Boston Scientific introduces the Intracept™ Intraosseous Nerve Ablation System for vertebrogenic low back pain in Europe

CE MDR approval for basivertebral nerve ablation therapy designed to provide long-lasting relief from single procedure

HEMEL HEMPSTEAD, United Kingdom, 24 July, 2025 — Boston Scientific Corporation (NYSE: BSX) today announced CE mark and introduction in Europe of the Intracept™ Intraosseous Nerve Ablation System. The Intracept system is the only treatment specifically designed to target the basivertebral nerve for the relief of chronic vertebrogenic pain, offering a new treatment option for patients affected by this type of low back pain. The minimally invasive procedure uses targeted radiofrequency energy to stop the basivertebral nerve from carrying pain signals to the brain, with 75 percent of patients experiencing long-lasting improvements in pain and back function after a single Intracept procedure. ¹

The first commercial Intracept procedure was performed by a team at Stoke Mandeville Hospital, Buckinghamshire Healthcare NHS Trust, in the United Kingdom led by Dr. David McKean, consultant musculoskeletal radiologist.

Almost six million people are suffering from chronic low back pain (CLBP) in the U.K., and it is the second leading cause of disability globally. Vertebrogenic pain is a distinct type of CLBP, caused by damage to the vertebral endplates, the interface between the disc and the vertebral body. Approximately one in six people with CLBP experience vertebrogenic pain. Typical symptoms include unrelenting pain in the centre of the lower back that worsens with certain movements or prolonged sitting. With the Intracept system, physicians can offer these patients a treatment that has been demonstrated to be safe, effective and long lasting.

"Our aim is to deliver outstanding care, and the Intracept system allows us to provide relief to patients with vertebrogenic low back pain and improve their quality of life," said Dr. McKean. "With this first purpose-built treatment for vertebrogenic pain, we can serve our patients in a targeted and precise way."

In clinical studies, patients experienced significant improvements in pain and back function at five years after a single treatment. As of June 2025, the Intracept procedure has already changed the lives of more than 50,000 patient across the United States, where the device received FDA clearance in 2016.

"Vertebrogenic pain can significantly impact people's quality of life, limiting mobility and causing severe discomfort for those affected," said Vincent Sourdaine, vice president, Neuromodulation in Europe, Middle East and Africa (EMEA) at Boston Scientific. "With the Intracept system, we have added a further evidence-based treatment option to our growing portfolio of therapies for chronic pain management, offering our customers more options to help these patients."

Boston Scientific is initiating a limited market release of the Intracept system in Europe, the Middle East and Africa over the coming months.

About Boston Scientific

Boston Scientific transforms lives through innovative medical technologies that improve the health of patients around the world. As a global medical technology leader for more than 45 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. Our portfolio of devices and therapies helps physicians diagnose and treat complex cardiovascular, respiratory, digestive, oncological, neurological and urological diseases and conditions. Learn more at www.bostonscientific.eu and connect on LinkedIn and X, formerly Twitter.

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 and product performance and impact, and new and anticipated product approvals and launches. 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; manufacturing, distribution and supply chain disruptions and cost increases; variations in outcomes of ongoing and future clinical trials and market studies; 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, except as required by law. This cautionary statement is applicable to all forward-looking statements contained in this document.

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- ¹ Khalil J, et al. Intraosseous basivertebral nerve ablation: 5-year outcomes from three long-term follow-upstudies. Interventional Pain Medicine, Volume 3, Issue 4, 2024,100529, ISSN 2772-5944, https://doi.org/10.1016/j.inpm.2024.100529.
- ² Hoy D, March L, Brooks P, et al. <u>The global burden of low back pain; estimates from the Global Burden of Disease 2010 study</u>. Annals of the Rheumatic Diseases 2014;73:968-974; The global point prevalence of LBP was 9.4% (95% CI 9.0 to 9.8), (333M U.S. pop * 9.4% = 31M); Lorio et al. <u>International Journal of Spine Surgery December 2022, 16 (6) 1084-1094</u>; DOI: https://doi.org/10.14444/8362; estimated that 15% of CLBP patients suffer from primary vertebrogenic pain
- ³ Fischgrund J, Rhyne A, Macadaeg K, et al. Long-term outcomes following intraosseous basivertebral nerve ablation for the treatment of chronic low back pain: 5-year treatment arm results from a prospective randomized double-blind sham-controlled multi-center study. Eur Spine J. 2020;29(8):1925-34. doi.org/10.1007/s00586-020-06448-x

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