
**Biological evaluation of medical
devices —**

Part 6:
Tests for local effects after implantation

Évaluation biologique des dispositifs médicaux —

Partie 6: Essais concernant les effets locaux après implantation



Reference number
ISO 10993-6:2007(E)

© ISO 2007

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 2007

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

Page

Foreword.....	iv
1 Scope	1
2 Normative references	1
3 Terms and definitions.....	2
4 Common provisions for implantation test methods	2
4.1 General.....	2
4.2 Preparation of specimens for implantation	2
5 Test methods, general aspects	3
5.1 Tissue and implantation site	3
5.2 Animals	3
5.3 Test periods.....	4
5.4 Surgery and testing conditions	5
5.5 Evaluation.....	6
6 Test report	8
Annex A (informative) General considerations regarding implantation periods and tissue responses to degradable/resorbable materials	9
Annex B (normative) Test methods for implantation in subcutaneous tissue	10
Annex C (normative) Test method for implantation in muscle.....	12
Annex D (normative) Test method for implantation in bone	14
Annex E (informative) Examples of evaluation of local biological effects after implantation.....	17
Bibliography	19