Designation: F3018 – 17

Standard Guide for Assessment of Hard-on-Hard Articulation Total Hip Replacement and Hip Resurfacing Arthroplasty Devices[1]

This standard is issued under the fixed designation F3018; 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 guide covers materials and design recommendations and general test methods for the chemical, mechanical, and preclinical assessment of implantable devices with hard-on-hard articulations intended to replace a hip joint. The provided guidance is intended to encompass both Total Hip Replacement (THR) devices with stems that extend or fix within the intramedullary canal as well as Hip Resurfacing Arthroplasty (HRA) wherein only the hip articulating surfaces are replaced. There has been long term clinical experience with metal-on-metal articulating components manufactured from cobalt-28 % chromium-6 % molybdenum (Co28Cr6Mo) alloy (Specifications F75, F799, or F1537) or high purity alumina (ISO 6474-1) and ceramic-on-ceramic articulating components manufactured from high purity alumina (ISO 6474-1) or alumina matrix composite ceramics (ISO 6474-2). There has also been some limited clinical experience with metal (Co28Cr6Mo) on alumina matrix composite ceramic articulating components. This guide has been created based on the current understanding derived from those clinical histories. Device articulating components manufactured from other metallic alloys, ceramics or with coated or elementally modified articulating surfaces could also be evaluated with this guide. However, such materials that do not have a history of clinical use may present different risks.

1.2 This guide applies to the acetabular and femoral articulating components of hard-on-hard hip replacement devices. Acetabular components can be monoblock, or a modular component with a separate acetabular shell and acetabular liner. As stated above, articulating components have been made from Co28Cr6Mo for a metal-on-metal bearing; high purity alumina or alumina matrix composite ceramics for a ceramic-on-ceramic bearing; and Co28Cr6Mo and alumina matrix composite (ISO 6474-2) for a metal-on-ceramic bearing. Modular acetabular shells have to date been made from Ti-6Al-4V or Co28Cr6Mo. The shell is considered part of the acetabular component. Acetabular components may have external coating and/or porous structure intended for uncemented, press-fit or biological fixation; or, for use with bone cement.

1.3 This standard is a summary of available specifications, test methods, practices, and guides from published standards or the scientific literature. Their clinical relevance is unproven. Most of the methods do not have an established precision and bias; therefore, their repeatability and reproducibility has not been established. As the clinical relevance of these methods have not been established, consequently, most do not have performance requirements. This document does not require that all the listed methodologies are always necessary to evaluate these implant systems provided justification for not using each unused method is provided. This document does not intend to prevent the use of new methodologies as they are developed.

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

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)

F136 Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)

[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.

F561 Practice for Retrieval and Analysis of Medical Devices, and Associated Tissues and Fluids
F799 Specification for Cobalt-28Chromium-6Molybdenum Alloy Forgings for Surgical Implants (UNS R31537, R31538, R31539)
F1537 Specification for Wrought Cobalt-28Chromium-6Molybdenum Alloys for Surgical Implants (UNS R31537, UNS R31538, and UNS R31539)
F1814 Guide for Evaluating Modular Hip and Knee Joint Components
F1820 Test Method for Determining the Forces for Disassembly of Modular Acetabular Devices
F1854 Test Method for Stereological Evaluation of Porous Coatings on Medical Implants
F1877 Practice for Characterization of Particles
F2033 Specification for Total Hip Joint Prosthesis and Hip Endoprosthesis Bearing Surfaces Made of Metallic, Ceramic, and Polymeric Materials
F2068 Specification for Femoral Prostheses—Metallic Implants
F2091 Specification for Acetabular Prostheses
F2345 Test Methods for Determination of Static and Cyclic Fatigue Strength of Ceramic Modular Femoral Heads
F2582 Test Method for Impingement of Acetabular Prostheses
F3047M Guide for High Demand Hip Simulator Wear Testing of Hard-on-hard Articulations

