



Standard Practice for Reporting and Assessment of Residues on Single Use Implants¹

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. 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 and health practices and determine the applicability of regulatory limitations prior to use.*

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 Dec. 1, 2010. Published January 2011. DOI: 10.1520/F2847-10.

2. Referenced Documents

2.1 ASTM Standards:²

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 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—

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.

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