



Designation: F 2079 – 04₂

Standard Test Method for Measuring Intrinsic Elastic Recoil of Balloon-Expandable Stents¹

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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 *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—the nominal deployed size of the delivery balloon—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 ~~The delivery balloon bearing a~~

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 expand the stent to slightly greater than its nominal expansion pressure indicated for the labeled diameter stent. The outer diameter of the stent is measured in a minimum of two approximately orthogonal projections rotational positions 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 positions at approximately the same location.~~

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

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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. 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 a single location near midlength unless otherwise warranted by the stent design. For example, if the stent is specifically designed to recoil less at the ends than in the middle, recoil should be measured at both locations.

7.3 Pressurize

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

7.4 Measure the outer diameter of the stent in ~~a minimum of two~~ approximately orthogonal projections. rotational positions.

7.5 Deflate the balloon.

7.6 Measure the outer diameter of the stent at the same location(s) 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 location(s) 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 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 $Diameter_{inflated}$ (mean \pm standard deviation, to the nearest 0.01 mm).

9.1.5 $Diameter_{final}$ (mean \pm standard deviation, to the nearest 0.01 mm).

9.1.6 Stent recoil average (mean \pm standard deviation, to the nearest 0.5 %) for each location measured.

9.1.7 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

APPENDIXES

(Nonmandatory Information)

X1. RATIONALE

X1.1 Balloon-expandable stents typically are deployed for permanent implant by plastically deforming the material of construction. Upon release of the balloon pressure, the diameter will decrease, the exact amount of which depends on the material used to construct the stent and the specific design of the stent. For optimal clinical results, it is critical that the final deployed diameter be appropriate for the exact location of deployment. Moreover, a stent with excessive recoil must be inflated to a larger diameter to achieve the desired final diameter. This larger required initial inflation diameter may cause more damage to the vessel than would the lower inflation diameter required for a stent with a lower recoil. The implanting physician must have guidance as to how much any given stent design will recoil so that the balloon may be inflated to the expanded diameter required to achieve the desired final diameter. This test method provides a standardized procedure to determine the recoil characteristics of stents so that consistent labeling can be written. Note that this test method measures the intrinsic recoil of the stent and may not predict how the stent will perform when implanted in a vessel in which stent recoil, stent stiffness, and vessel stiffness interact to determine the final diameter.

X2. REVISION HISTORY

X2.1 This standard was originally approved in 2001. It was revised in 2002 to clarify terminology, measurement procedures, and reporting requirements.

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