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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 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](#)

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.

[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.

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 9001 [ISO 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			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		
416 Mod	1800°F (982°C) + Oil quench	1100	593	31	420F Mod	1900°F (1038°C) + Warm oil quench	600	315	50		
		300	149	38			700	371	49		
		500	260	37			800 ^D	427	49		
		700	371	37			300	149	53		
		900 ^C	482	35			400	204	50		
416	1800°F (982°C) + Oil quench	1000 ^C	538	30	UNS S42026	1920°F (1050°C)+ oil quench or pressure gas	500	260	54/55		
		1100	593	22			600	315	53/54		
		300	149	41			431	1900°F (1038°C) + Oil quench	500	260	42
		500	260	39			700	371	42		
		700	371	41			900 ^C	482	45		
420A	1850°F (1010°C) + Warm oil quench	900 ^C	482	36	440A	1900°F (1038°C) + Warm oil quench	1100 ^C	593	34		
		1000 ^C	538	31			300	149	56/57		
		1100	593	26			400	204	56		
		300	149	53			500	260	54		
		400	204	50			600	315	51/52		
420B	1900°F (1038°C) + Warm oil quench	500	260	48	440B	1900°F (1038°C) + Warm oil quench	700	371	51		
		600	315	48			800 ^D	427	50		
		700	371	48			300	149	58/59		
		800 ^D	427	48			400	204	56/57		
		300	149	52			500	260	53/54		
420 Mod	180°F (1010°C) + oil quench or pressure gas	400	204	52	440C	1900°F (1038°C) + Warm oil quench	600	315	53		
		500	260	50			700	371	54		
		600	315	50			800 ^D	427	54		
		700	371	49			300	149	60		
		800 ^D	427	49			400	204	59		
420X	1900°F (1038°C) + Warm oil quench	350	177	56/57	440F	1900°F (1038°C) + Warm oil quench	500	260	57		
		400	204	55			600	315	56		
		500	260	54			700	371	56		
		600	315	53			800 ^D	427	56		
		300	149	52			300	149	60		
S42010	1900°F (1038°C) + Warm Oil Quench	400	204	50	S42027	1850°F (1010°C) + oil quench or pressure gas	400	204	57/58		
		500	260	47			500	260	57/58		
		600 ^E	316	47			600	315	56		
		700	371	48			700	371	56		
		850	454	48			800 ^D	427	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 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
303 304 410	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	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	burrs
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	
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.

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