

ADVANCES IN SINGLE-USE BRONCHOSCOPY: A STUDY OF THE aScope™ 5 BRONCHO ACROSS EUROPE

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INTRODUCTION

The introduction of single-use flexible bronchoscopes (SFB) has marked a significant milestone in the field of bronchoscopy. In 2009, Ambu introduced its first-generation aScope Broncho, initially designed to meet the need for intubation bronchoscopes. Since then, the demands from the medical community have evolved, reflecting a growing awareness of the risks associated with reusable flexible bronchoscopes (RFB). These risks include cross-contamination, time-consuming reprocessing, equipment maintenance, limited availability, and high costs.

OVERVIEW

This whitepaper presents the findings of a controlled market release (CMR) study using aScope 5 Broncho HD. It was conducted in multiple European countries involving 155 bronchoscopists (12 from Belgium, 5 from Denmark, 2 from

Finland, 25 from Germany, 21 from Italy, 5 from Norway, 7 from Switzerland, 38 from Spain, 1 from Sweden, and 39 from UK) from various specialties and clinical settings, collectively performing 338 procedures. The aScope 5 Broncho HD comes in two sizes; one with an outer diameter of 5.6 mm and a working channel of 2.8 mm and one with an outer diameter of 5.0 mm and a working channel of 2.2 mm, referred to as 5.6/2.8 and 5.0/2.2, respectively. The bronchoscopes are shown in **Figure 1** including the endoscopy systems. The aScope 5 Broncho HD 5.6/2.8 was used in 121 procedures and the aScope 5 Broncho HD 5.0/2.2 was used in 202 procedures. Further, there were 16 cases where the bronchoscopist used both sizes in the same procedure. The study encompassed dedicated bronchoscopy suites (65% of the cases), shared endoscopy suites (13%), operating rooms (12%), ICUs (7%), neurology rehabilitation units (<1%), pulmonology care stations (<1%) and hybrid operating rooms (<1%).

The aScope 5 Broncho System	
Component	Function
aScope™ 5 Broncho HD 5.6/2.8	Single-use bronchoscope
aScope™ 5 Broncho HD 5.0/2.2	Single-use bronchoscope
aScope™ 5 Broncho Sampler Set	Single-use device to enable aspiration and collection of fluid samples from bronchioles or alveoli
aView™ 2 Advance aBox™ 2	Endoscopy system

Figure 1: The aScope 5 Broncho HD system

COMPLETION RATES

Across both aScope 5 Broncho HD bronchoscope sizes, 96% of 338 cases were successfully completed.

There were six (6) incomplete procedures due to endoscope-related issues and nine (9) incomplete procedures due to other reasons (e.g., the need for a smaller bronchoscope, an uneasy patient or endotherapy instrument breakage). This underscores the reliability of the device in a variety of clinical settings.

Single-use bronchoscopes have previously, in general, not been considered for more advanced bronchoscopy procedures due to technological limitations such as image quality and performance with endotherapy instruments. In this CMR, the aScope 5 Broncho HD was used for both advanced therapeutic and diagnostic procedures involving various endotherapy tools as presented in **Table 1**. In simple procedures there was a further high procedural success rate, for example bronchoalveolar lavage (BAL) (n=77, 99% success), bronchial wash (n=9, 100% success), and inspection (n=19, 100% success).

Procedure	Success rate	Scope size 5.6/2.8	Scope size 5.0/2.2	Combination of sizes	Specific endotherapy tools used
Therapeutic Tumor ablation or resection	100% (12/12)	92% (n=11)	8% (n=1)	n/a	<ul style="list-style-type: none"> • APC probe (n=3) • Cryobiopsy probe (n=7) • Dilation balloon (n=1) • Electrosurgical snare (n=1) • Laser (n=1)
Stricture management	100% (9/9)	89% (n=8)	11% (n=1)	n/a	<ul style="list-style-type: none"> • Dilation balloon (n=9) • Silicone stent (n=1) • Self-expanding metal stent (n=1)
Diagnostic TBNA	100% (15/15)	60% (n=9)	27% (n=4)	13% (n=2)	n/a
Cryobiopsy	100% (11/11)	55% (n=6)	27% (n=3)	18% (n=2)	n/a
Sampling	95% (91/96)	50% (n=48)	43% (n=41)	7% (n=7)	<ul style="list-style-type: none"> • Biopsy forceps (n=93) • Cytology brush (n=15)

