

EVIDENCE DOSSIER

Ambu® aScope™ 4 Cysto



Ambu

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This document includes published peer-reviewed studies on health economics, organisational impact and infection control related to the aScope 4 Cysto single-use cystoscope.



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ABBREVIATIONS

CA: Clinical consultation appointment

CFU: Colony forming unit

DTC: Direct to cystoscopy

ED: Emergency department

JJ stent: Double-J stent

OR: Operating room

UTI: Urinary tract infection

PREFACE

This dossier gives you an overview of the evidence-based landscape related to Ambu® aScope™ 4 Cysto, a single-use cystoscope.

It comprises all studies published from January 2015 to September 2022 related to clinical performance, market readiness, workflow, procedure relocation, health economics, environmental impact, and contamination of reusable cystoscopes compared to contamination of fully disposable cystoscopes. The last section presents the benefits of aScope 4 Cysto.

While each study summary is true 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 our Associate Health Economist, Nicklas Mortensen (nhmo@ambu.com).

In an effort to include all known data irrespective of the outcome, a systematic literature search on cystoscopes has been conducted to generate the Evidence Dossier, giving the reader every opportunity to obtain a balanced overview of the data that exists relevant to disposable cystoscopes such as the aScope 4 Cysto. The study titles are taken from the publications as they appear in their original form, allowing the reader to make an accurate internet search should they wish to find out more.

We hope this evidence dossier provides you with an understanding of the overall clinical landscape concerning aScope 4 Cysto 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 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 and 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 deliver innovative quality products, like Ambu® aScope™ 4 Cysto, which have a positive impact on your work.

Headquartered near Copenhagen, Denmark, Ambu employs approximately 4,600 people in Europe, North America and the Asia-Pacific region.

For more information, please visit [ambu.com](https://www.ambu.com).

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 Evidence Dossier will not go into depth with the different levels of evidence but will instead provide an easy overview that indicates the quality of the particular study based on the system below.



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 October 1, 2022. Articles published in the English language within the areas of 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, unless deemed to relay important evidence not within the stated areas. In order to provide the reader with the most up-to-date studies, this document only includes studies published after 2015.



This Evidence Dossier includes summaries of 21 published peer-reviewed studies and two outbreak reports related to cystoscopy procedures.

CLINICAL PERFORMANCE

of the Ambu[®] aScope[™] 4 Cysto

Clinical
PerformanceNot open
access

TAKE AWAY

The new Ambu single-use aScope™ 4 Cysto demonstrates good flexion across instruments and comparable optics with reusable cystoscopes. In addition, initial inpatient bedside use of the aScope 4 Cysto and Monitor system compares favourably with the Olympus reusable cystoscope. Further testing in clinical scenarios such as haematuria, urothelial carcinoma, and operative endoscopy is warranted.

KEY FINDINGS

- Maximal upward flexion exceeded 200° and 163° for all working instruments in upward and downward flexion.
- Downward flexion demonstrated different flexion between instrument groups in pre- and post-cycling ($p < 0.001$). There was no clinical difference between the pre- and flexion.
- Flow rate decreased with increasing working instrument size.
- The optics of the Ambu aScope™ 4 Cysto were superior to the Olympus SD scope at all distances except 3 mm. The aScope 4 Cysto had higher Likert scale survey scores for clinical use. The Olympus HD cystoscope resolution was superior at 3 and 5 mm distance, but not at other distances.

Evolution of Single-Use Urologic Endoscopy: Benchtop and Initial Clinical Assessment of a New Single-Use Flexible Cystoscope, Journal of Endourology, 2021¹

[Whelan et al. 2021](#)

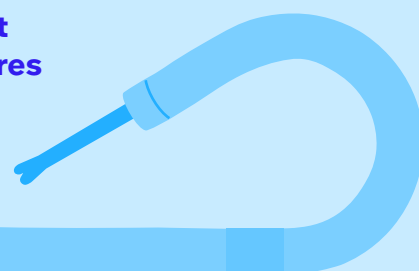
STUDY AIM

Office cystoscopy is one of the most frequently performed by a urologist. However, there has not been a great deal of focus on the development of single-use cystoscopes. Ambu® has developed single-use bronchoscopes, rhinolaryngoscopes, duodenoscopes and a gastroscope. Recently, they released a single-use cystoscope. In this study, a benchtop and an initial clinical assessment of the Ambu aScope™ 4 Cysto single-use cystoscope was performed and compared to the Olympus HD CYF-VH.

METHODS

- Ten new, never-used aScope 4 Cysto were assessed for optical performance, maximal tip flexion, and irrigation flow rate with empty working channel, 365 µm laser fiber, 0.035 in hydrophilic-tipped wire, 1.9F nitinol basket, and a 1.8 mm flexible stent grasper.
- All cystoscopes were then fully flexed 25 times in each direction, and maximal flexion angles were remeasured with and without instruments. Optical resolution, distortion, and depth of field were measured and compared with our reusable digital flexible cystoscopes.
- Assessment of clinical use was performed for inpatient bedside procedures using a Likert feedback survey and the NASA Task Load Index.

**The aScope 4 Cysto
had higher Likert
scale survey scores
for clinical use**





TAKE AWAY

The single-use Ambu® flexible cystoscope is non-inferior to standard flexible cystoscope in terms of procedure completion and light quality, image quality and maneuverability. Single-use flexible cystoscopes are an effective and safe alternative to reusable flexible cystoscopes and may act as a suitable alternative or adjunct in the urologist's armamentarium.

KEY FINDINGS

- All primary outcomes demonstrated non-inferiority of the single-use scope, compared to standard reusable flexible cystoscope, hereunder:
 - Successful completion rate
 - Image quality
 - Light quality
 - Maneuverability
 - Adverse events

Clinical utility of a single-use flexible cystoscopes compared with a standard reusable device: a randomized non-inferiority study, Journal of Endourology, 2021²

[Holmes et al. 2021](#)

STUDY AIM

Recent studies have suggested this novel device has comparable specifications, is well tolerated, and is more cost efficient compared to single use scopes. However, the practical utility of this device, in terms of image quality, light quality, and maneuverability, has not been determined in an appropriate randomized non-inferiority study.

