



Designation: F3690 – 24

Standard Test Method for Evaluating Suture Anchor Insertion and Pull Displacement Resistance¹

This standard is issued under the fixed designation F3690; 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 test method provides mechanical performance considerations and standard test methods for measuring basic properties of suture anchors that are implanted into bone. The suture anchors that may be evaluated by this test standard can have varying designs such as “all-suture” anchors (in which the device is made completely of monofilament or multifilament braided wire, tape, or any kind of flexible yarn), or multi-component anchors, such as those which have an anchor body intended for implantation in the bone and separate suture component (for example, threaded anchor, impact anchor, expandable anchors).

1.2 This standard does not address testing methods for absorbable or degradable devices (including anchors and/or sutures). This standard does not address testing methods for device removal or evaluation of device removal risks. The insertion verification testing presented in this standard does not address end user validation testing or usability testing/human factors testing which may need to replicate the operating environment (for example, visualization, knot tying under exposure to biological fluids). Multiple test methods are included in this standard for basic characterization. However, the test types in this standard may not address all end user/customer needs that are important for development of your suture anchor (for example, abrasion testing to evaluate the performance of the anchor/suture interface, characterization of insertion torque or force relative to human factors). The user is not necessarily obligated to use only the tests identified in this standard, nor are they obligated to test their device using all of the described methods. Instead, the user should only select, with justification, test methods that are appropriate for a particular device design. This may only be a subset of the test methods described herein. This test method does not address the evaluation of other soft tissue fixation devices including but not limited to interference screws or cortical buttons.

1.3 The values stated in SI units are to be regarded as standard. No other units of measurement are included in this standard.

1.4 Optional acceptance criteria are also presented within this standard for fatigue testing of anchors that is consistent with protected post-operative loading simulations of successful devices present in the literature. Optional acceptance criteria are also presented for anchor insertion testing which identify reasonable bone foam substrates to represent healthy bone. However, the user is not obligated to test their device to the acceptance criteria presented in the annexes. Users of this test method may instead use other well-supported justifications to demonstrate why the device’s insertion and tensile verification testing performance is acceptable for clinical use.

1.5 *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.*

1.6 *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
- E122 Practice for Calculating Sample Size to Estimate, With Specified Precision, the Average for a Characteristic of a Lot or Process
- F543 Specification and Test Methods for Metallic Medical Bone Screws
- F1839 Specification for Rigid Polyurethane Foam for Use as a Standard Material for Testing Orthopaedic Devices and Instruments

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 F04.21 on Osteosynthesis.

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

2.2 ISO Standards:³

ISO 1099 Metallic materials—Fatigue testing—Axial force-controlled method

ISO 7500-1 Metallic materials—Calibration and verification of static uniaxial testing machines—Part 1: Tension/compression testing machines—Calibration and verification of the force-measuring system

ISO 14602 Non-active surgical implants—Implants for osteosynthesis—Particular Requirements

ISO 14630 Non-active surgical implants—General requirements

ISO 14971 Medical devices—Application of risk management to medical devices

ISO 23788 Metallic materials—Verification of the alignment of fatigue testing machines

3. Terminology

3.1 Definitions of Terms Specific to This Standard:

3.1.1 0.1 mm offset yield load—yield load determined from the intersection of the load-displacement curve and a 0.1 mm offset line parallel to the linear portion of the load-displacement curve, representing the onset of plastic deformation when tested as described in **Annex A2**.

3.1.2 3 mm displacement load—the maximum load incurred by a suture anchor sample at or prior to a total displacement of 3 mm, potentially including contributions from both cyclic and static loading when tested as described in **Annex A2**.

3.1.3 cyclic displacement—the amount of plastic deformation that occurs within a suture anchor/foam block construct during cyclic loading when tested as described in **Annex A2**.

3.1.4 gage length—the minimum distance of the suture loop between the test machine grip and the test block or proximal surface of the anchor, whichever is closer to the grip.

3.1.5 insertion depth—the anchor length as inserted into the test block. This is measured as the length from the distal tip of the fully deployed anchor to the surface of the test block. Unless otherwise indicated in the manufacturer's instructions for use, suture anchors should be inserted until the proximal surface is flush with the surface of the test block.

