



**NATIONAL STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

GB/T 41428.1-2022

**Implants for surgery - Orthopaedic joint prosthesis - Part 1:
Procedure for producing parametric 3D bone models from CT
data of the knee**

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Table of Contents

foreword

Introduction

1 Scope

2 Normative references

3 Terms and Definitions

foreword

This document is in accordance with the provisions of GB/T 1.1-2020 "Guidelines for Standardization Work Part 1. Structure and Drafting Rules of Standardization Documents" drafted.

This document is part 1 of GB/T 41428 "Surgical Implants for Bone and Joint Prostheses". GB/T 41428 has issued the following part.

---Part 1. The process of generating a parametric 3D bone model based on knee CT data.

This document uses the redrafted method to amend ISO 19233-1.2017 "Surgical implants for bone and joint prostheses - Part 1. Based on knee

The process of generating parametric 3D bone model from joint CT data".

Compared with ISO 19233-1.2017, the structure of this document has been adjusted. Chapter 4 corresponds to 3.2 of ISO 19233-1.2017, and Chapter 5 corresponds to ISO 19233-1.2017.

Chapter 4 and Chapter 6 of ISO 19233-1.2017 should correspond to Chapter 5 of ISO 19233-1.2017.

The technical differences between this document and ISO 19233-1.2017 and their reasons are as follows.

--- Regarding normative reference documents, this document has made adjustments with technical differences to adapt to the technical conditions of our country and the circumstances of the adjustment.

The situation is reflected in Chapter 2 "Normative References", and the specific adjustments are as follows.

* Replace IEC 61223-2-6 with GB/T 17006.11 which is equivalent to adopting international

standards;

* Replacing IEC 60788 with GB/T 17857 which is equivalent to adopting international standards;

* Replacing ISO 14971 with YY/T 0316 which is equivalent to adopting international standards;

* Replacing ISO 21536 with YY/T 0919 which is equivalent to adopting international standards;

* Replacing ISO 7207-1 with YY/T 0924.1 which has been modified to adopt international standards.

The following editorial changes have been made to this document.

---Added "This document is suitable for the use of medical X-ray tomography equipment to generate 3D bone models" in the scope, which improved this document

applicable limits.

Please note that some content of this document may be patented. The issuing agency of this document assumes no responsibility for identifying patents.

Introduction

Existing standards for artificial joints specify the expected performance, design properties, materials, design evaluation,

Requirements for preclinical evaluation methods such as manufacturing, sterilization, packaging, information provided by the manufacturer, but lack of procedures or methods to design artificial joints.

GB/T 41428 aims to standardize the geometric measurements of bone and joint prostheses and the procedures and methods for optimally designing prostheses based on the measurement data.

GB/T 41428 is intended to consist of five parts.

---Part 1. The process of generating a parametric 3D bone model based on knee CT data. With Medical X-ray Computed Tomography

With the widespread use of scanning equipment, the technology of 3D bone model reconstruction based on digital electron tomography has been widely used in surgery.

Anterior design, surgical navigation, robotic surgery, patient-personalized surgical instruments, and personalized total knee prostheses.

However, the conditions for taking tomographic images vary among hospitals, and there is no international standard. for the skeletal

For accurate measurements, accurate 3D bone models reconstructed from tomographic images are recommended. On the other hand, since the conditions for the reconstruction process are

It is up to the operator and/or the medical institution to decide, therefore, this document will provide a standard method for reconstructing 3D bone models.

--- Part 2. Basic skeletal measurements for design.

--- Part 3. Design and safety assessment methods.

--- Part 4. Manufacturing methods.

--- Part 5. Positioning accuracy verification scheme.

Part 2 to Part 5 International Standards have not yet been formulated.

Surgical implant bone joint prosthesis

Part 1. Generation from knee CT data

The process of parametric 3D bone model

1 Scope

This document specifies specific requirements for the use of medical tomography equipment to obtain the necessary bone geometry and is intended for preoperative planning

It provides the necessary information for applications such as metrology, surgical navigation, robotic surgery, patient-personalized surgical instruments, and personalized total knee prostheses. This article

The document gives the conditions for bone image scanning and the conditions for 3D bone model reconstruction.

This file is suitable for the generation of 3D bone models using medical tomography equipment.

Note. See ISO /IEC 17025 for the competence requirements of CT scanning rooms to ensure the reliability and accuracy of calculations of electronic equipment.

2 Normative references

The contents of the following documents constitute essential provisions of this document through normative references in the text. Among them, dated citations

documents, only the version corresponding to that date applies to this document; for undated references, the latest edition (including all amendments) applies to

this document.

GB/T 17006.11 Evaluation and routine tests of medical imaging departments - Part 2-6.Imaging of X-ray computed tomography equipment

Performance stability test (GB/T 17006.11-2015, IEC 61223-2-6.2006, IDT)

GB/T 17857 Medical Radiology Terminology (Radiotherapy, Nuclear Medicine and Radiation Dosimetry Equipment) (eqvGB/T 17857-1999,

IEC 60788-1984)

YY/T 0316 Application of Medical Device Risk Management to Medical Devices (YY/T 0316-2016, ISO 14971.2007 Correction

version, IDT)

YY/T 0919 Passive Surgical Implants Joint Replacement Implants Particular Requirements for Knee Replacement Implants (YY/T 0919-

2014, ISO 21536.2007, IDT)

YY/T 0924.1 Surgical Implant Parts and Total Knee Prosthesis Parts Part 1.Classification, Definition and Dimensions

(YY/T 0924.1-2014, ISO 7207-1.2007, MOD)

3 Terms and Definitions

GB/T 17857, GB/T 17006.11, YY/T 0919, YY/T 0924.1 and the following terms and definitions apply to this

document.

ISO and IEC provide databases of terms used in standards at.

3.1

3D bone model 3Dbonemodel

According to the CT image and 3D morphological data, the corresponding skeleton model is reconstructed in the computer.