Designation: F2847 – 17

Standard Practice for Reporting and Assessment of Residues on Single-Use Implants and Single-Use Sterile Instruments[1]

This standard is issued under the fixed designation F2847; 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 The purpose of this practice is to describe how the cleanliness of single-use implants as manufactured shall be reported. This practice proposes how to approach the identification of critical compounds and suggests different analytical methods.

1.2 The practice does not address substances which are intrinsic to the implant properties or design. In particular, it does not address substances released during implant resorption, implant coatings, or leachables by design.

1.3 This practice does not address the cleanliness of implants which are re-processed, re-cleaned after unpacking for re-use in the hospital or by the manufacturer.

1.4 This practice does not establish limit values for residues.

1.5 This practice suggests appropriate test methods for the general specification of residues and residue requirements of implants and single-use sterile instruments. This practice may also be used to characterize semi-finished components for implants.

1.6 The test methods suggested and described herein refer to established analytical methods and to existing standard methods for chemical, biochemical, or biological analysis.

1.7 This practice is intended solely to provide guidance regarding suitable test methods and reporting conventions for residues, which may or may not affect implant biocompatibility. This practice does not suggest or recommend test methods for biocompatibility, which may be found in Practice F748 or in ISO 10993-1.

1.8 *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.*

1.9 *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]

E29 Practice for Using Significant Digits in Test Data to Determine Conformance with Specifications

E996 Practice for Reporting Data in Auger Electron Spectroscopy and X-ray Photoelectron Spectroscopy

E1078 Guide for Specimen Preparation and Mounting in Surface Analysis

E1504 Practice for Reporting Mass Spectral Data in Secondary Ion Mass Spectrometry (SIMS)

E1635 Practice for Reporting Imaging Data in Secondary Ion Mass Spectrometry (SIMS)

E1829 Guide for Handling Specimens Prior to Surface Analysis

F561 Practice for Retrieval and Analysis of Medical Devices, and Associated Tissues and Fluids

F748 Practice for Selecting Generic Biological Test Methods for Materials and Devices

F1251 Terminology Relating to Polymeric Biomaterials in Medical and Surgical Devices (Withdrawn 2012)[3]

F1877 Practice for Characterization of Particles

F2459 Test Method for Extracting Residue from Metallic Medical Components and Quantifying via Gravimetric Analysis

F2809 Terminology Relating to Medical and Surgical Materials and Devices

G121 Practice for Preparation of Contaminated Test Coupons for the Evaluation of Cleaning Agents

G131 Practice for Cleaning of Materials and Components by

[1] This practice 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.

Current edition approved Sept. 15, 2017. Published October 2017. Originally approved in 2010. Last previous edition approved in 2010 as F2847 – 10. DOI: 10.1520/F2847-17.

[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] The last approved version of this historical standard is referenced on www.astm.org.

Ultrasonic Techniques
G136 Practice for Determination of Soluble Residual Contaminants in Materials by Ultrasonic Extraction

2.2 *ISO Standards:*[4]
ISO 10993-1 Biological Evaluation of Medical Devices—Part 1: Evaluation and Testing
ISO 10993-17 Biological Evaluation of Medical Devices—Part 17: Establishment of Allowable Limits for Leachable Substances
ISO 10993-18 Biological Evaluation of Medical Devices—Part 18: Chemical Characterization of Materials
ISO 11737-1 Sterilization of Medical Devices—Microbiological Methods—Part 1: Determination of a Population of Microorganisms on Products
ISO 17294-1 Water Quality—Application of Inductively Coupled Plasma Mass Spectrometry (ICP-MS)—Part 1: General Guidelines
ISO 17294-2 Water Quality—Application of Inductively Coupled Plasma Mass Spectrometry (ICP-MS)—Part 2: Determination of Selected Elements Including Uranium Isotopes

