Designation: ~~F1357 – 14 (Reapproved 2019)~~ F1357 – 23

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,~~ 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, health, and environmental practices and determine the applicability of regulatory limitations prior to use.*

1.5 *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]

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

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[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.

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-28 Chromium-6 Molybdenum 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
F1108 Specification for Titanium-6Aluminum-4Vanadium Alloy Castings for Surgical Implants (UNS R56406)
F1223 Test Method for Determination of Total Knee Replacement Constraint
F1472 Specification for Wrought Titanium-6Aluminum-4Vanadium Alloy for Surgical Implant Applications (UNS R56400)
F1537 Specification for Wrought Cobalt-28Chromium-6Molybdenum Alloys for Surgical Implants (UNS R31537, UNS R31538, and UNS R31539)
F2003 Practice for Accelerated Aging of Ultra-High Molecular Weight Polyethylene After Gamma Irradiation in Air
F2129 Test Method for Conducting Cyclic Potentiodynamic Polarization Measurements to Determine the Corrosion Susceptibility of Small Implant Devices
F3306 Test Method for Ion Release Evaluation of Medical Implants

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

2.3 *ISO Standards:*[3]
ISO 5832-2 Implants for surgery—Metallic materials—Part 2: Unalloyed titanium
ISO 5832-3 Implants for surgery—Metallic materials—Part 3: Wrought titanium 6-aluminium 4-vanadium alloy
ISO 5832-4 Implants for surgery—Metallic materials—Part 4: Cobalt-chromium-molybdenum casting alloy
ISO 5832-5 Implants for surgery—Metallic materials—Part 5: Wrought cobalt-chromium-tungsten-nickel
ISO 5832-12 Implants for surgery—Metallic materials—Part 12: Wrought cobalt-chromium-molybdenum alloy
ISO 5834-2 Implants for surgery—Ultra-high-molecular-weight polyethylene—Part 2: Moulded forms

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.The choice of materials is

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

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.

5.2 ~~All metal implant components shall conform to one of the following specifications for implant materials: ASTM Specification~~ Some examples of materials from which wrist replacement components have been successfully fabricated include Specifications F67, F75, F90, F136, F562, ~~F563 (nonbearing use only),~~ F799, F1108, F1472~~or~~, F1537~~.~~, ISO 5832-2, ISO 5832-3, ISO 5832-4, ISO 5832-5, or ISO 5832-12. Polymeric bearing components have been fabricated from UHMWPE as specified in Specification F648 or ISO 5834-2. Not all of these materials may possess sufficient mechanical strength for critical highly stressed components nor for articulating surfaces.

~~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.~~

5.3 *Biocompatibility*—~~Materials~~ Devices made from materials with limited or no history of successful use for orthopedic implant ~~application~~applications shall be determined to exhibit acceptable biological ~~responses equal~~ response when tested in accordance with Practices F748, F981~~to or better than one of the~~ , or ISO 10993-1. While no known surgical implant material has ever been shown to be completely free of adverse reactions in the human body, long-term clinical experience has shown an acceptable level of biological response can be expected if materials listed in 5.2 ~~when tested~~ are used. However, the specifications listed in 5.2 cover raw materials and not finished medical devices, where the design and fabrication process of the device can impact biological response. Hence, for devices made from material listed in 5.2, then its biocompatibility shall be verified in accordance with Practices F748, F981~~and~~, ~~F981.~~or ISO 10993-1, unless justification can be provided for why design and processing will not impact the biocompatibility of the final, sterilized device.

5.4 *Polymeric Component Oxidation Resistance*—Polymeric components may be subject to degradation of mechanical or wear performance due to oxidation and may need to be aged prior to subsequent mechanical testing following Practice F2003.

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

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

5.7 *Corrosion Resistance*—Materials with limited or no history of successful use for orthopedic implant ~~application~~applications 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~~Methods ~~F746~~F2129 and F3306. The design and manufacturing process of the device can impact corrosion resistance; therefore, testing shall be conducted on final devices in their final finished form. Substitute test articles may be used for testing with adequate justification, if all processing steps, including sterilization and preconditioning, are comparable to the finished device. If the corrosion resistance of a material is less than one of the materials listed in 5.2 when tested in accordance with Test Methods F2129 and F3306, its use would need to be justified.

6. Performance Requirements

6.1 *Polymeric Creep (Cold Flow)*—~~Ultra-high-molecular-weight-polyethylene~~ Ultra-high-molecular-weight polyethylene in implant form shall conform to the requirements detailed in Specification F648~~.~~ or ISO 5834-2. 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 standard wear couple that has demonstrated good clinical performance is CoCrMo alloy ~~(Specification~~ (see Specification F75~~) against ultra-high-molecular-weight-polyethylene. This is an~~ or ISO 5832-4) against UHMWPE (see Specification F648 ~~industry wide referenced~~ or ISO 5834-2) both having prosthetic-quality finishes as described in 8.2~~wear couple and is considered by some to be the minimum. It has been proven to provide clinically acceptable results.~~. As implant design also impacts wear performance, functional (simulated) wear tests of the implant shall be performed to evaluate wear performance and results compared to a legally marketed reference implant.

