Designation: F 1829 – 98 (Reapproved 2003)

Standard Test Method for Static Evaluation of Glenoid Locking Mechanism in Shear[1]

This standard is issued under the fixed designation F 1829; 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 covers a method for determining the static shear disassembly force of modular glenoid components used in shoulder prostheses. It is intended to be used as a design validation and for comparison with other prostheses.

1.2 This test method covers modular glenoid components comprised of a separate articular insert and backing. The insert and backing can be fabricated from any combination of the following materials: metal alloys, polymeric materials, composite materials.

1.3 The values stated in SI units are regarded as the standard.

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:*

E 4 Practices for Force Verification of Testing Machines[2]

F 1378 Specification for Shoulder Prosthesis[3]

3. Terminology

3.1 *Definitions:*

3.1.1 *articular insert*—the polymeric prosthetic portion of a multiple piece glenoid component that articulates with the humeral head.

3.1.2 *"d"*—offset distance from the edge of the glenoid backing locking mechanism to the centerline of the point of load application on the articular insert as shown in Fig. 1 and Fig. 2.

3.1.3 *glenoid backing*—the metallic or composite material prosthetic portion of a multiple piece glenoid component that attaches to the scapula.

3.1.4 *glenoid component*—the prosthetic portion that replaces the glenoid fossa of the scapula and articulates with the natural humeral head or a prosthetic replacement.

4. Significance and Use

4.1 This test method can be used to describe the effects of materials, manufacturing, and design variables on the performance of metal backed glenoid prostheses locking mechanisms to resist static shear loading.

4.2 The glenoid component is used in shoulder replacements and should conform to the criteria specified in Specification F 1378.

4.3 The loading of metal backed glenoid prostheses *in vivo* will, in general, differ from the loading defined in this test method. The results obtained here can not be used to directly predict *in vivo* performance. However, this test method is designed to allow for comparisons between different metal backed glenoid locking mechanism designs, when tested under similar circumstances.

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

4.5 In order for the test data on metal backed glenoid components to be comparable, reproducible, and capable of being correlated among laboratories, it is essential that uniform procedures be established.

5. Apparatus

5.1 The test fixture shall be constructed so that the line of load application is parallel to the intended axis of the implant (that is, inferior to superior or anterior to posterior).

6. Equipment

6.1 The tests will be performed on either mechanical or hydraulic load frames with adequate load capacity and that meet the criteria of Practices E 4.

7. Sampling

7.1 A minimum of five samples with the load oriented in the inferior to superior direction shall be tested per device.

[1] This practice 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] *Annual Book of ASTM Standards*, Vol 03.01.

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

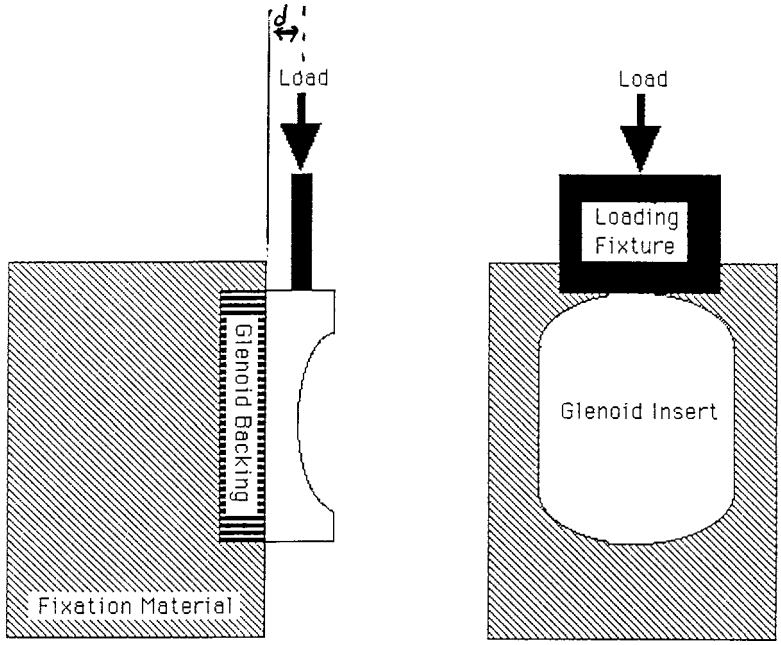

FIG. 1 Schematic of Static Glenoid Locking Strength Inferior to Superior Direction

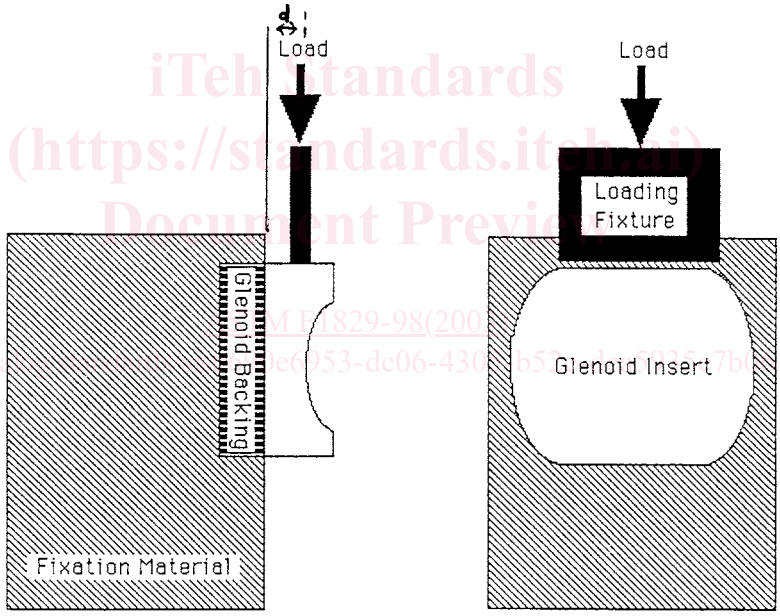

FIG. 2 Schematic of Static Glenoid Locking Strength Anterior to Posterior Direction

7.2 A minimum of five samples with the load oriented in the anterior to posterior direction shall be tested per device.

8. Sample and Test Specimen

8.1 All articular insert test components shall be representative of final manufactured implant quality products.

8.2 Glenoid backing test components may either be in the form of the final implant or may be a simplified model with the exact locking mechanism to be used on the final implant. The materials and surface shall be representative of implant quality products. All manufacturing processes (including heat treatment) should be followed.

8.3 All components should be sterilized according to manufacturer recommended specifications for clinical use, if this process could affect the results.

8.4 A new articular insert should be used for each test.