K-TUBE™ TECHNOLOGIES

Designation: K001-15a

Standard Specification for Miniature Laser Welded and Drawn Stainless Steel and Nickel-Chromium Alloy Tubing for General Use

This standard is issued under the fixed designation K001; immediately following the designation indicates the year of the original adoption or, in the case of revision, the year of the 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 chemistry requirements for wrought stainless steels used for general use. The data contained in Tables 1-3 of this specification, including typical hardness values, tensile strength values and surface finish values, are provided for ***reference only***. Mechanical property requirements and all other requirements except chemistry are governed by the appropriate material standards as referenced below or as agreed upon between the purchaser and supplier.

1.2. This specification covers as-welded or cold-reduced mechanical tubing in sizes less than .250 in. outside dimensions, and with a wall thickness 0.020 in. and under.

1.3. The values stated in inch-pounds units are to be regarded as standard. The values given in parentheses are mathematical conversions to SI units that are provided for information only and are not considered standard.

2. Referenced Documents

2.1. *ASTM Standards:*

A370 Standard Test Methods and Definitions for Mechanical Testing of Steel Products

A751 Test Methods, Practices, and Terminology for Chemical Analysis of Steel Products

A959 Standard Guide for Specifying Harmonized Standard Grade Compositions for Wrought Stainless Steels

B443 Standard Specification for Nickel-Chromium-Molybdenum-Columbium Alloy (UNS N06625) and Nickel-Chromium-Molybdenum-Silicon Alloy (UNS N06219) Plate, Sheet, and Strip

E384 Standard Test Method for Knoop and Vickers Hardness of Materials

F899 Standard Specification for Wrought Stainless Steels for Surgical Instruments

F2819 Standard Test Methods for Measurement of Straightness of Bar, Rod, Tubing and Wire to be used in Medical Devices

2.2. *ISO Standard:*

ISO 9001 Quality Management Systems – Requirements

ISO 9626 Stainless Steel Needle Tubing for Manufacture of Medical Devices

3. Classification and Type

3.1. *Classes* – Stainless steel material requirements for surgical instruments shall conform to one of the following classes, as specified:

3.1.1. Class 3 – Austenitic Stainless Steel

3.1.2. Class 4 – Martensitic Stainless Steel

3.1.3. Class 5 – Precipitation Hardening Stainless Steel

3.1.4. Class 6 – Ferritic Stainless Steel

3.1.5. Class 7 – Nickel-Chromium Alloy

4. Ordering Information

4.1. Inquiries and orders for material under this specification shall include the following information agreed upon by the purchaser and supplier:

4.1.1. Quantity, length or number of pieces

4.1.2. Classification (see 3.1)

4.1.3. Dimensions, including tolerances

4.1.4. Condition (see 5.1)

4.1.5. Length, specific or random (see 5.2)

4.1.6. Chemistry requirements (see 7.1)

4.1.7. Mechanical requirements, tensile strength, hardness, etc. (see 8)

4.1.8. Finish, Rq (see 9.1)

4.1.9. Drawing or specification number

5. Manufacture

5.1. Condition – Stainless steel tubing shall be laser welded from flat stock with no filler material. Stainless steels shall be furnished to the purchaser cold finished, annealed, heat treated, or as specified by the purchaser.

5.1.1. Free Sink – Refers to tubing that is drawn down through a series of dies without inner diameter support. Typically the default reduction method.

5.1.2. Plug Drawn – Refers to tubing that is drawn down through a die with a floating "plug" or "mandrel" to support the inner diameter.

5.2. Lengths – Tubing is normally furnished in mill lengths 5 ft and over. Definite cut lengths are furnished when specified, to the length tolerances as specified by the purchaser.

5.2.1. Tubing ordered in "footage" or "random lengths" will be furnished with pinched ends, no ID cleaning process and no length tolerance unless otherwise specified by purchaser.

6. Heat Analysis

6.1. An analysis of each heat of steel shall be made by the steel manufacturer to determine the percentages of the elements specified (see ASTM A751). The chemical composition thus determined, or determined from a product analysis made by the tubular product manufacturer, shall conform to requirements specified. A report of this analysis shall be furnished to the purchaser.

7. Chemical Requirements

7.1. The heat analysis shall conform to the requirements as to chemical composition specified in Table 3. Compositions referenced from ASTM A959 and ASTM B443.

7.2. Unified Numbering System (UNS) designations have been added to Table 3 to provide easy cross reference to a common numbering system.

7.3. Raw material is compliant with EU Directive 2011/65/EU (RoHS2) and Annex XIV of EU Directive 67/548/EEC (REACH).

8. Dimensional Requirements

8.1. Outside Diameter (OD) Dimension – Tolerance as agreed upon by the purchaser and supplier. Measured by laser/optical micrometer to ensure sample is not distorted during measurement. Reported OD is an average value taken around tubing circumference and displayed to 4 decimal points. No values are allowed to be outside the tolerance range.

8.2. Inside Diameter (ID) Dimension – Tolerance as agreed upon by the purchaser and supplier. Measured with Class X plus pin gauge (verified prior to use). The pin gauge that inserts only 1/16" represents the ID size. Smaller ID dimensions may also be verified optically, typically <.004".

8.3. Roundness – Difference in minimum and maximum OD measurements must be equal or less than half the OD tolerance.

9. Mechanical Requirements

9.1. Material shall conform to the mechanical property requirements specified by the purchaser.

9.2. When desired, Rockwell Hardness, B scale (HRB) or Rockwell Hardness, C Scale (HRC) limits may be specified. Typical micro-hardness values are listed in Table 1. These typical micro-hardness values are provided for reference only. Refer to ASTM E384 for testing procedure. Average of 5 test results reported per lot.

