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Standard Specification for Total Ankle Replacement Prosthesis[1]

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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Cobalt-20Nickel-20Chromium-3.5Molybdenum-3.5Tungsten-5Iron Alloy for Surgical Implant Applications (UNS R30563) (Withdrawn 2005)[4]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.

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[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.

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.

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.

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.

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

of 3600 N (approximately 5 average body weights) (**13**, **15**) and a combination of the translational and rotational extreme laxity motions claimed in the design without subluxation.

6.1.4 Total ankle replacement constraint data for internal-external rotation, anterior-posterior displacement, and medial-lateral displacement should be determined for all total ankle joints in a manner similar to Test Method F1223 for total knees. Implants should be tested at 0°, ±10° and maximum flexion at a minimum.

6.2 All modular components shall be evaluated for the integrity of their connecting mechanisms. As suggested in Guide F1814, static and dynamic shear tests, bending tests, and tensile tests or any combination may be necessary to determine the performance characteristics. The connecting mechanisms shall show sufficient integrity for the range of loads anticipated for the application.

6.3 It is important to understand the wear performance for articulating surfaces. Any new or different material couple shall not exceed the wear rates of the following material couple when tested under simulated physiological conditions, or if it does exceed these rates its use shall be further justified. The current standard wear couple is CoCrMo alloy (see Specification F75) against a fixed bearing UHMWPE (see Specification F648), both having prosthetic-quality surface finishes as described in 8.2 and 8.3.

6.3.1 Materials may be tested in a pin-on-flat or pin-on-disk test apparatus such as described in Test Method F732 with adequate controls for comparison. A number of different load levels may be used to cover the range of anticipated stresses between articulating components.

NOTE 4—In situations in which the pin-on-flat test may not be considered appropriate, other tests may be considered, for example, ankle simulation modes of prosthesis wear performance testing or those described in ISO 6474 or other published documents.

6.4 Porous metal coatings shall be tested in accordance with Test Method F1044 (shear strength) and Test Method F1147 (tensile strength) and the average for each test should exceed 20 MPa. The fatigue properties may be evaluated in accordance with Test Method F1160.

7. Dimensions

7.1 Dimensions of total ankle replacement components may be designated in accordance with Fig. 1 and the items specified in the glossary. The tolerance and methods of dimensional measurement shall conform to industry practice and be on an international basis, whenever possible.

8. Finishing and Marking

8.1 Metallic components conforming to this specification shall be finished and marked in accordance with Practice F86, where applicable.

8.2 *Metallic Bearing Surface*—The main bearing surfaces shall have a surface finish no rougher than 0.05 µm (2 µin.) roughness average, R_a, when measured in accordance with the

