ICS 11.040.40
CCS C35

NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

GB/T 24627-2023

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

Issued on: December 28, 2023 **Implemented on: January 1, 2025**

Issued by: State Administration for Market Regulation;
Standardization Administration of the PRC

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Foreword

This document was issued on 28 December 2023 by the State Administration for Market Regulation; Standardization Administration of the PRC and takes effect on 1 January 2025.

It is a GB/T standard: recommended rather than compulsory, but it is the text a Chinese reviewer applies when assessing a submission.

1 Scope

GB/T 24627-2023 covers wrought nickel-titanium shape memory alloy supplied as bar, sheet and tube for the manufacture of surgical implants, at a nominal nickel content of 54.5 % to 57.0 % by mass. It sorts the product forms and the surface finishes they are delivered in, says what the order form has to state, and fixes what the maker does in melting and subsequent working. Then come the chemical composition, sampled from the ingot against a table of limits, the phase-change temperature at which the alloy switches between its two crystal structures, the internal structure, and the mechanical properties. Tolerances on

dimensions and ovality, and phase-change temperatures that depend on shape, sampling position or heat treatment, are left to the order form, so a buyer who needs something particular has to write it down. The supplier issues a manufacturing and inspection report at shipment and keeps quality control procedures behind it. Phase-change temperature is the clause that decides the device: an implant that does not complete its transformation at body temperature will not open the way the surgeon expects, and inclusions left in the structure are where fatigue cracks begin in a part that is loaded again and again in the body. Informative annexes cover the underlying principle and biocompatibility. Written for implant manufacturers, their alloy suppliers and hospital procurement reviewers.

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; Ms

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; Mp

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; Mf