

ASTM F543 Test Methods for Metallic Medical Bone Screws

TEST METHOD SUMMARY

ASTM F543 provides performance considerations and standard test methods for measuring the mechanical properties in torsion of metallic bone screws that are implanted into bone. This test method is intended to measure the uniformity of the product tested or to compare the mechanical properties of different, yet similarly sized products. The following properties may be important when determining the suitability of a screw for a particular application:

- » Torsional Strength
- » Breaking Angle
- » Axial Pullout Strength
- » Insertion and Removal Torque
- » Self Tapping Force

A torsion testing apparatus is used for applying the required torque to the specimen and calibrated for the range of torques and rotational displacement, along with a suitable testing fixture for the torsional yield strength, maximum torque and breaking angle test. The testing apparatus provides torsional force at a constant rate of 1 to 5 rpm (revolutions per minute). A torque transducer is used to measure the applied torque in the clockwise and counterclockwise rotation that is encountered while performing the test method. Similarly, an Angular Displacement Transducer of some type is used to measure the angle of twist that is calibrated over the range of angles to be encountered in the test with an accuracy of 0.3° (clockwise or counterclockwise rotation).

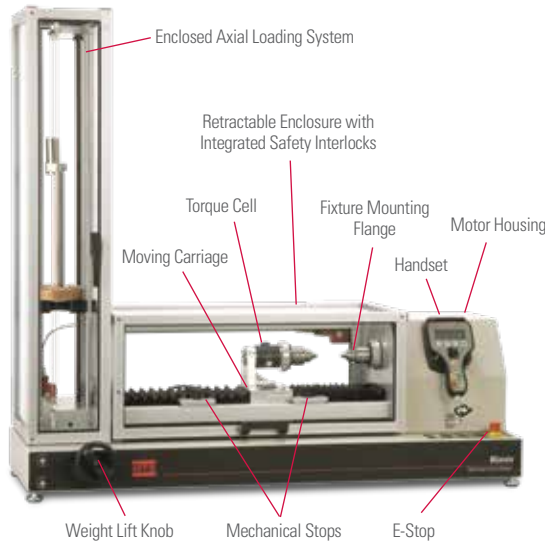
LOAD FRAME OPTION*

The MTS Bionix® Electromechanical Torsion Test System is a precision mechanical test system designed to meet the specific needs of orthopaedic and medical device developers. It integrates a compact electromechanical load frame, advanced MTS digital controls and powerful TestSuite™ software to provide safe, easy and reliable testing of components and tools subject to torque loading in biomedical service environments. The system accurately applies monotonic and multicycle torsion, in conjunction with an adjustable static axial load, to test orthopaedic bone screws, constructs and tools, and medical device components such as tubing, catheters, torsion springs and lead wires.

The tabletop Bionix EM Torsion System has been right-sized for orthopaedic and medical device testing applications. It is built to deliver the full range of torsional loads necessary for accurately simulating bone screw insertion and head twist-off, or testing the performance and durability of torque limiting screws, needle bonds, tubing and fine lead wires. High-performance components, such as a slotless AC servo motor, a digital sine drive amplifier, and a highly accurate direct drive provide users with precision control over the amount of torque applied to specimens throughout testing.

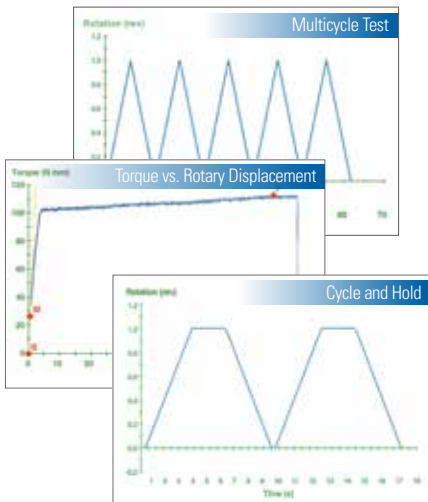


MTS Bionix®
Electromechanical Torsion Test System



THE TORSION FIXTURE/HOLDER

A Specimen Holder (a mechanical device that grips onto the bone screw) is used to prevent rotation within the clamp or grip while the screw is being stressed without significantly damaging its mechanical integrity. One such method is to insert a threaded stopper into the opposite side of a test block. In this case, the test block for this holding mechanism will accommodate the insertion of a threaded stopper on the other side of the test block. The threaded stopper will prevent the screw from being completely inserted into the test block and will allow the torsional strength of the screw to be measured. This holder will be modified according to the size of the testing specimen so that the gage length of the specimen can be accommodated.



SOFTWARE OPTIONS*

TestSuite™ for MTS Bionix System

Bionix EM Torsion System runs MTS TestSuite TW software that delivers powerful test design, execution and reporting plus advanced features for data analysis and reporting. TestSuite TW software enables you to streamline testing procedures and adapt quickly to changing requirements. You can readily configure the software to handle your most demanding requirements, while maintaining the easy-to-use user interface. The intuitive menus and controls make test definition, execution and report generation easy for both simple and complex testing.

MTS TestSuite TW provides users the flexibility to create, customize, and share test methods to meet industry-standard testing requirements, and perform a wide variety of more unique and advanced tests. Typical torque/rotation tests, creep testing and bone screw testing are easy to configure using the powerful test creation tools. Alternatively, test engineers can save development time and effort by turning to experience MTS consultants for custom TestSuite methods.

TestSuite TW software also has a suite of prepackaged torsion test methods to help users quickly and easily meet the requirements of established orthopaedic and medical device testing standards, such as ASTM A938 (testing of wire), ASTM F543 and ISO 6475 (mechanical testing of medical bone screws).

OTHER APPLICABLE STANDARDS

The following standards serve as additional reference for this application	
ASTM E8	Standard Test Method for Tension Testing of Metallic Materials
ASTM E4	Standard Practices for Force Verification of Testing Machines
ISO 6892	Tensile Testing of Metallic Materials at Ambient Temperature
ISO 5835	Implants for surgery – Metal bone screws with hexagonal drive connection, spherical under-surface of head, asymmetrical thread – Dimensions
ISO 6475	Implants for surgery – Metal bone screws with asymmetrical thread and spherical under-surface – Mechanical requirements and test methods
ISO 9268	Implants for surgery – Metal bone screws with conical under-surface of head – Dimensions

*NOTE: This technical note is intended to show one solution used for this particular application. Most often additional options are available and necessary to accomplish your more comprehensive test objectives.



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