METHODS

- Patients requiring flexible cystoscopy who met inclusion criteria were randomly assigned to have their procedure performed using a single-use cystoscope (Ambu aScope 4 Cysto System) or a standard reusable scope (Olympus CYF-VH flexible video cystoscope).
- Primary outcomes were non-inferiority of the single-use scope, in terms of successful procedure completion rate, image quality, light quality, maneuverability. Secondary objectives compared safety, operative and perioperative time.
- The non-inferiority margin was set at -10%.

“Single-use flexible cystoscopes are an effective and safe alternative to reusable flexible cystoscopes.”



TAKE AWAY

The Ambu® aScope™ 4 Cysto was found to perform well for the diagnostic and therapeutic procedures assessed. Results indicate that the risk for complication was low and pain levels were comparable with results for reusable cystoscopes based on existing literature. At 7 days follow up, patients appear to experience less pain during urination. Increase in urination frequency during day and night was less than reported in literature.

KEY FINDINGS

- Ambu® aScope™ 4 Cysto cystoscopy was successful in 79/81 (98%) procedures.
- The mean procedure time was 3.37 ± 0.90 minutes for diagnostic cystoscopies and 9.84 ± 3.79 minutes for therapeutic cystoscopies. These are consistent with the mean procedure times for most routine cystoscopy procedures.
- At 7-day Follow up, pain when urinating was reported as no pain or mild pain by 88% of the patients. Increased frequency of urination during day and night post-cystoscopy was less than reported using other cystoscopes.
- 10% of the patients reported increase in urination frequency during the day and 9% reported increase in urination frequency during the night.

The new single-use Ambu® aScope™ 4 Cysto: evaluation of successful flexible cystoscopies and patient experience in direct visualization of the urethra and bladder, ICS, 2022³

[Stillebroer et al. 2022](#)

STUDY AIM

Single-use cystoscopes mitigate several limitations of reusable cystoscopes, including high manufacturing and repair cost. This study evaluates the application of the single-use Ambu® aScope™ 4 Cysto in flexible cystoscopies and the patient experience during direct visualization of the urethra and bladder.

METHODS

- The primary endpoint was the rate of completion of procedures in patients undergoing outpatient diagnostic and therapeutic flexible cystoscopy.
- The secondary objectives were to evaluate patient tolerance to the procedure and the procedural time. The secondary endpoints included i) assessment of overall performance ii) procedure time iii) patient tolerance to the procedure and iv) adverse events evaluated during the procedure and 7 days post procedure at follow up call/visit.

The Ambu® aScope™ 4 Cysto was found to perform well for the **diagnostic and therapeutic** procedures assessed.



TAKE AWAY

The results indicate satisfaction with the aScope 4 Cysto system on important performance parameters, such as image quality, bending capabilities and navigation. Based on these results, the single-use cystoscope aScope 4 Cysto is a highly useful device for daily urology practices, with uncompromising quality with every use.

KEY FINDINGS

- For performance parameters concerning image quality, bending (with and without tool) and overall performance (of the aScope 4 Cysto as well as the aView™ 2 Advance Displaying Unit), more than 90% reported “very good” or “good” performance.
- For ratings on navigation, 93.6% reported “very easy” or “easy” navigation.

Clinical performance of the single-use cystoscope aScope™ 4 Cysto: An evaluation based on initial perceptions from urologists worldwide, Ambu Whitepaper, 2021⁴

[Rindorf et al. 2021](#)

STUDY AIM

The flexible cystoscope is an indispensable tool for diagnosing and treating disorders in the lower urinary tract. For this reason, uncompromised quality and satisfactory performance of the flexible cystoscope are prerequisites when used for cystoscopy procedures. A white paper from Ambu describes the results of 380 evaluation forms evaluating the performance of the aScope™ 4 Cysto after using the cystoscope for a cystoscopy procedure.

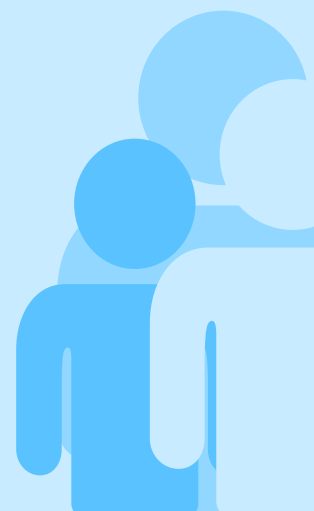
METHODS

The evaluation forms were filled in by urologists in Europe, Australia and Hong Kong. They rated the overall performance of the aScope 4 Cysto system, as well as the navigation, manoeuvrability, image quality, and bending capability with and without a tool in the working channel on a 5-point Likert scale (from “very poor” (1) to “very good” (5), or from “very difficult” (1) to “very easy” (5)).

More than

90%

reported “very good” or “good” performance



MARKET READINESS FOR SINGLE-USE CYSTOSCOPES

Market
ReadinessNot open
access

TAKE AWAY

Patients prefer to undergo cystoscopy using an SUC on the same day as their initial consultation. The increased contamination concerns due to the COVID-19 pandemic and WTP to reduce the risk of cystoscope contamination may explain patients' preferences for SUCs. The most important attributes related to their cystoscopy procedure are the ability to have their procedure performed on the same day as their initial consultation, the reduction of the environmental impact, and the reduction of the contamination risk.

KEY FINDINGS

- Of 300 respondents, 148 (49.33%) were female and 150 (50%) were male, and mainly between 18-49 years (247, 82.33%).
- Most (265, 88%) preferred to have their procedure performed with a SUC rather than a reusable cystoscope. Among these patients, 215 (80%) could imagine asking their doctor to use a SUC.
- A total of 231 (77%) respondents indicated an increased level of concern about the risk of exposure to contamination related to their cystoscopy following the COVID-19 pandemic.
- Patients would pay 62 EUR to have their initial consultation and cystoscopy procedure on the same day, 59 EUR to reduce the environmental impact, and 57 EUR to reduce the risk of contamination.

