

Technical Information Report

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Designing, testing, and labeling medical devices intended for processing by health care facilities: A guide for device manufacturers

Designing, testing, and labeling medical devices intended for processing by health care facilities: A guide for device manufacturers

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AAMI

Abstract: This technical information report (TIR) provides guidance to medical device manufacturers, who are required to provide instructions that detail the processing steps from pre-treatment at the point of use through the terminal process and storage to accompany reusable and single-use medical devices that are processed by a health care facility prior to clinical use.

Keywords: cleaning, decontamination, disinfection, instructions for use, medical device design, sterilization

AAMI Technical Information Report

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Comments on this technical information report are invited and should be sent to AAMI, Attn: Standards Department, 901 N. Glebe Road, Suite 300, Arlington, VA 22203.

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Committee representation

Association for the Advancement of Medical Instrumentation

Instructions for Reusable Device Reprocessing Working Group

This recommended practice was developed by the AAMI Instructions for Reusable Device Reprocessing Working Group under the auspices of the AAMI Sterilization Standards Committee. Approval of the recommended practice does not necessarily mean that all working group members voted for its approval.

At the time this recommended practice was published, the **AAMI Instructions for Reusable Medical Device Working Group** had the following members:

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NOTE Participation by federal agency representatives in the development of this technical information report does not constitute endorsement by the federal government or any of its agencies.

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Foreword

The following verbal forms are used within AAMI documents to distinguish requirements from other types of provisions in the document:

- “shall” and “shall not” are used to express requirements;
- “should” and “should not” are used to express recommendations;
- “may” and “may not” are used to express permission;
- “can” and “cannot” are used as statements of possibility or capability;
- “might” and “might not” are used to express possibility;
- “must” is used for external constraints or obligations defined outside the document; “must” is not an alternative for “shall.”

Suggestions for improving this document are invited. Comments and suggested revisions should be sent to Standards, AAMI, 901 N. Glebe Road, Suite 300, Arlington, VA 22203 or standards@aami.org.

Introduction

Scientific advances in diagnostic and therapeutic medicine have led to the development of new and sophisticated medical devices for use by health care personnel. These devices vary in size, complexity, fragility, and immersibility, as well as sensitivity to cleaning, disinfecting, and sterilizing agents and the processes that are used. Manufacturers of medical devices intended to be processed by facilities have the responsibility to support product label claims by providing complete and comprehensive written instructions for the handling, cleaning, disinfection, testing, packaging, sterilization, as applicable, of their products. Manufacturers also have the responsibility to conduct and document any testing necessary to validate the suitability of these instructions. Manufacturers have these obligations under U.S. Food and Drug Administration (FDA) labeling regulations (21 CFR 801 [67]). Detailed FDA recommendations are provided in the FDA guidance document, *Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling: Guidance for Industry and Food and Drug Administration Staff* (FDA, Issued March 17, 2015; Updated June 9, 2017). Similarly, ANSI/AAMI/ISO 17664, *Processing of health care products – Information to be provided by the medical device manufacturer for the processing of medical devices* also applies to manufacturers of medical devices that are intended to be processed by a health care facility to be made ready for use on the next patient.

This Technical Information Report (TIR) is intended to assist medical device manufacturers in designing, testing, and labeling devices intended to be processed by a health care facility and to provide information that complies with the requirements presented in FDA, ISO, and relevant AAMI documents. In addition, greater detail will be provided about the processes and resources that a health care facility can have for processing devices. This should provide further assistance to medical device manufacturers (MDMs) in developing their processing instructions.

Health care personnel have the responsibility to obtain and review manufacturers' data and recommendations and to ensure that they have the necessary resources to follow manufacturers' instructions thoroughly. This TIR can serve as a resource for identifying the questions health care personnel should ask manufacturers when considering a product for purchase or when devising a processing protocol for a product already being used. See also ANSI/AAMI ST40, ANSI/AAMI ST41, ANSI/AAMI ST58, ANSI/AAMI ST79, AAMI TIR55, and ANSI/AAMI ST91.

NOTE This technical information report is not a standard, and the material contained herein is not normative in nature. The committee has used the term "shall" in a few instances, based on their knowledge of requirements contained in relevant standards and regulatory requirements.

