Medical Device and Biomaterials Update

Volume 1

Features

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Welcome

Over the past decade, the medical device and biomaterials industries have undergone tremendous amounts of innovation and change. Materials and technologies have evolved to the point where surgeons are placing small metal stents weighing a few grams into the neurovascular system (in the brain!) to help patients avoid strokes caused by plaque or arterial buildup. Correspondingly, there have been substantial increases in regulatory involvement to ensure safety and efficacy in all devices. These evolutions have translated into a growing requirement for full evaluation of products from concept to product release within the research labs of medical device manufacturers around the world.

Instron® has been there to provide systems and solutions for research, production, development, and quality packaging throughout the industry. From assistance in the creation of testing standards within ISO and ASTM committees to collaborative projects at strategic universities, we continue to strive to provide cutting-edge systems and fixturing for future-looking research organizations, as well and standard systems for production processes found in quality assurance and control laboratories.

We welcome the opportunity to work with you regardless of project size or complexity. Solving medical device and biomaterial challenges has become the mission of our Instron Bio Team. If you have questions about how to pull, push, bend, fatigue, extrude, stretch, grab, hold, submerge, evaluate, measure, document processes, break, crush, squish, peel, tear, penetrate, heat, probe, impact, or simply test your devices... Let us know!

Biomimetic Muscles: New Possibilities from Spider Silk

Scientists and engineers have studied and measured the amazing mechanical properties of spider silk for decades. They're tough; they can absorb a large amount of energy without breaking, such as when a bee collides with the web. They're sticky; some silks are spun with glue droplets along their lengths to keep that bee secure. These studies have led to developments in textiles, notably Kevlar® from the DuPont Company, with properties that mimic some of those of spider silk.

One would think that given all the research that has taken place on the mechanical properties of spider silk that there was little more to discover. But scientists at the University of Akron have recently uncovered a fascinating new fact about this material that offers intriguing possibilities for the future.

Spider silk is a fiber comprising complex protein molecules. Spiders manufacture silk from their spinnerets; organs located on the spider's abdomen. Depending on the species, spiders can have anything from two to eight spinnerets, usually in pairs.

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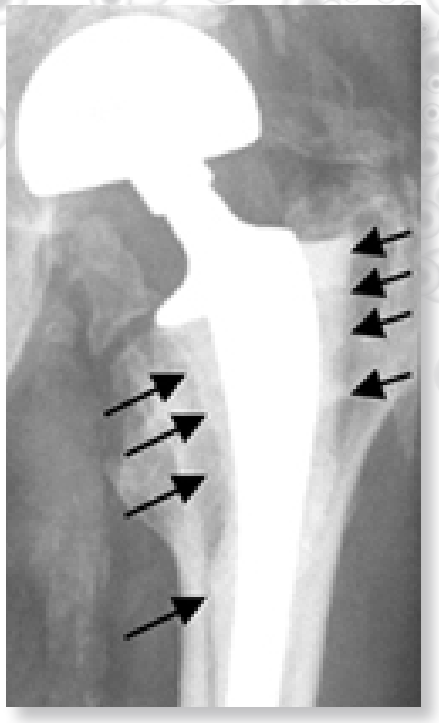
Interesting Medical Facts

- Out of the 6.8 billion people on our planet earth, almost 40% live in either China or India!
- Global life expectancy average in 1910 was 39 years. In 2010 it was 68 years
- The number one work loss injury/explanation in the world is lower back pain
- The average human heart beats 400 million times in 10 years
- More than 1,000,000 stents were placed in coronary arteries in 2010 within the USA alone

A New Hip Material



The first surgery to replace a damaged hip joint with an artificial joint was performed 50 years ago. Today, more than 190,000 hip replacement surgeries are performed in the USA alone. During this time, there have been many improvements to the surgical techniques and to the technologies and materials of the replacement joints; however inherent problems remain. One of these is the slow deterioration of bone tissue around the prosthetic material due to uneven load distribution between the prosthetic and the bone itself.

Dr. Afsaneh Rabiei, a professor of mechanical, aerospace, and biomedical engineering at North Carolina State University, recently developed a new composite metal foam material that offers, among many other possibilities, the development of new hip joint prostheses that may overcome this problem.

Artificial hip joints are usually manufactured using solid titanium, which is many times stiffer than the bone into which it is secured. Therefore, the implant assumes the majority of the loads exerted by walking and running. Regular load-bearing exercise is an important factor in good bone health. The bone around the implant, being now deprived of much of the load, loses density and strength, a phenomenon known as stress shielding. In time this deterioration, together with other changes due to biological reactions with the cement used to secure the implants to the bone, can cause the implant to loosen, resulting in the need for further surgery to reseat or replace the joint.

Metal foams have been around since the late 1940s. Most are developed by introducing gases into molten metal, which cools to form a matrix of thin-walled metal. However, the cellular structure is difficult to control, leading to variations in cell wall thickness and random cell shapes and sizes. The resulting mechanical properties of the material are unpredictable and inconsistent.

Dr. Rabiei's composite metal foam material uses preformed hollow metal spheres. Packed together randomly, the spaces between the spheres are filled with metal powder. The whole is then sintered to form a sturdy composite structure. The foam displays superior compressive strength and energy absorption capabilities as compared to existing metal foams, while exceeding strength to density ratios.

The ability to control the size, the wall thickness, and the percentage of spheres added to the matrix allows close control of the stiffness and durability of the metal foam. The foam can therefore be manufactured to closely match the stiffness of bone, thus eliminating stress shielding. Other benefits of the new material are energy absorption, so they cushion the shock of each step.

