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Standard Guide for Designing Reusable Medical Devices for Cleanability[1]

This standard is issued under the fixed designation F3357; 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 is intended to provide manufacturers of reusable medical devices design feature guidance to minimize debris retention after use and increase ease of removal of contaminants and cleaning product residuals from devices during cleaning/rinsing and also prepare for subsequent processing steps (for example, sterilization or disinfection).

1.2 *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.*

1.3 *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 *AAMI Standards:*[2]

AAMI TIR30:2011/(R)2016 A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices

AAMI TIR34:2014/(R)2017 Water for reprocessing of medical devices

ANSI/AAMI ST79:2010 and A1:2010 Comprehensive guide to steam sterilization and sterility assurance in health care facilities

ANSI/AAMI/ISO 11139:2018 Sterilization of health care products – Vocabulary of terms used in sterilization and related equipment and process standards

ANSI/AAMI/ISO 17665-1:2006(R)2013 Sterilization of health care products – Moist heat – Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices

ANSI/AAMI/ISO 17664:2017 Processing of health care product – Information to be provided by the medical device manufacturer for the processing of medical devices

2.2 *CDC Document:*[3]

CDC Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008

3. Terminology

3.1 *Definitions:*

3.1.1 *automated cleaning*—cleaning performed using a machine that soaks and flushes a device with detergent under specified conditions using pulsating or high pressure and then rinses it with suitable water allowing its subsequent use or further processing (AAMI TIR 34:2014/(R)2017).

3.1.2 *cleaning*—removal of contamination from an item to the extent necessary for further processing or for the intended use.

3.1.2.1 *Discussion*—In healthcare facilities, cleaning consists of the removal, usually with detergent and water, of adherent organic and inorganic soil (for example, blood, protein substances, and other debris) from the surfaces, crevices, serrations, joints, and lumens of instruments, devices, and equipment by a manual or mechanical process that prepares the items for safe handling and/or further decontamination (ANSI/AAMI ST79:2010 and A1:2010).

3.1.3 *manual cleaning*—removal of contaminants from an item to the extent necessary for further processing or for intended use without the use of an automated process (ANSI/AAMI/ISO 17664:2017).

3.1.4 *O-ring*—a circular gasket that serves to seal and fill the space between two objects or surfaces, generally to prevent leakage of liquids or gases.

3.1.5 *sterile*—free from viable microorganisms. (ANSI/AAMI/ISO 17665-1:2006 and ANSI/AAMI/ISO 11139:2018)

3.1.6 *sterilization*—a process that destroys or eliminates all forms of microbial life and is carried out in healthcare facilities by physical or chemical methods (CDC Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008).

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[2] Available from Association for the Advancement of Medical Instrumentation (AAMI), 901 N Glebe Rd Ste 300, Arlington, VA 22203, http://www.aami.org.

[3] Available from Centers for Disease Control and Prevention (CDC), 1600 Clifton Road, Atlanta, GA 30329, https://www.cdc.gov/infectioncontrol/guidelines/disinfection/index.html.

FIG. 1 Illustration of a Lumen

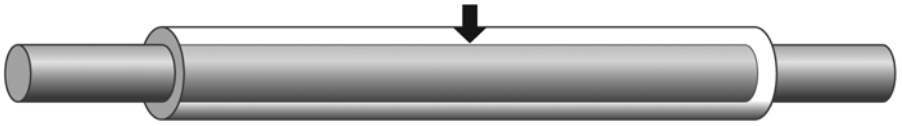

FIG. 2 Illustration of a Shaft within a Lumen

3.2 *Definitions of Terms Specific to This Standard:*

3.2.1 *cleanability*—ratio between the degree of cleanliness obtained and the amount of cleaning effort or resources invested.

3.2.2 *dead-end zones*—areas of stagnation and low fluid velocity.