Willingness to Pay and Preferences among Patients Undergoing Cystoscopies: Results from a Large Survey-based Study in Spain, Dove Press, 2022⁵

[Borja et al. 2022](#)

STUDY AIM

Cystoscopy procedures can cause distress among patients. Patient perspectives on health services are essential inputs in decision-making. This study investigated the patient preferences in Spain regarding single-use cystoscopes (SUC) compared to reusable cystoscopes and their willingness to pay (WTP) for cystoscopy procedures.

METHODS

- Between May and June 2021, an anonymous survey was distributed to Spanish patients who had previously undergone a cystoscopy.
- The survey included patient preference measures on reusable cystoscopes compared to SUCs and a discrete choice experiment.
- The survey was distributed through a human data science company (IQVIA), collected using an online survey tool (QuestionPro®), and analysed using Stata/MP, StataCorp.

88% of the patients preferred to have their procedures performed with a single-use cystoscope.

Market
ReadinessOpen
access

TAKE AWAY

This study investigated the market readiness for single-use cystoscopes according to urologists and PMs worldwide. Respondents indicated a willingness to convert to single-use cystoscopes in nearly half (44.5%) of their cystoscopy procedures. Respondents that were concerned about cystoscopy-related infections as a result of contaminated cystoscopes indicated a significantly higher anticipated conversion rate.

KEY FINDINGS

- A total of 415 urologists and PMs completed the survey (343 [82.7%] urologists and 72 [17.3%] PMs). Seventy (16.9%) were from Japan, 100 (24.1%) were from the US, and 245 (59.0%) were evenly distributed across the following European countries: France, Germany, Italy, Spain, and the UK.
- On average, respondents indicated that they would consider converting to single-use in 44.5% of their cystoscopy procedures.
- Respondents anticipated significantly higher conversion ($p < 0.05$) when they (1) used single-use ureteroscopes in their department, (2) were concerned about cystoscopy-related infection as a result of contaminated cystoscopes, (3) were members of their institution's value committee, or (4) considered cost-transparency to be important when purchasing cystoscopes.

Market Readiness for Single-Use Cystoscopes According to Urologists and Procurement Managers Worldwide, Dove Press, 2021⁶

[Rindorf et al. 2021](#)

STUDY AIM

Single-use endoscopes have been subjected to increased awareness in recent years, and several new single-use cystoscopes (e.g. Ambu® aScope 4 Cysto) have entered the market. However, the market readiness for such single-use cystoscopes remains unknown. This study investigates the worldwide market readiness for single-use cystoscopes among urologists and procurement managers (PMs) from Europe, Japan, and the US.

METHODS

- An online survey using QuestionPro® was distributed to urologists and PMs in France, Germany, Italy, Japan, Spain, the UK, and the US between March 10, 2020 and July 14, 2020.
- All surveys were translated into the respective local language. Statistical analyses were performed using the software package Stata/SE version 16.1, StataCorp. Fisher's exact test was used to analyse categorical variables and simple linear regression was applied to continuous variables.

RESPONDENTS INDICATED A WILLINGNESS TO CONVERT TO SINGLE-USE CYSTOSCOPES

in nearly half (44.5%) of their
cystoscopy procedures



Market
ReadinessOpen
access

TAKE AWAY

According to this study, the aScope 4 Cysto is a safe and cost-efficient device for cystoscopy procedures. Due to its portability, it proves to be a simple and efficient way of performing a cystoscopy procedure in an inpatient, outpatient or emergency setting.

KEY FINDINGS

- This study revealed that it costs £135.23 and £166.33 on average to perform a flexible cystoscopy using the aScope 4 Cysto and the traditional flexible cystoscopes, respectively.
- The mean satisfaction rate with use of reusable cystoscopes and single-use cystoscopes was 9.05 (range 6-10) and 9.65 (range 8-10), respectively ($p=0.045$). Further, 95% of patients preferred to have the procedure done with a single-use flexible cystoscope, whilst 5% had no preference.

The first UK experience with single-use disposable flexible cystoscopes: An in-depth cost analysis, service delivery and patient satisfaction rate with Ambu® aScope™ 4 Cysto, The Journal of Endoluminal Endourology⁷

[Wong et al. 2021](#)

STUDY AIM

Hereford County Hospital was the first hospital in the UK to try the Ambu® aScope 4 Cysto. The aim of this study was to do a cost analysis and to evaluate the service delivery and patient satisfaction when using the aScope 4 Cysto compared to a traditional reusable cystoscope at this community hospital.

METHODS

- The cost of performing flexible cystoscopies using the aScope 4 Cysto in 20 patients was compared with 20 patients using traditional Olympus® CYF-240 flexible cystoscopies.
- All costs, excluding staffing cost, were accrued from sources within the endoscopy, pharmacy, and procurement departments within the hospital, and the organisations which have supplied the products to our department.
- A patient satisfaction questionnaire was also provided to the patients, comparing the use of reusable cystoscopes to the aScope 4 Cysto on a 10-point Likert rating scale.
- An unpaired t-test was used for statistical analysis of patient satisfaction, with a statistical significance set at $P < 0.05$.

95%

of patients
preferred to have
the procedure done
with a single-use
flexible cystoscope



HEALTH ECONOMICS



TAKE AWAY

The cost of reprocessing reusable cystoscopes represents a large fraction of the total cost per procedure, especially for high-volume facilities. The per-procedure cost is highly dependent on the number of cystoscopes available and the annual procedure volume. However, according to this study, it may be more economical to adopt single-use cystoscopes.

