



Standard Guide for Coating Inspection and Acute Particulate Characterization of Coated Drug-Eluting Vascular Stent Systems¹

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1. Scope

1.1 This guide describes recommended *in vitro* test procedures for coating inspection and acute particulate characterization of coated drug-eluting vascular (balloon-expandable and self-expanding) stent systems.

1.2 Recommended practices for coating inspection and acute particulate characterization include baseline (deployment) testing and simulated use testing. This guide describes the capture and analysis of particulates. This guide describes the inspection of the coated stent surface. This guide was developed for characterization and not intended for production release testing of coated drug-eluting vascular stent systems although some sections may be appropriate.

1.3 Chronic particulate characterization and coating inspection are not included herein.

1.4 Coating systems specifically designed to degrade or otherwise intentionally separate themselves from the permanent stent structure may not be fully addressed herein.

1.5 The values stated in SI units are to be regarded as standard. No other units of measurement are included in this standard.

1.6 *The values stated in inch-pound units are to be regarded as standard. The values given in parentheses are mathematical conversions to SI units that are provided for information only and are not considered standard.*

2. Referenced Documents

2.1 Other Standards:

USP <788> Particulate Matter in Injections²

FDA Guidance for Industry and FDA Staff Non-Clinical Engineering Tests and Recommended Labeling for Intra-

vascular Stents and Associated Delivery Systems, April 18, 2010³

AAMI TIR42:2010 Evaluation of Particulates Associated with Vascular Medical Devices⁴

3. Terminology

3.1 Definitions:

3.1.1 *mock vessel*—physical simulation of the vasculature at the intended clinical deployment site.

3.1.2 *stent system*—a system comprised of a vascular stent and its delivery system.

3.1.3 *tracking*—navigation of a guide wire, guide catheter, and/or stent system through either actual or simulated vascular anatomy.

3.1.4 *tracking fixture*—a model that simulates or replicates the geometry of a representative vasculature through which the stent system will be passed.

3.2 Definitions of Terms Specific to This Standard:

3.2.1 *acute*—a test timeframe intended to include stent delivery and deployment beginning with the initial insertion of stent system until full removal of the delivery system and its accessory devices.

3.2.2 *baseline*—coating inspection and acute particulate characterization after stent expansion to the desired diameter in an unconstrained environment and without tracking.

3.2.3 *chronic*—a test timeframe intended to mimic the implantation time after full removal of the delivery system and its accessory devices.

3.2.4 *constrained environment*—a deployment site in which the stent is deployed into a mock vessel.

3.2.5 *simulated use*—coating inspection and acute particulate characterization after tracking in simulated anatomy and aqueous environment. It may also include deployment in bent configuration, deployment in overlapped configuration, post-dilatation, or other scenarios that can reasonably be expected in clinical use.

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² Available from U.S. Pharmacopeia (USP), 12601 Twinbrook Pkwy., Rockville, MD 20852-1790, <http://www.usp.org>.

³ Available from Food and Drug Administration (FDA), 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, <http://www.fda.gov>.

⁴ Available from Association for the Advancement of Medical Instrumentation (AAMI), 4301 North Fairfax Dr., Suite 301, Arlington, VA 22203-1633.