Designation: F 2091 – 01

Standard Specification for Acetabular Prostheses[1]

This standard is issued under the fixed designation F 2091; 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 standard describes acetabular resurfacing devices used to provide a functioning articulation between the bones of the acetabulum and the femur.

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

1.3 Acetabular prostheses included within the scope of this standard are intended for mechanical fixation between the prosthesis and host bone, by the use of bone cement or through biological fixation.

1.4 Custom (designed explicitly for a single patient), revision, or constrained acetabular prostheses are not covered within the scope of this standard.

1.5 This standard does not cover the details for quality assurance, design control, production control contained in 21 CFR 820 (Quality System Regulation) and ISO 9001.

2. Referenced Documents

2.1 *ASTM Standards:*

F 67 Specification for Unalloyed Titanium for Surgical Implant Applications[2]

F 75 Specification for Cobalt-28 Chromium-6 Molybdenum Casting Alloy and Cast Products for Surgical Implants (UNS R30075)[2]

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

F 90 Specification for Wrought Cobalt-20 Chromium-15 Tungsten-10 Nickel Alloy for Surgical Implant Applications (R30605)[2]

F 136 Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy (UNS R56401) for Surgical Implant Applications[2]

F 138 Specification for Wrought 18 Chromium-14 Nickel-2.5 Molybdenum Stainless Steel Bar and Wire for Surgical Implants (UNS S31673)[2]

F 562 Specification for Wrought Cobalt-35 Nickel-20 Chromium-10 Molybdenum Alloy for Surgical Implant Applications (UNS R30035)[2]

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

F 601 Practice for Fluorescent Penetrant Inspection of Metallic Surgical Implants[2]

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

F 629 Practice for Radiography of Cast Metallic Surgical Implants[2]

F 648 Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants[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 (UNS R31537, R31538, R31539)[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 Orthopedic Implant Components[2]

F 1044 Test Method for Shear Testing of Calcium Phosphate Coatings and Metallic Coatings[2]

F 1108 Specification for Titanium-6 Aluminum-4 Vanadium Alloy Castings for Surgical Implants (UNS R56406)[2]

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

F 1160 Test Method for Sheer and Bending Fatigue Testing of Calcium Phosphate and Metallic Medical Coatings[2]

F 1185 Specification for Composition of Ceramic Hydroxylapatite for Surgical Implants[2]

F 1377 Cobalt-28 Chromium-6 Molybdenum Powder for Coating of Orthopedic Implants (UNS R30075)[2]

F 1472 Specification for Wrought Titanium-6 Aluminum-4 Vanadium Alloy for Surgical Implant Applications (UNS R56400)[2]

F 1501 Test Method for Tension Testing of Calcium Phosphate Coatings[2]

F 1537 Specification for Wrought Cobalt-28 Chromium-8

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

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

Molybdenum Alloy for Surgical Implants (UNS R31537, UNS R31538, and UNS R31529)[2]

F 1580 Specification for Titanium and Titanium-6 % Aluminum-4 % Vanadium Alloy Powders for Coatings of Surgical Implants[2]

F 1714 Guide for Gravimetric Wear Assessment of Prosthetic Hip Designs in Simulator Devices[2]

F 1820 Test Method for Determining the Axial Disassembly Force of a Modular Acetabular Device[2]

F 1978 Test Method for Measuring Abrasion Resistance of Metallic Thermal Spray Coatings by Using the Taber™ Abraser[2]

F 2033 Specification for Total Hip Joint Prosthesis and Hip Endoprosthesis Bearing Surfaces Made of Metallic, Ceramic, and Polymeric Materials[2]

2.2 *ISO Standards:*

ISO 5832 Implants for surgery—Metallic materials for surgical implants[3]

ISO 5834 Implants for surgery—Ultra high molecular weight polyethylene[3]

ISO 6474 Implants for surgery—Ceramic materials based on alumina[3]

ISO 9001 Quality systems—Model for quality assurance in design/development, production, installation, and servicing[3]

2.3 *Code of Federal Regulations:*

21 CFR 820 Quality System Regulation[4]

3. Terminology

3.1 *Definitions:*

3.1.1 *bearing element*, *n*—articulating surface element between the femoral head and shell or bonding agent (bone cement).

3.1.2 *cavity*, *n*—any slot, cut, hole, or other feature within the shell intended to accommodate modular adjunct fixation elements; instruments for insertion, extraction, and so forth; or for manufacturing purposes.

3.1.3 *fixation element*, *n*—any peg, spike, threadform, or other protrusion from the exterior surface of the shell intended to increase the surface contact or mechanical interlock between the component, the bonding agent, or the natural acetabulum or a combination thereof.

