Designation: F1378 – 18

Standard Specification for Shoulder Prostheses[1]

This standard is issued under the fixed designation F1378; 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 shoulder prostheses for total or hemiarthroplasty used to provide functioning articulation by employing glenoid and humeral components.

1.2 Devices for custom applications are not covered by this specification. Modular prostheses are included in this specification.

1.3 The values stated in SI units are to be regarded as standard. No other units of measurement are included in this standard.

1.4 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

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)

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Cobalt-20Nickel-20Chromium-3.5Molybdenum-3.5Tungsten-5Iron Alloy for Surgical Implant Applications (UNS R30563) (Withdrawn 2005)[3]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

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for 18Chromium-12.5Nickel-2.5Molybdenum Stainless Steel for Cast and Solution-Annealed Surgical Implant Applications (Withdrawn 2012)[3]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

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

F1537 Specification for Wrought Cobalt-28Chromium-6Molybdenum Alloys for Surgical Implants (UNS R31537, UNS R31538, and UNS R31539)

F1820 Test Method for Determining the Forces for Disassembly of Modular Acetabular Devices

F1829 Test Method for Static Evaluation of Anatomic Glenoid Locking Mechanism in Shear

[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] 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.

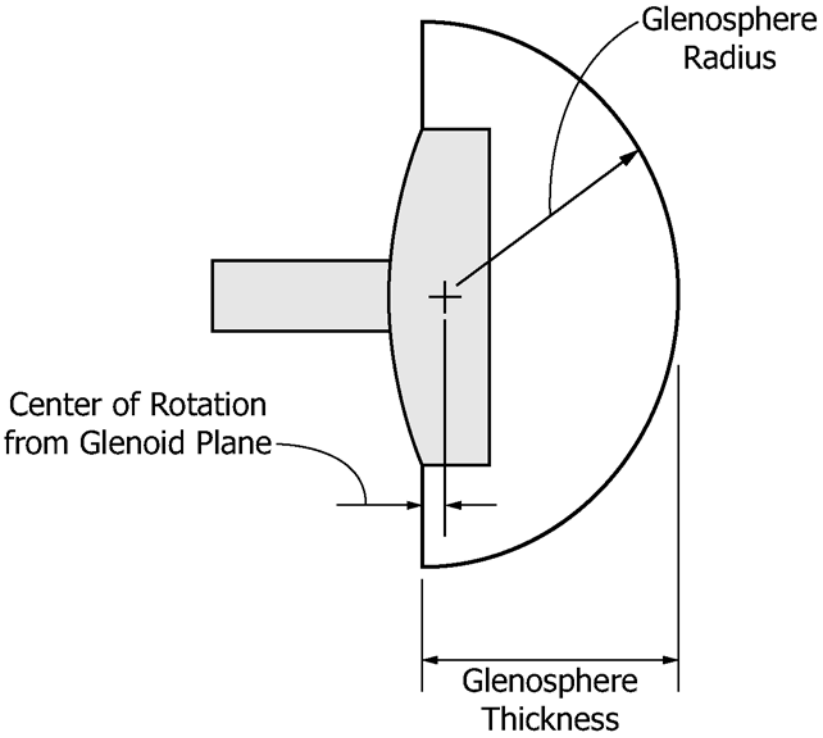

FIG. 1 Glenosphere Thickness

F2028 Test Methods for Dynamic Evaluation of Glenoid Loosening or Disassociation

2.2 *ANSI Standard:*[4]

ASME B46.1–1995

3. Terminology

3.1 *Anatomic Total Shoulder Replacement (TSR) Definitions*

3.1.1 *anatomic total shoulder arthroplasty system, n*—shoulder implant system that has a concave glenoid component and a convex humeral component design.

3.1.2 *anatomic glenoid component, n*—the concave prosthetic portion that replaces, in part or in total, the glenoid fossa of the scapula and articulates with the natural humeral head or a prosthetic replacement.

3.1.3 *glenoid backing, n*—the metallic or composite material prosthetic portion of a multi-piece anatomic glenoid component that attaches to the scapula.

3.1.4 *glenoid liner, n*—the polymeric prosthetic portion of a multiple-piece anatomic glenoid component that articulates with the humeral head.

3.2 *Reverse TSR Definitions*

3.2.1 *reverse total shoulder arthroplasty system, n*—shoulder implant system that has a convex glenoid component and a concave humeral component design.

3.2.2 *reverse glenoid component, n*—the convex prosthetic portion that replaces the glenoid fossa of the scapula and articulates with a concave prosthetic replacement of the humeral head in reverse total shoulder arthroplasty applications. The reverse glenoid may consist of one or more components from one or more materials; most commonly, the reverse glenoid is composed of a metal glenosphere that is modularly connected to a metal glenoid baseplate which is fixed to the glenoid fossa.

3.2.3 *glenoid baseplate, n*—the nonarticular portion of the reverse glenoid component that modularly connects to the glenosphere and is commonly fixed to the glenoid fossa of the scapula using bone screws without the use of cement.

