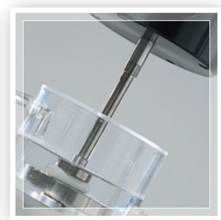
C220-E010A

SHIMADZU
Excellence in Science

Contributing to the Development and Reliability of Advanced Medical Treatments

# Physical Property Testing Equipment for Biomaterials and Medical Applications



# Shimadzu Material Testing Machines Support the Development of Advanced Medical Treatments

Although the world's population was just two billion in 1927, it reached seven billion in 2011 and is expected to hit ten billion by the end of the 21st century. Advanced countries such as Japan are becoming aging societies. Such dramatic growth in population and life-expectancy is said to result from more sophisticated medicine, which, in turn, will require more advanced medical technology.

The medical equipment and biomaterials industries have experienced a vast number of innovations and developments over the past ten years. In addition, great strides have been made in materials and technologies, and therapeutic strategies and surgical techniques have progressed dramatically. For instance, a broken femur can now be replaced by an implant, and inserting small metal stents weighing just a few grams into the neurovascular system can prevent strokes due to plaque or arterial stenosis.

To guarantee the safety and efficacy of medical equipment and technologies in the wake of such medical breakthroughs, more active efforts are being made to reinforce the evaluation criteria and the regulations governing the standardization of measuring instruments and test methods. Medical equipment manufacturers and research organizations around the world are conducting research and development into medical equipment based on mechanical properties evaluation and finite-element analysis.

Shimadzu Corporation is applying the technical expertise cultivated through physical testing, quality control, and full-scale testing in materials development to the fields of leading-edge medicine and biomaterials evaluation. Apply Shimadzu's extensive materials testing knowledge to achieve further developments in advanced medicine.

Autograph AG Series
Precision Universal Tester, Table-Top Type

EZTest Series
Compact Table-Top Universal Tester

Autograph AGS Series
Precision Universal Tester, Table-Top Type

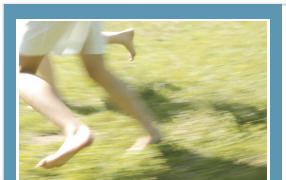
Autograph AG Series
Precision Universal Tester, Floor Type

Servopulser EMT Series
Electromagnetic Force Fatigue/
Endurance Testing System

Micro-Servo MMT Series
Electromagnetic Force Micro Material Tester

Servopulser EHF
Servo-Hydraulic Fatigue and
Endurance Tester, Table-Top Type

Servopulser EHF
Servo-Hydraulic Fatigue and
Endurance Tester, Floor Type





Introduces testers and jigs required to evaluate the tensile strength of biological tissue samples, such as blood vessels, ligaments, and tendons, and the bending strength of bone, as well as fatigue and endurance strength and torsional properties of biological samples.



Introduces applications for testing the static strength, fatigue strength, and endurance strength of bone implants and dental implants.



Introduces applications to evaluate the strength of medical equipment and the constituent materials for injectors, catheters, bandages, and contact lenses.



Introduces applications required for tablet manufacture and fundamental quality evaluation and for R&D and quality control of pharmaceuticals and their packaging.

# Evaluation of Biological Samples

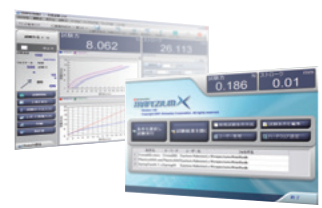
Medical breakthroughs always start with knowledge about human beings. Gaining an understanding of the structure and functions of the organs, skeleton, tendons, and blood vessels, as well as their physical strength, is indispensable when developing biomaterials.
Research into new materials and new regenerative medicine has made dramatic strides in recent years and remains at the forefront of research around the world. The research covers bone, soft tissue (such as tendons, ligaments, skin, muscle, and arteries), replacement biomaterials, artificial tissue and artificial bone. This includes characterization testing to understand the mechanical properties of such tissues and materials.
The testing covers a wide range from simple tensile, compression, and bending tests to dynamic tests using fatigue and endurance testers, and complex, multi-axial tests. Some examples of mechanical testing and evaluation of biological tissue from Shimadzu's extensive track record are introduced below.

The Autograph AG Series Precision Universal Tester combines technologies fostered over many years with sophisticated control and measurement performance. In addition, it offers great operability and convenient support functions. This is a testing system that offers excellent accuracy and ease-of-operation.
The smart controller permits instant data check and fine adjustment of the test position. The color TFT touch panel makes operation easier and allows the system to be operated without a computer. TRAPEZIUM X software was developed to offer even greater convenience, enabling more efficient test results evaluation and analysis operations.
The AG Series contributes to customers' testing work from three perspectives: performance, operation, and support.

Autograph AG Series, Table-Top Type

Smart Controller

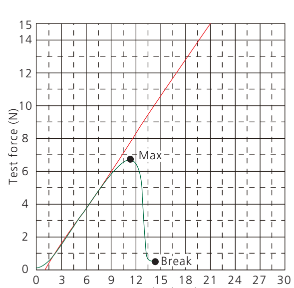
Color TFT Touch Panel



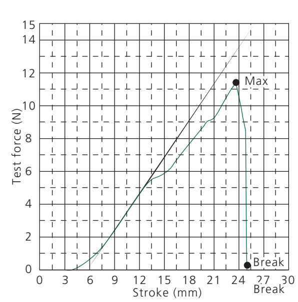
TRAPEZIUM X Software for Static Material Testing Machines

## Tensile Testing of Artificial Skin and Tubular Tissue Including Blood Vessels

Humans have to think and move around to stay alive. The energy source for these movements is provided though the blood vessels. Blood vessel disorders include hardening of the arteries (arteriosclerosis), aortic aneurysms and varicose veins that form bulges on blood vessels, and arterial occlusions that block blood flow. In some cases, artificial blood vessels are transplanted to treat such blood vessel disorders. The measurement of the mechanical properties of blood vessels, including the carotid artery, jugular vein, aorta, and inferior vena cava, and of tubular tissues such as ureters and ureter decellularized matrixes is extremely important. (A ureter decellularized matrix is a ureter with the cell components scientifically eliminated that is used as a matrix in regenerative medicine. It is seeded with autologous cells for ureteral regeneration.) The Autograph Series Universal Tester features a high-accuracy load cell and high-speed sampling to perform measurements at low test forces, while capturing the smallest sample deformations.
The S-S curves below plot the test force (N) along the vertical axis and the sample displacement (= stroke, mm) along the horizontal axis in tensile testing. It is apparent that the dog ureter achieves higher maximum test force and displacement, indicating superior strength and elasticity. Correct selection of the grips and grip faces is important for soft samples, like biological samples.




