Introduction: The M6-C artificial cervical disc (Spinal Kinetics, Sunnyvale, CA) is an advanced generation artificial disc developed to treat degenerative cervical radiculopathy. It is designed to replicate the anatomic structure of a natural disc by incorporating an artificial nucleus and annulus. The compressible polymer nucleus of the M6-C is designed to simulate the function of the native nucleus, while the surrounding multi-layer high tensile strength fiber annulus is intended to provide a controlled range of motion. This unique design allows the M6-C prosthesis to have all 6 degrees of freedom to include angular motion in flexion-extension, lateral bending and axial rotation as well as allowing independent translations along the 3 anatomic planes (anterior/posterior, side to side and axial compression).

Methods: The M6-C German Registry is a single arm, prospective registry intended to evaluate the safety and clinical performance of the M6-C artificial cervical disc for the treatment of symptomatic cervical radiculopathy at one or more levels. Ethics Committee approval was attained prior to initiation. Patients enrolled in the registry signed a study specific informed consent, met the requirements of the Instructions for Use for the device and underwent unsuccessful conservative care prior to surgery. Patients were evaluated pre-operatively and post-operatively at 3 months, 12 months and 24 months. Evaluations at each visit included a routine neurological examination, the Neck Disability Index (NDI), arm and neck pain assessments (VAS) and Quality of Life (SF-36v2). In addition, AP, Lateral and Flexion/Extension x-rays were obtained for both quantitative and qualitative assessment (Medical Metrics, Inc., Houston, TX). Adverse events were monitored to evaluate safety.

Results: Fifty patients (24 males and 26 females) have been followed for up to 24 months with a mean age of 44 yrs for the males and 43 yrs for the females. Forty-six patients were treated at 1 level and 4 at 2 levels for a total of 54 implanted discs. Thirty discs were implanted at C5/C6, 23 at C6/C7 and 1 at C4/C5. The mean duration of surgery was 78 minutes. The mean NDI decreased significantly from baseline to 24 months and on 10-point scales, both the neck and arm pain VAS also decreased significantly through 24 months. Both the Physical Component Summary (PCS) and Mental Component Summary (MCS) of the SF-36 increased significantly from baseline and have been maintained through 24 months. Surgeon assessment indicated excellent or good results for 88% of the patients, and 88% of the patients reported improvement to complete recovery. Index Level ROM, Global ROM and Disc Angle increased significantly after surgery and have been maintained over time. Device position has been maintained with no evidence of device migration or expulsion. The incidence of Heterotopic Ossification (HO) was somewhat higher than anticipated at 24 months. One patient had the disc removed at 3 months due to subsidence. There have been no additional serious device related adverse events.

Conclusion: Clinical and radiographic data from the M6-C German Registry indicates acceptable clinical and radiographic outcomes at 24 months post procedure.