Designation: ~~F2028 – 14~~ F2028 – 17

Standard Test Methods for Dynamic Evaluation of Glenoid Loosening or Disassociation[1]

This standard is issued under the fixed designation F2028; 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 These test methods measure how much a prosthetic anatomic glenoid component rocks or pivots following cyclic displacement of the humeral head to opposing glenoid rims (for example, superior-inferior or anterior-posterior). Motion is quantified by the tensile displacement opposite each loaded rim after dynamic rocking. Similarly, these test methods measure how much a prosthetic reverse glenoid component rocks or pivots following cyclic articulation with a mating humeral liner. Motion is quantified by the magnitude of displacement measured before and after cyclic loading.

1.2 The same setup can be used to test the locking mechanisms of modular glenoid components, for example, disassociation of both anatomic and reverse shoulder components.

1.3 These test methods cover shoulder replacement designs with monolithic or modular glenoid components for cemented fixation as well as reverse glenoid components for uncemented fixation.

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

1.5 *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.*

1.6 *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 Verification of Testing Machines

F1378 Specification for Shoulder Prostheses

F1839 Specification for Rigid Polyurethane Foam for Use as a Standard Material for Testing Orthopaedic Devices and Instruments

3. Terminology

3.1 *Anatomic Total Shoulder Replacement (TSR) Definitions*

3.1.1 *anatomic total shoulder arthroplasty system, n*—shoulder implant system that has a concave glenoid component and a convex humeral component design.

3.1.2 *anatomic glenoid component, n*—the concave prosthetic portion that replaces, in part or in total, the glenoid fossa of the scapula and articulates with the natural humeral head or a prosthetic replacement.

3.1.3 *glenoid backing, n*—the metallic or composite material prosthetic portion of a multi-piece anatomic glenoid component that attaches to the scapula.

3.1.4 *glenoid liner, n*—the polymeric prosthetic portion of a multiple-piece anatomic glenoid component that articulates with the humeral head.

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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.

3.2 ~~*Definitions:*~~*Reverse TSR Definitions*

3.2.1 ~~*anatomic*~~*reverse total shoulder* ~~*arthroplasty,*~~ *arthroplasty system, n*—shoulder implant system that has a ~~concave~~convex glenoid component and a ~~convex~~concave humeral component design.

~~3.1.1.1 *anatomic glenoid, n*—the concave prosthetic portion that replaces the glenoid fossa of the scapula and articulates with a convex prosthetic replacement of the humeral head in anatomic total shoulder arthroplasty applications. It may consist of one or more components from one or more materials, for example, either all-polyethylene or a metal baseplate with a polymeric insert.~~

~~3.1.1.2 *humeral head, n*—the convex prosthetic portion that replaces the proximal humerus or humeral head and articulates with the natural glenoid fossa or an anatomic prosthetic replacement.~~

3.2.2 *reverse* ~~*total shoulder arthroplasty,*~~ *glenoid component, n*—~~shoulder implants that have a convex glenoid component and a concave humeral component design.~~the convex prosthetic portion that replaces the glenoid fossa of the scapula and articulates with a concave prosthetic replacement of the humeral head in reverse total shoulder arthroplasty applications. The reverse glenoid may consist of one or more components from one or more materials; most commonly, the reverse glenoid is composed of a metal glenosphere that is modularly connected to a metal glenoid baseplate which is fixed to the glenoid fossa.

~~3.1.2.1 *glenoid baseplate, n*—the nonarticular portion of the reverse glenoid component that modularly connects to the glenosphere and is usually fixed to the glenoid fossa of the scapula using bone screws without the use of cement.~~

~~3.1.2.2 *glenosphere, n*—the convex prosthetic articular portion of the reverse glenoid component that articulates with the concave prosthetic replacement of the proximal humerus or humeral head (for example, the humeral liner).~~

~~3.1.2.3 *glenosphere thickness, n*—the height of the truncated section of the sphere which composes the glenosphere. Note that the difference between the glenosphere articular radius and thickness defines the medial/lateral position of the glenoid center of rotation (see Fig. 1). The glenosphere thickness could also be affected by the geometric relation between the glenosphere and the glenoid baseplate.~~