Tensile Testing of Artificial Blood Vessels
(Ureter Decellularized Matrixes)
Test Force-Displacement Diagram



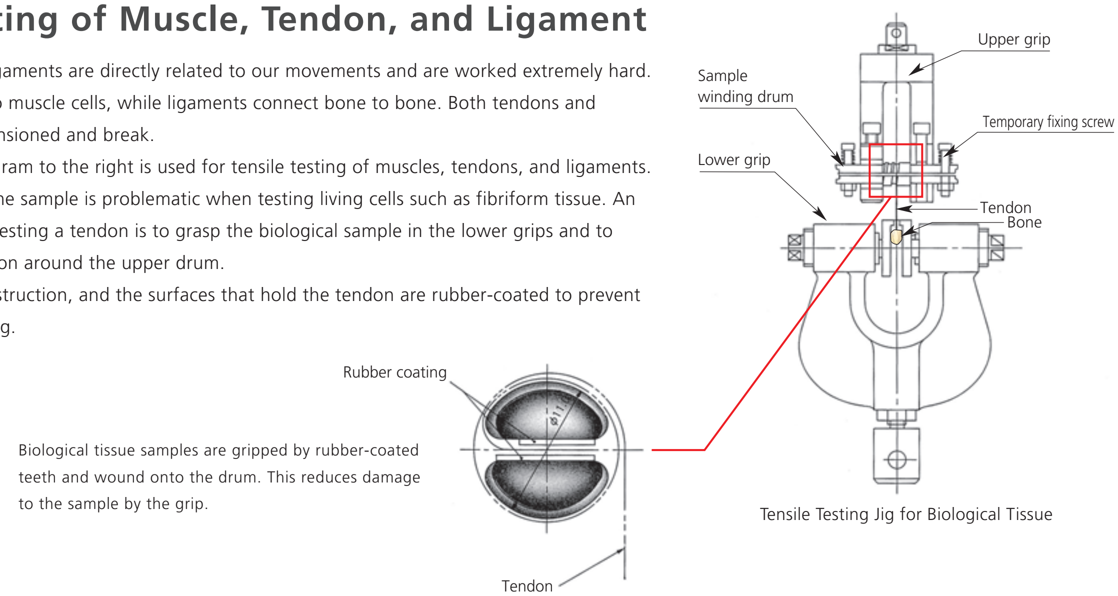

Tensile Testing of Dog Ureter
Test Force-Displacement Diagram

Pneumatic Flat Grips

Tensile Test Evaluation of
Dog Carotid Artery

# Tensile Testing of Muscle, Tendon, and Ligament

Muscles, tendons, and ligaments are directly related to our movements and are worked extremely hard. Tendons connect bone to muscle cells, while ligaments connect bone to bone. Both tendons and ligaments can be over-tensioned and break.
The jig shown in the diagram to the right is used for tensile testing of muscles, tendons, and ligaments. The method of holding the sample is problematic when testing living cells such as fibriform tissue. An appropriate method for testing a tendon is to grasp the biological sample in the lower grips and to wind the top of the tendon around the upper drum.
The drum has a split construction, and the surfaces that hold the tendon are rubber-coated to prevent the sample from rupturing.



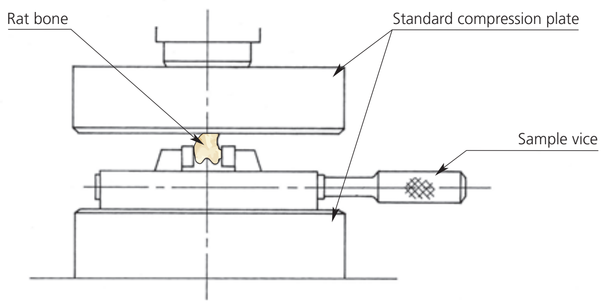

Tensile Testing Jig for Biological Tissue

# Mechanical Evaluation of Bone

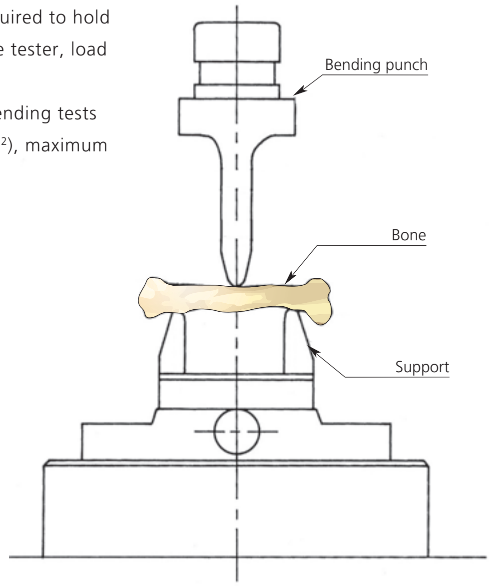
Our skeleton forms the framework of our bodies. There are about 200 major bones in the body, which are said to come in five basic shapes. These bones are linked in a specific arrangement to form the human skeleton. Bones must have adequate strength to support the person's body weight while walking or jumping but be light enough to allow nimble movement. They can break when excess force is applied. They also must have a degree of brittleness to absorb shocks.
Numerous tests are performed to understand a bone's mechanical properties, as well as to confirm the efficacy of osteoporosis medication and to develop artificial. Jigs for the testing and evaluation of bones are introduced below.

## Compression and Bending Testing

Generally, three-point bending tests are performed on tibias and femurs of rats, dogs, and monkeys, while compression testing is performed on the lumbar vertebrae. Due to the small size of mouse samples, three-point bending tests are performed on the tibia.
These tests are performed using a compression/bending test device. A special vice is required to hold the bone for compression testing. The size of the measured bone sample determines the tester, load cell, and capacity of the vice and jig that must be used.
The bone mechanical parameters obtained from the S-S curve (stress-strain curve) for bending tests include the maximum test force (N), maximum elongation (mm), maximum stress (N/mm$^2$), maximum strain (%), and the energy (N·mm).




Compression Tester




Three-Point Bending Tester

## Mechanical Evaluation of Bone—Fatigue and Endurance Testing

Bones are not subjected to constant loads; they experience forces in all directions due to a combination of various factors during walking and other movements. Consequently, instead of simple static testing, it is extremely important to mechanically evaluate bones through fatigue and endurance testing by applying repeated test forces.
To accurately evaluate biological samples and bones, it is essential to firmly fasten the test sample against the mechanical forces and displacements. This is doubly important during fatigue and endurance testing in which repeated test forces are applied over a long period of time.

