



Designation: F2887 – 23

Standard Specification for Total Elbow Prostheses¹

This standard is issued under the fixed designation F2887; 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 reappraisal. A superscript epsilon (ϵ) indicates an editorial change since the last revision or reappraisal.

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.

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

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-28 Chromium-6 Molybdenum 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 Medical Devices (UNS R30075, UNS R31537, and UNS R31538)

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)

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.

Current edition approved March 1, 2023. Published March 2023. Originally approved in 2012. Last previous edition approved in 2017 as F2887 – 17. DOI: 10.1520/F2887-23.

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.

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

F2759 Guide for Assessment of the Ultra-High Molecular Weight Polyethylene (UHMWPE) Used in Orthopedic and Spinal Devices

2.2 ISO Standards:³

ISO 5832-3 Implants for Surgery—Metallic Materials—Part 3: Wrought Titanium 6-Aluminum 4-Vandium Alloy

ISO 5832-4 Implants for Surgery—Metallic Materials—Part 4: Cobalt-Chromium-Molybdenum Casting Alloy

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

ISO 6018 Orthopaedic Implants—General Requirements for Marking, Packaging, and Labeling

ISO 10993-1 Biological Evaluation of Medical Devices—Part 1: Evaluation and Testing Within a Risk Management Process

ISO 14243-1 Implants for Surgery—Wear of Total Knee-Joint Prostheses—Part 1: Loading and Displacement Parameters for Wear-testing Machines with Load Control and Corresponding Environmental Conditions for Test

ISO 14243-2 Implants for Surgery—Wear of Total Knee-joint Prostheses—Part 2: Methods of Measurement

ISO 14243-3 Implants for Surgery—Wear of Total Knee-joint Prostheses—Part 3: Loading and Displacement Parameters for Wear-testing Machines with Displacement Control and Corresponding Environmental Conditions for Test

2.3 FDA Documents:⁴

21 CFR 888.3150 Elbow Joint Metal/Polymer Constrained Cemented Prosthesis

21 CFR 888.3160 Elbow Joint Metal/Polymer Semi-constrained Cemented Prosthesis

21 CFR 888.3170 Elbow Joint Radial (Hemi-elbow) Polymer Prosthesis

21 CFR 888.3180 Elbow Joint Humeral (Hemi-elbow) Metallic Uncemented Prosthesis

21 CFR 888.6 Degree of Constraint

Guidance Document for Testing Orthopedic Implants with Modified Metallic Surfaces Apposing Bone or Bone Cement

Guidance for Industry on the Testing of Metallic Plasma Sprayed Coatings on Orthopedic Implants to Support Reconsideration of Postmarket Surveillance Requirements

Guidance Document for Testing Non-articulating, Mechanically Locked Modular Implant Components

Class II Special Controls Guidance Document Knee Joint Patellofemoral and Femoral Tibial Metal/Polymer

Porous-Coated Uncemented Prostheses; Guidance for Industry and FDA

2.4 ANSI/ASME Standard:³

ANSI/ASME B46.1-1995 Surface Texture (Surface Roughness, Waviness, and Lay)

3. Terminology

3.1 Definitions of Terms Specific to This Standard:

3.1.1 *bearing surface, n*—part of the prosthetic component that articulates against the counter surface of the natural or prosthetic elbow joint.

3.1.2 *extension, n*—rotation of the ulna and radius away from the humerus around the elbow joint axis in the sagittal plane.

3.1.3 *flexion, n*—rotation of the ulna and radius towards the humerus around the elbow joint axis in the sagittal plane.

3.1.4 *hemi-elbow replacement (hemi), n*—prosthetic part that substitutes for the natural humero-ulnar, radio-ulnar, and/or humero-radial articulating surfaces in the human elbow in which only one half of the articulating surfaces is replaced. The prosthesis is expected to articulate with the remaining natural biological surface(s).

3.1.5 *humeral component, n*—component fixed to the humerus for articulation with the natural or prosthetic ulnar and/or radial component(s), typically consisting of two major components: a fixation stem, and a bearing surface.

3.1.6 *interlock, n*—mechanical design feature used to increase the capture of one component within another to restrict unwanted displacement between components (that is, locking mechanism for modular components such as a bearing surface to a metallic stem component).

3.1.7 *laxity, n*—intentional looseness in the fit between linked style elbow prosthetic components (typically the humero-ulnar components) that allows small, secondary out-of-plane motions during primary motion to avoid a “fully constrained” or “rigid” connection.

3.1.8 *linked, n*—a style of total elbow prosthesis in which the humeral and ulnar components are physically connected by a linking mechanism to prevent disassociation (dislocation) while allowing motion in selected directions.

3.1.9 *non-linked, n*—a style of total elbow prosthesis in which the humeral and ulnar components are not physically connected by a linking mechanism. These components rely on soft tissue or another mechanism to minimize the potential for disassociation (dislocation) of the two components.

3.1.10 *pronation, n*—rotation of the radius medially about the ulna around a superior-inferior axis.

3.1.11 *radial component, n*—component fixed to the radius for articulation with the natural or prosthetic humeral and/or ulnar component(s), typically consisting of two major components: a fixation stem and a bearing surface.

3.1.12 *subluxation, n*—instability or partial dislocation which occurs when the relative translational or rotational motion between the humeral and ulnar components reaches an extreme where the two components would cease to articulate over the designated low-friction bearing surfaces.

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

⁴ Available from Food and Drug Administration (FDA), 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, <http://www.fda.gov>.