



Standard Test Method for Driving Torque of Medical Bone Screws¹

This standard is issued under the fixed designation F 117; 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.

ε¹ NOTE—Editorial corrections have been made throughout in June 1996.

1. Scope

1.1 This test method establishes the recommended type of test fixtures and specimen for determining the standardized insertion torque of medical bone screws.

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 and health practices and determine the applicability of regulatory limitations prior to use.*

2. Referenced Documents

2.1 ASTM Standards:

E 122 Practice for Choice of Sample Size to Estimate the Average Quality of a Lot or Process²

3. Terminology

3.1 Definitions:

3.1.1 *insertion torque*—the amount of torque required to overcome the frictional force between screw and the material used for testing while driving the screw into the material (for example, clockwise rotation for a right-hand thread).

3.1.2 *removal torque*—the amount of torque required to overcome the frictional force between screw and the material used for testing while removing the screw from the material (for example, counter-clockwise rotation for right-hand thread).

4. Summary of Test Method

4.1 Determination of Driving Torque and Removal Torque:

This test method measures the insertion and removal torque as a bone screw is inserted and removed from a standard material. The material is prepared (drilled and tapped) in accordance with manufacturer's instruction for bone preparation.

5. Significance and Use

5.1 This test method is used to measure the torque required to drive a bone screw into a standard material as reported in

9.1.6. The results obtained in this test method bear no direct correlation to the insertion torque required to insert the subject bone screw in human or animal bone. This test method is used only for purposes of maintaining the uniformity of the product tested.

6. Apparatus

6.1 *Testing Fixture*—A suitable testing fixture shall be provided for conducting the test. It should incorporate the functions illustrated in Fig. 1 for the insertion-removal torque tests. It shall be sufficiently rigid to not deflect or deform under the conditions of loading encountered during the test.

6.2 *Torque Wrench*—A motor driven torque wrench capable of applying the torsional force at a constant rate of three revolutions per min.

6.3 *Torque Transducer*—A suitable transducer to translate the mechanical parameter of torque, both in the clockwise and counter-clockwise rotation, into an electrical signal amenable to continuous recording with an X-Y plotter.

6.4 *Potentiometer*—A variable resistance electrical component that changes resistance proportionally to the rotation of the armature, via a pulley, of the torque wrench. Other systems that can measure a minimum of two degrees may be used.

6.5 *DC Voltage Supply*—Used to supply a constant voltage supply to the potentiometer.

6.6 *X-Y Plotter*—A suitable recorder to plot torque vs. angle of rotation. This plot shall be calibrated in units of pounds-force-inches or newton-meters for torque and degrees for angle of rotation. The value of torque shall have a resolution of 10 % of the maximum measured torque. The angular displacement scale shall have a sensitivity such that at least four revolutions can be recorded on normal graph paper.

6.7 *Bushing*—A suitable replaceable bushing shall be incorporated into the testing fixture. This bushing shall be of sufficient length and rigidity to ensure that specimens are driven into the test block at an angle of 90° to the top surface of the test block. The bore of the bushing shall be of such dimension as to ensure guidance of the test specimen with minimum frictional resistance between the major diameter of the test specimen and the bore of the bushing. Worn bushings shall be discarded and replaced with new bushings before conducting the test.

6.8 *Test Block Clamp*—A clamp or holding device shall be incorporated into the testing fixture. This holding device shall

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² *Annual Book of ASTM Standards*, Vol 14.02.

