Designation: F3505 – 21

Standard Test Method for Stent and Endovascular Prosthesis Kink Resistance[1]

This standard is issued under the fixed designation F3505; 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 standard addresses the kink resistance of stents and endovascular prostheses (for example, stent grafts). The standard may also be applicable to scaffolds.

1.2 Test methods presented herein address the kink resistance of stents and endovascular protheses when exposed to bending in a single plane. While concurrent influences (for example, torque) are recognized to influence kinking properties, test methods other than single-plane bending are not addressed.

1.3 Test methods presented herein do not specifically address kink resistance of branched (for example, bifurcated) or multicomponent endovascular prostheses, but some aspects of this standard may be applicable to their application.

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

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]

F3172 Guide for Design Verification Device Size and Sample Size Selection for Endovascular Devices

3. Terminology

3.1 *Definitions:*

3.1.1 *endovascular prosthesis, n*—device used to treat disease by accessing target anatomy through the vasculature.

3.1.2 *kink, n*—a crease across the conduit where it has folded from excessive bending; the attribute of a stent or endovascular prosthesis to buckle in the region of the inner radius during bending at a particular bending radius or angle.

3.1.3 *kink radius, n*—the smallest bend radius achieved by the test article upon which a kink did not occur.

3.1.4 *mock vessel, n*—a simulated vessel typically manufactured from an elastomeric material. The mock vessel is made to approximate the inner diameter and diametric distention of a native vessel at physiological pressures or at non-physiological pressures, and should be translucent to permit visualization of the device during testing.

3.1.5 *vascular stent, n*—a tubular structure that is permanently implanted in the native or grafted vasculature and that is intended to provide mechanical radial support to enhance vessel patency. A stent is metallic and not covered by synthetic, textile, or tissue graft material.

3.1.6 *vascular stent graft, n*—transluminally placed tubular vascular prosthesis, with one or more integral stent components to provide fixation, radial support, or both, residing partially or completely within a vascular vessel to form an internal bypass or shunt between sections of the vascular system.

4. Summary of Test Method

4.1 Kink resistance of stents and endovascular prostheses may be evaluated using the following test methods: template of known radii, cylindrical gauges, and rigid bend models.

5. Significance and Use

5.1 Upon deployment of a stent or endovascular prosthesis, the device is intended to maintain the patency of the vascular vessel. In order to maintain vessel patency, the device must deform within the in-vivo loading environment without a flow-limiting loss in lumen area. Kinking induces a severe, localized loss of lumen area, typified by a slot-like lumen shape. Device resistance to kinking can be evaluated through multiple test methods, with the appropriate selection depending on the device.

[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 F04.30 on Cardiovascular Standards.

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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.

5.2 The purpose of this standard is to outline test methods to address the resistance to kinking of stents and endovascular prostheses. In the case where no kinking is observed, the radius at which a predefined narrowing criterion (for example, 50 % diameter reduction) occurs may be considered as the kink radius of the device.

5.3 When kink resistance properties are expected to vary along the length of the stent or endovascular prosthesis, testing should be performed at each of these sections.

5.4 This standard is not intended to evaluate the kink resistance of devices other than stents, endovascular prostheses, and scaffolds, although the specific procedures outlined here may be used if applicable.

6. Procedure

6.1 *Overview:*

6.1.1 Testing temperature (for example, 37 ± 2 °C) should be based on the intended clinical use of the device and on the materials of the device. Relevant dimensions such as initial length, diameter, or cell size should be measured at this same temperature. When devices that are sensitive to temperature variations between ambient and body temperature (for example, nitinol) are not tested at body temperature, a statement as to how the differences between ambient and body temperature affect the outcomes of the test should be provided.

6.1.2 Hydration should be based on the intended clinical use of the device and on the materials of the device. When devices that are sensitive to hydration are not maintained in a hydrated state during testing, a statement as to how the differences in hydration status affect the outcomes of the test should be provided.

