

ISO/TS 20721:2025-05 (E)

Implants for surgery - Absorbable implants - General guidelines and requirements for assessment of absorbable metallic implants

Contents

Page

| | |
|---|-----------|
| Foreword..... | iv |
| Introduction..... | v |
| 1 Scope..... | 1 |
| 2 Normative references..... | 1 |
| 3 Terms and definitions..... | 1 |
| 4 Absorbable metal considerations..... | 2 |
| 4.1 General..... | 2 |
| 4.2 Design considerations..... | 3 |
| 4.2.1 Composition..... | 3 |
| 4.2.2 Coatings..... | 4 |
| 4.2.3 Non-absorbable subcomponents..... | 4 |
| 4.2.4 Microstructure..... | 4 |
| 4.2.5 Implant design and functional performance..... | 4 |
| 4.3 Absorption process..... | 5 |
| 4.3.1 General outline..... | 5 |
| 4.3.2 Metallic conversion..... | 5 |
| 4.3.3 Subsequent degradation reactions..... | 6 |
| 4.3.4 Elemental impact on absorption..... | 6 |
| 4.3.5 Biological absorption..... | 6 |
| 4.3.6 Mechanical loss..... | 6 |
| 5 Metallurgical and manufacturing considerations..... | 7 |
| 5.1 General..... | 7 |
| 5.2 Composition..... | 8 |
| 5.3 Production process..... | 8 |
| 5.3.1 General..... | 8 |
| 5.3.2 Raw material purity..... | 8 |
| 5.3.3 Metal melting practice..... | 8 |
| 5.3.4 Metal casting..... | 8 |
| 5.3.5 Metal thermo-mechanical processing..... | 8 |
| 5.3.6 Surface considerations..... | 9 |
| 5.3.7 Implant cleaning, sterilization, packaging, storage and handling..... | 9 |
| 6 Evaluation of in vitro degradation characteristics..... | 9 |
| 6.1 General..... | 9 |
| 6.2 Additional considerations..... | 9 |
| 7 Biological evaluation..... | 10 |
| 7.1 General..... | 10 |
| 7.2 Biocompatibility of degradation products..... | 10 |
| 7.3 In vitro biological evaluation..... | 10 |
| 7.4 In vivo biological evaluation..... | 10 |
| 7.4.1 Biocompatibility end point studies..... | 10 |
| 7.4.2 Animal safety and implant performance studies..... | 11 |
| Annex A (informative) Nomenclature of absorb, degrade and related terms..... | 12 |
| Bibliography..... | 13 |