

Designation: F 1820 – 97 (Reapproved 2003)

Standard Test Method for Determining the Axial Disassembly Force of a Modular Acetabular Device¹

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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 means of comparing integrity of various locking mechanisms.²

1.2 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:

E 4 Practices for Force Verification of Testing Machines³

3. Terminology

3.1 Definitions of Terms Specific to This Standard: 3.1.1 acetabular liner—portion of the modular acetabular device with an internal hemispherical socket intended to articulate with the head of a femoral prosthesis. The external geometry of this component interfaces with the acetabular shell through a locking mechanism which may be integral to the design of the liner and shell or may rely upon additional components (for example, metal ring, screws, and so forth).

3.1.2 *acetabular shell*—the external, hollow structure (usually metal) 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, porous ingrowth, integral screw threads, anchoring screws, pegs, and so forth). The acetabular shell may be either solid or contain holes for fixation, or contain a hole for instrumentation, or all of these.

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

4. Summary of Test Method

4.1 The axial disassembly of an acetabular device test method provides a means to measure the axial locking strength of the acetabular liner for modular acetabular devices.

4.2 Following proper assembly of the acetabular liner in an acetabular shell, the assembled device is attached to a fixture such that the cup opening is facing downward. The acetabular shell is supported and an axial force is applied to the acetabular liner until it disengages. The load required to disengage the acetabular liner from the acetabular shell is recorded. The acetabular liner should only be tested one time; however, the acetabular shell may used more than once if no damage to the locking mechanism has occurred.

5. Significance and Use

7-5.1 This test method is intended to help assess the axial locking strength of the acetabular liner in a modular shell when subjected to a tensile loading condition. Additional means of evaluating the locking mechanisms of modular acetabular devices may be appropriate depending upon the design of the device (that is, lever-out, torsional strength, fatigue, and so forth).

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 this test method 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

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² Tradonsky M.D., Steve, et al, "A Comparison of the Disassociation Strength of Modular Acetabular Components," Clinical Orthopaedics and Related Research, Number 296, November 1993.

³ Annual Book of ASTM Standards, Vol 03.01.