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Standard Guide for Assessing the Compatibility of a Cleaning Brush Part with Different Substrates Used in the Construction of Medical Devices¹

This standard is issued under the fixed designation F3602; 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 describes methods for assessing the compatibility, under prescribed laboratory conditions, of a cleaning brush part with substrate materials used in the construction of medical devices. The method utilizes a force tester to mechanically actuate a brush part at a constant rate. This action continues until there is any level of visible degradation, including but not limited to scratching or shaving of the substrate material.

1.2 The test methods utilized in this guide are those described in Guide [F3276](#). In this guide, the number of repetitions is determined by the demonstrable degradation, if any, of the substrate, up to a specified maximum number of repetitions.

1.3 Brushes designed to clean medical devices after clinical use play an important role in the effective reprocessing of those medical devices. Instructions for use from the brush manufacturer should supply information related to the compatibility, or more importantly, incompatibility with materials that make up the composition of a medical device. This may be stated in terms of being suitable for specific materials, not suitable for specific materials, or suitable for a limited number of uses for specific materials.

1.4 Selecting the correct brush for the medical device to be cleaned is always a key factor to achieve effective cleaning. One of the significant factors when selecting a brush is selecting one that will not cause damage to the medical device, including the material the medical device is constructed of. Assessing if a brush part could damage a medical device because of the material the device is made of is an important step in determining the appropriate (and inappropriate) use of a brush.

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

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 [F04.15](#) on Material Test Methods.

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1.6 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, health, and environmental practices and determine the applicability of regulatory limitations prior to use.

1.7 This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.

2. Referenced Documents

2.1 *ASTM Standards:*²

[F3276](#) Guide for Using a Force Tester to Evaluate the Performance of a Brush Part Designed to Clean the External Surface of a Medical Device

3. Terminology

3.1 *Definitions:*

3.1.1 *brush part*—working end of the brush that comes in contact with the targeted surface of the substrate.

4. Summary of Guide

4.1 This guide describes the application of test methods described in Guide [F3276](#) to assess the compatibility of a brush part with the material substrate used in the construction of medical devices.

4.2 Through exhaustive repetitions of the applicable method, the compatibility of the brush part can be assessed and described.

4.3 The maximum number of repetitions may be specified and shall be justified.

² For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.