TBNA: Transbronchial needle aspiration, APC probe: Argon Plasma Coagulation probe

Table 1: Examples of advanced therapeutic and diagnostic procedures performed with aScope 5 Broncho HD and the associated endotherapy instruments used. More than one endotherapy tool could be used in a single procedure.

All therapeutic procedures (21 out of 21) using the aScope 5 Broncho HD were successfully completed. Additionally, 96% (117 out of 122) of diagnostic procedures performed with the aScope 5 Broncho HD and a diagnostic endotherapy instrument were successful.

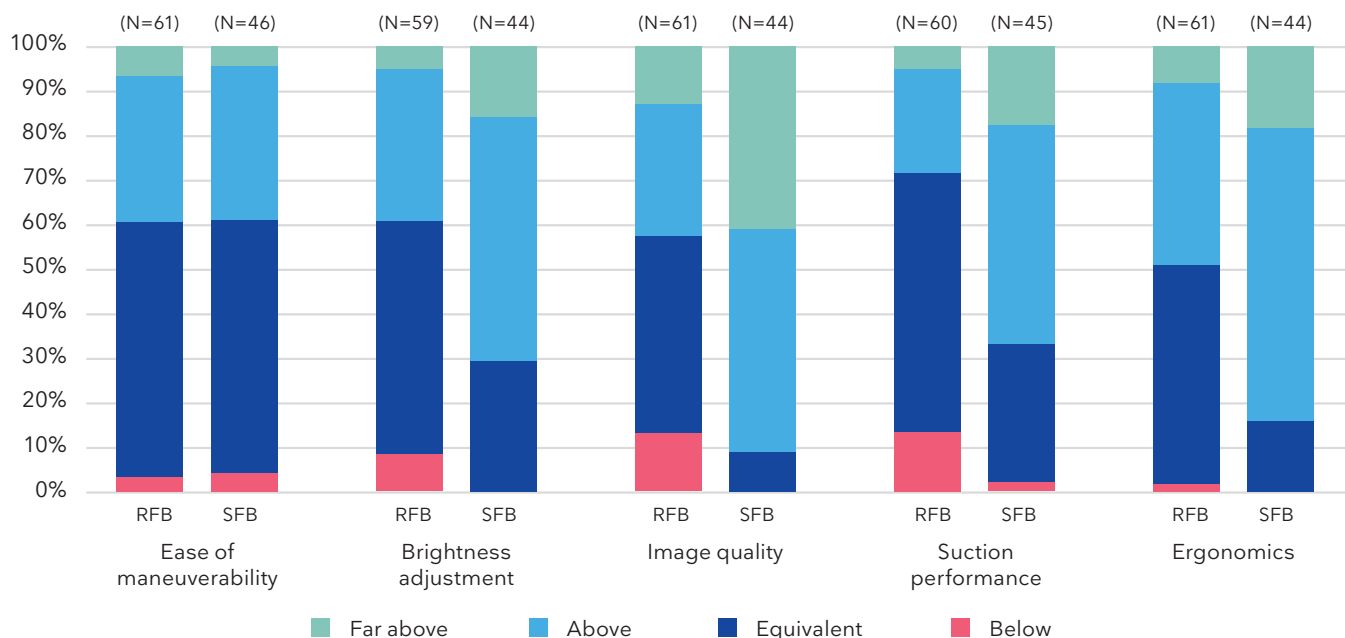
ASSESSMENT OF PERFORMANCE

Assessment of performance of the aScope 5 Broncho HD was recorded after each clinical use utilizing a detailed questionnaire. Their responses provided insights into key aspects of the device’s clinical performance, including ease of manoeuvrability, brightness adjustment, image quality, suction performance, ergonomics, torquability (force transmission from handle to distal tip), distal tip bending angles, scope tip bending force (when moving the bending lever) without

instrument, scope tip bending force (when moving the bending lever) with instrument and instrument passage through the working channel. All bronchoscopists were required to assess the performance of the aScope 5 Broncho HD in comparison to their existing reusable equipment (reusable flexible bronchoscope, RFB) and against their current single-use setup (single-use flexible bronchoscope, SFB), if they had one available.

