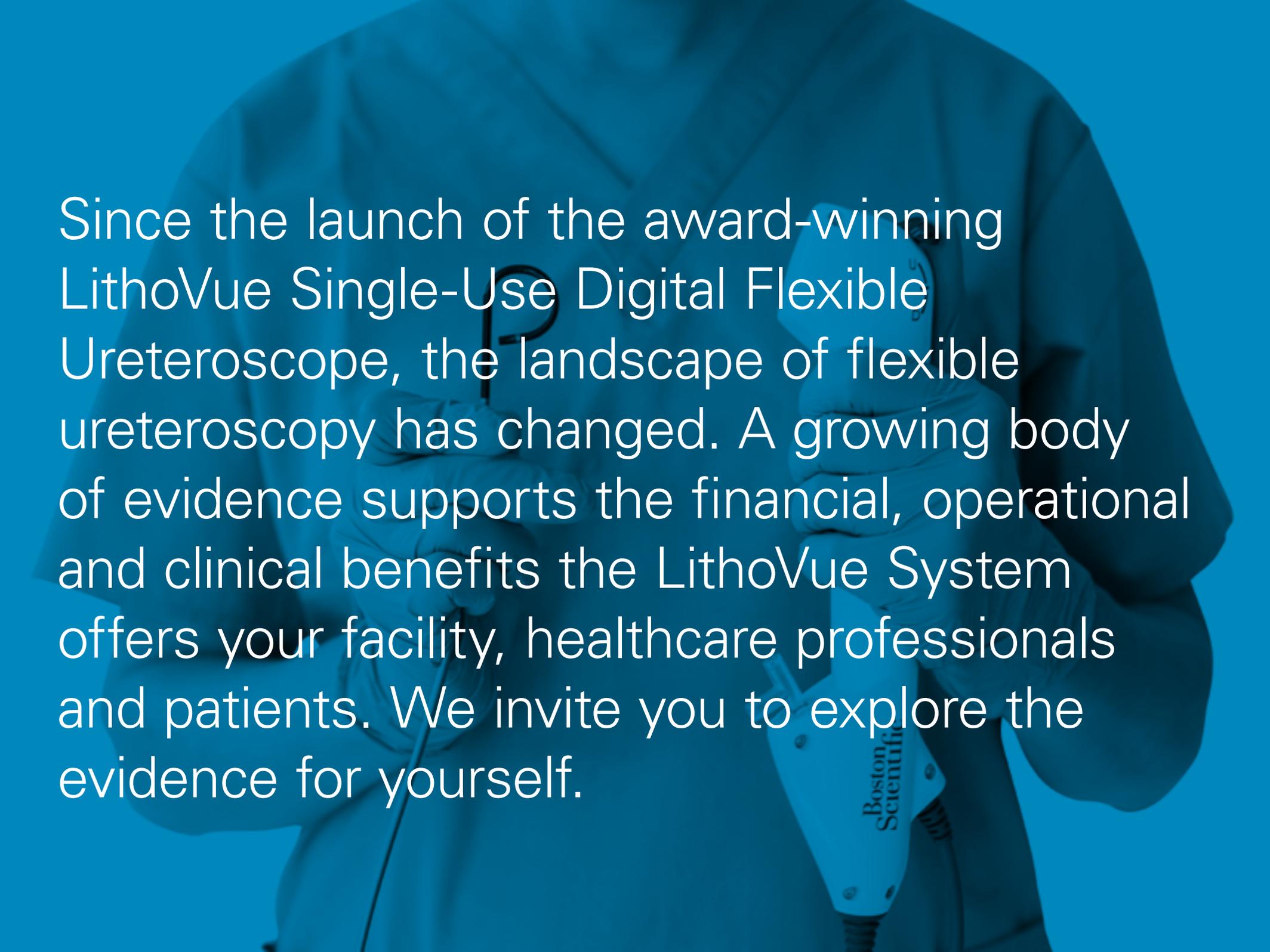




**LithoVue™
Single-Use
Digital Flexible
Ureteroscope:**

Financial, Operational
and Clinical Evidence

A person wearing a white lab coat is holding a Boston Scientific LithoVue Single-Use Digital Flexible Ureteroscope. The device is white and blue, with the Boston Scientific logo visible on the handle. The background is a solid blue color.