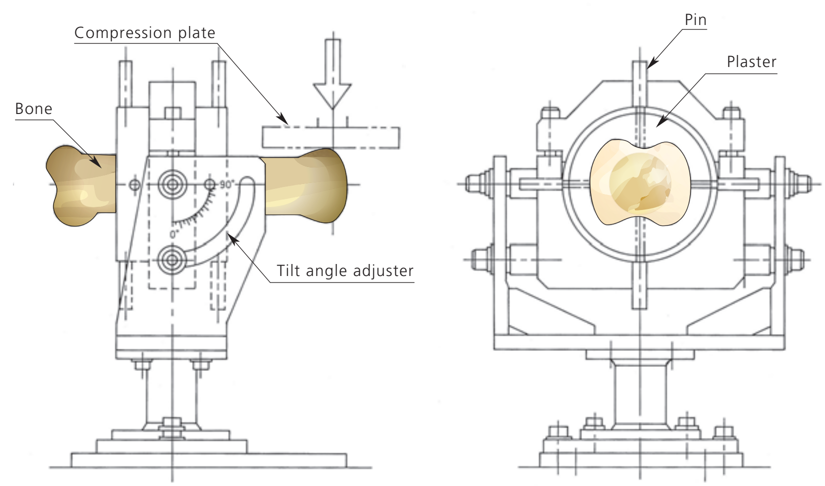
The table-top servo-hydraulic fatigue and endurance tester is an overhead-actuator type fatigue tester. Despite the small capacity, the overhead-actuator type tester can be applied to a wide range of tests, from small mouse bones to full-scale testing of comparatively large test samples and implant materials. The tester can faithfully reproduce various entered waveforms, including walking waveforms.

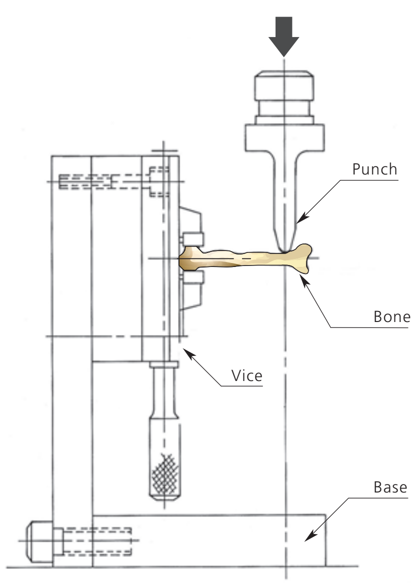
Servopulser EHF Series Table-Top Servo-Hydraulic Fatigue and Endurance Tester (with hydraulic supply stowed)

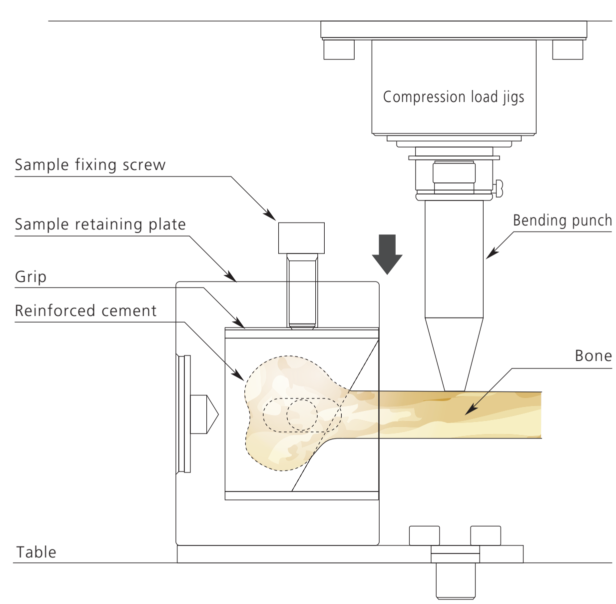
## Cantilever Bending Testing

This tester permits cantilever bending tests on bones and their replacement materials.

Four pins are inserted into the bone to mount it in the test jig. (Sometimes the bones and pins are fixed together using plaster.) The jig holder construction allows it to be tilted to any angle to perform bending testing or fatigue and endurance testing at any angle.



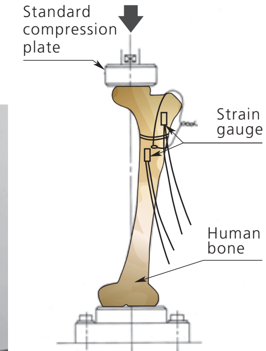




This is an example of a bending tester for a rat bone and orthopedic member. Designing the vice shape to match the sample shape permits the testing of various samples.

## Human Femoral Osteotomy—Load Testing After Fixation

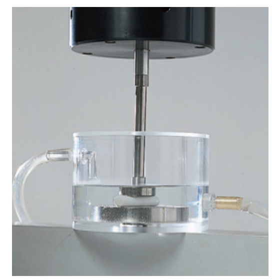
The femur is a long tubular bone that forms the central axis of the thigh. It is the longest bone in the human body. The central portion is the femoral body, which is cylindrical. The top of the femur features two protrusions called the greater trochanter and lesser trochanter, to which the muscles attach, and the spherical femoral head that forms the hip joint. At the bottom of the femur are two protrusions called the medial condyle and lateral condyle. The femoral bones play an extremely important role in human bipedal locomotion. Femoral neck fracture is the most common fracture that occurs when elderly people fall. The number of people bed-ridden due to this injury is increasing as society ages.
Against this background, accurate measurements of the mechanical properties of femoral bones provide extremely important data for the development of femoral implants. The Autograph series is widely used for the evaluation of bone joint strength and junction materials.
Dramatic technical innovations have occurred in ceramic and plastic composite materials, and developing technologies using these materials is a focus in medical fields.




Load Testing of Femoral Bone with Fixation

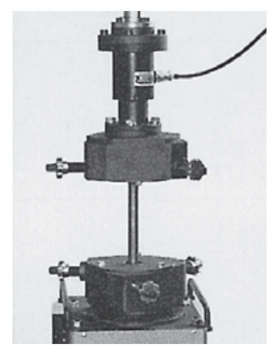
## Physiological Saline Solution Immersion Tester

It is sometimes necessary to test bone, biological samples, and biomaterials under conditions that model their normal environment.
The jigs to hold or compress the sample are immersed in a water bath, where the sample can be subjected to static tensile and compression testing, or dynamic fatigue and endurance testing.
This tester permits testing of samples immersed in physiological saline solution or some other prescribed solution that is maintained at a constant temperature ranging between +30°C and +40°C. A solution circulator is available as an accessory.



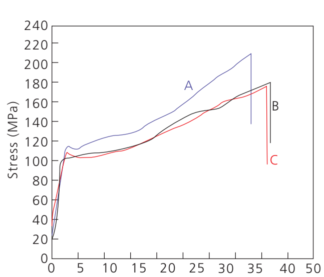
## Torsion Testing Device

Bones are not only subject to uniaxial tensile and compressive loads, but to complex forces that include shearing and torsional components. Bones can fracture in many ways, including shear fracture due to the actions of shear forces perpendicular to the long axis of the bone, compression fracture due to excessive compressive loads on the bone, spiral fracture (torsion fracture) due to torsional loads on the bone, and bending fracture due to forces acting to bend the bone. The torsion testing device is attached to an Autograph static tester to permit uniaxial torsion testing and repeated torsion testing of bone and artificial bone samples, including biological samples, metals, and resins.
The torsion testing device also supports fatigue and endurance testing. The rapid test cycles reduce the time required for the test.



