Designation: F 2081 – 01

Standard Guide for Characterization and Presentation of the Dimensional Attributes of Vascular Stents[1]

This standard is issued under the fixed designation F 2081; 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 guide covers the identification of and recommended measurement methods for those dimensional attributes of vascular stents that are deemed relevant to successful clinical performance. The delivery system packaged with and labeled specifically for use during the placement of the stent is also included within the scope of this guide.

1.2 This guide addresses only the *dimensional* characteristics of stents. Material property and stent functional characteristics are not addressed herein. All dimensional characteristics described in this guide refer to in-vitro ("bench-top") characterization. Because of variable patient factors, for example, vessel compliance, the actual in-vivo characteristics may be slightly different.

1.3 This guide includes recommendations generally applicable to balloon-expandable and self-expanding stents fabricated from metals and metal alloys. It does not specifically address any attributes unique to coated stents or polymeric or biodegradable stents, although the application of this guide to those products is not precluded.

1.4 While they are not specifically included within the scope of this guide, stents indicated for placement in nonvascular locations, such as the esophagus or bile duct, also might be characterized by the methods contained herein. Likewise, this guide does not include recommendations for endovascular grafts ("stent-grafts") or other conduit devices commonly used to treat aneurysmal disease or peripheral vessel trauma or to provide vascular access, although some information included herein may be applicable to those devices.

1.5 This guide does not include recommendations for balloon catheters sold as stand-alone angioplasty catheters, even though some of those catheters may be used for the delivery of unmounted stents supplied without a delivery system. Requirements for angioplasty catheters are contained in standards ISO 10555-1 and ISO 10555-4.

1.6 The units of measurements used throughout this guide reflect the hybrid system in common clinical use in the United States as of the time of the original approval of this guide. Since a primary purpose of this guide is to promote uniformity of labeling to facilitate the selection of devices by clinical users, the units most preferred by users were selected for this guide. Where those units are not SI units, or derivatives thereof, SI units are provided in parentheses.

2. Referenced Documents

2.1 *ISO Standards:*

ISO 10555-1, Sterile, Single-Use Intravascular Catheters, General Requirements[2]

ISO 10555-4, Sterile, Single-Use Intravascular Catheters—Balloon Dilation Catheters[2]

3. Terminology

3.1 *Definitions of Terms Specific to This Standard:*

3.1.1 *balloon-expandable stent*, *n*—a stent that is expanded at the treatment site by a balloon catheter. The stent is altered permanently by the balloon expansion such that the stent remains expanded after deflation of the balloon.

3.1.2 *bridge*, *n*—a connecting element between the radial support aspects of a stent. A bridge may have unique design features, as compared to a strut, to enhance longitudinal flexibility and minimize shortening.

3.1.3 *crimp*, *v*—to secure the stent on the delivery system by compressing the stent onto the balloon. Stents sold unmounted must be crimped manually by the clinical staff before use.

3.1.4 *crossing profile*, *n*—a linear measure of the maximum breadth of the stent/delivery system over the distal-most region of the delivery system.

3.1.5 *delivery system*, *n*—a system that is used to deliver and deploy a stent at the target site. A delivery system may be similar to a balloon dilatation catheter; a delivery system for a self-expanding stent might not have a balloon.

3.1.6 *diameter*, *n*—refers to the outside diameter of the stent unless otherwise noted.

3.1.7 *percent metal area*, *n*—that percentage of the projected cylindrical side surface area (π times outside diameter

[1] This guide is under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devicesand is the direct responsibility of Subcommittee F04.30on Cardiovascular Devices.

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

[2] Available from American National Standards Institute, 11 W. 42nd St., 13th Floor, New York, NY 10036.

times length at labeled diameter) that is covered by stent material, when the stent is expanded to its labeled diameter.

3.1.8 *premounted stent*, *n*—a stent supplied by a manufacturer already mounted on a delivery system.

3.1.9 *self-expanding stent*, *n*—a stent that expands without extrinsic force or pressure, to a size and shape close to the desired final size and shape, when released from the delivery system. The self-expanding nature of some stents is a design feature resulting from the materials of construction or the structural geometry, or both.

3.1.10 *sheath*, *n*—a movable cover that constrains a self-expanding stent on the delivery system until its desired release or protects a balloon-expandable stent during delivery before deployment.

