# YY

PHARMACEUTICAL INDUSTRY STANDARD

OF THE PEOPLE'S REPUBLIC OF CHINA

ICS 11.040.40
C 35

# YY 0118-2016

Replacing YY 0118-2005

# Joint Replacement Implants – Hip Joint Prostheses

关节置换植入物一髋关节假体



**Issued on: January 26, 2016** **Implemented on: January 1, 2018**

**Issued by: China Food and Drug Administration**

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# Foreword

Clause 7.7.4 of this Standard is recommendatory, while the rest are mandatory.

This Standard was drafted as per the rules specified in GB/T 1.1-2009.

This Standard replaces YY 0118-2005 *Hip Joint Prostheses.* Compared with YY 0118-2005, the main changes in this Standard are as follows:

--- Add the oxidation stability and morphological evaluation of ultrahigh molecular weight polyethylene (see Clause 7.3.1 of this version);

--- Add the requirements for extensively radiation cross-linked ultrahigh molecular weight polyethylene (see Clause 7.3.2 of this version);

--- Add the requirements for plasma spraying metal coating (see Clause 7.5.2 of this version);

--- Modify the applicable scope of surface defects (see Clause 8.3 of this version; and Clause 4.2.2 of Version 2005);

--- Add femoral head fixed anti-torque performance measurement against the stemmed femoral component (see Clause 8.6.1 of this version);

--- Add the combined femoral head anti-static load force (see Clause 8.6.2 of this version);

--- Add metal acetabular resistance to deformation (see Clause 8.6.3 of this version);

--- Modify the shank fatigue performance of stemmed femoral components, and amending it as mandatory clause (see Clause 8.7.2 of this version; and Clause 5.3.1 of Version 2005);

--- Modify the head and neck fatigue performance of stemmed femoral components, and amending it as mandatory clause (see Clause 8.7.3 of this version; and Clause 5.3.2 of Version 2005);

--- Add the maximum and minimum angles (see Clause 8.8 of this version);

--- Delete the inspection rules in the original standard (see Chapter 7 of Version 2005).

Please note that some contents of this document may involve patents. The releasing organization of this document shall not assume the responsibility for identifying these patents.

# Joint Replacement Implants - Hip Joint Prostheses

## 1 Scope

This Standard specifies the terms and definitions, classification and size marking, expected performance, design attributes, materials, design evaluation, manufacture, sterilization, packing, and manufacturer's information requirements for the total-hip and partial-hip joint prostheses.

This Standard is applicable to manufacture total-hip and partial-hip joint prostheses used the materials and processes specified in this Standard.

## 2 Normative References

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

GB/T 10610 Geometrical Product Specifications (GPS) - Surface Texture: Profile Method - Rules and Procedures for the Assessment of Surface Texture

GB/T 14233.1 Test Methods for Infusion, Transfusion, Injection Equipment for Medical Use - Part 1: Chemical Analysis Methods

GB/T 14233.2 Test Methods for Infusion, Transfusion, Injection Equipment for Medical Use - Part 2: Biological Test Methods

GB/T 16886.7 Biological Evaluation of Medical Devices - Part 7: Ethylene Oxide Sterilization Residuals

GB 18278 Sterilization of Health Care Products - Requirements for Validation and Routine Control - Industrial Moist Heat Sterilization

GB 18279 Medical Devices-Validation and Routine Control of Ethylene Oxide Sterilization

GB 18280 Sterilization of Health Care Products - Requirement for Validation and Routine Control - Radiation Sterilization

GB/T 19701.1 Implants for Surgery - Ultra-high Molecular Weight Polyethylene - Part 1: Powder Form

GB/T 19701.2 Implants for Surgery Ultra-high Molecular Weight Polyethylene - Part 2: Moulded Forms

GB 23101.2 Implants for Surgery - Hydroxyapatite - Part 2: Coatings of Hydroxyapatite

YY 0117.1 Implants for Surgery - Forgings, Castings for Bone Joint Prostheses - Ti6Al4V Titanium Alloy Forgings

