Designation: F2819 – 10 (Reapproved 2015)ε1

Standard Test Methods for Measurement of Straightness of Bar, Rod, Tubing and Wire to be used for Medical Devices[1]

This standard is issued under the fixed designation F2819; 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 were made in June 2016.

1. Scope

1.1 This standard covers the various test methods to be used for measurement of straightness of bar, rod, tubing, and wire. These test methods apply primarily to bar, rod, tubing, and wire that are ordered in the straightened and cut-to-length condition. They also apply to small diameter tubing and wire that has been specially processed to roll off a spool in the straightened condition.

1.2 These test methods apply to straightness of round wire that has a diameter between 0.05 and 4.78 mm (0.002 and 0.188 in.). They also apply to flatness (camber) of flat-shaped wire or ribbon with a maximum dimension between 0.05 and 4.78 mm (0.002 and 0.188 in.). For flatness (camber) measurement, refer to Test Method F2754/F2754M.

NOTE 1—The current version of Test Method F2754/F2754M covers a different diameter range (0.0127 to 4.78 mm (0.0005 to 0.188 in.)) and does not include superelastic NiTi. These exceptions would not affect the camber measurement as conducted by Test Method F2754/F2754M.

1.3 These test methods apply to straightness of round tubing that has an outer diameter between 0.05 and 6.35 mm (0.002 and 0.25 in.).

1.4 These test methods apply to straightness of round rod that has a diameter between 4.78 and 6.35 mm (0.188 and 0.25 in). It also applies to flatness (camber) of flat and shaped rod with a maximum dimension between 4.78 and 6.35 mm (0.188 and 0.25 in). For measurement of flatness (camber), refer to Test Method F2754/F2754M.

NOTE 2—The current version of Test Method F2754/F2754M covers a different diameter range (0.0127 to 4.78 mm (0.0005 to 0.188 in.)) and does not include superelastic NiTi. These exceptions would not affect the camber measurement as conducted by Test Method F2754/F2754M.

1.5 These test methods apply to straightness of round bar that has a diameter between 6.35 and 101.6 mm (0.25 and 4 in). It also applies to flatness (camber) of flat and shaped bar with a maximum dimension between 6.35 and 101.6 mm (0.25 and 4 in). For measurement of flatness (camber), refer to Test Method F2754/F2754M.

NOTE 3—The current version of Test Method F2754/F2754M covers a different diameter range (0.0127 to 4.78 mm (0.0005 to 0.188 in.)) and does not include superelastic NiTi. These exceptions would not affect the camber measurement as conducted by Test Method F2754/F2754M.

1.6 These test methods apply to ferrous and non-ferrous alloys including linear-elastic or superelastic nitinol. Refer to Terminology F2005 for more details on NiTi terminology.

1.7 The values stated in either SI units or inch-pound units are to be regarded separately as standard. The values stated in each system may not be exact equivalents; therefore, each system shall be used independently of the other. Combining values from the two systems may result in non-conformance with the standard.

1.8 *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:*[2]

F2005 Terminology for Nickel-Titanium Shape Memory Alloys

F2754/F2754M Test Method for Measurement of Camber, Cast, Helix and Direction of Helix of Coiled Wire

2.2 *Other Standards:*[3]

GGG-P-463 U.S. Federal Specification: Plate, Surface (Granite)

[1] These test methods are 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.

Current edition approved May 1, 2015. Published July 2015. Originally approved in 2010. Last previous edition approved in 2010 as F2819 – 10. DOI: 10.1520/F2819–10R15E01.

[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.

[3] Available from IHS, 321 Inverness Drive South Englewood, CO 80112, http://www.global.ihs.com.

3. Terminology

3.1 Fig. 1 and Fig. 2 show the physical meaning of straightness. Fig. 3 shows the definition of wobble in a straight wire or tube as it is being rotated.

3.2 *Definitions of Terms Specific to This Standard:*

3.2.1 *straightness—*Deviation of an axis or surface element from linearity over a unit length in the unloaded (force and moment free) condition. A perfectly straight condition is shown in Fig. 1. A non-straight condition is shown in Fig. 2.

3.2.2 *wobble—*Elliptical rotation observed in a small diameter wire or tube as it is being rotated around a central axis as is shown in Fig. 3.

4. Summary of Test Method

4.1 For bar, rod, tube, and wire, the deviation from the condition of resting flat on a smooth surface can be measured by using a quantitative or qualitative test method. Two quantitative and two qualitative methods are the gap and TIR (Total Indicator Readout) and inclined flat plate and finger roll tests, respectively

4.2 *Inclined Flat Plate Test (qualitative test method that can be made quantitative)—*A common method for measurement of straightness of wire or tubing with a diameter less than 4.78 mm (0.188 in.) is the inclined flat plate test. In this method, a sectioned piece of material is allowed to roll down an inclined table as is illustrated by Fig. 4 and Fig. 5. The material passes the test if it rolls freely down the table without stopping as is shown by Fig. 5.