3.1.4 *flange*, *n*—rim extending from the entry diameter of bearing element.

3.1.5 *porous coating*, *n*—a region on the exterior surface of the shell characterized by interconnecting subsurface pores, generally with volume porosity between 30 to 70 %, average pore size between 100 to 1000 µm, and a thickness between 500 to 1500 µm. This porous layer may be manufactured directly into the device by casting or by various electro/chemical/thermal/mechanical means, or applied as a coating of particles, beads, or mesh by processes such as sintering or plasma spray.

3.1.6 *radiographic marker*, *n*—nonstructural, generally thin wire, designed to be apparent on X-rays taken after placement of implants that otherwise would be unapparent on such X-rays.

3.1.7 *retention element*, *n*—any ring, taper, wire, or other protrusion or cavity from the interior surface of the shell or the exterior surface of the bearing element that is intended to affix the bearing element to the shell.

3.1.8 *shell*, *n*—metal structure supporting the articulating surface material, and which may be fixed rigidly to the articulating surface or fixed such that it allows the articulating surface to rotate or translate.

3.1.9 *surface texturing*, *n*—repetitive or random deviations from the nominal surface that forms the three dimensional topography of the surface.

3.2 Dimensions of acetabular prostheses should be designated in accordance with Figs. 1-3 or by an equally acceptable and detailed method.

NOTE 1—Figs. 1-3 are intended to be illustrative of typical acetabular prostheses and to designate dimensions, but representation of the components does not otherwise form part of the standard.

4. Types

4.1 Acetabular prostheses falling within the scope of this specification are of two types, as defined below. There are no distinguishing features (for example, augmentation or lack thereof, holes, and so forth) that would exempt any device from any requirement of this specification.

4.1.1 *Type I*—Single-piece acetabular prostheses.

NOTE 2—Specifications to both bearing elements and shell may apply.

4.1.2 *Type II*—Multipiece, modular structure prostheses.

5. Material

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.

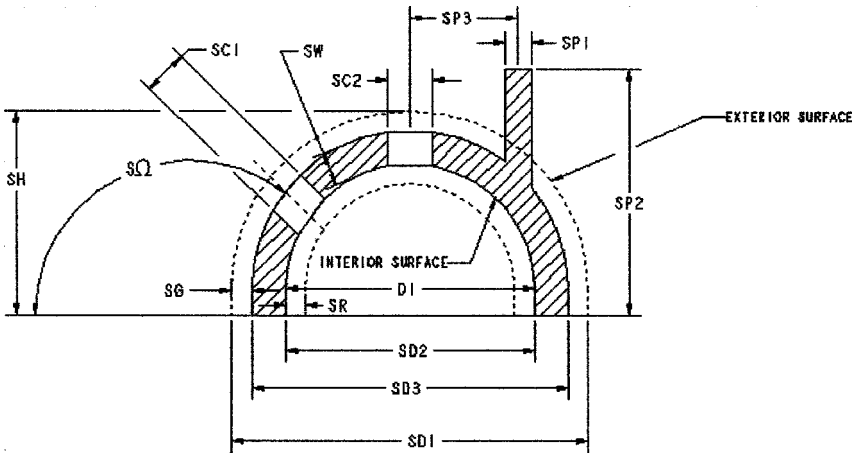
5.1.1 *Mechanical Strength*—Various components of acetabular prostheses have been successfully fabricated from the following materials: See Specifications F 67, F 75, F 90, F 136, F 138, F 562, F 563, F 603, F 648, F 745, F 799, F 1108, F 1185, F 1377, F 1472, F 1537, F 1580; and ISO 5832, ISO 5834, and ISO 6474. However, not all of these materials may possess sufficient mechanical strength for critical highly stressed components nor for articulating surfaces. Associated standards include Practices F 601 and F 629.

5.1.2 *Corrosion Resistance*—Materials with limited or no history of successful use for orthopaedic 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 to Test Method F 746.

5.1.3 *Biocompatibility*—Materials with limited or no history of successful use for orthopaedic 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 to Practices F 748 and F 981 for a given application.

[3] Available from International Organization for Standardization, 1 Rue de Varembé, Case Postale 56, CH-1211, Geneva 20, Switzerland.