2.2 *ISO Standards:*[3]
ISO 1302 Geometrical Product Specifications (GPS) -- Indication of surface texture in technical product documentation
ISO 4287 Geometrical Product Specifications (GPS) -- Surface texture: Profile method -- Terms, definitions and surface texture parameters
ISO 4288 Geometrical Product Specifications (GPS) -- Surface texture: Profile method -- Rules and procedures for the assessment of surface texture
ISO 5832-3 Implants for surgery -- Metallic materials – Part 3: Wrought titanium 6-aluminium 4vanadium 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-chromiummolybdenum alloy
ISO 6474-1 Implants for surgery -- Part 1: Ceramic materials based on high purity alumina
ISO 6474-2 Implants for surgery -- Part 2: Composite materials based on a high purity alumina matrix with zirconia reinforcement
ISO 7206-1 Implants for surgery -- Partial and total hip joint prostheses -- Part 1: Classification and designation of dimensions
ISO 7206-2 Implants for surgery -- Partial and total hip joint prostheses -- Part 2: Articulating surfaces made of metallic, ceramic and plastics materials
ISO 7206-4 Implants for surgery -- Partial and total hip joint prostheses -- Part 4: Determination of endurance properties and performance of stemmed femoral components
ISO 7206-6 Implants for surgery -- Partial and total hip joint prostheses -- Part 6: Endurance properties testing and performance requirements of neck region of stemmed femoral components
ISO 7206-10 Implants for surgery -- Partial and total hip joint prostheses -- Part 10: Determination of resistance to static load of modular femoral heads
ISO 7206-12 Implants for surgery -- Partial and total hip joint prostheses — Part 12: Deformation test method for acetabular shells
ISO 7206-13 Implants for surgery -- Partial and total hip joint prostheses -- Part 13: Determination of resistance to torque of head fixation of stemmed femoral components
ISO 14242-1 Implants for surgery -- Wear of total hip-joint prostheses -- Part 1: Loading and displacement parameters for wear-testing machines and corresponding environmental conditions for test
ISO 14242-2 Implants for surgery -- Wear of total hip-joint prostheses -- Part 2: Methods of Measurement
ISO 14242-3 Implants for surgery -- Wear of total hip-joint prostheses -- Part 3: Loading and displacement parameters for orbital bearing type wear testing machines and corresponding environmental conditions for test
ISO 17853 Wear of implant materials -- Polymer and metal wear particles -- Isolation, characterization and quantification
ISO 21535 Non-active surgical implants -- Joint replacement implants -- Specific requirements for hip-joint replacement implants
ISO 25178-6 Geometrical product specifications (GPS) -- Surface texture: areal -- Part 6: Classification of methods for measuring surface texture

2.3 *Other Standards:*
ASME Y14.36M Surface Texture Symbols
US FDA 510(k) Information needed for Hydroxyapatite Coated Orthopedic Implants March 10, 1995 (revised Feb. 20, 1997)[4]

3. Terminology

3.1 *Definitions of Terms Specific to This Standard:*

3.1.1 *alloy fabricated form, n*—the raw material form of the metallic alloy and any processing techniques used to fabricate the final form of the implant.

3.1.2 *breakaway wear, n*—a 'higher' unexpected wear rate that follows a period of steady-state wear as illustrated in Fig. 1. **(1)**[5]

3.1.3 *breakaway wear with recovery, n*—breakaway wear that returns to lower steady-state wear rates. The breakaway/recovery phenomenon can be a single event or multiple 'episodic' events during the steady-state conditions as illustrated in Fig. 1.

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

[4] Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile, issued January 21, 2016, updated March 16, 2016.

