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

This standard is issued under the fixed designation F2633; 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 requirements for wrought nickel-titanium shape memory alloy tube, nominally 54.5 to 57.0 mass/mass (weight) % nickel, in the superelastic condition, used for the manufacture of medical devices and surgical implants. Material shall conform to the applicable requirements of Specification F2063. This specification addresses those product variables that differentiate drawn medical grade tube from the raw material and mill product forms covered in Specification F2063.

1.2 This specification applies to tube with 10 mm (0.4 in.) and smaller nominal outside diameter and 2 mm (0.08 in.) and thinner nominal wall thickness.

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

1.4 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

2. Referenced Documents

2.1 *ASTM Standards:*[2]

A632 Specification for Seamless and Welded Austenitic Stainless Steel Tubing (Small-Diameter) for General Service
F2004 Test Method for Transformation Temperature of Nickel-Titanium Alloys by Thermal Analysis
F2005 Terminology for Nickel-Titanium Shape Memory Alloys
F2063 Specification for Wrought Nickel-Titanium Shape Memory Alloys for Medical Devices and Surgical Implants
F2082 Test Method for Determination of Transformation Temperature of Nickel-Titanium Shape Memory Alloys by Bend and Free Recovery
F2516 Test Method for Tension Testing of Nickel-Titanium Superelastic Materials

2.2 *ISO Standard:*[3]

ISO 9001 Quality Management Systems—Requirements
ISO 13485 Quality Management Standard for Medical Devices

3. Terminology

3.1 *Definitions of Terms Specific to This Standard:*

3.2 See Terminology F2005 for the definition of terms used in this specification that are specific to nickel-titanium alloys.

3.3 *individual wall thickness measurement, n*—any one of the wall thickness measurements taken around the circumference on any one transverse cross-section of a single sample of the tube.

3.4 *lot, n*—the total quantity of product produced from the same melt heat under the same conditions, at essentially the same time.

[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.

[3] 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**

3.4.1 *Discussion—*

For purposes of this specification, conversion from bar to tubular form by extrusion, gundrilling, or other method is included within the scope of this definition.

3.5 *lot average concentricity, n*—the arithmetic average of the sample concentricities measured on a statistically representative number of samples from the lot.

3.6 *lot average wall thickness, n*—the grand average of the sample average wall thicknesses measured on a statistically representative number of samples from the lot.

3.7 *nominal outside diameter (OD), n*—the outside diameter specified on the purchaser's order or engineering drawing without regard to tolerance.

3.8 *nominal wall thickness, n*—the wall thickness specified by the purchaser's order or engineering drawing without regard to tolerance.

3.9 *sample average wall thickness, n*—the arithmetic average of all individual wall thickness measurements measured on a single sample.

3.10 *sample concentricity, n*—two times the offset between the centers of the two circles representing the outside diameter (OD) and the inside diameter (ID) of the tube.

3.10.1 *Discussion—*

For purposes of this specification, the sample minimum wall and the sample maximum wall measured on any one transverse cross section of a single sample shall be used to calculate concentricity. Also, for purposes of this specification, sample concentricity shall be expressed as a percent and shall be calculated using the following equation:

$$\textit{Sample concentricity percent} = 2 \times \left[\frac{A - B}{A + B}\right] \times 100$$

where:

A = sample maximum wall, and
B = sample minimum wall.

3.11 *sample maximum wall thickness, n*—the largest individual wall thickness measurement taken around the circumference on any one transverse cross section of a single sample of tube.

3.11.1 *Discussion—*

In practice, the sample maximum wall thickness may be the largest of no less than four individual wall thickness measurements taken at uniformly spaced locations around the circumference of a single sample of the tube.

3.12 *sample minimum wall thickness, n*—the smallest individual wall thickness measurement taken around the circumference on any one transverse cross section of a single sample of tube.

3.12.1 *Discussion—*

In practice, the sample minimum wall thickness may be the smallest of no less than four individual wall thickness measurements taken at uniformly spaced locations around the circumference of a single sample of the tube.

