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

This standard is issued under the fixed designation F2081; 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 values stated in either SI units or inch-pound units are to be regarded separately as standard. The values stated in each system may not be exact equivalents; therefore, each system shall be used independently of the other. Combining values from the two systems may result in non-conformance with the standard.

1.6.1 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.

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[2] Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, http://www.ansi.org.

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 inside diameter (ID) of the stent unless otherwise noted.

3.1.7 *diameter, labeled, n*—single value representation of intended-use diameters, typically rounded to nearest 0.25 or 0.5 mm. The labeled diameter is within the range recommended in the Instructions for Use (IFU) for that particular stent and delivery system.

3.1.8 *percent solid area, n*—that percentage of the projected cylindrical side surface area (π times outside diameter times length at labeled diameter) that is covered by stent material, when the stent is expanded to its labeled diameter.

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

3.1.10 *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.

3.1.11 *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.

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

3.1.13 *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.

3.1.14 *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.

3.1.15 *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 dimensional 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 replicate test devices of each size to be measured or tested 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 inside 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 projector, laser micrometer, and so forth) with a resolution of 0.05 mm or better. Inside diameter can then be calculated by subtracting twice the wall thickness (7.4). Alternatively, the inside diameter can be measured by calibrated gauges.

7.1.2 *Labeled Diameter*—The labeled diameter is that used to identify the typical deployed size of a particular device, for example, 3.0 mm or 3.5 mm, and must be clearly identified as inside or outside diameter (ID or OD). ID is preferred. The labeled diameter is usually rounded to the nearest 0.25 or 0.5 mm.

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 replicate devices should be measured at each stent size at each labeled inflation pressure. The expanded stent inside diameter at each inflation pressure, rounded to the nearest 0.05 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 diameter measurement on a single stent deployed to its labeled diameter. Uniformity of expansion is not intended to characterize deliberate deviations from cylindricity, such as tapered construction, end flares, antimigration barbs, and so forth. Measurements for the uniformity of expansion should be taken at three axial locations (mid-length and close to each end) at each of two circumferential orientations at about 90° separation. The uniformity of expansion reflects both the deviation from circularity of the stent cross section and unintended differences in diameter along the stent length.

7.2 *Stent Length:*

7.2.1 *Measurement*—The length of mounted or expanded stents should be measured by noncontacting instruments (profile projection, laser micrometer, and so forth) with a resolution of 0.1 mm or better. Measurements should be taken on each stent in the mounted state and at the labeled diameter. Lengths should reflect measurements on a minimum of ten replicate devices and should be reported to the nearest 1 mm.

7.2.2 *Labeled Expanded Length*—The labeled expanded length is that used to identify the typical size of a particular device, for example, 20 mm. The labeled expanded length is usually rounded to the nearest 1 mm.

7.2.3 *Mounted (Undeployed) Length*—This attribute has no significance in and of itself. It provides a baseline for the determination of shortening/lengthening. Direct measurement of the mounted length may not be possible for sheathed systems. Other appropriate methods may be used.

7.2.4 *Shortening/Lengthening*—Refers to the percentage change in length between the undeployed mounted condition and the expanded labeled-diameter condition. Shortening/lengthening should be reported as a percentage of the mounted (undeployed) length to the nearest 1 %.

7.3 *Crossing Profile:*

7.3.1 *Measurement*—With the stent premounted or hand-crimped on the delivery system in accordance with the instructions for use, and the sheath (if any) in place, measure the maximum diameter over the length from the proximal end of the mounted stent to the distal tip of the delivery system. A minimum of ten replicate test articles should be measured. The measurement instrument should be either noncontacting (optical profilometer, laser micrometer, and so forth) or a ring/hole gage, and should have a resolution of 0.001 in. [0.025 mm] or better. The crossing profile should be reported as the mean measurement result to the nearest 0.001 in. [0.025 mm].

7.4 *Strut and Bridge Thickness:*

7.4.1 *Measurement*—Strut and bridge thicknesses of the expanded stent may be measured by subtraction of measured inside and outside diameters, by direct measurement with specialized instrumentation, by scanning electron microscopy, by profile projection, or destructively by cutting, or flattening, or both, a stent for access by standard micrometers. Since polishing or other manufacturing processes may change strut and bridge thickness from that of raw material, measurements from other-than-finished product should be used judiciously. Strut and bridge thickness should be measured at the stent mid-length and near each end, at two circumferential locations at each axial location. If strut and bridge thicknesses are systematically different by design, they should be measured and reported separately. Strut and bridge thickness should be reported in inches to the nearest 0.0005 in. [0.013 mm].

