

EVIDENCE DOSSIER

Ambu® aScope™ 5 Uretero



Ambu

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This document includes published peer-reviewed studies on health economics, elimination of costly repairs, improving clinical outcomes, decreasing operative time, and decreasing length of hospital stay related to single-use ureteroscopes.

CONTENTS

04 Preface

05 Concerns related to reprocessing of reusable ureteroscopes

06 The environmental impact of single-use ureteroscopes

07 Supporting evidence-based practice with best available evidence

08 Health Economics

- 09 Large et al. 2020
- 10 Al-Balushi et al. 2019
- 11 Mager et al. 2018
- 12 Taguchi et al. 2018
- 13 Martin et al. 2016

14 Elimination of costly repairs

- 15 Rindorf et al. 2022

16 Improving clinical outcomes

- 17 Unno et al. 2023
- 18 Bragaru et al. 2023
- 19 Meng et al. 2021
- 20 Li et al. 2021
- 21 Yang et al. 2021

22 Decreasing length of hospital stay

- 23 Huang et al. 2022
- 24 Bozzini et al. 2021

25 Decreasing operative time

- 26 Göger et al. 2021
- 27 Usawachintachit et al. 2018

28 References

ABBREVIATIONS

FDA: US Food and Drug Administration

MDRs: Medical Device Reports

fURS: Flexible ureteroscopes

CO₂: Carbon dioxide

SD: Standard deviation

SFR: Stone-free rate

OR: Odds ratio

95% CI: 95% confidence interval

RIRS: Retrograde intrarenal surgery

MDR: Medical Device Report

PREFACE

This dossier gives you an overview of the evidence-based landscape related to the Ambu® aScope™ 5 Uretero, a single-use ureteroscope. The introduction includes a description of concerns related to reprocessing of reusable ureteroscopes and explains the environmental impact of single-use ureteroscopes compared to reusable ureteroscopes.

The main section includes relevant published peer-reviewed studies on health economics, elimination of costly repairs, improving clinical outcomes, decreasing operative time, and decreasing length of hospital stay related to single-use ureteroscopes. The last section presents the benefits of the Ambu® aScope™ 5 Uretero.

While each study summary is true to the original publication, the original copies can be made available upon request if open access. Should you wish to discuss any publication in this dossier in more detail, do not hesitate to send an enquiry to the Global Health Economics team at Ambu - global_hema@ambu.com.

A literature search on ureteroscopes has been conducted to generate the evidence dossier in order to give the reader the opportunity to obtain a balanced overview of existing literature relevant to disposable ureteroscopes such as the aScope™ 5 Uretero. 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 clinical landscape concerning the aScope™ 5 Uretero 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 the aScope™ 5 Uretero, which have a positive impact on your work.

Headquartered near Copenhagen, Denmark, Ambu employs approximately 4,500 people in Europe, North America, Latin America and the Asia-Pacific region.

For more information, please visit ambu.com.

CONCERNS RELATED TO REPROCESSING OF REUSABLE URETEROSCOPES

On April 1, 2021, the US Food and Drug Administration (FDA) issued a safety alert by sharing a letter to health care providers about infections linked to reprocessed urological endoscopes. In this letter, the FDA stated that from January 2017 to April 2021 they had received more than 450 Medical Device Reports (MDRs) that described patient infections post procedure or other possible contamination issues associated with reprocessing urological endoscopes. In those reports that provided the name of the device manufacturer, either Olympus Corporation or Karl Storz was cited. According to the letter, three of the 450 MDRs included patient death; all three described patients who developed *Pseudomonas aeruginosa* infections post procedure. The FDA is currently reviewing the potential causes and contributing factors associated with the reported infections or contamination issues, including reprocessing methods, reprocessing instructions in the labelling, and device design. The full communication can be read [here](#).

On April 1, 2022, Karl Storz initiated a voluntary urgent medical device recall of specific ureteroscopes due to patient infection and contamination risk caused by inadequate reprocessing instructions. On request from FDA, Karl Storz conducted reprocessing validation tests and identified reprocessing failures following high-level disinfection. Recommendation was made to sterilize the affected urological endoscopes after each use by using sterilization methods recommended in the instructions for use specific to each device. The full communication can be read [here](#).

URETEROSCOPY MDR FREQUENCY

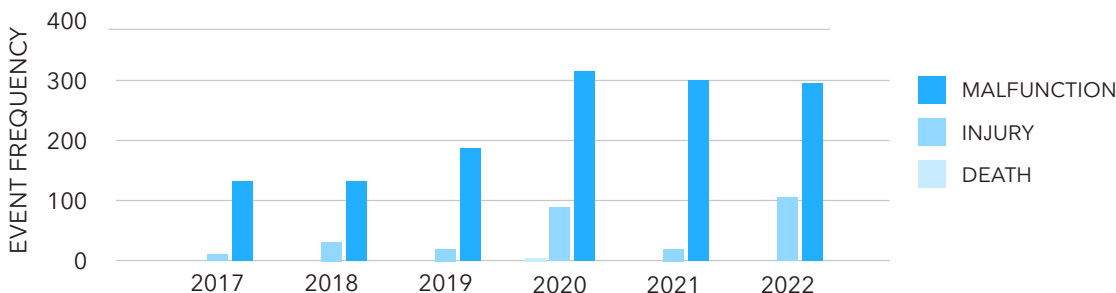


Figure 1: Ureteroscopy MDR Frequency based on data from FDA's MAUDE database ^o

In addition, studies have highlighted reprocessing of reusable ureteroscopes. In a recent narrative review, the authors urge urologists to: “engage in evidence-based initiatives to strengthen *fURS* reprocessing and maintenance guidelines, assess reprocessing and quality assurance practices in their institutions, make improvements as needed, and bolster the evidence base to support decision-making and patient safety initiatives in the field”¹. In another study, reprocessing activities that generate splashes were examined, and the distance of how far droplets can travel in decontaminated areas was determined. Routine reprocessing activities generated substantial splashing, and currently recommended personal protective equipment did not adequately protect sterile processing personnel from exposure². These studies, together with the FDA safety alert, highlight concerns related to reprocessing of reusable ureteroscopes. To accommodate these concerns, the single-use ureteroscope Ambu® aScope™ 5 Uretero may be a solution for daily urology practice, with uncompromising quality with every use.