3.2.3 *disinfection*—process that destroys pathogenic microorganisms and other kinds of microorganisms, but not necessarily all microbial forms, such as bacterial spores, on inanimate objects. Disinfection is a less lethal process than sterilization because it does not kill all forms of microorganisms (for example, bacterial spores).

3.2.4 *fenestration*—opening in the surface of a structure.

3.2.5 *flush port*—access point for introducing detergents and rinse water to facilitate the cleaning of internal surfaces.

3.2.6 *lumens*—open space, cavity, or bore of a tube (see Fig. 1).

3.2.7 *processing*—procedure carried out on a device to allow its subsequent safe use. Processing can include cleaning, disinfection, sterilization, and related procedures.

3.2.8 *sheath*—covering that closely adheres to a similarly shaped object.

3.2.9 *Spaulding*[4] classifications—an approach to develop sterilization and disinfection methods for subject devices based on the risk of infection. It classifies devices into three types: critical, semi-critical, and non-critical.

3.2.9.1 *critical device*—device that is introduced directly into the bloodstream or which contact normally sterile tissue or body space during use. Critical devices should be sterilized.

3.2.9.2 *non-critical device*—device that contacts intact skin, but not mucous membranes. Non-critical devices should be reprocessed by low-level disinfection.

3.2.9.3 *semi-critical device*—devices that contact intact mucous membranes or non-intact skin. Semi-critical devices should be reprocessed by sterilization or if sterilization is not feasible, by high-level disinfection.

[4] Spaulding EH. The role of chemical disinfection in the prevention of nosocomial infections. In: PS Brachman and TC Eickof (ed), Proceedings of International Conference on Nosocomial Infections, 1970. American Hospital Association, Chicago. 1971:254-274.

4. Significance and Use

4.1 Reusable medical devices have a range of cleanability. The equipment, effort, and time expended for cleaning devices should be feasible in the intended setting. For that reason, it is essential that cleanability be considered during the design phase.

4.2 The next section highlights features that either have a tendency to retain debris and/or make removing contamination difficult. Individually, the criteria listed in this document may not render a device difficult to clean. Furthermore, it is the manufacturer's responsibility to consider feasibility and ease of cleaning the device in the clinical environment when designing their device. Although it may not be feasible to remove or modify all of the problematic design features from a device, device manufacturers should be aware of challenging designs for cleaning and take appropriate action for minimizing the impact of these features on cleaning. For example, disassembly may be necessary to thoroughly clean a device, or it may be determined that a device cannot be adequately cleaned, in which case that device would be designated single-use only. In addition, manufacturers should consider the compatibility of their device design with subsequent sterilization or disinfection.

5. General Considerations

5.1 Reusable medical devices should be designed to withstand the rigors of processing (cleaning, disinfection, or sterilization). Therefore, potential damage to the device from processing should be considered. Where feasible, the device should be designed to withstand both a manual cleaning process and an automated cleaning process. Materials should be compatible with the recommended cleaning agents. Testing with processing accessories may determine the need for a device and/or accessory design modification to prevent damage to the device (for example, gouging by brushes, damage from sonication or other cleaning implements).

5.2 Some reusable devices may require the incorporation of difficult-to-clean designs. For these types of devices, special considerations should be taken to create accessibility for thorough cleaning of those areas. For example, flush ports and device disassembly may facilitate the removal of contaminants. When disassembly is required for thorough cleaning, the disassembly and subsequent reassembly should involve a

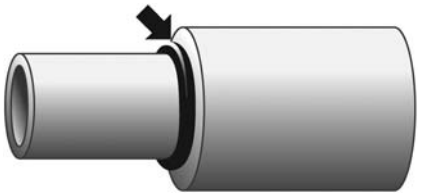

FIG. 3 Illustration of an O-ring

minimum number of components and be intuitive. In addition, manufacturers should provide clear instructions when disassembly and reassembly is required. Screws, nuts, or bolts should be interchangeable (for example, standard size) and readily available to allow for easy replacement.