Designing, testing, and labeling medical devices intended for processing by health care facilities: A guide for device manufacturers

1 Scope

This document provides guidance to medical device manufacturers, who are required to provide instructions that detail the processing steps from pre-treatment at the point of use through the terminal process and storage to accompany reusable and single-use medical devices that are processed by a health care facility prior to clinical use.

Textile devices used in patient draping systems or surgical clothing that are covered in ANSI/AAMI PB70 [5], and medical devices specified by the manufacturer as single-use and not to be processed by the health care facility are not included in the scope of this document.

2 Normative references

The following documents are provided for information.

ANSI/AAMI/ISO 17664:2017, *Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices*

AAMI TIR55, *Human factors engineering for processing medical devices*

AAMI/ANSI/ISO 11607³¹, *Packaging for terminally sterilized medical devices*

ANSI/AAMI/ISO 13485, *Medical devices - Quality management systems - Requirements for regulatory purposes*

ANSI/AAMI/ISO 15223-1:2016, *Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements*

AAMI ST41, *Ethylene oxide sterilization in health care facilities: Safety and effectiveness*

AAMI TIR30², *A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices*

AAMI ST98³, *Cleaning validation of health care products — Requirements for development and validation of a cleaning process for medical devices*

ANSI/AAMI ST58, *Chemical sterilization and high-level disinfection in health care facilities*

ANSI/AAMI ST77, *Containment devices for reusable medical device sterilization*

ANSI/AAMI ST79, *Comprehensive guide to steam sterilization and sterility assurance in health care facilities*

¹ Entire series.

² Document is intended to be superseded by AAMI ST98, which is currently under preparation.

³ Under preparation.

ANSI/AAMI ST91, *Flexible and semi-rigid endoscope processing in health care facilities*

AAMI TIR17, *Compatibility of materials subject to sterilization*

ISO 10993⁴, *Biological evaluation of medical devices*

ISO 15883-4, *Washer-disinfectors — Part 4: Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes*

ASTM F3208-18, *Standard Guide for Selecting Test Soils for Validation of Cleaning Methods for Reusable Medical Devices*

ASTM F3293-18, *Standard Guide for Application of Test Soils for the Validation of Cleaning Methods for Reusable Medical Devices*

ASTM F3321-19, *Standard Guide for Methods of Extraction of Test Soils for the Validation of Cleaning Methods for Reusable Medical Devices*

ASTM F3357-19, *Standard Guide for Designing Reusable Medical Devices for Cleanability*

ASTM F3275-19, *Standard Guide for Using a Force Tester to Evaluate Performance of a Brush Part Designed to Clean the Internal Channel of a Medical Device*

ASTM F3276-19, *Standard Guide for Using a Force Tester to Evaluate the Performance of a Brush Part Designed to Clean the External Surface of a Medical Device*

ASTM D8179-18, *Standard Guide for Characterizing Detergents for the Cleaning of Clinically-used Medical Devices*

Final Guidance for Industry and FDA Staff - *Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling*, June 6, 2017

Department of Health and Human Services (HHS), Food and Drug Administration (FDA). 2016. *Use of Symbols in Labeling*. June 15, 2016

Submissions for Liquid Chemical Sterilants/High Level Disinfectants — *Guidance for Industry and FDA Reviewers 2010*

3 Terms and definitions

3.1

bioburden

population of viable microorganisms on or in a product and/or sterile barrier system

Note to entry: When measured, bioburden is expressed as the total count of bacterial and fungal colony-forming units (CFUs) per single item.

[SOURCE: ISO 11139:2018, 3.23, modified—Added Note to entry.] [27]

3.2

biological indicator

BI

test system containing viable microorganisms providing a specified resistance to a specified sterilization process

Note 1 to entry: Performance requirement for biological indicators can be found in the ANSI/AAMI/ISO 11138 series, *Sterilization of health care products – Biological indicators*.

⁴ Entire series.

Note 2 to entry: According to the Code for Federal Regulations for FDA, “a biological sterilization process indicator is a device intended for use by a health care provider to accompany products being sterilized through a sterilization procedure and to monitor adequacy of sterilization. The device consists of a known number of microorganisms, of known resistance to the mode of sterilization, in or on a carrier and enclosed in a protective package. Subsequent growth or failure of the microorganisms to grow under suitable conditions indicates the adequacy of sterilization.” [21 CFR 880.2800(a)(1)]

Note 3 to entry: Biological indicators are intended to demonstrate whether the conditions were adequate to achieve sterilization. A negative BI does not prove that all items in the load are sterile or that all were exposed to adequate sterilization conditions.

