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Advancing science for life™

LithoVue™

Single-Use Digital Flexible Ureteroscope

Financial, operational, and clinical evidence

Since the launch of the award-winning LithoVue Single-Use Digital Flexible Ureteroscope, the landscape of flexible ureteroscopy has changed.

A growing body of evidence supports the clinical, financial, and operational benefits single-use ureteroscopes such as the LithoVue System offer your facility, health care professionals, and patients. We invite you to explore the evidence for yourself.

Financial efficacy

- Costs
- Risks

Operational efficacy

- Procedure times
- Reprocessing challenges
- Durability and repair challenges

Clinical efficacy

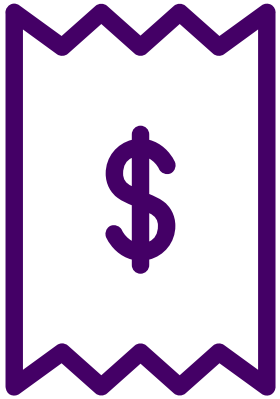
- Deflection, laser fibers, and access
- Lower complication rate

In a micro-cost analysis, the authors concluded **"LithoVue may provide value in conserving resources for labor, consumables, and repair."**

Taguchi K, Usawachintachit M, Tzou DT, et al. Micro-costing analysis demonstrates comparable costs for LithoVue compared to reusable flexible ureteroscopes. *J Endourol*. 2018;32:267–273. Poster session. 32nd Annual Meeting of Engineering and Urology Society; May 12, 2017; Boston, Massachusetts, USA.

"If fewer than 99 flexible URS cases were performed at our institution in that year, **a disposable URS would have been a better cost-effective alternative**."

Martin CJ, McAdams SB, Abdul-Muhsin H, et al. The economic implications of a reusable flexible digital ureteroscope: a cost benefit analysis. *J Urol*. 2017;197(3 Pt 1):730–735.



In a cost analysis, it was determined that **46%–59% of the cost of maintaining a flexible ureteroscopy program results from ureteroscope damage**.

Knudsen B, Miyaoka R, Shah K, et al. Durability of the next-generation flexible fiberoptic ureteroscopes: a randomized prospective multi-institutional clinical trial. *Urology*. 2010;75:534–539.

The results of this pilot study reveal a glimpse of the time and effort it takes to reprocess endoscopes in accordance with the new standards. **Despite being unable to account for every aspect of reprocessing, the costs are staggering—from USD $114.07 to $280.71 for one endoscope**.

Ofstead CL, Quick MR, Eiland JE, Adams SJ. A glimpse at the true cost of reprocessing endoscopes: results of a pilot project. *Communiqué*. 2017 Jan/Feb;63–78.

Reprocessing, maintenance, and repair costs for reusable flexible ureteroscopes can **approach USD $90,000 to $100,000 per year**.

Scotland KB, Chan JYH, Chew BH. Single-use flexible ureteroscopes: how do they compare with reusable ureteroscopes? *J Endourol*. 2019;33:71–78.

"We found that currently available flexible ureteroscopes require repair after only 3 to 14 cases or 105 to 494 minutes of use. These repairs are costly, usually thousands of dollars."

Monga M, Best S, Venkatesh R, et al. Durability of flexible ureteroscopes: a randomized, prospective study. *J Urol*. 2006;176:137–141.

Ofstead and her team found that from October 2020 through March 2021, **the FDA was receiving more than 20 medical device reports (MDRs) every month that were related just to ureteroscopes.** MDRs describe post-procedure patient infections or other possible contamination issues associated with reprocessing.

Ofstead CL. Ureteroscope reprocessing effectiveness. Whitepaper sponsored by Boston Scientific. Published by OR Manager. March 2022.

Approximately 70% of major ureteroscope repairs resulted from operator-induced damage that is **not covered by any manufacturer's warranty**.

Landman J, Lee DI, Lee C, Monga M. Evaluation of overall costs of currently available small flexible ureteroscopes. *Urology.* 2003;62:218–222.

