Medical Device Packaging Testing

DDL is a third party testing laboratory with over twenty years of experience in package validation testing. Specializing in ISO 11607-1, DDL carries out accelerated aging and shelf-life studies where packaging systems are subjected to distribution simulation, package integrity, package strength and other physical tests.

With two full-service dynamic and integrity labs complemented by a wide range of environmental chamber capabilities, DDL offers the medical device industry a combination of technical expertise, quality and capacity designed to provide device manufacturers with the best service possible.

Distribution Simulation Testing: ASTM versus ISTA

Distribution Simulation Testing

Packaging that protects medical devices must be able to withstand the typical events associated with distribution of the product without defect or loss of sterility. It is the manufacturer's responsibility to evaluate the package's ability to protect the product throughout handling, distribution and within a storage environment.

DDL regularly partners with MDMs by helping them understand and execute transportation simulation using accepted industry standards.

11 Frequently Asked Questions about ISO 11607-1

The primary goal is to have an effective shipping configuration that protects the product during transit and complies with ISO 11607-1.

"Distribution simulation testing is a uniform and repeatable way to evaluate packaging systems by utilizing laboratory equipment, subjecting the system to the specific hazards that may occur in the anticipated distribution environment."

Scott Levy, Packaging Engineer

Distribution Simulation Standards include;

<table>
<thead>
<tr>
<th>ASTM</th>
<th>ISTA</th>
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<tr>
<td>D4169</td>
<td>2 Series &quot;Partial Simulation Performance Tests&quot;</td>
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<tr>
<td>D7386</td>
<td>3 Series &quot;General Simulation Performance Tests&quot;</td>
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Distribution simulation testing can be thought of as a conditioning element of the test specimens. It is the tests that are carried out after distribution testing that determine whether the specimens pass or fail as there is no variable or attribute data associated with simulation testing.

Scott Levy on Distribution Simulation Testing

ISTA 3A and ASTM D7386

DDL Packaging Engineer, Scott Levy discusses distribution simulation package testing standards, test methodologies and the pitfalls associated with ISTA 3A and ASTM D7386. In this video, Mr. Levy explains how distribution simulation is an important part of package validation and clarifies some of the industry's common misconceptions.

Watch Video »

Package integrity and strength testing

NEXT ARTICLE
Package Integrity
In order to maintain the sterility of a packaged product to the point of end use, the package must have a microbial barrier in its post-sterilization environment. Manufacturers are required to demonstrate that a sterile package’s integrity is maintained throughout the device’s stated shelf life and after exposure to the rigors of distribution, storage, handling and aging. Physical test methods may be used to validate package integrity.

Package Integrity Testing Services:
- ASTM D2096 - Package Leak Testing by Bubble Emission
- ASTM D3078 - Vacuum Leak Testing, Flexible Packaging
- ASTM D4991 - Vacuum Leak Testing, Rigid Packaging

Package Strength
Two test methods are used to evaluate the package strength. Seal peel testing utilizes one inch coupons cut from the test specimen to determine the amount of force necessary to separate two adjoined tabs. Burst strength testing utilizes pressure to rupture the package along its seal. Both methods allow the medical device manufacturer to determine the consistency of their package sealing process.

Package Strength Testing Services:
- ASTM F88 - Package Strength Testing by Seal Peel Testing
- ASTM F1140 - Package Strength Testing by Burst Testing

Package Integrity and Strength Testing

Bubble Leak
ASTM F2096, ASTM D3078, ASTM D4991
Leak testing by bubble emission is a destructive method where manufacturers should expect to consume a certain amount of package material and product as part of the test.

Dye Leak
ASTM F1929
Dye penetration leak testing involves the even application of a dye solution within a flexible or rigid package followed by inspection for defects. After a specified contact time between the dye and test area, the package seals are visually inspected for evidence of leakage created by capillary action of the dye through the defect.