4.3 *Finger-Roll Test (qualitative test method)—*A second common method for measurement of straightness that is used for wire and tubing with a diameter less than 0.25 mm (0.010 in.) is the finger-roll test. In this test, a cut length of wire or tubing is laid on a flat surface. A finger, pencil, pen, or plastic card is used to rotate the center of the sample back and forth on the flat surface. The opposite ends of the sample should rotate smoothly without wobble as is defined in 3.2.2 of these test methods.

4.4 *Gap Test (quantitative test method)—*A common quantitative method for measurement of straightness of wire with a diameter less than 4.78 mm (0.188 in.) is the gap test. It can also be used for rod with a diameter between 4.78 and 6.35 mm (0.188 and 0.25 in.), tubing with diameter 0.05 to 6.35 mm (0.0002 to 0.25 in.) or bar with a diameter between 6.35 to 101.7 mm (0.25 to 4 in.), the gap test can be used to measure straightness. The gap test can also be used for flat or shaped wire and ribbon. In this method, a thickness gauge equal to the gap must not fit between the rod, tubing, or bar and flat surface at any point along its length when rolled or rotated 360°. The gap defines the straightness of the rod, tubing, or bar.

4.5 *Total Indicator Readout (TIR) test (quantitative test method)—*In this method, a round rod with a diameter between 4.78 and 6.35 mm (0.188 and 0.25 in.) or round bar with a diameter between 6.35 to 101.7 mm (0.25 to 4 in.), is placed on two or more V-blocks. The test specimen is then rotated one revolution between two or more V-blocks that are a fixed distance (*d*) apart while measuring in the center with an indicator. Total Indicator Readout (TIR) in the test specimen is then calculated.

5. Significance and Use

5.1 *Significance—*With the birth of minimally invasive surgery in the 1960s, there has been a requirement for guide wires. The guide wires serve as the access line by which procedures like balloon angioplasty and stent placement are conducted. A guide wire typically consists of a mandrel, coil and in some cases a safety wire is used. The market for guide wires continues to grow as the number of procedures increases. For successful manufacturing of guide wires, linearity or straightness of 304 stainless steel and nitinol wire that is used for the manufacture of guide wire mandrels is critical to their end use performance. Users of guide wires require that they must navigate a tortuous anatomy.

5.1.1 A second part of minimally invasive surgery is the use of machined or formed wire, tube, or rod. In this case, straightness of rod, tube, and wire that is going to be machined or subjected to a forming practice such as bending needs to be very linear or straight so it is accurately fed into the equipment that is used for the machining or forming practice. Laser machining is an example of a machining operation that requires a wobble-free piece of rod, tubing, or wire so that it can be properly fed into the alignment bushings of the laser. Wire forming equipment also requires wobble-free material for the same reason.

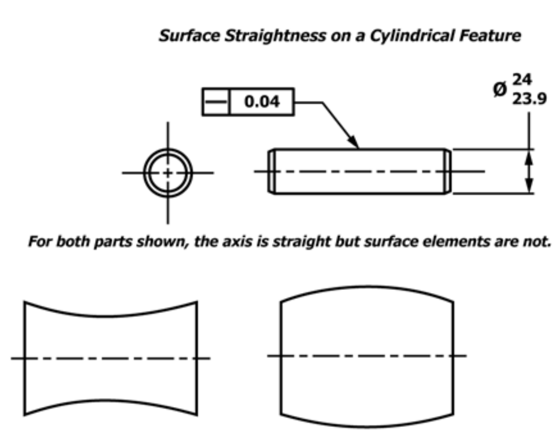

FIG. 1 Definition of a "Straight" Condition

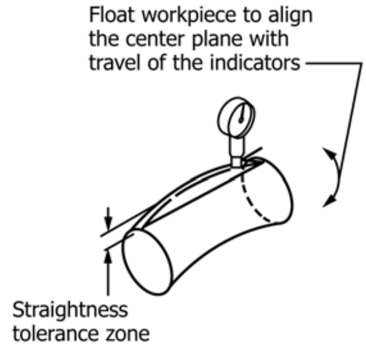

FIG. 2 Definition of a "Non-straight" Condition

FIG. 3 Definition of Wobble in a Small Diameter Tube or Wire as it is Being Rotated

FIG. 4 Example of a Table and Granite Parallel Used to Measure Straightness by the Roll Test

FIG. 5 Example of Inclined Surface Table and Protractor Used to Measure Straightness by the Roll Test Method

5.2 *Use*—These test methods can be used by users and producers of medical grade bar, rod, tubing, and wire to specify requirements to evaluate and confirm the straightness of material. Depending upon the type of material and its metallurgical condition, it may be possible to reprocess the material to reduce its non-linearity.

