

LithoVue™ Single-Use Digital Flexible Ureteroscope

**A new scope
for every patient**

**No repairs.
No sterilization.
No compromise.**

The LithoVue™ Single-Use Digital Flexible Ureteroscope is here

Now there's an innovative new technology that will change the way you think about flexible ureteroscopy.

The new Boston Scientific LithoVue System delivers high-resolution digital images for high-quality visualization and seamless navigation – to help you remove stones quickly, easily, safely and affordably.

With a new scope every time you open the LithoVue package, you eliminate the inconsistent performance¹⁻⁴ and maintenance hassles⁵⁻⁷ associated with reusable scopes. That means no costly scope repairs, no scope maintenance, no scope reprocessing and no degradation of scope performance over time.^{1,7} You and your team no longer need to spend time and money on sterilization. And there are no delays or cancellations due to lack of scope availability.

Instead, you can confidently start each case with a new high-quality, digital scope that delivers true 270° deflection in both directions, as well as image quality comparable to the leading digital reusable scopes – and superior to fiber-optic technology.⁸ So you can clearly see and confidently treat a wide range of stones and other urological conditions.



Because you have to see it to treat it. The LithoVue Single-Use Ureteroscope delivers detailed, high-resolution digital images across a broad depth of field – to guide the way during ureteroscopy procedures.

The system is the solution

The LithoVue™ System is an all-in-one solution, the ideal choice for a wide range of clinical environments. Its light source is built into the exceptionally lightweight, ergonomic control handle to help guide the way during procedures. And its workstation's monitor with integrated image processing software is mounted on a compact, rolling mobile cart. You can use the complete LithoVue System alone during a procedure or connect it to your OR's existing DVI monitors and recording systems. Plus, it's fully compatible with laser lithotripsy using existing technologies – with little or no interference from laser firing.

The LED light source is integrated, and there's no need to white balance.

Ergonomically designed, lightweight handle.

Flexible sheath has a 3.6F ID working channel.



A 7.7F tip diameter and 9.5F [$\leq 3.23\text{mm}$] outer diameter easily fits the average human ureter with renal colic.⁹



A digital CMOS imager in the tip has a working distance of 2mm–50mm to offer a deep field of view.



All-in-one, touch-screen PC includes the monitor, image processor and controller.



With full 270° scope deflection in both directions, as well as standard and reverse options, you have the flexibility to perform your procedures the way you prefer.



Discover the economic impact of reusable digital scopes

How much does a typical hospital really spend to acquire, repair, sterilize, reprocess, prepare and manage ureteroscopes? These numbers speak volumes about the true total cost of ownership.

Potential business costs per reprocessing incident:

\$1.79 to \$20.4 million²¹

Reprocessing labor time:

30-60 minutes²²

Purchase price for a digital flexible scope can exceed:

\$20,000^{19,20}

Repair cost per digital flexible scope after on average fewer than 12 uses can exceed:

