

# USER EVALUATION ON Ambu® aScope™ Duodeno

## An Analysis based on 505 User Evaluations of Ambu® aScope™ Duodeno used for ERCP procedures

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### Purpose

To evaluate user experience of the single-use aScope™ Duodeno by collecting feedback from endoscopists immediately following an ERCP procedure performed with the duodenoscope.

### Materials and Methods

Evaluations from 13 European countries completed a user evaluation after finalizing an ERCP procedure with the single-use aScope™ Duodeno. Descriptive statistics, standard deviation (SD) and regression analysis were calculated in Microsoft Excel and SAS JMP.

### Results

505 user evaluations were completed. In 93% of the cases the physician rated the overall satisfaction between neutral (32%), satisfied (51%) and very satisfied (10%).

21% of the evaluations (n=108) reported increased visualization and 99% (n=497) reported positive (76%) or neutral (23%) feedback on the radiolucent tip.

### Conclusions

Overall, endoscopists are satisfied and positive towards the single-use aScope™ Duodeno, which in the majority of cases met or exceeded their expectations. All the attributes of the duodenoscope that were asked for also met or exceeded the expectations of the endoscopists, indicating that ERCP procedures could be performed with the single-use aScope™ Duodeno without compromising the clinical needs of the endoscopists. Of the 505 endoscopists, zero complications or perforations were reported.

## INTRODUCTION

Endoscopic retrograde cholangiopancreatography (ERCP) is an advanced high-risk endoscopic procedure which combines X-ray imaging and the use of an endoscope. Endoscopists use ERCP to diagnose and treat problems in the liver, gallbladder, bile ducts and pancreas [1-3]. The risk of infections caused by contaminated duodenoscopes can be severe, and despite strict strategies of reprocessing, disposable end-caps and serial microbiologic tests, the risk of infection has not been eliminated [4-6].

Endoscopes are categorized as semi-critical devices, and reusable endoscopes require high-level disinfection by trained personnel after each use [7,8], which together with frequent time-consuming repairs bears the risk of endoscope unavailability.

Single-use duodenoscopes are developed to avoid duodenoscope-related contamination and infection, and to improve workflow and availability by having a positive organizational impact. Single-use duodenoscopes perform on par with reusable duodenoscopes, and allow successful completion of ERCP [9]. The single-use duodenoscope aScope™ Duodeno is sterile from the pack, with side-viewing optics, deflectable tip, an elevator, and an outer diameter of 11.3 mm.

This paper is the first study to evaluate user experience, by collecting endoscopists' feedback on the perceived performance after an ERCP procedure with the single-use aScope™ Duodeno.

## METHODS

**Evaluation design:** The aim of the user evaluation was to systematically collect subjective quality assessments of aScope™ Duodeno on ERCP procedures to ensure it met the expectations of the endoscopists. The setting of the data collection was non-controlled and non-interventional, and the data was collected from October 2021 to March 2022. Endoscopists from 13 different European countries (Belgium, Denmark, Finland, France, Germany, Hungary, Italy, Netherlands, Norway, Portugal, Spain, Sweden, and the United Kingdom) completed the user evaluation form after an ERCP procedure was performed with aScope™ Duodeno. As no data from human subjects was obtained, patient consent was not obtained.

**Data Collection:** Recruitment of endoscopists and instructions was done by Ambu® representatives. The data was collected on paper or by an online survey tool (Microsoft Forms) directly after finishing the procedure. The endoscopists received no payment or compensation for filling in the evaluation form. The evaluation forms were collected centrally, and all data was exported to Microsoft Excel.

The endoscopists were asked to grade the complexity of the ERCP procedure according to the ASGE ERCP grading system [10,11], ranging from 1 to 4, where 1 corresponds to the least difficult ERCP procedure and 4 corresponds to the most difficult procedure.

