BSI

BS 5194 : Part 1 : 1985

UDC [615.472:616–72]:669.14.018.8

British Standard

Surgical instruments

Part 1. Specification for stainless steels

Instruments chirurgicaux
Partie 1. Aciers inoxydables — Spécifications

Chirurgische Instrumente
Teil 1. Rostfreie Stähle

British Standards Institution

Contents

Foreword

This Part of BS 5194 has been prepared under the direction of the Health Care Standards Committee.

BS 5194 has been revised in a number of Parts and constitutes a major change in the approach to the standardization of surgical instruments.

Hitherto, requirements for individual types and patterns of instrument have been published as separate British Standards, each standard containing individual requirements for materials, design, dimensions and other features of the instrument. The number of types of instrument and the number of patterns of each type were necessarily limited to those in the most common use at the time the standards were prepared. As a consequence, many instruments were not covered by a standard because, although identical in general features, such as materials, surface finish and corrosion resistance, to instruments that were covered, they differed in physical characteristics such as dimensions and details of design.

The Technical Committee responsible for the revision of BS 5194 believes that the finer points of design that differentiate, say, Spencer Wells artery forceps from Dunhill's artery forceps are not relevant to the properties that ensure the quality and workmanship of the instrument. The committee believes that the value of a standard lies in ensuring the general quality of a large range of instruments and that adherence to the design features of particular named patterns of instrument is the province of the instrument manufacturer.

The committee has therefore adopted the approach of classifying most varieties of general surgical instrument into a small number of categories, based chiefly on similarities in materials and major constructional features, and preparing a Part of BS 5194 for each category giving requirements for those features that will ensure satisfactory quality. In addition, it has also been decided to gather together requirements for materials (initially stainless steel) for instruments and publish these as Parts of BS 5194.

BS 5194 was first published as BS 5194 : Part 1 in 1976 under the title 'Specification for surgical instruments with bow handles (excluding scissors)' Part 1 'General requirements' and was intended to be supplemented by further Parts dealing with specific types of bow handled forceps, although none were published because at that time work on the international standardization of surgical instruments began in Technical Committee 170 'Surgical instruments' of the International Organization for Standardization (ISO) and work in the UK was aligned with that in TC 170.

The number 'BS 5194' has been retained for the revision because of its familiarity among instrument manufacturers and purchasers, even though the revision differs considerably in content and intent from the 1976 edition. BS 5194 will cover all general surgical instruments to be standardized, except that the specification for detachable scalpel blades and their handles will continue as BS 2982, again because of familiarity with this number among users of the standard and BS 3259 (Peters' aural specula) and BS 3348 (antral trocars and cannulae) will be retained as separate standards, both having been declared obsolescent in 1984. The British Standards for surgical instruments currently published or in course of preparation are as follows:

BS 2982 Scalpels with detachable blades

BS 3259 Peters' aural specula (declared obsolescent)

BS 3348 Antral trocars and cannulae (declared obsolescent)

BS 5194 Surgical instruments
Part 1. Specification for stainless steels
Part 2. Specification for instruments with pivot joints (excluding cutting instruments)
Part 3. Specification for dissecting forceps
Part 4. Specification for scissors, shears and other jointed cutting instruments

Further Parts of BS 5194 covering other materials or categories of instrument may be prepared in future. BS 5194 is not intended to cover specialized instruments for use only in limited surgical specialities and attention is drawn to BS 3531 : Part 5 which specifies requirements for screwdrivers, taps and drills for use in orthopaedic surgery. BS 2820 (surgical scalpels) was withdrawn in 1984.

Notification of the British Standards superseded by the publication of each Part of BS 5194 will be given in the foreword to each Part. However, for information, attention is drawn to the following list.

New Part of BS 5194	British Standard to be superseded
Part 1	—
Part 2	BS 2805 : 1957 Straight artery (haemostatic) forceps. Spencer Wells pattern (screw joint)
	BS 2905 : 1957 Cheatle's sterilizer forceps (light and heavy patterns)
	BS 3039 : 1959 Rampley's sponge holding forceps
	BS 3147 : 1959 Dunhill's artery forceps
	BS 3204 : 1960 Harrison's bowl forceps
	BS 3246 : 1960 Halsted's mosquito forceps
	BS 3354 : 1961 Sinus forceps
	BS 3355 : 1961 Spencer Wells artery forceps (straight and curved) with box joints
	BS 3419 : 1961 Tilley's aural and nasal forceps
	BS 3742 : 1964 French pattern bow dressing forceps
	BS 3743 : 1964 Mayo's tongue and towel forceps
	BS 3744 : 1964 Allis tissue forceps
	BS 3991 : 1966 Doyen's mouth gag
	BS 5194 Specification for surgical instruments with bow handles (excluding scissors) Part 1 : 1976 General requirements

Part 3	BS 2821 : 1957 Dissecting forceps (plain ends) made of corrosion resisting steel
	BS 3741 : 1964 Treves's toothed dissecting forceps
Part 4	BS 3646 : 1963 Surgical dressing and stitch scissors
	BS 3793 : 1964 Mayo's operating scissors (with dished blades)

This Part of BS 5194 is technically equivalent to ISO 7153/1-1983 'Instruments for surgery — Metallic materials' Part 1. 'Stainless steel', prepared by Technical Committee 170 of ISO.