Most bronchoscopists reported positive impressions against several measures. Perception of ease of manoeuvrability, brightness adjustment, image quality, suction performance, and ergonomics in comparison to existing RFB and SFB are shown in **Figure 2** and **Table 2**. In summary, the data shows that the sum of Above and Far Above constitutes up to 91% of responses in each category. In **Figure 3** and **Table 3**, ratings of

torquability, distal tip bending angles, scope tip bending force without instrument, scope tip bending force with instrument, and instrument passage through the working channel are shown. In summary, the data shows that the sum of Above and Far Above constitutes for up to 84% of responses in each category.



RFB, reusable flexible bronchoscopes. SFB, single-use flexible bronchoscopes.

Figure 2: Bronchoscopists’ clinical performance measures of the aScope 5 Broncho HD in comparison to reusable flexible bronchoscopes and single-use flexible bronchoscopes. (N, number of respondents).

	Ease of maneuverability		Brightness adjustment		Image quality		Suction performance		Ergonomics	
	RFB	SFB	RFB	SFB	RFB	SFB	RFB	SFB	RFB	SFB
Below	3%	4%	8%	0%	13%	0%	13%	2%	2%	0%
Equivalent	57%	57%	53%	30%	44%	9%	58%	31%	49%	16%
Above	33%	35%	34%	55%	30%	50%	23%	49%	41%	66%
Far above	7%	4%	5%	16%	13%	41%	5%	18%	8%	18%
Above and Far Above combined	39%	39%	39%	70%	43%	91%	28%	67%	49%	84%

RFB, reusable flexible bronchoscopes. SFB, single-use flexible bronchoscopes.

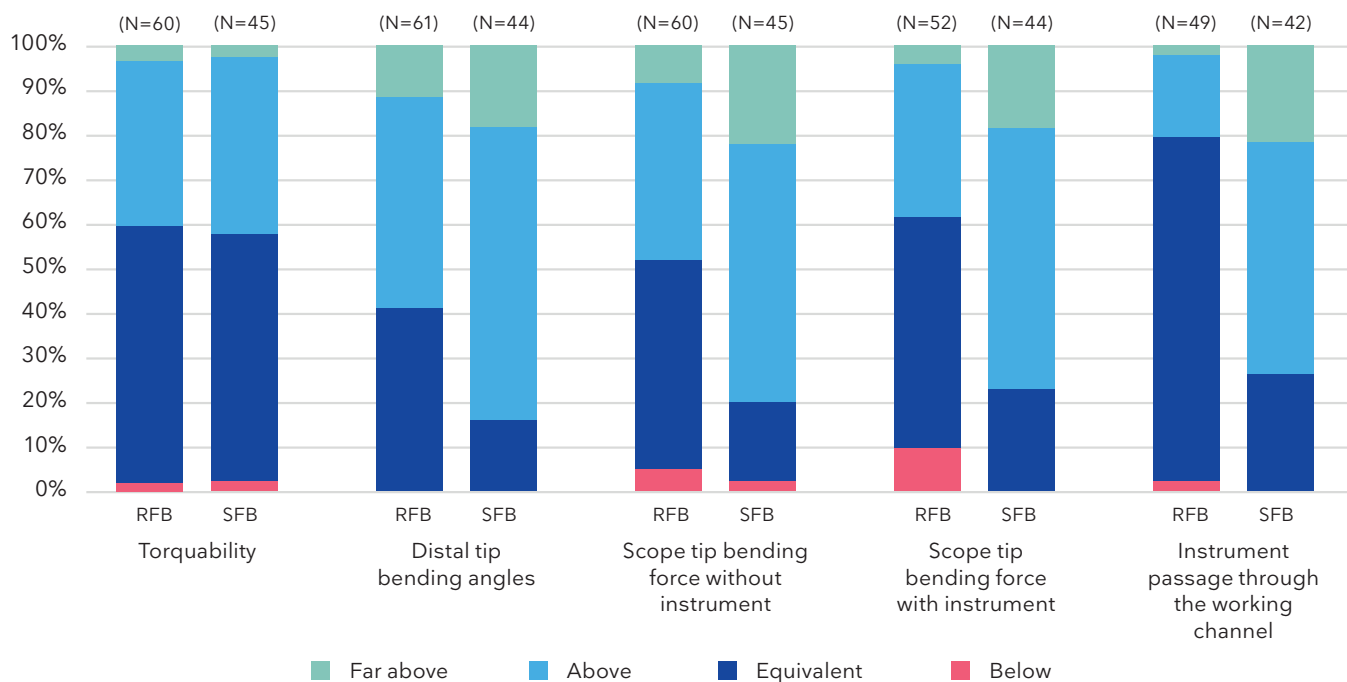
Table 2: Bronchoscopists’ clinical performance measures of the aScope 5 Broncho HD in comparison to reusable flexible bronchoscopes and single-use flexible bronchoscopes, percentage of total responses

