



Standard Specification for Resurfacing Patellar Prosthesis¹

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1. Scope

1.1 This specification covers patellar resurfacing devices used to provide a functioning articulation between the bones of the patella and the femur.

1.2 This specification is intended to provide basic descriptions of material and device geometry. Additionally, those characteristics determined to be important to in-vivo performance of the device are defined.

1.3 This specification does not cover the details for quality assurance, design control, and production control contained in 21 CFR 820 and ISO 9001.

NOTE 1—Devices for custom applications are not covered by this specification.

2. Referenced Documents

2.1 ASTM Standards:

- F 75 Specification for Cast Cobalt-Chromium-Molybdenum Alloy for Surgical Implant Applications²
- F 86 Practice for Surface Preparation and Marking of Metallic Surgical Implants²
- F 90 Specification for Wrought Cobalt-Chromium-Nickel-Tungsten Alloy for Surgical Implant Applications²
- F 136 Specification for Wrought Titanium 6Al-4V ELI Alloy for Surgical Implant Applications²
- F 138 Specification for Stainless Steel Bar and Wire for Surgical Implants (Special Quality)²
- F 451 Specification for Acrylic Bone Cement²
- F 562 Specification for Wrought Cobalt-35 Nickel 20-Chromium 10-Molybdenum Alloy for Surgical Implant Applications²
- F 563 Specification for Wrought Cobalt-Nickel-Chromium-Molybdenum-Tungsten-Iron Alloy for Surgical Implant Applications²
- F 603 Specification for High-Purity Dense Aluminum Oxide for Surgical Implant Applications²
- F 648 Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants³
- F 732 Practice for Reciprocating Pin-on-Flat Evaluation of

Friction and Wear Properties of Polymeric Materials for Use in Total Joint Prostheses²

- F 745 Specification for 18 Chromium-12.5 Nickel-2.5 Molybdenum Stainless Steel for Cast and Solution—Annealed Surgical Implant Applications²
- F 746 Test Method for Pitting or Crevice Corrosion of Metallic Surgical Implant Materials²
- F 748 Practice for Selecting Generic Biological Test Methods for Materials and Devices²
- F 799 Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Forgings for Surgical Implants²
- F 981 Practice for Assessment of Compatibility of Biomaterials for Surgical Implants with Respect to Effect of Materials on Muscle and Bone²
- F 983 Practice for Permanent Marking of Orthopaedic Implant Components²
- F 1044 Test Method for Shear Testing of Porous Metal Coatings²
- F 1108 Specification for Ti6Al4V Alloy Castings for Surgical Implants²
- F 1147 Test Method for Tension Testing of Porous Metal Coatings²
- 2.2 *Government Document:*
 - 21 CFR 820—Good Manufacturing Practice for Medical Devices⁴
- 2.3 *ISO Standard:*
 - ISO 9001—Quality Systems—Model for Quality Assurance in Design/Development, Production, Installation, and Servicing⁵

3. Terminology

3.1 *Definitions*—Dimensions defined as follows are measured in whole or in part in the sagittal, transverse, and coronal (or frontal) planes as appropriate. See Fig. 1 and Fig. 2.

3.1.1 T_1 —total overall prosthetic thickness, for example, from the apex of the dome to the free end of pegs or other fixation geometry.

3.1.2 T_2 —thickness of the patellar prosthesis from the plane of the bone-prosthesis interface (excluding pegs, keels, and so forth) to the apex of the articulating surface.

3.1.3 T_3 —minimum polymer thickness of the patellar

¹ This specification is under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devices and is under the direct responsibility of Subcommittee F04.22 on Arthroplasty.

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² *Annual Book of ASTM Standards*, Vol 13.01.

³ Discontinued; see 1994 *Annual Book of ASTM Standards*, Vol 13.01.

⁴ Available from Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402.

⁵ Available from American National Standards Institute, 11 W. 42nd St., 13th Floor, New York, NY 10036.