NOTICE: This standard has either been superseded and replaced by a new version or withdrawn.
Contact ASTM International (www.astm.org) for the latest information

Designation: F2665 – 09 (Reapproved 2014)

# Standard Specification for Total Ankle Replacement Prosthesis[1]

This standard is issued under the fixed designation F2665; 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 covers total ankle replacement (TAR) prostheses used to provide functioning articulation by employing talar and tibial components that allow for a minimum of 15° of dorsiflexion and 15 to 25° (**1**)[2] of plantar flexion, as determined by non-clinical testing.

1.2 Included within the scope of this specification are ankle components for primary and revision surgery with modular and non-modular designs, bearing components with fixed or mobile bearing designs, and components for cemented and/or cementless use.

1.3 This specification is intended to provide basic descriptions of material and prosthesis geometry. In addition, those characteristics determined to be important to *in vivo* performance of the prosthesis are defined.

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

## 2. Referenced Documents

2.1 *ASTM Standards:*[3]

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)
F138 Specification for Wrought 18Chromium-14Nickel-2.5Molybdenum Stainless Steel Bar and Wire for Surgical Implants (UNS S31673)
F451 Specification for Acrylic Bone Cement
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)[4]
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
F745 Specification for 18Chromium-12.5Nickel-2.5Molybdenum Stainless Steel for Cast and Solution-Annealed Surgical Implant Applications (Withdrawn 2012)[4]
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)
F981 Practice for Assessment of Compatibility of Biomaterials for Surgical Implants with Respect to Effect of Materials on Muscle and Bone

[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 July 15, 2014. Published September 2014. Originally approved in 2009. Last previous edition approved in 2009 as F2665 - 09. DOI: 10.1520/F2665-09R14.

[2] The boldface numbers in parentheses refer to a list of references at the end of this standard.

[3] 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.

[4] The last approved version of this historical standard is referenced on www.astm.org.

Copyright © ASTM International, 100 Barr Harbor Drive, PO Box C700, West Conshohocken, PA 19428-2959. United States

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
F1800 Practice for Cyclic Fatigue Testing of Metal Tibial Tray Components of Total Knee Joint Replacements
F1814 Guide for Evaluating Modular Hip and Knee Joint Components

2.2 *ISO Standards:*[5]
ISO 6474 Implants for Surgery—Ceramic Materials Based on Alumina
ISO 14243–2 Implants for Surgery—Wear of Total Knee-Joint Prostheses—Part 2: Methods of Measurement

2.3 *FDA Document:*[6]
21 CFR 888.6 Degree of Constraint
21 CFR 888.3110 Ankle Joint Metal/Polymer Semi-Constrained Cemented Prostheses
21 CFR 888.3120 Ankle Joint Metal/Polymer Non-Constrained Cemented Prostheses

2.4 *ANSI/ASME Standard:*[5]
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 *constraint, n*—the relative inability of a TAR, inherent to its geometrical and material design, to be further displaced in a specific direction under a given set of loading conditions.

3.1.2 *dorsiflexion, n*—rotation of the tibial component towards the anterior talar surface.

3.1.3 *flexion, n*—rotation of the talar component relative to the tibial component around the medial-lateral axis. Flexion is considered positive when it is dorsiflexion, and negative when it is plantar flexion.

3.1.4 *interlock, n*—mechanical design feature used to increase capture of one component within another and to restrict unwanted displacement between components, that is, component locking mechanism for modular components.

3.1.5 *plantar flexion, n*—rotation of the tibial component toward the posterior talar surface.

3.1.6 *talar component, n*—bearing member fixed to the talus for articulation with the tibial component. This could be metallic or from some other suitably hard surface material.

3.1.7 *radiographic marker, n*—a nonstructural wire or bead designed to be apparent on X-rays taken after implantation for those components that would otherwise not be apparent on such X-rays.

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

iTeh Standards
(https://standards.iteh.ai)
Document Preview
ASTM F2665-09(2014)
https://standards.iteh.ai/catalog/standards/sist/034c00a7-1cc

3.1.9 *tibial component, n*—fixed or mobile bearing member attached to the tibia for articulation with the talar component, typically consisting of two major components, a metallic tibial tray and an ultra-high-molecular-weight (UHMWPE) (see Specification F648) bearing surface.

3.1.10 *total ankle replacement (TAR), n*— prosthetic parts that substitute for the natural opposing tibial and talar articulating surfaces.

3.1.11 *IE rotation, n*—rotation of the tibial component relative to the talar component around the tibial axis. IE rotation is considered positive when the tibial component rotates internally (clockwise when viewed proximally on the left ankle). IE rotation is considered negative when the tibial component rotates externally.

## 4. Classification

4.1 The following classification by degree of constraint is suggested for all total joint prostheses including total ankle replacement systems based on the concepts adopted by the U.S. Food and Drug Administration (see 21 CFR 888.6).

4.1.1 *Constrained*—A constrained joint prosthesis prevents dislocation of the prosthesis in more than one anatomic plane and consists of either a single, flexible, across the-joint component or more than one component linked together or affined.

4.1.2 *Semi-constrained*—A semi-constrained joint prosthesis limits translation or rotation, or both translation and rotation of the prosthesis in one or more planes via the geometry of its articulating surfaces. Its components have no across-the-joint linkages.

4.1.3 *Non-constrained*—A non-constrained joint prosthesis minimally restricts prosthesis movement in one or more planes. Its components have no across-the-joint linkages.

