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Standard Specification for Articulating Total Wrist Implants[1]

This standard is issued under the fixed designation F1357; 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 describes total wrist implants, including solid ceramic implants, used to provide functioning articulation by employing radial and carpal components.

1.2 This specification excludes those implants with ceramic-coated or porous-coated surfaces, one-piece elastomeric implants (with or without grommets), and those devices used for custom applications.

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 standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.*

2. Referenced Documents

2.1 *ASTM Standards:*[2]

F67 Specification for Unalloyed Titanium, for Surgical Implant Applications (UNS R50250, UNS R50400, UNS R50550, UNS R50700)

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)

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Cobalt-20Nickel-20Chromium-3.5Molybdenum-3.5Tungsten-5Iron Alloy for Surgical Implant Applications (UNS R30563) (Withdrawn 2005)[3]

F601 Practice for Fluorescent Penetrant Inspection of Metallic Surgical Implants

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

F629 Practice for Radiography of Cast Metallic Surgical Implants

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

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

F983 Practice for Permanent Marking of Orthopaedic Implant Components

F1108 Specification for Titanium-6Aluminum-4Vanadium Alloy Castings for Surgical Implants (UNS R56406)

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

2.2 *ANSI/ASME Standard:*

ANSI/ASME B46.1 Surface Texture (Surface Roughness, Waviness, and Lay)[4]

3. Terminology

3.1 *Definitions:*

[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.

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

3.1.1 *carpal component*—articulating member inserted into or through the carpal bones.

3.1.2 *radial component*—articulating member inserted into the radius for articulation with the carpal component.

3.1.3 *total wrist replacement*—prosthetic parts substituted for the native opposing radial and carpal articulating surfaces.

4. Classification

4.1 *Constrained*—A constrained joint prosthesis is used for joint replacement and prevents 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 linkages.

5. Materials and Manufacture

5.1 Proper material selection is necessary, but insufficient to ensure suitable functioning of a device.

5.2 All metal implant components shall conform to one of the following specifications for implant materials: Specification F67, F75, F90, F136, F562, F563 (nonbearing use only), F799, F1108, or F1537.

5.3 All polymeric components shall conform to Specification F648 for implant materials.

5.4 All solid ceramic components shall conform to Specification F603 for implant materials.

5.5 *Biocompatibility*—Materials with limited or no history of successful use for orthopedic implant application shall be determined to exhibit acceptable biological responses equal to or better than one of the materials listed in 5.2 when tested in accordance with Practices F748 and F981.

5.6 When required for metallic implants, fluorescent penetrant inspection shall be performed in accordance with Practice F601.

5.7 When required for cast metallic implants, radiography shall be performed in accordance with Practice F629.

5.8 *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 5.2 when tested in accordance with Test Method F746.

6. Performance Requirements

6.1 *Polymeric Creep (Cold Flow)*—Ultra-high molecular weight polyethylene in implant form shall conform to the requirements detailed in Specification F648. When creep occurs, it must not impair the function or stability of the interface.

6.2 *Wear of Alternative Materials*—It is important to understand the wear performance for articulating surfaces. Any new or different material couple should not exceed the wear rates of the following material couple when tested under physiological conditions. The current wear couple is CoCrMo alloy (Specification F75) against ultra high molecular weight polyethylene. This is an industry wide referenced wear couple and is considered by some to be the minimum. It has been proven to provide clinically acceptable results.

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

6.3 *Range of Motion of the Device Before Implantation*—The implant shall be evaluated to determine the maximum dorsiflexion, palmar flexion, radial deviation, and ulnar deviation possible before subluxation occurs or the motion is arrested by the implant. These results shall be reported in the product labeling.

6.4 *Guidelines for In-Vitro Laboratory Testing*—No ASTM standards for testing articulating wrist implants have been developed. Laboratory testing that simulates the conditions of use is desirable to compare materials and designs and to provide an indication of clinical performance. Implant testing shall be done in keeping with the implant's intended function, that is, implants intended to partially stabilize or stabilize a joint shall be subjected to the maximum destabilizing force anticipated in clinical application during flexural testing.