The endoscopists were asked about their perception of the radiolucent tip and to report their subjective experience on 11 attributes (1: weight of aScope™ Duodeno; 2: navigation to the duodenum; 3: angulation capability, tip control and orientation; 4: suction capability; 5: image quality; 6: passing ERCP accessories through the working channel; 7: ERCP accessory control; 8: field of view; 9: silent suction button; 10: ease of setup; 11: workflow). The endoscopists were asked to rate the attributes on a 5-point scale (“far below expectations” (1 point); “below expectations” (2 points); “meets expectations” (3 points); “above expectations” (4 points); “far above expectations” (5 points)). Additionally, the endoscopists were asked about their overall satisfaction with the duodenoscope during the procedure on a 5-star scale (“very unsatisfied” (1 star); “unsatisfied” (2 stars); “neutral” (3 stars); “satisfied” (4 stars); “very satisfied” (5 stars)).

**Statistical Methods:** Descriptive statistics were calculated for sub-group analyses such as the endoscopist’s previous experience with aScope™ Duodeno and the complexity of the ERCP procedure. Means and SD were calculated individually and jointly for the 11 performance attributes, together with the reported overall satisfaction. In addition, a regression analysis examining the mean difference between the user satisfactions and the previous number of ERCP procedures with aScope™ Duodeno was performed. All calculations were performed in Microsoft Excel and SAS JMP.

## RESULTS

505 user evaluations were completed by endoscopists from 13 European countries. 20% (n=99) were from Northern Europe, 51% (n=256) were from Western Europe, 29% (n=149) were from Southern Europe, and 0.2% (n=1) were from Eastern Europe (Table 1). Of the 505 evaluations, zero complications or perforations were reported.

Country	Number (%) of evaluations
<b>Northern Europe</b>	<b>99 (20%)</b>
Denmark	41 (8%)
Finland	30 (6%)
Norway	11 (2%)
Sweden	17 (3%)
<b>Western Europe</b>	<b>256 (51%)</b>
Belgium	14 (3%)
France	108 (21%)
Germany	102 (20%)
Netherlands	3 (1%)
United Kingdom	29 (6%)
<b>Southern Europe</b>	<b>149 (29%)</b>
Italy	43 (9%)
Spain	97 (19%)
Portugal	9 (2%)
<b>Eastern Europe</b>	<b>1 (0.2%)</b>
Hungary	1 (0.2%)

Table 1: Location and number of forms completed after using aScope Duodeno

471 evaluations (93%) rated the overall physician satisfaction positive or neutral (Figure 1), represented by 3-5 stars on a 5-star scale (3 stars/neutral n=160 (32%), 4 stars/satisfied n=259 (51%), 5 stars/very satisfied n=52 (10%)), with an average satisfaction score of 3.6 (SD=0.78).

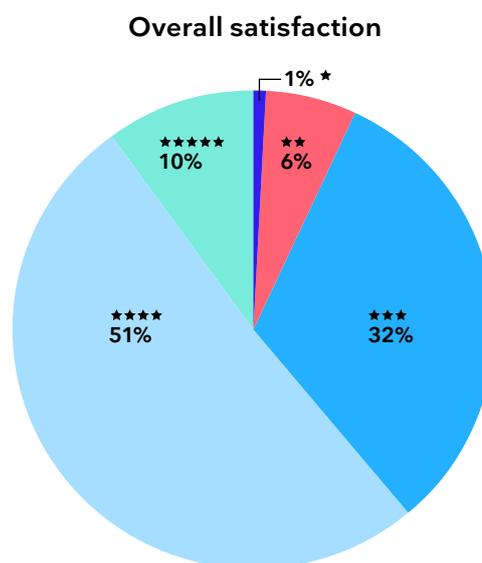


Figure 1: Overall satisfaction with aScope™ Duodeno (1 star: very unsatisfied; 2 stars: unsatisfied; 3 stars: neutral; 4 stars: satisfied; 5 stars: very satisfied)

90% of the forms reported that aScope™ Duodeno met or exceeded the physician expectations summed up on all 11 attributes (Figure 2). Every examined attributes met the expectations of the endoscopists or were above expectations.

The 4 attributes Weight of the endoscope, Suction capability, Silent suction button and Ease of setup all exceeded expectations with average ratings (mean±SD) of respectively  $3.7\pm 0.82$ ;  $3.6\pm 0.78$ ;  $3.7\pm 0.87$ ;  $3.6\pm 0.77$ .