KEY FINDINGS

- The cost of reusable flexible cystoscopes is highly dependent on the number of cystoscopes available and the annual procedural volume at individual urology practices. In a practice performing 1,000 cystoscopy procedures a year, the per-procedure cost ranges between \$155 and \$224.
- The total reprocessing cost per cycle was \$48.90, covering the cost of supplies and the labour cost spent on manual cleaning used in reprocessing one reusable flexible cystoscope. Labour cost accounted for 48% of the total reprocessing cost.

A micro-costing analysis of outpatient flexible cystoscopy: implications for adoption of single-use flexible cystoscopes, World J Urol⁸

[Su et al. 2021](#)

STUDY AIM

Micro-costing is a method that allows the precise valuation of the costs of health care interventions. To do a cost comparison of single-use vs reusable cystoscopes, this study employed micro-costing to evaluate the total potential costs and cost savings associated with the purchase, maintenance, and reprocessing of reusable flexible cystoscopes in urology practices.

METHODS

- All cost data regarding the purchasing, maintaining, and reprocessing of reusable flexible cystoscopes were obtained at a high-volume outpatient urology clinic (Johns Hopkins Outpatient Center, Baltimore, Maryland, United States).
- The total of all cost elements was used to calculate a per-procedure cost of reusable flexible cystoscopes with a range of annual procedures ranging from 1,000 to 3,000 procedures a year, performed with a fleet of cystoscopes ranging from 10 to 25 cystoscopes.

**The per-procedure cost
of reusable cystoscopes
ranges between
\$155 - \$224**





TAKE AWAY

There is a considerable contribution of capital equipment, maintenance, labour and supplies to the cost of cystoscopy. When compared to the cost of single-use cystoscopes, the profitability is highly dependent on the procedure volume and the amount of capital equipment available.

KEY FINDINGS

- A total of 3,739 flexible office cystoscopies were performed in 2019 with 9 reusable cystoscopes, equivalent to 415 procedures per cystoscope. Based on the micro-costing analysis, the total annual cost for reusable flexible cystoscopes was \$600,484, which corresponds to a per-procedure cost of \$161.
- An analysis of the urology clinic's use of reimbursement tariffs showed an average reimbursement rate of \$296.

The economics of cystoscopy: A microcost analysis, Urology⁹

[Kenigsberg et al. 2021](#)

STUDY AIM

The purpose of this study was to conduct a micro-costing analysis to estimate the per-procedure cost of reusable flexible cystoscopes and to compare this to reimbursement for procedures during the same time frame.

METHODS

- All costs were calculated using a micro-costing approach in an American urology clinic. The costs included:
 - Capital equipment: Reusable cystoscopes, storage supplies (e.g. scope hangers, cabinets, towers, etc.) and automated endoscope reprocessors.
 - Maintenance: Annual service contracts covering all reusable cystoscopes and automated endoscope reprocessors.
 - Reprocessing: Cleaning supplies (e.g. chemicals, syringes and personal protection equipment).
 - Labour cost: Labour time used for reprocessing and hourly rate.
- The per-procedure cost of reusable flexible cystoscopes was calculated by dividing the total costs from the micro-costing analysis with the number of procedures performed in 2019.

Total annual cost for reusable flexible cystoscopes
\$600,484

equivalent to
COST PER PROCEDURE
\$161



TAKE AWAY

This study shows that the single-use cystoscope significantly reduced stent dwell time and procedural time. It allowed the procedures to be done in an outpatient setting, thereby reducing the organisational pressure on endoscopy-related diagnostic procedures, and the cost associated with the procedure.

KEY FINDINGS

- A total of 72 patients (37 reusable cystoscopic stent removals, 35 single-use cystoscopic stent removals) were included in the study.
- The mean procedure time was 14.4 and 2.2 minutes for groups A and B, respectively ($p < 0.001$).
- The stent indwelling time was 26.8 and 15.4 days for groups A and B, respectively ($p < 0.001$).
- In group A, 5 patients (14%) developed stent encrustation, compared to none in group B.
- Using single-use cystoscopes for JJ stents released capacity in the endoscopy room to perform urgent diagnostic flexible cystoscopy or cancer surveillance. For this reason, the mean number of days patients waited for diagnostic cystoscopy was reduced from 21 days to 3 days.
- The cost per procedure for group A and group B was £365.40 and £252.62, respectively ($p < 0.001$), if the cost of managing complications was considered.

Comparison of ureteric stent removal procedures using reusable and single-use flexible cystoscopes: a micro cost analysis, Cent Eur J Urol¹⁰

[Pietropaolo et al. 2020](#)

STUDY AIM

The aim of this study was to compare the indwelling stent time, cost, stent-related complications and organisational impact for standard cystoscopic stent removal in the endoscopy room versus outpatient clinic-based stent removal with the single-use cystoscope (Isiris™).

METHODS

- The JJ stent removals with reusable cystoscopes took place in the endoscopy room (group A), while the procedure with single-use cystoscopes was done in the outpatient clinic (group B).
- A micro-costing analysis was performed, evaluating the impact on costs, complications and organisational benefit.

GROUP A

5 patients (14%)
developed stents
encrustation

REUSABLE

GROUP B

NONE
developed stents
encrustation

SINGLE-USE



TAKE AWAY

The cost-effectiveness of reusable cystoscopes is dependent on cystoscopy volume due to considerable upfront costs. Single-use cystoscopes are more cost effective if the total number of cases performed is less than 1265 per year.

KEY FINDINGS

- The capital, maintenance, reprocessing, and labor costs of reusable cystoscopy are \$96 000, \$99 867, \$247 855, and \$65 317, respectively.
- The total annual costs per case for reusable and single-use cystoscopy are \$149.06 and \$245.57, respectively.
- The costs of reusable cystoscopy decrease with the number of procedures per year and intersect the costs of single-use cystoscopes at 1265 procedures per year.

Micro-cost analysis of single-use vs. reusable cystoscopy in a single-payer healthcare system, Canadian Urological Association, 2022¹¹

[Kim et al. 2022](#)

STUDY AIM

The objective of this study was to compare costs of reusable cystoscopy (Olympus CYF-VH) to single-use cystoscopy (Ambu aScope Cysto 4) in a single-payer, socialized healthcare system.

