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StandardSpecification for Wrought Stainless Steels for Surgical Instruments[1]

This standard is issued under the fixed designation F899; 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.

This standard has been approved for use by agencies of the Department of Defense.

1. Scope*

1.1 This specification covers the chemistry requirements for wrought stainless steels used for the manufacture of surgical instruments. The data contained in Tables 1-4 of this specification, including typical hardness values, common heat treating cycles, and examples of selected stainless steels that have been used for surgical instruments, is provided for reference only. Mechanical property requirements, heat treating requirements, hardness 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 The values stated in inch-pound 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:*[2]

A276 Specification for Stainless Steel Bars and Shapes

A313/A313M Specification for Stainless Steel Spring Wire

A314 Specification for Stainless Steel Billets and Bars for Forging

A480/A480M Specification for General Requirements for Flat-Rolled Stainless and Heat-Resisting Steel Plate, Sheet, and Strip

A484/A484M Specification for General Requirements for Stainless Steel Bars, Billets, and Forgings

A555/A555M Specification for General Requirements for Stainless Steel Wire and Wire Rods

A564/A564M Specification for Hot-Rolled and Cold-Finished Age-Hardening Stainless Steel Bars and Shapes

A582/A582M Specification for Free-Machining Stainless Steel Bars

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

2.2 *ISO Standards:*[3]

ISO 7153/1 Instruments For Surgery—Metallic Materials—Part 1: Stainless Steel

ISO 9001 Quality Management Systems—Requirements

2.3 *American Society for Quality (ASQ) Standard:*[4]

ASQ C1 Specification of General Requirements for a Quality Program

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.

3.2 *Type*—Where applicable, the commercially recognized type of stainless steel is included in Tables 5 and 6.

4. Ordering Information

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

4.1.1 Quantity (weight or number of pieces),

4.1.2 Classification, optional,

4.1.3 Type,

4.1.4 Form,

4.1.5 Condition (see 5.1),

4.1.6 Finish (see 5.3),

4.1.7 Mechanical properties or hardness, and

4.1.8 Applicable dimensions including size, thickness, width, and length (exact, random, or multiples) or drawing number.

[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.

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

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

TABLE 1 Typical Maximum Hardness for Selected Class 4 Martensitic Stainless Steels in The Annealed Condition[A]

Type	Typical Maximum Brinell Hardness[B]
410	210
410X	220
416	262
416 Mod	262
420A	220
420B	235
420 Mod	255
420X	262
420C	262
420F	262
420F Mod	262
UNS S42027	255
431	285
440A	285
440B	285
440C	285
440F	285
UNS S42026	260
UNS S42010	235

[A] Excludes billets and bars for forging.
[B] Or equivalent Rockwell hardness.

5. Manufacture

5.1 *Condition*—Stainless steels shall be furnished to the purchaser, as specified, in the hot-finished, cold-finished, annealed, solution-treated, solution-treated and aged, quench-hardened and tempered, or as specified by the purchaser. (Note that highly hardenable martensitic stainless billets and bars such as Types 420A, 420B, 420C, 420 Mod, 420F, 420F Mod., 440A, 440B, and 440C intended for forging are commonly annealed prior to shipment and so specified in order to avoid the possibility of thermal cracking. Other hardenable martensitic grades such as Types 403, 410, 416, 416 Mod., and 431, which also may require annealing, depending on their composition and size, are furnished suitable for cold cutting when so specified on the purchase order.)

5.2 *Conditioning*—Billet and bar intended for forging may be conditioned by chipping, grinding, or other suitable means to remove injurious surface defects.

5.3 *Finish*—Types of finish available for bar and wire products are cold drawn, pickled, ground, ground and polished, or as specified in the purchase order.

6. General Requirements for Delivery

6.1 In addition to the chemistry requirements of this specification, all requirements of the current editions of Specifications A276, A313/A313M, A314, A480/A480M, A484/A484M, A555/A555M, A564/A564M, A582/A582M, and A751 shall apply where applicable, as agreed upon between the purchaser and supplier.

6.2 This specification compliments the applicable ISO document covering stainless steel for surgical instruments and, by reference, includes all of the stainless grades in ISO 7153/1.

7. Chemical Requirements

7.1 The heat analysis shall conform to the requirements as to chemical composition specified in Tables 5-8.

7.2 Unified Numbering System (UNS) designations have been added to Tables 5-8 to provide an easy cross reference to a common numbering system. In order to ensure consistency in the materials used for the manufacture of surgical instruments, compositional limits tighter than typical UNS limits have been established for certain elements (as denoted by an asterisk). For example, more restrictive carbon and sulfur limits are specified in Table 7.

7.3 The chemical composition requirements for Types 301, 303, 304, 316, 410, 420A, 420B, 420C, and 430F also meet the composition requirements in ISO 7153/1.

7.4 Methods and practices relating to chemical analysis required by this specification shall be in accordance with Test Methods, Practices, and Terminology A751.

8. Mechanical Requirements

8.1 Material shall conform to the mechanical property requirements cited in the appropriate ASTM standards (see 2.1) or shall meet the mechanical property requirements specified by the purchaser.