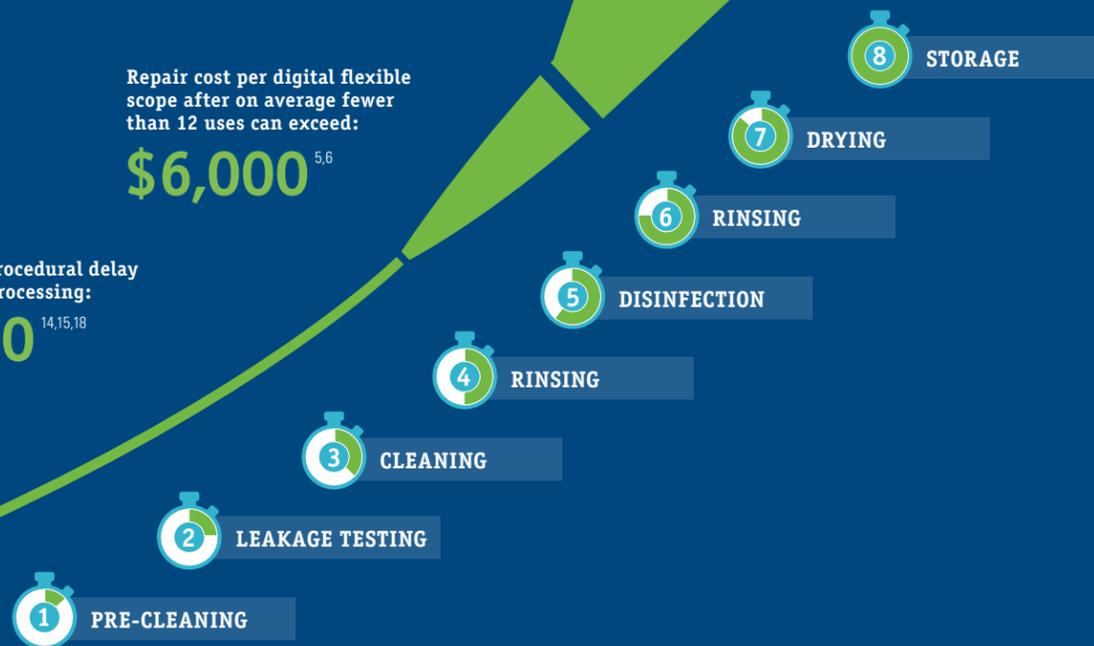
\$6,000^{5,6}

Cost per procedural delay due to reprocessing:

\$830^{14,15,18}

Cost savings using a digital flexible versus a fiber-optic scope:

\$780¹⁴⁻¹⁷



The benefits keep adding up

The capital expense of buying reusable ureteroscopes is just the beginning. In addition to the initial investment,^{19,20,23,24} it costs thousands of dollars to repair damaged scopes – ^{10,13,17,20-23} which may be necessary after as few as 15 uses for flexible fiber-optic scopes⁷ and just 12 uses for digital flexible scopes.^{5,6} Then factor in the high cost of sterilization. The time, expense and complexity of reprocessing alone are substantial.^{19,22,25-37} And don't forget the procedural delays due to reprocessing hold-ups,^{14,15,18,38} or the employee health issues associated with reprocessing.³⁸

The LithoVue™ Single-Use Ureteroscope not only eliminates many of these costs and hassles, it delivers tangible financial benefits that have a long-term economic and clinical impact.^{1-4,7,39,40} Now you can eliminate many of the steps required to use, maintain and handle a reusable ureteroscopes.²⁶ And reap the rewards of higher physician productivity and greater throughput.



What's your true cost? Every hospital is unique. So you should first evaluate your facility's reusable scope costs and consult with your Boston Scientific representative to help determine whether you could benefit from switching to the new digital, disposable LithoVue™ System.