The composite's pores also provide places where natural bone can grow and anchor the implant in place. The combination and predictability of these properties offers promise for use in other applications where light weight, high stiffness and energy absorption capabilities are important, such as automobile crumple zones, and structural member in air, naval, and space craft.

New Body Temperature Environment for Medical Device Testing

The Instron® BioBox Enclosure, the latest development for medical device and biomaterials testing, provides an enclosed temperature-controlled 37° C (98.6° F) environment for the 5940 Series of single-column frames. The entire frame fits within the enclosure and, unlike conventional temperature chambers, provides maximum flexibility to allow a variety of grips, bend fixtures and platens to be used, without compromising crosshead travel or space.

Focus on ISO 14801 for Dental Implants

Dental implants are an alternative to traditional crown and bridge solutions for replacing damaged and missing teeth. These endosseous dental implants are typically titanium based, and are securely and permanently anchored in the jawbone during routine surgery. This removes the need to grind down the adjacent healthy teeth to support a bridge, and it also provides mechanical stimulation to the underlying bone and gum structures that promotes healthy tissue growth around the implant.

The latest revision of ISO 14801, "Dentistry -- Implants -- Dynamic fatigue test for endosseous dental implants", specifies a common test method for comparing different implant designs or sizes and tests the implants at worse-case conditions.

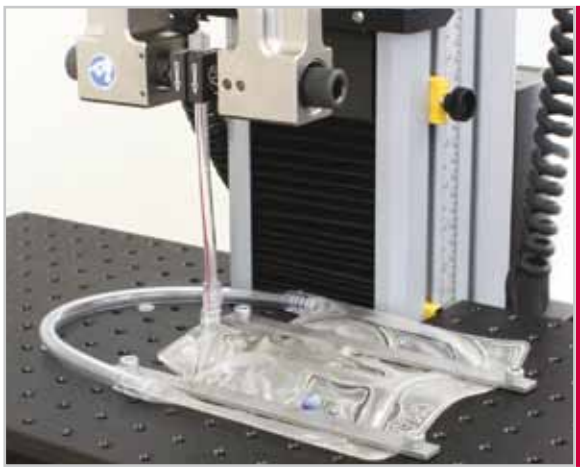
The specified fatigue tests are carried out on straight implants, which are orientated at 30° to the vertical. Pre-angled implants need to be aligned at an angle as calculated in the standard and a variable angle fixture can be used to help provide flexibility for different designs.

Where corrosion fatigue is reported or for implants that are made using polymeric materials, it is necessary to test the implant's performance in a bath. This could potentially cause new challenges in testing.

Innovation at its Best: ElectroPuls™ Test Instruments

Since the release of ElectroPuls systems in 2006, we have continued to develop all-electric dynamic test systems featuring linear motor technology. These systems are advancing biomaterials and medical devices around the globe, and we know from customer feedback that many owners love the environmentally friendliness and the fact that they only require single-phase electrical power to run.

In late 2009, we introduced the latest models, the E10000 and the E10000 Linear-Torsion, which provide 10 kN of axial force and are suitable for a variety of biomaterial and orthopaedic tests. The E10000 Linear-Torsion has the added capability to apply rotation of up to ±16 revolutions and torques up to 100 Nm. It comes complete with a Biaxial Dynacell™ to provide compensation of inertial errors in both axes.



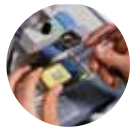
Overcoming the Challenges of Medical Device Testing

Medical manufacturers are following the ongoing trend of testing the final product instead of coupons or specimens. In so doing, their ability to use standard gripping techniques and fixtures is not practical. Although traditional grips, like pneumatic action or wedge action styles, worked well for standard materials, new test requirements force users to place the product into the testing system for evaluation or validation.
To satisfy this requirement, testing instruments must be designed to accommodate a wide range of device sizes and configurations. Additional fixtures – such as Instron®'s component plate – can help users by offering maximum flexibility.

Testing Solutions Update

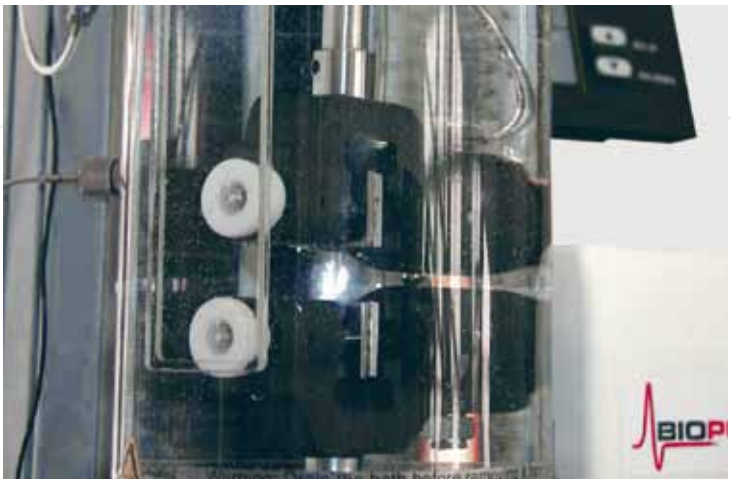
Grip Solution for Testing Polymer Hydrogels