5.3 The type of soil the device will encounter may also influence the design. Barriers such as O-rings (see Fig. 3) may prevent viscous materials from breaching inaccessible areas of the device; however, those same barriers may be ineffective against more fluid or oily contaminants. After cleaning, users should be instructed to perform visual inspection of the device for residual contamination using lighted magnification, for example. The choice of the color of the device may either camouflage residual contaminants or provide a contrast to allow visible determination of a clean device.

5.4 Dried soils on a device can be particularly difficult to remove. Where possible, devices should be designed to allow immersion of the entire device. Materials should not degrade in manufacturer-recommended cleaning solutions, and electrical components should either be isolated from the contaminated areas or be water-resistant.

6. Device Designs Considerations for Cleanability

6.1 Manufacturers should consider device feature impact on cleanability during device design (for example, automated and/or manual cleaning). Many of these design considerations are further discussed elsewhere (AAMI TIR30, Annex C of ANSI/AAMI/ISO 17664: 2017, and Table 1 of the FDA Guidance Document[5]).

6.2 *Small Internal Parts*—Small internal parts that will be exposed to patient material during use and cannot be removed from the larger device for cleaning present a challenge to cleaning.

6.3 *Lumens/channels*—Lumens/channels are sometimes critical features of devices, such as laparoscopic devices and flexible endoscopes. Advances in technology have led to more minimally invasive surgeries, which result in reduced pain, reduced recovery and healing time for patients. However, long, narrow lumens/channels are difficult to clean, and therefore present a challenge for thorough processing. Inadequately cleaned channels of endoscopes have been frequently associated with outbreaks of healthcare-associated infections. Lumens/channels may be difficult to access with a brush, or may be too narrow to allow a brush to penetrate the length of the lumen/channel, particularly for lumens/channels less than 2 mm in diameter. If a lumen/channel is present within a device, and if the device requires manual brushing, there should be commercially available brushes that are tight-fitting and can fully access all regions of the lumen/channel without causing damage to the lumen/channel. When an appropriate brush is not commercially available, it may be necessary to supply a cleaning brush as an accessory to the device. Where possible, the incorporation of narrow lumens/channels in reusable medical devices should be avoided.

6.4 *Shafts with Lumens*—Shafts with lumens, especially those with narrow lumens, may become soiled with patient material that may not be visible. Consideration should be given to designing this component to be completely disassembled prior to processing and to include fenestrations for brushing and/or flushing to access spaces between mated surfaces. It is important that shafts with lumens have accessible ports for brushing and flushing internal surfaces during cleaning.

6.5 *O-rings*—O-rings maintain the integrity of sealed, internal compartments by preventing leakage of liquids or gases at junctions where it is impractical for rigid materials to mate perfectly, such as rotating parts or removable fittings, in order to maintain the integrity of sealed areas. Poorly designed and/or damaged O-rings can allow contaminants to breach sealed areas of the device. Since these areas are typically difficult to access and are not cleaned as part of normal processing cycles, if they do become contaminated, they can increase the risk of transmitting infection. Minor damage to O-rings is especially problematic because users cannot visually detect contaminants within sealed regions of the device. Where possible, alternatives to the use of O-rings should be considered. If O-rings must be included in a device, it is important to consider the material, size, and placement. O-ring materials should have good chemical and thermal compatibility with products used in processing as well as resistance to abrasion and wear from brushes. O-ring size should be appropriate to prevent gaps even during worst-case combinations of tolerances caused by repeated exposure to processing agents. They should be placed in such a way as to accommodate cleaning requirements for a particular device and application. The impact of the cleaning requirements for a particular device design on the ability to achieve realistic O-ring maintenance schedules (including the ability to evaluate and replace worn O-rings as well as a reasonable frequency of replacement) should also be considered.

6.6 *Sleeves, Sheaths, and Covers Surrounding Rods, Blades, Activators, Inserters, etc. and Junctions Between Insulating Sheaths and Activating Mechanisms*—Sleeves and sheaths may

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