^o Data included in the graph are extracted from the US Food and Drug Administration (FDA) website: [MAUDE - Manufacturer and User Facility Device Experience \(fda.gov\)](https://www.fda.gov/maude)

THE ENVIRONMENTAL IMPACT OF SINGLE-USE URETEROSCOPES

Healthcare services in developed countries are a concerning source of environmental emissions, and the environmental impact of single-use ureteroscopes such as the aScope™ 5 Uretero may therefore cause concern. However, a comparative study by Davis et al. from 2018 has shown that the environmental impact of single-use fURS and reusable fURS is comparable.

The study showed that the total carbon footprint of a single-use ureteroscope was 4.43 kg CO₂ per case, and the total carbon footprint of a reusable ureteroscope was 4.47 kg CO₂ per case. The total carbon footprint of the life cycle of both single-use and reusable fURS was therefore <5 kg of CO₂ per case, which is favourable compared to other medical equipment and surgical procedures. Thus, the environmental impact of single-use ureteroscopes such as the aScope™ 5 Uretero is not of specific concern. The scientific paper by Davis et al. can be read [here](#).

Total carbon footprint (kg of CO₂) of components of single-use and reusable fURS³.

Components of the life cycle	Single-use fURS ^b	Reusable fURS ^c
Manufacturing cost	3.83	0.06
Solid waste	0.3	0.005
Washing/Sterilisation	0.3	3.95
Repackaging	-	<0.005
Repair	-	0.45
Total per case	4.43	4.47

The study by Davis et al. highlights the importance of environmental emissions due to ureteroscopy. Ambu A/S is extending its efforts to minimise negative environmental impact by introducing bio-attributed materials in the handle of the aScope 5 Uretero. This is a significant step forward, and one which aligns with Ambu's commitment to environmental responsibility. In addition to the introduction of bio-attributed material, all secondary packaging components in the aScope 5 Uretero are 100% recyclable. Explore more about Ambu's commitment to sustainability by reading [here](#).

^b LithoVue™

^c URV-FTM with a life cycle of 180 uses and 11 repairs

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 each 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 July 1, 2023. 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. To provide the reader with the most up-to-date studies, this document only includes studies published after 2017.



This evidence dossier includes summaries of 15 published studies related to ureteroscopy procedures.

HEALTH ECONOMICS



Cost

Open
access

TAKE AWAY

The Axis™ single-use digital ureteroscope is equivalent in function and reduces the cost of flexible ureteroscopy procedures compared with digital reusable ureteroscopes.

KEY FINDINGS

- A total of 93 flexible ureteroscopy procedures were performed with single-use ureteroscopes during the study period.
- The utilization of single-use ureteroscopes was associated with an average reduction of \$140 per case. When extrapolating the per-case savings over an annual case volume, the total savings were \$56,127.
- The mean \pm standard deviation (SD) score for image quality, mobility and ergonomics was 9.1 ± 1.1 , 8.9 ± 1.1 and 9.3 ± 1.1 , respectively. The 90-day complication rates were equal to the reusable ureteroscopes.

Initial Experience with Novel Single-Use Disposable Ureteroscopy: A Prospective, Single Arm 90-Day Trial of the Axis Ureteroscope, Urology Practice, 2020⁴

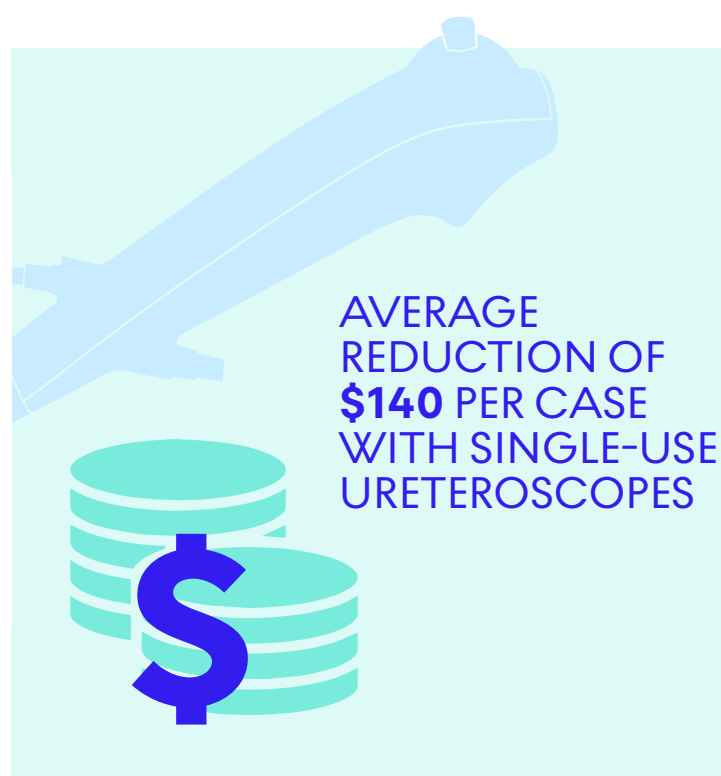
[Large et al. 2020](#)

STUDY AIM

The aim of the study was to demonstrate clinical equivalence and evaluate the cost of a single-use digital ureteroscope (Axis™) compared to a reusable platform.