Image quality

The image quality of the aScope 5 Broncho HD was rated as equivalent by 44% of participants, while 43% rated it as above or far above compared to a reusable flexible bronchoscope.

Ergonomics

The ergonomics of the aScope 5 Broncho HD were rated as equivalent by 49% of study participants, while further 49% rated them as above or far above compared to a reusable flexible bronchoscope.



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Figure 3: Bronchoscopists’ clinical performance measures of the aScope 5 Broncho HD in comparison to reusable flexible bronchoscopes and single-use flexible bronchoscopes. (N, number of respondents)

	Torquability		Distal tip bending angles		Scope tip bending force without instrument		Scope tip bending force with instrument		Instrument passage through the working channel	
	RFB	SFB	RFB	SFB	RFB	SFB	RFB	SFB	RFB	SFB
Below	2%	2%	0%	0%	5%	2%	10%	0%	2%	0%
Equivalent	58%	56%	41%	16%	47%	18%	52%	23%	78%	26%
Above	37%	40%	48%	66%	40%	58%	35%	59%	18%	52%
Far above	3%	2%	11%	18%	8%	22%	4%	18%	2%	21%
Above and Far Above combined	40%	42%	59%	84%	48%	80%	38%	77%	20%	74%

RFB, reusable flexible bronchoscopes. SFB, single-use flexible bronchoscopes.

Table 3: Bronchoscopists’ clinical performance measures of the aScope 5 Broncho HD in comparison to reusable flexible bronchoscopes and single-use flexible bronchoscopes, percentage of total responses.

PERCEPTIONS AS THE NEW STANDARD

A large proportion of doctors expressed their belief that the aScope 5 Broncho HD has the potential to become the new standard in bronchoscopy. As well as in comparison to RFBs, this sentiment extended to its comparison with other SFBs,

with many doctors either agreeing or completely agreeing. The perception of the bronchoscopists is that aScope 5 Broncho HD offers the closest performance to RFBs than any other SFB as shown in **Figure 4**.