## Tensile Testing of Hair

The strength of hair is dependent on moisture content, daily UV exposure, static electricity, and daily hair care.
Tensile testing was performed on hairs taken from a single subject under the same conditions. Sample A was untreated, while Samples B and C were degraded using different chemicals. These samples were mounted using pneumatic capstan type yarn grips.
The results show the relationship between stress (test force divided by the sample cross-sectional area) and displacement (movement of the crosshead). Sample A showed higher tensile strength values than the chemically-treated Samples B and C, while Samples B and C showed higher displacement values. Therefore, it can be said that the chemical treatment reduced the strength of the hair but increased its elasticity.




| Sample | Sample code | Tensile strength (MPa) | Max. displacement (mm) |
|---|---|---|---|
| Hair | A | 198.4 | 37.8 |
| | B | 173.3 | 41.8 |
| | C | 173.4 | 40.9 |

# Evaluation of Biomaterials

Intended for transplantation, mainly into humans, biomaterials are used in both the medical and dental fields. Many types of material are used, including ceramics and metals for artificial joints, dental implants, and artificial bone; polymers for artificial blood vessels; and stents combining metal wires in mesh to locally expand tubular tissue such as blood vessels. Mechanical testing of these biomaterials extends from static tensile testing, compression testing, and dynamic testing of constituent metals and alloys and compression and bending testing of entire devices, to fatigue testing and pressure pulsation simulations of stent materials. Some biomaterial testing applications for bone implants, dental implants, and stents are introduced below.

## Testing Bone Implants

The first surgery to replace a damaged hip joint with an artificial one was performed in the USA in 1922. The implant used for this surgery was quite different from what is used today. It involved simply covering the joint surfaces on the femur with metal. Subsequent research and development has led to improvements not only in the design of the artificial hip implants themselves, but also in the surgical procedure. It is now possible to install the implant with a smaller skin incision and minimal damage to muscles, and efforts to improve artificial hip implants will continue.

Highly biocompatible materials and the strength and fatigue properties of implants will be important factors determining the performance of bone implants. Some static strength testing machines and fatigue and endurance testing machines are introduced below, along with the knowledge required to evaluate various samples and the test results.

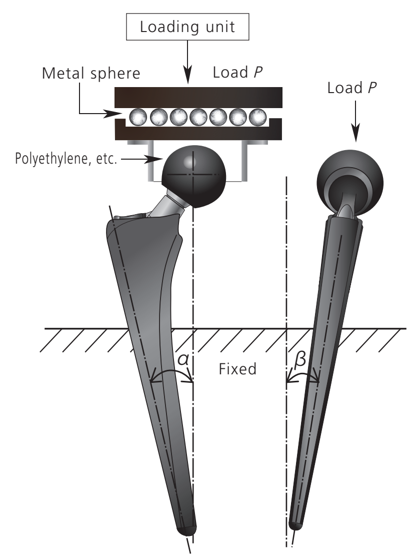
### Testing Femoral Implants

Femoral neck fractures often occur when elderly people fall and the number keeps increasing as the population ages. Femoral neck fractures can be broadly categorized into (A) neck fractures and (B) trochanteric and subtrochanteric fractures.

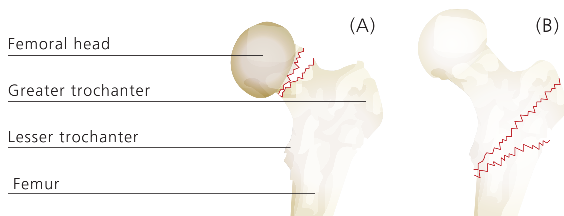
In the case of a neck fracture, bipolar hip arthroplasty (BHA) surgery is performed to remove the fractured femoral head and replace it with an implant. For trochanteric or subtrochanteric fractures, however, metal plates are inserted to fix the femoral head.

Fatigue and endurance testing of hip implants is performed to measure the endurance limit properties of the implant under dynamic forces simulating walking.

The implant is buried in plaster for testing. The testing methods are prescribed in ISO 7206-4, 7206-6, and 7206-8.



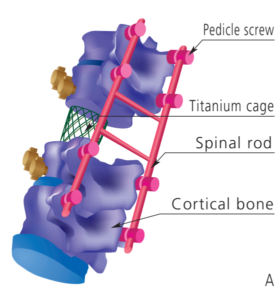

α: 9° (adduction / abduction)
β: 10° (flexion / extension)

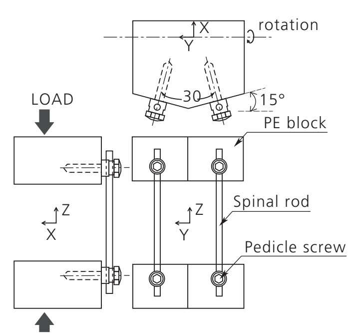



### Testing Spinal Fixators Components

During a patient's normal activities, spinal fixator components are subjected to large loads that can cause catastrophic failure. Consequently, static testing is first performed to determine the compressive, tensile, and torsional loads that lead to destruction of the spinal fixator components.

As fatigue failure occurs more easily than catastrophic failure, it is extremely important to perform endurance testing on the spinal fixator components. This testing is generally performed over five-million cycles with constant-amplitude, load-controlled sinusoidal loads. The standard test method is ASTM F1717: Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model, which prescribes both static and fatigue testing of spinal implant assemblies.

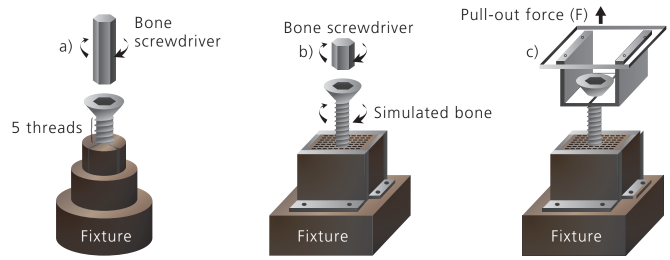



A Standard Bilateral Construct Containing Screw, Rod and Screw

# Testing Implant Screws

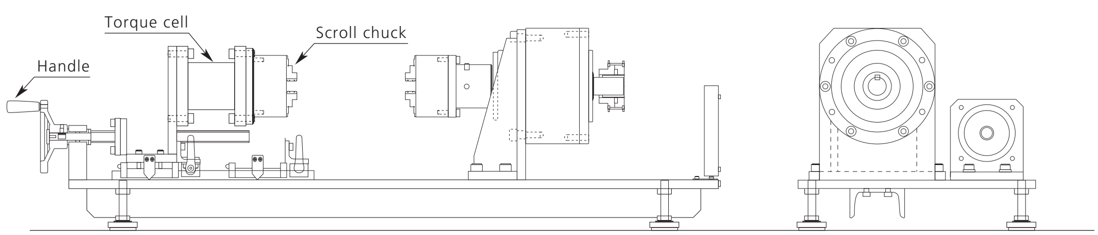
To ensure that implant screws do not become loose inside the body, it is important to perform endurance testing of the fixing force. Test jigs can test the screw loosening process under a variety of conditions. Vibration displacements are applied in the direction along and perpendicular to the tightening axis and the changes in fixing forces are measured with respect to the number of vibrations.
As bone screws for implants can break when inserted during surgery or during the trial period, it is important to evaluate the mechanical properties of the bone screws.
Testing of the mechanical properties of the bone screws includes torsional fracture testing, which applies torque at a constant rotational speed until the screw fails; screw-in testing by screwing bone screws at constant force and constant speed into simulated bone to evaluate the screw-in properties; and pull-out testing, which pulls screws out of simulated bone at a constant rate to evaluate the fixation of the bone screws.