METHODS

- The study was conducted as a prospective single-site 90-day trial with all flexible ureteroscopy procedures completed using a single-use ureteroscope.
- An immediate postoperative REDCAP® survey was used to monitor cases for scope failure, deficiencies, and surgeon satisfaction scores.
- A cost analysis between reusable and single-use ureteroscopes was also performed. The cost of reusable ureteroscopes included the amortized initial purchase, maintenance, and cleaning processing.





TAKE AWAY

The introduction of single-use fURS provides substantial help to maintain a standard level of flexible ureteroscopy procedures and reduce the rate of cancellation.

KEY FINDINGS

- The main cause of cancellation or rescheduling in 2017 was the unavailability of fURS due to breakdown or repair.
- In 2017, the repair costs of reusable fURS increased by 345% compared with the period 2011-2016.
- Single-use fURS accounted for 59% of flexible ureteroscopy procedures after they were introduced.
- Single-use fURS were more cost-effective compared to reusable fURS up to the 22nd procedure for the period 2011-2016 vs. the 73rd procedure in 2017, when taking costs of processing, maintenance and repair into account.
- Unavailability due to breakdown or repair of flexible ureteroscopes has been shown to account for 55% of all cancellations. Switching to single-use flexible ureteroscopes reduces the rate of cancellation due to fURS.

Comparative medico-economic study of reusable vs. single-use flexible ureteroscopes, *Int Urol Nephrol*, 2019⁵

[Al-Balushi et al. 2019](#)

STUDY AIM

The aim of the study was to evaluate the economic and practical advantages and disadvantages of using reusable vs. single-use fURS.

METHODS

- The study was a single-center retrospective study with the incidence of breakage and repairs of reusable fURS being evaluated in 2017.
- The overall operational costs of reusable fURS, including purchase, processing and repairing, were assessed from 2011 to 2017.
- The authors created a model to compare operation costs per procedure of single-use fURS with reusable fURS, depending on repair costs.

ACCOUNTS FOR ALL CANCELLATIONS

55%

Unavailability due to breakdown or repair of flexible ureteroscopes





TAKE AWAY

The study showed equal clinical effectiveness of reusable and single-use fURS, and partially overlapping ranges of costs for reusable and single-use fURS.

KEY FINDINGS

- The comparison of clinical outcomes between reusable and single-use fURS showed no significant difference for overall success rates (81 vs. 87%), stone-free rates (SFRs) (82 vs. 85%), operation time (76.2 ± 46.8 vs. 76.8 ± 40.2 min), radiation exposure time (3.83 ± 3.15 vs. 3.93 ± 4.43 min) or complication rates (7 vs. 17%).
- A wide range of repair and purchase costs resulted in a total cost of \$1,212-\$1,743 per procedure for reusable fURS, whereas the price for single-use fURS was \$1,300-\$3,180.

Clinical outcomes and costs of reusable and single-use flexible ureterorenoscopes: a prospective cohort study, Urolithiasis, 2018⁶

[Mager et al. 2018](#)

STUDY AIM

The aim of the study was to analyse the clinical outcomes and costs of single-use fURS in comparison with reusable fURS in a tertiary referral center.

METHODS

- 68 procedures with single-use fURS (LithoVue™) and 68 procedures with reusable fURS (Flex-X2S, Flex-XC) were prospectively collected.
- Clinical outcome parameters included overall success rate, complication rates according to Clavien-Dindo, operation time and radiation exposure time.
- The cost analysis was based on purchase costs and recurrent costs for repair and reprocessing divided by number of procedures.





TAKE AWAY

When accounting for costs in labour, consumables and repair, the total cost per ureteroscopy procedure was comparable between the reusable URF-P6™ and the single-use LithoVue™ ureteroscope.

KEY FINDINGS

- The mean total operating-room time was 93.4 ± 32.3 and 73.6 ± 17.4 minutes for URF-P6™ and LithoVue™, respectively ($p=0.093$).
- Labour and consumables during reprocessing of URF-P6™ had a cost of \$107. The cost of ureteroscopy repair and capital acquisition per ureteroscopy procedure using URF-P6™ was \$958 and \$116, respectively.
- The purchase cost per LithoVue single-use ureteroscope was \$1500.

Micro-Costing Analysis Demonstrates Comparable Costs for LithoVue Compared to Reusable Flexible Fiberoptic Ureteroscopes, J Endourol, 2018⁷

[Taguchi et al. 2018](#)

STUDY AIM

The aim of the study was to perform a micro-cost comparison between flexible reusable fiberoptic ureteroscopes (URF-P6™) and single-use digital ureteroscopes (LithoVue™).

METHODS

- The study was designed as a prospective, single-center micro-costing study with all consecutive ureteroscopies performed for one week in July and one week in August 2016 using LithoVue™ and URF-P6™ ureteroscopes, respectively.
- Workflow data included intraoperative events, postoperative reprocessing cycle timing, consumable usage, and ureteroscopy cost data.





TAKE AWAY

The financial viability of a flexible ureteroscope depends on case volume, rates of reusable ureteroscope repairs and the market price of single-use ureteroscopes.

KEY FINDINGS

- A reusable fURS was used in 160 procedures with a total of 11 repairs during the study period.
- The average time to failure for reusable fURS was 12.5 procedures.
- The cost analysis showed that the amortised cost per use of a reusable fURS was \$848, excluding the original purchasing costs.