6. Apparatus

6.1 For the inclined flat plate test, a flat table preferably made of granite that can be precisely inclined is required. The flat table should have an inspection grade; grade A, flatness as set forth by Federal Specification GGG-P-463. A precise measurement device and a protractor are also required. Examples of precise measurement devices that can be used are thickness gauges, gauge pins, a micrometer, and a linear scale. Fig. 4 and Fig. 5 show the equipment used for the roll test.

NOTE 4—A parallel can be used but it is optional.

6.2 For the finger roll test, a precision flat surface such as a bench or table is required. The surface of the bench or table should not be pitted, gouged, cracked, and so forth, but be in good condition.

6.3 For the gap test, a precision flat surface such as a bench or table is required. For heavy test specimens such as bar, the floor can be used. The surface of the bench, table, or floor should not be pitted, gouged, cracked, and so forth, but be in good condition. A measurement device such as a thickness gauge, gauge pin, micrometer, optical comparator, or a linear scale may be used to determine the gap. The deviation from flatness of the flat surface shall be at least one order of magnitude less than the straightness requirement of bar, rod, wire, or tubing that is going to be inspected.

6.4 For the TIR test, a dial indicator and two or more V-blocks are required.

7. Hazards

7.1 Ends of cut bar, rod, tube, and wire can be sharp. Cut pieces of material need to be handled with care. It may be necessary to wear gloves in order to avoid being injured.

7.2 A pinch point exists between the inclined table and parallel. Caution and safety precautions are required in order to avoid pinch point injuries.

7.3 Safety glasses and proper cutting techniques should be used when creating the test sample. Cutters should be in the sharpened condition.

8. Sampling, Test Specimens, and Test Units

8.1 The test sample for the finger roll and inclined flat plate tests shall consist of a minimum of 0.25 m (10 in.) cut piece of tubing or wire. The test sample for the gap and TIR tests shall consist of a 0.25 ± 0.02 m (10 ± 1 in.) cut piece of rod or tubing, bars, or wire.

8.2 The number of test specimens shall be agreed upon between the customer and supplier.

8.3 Whether or not the test specimens are cut from the same or separate pieces of straightened and cut to length rod, tube, or wire or spools, shall be agreed upon between the customer and supplier.

8.4 For small diameter wire and tubing, the straightened-to-length wire, tubing or spool, the test sample shall be sectioned from the lot by using a sharp cutter to ensure a burr-free edge after the cutting process. For larger diameter rod, tubing, and wire, an abrasive cut off or diamond blade saw shall be used to ensure a burr-free edge and that the edge was not permanently deformed during the cutting process.

8.5 For superelastic NiTi wire, tube, or rod, the straightness should be measured when the material is in the fully superelastic condition. If the austenite finish temperature (A_f) of the test sample is greater than the temperature of the environment, the sample should be preheated to a temperature greater than the austenite finish temperature (A_f)

9. Preparation of Apparatus

9.1 For the inclined flat plate test, the surfaces of the plate and parallel shall be clean and not damaged. For the finger roll and gap tests, the flat surface used for the inspection shall be clean and not damaged. For the TIR test, the V-blocks should be clean and in good condition.

10. Calibration and Standardization

10.1 All measurement devices used in the test procedure including precision surface plates, parallels, protractors, thickness gauges, gauge pins, micrometers, or linear scales, should be in calibration as defined by company quality assurance policy.

11. Procedure

11.1 *Inclined Flat Plate Test (qualitative test method):*

11.1.1 Ensure that the plate is clean, free of debris, and free of damage. Optional: if a parallel is used, ensure that it is clean, free of debris, and free of damage.

11.1.2 *Optional*—If a parallel is used, place parallel on the table and elevate it to a height above the table that is equal to the rod, tube, or wire diameter plus an acceptable maximum tolerance to be agreed upon by the customer or supplier. This can be done using gauge pins, thickness gauges, a micrometer, or linear scale (see Fig. 4).

11.1.3 With the aid of a protractor, incline the table as shown in Fig. 5. For wire or tubing with a diameter less than 0.50 mm (0.020 in.), the incline of the table is recommended to be 40 or as agreed upon by the customer and the supplier. For rod, tubing, or wire with a diameter greater than 0.50 mm (0.020 in.), the incline of the table is recommended to be 2° or as agreed upon by the customer and the supplier.

11.1.4 Rest the test sample at the end of the surface table parallel to the edge and release it. If it does not roll, gently touch it with a pencil or other object in order to overcome static friction.

