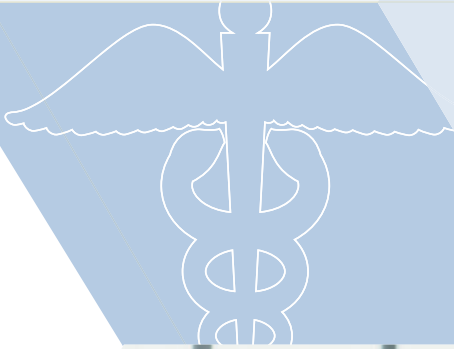


Industry Bulletin

Polymer Diagnostics Inc.



**Polymer
Diagnostics Inc.**

Comprehensive consulting and testing
expertise for medical materials and
device companies

A Trusted Resource

Polymer Diagnostics Inc. (PDI) is a complete solutions provider of plastics testing and polymer consulting within the medical materials and device industries. Our track record of thorough, timely, and cost-effective service is the backbone of our service offering. PDI scientists have on average 30 years each in the industry and are ready to take on any challenge. Our focus is on providing real-world solutions to our clients through characterization, problem solving, and analysis of polymers and plastics.

Value-Added Services & Solutions

With a wealth of experience in polymer research and technology, we are prepared to handle the most challenging problems facing medical manufacturers. At PDI, our goals are to help clients:

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

Core Competencies

We offer unmatched expertise in material, process, and end product polymer testing, including:

- Support studies for device qualification
- Material analysis and identification
- Suggestions on process improvement
- Advanced failure analysis
- Litigation support

The PDI Difference

We provide solutions—not just raw data

We help you determine the root cause of failure and recommend real-world solutions and better routes to successful commercialization.

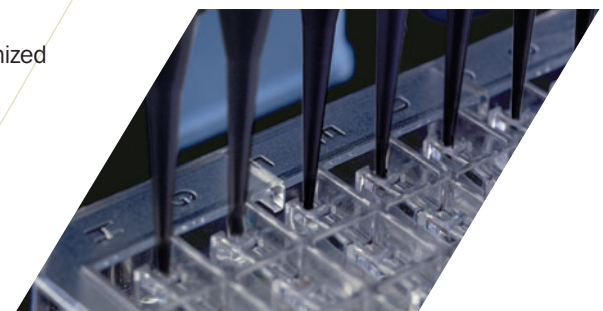
Our work is consistent and confidential

We have been servicing the medical device industry for decades and are recognized for our professional and confidential services.

We'll tell you how your product will perform—and why

Our experts work hand-in-hand with your technical staff to answer the most difficult questions—Why did your product fail? Was it due to composition? What is its useful lifetime?

Polymer Diagnostics Inc.
is a wholly-owned subsidiary
of PolyOne Corporation.



Delivering Real-World Solutions

No matter the technical challenge, we have the instrumentation and technical expertise to help you find precise, cost-effective, real-world solutions.

PDI has extensive experience with the testing of medical devices and materials including:

- Catheters
- Bio-implants
- Surgical diagnostic devices
- Medical tubing
- Other disposable medical devices

Issues often arise as a result of:

- Improper design or choice of material
- The environment of exposure
- Processing conditions

World-class people and capabilities under one roof

- Failure Analysis/Prevention
- Qualification Support
- Rheology
- Polymer Characterization
- Deformation
- Physical Testing
- Litigation Support
- Characterization of polymers in pharmaceutical delivery systems
- Phthalate and BPA testing

Case Study

Axiomed Spine Corporation: Replacement Disc for the Spine

Challenges:

Designers at Axiomed Spine Corp. seized an opportunity to create a revolutionary replacement disc for the spine using polymer and titanium. The challenge for PDI 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.

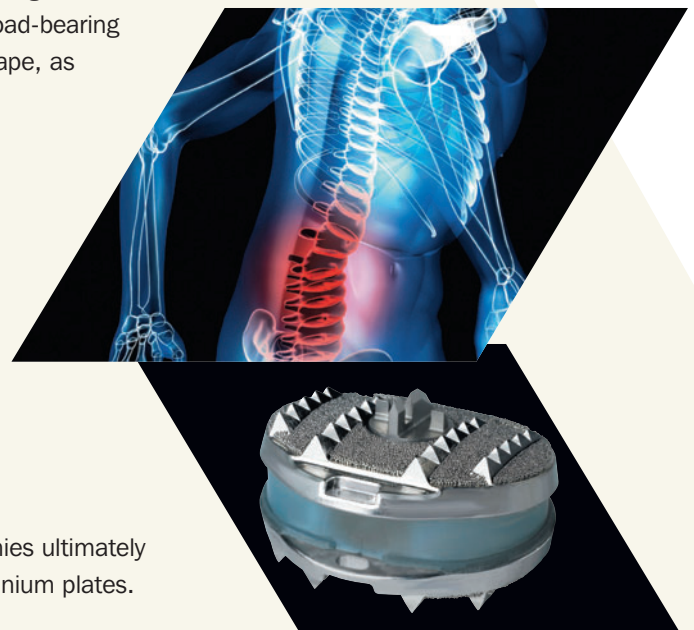
Solutions:

Using an innovative method to predict creep performance, the polymer's viscoelastic properties were characterized under conditions that simulated use in the human body over a 20-year span. Additionally, examination of the polymer-titanium bond using scanning electron microscopy and chemical analysis revealed potential factors that could compromise bonding integrity.

Benefits:

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.



Committed to Growing with the Medical Industry

Since 2009, PDI has invested over \$2 million to improve and extend our capabilities to serve our medical materials and device clients.

Equipment	Benefit
Scanning Electron Microscopy with Energy Dispersive X-ray System	Capability to look at material and property defects at the most detailed level with magnification up to 800,000x
Digital Optical Microscope	Ability to non-destructively capture fully-focused images with a depth-of-field 20x larger than conventional microscopes
Microwave Sample Digestion System	Aids in sample preparation for heavy metal analysis
Mechanical Spectrometer	Estimates how a medical device will structurally perform when subjected to the load within a human body
Differential Scanning Calorimeter	Analyzes the transition temperatures of materials and also determines the purity of the materials to predict likelihood of defects
Chromatography Accessories	Facilitates compositional analysis of materials and devices as well as the ability to analyze extractables

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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