The Economic Implications of a Reusable Flexible Digital Ureteroscope: A Cost-Benefit Analysis, J Urol, 2016⁸

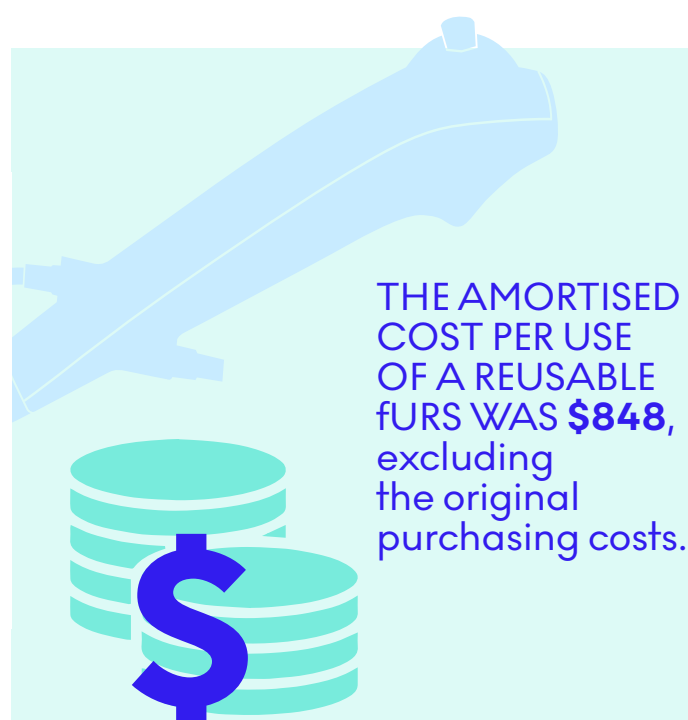
[Martin et al. 2016](#)

STUDY AIM

The aim of the study was to estimate the potential economic benefits of single-use flexible digital ureteroscopes compared to reusable flexible digital ureteroscopes.

METHODS

- Ureteroscopy procedures performed over a 12-month period from February 2014 to February 2015 were included in the study.
- All flexible ureteroscopy procedures were performed using a Karl Storz Flex-XC™ digital ureteroscope.
- The cost assessment was based on the original purchasing cost and repair-exchange fees divided by number of cases.
- An algorithm including per-case reprocessing costs was made to calculate a benefit-cost ratio.
- The costs of the reusable flexible digital ureteroscope were compared to potential costs of the single-use ureteroscope LithoVue™.



ELIMINATION OF COSTLY REPAIRS



Cost/Repair

Open
access

TAKE AWAY

The study showed a repair rate of 6.5%, equivalent to 15 ureteroscopy procedures before repair, which corresponds to an average repair cost of \$441 per procedure. The authors highlight that breakage rates and repair costs should be considered to optimise the use of reusable vs. single-use ureteroscopes.

KEY FINDINGS

- 18 studies were identified through the systematic literature search. These studies included a total of 411 repairs from 5,900 ureteroscopy procedures.
- The average repair rate was 6.5%±0.745% (95%CI: 5.0-7.9; I²=75.3%) equivalent to 15 ureteroscopy procedures before repair.
- The average cost per repair was \$6,808, which corresponds to an average repair cost of \$441 per procedure, according to a repair rate of 6.5%.

Repair Rate and Associated Costs of Reusable Flexible Ureteroscopes: A Systematic Review and Meta-analysis, Eur Urol Open, 2022⁹

[Rindorf et al. 2022](#)

STUDY AIM

The aim of the study was to systematically review the existing literature on repair rates of ureteroscopy procedures, and to estimate the total weighted repair rate and the average repair cost per procedure of reusable fURS.

METHODS

- A systematic review search according to PRISMA guidelines was conducted in PubMed, Embase, Web of Science and Cochrane Library databases.
- The average cost of all repairs was extracted from the included studies, and a random-effect model was used to calculate the pooled total fURS repair rate.
- Publication bias was assessed using funnel plots and an Egger's regression test.

\$441

AVERAGE REPAIR COST

per procedure
with reusable
ureteroscopes



IMPROVING CLINICAL OUTCOMES

Clinical
outcomesNot open
access

TAKE AWAY

This study demonstrates that single-use ureteroscopes are associated with a decreased risk of UTI after stone removal compared to reusable ureteroscopes.

KEY FINDINGS

- 991 patients were included, of which 50.4% underwent ureteroscopy with a single-use ureteroscope.
- Rates of postoperative UTI were lower for ureteroscopic stone removal with a single-use ureteroscope compared to a reusable ureteroscope (6.5% vs 11.9%, $p = 0.018$).
- Use of a single-use ureteroscope was associated with lower odds of postoperative UTI compared to a reusable ureteroscope when adjusting for risk (odds ratio 0.37, $p = 0.015$).
- Use of a single-use ureteroscope was associated with a higher subjective stone clearance rate compared to a reusable ureteroscope (90.0% vs 83.9%, $p = 0.005$).

Single-Use Ureteroscopes Are Associated with Decreased Risk of Urinary Tract Infection After Ureteroscopy for Urolithiasis Compared to Reusable Ureteroscopes. J Endourol. 2023¹⁰

[Unno et al. 2023](#)

STUDY AIM

The objective of the study was to compare rates of postoperative UTI after ureteroscopy for urolithiasis performed with single-use ureteroscopes vs. reusable ureteroscopes.

METHODS

- A single-center, retrospective cohort study of ureteroscopy for urolithiasis between June 2012 and March 2021, comparing patients who underwent stone removal with single-use and reusable ureteroscopes.
- Between 2012 and 2015, data were retrospectively extracted from the medical records, and, from 2015 and beyond, all data were prospectively captured in the Registry of Stones of the Kidney and Ureter. The decision as to the type of ureteroscope used during the surgery was at the surgeon's discretion.
- If positive preoperative urinalysis, a reflex urine culture was performed and treated appropriately. Perioperative antibiotics were given in keeping with AUA best-practice statements. Routine postoperative antibiotics were not given.

