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Standard Specification for Total Hip Joint Prosthesis and Hip Endoprosthesis Bearing Surfaces Made of Metallic, Ceramic, and Polymeric Materials[1]

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1. Scope

1.1 This specification covers the requirements for the mating bearing surfaces of total hip prostheses and hip endoprostheses. More specifically, this specification covers hip joint replacement of the ball-and-socket configuration.

1.2 This specification covers the sphericity, surface finish requirements, and dimensional tolerances for the spherical articulating metallic or ceramic femoral heads of total hip joint prostheses.

1.3 This specification covers the sphericity, surface finish requirements, and dimensional tolerances for the spherical concave mating surface of metallic and ceramic acetabular components, including the inner polymeric bearing surface of bipolar heads, and the surface finish requirements and dimensional tolerances for the spherical concave mating surface of polymeric acetabular components.

1.4 This specification covers the sphericity and surface finish requirements for the spherical metallic or ceramic femoral heads of hip endoprostheses, and the outer bearing surface of bipolar heads.

1.5 This specification is intended for standard practice regarding the design of total hip joint bearing surfaces. Additionally, the tolerances imposed on the polymeric portion of the bearing surface are intentionally large due to temperature-induced size changes and other manufacturing concerns. Some manufacturing methods or designs may intentionally reduce the diameter of the polymeric bearing to more closely mate with the diameter of the head.

1.6 The values stated in SI units are to be regarded as the standard. The values given in parentheses are for information only.

2. Referenced Documents

2.1 *ISO Documents:*[2]

ISO 4287/1 Surface Roughness—Terminology

ISO 4291 Methods for the Assessment of Departure from Roundness, Measurement of Variations, and Radius

ISO 5436 Surface Texture of Products—Calibration Specimens for Stylus Instruments

ISO 6318-1985 Measurement of Roundness—Terms, Definitions, and Parameters of Roundness (Equivalent to BS 3730 Part 1: 1987)

ISO 7206-1 Implants for Surgery—Partial and Total Hip Joint Prosthesis—Part I: Classification, Designation of Dimensions, and Requirements

ISO 7206-2 Implants for Surgery—Partial and Total Hip Joint Prosthesis—Part II: Bearing Surfaces Made of Metallic and Plastics Materials

2.2 *ANSI/ASME Document:*[2]

ANSI/ASME B46.1 -1995 Surface Texture

3. Dimensions and Characteristics

3.1 *Definition:*

3.1.1 *pole of the articulating surface*—The pole of an articulating surface is defined by a point at the intercept of the revolution axis of the component and the spherical articulation surface.

3.1.2 *equator of the articulating surface*—The equator of the articulating surface is the circle normal to the revolution axis of the component, the center of which is the center of the spherical articulating surface.

3.1.3 *cutoff length*—The cutoff length defines the maximal value of the mean twist of profile irregularities that shall be considered in the roughness measurement, that is, with a cutoff length of 0.8 mm, the profile irregularities with a mean twist higher than 0.8 mm shall not be considered.

3.1.3.1 Precise definitions of roughness parameters, cutoff length, and roundness are given in ISO 4287/1, ISO 5436, ISO 4291, and ISO 6318:1985.

[1] This specification 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] Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, http://www.ansi.org.

3.1.4 *stylus tip*—The stylus tip is the tip of the measuring device (diamond or Focodyn) which measures the surface roughness. A stylus has a pseudoconical shape with a hemispherical tip. Typical sizes for the tip are 2, 5, or 10 µm. The selection of the stylus tip is dependent on the range of the roughness measured.

3.2 *Total Hip Joint Prosthesis:*

3.2.1 *Femoral Head:*

3.2.1.1 When inspected visually under 5-diopter magnification, the bearing surface shall be free from particles, scratches, and score marks other than those arising from the finishing process.

3.2.1.2 *sphericity*—The metal or ceramic spherical bearing surface of a femoral hip component shall have a departure from roundness of not greater than 10 µm (390 µin.) This shall be measured as ΔZ_z in accordance with the Minimum Zone Center Method in ISO 4291 measuring the roundness in more than two planes, or by the method in Appendix X2. For metallic femoral heads used in conjunction with metallic acetabular components and ceramic femoral heads used in conjunction with ceramic acetabular components, the departure from roundness values shall not be greater than 5 µm (200 µin.).

