



PDI Solution Boosts Long-Term Medical Device Performance

Spinal disc replacement manufacturer relies on quality analysis and manufacturing solutions from Polymer Diagnostics to help its breakthrough product reach far beyond durability requirements.

Situation

Designers at AxioMed Spine Corp. seized an opportunity to create a revolutionary replacement disc for the spine, which they call the Freedom® Lumbar Disc. This device exemplifies the next generation in disc replacement and offers mobility equal to the body's natural components. AxioMed's breakthrough idea involves placing two titanium plates on either side of a polymer core. When bonded to the metal, the polymer core mimics a natural disc, absorbing impact and shock while bearing mechanical stresses from the vertebrae.

Polymer Diagnostics Inc. performed a series of analytical tests with an eye toward enhancing the polymeric core of the product. According to AxioMed COO Jim Kuras, "The challenge was to assure the polymer portion of the device would maintain its load-bearing properties without undergoing an excessive permanent change in shape, as well as to optimize and characterize the polymer-to-titanium bond."

The PDI Difference

Characterizing the polymer's viscoelastic properties under conditions that simulate the human body helped PDI to predict creep performance, which identifies the measurable strain put on a polymer over a given period of time. The predictions provided guidance in selecting the right temperatures to use in a 30-day compressive creep test that enabled PDI to more accurately estimate device performance over a 20-year span. Developed specifically for this application, the prediction method was recognized by the U.S. Patent and Trademark Office, which granted PDI two patents related to the process.

In further testing, scanning electron microscopy was used to examine the polymer-to-titanium bond. Suspicious areas were then subjected to chemical analysis, in which the primer, adhesive, and titanium surfaces revealed potential factors that could compromise bonding integrity. Cause-and-effect analysis of the adhesive bonding process gave PDI the information needed to develop a manufacturing process that would provide necessary bond integrity. Prior to development of this method, the discs were failing at 40,000 to 80,000 cycles.

As a result of side-by-side R&D and laboratory work, the two companies ultimately optimized a proprietary method for bonding the polymer disc and titanium plates. With the new method, the discs' ability to withstand failure during cycle testing was improved by a factor of 400, far exceeding the requirement of 180,000 cycles.



Simulated, in-vitro testing of the compressive creep and shear viscoelastic properties of the device assured designers that the Freedom Lumbar Disc™ would replicate the natural motion of the spine. Kuras said, "Working with PDI's PhD scientists gives us access to an exceptional knowledge of polymers. The R&D, brainstorming and solutions provided by the group are outstanding. It is essential to be able to count on this laboratory to help us through challenging processes."

Delivering Real-World Results

Research, development, and optimization of the Freedom® Lumbar Disc will help millions of patients across the world suffering from chronic back pain. Value-added services provided to AxioMed Spine Corp. by PDI include:

- Performance optimization
- Manufacturing improvements
- Shortened time-to-market timeline
- A clearer path for FDA submission

The scientists at PDI offer exclusive value-added services and solutions. With a wealth of experience in polymer research and technology, they are prepared to handle the most challenging problems. PDI has a track record of thorough, timely, and cost-effective service that remains the backbone of its service offering. At PDI, the goals are to help clients:

- Solve the toughest technical problems
- Grow their business
- Commercialize products quickly

Above all, PDI functions as a trusted R&D partner to its clients.

Polymer Diagnostics Inc. is a contract laboratory with accreditation to ISO/IEC 17025 by the American Association for Laboratory Accreditation (A2LA) for both chemical and mechanical capacities.

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