Rates of postoperative UTI were lower for ureteroscopic stone removal with a single-use ureteroscope compared to a reusable.

Clinical
outcomes
 Open
access

TAKE AWAY

Single-use and reusable fURS are at least comparable to one another in terms of their visibility, and their capacity and manoeuvrability. Further, the single-use fURS showed improved irrigation.

KEY FINDINGS

- Intraoperatively, there was no significant difference between the image quality of reusable and single-use fURS cameras ($p>0.4$).
- The reusable fURS URF-V2 and the single-use ureteroscope had similar manoeuvrability; however, the score of manoeuvrability was significantly less for the reusable fURS URF-V ($p=0.03$).
- The single-use fURS had more than 50% improved irrigation, both with an empty working channel and with the fibre laser inserted through it.

Comparison of Flexible Ureteroscope Performance between Reusable and Single-Use Models. J Clin Med, 2023¹¹

[Bragaru et al. 2023](#)

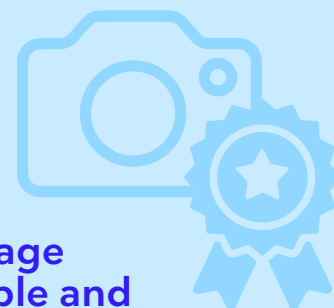
STUDY AIM

The aim of the study was to evaluate and compare reusable flexible ureteroscopes (fURS) with single-use flexible ureteroscopes in in-vitro and in-vivo scenarios, making use of both objective and subjective factors.

METHODS

- The influence of a variety of instruments on the flow of irrigation and its deflection was investigated ex vivo. 20 patients were treated with a reusable fURS (URF-V2), 20 patients with another reusable fURS (URF-V), and 20 patients with a single-use fURS (Uscope).
- The visibility and manoeuvrability of each fURS were evaluated by the same urologist during the procedures, and the results were compared.
- The urologist who carried out the procedure scored the manoeuvrability during the examinations of all the caliceal groups, to evaluate both the successfulness of the procedure and how easy it was to access all of the calyces.

**No significant
difference
between the image
quality of reusable and
single-use ureteroscopes**



Clinical
outcomesOpen
access

TAKE AWAY

This meta-analysis demonstrates that single-use fURS have similar effectiveness and better security for treating upper urinary calculi compared to reusable fURS.

KEY FINDINGS

- Seven studies were identified in the systematic literature review, including a total of 1,020 patients.
- A statistical difference was only found in the Clavien-Dindo grade II postoperative complication (OR: 0.47; 95% CI, 0.23-0.98; $p=0.04$).
- No significant statistical differences between single-use and reusable fURS were observed in operative time, estimated blood loss, length of hospital stays and SFR.

Comparison Between Single-Use Flexible Ureteroscope and Reusable Flexible Ureteroscope for Upper Urinary Calculi: A Systematic Review and Meta-Analysis, *Front Surg*, 2021¹²

[Meng et al. 2021](#)

STUDY AIM

The aim of the study was to compare the clinical efficacy and safety of the treatment of patients with upper urinary calculi between single-use and reusable fURS.

METHODS

- A systematic search following the PRISMA guidelines was performed in PubMed, Embase, Cochrane Library and Scopus databases, and China Academic Journals full-text database, to identify relevant studies published within a period from the date of the establishment of the databases to November 2020.
- The Jadad scale was used to assess the quality of randomised controlled trials, and the Newcastle-Ottawa Scale was used to assess non-randomised controlled trials.
- The results of the meta-analysis were reported as odds ratio (OR) and mean differences with a 95% confidence interval (95% CI) and a p-value. A p-value <0.05 was considered statistically significant.



Single-use ureteroscopes have similar effectiveness and better security for treating upper urinary calculi compared to reusables.

Clinical
outcomesOpen
access

TAKE AWAY

Single-use fURS is an effective and safe alternative to reusable fURS for the management of renal stones.

KEY FINDINGS

- A total of five studies, including 772 patients, were included in the meta-analysis.
- The pooled results showed that single-use fURS were associated with a higher SFR (OR: 1.50; 95% CI, 1.06-2.12; $p=0.02$), but a longer operative time (MD: 7.39 min; 95% CI, 1.75-13.03; $p=0.92$), compared to reusable fURS.
- Subgroup analyses showed no differences between single-use fURS and reusable fURS in terms of perioperative complications, stent migration or acute kidney injury.

Comparison of single-use and reusable flexible ureteroscope for renal stone management: a pooled analysis of 772 patients, *Transl Androl Urol*, 2021¹³

[Li et al. 2021](#)

STUDY AIM

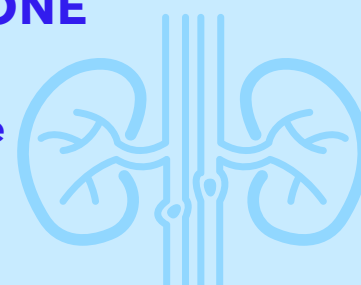
The aim of the study was to systematically assess the effectiveness and safety of single-use fURS compared to reusable fURS when treating renal stones.

METHODS

- A literature search following the PRISMA guidelines was carried out in PubMed, Web of Science, Cochrane Library and EMBASE online databases to identify relevant studies up to September 2019.
- The methodological quality of non-randomised controlled trials was assessed using the Newcastle-Ottawa Scale, and the methodological quality of randomised controlled trials was evaluated using the Jadad scale.
- For binary outcome variables, odds ratios (ORs) were reported; for continuous parameters, mean differences were reported.
- Chi-squared test and I^2 statistic were used to assess heterogeneity among included studies. Pooled estimates were calculated with a fixed-effect model in cases where heterogeneity among studies was not detected, and a random-effect model was used when there was evidence of heterogeneity.

