



Standard Guide for Evaluating Modular Hip and Knee Joint Components¹

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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 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 Implants²

F 897 Test Method for Measuring Fretting Corrosion of Osteosynthesis Plates and Screws²

F 1440 Practice for Cyclic Fatigue Testing of Metallic Stemmed Hip Arthroplasty Femoral Components Without Torsion²

F 1800 Test Method for Cyclic Fatigue Testing of Metal Tibial Components of Total Knee Joint Replacements²

2.2 ISO Standard:

ISO 7206 Implants for Surgery-Partial and Total Hip Joint Prosthesis³

Part 4 Determination of Endurance Properties of Stemmed Femoral Components With Application of Torsion³

Part 6 Determination of Endurance Properties of Head and Neck Region of Stemmed Femoral Components³

Part 8 Endurance Performance of Stemmed Femoral Components With Application of Torsion³

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.

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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.