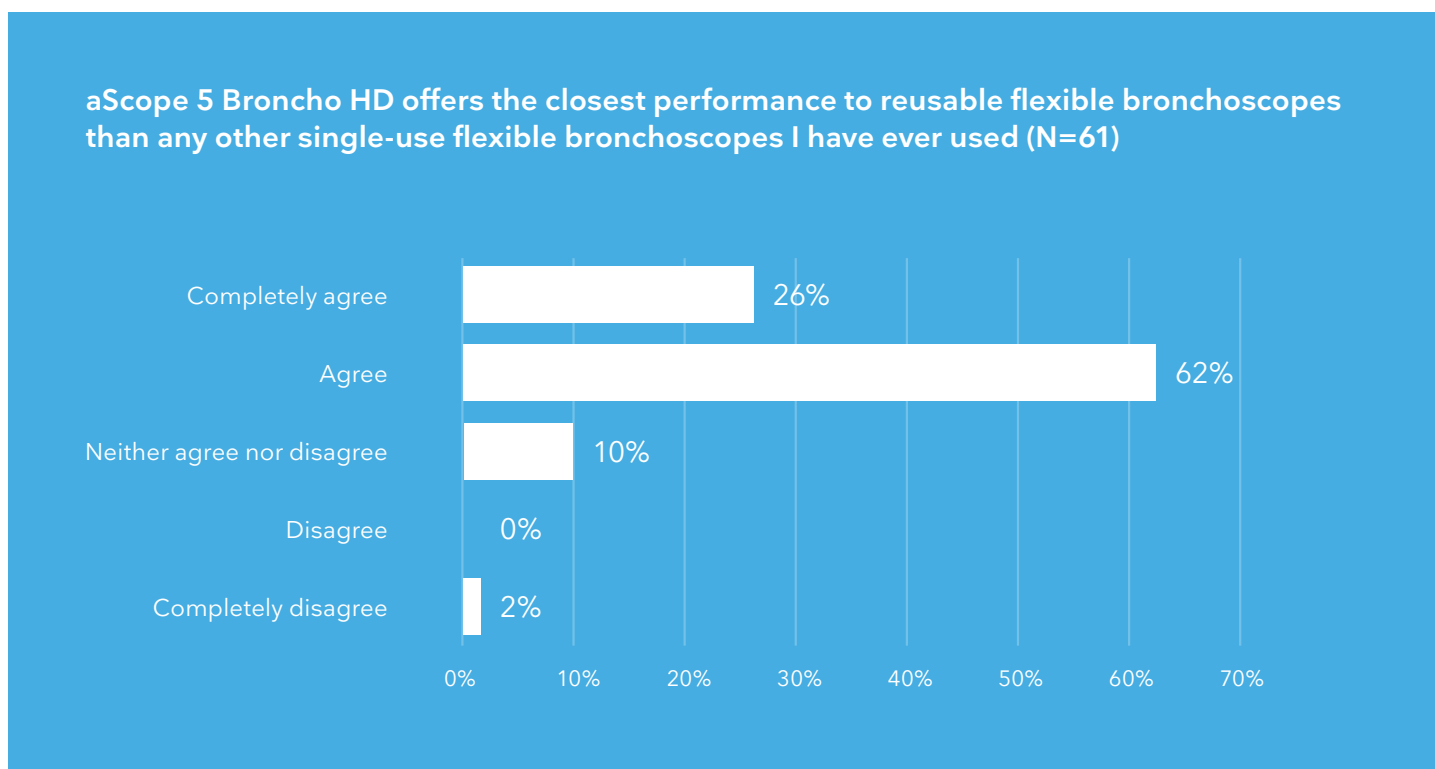


Figure 4: Bronchoscopists’ perception of the aScope 5 Broncho HD compared to other single-use bronchoscopes, against performance of reusable flexible bronchoscopes.

The performance of the aScope 5 Broncho HD is considered the closest to reusable flexible bronchoscopes by 88% of participants, surpassing any other single flexible bronchoscope they have ever used.

