Bionix® Spine Wear Simulator

Accurately simulate long-term wear, fatigue and durability on lumbar and cervical spinal disc implants

A Critical Component for Your Spinal Device Development

Bringing your innovative spinal implant technologies to market is a high-stakes endeavor. High-quality, meaningful wear data are critical for successfully pursuing implant approval, production and continued development. Working with MTS, the leader in orthopaedic kinematics and wear testing, helps you be certain that your device development is on the right track.

The MTS Bionix Spine Wear Simulator is the first wear system on the market designed specifically for spinal applications. The MTS Bionix Spine Wear Simulator enables you to perform highly accurate, long-term wear, fatigue and durability simulations on both lumbar and cervical spinal disc implants. You get precise, repeatable application of loads and motions to adhere to new and evolving ISO and ASTM standards, along with a host of additional capabilities demanded by leading researchers. Loads, motions and cycles are captured and archived in detailed time histories, providing you with the body of knowledge you need to build a clear, compelling case for your spinal implants.

Leading-Edge MTS Technology

The MTS Bionix Spine Wear Simulator employs an array of newly developed technologies to accurately replicate the forces, motions and conditions that spinal disc implants are subject to in the real world. These patents-pending innovations include user-friendly specimen containment modules, a host of high-performance mechanisms to deliver motion in a full six degrees of freedom, devices to accurately control fluid concentration and temperature, and more.

User-Friendly Specimen Containment Modules

The MTS Bionix Spine Wear Simulator features six active specimen–containment modules to provide a statistically valid sample size. Made of durable, insulated Delrin, each containment module is easily removed and disassembled for specimen preparation and cleaning that minimizes the risk of contamination. Locator pins guide each module into position to facilitate easier interval measurements. Containment modules can accommodate both one-piece and two-piece spinal implants.

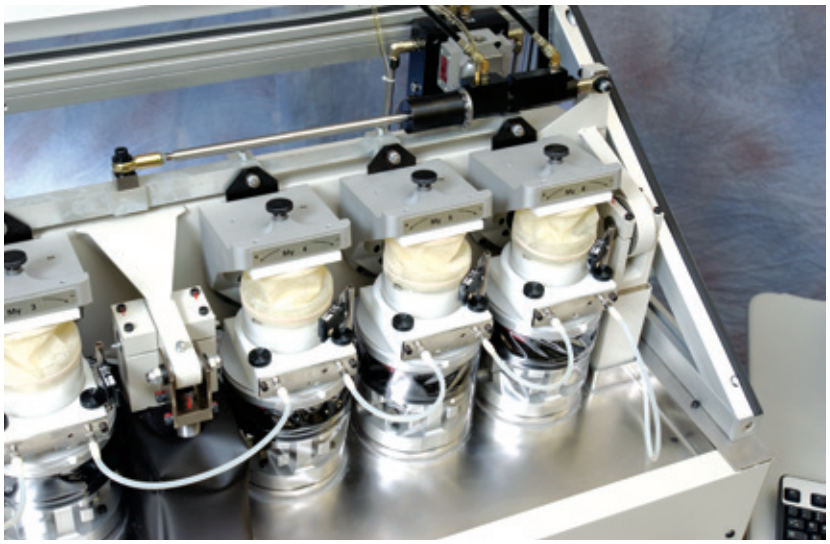
Six Degrees of Freedom

The MTS Bionix Spine Wear Simulator delivers a full six degrees of freedom. Advanced hydraulic actuation enables precise control in four active degrees of freedom, providing stiffness and power to handle both high- and low-force loads, with cooling and lubrication qualities that enhance system longevity. To minimize variability, dedicated actuators actively apply flexion/extension, lateral bending and axial rotation motions uniformly across all six specimens. Axial loads are also actively and evenly applied across all containment modules. Since each active motion and load is applied independently, you get near-infinite programmability of load profiles.

The X-Y translation platform passively accommodates motions in the remaining two degrees of freedom. With an ultra-low-friction design, the translation platform eliminates anterior/posterior and lateral forces on specimens, ensuring the utmost in simulation precision. The translation platform can be easily configured to simulate soft tissue surrounding an implant, or show how a device might perform if implanted in a less-than-ideal location in the spine.

Absolute System Reliability

MTS understands your need for constant uptime and absolute system reliability. That's why you'll find only top-notch components built into every detail of the Bionix Spine Wear Simulator. One such detail includes high-quality needle bearings, designed to maintain their pristine condition for many years and millions of cycles. In addition to keeping you up and running, the needle bearings' rugged design helps ensure highly consistent application of wear, even among tests performed years apart.

