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Standard Specification for Wrought Stainless Steels for Surgical Instruments¹

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 U.S. 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 SI units in this standard are the primary units. The values stated in either primary SI units or secondary inch-pound units are to be regarded separately as standard. The values stated in each system may not be exact equivalents; therefore, each system shall be used independently of each other. Combining values from the two systems may result in non-conformance with the standard.
- 1.3 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

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 Surgical instruments Instruments – Materials – Part 1: Metals

ISO 9001 Quality Management Systems—Requirements

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.

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.

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

Туре	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
440A Mod	285
440B	285
440C	285
440F	285
UNS S42026	260
UNS S42010	235

A Excludes billets and bars for forging.

- 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), iteh ai/catalog/standards/sist/39d34850-d5e4-4cf5-ab1a-7a4391b745aa/astm-f899-20
 - 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, 440A Mod, 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 Test Methods, Practices, and Terminology 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.

^B Or equivalent Rockwell hardness.



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

Type Typical Hardenin		Typical Hardness at Indicated Tempering		_	Typical Hardening ^A	٦	Typical Hardness at		
Type	Temperature		Temperature		Туре	Temperature		Tempering Tempe	
		°C	°F	(HRC)		'	°C	°F	(HRC)
410	1010°C [1850°F]	260	-500	43	420C	1038°C [1900°F]	149	300	58
410	1010 °C [1850 °F]	260	500		420C	1038 °C [1900 °F]	149	300	58
<u> </u>		371	700	43 43			204	400	55 /56
	482	900 ^C	42			260	500	53/54	
		538	1000 ^C	30			315	600	53/54
		593	1100	24			371	700	54/55
410X	1024°C [1875°F]	260	-500	46			427	800 ₽	55
410X	1024 °C [1875 °F]	260	500	46			427	800^{D}	55
		371	700	46/47	420F	1038°C [1900°F]	149	300	<u>55</u> 52
	_	371	700	46/47	420F	1038 °C [1900 °F]	149	300	<u>52</u>
		482	900 ^C	48			204	400	52
		538	1000 ^C	44			260	500	50
		593	1100	31			315	600	50
116 Mod	982°C [1800°F]	149	-300	38			371	700	49
416 Mod	982 °C [1800 °F]	149	300	<u>38</u>			371	<u>700</u>	<u>49</u>
		260	500	37			427	800 ^D	49
		371	-700	37	420F Mod	1038°C [1900°F]	149	300	53
		371	700	<u>37</u>	420F Mod	1038 °C [1900 °F]	149	300	<u>53</u>
		482	900 ^C	35			204	400	50
		538	1000 ^C	30			260	500	48
		593	1100	22			315	600	48
416	982°C [1800°F]	149	-300	41			371	700	48
<u>416</u>	982 °C [1800 °F]	149	300	<u>41</u>			371	700	48
		260	500	39			427	800 ^D	48
		371	-700	41	UNS	1050°C [1920°F]	204	400	56
					\$42026				
		371	700	<u>41</u>	UNS	1050 °C [1920 °F]	204	400	<u>56</u>
					S42026				
		482	900 ^C	36	andar		260	500	54/55
		538	1000 ^C	31	anuai		315	600	53/54
		593	1100	26	431	1038°C [1900°F]	260	500	42
		593	1100	26	431	1038 °C [1900 °F]	260	500	42 42
420A	1010°C [1850°F]	149	300	53	uarus		371	700	42
420A	1010 °C [1850 °F]	149	300	<u>53</u> 50			371	700	<u>42</u> 45
		204	400	50	A Duo		482	900 ^C	45
		260	500	48	nt rre		593	1100 ^C	34
		315	-600	48	440A	1038°C [1900°F]	149	300	56/57
		315	600	48	440A	103 8°C [1900 °F]	149	300	56/57
		371	700	48			204	400	56
		427	800 ^D	48 ASTV	l F899-20		260	500	54
420B	1038°C [1900°F]	149	-300	52.	4050 15 4		315	600	51/52
420B	1038 °C [1900 °F]	149	atalog/s <mark>300</mark> dar	ds <u>52</u> ist/39d3	48pu-ase4-4		315	0/45 600 astm	51/52
		204	400	52			371	700	51
		260	500	50			427	800 ^D	50
		315	-600	50	440A Mod	1080°C [1976°F]	149	300	58
		<u>315</u>	_600	<u>50</u>	440A Mod	1080 °C [1976 °F]	149	300	<u>58</u> 54
		371	700	49			204	400	
		427	800 ^D	49			260	500	53/54
120 Mod	1010°C [1850°F]	177	-350	56/57			315	600	53
420 Mod	1010 °C [1850 °F]	177	350	56/57			<u>315</u>	<u>600</u>	<u>53</u> 53
		204	400	55			371	700	
		260	500	54			427	800 ^D	53
-	-	315	-600	53	440B	1038°C [1900°F]	149	300	58/59
420X	1038°C [1900°F]	149	-300	52			204	400	56/57
		204	-400	52			260	500	53/54
		260	-500	50			315	600	53
		315	-600	50			371	700 _	54
		371	-700	49			427	800 ₽	54
		<u>315</u>	_600	53 52 52 50 50 49	<u>440B</u>	1038 °C [1900 °F]	149	300	58/59
420X 10	1038 °C [1900 °F]	149	300	<u>52</u>			204	400	56/57
		204	400	52			260	500	53/54
		260	500	<u>50</u>			315 371	600	<u>53</u>
		315	600	<u>50</u>			371	700	<u>54</u>
		371	700	<u>49</u>			427	800 ^D	53 54 54 60
		427	800 ^D	49	440C	1038°C [1900°F]	149	300	60
		427	_800 ^D	<u>49</u> 50	440C	1038 °C [1900 °F]	149	<u>300</u>	<u>60</u> 59
S42010	1038°C [1900°F]	204	-400	50			204	400	59
S42010	1038 °C [1900 °F]	204	400	50			204	<u>400</u>	<u>59</u> 57
	-	260	500	47			260	500	57
		316	600 [€]	47			315	600	56
		371	700	48			371	700	56
			0.50	48			427	800^{D}	56
		454	850	40	440F	1038°C [1900°F]	149	300	60