YY 0117.2 Implants for Surgery - Forgings, Castings for Bone Joint Prostheses-ZTi6Al4V Titanium Alloy Castings

YY 0117.3 Implants for Surgery - Forgings, Castings for Bone Joint Prostheses Cobalt Chromium Molybdenum Alloy Castings

YY/T 0772.3 Implants for Surgery - Ultra-High-Molecular-Weight Polyethylene - Part 3: Accelerated Ageing Methods

YY/T 0772.4 Implants for Surgery - Ultra-High-Molecular-Weight Polyethylene - Part 4: Oxidation Index Measurement Method

YY/T 0772.5 Implants for Surgery - Ultra-High-Molecular-Weight Polyethylene - Part 5: Morphology Assessment Method

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 Plastics Materials (YY/T 0809.2-2010, ISO 7206-2:1996, IDT)

YY/T 0811 Standard Guide for Extensively Irradiation - Crosslinked Ultrahigh Molecular Weight Polyethylene Fabricated Forms for Surgical Implant Applications

YY/T 0920 Non-Active Surgical Implants - Joint Replacement Implants - Specific Requirements for Hip-Joint Replacement Implants (YY/T 0920-2014, ISO 21535:2007, IDT)

ISO 4287 Geometrical Product Specification (GPS) - Surface Texture: Profile Method - Terms, Definitions and Surface Texture Parameters

ISO 6474-1 Implants for Surgery – Ceramic Materials – Part 1: Ceramic Materials Based on High Purity Alumina

ISO 6474-2 Implants for Surgery – Ceramic Materials – Part 2: Composite Materials Based on a High Purity Alumina Matrix with Zirconia Reinforcement

ISO 7206-4 Implants for Surgery – Partial and Total Hip Joint Prostheses – Part 4: Determination of Endurance Properties of Stemmed Femoral Components

ISO 7206-6 Implants for Surgery – Partial and Total Hip Joint Prostheses – Part 6: Determination of Endurance Properties of Head and Neck Region of Stemmed Femoral Components

ISO 7206-10 Implants for Surgery - Partial and Total Hip Joint Prostheses – Part 10: Determination of Resistance to Static Load of Modular Femoral Heads

ISO 13356 Implants for Surgery – Ceramic Materials Based on Yttria-Stablized Tetragonal Zirconia (Y-TZP)

ISO 14242-1 Implants for Surgery – Wear of Total Hip-Joint Prostheses - Part 1: Loading and Displacement Parameters for Wear-Testing Machines Corresponding Environmental Conditions for Test

ISO 4242-2 Implants for Surgery – Wear of Total Hip-Joint Prostheses – Part 2: Methods of Measurement

ISO 4242-3 Implants for Surgery – Wear of Total Hip-Joint prostheses - Part 3: Loading and Displacement Parameters for Orbital Bearing Type Wear Testing Machines and Corresponding Environmental Conditions for Test

ISO 14630 Non-Active Surgical Implants – General Requirements

ISO 21534 Non-Active Surgery Implants – Joint Replacement Implants – particular Requirements

ASTM F1044 Standard Test Method for Shear Testing of Calcium Phosphate Coating and Metallic Coating

ASTM F1147 Standard Test Method for Tension Testing of Calcium Phosphate Coating and Metallic Coating

ASTM F1160 Standard Test Method for Shear and Bending Testing of Calcium Phosphate and Metallic Medical and Composite Calcium Phosphate/metallic coating

ASTM F1377 Standard Specification for Cobalt-28Chromium-6Molybdenum Power for Coating of Orthopaedic Implants

ASTM F1580 Standard Specification for Titanium and Titanium-6Aluminum-4Vanadium Alloy Powders for Coating of Surgical Implants

ASTM F1854 Standard Test Method for Stereo-Logical Evaluation of Porous Coating on Medical Implants

ASTM F1978 Standard Test Method for Measuring Abrasion Resistance of Metallic Thermal Spray Coatings by Using the Taber Abraser

# 3 Terms and Definitions

The following terms and definitions defined in YY/T 0809.1, YY/T 0920, and ISO 21534 are applicable to this document.

