



Standard Practice for Characterization of Particles¹

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^{ε1} NOTE—Editorial changes were made throughout in April 2003.

1. Scope

1.1 This practice outlines a series of procedures for characterization of the morphology, number, size, and size distribution of particles. The methods utilized include sieves, optical, SEM, and electrooptical.

1.2 These methods are appropriate for particles produced by a number of different methods. These include wear test machines, total joint simulation systems, abrasion testing, methods for producing particulates, such as shatter boxes or pulverizers, commercially available particles, and particles harvested from tissues in animal or clinical studies.

1.3 The debris may include metallic, polymeric, ceramic, or any combination of these.

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

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

1.6 As a precautionary measure, removed debris from implant tissues should be sterilized or minimally disinfected by an appropriate means that does not adversely affect the particulate material. *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.*

2. Referenced Documents

2.1 ASTM Standards:

C 678 Test Methods for Particle Size Distribution of Alumina or Quartz by Electric Sensing Technique²

E 11 Specification for Wire Cloth and Sieves for Testing Purposes³

E 161 Specification for Precision Electroformed Sieves³

E 1617 Practice for Reporting Particle Size Characterization Data³

E 766 Practice for Calibrating the Magnification of Scanning Electron Microscopes⁴

F 561 Practice for Retrieval and Analysis of Implanted Medical Devices, and Associated Tissues⁵

F 660 Practice for Comparing Particle Size in the Use of Alternative Types of Particle Counters⁶

F 661 Practice for Particle Count and Size Distribution Measurement in Batch Samples for Filter Evaluation Using an Optical Particle Counter⁷

F 662 Method for Particle Count and Size Distribution in Batch Samples for Filter Evaluation Using an Electrical Resistance Particle Counter⁷

F 732 Test Method for Wear Testing of Polymeric Materials for Use in Total Joint Prostheses⁵

F 1714 Guide for Gravimetric Wear Assessment of Prosthetic Hip Designs in Simulator Devices⁵

F 1715 Guide for Wear Assessment of Prosthetic Knee Designs in Simulator Devices⁵

3. Terminology

3.1 Definitions of Terms Specific to This Standard:

3.1.1 *agglomerate, n*—a mass formed by the cementation of individual particles, probably by chemical forces.

3.1.2 *aggregate, n*—a mass formed of mixtures of particulate and agglomerate particles having a binding force intermediate between agglomerates and flocculates. Formation of aggregates can occur after sampling if the samples are improperly kept or treated.

3.1.3 *aspect ratio (AR), n*—a ratio of the major to the minor diameter of a particle, which can be used when the major axis does not cross a particle outline (see 11.3.3).

3.1.4 *elongation (E), n*—ratio of the particle length to the average particle width (see 11.3.4).

3.1.5 *equivalent circle diameter (ECD), n*—a measure of the size of a particle (see 11.3.2 and Appendix X1).

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 Discontinued; See 1995 *Annual Book of ASTM Standards*, Vol 15.02.

³ *Annual Book of ASTM Standards*, Vol 14.02.

⁴ *Annual Book of ASTM Standards*, Vol 03.01.

⁵ *Annual Book of ASTM Standards*, Vol 13.01.

⁶ *Annual Book of ASTM Standards*, Vol 11.01.

⁷ Discontinued; See 2001 *Annual Book of ASTM Standards*, Vol 14.04.