11.1.5 The test sample passes the test if it rolls freely down the incline without stopping.

NOTE 5—This test can be made quantitative by measuring the maximum gap between the table and the inner surface of the wire, tubing, and rod or the gap of the parallel and table.

11.2 *Finger Roll Test (qualitative test method):*

11.2.1 Ensure that the flat surface is clean, smooth, and free from damage.

11.2.2 The center of the test specimen should be pushed onto the flat surface with a finger.

11.2.3 Use your finger to roll the test specimen back and forth on the flat surface with your finger in the approximate center of the specimen length. If it does not roll using your finger, gently touch it with a pencil, pen, or plastic card so that the test specimen will overcome the friction of the table. The remote ends should rotate smoothly on the flat surface without wobble. If the test specimen wobbles, the small diameter tubing or wire is not straight.

11.3 *Gap Test (quantitative test method):*

11.3.1 Ensure that the flat surface to be used for the inspection is clean, smooth, and free of damage.

11.3.2 Place the test specimen on the flat surface. Roll the test specimen through an angle of 360° or greater taking care to not deform or distort the test specimen. Measure the largest gap perpendicular to the flat surface and the surface of bar, rod, tubing, or wire using a thickness gauge, gauge pins, micrometer, or linear scale (see Fig. 2).

11.3.3 The distance gap is the measurement of non-linearity in bar, rod, tubing, and wire. If the gap is less than the non-linearity tolerance, the material is defined to be straight. Depending upon the type of material and its metallurgical condition, it may be possible to reprocess the material to reduce its non-linearity.

11.4 *Total Indicator Readout (TIR) Test (quantitative test method):*

11.4.1 A test specimen shall be placed with the bow facing upward on top of two or more V-blocks that are spaced a distance apart as is shown in Fig. 6 that is agreed upon between manufacturer and customer. The midpoint of the test specimen should coincide with location of the indicator measurement specified in 11.4.2.

NOTE 6—More than two V-blocks may be used so that the weight of the specimen does not influence the test measurement. Typical distance between the V-blocks for a 6 m (20 ft) long bar is 1.2 to 1.5 m (4 to 5 ft).

11.4.2 The test specimen is then rotated one revolution between the V-blocks while measuring at the midpoint between the pair of V-blocks whose distance apart is specified in 11.4.1 with an indicator. The distance that the axial centerline of the test specimen deviates from a theoretically straight centerline directly below the indicator equals the extent to which the part is bowed, or warped, over the distance agreed upon in 11.4.1. The maximum and minimum indicator readings (I_x and I_N) are physically represented in Fig. 6. From this, TIR is derived as:

$$TIR = I_X - I_N = (R + |Bow|) - (R - |Bow|) = 2 \cdot |Bow| \quad (1)$$

where:

R = the radius of the material that is being measured, and
Bow = defined by Fig. 6.

Deviations in roundness, outside diameter (OD) size, and finish can adversely affect the measurement.

12. Calculation or Interpretation of Results

12.1 A calculation is required for the TIR test method.

12.2 The results should be interpreted according to the acceptance criteria agreed between the purchaser and supplier.

13. Report

13.1 The report shall include the following information unless otherwise specified:

13.1.1 Material and sample identification.

13.1.2 Specific straightness and flatness (camber) methods.

13.1.3 *Specification*—For the TIR method, include the location of each of the V-blocks used, the width of each V-block, the location at which the indicator measurements were taken, and the distance agreed upon in 11.4.1.

13.1.4 *Length of Sample*—If multiple samples were used, record their lengths individually or the average length and standard error of the mean.

13.1.5 Test temperature if shape memory alloys are being tested.

13.1.6 Straightness and flatness (camber) measurements (where measured).

13.1.7 Pass/Fail result.

14. Precision and Bias

14.1 A precision and bias study has not been conducted on these test methods since it is new.

15. Keywords

15.1 bar; linearity; non-linearity; rod; straightened and cut materials; straightened to roll off a spool flat material; straightness; tubing; wire

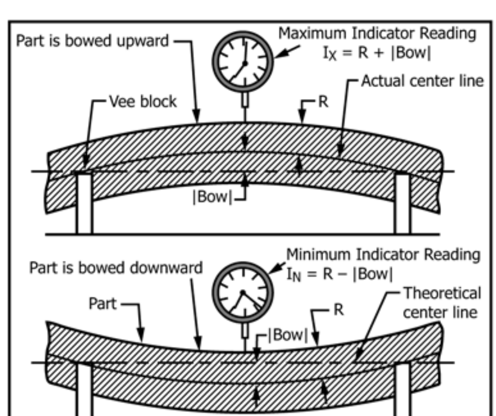

FIG. 6 TIR Method for Measurement of Straightness