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Minimus Spine Enrolls 30th Subject to Randomized Study Comparing Triojection® to Discectomy

Minimus Spine, the developer and manufacturer of the Triojection System, a novel system intended to facilitate the treatment of disc herniations with an intradiscal injection of ozone gas, announced that it has enrolled the 30th subject into its 50-patient randomized study comparing Triojection to discectomy.

"This is the first study to randomize patients between an intradiscal ozone injection and surgery. Hitting this enrollment milestone puts Minimus in position to complete enrollment by September of next year, resulting in primary endpoint data completed near the end of Q1-2018.", said David Hooper, PhD, Minimus Spine's Chief Executive Officer. "Triojection already has CE Mark, and if the product demonstrates comparable outcomes to surgery, Minimus will be well-positioned to expand launch activities in Europe. We recognize that new products must be supported with rigorous clinical data to justify their cost. There are no short cuts and that is why we have been pro-actively investing in this study."

Bruce Frankel MD, Professor of Neurosurgery at the Medical University of South Carolina and Co-Director of the MUSC Spine Center, added "Triojection has the potential to significantly impact the treatment of patients with disc herniations. The benefits of epidural steroid injections are limited and the injections simply do not work for everyone. Discectomy is the gold-standard for patients that have not responded to epidural injections or want more immediate benefit. If Triojection can offer a comparable outcome to surgery, then I envision it being used routinely before considering surgery. Triojection would be more attractive to patients and significantly reduce the cost of care. I am looking forward to the results from this study."

The study is listed on clinicaltrials.gov under identifier NCT02525120. Patients with a confirmed disc herniation and significant leg pain lasting more than 6 weeks are being presented with the option to enroll in the study. Upon consent, patients are randomized in a 1:1 ratio between Triojection and discectomy. The primary outcome is non-inferiority of Triojection to discectomy surgery for improvement in leg pain over six month following treatment. Back pain, disability and other outcomes are also being collected. While the primary endpoint is based on data up to and including six months, Minimus Spine is following these patients for two years. Clinical sites are in Italy, Switzerland and Greece.

About Minimus Spine: Established in 2006, Minimus Spine is a privately held medical device company dedicated to developing the Triojection technology the non-surgical treatment of herniated discs. Minimus Spine maintains its headquarters in Austin, TX. For more information on Minimus Spine, please visit www.minimusspine.com or email info@minimusspine.com