METHODS

- A retrospective micro-cost analysis of reusable cystoscopy in a combined inpatient and outpatient setting at a single institution was performed. The cost analysis was divided into capital, maintenance, reprocessing, and labor.
- Annual costs were averaged over two fiscal years. Costs were amortized over 5- and 10-year basis as appropriate. The results were compared to theoretical costs of single-use cystoscopes.



OPTIMISATION OF PROCEDURE LOCATION



Portability

Not open
access

TAKE AWAY

This study shows that single-use cystoscopes can provide financial benefits and enable JJ stent removals to be moved to the outpatient setting. This makes it possible to move patient care closer to patients in a time with increasing centralisation of health care delivery associated with negative patient experiences due to increased travel times.

KEY FINDINGS

- 147 JJ stent removal attempts using the single-use cystoscope were successful.
- One patient developed UTI following JJ stent removal. There were no other complications noted and no admissions required post-procedure.
- Substantial cost savings (£63,480 in savings for this cohort compared to conventional practice) were associated with the use of single-use cystoscopes. This was due to the increased income from reimbursement tariffs associated with moving this procedure to the outpatient setting.

Isiris™ for Ureteric Stent Removal in Renal Transplantation: An Initial Single-Centre Experience of 150 Cases, Surg Innov¹²

[Doherty et al. 2021](#)

STUDY AIM

Historically, JJ stent removal has been performed via flexible cystoscopy as an inpatient procedure in the operating room. Performing this procedure in the operating room is resource-intensive and has significant costs associated with room occupation time and subsequent instrument reprocessing. The aim of this study was to report initial experiences with utilising a single-use cystoscope (Isiris™) and to do a cost comparison of single-use vs reusable cystoscopes.

METHODS

- Transplant ureteric stent removal was performed by transplant surgical trainees with the assistance of a single nurse assistant in the outpatient clinic or at the bedside (in inpatients) between October 2017 and September 2018, utilising the single-use cystoscope (Isiris™).
- The presence of UTI was defined as the presence of elevated white blood cell count on microscopy, with confirmed bacterial growth on microbiological culture.

Single-use
cystoscopes can
provide financial
benefits



Portability makes
it possible to
move care closer
to patients





Portability

Not open
access

TAKE AWAY

The single-use cystoscope for JJ stent removal represents an efficient and versatile instrument to perform JJ stent removal or other cystoscopic procedures in different hospital settings. The cost-effectiveness of such instruments becomes particularly evident in institutions where JJ stent removal is performed in the OR, leading to a significant advantage in terms of money saved per procedure and OR time gained.

KEY FINDINGS

- The mean cost per procedure was estimated at €361 for in-office stent removal with the single-use cystoscope, and €1,126.80 for OR stent removal with Storz™ reusable flexible cystoscope.
- Due to 127 procedures being performed in-office rather than in the OR, 64 hours of OR time was saved.

Cost-effectiveness analysis of a single-use digital flexible cystoscope for double J removal, Urologia¹³

[Oderda et al. 2020](#)

STUDY AIM

In the absence of an endoscopy room, the institution performs all cystoscopy procedures in the OR, with obvious consequences in terms of OR occupancy and overbooking. After implementing single-use cystoscopes (Isiris™) the department was able to perform JJ stent removals in an in-office setting instead of in the OR. The aim of the study was to do a cost comparison of single-use cystoscopes vs. reusable cystoscopes for JJ stent removal in this institution.

METHODS

- A total of 127 consecutive patients undergoing in-office stent removal with a single-use cystoscope from March to December 2017 were prospectively included in the study.
- A questionnaire was filled in after each procedure: the urologist filled in the section concerning the efficiency of the device, whereas the patient filled in the section concerning the invasiveness and tolerability of the procedure.
- Costs involved in JJ stent removal using the single-use cystoscope versus the traditional 16-Ch Storz™ reusable flexible cystoscope included:
 - A Storz™ flexible cystoscope plus grasper
 - OR occupancy
 - Medical personnel, including the aid of a nurse
 - High-level cystoscope disinfection
 - Isiris™ cystoscope and Isiris™ monitor purchase
 - Repairs in the case of damage to reusable cystoscopes (including one repair order each year)

30 MINUTES
of OR time saved
per procedure



Portability

Not open
access

TAKE AWAY

The results demonstrate that introducing the single-use cystoscope for JJ stent removal helps reduce the strain on elective waiting lists, while also being financially beneficial. Besides the cost savings associated with single-use cystoscopes, the system freed up an extra 65 elective spaces for diagnostic flexible cystoscopy cases.

KEY FINDINGS

- During the study period, 75 patients had their JJ stent removed with the single-use cystoscope.
- In the 12 months prior to introducing the single-use cystoscope, 13 reusable cystoscopes were damaged, costing \$4,888 (AUD) in repairs and replacements per month.
- In the period after introducing the single-use cystoscope, one scope was damaged at a cost of \$920 (AUD) per month. This resulted in cost savings of approximately \$23,809 on repairs and replacement over this six-month period.
- The introduction of the single-used cystoscope produced a surplus of \$104,434 (AUD).

Prospective trial of single-use, flexible cystoscope for ureteric double-J stent removal: Cost and utility analysis, J Clin Urol¹⁴

[Donato et al. 2019](#)

STUDY AIM

Given the costs associated with additional staffing, the sterilisation process and the repairing of damaged scopes, the authors of this study introduced a single-use cystoscope (Isiris™) into their hospital. The introduction of single-use cystoscopes in their department enabled them to move JJ stent removals out from endoscopy rooms to consultation rooms. The aim of this study was to compare the cost of single-use vs. reusable cystoscopes and to investigate the benefits of the single-use system to patients and its effect on the workflow in the department.