TABLE 1 Typical Hardness for Stainless Steel Tubing

Class	Grade	Condition		
		Annealed	As Drawn[A]	Heat Treat
3. Austenitic	304	HRB 82	HRC 38	N/A
	304L	HRB 80	HRC 38	N/A
	316	HRB 79	HRC 38	N/A
	316L	HRB 79	HRC 38	N/A
	321	HRB 81	HRC 38	N/A
	347	HRB 81	HRC 38	N/A
4. Martensitic	410	HRB 83	HRC 27	HRC 43[B]
	420	HRB 89	HRC 35	HRC 52[C]
5. Precipitation Hardened	17-7	HRB 85	HRC 43	HRC 49[D]
6. Ferritic	430	HRB 82	HRC 25	N/A
7. Nickel-Chromium	I625	HRB 97	HRC 43	N/A

[A] *As Drawn values vary greatly based on amount of cold work*

[B] *Hardened at 1850F - 30 minutes, oil quench, tempered at 500F - 4 hours*

[C] *Hardened at 1900F, oil quench, tempered at 400F*

[D] *Assuming CH-900 Heat Treat*

9.3. When desired, ultimate tensile strength minimums or allowable range limits may be specified. Typical ultimate tensile strength values are listed in Table 2. These typical ultimate tensile strength values are provided for reference only. Refer to ASTM A370 for testing procedure. One test per lot reported.

TABLE 2 Typical Ultimate Tensile Strength (ksi) for Stainless Steel Tubing

Class	Grade	Condition		
		Annealed	As Drawn[A]	Heat Treat
3. Austenitic	304	90	170	N/A
	304L	85	170	N/A
	316	85	170	N/A
	316L	80	170	N/A
	321	85	170	N/A
	347	90	170	N/A
4. Martensitic	410	75	120	210[B]
	420	80	150	250[C]
5. Precipitation Hardened	17-7	130	200	260[D]
6. Ferritic	430	75	110	N/A
7. Nickel-Chromium	I625	130	200	N/A

[A] *As Drawn values vary greatly based on amount of cold work*

[B] *Hardened at 1850F - 30 minutes, oil quench, tempered at 500F - 4 hours*

[C] *Hardened at 1900F, oil quench, tempered at 400F*

[D] *Assuming CH-900 Heat Treat*

10. Finish

10.1. Tubes shall be free of scale

10.2. When desired, OD and ID surface finish (Rq or RMS) limits may be specified. ID and OD surface finish values are only reported for dimensions >.020".

10.2.1. Typical OD Surface is < 20 Rq.

10.2.2. ID Surface finish depends on the reduction (drawing) method. Free Sunk (see 5.1.1) tubing has a typical ID surface finish <150 Rq. Plug Drawn (see 5.1.2) tubing can have an ID surface finish range with values as low as < 25 Rq.

11. Straightness

11.1. The straightness is no deflection greater than 5% of the outside diameter for tubing with OD > .020" or .001" maximum deflection for tubing with OD <.020". Any special straightness requirements shall be agreed upon between the purchaser and supplier. Values are reported as deflection per 3" section.

11.2. Tubing should not "wobble" as defined per ASTM F2819.

12. Corrosion Resistant/Surface Chemistry

12.1. Annual audit test for ISO 9626 Annex A (Determination of Acidity and Alkalinity) and Annex E (Resistance to Corrosion) to ensure requirements/limits are not exceeded.

13. Heat Treatment

13.1. When desired, material shall be heat treated per the applicable referenced standard (i.e. ASTM F899) for the selected stainless steel.

13.2. Specifying a hardness or tensile strength requirement appropriate for the selected alloy and intended application is the responsibility of the purchaser

14. Quality Program Requirements

14.1. The supplier shall maintain a quality program, such as defined in ASQ C1 and ISO 9001.

14.2. The purchaser may audit the supplier's quality program for conformance to the intent of the recognized program.

15. Keywords

Austenitic; ferritic; martensitic; precipitation hardenable; stainless steel; miniature tubing; cannula;

TABLE 3 Composition of Multiple Classes of Stainless Steel

Class	Grade	UNS	Carbon, max	Manganese, max	Phosphorus, max	Sulfur, max	Silicon, max	Chromium	Nickel	Molybdenum	Other Elements
3. Austenitic	304	S30400	0.07	2.00	0.045	0.030	1.00	17.5-19.5	8.0-11.0		
	304L	S30403	0.03	2.00	0.045	0.030	1.00	17.5-19.5	8.0-12.0		
	316	S31600	0.08	2.00	0.045	0.030	1.00	16.0-18.0	10.0-14.0	2.00-3.00	
	316L	S31603	0.03	2.00	0.045	0.030	1.00	16.0-18.0	10.0-14.0	2.00-3.00	
	321	S32100	0.08	2.00	0.045	0.030	1.00	17.0-19.0	9.0-12.0		N 0.10; Ti 5x(C+N)-.070
	347	S34700	0.08	2.00	0.045	0.030	1.00	17.0-19.0	9.0-12.0		Cb 10xC-1.10
4. Martensitic	410	S41000	0.15	1.00	0.040	0.030	1.00	11.5-13.5			
	420	S42000	.15 min	1.00	0.040	0.030	1.00	12.0-14.0			
5. Precipitation Hardened	17-7	S17700	0.09	1.00	0.04	0.030	1.00	16.0-18.0	6.5-7.7		Al 0.75-1.50
6. Ferritic	430	S43000	0.12	1.25	0.040	0.030	1.00	16.0-18.0			
6. Nickel - Chromium	I625	N06625	0.1	0.5	0.015	0.015	0.50	20.0-23.0	58 min	8.0-10.0	Cb +Ta 3.15-4.15; Co 1.0; Fe 5.0; Al .4; Ti .4