Designation: F 1378 – 0~~0~~4

Standard Specification for Shoulder Prostheses[1]

This standard is issued under the fixed designation F 1378; 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 are to be regarded as the standard. The inch-pound units given in parentheses are for information only.

[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 A~~n~~rthroplasty.

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2. Referenced Documents

2.1 *ASTM Standards:* [2]

F 75 Specification for C~~ast C~~obalt-28Chromium-6Molybdenum Alloy Castings and Casting Alloy for Surgical ~~Implant Applications~~ Implants (UNS R30075)

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

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

F 136 Specification for Wrought Titanium-6A~~l~~luminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)

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

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

F 563 Specification for Wrought Cobalt-20Nickel-20Chromium-3.5 Molybdenum-3.5Tungsten-5Iron Alloy for Surgical Implant Applications (UNS R30563)

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

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

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

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

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

F 799 Specification for ~~Thermomechanically Processed Cobalt-Chromium-Molybdenum~~ Cobalt-28Chromium-6Molybdenum Alloy Forgings for Surgical Implants (UNS R31537, R31538, R31539)

F 981 Practice for Assessment of Compatibility of Bio-Materials (Non-Porous) for Surgical Implants with Respect to Effect of Materials on Muscle and Bone

F 983 Practice for Permanent Marking of Orthopaedic Implant Components

F 1044 Test Method for Shear Testing of ~~Porous Metal~~ Calcium Phosphate Coatings and Metallic Coatings

F 1108 Specification for Titanium-6A~~l~~luminum-4Vanadium Alloy Castings for Surgical Implants (UNS R56406)

F 1147 Test Method for Tension Testing of ~~Porous~~ Calcium Phosphate and Metal Coatings

F 1537 Specification for Wrought Cobalt-28Chromium-6Molybdenum Alloy for Surgical Implants (UNS R31537, UNS R31538, and UNS R31539)

F 1829 Test Method for Static Evaluation of the Glenoid Locking Mechanism in Shear

F 2028 Test Methods for the Dynamic Evaluation of Glenoid Loosening or Dissociation

2.2 *ANSI Standard:*[3]

ASME B46.1–1995

3. Terminology

3.1 *Definitions of Terms Specific to This Standard:*

3.1.1 *collar*—flange at junction of neck and stem.

3.1.2 *glenoid component*—the 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 *head*—bearing member for articulation with the glenoid.

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

3.1.5 *keel, (or pegs)*—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.

3.1.6 *neck*—segment connecting the head and the stem.

3.1.7 *reverse design shoulder implants*—implants that have a ball-shaped glenoid component and a concave humeral design.

3.1.8 *stem*—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.

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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*, ~~Vol 13.01.~~ volume information, refer to the standard's Document Summary page on the ASTM website.

[3] Available from American National Standards Institute (ANSI), ~~11~~ 25 W. ~~42nd~~ 43rd St., ~~13th~~ 4th Floor, New York, NY 10036.

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 F 75, F 90, F 136, F 138, F 562, F 563 (nonbearing use only), F 603, F 648, F 745, F 799, F 1108, and F 1537.

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 *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 F 75) against ultra high molecular weight polyethylene (Specification F 648), both having prosthetic quality surface finishes according to 8.2.

NOTE 1—In situations where the pin-on-flat test may not be considered appropriate, other test methods may be considered.

6.2 *Range of Motion of Shoulder Prosthesis Prior to Implantation*—Flexion shall be equal to or greater than 90°. Abduction shall be equal to or greater than 90°. Internal rotation shall be equal to or greater than 90°. External rotation shall be equal to or greater than 45°. Extension shall be equal to or greater than 45°.

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

6.4 *Guidelines for In-Vitro Laboratory Testing*:

6.4.1 Implant testing should reflect current clinical failures and potential failure modes particular to the implant. These tests may be directed towards subluxation, glenoid loosening, insert disassociation from a metal backing, and humeral head disassociation.