3.2.1.3 *surface finish*—When measured in accordance with ANSI/ASME B46.1, the spherical bearing surface of a femoral component shall have a R_a value not greater than 0.05 µm (2 µin.). The measurements shall be taken at the location of the pole and 30° from the pole.

3.2.1.4 *dimensional tolerances*—The spherical bearing surface shall have a diameter equal to the nominal diameter with a tolerance of +0.0, −0.2 mm (+0.000, −0.008 in.)

3.2.1.5 For metallic femoral heads used in conjunction with metallic acetabular components, or ceramic femoral heads used in conjunction with ceramic acetabular components, the manufacturer should report the diameters and tolerances of the heads, if different from the tolerance values in 3.2.1.4.

3.2.2 *Polymeric Acetabular Components:*

3.2.2.1 When inspected visually under 5-diopter magnification, the bearing surface shall be free from particles, scratches, and score marks other than those arising from the finishing process.

3.2.2.2 *surface finish*—When measured in accordance with ANSI/ASME B46.1, the spherical bearing surface of the acetabular component shall have a R_a value not greater than 2 µm (80 µin.)

3.2.2.3 *dimensional tolerances*—The spherical socket shall have a diameter equal to the nominal diameter within a tolerance of +0.3, −0.0 mm (+0.012, −0.0 in) at a temperature of 20 ± 2°C (68 ± 4°F). The socket should be oversized to the nominal within the given tolerance range.

3.2.3 *Metallic Acetabular Components:*

3.2.3.1 When inspected visually under 5-diopter magnification, the bearing surface shall be free from particles, scratches, and score marks other than those arising from the finishing process.

3.2.3.2 *sphericity*—The spherical bearing surface of the metal acetabular component shall have a departure from roundness of not greater than 15 µm (590 µin.). This shall be measured as ΔZ_z in accordance with the Minimum Zone Center Method in ISO 4291 measuring the roundness in more than two places, or as determined by the method in Appendix X2.

3.2.3.3 *surface finish*—When measured in accordance with ANSI/ASME B46.1, the spherical bearing surface of the acetabular component shall have a R_a value of not greater than 0.05 µm (2 µin.).

3.2.3.4 Diametral clearance values shall be as follows: for head diameters of 28 to 36 mm, the clearance between the articulating part of the socket and metallic head, when both components are at maximum material condition (MMC), shall never be less 40 µm. When both components are at least material condition (LMC) the clearance shall never be larger than 190 µm. For head diameters larger than 36 mm, the MMC clearances shall never be less than 70 µm or the LMC clearances greater than 360 µm.

3.2.3.5 Metallic heads and sockets from different manufacturers should not be mated because the combinations of tolerances within the family, surface finish, and configuration for the different manufacturers may not have been validated through appropriate testing.

3.2.4 *Ceramic Acetabular Components:*

3.2.4.1 When inspected visually under 5-diopter magnification, the bearing surface shall be free from particles, scratches, and score marks other than those arising from the finishing process.

3.2.4.2 *sphericity*—The ceramic spherical bearing surface of a acetabular component shall have a departure from roundness of not greater than 5 µm (200 µin.). This shall be measured as ΔZ_z in accordance with the Minimum Zone Center Method in ISO 4291 measuring the roundness in more than two planes, or as determined by the method in Appendix X2.

3.2.4.3 *surface finish*—When measured in accordance with ANSI/ASME B46.1, the spherical bearing surface of the acetabular component shall have a R_a value of not greater than 0.05 µm (2 µin.).

3.2.4.4 Under MMC, the articulating part of the socket and ceramic head, there should be clearance and both components never produce an interference fit.

3.2.4.5 Ceramic heads and sockets from different manufacturers should not be mated because the combinations of tolerances within the family, surface finish, and configuration for the different manufacturers may not have been validated through appropriate testing.

3.3 *Hip Endoprostheses:*

3.3.1 When inspected visually under 5-diopter magnification, the bearing surface shall be free from particles, scratches, and score marks other than those arising from the finishing process.

3.3.2 *sphericity*—The metal or ceramic spherical bearing surface of a femoral hip component shall have a departure from roundness of not greater than 100 µm (3940 µin.). This shall be measured as ΔZ_z in accordance with the Minimum Zone Center Method in ISO 4291 measuring the roundness in more than two planes, or as determined by the method in Appendix X2.

3.3.3 *surface finish*—When measured in accordance with ANSI/ASME B46.1, the spherical bearing surface of femoral endoprostheses components shall have a R_a value not greater than 0.5 µm (20 µin.).