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# Standard Test Methods for Sacroiliac Joint Fusion Devices[1]

This standard is issued under the fixed designation F3574; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

## 1. Scope

1.1 These test methods cover the materials and methods for the static and dynamic testing of sacroiliac joint (SIJ) fusion device assemblies, SIJ implants designed to promote arthrodesis at the sacroiliac joint.

1.2 These test methods are intended to provide a basis for the mechanical comparison among past, present, and future nonbiologic SIJ fusion device assemblies. These test methods allow for comparison of SIJ fusion device assemblies intended to be implanted with a trajectory in line with the joint space (in-line implant) or for comparison of SIJ fusion devices intended for implantation across the joint space (transverse implant). These test methods are intended enable the user to compare SIJ fusion device assemblies mechanically and do not purport to provide performance standards for SIJ fusion device assemblies.

1.3 These tests describe static and dynamic tests by specifying force types and specific methods of applying these forces. These tests are designed to allow for the comparative evaluation of SIJ device assemblies.

1.4 Guidelines are established for measuring displacements, determining the yield force or moment, and evaluating the stiffness and strength of the SIJ fusion device assemblies.

1.5 Some SIJ fusion device assemblies may not be testable in all test configurations.

1.6 The values stated in SI units are to be regarded as standard. No other units of measurements are included in this standard, with the exception of angular measurements, which may be reported in terms of either degrees or radians.

1.7 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety, health, and environmental practices and determine the applicability of regulatory limitations prior to use.*

1.8 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

## 2. Referenced Documents

2.1 *ASTM Standards:*[2]

E4 Practices for Force Calibration and Verification of Testing Machines

E6 Terminology Relating to Methods of Mechanical Testing

E691 Practice for Conducting an Interlaboratory Study to Determine the Precision of a Test Method

E1823 Terminology Relating to Fatigue and Fracture Testing

E2309/E2309M Practices for Verification of Displacement Measuring Systems and Devices Used in Material Testing Machines

F543 Specification and Test Methods for Metallic Medical Bone Screws

F1582 Terminology Relating to Spinal Implants

F1839 Specification for Rigid Polyurethane Foam for Use as a Standard Material for Testing Orthopaedic Devices and Instruments

F2077 Test Methods For Intervertebral Body Fusion Devices

F2193 Specifications and Test Methods for Components Used in the Surgical Fixation of the Spinal Skeletal System

## 3. Terminology

3.1 For definitions of terms, refer to Terminologies E6, E1823, and F1582, and the Terminology section in Specifications F543 and F2193.

3.2 *Definitions of Terms Specific to This Standard:*

3.2.1 *axial pullout strength, n*—the maximum tensile force per Annex A2 required to fail or remove a transverse sacroiliac joint fusion implant from a material into which the device has been inserted.

3.2.2 *bending fatigue runout moment (N-m), n*—value of the maximum moment under dynamic cantilever bending per

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[2] For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

Annex A2 that can be applied to a transverse sacroiliac joint fusion implant where all the tested specimens have experienced 2 500 000 loading cycles without a failure at a specific R-ratio.

3.2.3 *bending moment arm, L (mm), n*—distance in mm between the point where a transverse sacroiliac joint fusion implant test specimen is gripped (typically the axis of the longitudinal element) and the line of action for the applied force in cantilever bending per Annex A2 prior to any deformation of the assembly.

3.2.4 *bending stiffness, S (N/mm), n*—slope of the initial linear elastic portion of the load versus total displacement curve (slope of Line *Om* in Fig. A1.3) for static cantilever bending of a transverse sacroiliac joint fusion implant.

3.2.5 *bending ultimate moment (N-m), n*—maximum bending moment in static cantilever bending that can be applied to a transverse sacroiliac joint fusion implant test sample; Point *E* in Fig. A1.3.

3.2.6 *bending yield moment (N-m), n*—bending moment in static cantilever bending necessary to produce a 0.2 % offset displacement in the transverse sacroiliac joint fusion implant. If the specimen fractures before the test reaches the 0.2 % offset displacement point, the bending moment shall be defined as the bending moment at fracture.

