

ISO 7198:2016-08 (E)

Cardiovascular implants and extracorporeal systems - Vascular prostheses - Tubular vascular grafts and vascular patches

Contents		Page
Foreword		v
Introduction		vi
1	Scope	1
2	Normative references	2
3	Terms and definitions	2
4	General requirements	6
4.1	Configuration designation for tubular vascular grafts	6
4.2	Size designation	7
4.2.1	Uniform straight tubular vascular grafts	7
4.2.2	Uniform bifurcated tubular vascular grafts	7
4.2.3	Tapered tubular vascular grafts	7
4.2.4	Other configurations of tubular vascular grafts	7
4.2.5	Vascular patches	7
4.3	Materials	7
4.3.1	General	7
4.3.2	Classification of tubular vascular grafts and vascular patches	7
4.3.3	Nomenclature	8
4.4	Intended clinical use designation	8
5	Intended performance	9
6	Design attributes	9
6.1	General	9
6.2	Tubular vascular grafts	9
6.3	Vascular patches	9
6.4	Coatings	10
6.5	Drug coatings and drug-eluting coatings	10
7	Materials	10
8	Design evaluation	10
8.1	General	10
8.2	Sampling	11
8.3	Conditioning of test samples	11
8.4	Reporting	11
8.5	Biocompatibility	12
8.5.1	Residual chemicals	12
8.5.2	Biocompatibility	12
8.6	Biostability	12
8.7	Bench and analytical tests	13
8.7.1	General	13
8.7.2	Tubular vascular grafts	13
8.7.3	Vascular patches	15
9	Preclinical in vivo evaluation test methods for vascular prostheses	16
9.1	Preclinical in vivo evaluation	16

9.1.1	Purpose	16
9.1.2	Specific aims	17
9.1.3	Protocol considerations	17
9.1.4	Data acquisition	17
9.1.5	Test report and additional information	18
10	Clinical investigation methods for vascular prostheses	19
10.1	Clinical investigation	19
10.1.1	Purpose	19
10.1.2	Specific aims	19
10.1.3	Protocol considerations	19
10.1.4	Data acquisition	20
10.1.5	Final report	23
10.2	Post market surveillance	24
11	Manufacturing	24
12	Sterility	24
13	Packaging and labelling	25
13.1	General	25
13.2	Unit container	25
13.3	Outer container	25
13.4	Shipping container	25
13.5	Maintenance of sterility in transit	25
13.6	Marking	25
13.6.1	Container label	25
13.6.2	Record label	26
13.6.3	General information and instructions for use	26
Annex A (informative)	Test methods	27
Bibliography	54