# EVIDENCE DOSSIER

Ambu® aScope™ 4 Cysto



**Ambu** 

January 2023, 1st edition

This document includes published peer-reviewed studies on health economics, organizational 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 aScope<sup>™</sup> 4 Cysto, a single-use cystoscope. The introduction explains the clinical performance of aScope 4 Cysto and the market readiness of single-use cystoscopes, according to urologists worldwide.

The main section comprises studies published from November 2015 to November 2022 related to workflow, procedure relocation, health economics, and contamination of reusable cystoscopes compared to single-use. The last section presents the benefits of aScope 4 Cysto, which was launched to the U.S. market in May 2020.

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 our Global Health Economist, Dinah Rindorf (dihr@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 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, anesthesia, 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 positively impact your work.

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

For more information, please visit <u>ambuUSA.com</u>.

# CLINICAL PERFORMANCE: Ambu® aScope™ 4 Cysto¹

A flexible cystoscope is an indispensable tool for diagnosing and treating lower urinary tract disorders. For this reason, uncompromised quality and satisfactory performance of the flexible cystoscope are prerequisites when used for cystoscopy procedures.

A recently published whitepaper from Ambu describes the results from 380 evaluation forms evaluating the performance of the aScope 4 Cysto after using it for a cystoscopy procedure. Urologists in Europe, Australia, and Hong Kong filled out the evaluation forms. They rated the overall performance of the aScope™ 4 Cysto system, as well as the navigation, maneuverability, 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).

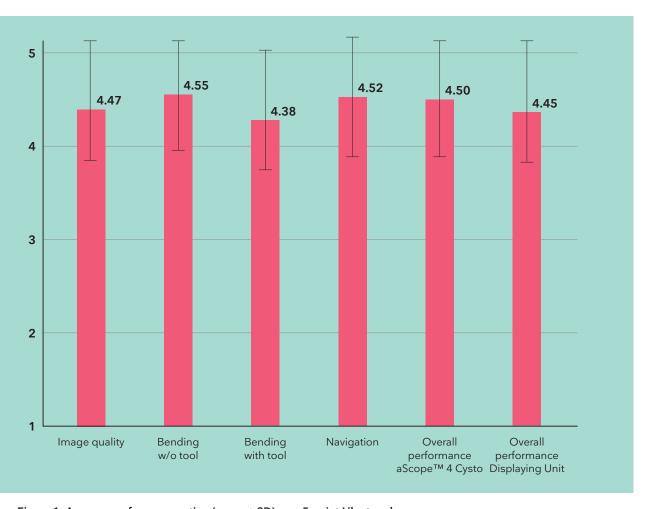


Figure 1: Average performance rating (mean  $\pm$  SD) on a 5-point Likert scale.

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.

These results indicate satisfaction with the aScope 4 Cysto system on the most critical 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. You can read the full white paper at <a href="mailto:ambuusa.com/endoscopy/urology">ambuusa.com/endoscopy/urology</a>.

# ARE UROLOGISTS AND PROCUREMENT MANAGERS READY FOR SINGLE-USE CYSTOSCOPES?

Reusable cystoscopes are why some cystoscopy procedures are delayed or canceled, because they are often unavailable due to reprocessing or repairs. Further, the U.S. Food and Drug Administration (FDA) recently announced an investigation of possible contamination issues associated with reprocessing urological endoscopes after receiving 450 medical device reports describing post-procedure patient infections or other possible contamination issues between Jan. 1, 2017, and Feb. 20, 2021. To avoid potential availability or reprocessing problems, single-use cystoscopes like the Ambu® aScope™ 4 Cysto are entering the market. Single-use cystoscopes offer a sterile scope with consistent quality and no need for reprocessing.

A recently published article investigated the market readiness for single-use cystoscopes by asking 415 urologists and procurement managers to indicate how many of their cystoscopy procedures they would consider using a single-use cystoscope.

