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Standard Specification for Wrought Stainless Steels for Surgical Instruments¹

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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:²

A 276 Specification for Stainless Steel Bars and Shapes

A 314 Specification for Stainless Steel Billets and Bars for Forging

A 480/A 480M Specification for General Requirements for Flat-Rolled Stainless and Heat-Resisting Steel Plate, Sheet, and Strip

A 484/A 484M Specification for General Requirements for Stainless Steel Bars, Billets, and Forgings

A 555/A 555M Specification for General Requirements for Stainless Steel Wire and Wire Rods

A 564/A 564M Specification for Hot-Rolled and Cold-Finished Age-Hardening Stainless Steel Bars and Shapes

A 582/A 582M Specification for Free-Machining Stainless Steel Bars

A 751 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.

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
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.

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),
- 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 A 276, A 314, A 480/A 480M, A 484/A 484M, A 555/A 555M, A 564/A 564M, A 582/A 582M, and A 751 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~~ 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.

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) + Oil quench or air cool	500	260	43	420C	1900°F (1038°C) + Warm oil quench	300	149	58
		700	371	43			400	204	55/56
		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) + Oil quench or air cool	500	260	46	420F	1900°F (1038°C) + Warm oil quench	800 ^D	427	55
		700	371	46/47			300	149	52
		900 ^C	482	48			400	204	52
		1000 ^C	538	44			500	260	50
		1100	593	31			600	315	50
416 Mod	1800°F (982°C) + Oil quench	300	149	38	420F Mod	1900°F (1038°C) + Warm oil quench	800 ^D	427	49
		500	260	37			300	149	53
		700	371	37			400	204	50
		900 ^C	482	35			500	260	48
		1000 ^C	538	30			600	315	48
416	1800°F (982°C) + Oil quench	1100	593	22	UNS S42026	1920°F (1050°C) + oil quench or pressure gas	400	204	56
		300	149	41			500	260	54/55
		500	260	39			600	315	53/54
		700	371	41			700	371	48
		900 ^C	482	36			800 ^D	427	48
		1000 ^C	538	31			900 ^C	482	45
		1100	593	26			1000 ^C	538	34
		1100	593	26			1100 ^C	593	34
		1100	593	26			1100 ^C	593	34
		1100	593	26			1100 ^C	593	34
		1100	593	26			1100 ^C	593	34
420A	1850°F (1010°C) + Warm oil quench	300	149	53	440A	1900°F (1038°C) + Warm oil quench	300	149	56/57
		400	204	50			400	204	56
		500	260	48			500	260	54
		600	315	48			600	315	51/52
		700	371	48			700	371	51
420B	1900°F (1038°C) + Warm oil quench	800 ^D	427	48	440B	1900°F (1038°C) + Warm oil quench	800 ^D	427	50
		300	149	52			300	149	58/59
		400	204	52			400	204	56/57
		500	260	50			500	260	53/54
		600	315	50			600	315	53
420 Mod	180°F (1010°C) + oil quench or pressure gas	700	371	49	440C	1900°F (1038°C) + Warm oil quench	700	371	54
		800 ^D	427	49			800 ^D	427	54
		350	177	56/57			300	149	60
		400	204	55			400	204	59
		500	260	54			500	260	57
420X	1900°F (1038°C) + Warm oil quench	600	315	53	440F	1900°F (1038°C) + Warm oil quench	300	149	60
		700	371	49			400	204	59
		800 ^D	427	49			500	260	57
		300	149	52			600	315	56
		400	204	52			700	371	56
S42010	1900°F (1038°C) + Warm Oil Quench	500	260	47	440F	1900°F (1038°C) + Warm oil quench	800 ^D	427	56
		600 ^E	316	47			300	149	60
		700	371	48			400	204	59
		850	454	48			500	260	57
		700	371	48			600	315	56

^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 indicated temperature and air cool. Large section sizes require longer time 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.

7.4 Methods and practices relating to chemical analysis required by this specification shall be in accordance with Test Methods, Practices, and Terminology A 751.

8. Mechanical Requirements

8.1 Material shall conform to the mechanical property requirements cited in the appropriate ASTM standards (see 2.1) or shall

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
303 304 410	Chisels and gouges, bone curettes	probes retractors 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 420C	bone rongeurs, scissors 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
431		cheek retractors, insertion wrenches, orthopaedic 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	
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 S420G26 may be used depending on instrument design and application.

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

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 A 564/A 564M.

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.