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Implants for surgery — Orthopaedic joint prosthesis —

Part 1: Procedure for producing parametric 3D bone models from CT data of the knee

Implants chirugicaux — Prothèses articulaires orthopédiques —

Partie 1: Mode opératoire de production de modèles paramétriques d'os en 3D à partir de données de CT du genou

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

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A list of all parts in the ISO 19233 series can be found on the ISO website.

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Introduction

In accordance with its widespread use of medical X-ray computed tomography apparatus, three-dimensional (3D) bone models reconstructed from digital tomographic images have been widely used for various applications such as preoperative planning, surgical navigation, robotic surgeries, patient matched instruments and personalized total knee joint prosthesis. However, the conditions of taking tomographic images are different among hospitals and not internationally unified. To measure bones accurately, precise 3D bone models reconstructed from tomographic images should be used. On the other hand, since conditions of this reconstruction process are left up to operators' and/or medical institutions' discretion, this document provides a standard way of reconstructing 3D bone models.

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Implants for surgery — Orthopaedic joint prosthesis —

Part 1: Procedure for producing parametric 3D bone models from CT data of the knee

1 Scope

This document provides requirements for capturing necessary bone geometries, when using a medical X-ray computed tomography apparatus, to provide the information for applications such as preoperative planning, surgical navigation, robotic surgeries, patient matched instruments and personalized total knee joint prosthesis. The conditions to scan images of bones and the conditions to reconstruct three-dimensional bone models are provided.

NOTE Requirements for the competence of testing laboratories appropriate to help to ensure the reliability and accuracy of the computational measurements can be found in ISO/IEC 17025.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 7207-1, *Implants for surgery — Components for partial and total knee joint prostheses — Part 1: Classification, definitions and designation of dimensions*

ISO 14971, *Medical devices — Application of risk management to medical devices*

ISO 21536, *Non-active surgical implants — Joint replacement implants — Specific requirements for knee-joint replacement implants*

IEC 61223-2-6, *Evaluation and routine testing in medical imaging departments — Part 26: Constancy tests — Imaging performance of computed tomography X-ray equipment*

IEC/TR 60788, *Medical electrical equipment — Glossary of defined terms*

3 Terms, definitions and abbreviated terms

3.1 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC/TR 60788, IEC 61223-2-6, ISO 21536, ISO 7207-1 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— IEC Electropedia: available at http://www.electropedia.org/

— ISO Online browsing platform: available at http://www.iso.org/obp

3.1.1
3D bone model
bone model that is reconstructed based on CT images and made from 3D shape data in the computer

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3.1.2
personalized artificial knee joint
knee joint prosthesis specifically designed for each patient

3.1.3
field of view
scanning field of view which includes the intended side of the lower limb

3.1.4
CT apparatus
X-ray computed tomography
technology that uses computer-processed x-rays to produce tomographic images (virtual "slices") of specific areas of the scanned object, allowing the user to see what is inside it without cutting it open

Note 1 to entry: Digital geometry processing is used to generate a three-dimensional (3D) image of an object from two-dimensional (2D) radiographic images taken by the CT apparatus in a spiral path around a single axis of rotation.

3.2 Abbreviated terms

2D two-dimensional

3D three-dimensional

CT computed tomography

4 Principles

In order to perform applications which require information on the bone shape of the patient, it may be necessary to accurately obtain the 3D bone geometry in detail. A medical CT apparatus, which has high spatial resolution and does not require surgical invasion, can be used to reconstruct and measure the 3D bones geometries.

One example may be the design of a personalized total knee joint prosthesis. In this example, at the time of implantation, leg alignments need to be considered. Therefore, it is necessary to measure the dimensions of bones after establishing proper leg alignments.

5 Requirements

5.1 Imaging conditions

5.1.1 Medical imaging apparatus

A CT apparatus shall be used for measuring bone geometry from medical images with accurate information. A multi-slice CT apparatus should be used for scanning in short times and to obtain clear images.

Consideration should be given to scan time and the amount of time a patient is required to not move during scanning to ensure that one obtains a quality image without distortion due to patient movement.

5.1.2 Region of interest

The selected region of interest shall include the knee articulation and is intended to take geometric measuring from the physiological bone structure. The selected region of interest can comprise:

a) the full length of the leg;

b) the femoral head, the knee joint, and the talocrural joint;

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