



DRAFT AMENDMENT ISO 21536:2007/DAM 1

ISO/TC 150/SC 4

Secretariat: BSI

Voting begins on
2012-03-08

Voting terminates on
2012-08-08

INTERNATIONAL ORGANIZATION FOR STANDARDIZATION • МЕЖДУНАРОДНАЯ ОРГАНИЗАЦИЯ ПО СТАНДАРТИЗАЦИИ • ORGANISATION INTERNATIONALE DE NORMALISATION

Non-active surgical implants — Joint replacement implants — Specific requirements for knee-joint replacement implants

AMENDMENT 1

Implants chirurgicaux non actifs — Implants de remplacement d'articulation — Exigences spécifiques relatives aux implants de remplacement de l'articulation du genou

AMENDEMENT 1

ICS 11.040.40

ISO/CEN PARALLEL PROCESSING

This draft has been developed within the International Organization for Standardization (ISO), and processed under the **ISO-lead** mode of collaboration as defined in the Vienna Agreement.

This draft is hereby submitted to the ISO member bodies and to the CEN member bodies for a parallel five-month enquiry.

Should this draft be accepted, a final draft, established on the basis of comments received, will be submitted to a parallel two-month approval vote in ISO and formal vote in CEN.

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Amendment 1 to ISO 21536:2007 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 4, *Bones and joint replacement*.

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2014

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Page 3, Clause 5

Add the following as the fourth subclause

' 5.4: Surface finish of articulating surfaces of knee joint components

The requirements for surface finish for UHMWPE, metal and ceramic articulating surface are prescribed in ISO 7207-2.'

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