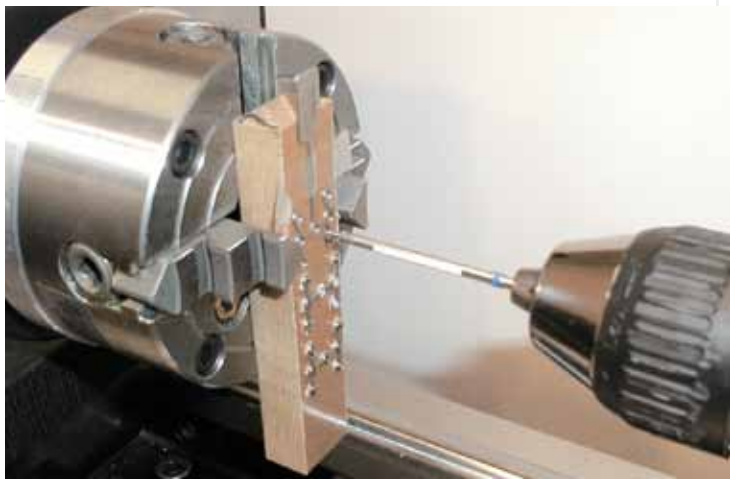
Due to the composition of polymer hydrogels, gripping and loading for the testing of mechanical properties can be difficult without the proper equipment. From testing in our application laboratory, we recommend using an 5940 or 3940 series of electromechanical testing system with a 50 N load cell and a grip that provides adjustable clamping force. For most accurate break results, we also recommend "dog-bone shape" specimen in accordance with ASTM D412.



Strength Properties of Tissue Adhesives by T-Peel Testing

Tissue adhesives are used for applications such as bandages, secondary dressings, wound closure, and surgical sealants. The adhesive strength of these products can be evaluated to ASTM F2256 before using in a clinical setting. The test should be carried out in simulated in vivo conditions and we recommend using submersible pneumatic grips, a temperature-controlled bath, and a low-force load cell on an electromechanical system.





Characterization and Fatigue of Spinal Intervertebral Body Fusion Devices

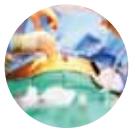
Intervertebral Body Fusion devices are used to promote arthrodesis of a spinal motion segment, following disc degeneration. ASTM F2077 and ASTM F2267 provide compression, shear and torsion test methods to help understand how these devices perform in an in vitro test. The complete ranges of tests can be performed using an axial-torsion testing instrument such as the ElectroPuls™ E10000 Linear-Torsion or the 8874 servohydraulic system.

Torsion Testing of Bone Screws to ASTM F543

Bone screws are used in surgical procedures for securing implants, osteosynthesis devices or fracture fixation plates to the skeletal system. ASTM F543 specifies a collection of methods for mechanical evaluation of bone screws. A majority of tests can be carried out using an MT1 static torsion testing system. Test A4, the self-tapping bone screw test, requires the use of ElectroPuls E10000 Linear-Torsion testing instrument, which is capable of synchronized linear and multi-rotation testing.

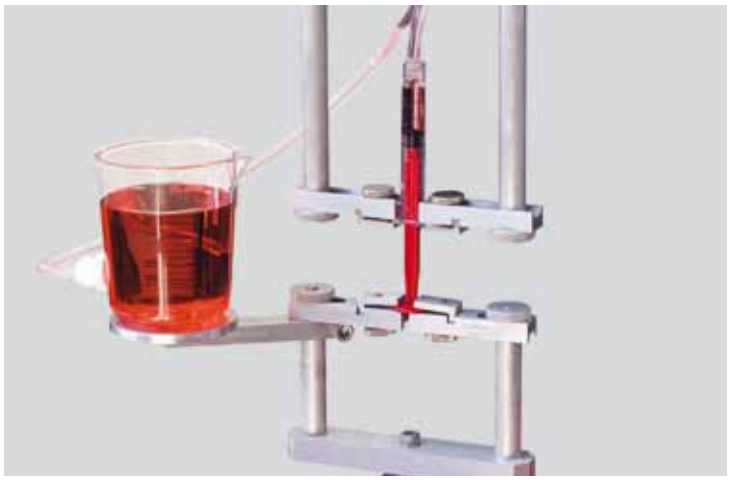
Sterile Hypodermic Syringes to ISO 7886-1

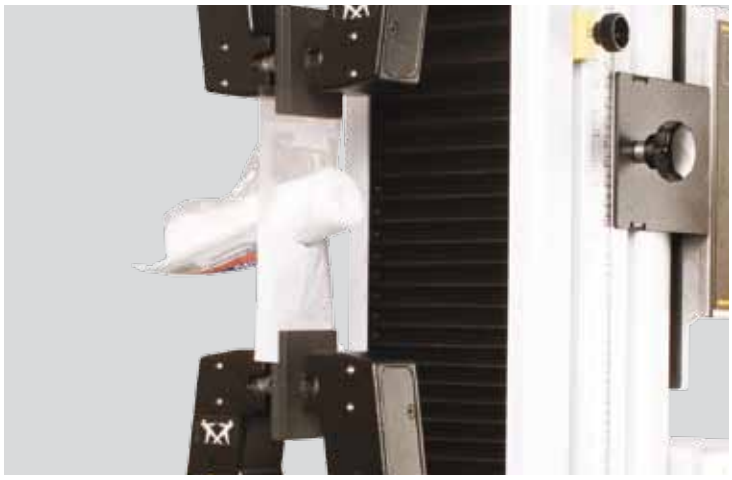
ISO 7886-1 specifies the test conditions for testing the aspiration and injection of fluids using sterile single-use hypodermic syringes. We suggest using an ISO 7886-1 compliant syringe fixture, which consists of a bottom plunger holder, a top syringe holder, a reservoir table, and a universal testing instrument. The fixture can be fitted to a electromechanical testing instrument and Test Profiler within Bluehill® Software used to perform the test.

