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Standard Specification for Resurfacing Patellar Prosthesis[1]

This standard is issued under the fixed designation F 1672; 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.

ϵ[1] NOTE—Editorial changes were made throughout in December 1996.

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 Applications[2]

F 86 Practice for Surface Preparation and Marking of Metallic Surgical Implants[2]

F 90 Specification for Wrought Cobalt-Chromium-Nickel-Tungsten Alloy for Surgical Implant Applications[2]

F 136 Specification for Wrought Titanium 6Al-4V ELI Alloy for Surgical Implant Applications[2]

F 138 Specification for Stainless Steel Bar and Wire for Surgical Implants (Special Quality)[2]

F 451 Specification for Acrylic Bone Cement[2]

F 562 Specification for Wrought Cobalt-35 Nickel 20-Chromium 10-Molybdenum Alloy for Surgical Implant Applications[2]

F 563 Specification for Wrought Cobalt-Nickel-Chromium-Molybdenum-Tungsten-Iron Alloy for Surgical Implant Applications[2]

F 603 Specification for High-Purity Dense Aluminum Oxide for Surgical Implant Applications[2]

F 648 Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants[3]

F 732 Practice for Reciprocating Pin-on-Flat Evaluation of Friction and Wear Properties of Polymeric Materials for Use in Total Joint Prostheses[2]

F 745 Specification for 18 Chromium-12.5 Nickel-2.5 Molybdenum Stainless Steel for Cast and Solution—Annealed Surgical Implant Applications[2]

F 746 Test Method for Pitting or Crevice Corrosion of Metallic Surgical Implant Materials[2]

F 748 Practice for Selecting Generic Biological Test Methods for Materials and Devices[2]

F 799 Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Forgings for Surgical Implants[2]

F 981 Practice for Assessment of Compatibility of Biomaterials for Surgical Implants with Respect to Effect of Materials on Muscle and Bone[2]

F 983 Practice for Permanent Marking of Orthopaedic Implant Components[2]

F 1044 Test Method for Shear Testing of Porous Metal Coatings[2]

F 1108 Specification for Ti6Al4V Alloy Castings for Surgical Implants[2]

F 1147 Test Method for Tension Testing of Porous Metal Coatings[2]

2.2 *Government Document:*

21 CFR 820-Good Manufacturing Practice for Medical Devices[4]

2.3 *ISO Standard:*

ISO 9001-Quality Systems-Model for Quality Assurance in Design/Development, Production, Installation, and Servicing[5]

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,

[1] This specification is under the jurisdiction of ASTM Committee F-4 on Medical and Surgical Materials and Devices and is under the direct responsibility of Subcommittee F04.22 on Arthroplasty.

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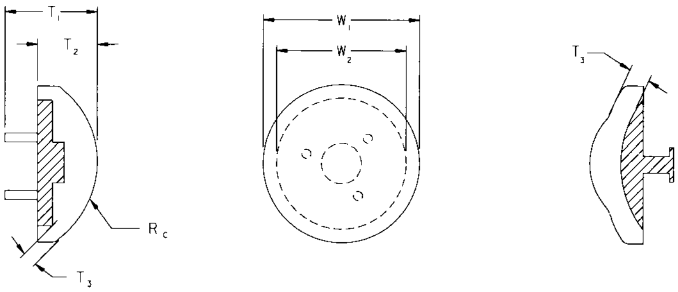
[2] *Annual Book of ASTM Standards,* Vol 13.01.

[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.

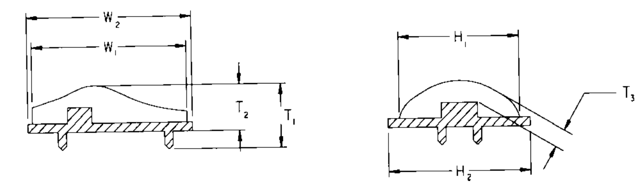
[5] Available from American National Standards Institute, 11 W. 42nd St., 13th Floor, New York, NY 10036.



(a) (b) (c)

NOTE 1—Figure 1(*a*) and (*b*) show a dome style and Fig. 1(*c*) shows a sombrero style.