a) Torsional Fracture Test b) Screw-In Test c) Pull-Out Test

## Torsional Testing of Screws

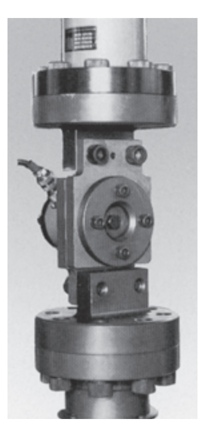
This machine can be used for strength testing of screws used in bone implants and dental implants and for materials testing of zirconia implant material. (Samples are attached to the testing machine via an adapter after being processed into a special shape.) Screws and other specially shaped samples are mounted in a 3-jaw scroll chuck. The torque applied to the sample is measured when it is subjected to torsional, compressive, and tensile test forces. The tester measures the mechanical properties of the sample, an essential process to ensure that implant materials do not break when screws are inserted and do not suffer fatigue failure during use.

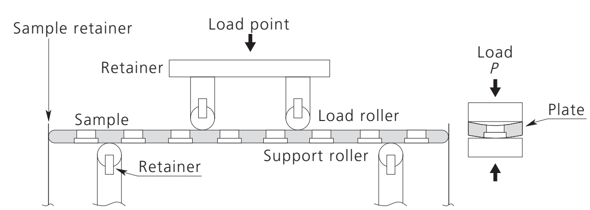



Servopulser Fatigue and Endurance Tester

## Testing Bolt Loosening

To ensure that implant screws do not become loose inside the body, it is important to perform endurance testing of the fixing force. Test jigs can test the screw loosening process under a variety of conditions. Vibration displacements are applied in the direction along and perpendicular to the tightening axis and the changes in fixing forces are measured with respect to the number of vibrations.






## Bending Testing of Bone Plates

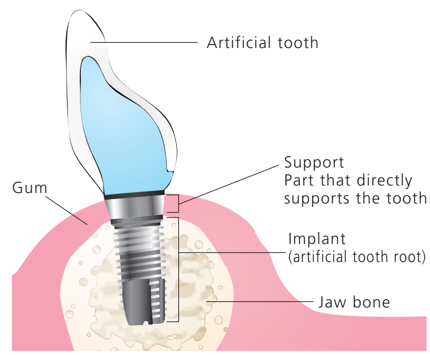
Bone plates are screwed onto the bone surface to immobilize the fracture site. They can be used as metal implants for fixation after limb bone or vertebrae fractures or in the period before bone adhesion is achieved after corrective osteotomy.
The mechanical properties of bone plates are evaluated by bending testing. The three-point bending test jig is comprised of load rollers that apply test forces to the sample and support rollers that support the sample. They are positioned symmetrically and the spacing between them can be altered. The sample retainers ensure that the sample cannot move during endurance testing.

# Testing Dental Implant Materials

Dental implant treatment involves firmly fixing an artificial tooth onto an artificial root inserted into the jaw bone where a tooth has been extracted.
Implants are made of highly biocompatible titanium. Many years of basic and clinical research have confirmed titanium to be both the safest implant material and the material that bonds best to the jaw bone. Once the implant has firmly bonded to the jaw bone, a strong and stable tooth can be made to fit on it.
Dental implant treatment, which has become more common, resolves problems with eating and speaking with dentures and returns the sensation of having your own teeth. This makes the evaluation of mechanical properties increasingly important for the development of implants. The Japanese Ministry of Health, Labour and Welfare has prescribed the fatigue and endurance testing of artificial tooth roots (Pharmaceutical and Food Safety Bureau Notice No. 0525004).

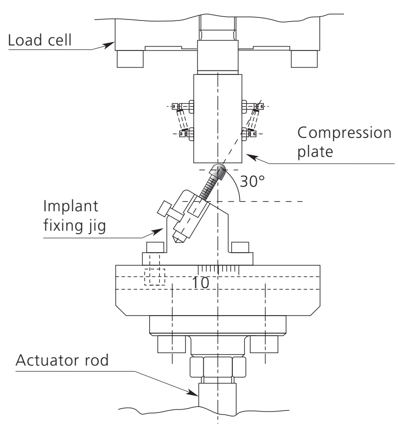
## Fatigue and Endurance Testing of Implants

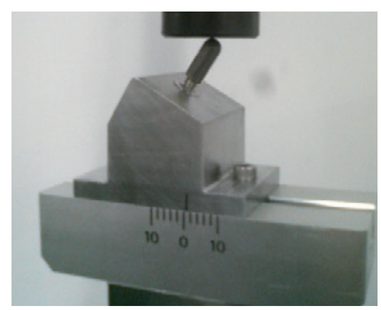
Artificial tooth roots directly fixed to the jaw bone are subjected to cyclical loads when chewing food in the mouth or when the teeth clench together. Consequently, fatigue testing is required to evaluate their durability and reliability. The Pharmaceutical and Food Safety Bureau of the Japanese Ministry of Health, Labour and Welfare released the "Establishment of approval standards for dental implants" (notification No. 0525004), which states that fatigue and endurance testing complying with ISO 14801 should be performed on final implant products as a general rule. ISO 14801 prescribes endurance testing using a suitable jig to apply test forces at a test frequency from 2 Hz to 10 Hz for two to five million cycles.
This demands fatigue and endurance testing that can generate test-force waveforms and frequencies that accurately match the test conditions. The MMT Series Electromagnetic Force Micro Material Testers use a high-response electromagnetic actuator with closed-loop control in the load mechanism to permit high-speed, high-accuracy testing at micro levels of test force and displacement. It's a powerful tool for fatigue and reliability testing of materials, such as implants and electronic components.





MMT Series
Electromagnetic Force Micro Material Tester



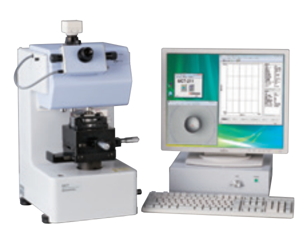



Fatigue and endurance testing is performed by mounting the sample at an angle of 30 degrees and applying vertical loads to it with the overhead actuator. This test assumes an extreme case to simulate the functional loading in the implant.

