Designation: F3574 – 22

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

[1] These test methods are under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devices and are the direct responsibility of Subcommittee F04.25 on Spinal Devices.

Current edition approved June 1, 2022. Published June 2022. DOI: 10.1520/F3574-22.

[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.