Type	Typical Hardaning ^A	Typical Hardness at Indicated Tempering Temperature ^B			Туре	Typical Hardening ^A Temperature	Typical Hardness at Indicated Tempering Temperature ^B		
		°C	°F	(HRC)		remperature	°C	°F	(HRC)
					440F	1038 °C [1900 °F]	149	300	<u>60</u> 59
							204	400	59
							260	500	57
							315	600	56
							371	700	56
							427	800^{D}	56
					\$42027	1010°C [1850°F]	149	300	58/59
					S42027	1010 °C [1850 °F]	149	300	58/59
							204	400	57/58
							260	500	57/58
							315	600	56/57

^A The temperatures listed are intended to be guides with the final heat treat cycle determined by the designer <u>and/oror</u> heat treatment <u>engineer engineer, or both,</u> to meet the intended use of the device. Time at temperature depends on section size. It is recommended that controlled heat treating atmosphere be used in accordance with good commercial practice. Heat treat cycles may use air, oil or gas for quench.

TABLE 3 Examples of Selected Stainless Steels That Have Been Used for Surgical Instruments in Accordance with ISO 7153 ISO 7153-

Type	Cutting Instruments	Non-Cutting Instruments
303	Chisels and gouges, bone curettes	probes
304		retractors
410		tissue, forceps, dressing forceps, retractors,
		probes
	Bone rongeurs, conchotomes, bone cutting	forceps, retractors, probes, forceps with bow
	forceps, chisels and gouges, bone curettes, scissors with carbide inserts	handles, branch forceps
420B	bone rongeurs, scissors	
420C	scissors, bone rongeurs, bone cutting forceps,	
	conchotomes, scalpels, knives, bone curettes,	
	chisels and gouges	
420 Mod	bone rongeurs, conchotomes, bone cutting	tissue forceps, dressing forceps, retractors,
	forceps, chisels and gouges, bone curettes,	probes, forceps, forceps with bow handles,
	scissors with carbide inserts, scissors, scalpels,	branch forceps
	knives	

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.
- 7.5 The cobalt content of the heat analysis shall be indicated for information only on the certificate issued by the manufacturer for the materials listed in Tables 5-8.

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.

^B Temper at least one hour-1 h at the indicated temperature and air cool. Large section sizes require longer times at temperature.

^C Tempering in the range of 399/566°C [750/1050°F]399/566 °C [750/1050°F] results in decreased impact strength and reduced corrosion resistance.

^D Tempering over 427°C [800°F]427 °C [800 °F] results in reduced corrosion resistance.

E Tempering above 316°C [600°F]316 °C [600 °F] results in reduced toughness.