

Cardiovascular implants —

**Part 1: Methods of test for heart valve
substitutes and requirements for their
packaging and labelling**

Committees responsible for this British Standard

The preparation of this British Standard was entrusted by the Health Care Standards Policy Committee (HCC/-) to Technical Committee HCC/23, upon which the following bodies were represented:

- Association of Anaesthetists of Great Britain and Ireland
- Association of Renal Technicians
- British Cardiac Society
- British Plastics Federation
- British Surgical Trades Association
- British Textile Technology Group
- Cardiac Surgical Research Club
- Cardiothoracic Institute
- Department of Health
- Institute of Physical Sciences in Medicine
- Medical Sterile Products Association
- Ministry of Defence
- Renal Association
- Royal College of Nursing
- Royal College of Physicians of London
- Royal College of Surgeons of England
- Scottish Office
- Society of Perfusionists (of Great Britain and Ireland)
- Society of Thoracic and Cardiovascular Surgeons
- Vascular Surgical Society of GB

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Contents

	Page
Committees responsible	Inside front cover
National foreword	ii
1 Scope	1
2 Definitions	1
3 Testing of materials	3
4 Testing of components	3
5 Testing of heart valve substitutes	3
6 Packaging and labelling	7
Annex A (informative) Test methods that may be of use in the evaluation of materials for heart valve substitutes	9
Annex B (informative) Rationale for the provisions of this International Standard	9
National appendix Z	10
Figure 1 — Designation of dimensions of heart valve substitutes	1
Figure 2 — Simulated flow wave-form showing regurgitant volume (closing volume plus leakage volume) for one cycle	2
Figure 3 — Diagrams of haemodynamic wave-forms simulating those of healthy humans	2
Publications referred to	Inside back cover

National foreword

This revision of this Part of BS 6444 has been prepared under the direction of the Health Care Standards Policy Committee. It is identical to ISO 5840:1989 “*Cardiovascular implants — Cardiac valve prostheses*”, published by the International Organization for Standardization (ISO). It supersedes BS 6444-1:1984, which is withdrawn.

BS 6444 is being published in a number of Parts to deal with cardiovascular implants of various types. The first edition of Part 1, published in 1984, only specified the designation, packaging and labelling of heart valve substitutes but, in this revision, the scope of the standard has been widened to encompass other attributes of heart valve substitutes, notably test methods.

There is, as yet, no heart valve substitute which can be regarded as ideal and, hence, there is no universal reference valve by which new and existing devices can be assessed. In addition, this Part of BS 6444 does not specify the design characteristics for heart valve substitutes because such details could be construed as inhibiting development and innovation. Certain essential performance characteristics are specified but, in order to avoid introducing restrictions which could limit the design of new products, these do not cover all the attributes of these devices. This second edition of this Part of BS 6444 does, however, specify types of tests, methods of testing and/or the requirements for test apparatus which are to be used in evaluating heart valve substitutes. It also requires the disclosure of the test methods that were used and the results obtained from the tests.

This Part of BS 6444 is primarily concerned with the areas which are intended to facilitate quality assurance, aid the surgeon in his choice of heart valve substitute, and ensure that the device will be presented in a convenient form at the operating table. Therefore, emphasis has been placed on specifying types of *in vitro* testing, on *in vivo* animal and clinical evaluations, on reporting of all *in vitro*, *in vivo* and clinical studies, and on the labelling and packaging aspects of the device. Such requirements, involving *in vitro*, *in vivo*, and clinical studies, are intended to ensure that verifiable procedures have been carried out prior to market release and to enable prompt identification and notification of any subsequent problems.

All who are involved in the evaluation of heart valve substitutes in human subjects share the responsibility for ensuring that the rights and integrity of human subjects are protected. Clinical evaluations should conform with codes such as those of the World Medical Association “Declaration of Helsinki” and its subsequent revisions, and of the World Health Organization and its associated bodies. Clinical evaluations should be subject to prior local research ethics committee approval.

After completing the clinical study (see 5.6.1.3), it is strongly recommended that the progress of each recipient of a heart valve substitute should be evaluated at regular intervals for as long as feasible. These follow-up studies should be carried out with the subject’s consent and the agreement of the subject’s physician.

Clinicians who complete the patient identification form (6.4.4) will know that personal health information is to be kept confidential and that the patient’s consent is a prerequisite for giving his/her name to a manufacturer. A prospective purchaser of a device may wish the manufacturer to make available valid data obtained as a result of post-market surveillance, but no subject should be identifiable.

With regard to *in vitro* testing and reporting, apart from basic material testing for mechanical, physical, chemical and biocompatibility¹⁾ characteristics, this Part of BS 6444 also covers important hydraulic and accelerated fatigue properties of heart valve substitutes. Although the exact test methods have not been specified for hydrodynamic and accelerated fatigue testing, the requirements for the test apparatus are given.

¹⁾ See National appendix Z.

This Part of BS 6444 will be revised and updated as knowledge of techniques and technology improves.

Further Parts of this British Standard to cover other cardiovascular implants are under consideration.

Assessed capability. Users of this British Standard are advised to consider the desirability of assessment and registration of a supplier's quality systems against the appropriate Part of BS 5750 by a third party certification body.

Cross-references. Although no normative standards are referred to in this standard, Annex A lists several International Standards for information. The correspondence of some of these standards with British Standards is given for convenience.

International Standard	Corresponding British Standard
	BS 2782 <i>Methods of testing plastics</i>
ISO 178:1975	Method 335A:1978 <i>Determination of flexural properties of rigid plastics</i> (Identical)
ISO 1133:1981	Method 720A:1979 <i>Determination of melt flow rate of thermoplastics</i> (Technically equivalent)
ISO 5832	BS 7252 <i>Metallic materials for surgical implants</i> (Technically equivalent)
	BS 3531 <i>Implants for osteosynthesis</i>
ISO 5834-1:1985	Part 20:1986 <i>Specification for ultra-high molecular mass polyethylene in powder form</i> (Identical)

Additional information. When considering the publication of ISO 5840 as a dual-numbered BS/ISO standard, the committee responsible decided that additional information should be provided to supplement the requirements given in clause 3. This information is presented in the National appendix Z to this British Standard.

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 10, 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.