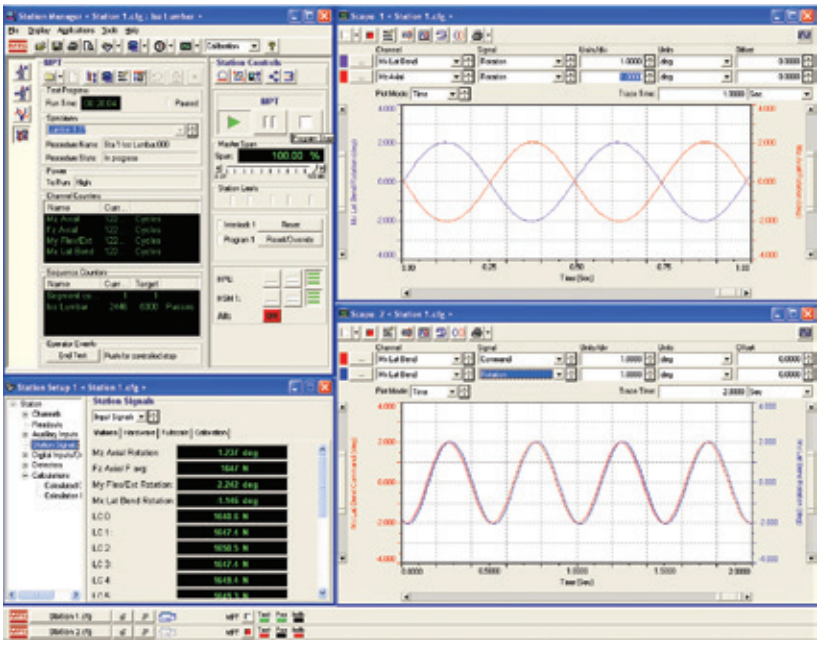


Tight Control of Simulation Temperature

Tight control of simulation temperature is maintained by circulating tempered water through a closed heat exchange system. This keeps water out of contact with the specimen and test fluid at all times. This methodology has been verified to keep all modules within a half-degree Celsius of human body temperature.

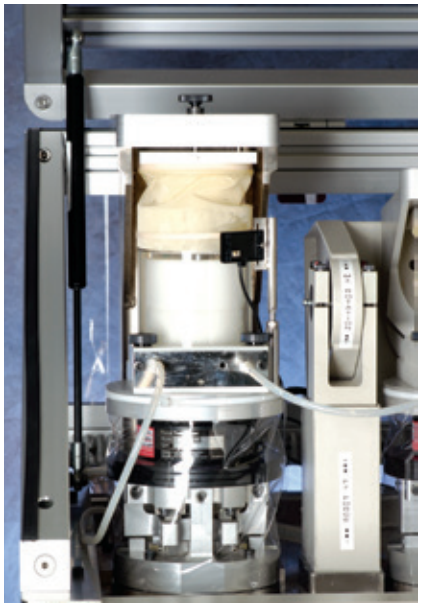
Sophisticated Digital Control and Software

The Bionix Spine Wear Simulator employs a sophisticated FlexTest® digital controller. User-friendly MPT™ software includes methods to easily run lumbar and cervical profiles, based on ASTM and ISO standards. You can generate far greater loads, displacements and test speeds than currently required, equipping you to meet future test requirements, no matter how demanding they become. You can also input other profiles of interest, such as duty cycle loading with varying end level, complex wave shapes and phasing, and simulations of periodic extreme loading to replicate heavy lifting and twisting.



Advanced Optional Features

Advanced optional features yield even greater productivity. A load soak control module accommodates up to two control specimens that undergo load conditions without motion. A fluid-level sensing capability alerts operators when fluids drop below predetermined levels for each specimen module, reducing the need for manual monitoring.



Exceptional Service and Support

The MTS Bionix Spine–Wear Simulator is supported by the largest, most experienced worldwide service and consulting staff of any biomedical testing solutions provider. This global team offers a wide range of on-site services to help maximize your test laboratory's productivity, such as preventive maintenance, system lifecycle management, problem solving, technology transfer, consulting engineering and process optimization.

Be Certain with MTS

The MTS Bionix Spine–Wear Simulator is a critical component for any structured spinal implant development methodology. Whether you seek implant approval, production or continued research, this system delivers the accuracy, repeatability and detailed time histories you need to generate high-quality wear data.

Product Specifications

Footprint		160 cm x 66 cm x 158 cm *(width x depth x height)*
Number of active stations		6
Number of load soak specimens		2 *(optional)*
Axial load*	Maximum force Displacement	4 kN + 12.7 mm / -3.2 mm
Flexion-extension*	Maximum torque Displacement	15 N-m +/- 10°
Lateral bending*	Maximum torque Displacement	15 N-m +/- 10°
Axial rotation*	Maximum torque Displacement	10 N-m +/- 7.5°
Anterior-posterior translation	Restraining force Displacement	Zero to fully locked +/- 4.5 mm
Lateral translation	Restraining force Displacement	Zero to fully locked +/- 4.5 mm

**Per station (per specimen) ratings*

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Specifications subject to change without notice.

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This technology is protected by patents 7,383,738 and 7,617,744; other U.S. and foreign patents pending.

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