Note 4 to entry: See ANSI/AAMI/ISO 14161 [28] for information on the selection, use, and interpretation of biological indicators.

[SOURCE: ISO 11139:2018, 3.29, added Notes to entry 1 to 4.] [27]

3.3

chemical germicide

disinfectant or sterilant that is labeled to disinfect or sterilize a medical device

3.4

chemical indicator/non-biological indicator

CI

test system that reveals change in one or more pre-specified process variables based on a chemical or physical change resulting from exposure to a process

Note 1 to entry: CIs assist in the detection of potential sterilization failures that could result from incorrect packaging, incorrect loading of the sterilizer, or sterilizer malfunctions. The “pass” response of a CI does not prove that the item monitored by the indicator is sterile.

Note 2 to entry: See ANSI/AAMI/ISO 15882:2008/(R)2013 [30] for information on the selection, use, and interpretation of chemical indicators.

[SOURCE: ISO 11139:2018, 3.43, modified—Added Notes to entry 1 and 2.] [27]

3.5

chemical vapor sterilization

specific sterilization process that uses a solution of alcohol, water, and inert ingredients, with trace formaldehyde (less than 0.25 %), which is heated to produce an unsaturated vapor with temperature, pressure, and exposure time within specified limits

Note to entry: Although “chemical vapor” can be taken to refer to gaseous chemical sterilants in general, the term is used here, as it is commonly used in the health care community, to refer to a specific process.

3.6

cleaning

removal of contaminants to the extent necessary for further processing or for its intended use

Note to entry: In health care facilities, cleaning consists of the removal, usually with detergent and water, of adherent organic and inorganic soil (e.g., blood, protein substances, and other debris) from the surfaces, crevices, serrations, joints, and lumens of medical devices, and equipment by a manual or mechanical process that prepares the items for safe handling and/or further decontamination.

[SOURCE: ISO 11139:2018, 3.46, modified—Added Note to entry.] [27]

3.7

containment device

reusable rigid sterilization container, instrument case, cassette, or organizing tray intended for use in health care facilities for the purpose of containing reusable medical devices for sterilization

3.8

D value

time or dose required under stated conditions to achieve inactivation of 90 % of a population of the test microorganism

Note to entry: The larger the D value, the more resistant the microorganism is to destruction. The value can be derived by plotting the logarithm of the number of microbial survivors against sterilization exposure time; the time corresponding to a 1-logarithm reduction in numbers can then be directly measured.

[SOURCE: ISO 11139:2018, 3.75, modified—Added Note to entry.] [27]

3.9

decontamination

the use of physical or chemical means to remove, inactivate, or destroy pathogens on a surface or item to the point where they are no longer capable of transmitting infectious particles and the surface or item is rendered safe for handling, use, or disposal

Note to entry: The term is generally used in health care facilities to refer to all pathogenic organisms, not just those transmitted by blood.

3.10

disinfection

process that kills pathogenic and other microorganisms by physical or chemical means

3.11

ethylene oxide sterilization

EO

sterilization process that uses EO gas under defined conditions of gas concentration (milligrams [mg] EO per liter), temperature, exposure time, and relative humidity, followed by an aeration phase

3.12

exposure time

period for which the process parameters required for sterilization or disinfection efficacy are maintained within their specified tolerances

3.13

health care facility

hospital, nursing home, extended care facility, free-standing surgical center, clinic, medical office, or dental office

3.14

high-level disinfectant

HLD

liquid chemical sterilant used for a shorter exposure time than that required for sterilization, under otherwise identical conditions

3.15

high-level disinfection

process that kills all microbial organisms, but not necessarily large numbers of bacterial spores

Note to entry: For a process that can be used for both liquid chemical sterilization and high-level disinfection, the contact time for high-level disinfection is shorter than that necessary for sterilization, under otherwise identical conditions.