3.1.6 maximum load—the tensile force required to fail or remove an anchor from a test block into which the suture anchor has been inserted when tested as described in **Annex A2**.

3.1.7 pilot hole—the hole created into the test block into which the suture anchor is inserted. Pilot holes may be created by the use of appropriate instrumentation such as either drills, awl/punch, or taps. The pilot hole is normally slightly smaller than the anchor's diameter. Not all suture anchors utilize pilot holes.

3.1.8 R-ratio—the algebraic ratio relating the minimum and maximum values of the loading parameters of a fatigue cycle. For the purposes of this test method, the R-ratio is defined as:

$$R = \frac{\text{minimum tensile load}}{\text{maximum tensile load}}$$

³ Available from American National Standards Institute (ANSI), 1180 Avenue of the Americas, 10th Floor, New York, NY 10036, <http://www.ansi.org>.

3.1.9 suture—monofilament or multifilament braided wire, tape, or any kind of flexible yarn intended for the fixation of soft tissues. The shape may be round or flat (for example, tapes are a subset of suture).

3.1.10 suture anchor—orthopedic implants used in the appendicular skeleton, intended for fixing soft tissues (for example, ligament and tendon) to the bone in various anatomical locations. The connection between these soft and hard tissues is provided by tying or cinching a suture to the soft tissue and approximating it to the bone or to a bone-anchoring component. Suture anchors are designed to be used with sutures. Sutures can either be provided together with the anchor, or anchors can be for use with a suture that is specified by the user. For the purpose of this standard, any suture that remains in the test block once inserted is considered part of the suture anchor (for example, “all-suture” anchors). Different suture anchor designs and different numbers of suture anchors may be suitable for use in different anatomical sites. A non-exhaustive list of suture anchor types is: threaded anchors, impact anchors, expandable anchors, all-suture anchors, knotted anchors, and knotless anchors.

4. Summary of Test Method

4.1 Two test methods are described in the annexes as follows:

4.1.1 Annex A1—Test Method for Determining Suture Anchor Insertion Performance. Anchors shall be inserted perpendicular to the surface of a bone substrate block using the specified surgical technique. For anchors that require a pilot hole, those anchors may also be tested for off-axis insertion. Reporting for the test includes test setup and insertion survival pass/fail.

4.1.2 Annex A2—Test Method for Determining Suture Anchor Tensile Performance (Cyclic and Static Performance). Anchors are inserted perpendicular to the surface of a bone substrate block to create a test specimen and the block is secured to a fixture. The suture is connected to a tensile test machine with minimal knot tying. An implant test specimen is cyclically loaded for at least 500 cycles while monitoring displacement (3 mm max). An implant test specimen is loaded in static tension until failure. Users may choose independent fatigue and static test specimens or test specimens that are tested sequentially in both fatigue and static testing (that is, test specimens that survive cyclic testing may also be evaluated in static tensile testing until failure). Reporting for the test includes test setup, 500 cycle load, and displacement during cyclic loading and static loading until failure.

5. Significance and Use

5.1 See **Annex A1** and **Annex A2** for the significance and use for the insertion and pullout testing methods, respectively.

6. Apparatus

6.1 See **Annex A1** and **Annex A2** for the apparatus descriptions for the insertion and pullout testing methods, respectively.

7. Procedure

7.1 See **Annex A1** and **Annex A2** for the procedure for the insertion and pullout testing methods, respectively.

8. Report

8.1 See [Annex A1](#) and [Annex A2](#) for the reporting descriptions for the insertion and pullout testing methods, respectively.

9. Precision and Bias

9.1 See [Annex A1](#) and [Annex A2](#) for the precision and bias of the insertion and pullout testing methods, respectively.

10. Rationale

10.1 These test methods cover the evaluation of insertion and tensile performance for suture anchors. Even though suture anchors may reside in the body for many years, their purpose is to provide short-term re-approximation of soft tissue to bone while healing occurs under low loads and motion constraint. Hence, these test methods do not address the long-term mechanical stability of suture anchors, nor do they address bioresorption. The choice of a minimum of 500 cycles for the fatigue testing is somewhat arbitrary but is consistent with the literature and the goal of characterizing the short-term properties of suture anchors.

