

ISO 16061:2021 (E)

Instruments for use in association with non-active surgical implants — General requirements

Contents

	Foreword
	Introduction
1	Scope
2	Normative references
3	Terms and definitions
4	Intended performance
5	Design attributes
6	Selection of materials
7	Design evaluation
7.1	General
7.2	Pre-clinical evaluation
7.3	Clinical evaluation
7.4	Post-market surveillance
8	Manufacture
9	Sterilization
9.1	Instruments supplied sterile
9.2	Instruments supplied non-sterile
9.3	Instruments that are resterilizable
10	Packaging
10.1	Protection from damage in transport, storage and handling
10.2	Maintenance of sterility in transport, storage and handling
11	Information supplied by the manufacturer
11.1	General
11.2	Marking on instruments
11.3	Label
11.4	Instructions for use
11.5	Additional information for instruments with a measuring function
Annex A	(informative) Examples of typical applications of instruments to be used in association with non-active surgical implants and materials found acceptable for instrument manufacture
A.1	General
A.2	Materials
A.2.1	Stainless steels
A.2.2	Cobalt/chromium alloys
A.2.3	Titanium/titanium alloys
A.2.4	Aluminium alloys
A.2.5	Polymers