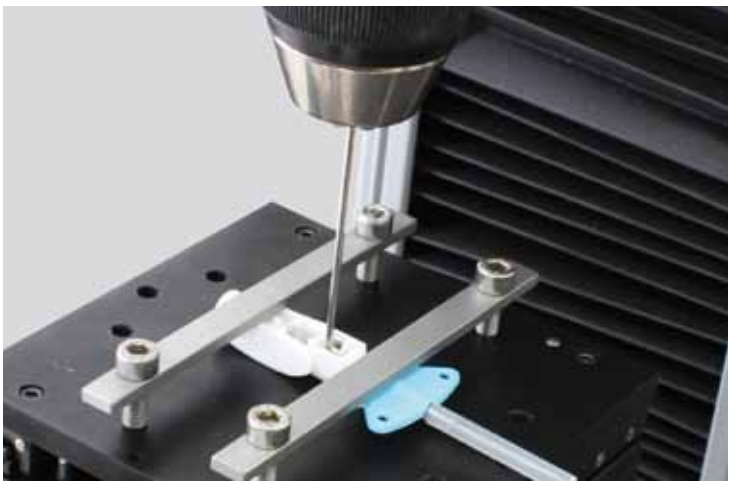


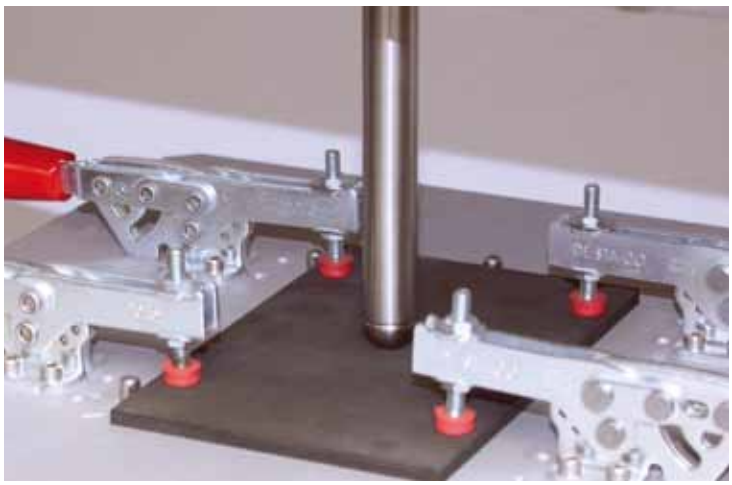
Adhesive Strength of Medical Packaging

The tensile strength of the adhesives used for medical packaging should be assessed according to ASTM F88 to ensure sterilization of devices and instruments during shipment and storage at the customer site. Using an electromechanical testing instrument with Bluehill Software, the Tear, Peel, Friction (TPF) module contains pre-configured methods for conducting three different peel tests: T-peel, 90° peel, and 180° peel.









Biomedical Components Testing Using an XY-Stage

With medical devices getting increasingly smaller and some more complex, there is a need to be able to productively test the subcomponents of the device during the development and production phases. Using an XY-Test Stage, the medical device can be mounted and the position can be precisely adjusted so that the upper probe interfaces with the sub-components as needed. This eliminates the need for multiple set-ups with a single device. The XY-Stage can be mounted to single-column or dual-column electromechanical testing instruments.

Impact Performance of Pharmaceutical Tablets

Common pharmaceutical pills and tablets are usually finished with a coating to facilitate swallowing, time-phased release of the medication, identification, and branding Impact testing can help pharmaceutical companies understand the performance of the coating and provide valuable data for development of new materials or processes. Using either a CEAST 9300 Series or a Droptower, various impact energies can be used to evaluate pills until they show no sign of failure.

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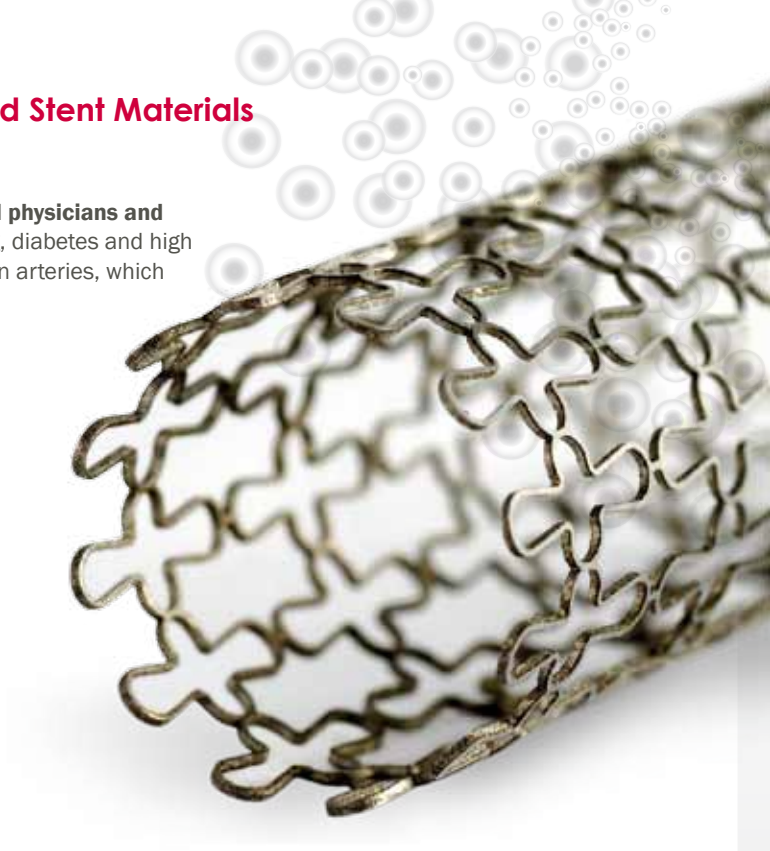
Industry Update: Mechanical Testing of Stents and Stent Materials

By Jim Ritchey and Toby Kemp



Stents are a wonderful creation of modern medical engineering that aid physicians and surgeons in the treatment of heart disease. Conditions, such as smoking, diabetes and high cholesterol help promote atherosclerosis, the build up of fatty plaque within arteries, which can ultimately lead to heart attack and stroke.

