



Designation: F3260 – 18

Standard Test Method for Determining the Flexural Stiffness of Medical Textiles¹

This standard is issued under the fixed designation F3260; 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 covers the measurement of flexural stiffness properties of medical textiles (for example, surgical mesh, films, and membranes). Bending length is measured and flexural rigidity is calculated.

1.2 This test method may be used for absorbable or non-absorbable medical textiles.

1.3 This test method measures the flexural stiffness at room temperature in air and, if used directly, may not provide an accurate measure of *in-vivo* behavior for implantable medical textiles.

1.4 This test method is not suitable for testing tubular samples.

1.5 The values stated in SI units are to be regarded as standard. Values in parentheses are for information only.

1.6 *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.*

1.7 *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

D747 Test Method for Apparent Bending Modulus of Plastics by Means of a Cantilever Beam

D1388 Test Method for Stiffness of Fabrics

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 F04.15 on Material Test Methods.

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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.

E141 Practice for Acceptance of Evidence Based on the Results of Probability Sampling

F1635 Test Method for *in vitro* Degradation Testing of Hydrolytically Degradable Polymer Resins and Fabricated Forms for Surgical Implants

3. Terminology

3.1 *Definitions:*

3.1.1 *flexural stiffness, n*—resistance to bending, measured as bending length and flexural rigidity.

3.1.2 *medical textile, n*—a fabric, film, or membrane used for medical purposes that may be woven, knit, braided, felted, or nonwoven.

3.2 *Definitions of Terms Specific to This Standard:*

3.2.1 *back, n*—with regard to textile orientation, (1) the downward facing surface of the textile during manufacture; (2) the inward or downward facing surface of the textile during normal use.

3.2.2 *bending length, n*—*general*—the length of textile that will bend under its own weight to a definite extent; *specific*—the measured length of overhang divided by two (per 11.2) at which the edge of the specimen touches the bend angle indicator per the test method (per 10.6).

3.2.3 *cross-machine direction, CD, n*—the direction in the plane of the textile perpendicular to the direction of manufacture, analogous to the weft direction for knit and woven textiles.

3.2.4 *face, n*—with regard to textile orientation, (1) the upward facing surface of the textile during manufacture; (2) the outward or upward facing surface of the textile during normal use.

3.2.5 *flexural rigidity, n*—the couple on either end of a textile strip of unit width bent into unit curvature.

3.2.6 *machine direction, MD, n*—the direction in the plane of the textile parallel to the direction of manufacture, analogous to the warp direction for knit and woven textiles.

3.2.7 *weight, n*—with regard to textiles, mass per unit area.

4. Summary of Test Method

4.1 A specimen is slid at a specified rate in a direction parallel to its long dimension, until its leading edge projects from the edge of a horizontal surface. The length of the

overhang is measured when the tip of the specimen is depressed under its own mass to the point where the line joining the top to the edge of the platform makes a 0.724 rad (41.5°) angle with the horizontal. From this measured length and the specimen's weight, the bending length and flexural rigidity are calculated.

5. Significance and Use

5.1 Consideration of the flexural stiffness of medical textiles is important, as these devices often need to possess properties that allow them to conform readily to the anatomic structures they are designed to support or protect. This test method outlines the materials and methods for the determination of flexural properties along the different textile directions (that is, machine and cross-machine) and for the effects of textile surface orientation (that is, face and back orientations).

5.2 This test method can be used for quality control purposes.

5.3 This test method can be used for non-absorbable, absorbable, and partially absorbable medical textiles including films and membranes. Testing should be performed on both dry and appropriately conditioned specimens. If the specimen is fabricated from a hydrolytically degradable absorbable material or contains an absorbable component, testing after hydrolytic conditioning at appropriate time intervals should be undertaken using Test Method F1635. For partially absorbable textiles, testing should be performed through at least two time intervals that exceed the point where the absorbable component no longer contributes to the specimen's measurable mechanical properties.