~~3.1.2.4 *humeral liner, n*—the concave prosthetic portion of the reverse humeral component that replaces the proximal humerus or humeral head and articulates with the convex prosthetic replacement of the glenoid (for example, the glenosphere).~~

~~3.1.2.5 *reverse glenoid, n*—the convex prosthetic portion that replaces the glenoid fossa of the scapula and articulates with a concave prosthetic replacement of the humeral head in reverse total shoulder arthroplasty applications. The reverse glenoid may consist of one or more components from one or more materials; most commonly, the reverse glenoid is composed of a metal glenosphere that is modularly connected to a metal glenoid baseplate which is fixed to the glenoid fossa.~~

~~3.1.3 *anterior/posterior (AP), n*—the AP axis is the widest dimension of the glenoid component (see Fig. 2 and Fig. 3).~~

3.2.3 ~~*axial load; axial translation,*~~ *glenoid baseplate, n*—the ~~force and displacement, respectively, perpendicular~~nonarticular portion of the reverse glenoid component that modularly connects to the glenosphere and is commonly fixed to the glenoid ~~plane. The axial load simulates the net compressive external and active and passive soft tissue forces (see~~ fossa of the scapula using bone screws without the use of cement.~~Fig. 4~~).

3.2.4 ~~*edge displacements,*~~ *glenosphere, n*—the ~~translation, perpendicular to the glenoid plane, of a specific point on the outside edge of the glenoid, when subjected to loading (see~~convex prosthetic articular portion of the reverse glenoid component that articulates with the concave prosthetic replacement of the proximal humerus or humeral head (for ~~Fig. 5,~~example, ~~Fig. 6 and~~the humeral ~~Fig. 7~~).liner).

~~3.1.6 *glenoid plane* (see X1.9),*n*—in symmetrical anatomic glenoids, the glenoid plane is defined by joining the two articular edges; in planar and asymmetric anatomic glenoids, it is defined by the back (medial) surface. For a reverse shoulder it is defined as the plane created by the face of the glenoid baseplate (see Fig. 4).~~

~~3.1.7 *runout, n*—a predetermined number of cycles at which the testing on a particular specimen will be stopped, and no further testing on that specimen will be performed.~~

3.2.5 ~~*shear load; shear translation,*~~ *glenosphere thickness, n*—the ~~force and displacement, respectively, parallel to the glenoid plane, applied, for example, in the superior/inferior or anterior/posterior direction. The shear load simulates the net external shear and active and passive soft tissue forces~~height of the truncated section of the sphere which composes the glenosphere. Note that the difference between the glenosphere articular radius and thickness defines the medial/lateral position of the glenoid center of rotation (see Fig. ~~4~~1). The glenosphere thickness could also be affected by the geometric relationship between the glenosphere and the glenoid baseplate.

~~3.1.9 *subluxation load, n*—the peak shear load required for subluxation (for example, the peak resistive force at the glenoid articular rim opposing movement of the humeral head).~~

3.2.6 ~~*subluxation translation,*~~*humeral liner, n*—the ~~distance from the glenoid origin (see~~concave prosthetic portion of the reverse humeral component ~~Fig. 2), parallel to the glenoid plane, to the point at which the subluxation load occurs.~~that replaces the proximal humerus or humeral head and articulates with the convex prosthetic replacement of the glenoid (for example, the glenosphere).

~~3.1.11 *superior/inferior (SI), n*—the SI axis is the longest dimension of the glenoid component (see Fig. 2 and Fig. 3).~~

