



Standard Guide for Characterization and Presentation of the Dimensional Attributes of Vascular Stents¹

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 Requirements²

ISO 10555-4, Sterile, Single-Use Intravascular Catheters—Balloon Dilation Catheters²

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 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

¹ This guide 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 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.