Designation: F2079 – 09 (Reapproved 2022)

Standard Test Method for Measuring Intrinsic Elastic Recoil of Balloon-Expandable Stents[1]

This standard is issued under the fixed designation F2079; 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 The purpose of this test method is to quantify the percentage by which the diameter of a stent decreases from its expanded diameter while still on the delivery balloon to its relaxed diameter after deflating the balloon. This test method is appropriate for stents manufactured from a material that is plastically deformed when the stent's diameter is increased from its predeployed size to its postdeployed size by mechanical means. This test method may be performed in air at room temperature unless there is a known temperature dependence of the material, in which case, the temperature at which the test is conducted shall be stated in the report.

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

1.3 *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.*

1.4 *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. Terminology

2.1 *Definitions:*

2.1.1 *labeled diameter, n*—the nominal deployed size of a stent as indicated on its manufacturer's label.

2.1.2 *stent recoil, n*—the amount, expressed as a percentage, by which the diameter of a stent changes from the expanded diameter measured with the stent on the inflated delivery balloon to the final value measured after deflating the balloon.

3. Summary of Test Method

3.1 A sample device representative of product that will be marketed is either premounted or mounted on the delivery balloon at the time of use. The delivery balloon is inflated to the nominal expansion pressure indicated for the labeled stent. The outer diameter of the stent is measured in at least three axial locations while the stent is still on the inflated delivery balloon. At each axial location, measurements are taken in two approximately orthogonal rotational positions. The balloon is deflated and the outer diameter of the stent is remeasured in the same positions at approximately the same locations.

4. Significance and Use

4.1 Minimal stent recoil is a desirable feature of a stent because it minimizes the maximum diameter to which a stent must be expanded to achieve its final relaxed diameter. A stent having a high recoil must be expanded to a greater diameter to achieve its final relaxed diameter than a stent having low recoil. Practically, excessive expansion of the vessel into which the stent is to be implanted may cause tissue damage resulting in a poor immediate result or poor long-term outcome. Stent recoil is affected by intrinsic properties of the material used to construct the stent and the specific geometric design of the stent; therefore, measuring stent recoil is an essential part of evaluating the design.

5. Apparatus

5.1 A means to inflate with noncompressible fluid, typically water, the delivery balloon on which the stent is mounted. The means used must be capable of achieving the pressure required to maintain the expanded diameter of the stent until it can be measured and may include a device to monitor pressure.

5.2 A means to measure the outer diameter of the stent without deforming the stent. Typically, a calibrated optical system, which does not require contact with the stent, is used. The resolution of the measurement system shall be 0.01 mm or better. The accuracy of the system shall be 2 % of reading or better.

6. Sampling, Test Specimens, and Test Units

6.1 Unless otherwise justified, all samples selected for testing should be taken from fully processed, clinical quality

[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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product. It is not required that these devices undergo terminal sterilization. Cosmetic rejects or other nonclinical samples may be used if the cause for rejection has been shown not to affect stent recoil.

6.2 The number of specimens tested for each unique stent geometry should be sufficient to meet sampling requirements for desired specification limits. In general, a minimum of ten specimens is recommended. If a single stent geometry is intended to be used for more than one labeled diameter, recoil shall be evaluated for test specimens expanded to the smallest and largest diameters intended for that geometry.

6.3 Most stents are comprised of a repetitious continuous pattern or of repeating subunits. If stents are made longer by additional repetition of the basic geometric pattern or by adding identical subunits, then recoil need be measured on only a single length of each diameter stent. If, however, dimensions of the substructure of the repeating pattern or of the subunits is altered to change the length, then recoil must be measured for each unique geometry.

7. Procedure

7.1 Corresponding paired outer diameter measurements (that is, $Diameter_{inflated}$ and $Diameter_{final}$) shall be obtained with the stent in approximately the same rotational position with respect to the measurement system.

7.2 The number of locations along the length of the stent at which recoil is measured should be determined by initial assessment of the stent geometry. Measurements should be made at multiple axial locations, including one location near midlength and locations near either end of the stent. Additional measurements may be warranted by the stent design. For example, if the stent is specifically designed to recoil differently at specific locations along its length, additional measurements should be taken at these locations.

7.3 Inflate the balloon to the nominal expansion pressure indicated on the stent labeling. To allow for full expansion of the stent, maintain the expansion pressure for 15 to 30 s before taking diameter measurements.

7.4 For each axial measurement location identified in 7.2, measure the outer diameter of the stent in two approximately orthogonal rotational positions.

7.5 Deflate the balloon.

7.6 Measure the outer diameter of the stent at the same locations and in the same rotational positions with respect to the measurement system as in 7.4. These measurements should be taken no sooner than 10 s after deflating the balloon.

8. Calculation

8.1 Calculate the stent recoil for the locations measured in 7.4 for each stent using the following equation:

$$\text{Stent Recoil}\,(\%) = \left(1 - \left(\frac{Diameter_{final}}{Diameter_{inflated}}\right)\right) * 100 \quad (1)$$

where:

$Diameter_{inflated}$ = outer diameter of stent while on inflated delivery balloon, and

$Diameter_{final}$ = outer diameter of stent after deflating delivery balloon.

8.2 Calculate the average and standard deviation of stent recoil for each axial location at which recoil is measured.

9. Report

9.1 Report the following information for each labeled diameter of each unique stent geometry:

9.1.1 Labeled stent diameter, in millimetres.

9.1.2 Labeled stent length.

9.1.3 Number of samples measured.

9.1.4 Locations at which measurements were taken.

9.1.5 $Diameter_{inflated}$ (mean ± standard deviation, to the nearest 0.01 mm).

9.1.6 $Diameter_{final}$ (mean ± standard deviation, to the nearest 0.01 mm).

9.1.7 Stent recoil average (mean ± standard deviation, to the nearest 0.5 %) for each location measured.

9.1.8 Temperature at which test is performed.

10. Precision and Bias

10.1 *Precision*—The precision of this test method has not yet been established. An interlaboratory comparison to determine the precision is being planned.

10.2 *Bias*—No information can be presented on the bias of this test method because no material having an acceptable reference value is available.

11. Keywords

11.1 recoil; stent