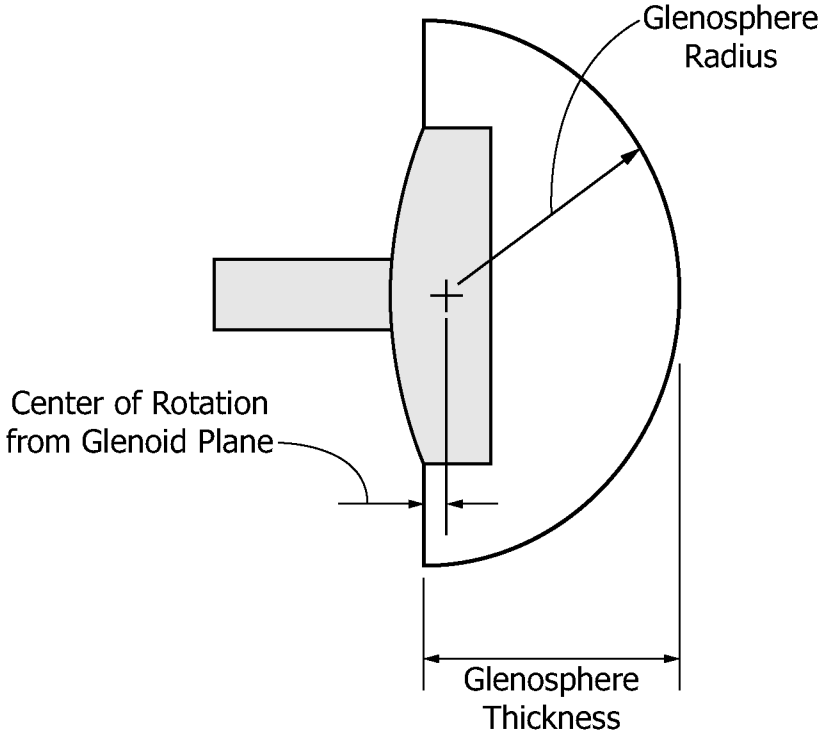

FIG. 1 Glenosphere Thickness

3.3 *Definitions Common to Anatomic and Reverse TSRs*

3.3.1 *collar, n*—flange at the junction of the humeral neck and stem.

3.3.2 *keel, (or pegs), n*—single or multiple projections that provide resistance to translation or rotation of the glenoid component, or both, by mating with cavities created in the glenoid fossa.

3.3.3 *neck*—segment connecting the head and the stem.

3.3.4 *glenoid plane, n*—in symmetrical anatomic glenoids, the glenoid plane is defined by joining the two articular edges; in planar and asymmetric anatomic glenoids, it is defined by the back (medial) surface. For a reverse shoulder it is defined as the plane created by the face of the glenoid baseplate (see Fig. 2).

3.3.4.1 *Discussion*—

Although the glenoid fossa is not truly a planar structure, the terms *plane of the glenoid* and *glenoid plane* have both been used in the scientific literature to describe the anatomic orientation of the glenoid.

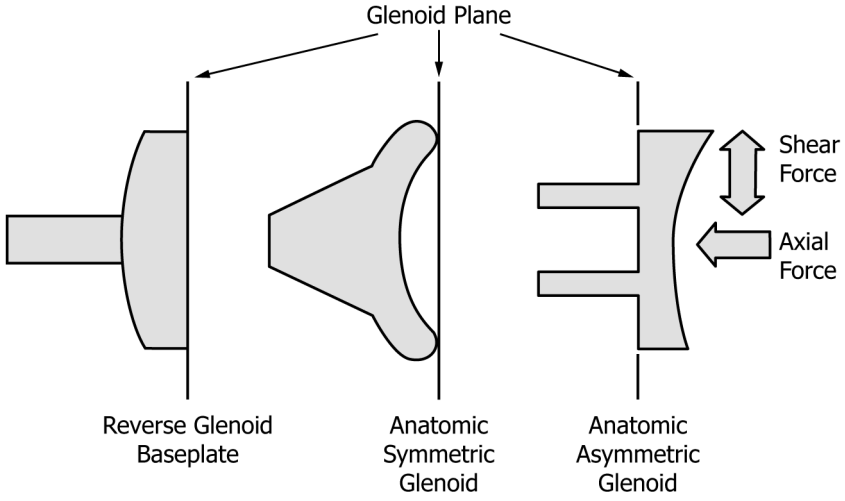

FIG. 2 ~~Anatomic~~ Glenoid ~~Axes~~Plane and ~~Origin~~Force Directions

3.3.5 *humeral head, n*—the bearing member that articulates with the glenoid.

3.3.6 *humeral component, n*—the prosthetic portion that replaces, in part or in total, the proximal humerus or humeral head and articulates with the natural glenoid fossa or a prosthetic replacement.

3.3.7 *humeral stem, n*—segment intended for insertion within the humeral medullary canal.

3.4 *Definitions of Terms Specific to This Standard:*

3.4.1 *anterior/posterior (AP), n*—the widest dimension of the glenoid component that is perpendicular to the SI axis (see Fig. 3 and Fig. 4).