10.2 These test methods outline basic evaluations of suture anchors and their ability to maintain relative position/resist displacement. They do not address all aspects of soft tissue approximation, nor do they address every unique aspect of particular implant designs. The purpose of these test methods is to provide a basic framework of tests which can be used to compare different implant designs in a consistent manner.

10.3 Axial insertion is prescribed for all anchors to confirm if an anchor system (that is, both implant and their instruments)

is able to achieve implantation in bone. However, since surgeons may need to change their anchor's trajectory during insertion (for example, sclerotic bone present), a non-axial insertion method is also available to assess if implantation can be achieved when the implant is not aligned with the pilot hole.

10.4 Uniaxial loads and moments are applied in this tensile test method, as multiaxial loading conditions *in vivo* are not yet fully defined. The use of co-axial tensile loading relative to the insertion axis is appropriate to standardize and also presents a reasonable worst-case assumption for post-operative loading. The methods outlined here are considered minimum test conditions, and more sophisticated tests are appropriate if deemed relevant such as suture abrasion from multiaxial loading.

10.5 The tensile testing cycle rate is not specified since it is dependent on the test machine and the specimen. However, a recommended maximum is 1 Hz due to the potentially large displacements involved.

10.6 Depending on the intent of the investigator, different numbers of specimens may be necessary to establish a meaningful sample size or to demonstrate acceptable tensile performance for the labeled clinical application (for example, comparison to a device with known performance). Hence, these test methods do not specify the number of specimens to be tested.

11. Keywords

11.1 fatigue; insertion; pullout; soft tissue; static; suture anchor; test method

ANNEXES

(Mandatory Information)

A1. TEST METHOD FOR DETERMINING SUTURE ANCHOR INSERTION ACHIEVEMENT

A1.1 Significance and Use

A1.1.1 This test method is a qualitative verification for hand insertion of the suture anchors which can be used to confirm the acceptability of the implants, instruments, and surgical technique to achieve successful implantation into a worst-case grade of healthy bone substrate. This test method also allows for qualitative evaluation of an implant and its instrumentation to achieve non-axial insertion (for example, patient anatomy and/or surgeon human factors). The results obtained in this test method are not intended to replace implant system design validation nor to predict *in vivo* performance (see [X2.2](#) for further information).

A1.2 Apparatus

A1.2.1 The test block shall be fabricated from a material that conforms to Specification [F1839](#). The top and bottom surfaces shall be flat, smooth, and parallel as required to ensure that the test block will be supported in the fixture with the top surface perpendicular to the centerline of the test specimen.

The edges of the test block shall be of such contour or squareness as required to ensure that the test block clamp shall hold the test block free of relative motion without deformation of the test block during clamping or testing. The test block thickness shall not be less than 1.25× the length of the deployed anchor or pilot hole, whichever is longer. Specification [F1839](#) is intended to simulate single-phase bone. However, biphasic materials can be used to simulate both the worst-case cortical bone and cancellous bone expected for specific anatomical locations. For example, the humeral head has a distinct cortical layer and underlying softer cancellous region that is appropriate for biphasic material selection, whereas the glenoid face and neck have a more uniform bone density and is therefore better suited for a monolithic test block. Recommendations for foam grades for various indications are included in [Appendix X2](#).

A1.2.2 *Pilot Holes in Test Block*—If in accordance with the manufacturer's surgical technique, pilot holes shall be prepared with the appropriate instrumentation

insertion of the test specimen. The drill/awl/tap diameter used shall be that specified by the anchor manufacturer for the size anchor and bone density being tested. Pilot holes will be created perpendicular to the top surface of the test block with a length of at least $5\times$ the diameter of the anchor from the edge (or less than $5\times$ the diameter if justified to not impact the results).

A1.2.2.1 If there are multiple holes in one test block, the pilot holes should be spaced a minimum distance of $5\times$ the diameter of the anchor (as recommended in A1.2.2) from each other just as is recommended in Specification F543. Smaller separation distances may be justified to demonstrate that performance is not affected by the neighboring specimens.

A1.2.2.2 For axial insertion, the suture anchor shall be perpendicular to the top surface of the test block (and therefore coaxial with the pilot hole, if one exists).

