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Standard Guide for Using a Force Tester to Evaluate Performance of a Brush Part Designed to Clean the Internal Channel of a Medical Device¹

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1. Scope

1.1 Brushes used to clean a medical device after clinical use play an important role in effective reprocessing. This guide describes methods for characterizing, under prescribed laboratory conditions, the efficacy of brush parts designed to clean the internal channels of medical devices. The methods utilize a force tester to mechanically actuate a brush part within a channel: (1) Methods to measure, at an established speed, the force required to move a brush within a channel; (2) Methods utilize the same force tester and protocols to measure soil removal from a soiled tube, another indicator of performance.

1.2 Inclusions:

1.2.1 This guide describes objective, quantifiable, and reproducible methods for evaluating the cleaning characteristics of a brush part under prescribed laboratory conditions, with test methods that simulate the cleaning challenge of a defined target area(s) of a medical device. This also makes possible the comparison of one design of a brush part to another.

1.2.2 In this guide, a brush part is one that is intended to be moved within a tube.

1.2.3 Tubes used for testing described in this guide are cylindrical and uniform in diameter. The test methods describe may not apply to non-cylindrical tubes.

1.2.4 By use of this guide, medical device manufacturers can characterize the brush part designed for cleaning their device.

1.2.5 By use of this guide, manufacturers of cleaning brushes can evaluate and characterize the cleaning performance of their brushes for the target area(s) of medical device(s), including allowing a comparison with existing brush part designs offered on the market. Further, they are able to

evaluate modifications to designs and construction that might improve performance.

1.2.6 This information can also be shared with the users of the brushes (medical device reprocessors) to help them evaluate the performance of commercially available brushes.

1.3 Exclusions:

1.3.1 This guide does not assess potential damage that may be inflicted by the brush. For instance, brushes with rigid bristles (for example, stainless steel or other metals) or other abrasive materials are more likely to damage medical devices than brushes with flexible bristles (for example, nylon) or more pliable materials. Potential damage from more abrasive materials should be assessed.

1.3.2 This guide does not specify acceptance criteria, and the results will be dependent on the specific parameters (for example, test soil, drying time, channel inside diameter and material, and so forth) that are tested.

1.3.3 This guide is not intended to constitute all steps required to conduct validation of cleaning instructions for a medical device, including the use of brushes for this purpose, but provides methods that may be part of a broader protocol to conduct a complete cleaning instructions validation.

1.3.4 If a brush is intended to clean a specific device(s), cleaning validation shall include testing with that device(s).

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

1.5 *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.*

1.6 *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.*

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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2. Referenced Documents

2.1 ASTM Standards:²

F3208 Guide for Selecting Test Soils for Validation of Cleaning Methods for Reusable Medical Devices

2.2 ISO Standards:³

ISO 17664 Processing of health care products—Information to be provided by the medical device manufacturer for the processing of medical devices

ISO 15883-1 Washer-disinfectors—Part 1: General requirements, terms and definitions and tests

ISO/TS 15883-5 Washer-disinfectors—Part 5: Performance requirements and test method criteria for demonstrating cleaning efficacy

2.3 AAMI Documents:⁴

AAMI TIR12 Designing, testing and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers

AAMI TIR30 A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices

2.4 FDA Document:⁵

Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling Guidance for Industry and Food and Drug Administration Staff, issued March 17, 2015

3. Terminology

3.1 Definitions:

3.1.1 *cleaning*—removal of contamination from a medical device to the extent necessary for further processing or for its intended use.

3.2 Definitions of Terms Specific to This Standard:

3.2.1 *brush part*—working end of the brush that is intended to come in contact with the targeted internal surface(s) of the lumen/tube.

3.2.2 *extraction of the brush part*—depending upon the method used, this may be the exit of the proximal end of the brush part from the tube (Section 8); or the exit of the distal end of the brush part from the distal end of the tube (Section 9).

3.2.3 *insertion of the brush part*—the introduction of the proximal end of the brush part to the proximal end of the tube.

3.2.4 *inside diameter (ID)*—the internal diameter of a lumen/tube.

3.2.5 *jig*—the apparatus which holds the lumen or tube still on the force tester during testing.

3.2.6 *moving the brush part*—the movement of the brush part inside the tube.

3.2.7 *outside diameter (OD)*—the external diameter of a lumen/tube or brush part.

3.2.8 *soiled tube*—for the purposes of this document, refers to a tube that has been inoculated with test soil.

3.2.9 *surface roughness*—the shorter frequency of real surfaces relative to the troughs.

3.2.10 *tube*—for the purposes of this document, refers to the tube that is mounted into the jig.

4. Summary of Practice

4.1 This guide provides details for testing the resistance of a brush part moved inside a tube to simulate the resistance of a brush used to clean the internal channels of a medical device.

4.2 This guide also provides details for soiling a tube, moving a brush part inside that tube, and measuring the soil removed from that tube to simulate the cleaning of the internal channels of a medical device.

4.3 Tube size should be selected based upon the range of the inside diameter (ID) of the different lumens the brush is intended to clean.

4.4 Composition and application of the test soil should be based upon an evaluation of the clinical use of the device (Guide **F3208**, ISO 17664, AAMI TIR12, AAMI TIR30).

5. Significance and Use

5.1 This guide provides test methods for evaluating the performance characteristics of a brush part designed to clean internal channel(s) of a medical device.

5.1.1 The force required to move a brush part within a tube, an indicator of the friction a brush exerts on a surface, is a parameter of cleaning effectiveness and should be measured.

5.1.2 The removal of soil from a tube by a brush part moved in a tube is a further indicator of the effectiveness of a brush to loosen and remove soil from a tube and should be measured.

5.2 By providing objective, repeatable methods for evaluating performance, this guide can improve the ability to assess the effectiveness, under test conditions, of various brush part designs.

6. Description of Test Apparatus

6.1 A force testing machine with moving crosshead, a load cell, a chuck for holding the brush part, a set of tubes with various diameters for the brush part to be actuated into, and a holder for the tubes (see Fig. 1).

6.1.1 The crosshead shall be programmable for the speed and the distance it actuates.

6.1.2 The force required to actuate the brush part up and down shall be measured.

6.1.3 The chuck attaches to the crosshead and holds the brush part in place. The chuck must be able to tighten on the brush part and hold it securely in place.

6.1.4 The tubes should be composed of a material similar to the composition of the lumens of medical devices. The tubes

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.

³ Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, <http://www.ansi.org>.

⁴ Available from Association for the Advancement of Medical Instrumentation (AAMI), 4301 N. Fairfax Dr., Suite 301, Arlington, VA 22203-1633, <http://www.aami.org>.

⁵ <https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm253010.pdf>