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Standard Guide for Evaluating Modular Hip and Knee Joint Components[1]

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1. Scope

1.1 This guide covers a procedure to assist the developer of a modular joint replacement implant in the choice of appropriate tests and evaluations to determine device safety.

1.2 This guide does not attempt to define all test methods associated with modular device evaluation.

1.3 The disassembly testing in this guide does not cover intentional intraoperative disassembly but is meant only to suggest testing necessary to determine inadvertent disassembly loads.

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]

F648 Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants
F897 Test Method for Measuring Fretting Corrosion of Osteosynthesis Plates and Screws
F1800 Practice for Cyclic Fatigue Testing of Metal Tibial Tray Components of Total Knee Joint Replacements
F1820 Test Method for Determining the Forces for Disassembly of Modular Acetabular Devices
F1875 Practice for Fretting Corrosion Testing of Modular Implant Interfaces: Hip Femoral Head-Bore and Cone Taper Interface
F2009 Test Method for Determining the Axial Disassembly Force of Taper Connections of Modular Prostheses
F2345 Test Methods for Determination of Cyclic Fatigue Strength of Ceramic Modular Femoral Heads
F2580 Practice for Evaluation of Modular Connection of Proximally Fixed Femoral Hip Prosthesis
F2582 Test Method for Dynamic Impingement Between Femoral and Acetabular Hip Components
F2723 Test Method for Evaluating Mobile Bearing Knee Tibial Baseplate/Bearing Resistance to Dynamic Disassociation
F3090 Test Method for Fatigue Testing of Acetabular Devices for Total Hip Replacement

2.2 *ISO Standards:*[3]

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 7206-13 Implants for surgery – Partial and total hip joint prostheses – Part 13: Determination of resistance to torque of head fixation of stemmed femoral components

3. Terminology

3.1 *Definitions of Terms Specific to This Standard:*

3.1.1 *modular femoral hip implant*—any device that is constructed of two or more mating parts intended for implantation into the femur for the purpose of replacing the femoral hip joint.

3.1.1.1 *bolts/screws*—a fastener used to secure modular pieces of a femoral or tibial component.

3.1.1.2 *collar*—medial platform located immediately distal to the femoral neck.

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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.

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

3.1.1.3 *distal hip bullets/sleeves*—modular accessories for increasing the length or distal diameter of the femoral component.

3.1.1.4 *femoral head*—a modular bearing, spherical in shape, that mates with the femoral component.

3.1.1.5 *neck extension*—an intermediate modular coupling between the femoral component and the femoral head. Attachments (for example, threads and tapers) can vary.

3.1.1.6 *proximal hip sleeves/pads*—modular accessories for varying the geometry of the femoral component in the metaphyseal area.

3.1.2 *modular knee implant*—any device that is constructed of two or more mating parts intended for implantation into the femur or tibia for the purpose of replacing the knee joint.

3.1.2.1 *knee sleeve*—a modular addition to a total knee replacement that serves the function of filling voids left by deficient or absent bone stock. Commonly a sleeve circumferentially surrounds the knee replacement component with which it mates.

3.1.2.2 *knee stem extension*—modular extension to either a knee-femoral or knee-tibial component which extends into the medullary canal. A stem extension may be attached to the femoral or tibial component by a variety of means including a taper, screw, etc.

3.1.2.3 *knee wedge*—a modular addition to a total knee replacement that serves the function of filling voids left by deficient or absent bone stock. Commonly a wedge does not circumferentially surround the knee replacement component with which it mates.

3.1.2.4 *metal-backed patella*—a modular patellar replacement consisting of an articular piece which is secured to a metal backing by means of a locking mechanism.

3.1.2.5 *metal tibial tray*—a metal component secured to the proximal tibia which provides mechanical support to and couples directly with the modular tibial inserts.

3.1.2.6 *tibial insert*—a modular bearing member of a tibial component, usually made in accordance with Specification F648, that is secured to a knee tibial tray by means of a locking mechanism.

4. Significance and Use

4.1 The tests suggested within this guide cover many different, but not all possible, areas of research and concern with regard to modular hip and modular knee components.

4.2 Due to the unlimited possible modular designs, this guide should be utilized as a guide for what should be considered with regard to device safety testing. There may be circumstances where alternative test methods may be useful. It is still the responsibility of the investigator to address all safety concerns that are inherent to individual modular designs.

4.3 The tests suggested herein should be utilized in such a way that the results reflect the effects of modularity, if any.

4.4 Tests that are checked in Table 1, Table 2, or Table 3 or indicated in this guide as a possible test to consider may not be applicable to every implant design.

5. Testing

5.1 *Assembly*—Static assembly parameters should be evaluated to determine the minimum required loads (axial or torsional) that ensure adequate assembly strengths. This testing can be performed in conjunction with 5.2, *Disassembly*, to ascertain how various assembly loads affect disassembly.