FIG. 1 Two Versions of Axisymmetric Patella Prostheses



(*a*) Transverse Cross Section With Lateral to the Right

(*b*) Sagittal Cross Section

FIG. 2 Example of a Nonsymmetric Patella Prosthesis

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 prosthesis in direct contact with the femoral component that is "at risk" for wear; this is measured perpendicular to the tangent of the wear surface at the point of contact with the femoral component.

3.1.4 *Discussion*—The dimension T_3 is described in Fig. 1 and Fig. 2 to be a distance from a surface contact point to an internal peg or an edge of the metal back. The exact location of the minimum thickness at risk may be at a different site and will depend on the design of the patella prosthesis and the mating femoral component. For devices manufactured from a single material, T_3 should be measured from the wear surface to the back of the fixation surface.

3.1.5 W_1—maximum medial-lateral width of the articulating surface in the frontal plane.

3.1.6 W_2—maximum medial-lateral width of the metal back in the frontal plane.

3.1.7 H_1—articulating surface superior-inferior height in the frontal plane.

3.1.8 H_2—metal back superior-inferior height in the frontal plane.

3.1.9 *Rc*—radius of curvature for single radius axisymmetric domes only.

3.2 *Definitions of Terms Specific to This Standard:*

3.2.1 *dome*—a style of axisymmetric prosthesis that has a single uniform radius of curvature (that is, button).

3.2.2 *fixation element*—any peg, keel, or other protrusion from the nonarticulating side of the patellar component intended to increase the surface contact or mechanical interlock between the component, the bonding agent (bone cement) or the natural patella, or both.

3.2.3 *marker wire*—a nonstructural, generally thin metallic wire, designed to be apparent on X-rays taken after placement of implants that otherwise would be nonapparent on such X-rays.

3.2.4 *metal back*—a metal structure supporting the articulating surface material. This may be fixed rigidly to the articulating surface or it may be fixed such that it allows the articulating surface to rotate or translate.

3.2.5 *radii of curvature*—the geometry of the articular surface may be described by a list of appropriate radii of curvature.

3.2.6 *sombrero*—a style of axisymmetric prosthesis that has multiple radii of curvature. (See Fig. 1Fig. 1c.)

4. Classification

4.1 Patellar replacement devices may be classified according to geometry:

4.1.1 *Axisymmetric*—The articulating surface is symmetric on an axis perpendicular to the prepared bonding surface (for example, Dome patellas and sombrero-type patellas). See Fig. 1.

4.1.2 *Nonsymmetric*—The articulating surface is not axisymmetric but may be symmetric on a plane. Examples of this type are anatomical or oblong prosthesis. See Fig. 2.

4.2 It is important to define the type of fixation geometry so that the user can understand the degree of bone invasion:

4.2.1 *Peg*—Number, size (for example: length, width, diameter, and so forth), and location and

4.2.2 *Keel*—Width, length, thickness, geometry, and location.

5. Materials and Manufacture

5.1 The choice of materials is understood to be a necessary but not sufficient ensurance of function of the device made from them. All devices conforming to this specification shall be fabricated from materials, with adequate mechanical strength and durability, corrosion resistance and biocompatibility.

5.1.1 *Mechanical Strength*—Components of various prostheses have been successfully fabricated from the following materials. See Specifications F 75, F 90, F 136, F 138, F 562, F 563, F 603, F 648, F 745, F 799, and F 1108. The articulating surface should be fabricated from a material such as UHMWPE in accordance with Specification F 648.

5.1.2 *Corrosion Resistance*—Materials with limited or no history of successful use for orthopedic implant application must be determined to exhibit corrosion resistance equal to or better than one of the materials listed in 5.1.1 when tested in accordance with Test Method F 746.

5.1.3 *Biocompatibility*—Materials with limited or no history of successful use for orthopedic implant application must be determined to exhibit acceptable biological response equal to or better than one of the materials listed in 5.1.1 when tested in accordance with Practices F 748 and F 981.

6. Performance Requirements

6.1 The implant shall be capable of withstanding sustained