5.4 If flexural rigidity values are found to show effects related to planar and surface orientation, results from this test method could potentially help in determining if devices should be implanted or used only at specific textile directions and surface orientations. Considerations for determining device planar and surface orientations for use would include, but are not limited to, primary direction of bending once implanted or during use, anatomic structures that will interact with the device, and physiologic loads (normal, pathological, and worst-case) the device would experience during use.

5.5 No evidence has been found showing that bending length is dependent on the width. However, the tendency for specimens to curl or twist can affect the result through the rigidity provided at the edge. Consequently, use of test specimens with greater width can help to reduce this edge effect.

5.6 This test method differs from Test Method D1388 in that it requires tracking of sample surface orientation and includes absorbable and partially absorbable medical textiles. Medical textiles with stiffness higher than is measurable using this cantilever bending method should consider evaluation using the cantilever beam method described in Test Method D747.

6. Apparatus

6.1 *Cantilever Bending Tester*³ (Fig. 1):

6.1.1 *Horizontal Platform*, with a minimum area of 38 by 200 mm and having a smooth, low-friction, flat surface such as polished metal or plastic. A linear scale (1-mm divisions) should be included on the front of the platform to allow for measurement of overhang lengths. A leveling bubble shall be incorporated in the platform or movable specimen slide.

6.1.2 *Movable Specimen Slide and Weight*, consisting of a metal bar not less than 25 by 200 mm by approximately 3 mm thick and having a mass of 270 ± 5 g.

6.1.3 *Bend Angle Indicator*, inclined at an angle of 0.724 ± 0.01 rad (41.5 ± 0.5°) below the plane of the horizontal platform surface.

6.1.4 *Leveling Legs*, independently adjustable to ensure that the horizontal platform is level during testing.

6.1.5 *Cutting Die*, 25 ± 1 mm by 200 ± 1 mm (optional; not shown).

6.1.6 *Analytical Balance*, capable of weighing each specimen to within ±0.1 % of mass.

7. Sampling and Test Specimens

7.1 Specimens shall be taken from fully processed, finished products. Specimens should be free of folds, creases, or wrinkles.

³ Apparatus is available commercially.

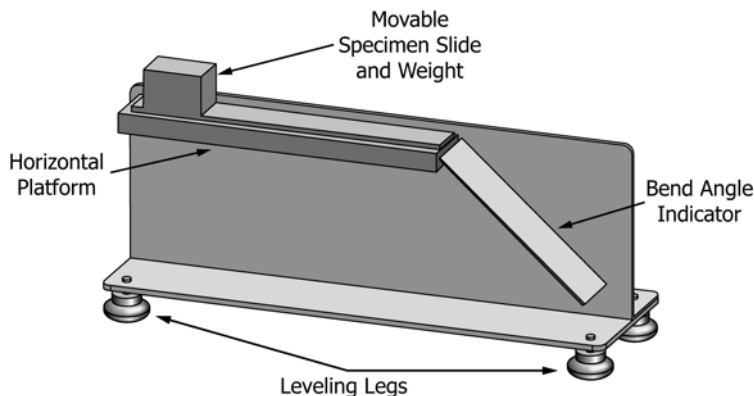


FIG. 1 Example of Cantilever Test Apparatus

NOTE 1—Avoid getting oil, water, grease, etc. on the specimens when handling because they can affect the measured flexural rigidity.

7.1.1 For devices that are too small to provide sufficiently sized specimens or devices that have substantial folds, creases, or wrinkles, specimens may be taken from the uncut textile sheet or roll used in the manufacture of the device. These specimens should be subjected to the same processing (cleaning, sterilization, etc.) experienced by the finished product. Note in the testing report if specimens are taken from uncut textile sheets or rolls.

7.2 Include in the report the number of samples and rationale used for determining the number of samples.

NOTE 2—Practice E141 may be helpful in determining an appropriate sample size.

7.3 *Direction of Test*—The long dimension of the test specimen is the direction of test.

7.4 *Surface Orientation*—The surface orientation of specimens shall be tracked during testing.

NOTE 3—For implantable devices, it is suggested that definition 1 for ‘face’ (see 3.2.4) and ‘back’ (see 3.2.1) is most appropriate. For non-implantable devices, definition 2 is most appropriate.