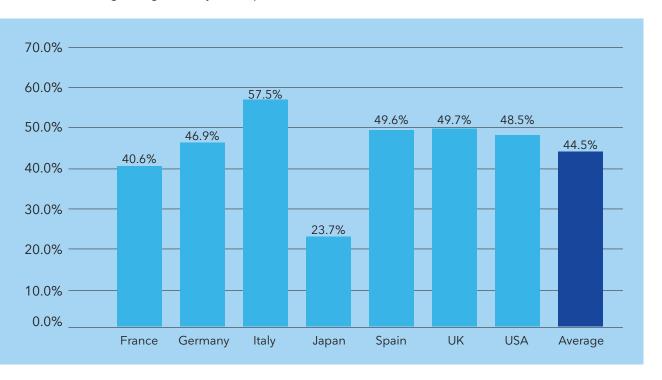


Figure 1: Average stated conversion rates from reusable to single-use cystoscopes by country

The respondents indicated they would consider converting to single-use in 44.5% of their cystoscopy procedures. Italian respondents reported the highest average conversion rate, at 57.5% of their procedures.

Further, the results also showed that respondents indicated a significantly higher conversion rate under the following circumstances:

- There was concern about cystoscopy-related infections as a result of a contaminated cystoscope.
- They were members of their institution's value committee.
- They considered cost transparency to be important when purchasing cystoscopes.
- They used single-use ureteroscopes in their department.

These results show that many urologists are open to using single-use instead of reusable cystoscopes for cystoscopy procedures. The *Research and Reports in Urology* journal offers unobstructed access to the entire paper. You can find the link to the full article at <a href="mailto:ambu.com/urology">ambu.com/urology</a>.

# 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 June 1, 2021. 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 2015.



This evidence dossier includes peer-reviewed published studies and outbreak reports related to cystoscopy procedures.

# HEALTH ECONOMICS





Due to extensive upfront costs, the value of reusable cystoscopes depends on cystoscopy volume. Disposable cystoscopes are a more affordable option if the number of cystoscopy procedures is lower than 1,265 annually.

# KEY <u>Findings</u>

- Reusable cystoscopes have considerable capital expenditures compared with disposable cystoscopes.
- Single-use cystoscopes are more economical at yearly cystoscopy volume <1,265 cases.</li>
- Disposable cystoscopes are a convenient substitute for reusable cystoscopes to bolster outpatient volume or minor capacity circumstances.

#### Micro-Cost Analysis of Single-Use vs. Reusable Cystoscopy in a Single-Payer Healthcare System<sup>2</sup>

Kim et al. 2022

#### **STUDY AIM**

To analyze the costs of reusable and single-use cystoscopy in a single-payer healthcare environment.

#### **METHODS**

- A retroactive micro-cost analysis of reusable cystoscopy in a mixed inpatient and outpatient environment at a single-use institution was completed. The costs were then separated into capital, maintenance, reprocessing, and labor.
- Yearly expenditures were then also calculated over two years.
- Costs were paid over a five- to 10-year period. The outcomes were then compared with the hypothetical cost of single-use cystoscopes.

#### Costs of reusable cystoscopy:

\$96,000 | capital | \$99,867 | maintenance | \$247,855 | reprocessing | \$65,317 | labor costs





This single-center 90-day trial of disposable flexible cystoscopy identified per-use costs to be less when a single-use flexible cystoscope was utilized at a high-volume tertiary care center.

# KEY FINDINGS

- The per-use cost for a reusable cystoscope was \$272.41 compared with \$185 for a single-use device.
- Based on the average number of cystoscopes used in procedures over a period of three months, the healthcare clinic identified in this study can expect to save \$39,142.82 annually by transitioning exclusively to a single-use cystoscope.

#### Cost Effectiveness of 90-Day Single-Use Flexible Cystoscope Trial: Single Center Micro-Costing Analysis and User Satisfaction<sup>3</sup>

Assmus et al. 2022

#### **STUDY AIM**

This study aimed to evaluate the cost-effectiveness and user satisfaction of a single-use flexible cystoscope at a tertiary care center over a 90-day period.