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 financial, operational and clinical benefits the LithoVue System offers your facility, healthcare professionals and patients. We invite you to explore the evidence for yourself.

Contents

- ▶ **Financial Efficacy**

- ▶ Cost Reduction
- ▶ Risk Reduction

- ▶ **Operational Efficacy**

- ▶ Reduction in Procedure Times
- ▶ An Alternative to Effective Reprocessing Challenges
- ▶ An Alternative to Durability and Repair Challenges

- ▶ **Clinical Efficacy**

- ▶ Deflection, Laser Fibers and Access
- ▶ Lower Complication Rate



“Micro-cost analysis revealed the total cost per case for reusable and disposable flexible ureteroscopes were comparable. **LithoVue may provide value in conserving resources for labor, consumables, and repair.**”

Taguchi K, et al. Micro-cost analysis demonstrates comparable costs for LithoVue versus reusable flexible ureteroscope use. Poster session presented at the 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 Mar;197(3 Pt 1):730-5.

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 Mar;75(3):534-9.



“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 \$114.07 to \$280.71 for one endoscope.”

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



Digital scope acquisition can cost on average \$20,000.

User HM, Hua V, Blunt LW, et al. Performance and durability of leading flexible ureteroscopes. *J Endourol*. 2004 Oct;18(8):735-8.

Olympus Corporation of the Americas. Olympus, Your Vision, Our Future. Olympus Product Catalog 2015. Olympus website. Accessed May 12, 2015.

Fiber-optic scope acquisition can range on average from \$15,000–\$19,000.

User HM, Hua V, Blunt LW, et al. Performance and durability of leading flexible ureteroscopes. *J Endourol*. 2004 Oct;18(8):735-8.

Boylu U, Oommen M, Thomas R, et al. In vitro comparison of a disposable flexible ureteroscope and a conventional flexible ureteroscope. *J Urol*. 2009 Nov;182(5):2347-51.

A reprocessing breach is estimated to cost between \$1.79 million and \$20.4 million per incident depending on the number of patients impacted.

Strategic Health Resources. National SGNA Congress Presentation 2012. Aggregate figures include the costs of patient notification testing, incident investigation, medical malpractice defense, settlement/verdict, loss of volume.



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

Landman J, Lee DI, Lee C, et al. Evaluation of overall costs of currently available small flexible ureteroscopes. *Urology*. 2003 Aug;62(2):218-22.

“The use of LithoVue was associated with a 14- and 15.5-minute shortening of procedure and operating room durations, respectively.”

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 May;31(5):468-75.



The entire ureteroscope sterilization process was a combined 31 steps. Mean cumulative time for the entire process was 15.5 hours. Only 25% of the ureteroscopes completed the entire process in a single day, with the remaining ureteroscopes (75%) delayed due to personnel task assignments.

Druskin S, Ziembra J, Cao S, et al. Ureteroscope reprocessing: a time-in-motion study of a lengthy journey. *J Urol.* 2016 Apr;195(4 Suppl):e509-10.

“Matched pair analysis demonstrates that handing a surgeon a broken, non-usable, catastrophically damaged refurbished flexible ureteroscope from a flawed inventory of similar scopes results in an operative room time increase of 23 minutes (26.6%) and an operative procedure time increase of 19 minutes (35.5%).”

Carey RI, Carey MS. The ureteroscope matters: matched pari analysis reveals increased operative time and reoperation associated with the use of refurbished flexible ureteroscopes from a third party out-sourced vendor. Poster session presented at the Southeast Section American Urological Association Annual Meeting; March 24, 2017; Austin, Texas, USA.



Research suggests three procedures per day are delayed per operating room.
(Massachusetts General Hospital endoscopy unit)

Hession SM. Endoscope disinfection by orthophthalaldehyde in a clinical setting: an evaluation of reprocessing time and costs compared with glutaraldehyde. *Gastroenterol Nurs.* 2003 May-Jun;26(3):110-4.



The average reprocessing delay is 10 minutes.

