



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, flat rolled products, and tubes containing nominally 54.5- to 57.0-weight percent nickel and used for the manufacture of medical devices and surgical implants.

1.2 Requirements are for mill product, measuring 5.50 to 94.0 mm [0.218 to 3.70 in.] diameter or thickness. Mill product is not intended to have the final shape, final surface finish, or final properties of the medical device, implant, or their components. Finished NiTi cold-worked tube should be considered under Specification **F2633**.

1.3 The values stated in either SI units or inch-pound units are to be regarded separately as standard. The values stated in each system may not be exact equivalents; therefore, each system shall be used independently of the other. Combining values from the two systems may result in non-conformance with the standard.

2. Referenced Documents

2.1 *ASTM Standards*:²

- E4** Practices for Force Verification of Testing Machines
- E8/E8M** Test Methods for Tension Testing of Metallic Materials
- E29** Practice for Using Significant Digits in Test Data to Determine Conformance with Specifications
- E112** Test Methods for Determining Average Grain Size
- E1019** Test Methods for Determination of Carbon, Sulfur, Nitrogen, and Oxygen in Steel, Iron, Nickel, and Cobalt Alloys by Various Combustion and Fusion Techniques
- E1097** Guide for Determination of Various Elements by Direct Current Plasma Atomic Emission Spectrometry

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 For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

- E1172** Practice for Describing and Specifying a Wavelength-Dispersive X-Ray Spectrometer
- E1245** Practice for Determining the Inclusion or Second-Phase Constituent Content of Metals by Automatic Image Analysis
- E1409** Test Method for Determination of Oxygen and Nitrogen in Titanium and Titanium Alloys by the Inert Gas Fusion Technique
- E1447** Test Method for Determination of Hydrogen in Titanium and Titanium Alloys by Inert Gas Fusion Thermal Conductivity/Infrared Detection Method
- E1479** Practice for Describing and Specifying Inductively-Coupled Plasma Atomic Emission Spectrometers
- E1941** Test Method for Determination of Carbon in Refractory and Reactive Metals and Their Alloys by Combustion Analysis
- F1710** Test Method for Trace Metallic Impurities in Electronic Grade Titanium by High Mass-Resolution Glow Discharge Mass Spectrometer
- F2004** Test Method for Transformation Temperature of Nickel-Titanium Alloys by Thermal Analysis
- F2005** Terminology for Nickel-Titanium Shape Memory Alloys
- F2633** Specification for Wrought Seamless Nickel-Titanium Shape Memory Alloy Tube for Medical Devices and Surgical Implants
- IEEE/ASTM SI 10** American National Standard for Metric Practice

2.2 *Other Standards*:

- ASQ C1** General Requirements for a Quality Program³
- ISO 9001** Quality Management Systems—Requirements⁴

3. Terminology

3.1 The terminology describing the physical and thermal properties of these alloys shall be as defined in Terminology **F2005**.

3.2 See also Practice **E4**: General Terminology.

³ Available from American Society for Quality (ASQ), 600 N. Plankinton Ave., Milwaukee, WI 53203. Available from American Society for Quality (ASQ), 600 N. Plankinton Ave., Milwaukee, WI 53203, <http://www.asq.org>.

⁴ Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, <http://www.ansi.org>.

*A Summary of Changes section appears at the end of this standard