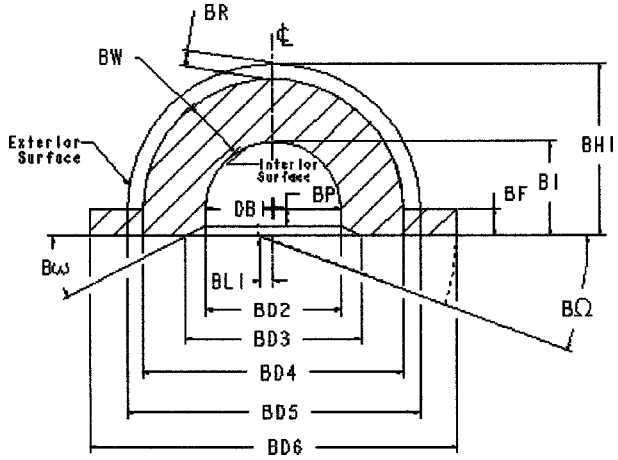
[4] Available from Standardization Documents Order Desk, Bldg. 4 Section D, 700 Robbins Ave, Philadelphia, PA 19111-5094, Attn: NPODS.



Key:

SD1	Diameter of spherical socket	SR	Retention element distance from SD2
SD2	Retentive or nonretentive entry diameter	SH	Overall height
SD3	Effective spherical external diameter	SΩ	Angle from shell face to SC1 center
SC1	Dome cavity diameter (when present)	SP1	Fixation element width or diameter
SC2	Apical cavity diameter (when present)	SP2	Fixation element height
SW	Minimum wall thickness	SP3	Distance to fixation element from shell face
SG	Surface texture or coating depth		

FIG. 1 Shell Cross Section



Key:

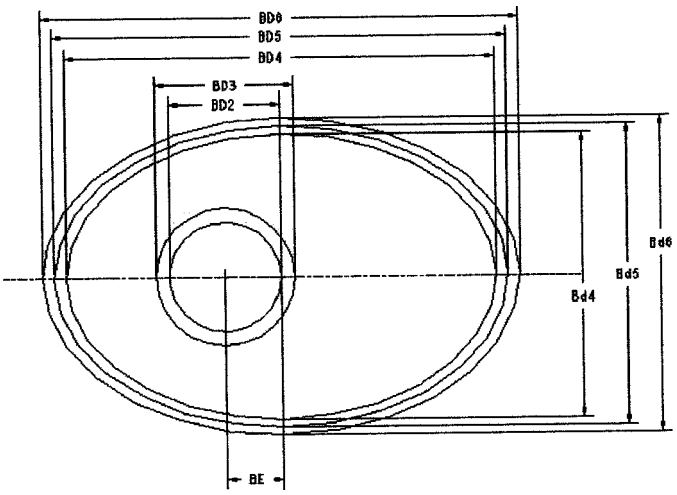
BD1	Diameter of spherical socket	BH1	Distance from bearing element face to dome
BD2	Retentive or nonretentive entry diameter	BH2	Distance from augmentation to dome
BD3	Relief diameter (entry chamfer, if present, need not extend through the whole circumference)	BI	Inside depth
		BR	Retention element depth
		Bω	Angle of chamfer element from BD2 to BD3
BD4	Effective spherical external diameter	BΩ	Angle of augmentation of an extended lip
BD5	Outside diameter of the bearing element	BL1	Offset of β from center of BD4
BD6	Flange diameter (when present)		
BP	Depth of BD2		
BW	Minimum wall thickness		
BF	Flange thickness (when present)		

FIG. 2 Bearing Element Cross Section

6. Performance Requirements

6.1 *Structural Requirements*—Acetabular prostheses conforming to this specification shall be capable of withstanding normal static and dynamic loading in the physiological range. It shall also demonstrate wear rates substantially equivalent to or less than sterile ultra-high-molecular-weight polyethylene (Specification F 648) with a cobalt chromium couple. See Test Method F 1820 and Guide F 1714.

6.2 *Metal and Ceramic Coating or Surface Texture Integrity*—The coating shall be free of detrimental blisters, delaminations, contamination, or poorly defined coating boundaries when viewed with no magnification. It shall not fail by spalling, cracking, detrimental material loss, or detrimental degradation. The following test methods shall be used (if applicable): Test Methods F 1044, F 1147, F 1160, F 1501, and F 1978.



Key:
BD2 Retentive or nonretentive entry diameter
BD3 Relief diameter (entry chamfer, if present, need not extend through the whole circumference)
BD4 Effective spherical external diameter
BD5 Major external diameter
BD6 Major flange diameter (when present)
Bd4 Minor effective spherical external diameter
Bd5 Minor external diameter
Bd6 Minor flange diameter (when present)
BE Eccentricity

FIG. 3 Plan View of Oval/Eccentric Configuration of Bearing Element and Shell

NOTE 3—In situations in which these tests may not be considered appropriate, other test methods may be considered.

6.3 There are relevant failure modes listed below which, at a minimum, shall be considered in the evaluation of safety and efficacy of an acetabular prosthesis. The failure modes may be addressed through relevant physical testing, or analytical analysis (for example, internal stress analysis as a result of loading).

