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Australian Standard 2320, Part 1—1981

METALS FOR THE MANUFACTURE OF SURGICAL IMPLANTS

Part 1—WROUGHT STAINLESS STEEL

STANDARDS ASSOCIATION OF AUSTRALIA
Incorporated by Royal Charter

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THE FOLLOWING SCIENTIFIC, INDUSTRIAL AND GOVERNMENTAL ORGANIZATIONS and departments were officially represented on the committee entrusted with the preparation of this standard:

Australian Chamber of Commerce

Australian Orthopaedic Association

Bureau of Steel Manufacturers of Australia

Confederation of Australian Industry

Department of Defence

Department of Health

Metal Trades Industry Association of Australia

Plastics Institute of Australia Incorporated

Royal Australasian College of Surgeons

Royal Newcastle Hospital

Royal Perth Hospital

University of Melbourne

University of Newcastle

University of New South Wales

University of Sydney

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AUSTRALIAN STANDARD

METALS FOR THE MANUFACTURE OF SURGICAL IMPLANTS

Part 1
WROUGHT STAINLESS STEEL

AS 2320, Part 1—1981

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PREFACE

This standard was prepared by the Association's Committee on Surgical Implants and was authorized by the Medical Materials and Equipment Standards Committee. It is one of a series of standards for surgical implants aimed at implementing for Australian purposes international standards emanating from ISO/TC 150, Implants for surgery.

Prior to publication of this standard, requirements for metals for the manufacture of implants were set out in AS T35. The new series accordingly supersedes that standard.

The standard specifies two types of wrought stainless steel—Type A for short-term applications, and Type B for long-term implants. The technical requirements specified herein for Type A steels are identical with those set out in ISO 5832/1, Implants for surgery—Metallic materials, Part 1: Wrought stainless steel. Australian standard methods of test have been specified and these are believed to be equivalent to the ISO methods given in ISO 5832.

In regard to Type B, the chemical compositional requirements have been amended in respect of nickel, chromium and molybdenum to improve resistance to corrosion. Steel to this standard remains capable of complying with the mechanical requirements of ISO 5832/1.

The national committee that recommended to the Association the adoption of ISO 5832/1 as an Australian standard, viz MD/3, made known to ISO/TC 150 its view that the upper limit specified for copper, i.e. 0.50 percent by mass should be reduced to 0.10 percent as this limit could be achieved relatively easily. The international committee was not convinced that this change was necessary but, conceding that there was no firm medical opinion as to the effects on the body if copper did go into solution, agreed that the 0.50 percent limit should be reviewed in 1985.

Committee MD/3 also was of the opinion that a marking requirement to differentiate between stainless steel compositions A and B should be included. ISO/TC 150 pointed out that such a requirement would be important in any standard dealing with a finished implant made of stainless steel but not appropriate in this present standard for stainless steel as an intermediate product.

STANDARDS ASSOCIATION OF AUSTRALIA

Australian Standard
for
METALS FOR THE MANUFACTURE OF SURGICAL IMPLANTS

PART 1—WROUGHT STAINLESS STEEL

1 SCOPE. This standard specifies the characteristics of, and corresponding test methods for, wrought stainless steel for use in the manufacture of surgical implants.

Provision is made for two types of stainless steel based on composition (see Table 1).

NOTE: The mechanical properties of a sample obtained from a finished product made of this alloy may not necessarily comply with those specified in this standard.

2 FIELD OF APPLICATION. The lower carbon steel (composition B) is intended for the manufacture of implants of a permanent nature. The higher carbon steel (composition A) is suitable for the production of higher strength surgical implants such as wires and pins.

3 REFERENCES.

AS K1 Methods for the sampling and analysis of iron and steel
- Part 11—Determination of nickel in iron and steel and permanent magnet alloys
- Part 15—Determination of copper in iron and steel (volumetric method)
- Part 16—Determination of sulphur in steel (gravimetric method)
- Part 18—Determination of phosphorus in iron and steel
- Part 23—Determination of molybdenum in iron and steel (photometric method)

AS 1050 Methods for the analysis of iron and steel (metric units)
- Part 8— Determination of manganese content in iron and steel (spectrophotometric method)
- Part 26—Determination of silicon in iron and steel (spectrophotometric method)

AS 1391 Methods for tensile testing of metals

AS 1733 Methods for the determination of grain size in metals

AS 2038 Methods for detecting the susceptibility of austenitic stainless steel to intergranular corrosion

AS 2197 Method for the micrographic assessment of the non-metallic inclusion content in wrought steel

4 CHEMICAL COMPOSITION.

4.1 Test Samples. The selection of samples for analysis shall be in accordance with the provisions of AS 1391.

4.2 Cast Analysis. The cast analysis of the steel shall comply with the relevant chemical composition specified in Table 1 (for test methods, see Clause 8).

TABLE 1
CHEMICAL COMPOSITION

Element	Compositional limits, %	
	Composition A	Composition B
Carbon	0.08 max.	0.03 max.
Silicon	1.00 max.	1.00 max.
Manganese	2.00 max.	2.00 max.
Nickel	10.0 to 14.0	13.0 to 16.0
Chromium	16.0 to 19.0	18.0 to 20.0
Molybdenum	2.0 to 3.5	2.5 to 3.0
Sulphur	0.015 max.	0.015 max.
Phosphorus	0.025 max.	0.025 max.
Copper	0.50 max.	0.50 max.
Iron	Balance	Balance

5 MICROSTRUCTURE IN FULLY ANNEALED CONDITION.

5.1 Grain Size. The austenitic grain size determined as specified in Clause 8 shall be not coarser than grain size No 4.

5.2 Absence of Delta Ferrite. The steel shall have a structure free from delta ferrite when examined as described in Clause 8.

5.3 Inclusion Content. The non-metallic inclusion content of the steel, determined at the billet stage, from a billet not exceeding 15 cm thickness, and as specified in Clause 8, shall not exceed the limits given in Table 2.

NOTE: It may be necessary to use a special manufacturing technique such as vacuum or electroslag melting to produce a steel complying with these cleanliness requirements.

TABLE 2
INCLUSION CONTENT LIMITS

Type of inclusion	Inclusion rating, max.*	
	Thin	Thick
A—Sulphides	1.5	1
B—Aluminates	1.5	1
C—Silicates	1.5	1
D—Oxides, globular	1.5	1

*Rating number (worst field) in accordance with AS 2197 (Plate II).