3.16

instrument air

medical gas that falls under the general requirements for medical gases as defined by the National Fire Protection Association (NFPA) 99 [73] is not respired, is compliant with the ANSI/ISA 7.0.01 [74], and is filtered to 0.01 microns, free of liquids and hydrocarbon vapors, and dry to a dew point of -40 °C (-40 °F)

3.17

intermediate-level disinfection

process that kills most viruses, mycobacteria, most fungi, and vegetative bacteria, but not necessarily bacterial spores

3.18

liquid chemical sterilant

LCS

solution of a chemical that has been validated to provide microbial kill adequate to obtain FDA clearance for a sterilization label claim

3.19

low-level disinfection

process that kills most vegetative bacteria, some viruses, and some fungi, but not mycobacteria or bacterial spores

3.20

master product

medical device or procedure set used to represent the most difficult to sterilize item in a product family or processing category

Note to entry: For the purpose of this document, the “master product” may be different for each process (e.g., cleaning, disinfection, sterilization).

[SOURCE: ISO 11139:2018, 3.160] [27]

3.21

medical device

instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software material, and other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of:

- diagnosis, prevention, monitoring, treatment, or alleviation of disease;
- diagnosis, monitoring, treatment, alleviation of, or compensation for an injury;
- investigation, replacement, modification, or support of the anatomy, or of a physiological process;
- supporting or sustaining life;
- control of conception;
- disinfection of medical devices;
- providing information by means of in vitro examination of specimens derived from the human body;

and does not achieve its primary intended action by pharmacological, immunological, or metabolic means, but which may be assisted in its intended function by such means

[SOURCE: ISO 11139:2018, 3.166, modified—Note 1 to entry deleted.] [27]

3.22

minimum effective concentration

MEC

lowest concentration of a chemical or product, used in a specified process, that achieves a claimed activity

[SOURCE: ISO 11139:2018, 3.177] [27]

3.23

minimum recommended concentration

MRC

lowest concentration chemical or product specified for use in a process

[SOURCE: ISO 11139:2018, 3.178] [27]

3.24

moist heat

thermal energy in the presence of moisture released by gaseous or liquid water

[SOURCE: ISO 11139:2018, 3.179] [27]

3.25

non-critical devices

medical devices that contact only intact patient skin

3.26

pasteurization

disinfection process using hot water at temperatures of 65 °C to 77 °C (150 °F to 170 °F) for a contact time of at least 30 minutes

3.27

permissible exposure limits

PELs

limits developed by Occupational Safety and Health Administration (OSHA) to indicate the maximum airborne concentration of a contaminant to which an employee may be exposed over the duration specified by the type of PEL assigned to that contaminant

[SOURCE: 29 CFR 1910.1000 [71]]

3.28

point of use

physical location and interface where the medical device is used according to its intended use, or proximal location to where the device is used

3.29

process challenge device

PCD

item designed to constitute a defined resistance to a sterilization process and used to assess performance of the process

[SOURCE: ISO 11139:2018, 3.205] [27]

3.30

pyrogen

fever-producing substance

3.31

reusable medical device

medical device designated or intended by the manufacturer as suitable for processing and reuse

Note 1 to entry: This is not a medical device that is designated or intended by the manufacturer for single use only.

Note 2 to entry: This includes devices intended for repeated use on different patients, and devices intended for repeated use on the same patient.

[SOURCE: ISO 11139:2018, 3.236, modified—Added Note 2 to entry.] [27]

3.32

service-life

number of processing cycles and/or lifetime up to which a product is claimed to remain suitable and safe for its intended use when used according to the labelling

[SOURCE: ISO 11139:2018, 3.251] [27]

3.33

steam sterilization

sterilization process that uses saturated steam under pressure, for a specified exposure time and at a specified temperature, as the sterilizing agent (see 3.24)

3.34

sterile

free from viable microorganisms

Note to entry: In practice, no such absolute statement regarding the absence of microorganisms can be proven. See 3.36.

[SOURCE: ISO 11139:2018, 3.271] [27]

3.35

sterility assurance level

SAL

probability of a single viable microorganism occurring on an item after sterilization

Note 1 to entry: It is expressed as the negative exponent to the base 10.

Note 2 to entry: A SAL of 10^{-6} means that there is less than or equal to one chance in a million that a single, viable microorganism is present on a sterilized item. It is generally accepted that a SAL of 10^{-6} is appropriate for items intended to come into contact with compromised tissue (i.e., tissue that has lost the integrity of the natural body barriers).