Stents are small tube-like medical devices, usually constructed of a biocompatible stainless steel or metal alloy. Used by surgeons to widen or unblock clogged arteries, they help restore normal blood flow and reduce risk of heart attack. Today, stenting is a common practice, making more than 70% of total coronary angioplasty procedures.

More recently, smart materials such as Nitinol (Nickel Titanium Alloy) have been used by stent manufacturers in the production of stents. Nitinol exhibits both shape memory and superelastic properties, which makes it perform particularly well when used for self-expanding stents. Nitinol stents are slightly larger than the size of the intended artery, and after deployment they exhibit a chronic radial force to maintain position.

Mechanical Testing

With stringent requirements from regulations, manufacturers must demonstrate that they have considered risks of device failure and satisfactorily mitigated against them. Mechanical testing of stent and stent materials is performed in vitro to aide designers and researchers gather performance data ahead of device approval and clinical use. Although mechanical testing does not begin to simulate the complete in vivo conditions that devices undergo, it does allow experimental validation and provides more accurate data for Finite Element Analysis (FEA) and computer modelling of cardiovascular devices to be undertaken.

Tensile Testing of Stent Materials

Tensile properties of Nitinol can be evaluated using ASTM F2516 “Standard Test Method for Tension Testing of Nickel-Titanium Superelastic Materials”, which specifies a method to understand the upper and lower plateau strengths, tensile strength and elongation of this superelastic material. Nitinol is a challenging material as it presents problems in clamping using conventional jaws, and using standard clip-on extensometers can cause premature failure.

Techniques for gripping have often revolved around using jaws with adjustable clamping forces, such as pneumatic or hydraulic grips, or specialist strain measurement is carried out using a non-contacting video based extensometer.

Flexural Testing of Stents

ASTM F2606 “Standard Guide for Three-Point Bending of Balloon Vascular Stents and Stent Systems” provides a method to characterize the bending flexibility of stents and the guide catheter to help understand how the behaviour as they pass through the vascular track. The test involves subjecting either a deployed stent or a stent system to a three-point bend to generate a force-displacement curve for both loading and unloading.

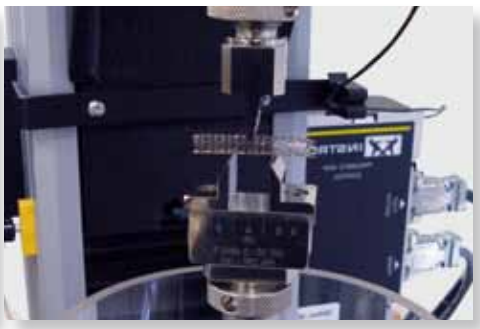
Radial Force Testing of Stents

A critical parameter for successful procedures is the radial force a stent or graft imparts onto the arterial wall. Using a specialist fixture incorporating a segmental compression mechanism, it is possible to determine radial stiffness, chronic outward forces during expansion and compression, as well as the radial reactive force during compression of different devices. This approach provides uniform application of radial forces for easy comparison to FEA generated data. Although several testing techniques exist including the sling apparatus and the pneumatic/hydraulic apparatus, the segmented approach has gained growing acceptance within the testing community.

Stent Securement Testing

ASTM F2394 “Standard Guide for Measuring Securement of Balloon Expandable Vascular Stent Mounted on Delivery System” provides guidance in the evaluation of the securement characteristics associated with endovascular stents to the delivery balloon catheter. This guide is intended for use by researchers and manufacturers for the development and selection of pre-test treatments, tests and test endpoints to measure stent securement (displacement distances and dislodgment forces).

NiTi wire being tensile tested with a video extensometer measuring strain

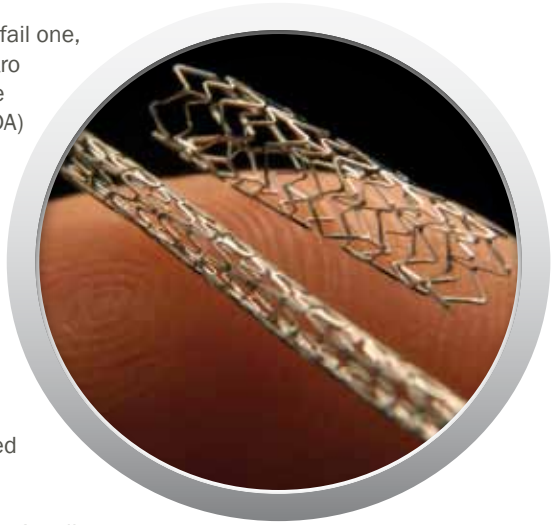


Flexural test of a Co-Cr coronary stent

Radial force testing on a coronary stent

Fatigue Testing of Stents and Stent Materials

Traditional fatigue testing of complete stent devices is addressed by ASTM F2477 "Standard Test Methods for in vitro Pulsatile Durability Testing of Vascular Stents", which specifies methods for fatigue of complete devices through hydrodynamic pulsation. The method involves placing complete devices into mock arteries and subjecting them to 400 million cycles of internal pressure pulsation (10 years of human heartbeats), forcing them to radially expand and contract in each cycle. The test can either be performed between pressure limits, simulating diastolic and systolic pressures; or displacement controlled, reproducing the minimum and maximum diameters that a stent would see in vivo under worse case conditions. Tests are typically performed at frequencies of up to 50 cycles per second, resulting in typical test durations in the three to six month range.