~~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~~ extension, flexion, radial deviation, and ulnar deviation possible before subluxation occurs or the motion is arrested by the implant. These results ~~shall~~should be reported in the product labeling. The necessary wrist motion needed for successful total wrist replacement is not known, but it is suggested that total wrist replacement, before implantation, shall have at least the motion available of clinically successful wrist arthroplasty devices.

6.4 *Range of Motion of the Device After Implantation*—The implant range of motion after implantation shall be measured in a cadaver bone setting that includes soft tissue and ligamentous constraints. The cadavers selected shall have non-rheumatoid arthritis joint degeneration, as cadavers with rheumatoid arthritis have stiffer joints which can limit the range of motion of the device, thereby confounding the results. Implant motion can be measured as the motion of the long axis of the third metacarpal relative to the long axis of the radius. Neutral flexion/extension and neutral radioulnar deviation is defined when the axes of the third metacarpal and radius are collinear. Motion can be measured by moving the hand passively. Care should be taken to determine the maximal range of motion prior to subluxation or dislocation of the metacarpal component. Flexion and extension maximums should be determined with the wrist (third metacarpal) in neutral radioulnar deviation. Radial and ulnar deviation maximums should be determined with the wrist in neutral flexion/extension. These results should be reported in the product labeling. The necessary wrist motion needed for successful total wrist replacement is not known, but it is suggested that total wrist replacement, after implantation, shall have at least the motion available of clinically successful wrist arthroplasty devices. When evaluating the range of motion of the device after implantation, there shall be similar joint degeneration in the cadavers used for the implant under evaluation and the legally marketed reference implant.

6.5 Total wrist replacement constraint data for dorsal-volar displacement, radial-ulnar displacement, and supinationpronation rotation shall be determined. One test method which can be modified to evaluate wrist constraint is Test Method F1223. Justification for the loads and angles chosen for testing shall be provided and shall include maximum ranges of motion (that is, flexion, extension, radial and ulnar deviation). In order to verify that there is sufficient implant constraint against subluxation and sufficient laxity at the maximum flexion, maximum extension, maximum radial deviation, and maximum ulnar deviation angles (as measured in 6.3), the device should be able to support anticipated physiologic loading conditions at these angles. Depending on the device design, performing constraint testing at less than the maximum flexion, extension, and deviation angles can be justified based on scientific or clinical evidence. Constraint testing results shall be similar to clinically successful wrist arthroplasty devices.

6.6 All modular components shall be evaluated for their performance of their connecting mechanisms including assembly and disassembly strength, fatigue strength, and corrosion resistance. The connecting mechanisms shall show sufficient performance for the range of loads anticipated for the application.

6.7 *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.

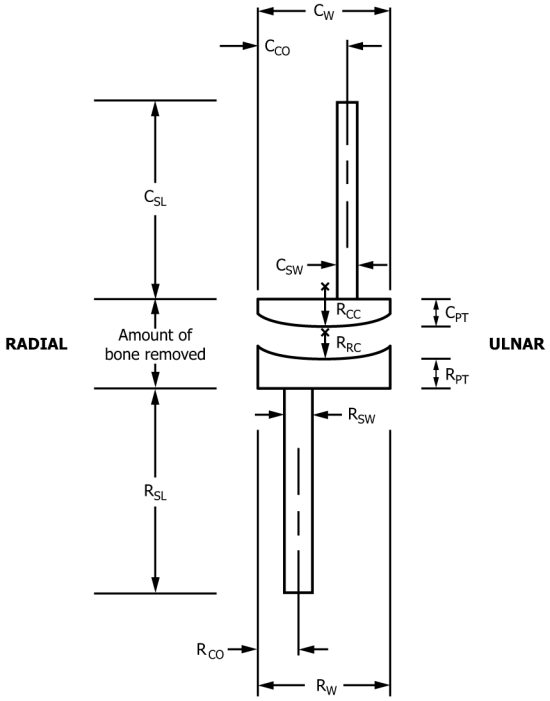
8. Finish and Marking

8.1 Items conforming to this specification shall be finished and marked in accordance with Practice F86 where applicable.

8.2 *Articulating Surface Finishes:*

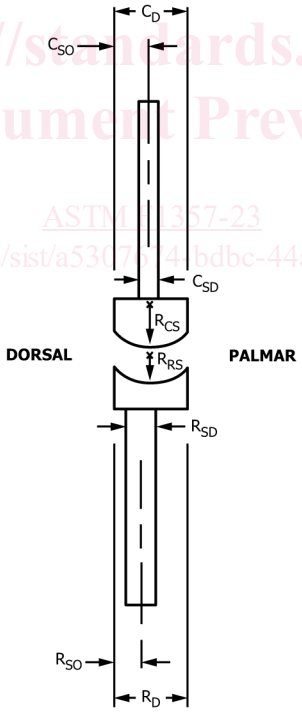
8.2.1 *Metallic Bearing Surface*—The main bearing surface shall have a surface finish no rougher than 0.10 µm roughness average, *Ra*, with a cutoff length of 0.25 mm, when measured in accordance with the principles given in ANSI/ASME B46.1–1995.

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.



For explanation of terms, see Appendix X1, Glossary.

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



For explanation of terms, see Appendix X1, Glossary.

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

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,