Designation: F 1874 – 98 (Reapproved 2004)

Standard Test Method for Bend Testing of Needles Used in Surgical Sutures[1]

This standard is issued under the fixed designation F 1874; 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 describes the procedure for bend testing needles used for the placement of surgical sutures.

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:*

F 1840 Terminology for Surgical Suture Needles[2]

3. Terminology

3.1 *Definitions*—Definitions of terms used in this test method are in accordance with Terminology F 1840.

3.2 *Definitions of Terms Specific to This Standard:*

3.2.1 *needle test gripping location, n*—for test methods, the needle will be clamped two-thirds of the distance back from the point of the needle. Since the needle will deform during the bend test, the needle test gripping location only applies to an unbent needle.

3.2.2 *test chord length, n*—the straight line distance from the center of rotation of the needle in the test fixture to the initial point of contact with the bending platform or knife edge.

4. Summary of Test Method

4.1 Surgical needles are grasped approximately two-thirds of the distance from the point of the needle, then bent against a knife edge or platform. The force deflection data obtained from the test will be used to calculate the yield bend moment and the maximum bend moment.

4.2 The decision to use a knife edge or a platform for the bending surface will be determined by the equipment available.

5. Significance and Use

5.1 This test method provides a means of assessing the yield moment and maximum moment of a surgical needle.

5.2 The needle is bent against a platform or knife edge, and it is bent at the approximate location where a pair of needle holders would grip it. This simulates the actual bending of a needle while in surgical use.

6. Apparatus

6.1 *Clamping Fixture*—A device to firmly clamp and rotate the needle.

6.2 *Bending Platform*—The surface on which the curved needle will exert force during the test. The bending platform will have its top surface located along the horizontal axis of the center of rotation of the clamping fixture.

6.3 *Knife Edge*—The knife edge will be placed parallel to the centerline of rotation to provide a single point contact for reading the torque generated by the needle.

6.4 *Data Collection System*—The data will be collected as a function of rotational angle.

6.5 *Rotation Speed*—The clamping fixture must be rotated at a continuous and constant speed. This speed will be less than 30°/s.

7. Sampling

7.1 A sample size of no less than five needles shall be used.

8. Procedure (see Fig. 1)

8.1 Securely clamp the needle into the clamping fixture at a position approximately two-thirds of the distance back from the tip of the needle.

8.2 Rotate the clamping fixture forward until the needle touches the bending platform or knife edge. Continue rotating the clamping fixture through a sufficient angle to generate the required data. While the needle is bending, collect the bending force data as a function of the bend angle.

9. Calculation (see Fig. 2)

9.1 Data will be reported as a moment versus degrees of rotation. Units will be reported.

9.2 *Yield Bend Moment*—Using the graph obtained during the needle bend test, calculate the initial slope of the graph. Draw a line with the same slope through the 2° offset on the

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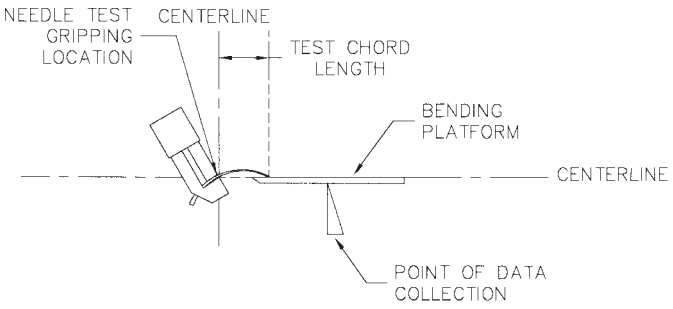
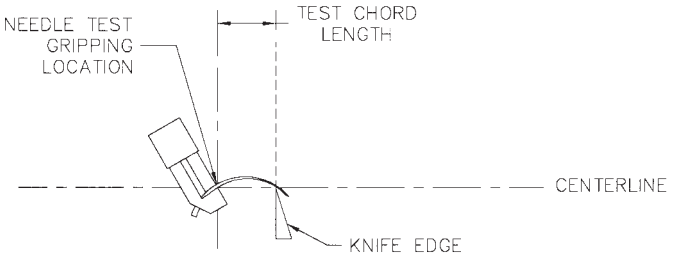
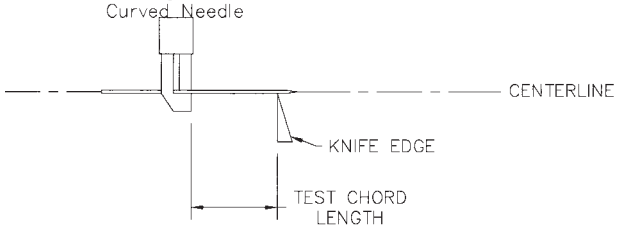
[2] For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.



Platform Bend Test

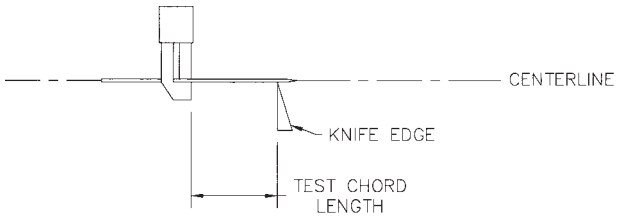


Knife Edge Bend Test
Curved Needle



Knife Edge Bend Test
Straight Needle

FIG. 1 Sample Bend Tests



Knife Edge Bend Test
Straight Needle

FIG. 2 Bend Test Data Curve

degree axis. Read the bending moment at the point where the 2° offset slope crosses the data line. This is the yield bend moment.

9.3 *Yield Bend Angle*—Read the angle at the point where the 2° offset slope line crosses the data line.

9.4 *Maximum Bend Moment*—The maximum bend moment is the largest bending moment achieved by the needle during the bend test.

10. Report

10.1 Include the following information:

10.1.1 Sample identification, test conditions, and apparatus.

10.1.2 Test chord length.

10.1.3 Yield bend moment.

10.1.4 Yield bend angle.

10.1.5 Maximum bend moment (angle at which it was achieved should be reported).

11. Precision and Bias

11.1 *Precision*—The precision of the results of this test method are dependent on the equipment selected.

11.2 *Bias*—No standard material has been selected for reference; therefore, bias for this test method cannot be determined.

12. Keywords

12.1 bend test; needle; strength; surgical; suture

APPENDIX

(Nonmandatory Information)

X1. RATIONALE

X1.1 It is understood that the needle contact with the platform or knife edge will change as the needle is deformed during the test, effecting the value of the test chord length. This is an agreed upon convention by the users of the test.

X1.2 It is understood that the test chord length will be large enough to prevent shear effect on the test and allow measurement of bend moment.

X1.3 When comparing results, it is understood that the test chord lengths will be the same.