

Specification for

Materials and packaging of surgical scalpels with detachable blades

ICS 11.040.30; 55.040

Committees responsible for this British Standard

The preparation of this British Standard was entrusted by the Healthcare Standards Policy Committee (HCC/-) to Technical Committee HCC/43, upon which the following bodies were represented:

British Steel Industry
 British Surgical Trades Association
 Department of Health
 Institute of Sterile Services Management
 Medical Sterile Products Association
 National Association of Theatre Nurses
 Royal College of Nursing
 Royal College of Surgeons of Edinburgh
 Royal College of Surgeons of England

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Foreword

This British Standard has been prepared under the direction of the Healthcare Standards Policy Committee and supersedes BS 2982:1986 which is withdrawn. BS 2982 was first published in 1958 and was revised in 1974. The first revision introduced provisions for scalpel blades made of stainless steel and for sterile packages of blades.

The second revision of BS 2982 introduced amended dimensions for the fittings whereby blades are attached to handles. Two sizes of fitting were specified, namely the small size (no. 3 fitting) and the large size (no. 4 fitting). The revised dimensions were identical to those given in ISO 7740:1985 prepared by Technical Committee 170, Surgical instruments, of the International Organization for Standardization (ISO), and the objective was to ensure that a satisfactory fit was achieved between any combination of blade and handle manufactured in accordance with the British Standard, ISO 7740:1985 or any foreign national standards having the same dimensional requirements.

This revision of BS 2982 accommodates the implementation of BS EN 27740:1992 *Specification for dimensions of surgical scalpels with detachable blades* which now specifies only the dimensional requirements. This allows BS 2982 to now restrict its provisions to requirements for the materials used for surgical scalpels and requirements for the packaging of blades and handles.

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 continued product surveillance which may be coupled with assessment of a supplier's quality systems against BS EN ISO 13485:2003.

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Summary of pages

This document comprises a front cover, an inside front cover, pages i and ii, pages 1 to 4, 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 Scope

This British Standard specifies requirements for materials and for the packaging of blades and handles of surgical scalpels with detachable blades.

NOTE Dimensional requirements for surgical scalpels are specified in BS EN 27740:1992.

2 References

2.1 Normative references

This British Standard incorporates, by reference, provisions from specific editions of other publications. These normative references are cited at the appropriate points in the text and the publications are listed on the inside back cover. Subsequent amendments to, or revisions of, any of these publications apply to this British Standard only when incorporated in it by updating or revision.

2.2 Informative reference

This British Standard refers to another publication that provides information or guidance. The edition of this publication current at the time of issue of this standard is given on the inside back cover, but reference should be made to the latest edition.

3 Dimensions of blades and handles

The dimensions of blades and handles shall be in accordance with BS EN 27740:1992.

4 Handle

4.1 Hardness

The Vickers hardness of metal handles shall be not less than 140 HV. The Vickers hardness shall be determined on the face of the head of the handle [see Figure 1 a)] in accordance with BS EN ISO 6507-1:1998.

4.2 Construction

The handle shall be of one-piece construction.

4.3 Groove

There shall be a groove in the head of the handle [see Figure 1 b)]. The groove shall be such that when a blade is fitted into the groove, the cutting edge of the fitted blade shall lie in a plane through the linear axis of the handle [see Figure 1 b)].

4.4 Finish

The handle shall be free from burrs and sharp or rough edges.

NOTE The handle may have a matt, polished or other finish, as agreed between the manufacturer and the purchaser.

5 Blade

5.1 Material

5.1.1 Carbon steel

Blades made of carbon steel shall have the composition given in Table 1.

Table 1 — Composition of carbon steel for scalpel blades

	Range % (m/m)
Carbon	1.20 to 1.30
Silicon	0.10 to 0.35
Manganese	0.20 to 0.45
Chromium	0.10 to 0.40
Sulfur	0.025 max.
Phosphorous	0.035 max.