METHODS

- A prospective analysis of all JJ stent removals with the single-use cystoscopes was performed between April and September 2017.
- Data assessed included intended and actual stent indwelling time, successful removal rate, duration of the delay to stent removal, location of procedure and rates of reusable scope damage over the period.
- The cost of the single-use cystoscope and the repair costs of reusable scopes over the 12 months prior to introducing single-use cystoscopes and the six months following introduction were calculated.
- Whilst performing cystoscopies with reusable cystoscopes in their endoscopy room, they used a small consulting room to remove the majority of the stents with the single-use cystoscopes.



The single-use
system freed
up an extra

**65
ELECTIVE
SPACES**



Portability

Open
access

TAKE AWAY

Performing the JJ stent removal in a consultation room instead of the OR or endoscopic room would lead to cost savings of €45 or €140, respectively. Hence, hospitals should consider the option of single-use cystoscopes for JJ stent removal, as single-use cystoscopes do not require a dedicated place and can therefore enable cost savings. Furthermore, moving procedures such as JJ stent removals to a consultation room will enable time for other activities in the endoscopic room and OR and decrease the risk of UTI.

KEY FINDINGS

- During the year 2016, 603 JJ stent removals were performed in the endoscopic room and 6 in the OR. Total occupancy times were 301.5 hours for the endoscopic room and 3.0 hours for the OR.
- Total cost per JJ stent removal in the endoscopic room, OR and consultation room was €330, €425 and €285, respectively.

Impact of double-J stent removal with a single-use cystoscope dedicated to this procedure: A cost analysis, World J Urol¹⁵

[Doizi et al. 2018](#)

STUDY AIM

In many institutions, JJ stent removal is performed in an endoscopic room or OR and requires video equipment and reusable cystoscopes that need to be disinfected after each procedure. The aim of this study was to compare the cost of a JJ stent removal in the endoscopic room or OR with reusable instruments to the cost of a JJ stent removal with a single-use cystoscope (Isiris™) in a consultation room.

METHODS

- This retrospective monocentric study included all the JJ stent removals performed in 2016 in a French academic institution.
- The cost analysis of JJ stent removals included: costs of reusable cystoscope and grasper (including material purchase, maintenance, reprocessing by disinfection or sterilisation), cost of video equipment (including material purchase, maintenance and light cable reprocessing), and cost of endoscopic room or OR occupancy for 30 minutes.
- The cost of JJ stent removals in an endoscopic room or OR was compared to the cost of a JJ stent removal performed in an outpatient consultation room with the single-use cystoscope, including its purchase, waste process, and room occupancy for 30 minutes.

Hospitals should consider the option of single-use cystoscopes for JJ stent removal, as single-use cystoscopes do not require a dedicated place and can therefore enable cost savings.

OPTIMISED WORKFLOW

Optimised
workflowOpen
access

TAKE AWAY

The study identifies a patient preference for DTC among cystoscopy patients. Hence, single-use cystoscopes can be a good alternative in situations where DTC would otherwise be impossible due to a limited number of cystoscopes being available.

KEY FINDINGS

- Overall, most patients (85%) who responded to this question preferred DTC (8.4% omitted a response).
- According to univariate and multivariate logistic regressions analysis, there was no difference in age, gender, whether it was their first-time cystoscopy, or what the indication for cystoscopy was when comparing those who preferred DTC vs. clinical consultation appointment prior to cystoscopy ($p > 0.05$).

Direct to cystoscopy: A prospective quality assessment of patient preferences, Can Urol Assoc J¹⁶

[Assmus et al. 2020](#)

STUDY AIM

In many outpatient centres, patients need to schedule a follow-up appointment to have a cystoscopy after a clinical consultation, instead of going directly to cystoscopy (DTC). This is often due to the limited number of cystoscopes available for unplanned cystoscopies. Single-use cystoscopes are always available, enabling the possibility of going directly to cystoscopy at any time. But what do patients prefer? The aim of this study was to identify whether patients preferred to be seen DTC or after a clinical consultation appointment prior to cystoscopy.

METHODS

- A six-part patient questionnaire was distributed to adult (>18 years old) patients after their cystoscopies to evaluate their preferences. The questionnaires were provided to the patient by healthcare aids and cystoscopy nursing staff. Completion of the questionnaire occurred in a private room at the completion of their clinical interaction with the urological team.
- Prospective survey collection continued over a four-week period from September to October 2017, until 500 consecutive completed questionnaires were obtained.

85% PATIENTS
preferred going
direct to
cystoscopy after
a clinical
consultation



Optimised
workflowOpen
access

TAKE AWAY

Removal of stents in an office environment is both feasible and safe and appears to be associated with a significant potential cost saving. Patient experience has been enhanced, as evidenced by the timelier removal of stents and the reduction in complications.

KEY FINDINGS

- The excess dwell time was significantly reduced in the single-use group compared with the Standard group.
- The rate of ED attendance whilst the stent was in situ was reduced by 33.5% in the single-use group (equating to approximately £1,110 cost saving per 100 stent removals) compared with the Standard group (14.7% vs. 22.1%, $p = 0.47$).
- Fewer patients from the single-use group (11% vs. 14%) were readmitted to hospital, a reduction of 22% ($p = 0.78$) (equating to approximately £750 cost saving per 100 stent removals).
- The rate of stent removal procedures cancelled on the appointed day was lower in the single-use group compared with the Standard group, realising a 59.2% improvement in the rate of cancellations and attracting a further £1,620 per 100 cases of efficiency savings.

Office-based ureteric stent removal is achievable, improves clinical flexibility and quality of care, whilst also keeping surgeons close to their patients, Cent Eur J Urol¹⁷

[Baston et al. 2018](#)

STUDY AIM

The aim of this study was to determine whether adoption of a single-use cystoscope (Isiris™) had shortened the dwell time of stents and whether this subsequently improved the rates of post-procedure-related events observed.

