Designation: F3292 – 19

Standard Practice for Inspection of Spinal Implants Undergoing Testing[1]

This standard is issued under the fixed designation F3292; 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 This practice provides guidance for non-destructive photographic analysis of spinal implants prior to, during, and after testing. The purpose of this practice is to provide methods for documenting notable changes in implant characteristics (e.g., surface defects, cracks, plastic deformation) that have occurred during the course of a mechanical test. Documenting these changes may assist in understanding if mechanical failure has occurred, and how.

1.2 *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.*

1.3 *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]

F1582 Terminology Relating to Spinal Implants

F1717 Test Methods for Spinal Implant Constructs in a Vertebrectomy Model

F1798 Test Method for Evaluating the Static and Fatigue Properties of Interconnection Mechanisms and Subassemblies Used in Spinal Arthrodesis Implants

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

F2267 Test Method for Measuring Load Induced Subsidence of Intervertebral Body Fusion Device Under Static Axial Compression

F2346 Test Methods for Static and Dynamic Characterization of Spinal Artificial Discs

F2423 Guide for Functional, Kinematic, and Wear Assessment of Total Disc Prostheses

F2624 Test Method for Static, Dynamic, and Wear Assessment of Extra-Discal Single Level Spinal Constructs

F2694 Practice for Functional and Wear Evaluation of Motion-Preserving Lumbar Total Facet Prostheses

F2706 Test Methods for Occipital-Cervical and Occipital-Cervical-Thoracic Spinal Implant Constructs in a Vertebrectomy Model

F2789 Guide for Mechanical and Functional Characterization of Nucleus Devices

F2790 Practice for Static and Dynamic Characterization of Motion Preserving Lumbar Total Facet Prostheses

3. Terminology

3.1 *Definitions of Terms Specific to This Standard:*

3.1.1 *areas of interest, n*—regions of the implant identified by the user to be inspected. Note that all areas may not be easily visualized by the naked eye (e.g., mating surfaces, holes, internal components).

3.1.2 *failure mode, n*—how the test specimen physically failed, (e.g., fracture, plastic deformation, wear).

3.1.3 *feature, n*—a specific part of a test specimen, such as a crack, bend, scratch, vacancy, bulge, etc.

3.1.4 *mechanical failure, n*—the onset of a material defect, initiation of a fatigue crack, or failure to maintain construct integrity (e.g., polyaxial screw slippage).

3.1.5 *test specimen, n*—an individual spinal implant or a collection of parts that have been or are intended to be used or tested together as an assembled spinal implant construct.

4. Summary of Practice

4.1 This practice provides guidance for evaluating and documenting physical changes in spinal devices tested according to other ASTM standards under the jurisdiction of Subcommittee F04.25.[1]

4.2 This practice does not determine if a failure has occurred.

[1] This test method is under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.25 on Spinal Devices.

Current edition approved March 1, 2019. Published April 2019. DOI: 10.1520/F3292-19.

[2] The boldface numbers in parentheses refer to a list of references at the end of this standard.

5. Significance and Use

5.1 ASTM standards under the jurisdiction of Subcommittee F04.25 (such as, Test Methods F1717, F1798, F2077, F2267, F2346, F2624, and F2706, Specifications and Test Methods F2193, Guides F2423 and F2789, Practices F2694 and F2790) describe test methods and prescribe guidelines for evaluating different types of spinal implants (as defined in Terminology F1582). Adherence to many of these standards may result in mechanical failure. In some cases, however, the failure may not be obvious. Because none of these standards discuss, describe, or provide methods for inspecting the devices for failure, this practice provides guidelines for inspection such that the end user can effectively identify and characterize physical changes in test parts.

5.2 The reporting of a mechanical failure and/or changes in device characteristics is one source of error in precision and bias. Varying levels and types of characterization have the potential to affect data reporting. This practice may reduce bias by providing guidance that can aid in effectively analyzing changes in test parts.

5.3 Non-destructive evaluation allows continued testing of a specimen if performed mid-test and preserves the specimen for post-test examination. Examination may also be limited to non-destructive evaluation in a limited permission environment.

6. Apparatus

6.1 For visual inspection, equipment must be able to provide the right kind and amount of lighting, and an image size with sufficient pixel density (magnification).

6.2 *Equipment:*

6.2.1 *Appropriate Lighting.*

6.2.2 *Non-marring Forceps (or Similar Instrument)*, for handling test specimens.

6.2.3 *Stereomicroscope.*

6.3 *Image Acquisition:*

6.3.1 *Digital Camera and/or Digital Microscope.*

7. Procedure

7.1 *General:*

7.1.1 Inspect/examine each test specimen using a stereomicroscope with a minimum of 10× magnification to explore any areas of interest. Note that by use of the terms “inspect” and/or ”examine,” the standard dictates a practice of surveying the entire test specimen before any images are captured. If a failure can be seen at 10×, then an appropriate magnification shall be used to capture/photograph/document the defect. While inspection/examination occurs at 10×, the user of this practice must determine the appropriate magnification to adequately and clearly capture/photograph/document any areas of interest. For example, 2.5× magnification may be adequate for documenting a gross failure, while 10× magnification may be required for documenting a fatigue crack.

7.1.2 All photographic records of test specimens must have either a scale contained in the image, or a fixture, entire component, or similar reference of known size.

7.1.3 The investigator may introduce fixtures in order to alter the orientation of the constructs to optimize visualization. The fixtures should not be used in such a way that would initiate or cause additional plastic deformation (for example, clamping).

7.2 *Pre-test Inspection:*

7.2.1 If the implants are packaged and labeled “For Clinical Use,” then Section is optional.

NOTE 1—The rationale for not including further pre-test inspection for these implants is due to the prior final inspection as part of the manufacturing process.

7.2.2 Inspect each test specimen according to . Note any plastic deformations, machine/surface markings, or any additional anomalies that are of interest prior to testing.

7.2.3 At a minimum, a pre-test specimen image shall be taken using a digital camera or a digital camera mounted on a stereomicroscope, or equivalent, to capture the overall condition of each test specimen or representative specimen prior to testing.

7.2.4 Capture additional images of areas of interest for documentation.

NOTE 2—Since this is a pre-inspection image capture, the user should capture images that represent the pre-test disposition of the test specimen, with particular attention to areas of predicted or probable failure.

7.3 *During Testing:*

7.3.1 While it is not recommended to remove test specimens during testing (unless specifically directed to do so under the test methods section for the particular standard), the investigators should make an effort to identify any abnormalities that may be present during testing, for example, debris, screw rotation, screw pull-out, crack initiations, fractures. To the degree possible, inspect and document the test specimen according to 7.1.

NOTE 3—Depending on the test set up and fixtures employed, obtaining 10× magnification may not be possible.

7.3.2 In the event that the investigator notes any abnormalities prior to removing the test specimen from the test frame, an image using a digital camera will be taken in order to capture the overall condition of each test specimen. This image may or may not be with magnification.

7.3.3 The investigator shall determine the frequency and timing of any digital images that should be taken during testing.

7.3.4 A high speed video camera focused on areas of interest, while not required, may be useful to understand and document specimen failure.

7.3.5 If for any reason the test is stopped, the post-test procedure should be followed, as outlined in 7.4.

7.4 *Post-Test Procedure:*

7.4.1 Each test specimen shall be visually inspected according to 7.3.1 on the test frame prior to removal.

7.4.2 Care shall be taken to identify any abnormalities that may be affected by removing the test specimen (for example, debris, screw rotation, screw pull-out, fractures, etc.).

7.4.3 Any noted abnormalities shall be recorded for the final report.