### Endoscopists experience on 11 attributes of the aScope™ Duodeno

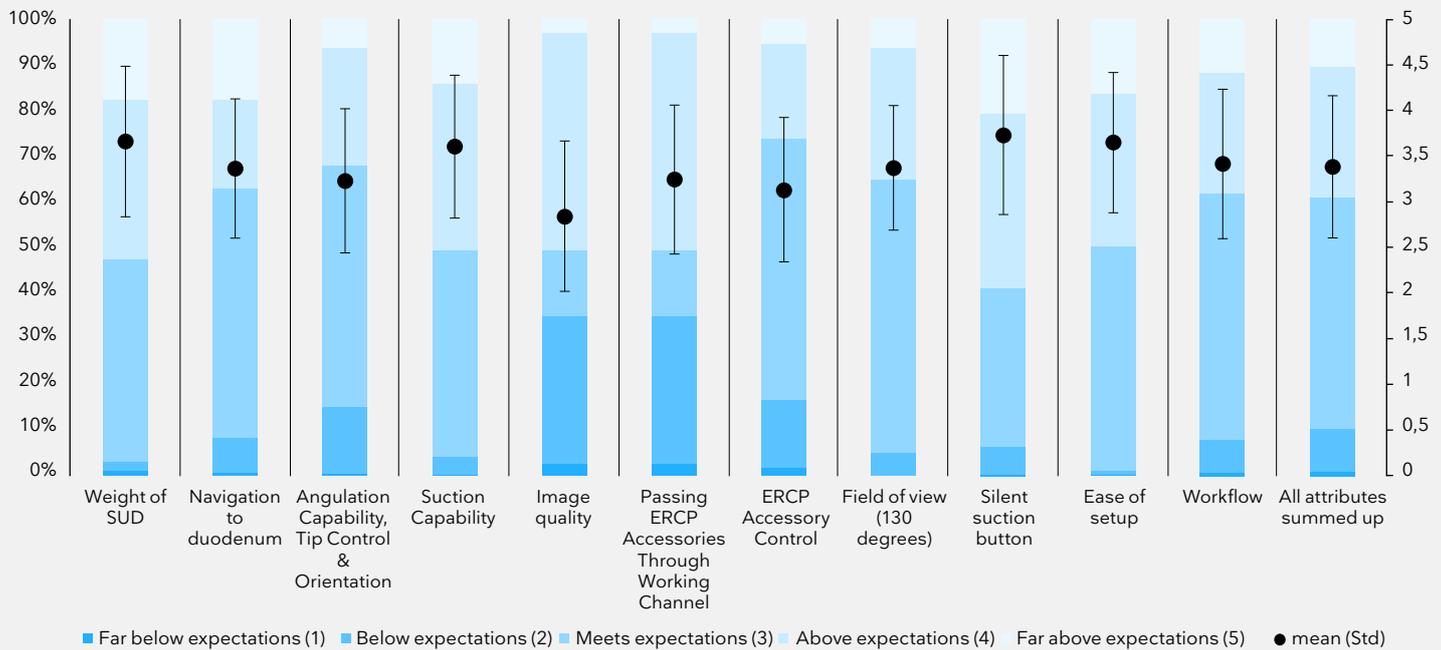


Figure 2: Average Results of Each Attribute of the User Evaluation

The mean number of ERCP procedures performed with a single-use duodenoscope previously by the endoscopist was 2.27 (SD=1.99, range [0;12]) and the mean ASGE grading of the ERCP procedures was 2.17 (SD=0.83, range [1;12]) (Figure 3).

The endoscopist's experience based on the reported satisfactions was found to be significantly correlated with the number of previously performed ERCP procedures with aScope™ Duodeno (Figure 4).

The overall rating of the radiolucent tip of aScope™ Duodeno was positive, with 76% (n=383) commenting positively on it (23%; n=114 finding it neutral; 1%; n=7 finding it negative). More than one in five of the forms (21%; n=104) specified visual benefits of the duodenoscope, with visualization of the bile duct (28%), visualization behind the endoscope (16%), visualization of stone behind the endoscope (15%) and visualization of instruments (12%) being the most frequently reported feedback.

