CEN

WORKSHOP

AGREEMENT

CWA 17253-1

March 2018

ICS 11.040.40

English version

Joint implants - Part 1: Novel methods for isolating wear particles from joint replacements and related devices

This CEN Workshop Agreement has been drafted and approved by a Workshop of representatives of interested parties, the constitution of which is indicated in the foreword of this Workshop Agreement.

The formal process followed by the Workshop in the development of this Workshop Agreement has been endorsed by the National Members of CEN but neither the National Members of CEN nor the CEN-CENELEC Management Centre can be held accountable for the technical content of this CEN Workshop Agreement or possible conflicts with standards or legislation.

This CEN Workshop Agreement can in no way be held as being an official standard developed by CEN and its Members.

This CEN Workshop Agreement is publicly available as a reference document from the CEN Members National Standard Bodies.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

Ref. No.:CWA 17253-1:2018 E

Contents

Page

European foreword

CWA 17253-1:2018 was developed in accordance with CEN-CENELEC Guide 29 "CEN/CENELEC Workshop Agreements – The way to rapid agreement" and with the relevant provisions of CEN/CENELEC internal Regulations – Part 2. It was agreed in a Workshop on 2017-09-26 to 2017-09-28 by representatives of interested parties, approved and supported by CEN following a public call for participation made on 2017-06-15. It does not necessarily reflect the views of all stakeholders that might have an interest in its subject matter.

The final text of CWA 17253-1 was submitted to CEN for publication on 2018-01-30. It was developed and approved by the following organizations listed below:

- Aesculap AG, Dr Jens Schweiesau
- CeramTec GmbH, Dr Alessandro Alan Porporati
- DePuy Synthes Joint Reconstruction, Dr Peter Liao
- Institut Strauman AG, Dr Robert Weedall
- Ionbond UK Ltd., Dr Peter Hatto
- Loughborough University, Dr Liu Yang
- Medicines and Healthcare Products Regulatory Agency (MHRA), Ms Michelle Kelly
- University of Leeds, Prof. Richard Hall, Dr Saurabh Lal, Dr Pirkko Muhonen
- Peter Brehm GmbH, Dr Gerhard Kappelt
- Protheos Industrie, Mr Rémi Brandt
- Queen Mary University of London, Ms Jennifer Quiros

Along with the following individuals:

- Prof. Joanne Tipper, Chairperson
- Prof. Mary Helen Grant, Professor of Biomedical Engineering
- Prof. Thomas Joyce, Professor of Orthopaedic Engineering
- Dr Susan Claire Scholes, Research Fellow.

Those CEN Technical committees supporting technical consensus are as follows:

- CEN/TC 206, *Biological and clinical evaluation of medical devices*
- CEN/TC 285, *Non-active surgical implants*

The development of CWA 17253-1 has received funding from the European Union's Seventh Framework Programme (FP7/2007-2013) under grant agreement no. GA-310477 LifeLongJoints.

The secretariat was held by the British National Standards Institution (BSI).

It is possible that some elements of CWA 17253-1 may be subject to patent rights. The CEN-CENELEC policy on patent rights is set out in CEN-CENELEC Guide 8 "Guidelines for Implementation of the Common IPR Policy on Patents (and other statutory intellectual property rights based on inventions)". CEN shall not be held responsible for identifying any or all such patent rights.

The Workshop participants have made every effort to ensure the reliability and accuracy of the technical and non-technical content of CWA 17253-1, but this does not guarantee, either explicitly or implicity, its correctness. Users of CWA 17253-1 should be aware that neither the Workshop participants, nor CEN can be held laible for damages or losses of any kind whatsoever which may arise from its application. Users of CWA 17253-1 do so on their own responsibility and at their own risk.

Comments or suggestions from the users of the CEN Workshop Agreement are welcome and should be addressed to the CEN-CENELEC Management Centre.

