Designation: F2063 – 05

StandardSpecification for Wrought Nickel-Titanium Shape Memory Alloys for Medical Devices and Surgical Implants[1]

This standard is issued under the fixed designation F2063; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

1. Scope*

1.1 This specification covers the chemical, physical, mechanical, and metallurgical requirements for wrought nickel-titanium bar, 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 Requirements are for mill product, measuring 6 to 130 mm (0.24 to 5.12 in.) diameter or thickness, in its annealed condition.

1.3 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:*[2]

E4 Practices for Force Verification of Testing Machines
E8 Test Methods for Tension Testing of Metallic Materials
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
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
F2082 Test Method for Determination of Transformation Temperature of Nickel-Titanium Shape Memory Alloys by Bend and Free Recovery

2.2 *ASQ Standard:*

C1 General Requirements for a Quality Program[3]

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.

4. Product Classification

4.1 *Bar*—Round bars and flats (other sizes or shapes by special order).

4.2 *Plate*—Any product with width equal to or greater than five times the thickness.

4.3 *Tubing*—Hollow cylindrical shapes.

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.

[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.

Current edition approved Nov. 1, 2005. Published November 2005. Originally approved in 2000. Last previous edition approved in 2000 as F2063 – 00. DOI: 10.1520/D2063–05.

[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.

[3] Available from American Society for Quality (ASQ), 600 N. Plankinton Ave., Milwaukee, WI 53203.

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

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

5.1.3 *Form:* bar, plate, 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).

5.1.6 *Surface Condition* (see Sections 6.4).

5.1.7 *Applicable Dimensions,* including diameter, thickness, width, and length (exact, random, multiples) or print number.

5.1.8 *Special Tests,* for example, chemical analysis on the finished mill product.

5.1.9 *Special Requirements* (see section 11).

6. Manufacture

6.1 The material shall be made from ingot made from nickel and titanium with no other intentional alloy additions.

6.2 The material shall be vacuum or inert atmosphere melted to control metallurgical cleanliness and alloy chemistry.

6.3 Bar, plate, and tubing shall be supplied as hot finished or cold finished and annealed or heat treated as specified in the purchase order.

6.4 Surface condition may be oxidized, descaled, pickled, blasted, machined, ground, mechanically polished, or electropolished.

7. Chemical Composition

7.1 The heat analysis shall conform to the requirements of Table 1. Ingot analysis may be used for reporting all chemical requirements except hydrogen. Samples for hydrogen analysis shall be taken from the finished mill product (see Section 4) or as agreed upon between the customer and supplier. The supplier shall not ship material that is outside the limits specified in Table 1.

7.1.1 Requirements for major and minor elements are listed in Table 1. Important residual elements are also listed. Analysis for elements not listed in Table 1 is not required to verify compliance with this specification.

7.2 *Analytical Methods*—Major elements shall be analyzed by direct current plasma spectrometry according to Guide E1097; atomic absorption, inductively coupled plasma spectrometry according to Practice E1479; X-ray spectrometer according to Practice E1172; glow discharge mass spectrometry according to Test Method F1710; or an equivalent method. Carbon shall be measured by combustion according to Test Methods E1019 or E1941. Hydrogen shall be measured by inert gas fusion or vacuum hot extraction according to Test Method E1447. Nitrogen and oxygen shall be measured by inert gas fusion according to Test Method E1409.

7.3 The titanium content of these alloys shall be determined by difference and need not be analyzed.

7.4 Product analysis limits shall be as specified in Table 2. Product analysis tolerances do not broaden the specification heat analysis requirements, but cover variation between laboratories in the measurement of chemical content. The manufacturer shall not ship material that is outside the limits specified in Table 1.

TABLE 1 Chemical Requirements

Element	% (mass/mass)
Nickel	54.5 to 57.0
Carbon, maximum	0.050
Cobalt, maximum	0.050
Copper, maximum	0.010
Chromium, maximum	0.010
Hydrogen, maximum	0.005
Iron, maximum	0.050
Niobium, maximum	0.025
Nitrogen plus Oxygen, maximum	0.050
Titanium[A]	Balance

[A] Approximately equal to the difference between 100 % and the sum percentage of the other specified elements. The percentage titanium content by difference is not required to be reported.

8. Transformation Temperature

8.1 The nickel and titanium contents of nickel-titanium shape memory alloys cannot be measured to a precision required to guarantee shape memory or superelastic properties. Calorimetry or an equivalent thermomechanical test method must be used to assure the alloy formulation in terms of transformation temperature.

8.2 Alloy formulation shall be specified in terms of the transformation temperature parameter(s) required by the purchase order. This parameter shall be one of the following: M_f, M_p, M_s, A_s, A_p, A_f as defined in Terminology F2005 and as measured in accordance with Test Method F2004, Test Method F2082 or as measured in accordance with another appropriate thermomechanical test method.

8.3 When measured in accordance with Test Method F2004 for transformation temperature by thermal analysis, the A_s shall be uniform to within the process capability of ±10°C on the purchased product or as agreed upon by the customer and supplier.

8.4 Transformation temperature parameters are normally specified in the wrought product in the annealed condition as defined in F2005. Other conditions for the certification of alloy transformation temperature shall be considered a special requirement.

9. Metallurgical Structure

9.1 *Microstructure:*

TABLE 2 Product Analysis Tolerance[A]

Element	Tolerance Under the Minimum Limit or Over the Maximum Limit, % (mass/mass)[B]
Carbon	0.002
Cobalt	0.001
Copper	0.001
Chromium	0.001
Hydrogen	0.0005
Iron	0.01
Nickel	0.2 under min; 0.2 over max
Niobium	0.004
Nitrogen	0.004
Oxygen	0.004

[A] Product analysis tolerance limits are based on analytical capabilities that have been demonstrated for this composition.

[B] Under minimum limit not applicable for elements where only a maximum percentage is indicated.