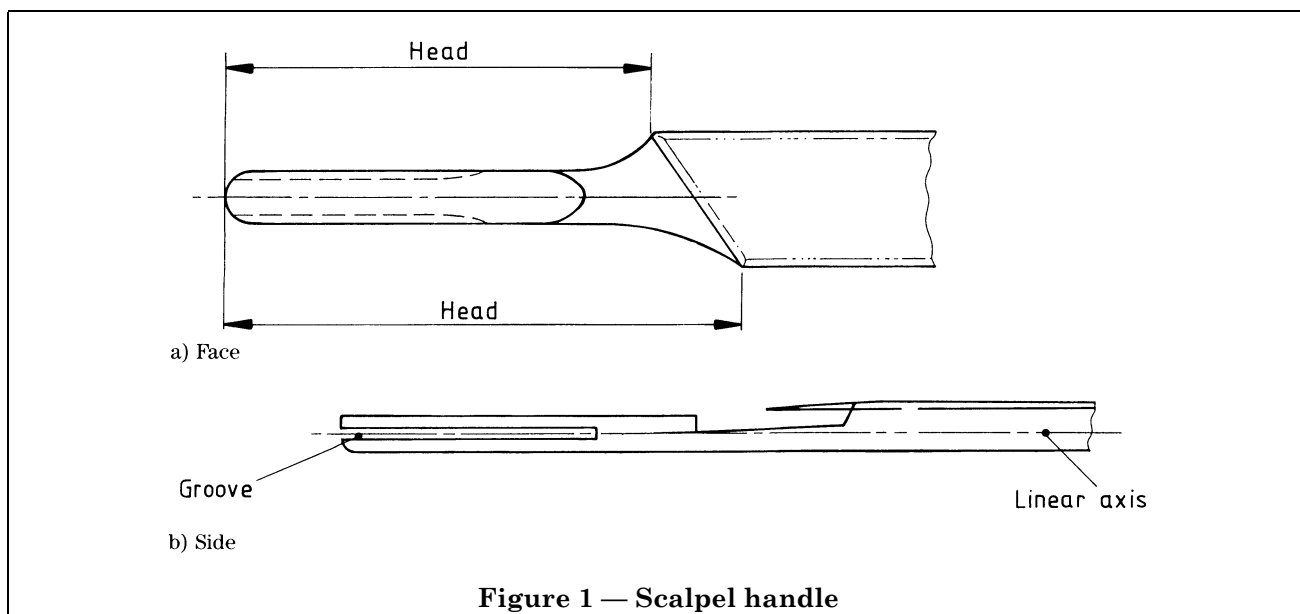


Figure 1 — Scalpel handle

5.1.2 Stainless steel

Blades made of stainless steel shall be made of steel of compositions D, E, F or G in accordance with BS 5194-1:1991.

5.2 Hardness

5.2.1 Blades made from carbon steel

The Vickers hardness of carbon steel blades shall be not less than 800 HV. The Vickers hardness shall be determined as near to the cutting edge as practicable in accordance with BS EN ISO 6507-1:1998.

5.2.2 Blades made from stainless steel

The Vickers hardness of stainless steel blades shall be not less than 700 HV. The Vickers hardness shall be determined as near to the cutting edge as practicable in accordance with BS EN ISO 6507-1:1998.

5.3 Finish

When inspected by normal or corrected vision, the blade shall have a smooth finish and shall be free from burrs and corrosion.

5.4 Cutting edge

The central plane of the cutting edge shall be central with respect to the blade and, when inspected by normal or corrected vision, shall be free from nicks, burrs and feathered edges.

5.5 Freedom from extraneous matter

The blade shall be clean and free from extraneous matter when inspected by normal or corrected vision.

6 Packaging of handles

Handles shall be individually packed.

7 Packaging of blades

7.1 Packages of non-sterile blades

7.1.1 Unit container

Except for blades made of stainless steel, the package shall contain a corrosion-inhibiting material. The blades shall be either individually wrapped or wrapped in such a manner that the edges cannot come into contact with each other.

7.1.2 Outer container

Unit containers shall be packed in an outer container.

NOTE The outer container should be sufficiently robust to protect the contents during transit and storage.

