



SeaSpine Announces Publication of Results from a Cellular Bone Graft Study in The Journal of Bone and Joint Surgery (JBJS)

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Study shows cells in cellular bone matrix products did not improve fusion SeaSpine's DBM outperformed the tested CBM products

CARLSBAD, Calif., Nov. 03, 2020 (GLOBE NEWSWIRE) -- SeaSpine Holdings Corporation (NASDAQ: SPNE), a global medical technology company focused on surgical solutions for the treatment of spinal disorders, today announced the publication of results from a preclinical study, "Examination of the Role of Cells in Commercially Available Cellular Allografts in Spine Fusion: An *in vivo* animal study," in The Journal of Bone and Joint Surgery (JBJS). JBJS is the highest regarded scientific publication in the fields of orthopedics and spine.

The study concluded that the cells in cellular bone matrix (CBM) products did not improve fusion or bone formation. The study also demonstrated that SeaSpine's demineralized bone matrix (DBM) product, OsteoStrand Plus, outperformed the tested CBM products. The study was conducted by leading investigators from the University of Southern California (USC) and Emory University in collaboration with SeaSpine.

"The class of cellular bone matrices has become ubiquitous in spinal surgery, yet there is no compelling data that the cells offer any clinical benefit to justify the high price point," said Dr. Jeffrey Wang, co-author of the publication and Professor of Clinical Orthopaedic Surgery and Neurosurgery at USC, a director of the Spine Center at USC, and a past President of the North American Spine Society (NASS) and the Cervical Spine Research Society (CSRS). "I'm honored to have participated in this study, which was led by my colleague Dr. Zorica Buser, with support from USC fellows and researchers. This project is a positive example of how academics and industry can collaborate to generate solid evidence around the clinical- and cost-effectiveness of the many different bone graft options available to a spine surgeon today."

Cellular allografts, or cellular bone matrices, are a class of tissue product containing a viable cellular component and often are marketed as providing a potential clinical benefit for bone formation. The CBM market has grown dramatically over the last 10 years to an estimated \$400 million to \$500 million, driven in part by the significant price premium for CBM products relative to DBM products and traditional bone substitutes. Payor approval of CBMs has come under increasing pressure in recent years because of the lack of strong evidence supporting its clinical efficacy.

"The team started with a simple question: *Do the cells in cellular bone matrices help spinal fusion?*" said Frank Vizesi, Vice President of Orthobiologics R&D at SeaSpine. "That led to a simple study design of testing the CBM products both with and without the cells, so that there was only one variable. When the data showed no difference in performance with or without the cells, we concluded that the cells had no positive effect. Furthermore, the study demonstrated that it's the DBM driving fusion, with OsteoStrand Plus, a 100% allograft DBM fiber product, outperforming the more expensive CBMs in this model."

"To effectively challenge the value and efficacy of the CBM class of products, it was critical that we partnered with trusted academics to design and execute this study," added Tyler Lipschultz, Senior Vice President, Orthobiologics and Business Development at SeaSpine. "Dr. Wang, Dr. Buser, and Dr. Scott Boden of Emory are among the most published and respected researchers in spine and orthobiologics. We are proud of this collaboration and in the quality of the study that was conducted, which reflects SeaSpine's commitment to differentiating our products through strong science and compelling data in an otherwise crowded field."

This study substantiates payor and provider pushback for CBMs and, combined with the previously published pre-clinical study comparing the OsteoStrand DBM fibers to six leading competitive DBMs, provides strong scientific support for SeaSpine's differentiated DBM offerings.

For a copy of the JBJS study abstract, please reference https://journals.lww.com/jbjsjournal/Abstract/9900/Examination_of_the_Role_of_Cells_in_Commercially.34.aspx

For a copy of the Frontiers in Surgery DBM Comparison study please reference <https://doi.org/10.3389/fsurg.2020.00010>

About SeaSpine

SeaSpine (www.seaspine.com) is a global medical technology company focused on the design, development and commercialization of surgical solutions for the treatment of patients suffering from spinal disorders. SeaSpine has a comprehensive portfolio of orthobiologics and spinal implants solutions to meet the varying combinations of products that neurosurgeons and orthopedic spine surgeons need to perform fusion procedures on the lumbar, thoracic and cervical spine. SeaSpine's orthobiologics products consist of a broad range of advanced and traditional bone graft substitutes that are designed to improve bone fusion rates following a wide range of orthopedic surgeries, including spine, hip, and extremities procedures. SeaSpine's spinal implants portfolio consists of an extensive line of products to facilitate spinal fusion in degenerative, minimally invasive surgery (MIS), and complex spinal deformity procedures. Expertise in both orthobiologic sciences and spinal implants product development allows SeaSpine to offer its surgeon customers a differentiated portfolio and a complete solution to meet their fusion requirements. SeaSpine currently markets its products in the United States and in approximately 30 countries worldwide through a committed network of increasingly exclusive distribution partners.

Forward-Looking Statements

SeaSpine cautions you that statements included in this news release that are not a description of historical facts are forward-looking statements that are based on the Company's current expectations and assumptions. Such forward-looking statements include, but are not limited to, statements relating to the Company's research activities, including the quality of scientific evidence from the Company's R&D personnel and collaborating researchers. Among the factors that could cause or contribute to material differences between the Company's actual results and the expectations indicated by the forward-looking statements are risks and uncertainties that include, but are not limited to: risks inherent in scientific research and development; the quality of information published by scientific journals; and other risks and uncertainties more fully described in the Company's news

releases and periodic filings with the Securities and Exchange Commission. The Company's public filings with the Securities and Exchange Commission are available at www.sec.gov.

You are cautioned not to place undue reliance on forward-looking statements, which speak only as of the date when made. SeaSpine does not intend to revise or update any forward-looking statement in this news release to reflect events or circumstances arising after the date hereof, except as may be required by law.

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Source: SeaSpine Holdings Corporation