2.3 *United States Pharmacopeia (USP) Documents:*[5]
<85> Bacterial Endotoxin Test
<161> Transfusion and Infusion Assemblies and Similar Medical Devices
<232> Elemental Impurities – Limits
<233> Elemental Impurities – Procedures
<631> Chromatography
<643> Total Organic Carbon
<730> Plasma Spectrochemistry
<731> Loss on Drying
<851> Spectrophotometry and Light Scattering

2.4 *European Pharmacopoeia (PhEUR) Documents:*[6]
2.2.23 Atomic Absorption Spectrometry
2.2.24 Absorption Spectrophotometry, Infrared
2.2.25 Absorption Spectrophotometry, Ultraviolet and Visible
2.2.28 Gas Chromatography
2.2.29 Liquid Chromatography
2.2.43 Mass Spectrometry
2.2.44 Total Organic Carbon in Water for Pharmaceutical Use
2.2.48 Raman Spectrometry
2.2.57 Inductively Coupled Plasma-Atomic Emission Spectrometry
2.2.58 Inductively Coupled Plasma-Mass Spectrometry

2.5 *Association for the Advancement of Medical Instrumentation (AAMI) Document:*[7]
AAMI ST72 Bacterial Endotoxins—Test Methodologies, Routine Monitoring, and Alternatives to Batch Testing

2.6 *Other References:*
FDA Guidance for Industry Pyrogen and Endotoxins Testing: Questions and Answers, June 2012[8]
8270C EPA Methodologies for GC-MS[9]

3. Terminology

3.1 Unless provided otherwise in 3.2, terminology shall be in conformance with Terminology F1251 and with Terminology F2809.

3.2 *Definitions:*

3.2.1 *action value, n*—the amount(s) of substance(s) tolerated at the surface of an implant by the manufacturer before it will interfere with the manufacturing process.

3.2.2 *exhaustive extraction, n*—extraction until the cumulative residue change is analytically insignificant or less than 10 % of the initial extract.

3.2.3 *limit value, n*—the maximum allowable amount(s) of substance(s) at the surface of an implant not yet found to be harmful for the surrounding tissues and organs. Its value is established and defined by the manufacturer.

3.2.4 *model residue, n*—a single substance or a mixture of substances that reflect the process materials likely to be encountered and used during the manufacturing of the device.

3.2.5 *residue, n*—a substance present at the surface of an implant or embedded therein that is not explicitly recognized and defined as part of the implant specification (special definition for residue analysis of surfaces). It includes process-based residues as well as contamination by environmental factors (adsorbates).

3.2.6 *single-use implant, n*—a medical device which is intended to be implanted permanently and that is not re-cleaned or re-worked for a second implantation after eventual removal.

3.2.7 *soiling, n*—procedure of applying known amounts of a substance onto a medical device for determination of process capability, that is, cleaning efficiency and extraction yields.

3.2.8 *spiking, n*—procedure of applying exact quantities of a substance to an analyte for instrumental calibration and determination reaction yield.

3.2.9 *surface area, n*—the projected surface area of a part. This area does not include the internal porosity of parts with

[4] Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, http://www.ansi.org.
[5] Available from U.S. Pharmacopeia (USP), 12601 Twinbrook Pkwy., Rockville, MD 20852-1790, http://www.usp.org.
[6] Available from European Directorate for the Quality of Medicines and HealthCare (EDQM), 7 allee Kastner, CS 30026, F67081, Strasbourg, France, http://www.edqm.eu/en/News-and-General-Information-43.html.
[7] Available from Association for the Advancement of Medical Instrumentation (AAMI), 4301 North Fairfax Drive, Suite 301, Arlington, VA 22203, http://www.aami.org.
[8] Available from Food and Drug Administration (FDA), 5600 Fishers Ln., Rockville, MD 20857, http://www.fda.gov.
[9] Available from United States Environmental Protection Agency (EPA), Ariel Rios Bldg., 1200 Pennsylvania Ave., NW, Washington, DC 20460, http://www.epa.gov.