### 3.1 Conventional UHMWPE

UHMWPE manufactured through molding or extrusion forming, undergone no cross-linked treatment before the final sterilization.

### 3.2 Extensively radiation-cross-linked UHMWPE

UHMWPE manufactured through molding or extrusion forming, and to improve the wear resistance by using gamma ray or electron beam irradiation of which the dosage is higher than 40kGy.

# 4 Classification and Size Marking

### 4.1 Classification

It shall conform to the requirements of YY/T 0809.1.

### 4.2 Size marking

It shall conform to the requirements of YY/T 0809.1.

# 5 Expected Performance

It shall conform to the requirements of YY/T 0920.

# 6 Design Attributes

It shall conform to the requirements of YY/T 0920.

# 7 Materials

### 7.1 General

coating.

### 8.4 Surface roughness

#### 8.4.1 Articulating surface roughness

**8.4.1.1** As for spherical articulating surface of metallic and ceramic femoral components matched the plastic acetabular components in the total hip joint prostheses, its surface roughness $R_a$ shall be no more than 0.05μm and 0.02μm respectively.

**8.4.1.2** As for spherical articulating surface of plastic acetabular components in total hip joint prostheses, it surface roughness $R_a$ is no more than 2μm.

**8.4.1.3** As for spherical articulating surface of metallic and ceramic femoral components matched the physiological acetabular components in the partial hip joint prostheses, its surface roughness $R_a$ shall be no more than 0. 5μm.

**8.4.1.4** As for concave (internal) spherical articulating surface of bipolar head plastic component, its surface roughness $R_a$ shall be no more than 2μm.

**8.4.1.5** As for spherical articulating surface of metallic and ceramic femoral components with bipolar head matched physiological acetabular, its surface roughness $R_a$ shall be no more than 0.5μm.

**8.4.1.6** Manufacturer shall specify the surface roughness $R_a$ of the ceramic-to-ceramic articulating surface, and metallic-to-metallic articulating surface.

Note: the surface roughness of articulating surface shall be tested as per the method specified in YY/T 0809.2.

#### 8.4.2 Tapered joint surface roughness

Manufacturer shall specify the requirements of tapered joint surface roughness $R_a$ and/or $R_z$, which shall be tested as per the method specified in GB/T 10610.

#### 8.4.3 Coating surface roughness

Manufacturer shall specify the requirements of coating surface roughness $R_a$ or $R_z$, which shall be tested as per the method specified in GB/T 10610.

### 8.5 Dimensions and tolerances of important parts

Test of each part's dimension and tolerance is implemented through the measuring tool, special gages or measuring instrument, while spherical roundness radial deviation of articulating surface shall be carried out as per the provision in YY/T 0809.2.

--- 6mm is applicable to the components without rear lining.

### 8.5.5 Bipolar head

As for the bipolar head with outer diameter 44m or larger, the minimum thickness of its liner manufactured by conventional UHMWP shall be 5mm.

Note: when special people's bone size needs implants, the acetabular component diameter is less than 42mm, and bipolar head component diameter is less than 44mm; then thickness of component manufactured by conventional UHMWP can be less than the above-mentioned value.

## 8.6 Static mechanical properties

### 8.6.1 Femoral fixed anti-torque performance measurement of stemmed femoral components

Note: Relevant standard of test method is under preparation, which shall be implemented after the publication.

### Combined femoral anti-static load force

It shall be carried out as per the method specified in ISO 7206-10.

### 8.6.3 Metal acetabular resistance to deformation

Note: Relevant standard of test method is under preparation, which shall be implemented after the publication.

## 8.7 Dynamic performance

### 8.7.1 Test principle

When dynamic performance test is carried out, it shall test the same series of prostheses' worst situations (such as maximum stress level, most serious wearing and etc.). The evaluation of worst situation shall combine the product's expected performance, design attributes, and adopt the finite element analysis method or other verification methods.

### 8.7.2 Stem fatigue performance of stemmed femoral component

Stem fatigue performance of stemmed femoral component shall test as per ISO 7206-4, and shall conform to the requirements.