HIGHER STONE FREE RATE

with single-use
ureteroscopes
compared to
reusables.



Clinical
outcomesNot open
access

TAKE AWAY

Single-use digital fURS is a safe and effective option with a higher SFR than reusable fURS in the treatment of lower pole stones smaller than 20 mm.

KEY FINDINGS

- Demographic and preoperative parameters were comparable between the two groups.
- The 1-month stone free rate was 84% for procedures with single-use fURS and 58% for reusable fURS procedures ($p < 0.05$).
- No difference was observed between the two groups in terms of operative time ($p = 0.665$), length of hospital stays ($p = 0.308$), presence of postoperative complications ($p = 0.307$), presence of adverse events ($p = 0.483$) or presence of severe adverse events ($p = 0.141$).

Single-Use Digital Flexible Ureteroscopes as a Safe and Effective Choice for the Treatment of Lower Pole Renal Stones: Secondary Analysis of a Randomized Controlled Trial, J Endourol, 2021¹⁴

[Yang et al. 2021](#)

STUDY AIM

The aim of the study was to compare the efficacy and safety of single-use digital fURS and reusable fURS for the treatment of lower pole stones smaller than 20 mm.

METHODS

- The study included 49 patients with lower pole stones from a previous multicenter, randomised, open-label clinical trial in four hospitals in China.
- All patients underwent fURS for lower pole stones with either single-use fURS (ZebraScope™) or reusable fURS (URF-V).
- The efficacy endpoints assessed were 1-month postsurgical SFR, operative time, length of postoperative hospital stay, and mean reduction in haemoglobin level.
- The safety outcomes assessed were presence of adverse events, severe adverse events, and postoperative complications.

1-MONTH STONE
FREE RATE WAS

84%

for procedures with
single-use ureteroscopes
and 58% with reusables.



DECREASING LENGTH OF HOSPITAL STAY



Decreasing
length of
hospital stay



Open
access

TAKE AWAY

Single-use fURS is an alternative to reusable fURS in terms of surgical efficacy and safety for upper urinary calculi. In terms of costs, institutions should consider their financial situation, the number of fURS procedures, the volume of the patient's calculus, surgeon experience and local dealerships' annual maintenance contract when choosing between reusable and single-use digital fURS.

KEY FINDINGS

- No statistically significant difference was observed between the two group in terms of mean operation time ($p=0.666$).
- Procedures with single-use digital fURS had a shorter mean length of hospital stay than reusable digital fURS ($p=0.026$), and the incidence of postoperative complications was similar in the two groups ($p=0.678$).
- The repair cost per procedure for reusable fURS was \$408. After the original purchasing costs, the average cost per procedure for reusable fURS was ~\$528.

Single-use vs. Reusable Digital Flexible Ureteroscope to Treat Upper Urinary Calculi: A Propensity-Score Matching Analysis, *Front Surg*, 2022¹⁵

[Huang et al. 2022](#)

STUDY AIM

The aim of the study was to compare clinical performance and costs of single-use digital fURS with reusable digital fURS.

METHODS

- A total of 440 patients were treated for upper urinary calculi with a reusable digital fURS, and 151 patients were treated with a single-use digital fURS. Both groups were included in the study.
- Through 1:1 propensity-score matching analysis based on baseline characteristics, 238 patients (119:119) were compared in terms of treatment outcomes.
- The cost analysis was based on the costs of purchase, repair and reprocessing divided by the number of all procedures in each group (450 procedures with reusable digital fURS and 160 procedures with single-use digital fURS).

A SHORTER MEAN LENGTH OF HOSPITAL STAYS THAN REUSABLES

Procedures
with single-use
ureteroscopes





Decreasing
length of
hospital stay



Open
access

TAKE AWAY

Single-use fURS are characterized by significantly lower overall postoperative complications and infection rates, while having comparable costs and SFRs to reusable fURS.

KEY FINDINGS

- Demographic characteristics of patients, stone features and preoperative urine cultures were comparable between groups.
- Stone free rates were not significantly different ($p=0.11$), and the mean cost per procedure was comparable (€2,321 in group A vs. €2,543 in group B, $p=0.09$).
- Days of hospitalization and duration of antibiotic treatment were higher in group A compared to group B ($p<0.05$). The overall complication rate was 8.8% in group A and 3.3% in group B ($p<0.05$), and the number of major complications (Clavien score IIIa-V) was higher in group A. The overall postoperative infection rate was 16.6% in group A and 3.3% in group B ($p<0.05$). No patients in group B developed urosepsis or had a positive blood culture, whereas 3 patients in group A did ($p<0.05$).

Disposable versus reusable ureteroscopes: A prospective multicenter randomized comparison, Res Rep Urol, 2021¹⁶

[Bozzini et al. 2021](#)

STUDY AIM

The aim of the study was to compare single-use and reusable fURS in terms of efficacy and safety for patients undergoing RIRS.

METHODS

- The study was designed as a prospective, multicenter, randomised, clinical trial study, and included patients with a renal stone eligible for RIRS.
- Patients enrolled in the study were randomised into two groups: group A (90 patients) underwent RIRS with reusable fURS, and group B (90 patients) were treated with single-use fURS.

Significantly lower overall postoperative complications and infection rates with single-use ureteroscopes compared to reusables.

DECREASING OPERATIVE TIME

Decreasing
operative timeOpen
access

TAKE AWAY

Reusable and single-use fURS have similar clinical efficiency and complication rates in the management of lower pole renal stone disease with retrograde intrarenal surgery (RIRS). However, single-use fURS have advantages such as shorter operative time.