3.4.2 *axial force; axial translation, n*—the force and displacement, respectively, perpendicular to the glenoid plane. The axial force simulates the net compressive external and active and passive soft tissue forces (see Fig. 2).

3.4.3 *edge displacement, n*—the translation, perpendicular to the glenoid plane, of a specific point on the outside edge of the glenoid, when subjected to loading (see Fig. 5, Fig. 6 and Fig. 7).

3.4.4 *runout, n*—a predetermined number of cycles at which the testing on a particular specimen will be stopped, and no further testing on that specimen will be performed.

3.4.5 *shear force; shear translation, n*—the force and displacement, respectively, parallel to the glenoid plane, applied, for example, in the superior/inferior or anterior/posterior direction. The shear force simulates the net external shear and active and passive soft tissue forces (see Fig. 2).

3.4.6 *subluxation force, n*—the peak shear force required for subluxation (for example, the peak resistive force at the glenoid articular rim opposing movement of the humeral head).

3.4.7 *subluxation translation, n*—the distance from the glenoid origin (see Fig. 3), parallel to the glenoid plane, to the point at which the subluxation load occurs.

3.4.8 *superior/inferior (SI), n*—the longest dimension of the glenoid component (see Fig. 3 and Fig. 4).

ANATOMIC SHOULDER GLENOID LOOSENING TEST METHOD

4. Summary of Test Method

4.1 The prosthetic glenoid component is fixed with bone cement into a bone substitute using the normal surgical technique.

4.2 The subluxation translation is determined experimentally on additional components. This is accomplished using a biaxial apparatus (see Fig. 5) by applying an axial load perpendicular to the glenoid, then translating the humeral head parallel to the glenoid plane until encountering a peak shear load. This is performed in both directions, corresponding to the direction of intended rocking (for example, superior-inferior, anterior-posterior, or an alternative angle).

4.3 The edge displacements of the glenoid are measured before cycling: a given axial load is first applied perpendicular to the glenoid, then the edge displacements are measured with the humeral head in three positions: at the glenoid origin, and positioned to 90 % of the subluxation translation (see X1.2), in both directions, as defined in 4.2. (Cycling to 90 % of the subluxation load would be acceptable, but is not practical because of the large displacements, quick speeds, and deformable polyethylene).

4.4 The humeral head is cycled to 90 % of the subluxation distance for a fixed number of cycles.

4.5 The edge displacements (4.3) are either repeated following the cycling or measured continuously during the cycling.

5. Significance and Use

5.1 This test method is intended to investigate the resistance of a glenoid component to loosening. Glenoid loosening is the most common clinical complication in total shoulder arthroplasty (see X1.1). The method assumes that loosening occurs because of edge loading, often called the rocking-horse phenomenon.