This Part of BS 5194 gives the compositions of a number of grades of stainless steel suitable for the manufacture of surgical instruments and, in appendix A, presents recommendations for the suitability of these grades for the manufacture of different types of instrument. It is intended that subsequent Parts of BS 5194 dealing with particular types of instrument will give requirements for the grade of stainless steel that will implement some of these recommendations. The recommendations in appendix A are intended to foster the use of suitable materials until such time as subsequent Parts are published and, in the case of instruments for which the preparation of a subsequent Part is not foreseen, to act as a permanent guide.

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

Specification

1 Scope

This Part of BS 5194 specifies the chemical composition of grades of stainless steel suitable for the manufacture of surgical instruments. Recommendations for applications for stainless steels are given in appendix A.

This Part of BS 5194 does not apply to specialized instruments for orthopaedic surgery. Attention is drawn to BS 3531 : Part 5.

NOTE 1. Reference should be made to other Parts of BS 5194 and to other British Standards for particular types of surgical instruments as they become available, as they will contain requirements in which the recommendations given in appendix A have been adopted.

NOTE 2. The titles of the publications referred to in this Part of BS 5194 are listed on page 5.

2 Chemical composition of stainless steels

Each grade of steel shall contain the chemical elements given in table 1 in the proportions given in table 1.

NOTE. Elements not listed in table 1 should not intentionally be added to the steel without the agreement of the purchaser. Precautions should be taken to prevent the addition, from scrap or other material used in manufacture, of such elements that affect hardenability, mechanical properties and applicability.

Table 1. Chemical composition (cast analysis) of stainless steels for surgical instruments

Steel grade			Chemical composition								
Reference letter	Grade no.* according to:		C	Si max.	Mn max.	P max.	S	Cr	Mo	Ni	Other elements
	ISO 4957	ISO 683/13									
Martensitic steels											
			%	%	%	%	%	%	%	%	%
A	–	3	0.09 to 0.15	1.0	1.0	0.040	0.030 max.	12.0 to 13.5	–	1.0 max.	–
B	27	4	0.16 to 0.25	1.0	1.0	0.040	0.030 max.	12.0 to 14.0	–	1.0 max.	–
C	28	5	0.26 to 0.35	1.0	1.0	0.040	0.030 max.	12.0 to 14.0	–	1.0 max.	–
D	–	–	0.42 to 0.50	1.0	1.0	0.040	0.030 max.	12.5 to 14.5	–	1.0 max.	–
E	–	–	0.47 to 0.57	0.50	1.0	0.030	0.025 max.	13.7 to 15.2	–	0.50 max.	–
F	–	–	0.60 to 0.70	0.50	1.0	0.030	0.025 max.	12.0 to 13.5	–	0.50 max.	–
G	–	–	0.65 to 0.75	1.0	1.0	0.040	0.030 max.	12.0 to 14.0	0.50 max.	1.0 max.	–
H	–	–	0.35 to 0.40	1.0	1.0	0.045	0.030 max.	14.0 to 15.0	0.40 to 0.60	–	V 0.10 to 0.15
I	–	–	0.42 to 0.55	1.0	1.0	0.045	0.030 max.	13.5 to 15.0	0.45 to 0.60	–	V 0.10 to 0.15
K	30	–	0.33 to 0.43	1.0	–	0.030	0.030 max.	15.0 to 17.0	1.0 to 1.5	1.0 max.	–
Ferritic steels											
L	–	8a	0.08 max.	1.0	1.5	0.060	0.15 to 0.35	16.0 to 18.0	0.60 max.	1.0 max.	–
Austenitic steels											
M	–	11	0.07 max.	1.0	2.0	0.045	0.030 max.	17.0 to 19.0	–	8.0 to 11.0	–
N	–	17	0.12 max.	1.0	2.0	0.060	0.15 to 0.35	17.0 to 19.0	0.70 max.	8.0 to 10.0	–
O	–	14	0.15 max.	1.0	2.0	0.045	0.030 max.	16.0 to 18.0	–	6.0 to 8.0	–
P	–	20	0.07 max.	1.0	2.0	0.045	0.030 max.	16.5 to 18.5	2.0 to 2.5	10.5 to 13.5	–

*These grade numbers are given for information only.