for PDT.
- Criteria consisted of articles analyzing the cost of single-use or reusable bronchoscopes and were separated according to the acquisition, reprocessing, and repair costs.
- A questionnaire was sent to 366 hospitals in Germany, the U.S., and the U.K. consisting of repair rates and costs for reusable bronchoscopes to supplement the identified literature.



Cost-effectiveness Open access

TAKEAWAY

This CUA demonstrates that Ambu aScope 4 Broncho is cost-effective in comparison to RFBs, and is associated with a cost saving of $273.39 and a small gain in QALYs (0.0105).

KEY FINDINGS

In the base-case analysis, the total cost and QALYs gained (discounted) regarding the aScope 4 Broncho and RFBs were estimated to be $284.89 and 1.59 QALYs, and $558.31 and 1.58 QALYs, respectively. This resulted in an incremental cost of $273.39 (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 PSA scatterplot demonstrates that the aScope 4 Broncho was dominant in all iterations. The incremental costs ranged from -$28.49 up to -$549.08 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[27]

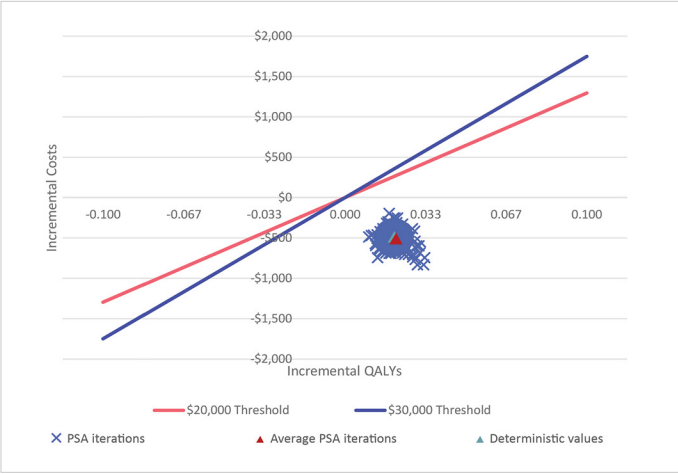
Mærkedahl et al. 2020

STUDY AIM

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

METHODS

- They developed a simple decision tree model to estimate the cost-utility of aScope 4 Broncho vs. RFB for bronchoscopy procedures in intensive care units (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 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 (TB). The probability of no infection was set to 1 minus the total probability of the three infection outcomes.
- As the aScope 4 Broncho has demonstrated equal performance to RFBs for bronchoscopy procedures, they assumed that both cohort pathways were identical, with the only differences being the costs associated with the use of each device, costs of infections, risks of infections, and the associated utility scores, based on health-related quality of life (HRQoL) scores.



ORGANIZATIONAL IMPACT

Organizational impact

Open access

TAKEAWAY

Organizational impact should be considered when assessing medical devices. This study shows that, from an organizational 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 organizational 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 ($190) per procedure.**
- **Single-use and reusable devices would in theory have the same cost (€232/$287 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 Organizational impact but a costly solution[28]

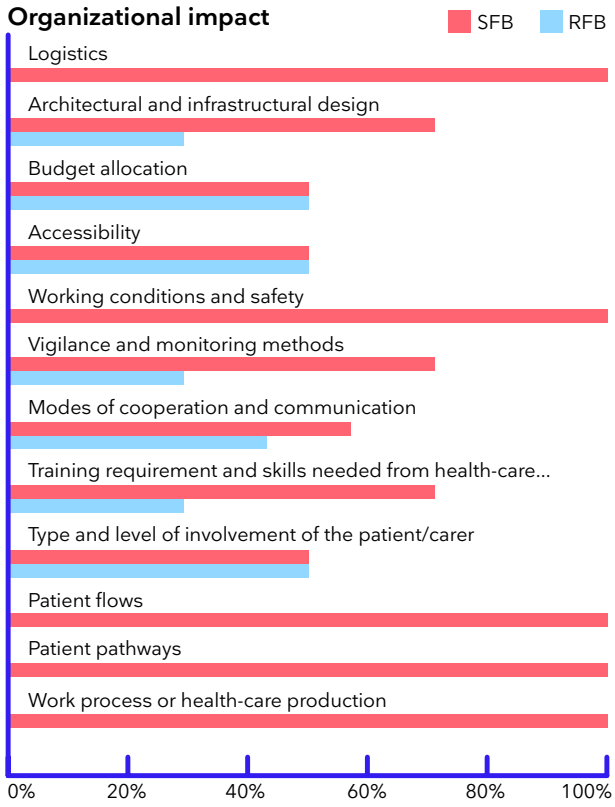
Châteauvieux et al., 2018

STUDY AIM

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

METHODS

- Both the organizational and economic impacts of the SFB were evaluated in comparison with the RFB.
- Based on the 12 types of organizational 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 analyzed.
- Micro-costing analysis was conducted to determine the most economical balance in the use of the two technologies.



