Designation: F 1357 – 99

Standard Specification for Articulating Total Wrist Implants[1]

This standard is issued under the fixed designation F 1357; 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 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 standard. The English values in parentheses are for information only.

2. Referenced Documents

2.1 *ASTM Standards:*

F 67 Specification for an Unalloyed Titanium for Surgical Implant Application[2]

F 75 Specification for Cast Cobalt-Chromium-Molybdenum Alloy for Surgical Implant Applications[2]

F 86 Practice for Surface Preparation and Marking of Metallic Surgical Implants[2]

F 90 Specification for Wrought Cobalt-Chromium-Tungsten-Nickel Alloy for Surgical Implant Applications[2]

F 136 Specification for Wrought Titanium 6A1-4V ELI Alloy for Surgical Implant Applications[2]

F 562 Specification for Wrought Cobalt-Nickel-Chromium-Molybdenum Alloy for Surgical Implant Applications[2]

F 563 Specification for Wrought Cobalt-Nickel-Chromium-Molybdenum-Tungsten-Iron Alloy for Surgical Implant Applications[2]

F 601 Practice for Fluorescent Penetrant Inspection of Metallic Surgical Implants[2]

F 603 Specification for High-Purity Dense Aluminum Oxide for Surgical Implant Application[2]

F 629 Practice for Radiography of Cast Metallic Surgical Implants[2]

F 648 Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants[2]

F 748 Practice for Selecting Generic Biological Test Methods for Materials and Devices[2]

F 799 Specification for Thermomechanically Processed Cobalt-Chromium-Molybdenum Alloy for Surgical Implants[2]

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[2]

F 983 Practice for Permanent Marking of Orthopaedic Implant Components[2]

F 1108 Specification for Ti6A14V Alloy Castings for Surgical Implants[2]

F 1537 Specification for Wrought Cobalt-28 Chromium-6 Molybdenum Alloy for Surgical Implants[2]

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.

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[2] *Annual Book of ASTM Standards,* Vol 13.01.

5. Materials and Manufacture

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

5.2 All metal implant components shall conform to one of the following specifications for implant materials: Specification F 67, F 75, F 90, F 136, F 562, F 563 (nonbearing use only), F 799, F 1108, or F 1537.

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

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

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

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

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

6. Performance Requirements

6.1 *Polymeric Creep (Cold Flow)*—Ultra-high molecular weight polyethylene in implant form must conform to the requirements detailed in Specification F 648. 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 (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 implants 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 be as designated 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 where applicable.

8.2 *Metallic Bearing Surface*—Articulate surfaces shall be finished to an average roughness of 0.125 µm.

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, and F 983. Radial and carpal component marking shall include, as possible, the items below in the following order of importance:

8.4.1 Manufacturer,

8.4.2 Size,

8.4.3 Catalog Number,

8.4.4 Lot Number, and

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

8.5 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.

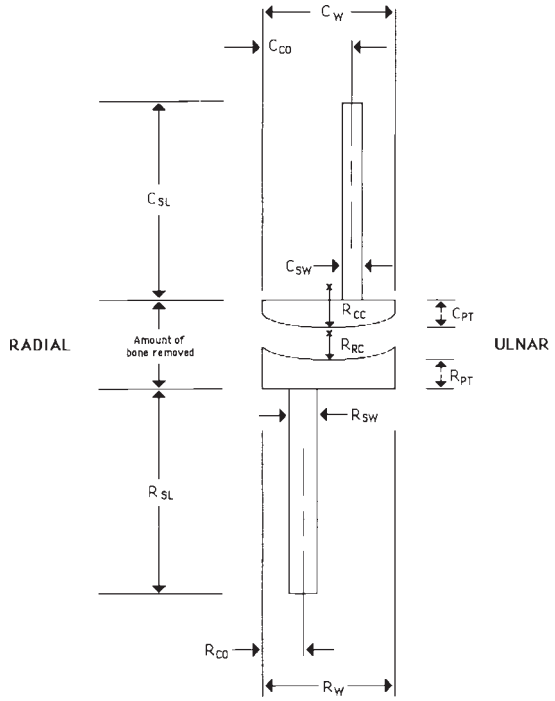

FIG. 1 Dimensions of Wrist Joint Replacements (Coronal Plane)

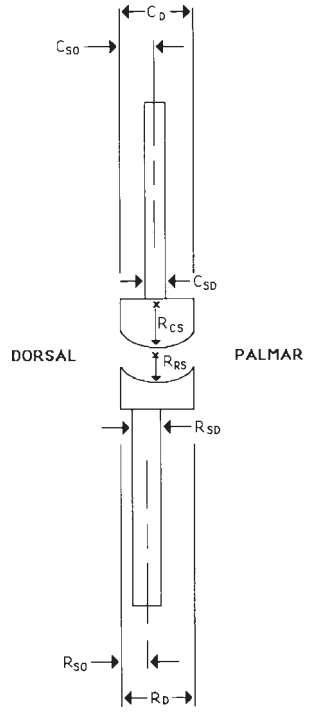

FIG. 2 Dimensions of Wrist Joint Replacements (Sagittal Plane)

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.

RATIONALE

X2. RATIONALE

X2.1 The objective of this standard 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 document identifies those factors felt 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.

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 with wear between two materials can have both mechanical detrimental and biological 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 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.

X2.6 Specific criteria need to be established in assessing the biocompatibility of articulating wrist implants made of new materials. F 748, Practice for Selecting Generic Biological Test Methods for Materials and Devices, 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 documents 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 if needed at the time of explanation that the material composition can be determined by referring to the manufacturers' information, instead of marking the material on each implant.

X2.10 If one of the components is not radiographic 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 manufacturers 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.