Designation: F2079 – 09

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

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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 and health practices and determine the applicability of regulatory limitations prior to use.*

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 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.

[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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