KEY FINDINGS

- No differences were observed between reusable and single-use fURS in terms of stone size, demographic characteristics, or intraoperative and postoperative outcomes.
- Operative time was significantly longer among patients treated with reusable fURS (47.02 ± 9.91) compared to patients treated with single-use fURS (57.97 ± 14.28) ($p=0.001$).
- Single-use fURS were associated with an 11-minute decrease in procedure duration ($p<0.001$).

Efficiency of retrograde intrarenal surgery in lower pole stones: disposable flexible ureterorenoscope or reusable flexible ureterorenoscope? World J Urol, 2021¹⁷

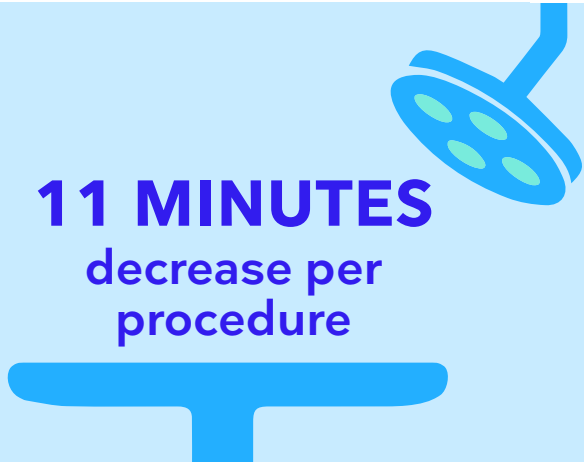
[Göger et al. 2021](#)

STUDY AIM

The aim of the study was to compare the efficiency of reusable and single-use fURS in the management of lower pole renal stone disease.

METHODS

- The study was designed as a prospective case-control study using data from 122 consecutive ureteroscopy procedures between January 2018 and May 2020.
- Patients were divided into two groups according to the ureteroscope used. Fifty-two patients were treated with single-use fURS, and 70 patients were treated with reusable fURS.
- Parameters analysed in the study were: demographic characteristics, stone size, infundibulopelvic angle, SFR, hospitalisation time, intraoperative complication rate, operative time, preoperative or postoperative JJ stenting, and postoperative complication rate.
- The Clavien-Dindo scale was used to classify intraoperative and postoperative complications.



11 MINUTES
decrease per
procedure

Decreasing
operative timeOpen
access

TAKE AWAY

The single-use ureteroscope LithoVue™ is a feasible alternative to a reusable ureteroscope, with a low rate of scope failure compared to reusable ureteroscopes.

KEY FINDINGS

- A total of 115 ureteroscopy procedures were performed using LithoVue™, and 65 procedures were performed with a reusable ureteroscope.
- Patient demographic, surgical indication, stone size, location, total stone burden, composition, procedural outcomes and complications were comparable between groups.
- Single-use flexible ureteroscopes had a shorter procedure duration compared to reusable. For all cases, LithoVue™ procedures lasted 54.1 ± 25.7 min compared to 64.5 ± 37.0 min for reusable scope procedures ($p < 0.05$), and for stone removal cases 57.3 ± 25.1 vs. 70.3 ± 36.9 min, respectively ($p < 0.05$).
- Scope failure occurred in 4.4% of procedures using LithoVue™ and 7.7% of procedures using a reusable ureteroscope ($p = 0.27$).

A Prospective Case-Control Study Comparing LithoVue, a Single-Use, Flexible Disposable Ureteroscope, with Flexible, Reusable Fiber-Optic Ureteroscopes, J Endourol, 2018¹⁸

[Usawachintachit et al. 2018](#)

STUDY AIM

The aim of the study was to compare LithoVue™ with reusable flexible fibre-optic ureteroscopes in patients undergoing ureteroscopy for upper urinary tract pathology.

METHODS

- The study was designed as a prospective case-control study at a single facility.
- Clinical outcomes between two groups of patients undergoing flexible ureteroscopy for upper urinary tract pathology were analysed.
- In the first group the single-use ureteroscope LithoVue™ was used, and in the second group a reusable fURS was used.
- Differences in procedural outcomes, operative time and time spent in the hospital were analysed using two-tailed t-tests, Chi-squared tests and Fisher's exact tests.

Shorter procedure time with single-use ureteroscopes compared to reusables.



