



Standard Specification for Composition of Anorganic Bone for Surgical Implants¹

This standard is issued under the fixed designation F 1581; 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 material requirements for anorganic xenogeneic or allogeneic bone (apatite) intended for surgical implants. For a material to be called anorganic or deorganified bone, it must conform to this specification (see Appendix X1).

1.2 The biological response to apatite in soft tissue and bone has been characterized by a history of clinical use² and by laboratory studies (1,2,3). Xenogeneic bone, with organic components present, has been shown to be antigenic in the human host (4) whereas the same material that has been completely deorganified has been shown to elicit no inflammatory or foreign body reactions in human clinical use (5, 6, 7).

1.3 This specification specifically excludes synthetic hydroxylapatite, hydroxylapatite coatings, ceramic glasses, tribasic calcium phosphate, whitlockite, and alpha- and beta-tricalcium phosphate.

1.4 *This standard does not purport to address all of the safety concerns, such as health concerns due to the presence of transmissible disease, 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.* (See Appendix X2).

2. Referenced Documents

2.1 ASTM Standards:

- D 513 Test Methods for Total and Dissolved Carbon Dioxide in Water³
- D 1688 Test Methods for Copper in Water³
- D 2972 Test Methods for Arsenic in Water³
- D 3557 Test Methods for Cadmium in Water³
- D 3559 Test Methods for Lead in Water³
- D 3919 Practice for Measuring Trace Elements in Water by Graphite Furnace Atomic Absorption Spectrophotometry³
- D 4129 Test Method for Total and Organic Carbon in Water

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

Current edition approved Feb. 10, 1999. Published June 1999. Originally published as F 1581 – 95. Last previous edition F 1581 – 96.

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

³ *Annual Book of ASTM Standards*, Vol. 11.01.

High Temperature Oxidation and Coulometric Detection⁴
E 1184 Practice for Electrothermal (Graphite Furnace)
Atomic Absorption Analysis⁵

F 748 Practice For Selecting Generic Biological Test Methods for Materials and Devices⁶

F 1185 Specification for Composition of Ceramic Hydroxylapatite for Surgical Implants⁶

2.2 *Code of Federal Regulations*:⁷

Title 21, Part 820

2.3 *National Formulary*:⁸

Tribasic Calcium Phosphate

2.4 *United States Pharmacopeia*:⁹

Identification Tests for Calcium and Phosphate <191>

Lead <251>

Mercury <261>

Cadmium <461>

Arsenic <211>

Heavy Metals <231> Method 1

Nitrogen Determination <4617>

2.5 *U.S. Geological Survey Method*:¹⁰

Cadmium

3. Terminology

3.1 Definitions:

3.1.1 *allogeneic, adj*—derived from different individuals of the same species.

3.1.2 *anorganic, adj*—denoting tissue (for example, bone) from which the organic material has been totally removed. Also referred to as *deorganified*, *deproteinized* or *deproteinated*.

3.1.3 *apatite, n*—the mineral substance having the molecular formula $\text{Ca}_{10}(\text{X})_2(\text{PO}_4)_6$ where X=OH (hydroxyapatite or hydroxylapatite), CO_3 (carbonated apatite), F or Cl (8).

⁴ *Annual Book of ASTM Standards*, Vol. 11.02.

⁵ *Annual Book of ASTM Standards*, Vol. 03.06.

⁶ *Annual Book of ASTM Standards*, Vol. 13.01.

⁷ Available from Standardization Documents Order Desk, Bldg. 4 Section D, 700 Robbins Ave., Philadelphia, PA 19111-5094, Attn: NPODS.

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

⁹ United States Pharmacopeia XXI. Available from U.S. Pharmacopeia Convention, Inc., 12601 Twinbrook Parkway, Rockville, MD 20852.

¹⁰ 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.