Designation: F 2063 – 00

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

This standard is issued under the fixed designation F 2063; 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, 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 Materials[2]

E 112 Test Method for Determining Average Grain Size[2]

E 120 Test Method for Chemical Analysis of Titanium and Titanium Alloys[3]

E 1019 Test Method for Determination of Carbon, Sulfur, Nitrogen and Oxygen in Steel and in Iron, Nickel, and Cobalt Alloys[4]

E 1097 Guide for Direct Current Plasma Emission Spectrometry Analysis[4]

E 1172 Practice for Describing and Specifying a Wavelength-Dispersive X-Ray Spectrometer[4]

E 1245 Practice for Determining the Inclusion or Second-Phase Constituent Content of Metals by Automatic Image Analysis[2]

E 1409 Test Method for Determination of Oxygen in Titanium and Titanium Alloys by the Inert Gas Fusion Technique[4]

E 1447 Test Method for Determination of Hydrogen in Titanium and Titanium Alloys by the Inert Gas Fusion Thermal Conductivity Method[4]

E 1479 Practice for Describing and Specifying Inductively-Coupled Plasma Optical Emission Spectrometers[4]

F 2004 Test Method for Transformation Temperature of Nickel-Titanium Alloys by Thermal Analysis[5]

F 2005 Terminology for Nickel-Titanium Shape Memory Alloys[5]

F 2082 Method for the Determination of Transformation Temperature of Nickel-Titanium Shape Memory Alloys by Bend and Free Recovery[5]

2.2 *ASQ Standard:*

C1 General Requirements for a Quality Program[6]

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).

[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.

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, spool size, coil diameter, 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, tubing, wire, and flat rolled products 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 E 1097; atomic absorption, inductively coupled plasma spectrometry according to Practice E 1479; X-ray spectrometer according to Practice E 1172 or an equivalent method. Carbon shall be measured by combustion according to Test Method E 1019. Hydrogen shall be measured by inert gas fusion or vacuum hot extraction according to Test Methods E 120 or E 1447. Nitrogen and oxygen shall be measured by inert gas fusion according to Test Method E 1409.

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

TABLE 1 Chemical Requirements

Element	Weight Percent
Nickel	54.5 to 57.0
Carbon, maximum	0.070
Cobalt, maximum	0.050
Copper, maximum	0.010
Chromium, maximum	0.010
Hydrogen, maximum	0.005
Iron, maximum	0.050
Niobium, maximum	0.025
Oxygen, maximum	0.050
Titanium	Balance

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.

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 F 2005 and as measured in accordance with Method F 2004, Method F 2082 or as measured in accordance with another appropriate thermomechanical test method.

8.3 When measured in accordance with Method F 2004 for transformation temperature by thermal analysis, the A_s shall be uniform to within ±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 F 2005. Other conditions for the certification of alloy transformation temperature shall be considered a special requirement.

9. Metallurgical Structure

9.1 *Microstructure*:

9.1.1 Annealed product 6 mm (0.236 in.) to 50 mm (1.96 in.) in section shall have a grain size of ASTM 4 or finer as measured by Test Method E 112.

9.2 *Non-metallic Inclusions and Porosity*:

9.2.1 For all mill products, porosity and nonmetallic inclusions such as $Ti_4Ni_2O_x$ and TiC particles shall be no larger than 12.5 µm (0.0005 in.). Furthermore, porosity and nonmetallic inclusions shall not constitute more than 1.0 % (area percent) of the structure as viewed at 400X to 500X in any field of view. Porosity and nonmetallic inclusions shall be evaluated in mill

TABLE 2 Product Analysis Tolerance[A]

Element	Tolerance Under the Minimum or Over the Maximum, (wt. %)
Nickel	0.2
Element	**Tolerance Over the Maximum, (wt. %)**
Carbon	0.002
Cobalt	0.001
Copper	0.001
Chromium	0.001
Hydrogen	0.0005
Iron	0.01
Niobium	0.004
Oxygen	0.004

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