[SOURCE: ISO 11139:2018, 3.275, modified—Added Note 2 to entry.] [27]

3.36

sterilization

validated process used to render product free from viable microorganisms

Note 1 to entry: In a sterilization process, the nature of microbial inactivation is exponential and thus the survival of a microorganism on an individual item can be expressed in terms of probability. While this probability can be reduced to a very low number, it can never be reduced to zero. See also 3.35.

[SOURCE: ISO 11139:2018, 3.277, modified—Note 1 to entry modified.] [27]

3.37

terminal process

final step of processing to render a medical device safe and ready for its intended use

[SOURCE: ISO 11139:2018, 3.294] [27]

3.38

terminal sterilization

process whereby product is sterilized within its sterile barrier system

[SOURCE: ISO 11139:2018, 3.295] [27]

3.39

test soil

formulation designed for use as a substitute for a contaminant or debris found on a device after use

[SOURCE: ISO 11139:2018, 3.300] [27]

3.40

user verification

documented procedures, performed in the user environment, for obtaining, recording, and interpreting the results required to establish that predetermined specifications have been met

[SOURCE: ANSI/AAMI/ST79:2017] [14]

3.41

validation

documented procedure for obtaining, recording, and interpreting the results required to establish that a process will consistently yield product complying with predetermined specifications

Note to entry: Validation is performed by the device manufacturer.

4 Device design considerations

4.1 Overview

Devices intended to be processed in health care facilities should be designed to facilitate effective cleaning, disinfection and/or sterilization.

NOTE Consideration should be given to the efficiency of the process.

ANSI/AAMI/ISO 17664 [15] states manufacturers of medical devices that are to be processed have a responsibility to ensure that the design of the medical devices facilitates achievement of effective processing. This includes consideration of commonly used health care facility processes. Annex A of ANSI/AAMI/ISO 17664:2017 and Annex D and Annex E [15] of this document provide information about common processing methods in health care facilities. Annex B of this document and Appendix C of the FDA guidance document [59] provide information about sterilization cycles used in the United States.

Several major design aspects of devices intended for processing should be considered during the design process of the medical device:

- a) risk of patient infection based on intended clinical use;
- b) physical design;
- c) material selection;
- d) human factors;
- e) cleaning;
- f) total system design;
- g) packaging design considerations, if applicable;
- h) disinfection;
- i) sterilization.

In addressing each of these considerations, the design process should incorporate the intended function of the device. The function of the end product is affected by the expertise and training of the person who uses it, the conditions of use (e.g., where it is used), the function of the device (what it does or is used for), the operation of the device (how it works), and the need for the device (why it is used).

4.2 Risk of patient infection based on intended clinical use

Both the FDA document (Criterion 3) and Annex C of ANSI/AAMI/ISO 17664:2017 [15] reference the modified Spaulding Classification [56] for categorizing medical devices. The modified Spaulding Classification divides medical devices into three categories; critical, semi-critical, and non-critical, based on how each will be used and the risk of infection from contamination on the item.

- a) **Critical devices** are medical devices that are introduced directly into the human body, into the bloodstream or into other normally sterile areas of the body, and products with sterile fluid pathways. Critical items present a high degree of risk for transmission of infection if contaminated and therefore, must be sterile at the time of use.

NOTE Examples include, but are not limited to, implants and surgical instruments.

- b) **Semi-critical devices** are medical devices that contact intact mucous membranes or nonintact skin of the patient during use, but do not usually penetrate the blood barrier or other normally sterile areas of the body. All semi-critical devices should be sterilized. However, if the device design does not permit sterilization, then it must be subjected to a high-level disinfection process.

- c) **Non-critical devices** are instruments and other devices whose surfaces:

- 1) contact only intact skin and do not penetrate it, or

- 2) do not directly contact the patient but can be contaminated during patient care.

Non-critical devices that are soiled with blood or Other Potentially-Infectious Materials (OPIMs) and come in contact with the health care personnel or intended to have direct contact with the patient should be visibly clean and at a minimum, be intermediate-level disinfected.

Non-critical devices that are likely soiled with blood or OPIM and not intended to have direct contact with health care personnel or the patient should be visibly clean and at a minimum be low-level disinfected.