#### **METHODS**

- Assmus and others conducted a 90-day trial where all flexible, transurethral and percutaneous urologic care was provided using an Ambu<sup>®</sup> aScope<sup>™</sup> 4 Cysto.
- Urologists also conducted a micro-costing analysis examining payer per case cost of the reusable flexible cystoscope and disposable units.
- Provider surveys assessed visual quality, deflection, ease of working channel and overall satisfaction on a 10-point Likert scale.

Over 90 days, urologists encountered 84 cases where flexible cystoscopy was required. The Ambu® aScope™ 4 Cysto, was successfully used in 93 percent of the cases.





Single-use flexible cystoscopes are effective and safe for ureteric stent removal. They offer greater flexibility and, in most cases, are cost-effective compared with reusable flexible cystoscopes. Single-use cystoscopes are most useful in small and rural cystoscopy centers, in less well-developed countries and in facilities with heavy demand on endoscopy resources.

# KEY FINDINGS

- Compared with a reusable flexible cystoscope, a single-use device with a builtin grabber significantly reduced procedure time. It also provides a cost benefit when used in a ward or outpatient clinic setting.
- The use of a disposable flexible cystoscope allowed endoscopy slots to be used for other urgent diagnostic procedures.

#### Outcomes and Cost Evaluation Related to a Single-Use, Disposable Ureteric Stent Removal: A Systematic Review of Literature<sup>4</sup>

Hughes et al. 2022

#### **STUDY AIM**

To present the latest evidence related to the outcomes and cost of a single-use, disposable ureteric stent removal system (Isiris).

#### **METHODS**

- Evidence Acquisition A research strategy was applied to the bibliographic databases, including Medline, Embase, CINAHL, and Google Scholar. The research was limited to English articles published between 2014 and 2020. This time period coincides with the first available disposable flexible cystoscopes.
- *Inclusion Criteria* Articles recording clinical outcomes and/or cost associated with using flexible cystoscopes for ureteric stent removal.
- Exclusion Criteria Review articles or case reports articles with fewer than 10 patients.
- Data Extraction and Analysis Microsoft Excel was used to collect data. Data used included the year of publications, study location, study type, sample size, success rate, the indication of the stent, length of procedure, stent dwell time, cost, and complications.

One study in this review noted a substantial reduction in breakages and repair costs after introducing a single-use flexible cystoscope for



stent removal

- \$23,800 in
savings over a
six-month period.





Reprocessing reusable cystoscopes represents a significant fraction of the total cost per procedure, especially for high-volume facilities. The per-procedure cost depends 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 perprocedure cost ranges between \$155 and \$224
- The total reprocessing cost per cycle was \$48.90, covering the cost of supplies and labor spent on manual cleaning used in reprocessing one reusable flexible cystoscope. Labor cost accounted for 48% of the total reprocessing cost. Typically and in other published studies, reprocessing costs are greater.

A micro-costing analysis of outpatient flexible cystoscopy: implications for the adoption of single-use flexible cystoscopes, World J Urol<sup>5</sup>

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 purchasing, maintaining, and reprocessing reusable flexible cystoscopes was 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





There is a considerable contribution of capital equipment, maintenance, labor, and supplies to the cost of cystoscopy. Compared to the cost of single-use cystoscopes, the profitability depends on the procedure volume and the amount of capital equipment available.

# KEY FINDINGS

- A total of 3,739 office cystoscopies were performed in 2019 with nine 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, corresponding 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 micro-cost analysis, Urology<sup>6</sup>

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 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).
  - Labor cost: Labor time used for reprocessing and hourly rate.
- The per-procedure cost of reusable cystoscopes was calculated by dividing the total costs from the micro-costing analysis by the number of procedures performed in 2019.

Total annual cost for reusable flexible cystoscopes

\$600,484

equivalent to

**COST PER PROCEDURE** 

\$161





The per-use cost for stent removal procedures using a reusable cystoscope was estimated to be \$161.85. If the number of stent pulls exceeds 704, this cost analysis favors the single-use cystoscope over the reusable cystoscope.

# KEY FINDINGS

- A total of 1,775 cystoscopic procedures were performed, and the reusable cystoscope was used for stent removal in 871 (49%) cases.
- The estimated cost per use for stent removal procedures was \$161.85 per reusable cystoscope.
- Based on the current volume, the break-even point was calculated to be 704 stent pulls when compared to the cost of the single-use cystoscope (\$200).