### Experience and procedure complexity

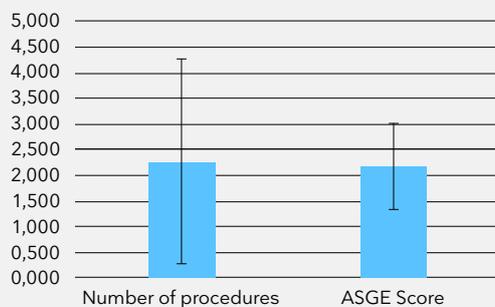


Figure 3: Average previous single-use duodenoscopy experience and procedure complexity

### Satisfaction vs. procedures conducted with aScope™ Duodeno

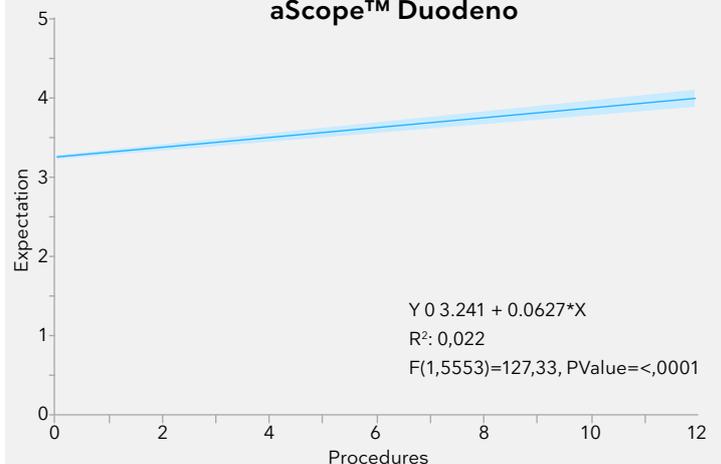


Figure 4: Correlation between User Satisfaction and Ambu® aScope™ Duodeno Experience

## DISCUSSION

Medical device companies continue to improve and launch endoscopes as they strive to provide endoscopists and patients with the best possible scope. They do this by incorporating and improving on several aspects of the endoscopes, including clinical performance, ergonomics, visualization, safety, workflow, and price.

Single-use duodenoscopes represent an alternative to reusable duodenoscopes, and studies have shown that single-use duodenoscopes are capable of performing ERCP procedures with optimal success rate [9,12].

Single-use duodenoscopes come with the advantage of being sterile, thus eliminating the risk of patient infection caused by cross-contamination. Reusable endoscopes require special storage and high-level disinfection after each use, performed by trained staff [7,8]. An accurate endoscope-reprocessing procedure is crucial, and it involves multiple steps and requires skills and awareness of the guidelines associated with the procedure [8]. Reprocessing serves to clean for material left inside and outside the endoscope to prevent a potential shelter for bacteria. The reprocessing guidelines can be challenging to adhere to, and they might not always be sufficient, as recent studies have shown that up to 19.98% of the reprocessed gastrointestinal reusable endoscopes might be contaminated when used in patients [5,6,13].

While eliminating concerns of cross-contamination by being sterile straight from the pack, single-use endoscopes have no need for reprocessing or repair, which are two time-consuming and costly processes that might threaten endoscope availability.

### Radiolucent tip

A distinct difference between reusable duodenoscopes and the single-use aScope™ Duodeno is the radiolucent tip. The endoscopists in this study found the radiolucent tip satisfactory, with 76% (n=383) commenting positively on it and 23% (n=114) finding it neutral compared to their conventional setup with a reusable duodenoscope. The radiolucent tip of aScope™ Duodeno allows for additional visualization (Figure 5) compared to a conventional reusable, but further research is needed to fully understand the clinical advantages and implications of it.

