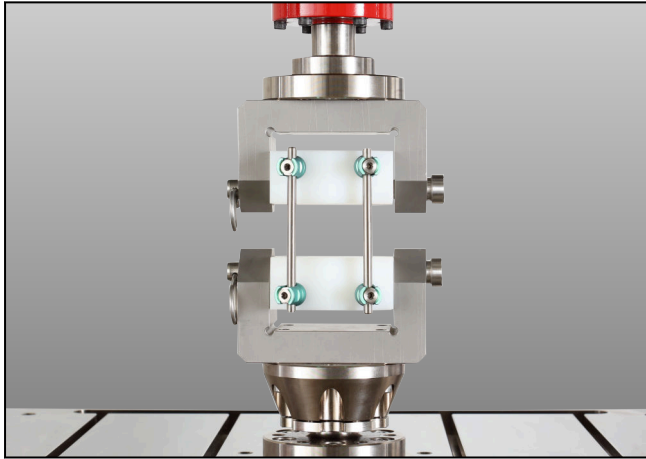


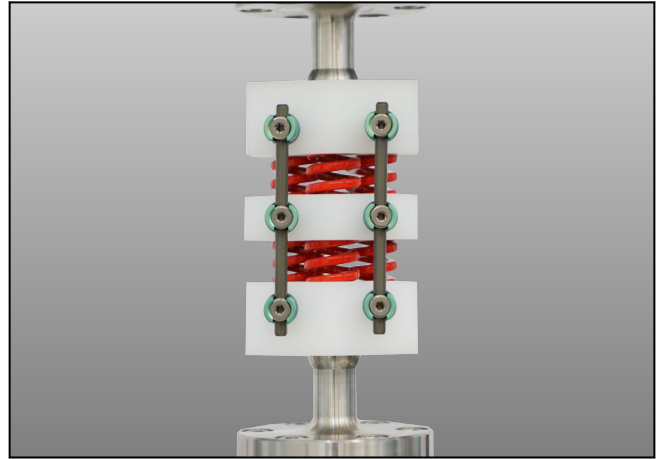
Product Information

Testing Solutions for Spinal Implants

CTA: 280358 280359



Test fixture for spinal implants to ASTM F1717 and ASTM F2706



Test fixture for spinal implants to ISO 12189

Applications

Screw and rod systems are used to stabilize the spine. For this purpose, adjacent vertebrae are connected with the help of screws, hooks, rods or plates and thus permanently fixed in place.

The mechanical investigation of screw and rod systems of the spine under static and dynamic load is an important part of R&D and approval tests.

The implants are mounted on a vertebral body replacement test block made of ultra-high molecular weight polyethylene (UHMWPE). The use of simulated vertebral bodies improves test reproducibility compared to using human preparations.

The following standards require purely axial tensile tests, compression tests, dynamic fatigue tests, and pure or combined torsion loading.

- ASTM F1717
Standard test methods for spinal implant constructs in a vertebrectomy model
- ASTM F2706
Standard test methods for occipital-cervical and occipital-cervical-thoracic spinal implant constructs in a vertebrectomy model
- ISO 12189
Implants for surgery—Mechanical testing of implantable spinal devices, fatigue test method for spinal implant assemblies using an anterior support

Advantages and features

- With one test fixture, you can cover all static and dynamic tests included in the standards ASTM F1717 and ASTM F2706. This is possible due to the modularity and easy interchangeability of the test blocks and reduces acquisition costs.
- The compensating bearing enables free rotation around the Z-axis required by the ASTM F1717 and F2706 standards for tensile, compression and fatigue testing
- The test fixture for ISO 12189 contains all compression dies, test blocks and springs with the required spring stiffness and is therefore immediately ready for use.
- Standard test programs fully meet the specifications of the industry standards and thus guarantee reliable test results. Time-consuming setup of the test sequence is no longer necessary, which saves you time and money.
- Alternatively, as with testXpert R Sequencer, programming of the test sequence can be customized.
- Validation of the testing system is supported by ZwickRoell qualification documentation.
- You can also output the test results via testXpert Analytics in a Wöhler diagram.
- In addition to testing at ambient temperature, testing under physiological (in vivo) conditions is also possible by using the ZwickRoell temperature-controlled bath.

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Software

testXpert R enables static and dynamic testing of spinal implants. The software solution provides a suitable standard test program for the respective application, reflecting the requirements of the standard. This allows you to run standard-compliant tests with just a few clicks. The design of all test programs is workflow-based and mirrors a lab's operating processes so that the user is guided through the test in logical steps.