#### Single-Use Grasper Integrated Flexible Cystoscope for Stent Removal: A Micro-Costing Analysis-Based Comparison, J Endourol<sup>7</sup>

Beebe et al. 2020

#### **STUDY AIM**

The study aimed to perform a micro-costing analysis comparing a single-use cystoscope for JJ stent removal (Isiris™) to the cost of using a reusable cystoscope.

#### **METHODS**

- The number of stent removal procedures at the hospital was recorded as a proportion of all cystoscopic procedures performed between February 2016 and February 2017.
- Costs involved in JJ stent removal using the Olympus<sup>®</sup> (CYF-VH) reusable flexible cystoscope versus a singleuse cystoscope include:
  - Original purchasing price of an Olympus digital reusable cystoscope
  - Servicing contract for repairs (per scope, per annum)
  - Reprocessing costs, including all materials to properly decontaminate and repackage the scope and associated equipment
  - Personnel performing the reprocessing (labor cost based on the time and salary)
  - Sterilization equipment and the accompanying accessories, as well as the service contract for the sterilizing equipment

Cost per use for reusable cystoscopes, for JJ Stent Removal was estimated to be

\$161.85

# PHYSICIAN AND PATIENT SATISFACTION





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

# KEY FINDINGS

• The mean satisfaction rate with the 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, while 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 Endourology<sup>8</sup>

Wong et al. 2021

#### **STUDY AIM**

Hereford County Hospital was the first hospital in the UK to try the Ambu® aScope 4 Cysto. This study aimed 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 20 cystoscopy procedures using the aScope 4 Cysto was compared against 20 other patients using a traditional Olympus® CYF-240 flexible cystoscope.
- All costs, excluding staffing costs, were accrued from sources within the hospital's endoscopy, pharmacy, and procurement departments, and organizations that have supplied the products to these departments.
- A patient satisfaction questionnaire was also provided, comparing reusable cystoscopes to the aScope 4 Cysto on a 10-point Likert rating scale.
- $\bullet$  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





Physicians say they prefer the Ambu® aScope™ 4 Cysto over the Olympus HD cystoscope, according to a Likert survey, because of its visibility, handling, flexion, and eagerness to use the single-use device for bedside procedures.

# KEY FINDINGS

- Evidence collected from 17 inpatient procedures - 10 completed using a new disposable cystoscope and seven with a reusable one.
- The disposable cystoscope eclipsed 200° in median upward flexion and 160° in median downward flexion, both with and without tools inside its channel.

#### Evolution of Single-Use Urologic Endoscopy: Benchtop and Initial Clinical Assessment of a New-Single-Use Flexible Cystoscope<sup>9</sup>

Whelan et al. 2021

#### **STUDY AIM**

To conduct a benchtop and clinical evaluation of the Ambu® aScope™ 4 Cysto disposable cystoscope.

#### **METHODS**

- Disposable cystoscopes were analyzed based on their efficiency, maximum tip flexion, and irrigation flow rate with an empty working channel.
- •The aScope™ 4 Cysto cystoscopes were flexed on several occasions in every conceivable direction possible, and flexion angles were rescaled with and without instruments.
- •A review of clinical use was performed using a Likert survey and NASA Task-Load Index to access inpatient bedside practices.

25x



# **OUTCOMES**





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 organizational pressure on endoscopy-related diagnostic procedures and the cost associated with the process.

# KEY FINDINGS

- A total of 72 patients (37 reusable cystoscopic stent removals, 35 single-use 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).</li>
- The stent indwelling time was 26.8 and 15.4 days for groups A and B, respectively (p < 0.001).</li>
- In group A, five patients (14%) developed stent encrustation, compared to none in group B.
- Using single-use scopes for JJ stents released capacity in the endoscopy room to perform urgent, 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.
- If the cost of managing complications was considered, the cost per procedure for group A and group B was £365.40 and £252.62 (This would equate to roughly \$417.03 and \$288.32 USD) (p<0.001).

