Designation: F 1814 – 97a (Reapproved 2003)

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

This standard is issued under the fixed designation F 1814; 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 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 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 and health practices and determine the applicability of regulatory limitations prior to use.*

2. Referenced Documents

2.1 *ASTM Standards:*

F 648 Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants[2]

F 897 Test Method for Measuring Fretting Corrosion of Osteosynthesis Plates and Screws[2]

F 1440 Practice for Cyclic Fatigue Testing of Metallic Stemmed Hip Arthroplasty Femoral Components Without Torsion[2]

F 1800 Test Method for Cyclic Fatigue Testing of Metal Tibial Components of Total Knee Joint Replacements[2]

2.2 *ISO Standard:*

ISO 7206 Implants for Surgery-Partial and Total Hip Joint Prosthesis[3]

Part 4 Determination of Endurance Properties of Stemmed Femoral Components With Application of Torsion[3]

Part 6 Determination of Endurance Properties of Head and Neck Region of Stemmed Femoral Components[3]

Part 8 Endurance Performance of Stemmed Femoral Components With Application of Torsion[3]

3. Terminology

3.1 *Definitions of Terms Specific to This Standard:*

3.1.1 *modular femoral hip implant*—any device, 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 component.

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

3.1.1.3 *collars*—a medial platform located immediately distal to the femoral neck.

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

3.1.1.5 *neck extensions*—an intermediate modular couple between the femoral component and the femoral head. Attachment can vary (for example, threads, tapers).

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

3.1.2 *modular knee implant*—any device, 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 *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.

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

3.1.2.3 *stem extensions or sleeve*—any modular extension to either a knee femoral or tibial component which extends into the medullary canal. Stem extensions may be attached to the femoral or tibial component by a variety of means including tapers, screws, etc.

3.1.2.4 *tibial insert*—a modular bearing member of a tibial component, usually made in accordance with Specification F 648, that is secured to a knee tibial tray by means of a locking mechanism.

---

[1] This guide 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 Apr. 10, 2003. Published June 2003. Originally approved in 1997. Last previous edition approved in 1997 as F 1814 – 97a.

[2] *Annual Book of ASTM Standards*, Vol 13.01.

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

3.1.2.5 *wedge*—a modular addition to a total knee replacement that serves the function of filling voids left by deficient or absent bone stock.

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 stems 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 Fig. 1 or Fig. 2 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), and

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

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, force required to disassociate a tapered junction).

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

5.2.3 *Bending*—The possibility of static disassociation under combined loading. Consider the following:

5.2.3.1 Reporting a load versus deflection curve.

5.2.4 *Torsion*—The torque required to disconnect the components (for example, bolt or screw). This may only be applicable for threaded connections.

5.3 *Cyclic Fatigue Properties*—The nature of *in vivo* loading generates the need for cyclic fatigue evaluation. Tests should be designed to examine pre-cycle and post-cycle properties to gain an understanding of how the design withstands, and is affected by, cyclic loading.

5.3.1 *Fracture*—The possibility of fracture of either a modular construct or the connections under fatigue loading. Consider the following:

5.3.1.1 Loading that represents that applied to the component *in vivo*,

5.3.1.2 An P-N curve to determine the load levels at which the construct can withstand cyclic loading without fracture, and

5.3.1.3 Test Method F 1440, Test Method F 1800, and ISO 7206-4,6, 8.

5.3.2 *Disassembly*—The possibility of disassembly of the modular components under fatigue loading. Consider the following:

5.3.2.1 Loading that represents that applied to the component *in vivo*, and

5.3.2.2 Measuring the disassembly force after fatigue loading and comparing to static values.

5.3.3 *Sterilization*—The effects of sterilization on the fatigue integrity of the modular connection. Sterilization may cause material changes which could affect the performance of the modular connection. Sterilization should be performed according to manufacturer specifications. Consider the following:

5.3.3.1 The effect of sterilization of plastic components.

5.3.4 *Corrosion*—The environment in which the modular connection will be used may affect the ability of the connection to resist disassociation or fracture. Consider the following:

5.3.4.1 Corrosion of similar metal connections,

5.3.4.2 Corrosion of dissimilar metal connections,

5.3.4.3 The fluid environment,

5.3.4.4 The temperature,

5.3.4.5 The frequency, and

5.3.4.6 See Test Method F 897.

5.3.5 *Fretting*—Micromotion between two components of a modular connection may produce adverse effects (that is, wear debris, increased risk for disassociation). Consider the following:

5.3.5.1 Fretting of taper junctions

5.3.5.2 Fretting of mating, non articulating surfaces

5.3.5.3 Environmental test, and

5.3.5.4 See Test Method F 897.

6. Keywords

6.1 arthroplasty; disassembly; hip arthroplasty; knee arthroplasty; modular; orthopaedic medical devices

	ASSEMBLY		DISASSEMBLY				CYCLIC FATIGUE PROPERTIES				
	Axial	Torsional	Axial	Shear	Bending	**Torsional**	Fatigue	Disassembly Post-fatigue	**Effects of Sterilization**	Corrosion	Fretting
Proximal Modularity											
Femoral Heads	X		X				X	X	X	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											
Sleeves	X	X	X	X	X	**X**	X	X	X	X	X
Pads	X	X	X	X	X	**X**	X	X	X	X	X
Distal Modularity											
Bullets	X	X	X		X	**X**	X	X	X	X	X
Sleeves	X	X	X		X	**X**	X	X	X	X	X
Total Implant							X			**X**	**X**

Note: This document is intended to address modular connections of a femoral hip system. This list includes the majority of modular devices utilized today. This list is not all inclusive. Modular attachments not addressed in this document should be evaluated at the user's discretion.

FIG. 1 Total Hip Implants

	ASSEMBLY		DISASSEMBLY				CYCLIC FATIGUE PROPERTIES				
	Axial	Torsional	Axial	Shear	Bending	**Torsional**	Failure	Disassembly	Sterilization	Corrosion	Fretting
Stem Extensions	X	**X**	X		X	**X**	X	X	X	X	X
Wedge		**X**		X		**X**		X			X
Modular tibial insert (cruciate retaining)		**X**		X		**X**		X	X		
Modular tibial insert (posterior stabilized) or semi-constrained		**X**		X	X	**X**	X	X	X		
Metal backed patella			X	X	X		X	X	X		
Total Implant		~~X~~	X	X			X			X	X

Note: This document is intended to address modular connections of a total knee system. This list includes the majority of modular devices utilized today. This list is not all-inclusive. Modular attachments not addressed by this document should be evaluated at the user's discretion.

FIG. 2 Total Knee Implant

APPENDIX

(Nonmandatory Information)

X1. RATIONALE

X1.1 This guide is intended to be used to direct the reader to some of the most common areas of concern for modular hip and knee prosthetic implants. For each area of concern, there is a checklist of possible junctions to evaluate with appropriate topics to consider for each test. This guide is not intended to be all inclusive of the potential areas of concern or tests that can be performed for modular implants but is meant to cover some of the more common topics of modular implants. It is felt that this document will be particularly useful to the novice investigator in directing their efforts in the investigation of safety and efficacy of a modular hip or knee implant, or both.

X1.2 Assembly and disassembly may be useful to the investigator in determining the strength of a modular connection. The strength of the modular connection may be determined as a ratio if disassembly force to assembly force. This number may also provide information as to the strength of the modular connection over time.