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# Standard Specification for Wrought Stainless Steels for Surgical Instruments<sup>1</sup>

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 ( $\varepsilon$ ) 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 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:<sup>2</sup>

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:<sup>3</sup>

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

ISO 9001 Quality Management Systems—Requirements M F899-1

2.3 American Society for Quality (ASQ) Standard:<sup>4</sup>

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.

<sup>&</sup>lt;sup>1</sup> 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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<sup>&</sup>lt;sup>2</sup> 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.

<sup>&</sup>lt;sup>3</sup> Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, http://www.ansi.org.

<sup>&</sup>lt;sup>4</sup> Available from American Society for Quality (ASQ), 600 N. Plankinton Ave., Milwaukee, WI 53203, http://www.asq.org.

TABLE 1 Typical Maximum Hardness for Selected Class 4 Martensitic Stainless Steels in The Annealed Condition<sup>A</sup>

Туре	Typical Maximum Brinell Hardness <sup>B</sup>				
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				
431	285				
440A	285				
440B	285				
440C	285				
440F	285				
UNS S42026	260				
UNS S42010	235				

<sup>&</sup>lt;sup>A</sup> Excludes billets and bars for forging.

#### 4. Ordering Information

- 4.1 Inquiries and orders for material under this specification shall include the following information as agreed upon by 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), (11108)/8121102108.1101.21
  - 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.

## 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 purchaser and supplier.
- 6.2 This specification compliments the ISO applicable 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 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.

<sup>&</sup>lt;sup>B</sup> Or equivalent Rockwell hardness.

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

Туре	Typical Hardening <sup>A</sup> Heat Treatment	Typical Hardness at Indicated Tempering Temperature <sup>B</sup>			Туре	Typical Hardening <sup>A</sup> Heat Treatment	Typical Hardness at Indicated Tempering Temperature <sup>B</sup>			
		°F	°C	(HRC)	_		riodi frodimoni	°F	°C	(HRC)
410	1850°F (1010°C) +	500	260	43		420C	1900°F (1038°C) +	300	149	58
	Oil quench	700	371	43			Warm oil quench	400	204	55/56
	or air cool	900 <sup>C</sup>	482	42			•	500	260	53/54
		1000 <sup>C</sup>	538	30				600	315	53/54
		1100	593	24				700	371	54/55
410X	1875°F (1024°C) +	500	260	46				800 <sup>D</sup>	427	55
	Oil quench	700	371	46/47		420F	1900°F (1038°C) +	300	149	52
	or air cool	900 <sup>C</sup>	482	48		4201	Warm oil guench	400	204	52
	or all cool	1000 <sup>C</sup>	538	44			waitii oli quelicii	500	260	50
	10000E (0000C)	1100	593	31				600	315	50
116 Mod	1800°F (982°C) +	300	149	38				700	371	49
	Oil quench	500	260	37				800 <sup>D</sup>	427	49
		700	371	37		420F Mod	1900°F (1038°C) +	300	149	53
		900 <sup>C</sup>	482	35			Warm oil quench	400	204	50
		1000 <sup>C</sup>	538	30				500	260	48
		1100	593	22				600	315	48
116	1800°F (982°C) +	300	149	41				700	371	48
	Oil guench	500	260	39				800 <sup>D</sup>	427	48
	3 quo	700	371	41		UNS	1920°F	400	204	56
		700	071	71		S42026	(1050°C)+	400	204	30
		900 <sup>C</sup>	482	36		042020	oil quench or	500	260	54/55
		1000 <sup>C</sup>	538	31				600	315	53/54
						404	pressure gas			
		1100	593	26		431	1900°F (1038°C) +	500	260	42
							Oil quench	700	371	42
								900 <sup>C</sup>	482	45
								1100 <sup>C</sup>	593	34
420A	1850°F (1010°C) +	300	149	53	40.	440A	1900°F (1038°C) +	300	149	56/57
	Warm oil quench	400	204	50	1.21		Warm oil quench	400	204	56
		500	260	48				500	260	54
		600	315	48	-			600	315	51/52
		700	371	48	n d l	arde		700	371	51
		800 <sup>D</sup>	427	48		ai us		800 <sup>D</sup>	427	50
120B	1900°F (1038°C) +	300	149	52		440B	1900°F (1038°C) +	300	149	58/59
1200	Warm oil quench	400	204	52	-a 4		Warm oil quench	400	204	56/57
	vvaiiii oii queiioii	500	260	50		rrev	Traini on quenon	500	260	53/54
		600	315	50				600	315	53/54
			371	49						53 54
		700						700 800 <sup>D</sup>	371	
00 M- 1	4000E (404000)	800 <sup>D</sup>	427	49 50/54 ST	M F8	99-11		8005	427	54
20 Mod	180°F (1010°C)	350	177	56/57						
	+ oil quench or	400 atalog/s	204 dards	55st/cb9	78bb	d-8ace-40				
	pressure gas	500	260	54						
		600	315	53						
20X	1900°F (1038°C) +	300	149	52		440C	1900°F (1038°C) +	300	149	60
	Warm oil quench	400	204	52			Warm oil quench	400	204	59
		500	260	50				500	260	57
		600	315	50				600	315	56
		700	371	49				700	371	56
		800 <sup>D</sup>	427	49				800 <sup>D</sup>	427	56
S42010	1900°F	400	204	50		440F	1900°F (1038°C) +	300	149	60
		500		50 47		44UF			204	
	(1038°C) + Warm	600 <sup>E</sup>	260				Warm oil quench	400		59 57
	Oil Quench		316	47				500	260	57
		700	371	48				600	315	56
		850	454	48				700	371	56
								$800^{D}$	427	56

<sup>&</sup>lt;sup>A</sup> Time at temperature depends on section size. Controlled heat treating atmosphere or alternate quench media may be used in accordance with good commercial practice.

### 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

<sup>&</sup>lt;sup>B</sup> Temper at least one hour at indicated temperature and air cool. Large section sizes require longer time at temperature.

<sup>&</sup>lt;sup>C</sup> Tempering in the range of 750/1050°F (399/566°C) results in decreased impact strength and reduced corrosion resistance.

<sup>&</sup>lt;sup>D</sup> Tempering over 800°F (427°C) results in reduced corrosion resistance.

<sup>&</sup>lt;sup>E</sup> Tempering above 600°F (316°C) results in reduced toughness.

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