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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)

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

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:*

[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.

ANSI/ASME B46.1 Surface Texture (Surface Roughness, Waviness, and Lay)[3]

3. Terminology

3.1 *Definitions:*

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 ~~F 67~~F67~~, F 75~~, F75~~, F 90~~, F90~~, F 136~~, F136~~, F 562~~, F562~~, F 563~~, F563 (nonbearing use only), ~~F 799~~F799~~, F 1108~~, F1108~~, or F 1537~~, or F1537.

~~5.3All polymeric components shall conform to the following specification for implant materials: Specification F 648~~

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

5.4 All solid ceramic components shall conform to Specification ~~F 603~~F603 for implant materials.

5.5 *Biocompatibility*—Articulating implants shall be manufactured from the materials listed in 5.2-5.4. ~~Before~~If implants ~~can be~~ are manufactured from other materials, their biocompatibility ~~will~~shall be considered suitable only if they produce an acceptable response after testing in accordance with Practice ~~F 981~~ 981F981.

5.6 When required for metallic implants, fluorescent penetrant inspection shall be performed in accordance with Practice ~~F 601~~F601.

5.7 When required for cast metallic implants, radiography shall be performed in accordance with Practice ~~F 629~~F629.

6. Performance Requirements

6.1 *Polymeric Creep (Cold Flow)*—Ultra-high molecular weight polyethylene in implant form ~~must~~shall conform to the requirements detailed in Specification ~~F 648~~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 ~~F 75~~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 ~~not~~ 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 ~~shall~~should be ~~as~~ 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 ~~F 86~~F86 where applicable.

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

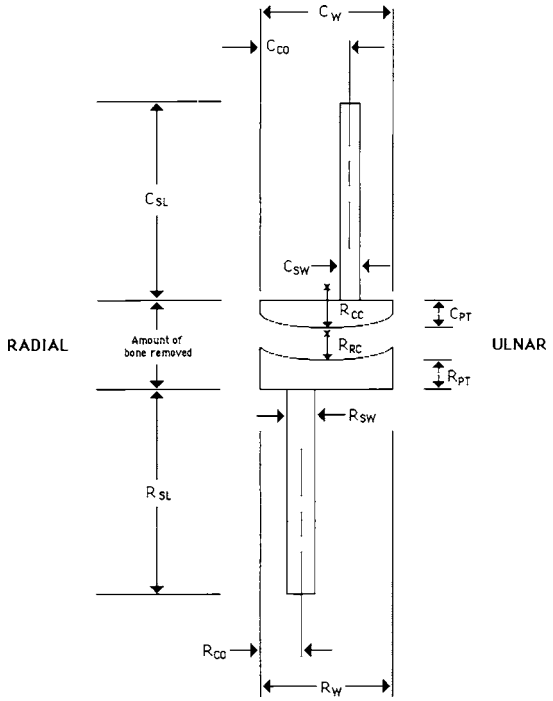

FIG. 1 Dimensions of Wrist Joint Replacements (Coronal Plane)

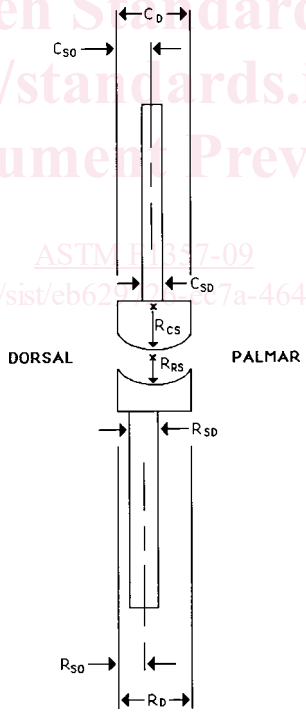

FIG. 2 Dimensions of Wrist Joint Replacements (Sagittal Plane)

8.2 *Metallic Bearing Surface*—~~Articulate surfaces shall be finished to an average roughness of 0.125 μm.~~ —Articulating surfaces shall be finished to an average roughness of 0.125 μm when measured in accordance with the principles given in ANSI/ASME B46.1.

8.3 *Polymeric Bearing Surface Finish*— shall conform to manufacturer's documented standards concerning concentricity, sphericity, and surface roughness, when applicable.

8.4 Items conforming to this specification shall be marked in accordance with Practices ~~F 86~~F86 ~~and F 983~~and F983. Radial and carpal component marking shall include, ~~as~~if possible, the items below in the following order of importance:

8.4.1 Manufacturer,