Designation: F1877 – 24

Standard Practice for Characterization of Particles[1]

This standard is issued under the fixed designation F1877; 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 practice covers a series of recommendations, generally applicable to all medical devices, for characterization of the morphology, shape, size, and size distribution of particles. The methods utilized include sieves, optical, scanning electron microscopy (SEM), transmission electron microscopy (TEM), and electrooptical.

1.2 While characterizing the quantity or number of particles shed from medical devices is important, this is not covered within the scope of the current document. AAMI TIR 42 and USP <788> provide guidelines for determination of particle quantities in various size ranges.

1.3 These methods are appropriate for particles produced by a number of different methods. These methods can include simulated use approaches such as *in vitro* wear test machines (Test Method F732), total joint simulation systems (Guides F1714 and F1715), abrasion testing, and vascular durability testing (Guide F2942). Other methods for producing particles such as shatter boxes or pulverizers, as well as commercially available particles, and particles harvested from tissues in animal or clinical studies can be used.

1.4 Except for chemical composition, this standard does not address sample preparation procedures and/or test systems that can be affected by chemical properties (for example, solubility, miscibility). While this standard does not provide detailed recommendations regarding assessment of chemical properties of particles, these should be considered.

1.5 The particles may be metallic, polymeric, or ceramic and are released from medical device materials either acutely or chronically (for example, due to wear).

1.6 The digestion procedures to be used and issues of sterilization of retrieved particles are not the subject of this practice.

1.7 A classification scheme for description of particle morphology is included in Appendix X3.

1.8 When nanoparticles (that is, having at least one dimension less than 100 nm) are known to be present or are expected, other characterization methods may be needed. For information regarding nanoparticle characterization, refer to standards that address nanoparticles (for example, ISO 21363, ISO/TR 10993-22, ISO/TR 16196).

1.9 This standard does not address ions released from medical devices.

1.10 The values stated in SI units, including units officially accepted for use with SI, are to be regarded as standard. No other systems of measurement are included in this standard.

1.11 As a precautionary safety measure for handling test samples during particle characterization analyses, removed particles from implant tissues should be sterilized or minimally disinfected by an appropriate means that does not adversely affect these particles.

1.12 *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.*

1.13 *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]

C678 Test Method for Determination of Particle Size Distribution of Alumina or Quartz Using Centrifugal Sedimentation (Withdrawn 1995)[3]

E11 Specification for Woven Wire Test Sieve Cloth and Test Sieves

E161 Specification for Electroformed Material and Test Sieves

[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 F04.16 on Biocompatibility Test Methods.

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[2] For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at www.astm.org/contact. 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.

E766 Practice for Calibrating the Magnification of a Scanning Electron Microscope
E1617 Practice for Reporting Particle Size Characterization Data
F561 Practice for Retrieval and Analysis of Medical Devices, and Associated Tissues and Fluids
F660 Practice for Comparing Particle Size in the Use of Alternative Types of Particle Counters
F661 Practice for Particle Count and Size Distribution Measurement in Batch Samples for Filter Evaluation Using an Optical Particle Counter (Withdrawn 2000)[3]
F662 Test Method for Measurement of Particle Count and Size Distribution in Batch Samples for Filter Evaluation Using an Electrical Resistance Particle Counter (Withdrawn 2002)[3]
F732 Test Method for Wear Testing of Polymeric Materials Used in Total Joint Prostheses
F1714 Guide for Gravimetric Wear Assessment of Prosthetic Hip Designs in Simulator Devices
F1715 Guide for Wear Assessment of Prosthetic Knee Designs in Simulator Devices (Withdrawn 2006)[3]
F2942 Guide for ***in vitro*** Axial, Bending, and Torsional Durability Testing of Vascular Stents

2.2 *ISO Standards:*[4]

