

Second edition
2018-03

Ophthalmic implants — Intraocular lenses —

Part 10: **Clinical investigations of intraocular lenses for correction of ametropia in phakic eyes**

Implants ophthalmiques — Lentilles intraoculaires —

Partie 10: Investigations cliniques de lentilles intraoculaires pour la correction de l'amétropie des yeux phakes



Reference number
ISO 11979-10:2018(E)



COPYRIGHT PROTECTED DOCUMENT

© ISO 2018

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Fax: +41 22 749 09 47
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Contents

| | Page |
|------------------------------------------------------------------------------------------|-----------|
| Foreword | iv |
| Introduction | v |
| 1 Scope | 1 |
| 2 Normative references | 1 |
| 3 Terms, definitions and abbreviated terms | 2 |
| 3.1 Terms and definitions | 2 |
| 3.2 Abbreviated terms | 2 |
| 4 Optical requirements | 2 |
| 5 Mechanical requirements | 2 |
| 6 Biocompatibility requirements | 2 |
| 7 Shelf-life and transport stability requirements | 2 |
| 8 Fundamental requirements | 2 |
| 9 Justification for a clinical investigation | 3 |
| 10 General clinical requirements | 3 |
| 10.1 General | 3 |
| 10.2 Design of a clinical investigation | 3 |
| 10.2.1 Requirements for all types of phakic IOLs | 3 |
| 10.2.2 Additional requirements for PTIOLs | 3 |
| 10.2.3 Additional requirements for PMIOLs | 4 |
| 10.3 Characteristics | 4 |
| 10.3.1 General | 4 |
| 10.3.2 Characteristics applying to the clinical evaluations for all types of phakic IOLs | 4 |
| 10.3.3 Additional characteristics applying to PTIOLs | 5 |
| 10.3.4 Additional characteristics applying to PMIOLs | 5 |
| 10.4 Duration of the investigation | 5 |
| 10.5 Enrolment | 5 |
| 10.6 Bilateral implantation | 5 |
| 10.7 Surgical technique | 6 |
| 10.8 Examination and treatment of subjects | 6 |
| 10.9 Adverse events reports | 6 |
| 10.10 Inclusion and exclusion criteria | 6 |
| 10.10.1 General criteria for all phakic IOLs | 6 |
| 10.10.2 Additional criteria for PTIOLs | 9 |
| 10.10.3 Additional criteria for multifocal IOLs | 9 |
| 11 Information supplied by the manufacturer | 9 |
| Annex A (informative) Elements in a phakic IOL clinical investigation | 10 |
| Annex B (informative) Statistical methods and sample size calculations | 16 |
| Bibliography | 17 |