7.4.1 If the surface orientation is not known based on the provided definitions, the user shall define and maintain consistent surface orientation during testing. For this case, the orientations shall be referred to as top and bottom instead of face and back.

NOTE 4—For example, warp-knit textiles may have one surface that is tactilely rough compared to the other. The user may define the relatively rough surface as the top orientation and the relatively smooth surface as the bottom orientation.

7.5 *Cutting Test Specimens*—Cut the specimens to be used for the measurement of machine direction with the longer dimension parallel to the machine direction. Cut the specimens to be used for the measurement of the cross-machine direction with the longer dimension parallel to the cross-machine direction. Label to maintain specimen identity.

7.5.1 Cut test specimens 25 by 200 ± 1 mm.

7.5.1.1 Deviation from these dimensions is allowed, provided the specimens do not twist or curl substantially at a smaller width and the specimen length is sufficient to allow the specimen to reach the prescribed bend angle for both surface orientations.

7.5.1.2 In no situation shall the test specimen width exceed the working width of the horizontal platform.

8. Preparation of Test Apparatus

8.1 Set the tester on a table or bench and adjust the platform to horizontal as indicated by the leveling bubble.

8.2 Verify that the bend angle indicator is at the 0.724 rad (41.5°) angle marked on the scale.

9. Conditioning

9.1 For testing of non-absorbable textiles, if minor folds, creases, or wrinkles are present, specimens should be pre-conditioned by placing them flat in a standard letter envelope. The envelope should be placed on a flat surface and left

undisturbed for a sufficient time (for example, 7 days) to allow the specimens to flatten. If specimens do not flatten, new specimens may be taken from uncut textile sheets or rolls. Note in the test report if specimens were subjected to this pre-conditioning and for what duration.

9.2 For testing of hydrolytically degradable absorbable textiles, degradation testing should be performed using Test Method F1635. Initial “un-degraded” specimens shall be pre-conditioned in phosphate buffered saline at 37 ± 0.2 °C as specified in Test Method F1635 for at least 1 h before testing. The pre-conditioning time to reach moisture equilibration of the specimen may be as long as 24 h (or more), depending on both the fiber cross-section and the hydrophobic nature of the polymer. Include in the test report the length of the pre-conditioning time period before testing and a rationale for the chosen time period. For partially and fully absorbable textiles, testing should be done on un-degraded specimens and on specimens at intermediate levels of degradation. Note all degradation time points in the test report. Partially absorbable textiles should be tested through at least two time intervals that exceed the point where the absorbable component no longer contributes to the specimen’s measurable mechanical properties. The same sample forms (that is, raw material, processing methods, as-cut dimensions, etc.) should be used for both the dry and appropriately conditioned test specimens.

10. Procedure

10.1 Record the room temperature and relative humidity.

10.2 Weigh each specimen to within ± 0.1 % of its initial mass using a balance with suitable repeatability.

NOTE 5—Using a consistent drying method throughout testing, remove any excess conditioning solution prior to weighing.

10.3 Remove the movable slide. Place the specimen on the horizontal platform, face-side up, with the length of the specimen parallel to the platform edge. Align the leading edge of the specimen with the right-hand edge of the platform (that is, the horizontal platform edge closest to the bend angle indicator) (see Fig. 1).

10.4 Place the movable slide on the specimen, being careful not to change its initial position.

10.5 For automatic testers, turn the tester switch on and watch the leading edge of the specimen closely. Turn the switch off the instant the edge of the specimen touches the bend angle indicator.

10.6 For manual testers, move the specimen slide by hand in a smooth manner at approximately 120 ± 5 % mm/min until the edge of the specimen touches the bend angle indicator.

10.7 Read and record the overhang length from the linear scale to the nearest 1 mm.

NOTE 6—If the specimen has a tendency to twist, take the reference point at the center of the leading edge.

10.8 Repeat 10.2 – 10.6 to test the face and back of both ends of each specimen for a minimum of four readings per specimen. Test the face and back of one specimen end before proceeding to test the face and back of the other end of the specimen.