A commitment to a healthy environment – and you

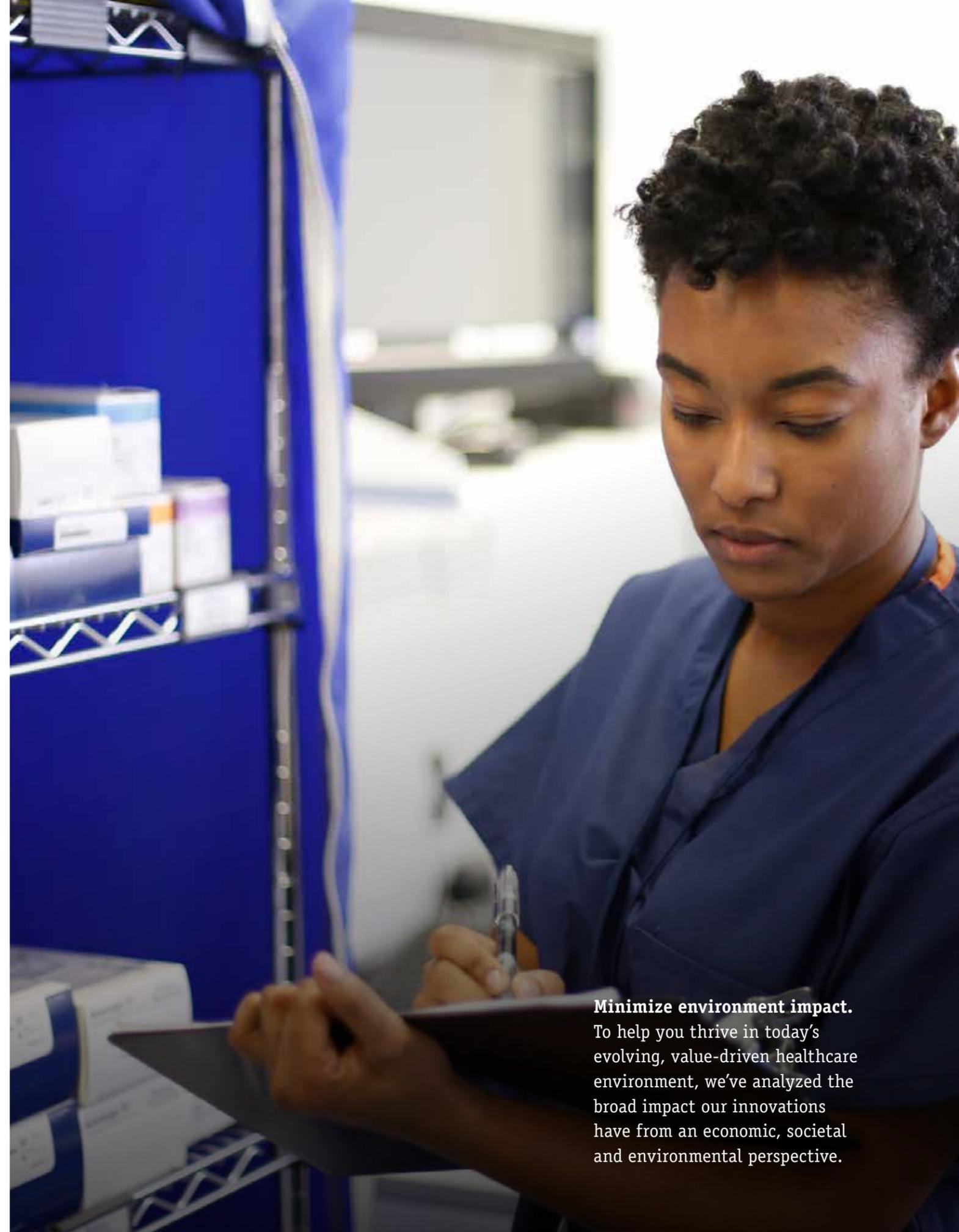
Boston Scientific is committed to helping you meet your organization's environmental goals. With this in mind, we've designed the LithoVue™ System to minimize its effect on the environment. It decreases waste from disinfecting consumables such as brushes, towels and test strips.⁴¹⁻⁴⁴ It helps reduce your water⁴⁵ and energy costs,¹² as well as your reprocessing burden. Plus, it eliminates staff exposure to harmful toxic chemicals and disinfecting consumables used to reprocess reusable scopes after every single use.^{33,46-50}



Easy-to-recycle packaging

Boston Scientific has worked with suppliers to optimize content without impacting the packaging's strength or durability. We have purposely left off any stickers and labels from the plastic to ensure the simplest recycling possible.

In addition, two components of the package can be easily recycled. The corrugated cardboard delivery box is 100% recyclable. And the plastic tray holding the scope is plastic type #1. Not only is it 100% recyclable, it is one of the most convenient types of plastics to recycle. The Tyvek™ pouch around the tray is not recyclable.



Minimize environment impact. To help you thrive in today's evolving, value-driven healthcare environment, we've analyzed the broad impact our innovations have from an economic, societal and environmental perspective.



Evolving urology together

At Boston Scientific, we help you meet the challenges of constant change by delivering innovations across five urology subspecialties – more than any other company. Working together, we can advance patient outcomes, reduce procedure costs and enhance quality.

We believe that partnership is the key to solving clinical and operational challenges in today's complex healthcare environment. And for more than 30 years, we've worked closely with healthcare professionals like you to advance the science of urology. Boston Scientific's breakthrough technologies and insightful solutions include our Sensor™ PTFE-Nitinol Guidewire and Flexiva™ TracTip Laser Fiber. We achieved a major milestone on this journey with the acquisition

of the American Medical Systems (AMS) Men's Health and Prostate Health businesses. Now we continue to move the science of urology forward with game-changing technologies like the new LithoVue™ Single-Use Digital Flexible Ureteroscope.

At Boston Scientific, we are delivering on a urology vision rooted in firsthand experience and inspired by insights from patients, physicians, OR leaders and partners like you.