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

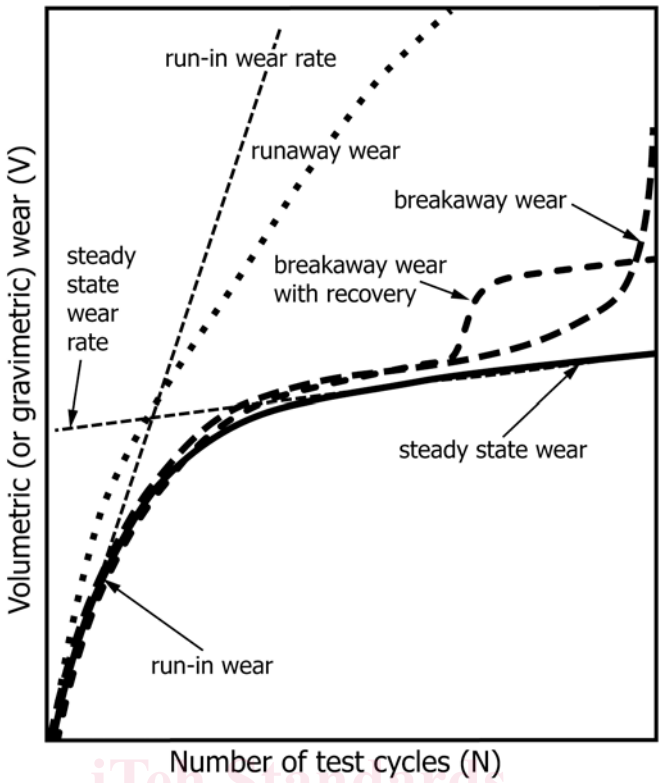

FIG. 1 Modes/Phases of Wear Illustrated Schematically (1)

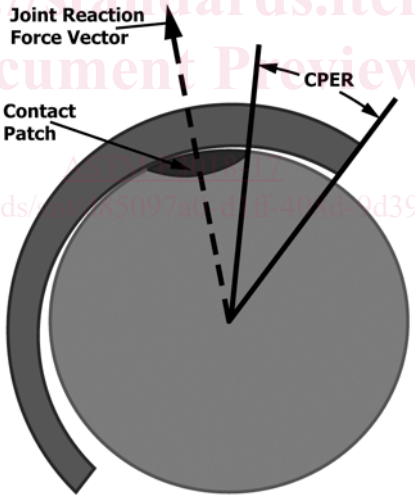

FIG. 2 Illustration of Contact Patch Edge to Rim Distance

3.1.4 *ceramic material sample, n*—ny bulk shape of hard inorganic non-metallic ceramic materials that is prepared to the final physical, chemical, and mechanical material properties specified for the implant component before packaging and sterilization.

3.1.5 *ceramic-on-ceramic hip articulation, n*—a device intended to replace a human hip joint in which the femoral and acetabular articulating surfaces are composed of ceramic. Clinical history exists for high purity alumina or alumina matrix composite ceramics in this application. Other ceramic materials have not yet had a history of clinical use.

3.1.6 *contact patch, n*—an estimated contact area between the acetabular and the femoral articulating surfaces for a given joint reaction force

3.1.7 *contact patch edge to rim (CPER) distance, n*—for a given acetabular component orientation the arc distance between the edge of the contact patch at a 3 kN joint reaction

