



Standard Practice for Characterization of Particles¹

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1. Scope

1.1 This practice covers a series of procedures for characterization of the morphology, number, size, and size distribution of particles. The methods utilized include sieves, optical, scanning electron microscopy (SEM), transmission electron microscopy (TEM), and electrooptical.

1.2 These methods are appropriate for particles produced by a number of different methods. These include wear test machines (Test Method F732), total joint simulation systems (Guides F1714 and F1715), 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 The values stated in SI units are to be regarded as standard. No other units of measurement are included in this standard.

1.7 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.

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 F04.16 on Biocompatibility Test Methods.

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2. Referenced Documents

2.1 ASTM Standards:²

C242 Terminology of Ceramic Whitewares and Related Products

C678 Test Method for Determination of Particle Size Distribution of Alumina or Quartz Using Centrifugal Sedimentation (Withdrawn 1995)³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

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 (Discontinued 2000) (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 (Discontinued 2002) (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

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

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.