A1.2.2.3 For off-axis insertion, the suture anchor shall be 15° misaligned from the pilot hole created in the test block in the test fixture (Fig. A1.1). This is based on the difference between insertion angles in a meta-analysis where the majority of researchers inserted anchors at the ideal angle, but several researchers used an angle 15° off from this ideal (1).⁴ A 15° amount of placement error allows for some assessment of

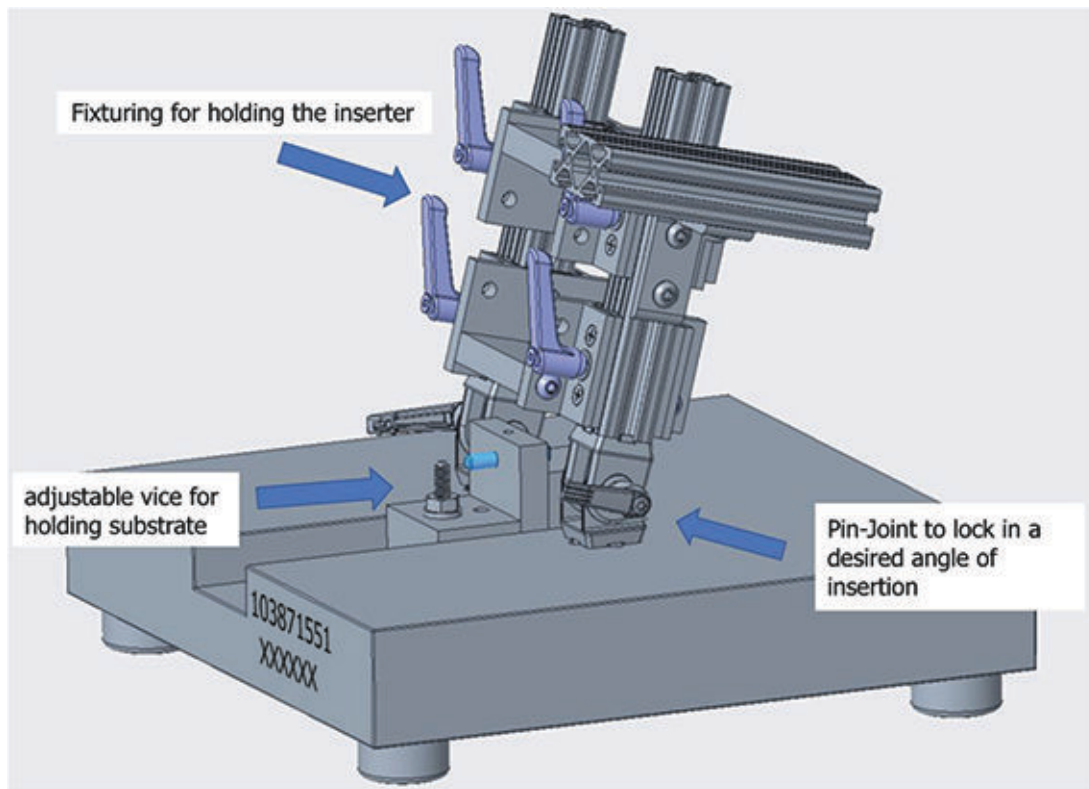
improper placement due to human factors, and this amount of malalignment is consistent with error in surgical hand placement of other osteosynthesis devices, like variable angle locking screws used in fracture fixation plates. Off-axis insertion is not required for suture anchors that do not utilize a pilot hole. In general, the suture anchor may have any orientation as long as it is at the correct angle to the pilot hole; however, some designs might require that a specific orientation is required in order to test the worst-case scenario.

A1.3 Sampling/Specimen Selection

A1.3.1 The test specimen shall be a production equivalent suture anchor and inserter. When considering a particular suture anchor diameter and type, the size should be selected to allow for the most contact between the substrate and the device to establish worst-case conditions. Depending on the suture anchor design and indications, it may be necessary to test more than one size. For example, the largest size anchor might have the highest frictional forces, but smaller anchors might have thinner walls, which could make them more susceptible to fracture when inserting.

A1.3.2 Representative random samples may be taken from each lot or processing quantity in accordance with Practice E122.

⁴ The boldface numbers in parentheses refer to a list of references at the end of this standard.



The test setup uses a pin joint to allow for manipulation of the fixturing angle relative to the test block prior to stabilizing the angle in place for testing.

FIG. A1.1 Sample Off-Axis Test Fixture