7. Dimensions

7.1 Dimensions of wrist joint replacement components should be designated as in Figs. 1 and 2.

8. Finish and Marking

8.1 Items conforming to this specification shall be finished and marked in accordance with Practice F86 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 roughness average, *Ra*, with a cutoff length of 0.25 mm, when measured in accordance with the principles given in ANSI/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, *Ra*, with a cut-off length of 0.8 mm, when measured in accordance with the principles given in ANSI/ASME B46.1–1995.

8.3 Items conforming to this specification shall be marked in accordance with Practices F86 and F983. Radial and carpal component marking shall include, if possible, the items below in the following order of importance:

8.3.1 Manufacturer,

8.3.2 Size,

8.3.3 Catalog Number,

8.3.4 Lot Number, and

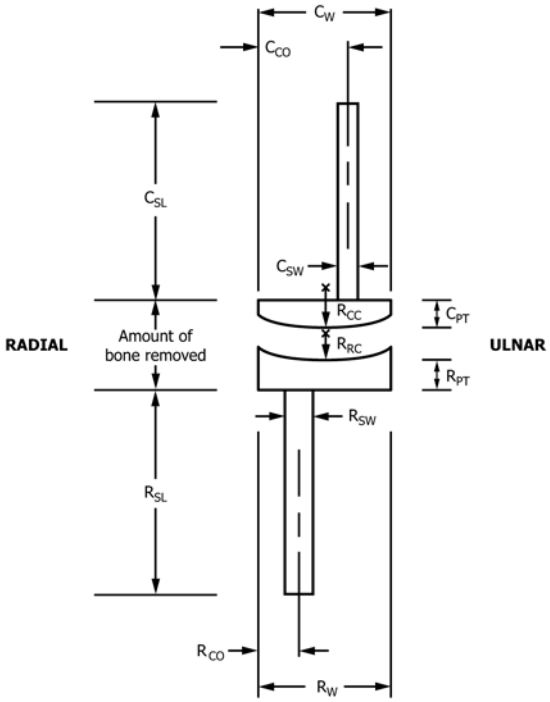

FIG. 1 Dimensions of Wrist Joint Replacements (Coronal Plane)

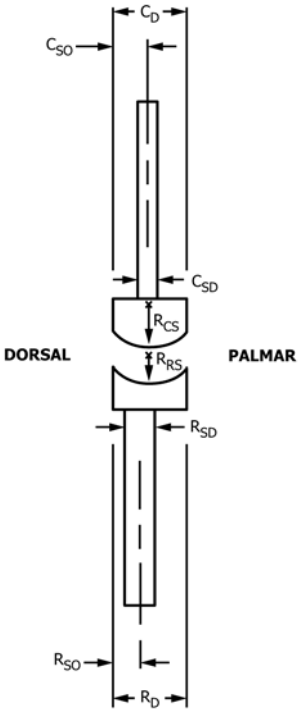

FIG. 2 Dimensions of Wrist Joint Replacements (Sagittal Plane)

8.3.5 Orientation (dorsal/palmar/radial/ulnar/left/right as appropriate).

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

9. Packaging and Package Marking

9.1 The maximum range of motion values as determined by 6.3 shall be included in the product labeling.

9.2 The dimensions shown in Figs. 1 and 2 and described in the glossary in Appendix X1 shall be included in the product labeling.

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

10. Keywords

10.1 arthroplasty; prosthesis; total wrist replacement

APPENDIXES

(Nonmandatory Information)

X1. GLOSSARY

X1.1 Descriptions of dimensions used in Figs. 1 and 2.

X1.1.1 C_{sl} —carpal component stem length.

X1.1.2 R_{sl} —radial component stem length.

X1.1.3 C_{sw} —maximum width of the stem of the carpal component in the radial/ulnar plane.

X1.1.4 R_{sw} —maximum width of the stem of the radial component in the radial/ulnar plane.

X1.1.5 *C*—maximum depth of the stem of the carpal component in the dorsal/palmar plane.