METHODS

- All patients that had undergone a rigid or flexible ureteroscopy or percutaneous nephrolithotomy and received a stent between August 2013 and December 2016 were identified.
- In April 2016, in an attempt to standardise the procedure of stent removal, the process of cystoscopic stent removal was moved to the office/clinic environment, utilising the single-use cystoscope.
- Blinded to the method of stent removal employed, the operating surgeon retrospectively reviewed the operation note and recorded an ideal dwell time for that particular patient's stent.

**REDUCTION IN
READMISSION OF
22%**

**with single-use
cystoscopes**



ENVIRONMENTAL IMPACT



TAKE AWAY

Implementing a strategy of using 100% disposable cystoscopes was associated with similar costs and reduced waste generation and water consumption compared to reusable devices.

KEY FINDINGS

- A total of 1578 flexible cystoscopies using reusable cystoscopes were performed in 2020, and 550 cystoscopies were performed using the aScope 4 Cysto endoscope from October 2021 to February 2022.
- The cost of flexible cystoscopy with a reusable and a disposable endoscope was €196 and €192, respectively.
- The amount of waste generated by reprocessing reusable and disposable cystoscopes was 800g and 200g per procedure, respectively. Water consumption for sterilization of the reusable cystoscope was 60 L per procedure, whereas no water consumption was required with the Ambu® aScope™ 4 Cysto.
- A 100% use of the aScope 4 Cysto endoscope would reduce waste generation and water consumption by 946.8 kg and 94.68 m³ per year.

Cost and Environmental Impact of Disposable Flexible Cystoscopes Compared to Reusable Devices, Journal of Endourology, 2022¹⁸

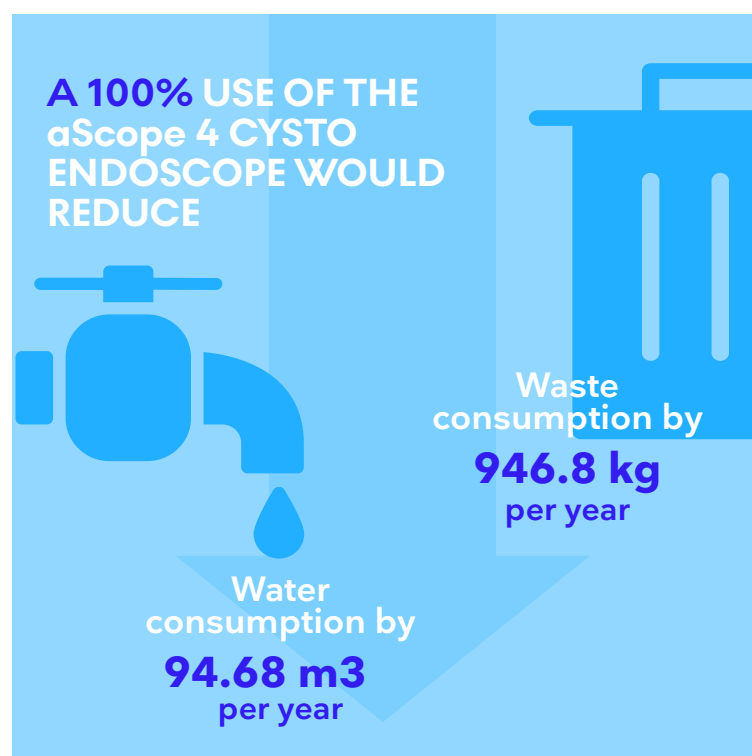
[Boucheron et al. 2018](#)

STUDY AIM

To quantify the environmental impact and costs associated with flexible cystoscopy procedures from an institutional perspective, with particular attention for the comparison between disposable and reusable cystoscopes.

METHODS

- The Ambu® aScope™ 4 Cysto single-use cystoscope (gradually replaced the reusable device in the single centre, with exclusive use from October 2021. Reprocessing costs for reusable cystoscopes were evaluated using a micro-costing approach.
- The environmental impact of reusable and disposable cystoscopes was assessed by the amount of waste and water consumed for each procedure.





TAKE AWAY

Environmental accountability is essential in modern health care. This study highlights that disposable flexible cystoscopes have a significantly lower impact on the environment in terms of carbon footprint and landfill. The authors propose that environmental impact studies should be a routine part of device development for a sustainable future.

KEY FINDINGS

- A total of 40 flexible cystoscopies (20 single-use and 20 reusable) were analysed. Median total weight of waste produced was 622 g (interquartile range [IQR] 621-651) for the single-use cystoscope compared with 671.5 g (IQR 659-677.5) for the reusable cystoscope ($p < 0.0001$).
- More waste was disposed of by incineration after single-use than reusable cystoscopy (496 g [IQR 495-525] vs 415 g [IQR 403-421.5], $p < 0.0001$). However, more waste went to landfill after reusable cystoscopy ($256 \text{ g} \pm 0$ vs $126 \text{ g} \pm 0$, $p < 0.0001$).
- There was no difference in weight of waste produced based on the indication for cystoscopy ($p = 0.1570$).
- A total of 2.41 kg of CO_2 (IQR 2.40-2.44) was produced per case for the single-use flexible cystoscope compared with 4.23 kg of CO_2 (IQR 4.22-4.24) for the reusable cystoscope ($p < 0.0001$).

The Carbon Footprint of Single-Use Flexible Cystoscopes Compared with Reusable Cystoscopes, Journal of endourology, 2022¹⁹

[Hogan et al. 2022](#)

STUDY AIM

Single-use devices for endourologic procedures are becoming more popular. The environmental impact of single-use instruments is relatively unknown. This study aimed to compare the carbon footprint of single-use vs reusable flexible cystoscopes based on waste production and estimated carbon emissions.

METHODS

- An analysis of the solid waste produced when using the single-use Ambu® aScope™ 4 Cysto endoscope compared with the reusable Cysto-Nephro Videoscope CYF-VA2 (Olympus®) was performed.
- The solid waste generated was measured (grams) and recorded as either recyclable, landfill, or contaminated, and carbon dioxide (CO_2) produced by disposal, manufacture, and cleaning was calculated.

