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Standard Test Method for Determining the Forces for Disassembly of Modular Acetabular Devices¹

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1. Scope

1.1 This test method covers a standard methodology by which to measure the attachment strength between the modular acetabular shell and liner. Although the methodology described does not replicate physiological loading conditions, it has been described as a means of comparing the integrity of various locking mechanisms.

1.2 The values stated in SI units are to be regarded as standard. No other units of measurement are included in this standard.

1.3 *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.*

1.4 *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

E4 Practices for Force Calibration and Verification of Testing Machines

F2345 Test Methods for Determination of Cyclic Fatigue Strength of Ceramic Modular Femoral Heads

3. Terminology

3.1 *Definitions of Terms Specific to This Standard:*

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.

3.1.1 *acetabular liner*—portion of the modular acetabular device with an internal hemispherical socket intended to articulate with a femoral prosthesis. This can include acetabular liners used for dual mobility or constrained applications. The external geometry of this component interfaces with the acetabular shell through a locking mechanism which may be integral to the design of the acetabular liner and shell or may rely upon additional components (for example, a metal ring or screws).

3.1.2 *acetabular shell*—the external, hollow (usually metal) structure 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, or pegs). The acetabular shell may be either solid or contain holes for fixation, or contain a hole for instrumentation.

3.1.3 *locking mechanism*—any structure, design feature, or combination thereof that provides mechanical resistance to movement between the acetabular liner and shell.

3.1.4 *polar axis*—the axis of revolution of the rotationally symmetric portions of the acetabular liner or shell.

4. Summary of Test Method

4.1 *Axial Disassembly (Push-Out):*

4.1.1 The axial disassembly test method of an acetabular liner and shell system provides a means to measure the axial locking strength of the acetabular liner for modular acetabular devices.

4.2 *Offset Pull-Out or Lever-Out Disassembly:*

4.2.1 The offset pull-out or the lever-out disassembly method is intended to assess the resistance of the locking mechanism to edge forces that could occur when the neck of a hip prosthesis impinges on the edge of the acetabular liner. An impinging force could cause the edge of the acetabular liner opposite the area of impinging contact to be pushed out of the acetabular shell. The resistance of the acetabular liner edge to being pulled loose from the acetabular shell is a measure of the resistance to impingement causing loosening of the acetabular liner.

4.3 Torque-Out Disassembly:

4.3.1 The torque-out disassembly method is intended to assess the resistance of the locking mechanism to high-friction events that would attempt to rotate the acetabular liner within the acetabular shell.

5. Significance and Use

5.1 This test method is intended to assess the locking strength of the acetabular liner in a modular acetabular shell when subjected to three different force application conditions.

5.2 This test method may not be appropriate for all implant applications. The user is cautioned to consider the appropriateness of the method in view of the materials and design being tested and their potential application.

5.3 While these test methods may be used to measure the force required to disengage modular acetabular devices, comparison of such data for various device designs must take into consideration the size of the implant and the type of locking mechanism evaluated. The location of the locking mechanism relative to the load application may be dependent upon the size and design of the acetabular device. In addition, the locking mechanism itself may vary with size, particularly if the design is circumferential in nature (for example, a larger diameter implant would have a greater area of acetabular shell and liner interface than a small diameter implant).

5.4 Material failure is possible before locking mechanism failure during either push-out or offset pull-out/lever-out conditions. This is due to the possibility that the shear strength of the material may be exceeded before the locking mechanism is fully tested.

6. Apparatus

6.1 An apparatus capable of supporting only the acetabular shell while allowing the acetabular liner to be freely disassembled from the acetabular shell is required.

6.2 The testing machine shall conform to the requirements of Practices E4. The loads used to determine the attachment strength shall be within the range of the testing machine as defined in Practices E4.

6.3 The test machine shall be capable of delivering a compressive or tensile force at a constant displacement rate. The test machine shall have a load monitoring and recording system.

7. Sampling

7.1 All acetabular liners shall be representative of implant quality products. This shall include any sterilization or thermal processes which may alter the material properties or geometry.

7.2 A partially finished acetabular shell or permanent fixture block may be substituted for a completed acetabular shell provided that the internal materials, finish, locking mechanism, geometry, and manufacturing conditions are identical to the actual acetabular shell.

7.3 A minimum of five acetabular shell and liner assemblies shall be tested in each of the three test methods (axial, offset pull-out or lever-out, and torque-out disassembly) to determine

the disassembly values. For statistical comparisons, the sample size used for testing and comparison shall be justified. Pairing of the acetabular shells and liners shall be at random unless otherwise reported. For tests with polyethylene acetabular liners, the same set of five acetabular shells may be used for each of the three tests provided that none of the acetabular shells is damaged by any of the preceding tests. Damage includes any fracture of the acetabular shell or any deformation which could affect the locking mechanism integrity.

8. Procedure

8.1 Assembly Procedure:

8.1.1 The liner shall be assembled in the acetabular shell with a peak force of 2000 ± 50 N. The line of force application shall be coincident with the polar axis of the acetabular liner. The force may be applied with the appropriate surgical instrument for the specific device, or a sphere of the same diameter as the diameter of the articulating surface on the acetabular liner. The following loading conditions are suggested for assembly:

8.1.2 For hard-bearing acetabular liners with a taper-locking mechanism, the force may be applied in displacement control at a rate of 0.04 mm/s or force control at a rate of 500 ± 100 N/s.

8.1.3 For polyethylene acetabular liners, the force may be applied in displacement control at a rate of 0.85 mm/s or force control at a rate of 500 ± 100 N/s.

8.1.4 Alternatively, the assembly method specified by the manufacturer in the appropriate surgical technique may be used to assemble the acetabular liner in the acetabular shell. If this method is used, it shall be reported and justified.

8.2 Axial Disassembly:

8.2.1 Once assembled, the acetabular liner and shell construct shall be placed in a solid fixture with continuous support of the acetabular shell as illustrated in Fig. 1. The fixture that supports the acetabular shell shall do so without visual evidence of deformation during or after the test.

8.2.2 An axial force shall be applied (coincident with the polar axis of the liner and shell) to the acetabular liner through a center hole (polar axis of the acetabular shell) in the acetabular shell with a round rod at a rate no greater than 0.04 mm/s for hard-bearing acetabular liners with a taper-locking mechanism or no greater than 0.85 mm/s for polyethylene acetabular liners. If a faster rate is used for hard-bearing liners, it shall be demonstrated that this does not affect the test results.

8.2.3 The direction of force application and rod longitudinal axis shall be collinear to the polar axis of the acetabular liner and shell to within 2° , and the center of the rod contact with the acetabular liner shall be less than 2 mm from the polar axis of the acetabular liner.

8.2.4 A small diameter drill blank or rod could be used as a force applicator. The rod shall not be less than 5 mm in diameter. If the rod diameter is too small, it may punch a hole in the acetabular liner during the test. The drill blank or rod shall be stiff enough that it does not buckle under the test forces, and there shall be sufficient clearance between any hole