## Surface Hardness Testing of Implants / Compression Testing of Microparticles

Artificial teeth may be dentures or teeth mounted on implants. To maintain the tooth function of repeated chewing and biting over a long period of time, teeth must have a certain level of wear resistance and surface hardness.
JIS T6506 prescribes that tooth enamel shall have a surface hardness not lower than 21HV0.2 (Vickers hardness not lower than 21 at 1.96 N test force).
The HMV Series Micro Vickers Hardness Testers are used for these tests and are recommended to evaluate the hardness of various materials.
Due to advances in manufacturing technologies for ceramic and metal particles, it is now necessary to measure the properties of microparticle powders with particle sizes from several micrometers to several hundred micrometers. The MCT Series Micro Compression Testers can perform compression testing on individual particles and are used for the development of dental and bone implant materials.

HMV Series
Micro Hardness Tester

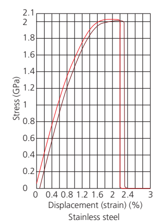


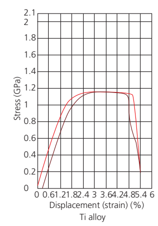
MCT Series
Micro Compression Tester

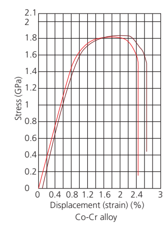
### Testing Dental Wire

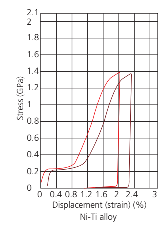
Tensile Testing of Dental Wire

Some examples of the evaluation of the mechanical properties (tensile properties) of wire used in orthodontics are given below. Results are shown for tests on four wires: stainless steel, titanium alloy (beta phase), Co-Cr alloy, and Ni-Ti alloy. The wires were held in special grips for thin wire. A TRViewX Video Type Non-Contact Extensometer was used for accurate strain measurements.
It is apparent that the stainless-steel and Co-Cr alloy wires exhibit high tensile strength but low extension, while the titanium alloy and Ni-Ti alloy wires exhibit large extension but relatively low tensile strength. Ni-Ti alloy wire has shape-memory properties and exhibits ultra-elasticity in the martensite-austenite transition zone. It is attracting attention as a material that alleviates the load on the body because of its flexible properties (little change in force due to extension) and offers a modulus of elasticity close to that of human bone (approx. 30 GPa).



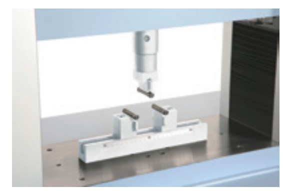




### Evaluating Denture Adhesive Strength and Testing Denture Base Resins

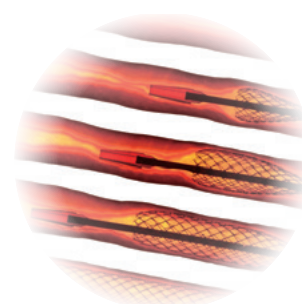
A tensile tester is used to measure tensile forces applied to teeth mounted in the denture base.
The mechanical properties of denture base resins are evaluated mainly by bending testing. This requires the use of test jigs conforming to ISO, ASTM, and JIS standards.


Evaluating Denture Adhesive Strength

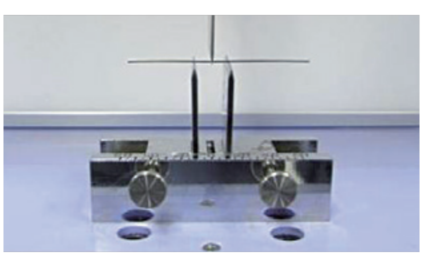

Three-Point Bending Testing Jigs for Resin

## Mechanical Properties Evaluation for Stents and Stent Grafts

Stents are medical devices that expand tubular tissue in the body (blood vessels, trachea, esophagus, duodenum, colon, biliary tract, etc.). They are inserted at lesions where tubular tissue is constricted due to angina pectoris, cerebral infarction, or cancer. A catheter is inserted up to the position of the lesion and a balloon is used to expand the stent. The catheter is withdrawn and only the stent remains. In many cases, the stent is a cylindrical metal mesh and the appropriate stent is selected for the treatment site. This advanced medical technique has been attracting attention in recent years.
Stents may be made from medical-grade 316L stainless steel, tantalum, cobalt alloy, or nitinol (nickel-titanium alloy). It is not adequate to test the material alone; it must be tested in an environment that simulates its actual use.

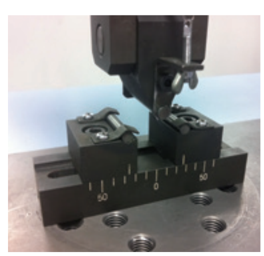


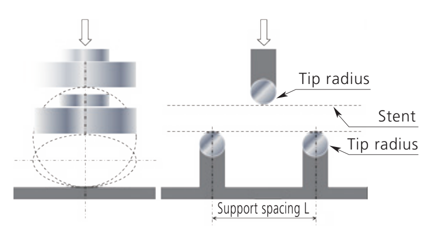
### Testing Wire Used in Stents



Tensile and bending testing is performed on the materials of metal wires used in stents to determine their fundamental mechanical properties. The wires must smoothly expand inside the tubular cells and offer fatigue and endurance properties to withstand repeated loads from blood vessel pulsation.
As in the case of testing dental wire, the TRViewX Video Type Non-Contact Extensometer is recommended for tensile testing stent wire.

### Three- and Four-Point Bending Testing and Compression Testing of Stents


Three-/Four-Point Bending Test Jig for Small Samples



Compression Test
Evaluation of Blood Vessel Bearing Capacity

Bending Test
Evaluation of Stent Flexibility

Stents must offer mechanical functionality to support the blood vessel walls at a uniform pressure, while not allowing a recoil phenomenon, which causes the inner diameter to reduce after expansion or no stress concentration across a narrow range. The capacity to support blood vessel walls is evaluated through tightening tests with forces in the radial direction and compression testing with compression forces on the side walls. Flexibility is measured by three- and four-point bending testing. Stents offer high compression stiffness in the circumferential direction and low bending stiffness in the longitudinal direction. This ensures high support force for the blood vessel wall and a flexible fit to the shape of the blood vessel. ASTM F2606 prescribes bending testing for stents. The bending jigs can be modified to meet test standards or customer requirements.

# Evaluation of Medical Equipment

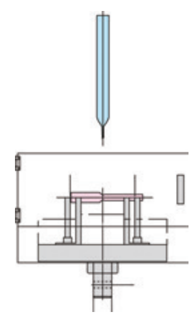
Medical equipment is classified by the risk of a defect occurring as follows: general medical equipment including scalpels, scissors, X-ray film, and external diagnostic equipment such as blood analysis equipment; controlled medical equipment including catheters for the gastrointestinal tract, dental alloys and electronic endoscopes; and specially controlled medical equipment including orthopedic implants, balloon catheters, contact lenses and stent grafts. Medical equipment manufacturers implement a variety of evaluations to ensure the functionality, performance, and safety of their products. The assessment of strength properties through physical testing is one such important item.
Evaluation of the mechanical properties of variously shaped medical equipment requires the use of jigs suited to each piece of equipment. Here, we will introduce practical testing equipment selected from Shimadzu's diverse portfolio.

