

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



Rubber. Plastic. Latex.

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 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 | Phase 2 | Phase 3 |
|--|---|---|
| Product Definition <ul style="list-style-type: none"> • Quality Plan • Product Functionality • Product Material Specification • Initial Risk Analysis | Product Development <ul style="list-style-type: none"> • Concept Development • Preliminary Product Review • Detailed Geometry • Critical Geometry Review | Implementation <ul style="list-style-type: none"> • Test Plans • 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 on 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.

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 |

