

Sterile intravascular catheters and ancillary devices for single use —

Part 4: Specification for introducer needles, introducer cannulae, guide wires, dilators, valves and connectors

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Contents

	Page
Committees responsible	Inside front cover
Foreword	ii
Section 1. General	
1 Scope	1
2 Definitions	1
Section 2. Introducer needles	
3 General	2
4 Size designation	2
5 Needle tube	2
6 Needle hub	2
7 Marking	2
Section 3. Introducer cannulae	
8 General	3
9 Size designation	3
10 Materials	3
11 Tip	3
12 Hub	3
13 Mechanical properties	3
14 Lubrication	3
15 Marking	3
Section 4. Guide wires	
16 General	5
17 Materials	5
18 Size designation	5
19 Safety wire	5
20 Mechanical properties	5
21 Marking	5
Section 5. Dilators	
22 General	7
23 Materials	7
24 Size designation	7
25 Tip	7
26 Shaft	7
27 Hub	7
28 Marking	7
Section 6. Valves and connectors	
29 General	8
30 Materials	8
31 Type or size designation	8
32 Hub	8
33 Security of attached tubing	8
34 Freedom from leakage	8
35 Freedom from leakage and damage under high pressure	8
36 Marking	8
Appendix A Guidance on materials and design of ancillary devices	9
Appendix B Method of test for breakage of guide wires	10
Appendix C Method of test for flexibility of guide wires	10
Appendix D Method of test for strength of component parts of guide wire	12

	Page
Figure 1 — Schematic diagram of introducer needle and introducer cannula	4
Figure 2 — Schematic diagram of guide wires	6
Figure 3 — Apparatus for testing guide wires for breakage	9
Figure 4 — Test rig for testing flexibility of guide wires	10
Figure 5 — Split tapered clamp	11
Figure 6 — Details of clamping guide wire in split tapered clamp	13
Table 1 — Designation of needle size	2
Table 2 — Forces for testing safety wire and core wire	12
Publications referred to	Inside back cover

Foreword

BS 7174 has been prepared under the direction of the Health Care Standards Policy Committee. It embraces a combined revision of BS 5322:1976 and BS 5616:1981, which it supersedes and which are withdrawn, but it also extends the scopes of those standards to cover other types of intravascular catheter and their ancillary devices.

BS 7174 is published in several Parts. Part 1 gives general requirements for intravascular catheters and ancillary devices; Part 2 gives specific requirements for angiographic catheters (previously covered, as radiographic diagnostic catheters, by BS 5322); Part 3 gives specific requirements for central venous catheters (previously covered, as intravascular catheters, by BS 5616); and this Part specifies requirements for a range of ancillary devices, some of which were previously covered by BS 5322 and BS 5616. It is intended that further Parts of BS 7174, giving specific requirements for other types of intravascular catheter will be prepared in future.

It has not yet been found possible to specify a satisfactory method of measuring radio-opacity. Consequently the packaging of ancillary devices that are made of material which is inherently radio-opaque, or to which a radio-opacifying agent has been admixed, is to be marked "RADIO-OPAQUE".

Guidance on materials and design of ancillary devices is given in Appendix A. Ancillary devices should be manufactured and sterilized in accordance with the recommendations in the "Guide to Good Manufacturing Practice for Sterile Medical Devices and Surgical Products"¹⁾. Attention is also drawn to the manufacturer's registration scheme administered by the Department of Health.

Product certification. Users of this British Standard are advised to consider the desirability of third party certification of product conformity with this British Standard based on testing and continuing surveillance, which may be coupled with assessment of a supplier's quality systems against the appropriate Part of BS 5750.

Enquiries as to the availability of third party certification schemes will be forwarded by BSI to the Association of Certification Bodies. If a third party certification scheme does not already exist, users should consider approaching an appropriate body from the list of Association members.

A British Standard does not purport to include all the necessary provisions of a contract. Users of British Standards are responsible for their correct application.

Compliance with a British Standard does not of itself confer immunity from legal obligations.

Summary of pages

This document comprises a front cover, an inside front cover, pages i to iv, pages 1 to 14, an inside back cover and a back cover.

This standard has been updated (see copyright date) and may have had amendments incorporated. This will be indicated in the amendment table on the inside front cover.

¹⁾ Compiled by the Department of Health and Social Security; published and available from Her Majesty's Stationery Office. ISBN 011 320770 0

Section 1. General

1 Scope

This Part of BS 7174 specifies requirements for introducer needles, introducer cannulae, guide wires, dilators, valves and connectors supplied in the sterile condition and intended for single use in conjunction with intravascular catheters specified in Parts 1, 2 and 3 of BS 7174.

It excludes intravascular cannula units and introducer needles for epidural catheters.

NOTE 1 The requirements in this Part of BS 7174 are additional to those given for ancillary devices in BS 7174-1.

NOTE 2 Notes on the materials and design of ancillary devices are given in Appendix A.

NOTE 3 Attention is drawn to BS 4843 regarding intravascular cannula units and to BS 6196 regarding epidural catheters and their introducer needles.

NOTE 4 The titles of the publications referred to in this standard are listed on the inside back cover.

2 Definitions

For the purposes of this Part of BS 7174, the definitions given in BS 7174-1 apply, together with the following.

2.1

patient end (of guide wire)

flexible end of the guide wire which is inserted into the patient

2.2

tip (of guide wire)

rounded, sealed portion at the extremity of the patient end of the guide wire

2.3

core wire (of guide wire)

inner wire used to achieve stiffness of the guide wire, and to assist in the steering of the tip

NOTE The core wire may not extend to the tip of the guide wire.

2.4

coil (of guide wire)

outer wire of one continuous length helically wound round the core of the guide wire

2.5

safety wire (of guide wire)

additional wire joining the free end and tip of the guide wire

2.6

free end (of guide wire)

end of the guide wire opposite the patient end, containing the area of attachment of the core wire and coil