The insights from a poster presented at the CHEST 2021 conference and a study published by Sohrt et al. (2018) collectively underscore the imperative to integrate SFBs in advanced bronchoscopy procedures. Notably, the correlation between procedure complexity, breakage rates, and the suitability of bronchoscope types presents a compelling case for the strategic adoption of innovative technologies.^{1, 2} The observed positive correlation between procedure complexity and breakage rates, coupled with the negative correlation between procedure complexity and SFB suitability, accentuates the demand for advanced SFB technology in sophisticated bronchoscopy procedures. Notably, the aScope 5 Broncho HD stands out as a promising solution, offering the potential to

address the challenges posed by complex interventions. In the context of healthcare resource optimization and cost-effectiveness, the aScope 5 Broncho HD aligns with the emerging need for SFBs capable of handling advanced procedures. The elimination of repair costs, as demonstrated in the CHEST 2021 findings, positions the aScope 5 Broncho HD as a viable alternative. The data collectively advocates for the integration of innovative SFBs, such as the aScope 5 Broncho HD, in bronchoscopy practices, ensuring enhanced adaptability to the evolving landscape of advanced clinical interventions.

ADVANTAGES OF THE aScope 5 BRONCHO

Economic Benefits

While not addressed in the questionnaire, Andersen et al., (2022) addressed the economic impact of SFBs in a meta-analysis, which suggested that their adoption could yield economic benefits.³ Further, the economic impact of adopting aScope 5 Broncho HD has been addressed in a newly-published cost-comparison by Kristensen et al., (2023), concluding that more than 80% of hospitals in the US would potentially have an economical advantage from using aScope 5 Broncho HD in their bronchoscopy suites.⁴ The reduced need for equipment maintenance, reprocessing and the availability of a reliable device can contribute to cost savings and improved organizational impact in healthcare settings.

Patient Safety

The aScope 5 Broncho HD offers benefits for patient safety. Its single-use nature reduces the risk of cross-contamination, ensuring a higher level of hygiene in bronchoscopy procedures. This is a critical advantage, particularly in high-risk scenarios.⁵

Environmental Considerations

This study underscores the importance of considering the environmental impact of single-use bronchoscopy. Although a comprehensive life cycle assessment in full accordance with ISO 14044 standards is yet to be conducted in the field, a study by Sørensen et al., (2018) found that SFBs have a smaller carbon footprint than reprocessing on RFB or similar to reprocessing two RFBs.⁶ The reduction in waste generated by reprocessing RFBs and the environmental implications of their production, repair/maintenance, and capital equipment, such as automated endoscope reprocessors (AER), should be considered.⁶⁻⁸ Ambu is proactively advancing its carbon reduction efforts. The incorporation of bioplastics, exemplified by the recent launch of the Ambu® aScope™ Gastro Large, signifies a significant step towards sustainable endoscopy. Accelerating the integration of bioplastics in all single-use endoscopes from early in fiscal year 2024/25 further emphasizes Ambu's commitment, with handles made from the Bio-attributed acrylonitrile, butadiene, and styrene (ABS) material boasting a substantial 70% lower carbon footprint compared to traditional plastics (ABS).#

CONCLUSION

In conclusion, this study on the aScope 5 Broncho HD across Europe demonstrates its efficacy and potential to redefine the landscape of bronchoscopy. The device exhibits impressive completion rates in various clinical settings, successfully accommodating both diagnostic and advanced therapeutic procedures. Bronchoscopists expressed positive impressions, with a significant majority considering the aScope 5 Broncho HD as a potential new standard in bronchoscopy.

The study highlights the device's notable advantages, including its patient safety enhancements. Economic analyses further support the adoption of SFBs such as the aScope 5 Broncho HD, indicating potential cost savings in maintenance and reprocessing.

Moreover, the results of the study emphasize the importance of the crucial environmental considerations associated with single-use bronchoscopy. Although a comprehensive life cycle assessment is pending, the broader shift towards sustainable practices in the medical industry is evident. Ambu's proactive measures, such as the integration of bioplastics with a significantly lower carbon footprint, exemplify the commitment to reducing environmental impact.

Considering these findings, the aScope 5 Broncho HD emerges as a promising solution, addressing the challenges posed by complex interventions, optimizing healthcare resources, and aligning with the evolving landscape of advanced clinical interventions. This study underscores the device's potential to contribute to a more patient-safe and environmentally conscious future for bronchoscopy practices.

Based on cradle to gate LCAs on the raw material from supplier. This does not translate to 71% savings for the carbon footprint of the full lifecycle for the finished good.

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