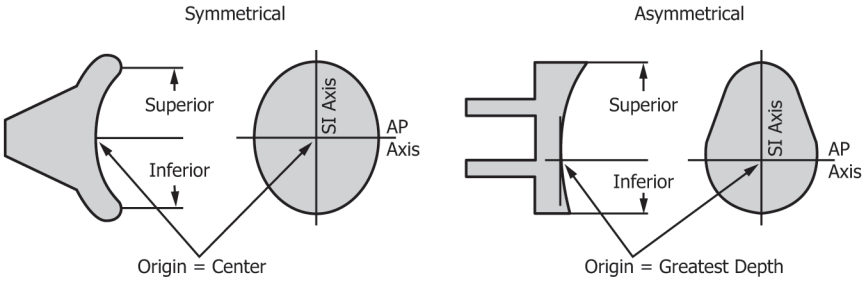

FIG. 3 ~~Reverse Glenoid Baseplate Axes~~Anatomic Glenoid Axes and Origin

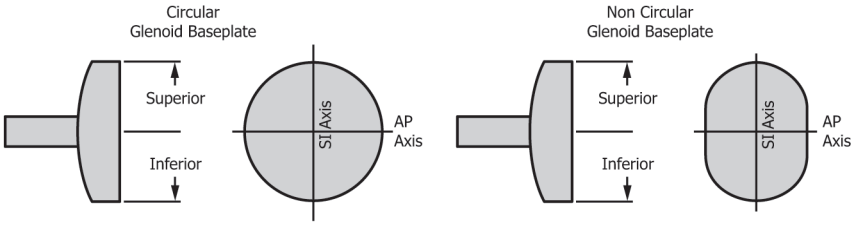

FIG. 4 ~~Glenoid Plane and Load Directions~~Reverse Glenoid Baseplate Axes

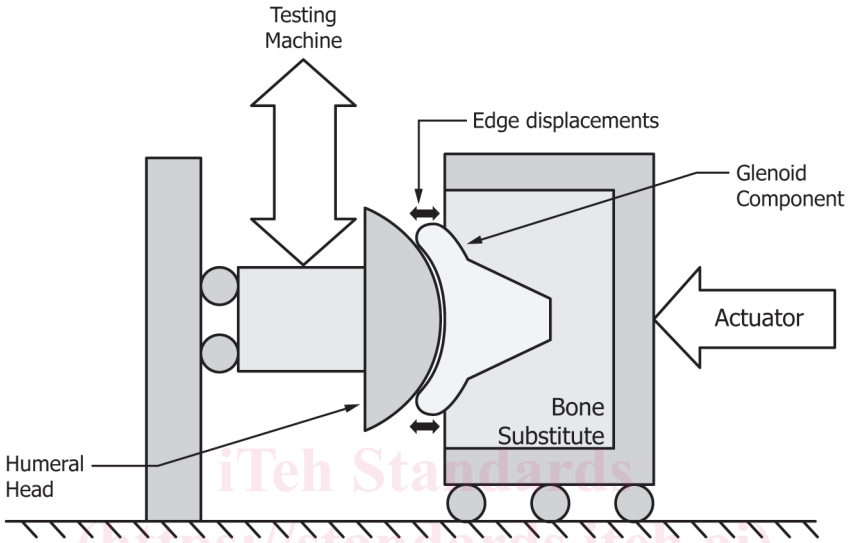

FIG. 5 Biaxial Testing Apparatus for Anatomic Shoulders

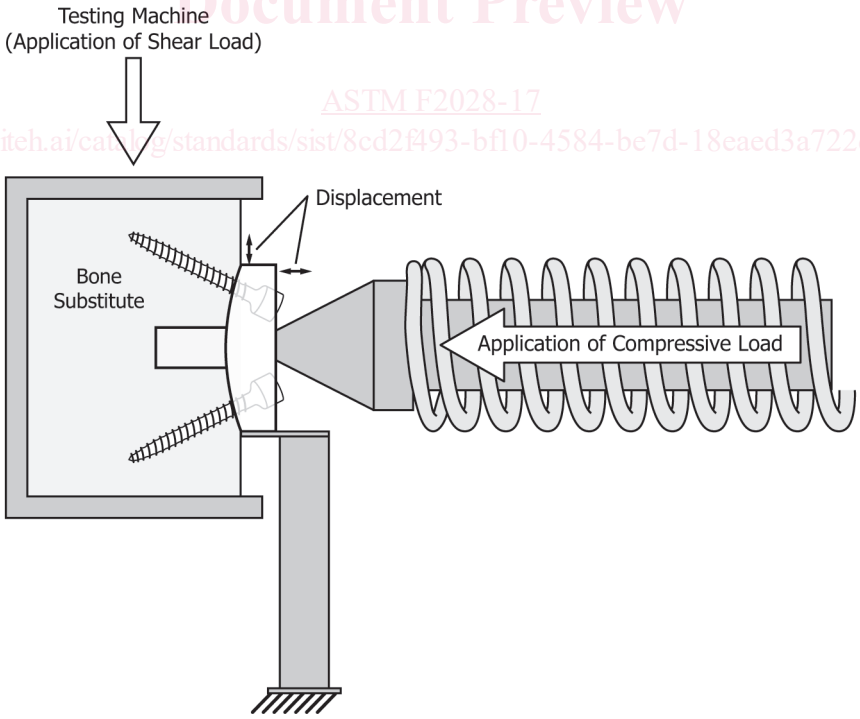

FIG. 6 Displacement Test Configuration

5.2 This test method can be used both to detect potential problems and to compare design features. Factors affecting loosening performance include articular geometry, flange geometry, materials, fixation design, bone quality, and surgical technique.