7.2 Packages of sterile blades

7.2.1 Unit container

Except for blades made of stainless steel, the package shall contain a corrosion-inhibiting material. Each sterile blade shall be individually packed in a sealed container.

NOTE The sealed container should be sufficiently robust to maintain the sterility of its contents under the conditions of handling and storage normally encountered in hospitals and medical practice.

7.2.2 Outer container

Unit containers shall be packed in an outer container.

NOTE The outer container should be sufficiently robust to protect the contents during transit and storage.

8 Marking

8.1 Handles

Handles shall be permanently marked with the following:

- the size number appropriate to either small or large fittings in accordance with BS EN 27740:1992;
- name or registered trade mark of the manufacturer;
- the number of this British Standard, i.e. BS 2982¹⁾.

8.2 Packages of handles

Packages containing handles shall be marked with the following:

- the size number appropriate to either small or large fittings in accordance with BS EN 27740:1992, i.e. No. 3 or No. 4;
- the size of fitting, i.e. small or large in accordance with BS EN 27740:1992;
- the name or registered trade mark of the manufacturer and/or supplier;
- the number of this British Standard, i.e. BS 2982:1992¹⁾.

8.3 Blades

Blades shall be permanently marked with the following:

- the manufacturer's designation of blade pattern;
- the name or registered trade mark of the manufacturer.

¹⁾ Marking BS 2982:1992 on or in relation to a product represents a manufacturer's declaration of conformity, i.e. a claim by or on behalf of the manufacturer that the product meets the requirements of the standard. The accuracy of the claim is solely the claimant's responsibility. Such a declaration is not to be confused with third party certification of conformity, which may also be desirable.

8.4 Packages of non-sterile blades

8.4.1 Unit containers for non-sterile blades

Packages of non-sterile blades shall be marked with the following:

- a) the quantity;
- b) the manufacturer's designation of blade pattern;
- c) the name or registered trade mark of the manufacturer and/or supplier;
- d) the number of this British Standard, i.e. BS 2982:1992²⁾.

8.4.2 Outer containers for non-sterile blades

Outer containers for packages of blades shall be marked as specified in 8.4.1 with the addition of the size of fitting.

8.5 Packages of sterile blades

8.5.1 Unit containers for sterile blades

Sterile packages shall be marked with the following:

- a) the description of the contents, including the manufacturer's designation of blade pattern;
- b) the word "STERILE" in prominent lettering;
- c) the date of manufacture and/or batch number;
- d) the name or registered trade mark of the manufacturer and/or supplier;
- e) the number of this British Standard, i.e. BS 2982:1992²⁾.

8.5.2 Outer containers for sterile blades

Outer containers for sterile blades shall be marked with the following:

- a) description of contents, including quantity, manufacturer's designation of blade pattern and the size of fitting;
- b) the word "STERILE" or equivalent in prominent lettering;
- c) date of manufacture and/or batch number;
- d) date of sterilization (month and year);
- e) name and address of the manufacturer and/or supplier;
- f) the number of this British Standard, i.e. BS 2982:1992²⁾.

²⁾ Marking BS 2982:1992 on or in relation to a product represents a manufacturer's declaration of conformity, i.e. a claim by or on behalf of the manufacturer that the product meets the requirements of the standard. The accuracy of the claim is solely the claimant's responsibility. Such a declaration is not to be confused with third party certification of conformity, which may also be desirable.

List of references (see clause 2)

Normative references

BS 5194, *Surgical instruments*.

BS 5194-1:1991, *Specification for stainless steel*.

BS EN 27740:1992, *Specification for the dimensions of surgical scalpels with detachable blades*.

BS EN ISO 6507-1:1998, *Metallic materials — Vickers hardness test — Part 1: Test method*.

Informative reference

BS EN ISO 13485:2003, *Medical devices — Quality management systems — Requirements for regulatory purposes*³⁾.

ISO 7740:1986, *Instruments for surgery, Scalpels with detachable blades, Fitting dimensions*³⁾.

³⁾ Referred to in the foreword only.

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