6.4.2 All modular implants should be tested in accordance with Test Method F 1829.

6.4.3 All prosthetic glenoid components should be tested in accordance with Test Method F2028.

7. Dimensions

7.1 Dimensions of shoulder joint replacement components shall be as designated in Figs. 1-3.

8. Finish and Product Marking

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

8.2 *Articulating Surface Finishes* :

8.2.1 *Metallic Bearing Surface*—The main bearing surface shall have a surface finish no rougher than 0.10 µm (4 µin.) roughness average, R_a, with a cutoff length of 0.25 mm, when measured according to the principles given in ASME B46.1–1995.

8.2.2 *Polymeric Bearing Surface (if used)*—The main bearing surface shall have a surface finish no rougher than 2 µm roughness, R_a, with a cut-off length of 0.8 mm, when measured according to the priniciples given in ASME B46.1–1995.

8.3 In accordance with Practices F 86 and F 983, items conforming to this specification 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 left or right and front.

8.3.1 Optional glenoid marking may specify orientation (top, if applicable; right or left, if applicable).

8.4 If one of the components is not radiographic opaque, it is strongly encouraged that it shall contain a marker wire or other means of radiographic detection. It may be located at the manufacturer's discretion.

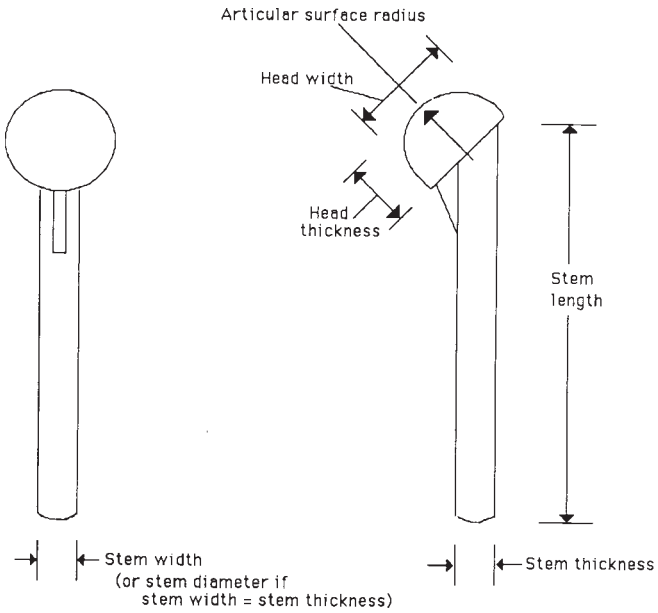
9. Labeling

9.1 The dimensions shown in Figs. 1-3 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.

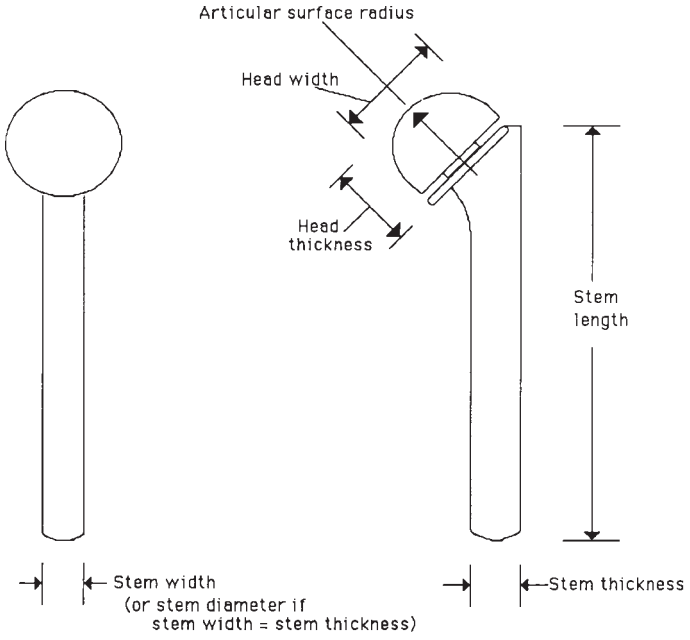
10. Keywords

10.1 arthroplasty; glenoid; humeral; prostheses; hemi-shoulder replacement; total shoulder replacement-



