



Designation: F 2079 – 01

Standard Test Method for Measuring Recoil of Balloon-Expandable Stents¹

This standard is issued under the fixed designation F 2079; 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 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 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 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 *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*—desired final stent (inner/outer) diameter after deflation of the delivery balloon.

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 The delivery balloon bearing a sample device representative of product that will be marketed either premounted, or mounted on the delivery balloon at the time of use, is inflated to expand the stent to slightly greater than its labeled diameter. The outer diameter of the stent is measured in a minimum of two approximately orthogonal projections while the stent is still on the inflated delivery balloon. The balloon is deflated and the outer diameter of the stent is remeasured in the same projections at approximately the same location.

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.

Current edition approved Jan. 10, 2001. Published March 2001.

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.

6.2 The number of specimens tested for each unique stent geometry should be sufficient to meet sampling requirements for desired specification limits. 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