

SPINAL FIXTURES

ASTM F1717 | 2014-003

During normal patient activity, spinal constructs can be subjected to high in vivo loading that can result in catastrophic failure. Spinal injuries often occur due to rotation, dislocation, bending, and axial loading.

Simple static testing is able to evaluate the load required to result in spinal fracture. Cyclic testing is also performed in order to evaluate the amount of cycles it takes for fatigue failure to occur.

ASTM F1717-21 'Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model' provides a guidance for the mechanical comparison between past, present, and future spinal implant assemblies through four different test methods: static compression bending, static tension bending, static torsional test, and fatigue testing.

As spine implants are manufactured and designed from different companies, the standard also offers a guidance on the ultra-high molecular weight polyethylene (UHMWPE) blocks, including their size and geometry. ASTM F1717-21 provides test methods that set guidelines for load types and offers a comparative evaluation of spinal implant assemblies, but it does not define the levels of performance.

The Instron® spinal fixture is designed to meet ASTM F1717-21 requirements. In accordance to the standard, the UHMWPE blocks are attached to the spinal fixture. The design of the blocks can differ, according to the clinical application at the intended spinal location. The way that the blocks are connected to the fixture allow a degree of freedom when performing bending compression, bending tensile, and torsional testing.

The spinal fixture is compatible with all ElectroPuls® Test Instruments, but it is ideally used with the E3000 and E10000 models for customers performing torsional testing.



PRINCIPLE OF OPERATION

Instron's spinal implant was designed to meet all ASTM F1717-21 requirements, including the tension, compression and torsional sections of the standard. The fixture is easily assembled and mounted on the base of an ElectroPuls Test Instrument. Moreover, it is compatible with the saline bath (CP100543) for in vivo testing when fitted with a longer saline bath tube (CP111212). The fixture is attached on the saline bath and the load cell through clevis fixtures. Also, support straps fit between the clevis grips to maintain rigidity of fixture assembly during installation in the saline bath.

The maximum load rating of the fixture is 3 kN tension/tension, 3 kN compression/compression, and 50 Nm static torsion. The spine fixture is designed to be used with an ElectroPuls E3000 and E10000 models.

FEATURES & BENEFITS

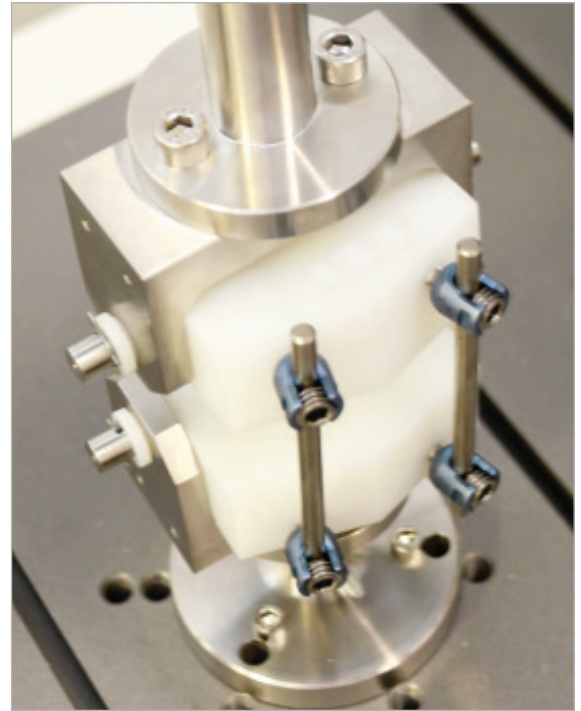
- The ElectroPuls E3000, E10000 and E20000, with the biaxial actuator, can perform both static and dynamic testing on a single machine, meeting the ASTM F1717-21 requirements
- The saline bath can be easily mounted on the ElectroPuls for simulating in vivo testing
- Instron's patented stiffness based-tuning ensures waveform fidelity and repeatability
- The ElectroPuls, when using WaveMatrix™2 Software, is perfect for testing spinal constructs for exceptional response and accuracy across the frequency range
- Instron's patented Dynacell load cell compensates for load inertia errors providing accurate and reliable data

SPECIFICATIONS

| 2014-003 | | |
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| Upper Fixture Dimensions (h × w × d) | mm | 236 × 120 × 40 |
| | in | 9.29 × 4.72 × 1.57 |
| Lower Fixture Dimensions (h × w × d) | mm | 130 × 120 × 40 |
| | in | 5.12 × 4.72 × 1.57 |
| E3000 Upper Base Interface | | 3 × M6 × 57 PCD |
| E10000 Upper Base Interface | | 3 × M6 × 57 PCD |
| E3000 Biaxial Lower Base Interface | | 3 × M6 × 57 PCD (Ambient Temperature) 3 × M6 × 57 PCD (When in CP100543) |
| E10000 Biaxial Lower Base Interface | | 3 × M8 × 75 PCD (Ambient Temperature) 3 × M6 × 57 PCD (When in CP100543) |
| Maximum Static Force | ±N | 3000 |
| Maximum Torsional Force | ±Nm | 50 |

ACCESSORIES

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| CP100543 | 6 Liter Fluid Bath for Biomedical Applications |
| CP111212 | Longer Saline Bath Tube |



Spinal Fixture