

# Medical Device Testing & Development Services

## Why Choose ARDL?

Clients contract ARDL for medical product technology solutions because ARDL is an independent laboratory that is focused on helping clients find solutions. An experienced staff of over 100 professionals is dedicated to providing the best product development and testing services available and they understand the need to rapidly commercialize medical device and product technologies. ARDL has a proven, quality-based medical device development process, and intellectual property developed for a client always becomes the property of the client. ARDL can assist you with test protocol design, mechanical fixturing, data gathering, in-depth analysis and the interpretation of your results.

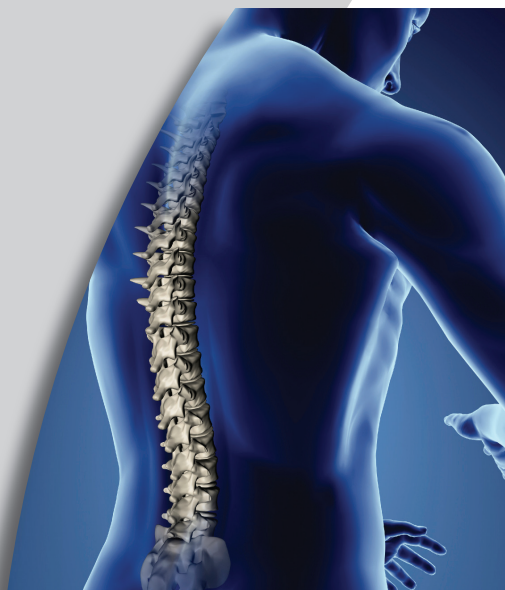
- Chemotherapy Drug & Toxic Chemical Permeability
- Electrical Testing
- Fatigue & Durability Testing
- High Strain Rate & Impact Testing
- Medical Device Performance Testing
- Package Integrity Testing
- Reverse Engineering
- Shelf Life & Service Life Prediction
- Shock, Vibration, Thermal & Humidity Testing



## Medical Devices & Products ARDL has Worked with Include:

Balloons	<i>Flexural Bend Testing for Finger, Toe, Spine, Jaw and Other Implants</i>
Catheters ( <i>Catheter Compliance Measuring per AAMI &amp; ISO Standards</i> )	
Condoms	Orthopedic Implant Testing
Cups	• <i>Multiaxis Testing for Advanced Wear and Kinematic Studies</i>
Diaphragms	• <i>Materials Characterization per ASTM, AAMI and ISO Standards</i>
Drug Sundries	• <i>Custom Fixture Design and Test Protocol Development</i>
Engineered Tissue	• <i>Ultimate Strength and Attachment/ Detachment Measurements</i>
Gloves ( <i>Chemical, Electrical, Examination, Industrial, Surgical, etc.</i> )	Stents
Graft Devices	Stoppers
Heart Valve Components	Spinal Disks
Orthopedic Implant Testing	And Many Other Medical Goods!

# Medical Device Testing & Development Services (cont.)



## Product Development

ARDL utilizes a proven, quality-based medical product development process to transform your product concepts into reality. Our three-phase process has resulted in the successful commercialization of medical products for some of the largest medical device manufacturers in the world. Project managers at ARDL work closely with clients to develop project schedules that include well-defined tasks and milestones for each phase of development.

ARDL believes the most successful approach to product development begins with a thorough product definition based on your requirements. Engineers use the product definition as the basis for the development of system specifications, pre-production prototypes and test plans. As part of a rigorous quality process, ARDL conducts functional reviews throughout product development to reduce overall time to market and to improve product performance, reliability and conformance.

ARDL provides weekly data updates and reports so you can continuously track your project from start to finish. ARDL's product development process incorporates the FDA requirements for medical device development.

### Phase 1

#### Product Definition

- Quality Plan
- Product Functionality
- Product Material Specification
- Initial Risk Analysis

### Phase 2

#### Product Development

- Concept Development
- Preliminary Product Review
- Detailed Geometry
- Critical Geometry Review

### Phase 3

#### Implementation

- Test Plan
- Quality Plan
- Product Testing
- Prototype Building

## Product Failure Analysis

Failure Analysis of medical products requires the use of unique mechanical and analytical techniques. The final goal of a product failure analysis is the determination of the mode and cause of failure. The first step is to perform a thorough inspection of the failed part, initially with an optical stereomicroscope and subsequently with a scanning electron microscope. Mechanical testing provides the tensile, dynamic, impact, thermal and stiffness properties of the material(s). While procedures vary, the primary mechanical tests provide a comparison between measured data to a specification, or to data generated by a known benchmark. Computer-aided stress analysis can provide the stress distribution of the part in service with the results detailing the geometrical effect of the failure. It is best, whenever possible, to provide a "control" product for comparison with the failed product.

*Testing that may be performed during failure analysis includes:*

Chemical Testing	Finite Element Analysis	Mechanical/Physical Testing
Compound Analysis	Formula Reconstruction	Microscopic Analysis
Fatigue Testing	Impact Testing	Ultra High Strain Rate Analysis



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