The acceptance criterion of devices is a simple pass/fail one, in that no fracture of the stent can occur during these in vitro tests for success. Many devices from varying manufacturers have undergone Pre-Market Approval (PMA) by Food Drug Administration (FDA) and have gone into clinical use. Although this traditional "Test to Success" approach of fatigue testing has not resulted in failures, the reality is that many of these devices are fracturing in vivo.

In early 2006, the FDA and ASTM started looking at ways that could eventually improve the current durability assessment of cardiovascular devices. Initially, two working groups under the ASTM F04.30.06 Endovascular Devices Task Group were established; the first group concentrates on better understanding of the physiological conditions devices undergo in vivo and transferring this knowledge into boundary conditions for use in testing, evaluation and modelling. The second group, entitled "Fatigue to Fracture" (FtF) group, was charged with developing alternative and improved test methods for fatigue testing of cardiovascular devices.

An alternative method that is being rapidly adopted is a "Fatigue to Fracture" approach. A rudimentary technique that is more akin to aerospace testing, this methodology involves a combination of FEA modelling and in vitro testing to assess the durability of stents through established fracture mechanics techniques. These testing guidelines and standards are still under development. Several testing techniques have been developed recently that provide testing results that provide support as manufacturers submit products for regulatory approval. To enable a representative sample of specimens to be evaluated and to reduce overall test time, multiple samples must be tested. The multi-specimen fixtures are available to assist cardiovascular implant manufacturers to assess these long-term fatigue characteristics of nickel-titanium (Nitinol), CoCr, stainless-steel and other stent materials and structures. It is important that each specimen station feature a fatigue-rated load cell, precision alignment adjustment and applicable grips for the material or structure undergoing test. The specimens should be tested in vitro at body temperatures. Results should include trend monitoring of forces to determine each specimen fracture.

Test fixture on an Instron E3000 testing 12 stents simultaneously in a bath

Summary

Although stents have proven to be effective and important devices for the medical device community and the general patient population, they continue to evolve. Larger and smaller stents designed for peripheral networks in distal extremities like the superficial arteries, carotid arteries and neural pathways; test the limits of existing materials and testing technology. Continued material evaluation, development, and delivery of new testing methods will be important for the evolution and success of these devices. Close monitoring of new requirements will be required by manufacturers as these products mature.

References

1. X.-Y. Gong, D. J. Chwirut, M. R. Mitchell, and B. D. Choules, 2009. Fatigue to Fracture: An Informative, Fast, and Reliable Approach for Assessing Medical Implant Durability; Journal of ASTM International
2. ASTM F2477 Standard Test Methods for in vitro Pulsatile Durability Testing of Vascular Stents
3. Cavanaugh, KJ, Holt, VM, Goode, JL, Anderson, E, 2006. FDA Recommendations for Nitinol Stent and Endovascular Graft Fatigue Characterization and Fracture Reporting; Journal of ASTM International
4. WK15227 Test Methods for Radial Stiffness and Strength of Balloon Expandable Stents, ASTM F04.30.06

The Need for Accredited Calibration in Medical Device Testing

Why does a mechanical testing instrument need calibration?
Our customers expect confidence, integrity of data, and reliable test results. Regular calibration of a mechanical testing machines to internationally recognized standards by an accredited organization, such as Instron®, helps provide this reassurance and are vital contributors in reducing business risk and cost.

How often should a system be calibrated?
In many cases, the frequency of calibration is dictated by the requirements provided in standards or procedures specified by the company's quality assurance requirements. The most frequently used materials testing standards recommend that a system is calibrated annually. Best practice also dictates that the equipment should be calibrated if it has undergone significant repair, configuration or has moved locations.

What's the difference between accredited and unaccredited calibration?
An accredited calibration laboratory is subject to an independent, third party evaluation of its competence to perform calibration procedures meeting ISO 17025, the international standard for requirements and competence of calibration and testing laboratories. This includes verification that the laboratory provides measurement results traceable to recognized National Measurement Institutes (NMIs), such as National Institute of Standards and Technology (NIST) in US, National Physical Laboratory (NPL) in the UK, and Physikalisch-Technische Bundesanstalt (PTB) in Germany. Using an accredited calibration laboratory provides confidence that the calibration certificates will be recognized and accepted worldwide.

Which standard should I calibrate to?
This depends on the testing procedure or quality control requirements. Many testing procedures and standards require that the testing machine has to be calibrated to a particular calibration standard. For tensile testing, the most commonly specified calibration standards are ASTM E4 or ISO 7500-1. Additionally, where strain measurement devices are used, ASTM E83 or ISO 9513 are often specified.

Spotlight on Contract Testing Laboratories

We often get asked to help our customers with specific tests that they are struggling to do with their existing test facilities. Where we are not able to offer equipment to meet their needs, we have many customers around the world that offer services for contract testing or research. We are happy to include a small selection of these here.

