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YY/T 0920-2014 / ISO 21535:2007

Non-active surgical implants - Joint replacement implants - Specific requirements for hip-joint replacement implants

无源外科植入物 关节置换植入物 髋关节置换植入物的专用要求

(ISO 21535:2007, IDT)

Issued on: June 17, 2014 **Implemented on: July 1, 2015**

Issued by: China Food and Drug Administration

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Foreword

This standard was drafted in accordance with the rules given in GB/T 1.1-2009.

This standard is translated and identical to ISO 21535:2007 *Non-active surgical implants - Joint replacement implants - Specific requirements for hip-joint replacement implants*.

The Chinese documents that have consistent correspondence with the international documents normatively cited in this standard are as follows:

-- YY/T 0640-2008 Non-active surgical implants - General requirements (ISO 14630:2005, IDT)

-- YY/T 0809.1 Implants for surgery - Partial and total hip joint prostheses - Part 1: Classification and designation of dimensions (YY/T 0809.1-2010, ISO 7206-1:2008, IDT)

-- YY/T 0809.2 Implants for surgery - Partial and total hip joint prostheses - Part 2: Articulating surfaces made of metallic, ceramic and plastic materials (YY/T 0809.2-2010, ISO 7206-2:1996, MOD)

-- YY/T 0809.4 Implants for surgery - Partial and total hip joint prostheses - Part 4: Determination of endurance properties of stemmed femoral components (YY/T 0809.4-2010, ISO 7206-4:2002, MOD)

-- YY/T 0809.6 Implants for surgery - Partial and total hip joint prostheses - Part 6: Determination of endurance properties of head and neck region of stemmed femoral components (YY/T 0809.6-2010, ISO 7206-6:1992, MOD)

-- YY/T 0809.10 Implants for surgery - Partial and total hip joint prostheses - Part 10: Determination of resistance to static load of modular femoral heads (YY/T 0809.1-2010, ISO 7206-10:2003, MOD)

Please note that some of the contents of this document may involve patents. The issuing agency of this document is not responsible for identifying patents.

This standard was proposed by China Food and Drug Administration.

This standard shall be under the jurisdiction of the Sub-Technical Committee on Orthopedics Implants of the National Technical Committee on Implants for Surgery and Orthopedic Devices of Standardization Administration of China (SAC/TC110/SC1).

Drafting organizations of this standard: Committee for Surgical Implants Chinese Association of Medical Device Industry, Tianjin Medical Devices Quality Supervision

Non-active surgical implants - Joint replacement implants - Specific requirements for hip-joint replacement implants

1 Scope

This standard specifies specific requirements for hip joint replacement implants.

With regard to safety, this standard specifies requirements for expected performance, design attributes, materials, design evaluation, fabrication, sterilization, packaging, and information provided by the manufacturer, as well as test methods.

2 Normative references

The following documents are essential to the application of this document. For the dated referenced documents, only the versions with the indicated dates are applicable to this document; for the undated referenced documents, only the latest version (including all the amendments) is applicable to this document.

YY/T 0640-2008 Non-active surgical implants - General requirements (ISO 14630:2005, IDT)

YY/T 0809.1 Implants for surgery - Partial and total hip joint prostheses - Part 1: Classification and designation of dimensions (YY/T 0809.1-2010, ISO 7206-1:2008, IDT)

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YY/T 0809.10 Implants for surgery - Partial and total hip joint prostheses - Part 10: Determination of resistance to static load of modular femoral heads (YY/T 0809.10-2010, ISO 7206-10:2003, MOD)

11.3 Structural and functional compatibility of components

11.3.1 If a femoral component or modular femoral head is only expected to be compatible with the structures and functions of specific acetabular cups, the compatible acetabular cups shall be stated in its label, instruction leaflet, or manual.

11.3.2 If an acetabular component is only expected to be compatible with the structures and functions of specific femoral components, the compatible femoral components shall be stated in its label, instruction leaflet, or manual.

11.3.3 For a femoral component and head of modular construction, the label, instruction leaflet, or manual shall state for each, the corresponding components with which they are structurally and functionally compatible.

NOTE: In general, components made by different companies may not match. This applies in particular to modular components with male or female tapered connections.

11.4 Marking

11.4.1 The nominal diameter of the femoral head shall be marked on a monobloc femoral component.

11.4.2 A modular femoral head shall be marked to identify its nominal outer diameter and the characteristics of the cone and bore connection. In normal or corrected vision, these markings shall be legible.

11.4.3 For the stemmed femoral component of the hip joint replacement implant matched with the modular femoral head in the way of a male/female tapered connection, as long as the expected function of the component is not damaged, there shall be a mark indicating the connection method. Markings required for identification or other reasons may be located on the neck of the femoral component of a hip joint replacement implant only if it is proven that endurance property will not be impaired. For stemmed femoral components fitted with modular femoral heads, the marking shall be located on the proximal end face of the conical region where the femoral head is fitted. In normal or corrected vision, the marking shall be clear.

11.4.4 The acetabular component with the articular surface of a total hip joint arthroplasty shall be marked with the nominal diameter of the articular surface. In normal or corrected vision, the marking shall be clear.

11.5 Information provided to patients

The manufacturer shall at least make the following statement or equivalent statement in the instruction leaflet or manual:

“Patients receiving hip joint replacements should be advised that the longevity of the

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