Second edition 2011-03-01

Implants for surgery — Wear of total intervertebral spinal disc prostheses —

Part 1:

Loading and displacement parameters for wear testing and corresponding environmental conditions for test

Implants chirurgicaux — Usure des prothèses totales de remplacement des disques intervertébraux lombaires —

Partie 1: Paramètres de charge et de déplacement pour essais d'usure et conditions environnementales correspondantes



Reference number ISO 18192-1:2011(E)

PDF disclaimer

This PDF file may contain embedded typefaces. In accordance with Adobe's licensing policy, this file may be printed or viewed but shall not be edited unless the typefaces which are embedded are licensed to and installed on the computer performing the editing. In downloading this file, parties accept therein the responsibility of not infringing Adobe's licensing policy. The ISO Central Secretariat accepts no liability in this area.

Adobe is a trademark of Adobe Systems Incorporated.

Details of the software products used to create this PDF file can be found in the General Info relative to the file; the PDF-creation parameters were optimized for printing. Every care has been taken to ensure that the file is suitable for use by ISO member bodies. In the unlikely event that a problem relating to it is found, please inform the Central Secretariat at the address given below.



COPYRIGHT PROTECTED DOCUMENT

© ISO 2011

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

Published in Switzerland

Contents Foreword			Page
			iv
1	Scope		1
2	Normative refe	erences	1
3	Terms and def	finitions	1
4	Principle		2
5	Reagents and	materials	3
5.1 5.2		liumrol specimen	
6		ioi specimen	
7	• •		
8			
9	•	st specimenst	
-	-	Statement of rationale for test methods	
		Load and displacement data for cervical implants	
		Load and displacement data for lumbar implants	
	,	Alternative loading conditions	
	` ,	Alternative loading conditions	
DIDIIO	// aprily		∠ɔ

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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 18192-1 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 5, Osteosynthesis and spinal devices.

This second edition cancels and replaces the first edition (ISO 18192-1:2008), of which it constitutes a minor revision. The main modifications are the introduction of the term "cycle limit" (an explicit statement that a different cycle limit can be used with appropriate justification) and the change of the required concentration of calf serum in the fluid test medium to 20 g protein/l.

ISO 18192 consists of the following parts, under the general title *Implants for surgery — Wear of total intervertebral spinal disc prostheses*:

- Part 1: Loading and displacement parameters for wear testing and corresponding environmental conditions for test
- Part 2: Nucleus replacements