ISO 21363 Nanotechnologies—Measurements of particle size and shape distributions by Transmission Electron Microscopy
ISO 13322-1 Particle size analysis—Image analysis methods—Part 1: Static image analysis methods
ISO/TR 10993-22 Biological evaluation of medical devices—Part 22: Guidance on nanomaterials
ISO/TR 16196 Nanotechnologies—Compilation and description of sample preparation and dosing methods for engineered and manufactured nanomaterials

2.3 *AAMI Document:*[5]

AAMI TIR 42:2021 Evaluation of Particulate Associated with Vascular Medical Devices

2.4 *U.S. Pharmacopeia:*[6]

USP <788> Particulate Matter in Injections[7]

3. Terminology

3.1 *Definitions of Terms Specific to This Standard:*

3.1.1 *agglomerate, n*—a jumbled mass or collection of two or more particles or aggregates, or a combination thereof, held together by relatively weak cohesive forces caused by weak chemical bonding or an electrostatic surface charge generated by handling or processing.

3.1.2 *aggregate, n*—a dense mass of particles held together by strong intermolecular or atomic cohesive forces that is stable with normal mixing techniques, including high-speed stirring and ultrasonics.

3.1.3 *aspect ratio (AR), n*—a ratio of the major to the minor Feret diameters of a particle (see 12.3.3).

3.1.4 *elongation (E), n*—ratio of the particle length to the average particle width (see 12.3.4).

3.1.5 *equivalent circle diameter (ECD), n*—the diameter of a circle with an area equivalent to the area of the particle (see 12.3.2 and Appendix X1).

3.1.6 *Feret diameter, n*—the mean value of the distance between pairs of parallel tangents to a projected outline of a particle.

3.1.7 *form factor (FF), n*—a dimensionless number relating area and perimeter of a particle, as determined in 12.3.6.

3.1.8 *irregular, adj*—referring to a particle that cannot be described as round or spherical. A set of standard nomenclature and reference figures are given in Appendix X2.

3.1.9 *matrix, n*—particle-free sample that represents the starting composition of test samples prior to preparation (for example, digestion/harvest) or analysis.

3.1.10 *method qualification, n*—the process of evaluating the accuracy, precision, and bias of sample preparation and particle characterization analyses of test particle suspensions based on comparison with defined samples of particles with similar properties. The purpose is to qualify the acceptability of the analytical outcomes.

3.1.11 *morphology, n*—referring to size, shape, structure, and texture.

3.1.12 *particle, n*—the smallest discrete unit detectable as determined in test methods.

3.1.13 *particle breadth, n*—distance between touch points of the shortest Feret pair, orthogonal to length.

3.1.14 *particle length, n*—distance between the touch points of maximum Feret pair. This value will be greater than or equal to the maximum Feret diameter.

3.1.15 *reference particles, n*—particle samples with defined properties (for example, size, shape, composition, density, population distribution, agglomeration) that are used for method qualification.

3.1.16 *rectangular, adj*—referring to a particle that approximates a square or rectangle in shape.

3.1.17 *roundness (R), n*—a measure of how closely an object represents a circle as determined in 12.3.5.

3.1.18 *spherical, adj*—referring to a particle that approximates a sphere in a three-dimensional space and that projects as a round (or circular) shape in a two-dimensional space. A sphere is a three-dimensional, geometrical shape that has all its surface points equidistant from a common point.

3.1.19 *spiked matrix, n*—matrix with reference particles added at known concentration(s).

[4] Available from American National Standards Institute (ANSI), 1180 Avenue of the Americas, 10th Floor, New York, NY 10036, http://www.ansi.org.

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

[6] Available from U.S. Pharmacopeial Convention (USP), 12601 Twinbrook Pkwy., Rockville, MD 20852-1790, http://www.usp.org.

[7] USP <788> is intended to provide recommendations for particulate evaluations of injections and parenteral infusions, and is generally not applicable to medical devices. While limitations of this standard exist and the method used should be validated, it provides some useful information (for example, particle quantification methods, system cleanliness recommendations).