

Boston Scientific Receives FDA Clearance for LithoVue™ Elite Single-Use Digital Flexible Ureteroscope System

New technology designed to help inform real-time clinical decisions during kidney stone procedures

MARLBOROUGH, Mass., Feb. 3, 2023 /PRNewswire/ -- Boston Scientific Corporation (NYSE: BSX) today announced U.S. Food and Drug Administration (FDA) 510(k) clearance of the LithoVue™ Elite Single-Use Digital Flexible Ureteroscope System, the first ureteroscope system with the ability to monitor intrarenal pressure in real-time during ureteroscopy procedures.

Ureteroscopy is a common procedure performed by urologists to diagnose and treat a variety of problems in the urinary tract, most commonly kidney stones.¹ Research shows that about one in 10 people will develop a kidney stone at some point in their lives.² During ureteroscopies, elevated intrarenal pressure (IRP) can occur in response to fluid irrigation which is used to maintain a clear visual field. High IRP may contribute to a range of post-operative complications including systemic inflammatory response syndrome (SIRS), sepsis and renal damage.^{3,4} The built-in pressure sensor on the LithoVue Elite ureteroscope tip is designed to allow urologists to make informed, pressure-related clinical decisions.

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"Multiple studies have shown the importance of understanding intrarenal pressure during ureteroscopy procedures to mitigate potential complications, but until now, urologists have lacked an easy way to measure pressure in real-time," said Ben Chew, M.D., M.Sc., associate professor, University of British Columbia.⁵ "This device represents an important and needed advancement in single-use ureteroscopes, which could help improve patient care and potentially lead to a clearer understanding of the impact of elevated intrarenal pressure on patient outcomes."

The LithoVue Elite System, comprised of the single-use digital flexible ureteroscope and the StoneSmart™ Connect Console, builds on many of the features of the original LithoVue™ System with significant next-generation innovations. In addition to intrarenal pressure monitoring, device enhancements include:

- **upgraded image quality:** high-resolution digital chip and advanced imaging software designed to provide faster, sharper image quality and greater depth of field compared to the original LithoVue System;
- **updated control features:** two programmable buttons on the lightweight, single-use ureteroscope handle enable direct control of video and image capture without the need to coordinate with staff; and
- **streamlined integration:** the StoneSmart Connect Console, LithoVue Elite's compact processing unit, is designed to work with existing operating room visualization towers and endoscopic monitors to reduce clutter and capital footprint.

"We're at a critical moment in kidney stone care where patient demand is outpacing the number of urologists needed to address it," said Meghan Scanlon, senior vice president and president, Urology, Boston Scientific. "We designed the next-generation LithoVue Elite System to bring a greater level of precision and functionality in the way urologists diagnose and treat kidney stones, an increasingly common condition among adults.⁶ We are committed to developing clinical solutions, like the LithoVue Elite System, that are intended to make procedures more efficient, empower surgical decisions, optimize patient care and ultimately improve the treatment of kidney stone disease globally."

The LithoVue Elite System is the latest device in the Boston Scientific single-use imaging portfolio, developed with physician feedback to advance patient care and eliminate infection risk associated with ineffective reprocessing of reusable scopes. It is also the first device built on the company's next-generation StoneSmart technology platform, intended to support potential interoperability with future Boston Scientific devices.

Limited market release of the device in the U.S. will begin in the coming weeks.

For more information about kidney stone solutions from Boston Scientific, please visit www.bostonscientific.com/LithoVueElite or StoneSmart.com.

About Boston Scientific

Boston Scientific transforms lives through innovative medical solutions that improve the health of patients around the world. As a global medical technology leader for more than 40 years, we advance science for life by providing a broad range of high performance solutions that address unmet patient needs and reduce the cost of healthcare. For more information, visit www.bostonscientific.com and connect on [Twitter](#) and [Facebook](#).

Cautionary Statement Regarding Forward-Looking Statements

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Forward-looking statements may be identified by words like "anticipate," "expect," "project," "believe," "plan," "estimate," "intend" and similar words. These forward-looking statements are based on our beliefs, assumptions and estimates using information available to us at the time and are not intended to be guarantees of future events or performance. These forward-looking statements include, among other things, statements regarding our business plans, clinical trials, product launches and product performance and impact. If our underlying assumptions turn out to be incorrect, or if certain risks or uncertainties materialize, actual results could vary materially from the expectations and projections expressed or implied by our forward-looking statements. These factors, in some cases, have affected and in the future (together with other factors) could affect our ability to implement our business strategy and may cause actual results to differ materially from those contemplated by the statements expressed in this press release. As a result, readers are cautioned not to place undue reliance on any of our forward-looking statements.

Factors that may cause such differences include, among other things: future economic, competitive, reimbursement and regulatory conditions; new product introductions; demographic trends; intellectual property; litigation; financial market conditions; and future business decisions made by us and our competitors. All of these factors are difficult or impossible to predict accurately and many of them are beyond our control. For a further list and description of these and other important risks and uncertainties that may affect our future operations, see Part I, Item 1A – Risk Factors in our most recent Annual Report on Form 10-K filed with the Securities and Exchange Commission, which we may update in Part II, Item 1A – Risk Factors in Quarterly Reports on Form 10-Q we have filed or will file hereafter. We disclaim any intention or obligation to publicly update or revise any forward-looking statements to reflect any change in our expectations or in events, conditions or circumstances on which those expectations may be based, or that may affect the likelihood that actual results will differ from those contained in the forward-looking statements. This cautionary statement is applicable to all forward-looking statements contained in this document.

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References:

¹ National Institute of Diabetes and Digestive and Kidney Diseases. Cystoscopy & Ureteroscopy. Available at: <https://www.niddk.nih.gov/health-information/diagnostic-tests/cystoscopy-ureteroscopy>. Accessed June 2022.

² National Kidney Foundation. Kidney Stones. Available at: <https://www.kidney.org/atoz/content/kidneystones>. Accessed July 2022.

³ Tokas T, Herrmann TRW, Skolarikos A, et al. Pressure matters: intrarenal pressures during normal and pathological conditions, and impact of increased values to renal physiology. *World J Urol.* 2019 Jan;37(1):125-31.

⁴ Proietti S, Dragos L, Somani B, et al. In vitro comparison of maximum pressure developed by irrigation systems in a kidney model. *J Endourol.* 2017 May;31(5):522-7.

⁵ Dr. Ben Chew is a paid consultant of Boston Scientific Corporation. He has not been compensated for his quote within this press release.

⁶ Romero, V., Akpinar, H., & Assimos, D. G. (2010). Kidney stones: a global picture of prevalence, incidence, and associated risk factors. *Reviews in urology*, 12(2-3), e86–e96.

SOURCE Boston Scientific Corporation

<https://stage.mediaroom.com/bostonscientific/2023-02-03-Boston-Scientific-Receives-FDA-Clearance-for-LithoVue-TM-Elite-Single-Use-Digital-Flexible-Ureteroscope-System>