



Designation: F 1609 – 95

Standard Specification for Calcium Phosphate Coatings for Implantable Materials¹

This standard is issued under the fixed designation F 1609; 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 specification covers the material requirements for calcium phosphate coatings for surgical implant applications.

1.2 In particulate and monolithic form, the calcium phosphate materials system has been well-characterized regarding biological response (1, 2)² and laboratory characterization (2–4). Several publications (5–10) have documented the in vitro and in vivo properties of selected calcium phosphate coating systems.

1.3 This specification includes hydroxylapatite coatings, tricalcium phosphate coatings, or combinations thereof, with or without intentional minor additions (10 % or less, as opposed to trace elements) of other ceramic or metallics, and applied by methods including, but not limited to, the following: (1) mechanical capture, (2) plasma spray deposition, (3) dipping/sintering, (4) electrophoretic deposition, (5) porcelainizing, and (6) sputtering.

1.4 Substrates may include smooth, porous, textured, and other implantable topographical forms.

1.5 This specification excludes organic coatings that may contain calcium and phosphate ionic species.

2. Referenced Documents

2.1 ASTM Standards:

- C 313 Test Method for Adherence of Porcelain Enamel and Ceramic Coatings to Sheet Metal³
- C 501 Test Method for Relative Resistance to Wear of Unglazed Ceramic Tile by the Taber Abraser⁴
- C 633 Test Method for Adhesion or Cohesive Strength of Flame-Sprayed Coatings⁵
- C 674 Test Methods for Flexural Properties of Ceramic Whiteware Materials⁴
- C 949 Test Method for Porosity in Vitreous Whitewares by Dye Penetration⁴
- E 376 Practice for Measuring Coating Thickness by

Magnetic-Field or Eddy-Current (Electromagnetic) Test Methods⁶

F 1044 Test Method for Shear Testing of Porous Metal Coatings⁷

F 1088 Specification for Beta-Tricalcium Phosphate for Surgical Implantation⁷

F 1147 Test Method for Tension Testing of Porous Metal Coatings⁷

F 1185 Specification for Composition of Ceramic Hydroxylapatite for Surgical Implants⁷

2.2 Pharmacopeia Convention Documents:⁸

National Formulary XVI, Tribasic Calcium Phosphate
United States Pharmacopeia:

U.S. Pharmacopeia XXI, Chemical Tests CaP (191), Lead <251>, Mercury <261>, Arsenic <211>, and Heavy Metals <231> Method (1)

2.3 Other Documents:

U.S. Geological Survey Method, Cadmium⁹

21 CFR 820¹⁰

X-Ray Diffraction Analyses¹¹

3. Terminology

3.1 Definitions:

3.1.1 *beta tricalcium phosphate*—a calcium phosphate substance of empirical chemical formula, $\text{Ca}_3(\text{PO}_4)_2$ (see Specification F 1088).

3.1.2 *calcium phosphate*—any one of a number of inorganic chemical compounds containing calcium and phosphate ions as its principal constituents.

3.1.3 *coating*—a layer of mechanically or chemically attached material covering a substrate material.

¹ This specification is under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.13 on Ceramic Materials.

Current edition approved Aug. 15, 1995. Published September 1995.

² The boldface numbers in parentheses refer to the list of references at the end of this specification.

³ Discontinued 1991—See 1990 *Annual Book of ASTM Standards*, Vol 15.02.

⁴ *Annual Book of ASTM Standards*, Vol 15.02.

⁵ *Annual Book of ASTM Standards*, Vol 02.05.

⁶ *Annual Book of ASTM Standards*, Vol 03.03.

⁷ *Annual Book of ASTM Standards*, Vol 13.01.

⁸ Available from U.S. Pharmacopeia Convention, Inc., 12601 Twinbrook Parkway, Rockville, MD 20852.

⁹ Crock, J. G., Felichte, F. E., and Briggs, P. H., "Determination of Elements in National Bureau of Standards Geological Reference Materials SRM 278 Obsidian and SRM 688 Basalt by Inductively Coupled Argon Plasma—Atomic Emission Spectrometry," *Geostandards Newsletter*, Vol 7, 1983, pp. 335–340.

¹⁰ Available from Standardization Documents Order Desk, Bldg. 4 Section D, 700 Robbins Ave., Philadelphia, PA 19111-5098, Attn: NPODS.

¹¹ The Joint Committee on Powdered Diffraction has established a Powder Diffraction File. The committee operates on an international basis and cooperates closely with the Data Commission of the International Union of Crystallinity and ASTM. Hydroxylapatite data can be found on file card No. 9-432; beta tricalcium phosphate data can be found on file card No. 9-169.