8.2 When desired, Brinell hardness number (HB), Rockwell hardness, B scale (HRB) or Rockwell hardness, C scale (HRC), limits may be specified. Typical hardness values for selected Class 4 martensitic stainless steels in the annealed condition are listed in Table 1. These typical hardness values are provided for reference only.

9. Heat Treatment

9.1 Material shall be heat treated per the applicable referenced ASTM standard (see 2.1) for the selected stainless steel.

9.2 Commonly used heat treating cycles guidelines and the resulting typical hardness values for selected Class 4 martensitic stainless steels are listed in Table 2 and are provided for reference only.

9.3 Heat treating guidelines for Class 5 precipitation hardening stainless steels are included in Specification A564/A564M.

9.4 Specifying a hardness requirement appropriate for the selected alloy and intended application is the responsibility of the purchaser.

10. Special Information

10.1 Some examples of selected stainless steels that have been used for various surgical instrument applications are listed in Table 3 and Table 4 for information purposes.

NOTE 1—Re-sulphurized free-machining grades can exhibit lower general corrosion resistance, lower pitting corrosion resistance, and difficulty in polishing or welding. It is suggested that these grades be utilized only for applications where the appropriate steps in manufacture can be taken in order to avoid such issues thus resulting in satisfactory long-term performance of the device.

11. Quality Program Requirements

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

TABLE 2 Typical Heat Treating Cycles and Resultant Hardness Values for Selected Class 4 Martensitic Stainless Steels

Type	Typical Hardening[A] Heat Treatment	Typical Hardness at Indicated Tempering Temperature[B]		
		°F	°C	(HRC)
410	1850°F (1010°C) + Oil quench or air cool	500	260	43
		700	371	43
		900[C]	482	42
		1000[C]	538	30
		1100	593	24
410X	1875°F (1024°C) + Oil quench or air cool	500	260	46
		700	371	46/47
		900[C]	482	48
		1000[C]	538	44
		1100	593	31
416 Mod	1800°F (982°C) + Oil quench	300	149	38
		500	260	37
		700	371	37
		900[C]	482	35
		1000[C]	538	30
		1100	593	22
416	1800°F (982°C) + Oil quench	300	149	41
		500	260	39
		700	371	41
		900[C]	482	36
		1000[C]	538	31
		1100	593	26
420A	1850°F (1010°C) + Warm oil quench	300	149	53
		400	204	50
		500	260	48
		600	315	48
		700	371	48
		800[D]	427	48
420B	1900°F (1038°C) + Warm oil quench	300	149	52
		400	204	52
		500	260	50
		600	315	50
		700	371	49
		800[D]	427	49
420 Mod	180°F (1010°C) + oil quench or pressure gas	350	177	56/57
		400	204	55
		500	260	54
		600	315	53
420X	1900°F (1038°C) + Warm oil quench	300	149	52
		400	204	52
		500	260	50
		600	315	50
		700	371	49
		800[D]	427	49
S42010	1900°F (1038°C) + Warm Oil Quench	400	204	50
		500	260	47
		600[E]	316	47
		700	371	48
		850	454	48

Type	Typical Hardening[A] Heat Treatment	Typical Hardness at Indicated Tempering Temperature[B]		
		°F	°C	(HRC)
420C	1900°F (1038°C) + Warm oil quench	300	149	58
		400	204	55/56
		500	260	53/54
		600	315	53/54
		700	371	54/55
		800[D]	427	55
420F	1900°F (1038°C) + Warm oil quench	300	149	52
		400	204	52
		500	260	50
		600	315	50
		700	371	49
		800[D]	427	49
420F Mod	1900°F (1038°C) + Warm oil quench	300	149	53
		400	204	50
		500	260	48
		600	315	48
		700	371	48
		800[D]	427	48
UNS S42026	1920°F (1050°C)+ oil quench or pressure gas	400	204	56
		500	260	54/55
		600	315	53/54
431	1900°F (1038°C) + Oil quench	500	260	42
		700	371	42
		900[C]	482	45
		1100[C]	593	34
440A	1900°F (1038°C) + Warm oil quench	300	149	56/57
		400	204	56
		500	260	54
		600	315	51/52
		700	371	51
		800[D]	427	50
440B	1900°F (1038°C) + Warm oil quench	300	149	58/59
		400	204	56/57
		500	260	53/54
		600	315	53
		700	371	54
		800[D]	427	54
440C	1900°F (1038°C) + Warm oil quench	300	149	60
		400	204	59
		500	260	57
		600	315	56
		700	371	56
		800[D]	427	56
440F	1900°F (1038°C) + Warm oil quench	300	149	60
		400	204	59
		500	260	57
		600	315	56
		700	371	56
		800[D]	427	56
S42027	1850°F (1010°C) + oil quench or pressure gas	300	149	58/59
		400	204	57/58
		500	260	57/58
		600	315	56/57

[A] Time at temperature depends on section size. Controlled heat treating atmosphere or alternate quench media may be used in accordance with good commercial practice.
[B] Temper at least one hour at the indicated temperature and air cool. Large section sizes require longer times at temperature.
[C] Tempering in the range of 750/1050°F (399/566°C) results in decreased impact strength and reduced corrosion resistance.
[D] Tempering over 800°F (427°C) results in reduced corrosion resistance.
[E] Tempering above 600°F (316°C) results in reduced toughness.