

New Four-Year Data Demonstrate Rezūm™ Water Vapor Therapy Offers Significant Durable Improvement of Benign Prostatic Hyperplasia Symptoms

MARLBOROUGH, Mass., Jan. 25, 2019 [/PRNewswire/](#) -- Boston Scientific Corporation (NYSE: BSX) today announced that [data](#) from a randomized clinical trial demonstrate that Rezūm™ Water Vapor Therapy, a minimally invasive treatment for benign prostatic hyperplasia (BPH), provides durable results and preserves sexual function four years after treatment. The study, published online ahead of print by *Urology*, found that patients continued to experience significant and sustained improvement in their symptoms and quality of life over this period.

BPH, which affects 110 million men worldwide, is an enlargement of the prostate in which prostate adenoma cells form excess tissue that may cause symptoms, which impact a patient's quality of life, such as a frequent and urgent need to urinate.^{1,2}

The Rezūm System treats the symptoms of BPH by using water vapor to kill prostate adenoma cells, leading to the cell remnants being absorbed by the body. The procedure can be performed in a physician's office without general anesthesia in a single visit and does not require implants to be placed in the body. The Rezūm System is included in The American Urological Association's BPH treatment guidelines and now has four-year follow-up data showing it can reduce the size of the prostate in all areas of enlarged prostate zones.

"This four-year study supports the use of the first-of-its-kind Rezūm System as a minimally invasive alternative for men with moderate-to-severe BPH who do not want to rely on pharmaceutical management of their symptoms," said Kevin McVary, MD, FACS, lead author and co-principal investigator of the Rezūm II Trial. "The data demonstrate that this advanced technology can empower urologists to achieve significant clinical improvements and deliver an impactful, durable response for their patients."

Over the four years, the trial showed a surgical retreatment rate of 4.4 percent and no new adverse events noted between years three and four. The clinical results also highlighted continued preservation of sexual function, including no de novo erectile dysfunction reported at four years.

"With this study, we continue to build a strong body of clinical evidence supporting the Rezūm System as the preferred minimally invasive treatment for BPH, providing long-lasting symptom relief, while preserving sexual function," said Dave Pierce, executive vice president and president, MedSurg, Boston Scientific. "More than 35,000 patients have already been successfully treated with the Rezūm System and we have recently worked with major insurance providers to extend coverage of the procedure, providing even more men with access to this transformative technology."

Boston Scientific acquired the Rezūm System in 2018, expanding the company's offerings for the treatment of symptomatic BPH, including the Greenlight XPS™ Laser Therapy system and holmium platforms.

¹ <https://www.healthline.com/health/enlarged-prostate#symptoms>

² <https://www.physiciansweekly.com/tag/benign-prostatic-hyperplasia/>

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 35 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 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; the closing and integration of acquisitions; 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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