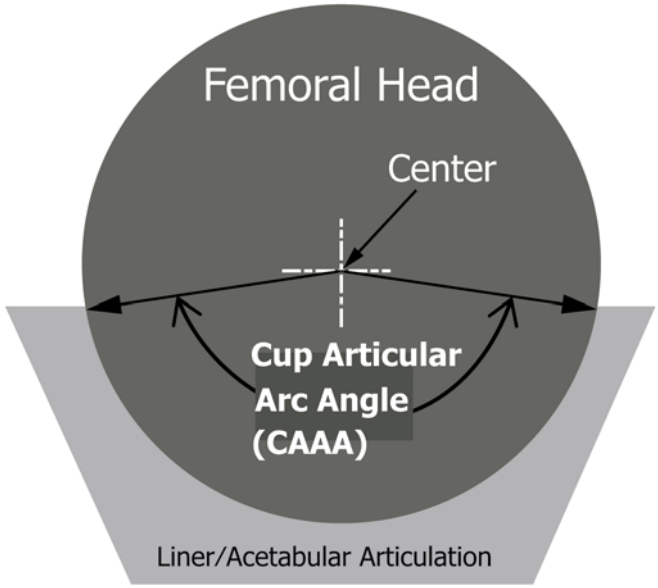

FIG. 3 Illustration of Cup Articular Arc Angle

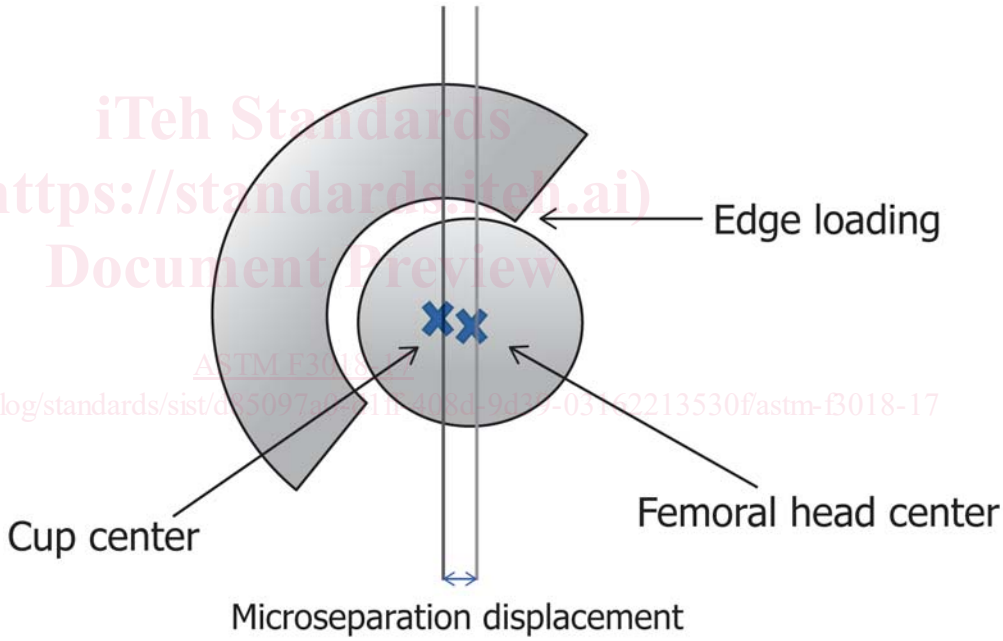

FIG. 4 Illustration of Edge Loading Due to Microseparation

force and the last portion of articulating surface on the acetabular component as illustrated in Fig. 2.

3.1.8 *cup articular arc angle (CAAA), n*—the angle subtended by the articular surface of the acetabular component. It can be determined with a computeraided design system or manual measurements. With a head placed in the acetabular liner, it is the minimum angle in a plane bisecting the femoral head and the liner, formed by the last contacts between the head and liner, and the rotational center of the head. It is illustrated in Fig. 3. The measurement applies to both THR and HRA systems.

3.1.9 *diametral clearance, n*—the diameter of the acetabular articulating surface minus the diameter of the femoral articular surface.

3.1.10 *hip bearing couple, n*—a usually spherical ball and cup system intended to articulate against each other as a replacement for the articulating surfaces of the natural hip.

3.1.11 *metal-on-metal hip prosthesis, n*—a device intended to replace a human hip joint in which the ball and cup articulating surfaces are historically composed of Co28Cr6Mo cobalt alloy. The ball is attached to an intramedullary stem in THR systems.

3.1.12 *microseparation, n*—a dynamic condition that can occur in where the centers of rotation of the femoral head and the acetabular cup are displaced during an activity. This can lead to edge loading where the femoral head contacts the rim. It is illustrated in Fig. 4. The phenomenon is relevant to both THR and HRA systems.

3.1.13 *modular acetabular device, n*—a modular acetabular system consisting of a minimum of two components, one of which includes the bearing surface and the second component is a modular acetabular shell intended to contain the bearing liner and contact bone or bone cement.

3.1.14 *modular acetabular liner*—portion of the modular acetabular device with an internal hemispherical socket intended to articulate with the head of a femoral prosthesis. The external geometry of this component interfaces with the acetabular shell through a locking mechanism which may be integral to the design of the liner and shell or may rely upon additional components (for example, metal ring, screws, and so forth).

3.1.15 *modular acetabular shell, n*—the external, hollow structure, usually metallic, that provides additional mechanical support or reinforcement for an acetabular liner and whose external features interface directly with the bones of the pelvic socket (for example, through bone cement, intimate press-fit, coatings for attachment to bone cement or tissue, integral screw threads, anchoring screws, pegs, and so forth). The acetabular shell may be solid or contain holes for fixation or attachment of instrumentation.

3.1.16 *monoblock acetabular device, n*—an acetabular system manufactured as a single piece

3.1.17 *runaway wear, n*—an initial high wear rate that shows no sign of achieving a lower steady-state wear rate as illustrated in Fig. 1.

3.1.18 *run-in wear, n*—wear rate that occurs when the components are first implanted in vivo, or during the initial phase of an in vitro hip simulator test. During this period, wear rates are typically higher than during steady state as the articulating surfaces wear into conformity with each other and any initially contacting surface asperities or form errors are worn away as illustrated in Fig. 1. In hip simulator wear tests it is often considered to be about one million cycles. The transition to steady-state wear can be estimated graphically from the plot of total wear vs. number of cycles.