Is the LithoVue Single-Use Ureteroscope right for you? Contact your Boston Scientific representative or visit www.bostonscientific.com/LithoVue to find out how this innovative disposable system can reduce costs, streamline workflow and improve the stone removal experience – for you and your patients.

References

1. Mues AC, Knudsen BE. Evaluation of 24 holmium: YAG laser optical fibers for flexible ureteroscopy. *J Urol*. 2009;182:348-54.
2. Carey RI, Gomez CS, Maurici G, et al. Frequency of ureteroscope damage seen at a tertiary care center. *J Urol*. 2006;176:607-10.
3. Collins JW, Keeley FX, Timoney A. Cost analysis of flexible ureterorenoscopy. *Br J Urol*. 2004;93(7):1023-6.
4. 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;84:42-5.
5. 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(6):1267-71.
6. Knudsen BE, Ferraro M. Digital video flexible ureteroscopy: GyruSACMI/Olympus Invisio®DUR®-D twelve month failure and repair experience. NCS 2009.
7. 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;75:534-9.
8. Eisner B. Evaluating the image quality of a novel single-use digital flexible ureteroscope. *J Endourol*. 2015;29(1):A348.
9. Song HJ, Cho ST, Kim KK. Investigation of the location of the ureteral stone and diameter of the ureter in patients with renal colic. *Korean J Urol*. 2010;51(3):198-201.
10. 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.
11. ECRI Institute. Inadequate reprocessing of endoscopes and surgical instruments [hazard no. 4]. In: Top10 health technology hazards for 2015: key safety threats to manage in the coming year [guidance article]. Nov. 2014.
12. ECRI Institute. Endoscope Reprocessing Systems. Tech IQ. 2014.
13. Public Health Agency of Canada. Infection Prevention and Control Guideline for Flexible Gastrointestinal Endoscopy and Flexible Bronchoscopy. October 2, 2011. Accessed August 3, 2015
14. Macario A. Editorial. What does one minute of operating room time cost? *J Clin Anesth*. 2010;22:233-6.
15. United States Bureau of Labor Statistics. Consumer Price Index. Medical Care Services. June 30, 2015
16. Binbay M, Yuruk E, Akman T, et al. Is there a difference in outcomes between digital and fiberoptic flexible ureteroscopy procedures? *J Endourol*. 2010;24(12):1929-34.
17. Somani BK, Al-Qahtani SM, de Medina SD, et al. Outcomes of flexible ureteroscopy and laser fragmentation for renal stones: Comparison between digital and conventional ureteroscope. *Urology*. 2013;82(5):1017-9.
18. Hession SM. Endoscope disinfection by orthophthalaldehyde in a clinical setting: An evaluation of reprocessing time and costs compared with glutaraldehyde. *Gastroenterol Nurs*. 2003;26(3):110-4.
19. Sung C, Singh H, Schwartz M, et al. Evaluation of efficacy of novel optically activated digital endoscope protection system against laser energy damage. *Urology*. 2008;72(1):57-60.
20. Olympus Corporation of the Americas. Olympus Product Catalog. Olympus, Your Vision, Our Future. 2015. Web. Accessed May 12, 2015.
21. Strategic Health Resources. National SGNA Congress Presentation. 2012.
22. Muggeo E, Boissel A, Martin L, et al. Cost comparison of two reprocessing procedures of flexible ureteroscopes at the University Hospital of Dijon [CHU de Dijon]. *Prag Urol*. 2015;25(6):318-24.
23. User HM, Hua V, Blunt LW, et al. Performance and durability of leading flexible ureteroscopes. *J Endourol*. 2004;18(8):735-8.
24. Boylu U, Oommen M, Thomas R, et al. In vitro comparison of a disposable flexible ureteroscope and a conventional flexible ureteroscope. *J Urol*. 2009;182:2347-51.
25. Semins MJ, George S, Allaf ME, et al. Ureteroscope cleaning and sterilization by the urology operating room team: the effect on repair costs. *J Endourol*. 2009;23(6):903-5.
26. Value Vantage. Day-in-the-Life Research. May 2014.
27. Laurentian Bank Securities. Analyst Report. 2013.
28. United States Bureau of Labor Statistics. Occupational Employment and Wages. May 2014: 31-9093 Medical Equipment Preparers. Occupational Employment Statistics. March 2015. Last accessed May 27, 2015