NOTE 4—There is no current ASTM standard for analytical analysis, but this is an important consideration. Testing may encompass some combination of static and dynamic loading environments.

6.3.1 *Component Disassociation*—Devices made from multiple layers or components have disassociated under clinical use (for example, articulating surface from the shell, porous coating from the shell, and so forth). See Test Method F 1820.

6.3.2 *Fixation Failure*—Devices have loosened at the interface with the bone or bone cement. Fixation elements have failed.

6.3.3 *Device Fracture*—Partial or complete fracture of either the bearing element or the shell.

6.3.4 *Articular Surface Wear*—Acetabular prostheses have failed because of excessive wear through the bearing element resulting in particle debris (see Guide F 1714).

7. Dimensions

7.1 Acetabular prostheses conforming to this specification should be fabricated in accordance with the general configuration illustrated in Figs. 1-3.

7.2 If one of the components is not radiopaque, it may be appropriately marked for radiographic evaluation. Radiographic markers have been used in the past and are considered noncritical and may not be necessary. If a radiographic marker is used, it should be placed in a noncritical area to avoid degrading the structural and functional properties of the device.

8. Finish and Appearance

8.1 *Bearing Element Finish*—Acetabular prostheses conforming to this standard shall be finished in accordance with Specification F 2033.

8.2 In accordance with Practices F 86 and F 983, items conforming to this standard shall be marked as follows in order of priority where space permits: manufacturer, material, lot number, catalog number, and size. Additional information may include a designation for alignment.

9. Supplementary Requirements

9.1 *Sterilization*:

9.1.1 The component shall receive a dosage/exposure sufficient to assure sterility. The dose/exposure shall be applied so as to maintain the functional geometry of the component.

9.1.2 The packaging materials of all components that are to be resterilized shall be discarded and the component repackaged before sterilization.

10. Keywords

10.1 acetabulum; arthroplasty; prosthesis

APPENDIX

(Nonmandatory Information)

X1. RATIONALE STATEMENT

X1.1 The objectives of this standard are to establish common terminology, define currently acceptable materials, set forth dimensional requirements, and provide guidelines for their mechanical performance for acetabular components used for total hip replacement. The devices are intended for use in patients who are skeletally mature, under conditions of imposed dynamic loads, in corrosive environment, with virtually continuous motion at the bearing surfaces.

X1.2 Total hip replacement parts are intended for use in patients who are skeletally mature and have joint degeneration on both femoral head and acetabulum. The requirements of this specification are based upon more than 40 years of successful clinical experience with this type of implant. They identify those factors recognized to effect prosthesis performance and longevity. It is recognized, however, that failure of an arthroplasty can occur as a result of factors completely unrelated to the characteristics of the prostheses.

X1.3 This document identifies those factors felt by the committee to be important to provide useful, safe prosthesis life. Specific performance limits are drawn from in vitro data on devices and materials that have shown acceptable clinical experience.

X1.4 It is recognized that failures of an arthroplasty can occur even though the components are intact. This is true owing to the composite which is the goal of the surgical procedure, comprising of the implant components, host bone, and surrounding tissue and body fluids. Failure of the procedure may occur solely as a result of host factors not at all influenced by properties of the device components.

X1.5 *Range of Motion*—In addition, failures as a result of limited range of motion may be caused by inappropriate sizing of implants, malpositioning of implants, and the influence of soft tissue. It is strongly recommended that a range of motion analysis be conducted on the "worst case" acetabular component, femoral head, and stem combinations.

X1.6 *Performance Requirements*—Laboratory testing, even with accurately simulated imposed loading, a corrosive environment of electrolytes, and complex constituents of body fluids, cannot accurately predict performance over many decades of use in vivo. In vivo performance is influenced by many factors including patient weight, activity, and so forth.

X1.7 *Materials*—The materials listed in 5.1 document the state of the art of those clinical uses for this application as of the time of initial approval of this specification. Use of these materials does not, in and of itself, guarantee a successful design, and use of other materials may be equally successful. The necessary corrosion resistance and biocompatibility requirements provide baseline assurance for the acceptance of new materials by the body.

X1.8 *Dimensions and Tolerances*—Dimensions and tolerances are described by standard ANSI documents for engineering design for sphericity, concentricity, and surface finish. Because of the modularity of designs, standard nomenclature and dimensioning of parts should be assured to assist the surgeon in selecting appropriate matching components.

X1.9 *Finishing and Appearance*—The information listed in 8.2 was felt by the committee to be necessary to assist the surgeon in assuring the implantation of the proper device and in assisting in the proper analysis of explanted devices.