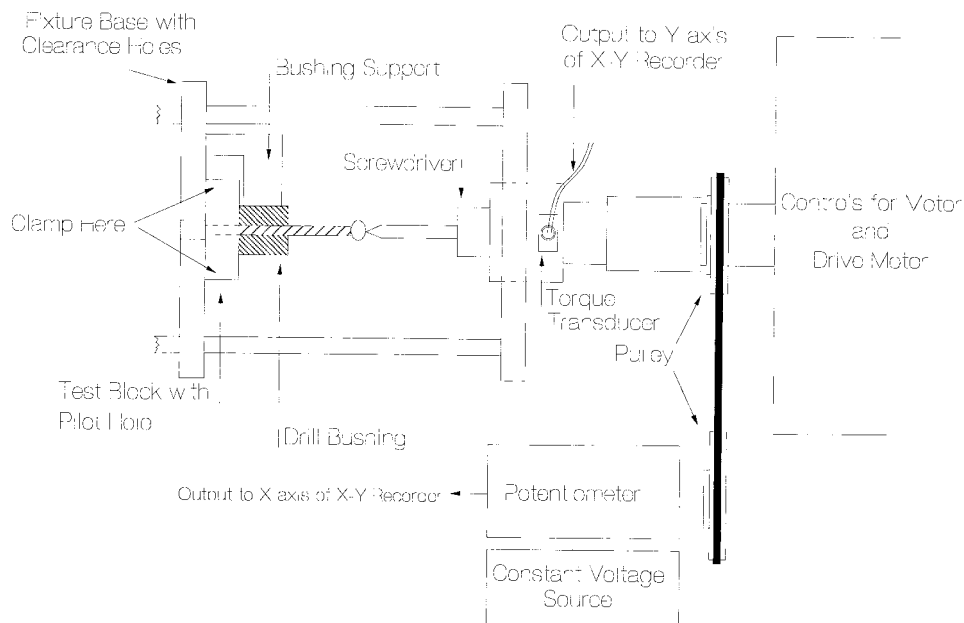


FIG. 1 Apparatus for Insertion and Removal Torque Procedure

maintain the drilled pilot hole in the test block in line with the test specimen. The holding device shall not deform the test block during clamping of the test block or performance of the test.

6.9 *Test Specimen*—The test specimen shall be a completely fabricated and finished bone screw of sufficient length to transverse the bushing and test block.

6.10 *Test Block*—The test block shall be fabricated from a uniform material. The top and bottom surfaces shall be flat, smooth, and parallel (within $\pm 1/64$ in. (0.4 mm)) as required to ensure that the test block will be supported in the fixture with the top surface at an angle of 90° to the center line 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 be not less than $3/16$ in. (4.8 mm).

6.11 *Pilot Holes in Test Block*—Pilot holes shall be drilled in the test block for insertion and removal of the test specimen. The holes shall be drilled with a sharp drill. The drill size used shall be that specified by the screw manufacturer, for the size screw being tested. If specified by the screw manufacturer the specified sized tap shall be used to tap the pilot hole before testing. The holes shall be drilled at 90° to the top surface of the test block. The holes shall be drilled straight and true, free of taper, bell mouth, or barrel shape. If there are multiple holes in one test block, the pilot holes shall be spaced sufficiently far away from test block edges so that testing does not deform test block edges. Spacing should have as minimum distance of 2X the diameter of the screw. When the test block is inserted into the test fixture (Fig. 1), the pilot hole, screw, and screwdriver shall be on the same axis.

7. Sampling

7.1 Representative random samples may be taken from each lot or processing quantity in accordance with Practice E 122.

8. Procedure

8.1 Insertion and Removal Torque:

8.1.1 Place the specimen in the test fixture in the manner illustrated in Fig. 1. Drive the specimen into the test block, using the appropriate size and configured screwdriver bit, by applying a torsional force at a rate of three revolutions per minute, to the head of the specimen with the motor-driven torque wrench. The insertion torque shall be the maximum reading indicated on the X-Y plotter during the initial four revolutions of the specimen. The removal torque will be measured by reversing the direction of rotation and recording the maximum torque reading on the X-Y plotter during the four revolutions required to remove the screw from the test block. Values should be reported in inch-pounds (newton-meters). A2.5 pound (1.14 kgf) or less axial load should be utilized to maintain the screwdriver bit in the screw head during both the insertion and removal procedures. If a larger axial load is applied, this load shall be recorded on the report form. This load may be measured by any appropriate method.

9. Report

9.1 The report shall include the following for each specimen tested: (all standards units for reporting shall be in SI units)

9.1.1 Screw Identification:

Reference any applicable ASTM or ISO standard specification that may apply to the specimen. If specifications do not exist, provide head form, thread form, helix angle, major and minor diameter, thread pitch, overall screw length, head and shank (unthreaded portion of the screw excluding the head) length, and type of screw point.

9.1.2 Screw Chemical Composition,

9.1.3 Surface Finish,

9.1.4 Insertion Torque,

9.1.4.1 Axial load required

9.1.4.2 Insertion depth (may be calculated or measured)

9.1.4.3 Specification of whether the pilot hole was pre-drilled