

ICS 11.040.40  
CCS C35

**YY**

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

**YY/T 1924-2025**

---

**Implants for surgery - Nickel-titanium shape memory alloy  
ropes**

外科植入物 镍钛形状记忆合金绳材

**Issued on: February 26, 2025**

**Implemented on: March 1, 2026**

---

**Issued by: National Medical Products Administration**

## Table of Contents

|                               |   |
|-------------------------------|---|
| 1 Scope .....                 | 1 |
| 2 Normative references .....  | 1 |
| 3 Terms and Definitions ..... | 1 |
| 4 Categories .....            | 2 |
| 5 Requirement .....           | 2 |
| 6 Test methods .....          | 4 |
| 7 Inspection Rules .....      | 5 |
| 7 References .....            | 8 |

### Foreword

This document is in accordance with the provisions of GB/T 1.1-2020 "Guidelines for standardization work Part

1. Structure and drafting rules for standardization documents" Drafting. Please note that some of the contents of this document may involve patents. The issuing organization of this document does not assume the responsibility for identifying patents. This document is proposed by the State Food and Drug Administration. This document is under the jurisdiction of the National Technical Committee for Standardization of Surgical Implants and Orthopedic Devices (SAC/TC110). This document was drafted by: Jiangyin Perl Technology Co., Ltd., Northeastern University, Tianjin Medical Device Quality Supervision and Inspection Center, Beijing Medical Medical Device Inspection Institute (Beijing Medical Biological Protection Equipment Inspection and Research Center), LifeTech Scientific (Shenzhen) Co., Ltd., Dabo Medical Technology Limited by Share Ltd. The main drafters of this document are: Chen Qingfu, Zhang Kai, Qin Gaowu, Zhang Erlin, Ma Chunbao, Chen Sibin, Chen Yu, Hao Fengyang, Hu Junyuan, Liu Panpan, Zeng Da, Liang Xiongwei. NiTi Shape Memory Alloy Cables for Surgical Implants

### 1 Scope

YY/T 1924 is the material standard for nickel-titanium shape memory alloy rope used in surgical implants, the stranded nitinol from which braided and woven implantable structures are built. It specifies the classification, the requirements and the inspection rules, together with the marking, packaging, transport, storage and quality certificate requirements. A rope behaves differently from the wire it is made of: the strand geometry changes the effective stiffness and the transformation behaviour, and it introduces interfaces where corrosion and fretting can start. Standardising the rope as its own product is what lets an implant maker

specify it rather than characterise every batch from first principles. For a manufacturer of nitinol-based implants or a material supplier serving the Chinese market, this is the specification the material is bought against.

This document specifies nickel-titanium with a nominal composition (mass fraction) of 54.5% to 57.0% nickel for the manufacture of medical devices such as surgical implants. The classification, requirements, inspection rules and requirements for marking, packaging, transportation, storage and quality certification of shape memory alloy ropes describe the corresponding Test method. This document is suitable for the production of orthopedic wire guides, cables, grabbers, capture rings, baskets, guide ropes and other medical devices and surgical implants. Nickel-titanium shape memory alloy rope.

## 2 Normative references

The contents of the following documents constitute essential clauses of this document through normative references in this document. For referenced documents without a date, only the version corresponding to that date applies to this document; for referenced documents without a date, the latest version (including all amendments) applies to This document.

GB/T 6394 Determination of average grain size of metals

GB/T 8180 Packaging, marking, transportation and storage of titanium and titanium alloy processed products

GB/T 8706 Terminology, marking and classification of wire ropes

GB/T 8834 Determination of physical and mechanical properties of fiber ropes

GB/T 18876.1 Standard test for determination of metallographic structure, inclusion content and grade in steel and other metals using automated image analysis Methods - Part

1. Image analysis and stereological determination of inclusion or second phase content in steel and other metals

GB/T 24627 Nickel-titanium shape memory alloy materials for surgical implants YS/T 1064 Terminology of Nickel-Titanium Shape Memory Alloys YS/T 1147 Superelastic NiTi Alloy Tensile Test Method

YY/T 1771 Bend-free recovery method for testing phase transition temperature of nickel-titanium shape memory alloy

## 3 Terms and definitions

The terms and definitions defined in GB/T 8706, GB/T 8834, YS/T 1064 and the following apply to this document.

3.1 diameter The distance from the center of the circumscribed circle of the rope cross section to two points on the edge.

3.2 MxN The name of a rope structure in which M refers to the number of strands and N refers to the number of wires in the strand.

3.3 laydirection The twisting direction of the outer metal wire in a single-twist metal wire rope and the outer strands in a multi-strand metal wire rope along the rope axis.

Note. Conventional rope products can be twisted left or right, and the default twist is left twist. According to the requirements of the purchaser, right twist or other twist directions can also be produced.