



Designation: F3090 – 24

Standard Test Method for Fatigue Testing of Acetabular Devices for Total Hip Replacement and Performance Requirements¹

This standard is issued under the fixed designation F3090; 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 test method is intended to evaluate the fatigue strength and performance of metallic acetabular shells with hemispheric outer surfaces.

1.2 This test method, as described, is not intended to evaluate the following: the strength of components that may be mated with the acetabular shells (for example, augments, acetabular liners); attributes of the shells not related to strength (for example, fixation, coating adhesion); the strength of acetabular shell features away from, or loaded differently than, the primary load bearing region of the shell (for example, screws, spikes, flanges); non-hemispherical shells (for example, patient-matched geometries); or corrosion between modular components.

1.3 Modifications to this test method (for example, different support medium, different size/position of unsupported region, different testing environment) may result in a method appropriate to evaluate the characteristics listed in 1.2. Such modification must have adequate justification.

1.4 Although the methodology described does not replicate all physiological force conditions, it is a means of *in vitro* comparison of acetabular device designs under repeated forces.

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

1.6 *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.*

1.7 *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 Recom-*

mendations 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

F1820 Test Method for Determining the Forces for Disassembly of Modular Acetabular Devices

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

2.2 ISO Standards:³

ISO 21920-2 Geometrical product specifications (GPS)—Surface texture: Profile—Part 2: Terms, definitions and surface texture parameters

ISO 21920-3 Geometrical product Specifications (GPS)—Surface texture: Profile—Part 3: Specification operators

ISO 7206-4:2010 Implants for surgery—Partial and total hip joint prostheses—Part 4: Determination of endurance properties and performance of stemmed femoral components

ISO 7206-6:2013 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 21535:2023 Non-active surgical implants—Joint replacement implants—Specific requirements for hip-joint replacement implants

3. Terminology

3.1 Definitions of Terms Specific to This Standard:

3.1.1 *acetabular liner, n*—portion of a modular acetabular device with a concave spherical shape intended to articulate with the head of a femoral prosthesis; the external geometry of this component interfaces directly with the acetabular shell through a locking mechanism which may be integral to the

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.

Current edition approved Oct. 1, 2024. Published October 2024. Originally approved in 2020. Last previous edition approved in 2020 as F3090 – 20. DOI: 10.1520/F3090-24.

² For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at www.astm.org/contact. 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>.

design of the liner and shell or may rely upon additional components or fixation methods (for example a metal ring or bone cement).

3.1.2 *acetabular shell, n*—the metallic external, concave structure that mechanically supports the acetabular liner, whose external features interface 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, pegs, and so forth); the acetabular shell may have hole(s) for fixation or instrumentation, or have no holes.

3.1.3 *clocking reference point, n*—a location on the shell face that can be used to control shell clocking; in cases where the shell face does not have any clear features to use as a reference point it may be necessary to mark a location. The location of the clocking reference point to any other shell features shall be noted.

3.1.4 *modular acetabular device, n*—the acetabular component of a total hip replacement (THR) system with multiple components including acetabular liner component(s) and acetabular shell component(s); it is possible that a modular acetabular device might be pre-assembled in a manufacturing process.

3.1.5 *monoblock acetabular device, n*—the acetabular component of a THR system that, excluding any exterior surface coatings intended for contact with bone cement or tissue, is fabricated as a single piece.

3.1.6 *shell clocking, n*—the rotational orientation of the shell about the polar axis to the load axis or the center of the unsupported portion of the shell from a clocking reference point on the shell.

3.1.7 *shell face, n*—the plane defined by the rim of the acetabular shell that surrounds the opening that the acetabular liner is placed into; for a precisely hemispherical shell, the shell face is the equatorial plane.

4. Summary of Test Method

4.1 A modular or monoblock acetabular device is fixed in a polymer block with a portion of the acetabular device unsupported. This construct is placed in a fatigue test machine in such a way that the polar axis of the acetabular device is at a 55° angle relative to the line of force application of the test machine, as illustrated in Figs. 1 and 2. A head of the appropriate diameter for the acetabular device shall be used to apply cyclic forces to the acetabular device.

4.2 After completion of fatigue testing, the acetabular liner may be axially disassembled according to Test Method F1820.

4.3 Following liner disassembly, the acetabular shell and liner shall be either examined optically at a magnification in the range of 10× to 30×, or subject to dye penetrant testing to inspect for evidence of cracks.