Comparison of ureteric stent removal procedures using reusable and single-use flexible cystoscopes: a micro cost analysis, Cent Eur J Urol<sup>10</sup>

Pietropaolo et al. 2020

#### **STUDY AIM**

This study aimed to compare the indwelling stent time, cost, stent-related complications and organizational impact of standard cystoscopic stent removal in the endoscopy room versus outpatient clinic-based stent removal with the single-use cystoscope (Isiris $^{\text{M}}$ ).

#### **METHODS**

- The JJ stent removals with reusable cystoscopes took place in the endoscopy room (group A). 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 organizational benefit.

GROUP A

5 patients (14%)
developed stents
encrustation

REUSABLE

GROUP B

NONE developed stents encrustation **SINGLE-USE** 

# OPTIMIZATION OF PROCEDURE LOCATION





The single-use cystoscope for JJ stent removal is 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

- Due to 127 procedures being performed in-office rather than in the OR, 64 hours of OR time was saved.
- 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<sup>™</sup> reusable flexible cystoscope. (These costs would be roughly \$1,127.48 and \$\$361.22 USD)

#### Cost-effectiveness analysis of a single-use digital flexible cystoscope for double J removal, Urologia<sup>11</sup>

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 study aimed 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 out 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<sup>™</sup> flexible cystoscope plus grasper
  - OR occupancy
  - Medical personnel, including the aid of a nurse
  - High-level cystoscope disinfection
  - Isiris<sup>™</sup> cystoscope and Isiris<sup>™</sup> monitor purchase
  - Repairs in the case of damage to reusable cystoscopes (including one repair order each year)







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 before introducing the single-use cystoscope, 13 reusable cystoscopes were damaged, costing \$4,888 (AUD), or \$3,280.70 USD, in repairs and replacements per month.
- After introducing the single-use cystoscope, 65 extra spaces were freed up for diagnostic cases. Additionally, the switch resulted in repair and replacement cost savings of approximately \$23,809 over the study's sixmonth period.
- The introduction of the single-used cystoscope produced a surplus of \$104,434 (AUD), or \$70,093.49 USD.

#### Prospective trial of single-use, flexible cystoscope for ureteric double-J stent removal: Cost and utility analysis, J Clin Urol<sup>12</sup>

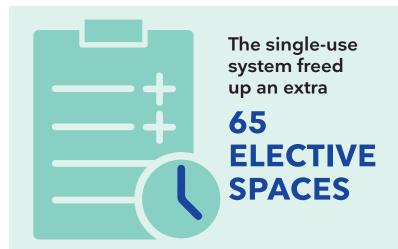
#### Donato et al. 2019

#### **STUDY AIM**

Given the costs associated with additional staffing, the sterilization process and the repairing of damaged scopes, the authors of this study introduced a single-use cystoscope (Isiris™) into their hospital. Introducing single-use cystoscopes in their department enabled them to move JJ stent removals out from endoscopy rooms to consultation rooms. This study aimed 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 were 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 introduce single-use cystoscopes and the six months following introduction were calculated.
- While performing cystoscopies with reusable cystoscopes in their endoscopy room, they used a small consulting room to remove the majority of the stents with single-use cystoscopes.







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 (This would equate to roughly \$45.04 and \$140.11 USD), 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 allow 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, (This would equate to roughly \$330.26, \$425.33, and \$285.22 USD) respectively.

#### Impact of double-J stent removal with a single-use cystoscope dedicated to this procedure: A cost analysis, World J Urol<sup>13</sup>

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 amount of a JJ stent removal with a single-use cystoscope (Isiris $^{\text{\tiny{M}}}$ ) in a consultation room.

#### **METHODS**

- This retrospective monocentric study included all the JJ stent removals were 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 sterilization). It also included 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 value 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.

# IMPROVED WORKFLOW





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 before cystoscopy (p>0.05).

#### Direct to cystoscopy: A prospective quality assessment of patient preferences, Can Urol Assoc J<sup>14</sup>

Assmus et al. 2020

#### **STUDY AIM**

In some outpatient centers, patients are required to schedule a follow-up appointment to have a cystoscopy after 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 2017 to October 2017, until 500 consecutive completed questionnaires were obtained.

