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**Wrought Nickel-Titanium Shape Memory Alloys for
Surgical Implants**

外科植入物用镍-钛形状记忆合金加工材

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Wrought Nickel-Titanium Shape Memory Alloys for Surgical Implants

1 Scope

This Document specifies the chemical, physical, mechanical and metallurgical requirements for nickel-titanium memory alloy rods, sheets and tubes with a nominal composition (mass fraction) of 54.5%~57.0% nickel for the manufacture of surgical implants.

NOTE 1: Nickel-titanium memory alloy materials used to manufacture other medical devices also refer to this Document, and the user shall evaluate its applicability.

This Document applies to mill products with a diameter or thickness of 5.5mm~94.0mm.

NOTE 2: Mill products do not limit the final shape, final surface state or final performance of the product.

NOTE 3: Cold-worked tube finished products refer to YS/T 1136.

2 Normative References

The provisions in following documents become the essential provisions of this Document through reference in this Document. For the dated documents, only the versions with the dates indicated are applicable to this Document; for the undated documents, only the latest version (including all the amendments) is applicable to this Document.

GB/T 228.1 Metallic materials – Tensile testing – Part 1: Method of test at room temperature

GB/T 4698.7 Methods for chemical analysis of titanium sponge, titanium and titanium alloys -Determination of oxygen and nitrogen content

GB/T 4698.14 Methods for chemical analysis of titanium sponge, titanium and titanium alloys - Determination of carbon content

GB/T 4698.15 Methods for chemical analysis of titanium sponge, titanium and titanium alloys - Determination of hydrogen content

GB/T 6394 Metal - Methods for estimating the average grain size

GB/T 16597 Analytical methods of metallurgical products - General rule for X-ray fluorescence spectrometric methods

GB/T 18876.1 Standard practice for determining the metallographic constituent and inclusion content of steels and other metals by automatic image analysis - Part 1: Determining the inclusion or second-phase constituent content of steels and other metals by automatic image analysis and stereology

GB/T 23614.1 Methods for chemical analysis of titanium nickel shape memory alloy - Part 1: Determination of nickel content - Dimethylglyoxime precipitate separation-EDTA complex-zinc chloride back titration

YS/T 970 Phase change temperature measuring method for nickel-titanium shape memory alloys

YS/T 1064-2015 Terminology for nickel-titanium shape memory alloys

YY/T 0641 Standard test method for transformation temperature of nickel-titanium alloys by thermal analysis

YY/T 1771 Standard test method for determination of transformation temperature of nickel-titanium shape memory alloys by bend and free recovery

ASTM E1409 Standard Test Method for Determination of Oxygen and Nitrogen in Titanium and Titanium Alloys by Inert Gas Fusion

ASTM E1447 Standard Test Method for Determination of Hydrogen in Titanium and Titanium Alloys by the Inert Gas Fusion Thermal Conductivity Method

ASTM E1941 Standard Test Method for Determination of Carbon in Refractory and Reactive Metals and Their Alloys

3 Terms and Definitions

For the purposes of this Document, the terms and definitions given in YS/T 1064-2015 and the following apply.

3.1 Ingot

Cast metal that is used for processing into mill product.

3.2 Mill product

The mill semi-finished or finished products.

NOTE: It is a bar, wire or coil. Product states include hot-processed, hot-processed and cold-formed, hot-processed and cold-processed, hot-processed and annealed, and cold-processed and annealed products.

3.3 Martensite start temperature; M_s

The start temperature of the transformation from the parent phase to the martensite phase during the one-step phase-change cooling process, or the start temperature of the transformation from the *R*-phase (transition phase) to the martensite phase during the two-step phase-change cooling process.

[SOURCE: YS/T 1064-2015, 3.7, modified]

3.4 Martensite peak temperature; M_p

The temperature at which the parent phase transforms to the martensite phase at the maximum exothermic peak on the one-step phase-change differential scanning calorimetry cooling curve, or the temperature at which the *R*-phase transforms to the martensite phase at the maximum exothermic peak on the two-step phase-change differential scanning calorimetry exothermic curve.

[SOURCE: YS/T 1064-2015, 3.8, modified]

3.5 Martensite finish temperature; M_f

The final temperature of the transformation from the parent phase to the martensite phase during the one-step phase-change cooling process, or the completion temperature of the transformation from the *R*-phase to the martensite phase during the two-step phase-change cooling process.

3.6 Austenite start temperature; A_s

The start temperature of the transformation from martensite phase to austenite phase in a one-step phase-change heating process, or the start temperature of the transformation from *R*-phase to austenite phase in a two-step phase-change heating process.

3.7 Austenite peak temperature; A_p

The temperature at which the martensite phase transforms to the austenite phase corresponding to the maximum value of the endothermic peak on the one-step phase-change differential scanning calorimetry heating curve, or the temperature at which the *R*-phase transforms to the austenite phase corresponding to the maximum value of the endothermic peak on the two-step phase-change differential scanning calorimetry heating curve.