6.1.3 Excessive tension or compression applied during the kink assessment can affect results. Therefore, when handling the device during testing, avoid applying undue tension or compression.

6.1.4 Test article length and diameter should be selected based on the evaluation of the device's intended use. Rationale for test article selection should be provided (see Guide F3172 for more information on sample selection).

6.1.5 Test article orientation should be considered during testing, and the worst-case stent design orientation should be evaluated. That is, given that certain stent and endovascular prosthesis designs may have differing properties depending on circumferential direction, these potential design effects should be accounted for during testing. Orientation of the test article should remain constant throughout the test, unless justified otherwise.

6.1.6 Unless otherwise justified, testing should be conducted without pressurization of the test article lumen. In cases where lumen pressurization may be justified (for example, when testing endovascular prostheses that are only partially stented), the lumen pressure shall be established and justified prior to testing.

6.2 *Template of Known Radii:*

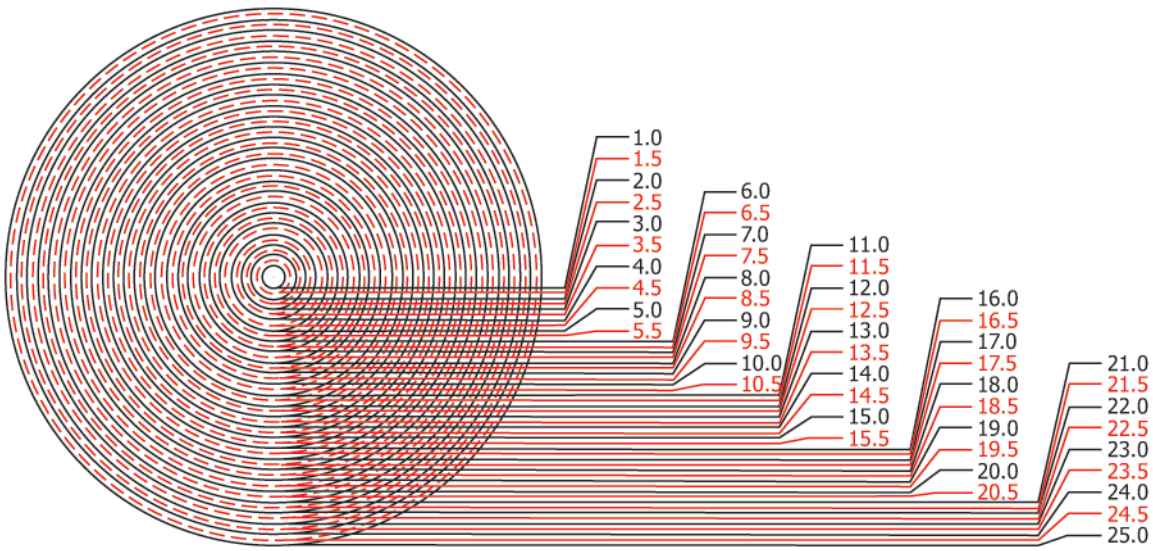
6.2.1 *Summary:*

6.2.1.1 This test method is intended to determine the minimum radius that a stent or endovascular prosthesis can accommodate using a visual template of known radii in appropriate increments.

6.2.2 *Apparatus:*

6.2.2.1 Template of known radii in appropriate increments. Increments should be based on the intended clinical use of the device. For example, some devices may reside within small-diameter vascular beds where the use of a template with small increments (for example, 0.5 mm) might be appropriate. For devices within larger diameter vascular beds, however, it may be sufficient to test using larger increments (for example, up to 1.5 mm). See Fig. 1.

6.2.2.2 Mock vessel(s), if applicable.



NOTE 1—Image is not to scale; values shown in millimeters.

FIG. 1 Representative Template of Known Radii Consisting of Concentric Rings with Increasing Radii at Increments of 0.5 mm