

ISO/TS 20721:2020 (E)

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

Contents

	Foreword
	Introduction
1	Scope
2	Normative references
3	Terms and definitions
4	Absorbable metal considerations
4.1	General
4.2	Design considerations
4.2.1	Composition
4.2.1.1	General
4.2.1.2	Base element
4.2.1.3	Alloying elements
4.2.1.4	Impurities
4.2.2	Coatings
4.2.3	Non-absorbable subcomponents
4.2.4	Microstructure
4.2.5	Implant design and functional performance
4.3	The absorption process
4.3.1	General outline
4.3.2	Metallic conversion
4.3.3	Subsequent degradation reactions
4.3.4	Elemental impact on absorption
4.3.5	Biological absorption
4.3.6	Mechanical loss
5	Metallurgical and manufacturing considerations
5.1	General
5.2	Composition
5.3	Production process
5.3.1	General
5.3.2	Raw material purity
5.3.3	Metal melting practice
5.3.4	Metal casting
5.3.5	Metal thermo-mechanical processing
5.3.6	Surface considerations
5.3.7	Implant cleaning, sterilization, packaging, storage, and handling
6	Evaluation of in vitro degradation characteristics
6.1	General
6.2	Additional considerations
7	Biological evaluation
7.1	General
7.2	Biocompatibility of degradation products
7.3	In vitro biological evaluation
7.4	In vivo biological evaluation
7.4.1	Biocompatibility end point studies
7.4.2	Animal safety and implant performance studies

Annex A (informative) Nomenclature of absorb, degrade and related terms7 7 Adopted and modified with permission from ASTM F2902-16, X4. Copyright ASTM International. The most current edition can be obtained from www.astm.org.

Page count: 14