Hession SM. Endoscope disinfection by orthophthalaldehyde in a clinical setting: an evaluation of reprocessing time and costs compared with glutaraldehyde. *Gastroenterol Nurs.* 2003 May-Jun;26(3):110-4.

“This systematic evaluation of reprocessing effectiveness found that 100% of patient-ready flexible ureteroscopes had visible irregularities and residual contamination that exceeded benchmarks for manually cleaned gastrointestinal endoscopes.”

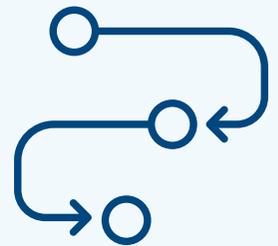
Ofstead CL, Heymann OL, Quick MR, et al. The effectiveness of sterilization for flexible ureteroscopes: A real-world study. *Am J Infect Control*. 2017 May 4. [Epub ahead of print]

“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, Quick MR, Eiland JE, et al. A glimpse at the true cost of reprocessing endoscopes: results of a pilot project. *Communiqué*. 2017 Jan/Feb;63-78.

Reprocessing guidelines are difficult to adhere to – lapses, errors and non-compliance with standards are common.

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;34:561-70.

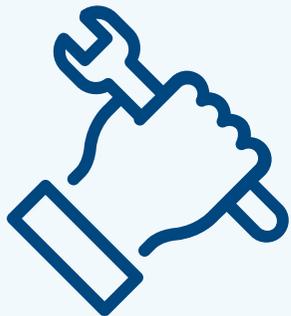


“Concern for scope function was expressed in 48 (12.8%) cases, while image quality was compromised or unusable in 107 (28%) of cases.”

Chi T, et al. Durability of flexible ureteroscopy and predictors of repair: a prospective multi-center study. Poster session presented at The European Association of Urology Annual Congress; March 2016; Munich, Germany.

“Working in the lower pole results in stress and fatigue of the deflection mechanism, which leads to a loss of scope deflection and in some cases to scope failure.”

Mues AC, Knudsen BE. Evaluation of 24 holmium: YAG laser optical fibers for flexible ureteroscopy. *J Urol*. 2009 Jul;182(1):348-54.



Once repaired, a flexible ureteroscope can expect to require a major repair after less than eight uses.

Monga M, Best S, Venkatesh R, et al. Durability of flexible ureteroscopes: A randomized, prospective study. *J Urol*. 2006 Jul;176(1):137-41.

Carey RI, Gomez CS, Maurici G, et al. Frequency of ureteroscope damage seen at a tertiary care center. *J Urol*. 2006 Aug;176(2):607-10.

Carey RI, Martin CJ, Knego JR. Prospective evaluation of refurbished flexible ureteroscope durability seen in a large public tertiary Care center with multiple surgeons. *Urology*. 2014 Jul;84(1):42-5.

On average, new flexible, fiberoptic ureteroscopes require repair after fewer than 15 uses.

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 Mar;75(3):534-9.

Flexible ureteroscope repairs were necessary on average in as few as 12 uses for digital scopes.

Knudsen B et al. Prospective randomized trial comparing 2 flexible digital ureteroscopes: ACMI/Olympus Invisio DUR-D and Olympus URF-V. *Urology* ePub ahead of publication.

Knudsen BE, Ferraro M. Digital video flexible ureteroscopy: GyurusACMI/Olympus Invisio®DUR®-D twelve month failure and repair experience. NCS 2009.

“70% of current ureteroscope major repairs result from damage to the working channel from malfunction or incorrect use of the holmium laser.”

Sung JC, Springhart WP, Marguet CG, et al. Location and etiology of flexible and semirigid ureteroscope damage. *Urology*. 2005 Nov;66(5):958-63.

“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, et al. Evaluation of the mechanisms of damage to flexible ureteroscopes and suggestions for ureteroscope preservation. *Asian J Androl*. 2005 Dec;7(4):433-8.

Approximately 15% of user-related damage is due to loss of scope deflection.

