

# Single-use cystoscopy with Ambu® aScope™ 4 Cysto: Initial physician perceptions of clinical performance

## Background

aScope 4 Cysto is a new flexible cystoscope and monitor platform available in the United States, which is designed for both diagnostic and therapeutic procedures.

**Rapid adoption:** The aScope 4 Cysto solution, including the completely disposable cystoscope and monitor platform, was adopted in over 100 accounts in less than 150 days after its launch in the US in March 2020. Over 7,000 single-use cystoscopes and 350 portable monitors have been sold for urological use in outpatient, ICU, inpatient and office-based care settings, which suggests strong potential for shifting practice patterns and eliminating endoscope reprocessing. Five of the top 100 US hospitals (determined by # of beds) and 10 of the top 100 US hospitals (determined by cystoscopy procedure volume) have adopted the aScope™ 4 Cysto for clinical use.

**Costs:** An analysis\* of per procedure costs from 28 hospitals utilizing AERs or ETO sterilization suggests an average of \$245 (53% reprocessing, 47% equipment and repair costs). The majority of hospitals realized significant direct cost savings with the adoption of the aScope 4 Cysto, in addition to potential operational efficiencies that were not accounted for.

The initial success of the aScope 4 Cysto in hospitals with high procedural volumes where reprocessing is often managed efficiently may suggest single-use cystoscopy holds promise as a cost-effective alternative, which may be used in combination with reusable cystoscopes.

## Objective

With the rapid adoption and potential cost savings in mind, we wanted to get input on urologists' views of the clinical performance. This paper summarizes initial physician perceptions related to product performance to confirm the primary endpoint of clinical acceptability for a variety of procedure types with various working channel instruments.

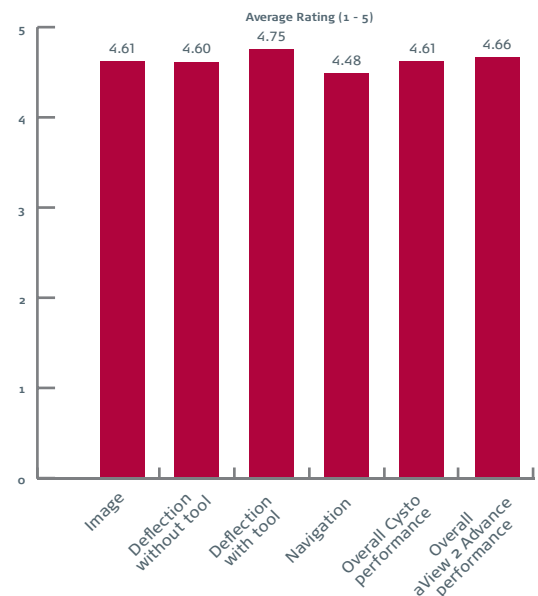
## Methods

A total of 31 physicians across 12 sites utilized aScope 4 Cysto for a total of 65 cystoscopic procedures.

Qualitative information included total years of cystoscopy experience, procedural type and endoscopic tools and accessories utilized. A five-point rating system was used to quantify product performance from very poor (1) to very good (5) for various performance characteristics including image quality, navigation, bending capability, and overall scope and monitor performance. The primary endpoint of procedural success was defined by the ability to complete all aspects of the procedure without the use of a secondary scope. Basic descriptive statistics and 95% confidence intervals were calculated for all secondary endpoints related to performance.



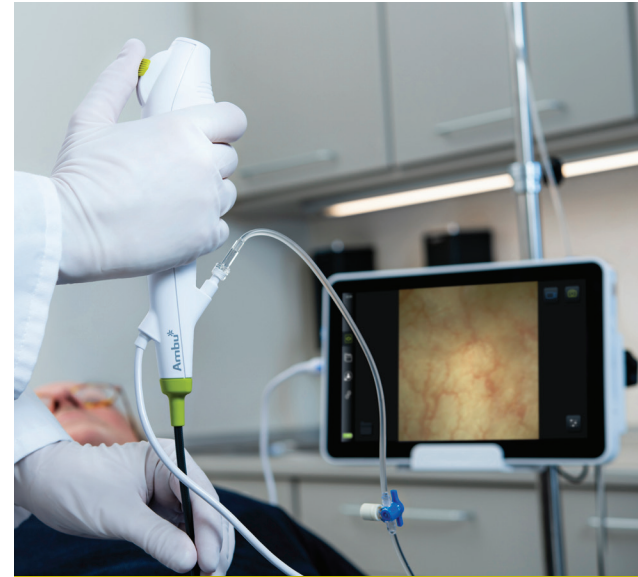
Figure 1: Average user ratings +/- 1 standard deviation



\*Internal Ambu cost-analysis.

## Results

A total of 62/65 data collection forms were completed in full. Of the 62 cases with completed evaluation forms, a 100% procedural success rate was observed. Approximately 71% (46/65) of procedures were diagnostic examinations, with bladder cancer surveillance listed as the most common reason for an examination (6/46). Ureteral stent removals and exchanges accounted for 14% (9/65) of therapeutic procedures, while urethral strictures (2), bladder biopsies (2), bladder fulguration (1), cytology (1), ureteral dilation (1), wire placement (1), foley catheter placement (1), and bladder neck reconstruction (1) procedures made up the remainder of the treatments performed. Figure 1 demonstrates the average ratings for each of the attributes listed. Approximately 93% (300/322) of all performance ratings specific to image quality, bending capability with and without tools, and overall scope and monitor performance were "Very Good" or "Good." Instrumentation included stent graspers (9), Bugbee electrodes (2), biopsy forceps (2), guidewires (2) and ureteral catheter (1), all of which were associated with procedural success. Physician experience with cystoscopy varied from 16% (5/31) with <5 years, 16% (5/31) with 6-10 years, 23% (7/31) with 11-20 years, and 42% (13/31) with >20 years of experience (1/31 undisclosed)



## Discussion

Initial clinical evaluations of aScope 4 Cysto suggest potential for single-use flexible cystoscopy to serve as an effective alternative to reusable scopes for both diagnostic and therapeutic procedures. The first 65 documented evaluations of aScope 4 Cysto hold strong promise for widespread adoption across a variety of care settings and disease states. Years of physician experience with cystoscopy did not impact rates of procedural success, suggesting a minimal learning curve is associated with this new technology.

Additional larger scale randomized studies are warranted to thoroughly understand the comparative performance of single-use versus reusable scopes for a wider range of interventional procedures. Initial physician perceptions from the first 65 documented procedures with this platform combined with the rapid commercial success is promising. It may indicate that single-use flexible cystoscopy holds promise as an effective alternative that could completely replace traditional cystoscopes.

## Conclusions

Initial physician perceptions of aScope 4 Cysto combined with rapid adoption rates suggest there is strong potential for widespread adoption of single-use cystoscopes as an alternative to reusable cystoscopes in the hospital setting. Further investigations are warranted to quantify potential operational and financial efficiencies in both office-based and hospital settings. In addition, clinical studies are needed to test clinical effectiveness when treating a wider range of disease states.

## Summary Table:

Attribute	Very Good or Good	Acceptable	Less than Acceptable
Image quality	95% (59/62)	5% (3/62)	0%
Deflection without tool	92% (57/62)	8% (5/62)	0%
Deflection with tool	100% (16/16)	0% (0/16)	0%
Navigation	85% (53/62)	15% (9/62)	0%
Overall Cysto performance	90% (56/62)	10% (6/62)	0%
Overall monitor performance	95% (59/62)	5% (3/62)	0%

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