In a study comparing 115 LithoVue cases to a reusable scope cohort of 65 cases,

the LithoVue System showed a 15.5-minute reduction ($p<0.05$) in operating room time

using a multivariate analysis.

Usawachintachit M, Isaacson DS, Taguchi K, et al. A prospective case-control study comparing LithoVue, a single-use, flexible disposable ureteroscope, with flexible, reusable fiber-optic ureteroscopes. *J Endourol*. 2017;31:468–475.

Reprocessing one flexible endoscope requires approximately 76 minutes of hands-on staff time. These findings likely underestimate the time and cost associated with endoscope reprocessing.

Ofstead CL, Quick MR, Eiland JE, Adams SJ. A glimpse at the true cost of reprocessing endoscopes: results of a pilot project. *Communiqué*. 2017 Jan/Feb;63–78.

Procedures could be canceled and rescheduled owing to the unavailability of a reusable URS (broken or in repair). Moreover, the fear of damaging a reusable URS and their associated downtime could place constraints on the surgeon's technique, particularly in the case of complex urolithiasis.

Dubnitskiy-Robin S, Pradère B, Faivre d'Arcier B, et al. Switching to single-use flexible ureteroscopes for stones management: financial impact and solutions to reduce the cost over a 5-year period. *Urology*. 2020;143:68–74.

Research suggests three procedures per day are delayed per operating room.

(Massachusetts General Hospital endoscopy unit)

Hession SM. Endoscope disinfection by ortho-phthalaldehyde in a clinical setting: an evaluation of reprocessing time and costs compared with glutaraldehyde. *Gastroenterol Nurs*. 2003;26:110–114.

A reusable ureteroscope used in the first case of the day would not be ready until the fourth case.

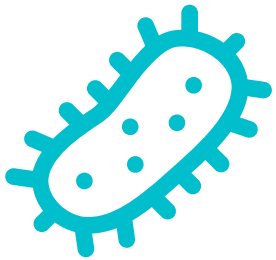
Isaacson D, Ahmad T, Metzler I, et al. Defining the costs of reusable flexible ureteroscope reprocessing using time-driven activity-based costing. *J Endourol*. 2017;31:1026–1031.

"**Given the documented occurrence of infections and patient injury associated with the use of damaged or contaminated ureteroscopes**, infection preventionists (IPs) should frequently audit endoscope reprocessing practices and identify suboptimal practices that could contribute to the formation of biofilm and the transmission of infection."

Ofstead CL, Heymann OL, Quick MR, Johnson EA, Eiland JE, Wetzler HP. The effectiveness of sterilization for flexible ureteroscopes: a real-world study. *Am J Infect Control*. 2017;45:888–895.

One study showed **100% of 16 patient-ready, reusable flexible ureteroscopes had visible irregularities and residual contamination**.

Ofstead CL, Heymann OL, Quick MR, Johnson EA, Eiland JE, Wetzler HP. The effectiveness of sterilization for flexible ureteroscopes: a real-world study. *Am J Infect Control*. 2017;45:888–895.



Any slight deviation from the recommended reprocessing protocol **can lead to the survival of microorganisms and an increased risk of infection**.

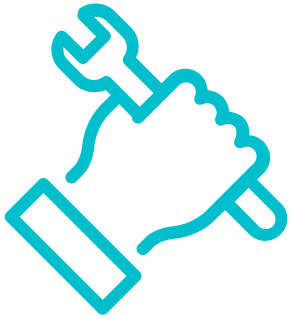
Alfa MJ, Olson N, DeGagne P. Automated washing with the Reliance Endoscope Processing System and its equivalence to optimal manual cleaning. *Am J Infect Control*. 2006;34:561–570.

In a study comparing two digital flexible ureteroscopes, each ureteroscope was used until it was damaged to the point that a major repair was required. **The Gyrus ACMI/Olympus Invisio DUR-D scope lasted 11.25 cases per repair, and the Olympus URF-V lasted 14 cases per repair.**

Shah K, Monga M, Knudsen B. Prospective randomized trial comparing 2 flexible digital ureteroscopes: ACMI/Olympus Invisio DUR-D and Olympus URF-V. *Urology*. 2015;85:1267–1271.

