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Standard Specification for Resurfacing Patellar Prosthesis[1]

This standard is issued under the fixed designation F1672; 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 patellar resurfacing devices used to provide a functioning articulation between 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*:[2]

F75 Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Castings and Casting Alloy for Surgical Implants (UNS R30075)

F86 Practice for Surface Preparation and Marking of Metallic Surgical Implants

F90 Specification for Wrought Cobalt-20Chromium-15Tungsten-10Nickel Alloy for Surgical Implant Applications (UNS R30605)

F136 Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)

F138 Specification for Wrought 18Chromium-14Nickel-2.5Molybdenum Stainless Steel Bar and Wire for Surgical Implants (UNS S31673)

F451 Specification for Acrylic Bone Cement

F562 Specification for Wrought 35Cobalt-35Nickel-20Chromium-10Molybdenum Alloy for Surgical Implant Applications (UNS R30035)

F563 Specification for Wrought Cobalt-20Nickel-20Chromium-3.5Molybdenum-3.5Tungsten-5Iron Alloy for Surgical Implant Applications (UNS R30563) (Withdrawn 2005)[3]

F603 Specification for High-Purity Dense Aluminum Oxide for Medical Application

F648 Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants

F732 Test Method for Wear Testing of Polymeric Materials Used in Total Joint Prostheses

F745 Specification for 18Chromium-12.5Nickel-2.5Molybdenum Stainless Steel for Cast and Solution-Annealed Surgical Implant Applications (Withdrawn 2012)[3]

F746 Test Method for Pitting or Crevice Corrosion of Metallic Surgical Implant Materials

F748 Practice for Selecting Generic Biological Test Methods for Materials and Devices

F799 Specification for Cobalt-28Chromium-6Molybdenum Alloy Forgings for Surgical Implants (UNS R31537, R31538, R31539)

F981 Practice for Assessment of Compatibility of Biomaterials for Surgical Implants with Respect to Effect of Materials on Muscle and Bone

[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] 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.

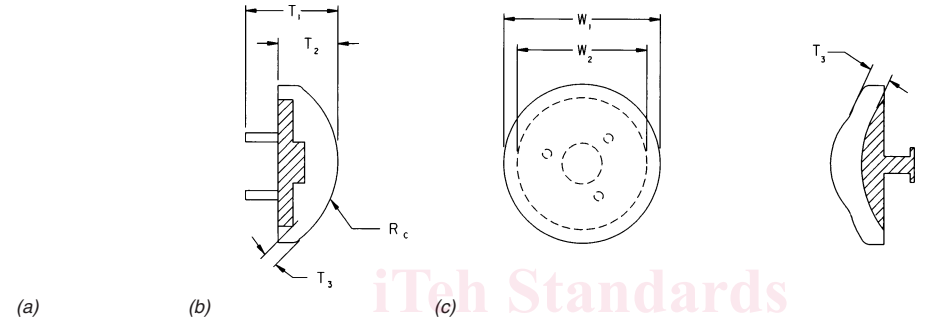
[3] The last approved version of this historical standard is referenced on www.astm.org.

F983 Practice for Permanent Marking of Orthopaedic Implant Components
F1044 Test Method for Shear Testing of Calcium Phosphate Coatings and Metallic Coatings
F1108 Specification for Titanium-6Aluminum-4Vanadium Alloy Castings for Surgical Implants (UNS R56406)
F1147 Test Method for Tension Testing of Calcium Phosphate and Metallic Coatings
F1160 Test Method for Shear and Bending Fatigue Testing of Calcium Phosphate and Metallic Medical and Composite Calcium Phosphate/Metallic Coatings

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]

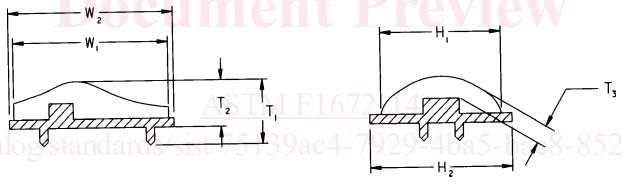
3. Terminology

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.



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

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 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 shown in Fig. 1 and Fig. 2 to be the 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.

[4] Available from Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402.
[5] Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036.

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 axisymmetrical 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 not be apparent 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. 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 assurance 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 materials in the following Specifications: F75, F90, F136, F138, F562, F563, F603, F648, F745, F799, and F1108. The articulating surface should be fabricated from a material such as UHMWPE in accordance with Specification F648.

5.1.2 *Corrosion Resistance*—Materials with limited or no history of successful use for orthopedic implant application shall exhibit corrosion resistance equal to or better than one of the materials listed in 5.1.1 when tested in accordance with Test Method F746.

5.1.3 *Biocompatibility*—Materials with limited or no history of successful use for orthopedic implant application shall exhibit an acceptable biological response equal to or better than one of the materials listed in 5.1.1 when tested in accordance with Practices F748 and F981.

6. Performance Requirements

6.1 The implant shall be capable of withstanding sustained static and dynamic physiologic loads without compromise of its function for the intended use and environment. ~~At this time there are no device-specific test methods and there are no acceptable performance levels.~~ Device testing shall be done in keeping with the implant's intended function.

6.2 There are relevant failure modes listed as follows which, at a minimum, shall be considered in the evaluation of the safety and efficacy of a patella prosthesis. Literature references ~~**(1–8)**~~ **(1-8)**[6] have been included in the rationale statement in support of these failure modes.

6.2.1 *Dislocation or Lateral ~~Subluxation—~~Subluxation (Over the Lateral Portion of the Femoral Articular Surface)—* ~~Subluxation over the lateral portion of the femoral articular surface~~ This has occurred in the past and is ~~design-~~design and ~~patient-specific.~~ patient specific.

6.2.2 *Component Disassociation*—Devices made from multiple layers or components have disassociated under clinical use (for example, the articulating surface from the metal back, the porous coating from the metal back, and so forth). This disassociation may be evaluated through shear loading or compression loading, or a combination of the two.

6.2.3 *Fixation Failure*—Devices have loosened at the interface with bone. Attachment mechanisms such as pegs have sheared or failed. Components have become loose within the bone cement.

[6] The boldface numbers given in parentheses refer to a list of references at the end of the text.