ISO 21534:2007-10 (E)

Non-active surgical implants - Joint replacement implants - Particular requirements

Contents

Page

Foreword v

Introduction vi

1 Scope 1

2 Normative references 1

3 Terms and definitions 2

4 Intended performance 2

5 Design attributes 3
5.1 General 3
5.2 Surface finish of metallic or ceramic implants articulating on ultra-high-molecular-weight polyethylene (UHMWPE) 3
5.3 Surface finish of metallic or ceramic partial implants 3
5.4 Surfaces of convex, spherically-conforming metallic or ceramic implants articulating on UHMWPE 3
5.5 Surfaces of spherically-conforming metallic or ceramic partial implants 3
5.6 Surfaces of concave, spherically-conforming UHMWPE components 3

6 Materials 4
6.1 General 4
6.2 Dissimilar metals or alloys 4

7 Design evaluation 4
7.1 General 4
7.2 Preclinical evaluation 4
7.3 Clinical investigation 5
7.4 Post market surveillance 5

8 Manufacture and inspection 5
8.1 General 5
8.2 Metal surfaces 5
8.3 Plastic surfaces 5
8.4 Ceramic surfaces 5

9 Sterilization 6
9.1 General 6
9.2 Expiry 6

10 Packaging 6

11 Information supplied by the manufacturer 6
11.1 General 6
11.2 Labelling of implants for use on one side of the body only 6
11.3 Instructions for orientation of implants 6
11.4 Markings for orientation of the implants 6
11.5 Placing of markings on implants 6
11.6 Restrictions on use 7
11.7 Re-sterilization of zirconia ceramics 7

11.8 Labelling of implants for use with or without bone cement 7

Annex A (informative) List of International Standards for materials found acceptable for the manufacture of implants 8

Annex B (informative) List of International Standards for materials found acceptable or not acceptable for articulating surfaces of implants 9

Annex C (informative) List of materials found acceptable or non-acceptable for metallic combinations for non-articulating contacting surfaces of implants 11

Bibliography 12