Designation: 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 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)

F601 Practice for Fluorescent Penetrant Inspection of Metallic Surgical Implants

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-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

[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.

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 The choice of materials is 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 Some examples of materials from which wrist replacement components have been successfully fabricated include Specifications F67, F75, F90, F136, F562, F799, F1108, F1472, 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 *Biocompatibility*—Devices made from materials with limited or no history of successful use for orthopedic implant applications shall be determined to exhibit acceptable biological response when tested in accordance with Practices F748, F981, 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 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, 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 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 Methods 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 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

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