## Mechanical Evaluation of Injection Needles and Injectors

Pharmaceutical manufacturers need to measure the force required when injecting medical liquids from injection needles and injectors. It is important that the force with which liquid medicine is injected when the plunger moves be maintained within a suitable range. In tests for this type of evaluation, in addition to collecting data on extrusion force versus time, it is also necessary to measure the average test force value and the peak test force at specific positions of plunger displacement. Such values are significantly affected by the material from which the injector is constructed, as well as sterilization treatments, and the viscosity of the medical liquid.
The Shimadzu EZTest Compact Table-Top Universal Tester and TRAPEZIUM X software are capable of performing such mechanical evaluations quickly and easily.
Evaluations are possible with respect to injection force, which indicates the force required to start the injection of the liquid medicine (i.e. the initial injector press), as well as continuous force, which indicates the force required to maintain an even flow after the medical liquid is extruded from the injector.

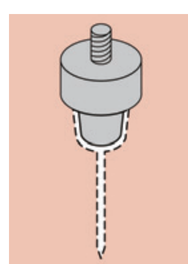
### Three-Point Bending Testing of Ampoules

Injectable drug and medical liquid containers must sterilized and stable with respect to the drug. Glass ampoules and vials are common, but in recent years, the number of plastic containers has increased. Their strength properties have a significant effect not only on the storage of medical liquids, but also on the ease of transportation and handling. Ampoule breakage strength is measured by bending tests. Vials are subjected to compression tests, and vial stoppers are subjected to needle penetration tests. In such tests, it is important to use test jigs suited to the sample.



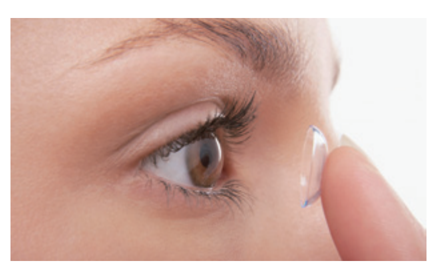
### Strength Testing of Injection Needles

Several tests are performed to evaluate the mechanical properties of injection needles. In elasticity tests, a cantilever force is applied to the needle for one minute to evaluate whether the needle returns to the horizontal position. In bending tests, the center of the needle shaft is bent 90 degrees to examine whether it breaks. In pulling tests, the needle is pulled out from its base. The tests must be performed with suitable test jigs, and the EZTest Compact Table-Top Universal Tester is recommended for accurate test force measurements and deflection measurements.



## Evaluating the Mechanical Properties of Contact Lenses

Contact lenses are currently used by millions of people. More popular than eyeglasses, they are prescribed to correct a variety of vision problems, and are manufactured in a variety of styles ranging from hard to soft lenses. Contact lenses must withstand repeated daily usage, so suitable strength is required. For this reason, tensile and compression tests are performed.
Soft contact lens material slips easily, is delicate, and is damaged by very small forces. When performing contact lens tensile tests, the sample grip method and the limited grip area can cause problems. When testing in air, the material may dry and crack, so contact lens tests are performed in environments simulating physiological conditions.



# Mechanical Evaluation of Medical Equipment

A broad array of materials is used in medical equipment. These include metals for catheters, guide wires, and needles; plastics, films, and other resin materials; and textile materials typified by bandages. They are also used in various environments: some materials are used after sterilization and other treatments; some are used repeatedly; and others are disposed of after single use. The AGS Series of Table-Top Precision Universal Testers are all-purpose testers that can be used in a variety of situations, from research and development of such materials to quality control.

Left) Jog controller
Control of the crosshead position is at your fingertips.

Right) Multipurpose tray
This can be used for a variety of applications, from arranging test samples to placing jigs.

Autograph AGS Series
Table-Top Precision Universal Tester

## Tensile Testing of Surgical Tubes

Surgical tubes are used for a variety of surgical procedures and applications including drainage, feed tubes (liquid delivery tubes), and injections. Their shape and size vary significantly, and there are dozens of connectors and accessories. If a defect occurs, the patient will be put at risk; therefore, determining the mechanical properties of surgical tubes extremely important. Test requirements involve material defects, junction defects, and physiological parameter simulations. To this end, material/final product tensile strength, durability and friction properties are measured.

Regardless of the test application, in order to obtain accurate measurement values, it is important that the tube is suitably gripped. This applies both to the evaluation of the mechanical properties of surgical tubes themselves, and to evaluations of the connection strength between tubes and accessories.

## Tensile Testing of Catheters

Catheters are hollow flexible tubes applied for medical purposes. They are inserted into the thoracic cavity, the abdominal cavity and other body cavities, as well as the gastrointestinal tract, urinary duct and other ducts or blood vessels, where they eliminate bodily fluids, or inject or drip liquid medicines or contrast media. In addition, medical treatments are performed by passing intravascular enlarging stents and balloons, and embolization coils through catheters.

The operability of catheters is significantly affected by their mechanical properties, such as a lack of intra-tubular flexion, and whether torsion is accurately transmitted in order to change direction via guide wires. Tensile tests are typically performed, where pneumatic grips are recommended to grip samples accurately. Even samples that become thinner as tension is applied can be accurately gripped all the way to the breakage point. More accurate measurement values are obtained by using the SES-1000 extensometer for soft samples.

Pneumatic flat grips

SES-1000
Extensometer for Soft Samples

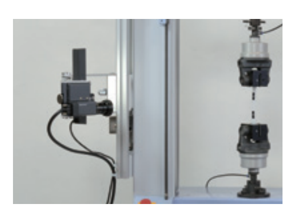
## Tensile Testing of Bandages and Textile Materials

Bandages function to stop bleeding through compression of wounds, and to absorb blood and pus using highly moisture-absorbent cotton. For this reason, a suitable tensile strength is required, and the bandage must be elastic enough to compress the affected part and to hold other medical instruments in place.

Individual fibers can be tested at constant test conditions by using capstan type grips (also used for tensile tests of hair) to maintain a uniform clamping pressure while preventing the application of unnecessary force.

## Tensile Testing of Silicon Rubber and Other Soft Materials

In the therapeutic arena, a variety of rubber products and thin resin materials such as silicon rubber are widely used. The TRViewX Video Type Non-Contact Extensometer is optimal for accurate extension measurements in tensile tests of soft stretchable samples. Since extension is measured without contact, displacement is measured accurately all the way to the breakage point, without being subjected to unnecessary loads. Measurements of displacement in the width direction are also possible.