ENVIRONMENTAL IMPACT

Environmental impact

Open access

TAKEAWAY

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[29]

Sørensen et al., 2018

STUDY AIM

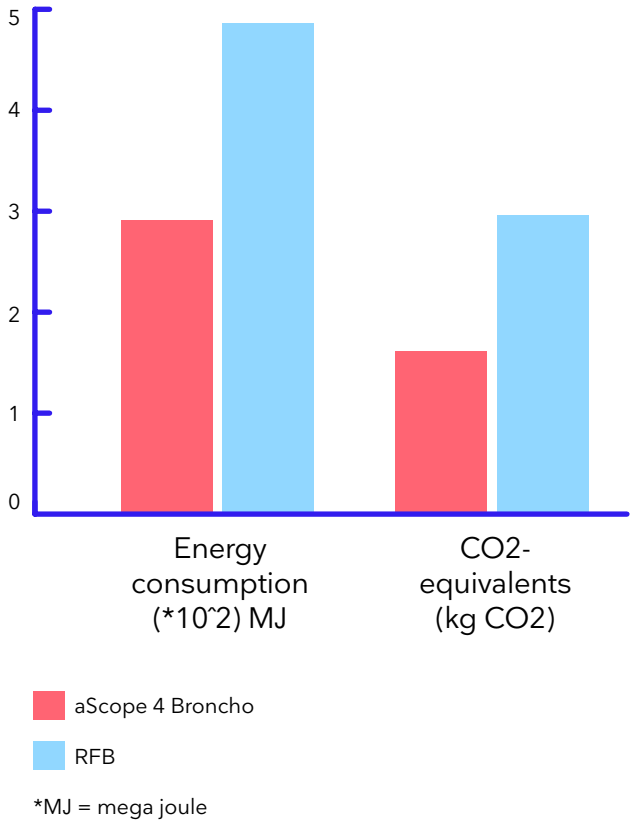
This study aims to compare CO_2 equivalent emissions and energy consumption from a SFB (Ambu aScope 4 Broncho) with an RFB.

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 sterilization 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 wants 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 toward 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 prioritization 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 organization 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: ambuUSA.com/about/sustainability

Ambu aScope 4 Broncho

Choosing Ambu aScope 4 Broncho is about improving patient safety and workflow. It is about ensuring immediate access to a flexible bronchoscope and eliminating the risk of cross-contamination. It is about delivering clear, sharp imaging and easy navigation during your bronchoscopy procedures. aScope 4 Broncho comes in three sizes in one system at no additional cost:

Ambu® aScope™ 4 Broncho Slim

Ambu® aScope™ 4 Broncho Regular

Ambu® aScope™ 4 Broncho Large

The risk of cross-contamination is completely avoided by ensuring that optimal steps to safeguard the patient are taken. The single-use scope is easy to set up and requires zero handling or reprocessing after use. As a result, the risk of sample loss and contamination is reduced.

Ready when you are
Reduces the risks and frustrations associated with waiting for an available endoscope. aScope 4 Broncho can be stored directly in the units.
The aScope 4 Broncho single-use bronchoscopy solution is portable, easy to set up and intuitive to use, thus saving valuable time.

Sterile straight from the pack
There is growing concern that even with the most stringent high-level disinfection procedures, sterility cannot be assured. This potentially puts the patients at risk.
With the aScope 4 Broncho solution, there is a brand-new, sterile bronchoscope straight from the pack every time.

Hassle-free bronchoscopy solution
An integrated solution that helps deliver the very best in-patient care.

KEY FEATURES:

Hassle-free solution: Fully integrated, easy-to-set-up, closed-loop system with three models at no additional cost
Guaranteed sterility: No risk of cross-contamination
Brand new every time you use it: A single-use solution improves patient safety
Ready when you are: Portable, intuitive, lightweight and ergonomic
Cost-effective: No handling, zero reprocessing, nothing to repair
High-quality bronchoscopy: Clear, crisp images and smooth and easy navigation

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