3.2.7 *coordinate system/axes (in-line implants), n*—three orthogonal axes for an in-line SIJ fusion implant are defined in terms of the joint space and the implant design (Figs. 1-4). The origin of the in-line SIJ coordinate system is located at the geometric center of the device assembly. The X-axis corresponds to the trajectory of the implant. The Y-axis passes tangentially through the joint space. The Z-axis passes normal to the joint space. The XY plane is to bisect the joint space between iliac (lateral) and sacral (medial) surfaces. Force components parallel to the XY plane are shear components of loading. Torsional force is defined to be the component of moment about the Z-axis.

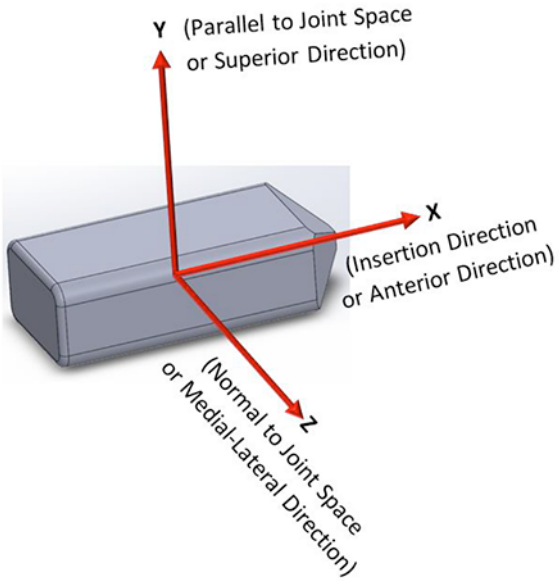


**FIG. 1 Orthogonal Coordinate System for Testing of an In-Line SIJ Fusion Implant**

3.2.8 *coordinate system/axes (transverse implants), n*—three orthogonal axes for a transverse SIJ fusion implant are defined in terms of the implant design and the joint space (Fig. 5). The origin of the transverse SIJ coordinate system is located at the geometric center of the device assembly. The X-axis corresponds to the long axis of the implant in the direction of trajectory. The Y passes in the superior-inferior direction through a plane parallel to the plane tangential to the joint space. The Z-axis is the resultant axis dependent on the implant trajectory. Torsional force is defined to be the component of moment about the X-axis.

3.2.9 *core diameter, n*—the smallest diameter of the threaded portion of a threaded transverse sacroiliac joint fusion implant measured at the thread root. This is also known as the minor diameter.

3.2.10 *crack, n*—an externally visible physical discontinuity in the form of a narrow opening that arises from mechanical forces.

3.2.11 *fatigue life, n*—the number of cycles, *N*, that the SIJ fusion device assembly can sustain at a particular force or moment before mechanical or functional failure.

3.2.12 *force point, n*—the point through which the resultant force on the SIJ device passes.

3.2.13 *functional failure, n*—permanent deformation that renders the SIJ fusion device assembly ineffective or unable to resist force and/or maintain attachment adequately.

3.2.14 *gauge length, n*—the distance between the holding device (for example, a split collet) and the underside of the head for a transverse sacroiliac joint fusion implant in torsional testing.

3.2.15 *grip length, n*—the number of threads held fast in the split collet or holding mechanism during torsional testing of a transverse sacroiliac joint fusion implant.

3.2.16 *ideal insertion location, n*—the implant location with respect to the simulated ilium (lateral) and sacrum (medial) articulating surfaces (bone cement) dictated by the type, design, and manufacturer's surgical installation instructions.

3.2.17 *in-line implant, n*—a device intended to be implanted with a trajectory primarily within the sacroiliac joint space (Figs. 1-4); this kind of device may have integrated fixation (that is, screws, blades) into the sacrum and ilium.

3.2.18 *insertion depth, n*—the length of a transverse sacroiliac joint fusion implant that is inserted into the test block for axial pullout testing.

3.2.19 *intended method of application, n*—SIJ fusion device assemblies may contain different types of stabilizing anchors such as threads, spikes, and knurled surfaces. Each type of anchor has an intended method of application or attachment to the sacral and iliac bones.

3.2.20 *intended SIJ location, n*—the anatomic region of the sacroiliac joint intended for the SIJ fusion device assembly. SIJ fusion device assemblies may be designed and developed for specific anatomical regions such as primarily within the joint space or across the joint space. Also, there exist different