3.1.19 *steady-state wear, n*—an average wear rate that occurs after a transient run-in wear period as illustrated in Fig. 1. Typically, the steady-state wear rate is less than the run-in wear rate. In hip simulator wear tests it is generally considered to be estimated from values at 1 million cycles and above.

3.1.20 *ZTA, n*—Zirconia Toughened Alumina A ceramic with an Alumina matrix than has Zirconia added to toughen and strengthen the resultant composite ceramic.

4. Significance and Use

4.1 This document provides guidance for a range of assessments and evaluations to aid in preclinical research and device development of hard-on-hard total hip replacement and hip resurfacing devices used for the repair of musculoskeletal disorders.

4.2 The user is encouraged to use appropriate ASTM International or ISO standards to conduct the physical, chemical, mechanical, biocompatibility, and preclinical tests on alloy fabricated forms, ceramic material samples, device components, or devices before assessment in an in vitro model.

4.3 Studies to support regulatory submissions should conform to appropriate regulatory requirements and guidelines for the development of medical devices.

4.4 Assessments with physical, chemical, mechanical, biocompatibility, and preclinical tests on hard-on-hard hip prosthesis components are not necessarily predictive of human results and therefore should be interpreted cautiously with respect to potential applicability to clinical conditions. Referenced metal-onmetal or ceramic-on-ceramic hip prosthesis publications can be found in the Bibliography section at the end of this guide for further review.

5. Guidance for Device Description

5.1 Specification F2068 provides appropriate descriptions and performance requirements for the femoral prostheses portion of the THR system.

5.2 Specification F2091 provides appropriate descriptions for the acetabular component of a THR and HRA systems. Additional features as described below are useful for defining the hard-on-hard articulation of a total hip replacement and hip resurfacing device.

5.2.1 Monoblock acetabular system

5.2.1.1 The location and size of features such as screw holes, specific geometry intended for fixation, or an exterior surface coating intended for attachment to bone cement or tissue, Note: There should be no interference of these features with the articulation of the system.

5.2.2 Modular acetabular systems

5.2.2.1 Features intended to hold the modular system together in clinical use.

5.2.2.2 Screw holes, specific geometry intended for fixation of the shell, or an exterior surface structure intended for attachment to bone cement or tissue. Note: there should be no interference of these features with the attachment of the shell to the liner or the articulation with the head.

5.2.2.3 Dimensional requirements of the modular interface of both the acetabular liner and the acetabular shell shall be reported.

5.2.2.4 The surface finish requirements of the contacting modular surfaces of both the acetabular liner and the acetabular shell shall be reported before and after wear testing.

5.3 Materials

5.3.1 Hard on hard articulation components have been made from material conforming to the requirements of Specifications F75, F799, F1537, ISO 5832-4, ISO 5832-12, ISO 6474-1, or ISO 6474-2. These specifications include, but are not limited to, chemical, mechanical, inspection (including microstructural), and supplier quality system requirements.

5.3.2 Modular acetabular shells have been manufactured from one of the following materials: Specifications F75, F136, F799, F1537, ISO 5832-3, ISO 5832-4, and ISO 5832-12. Any surface modification or coating on the exterior of the acetabular component intended for contact with bone or bone cement should be tested for its intended purpose.

5.3.2.1 Test Method F1854 provides information on porous coating characterization (coating thickness, void content, and mean intercept length).

5.3.2.2 Other important guidance includes the FDA Guidance Documents for Testing Orthopedic Implants with Modified Metallic Surfaces Opposing Bone or Bone Cement **(2)** and Guidance for Industry on the Testing of Metallic Plasma Sprayed Coatings on Orthopedic Implants to Support Reconsideration of Postmarket Surveillance Requirements **(3)**.

5.3.2.3 The FDA Guidance Documents for "510(k) Information needed for Hydroxyapatite Coated Orthopedic Implants" provides guidance for characterizing hydroxyapatite coatings.

5.4 Dimensional and Physical Specifications

5.4.1 The diametral clearance requirements are described in Specification F2033.

5.4.2 Articulating Surface Roughness

5.4.2.1 Surface roughness of all bearing surfaces should be specified on drawings using suitable indications, such as ASME Y14.36M or ISO 1302.