Working in the lower pole results in stress and fatigue of the deflection mechanism, which may lead to a **loss of scope deflection and in some cases to scope failure**.

Mues AC, Teichman JMH, Knudsen BE. Evaluation of 24 holmium: YAG laser optical fibers for flexible ureteroscopy. *J Urol*. 2009;182:348–354.



A study analysis suggests that **after damage occurs to a ureteroscope more damage may occur with greater frequency.** The cost of maintaining previously used ureteroscopes should be carefully considered in comparison to the cost of purchasing a new ureteroscope.

Carey RI, Gomez CS, Maurici G, Lynne CM, Leveillee RJ, Bird VG. Frequency of ureteroscope damage seen at a tertiary care center. *J Urol*. 2006;176:607–610; discussion 610.

For flexible ureteroscopes, the working channel accounted for the greatest percentage of repairs (52%), followed by the shaft of the scope (27%), deflection components (15%), and eyepiece components (8%).

Sung JC, Springhart WP, Marguet CG, et al. Location and etiology of flexible and semirigid ureteroscope damage. *Urology.* 2005;66:958–963.

"Somewhat to our surprise, and in contrast to other reports, it emerged that

72% of damages occurred during out-of-patient handling, cleaning, and storage

where usually the surgeon is not involved."

Sooriakumaran P, Kaba R, Andrews HO, Buchholz NPN. Evaluation of the mechanisms of damage to flexible ureteroscopes and suggestions for ureteroscope preservation. *Asian J Androl.* 2005;7:433–438.

The authors of this case report concluded "**deflection characteristics (with the LithoVue System) are maintained** even when thicker laser fibers are passed through the working channel."*

Leveillee RJ, Kelly EF. Impressive performance: new disposable digital ureteroscope allows for extreme lower pole access and use of 365 um holmium laser fiber. *J Endourol Case Rep*. 2016;2:114–116.

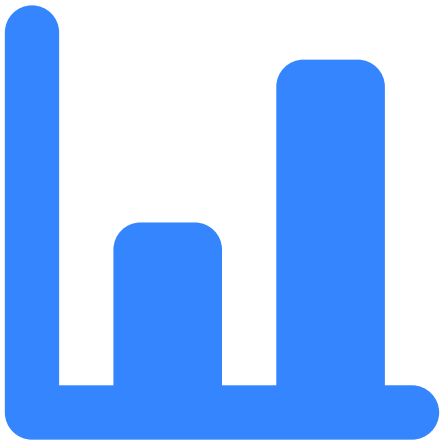
In a case report, **the physician was able to access the lower pole of the kidney, a challenging location, with the LithoVue Ureteroscope** while using a 365 micron holmium laser fiber.*

Leveillee RJ, Kelly EF. Impressive performance: new disposable digital ureteroscope allows for extreme lower pole access and use of 365 um holmium laser fiber. *J Endourol Case Rep*. 2016;2:114–116.

"It is thought that the deflection of a ureteroscope into the lower pole or the placement of instruments in the working channel for extended periods may put extra stress on the deflection wires of the device, stretching them and resulting in weakened deflection. For example, **a single 1-hour procedure fragmenting and removing lower pole calculi with the laser may have greater wear and tear effects** than six, 10-minute diagnostic ureteroscopies, although total use time is the same."

Monga M, Best S, Venkatesh R, et al. Durability of flexible ureteroscopes: a randomized, prospective study. *J Urol*. 2006;176:137–141.

* Results from case studies are not necessarily predictive of results in other cases. Results in other cases may vary.



A prospective case-control study showed

a lower complication rate in the LithoVue Single-Use Digital Flexible Ureteroscope group (5.4%)

in 142 cases performed for stone removal compared with the reusable fiber optic flexible ureteroscope group (18.0%), $p<0.05$.

Usawachintachit M, Isaacson DS, Taguchi K, et al. A prospective case-control study comparing LithoVue, a single-use, flexible disposable ureteroscope, with flexible, reusable fiber-optic ureteroscopes. *J Endourol.* 2017;31:468–475.

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