**REDUCTION OF
50% LANDFILL**
with aScope 4 Cysto
compared to reusables



CONTAMINATED CYSTOSCOPES



TAKE AWAY

This outbreak strongly suggests that we should not trivialise UTIs occurring after an elective cystoscopy. Patients should be advised to signal the occurrence of urologic symptoms after urologic exploration. In the case of concomitant infections caused by *P aeruginosa*, the cystoscope should be suspected as a potential reservoir.

KEY FINDINGS

- Between July 7, 2015, and May 31, 2016, 389 patients underwent cystoscopies, including 104 patients using the cystoscope number 419. Four of the 104 patients exposed to the cystoscope number 419 had a *P aeruginosa* positive sample after cystoscopy.
- None of the 285 patients exposed to the three other cystoscopes were contaminated with *P aeruginosa*. Between May and October 2016, the urologists reported four further cases, all exposed to cystoscope number 419. After returning cystoscope number 419 to the manufacturer, a scratch in the cystoscope channel was identified.
- Altogether, 11 patients contracted a *P aeruginosa* UTI after cystoscopy with the cystoscope number 419, and the outbreak lasted 9 months.

An outbreak of *Pseudomonas aeruginosa* urinary tract infections following outpatient flexible cystoscopy, Am J Infect Control²⁰

[Sorbets et al. 2019](#)

STUDY AIM

The most frequent microorganisms involved in UTIs after flexible cystoscopy are *Escherichia coli*, enterococci and staphylococci, whereas *Pseudomonas aeruginosa* (*P aeruginosa*) is one of the rarer microorganisms involved in UTIs. This study reports an outbreak of *P aeruginosa* UTIs after ambulatory cystoscopies.

METHODS

- The four reusable cystoscopes used in urology consultation were hand-cleaned and disinfected according to the national recommendations in France.
- The patients who developed *P aeruginosa* UTIs between 9 July 2015 and 30 June 2016 were identified by searching data from several relevant units in the hospital. The list of identified cases of *P aeruginosa* was then compared with the list of patients who underwent a cystoscopy between 7 July 2015 and 31 May 2016.

11 PATIENTS
contracted a *P aeruginosa*
UTI after cystoscopy with
the same reusable
cystoscope

**The outbreak
lasted 9 months**



Infection
ControlNot open
access

TAKE AWAY

The rate of microbiological tests performed on cystoscopes with unacceptable CFU (colony forming unit) levels is relatively high (19.5%). Cystoscopes returning from the manufacturer following maintenance or repair are sometimes contaminated. Hidden microorganisms are present in small quantities, and identified germs are not known to be responsible for UTIs.

KEY FINDINGS

- 19.5% (17/87) of the microbiological tests showed a CFU level ≥ 1 , indicating that the cystoscopes were contaminated. This rate reached 24.5% (12/49) of the programmed controls.
- The microorganisms identified were present in small amounts, corresponding mainly to bacteria from the environment.

Microbiological evaluation of cystoscope reprocessing at Brest university hospital from January 2007 through December 2014²¹

[Saliou et al. 2016](#)

STUDY AIM

Flexible cystoscopes are relatively simple devices with an internal channel in which mineral and organic soils can accumulate in the form of biofilm. Hence, microbiological tests of cystoscopes must be carried out to ensure the effectiveness of the disinfection process. The aim of this study was to determine the success rate of disinfection and to describe the main microorganisms identified.

METHODS

- Prospective study of all the results of microbiological samples taken over an eight-year period at the Brest teaching hospital: a total of 87 microbiological tests.
- The analysis results were interpreted according to ministerial recommendations, after indications that a cystoscope was contaminated at CFU level ≥ 1 .

19.5% (17/87) of the microbiological tests showed a CFU level ≥ 1



Ambu® aScope™ 4 Cysto

Ambu® aScope™ 4 Cysto is a single-use flexible endoscope solution that gives you a way to take control of your schedule and be more productive - without compromising on the quality of your work.

It offers consistent quality because you get a brand-new cystoscope for every procedure. It has the image quality and bending performance you need to perform your cystoscopies confidently. In addition, it is always available and portable, making it easier to manage your schedule and deal with in-house consult procedures. Finally, it eliminates the need for reprocessing, costly repairs and the risk of cross-contamination. As a result, the aScope 4 Cysto simplifies workflow, frees up resources and enables you to treat more patients.



ALWAYS AVAILABLE AND PORTABLE

aScope 4 Cysto is always available and portable, making it easy for physicians to manage their schedule and deal with in-house consult procedures.

SIMPLE SET-UP

aScope 4 Cysto makes it easy for the physician to plan and manage the day. From the outpatient clinic to inpatient consult procedures, physicians can take the lightweight single-use cystoscope and portable monitor with them under their arm. And when they finish the procedure, they simply dispose of the scope, so there is no more hassle with cleaning.

EXCELLENT IMAGING AND MANOEUVRABILITY

With aScope 4 Cysto, physicians can count on clear, sharp images that make it easy to identify anatomical structures. High bending angles of 210°/120° enable the physician to manoeuvre and navigate smoothly in the urethra and bladder. The physician can advance and completely retroflex the cystoscope to inspect the bladder neck with or without forceps inserted. aScope 4 Cysto offers consistent quality without any deterioration of image or bending quality, because the physician gets a brand-new cystoscope for every procedure.

KEY FINDINGS

- **Sterile straight from the pack** - eliminates the risk of patient cross-contamination.
- **No need for post-procedure cleaning or repair** - eliminates various steps in order to optimise daily workflow.
- **Ready when you are** - hassle-free portable solution makes it easy to manage your schedule and deal with in-house consult procedures.
- **Offers cost transparency** - one cystoscope, one price and no long-term service contracts or leasing agreements.
- **Brand new every time** - ensures excellent imaging and smooth manoeuvrability with every cystoscope.
- **Frees up resources** - eliminates reprocessing and costly repairs because it is single-use. Resources can be used for other purposes.

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