4. Ordering Information

4.1 Inquiries and orders for material under this specification may include the following information:
4.1.1 Quantity (total length or number of pieces),
4.1.2 This ASTM specification and date of issue,
4.1.3 Condition (see 5.2),
4.1.4 Active Austenite Finish Temperature (see 7.3),
4.1.5 Mechanical Properties (see Table 1),
4.1.6 Surface Finish (see 5.3),
4.1.7 Nominal Dimensions including either OD and ID, OD and wall, or ID and wall, or engineering drawing number,
4.1.8 Length (exact or random, see 9.4),
4.1.9 Dimensional Tolerances (see Table 2 and Table 3),
4.1.10 Certification requirements (see Section 11), and

TABLE 1 Mechanical Properties

Condition	UTS Min MPa (ksi)	Uniform Elongation Min % in 50 mm (2 in.) or 4D	Upper Plateau Strength Min MPa (ksi) at 3 % strain	Lower Plateau Strength Min MPa (ksi) at 2.5 % strain	Residual Elongation Max % after 6 % strain
Superelastic[A]	1000 (145)	10	380 (55)	[B]	0.3 %

[A]Superelastic properties are measured per Test Method F2516 at room temperature.
[B]Lower plateau strength value may be measured and reported for information only.

TABLE 2 Permissible Variation in OD or ID Dimensions

Nominal OD or ID in mm (in.)	Permissible Variation from Nominal in mm (in.)
Less than or equal to 1.5 (0.059)	±0.025 (0.001)
1.5 to 6.5 (0.059 to 0.256) incl	±0.050 (0.002)
6.5 to 10 (0.256 to 1.2) incl	±0.075 (0.003)

TABLE 3 Permissible Variation in Wall Thickness Dimensions

Nominal Wall Thickness	Permissible Wall Thickness Variation
Less than 0.2 mm (0.008 in.)	±0.025 mm (0.001 in.) from nominal wall thickness
Greater than or equal to 0.2 mm (0.008 in.)	±12 % of nominal wall thickness[A]

[A]The ±12 % tolerance for a particular nominal wall thickness may be converted to a decimal by multiplying 0.12 times the nominal wall thickness and rounding to the appropriate decimal place.

4.1.11 Special requirements or supplementary requirements, if any.

5. Materials and Manufacture

5.1 *Method of Manufacture:*

5.1.1 Seamless tube shall be made from bar, hollow bar, or tube raw material forms that meet the requirements of Specification F2063.

5.1.2 Seamless tube shall be made by a process in which the tube periphery is continuous at all stages of the process.

5.2 *Condition*—Tube shall be furnished in the superelastic condition or as agreed upon between purchaser and supplier.

5.3 *Surface Finish:*

5.3.1 The tube outer surface shall be furnished, as specified by the purchaser, with a uniform, adherent oxide of any color, chemically etched, ground, or mechanically polished finish. Other finishes may be agreed upon between purchaser and supplier.

5.3.2 The tube inner surface shall be furnished, as specified by the purchaser, with a uniform, adherent oxide of any color, chemically etched, or mechanically conditioned finish.

5.3.3 Inner and outer surface roughness and the method of measurement shall be as agreed upon between the purchaser and supplier.

6. Chemical Composition

6.1 Seamless tube shall be made from bar, hollow bar, or tube raw material forms that meet the chemical composition requirements of Specification F2063.

~~NOTE 1—Non-metallic inclusions shall be rated and reported on the starting bar, hollow bar, or tube raw material forms by the raw material supplier per Specification F2063. Alternate non-metallic inclusion requirements and rating methods may be agreed upon between purchaser and supplier.~~

6.2 Hydrogen content shall be analyzed and reported when required by the purchaser. The analysis shall be made on the finished tube.

7. Transformation Temperature

7.1 The raw material manufacturer shall measure the ingot transformation temperature of the raw material on fully annealed samples per Test Method F2004 as required in Specification F2063. The raw material supplier shall report the ingot austenite finish (ingot A_f) transformation temperature as well as any of ingot Martensite finish (M_f), Martensite peak (M_p), Martensite start (M_s), Austenite start (A_s), or Austenite peak A_p transformation temperatures as required by the raw material purchaser. Each ingot transformation temperature reported will be clearly labeled by transformation type.