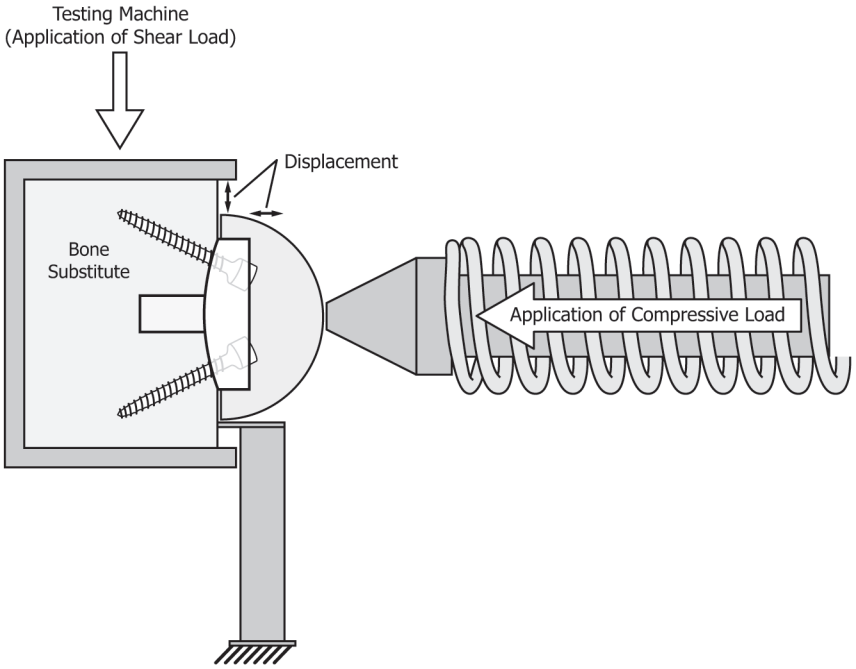

FIG. 7 Alternative Displacement Test Configuration

6. Apparatus and Equipment

6.1 The test apparatus shall be constructed such that an axial ~~load~~force is applied perpendicular to the glenoid plane and a shear ~~load~~force is applied parallel to the glenoid plane (see Fig. 42). Fig. 5 shows the axial ~~load~~force to be horizontal and the shear ~~load~~force to be vertical; however, this arrangement may be reversed.

6.2 A bone substitute representing the strength or glenoid cancellous bone (see X1.5) shall be used. If a polyurethane foam is used, it shall conform to Specification F1839.

6.3 The glenoid and humeral head shall be enclosed in a chamber with water heated to 37 ± 2°C, at least for the dynamic portion of the test (see X1.6). A buffer may be added, if the tester deems this necessary.

6.4 A means to measure the axial load, shear load, shear translation, and glenoid edge displacements is required. A means to measure the axial translation is desirable.

6.5 The tests shall be performed on either mechanical or hydraulic load frames with adequate load capacity and shall meet the criteria of Practices E4.

7. Sampling and Test Specimens

7.1 A minimum of three samples shall be tested. Additional samples may be used to reflect test variability. At least two additional components should be used to determine the subluxation translation. The test may be conducted along the superior-inferior axis, the anterior-posterior axis, or another axis of interest to the user.

7.2 All glenoid components shall be in the final manufactured condition. All plastic components shall be sterilized according to the manufacturer-recommended specifications for clinical use.

7.3 The humeral head shall include the identical radius or radii and material as the actual implant. Other features of the humeral component such as the shaft may be omitted. The same head may be used for all tests unless the surface becomes damaged.

7.4 Glenoid and humeral components are used in total shoulder arthroplasty and should conform to the criteria specified in Specification F1378.

8. Procedure

8.1 The following steps are common to both the subluxation (4.2) and rocking (4.3 – 4.5) tests:

8.1.1 Secure the glenoid component in a bone substitute with bone cement using the normal surgical procedure and instrumentation. Do not perform tests until the cement has cured properly.

8.1.2 Position the path of the humeral head on the glenoid within ±0.5 mm (sideways) of the desired path, for example, by using a dye to locate the contact point of the humeral head; a dye is unnecessary for congruent prostheses. Locate the center of the path