Non-critical devices that are not expected to be soiled by blood or OPIM should be, at a minimum, visibly clean (see F.7).

4.3 Physical design considerations

Annex C.3.2 of ANSI/AAMI/ISO 17664:2017 [15] identifies key design considerations that have an impact on the ability to clean, disinfect and/or sterilize a device to the extent possible to allow the device to function as intended using currently available technology. Device manufacturers should establish whether the design of their device imposes any constraints on the ability of health care personnel to clean, disinfect, and/or sterilize the device (see ASTM F3357-19 for additional information regarding design considerations for cleanability of medical devices). The FDA states that from the earliest stages of device design and engineering, manufacturers should consider designs that facilitate effective processing. Design considerations can include:

- a) areas that are not accessible for visual inspection to determine adequate cleaning;
- b) areas that could result in retention of residues from cleaning, disinfecting or sterilizing agents;
- c) scoring of the device due to angulation within a lumen;
- d) internal stresses built into them by their design or manufacturer;
- e) potential for external stresses applied during the intended use (e.g., mechanical, electrical, environmental);
- f) effects of cleaning, disinfection, and sterilization procedures;
- g) ease of disassembly and reassembly, including the number of parts and potential for incorrect reassembly;
- h) number and size of parts to be disassembled and reassembled;
- i) potential for incorrect reassembly by the user;
- j) need for lubricants, adhesives, or chemicals established as safe to use;
- k) inner channels exposed to blood and body fluids which cannot be disassembled;
- l) brushing and/or flushing required for cleaning; and
- m) drying and storage of the device.

Design features of critical medical devices, like surgical instruments, pose various challenges for cleaning and/or sterilization. Devices designed with surfaces that are accessible for processing present fewer processing challenges in a clinical setting. Typically, processing requirements will increase as the complexity of the device design increases. The following design categories reflect the varying degrees of processing challenges to be considered in the development of processing steps that are appropriate and effective for the intended purpose. Examples of processing considerations can be found in Annex D and Annex E of this document. These include:

- a) Easy to clean devices:

- 1) simple device structure;
 - 2) all surfaces can be exposed for cleaning;
 - 3) limited or no moving parts;
 - 4) Devices requiring intervention, e.g., brush, flush, and/or soak;
 - 5) rough/textured surfaces, or surfaces that soil can be embedded into or dried on;
 - 6) lumens;
 - 7) accessible surfaces that cannot be exposed, e.g., cannulas;
 - 8) multiple mated surfaces, joints, and/or hinges that are difficult to access;
 - 9) areas that are difficult to dry.
- b) Complex devices requiring use of ultrasonic cleaning:
- 1) inaccessible surfaces;
 - 2) large hidden sliding surfaces;
 - 3) flexible components;
 - 4) blind channels;
 - 5) devices that have multiple components and cannot be disassembled during processing.
- c) Non-critical devices not intended to be sterilized.

4.4 Material design considerations

4.4.1 General considerations

Materials used in the construction of devices should be stable in the presence of recommended chemical agents and processing conditions (e.g., temperature, pressure, vacuum, humidity, time). The biocompatibility of the material and any potential material byproduct or chemical residual should be considered for the intended use of the device. The ISO 10993 series of standards provide detailed guidance for the evaluation of biological safety. The effect of the cleaning, disinfection, and/or sterilization process on degradation of materials should also be evaluated (FDA Criterion 5, L).

See also AAMI TIR17 [19].

4.4.2 Polymeric materials

Polymers vary greatly in chemical formulation and will react differently to various cleaning, disinfecting, and sterilizing agents. Reusable medical devices that are made in whole or in part of polymeric or elastomeric materials can absorb or have a surface reaction with various chemical sterilants and disinfectants, thereby resulting in the formation of toxic residues. In some cases, such as EO sterilization, methods of quantifying the residues are well characterized. This is not true for all chemical disinfectants and sterilants, and each must be evaluated for compatibility with the process and residual toxicity.

Many factors affect the chemical interaction between polymeric materials and cleaning agents, disinfectants or sterilants.

4.4.3 Metals

Devices that are manufactured from metal or that contain metal components might be susceptible to corrosion by body fluids, cleaning, disinfecting, or sterilizing agents. Metal surfaces should be treated to enhance corrosion resistance (e.g., passivation of stainless-steel anodization of aluminum).