3.2.4 *glenosphere, n*—the convex prosthetic articular portion of the reverse glenoid component that articulates with the concave prosthetic replacement of the proximal humerus or humeral head (for example, the humeral liner).

3.2.5 *glenosphere thickness, n*—the height of the truncated section of the sphere which composes the glenosphere. Note that the difference between the glenosphere articular radius and thickness defines the medial/lateral position of the glenoid center of rotation (see Fig. 1). The glenosphere thickness could also be affected by the geometric relationship between the glenosphere and the glenoid baseplate.

3.2.6 *humeral liner, n*—the concave prosthetic portion of the reverse humeral component that replaces the proximal humerus or humeral head and articulates with the convex prosthetic replacement of the glenoid (for example, the *glenosphere*).

[4] Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036.

3.3 *Definitions Common to Anatomic and Reverse TSRs*

3.3.1 *collar, n*—flange at the junction of the humeral neck and stem.

3.3.2 *keel (or pegs), n*—single or multiple projections that provide resistance to translation or rotation of the glenoid component, or both, by mating with cavities created in the glenoid fossa.

3.3.3 *neck, n*—segment connecting the head and the stem.

3.3.4 *glenoid plane, n*—in symmetrical anatomic glenoids, the glenoid plane is defined by joining the two articular edges; in planar and asymmetric anatomic glenoids, it is defined by the back (medial) surface. For a reverse shoulder it is defined as the plane created by the face of the glenoid baseplate (see Fig. 2).

3.3.4.1 *Discussion*—Although the glenoid fossa is not truly a planar structure, the terms *plane of the glenoid* and *glenoid plane* have both been used in the scientific literature to describe the anatomic orientation of the glenoid.

3.3.5 *humeral head, n*—the bearing member that articulates with the glenoid.

3.3.6 *humeral component, n*—the prosthetic portion that replaces, in part or in total, the proximal humerus or humeral head and articulates with the natural glenoid fossa or a prosthetic replacement.

3.3.7 *humeral stem, n*—segment intended for insertion within the humeral medullary canal.

4. Classification

4.1 *Constrained*—A constrained joint prosthesis is used for joint replacement and resists dislocation of the prosthesis in more than one anatomical plane and consists of either a single, flexible, across-the-joint component or more than one component linked together or affined.

4.2 *Partially Constrained*—A semi-constrained joint prosthesis is used for partial or total joint replacement and limits translation and rotation of the prosthesis in one or more planes via the geometry of its articulating surfaces. It has no across-the-joint linkages.

4.3 *Unconstrained*—An unconstrained joint prosthesis is used for partial or total joint replacement and restricts minimally prosthesis movement in one or more planes. Its components have no across-the-joint linkage.

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*—Various components of shoulder prostheses have been successfully fabricated from the following materials. However, not all of these materials may possess sufficient mechanical strength for critical highly-stressed components. See Specifications F75, F90, F136, F138, F562, F563 (nonbearing use only), F603, F648, F745, F799, F1108, and F1537.

5.1.2 *Corrosion Resistance*—Materials with limited or no history of successful use for orthopedic implant application shall 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 F746.

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 F748 and F981.

6. Performance Requirements

6.1 *Wear of Alternative Materials*—It is important to understand the wear performance for articulating surfaces. Any new or different material should not exceed the wear rates of the following material couple when tested under physiological conditions. The current standard wear couple is CoCrMo alloy (Specification F75) against ultra high molecular weight polyethylene (Specification F648), both having prosthetic quality surface finishes in accordance with 8.2.

NOTE 1—In situations where the pin-on-flat test may not be considered

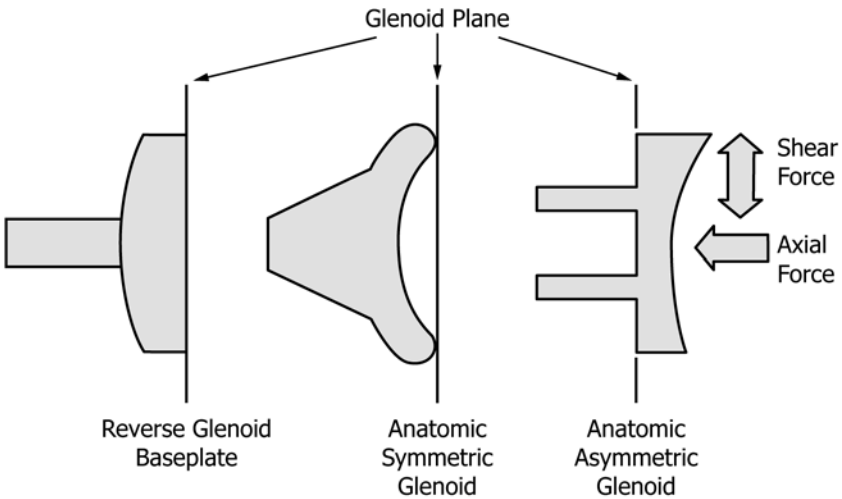

FIG. 2 Glenoid Plane and Force Directions