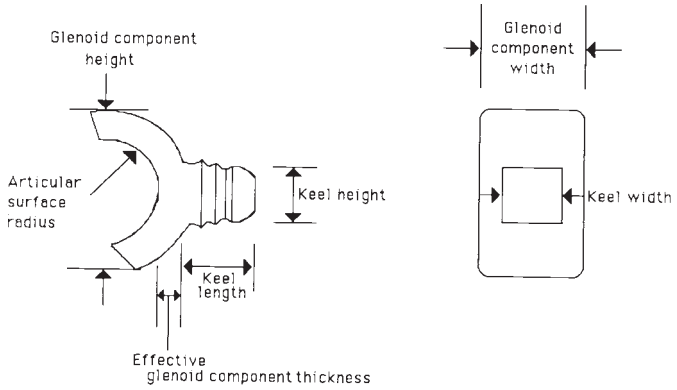
NOTE—A modular connection may be included in this device.

FIG. 1 Humeral Collarless Design



NOTE—A modular connection may be included in this device.

FIG. 2 Humeral Collared Design



NOTE 1—If the glenoid component is not symmetric about the transverse plane, a minimum and maximum component width shall be specified.

NOTE 2—A modular connection may be included in this device.

FIG. 3 Glenoid Components

APPENDIX

(Nonmandatory Information)

X1. RATIONALE

X1.1 The objectives of this specification are the provision of guidelines for the manufacture and use of the components for total shoulder replacement. Total shoulder replacement parts are intended for use in a patient who is skeletally mature, under conditions of imposed dynamic loads, in a corrosive environment, and virtually continuous motion at the bearing surfaces. Laboratory tests to accurately simulate imposed loads, aggressive electrolytes, and complex constituents of body fluids have not been usefully accelerated at the present time for a complete joint evaluation. Long-term projections of satisfactory performance over many decades can be suggested but not accurately predicted using available screening procedures. This specification identifies those factors considered to be important to assure a satisfactory useful prosthetic life. It is here recognized that failure of an arthroplasty can occur, even while the components are intact. This is true owing to the composite nature of the arthroplasty procedure, which includes the implant, cement if any, and the physiological environment.

X1.2 Under applicable documents and materials, the list reflects 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.

X1.2.1 *Performance Considerations* —Component performance should be considered with regard to patient anatomy. It is well recognized that physical stresses resulting from events or activities out of the ordinary range, as in accidents or especially vigorous sports, predictably exceed allowable stress levels in any component design. It is also recognized here that other forms of arthroplasty failure are known to occur, related primarily to patient factors, such as osteoporosis, Paget's disease, misuse and disuse, and others.

X1.2.1.1 No device specific wear test is specified in this specification. It is felt that at this time wear is not a major issue in existing or potential implant designs, that presently there are no techniques available to do device specific wear tests and that this consideration is already partly covered in 6.1.

X1.2.1.2 The range of motion parameters are specified as minimum values so that the implant itself does not restrict patient shoulder motion and thus allow potential dislocation or loosing of the implant. Initially the minimum range of motion parameters were larger but they were decreased to those given in 6.2.

X1.2.2 *Dimensions*— The method of dimensional measurement must be sought to conform with industry practice and, whenever possible, on an international basis.

X1.2.3 *Finish and Markings*—Dimensions and tolerances are as described by ANSI documents for sphericity, concentricity, and surface finish.

X1.2.3.1 The manufacturer's trademark must appear legibly on each of the components. It is desirable to have complete information, where space is available to do so, including size, orientation if any, and catalog number with date.

X1.3 This specification was revised in 2004 to include reverse design shoulder implants.