### 8.7.3 Head and neck fatigue performance of stemmed femoral component

Head and neck fatigue performance of stemmed femoral component shall test as per ISO 7206-6, and shall conform to the requirements.

# Appendix A

**(Normative)**

**List of Material Standards That Are Acceptable for the Manufacture of Hip Joint Prostheses**

The following materials have been found acceptable through proven use for the manufacture of hip joint prostheses.

The inclusion of materials in this appendix does not imply their satisfactory use in any particular application; neither does it relieve the manufacturer from the obligation to undertake a design evaluation.

ISO 5832-1 Implants for Surgery - Metallic Materials - Part 1: Wrought Stainless Steel

ISO 5832-2 Implants for Surgery - Metallic Materials - Part 2: Unalloyed Titanium

ISO 5832-3 Implants for Surgery - Metallic Materials - Part 3: Wrought Titanium 6-aluminium 4-vanadium Alloy

ISO 5832-4 Implants for Surgery - Metallic Materials - Part 4: Cobalt-chromium-molybdenum Casting Alloy

ISO 5832-5 Implants for Surgery - Metallic Materials - Part 5: Wrought Cobalt-chromium-tungsten-nickel Alloy

ISO 5832-6 Implants for Surgery - Metallic Materials - Part 6: Wrought Cobalt-nickel-chromium-molybdenum Alloy

ISO 5832-7 Implants for Surgery - Metallic Materials - Part 7: Forgeable and Cold-formed Cobalt-chromium-nickel-molybdenum-iron Alloy

ISO 5832-8 Implants for Surgery - Metallic Materials - Part 8: Wrought Cobalt-nickel-chromium-molybdenum-tungsten-iron Alloy

ISO 5832-9 Implants for Surgery - Metallic Materials - Part 9: Wrought High Nitrogen Stainless Steel

ISO 5832-11 Implants for Surgery - Metallic Materials - Part 11: Wrought Titanium 6-aluminium 7-niobium Alloy

ISO 5832-12 Implants for Surgery - Metallic Materials - Part 12: Wrought

# Appendix B

**(Normative)**

**List of Materials That Are Acceptable or not Acceptable for the Manufacture of Articulating Surfaces of Hip Joint Prostheses**

## B.1 Suitable material combinations

For the articulating surfaces of hip joint replacement implants, the following combinations of the materials listed in Appendix A have been found to be acceptable in particular applications, provided that adequate attention is paid to in design, surface finish and surface treatment:

a) Wrought stainless steel (ISO 5832-1) / UHMWPE (ISO 5834-1, ISO 5834-2);

b) Wrought high nitrogen stainless steel (ISO 5832-9) / UHMWPE (ISO 5834-1, ISO 5834-2);

c) Cobalt-chromium-molybdenum casting alloy (ISO 5832-4, GB 17100) / UHMWPE (ISO 5834-1, ISO 5834-2);

d) Wrought cobalt-chromium tungsten-nickel alloy (ISO 5832-5) / UHMWPE (ISO 5834-1, ISO 5834-2);

e) Forgeable and cold-formed cobalt-chromium-nickel-molybdenum-iron alloy (ISO 5832-7) / UHMWPE (ISO 5834-1, ISO 5834-2);

f) Wrought cobalt-nickel-chromium-molybdenum-tungsten-iron alloy (ISO 5832-8) / UHMWPE (ISO 5834-1, ISO 5834-2);

g) Wrought titanium 6-aluminium 4-vanadium alloy [1)] (ISO 5832-3) / UHMWPE (ISO 5834-1, ISO 5834-2);

h) Wrought titanium 6-aluminium 7-niobium alloy [1)] (ISO 5832-11) / UHMWPE (ISO 5834-1, ISO 5834-2);

i) Ceramic materials based on alumina (ISO 6474) / UHMWPE (ISO 5834-1, ISO 5834-2);

j) Ceramic materials based on zirconia (ISO 13356) / UHMWPE (ISO 5834-1, ISO 5834-2);

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1) Particular attention to surface treatment of the articulating surface may be necessary.