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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.

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, 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

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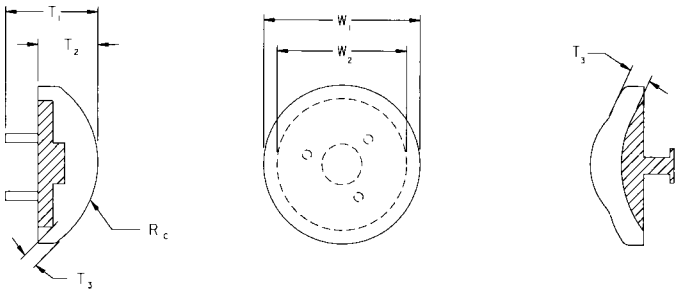
[2] *Annual Book of ASTM Standards*, Vol 13.01.

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

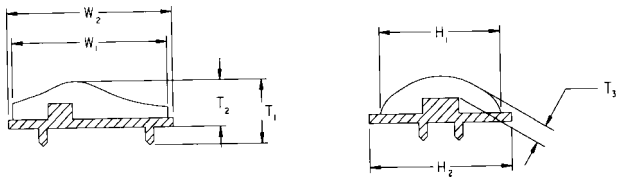
[4] Available from Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402.

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



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

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 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 minimum, shall be considered in the evaluation of safety and efficacy of a patella prosthesis. Literature references **(1–8)** have been included in the rationale statement in support of these failure modes.

6.2.1 *Dislocation or Lateral Subluxation*—The subluxation over the lateral portion of the femoral articular surface. This has occurred in the past and is design and patient specific.

6.2.2 *Component Disassociation*—Devices made from multiple layers or components have disassociated under clinical use (for example, articulating surface from the metal back, 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.

6.2.4 *Device Fracture*— Partial or complete fracture of either the articular surface or the metal back.

6.2.5 *Articular Surface Wear*—Patella prostheses have failed due to excessive wear of the articulating surface resulting in polymer debris and in some cases "wear through" of the articular surface with subsequent metal-on-metal wear debris. Thin UHMWPE may accelerate this wear but it is design dependent.

6.3 The failure modes may be addressed through relevant testing (for example, shear testing of device component interfaces) and analysis (for example, internal stress analysis due to loading). The testing may encompass some combination of static and dynamic loading environments.

6.4 Polymeric components as manufactured shall be made from materials demonstrating wear rates substantially equivalent to or less than UHMWPE as determined by Practice F 732.

NOTE 2—In situations where the pin-on-flat test may not be considered appropriate, other test methods may be considered.

6.5 Porous metal coatings shall be tested according to Test Method F 1044 (shear strength) and Test Method F 1147 (tensile strength).

7. Dimensions, Mass, and Permissible Variations

7.1 Dimensions of patellar resurfacing devices shall be as designated, but not limited to those described, in Fig. 1 and Fig. 2. The tolerance and methods of dimensional measurement must be sought to conform with industry practice and, whenever possible, on an international basis.

8. Finish and Product Marking

8.1 Items conforming to this specification shall be finished in accordance with Practice F 86, where applicable.

8.2 *Polymeric Bearing Surface Finish*—Shall conform to the manufacturer's documented standards concerning concentricity, sphericity, and surface roughness, where applicable.

8.3 The manufacturer, lot number, and material type shall be marked, space permitting, on the device in accordance with Practices F 86 and F 983 in the order of priority listed.

8.4 Optional marking shall specify orientation for nonsymmetric devices.

8.5 If one of the components is not radiographically opaque, it may be appropriately marked for radiographic evaluation. The marker wire is a noncritical element and may not be necessary. If a marker wire is used it should be placed in a noncritical area to avoid degrading the structural and functional properties of the device.

9. Packaging and Package Marking

9.1 Adequate dimensioning to describe overall size and shape (see Fig. 1 and Fig. 2 for examples) shall be included in the product labeling.

9.2 The material(s) used for the implant shall be specified on the package labels and inserts.

10. Keywords

10.1 arthroplasty; patella; prosthesis

APPENDIX

(Nonmandatory Information)

X1. RATIONALE STATEMENT

X1.1 The objectives of this specification are to establish guidelines for the manufacture and function of components for patellar replacement. Current prostheses include single material designs and multiple material/component designs all preassembled at the manufacturing site. Some multicomponent design allow a certain degree of mobility of the bearing surface over the fixation surface. Patellar replacement parts are intended for use in a patient who is skeletally mature. They will be subjected to considerable dynamic loads in a corrosive environment and virtually continuous motion at the bearing surfaces.

X1.2 This specification is designed to provide a standardization of device terminology, classification, dimensions, and labeling; alert designers to potential failure mechanisms such as disassociation, excessive wear, dislocation, and so forth (Refs (**1-8**));[6] and provide guidance regarding suitable materials for fabrication based on current technology and clinical use.

X1.3 Laboratory tests to accurately simulate physiological loads, aggressive electrolytes, and complex constituents of body fluids cannot to date entirely simulate long-term in-vivo

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

performance. It is recognized that failure of the arthroplasty can occur without failure of the device itself. Long-term projections of satisfactory performance can be suggested but not accurately predicted using available testing procedures. This specification identifies those factors felt to be important to ensure a satisfactory useful prosthetic life.

X1.4 Under applicable documents and materials, the lists reflect the current state of the art. It is recognized that should materials not now included appear and be proved acceptable, they shall be inserted in the process of revision. To date the vast majority of patella prostheses have been implanted using a bone bonding agent such as acrylic bone cement in accordance with Specification F 451. Although the bone bonding agent is not considered part of the patella prosthesis it may play an important role in the performance of the prosthesis and therefore should be considered during testing and evaluation.

X1.5 Marker wires have been used to make components radiographically detectable. They may not be necessary but when they are used, shall be located in a noncritical area to avoid any contribution to device failure. They shall not be located in critical wear areas nor regions that may see high stresses.

X1.6 *Performance Considerations*—Component performance can be predicted only indirectly at this stage, by referring to strength levels and other parameters. Reference to parameters applicable to materials may or may not adequately describe structures made from them. In a period of transition from device specifications standards to device performance standards, both methods of description may be appropriate. At this time there are no device specific standard test methods to evaluate the performance of resurfacing patella prostheses.

X1.7 The thickness of the UHMWPE may help in the distribution of contact stress, increase the resistance to bending under load, and provide sufficient material to resist normal wear, thus contributing to increased longevity of a device. Thin UHMWPE in some prosthetic designs may contribute to accelerated wear.

X1.8 For labeling of the implant, it is desirable to have complete information where space is available to do so, including manufacturer's trademark material, lot number, size, orientation, if any, and catalog number with date, in that order.

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