

AxioMed® Has Initiated Clinical Investigation of Its Lumbar Disc Using a PTG Polymer

by Ronald Trahan

USING A PATENTED POLYMER under exclusive license from the Polymer Technology Group (PTG), AxioMed Spine Corporation is developing and conducting clinical trials of an artificial disc intended to replicate the natural function of a human disc. AxioMed hopes that its investigational device will represent a significant improvement over currently approved artificial discs. At this time, AxioMed is conducting a pilot clinical study in Europe on its lumbar disc for symptomatic *degenerative disc disease* (DDD). AxioMed's disc was developed and designed by a team of clinicians and experts in the fields of biomechanics, pathology, spine surgery and polymer science. AxioMed believes that the material characteristics of PTG's polymer, in combination with AxioMed's implant design, may be proven to provide three-dimensional motion that functions within the natural biomechanics of the spine.



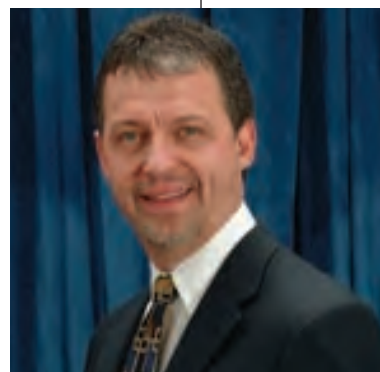
Patrick McBrayer, President/CEO
AxioMed Spine Corporation

R and D Partnership

AxioMed designed its disc with the goal of achieving the geometry, motion, deformability, inherent stiffness, and damping characteristics necessary to restore normal function to a spinal segment. "We believe our Freedom® disc may represent the next generation of technology for treating degenerative disc disease," says Patrick McBrayer, President and CEO. "The goal of our technology is to restore the natural function of the spine. PTG's polymer is well-suited to this goal. Its viscoelastic properties allow for compression, rotation and translation, while simultaneously providing load transfer and damping."

PTG presented biocompatibility test data related to the polymer used in the AxioMed lumbar device in April 2007 at the annual meeting of the Society for Biomaterials in Chicago. The test results showed that the thermoplastic silicone-polycarbonate-urethane used in the PTG polymer met FDA and international standards for use in orthopedic implants. Performance testing on the polymer also showed that it met appropriate specifications for strength and viscoelastic properties. AxioMed has an exclusive license to the patented PTG polymer for prosthetic spinal disc applications.

"We chose to work with PTG because of their great reputation," adds James Kuras, AxioMed's COO. "In the implant-grade biomaterials sector, PTG has to be ranked number one. I have not found another group that has the kind of broad capabilities which PTG has. Surely, they offer the best implant-grade polymers in the industry. But it has to go beyond just



James Kuras, COO
AxioMed Spine Corporation

providing something that gives you the mechanical characteristics you want. For example, they have a really good fundamental understanding of the regulatory issues involved with biocompatibility. And they possess a strong understanding of how these biomaterials can be processed after they're in pelletized form," says Kuras. "For these and many other good reasons, we are in discussions with PTG to assume a significant portion of the manufacturing of our lumbar disc."

AxioMed is preparing an IDE submission to the U.S. Food and Drug Administration (FDA) for ultimate regulatory approval.

In addition, following European pilot studies, AxioMed will pursue a

CE Mark for the Freedom Lumbar Disc in 2008 and is formulating a complementary marketing strategy.

"We're very proud of the fact that it's a PTG-polymer inside our novel device," says CEO McBrayer.