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

[6] Available from Food and Drug Administration (FDA), 5600 Fishers Ln., Rockville, MD 20857, http://www.fda.gov.

4.2 Currently, most ankle designs are considered either semi-constrained or non-constrained. Most mobile bearing ankle components are considered non-constrained. The US government 21 CFR 888.3110 identifies ankle joint metal/polymer semi-constrained cemented prosthesis and 21 CFR 888.3120 identifies ankle joint metal/polymer non-constrained cemented prosthesis.

## 5. Material

5.1 All devices conforming to this specification shall be fabricated from materials with adequate mechanical strength, durability, corrosion resistance, and biocompatibility.

NOTE 1—The choice of materials is understood to be a necessary but not totally sufficient assurance of proper function of the device made from them.

5.1.1 *Mechanical Strength*—Various metallic components of total ankle replacement devices have been successfully fabricated from materials, as examples, found in Specifications F75, F90, F136, F138, F562, F563, F745, F799, F1108, F1377, F1472, F1537, and F1580. Polymeric bearing components have been fabricated from UHMWPE, as an example, as specified in Specification F648. Porous coatings have been fabricated from example materials specified in Specifications F67 and F75. Not all of these materials may possess sufficient mechanical strength for critical, highly stressed components or for articulating surfaces. Conformance of a selected material to its standard and successful clinical usage of the material in a previous implant design are not sufficient to ensure the strength of an implant. Manufacturing processes and implant design can strongly influence the device's performance characteristics. Therefore, regardless of the material selected, the ankle implant must meet the performance requirements of Section 6.

5.1.2 *Corrosion Resistance*—Materials with limited or no history of successful use for orthopaedic implant application shall exhibit corrosion resistance equal to or better than one of the materials listed in 5.1.1 when tested in accordance with Test Method F746.

5.1.3 *Biocompatibility*—Materials with limited or no history of successful use for orthopaedic implant application shall exhibit acceptable biological response equal to or better than one of the materials listed in 5.1.1 when tested in accordance with Practices F748 and F981 for a given application.

## 6. Performance Requirements

6.1 *Component Function*—Each component for total ankle arthroplasty is expected to function as intended when manufactured in accordance with good manufacturing practices and to the requirements of this specification. The components shall be capable of withstanding static and dynamic physiologic loads (**1**) without compromising their function for the intended use and environment. All components used for experimental measures of performance shall be equivalent to the finished product in form and material. Components shall be sterilized if the sterilization process will affect their performance.

NOTE 2—Computer models may be used to evaluate many of the functional characteristics if appropriate material properties and functional constraints are included and the computer models have been validated with experimental tests.

6.1.1 Individual tibial (that is, tibial tray and bearing surface components) and talar components should be fatigue tested using relevant or analogous test methods under appropriate loading conditions (including worst-case scenarios) to address loss of supporting foundation leading to potential deformation and/or component fracture.

6.1.1.1 Tibial tray components may be evaluated in a manner similar to Test Method F1800, with a loading moment value chosen to compare with a clinically successful implant, or justified in other suitable ways for the design being tested) (**2**). In choosing the loading moment, both the moment arm and the load used shall be specified with explanation as to how and why they were chosen. Each of five specimens shall be tested for 10 million cycles with no failure. All tibial components designated by this specification shall pass this minimum requirement.

6.1.1.2 Tibial bearing surface components shall be fatigue tested considering worst-case scenarios to demonstrate that the component is able to withstand anticipated physiological loading conditions and is not susceptible to the failure modes that have been reported in the literature (**3-5**). The worst-case scenarios should take into consideration loads, component sizes, thickness of the plastic bearing insert, bony support, locking mechanism, edge loading, misalignments and how these can affect the individual design.

iTeh Standards (https://standards.iteh.ai) Document Preview

6.1.2 Contact area and contact pressure distributions may be determined at various flexion angles using one of several published methods (**6-11**) to provide a representation of stresses applied to the bearing surfaces and to the components. Flexion angles of 0, ±10, and ±15° are recommended. If the prosthesis is designed to function at higher angles of dorsiflexion or plantar flexion, then it is recommended that these measurements be continued at 5° increments to the full range of motion. If these tests are performed, it is important to maintain consistent test parameters and to evaluate other TAR prostheses under the same conditions.

ASTM F2665-09(2014)

6.1.3 Range of motion in dorsiflexion and plantar flexion shall be greater than or equal to 15° (each) which is required for walking (**12-14**). These measurements apply to components mounted in neutral alignment in bone or in an anatomically representative substitute. It is critical to define the location of the neutral alignment position, for example, center of contact areas or patches, in terms of dimensions from outside edges of the components. The initial positioning or location of the neutral alignment point will affect the range of motion values for certain TAR prostheses. The range of flexion determined from non-clinical testing, therefore, can be compromised by misalignments in various degrees of freedom. Worst-case scenario misalignments as well as neutral alignment should be evaluated for dorsiflexion and plantar flexion range of motion testing.

NOTE 3— The nominal range of motion of a total ankle replacement can be estimated using the computer-aided drawings (CAD) of an implant. The definition of zero degrees of ankle flexion for the implant should be reported. The actual maximum dorsiflexion and maximum plantar flexion should be defined as the maximum angle at which the following conditions are met: (*a*) bony impingement is not expected, (*b*) the edges of the talar component or tibial component do not dig into the UHMWPE bearing (if any), and (*c*) the implant system can sustain a compressive load