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Standard Specification for Wrought Stainless Steels for Surgical Instruments



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Reference number
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Foreword

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- (a) a member of International Organisation for Standardisation (ISO) and
- (b) a contact point for the WHO/FAO Codex Alimentarius Commission on Food Standards, and
- (c) the National Enquiry Point on TBT Agreement of the World Trade Organisation (WTO).

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The committee responsible for this document is Technical Committee UNBS/TC 14, *Medical devices*'.

Wherever the words, "ASTM Standard" appear, they should be replaced by "Uganda Standard."



INTERNATIONAL Designation: F899 – 12b

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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 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.

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

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



^A Excludes billets and bars for forging.

^B Or equivalent Rockwell hardness.

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			Type	Typical Hardening ^A Heat Treatment	Typical Hardness at Indicated Tempering Temperature ^B			
		°F	°C	(HRC)			°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 ^C	482	42			500	260	53/54	
		1000 ^C	538	30			600	315	53/54	
		1100	593	24			700	371	54/55	
410X	1875°F (1024°C) +	500	260	46	420F	1900°F (1038°C) +	300	149	52	
	Oil quench	700	371	46/47		Warm oil quench	400	204	52	
	or air cool	900 ^C	482	48			500	260	50	
		1000 ^C	538	44			600	315	50	
		1100	593	31			700	371	49	
416 Mod	1800°F (982°C) +	300	149	38	420F Mod	1900°F (1038°C) +	300	149	53	
	Oil quench	500	260	37		Warm oil quench	400	204	50	
		700	371	37			500	260	48	
		900 ^C	482	35			600	315	48	
		1000 ^C	538	30			700	371	48	
416	1800°F (982°C) +	300	149	41	UNS S42026	1920°F (1050°C) +	400	204	56	
	Oil quench	500	260	39		oil quench or	500	260	54/55	
		700	371	41		pressure gas	600	315	53/54	
		900 ^C	482	36		431	1900°F (1038°C) +	500	260	42
		1000 ^C	538	31			Oil quench	700	371	42
	1100	593	26		900 ^C		482	45		
420A	1850°F (1010°C) +	300	149	53		1100 ^C	593	34		
	Warm oil quench	400	204	50	440A	1900°F (1038°C) +	300	149	56/57	
		500	260	48		Warm oil quench	400	204	56	
		600	315	48			500	260	54	
		700	371	48			600	315	51/52	
	800 ^D	427	48			700	371	51		
420B	1900°F (1038°C) +	300	149	52	440B	1900°F (1038°C) +	300	149	58/59	
	Warm oil quench	400	204	52		Warm oil quench	400	204	56/57	
		500	260	50			500	260	53/54	
		600	315	50			600	315	53	
		700	371	49			700	371	54	
420 Mod	180°F (1010°C) + oil quench or pressure gas	350	177	56/57		800 ^D	427	54		
		400	204	55	440C	1900°F (1038°C) +	300	149	60	
		500	260	54		Warm oil quench	400	204	59	
		600	315	53			500	260	57	
	420X	1900°F (1038°C) +	300	149		52		600	315	56
Warm oil quench		400	204	52						
		500	260	50						
		600	315	50						



Type	Typical Hardening ^A Heat Treatment	Typical Hardness at Indicated Tempering Temperature ^B			Type	Typical Hardening ^A Heat Treatment	Typical Hardness at Indicated Tempering Temperature ^B		
		°F	°C	(HRC)			°F	°C	(HRC)
S42010	1900°F (1038°C) + Warm Oil Quench	700	371	49	440F	1900°F (1038°C) + Warm oil quench	700	371	56
		800 ^D	427	49			800 ^D	427	56
		400	204	50			300	149	60
		500	260	47			400	204	59
		600 ^E	316	47			500	260	57
		700	371	48			600	315	56
		850	454	48	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.

TABLE 3 Examples of Selected Stainless Steels That Have Been Used for Surgical Instruments in Accordance with ISO 7153/1

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

TABLE 4 Examples of Selected Stainless Steels That Have Been Used For Surgical Instruments in the United States

Type	Cutting Instruments	Non-Cutting Instruments
302	knives, chisels, gouges, curettes	cannula, forceps, guides, needle vents, retractors, specula, spreaders, tendon passers, springs
303 ^A	chisels, curettes, knives	cannula, clamps, drills, forceps, handles, hammers, mallets, needle vents, punches, retractors, rulers, screws, skin hooks, specula, spreaders, suction tubes, tendon strips, tongs, tunnelers, probes
304		cannula, clamps, forceps, holders, handles, needle vents, retractors, specula, spreaders, suction tubes, tendon passers
316		specula
410	chisels, curettes, dissectors, osteotomes, reamers, scissors with inserts	clamps, clip applicators, elevators, forceps, hemostats, holders, needle holders, punches, retractors, skin hooks, sounds, spreaders, probes, dilators
410X	curettes, dissectors, rongeurs	clamps, forceps, hemostats, holders, punches, retractors
416 ^A	chisels, curettes, dissectors	clamps, punches, retractors, skin hooks, spreaders
420 ^B	chisels, curettes, cutters, bone cutting forceps, knives, scissors, rongeurs, scalpels, skin punches, conchotomes	clamps, elevators, punches, rounds, dissectors, retractors, skin hooks, needles
420F ^A	cutters	burs
431		cheek retractors, insertion wrenches, orthopaedic instruments



