

DIN EN ISO 11070:2019-04 (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