5.1.1 *Axial Engagement Force*—The force required to connect the components (for example, to engage a tapered connection). Consider the following:

5.1.1.1 The procedure for applying the engagement force (clinical relevance);

5.1.1.2 The environment in which the components are connected (contamination); and

5.1.1.3 Test Method F2009, ISO 7206-10.

5.1.2 *Torsional*—The torque required to connect the components (for example, bolt or screw). This may only be applicable for threaded connections. Consider the following:

5.1.2.1 The procedure for applying the torsional force (clinical relevance).

5.2 *Disassembly*—Static disassembly parameters should be evaluated to assess minimum design requirements for preventing unintentional *in vivo* disassembly.

5.2.1 *Axial*—The axial force required to disassemble mating components (for example, the force required to disassociate a tapered junction, femoral head/bipolar head pull-out, femoral head/dual mobility head pull-out, or femoral head/constrained liner pull-out, acetabular liner/acetabular shell push-out). Consider the following:

5.2.1.1 Test Method F1820 includes a push-out test method for an acetabular liner component connection to an acetabular shell. Test Method F1820 does not specify applicability to bipolar head, dual mobility head, and constrained liner connection to a femoral head, but certain elements may be applicable.

5.2.1.2 Test Method F2009, ISO 7206-10, Test Method F1820.

5.2.2 *Shear*—The shear force required to disassemble mating components (for example, the force required to shear a wedge from a tray).

5.2.3 *Bending* (or lever-off for bipolar head, dual mobility head, and constrained liner connection to a femoral head; and lever-out/offset pull-out for acetabular liner component connection to an acetabular shell)—The possibility of static disassociation under combined loading. Consider the following:

5.2.3.1 Test Method F1820 includes lever-out/offset pull-out methods for an acetabular liner component connection to an acetabular shell. Test Method F1820 does not specify applicability to bipolar head, dual mobility head, and constrained liner connection to a femoral head, but certain elements may be applicable.

5.2.4 *Torsion*—The torque required to disconnect the components (for example, bolt, screw, or taper locked components). Consider the following:

5.2.4.1 Test Method F1820, ISO 7206-13.

5.3 *Cyclic Fatigue Properties*—The nature of *in vivo* loading generates the need for cyclic fatigue evaluation. Tests

TABLE 1 Modular Femoral Hip Implants

NOTE 1—This guide is intended to address modular connections of a femoral hip system. The table below includes the majority of modular devices utilized today. The table is not all inclusive. Modular attachments not addressed in this guide should be evaluated at the user's discretion. For possible applicable testing standards for the conditions outlined in the table, see Section 5.

	ASSEMBLY		DISASSEMBLY				CYCLIC FATIGUE PROPERTIES				
	Axial	Torsional	Axial	Shear	Bending	Torsional	Fracture	Disassembly Post-Fatigue	Effects of Sterilization	Corrosion	Fretting
Proximal Modularity											
Femoral Heads	X		X			X	X	X	X	X	X
Bipolar Head Connection to Femoral Head	X		X		X (Lever-Off)		X (e.g., F2582)	X	X		
Dual Mobility Head Connection to Femoral Head	X		X		X (Lever-Off)		X (e.g., F2582)	X	X		
Constrained Liner Connection to Femoral Head	X		X		X (Lever-Off)		X (e.g., F2582)	X	X		
Neck Extensions	X		X				X	X	X	X	X
Collars	X		X	X			X	X	X	X	X
Bolts		X		X		X	X	X	X	X	X
Mid-Body Modularity											
Proximal Hip Sleeves	X	X	X	X	X	X	X	X	X	X	X
Proximal Hip Pads	X	X	X	X	X	X	X	X	X	X	X
Distal Modularity											
Distal Hip Bullets	X	X	X		X	X	X	X	X	X	X
Distal Hip Sleeves	X	X	X		X	X	X	X	X	X	X
Total Implant							X			X	X

TABLE 2 Modular Acetabular Components

NOTE 1—This guide is intended to address modular acetabular components. The table below includes the majority of modular devices utilized today. The table is not all inclusive. Modular attachments not addressed in this guide should be evaluated at the user's discretion. For possible applicable testing standards for the conditions outlined in the table, see Section 5.

	ASSEMBLY		DISASSEMBLY				CYCLIC FATIGUE PROPERTIES				
	Axial	Torsional	Axial	Shear	Bending (Lever-Out or Offset Pull-Out)	Torsional	Fracture	Disassembly Post-Fatigue	Effects of Sterilization	Corrosion	Fretting
Liner/Shell Modularity											
Semi-Constrained Liner Connection to Acetabular Shell	X		X		X	X	X	X	X	X	X
Dual Mobility Liner Connection to Acetabular Shell	X		X		X	X	X	X	X	X	X
Constrained Liner Connection to Acetabular Shell	X		X		X	X	X	X	X	X	X