Type	Cutting Instruments	Non-Cutting Instruments
440 ^C	chisels, knives, osteotomes, scalpels	drills, retractors, spreaders, tongs
420 Mod	chisels, curettes, cutters, bone cutting forceps, knives, scissors, rongeurs, scalpels, skin punches, conchotomes, osteotomes, reamers	clamps, elevators, punches, rounds, dissectors, retractors, skin hooks, needles, cheek retractors, insertion wrenches, orthopaedic instruments, drills, spreaders, tongs, screwdrivers
630	reamers	
XM-16	scissors	drills, needles
XM-13	reamers, rasps	
S11100	reamers, scissors, rasps, knives	Clamps, punches, impactor guides, strike plates, screwdrivers, hex drivers
S46500	reamers, scissors, rasps, knives	Clamps, punches, impactor guides, strike plates, screwdrivers, hex drivers

^A It is not recommended that free-machining grades be used for critical portions of surgical instruments. Free machining grades should only be considered for instrument applications when appropriate steps can be taken during manufacture to minimize the inherent limitations of this class of alloys (see section 10.1)

^B Types 420A, 420B, 420C, or UNS S42026 may be used depending on instrument design and application.

^C Types 440A, 440B, or 440C may be used depending on instrument design and application.

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**.

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>.



TABLE 5 Composition of Class 3, Austenitic Stainless Steels, %

UNS	Type	Carbon, max ^A	Manganese	Phosphorus, max	Sulfur	Silicon, max ^A	Chromium	Nickel	Other Elements
S30100	301	0.15	2.00 max	0.045	0.030 max	1.00	16.00–18.00	6.00–8.00	—
S30151		0.07–0.09	1.50–2.00	0.025	0.010 max	1.20–1.80	16.0–18.0	7.0–9.0	Cu 0.40 max Mo 0.50–1.00 N 0.07–0.11
S30200	302	0.15	2.00 max	0.045	0.030 max	1.00	17.00–19.00	8.00–10.00	N 0.10 max ^B
S30300	303	0.12 ^B	2.00 max	0.06 ^B	0.15–0.35 ^B	1.00	17.00–19.00	8.00–10.00	Mo 0.70 max ^B
S30400	304	0.07 ^B	2.00 max	0.045	0.030 max	1.00	17.00–19.00 ^B	8.00–11.00 ^B	N 0.10 max ^B
S31600	316	0.07 ^B	2.00 max	0.045	0.030 max	1.00	16.50–18.50 ^B	10.50–13.50 ^B	Mo 2.00–2.50 ^B N 0.10 max ^B
S31700	317	0.08	2.00 max	0.045	0.030 max	1.00	18.00–20.00	11.00–15.00	Mo 3.00–4.00 N 0.10 max ^B
S30430	XM-7	0.1	2.00 max	0.045	0.030 max	1.00	17.00–19.00	8.00–10.00	Cu 3.00–4.00
S28200		0.15	17.00–19.00	0.040	0.04 max	1.00	17.00–19.00	—	Mo 0.75–1.25 Cu 0.75–1.25 N 0.40–0.60
S20161		0.15	4.0–6.0	0.045	0.030	3.0–4.0	15.00–18.00	4.0–6.0	N 0.08–0.20
S20162		0.15	4.0–8.0	0.040	0.040	2.5–4.5	16.50–21.00	6.0–10.0	N 0.05–0.25
S21800		0.10	7.0–9.0	0.060	0.030	3.5–4.5	16.0–18.0	8.0–9.0	N 0.08–0.18
S30117	1.4310	0.050–0.150	2.00 max	0.045	0.015 max	2.00	16.00–19.00	6.00–9.50	Mo 0.80 max, N 0.110 max

^A Max if not expressed as a range.

^B Denotes more restrictive limit than UNS.