Introduction

Articulating human joint replacements for hips and knees currently constitute a global market exceeding 15 billion USD p.a. which is expected to rise as demographics reflect an ageing population [1]. Furthermore, a significant number of revision operations are performed, with 97 569 hips and 60 818 knees revised between April 2003 and December 2016 in the UK (excluding Scotland) [2]. The most commonly recorded indication for revision is aseptic loosening [2], which has been shown to be often associated with the presence of wear particles [3] and is a limiting factor to hip prostheses achieving long-term performance. In addition, adverse or extreme loading has been shown to have a detrimental effect on implant function [4,5]. Thus, device failure still occurs too frequently, leading to the conclusion that it is necessary for both longevity and reliability of implants to be improved. Improvements in implant performance have resulted from enhanced clinical practice (many failures are directly attributable to imprecise or inadequate surgical procedures) [6], improvements in resistance to wear and corrosion, and the ability of the articulating surfaces to resist mechanical damage.

Whilst improved wear resistance might enhance device longevity [7], in the future such devices are likely only to be successfully placed on the market if, amongst other requirements, the size, volume, morphology and biological impact of wear debris generated during the anticipated functional life of the implant are assessed [8]. Wear is usually assessed on the basis of short- to medium-term joint simulator studies, performed according to international norms (e.g. ISO 14242-1:2014, ISO 14243-3:2014, ISO 18192-1:2011 and ISO 18192-3:2017), from which the wear particles generated per million cycles are isolated. Such evaluation is typically undertaken using wear particle isolation procedures described in ISO 17853:2011. However, as materials are improved and wear volumes reduce, existing methodologies are likely to become obsolete as their isolation capability (of the order of 1 mm^3) is not sufficient to isolate the very low wear volumes (of the order 0,01 mm^3 per million cycles) generated from modern materials. In addition, it is increasingly recognized that particles are generated from multiple interfaces and materials, not just from the bearing surfaces, and therefore there is interest in isolating multiple particle types from a single sample, using minimal steps to limit particle loss, something that is not currently possible using existing published methodologies.

The test method described in CWA 17253-1 has been used successfully to isolate particles of cobalt chrome alloy, zirconia-toughened alumina, silicon nitride, titanium alloy and ultra-high molecular weight polyethylene [9,10]. The methodology might also be applicable to other materials.

1 Scope

This CEN Workshop Agreement (CWA) describes test methods for the isolation and characterization of wear particles generated by joint replacement implants and related devices in animals, humans and in joint simulators. It specifies the apparatus, reagents and methodologies to isolate polyethylene, metallic, ceramic and ceramic-like coating wear particles from both fixed and unfixed tissue samples that are harvested from the periprosthetic site, obtained at revision or post mortem, and from samples of joint simulator test fluids. CWA 17253-1 complements the existing test methods for isolating wear particles of conventional ultra-high molecular weight polyethylene (UHMWPE) from tissues and test fluids from joint simulators, as described in ISO 17853:2011.

The methods described in CWA 17253-1 do not allow quantification of the volume of wear an implant generates; neither do they determine the amount of wear from any particular interface or surface.

CWA 17253-1 does not address the biological impact of wear particles released from joint replacements, which is the topic of CWA 17253-2.

CWA 17253-1 is for use by researchers in the orthopaedic field, implant manufacturers and regulators, with an interest in the wear of implants and analysis of wear particles with the aim of enhancing understanding of implant performance.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

EN ISO 8655-2:2002/AC2009, *Piston-operated volumetric apparatus — Part 2: Piston pipettes (ISO 8655-2:2002/Cor 1:2008)*

ISO 3696:1995, *Water for analytical laboratory use — Specification and test methods (ISO 3696:1995 incorporating Amd 1)*

ISO 4787:2011, *Laboratory glassware — Volumetric instruments — Methods for testing of capacity and for use (ISO 4787:2010/Cor. 2010-06-15)*

ISO 14242-1:2014, *Implants for surgery — Wear of total hip-joint prostheses — Part 1: Loading and displacement parameters for wear-testing machines and corresponding environmental conditions for test*

ISO 16700:2016, *Microbeam analysis — Scanning electron microscopy — Guidelines for calibrating image magnification*

ISO 17853:2011, *Wear of implant materials — Polymer and metal wear particles — Isolation and characterization*

3 Terms, definitions and abbreviations

3.1 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1.1
coated implant
implant that has had a coating applied (usually ceramic-like, e.g. titanium nitride) in order to improve wear resistance or corrosion resistance