	Static		Dynamic	
	Compression/ tensile	Axial/torsion	Compression/ tensile	Axial/torsion
ASTM F1717 Item No. ¹⁾	Section 8.1.1-2 1108123	Section 8.1.1-3 1105957	Section 8.2 1105959	-
ASTM F2706 Item No. ¹⁾	Section 8.1.1-2 1108122	(Section 8.1.3) 1105961	(Section 8.2.1) 1105963	(Section 8.2.2) 1105967
ISO 12189 Item No. ¹⁾	-	-	1105968	-
Machine type				
LTM Torsion / HC Tor- sion	•	•	•	•
LTM / HC	•	-	•	-

¹⁾ Additionally, you will need the testXpert R basic package.

The testXpert R standard industry packages include all important standards and test methods specific to the spinal implant (screw and rod system) industry segment, with guaranteed standard compliance. They provide the ideal solution for different standard tests within an industry.

testXpert R Standard industry package Biomechanics Spine	Static	Dynamic
Item ¹⁾	1108113	1105970
Contains:	<ul style="list-style-type: none"> • ASTM F1717 (Section 8.1.1 -8.1.3) • ASTM F2706 (Section 8.1.1 - 8.1.3) • Traceability option 	<ul style="list-style-type: none"> • ASTM F1717 (Section 8.2) • ASTM F2706 (Section 8.2.1 - 8.2.2) • ISO12189 (2008) • Traceability option

¹⁾ Additionally, you will need the testXpert R basic package.

Test tools for ASTM F1717 and ASTM F2706

In the standards ASTM F1717 / ASTM F2706, reference is made to the spinal segments such as occipital, cervical and lumbar. ZwickRoell offers the right specimen grip for each of them. The implant system to be tested (e.g. screw

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Testing Solutions for Spinal Implants

and rod system) is attached to a special test block pair and mounted in the specimen grip. The ease with which the test blocks can be interchanged enables a high degree of flexibility and reduces acquisition costs.

	ASTM F1717		ASTM F2706	
	Cervical	Lumbar	Occipital + Cervical	Lumbar
Test fixture for cervical spinal implants (9.6 mm) to ASTM F1717 + ASTM F2706	1098925		1098925	
Test fixture for lumbar spinal implants (12.8 mm) ASTM F1717 + ASTM F2706		1098927		
Axial bearing for accepting 2 kN compression forces		1057525 ¹⁾		1057525 ¹⁾
Test blocks, occipital bilateral to ASTM F2706			1116037 ²⁾	
Test blocks, cervical unilateral to ASTM F1717 for a screw and rod system	1111362 ³⁾			
Test blocks, cervical bilateral to ASTM F1717 for a hook, cable and wire system	1111363 ³⁾		1116039 ²⁾	
Test blocks, cervical bilateral to ASTM F1717 for a screw and rod system	1111365 ³⁾		1116041 ²⁾	
Test blocks, lumbar unilateral to ASTM F1717 for a screw and rod system		1111372 ³⁾		
Test blocks, lumbar unilateral to ASTM F1717 for a screws and rod system		1111366 ³⁾		
Test blocks, lumbar bilateral to ASTM F1717 for a hook, cable and wire system		1111367 ³⁾		
Pair of compression dies for alternate lumbar bilateral		049414		049414
Test blocks alternate lumbar bilateral for a screw and bolt system		1111369 ³⁾		1116044 ²⁾
Optional – Test tools for axial static applications				
Pair of adapters for pitch circle 70 / plug-in system Ø 20 mm negative		1111370		1111370

1) Not required for torsion tests and “alternate lumbar” compression die (049414).

2) Contains polyacetal blocks, required for one test. This item is a consumable and can be used once per test.

3) Contains 2 x UHMWPE blocks, required for one test. This item is a consumable and can be used once per test.

Test tools for ISO 12189

Description	ISO 12189
Test fixture for spinal implants ISO 12189	1098919
Test blocks, lumbar bilateral to ISO 12189	1098920¹⁾
Test blocks, cervical bilateral o ISO 12189	1098922¹⁾

1) Contains 2 x UHMWPE blocks, required for one test. This item is a consumable and can be used once per test.

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Options

The tests can optionally be performed under the conditions of tempered mediums. The fluid bath from ZwickRoell can also be easily adapted to support test tools for dental tests (ISO 14801), femoral stem testing (ISO 7206-4; -6) and many more.

Description	ArticleNumber
Fluid bath, biomechanics	3006023
Heat exchanger ~ 37 °C	3006024
Thermostat ~ 37 °C	1015916

Example for a dynamic test task

Specimen: Spinal implant, occipital-cervical screw and rod system

Dynamic torsion testing

Description	ArticleNumber
Test fixture for cervical spinal implants (9.6 mm) ASTM F1717 + ASTM F2706	1098925
Test blocks, occipital bilateral to ASTM F2706	1098923
Test blocks, cervical bilateral to ASTM F1717 for a screw and rod system	1111365
testXpert R standard test program ASTM F2706 (Section 8.2.2)	1105967

CTA: 280568



LTM 3 Torsion