29. Forte L, Shum C. Comparative cost-efficiency of the EVOTECH endoscope cleaner and reprocessor versus manual cleaning plus automated endoscope reprocessing in a real-world Canadian hospital endoscopy setting. *BMC Gastroenterol*. 2011;11:105.
30. Xrates. Exchange Rate Average (Euro, US Dollar). Web. Accessed May 28, 2015.
31. ASGE Technology Committee. Technology status evaluation report. Automated endoscope reprocessors. *Gastrol Endoscopy*. 2010;72(4):675-80.
32. Communication from FDA, CDC and the VA. Preventing Cross-Contamination in Endoscope Processing: FDA Safety Communication. Issued November 19, 2009. <http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm190273.htm>. Accessed May 20, 2015.
33. Rutala WA, Weber DJ. Healthcare Infection Control Practices Advisory Committee HICPAC. Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008. Department of Health and Human Services; 2008.
34. Association for the Advancement of Medical Instrumentation. Standard 58: Chemical sterilization and high-level disinfection in health care facilities. AAMI, 2013.
35. Sterile Processing University, LLC. Announcing the reprocessing of flexible endoscopes course on line. 2015. <http://www.spdceus.com/modules/first/gj/>. Accessed May 12, 2015.
36. CBSPD, INC. Announcing the reprocessing of flexible endoscopes courses on-line. June 2015. <http://sterileprocessing.org/courses/courses1.htm>. Accessed June 8, 2015.
37. Olympus Corporation of the Americas. Reprocessing Specialist Training. 2015. <http://www.olympusuniversity.com/coursedetail.aspx?lpid=32>. Accessed May 12, 2015.
38. Ofstead CL, et al. Factors that contribute to nonadherence with endoscope reprocessing guidelines: A prospective study overview of findings from the CLEANR study. CLEANR Endoscope Nonadherence Study, 2010.
39. 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;66:958-63.
40. Landman J, Lee DJ, Lee C, et al. Evaluation of overall costs of currently available small flexible ureteroscopes. *Urology*. 2003;62:218-22.
41. Olympus Medical Systems Corporation. Uretero-reno videoscope Olympus URF Type V. Japan, 2014.
42. PENTAX Medical Company. Pentax ureteroreno fiberscope FUR-9P. Japan, 2011.
43. Richard Wolf Medical Instruments Corporation. Flexible fiber ureteroscope 7325.071/7325.076. United States, 2013.
44. Stryker Corporation. Stryker ideal eyes HD URT-7000S/7000Si flexible video ureteroscope. United States, 2012.
45. Pfedler Enterprises. The care and handling of rigid and flexible scopes (an online continuing education activity). Aurora, CO, 2013.
46. Clemens JO, Dowling R, Foley F, et al. Joint AUA/SUNA white paper on reprocessing of flexible cystoscopes. *J Urol*. 2014;184(6):2241-5.
47. Park S, Jang JY, Koo JS, et al. A review of current disinfectants for gastrointestinal endoscopic reprocessing. *Clin Endosc*. 2013;6(4):337-41.
48. Smith DR, Wang RS. Glutaraldehyde exposure and its occupational impact in the health care environment. *Environ Health Prev Med*. 2006;11(1):3-10.
49. Takigawa T, Endo Y. Effects of glutaraldehyde exposure on human health. *J Occup Health*. 2006;48(2):75-87.
50. Rideout K, Teschke K, Dimich-Ward H, et al. Considering risks to healthcare workers from glutaraldehyde alternatives in high-level disinfection. *J Hosp Infect*. 2005;59(1):4-11.

**Boston
Scientific**
Advancing science for life™

Boston Scientific Corporation
300 Boston Scientific Way
Marlborough, MA 01752
www.bostonscientific.com

© Boston Scientific Corporation or its affiliates. All rights reserved.

URO-350107-AA

Caution: Federal (U.S.) law restricts this device to sale by or on the order of a physician.

CAUTION: The law restricts this device to sale by or on the order of a physician. Please refer to package insert provided with the product for complete indications for use, contraindications, warnings, precautions, adverse events, and instructions prior to using these products. Information for the use only in countries with applicable health authority product registrations.

Bench test results on file with Boston Scientific. Bench test results may not necessarily be indicative of clinical performance. All trademarks are the property of their respective owners.