ISO 11979-7:2024-01 (E)

Ophthalmic implants - Intraocular lenses - Part 7: Clinical investigations of intraocular lenses for the correction of aphakia

Contents

Page

Contents

Page

Foreword ... **iv**

Introduction ... **v**

1 Scope ... **1**

2 Normative references ... **1**

3 Terms and definitions and abbreviated terms ... **1**
3.1 Terms and definitions ... 1
3.2 Abbreviated terms ... 1

4 Justification for a clinical investigation ... **2**

5 Ethical considerations ... **2**

6 General requirements ... **2**
6.1 General ... 2
6.2 Design of a clinical investigation ... 3
6.2.1 Requirements for all types of IOL ... 3
6.2.2 Additional requirements for toric IOLs (TIOL) ... 3
6.2.3 Additional requirements for Simultaneous Vision IOL (SVIOL) including MIOL, EDF and FVR lenses ... 3
6.2.4 Additional requirements for accommodating IOLs (AIOL) ... 4
6.2.5 Additional requirements for anterior chamber IOLs ... 5
6.3 Characteristics of clinical investigations ... 5
6.3.1 General ... 5
6.3.2 Characteristics to be studied for all types of IOL ... 5
6.3.3 Additional characteristics to be studied for toric IOL ... 6
6.3.4 Additional characteristics to be studied for SVIOLs ... 6
6.3.5 Additional characteristics to be studied for accommodating IOL ... 6
6.3.6 Additional characteristics applying to anterior chamber IOLs ... 6
6.3.7 Additional characteristics ... 6
6.4 Duration of the investigations ... 7
6.5 Enrolment ... 7
6.6 Bilateral implantation ... 7
6.7 Surgical technique ... 8
6.8 Examination and treatment of subjects ... 8
6.9 Adverse events reports ... 8
6.10 Inclusion and exclusion criteria ... 8
6.10.1 General ... 8
6.10.2 General inclusion criteria ... 8
6.10.3 Additional inclusion criteria for toric IOL ... 8
6.10.4 General exclusion criteria ... 9
6.10.5 Additional exclusion criteria for simultaneous vision IOL ... 9
6.10.6 Additional exclusion criteria for anterior chamber IOL ... 9

Annex A (normative) **General elements in the clinical investigation of IOLs** ... **11**

Annex B (informative) **Additional elements for the clinical investigation of toric IOLs** ... **16**

Annex C (informative) **Additional elements for the clinical investigation of simultaneous vision (SVIOL) IOLs** **21**
Annex D (informative) **Additional elements for the clinical investigation of accommodating IOLs** **29**
Annex E (informative) **Evaluation of post operative adverse events and visual acuity rates** **34**
Annex F (informative) **Clinical tests** **38**
Annex G (informative) **Statistical methods and sample size calculations** **46**
Bibliography **51**