
International Standard



7153/1

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**Instruments for surgery — Metallic materials —
Part 1 : Stainless steel**

Instruments chirurgicaux — Matériaux métalliques — Partie 1 : Acier inoxydable

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Foreword

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Draft International Standards adopted by the technical committees are circulated to the member bodies for approval before their acceptance as International Standards by the ISO Council.

International Standard ISO 7153/1 was developed by Technical Committee ISO/TC 170, *Surgical instruments*, and was circulated to the member bodies in April 1982.

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It has been approved by the member bodies of the following countries :

| | | |
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| Australia | Germany, F.R. | Romania |
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The member body of the following country expressed disapproval of the document on technical grounds :

Austria

Instruments for surgery — Metallic materials — Part 1 : Stainless steel

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1 Scope and field of application

This part of ISO 7153 contains a survey and a selection of stainless steels available for use in the manufacture of surgical instruments, excluding specific instruments for orthopaedic surgery.

NOTE — In selecting grades of steel, shape and dimensions and the delivery condition of the raw products for the manufacture of surgical instruments, it is necessary to take into account aspects, for example the design of the instruments or the production facilities of the manufacturer, which do not conform to the requirements of this part of ISO 7153. For this reason, it is not intended, nor is it possible, that the information given in this part of ISO 7153 should remove the decision-making responsibility from the instrument manufacturer for selecting an appropriate raw product with suitable properties, nor is it intended

to preclude the use of other types of steel in the manufacture of instruments, such as the use of carbon steel for cutting instruments. International Standards for surgical instruments, when published, should be observed when making this decision as they may contain additional or new information to be taken into account when selecting adequate steel grades.

Subsequent parts of ISO 7153 will deal with other metallic materials.

2 References

ISO 683/13, *Heat-treated steels, alloy steels and free-cutting steels — Part 13 : Wrought stainless steels.*

ISO 4957, *Tool steels.*

3 Survey

Table 1 — Steel grades

| Reference letter of steel grade (see table 2) | Preferably used for | | |
|--|--|---|--|
| | cutting instruments | non-cutting instruments | fitting parts and other assemblies |
| | Examples | Examples | Examples |
| A | | tissue forceps, dressing forceps, retractors, probes | rivets, handles, solid guide pins, screws, nuts |
| B | bone rongeurs, bone cutting forceps, conchotomes, chisels and gouges, bone curettes, scissors with carbide inserts | forceps, forceps with bow handles, branch forceps, retractors, probes | springs, handles, solid screws, nuts, rivets |
| C | bone rongeurs, scissors | | |
| D | scissors, bone rongeurs, bone cutting forceps, conchotomes, scalpels, knives, chisels and gouges, bone curettes | | |
| E | scalpels | | |
| F | scalpels | | |
| G | scalpels, chisels and gouges, shears | | |
| H | scissors, bone rongeurs, conchotomes, chisels and gouges, bone curettes | | |
| I | scissors, bone rongeurs, bone cutting forceps, conchotomes, scalpels, knives, chisels and gouges, bone curettes | | |
| K | chisels and gouges, bone curettes | | |
| L | | | handles, solid guide pins, screws, nuts |
| M | | retractors | hollow handles, guide pins, rivets, screws |
| N | chisels and gouges, bone curettes | probes | handles, solid guide pins, screws, nuts, rivets |
| O | | | springs, screws, rivets |
| P | | | screws, rivets |

4 Chemical composition

The chemical composition of those steels specified in ISO 4957 and ISO 683/13, indicated by grade numbers, are given for information only.

The chemical composition of the steels shall be in accordance with table 2.

Table 2 — Steel grades and specified chemical composition (cast analysis)¹⁾

| Steel grade | | | Chemical composition, % | | | | | | | | |
|--------------------------------|--------------------------------------|--------------------------|-------------------------|---------|---------|--------|--------------|--------------|-----------------|--------------|-----------------|
| Reference letter ²⁾ | Grade No. according to ³⁾ | | C | Si max. | Mn max. | P max. | S | Cr | Mo | Ni | Other elements |
| | ISO 4957 | ISO 683/13 ⁴⁾ | | | | | | | | | |
| Martensitic steels | | | | | | | | | | | |
| A | — | 3 | 0,09 to 0,15 | 1,0 | 1,0 | 0,040 | 0,030 max. | 11,5 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 | 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 | — ⁵⁾ | 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 | |

1) Elements not quoted in table 2 shall not be intentionally added to the steel without the agreement of the purchaser, other than for the purpose of finishing the heat. All reasonable precautions shall be taken to prevent the addition, from scrap or other material used in manufacture, of such elements which affect hardenability, mechanical properties and applicability.

2) The reference letters are used for the purpose of cross-referencing.

3) The grade numbers are tentative and will be subject to alteration when the relevant International Standards are published.

4) The values for the steels covered by ISO 683/13 are in accordance with the values adopted for the revision of ISO 683/13-1974.

5) The manufacturer has the option of adding molybdenum up to 0,70 %.