Most patients (85%) preferred going direct to cystoscopy after a clinical consultation







Removal of stents in an office environment is both feasible and safe and appears to be associated with significant potential cost savings. 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.

Office-based ureteric stent removal is achievable, improves clinical flexibility and quality of care, while also keeping surgeons close to their patients, Cent Eur J Urol<sup>15</sup>

Baston et al. 2018

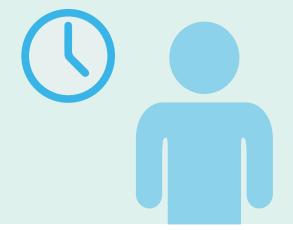
#### **STUDY AIM**

This study aimed to determine whether adoption of a single-use cystoscope ( $Isiris^{m}$ ) 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 standardize the procedure of stent removal, the process of cystoscopic stent removal was moved to the office/clinic environment, utilizing 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.

Excess dwell time was significantly reduced in the single-use group compared with the standard group, enhancing patient experience.



# CONTAMINATED CYSTOSCOPES





This outbreak strongly suggests that we should not trivialize 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 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 2016 and October 2016, the urologists reported other 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 cystoscope number 419, and the outbreak lasted nine months.

#### An outbreak of Pseudomonas aeruginosa urinary tract infections following outpatient flexible cystoscopy, Am J Infect Control<sup>16</sup>

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 a urology consultation were hand-cleaned and disinfected according to the national recommendations in France.
- The patients who developed P aeruginosa UTIs from July 9, 2015, to June 30, 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 from July 7, 2015, to May 31, 2016.

## 11 PATIENTS

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

The outbreak lasted nine months





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 contamination of the cystoscopes. 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 2014<sup>17</sup>

Saliou et al. 2016

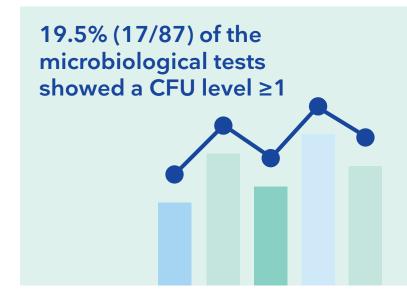
#### **STUDY AIM**

Flexible cystoscopes are relatively simple devices with an internal channel in which mineral and organic soils can accumulate in the form of biofilm. Microbiological tests of cystoscopes must be carried out to ensure the effectiveness of the disinfection process.

The study aimed to determine the success rate of disinfection and to describe the main microorganisms identified.

#### **METHODS**

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







Infectious outbreaks have previously been associated with reusable cystoscopes; however, this is the first study to report an infectious outbreak caused by Salmonella spp.

Strict control of cleaning and disinfection of reusable cystoscopes should be carried out to avoid transmission of infections related to the use of these devices.

# KEY FINDINGS

- A total of 4 patients contracted a Salmonella spp. UTI after cystoscopy within a period of three weeks between October 2014 and November 2014.
- The index patient was subsequently identified as a faecal carrier of Salmonella spp., suggesting that urethral colonization may be due to contiguity.
- After reinforcing the cleaning and disinfection of all reprocessing equipment and cystoscopes, no additional cases were identified up until December 2014.

#### Outbreak of Urinary Tract Infections by Salmonella Spp. after Cystoscopic Manipulation, Actas Urol Esp<sup>18</sup>

Jimeno et al. 2016

#### **STUDY AIM**

Over a few months, a university hospital in Spain identified a worrying increase in urine cultures positive for Salmonella spp. This study reports an outbreak of Salmonella spp. UTIs after cystoscopy procedures at their hospital.

#### **METHODS**

- The cystoscopes were cleaned first by soaking the cystoscope in enzymatic detergent (Enzym®) and second in a highly disinfecting solution (Instrunet®). Finally, the system was rinsed with saline.
- The presence of an infectious outbreak was considered after experiencing a worrying increase in urine cultures positive for Salmonella spp. in the period between October and November 2014. All patients that developed Salmonella spp. UTIs were identified, and their records showed that all these patients had once undergone a cystoscopy.

