



Designation: F3018 – 17

Standard Guide for Assessment of Hard-on-Hard Articulation Total Hip Replacement and Hip Resurfacing Arthroplasty Devices¹

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.

Current edition approved Sept. 1, 2017. Published September 2017. DOI: 10.1520/F3018-17

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.

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.

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

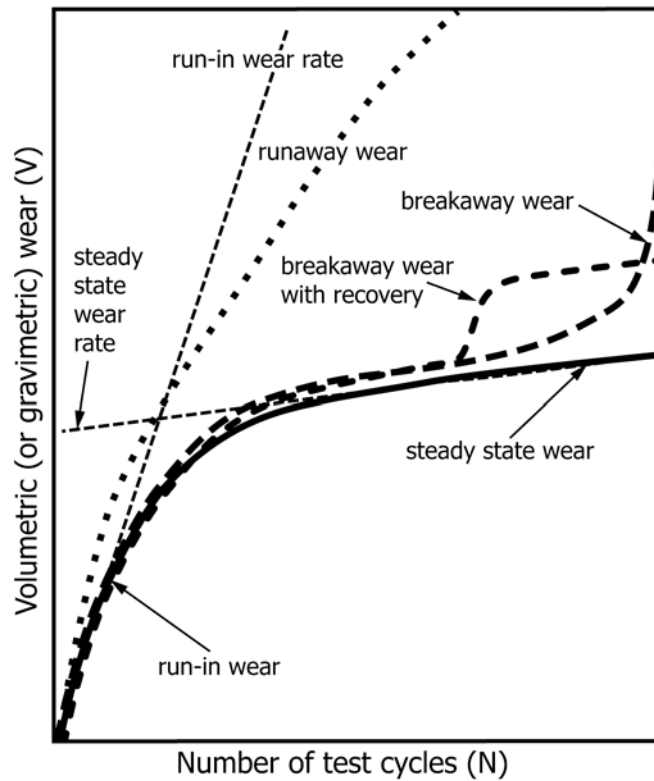


FIG. 1 Modes/Phases of Wear Illustrated Schematically (1)

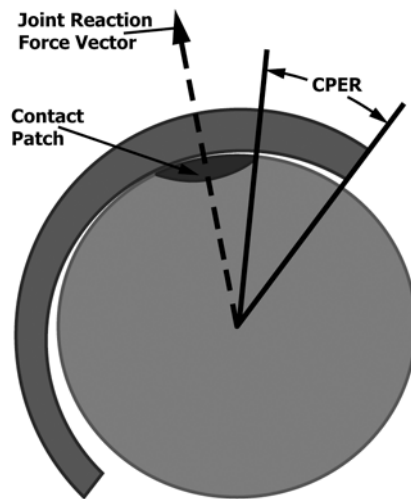


FIG. 2 Illustration of Contact Patch Edge to Rim Distance

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

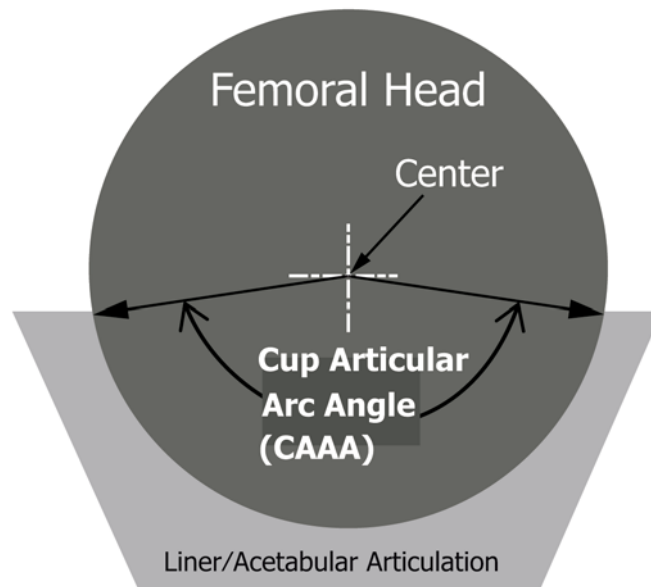


FIG. 3 Illustration of Cup Articular Arc Angle

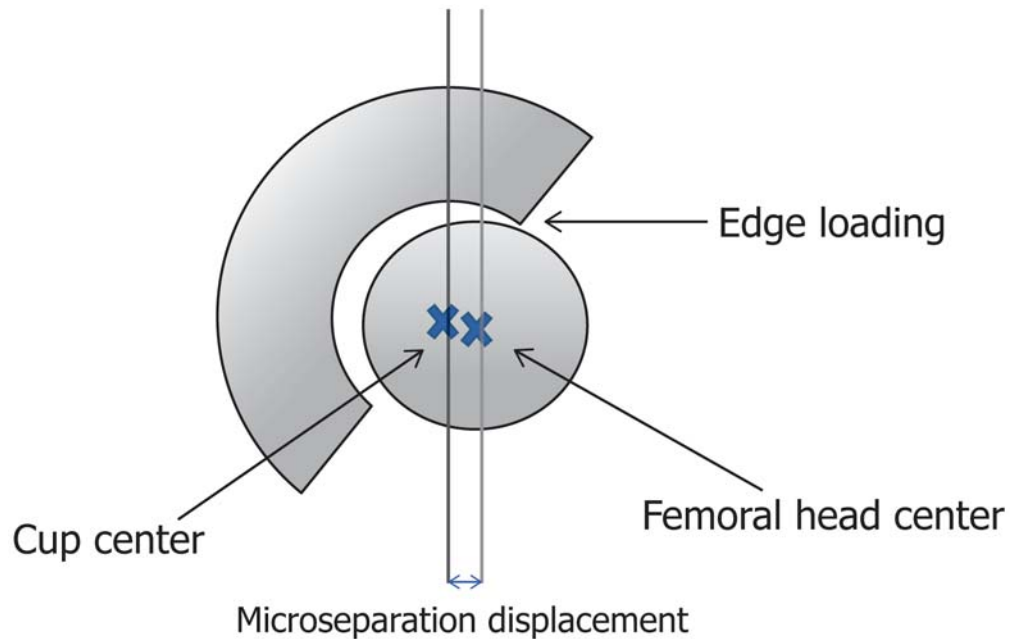


FIG. 4 Illustration of Edge Loading Due to Microseparation

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.