X1.1.6 *R*—maximum depth of the stem of the radial component in the dorsal/palmar plane.

X1.1.7 C_w —carpal component maximum width (radial/ulnar plane).

X1.1.8 R_w —radial component maximum width (radial/ulnar plane).

X1.1.9 C_d —carpal component maximum dorsal/palmar dimension.

X1.1.10 R_d —radial component maximum dorsal/palmar dimension.

X1.1.11 C_{co} —carpal component coronal plane stem offset (distance of stem centerline from radial edge of carpal component).

X1.1.12 R_{co} —radial component coronal plane stem offset (distance of stem centerline from radial edge of radial component).

X1.1.13 C_{so} —carpal component sagittal plane stem offset (distance of stem centerline from dorsal edge of carpal component).

X1.1.14 R_{so} —radial component sagittal plane stem offset (distance of stem centerline from dorsal edge of radial component).

X1.1.15 R_{pt} —radial plateau thickness; thickness of radial component from transverse resection plane to functional surface.

X1.1.16 C_{pt} —carpal plateau thickness; thickness of carpal component from transverse resection plane to functional surface.

X1.1.17 R_{cc} —radii of curvature at the low point of the carpal component in the radial/ulnar (coronal) plane.

X1.1.18 R—radii of curvature at the low point of the radial component in the radial/ulnar (coronal) plane.

X1.1.19 R_{cs} —radii of curvature at the low point of the carpal component in the dorsal/palmar (sagittal) plane.

X1.1.20 R_{rs} —radii of curvature at the low point of the radial component in the dorsal/palmar (sagittal) plane.

X1.1.21 *amount of bone resected*—amount of bone removed to allow insertion and use of implant ($R_{pt} + C_{pt}$).

X1.1.22 *palmarflexion (flexion)*—movement of the palm of the hand toward the palmar surface of the forearm.

X1.1.23 *dorsiflexion (extension)*—movement of the dorsum of the hand toward the dorsal surface of the forearm.

X1.1.24 *radial deviation*—movement of the hand toward the radius.

X1.1.25 *ulnar deviation*—movement of the hand toward the ulna.

X1.1.26 *neutral position*—a position of the hand that is parallel to the forearm.

X2. RATIONALE

X2.1 The objective of this specification is the provision of guidelines for the physical characteristics of the components for total wrist replacement. Total wrist 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 felt to be important to assure a satisfactory useful prosthetic life. It is 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.

X2.2 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.

X2.3 *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 specification standards to device performance standards, both methods of description may be appropriate.

X2.4 It is recognized that wear between two materials can have both mechanically and biologically adverse effects. However, section 6.2, *Wear of Alternative Materials*, applies only to the mechanical effect of minimizing wear and does not apply to the biological issues related to wear.

X2.5 Component performance shall 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 that other forms of arthroplasty failure are known to occur, related primarily to patient factors, such as osteoporosis, Paget's disease, and misuse.

X2.6 Specific criteria need to be established in assessing the biocompatibility of articulating wrist implants made of new materials. Practice F748 will need to be used to determine which additional biocompatibility tests are required.

X2.7 Range-of-motion data of devices before implantation will provide comparative information among implants.

X2.8 *Dimensions* —The methods of dimensional measurement must be sought to conform with the industry practice and, whenever possible, on an international basis.

X2.9 *Finish and Markings*—Dimensions and tolerances are as described by ANSI/ASME B46.1 for sphericity, concentricity, and surface finish. A maximum allowable roughness for the polymeric bearing surface is not specified at this time, but will be in the future. It is suggested that the material composition can be determined by referring to the manufacturer's information, instead of marking the material on each implant.

X2.10 If one of the components is not radiographically opaque, it should be appropriately marked for radiographic evaluation. If a marker wire is used, it is considered to be a

non-critical element, as long as it is radiographically detectable.

X2.11 The manufacturer's trademark must appear legibly on each of the components. It is desirable to have complete information, including size, orientation (if any), and catalog number with date, if adequate space is available.