3.8 Austenite finish temperature; A_f

The final temperature of the transformation from martensite phase to austenite phase in a one-step phase-change heating process, or the completion temperature of the transformation from *R*-phase to austenite phase in a two-step phase-change heating process.

4 Classification of Product

4.1 Bars

grinding, mechanical polishing or electrolytic polishing.

NOTE: The material principle and biocompatibility involved in this Document are described in Annexes A and B.

7 Chemical Compositions

7.1 Requirements

The chemical compositions of the ingot shall meet the requirements of Table 1. Except for hydrogen, the elements in Table 1 can be sampled and analyzed from the ingot. Hydrogen shall be sampled and analyzed from the final product (see Clause 4) or in a manner agreed upon by the supplier and the purchaser. The supplier shall not ship if the chemical composition exceeds the range given in Table 1.

The purpose of product analysis is to verify the chemical compositions of the ingot, the processing batch, and determine the variation of the chemical composition within the ingot. Based on the product analysis, the purchaser decides whether to accept the ingot or the batch of processed materials.

The requirements for the content of main compositions and impurity elements are shown in Table 1.

7.2 Analysis methods

The main components shall be analyzed according to the method specified in GB/T 23614.1, X-ray spectrometry specified in GB/T 16597, inductively coupled plasma atomic emission spectrometry or equivalent methods; the carbon content shall be determined according to the method specified in GB/T 4698.14 and ASTM E1941; the hydrogen content shall be determined according to the method specified in GB/T 4698.15 or the inert gas fusion method or vacuum extraction method specified in ASTM E1447; the oxygen and nitrogen contents shall be determined according to the method specified in GB/T 4698.7 or the inert gas fusion method specified in ASTM E1409; the contents of cobalt, copper, chromium, iron, niobium, etc. shall be analyzed according to inductively coupled plasma atomic emission spectrometry or equivalent methods. The titanium content is determined by the difference-method and does not require analysis.

a standard-length sample suitable for the size of the product to be tested; the tensile strain rate is between (0.003~0.1)/min; and for annealed samples, the tensile temperature is 5°C~10°C higher than A_r . The tensile properties shall meet the requirements of Table 4.

10.6 Other special mechanical property tests shall be specified in the order form.

11 Special Requirements

11.1 Dimensional tolerances and ovality tolerances shall be specified in the order form.

11.2 Special phase-change temperature requirements due to product shape, sampling location or heat treatment shall be specified in the order form.

11.3 Surface roughness shall be specified in the order form.

12 Report

The supplier shall provide a report on the manufacture and inspection of the material in accordance with this Document at the time of shipment. The report shall include the manufacturing, inspection, sampling and test methods consistent with this Document. The report shall include the summary of chemical composition, phase-change temperature, structure, description of structure analysis and mechanical property test results agreed upon by the purchaser and the supplier (see Clause 7 to 10). The report includes the sampling material size, location, condition and test method. For metallurgical micro cleanliness, the report shall include the sampled product size, product sampling quantity and location, relationship between field of view direction and processing direction, sample preparation, field of view quantity and measurement method. The report shall include the melting ingot method and processing method (including hot rolling, forging, extrusion or cold processing) agreed upon by the supplier and the purchaser.

13 Quality Control Procedures

The supplier shall maintain certain quality control procedures, such as meeting the requirements of GB/T 42061.

Appendix A

(Informative)

Principles

A.1 The user selects the phase-change temperature and mechanical properties of the shape memory alloy according to the design and use requirements of the product.

A.2 Thermo-mechanical processing (especially cold processing and heat treatment) affects the phase-change temperature and other physical and mechanical properties of nickel-titanium shape memory alloy. The annealing state specified in 8.4 and 10.1 refers only to test samples, and the finished products are usually delivered in cold processing state or cold processing and heat-treating state.

A.3 Thermo-mechanical treatment and chemical treatment can affect the chemical analysis results of the ingot. For example, pickling shall lead to an increase in hydrogen content. Therefore, it is specified to sample and analyze the hydrogen content on the final rolled product (see 7.1).

A.4 The nickel-titanium alloy involved in this Document is usually called "nickel-titanium memory alloy". It is not a single alloy, but a family of alloys marked with a phase-change temperature, which is measured under controlled conditions after the specified thermo-mechanical treatment process.

A.5 Phase-change temperature consistency refers to the A_s range measured by a laboratory for a certain composition alloy according to the test method of YY/T 0641.

A.6 Elements carbon, cobalt, copper, hydrogen, iron, niobium and oxygen are residual elements in the alloy (see Table 1). In order to ensure that the shape memory alloy has good physical and mechanical properties, these residual elements are controlled within the specified range. The analysis tolerance range of the product is determined based on the proven analytical capability of the content of these elements.

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