TABLE 6 Composition of Class 6, Ferritic Stainless Steels, %

UNS	Type	Carbon, max	Manganese, max	Phosphorus, max	Sulfur	Silicon, Max	Chromium	Other Elements
S43020	430 F	0.08 ^A	1.25	0.06	0.15–0.35 ^A	1.00	16.00–18.00	Mo 0.60 max Ni 1.00 max ^A
S18200	XM-34	0.08	1.25–2.5 ^A	0.04	0.28–0.41 ^A	1.00	17.50–19.50	Mo 1.50–2.50
S18235		0.025	0.50	0.040	0.15–0.35	1.00	17.5–18.5	Mo 2.00–2.50 Ni 1.00 max N 0.025 max Ti 0.030–1.00 C+N 0.035 max

^A Denotes more restrictive limit than UNS.

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.

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](#).

TABLE 7 Composition of Class 4, Martensitic Stainless Steels, %

UNS	Type	Carbon ^A	Manganese Max	Phosphorus Max	Sulfur ^A	Silicon Max	Chromium	Other
S41000	410	0.09–0.15 ^A	1.00	0.04	0.030 max	1.00	11.50–13.50	Ni 1.00 max ^A
S41000	410X	0.16–0.21 ^A	1.00	0.04	0.030 max	1.00	11.50–13.50	Ni 1.00 max ^A
S41600	416	0.09–0.15 ^A	1.25	0.06	0.15–0.27 ^A	1.00	12.00–14.00	...
S41600	416 Mod	0.09–0.15 ^A	1.25	0.06	0.28–0.41 ^A	1.00	12.00–14.00	...
S42000	420A	0.16–0.25 ^A	1.00	0.04	0.030 max	1.00	12.00–14.00	Ni 1.00 max ^A
S42000	420B	0.26–0.35 ^A	1.00	0.04	0.030 max	1.00	12.00–14.00	Ni 1.00 max ^A
S42000	420 Mod	0.37–0.45 ^A	0.60	0.02	0.005 max	0.60	15.00–16.50	Mo 1.50–1.90 V 0.20–0.40 N 0.16–0.25
S42027	...	0.28–0.34	0.3–0.6	0.02	0.010 max	0.3–0.8	14.5–16.0	Mo 0.95–1.10 Ni 0.3 max N 0.35–0.44
S42000	420X	0.36–0.41 ^A	1.00	0.04	0.030 max	1.00	12.00–14.50	Ni 1.00 max ^A
S42000	420C	0.42–0.50 ^A	1.00	0.04	0.030 max	1.00	12.50–14.50	Ni 1.00 max ^A
S42020	420F	0.30–0.40 ^A	1.25	0.06	0.20–0.34 ^A	1.00	12.50–14.00	Cu 0.60 max ^B Ni 0.50 max ^B
	420F Mod	0.20–0.26 ^A	2.00	0.04	0.15–0.27 ^A	1.00	12.50–14.00	Mo 1.10–1.50 Ni 0.75–1.50
S42026	...	0.33–0.43	1.00	0.03	0.030 max	1.00	12.5–14.5	Ni 1.00 max Mo 0.8–1.2
S43100	431	0.20 max	1.00	0.04	0.030 max	1.00	15.00–17.00	Ni 1.25–2.50
S44002	440A	0.60–0.75	1.00	0.04	0.030 max	1.00	16.00–18.00	Mo 0.75 max
S44003	440B	0.75–0.95	1.00	0.04	0.030 max	1.00	16.00–18.00	Mo 0.75 max
S4404	440C	0.95–1.20	1.00	0.04	0.030 max	1.00	16.00–18.00	Mo 0.75 max
S44020	440F	0.95–1.20	1.25	0.06	0.15–0.27 ^A	1.00	16.00–18.00	Cu 0.60 max ^B Ni 0.50 max ^B
S42010		0.15–0.30	1.00	0.04	0.03	1.00	13.5–15.0	Ni 0.35–0.85



UNS	Type	Carbon ^A	Manganese Max	Phosphorus Max	Sulfur ^A	Silicon Max	Chromium	Other		
										Mo 0.40–0.85

^A Denotes more restrictive limit than UNS.

^B Optional per UNS designation.