7.5 *Percent Solid Area:*

7.5.1 *Measurement*—The reference area is the full cylindrical side surface area for the stent expanded to the labeled diameter ($\pi \cdot$ outside diameter $\cdot$ length at labeled diameter). The solid area may be estimated by stereology or image analysis of suitably magnified photographs, by calculation based on stent mass, material density, and strut thickness, by CAD software, or by other suitable means. The solid area may be determined on unexpanded stents and assumed not to change significantly during expansion. The percent solid area is the ratio of the solid area to the reference area and should be reported as a percentage to the nearest 1 %. A range may be measured and reported by performing separate calculations for expansion to the minimum and maximum diameters per the IFU.

7.6 *Delivery System Dimensions*—The requirements for delivery system dimensions are detailed in ISO 10555, Parts 1 and 4. These include the following:

7.6.1 The effective length of the catheter.

7.6.2 The catheter outside diameter.

7.6.3 The maximum guidewire diameter (if applicable).

7.6.4 The effective length of the balloon (if applicable).

8. Keywords

8.1 angioplasty; coronary artery; dimensional characteristics; dimensions; vascular stent

APPENDIXES

(Nonmandatory Information)

X1. RATIONALE

X1.1 This guide contains a listing of and methods for characterizing those dimensional attributes deemed necessary or prudent to demonstrate successful performance of vascular stents in humans. As of the time of adoption of this guide, there is adequate clinical evidence to support that the dimensional characteristics addressed herein are at least somewhat predictive of clinical utility and success in most patients.

X1.2 *Expanded Diameter (Nominal and Uniformity)*—It is desirable to achieve the maximum vessel lumen diameter with a minimum of injury to the vessel. Too small a minimum lumen diameter (MLD) has been shown to correlate with a higher restenosis rate, while too large an MLD may be accompanied with increased vessel injury, which also may result in increased restenosis. Proper sizing of the stent *in vivo* requires a thorough knowledge of the expansion characteristics of the stent when used in accordance with the Instructions for Use (IFU), including the delivery system pressure required to achieve the desired stent diameter (for balloon-expandable stents).

X1.3 *Expanded Length (Nominal, Lengthening/Shortening)*—Accurately placing the expanded stent in the lesion minimizes restenosis and dissections. It is desirable to use a stent that is no longer than necessary because longer stents might compromise side branches and may relate to a higher incidence of restenosis. Shortening of the stent during expansion makes placement of the stent more difficult and sometimes forces the clinician to choose a stent that is longer than desirable to ensure full lesion coverage. Devices deemed clinically useful as of the time of adoption of this guide have reported length changes (shortening) during expansion in the range 0 to 20 %.[3]

X1.4 *Crossing Profile*—The ability of a mounted stent to be delivered across a lesion depends in part on the diameter of the mounted stent relative to the size of the lumen. A smaller crossing profile is beneficial for crossing tight lesions, especially for direct stenting. Devices deemed clinically useful as of the time of adoption of this guide had crossing profiles in the range <1.0 to 2.0 mm.

NOTE X1.1—Crossing profile is not the same as compatibility with a guiding catheter.

X1.5 *Strut and Bridge Thicknesses*—Strut and bridge thicknesses indirectly affect several other stent attributes and are important primarily because of this indirect effect. Knowledge of strut and bridge thickness allows one to estimate the stent internal diameter from the outside diameter, and vice versa. Strut thickness is one of several factors that influence radial strength, radiopacity, flexibility, and crossing profile. It directly influences the amount of the lumen diameter occupied by the stent. Bridge thickness is one of several factors that may influence predeployment flexibility and postdeployment conformability. Devices deemed clinically useful[3] as of the time of adoption of this guide had strut thicknesses in the range 0.025 to 0.177 mm.

X1.6 *Percent Solid Area*—The percent solid area is an indicator of the overall amount of vessel wall area covered by solid. This is important in evaluating the response of the body to a foreign material. This parameter also has been used as a crude measure of vessel wall coverage related to tissue prolapse; however, tissue prolapse is also strongly dependent on the distribution of solid rather than simply the gross percentage area. Devices deemed clinically useful as of the time of adoption of this guide have percent solid area values in the range 7 to 20 %.

X1.7 *Delivery System Dimensions*—The delivery system dimensions that are clinically important are the same as those for balloon angioplasty catheters. These dimensions help assure the suitability of a particular device for a specific application and the dimensional compatibility of mating devices.

[3] Serruys, Patrick, W., and Kutryk, Michael, J. B., Eds., *Handbook of Coronary Stents, Second Edition*, Martin Dunitz Ltd., London, 1998.

X2. DOCUMENT CHANGE HISTORY

X2.1 This guide was originally approved in 2001 and revised in 2006. Most changes were editorial in nature, with the intent of bringing nomenclature and labeling language more into line with clinical utility. The term "labeled" as applied to dimensions was maintained over "nominal." In places, ID was specified, that being of more relevance to clinicians trying to establish a minimum lumen diameter. Finally, the resolution for diameter labeling in the compliance chart was changed from 0.1 mm to 0.05 mm for clinical utility.