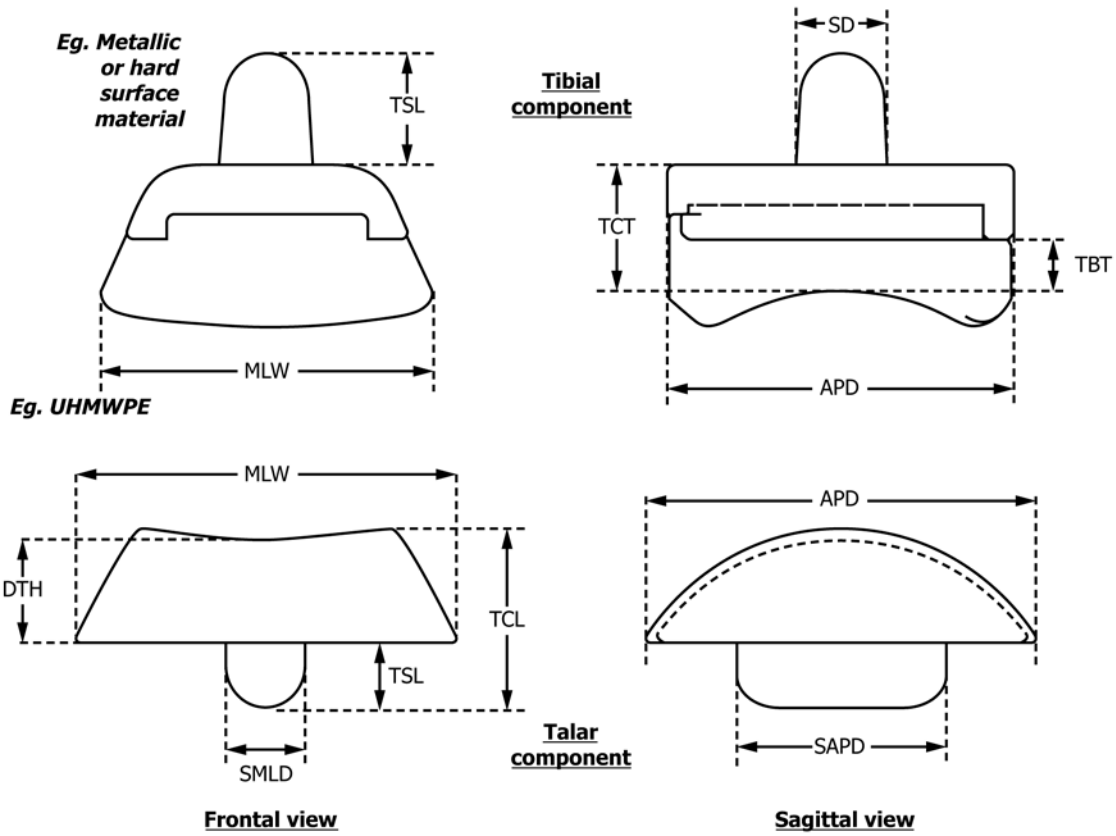

FIG. 1 General Depiction of Important Attributes of One Example Set of Semi-constrained Fixed Bearing Total Ankle Arthroplasty Components

principles given in ANSI/ASME B46.1–1995. The following details should be documented: stylus tip radius, cutoff length of measuring instrument (0.25 mm is recommended), and position of measurement on the specimen. When inspected visually, the component shall be free from embedded particles, defects with raised edges, scratches and score marks.

8.3 *Polymeric Bearing Surface*—The main bearing surface of a UHMWPE component shall have a surface roughness no greater than 2-µm (80-µin.) roughness average, R_a, when measured in accordance with the principles given in ANSI/ASME B46.1-1995. The following details should be documented: stylus tip radius, cutoff length of the measuring instrument (0.80 mm is recommended), and the position of measurement on the specimen. When inspected with normal or corrected vision, the bearing surface shall be free from scale, embedded particles, scratches and score marks other than those arising from the finishing process.

NOTE 5—Measurements should be taken in at least two orthogonal directions.

8.4 In accordance with Practices F86 and F983, items conforming to this specification shall be marked in the following as follows in order of priority where space permits: manufacturer, material, lot number, catalog number, and size. Additional markings may be included, for example, left, right, front, and so forth.

8.5 If one of the components is not radiographically opaque, it may be appropriately marked for radiographic evaluation. If a radiographic marker is used, it should be placed in a non-critical area to avoid degrading the structural and functional properties of the device.

NOTE 6—Radiographic markers have been used in the past. They are considered non-critical and may not be necessary.

9. Packaging and Package Marking

9.1 An adequate description of overall size and shape shall be included in the packaging. Dimensions, when used, shall conform to 3.1.1, Appendix X1, and Fig. 1.

9.2 The end user shall be able to determine the minimum tibial bearing insert thickness (TBT) of the UHMWPE in the main bearing area for integral or modular systems from the package material. This may be achieved by directly specifying the TBT dimension or by providing a means to calculate the TBT dimension (see X2.12).

9.3 Packaging material for the TAR prosthesis system (talar and tibial components) may include information developed from a test similar to Test Method F1223.

10. Keywords

10.1 ankle; ankle constraint; ankle prosthesis; arthroplasty; ankle wear; contact area; contact pressure; fatigue; particles; surface roughness; total ankle replacement (TAR); UHMWPE

APPENDIXES

(Nonmandatory Information)

X1. GLOSSARY (See Fig. 1)

X1.1 *anteroposterior distance (APD)*, for both talar and tibial components, the maximum A-P distance sagittally.

X1.2 *distal talar height (DTH)*, thickness of the talar component from the transverse resection plane to the functional surface at its center sagitally and frontally.

X1.3 *mediolateral distance width (MLW)*, for both the talar and tibial components, the maximum width of the components in the frontal elevation.

X1.4 *effective bone resection distance or overall thickness (OT)*, the minimum distance that must exist between the talus and tibia to enable implantation of the device. Numerically equal to the distal condylar height (DTH) plus the tibial component thickness (TCT).

X1.5 *stem anterioposterior dimension (SAPD)*, cross-sectional anterior-posterior distance of a non-symmetrical stem at its midpoint in the sagittal plane.

X1.6 *stem diameter (SD)*, stem diameter for either talar or tibial components. If the stem is not of uniform diameter, such as wedge- or keel-shaped, then specify the mediolateral and anteroposterior dimensions.

X1.7 *stem mediolateral dimension (SMLD)*, cross-sectional mediolateral width of a non-symmetrical stem at its midpoint on the frontal plane.

X1.8 *tibial bearing insert thickness (TBT)*, minimum thickness of the bearing insert of the tibial component.

X1.9 *overall talar component length (TCL)*, overall length of the talar component from the most proximal articular surface to the most distal surface.

X1.10 *tibial component thickness (TCT)*, minimum thickness from the functional articular surface to the proximal superior surface of the plateau. This is equal to TBT plus TTT for any multi-component system. This is equal to TBT for all single component systems.