TABLE 8 Composition of Class 5, Precipitation Hardening Stainless Steels, %

UNS	Type	Carbon, max	Manganese, max	Phosphorus, max	Sulfur, max	Silicon, max	Chromium	Nickel	Copper	Nb+Ta	Other Elements
S11100	...	0.02	0.25	0.015	0.01	0.25	11–12.5	10.25–11.25	Al 1.35–1.75 Mo 1.75–2.25 Ti 0.2–0.5 N 0.01 max
S17400	630	0.07	1.00	0.040	0.030	1.00	15.00–17.50	3.00–5.00	3.00–5.00	0.15–0.45	...
S17700	631	0.09	1.00	0.040	0.030	1.00	16.00–18.00	6.50–7.75	Al 0.75–1.50
S45000	XM-25	0.05	1.00	0.030	0.030	1.00	14.00–16.00	5.00–7.00	1.25–1.75	...	Mo 0.50–1.00 Cb 8 x C min
S45500	XM-16	0.03	0.50	0.015 ^A	0.015 ^A	0.50	11.00–12.50	7.50–9.50	1.50–2.50	0.10–0.50	Ti 0.90–1.40 Mo 0.50 max
S13800	XM-13	0.05	0.1 ^A	0.01 ^A	0.008	0.10	12.25–13.25	7.50–8.50	Al 0.90–1.35 Mo 2.00–2.50 N 0.01 max
S46500		0.02	0.25	0.015	0.010	0.25	11.00–12.50	10.75–11.25	Ti 1.50–1.80 Mo 0.75–1.25 N .01 max
S46910		0.030	1.00	0.030	0.015	0.70	11.0–13.0	8.0–10.0	1.5–3.5		Al 0.15–0.50 Mo 3.0–5.0 Ti 0.50–1.20

^A Denotes more restrictive limit than UNS.

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 9001 [ISO 9001](#).

11.2 The purchaser may audit the supplier's quality program for conformance to the intent of ASQ C1, or other recognized program.

12. Keywords

12.1 austenitic; ferritic; instruments; martensitic; precipitation hardenable; stainless steel; surgical

APPENDIX

(Nonmandatory Information)

X1. STATEMENT OF RATIONALE FOR SPECIFICATION F899

X1.1 The primary reason for this specification is to characterize composition requirements to ensure consistency in wrought materials used directly or modified by forging in the manufacture of stainless steel surgical instruments. Mechanical property requirements are not contained specifically within this specification. Those requirements are found in the appropriate specifications as referenced in section [2.1](#).

X1.2 The chemical compositions of certain grades covered by this specification have been modified in order to meet the composition requirements in the most recent ISO 7153/1 standard for stainless steels used in the manufacture of surgical instruments.

X1.3 Carbon and sulfur limits have been modified to provide an extra measure of uniformity for certain Class 4 stainless steel compositions used in the manufacture of surgical instruments.

X1.4 Acceptable metal conditions supplied to the instrument manufacturer include hot-finished, cold-finished, annealed, solution-treated, solution-treated and aged, or quench-hardened and tempered, the choice dependent upon the alloy type, instrument design, and application.

X1.5 Mechanical requirements for Classes 3, 5, and 6 stainless steels covered in this specification are included in the appropriate ASTM standards listed in Section 2.

X1.6 Typical heat-treating cycles and resultant hardness values for selected Class 4 stainless steels are included in this specification since the martensitic grades are a very common class of stainless steel used for surgical instruments. Hardness and heat-treating guidelines for Class 5 martensitic precipitation hardening grades are included in specification [A564/A564M](#).

X1.7 Examples of selected stainless steels that have been used for surgical instrument applications are included in this standard for information purposes.



X1.8 UNS designations are documented in the appropriate ASTM specifications listed in 2.1, Referenced Documents.

X1.9 ISO standards are listed for reference only. Although the ISO standards listed in section 2 are similar to the corresponding ASTM standards, they may not be identical. Use of an ISO standard in addition to or instead of a preferred ASTM standard may be negotiated between the purchaser and the supplier.

X1.10 The committee responsible for this specification (F04.12) has adopted bylaws similar to the A01 committee regarding the addition of new alloys to this specification. In order to add a new alloy to this specification the following minimum requirements shall be satisfied:

X1.10.1 Provide statements from at least one user that the alloy to be added is commercially available and there is a need for inclusion in this specification.

X1.10.2 Provide chemistry and mechanical property data from at least three commercial heats.

X1.10.3 Provide data of the expected corrosion based on chemistry and actual corrosion data compared to other alloys in the same class.

X1.10.4 Recommend chemical, mechanical and any special processing requirements.

X1.10.5 Inform the subcommittee if the grade or alloy is currently covered by patent.

SUMMARY OF CHANGES

Committee F04 has identified the location of selected changes to this standard since the last issue (F899 – 12a) that may impact the use of this standard. (Approved Dec. 1, 2012.)

(1) Added UNS 18235 to **Table 6**.

Committee F04 has identified the location of selected changes to this standard since the last issue (F899 – 12) that may impact the use of this standard. (Approved Nov. 1, 2012.)

(1) Added Type 1.4310 to **Table 5**.

(2) Added new Footnote A to **Table 5** to indicate that carbon and silicon is a max unless expressed as a range; renamed other footnote in table as appropriate.

Committee F04 has identified the location of selected changes to this standard since the last issue (F899 – 11) that may impact the use of this standard. (Approved June 1, 2012.)

(1) Added UNS S42027 to **Table 1**, **Table 2**, and **Table 7**.

(2) Added new clause **X1.10.3**.

(3) Removed former Table X1.1 and citation from **X1.10.2**.

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