### User adoption curve

The significant correlation between product usage and satisfaction of aScope™ Duodeno indicates that an adoption curve must be expected when changing the endoscopy setup from reusable to single-use. No study of the adoption curve for single-use endoscopes within the field of gastrointestinal endoscopy has been published, but a study within bronchoscopy found an adoption curve of 9 procedures for single-use bronchoscopy [14]. To objectively estimate the adoption curve of duodenoscopy would require a controlled trial using well-defined outcome measures.

### Strengths and limitations

The results of this study represent new knowledge, since no study has been published examining the user experience of aScope™ Duodeno. The study's multicenter design including endoscopists from 13 different European countries

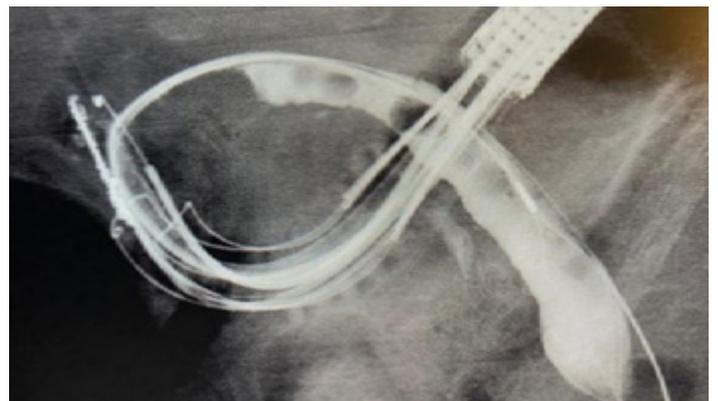
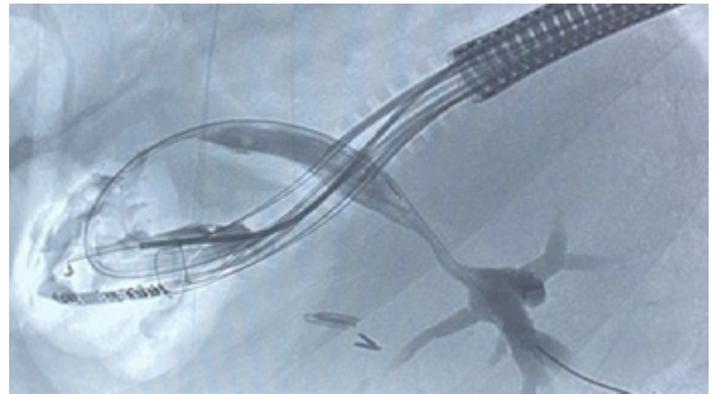
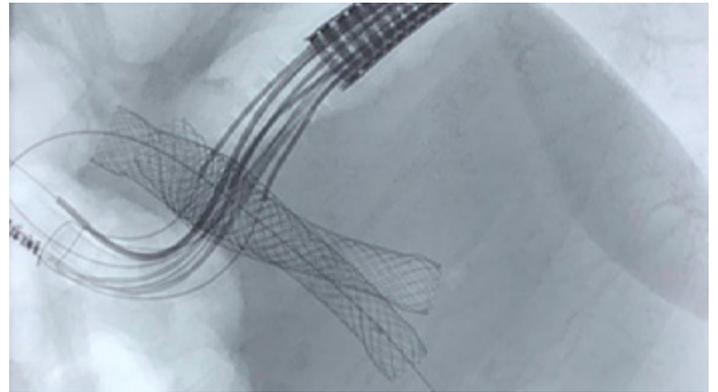


Figure 5: Examples of X-ray visualization by the radiolucent tip of aScope™ Duodeno

is a strength, which provides generalizability of the findings. Selection bias was addressed by targeting endoscopists from several European countries with a wide spectrum of clinical single-use duodenoscopy experience. Non-response bias was limited by evaluation directly after finalizing the ERCP procedure, and response bias was aimed to be avoided by clear and short questions and by providing scale-based answers to avoid leading questions.

## CONCLUSION

This study evaluated endoscopists' experience of aScope™ Duodeno on ERCP procedures. The results show an overall positive satisfaction with the duodenoscope, which with 93% of the cases meeting or exceeding the physician's expectations. The findings indicate that endoscopists find aScope™ Duodeno to be a reliable and safe medical device for ERCP procedures.

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