X1.11 *talar stem angle frontally (TSAF)*, angle formed by the talar stem relative to the neutral axis of the talar component in the frontal plane.

X1.12 *talar stem angle sagittally (TSAS)*, angle formed by the talar stem relative to the neutral axis of the talar component in the sagittal plane.

X1.13 *tibial stem length (TSL)*, that portion (if any) of the talar or tibial components intended for intramedullary or other bony fixation measured from stem origin to the tip of the stem. The length of a modular stem attachment shall also be described this way.

X1.14 *tibial tray thickness (TTT)*, minimum thickness of the tibial tray/baseplate when measured from the superior surface to the inferior surface. In the case of a single component, this dimension is the TBT.

X2. RATIONALE

X2.1 The objectives of this specification are to establish guidelines for the manufacture and function of components for total ankle replacement. This specification describes the talar and tibial components. These total ankle 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 simulate accurately imposed loads, aggressive electrolytes, and complex constituents of body fluids cannot be usefully accelerated. Long-term durability may not be predictive through the currently available screening procedures

X2.2 This specification identifies those factors felt to be important to ensure a satisfactory useful prosthesis life. It is recognized that failure of an arthroplasty can occur even while the components are intact. Other factors affecting the outcome of the arthroplasty not addressed by this specification include infection, surgical technique, component misalignment, soft tissue balance, unpredicted tissue response, weight gain, and extreme use or misuse by the patient.

X2.3 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 added during revision of this specification. To date, a majority of ankle prosthesis components have either been uncemented or cemented with acrylic bone cement in accordance with Specification F451. Although the poly(methyl methacrylate) (PMMA) bone cement is not considered part of the ankle prosthesis, it may play an important role in the performance of the prosthesis and, therefore, should be considered during testing and evaluation.

X2.4 *Constraint Classification* —Total ankle prosthetic components can be categorized into two types of prosthetic pairs: semi-constrained and non-constrained. No general consensus has emerged to establish clearly the most widely acceptable classification; however, the qualitative descriptors included herein have been adopted by the Food and Drug Administration (21 CFR 888.6) for the purpose of evaluating new device applications. It is also anticipated that through the application of a test method similar to Test Method F1223 appropriate categorization may be achieved and data sufficient to allow selection of a proper device for a particular patient will be available. Note that devices within a particular classification may allow significantly different degrees of freedom (that is, translation, rotation, or flexion ranges or limits) from other devices within the same classification, depending on device geometry and the means and relative amount of constraint. Conversely, devices in different classifications may allow similar degrees of freedom and provide comparable motion and clinical results.

X2.5 In the course of evaluating new materials, it is recommended that if the material is used in an application that causes small particle formation from abrasion or normal wear processes then the biocompatibility of these particles be determined in addition to that of the bulk material.

X2.6 *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. Mechanical values derived from materials testing and cited as minimum allowable levels must be applicable to the structures described in the specifications. Usual and customary sampling procedures shall be considered adequate evidence of compliance. Exemption from sampling is justified where no degradation in mechanical properties is expected during fabrication of components.

X2.7 It is anticipated that as new performance data become available, they will be incorporated into the body of this specification.

X2.8 Component performance should be considered with regard to body weight, with unusually small patients being better served by small components. On the other hand, overweight patients may not necessarily accommodate larger components but need a thicker plastic bearing insert to withstand the higher loads and stresses. Overweight patients can be catered for in testing with worst-case loading scenarios to correspond to a heavier patient (for example. Body Weight BW= 1112 N (250 lbf)) subjected to the usual multiplier (for example, 5 BW with average normal patients) when calculating testing loads. An alternative is to test an implant less severely but exclude heavier patients from the indications for the implant use. It is also 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, disuse, and so forth.

X2.9 Radiographic markers have been used to make components radiographically detectable. They may not be necessary but, when used, they shall be located in a noncritical area to avoid any contribution to device failure. They shall not be located in critical wear areas or in regions that may experience high stresses since this could reduce the service life of the component.

X2.10 For marking of the components, it is desirable to have complete information, where space is available to do so, including the manufacturer's trademark, material, lot number, size, orientation (if any), and date, in that order.

X2.11 For the purposes of this specification, packaging may include product brochures and associated literature.

X2.12 It is important to inform the end user of the minimum thickness of a bearing material in the articulated areas. Although the thickness does not necessarily determine clinical performance, it may be helpful to the end user.

X2.13 The knee tibial tray Test Method F1800 (the principle of which is applicable when a baseplate is used to hold the UHMWPE bearing of an ankle prosthesis) is a simplified means to evaluate performance and does address some, but not all, clinical failure modes. The minimum performance level of 900 N is based on literature and the experience of several test laboratories on the tibial tray component of a total knee replacement. It is recognized that investigators have used other test methods to evaluate the tibial and talar components of total ankle prostheses for similar and different failure modes.

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