REFERENCES

1. Ofstead C., Hopkins K., Smart A., Eiland J., Wetzler H., Bechis S. (2022). Reprocessing Effectiveness for Flexible Ureteroscopes: A Critical Look at the Evidence. *Urology*. 2022;164:25-32. doi:10.1016/J.UROLOGY.2022.01.033
2. Ofstead C., Hopkins K., Smart A., Brewer M. (2021). Droplet dispersal in decontamination areas of instrument reprocessing suites. *Am J Infect Control*. 2022;50(2):126-132. doi:10.1016/J.AJIC.2021.10.023
3. Davis N., McGrath S, Quinlan M, Jack G, Lawrentschuk N, Bolton D. (2018). Carbon Footprint in Flexible Ureteroscopy: A Comparative Study on the Environmental Impact of Reusable and Single-Use Ureteroscopes. *J Endourol*. 2018;32(3):214-217. doi:10.1089/END.2018.0001
4. Large, T., Rivera, M., Nottingham, C., Agarwal, D., Mellon, M., & Krambeck, A. (2021). Initial Experience with Novel Single-Use Disposable Ureteroscopy: A Prospective, Single Arm 90-Day Trial of the Axis Ureteroscope. *Urology Practice*, 8(2), 196-203. <https://doi.org/10.1097/UPJ.0000000000000194>
5. Al-Balushi, K., Martin, N., Loubon, H., Baboudjian, M., Michel, F., Sichez, P. C., Martin, T., Di-Crocco, E., Gaillet, S., Delaporte, V., Akiki, A., Faure, A., Karsenty, G., Lechevallier, E., & Boissier, R. (2019). Comparative medico-economic study of reusable vs. single-use flexible ureteroscopes. *International Urology and Nephrology*, 51(10), 1735-1741. <https://doi.org/10.1007/s11255-019-02230-1>
6. Mager, R., Kurosch, M., Höfner, T., Frees, S., Haferkamp, A., & Neisius, A. (2018). Clinical outcomes and costs of reusable and single-use flexible ureterorenoscopes: a prospective cohort study. *Urolithiasis*, 46(6), 587-593. <https://doi.org/10.1007/s00240-018-1042-1>
7. Taguchi, K., Usawachintachit, M., Tzou, D. T., Sherer, B. A., Metzler, I., Isaacson, D., Stoller, M. L., & Chi, T. (2018). Micro-Costing Analysis Demonstrates Comparable Costs for LithoVue Compared to Reusable Flexible Fiberoptic Ureteroscopes. *Journal of Endourology*, 32(4), 267-273. <https://doi.org/10.1089/end.2017.0523>
8. Martin, C. J., McAdams, S. B., Abdul-Muhsin, H., Lim, V. M., Nunez-Nateras, R., Tyson, M. D., & Humphreys, M. R. (2017). The Economic Implications of a Reusable Flexible Digital Ureteroscope: A Cost-Benefit Analysis. *Journal of Urology*, 197(3), 730-735. <https://doi.org/10.1016/j.juro.2016.09.085>
9. Rindorf, D. K., Tailly, T., Kamphuis, G. M., Larsen, S., Somani, B. K., Traxer, O., & Koo, K. (2022). Repair Rate and Associated Costs of Reusable Flexible Ureteroscopes: A Systematic Review and Meta-analysis. In *European Urology Open Science* (Vol. 37, pp. 64-72). Elsevier B.V. <https://doi.org/10.1016/j.euros.2021.12.013>
10. Unno, R., Hosier, G., Hamouche, F., Bayne, D. B., Stoller, M. L., & Chi, T. (2023). Single-Use Ureteroscopes Are Associated with Decreased Risk of Urinary Tract Infection After Ureteroscopy for Urolithiasis Compared to Reusable Ureteroscopes. *Journal of Endourology*, 37(2), 133-138. <https://doi.org/10.1089/end.2022.0480>

11. Bragaru, M., Multescu, R., Geavlete, P., Popescu, R., & Geavlete, B. (2023). Comparison of Flexible Ureteroscope Performance between Reusable and Single-Use Models. *Journal of Clinical Medicine*, 12(3). <https://doi.org/10.3390/jcm12031093>
12. Meng, C., Peng, L., Li, J., Li, Y., Li, J., & Wu, J. (2021). Comparison Between Single-Use Flexible Ureteroscope and Reusable Flexible Ureteroscope for Upper Urinary Calculi: A Systematic Review and Meta-Analysis. *Frontiers in Surgery*, 8. <https://doi.org/10.3389/fsurg.2021.691170>
13. Li, Y., Chen, J., Zhu, Z., Zeng, H., Zeng, F., Chen, Z., Yang, Z., Cui, Y., Chen, H., & Li, Y. (2021). Comparison of single-use and reusable flexible ureteroscope for renal stone management: a pooled analysis of 772 patients. In *Translational Andrology and Urology* (Vol. 10, Issue 1, pp. 483-493). AME Publishing Company. <https://doi.org/10.21037/TAU-20-1009>
14. Yang, E., Jing, S., Niu, Y., Qi, S., Yadav, P. K., Yang, L., Bao, J., Tian, J., Wang, J., Li, N., Ou, T., & Wang, Z. (2021). Single-Use Digital Flexible Ureteroscopes as a Safe and Effective Choice for the Treatment of Lower Pole Renal Stones: Secondary Analysis of a Randomized-Controlled Trial. *Journal of Endourology*, 35(12), 1773-1778. <https://doi.org/10.1089/end.2021.0170>
15. Huang, F., Zhang, X., Cui, Y., Zhu, Z., Li, Y., Chen, J., Zeng, F., Li, Y., Chen, Z., & Chen, H. (2022). Single-Use vs. Reusable Digital Flexible Ureteroscope to Treat Upper Urinary Calculi: A Propensity-Score Matching Analysis. *Frontiers in Surgery*, 8. <https://doi.org/10.3389/fsurg.2021.778157>
16. Bozzini, G., Filippi, B., Alriyalat, S., Calori, A., Besana, U., Mueller, A., Pushkar, D., Romero-Otero, J., Pastore, A., Sighinolfi, M. C., Micali, S., Buizza, C., & Rocco, B. (2021). Disposable versus reusable ureteroscopes: A prospective multicenter randomized comparison. *Research and Reports in Urology*, 13, 63-71. <https://doi.org/10.2147/RRU.S277049>
17. Göger, Y. E., Özkent, M. S., Kılınç, M. T., Taşkapu, H. H., Göger, E., Aydın, A., Sönmez, M. G., & Karalezli, G. (2021). Efficiency of retrograde intrarenal surgery in lower pole stones: disposable flexible ureterorenoscope or reusable flexible ureterorenoscope? *World Journal of Urology*, 39(9), 3643-3650. <https://doi.org/10.1007/s00345-021-03656-y>
18. Usawachintachit, M., Isaacson, D. S., Taguchi, K., Tzou, D. T., Hsi, R. S., Sherer, B. A., Stoller, M. L., & Chi, T. (2017). A Prospective Case-Control Study Comparing LithoVue, a Single-Use, Flexible Disposable Ureteroscope, with Flexible, Reusable Fiber-Optic Ureteroscopes. *Journal of Endourology*, 31(5), 468-475. <https://doi.org/10.1089/end.2017.0027>