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**PHARMACEUTICAL INDUSTRY STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

YY/T 0294.1-2024

**Surgical instruments - Materials - Part 1: Metals
(English Translation)**

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Foreword

This document was drafted in accordance with the provisions of GB/T 1.1-2020

Directives for standardization - Part 1.Rules for the structure and drafting of standardizing documents.

This document is part 1 of YY/T 0294 Surgical instruments - Materials. YY/T 0294 has been published in the following parts.

-- Part 1.Metals.

This document replaces YY/T 0294.1-2016 Surgical instruments - Metallic materials - Part 1.Stainless steel. Compared with YY/T 0294.1-2016, in addition to structural adjustments and editorial changes, the main technical changes are as follows.

-- The overview is deleted (see Chapter 3 of the 2016 edition);

-- The scope of application of materials is added (see Chapter 4);

-- The table of the applicable scope of stainless steel is modified (see Table 1; see Table 1 of the 2016 edition);

-- The table of the applicable scope of cemented carbide is added (see Table 2);

-- The table of the applicable scope of titanium and titanium alloys is added (see Table 3);

- The chapter "Materials" is added (see Chapter 5);
- The chapter "Chemical composition" is deleted (see Chapter 4 of the 2016 edition);
- The table of the stainless steel is added (see Table 4);
- The table of the correspondence between EN 10088-1.2014 and other standards is added (see Table 5);
- The table of cemented carbide is added (see Table 6);
- The table of titanium and titanium alloys is added (see Table 7).

This document is modified in relation to ISO 7153-1.2016 Surgical instruments - Materials - Part 1. Metals.

This document has made the following structural adjustments compared to ISO 7153-1.2016.

- Chapter 4 corresponds to Chapter 3 of ISO 7153-1.2016;
- Chapter 5 corresponds to Chapter 4 of ISO 7153-1.2016.

The technical differences between this document and ISO 7153-1.2016 and their reasons are as follows.

- The normative reference GB/T 4340.1 replaces ISO 6507-1 (see Table 4). The degree of consistency between the two documents is modification;
- The normative reference GB/T 230.1 replaces ISO 6508-1 (see Table 4). The degree of consistency between the two documents is modification;
- GB/T 20878-2007 is added (see Chapter 4, Table 1 and Table 4);
- Chinese stainless-steel grades are added to adapt to Chinese technical conditions and meet the selection of surgical instrument materials in China;
- The applicability of 12Cr18Ni9 stainless steel components is added to adapt to Chinese technical conditions and meet the selection of surgical instrument components in China (see Table 1).

The following editorial changes were made to this document.

- Examples of forceps and forceps with inserts or coatings are added (see Table

1~Table 3).

1 Scope

This document gives examples of conventional stainless-steel materials, cemented carbides, titanium and titanium alloys used to manufacture various standard surgical instruments and components, as well as information on grades and hardness ranges of commonly used materials.

This document applies to the selection of metal materials used in the manufacture of surgical instruments, including but not limited to general surgical, orthopedic, and dental instruments.

NOTE 1: Although this document is not intended to apply to surgical instruments for special applications

such as implantology and minimally invasive surgery, some parts of it may be applicable to these

instruments.

NOTE 2: When selecting metal materials, manufacturers need to consider the instrument design and

factory manufacturing in addition to the metal grade, shape, size, and delivery status. Therefore,

manufacturers are responsible for the selection of materials and shall not exclude the possibility of

referring to other current standards. When appropriate standards are released, the applicability of new

standards needs to be considered.

2 Normative references

The provisions of the following documents constitute the essential clauses of this document through normative references in this text. Among them, for referenced documents with dates, only the versions corresponding to the dates are applicable to this document; for referenced documents without dates, the latest versions (including all amendments) are applicable to this document.

GB/T 230.1 Metallic materials - Rockwell hardness test - Part 1.Test method

(GB/T 230.1-2018, ISO 6508-1.2016, MOD)

GB/T 4340.1 Metallic materials - Vickers hardness test - Part 1.Test method (GB/T

4340.1-2009, ISO 6507-1.2005, MOD)

GB/T 20878-2007 Stainless and heat-resisting steels - Designation and chemical composition

ISO 5832-2 Implants for surgery - Metallic materials - Part 2.Unalloyed titanium

ISO 5832-3 Implants for surgery - Metallic materials - Part 3.Wrought titanium 6-aluminium 4-vanadium alloy

ASTM B 265 Standard Specification for Titanium and Titanium Alloy Strip, Sheet, and Plate

ASTM B 348 Standard Specification for Titanium and Titanium Alloy Bars and Billets

EN 10088-1.2014 Stainless steels Part 1.List of stainless steels

3 Terms and definitions

There are no terms or definitions that require definition in this document.

4 Scope of application of materials

Because various surgical instruments have different needs and different requirements for the materials used to make them, not all materials listed in Chapter 5 are suitable for every type of instrument. For most types of surgical instruments, Tables 1~3 give materials that are suitable for these instruments based on known experience. Other materials may also be suitable for the manufacture of certain types of instruments, although these materials are not included in this document.

Table 1 lists the conventional stainless-steel materials used to manufacture various standard surgical instruments and components. The codes in the first column correspond to the stainless-steel materials specified in Table 4.In addition, the codes in the second column are from ISO 7153-1.1991, and the grades in the third column are from GB/T 20878-2007.The information in the second and third columns is only for users familiar with YY/T 0294.1-2016.