BDC Laboratories provides custom test fixture design as well as both GLP and non-GLP testing services to the medical device industry encompassing both bench and durability studies. In addition to these comprehensive testing and R&D support solutions, BDC offers silicone mock vessels for device evaluations. Stents and stent grafts, heart valves, and catheters are a small subset of BDC's expertise in implantable technologies.
www.bdclabs.com

Confirmd LLC provides medical device testing and characterization services, including corrosion testing per ASTM F2129, Nitinol device transformation temperature testing per ASTM F2082, tensile testing per ASTM F2516, fatigue testing/FEA services, and custom device-specific test development. Confirmed LLC has significant expertise in the development, manufacturing and testing of Nitinol-based medical devices, as well as broader expertise with 300-series stainless steel, MP35N, L605, other Co-Cr alloys, Ti, and Ti-based alloys. Their mission is to not just give you data, but to provide the technical expertise you need to achieve your development goals.
www.confirmd.com

CRITT MTDS (Centre Régional d'Innovation et de Transfert de Technologie - Matériaux Dépôts et Traitements de Surface), based in Charleville Mézières & Nogent, France, are providers of medical device testing and characterization services COFRAC-Accredited Laboratory for work area n° 136 on Orthopaedic Implants. Their capability in material characterization has been developed to various standards for Stainless Materials, Ti, CO-CR according to various standards like ISO 5832; for ceramics, for Polymers, PEEK and for porous coatings. They also offer tests of medical devices according to various standards such as ISO 7206 and ISO 14242 for hip implants; ISO 14243 and ISO 14879-1 for knee implants; ASTM F2077, ASTM 1798, and ASTM F1717 for spinal devices; ASTM F543 on metallic screws; and ISO 14801 on dental implants. Their broad capability covers the development cycle from raw material characterization, process qualification, through to final product validation.
www.critt-mdts.com

Standards Update

Mechanical testing standards are regularly being revised or changed and it is imperative to stay up to date with these, particularly if they form part of any regulatory compliance. The following is a selection of different standards that have recently updated.

Standard	Description
ISO 6474-1	Implants for surgery -- Ceramic materials Part 1: Ceramic materials based on high purity alumina
ISO 7206-4	Implants for surgery -- Partial and total hip joint prostheses -- Part 4: Determination of endurance properties and performance of stemmed femoral components
ISO 11953	Dentistry -- Implants -- Clinical performance of hand torque instruments
ISO 9917-2	Dentistry -- Water-based cements -- Part 2: Resin-modified cements
ISO 20795-2	Dentistry -- Base polymers -- Part 2: Orthodontic base polymers
ASTM F1717	Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model
ASTM F2789	Standard Guide for Mechanical and Functional Characterization of Nucleus Devices
ASTM F2790	Standard Practice for Static and Dynamic Characterization of Motion Preserving Lumbar Total Facet Prostheses
ASTM F564	Standard Specification and Test Methods for Metallic Bone Staples
ASTM F2118	Test Method for Constant Amplitude of Force Controlled Fatigue Testing of Acrylic Bone Cement Materials

Latest Biomedical Collateral

A new series of application updates have been developed that help collate our product solutions for different segments of the medical community. This includes areas such as orthopaedics, dentistry, hospital and surgical supplies, biomaterials, and implantable devices.

Bluehill® 3 Aids Medical Device Testing

In 2010 Instron® introduced Bluehill 3, the latest version of the leading materials testing software, which includes a new module packaged with test methods intended to meet specific medical standards such as ASTM F88, F2256 or F2516. In addition to new features such as Real-Time Calculations that can be performed and displayed during the test, Expression Builder to produce custom calculations and One-click testing that speeds up testing; the biomedical module is designed to help medical device manufacturers test more easily. Check out the latest software online using the link below.

Read More Online: go.instron.com/ibio1

What is 21 CFR Part 11 and how does it affect me?

21 CFR Part 11 is a set of compliance requirements that allow for safe and secure storage and submission of electronic records for industries regulated by the U.S. Food and Drug Administration (FDA). In other words, this is the FDA's procedure for quality control of electronic data. Any company storing electronic data that could be audited by the FDA must comply with this set of requirements. Although the FDA still permits paper based data storage and submission, this approach can lead to higher costs, increased time to market, decreased quality, and challenges with information storage availability, retrieval and portability, as compared with electronic methods.

There are two electronic approaches:

1. Partial Electronic – This approach stores the electronic records as equivalent to paper records with handwritten signatures. It still requires a large amount of printed documentation that carries the same risks and challenges as a full-paper approach.

2. Electronic – This approach uses all electronic records and electronic signatures, so no paper documentation is necessary. This approach is less subject to human error and can save significant time and money with automation of processes. Further, a completely electronic approach allows for electronic submission of data and reports to the FDA, which can save additional time and costs to the organization.

The Best Solution for Gripping Low-Force Specimens

Low-force biomaterial and tissue testing applications vary widely, and include specimens such as native tissue, bio-engineered tissues, hydrogels, and contact lenses. In most cases, these specimens are tested in a heated, fluid environment that simulates physiological conditions; in other cases, the specimens are hydrated for several hours before testing. Generally, most customers assume that rubber-coated or serrated faces provide the ideal gripping solution. But do they?

Rubber-coated faces tend to cause specimen slippage, while serrated faces cause premature failure.

A study conducted by the Instron Application Lab proved one of the best gripping solution to be sandpaper or a grip surface called SurfAlloy®, a surface that resembles sandpaper. This slightly roughened surface provides enough friction to prevent slipping, and not too much grit that could cause premature failure.

Capturing Testing in Action

We find that many of our customers are faced with questions like "How did this specimen fail?" and "Why does one result look different than the others?". They often need to verify that the test was conducted and that it was conducted properly. The answer to many of these questions is to use a camera to record the specimen during testing. Bluehill® software includes video recording ability that provides R&D engineers, lab managers, university professors, and students point-by-point playback of the specimen throughout the test. This source of invaluable information captures failure analysis and gives a better understanding of materials science.

Instron® Around the World

Instron continues to invest in conference, exhibitions and trade shows around the globe, providing a valuable opportunity for customers and testers around the globe to interact with our industry professionals. We also undertake a number of customer focused bio seminars and events in many different countries, where we bring external speakers and Instron Bio Team members together to collaborate on this important industry.