3.1.11 *shortening/lengthening*, *n*—the percentage change in length between the undeployed mounted condition and the expanded labeled-diameter condition.

3.1.12 *stent, vascular*, *n*—a synthetic 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. For the purposes of this guide, a stent is metallic and not covered by synthetic textile or tissue graft material.

3.1.13 *strut*, *n*—the smallest individual element of the radial support aspect of a stent that has a solid cross section in both the radial and circumferential directions.

3.1.14 *unmounted stent*, *n*—a stent that is not crimped on a delivery system as supplied by the manufacturer. Before use, the clinical staff must manually crimp unmounted stents onto a delivery device.

4. Significance and Use

4.1 Vascular stents are intended for permanent implant in the human vasculature (native or graft) for the purposes of maintaining vessel patency. The dimensional attributes of vascular stents are critical parameters that aid clinicians in the selection of devices for individual patients. This guide contains a listing of those attributes that are directly related to the clinical utility and performance of these devices, along with recommendations for consistent methods of measuring these attributes and presenting the information for use in clinical decision making. This guide can be used by the manufacturers and researchers of stents to provide consistency of measurement and labeling of these dimensional characteristics. It may have use in the regulation of these devices by appropriate authorities.

4.2 The dimensional attributes included in this guide are those that are deemed related to or possibly predictive of successful clinical performance of the stent, based on prior clinical experience; however, because of the myriad patient and medical factors that influence the clinical outcome of any individual treatment, conformance of a stent and delivery system with the recommendations in this guide should not be interpreted as a guarantee of clinical success in any individual patient or group of patients.

5. Classification

5.1 Stents may be classified by the following characteristics, as defined in Section 3.

5.1.1 *Mounting*—Premounted or unmounted.

5.1.2 *Expansion*—Balloon expandable or self-expanding.

6. Test Devices and General Procedures

6.1 Unless otherwise justified, all samples selected for testing or measuring the attributes described in this guide should be taken from finished, clinical-quality product. Cosmetic rejects or other nonclinical samples may be used if the cause for rejection is not related to the attribute being assessed. Sterilization can be omitted if it can be demonstrated that sterilization has no affect on the attribute being assessed.

6.2 When specimen preparation (for example, manual crimping onto a delivery system, balloon expansion), is required before testing, this should be done in accordance with the Instructions for Use (IFU).

6.3 The preconditioning and test environments must be appropriately selected for each design and attribute. Temperature and fluid immersion may have a significant effect on some attributes but a negligible affect on others. For example, fluid sorption may swell catheters and affect the measurement of crossing profile. Temperature may affect the final deployed diameter for stents made from shape memory materials. For measurements for which deployment, or measurement, or both, is to be made in a controlled environment, the stent or delivery system, or both, should be immersed in a water bath maintained at 37 ± 2°C and allowed to equilibrate.

6.4 The number of specimens evaluated for each diameter for each stent design should be sufficient to meet the sampling requirements for the desired labeling. In general, a minimum of ten test devices is recommended. If a single stent design is intended to be deployed over a broad range of diameters by use on different size delivery systems, the dimensional attributes should be evaluated for each stent/delivery system combination.

7. Dimensions and Measurement Methods

7.1 *Deployed Diameter*—Unless otherwise specified, all deployed diameters refer to the outside diameter, reported in millimetres to the nearest 0.1 mm, after balloon deflation (for balloon-expandable stents).

7.1.1 *Measurement*—The outside diameter of deployed stents should be measured by noncontacting instruments (profile projection, laser micrometer, and so forth) with a resolution of 0.05 mm or better.

7.1.2 *Labeled Diameter*—The labeled diameter is that typically used to identify the nominal deployed size of a particular device, for example, 3 mm, 3.5 mm, and must be clearly identified as inside or outside diameter (ID or OD).

7.1.3 *Stent System Compliance*—For balloon-expandable stents, a table or graph of inflation pressure versus expanded diameter should be developed and included in the labeling. A minimum of ten devices should be measured at each labeled inflation pressure. The expanded stent outside diameter at each inflation pressure, reported to the nearest 0.1 mm, should be the mean of all measurements taken on all stents at that pressure. The inflation pressure should be expressed in atmospheres. This attribute does not apply to self-expanding stents.

7.1.4 *Uniformity of Expansion*—The uniformity of expansion refers to the difference between the largest and smallest