TRViewX
Video Type Non-Contact Extensometer

# Evaluation of Pharmaceuticals and Packaging

Medicinal agents are administered in a variety of forms including tablets, capsules, granules, and liquids. Storage containers also vary from glass to plastic, and are used in response to respective applications. Pharmaceuticals and packaging are manufactured with attention to even the smallest aspects, including functionality, ease of conveyance and removal, ease of administration, and visibility.

Pharmaceuticals, packaging, and materials manufacturers use testing equipment for quality control and new product development. The applications include the development of materials, evaluation of the result of sterilization, and evaluation of physical properties such as the force required to open the packaging.

## Evaluating the Strength of Tablets

Tablets are solid pharmaceutical products, formed into a set shape by methods such as compression molding of active ingredients, or a combination of active ingredients and diluents. Tablets are portable, making it easy to administer a set dose, and represent the most familiar method of administering medicine in our daily lives.

With consideration to ease of handling and swallowing, most tablets weigh between 200 mg and 500 mg, and have a diameter of about 8 mm to 15 mm. They come in a variety of shapes including disc-shaped, lens-shaped, and rod-shaped tablets.

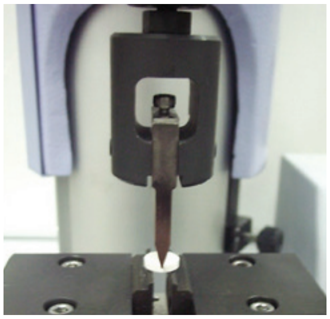
Equipped with a wealth of testing functions, EZTest is a compact table-top universal tester that can be used for a variety of testing applications, including evaluations of tablets, solder peeling strength measurements for electronic parts in medical devices, and strength tests and peeling tests for packaging. Naturally, EZTest is compatible with various grips and extensometers, as well as testing in thermo-constant environments.

EZTest Series
Compact Table-Top Universal Testers

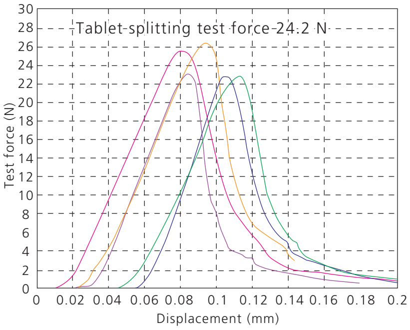
### Compression Testing and Score Line Strength Evaluation of Tablets

Many tablets are formed with a midline splitting groove to make them easier to swallow and for use with children. The depth of the depression is investigated to ensure that the tablet can be split in half easily. Here, a three-point bending test jig is used to perform a three-point bending test on a tablet in order to measure the midline splitting strength.

Tablet Compression Test



Tablet Score Line Strength Test




### Molding Test of Tablet Powder

Tablets are produced through compression molding of pharmaceutical powders. When a tablet is molded, a set quantity of powder must be formed into a single tablet. It is also important that the tablet satisfies a number of functional conditions. For example, it must not break if dropped and must dissolve easily. Accordingly, when compressing the powder, the loading and compression speed must be controlled very accurately.

This test device is suitable for experimental determination of the affinity of particles, work load required for molding, and the influence of additives when molding powders, at different molding speeds and load levels.

The test forces of the upper and lower mallets are individually detected by load cells, and the displacement between the upper and lower mallets is detected by the differential transformer detector. These enable effective data measurements with respect to molding powders, including wall friction and compression volume.

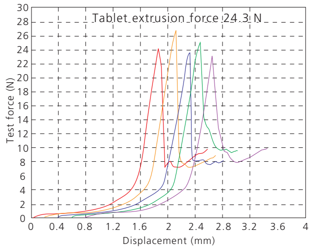
Molding Property Test Device for Powder Samples

# PTP Packaging Evaluations

Most tablets and capsules are packaged with a combination of aluminum or other thin metals and plastic. This sort of packaging is referred to as PTP (press through package) or a PTP sheet. It functions to protect tablets and capsules. Accordingly, quality control is necessary to ensure that the packaging does not come unstuck indiscriminately, and that the medicine is not hard to extrude.

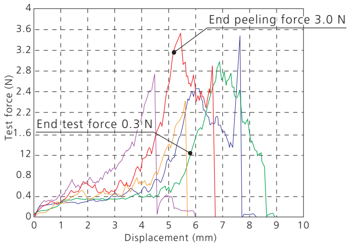
## Extrusion Testing of PTP Packaged Tablets

PTP packaging extrusion tests involve evaluating the ease of use when a person removes the tablets. The PTP packaged tablet is pressed between top and bottom plates with holes in them. The tablet is extruded from the top by an extrusion jig, at which point the amount of jig movement and the test force are measured. The maximum test force at this point is equivalent to the PTP packaged tablet's extrusion strength. The strength must be such that the tablet is easy to remove but is not extruded arbitrarily.



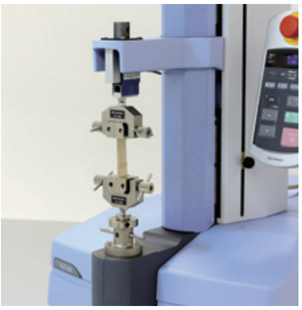

## Peeling Testing of PTP Packaging

When medicines are transported, friction may lead the packaging to come unstuck. PTP packaging peeling tests simulate such circumstances. The PTP packaging peeling test is performed by unsticking a part of the PTP packaging, and then gripping the peeling part and applying tension.

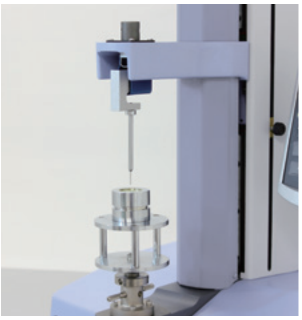



# Tear Off and Tensile Testing of Adhesive Bandages

Adhesive bandages, a type of hygienic material used to prevent infections and the penetration of bacteria by adhering to an affected body part, are classified as general medical equipment. A variety of evaluations is performed on bandages, which are an everyday part of our lives. These include adhesion to skin, ease of peeling, tensile strength, and the force required to open the packaging. In peeling tests, a bandage affixed to a stainless steel flat plate is peeled off at a 180° angle. Sometimes, peeling tests are performed on bandages actually stuck to a person's skin. The same tests are also performed on compresses and other medical goods besides bandages that are affixed directly to the skin.

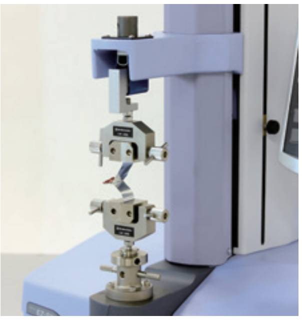


# Strength Test of Packaging



Piercing Test of Film

Compression Test of Containers



180° Peeling Test on Package Crimping

Press-Dispense Test of Tablets

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