

ISO 10555-4:2023-11 (E)

Intravascular catheters - Sterile and single-use catheters - Part 4: Balloon dilatation catheters

Contents		Page
Foreword		iv
1	Scope	1
2	Normative references	1
3	Terms and definitions	1
4	Requirements	2
4.1	General	2
4.2	Detectability of the balloon position	2
4.3	Designation of nominal size	2
4.4	Physical requirements	2
4.4.1	Balloon rated burst pressure (RBP)	2
4.4.2	Balloon fatigue; freedom from leakage and damage on inflation	2
4.4.3	Balloon deflation time	2
4.4.4	Balloon diameter to inflation pressure (balloon compliance)	2
4.4.5	Crossing profile	3
4.4.6	Balloon removal	3
4.5	Information to be supplied with the catheter	3
Annex A (normative) Test for rated burst pressure (RBP)		4
Annex B (normative) Balloon fatigue test for freedom from leakage and damage on inflation		6
Annex C (normative) Test for balloon deflation time		8
Annex D (normative) Test for balloon diameter to inflation pressure (balloon compliance)		10
Annex E (normative) Determination of crossing profile		12
Annex F (normative) Test method for balloon removal		14
Annex G (informative) Rationale and guidance		16
Bibliography		17