Instron® at Human Life Science Test Expo (HULST)

Instron continues to invest in conference and exhibitions around the globe, providing a valuable opportunity for customers and testers around the globe to interact with our industry professionals**.** Instron took a leading position at the HuLST Expo in Cologne, Germany, where we demonstrated a variety of equipment and service solutions. HuLST is a new umbrella event that encompasses the Medical Device and Technology Test Expo, Pharma Test Expo, Food & Beverage Test Expo and a BioTech Test Expo.

Our medical device solutions exhibited on the booth included a 5944 electromechanical instrument with a saline bath and non-contacting video extensometer for tissue engineering and biomaterial studies; a MT1 torsion machine for a variety of device tests; and an ElectroPuls™ E1000 all-electric fatigue testing instrument configured for dental implant testing to the ISO 14801 standard.

Bio-Events Calendar

Instron will be attending various conferences, exhibitions and trade shows throughout the year. Listed below is just a small selection.

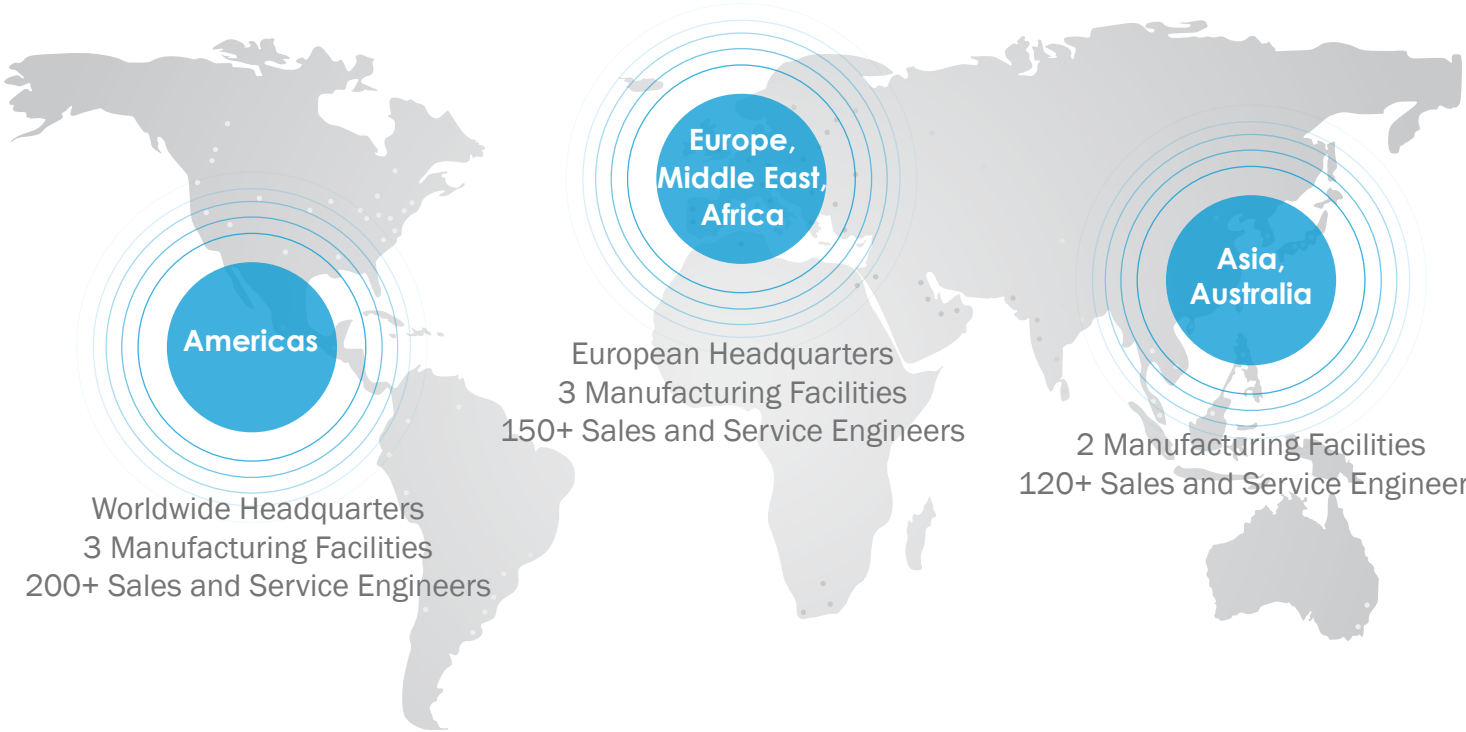
March	April	June	August
- **Medical Device Summit,** Boston USA - **International Association of Dental Research, San Diego, CA, USA, San Diego**, CA - **Medtec Germany,** Germany - **Society for Biomaterials,** Florida USA	- **Medtec France,** Besançon, France - **Medtec Japan,** Yokohama, Japan - **China International Medical Equipment Fair CMEF,** China	- **Termis EU,** Granada Spain - **MD&M East,** New York USA	- **Termis AP,** Singapore
September	**October**	**November**	**December**
- **European Society of Biomaterials,** Dublin, Ireland - **Medtec China,** Shanghai China	- **MD&M Minneapolis,** MN USA - **Medtec India,** Mumbai India	- **North American Spine Society,** Chicago, IL, USA - **The International Conference on Shape Memory and Superelastic Technologies,** Hong Kong	- **Termis NA,** Houston TX - **BIOMEDevice,** San Jose, CA, USA

Read More Online: go.instron.com/ibio1

Medical Device and Biomaterials Update

Instron® has a global infrastructure that is local to you and remains committed to providing our customers the best ownership experience by delivering the highest quality products, expert support and world-class service.

To read more online, subscribe to our enewsletters, submit a story or connect to our industry professionals, check out the following: go.instron.com/ibio1



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