

DIN EN ISO 11070:2018-10 (E)

Sterile single-use intravascular introducers, dilators and guidewires (ISO 11070:2014 + Amd 1:2018) (inclu des Amendment :2018)

Contents		Page
European foreword		4
European Foreword to Amendment A1		5
Foreword to Amendment 1		6
Introduction		7
1	Scope	8
2	Normative references	8
3	Terms and definitions	8
4	General requirements	12
4.1	Sterilization	12
4.2	Biocompatibility	12
4.3	Surface	12
4.4	Corrosion resistance	12
4.5	Radio-detectability	12
4.6	Information to be supplied by the manufacturer	12
5	Additional requirements for introducer needles	13
5.1	General	13
5.2	Size designation	13
5.3	Needle point	13
5.4	Hub	13
5.5	Information to be supplied by the manufacturer	13
6	Additional requirements for introducer catheters	13
6.1	General	13
6.2	Tip	14
6.3	Peak tensile force	14
6.4	Hub	14
6.5	Size designation	14
6.6	Information to be supplied by the manufacturer	15
7	Additional requirements for sheath introducers	15
7.1	General	15
7.2	Size designation	15
7.3	Freedom from leakage from sheath introducer	15
7.4	Freedom from leakage through haemostasis valve	15
7.5	Hub	15
7.6	Peak tensile force	15
7.7	Information to be supplied by the manufacturer	15
8	Additional requirements for guidewires	15
8.1	General	15
8.2	Size designation	16
8.3	Safety wire	16
8.4	Fracture test	16

8.5	Flexing test	16
8.6	Peak tensile force of guidewire	16
8.7	Information to be supplied by the manufacturer	17
9	Additional requirements for dilators	17
9.1	General	17
9.2	Size designation	17
9.3	Hub	17
9.4	Information to be supplied by the manufacturer	17
10	Additional requirements for kits containing combinations of devices specified in this International Standard	17
Annex A (informative) Guidance on materials and design		19
Annex B (normative) Test method for corrosion resistance		20
Annex C (normative) Method for determining peak tensile force of introducer catheters, sheath introducers, and dilators		21
Annex D (normative) Test method for liquid leakage from sheath introducers under pressure		23
Annex E (normative) Test method for liquid leakage through haemostasis valves of sheath introducers		25
Annex F (normative) Test method for fracture of guidewires		26
Annex G (normative) Test method for resistance of guidewires to damage by flexing		28
Annex H (normative) Method for determining peak tensile force of guidewires		30
Annex I (normative) Determination of strength of union of needle hub and needle		31
Bibliography		32