5.4.2.2 Surface roughness of bearing surfaces should be measured according to the procedures described in a) ISO 4287 and ISO 4288, or b) ISO 25178-6 for three-dimensional areal measurements.

5.4.2.3 Specification F2033 and ISO 7206-2 describe surface finish requirements.

5.4.3 Articulating Surface Form Deviation (Sphericity)

5.4.3.1 The surface deviation from the nominal print form of the bearing surfaces should be specified and measured. In the special case of an intentionally spherical bearing surface, this measurement is termed sphericity.

5.4.3.2 Specification F2033 and ISO 7206-2 describe sphericity form deviation requirements.

5.4.4 Monoblock acetabular bearing minimum thickness, variation of thickness by size, and approximate location shall be according to Specification F2091.

5.4.5 Minimum thickness of the modular acetabular bearing component, variation of minimum thickness by size and the approximate location shall be according to Specification F2091 or ISO 7206-1.

5.4.6 Describe the cup articular arc angle (CAAA) of all liners according to .

5.4.7 One basis for comparison, the "worst-case" minimum contact patch edge to rim (CPER) distance shall be estimated for all articulating couples at an acetabular system inclination of 65º, anteversion of 35º, and a vertical reaction force of 3kN. Selection of "worst-case" couples should take into consideration those couples with the smallest articular diameter, cup articulating arc angle (CAAA), and diametral clearance. The CPER distance shall also be estimated in any steep cup angle tests such as those described in 6.1.3.1.1 **(4)**.

6. Device Evaluation

6.1 *Hip Simulator Testing for Hard-on-hard Systems:*

6.1.1 *Standard Wear Tests*—Test specimen selection and justification.

6.1.1.1 The test procedures shall be as described in ISO 14242-1, ISO 14242-2, and ISO 14242-3 with the following specific provisions:

6.1.1.2 The test shall include a minimum of 5 million cycles of standard walking gait cycle as per ISO 14242-1 or ISO 14242-3.

6.1.2 *Test Specimen Selection and Justification:*

6.1.2.1 Depending on the system design, the worst-case construct for 'adverse conditions' testing could possibly be different from the worstcase construct for 'standard-pristine' wear testing. It is recommended that the worst-case construct for adverse conditions testing be investigated experimentally with shorter tests with fewer high demand conditions before undertaking any five million cycle test. The Finite Element Method (FEM) may also be useful for some of these preliminary evaluations. The specific bearings used in the simulator test should include the potentially worst-case (highest wear) combinations taking into consideration the following design parameters:

6.1.2.2 The diameter of the articulating surface; the minimum thickness of the acetabular component; and in the case of modular acetabular systems, the minimum thicknesses of the liner and the shell.

6.1.2.3 Small diametral clearance (highest contact area) and largest diametral clearance (smallest contact area, potentially highest contact stress) allowed by articulating surface manufacturing tolerances are potential worst cases. Since the tolerances are usually normal distributions, producing test samples to the exact worst-case tolerances would be extremely difficult. Sufficient numbers of components shall be measured prior to testing and paired to achieve the worst case diametral clearance possible within the samples available.

6.1.2.4 Some of these tests may require evaluation of all sizes. Other tests may require the justification of one or more possible "worst case" sizes/combinations.

6.1.2.5 The choice of samples for each of these tests shall be justified.

6.1.3 *Adverse/high Demand Hip Simulator Testing for Hard-on-hard Systems:*

6.1.3.1 The Adverse/high demand wear testing should follow the requirements of Guide F3047M. Previous adverse/high demand tests for hard on hard THR articulations have included:

(1) A steep cup angle test, with cup inclinations up to 65° to horizontal **(5, 6, 7)**.

(2) Microseparation tests **(8, 9, 10, 11, 12, 13, 14)**.

(3) A combined steep cup angle plus microseparation **(15, 16, 10, 17)**.

(4) High demand gait cycles such as 'fast jogging' with higher peak loads and faster test frequencies **(18)**.

(5) Third body abrasive wear with bone cement, ceramic, or titanium particles **(19, 20, 21)**.

(6) Stop-Dwell-Start tests with dwell times and stop-dwell-start cyclic rates representative of typical patient activities **(22, 23)**.