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Standard Specification for Total Elbow Prostheses¹

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1. Scope

1.1 This specification covers total elbow replacement (TER) prostheses and hemi-elbow replacement (“hemi”) prostheses used to provide functioning articulation by employing humeral, ulnar, and/or radial components that allow for the restoration of motion of the human elbow joint complex.

1.2 Included within the scope of this specification are elbow prosthesis components for primary and revision surgery with linked and non-linked designs and components implanted with or without use of bone cement.

1.3 This specification is intended to provide basic descriptions of material and prosthesis geometry. In addition, those characteristics determined to be important to the *in vivo* performance of the prosthesis are defined. However, compliance with this specification does not itself mean that a device will provide satisfactory clinical performance.

1.4 The values stated in SI units are to be regarded as standard. No other units of measurement are included in this standard.

2. Referenced Documents

2.1 ASTM Standards:²

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)

F451 Specification for Acrylic Bone Cement

F565 Practice for Care and Handling of Orthopedic Implants and Instruments

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

F732 Test Method for Wear Testing of Polymeric Materials Used in Total Joint Prostheses

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)

F983 Practice for Permanent Marking of Orthopaedic Implant Components

F1044 Test Method for Shear Testing of Calcium Phosphate Coatings and Metallic Coatings

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

F1147 Test Method for Tension Testing of Calcium Phosphate and Metallic Coatings

F1160 Test Method for Shear and Bending Fatigue Testing of Calcium Phosphate and Metallic Medical and Composite Calcium Phosphate/Metallic Coatings

F1223 Test Method for Determination of Total Knee Replacement Constraint

F1377 Specification for Cobalt-28Chromium-6Molybdenum Powder for Coating of Orthopedic Implants (UNS R30075)

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)

F1580 Specification for Titanium and Titanium-6 Aluminum-4 Vanadium Alloy Powders for Coatings of Surgical Implants

F1814 Guide for Evaluating Modular Hip and Knee Joint Components

¹ This test method 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.