Strict control of cleaning and disinfection of reusable cystoscopes should be carried out to avoid transmission of infections related to the use of these devices.

# **SUSTAINABILITY**





Performing a cystoscopy with a singleuse cystoscope produced less waste and generated less carbon dioxide (CO<sub>2</sub>) than when the procedure was done with a reusable scope.

# KEY <u>Finding</u>s

Median total weight of waste produced was 622 grams (g) for the single-use cystoscope and 671.5 g for the reusable cystoscope. More waste was incinerated after single-use than cystoscopy with a reusable scope, though more waste went to landfill after reusable cystoscopy. A total of 2.41 kg of CO<sub>2</sub> was produced per case for the single-use flexible cystoscope compared with 4.23 kg of CO<sub>2</sub> for the reusable cystoscope.

#### The Carbon Footprint of Single-Use Flexible Cystoscopes Compared with Reusable Cystoscopes, Journal of Endourology<sup>19</sup>

Hogan et al. 2022

#### **STUDY AIM**

The environmental impact of single-use urologic devices is relatively unknown despite their growing popularity. This study compares the carbon footprint of single-use flexible cystoscopes against reusable ones based on waste production and estimated carbon emissions.

#### **METHODS**

• Researchers analyzed the solid waste produced by using the Ambu® aScope™ 4 Cysto single-use flexible cystoscope compared to the reusable Olympus® Cysto-Nephro Videoscope CYF-VA2. The solid waste generated was measured in grams and recorded as either recyclable, landfill, or contaminated. Researchers also calculated carbon dioxide produced by disposal, manufacture, and cleaning.

This study highlights that disposable flexible cystoscopes have a significantly lower impact on the environment in terms of carbon footprint and landfill.







According to the study, single-use cystoscopes significantly reduce water consumption and waste generation associated with a cystoscopy procedure when compared with their reusable counterparts.

# KEY FINDINGS

- More than two pounds of waste were generated per procedure using a reusable cystoscope, compared with seven ounces per procedure for a single-use device. In addition, it takes nearly 15 gallons of water per endoscope cleaning cycle to reprocess a reusable scope.
- The researchers write that by exclusively using single-use cystoscopes, a clinic would reduce waste by 2,087 pounds and water by more than 25,000 gallons per year.

#### Cost and Environmental Impact of Disposable Flexible Cystoscopes Compared to Reusable Devices, Journal of Endourology<sup>20</sup>

Boucheron et al. 2022

#### **STUDY AIM**

The study aimed to quantify the environmental impact and costs associated with a flexible cystoscopy procedure from an institutional perspective, with particular attention to the comparison between disposable and reusable cystoscopes.

#### **METHODS**

- This single-center retrospective study includes information about all flexible cystoscopies performed between 2020 and 2021 using reusable and singleuse devices.
- The Ambu<sup>®</sup> aScope<sup>™</sup> 4 Cysto single-use cystoscope gradually replaced the reusable device in the singlecenter study, with exclusive use from October 2021 to February 2022.
- Reprocessing cost for reusable cystoscope procedures
  was evaluated using a micro-costing approach (what
  the researchers call a more accurate method of
  resource-use assessment in economic analyses of
  surgical interventions).
- The amount of waste and water consumed for each procedure was used to assess the environmental impact of reusable and disposable cystoscopes.

Based on the number of cystoscopy procedures performed in 2020 (1,578), the clinic identified in the study expects to save more than \$6,400 a year by switching to the Ambu aScope 4 Cysto

# 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 their day. From the outpatient clinic to inpatient consult procedures, physicians can take the lightweight single-use cystoscope and portable monitor under their arm. And when they finish the procedure, they dispose of the scope, so there is no more hassle with cleaning.

#### **EXCELLENT IMAGING AND MANEUVERABILITY**

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 maneuver and navigate the urethra and bladder smoothly. 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 to optimize daily workflow.
- **Ready when you are** hassle-free portable solution makes managing your schedule and dealing with in-house consult procedures easy.
- 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 maneuverability 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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