4.4 The specimens shall satisfy the performance requirements outlined in 9.1 of this standard.

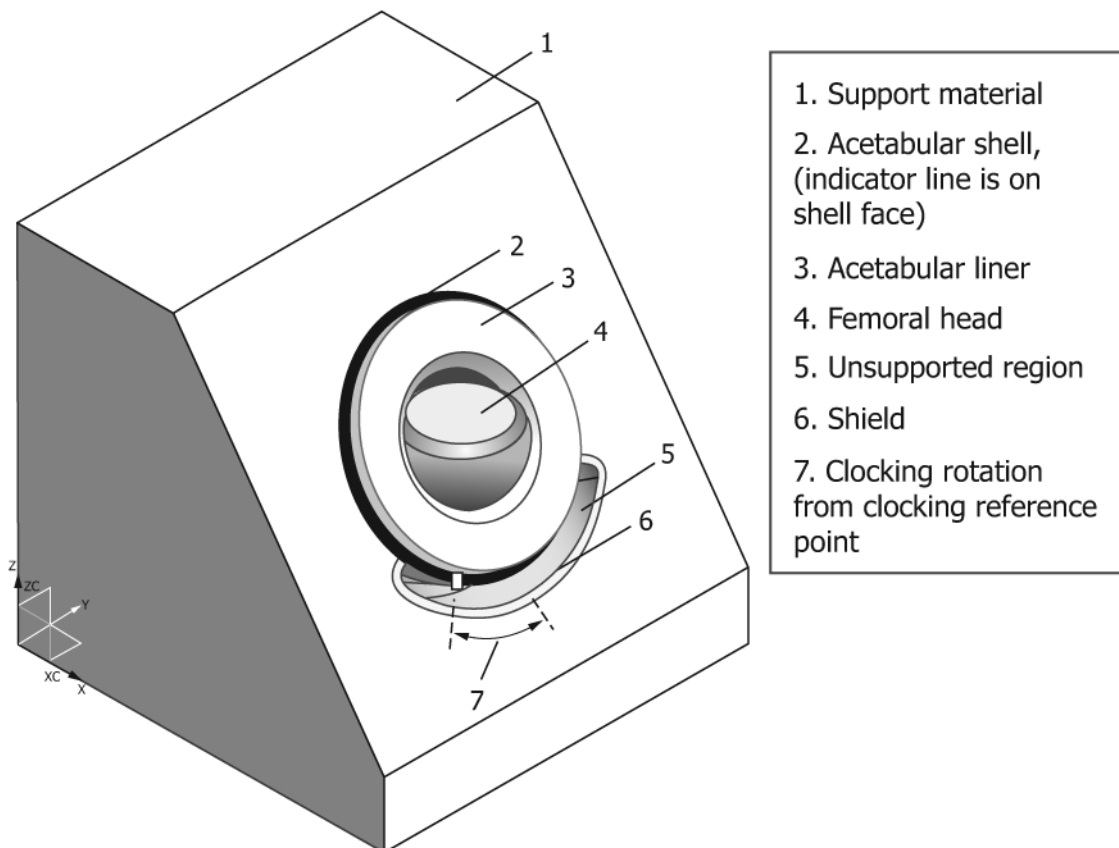


FIG. 1 Terminology and Schematic of Test Setup

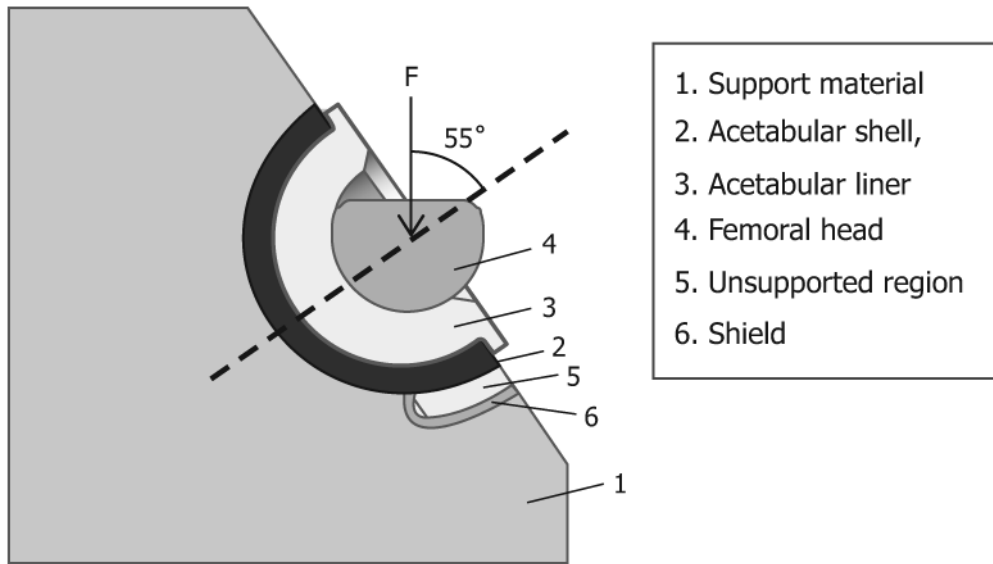


FIG. 2 Cross Section of Test Setup

5. Significance and Use

5.1 This *in vitro* test method includes the use of cyclic forces to evaluate the fatigue strength of acetabular shells or monoblock acetabular devices used in THR.

5.2 Fracture or cracking of acetabular shells or monoblock acetabular devices in THR, although rare, does occur.

6. Apparatus

6.1 The specimens under test shall be supported on the exterior surface of the acetabular device with a polymeric support material such as acrylic bone cement or any other material that meets the requirements in 5.1 of ISO 7206-4:2010.

6.1.1 The support shall only be partial. The acetabular shell shall be unsupported extending $36 \pm 3^\circ$ from the shell face and $120 \pm 3^\circ$ circumferentially (see Fig. 3). This unsupported