Sung JC, Springhart WP, Marguet CG, et al. Location and etiology of flexible and semirigid ureteroscope damage. *Urology*. 2005

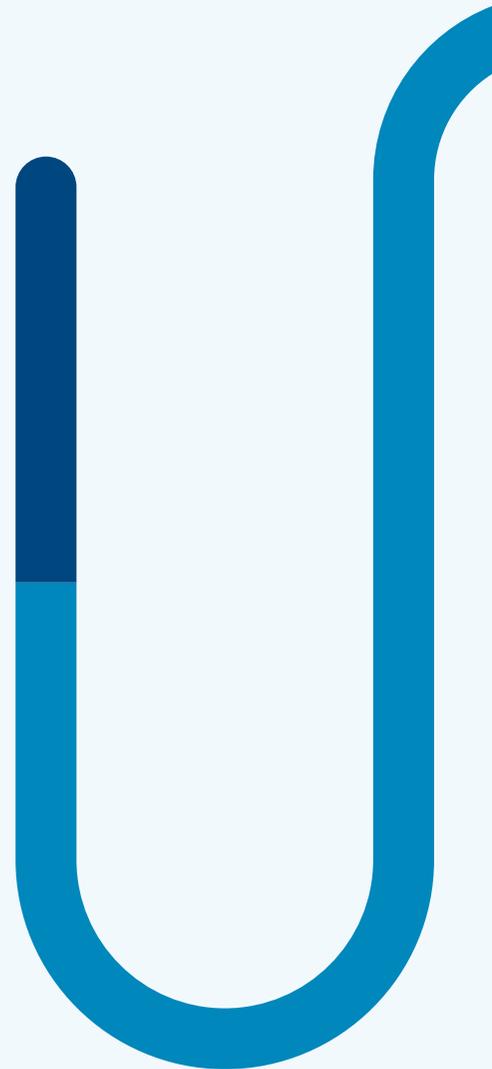


“Deflection characteristics (with LithoVue) are maintained even when thicker laser fibers are passed through the working channel.”*

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(1):114-6.

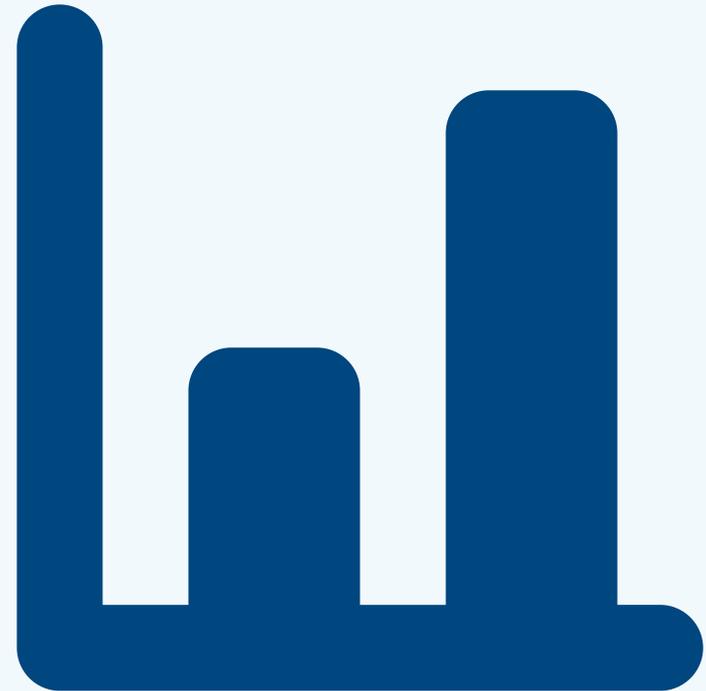
“Impressive performance:
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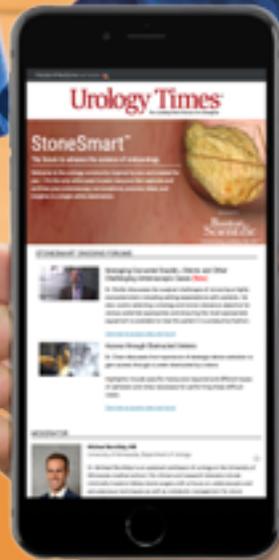


“The complication rate was lower in the LithoVue group compared with the reusable scope group (5.4% vs. 18.0%, $p < 0.05$).”

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 May;31(5):468-75.



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