



Standard Specification for Wrought Nickel-Titanium Shape Memory Alloys for Medical Devices and Surgical Implants¹

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1. Scope

1.1 This specification covers the chemical, physical, mechanical, and metallurgical requirements for wrought nickel-titanium bar, wire, flat rolled products, and tubing containing nominally 54.5 % to 57.0 % nickel and used for the manufacture of medical devices and surgical implants.

1.2 The values stated in SI units are to be regarded as the standard. The values given in inch-pound units are for information only.

2. Referenced Documents

2.1 ASTM Standards:

E 8 Test Methods for Tension Testing of Metallic Materials²

E 112 Test Method for Determining Average Grain Size²

E 120 Test Method for Chemical Analysis of Titanium and Titanium Alloys³

E 1019 Test Method for Determination of Carbon, Sulfur, Nitrogen and Oxygen in Steel and in Iron, Nickel, and Cobalt Alloys⁴

E 1097 Guide for Direct Current Plasma Emission Spectrometry Analysis⁴

E 1172 Practice for Describing and Specifying a Wavelength-Dispersive X-Ray Spectrometer⁴

E 1245 Practice for Determining the Inclusion or Second-Phase Constituent Content of Metals by Automatic Image Analysis²

E 1409 Test Method for Determination of Oxygen in Titanium and Titanium Alloys by the Inert Gas Fusion Technique⁴

E 1447 Test Method for Determination of Hydrogen in Titanium and Titanium Alloys by the Inert Gas Fusion Thermal Conductivity Method⁴

E 1479 Practice for Describing and Specifying Inductively-Coupled Plasma Optical Emission Spectrometers⁴

F 2004 Test Method for Transformation Temperature of Nickel-Titanium Alloys by Thermal Analysis⁵

F 2005 Terminology for Nickel-Titanium Shape Memory Alloys⁵

F 2082 Method for the Determination of Transformation Temperature of Nickel-Titanium Shape Memory Alloys by Bend and Free Recovery⁵

2.2 ASQ Standard:

C1 General Requirements for a Quality Program⁶

3. Terminology

3.1 The terminology describing the physical and thermal properties of these alloys shall be as defined in Terminology F 2005.

3.2 E4: General Terminology

4. Product Classification

4.1 *bar*—Round bars and flats from 5 mm (0.196 inches) to 130 mm (5.1 inches) in diameter or thickness (other sizes or shapes by special order).

4.2 *plate*—Any product 5 mm (0.196 inches) thick and over and 250 mm (9.8 inches) wide and over, with width equal to or greater than five times the thickness.

4.3 *strip*—Any product under 5 mm (0.196 inches) thick and under 600 mm (23.6 inches) wide.

4.4 *sheet*—Any product under 5 mm (0.196 inches) thick and 600 mm (23.6 inches) or more wide.

4.5 *wire*—Rounds less than 5 mm (0.196 inches) in diameter.

4.6 *tubing*—Hollow cylindrical shapes up to 50 mm (1.96 inches) in outside diameter.

5. Ordering Information

5.1 Inquiries and orders for material under this specification shall include the following information:

5.1.1 *Quantity*: weight, length, or number of pieces.

5.1.2 *Alloy formulation*, in terms of transformation temperature parameter (see Section 8).

5.1.3 *Form*: bar, plate, strip, sheet, wire, or tubing (see Section 4).

5.1.4 *Condition* (see Sections 6.3 and 10.1).

5.1.5 *Mechanical Properties*, if applicable for special conditions (see Section 10).

¹ This specification is under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.12 on Metallurgical Materials.

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² *Annual Book of ASTM Standards*, Vol 03.01.

³ *Annual Book of ASTM Standards*, Vol 03.05.

⁴ *Annual Book of ASTM Standards*, Vol 03.06.

⁵ *Annual Book of ASTM Standards*, Vol 13.01.

⁶ Available from the American Society for Quality, 611 East Wisconsin Ave., Milwaukee, WI 53203.