Burst Strength
ASTM F1140
Burst testing is a strength test that induces a seal failure when the package is exposed to a pressure differential. This test method indicates the burst strength of a package and detects the weakest area of the seal, providing a measurement of the pressure required to “burst” the package. DDL performs burst testing per ASTM F1140 “Standard Test Methods for Internal Pressurization Failure Resistance of Unrestrained Packages.”

What is Test Method Validation and What Can it Do for Me?

Read the White Paper »

Product & Material Testing

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Product and Materials Testing

Materials Testing
Testing the Materials from Which the Package is Made
In addition to distribution simulation, package integrity and package strength, ISO 11607-1 states the need for manufacturers to ensure that the materials used in a package’s design comply to established physical properties. To complement its packaging testing, DDL’s Product & Materials Division takes design understanding to a deeper level by testing and evaluating the materials that make up the package itself. From tensile and tear testing of poly films and trays to applying compression and tension to packaging components, materials testing can increase a packaging engineer’s understanding of available options, allowing for more informed design decisions.

Processing variables, vendor changes, effects of aging, different sterilization treatments and material changes can be explored through material testing. The engineering staff within DDL’s Product & Materials Division has a thorough understanding of today’s test standards and the principles behind them.

Product Testing
Testing the Product Inside the Package
DDL’s Product & Materials Division also tests medical devices for safety and performance. Specializing in testing catheters, luer fittings, cannulae, guidewires, needles, syringes and electrosurgical devices, products can be tested for flow, leakage, cyclic fatigue, flexion, adhesion, force to operate, coefficient of friction and electrical properties. Products can be exposed to compression, tension, physical shock, thermal shock and vibration.

ANSI, ASTM, IEC, ISO, JIS and EN standards are used to help the medical device developers better understand their products performance. Custom test development and protocol creation can also be provided. Medical device manufacturers utilize this wide range of services for one-stop package, product and materials testing in order to prepare for regulatory submissions.

A Dozen Words of Wisdom from a Product & Materials Testing Lab

ISO 80369-1 Testing
ISO 80369-1 is a relatively new test standard for medical connectors including luer and other small bore connectors. ISO 80369 will eventually consist of seven parts with part one (ISO 80369-1) addressing general requirements and the remaining parts addressing specific applications. The overall intent of the standard is to reduce the risk of misconnections in the field. Prior to ISO 80369-1 the prevalent standards for luer and small bore connectors have been ISO 594-1 and ISO 594-2.
Customer Service & Technical Depth

Bringing technical expertise and a depth of knowledge unmatched in the packaging testing industry DDL has completed over 23,000 testing projects since its founding. Our team of Packaging Engineers, Product & Materials Engineers and a dedicated, in-house staff of quality and calibration personnel helps device manufacturers succeed in achieving their regulatory compliance goals.

DDL recognizes the pressures faced by the medical device industry and helps remove those pressures by taking an informed and involved approach to each customer’s specific needs. Our Sales Engineers work directly with customers to ensure that the right tests are selected for the right reasons. Our Project Engineers work one on one with customers throughout the project lifecycle to ensure good and timely communication. The DDL team values strong client relationships founded on outstanding customer service, technical expertise, quality results, and open and honest communication.

Complete list of Services

- Combination Product Testing
- Luer Testing
- Customized Package Testing
- Electrosurgical Testing
- Environmental Package Testing
- Catheter Testing
- Mechanical Testing
- Packaging Materials Testing
- Film Testing
- Package Validation Consulting
- Package Validation Testing
- Product Testing
- Test Method Validation
- Sustainable Package Testing
- Thermal Performance Testing
- Thermal Shock Testing

DDL, Inc. is a third party test lab specializing in product, materials and package validation testing per ISO 11607-1. DDL also carries out accelerated aging, thermal conditioning, environmental data acquisition, protective cushion evaluation and random vibration simulation. Other tests include shock, compression, and ASTM standards such as D3580, D3332, D4169, D642, D999, F88 and F1140. DDL takes an informed, impartial and involved approach to every test in order to ensure the highest level of quality and customer service.