region can be created using a shield that keeps support material out of the unsupported region (see Fig. 4). This shield may stay in place if it has an elastic modulus that meets the requirements in 5.1 of ISO 7206-4:2010. Another option to form the unsupported region is to make a spacer from very low modulus (less than 10 MPa) elastic/rubber foam. Such a very low modulus spacer can stay embedded during the fatigue loading.

6.1.2 The height of the unsupported region shall be at least large enough that any deflection of the acetabular shell during testing does not result in contact between any part of the support and the shell in the unsupported region during testing.

6.1.3 The remaining support thickness surrounding the exterior surface need not be of uniform thickness, but the minimum thickness at any point shall be at least 5 mm.

6.2 A single axis load frame with a force transducer meeting the requirements of Practices E4 with closed-loop feedback

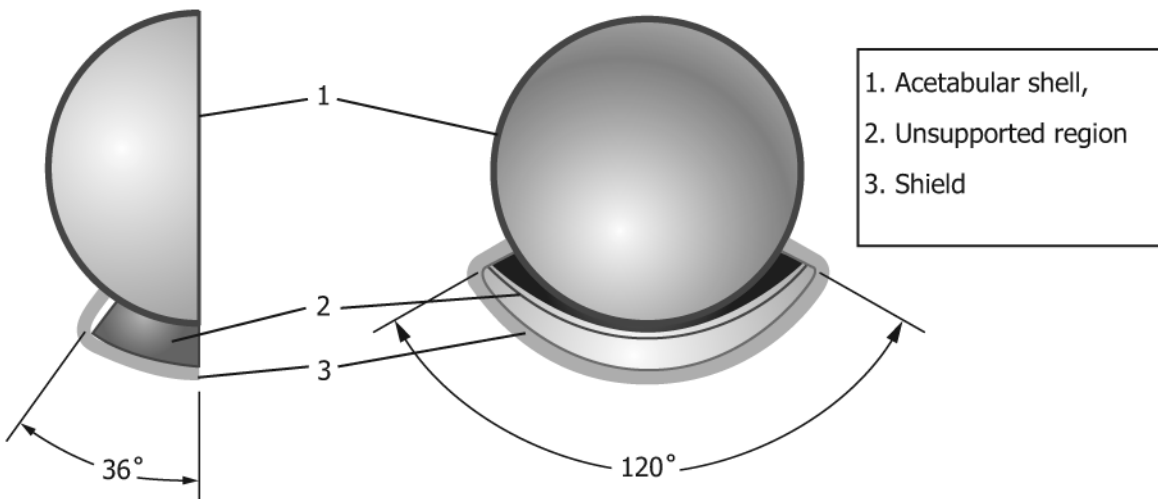


FIG. 3 Schematic of Unsupported Region