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Standard Specification for Wrought Stainless Steels for Surgical Instruments[1]

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 – 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.

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),

[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.

***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
440A Mod	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.

4.1.7 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.

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 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 ISO 9001.

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

Type	Typical Hardening[A] Temperature	Typical Hardness at Indicated Tempering Temperature[B]		
		°C	°F	(HRC)
410	1010°C [1850°F]	260	500	43
		371	700	43
		482	900[C]	42
		538	1000[C]	30
		593	1100	24
410X	1024°C [1875°F]	260	500	46
		371	700	46/47
		482	900[C]	48
		538	1000[C]	44
		593	1100	31
416 Mod	982°C [1800°F]	149	300	38
		260	500	37
		371	700	37
		482	900[C]	35
		538	1000[C]	30
		593	1100	22
416	982°C [1800°F]	149	300	41
		260	500	39
		371	700	41
		482	900[C]	36
		538	1000[C]	31
		593	1100	26
420A	1010°C [1850°F]	149	300	53
		204	400	50
		260	500	48
		315	600	48
		371	700	48
		427	800[D]	48
420B	1038°C [1900°F]	149	300	52
		204	400	52
		260	500	50
		315	600	50
		371	700	49
		427	800[D]	49
420 Mod	1010°C [1850°F]	177	350	56/57
		204	400	55
		260	500	54
		315	600	53
420X	1038°C [1900°F]	149	300	52
		204	400	52
		260	500	50
		315	600	50
		371	700	49
		427	800[D]	49
S42010	1038°C [1900°F]	204	400	50
		260	500	47
		316	600[E]	47
		371	700	48
		454	850	48
420C	1038°C [1900°F]	149	300	58
		204	400	55/56
		260	500	53/54
		315	600	53/54
		371	700	54/55
		427	800[D]	55
420F	1038°C [1900°F]	149	300	52
		204	400	52
		260	500	50
		315	600	50
		371	700	49
		427	800[D]	49
420F Mod	1038°C [1900°F]	149	300	53
		204	400	50
		260	500	48
		315	600	48
		371	700	48
		427	800[D]	48
UNS S42026	1050°C [1920°F]	204	400	56
		260	500	54/55
		315	600	53/54
431	1038°C [1900°F]	260	500	42
		371	700	42
		482	900[C]	45
		593	1100[C]	34
440A	1038°C [1900°F]	149	300	56/57
		204	400	56
		260	500	54
		315	600	51/52
		371	700	51
		427	800[D]	50
440A Mod	1080°C [1976°F]	149	300	58
		204	400	54
		260	500	53/54
		315	600	53
		371	700	53
		427	800[D]	53
440B	1038°C [1900°F]	149	300	58/59
		204	400	56/57
		260	500	53/54
		315	600	53
		371	700	54
		427	800[D]	54
440C	1038°C [1900°F]	149	300	60
		204	400	59
		260	500	57
		315	600	56
		371	700	56
		427	800[D]	56
440F	1038°C [1900°F]	149	300	60
		204	400	59
		260	500	57
		315	600	56
		371	700	56
		427	800[D]	56
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 and/or heat treatment engineer 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.
[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 399/566°C [750/1050°F] results in decreased impact strength and reduced corrosion resistance.
[D] Tempering over 427°C [800°F] results in reduced corrosion resistance.
[E] Tempering above 316°C [600°F] 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, tendor 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, orthopeadic instruments
440[C]	chisels, knives, osteotomes, scalpels	drills, retractors, spreaders, tongs
440A Mod[C]	chisels, knives, osteotomes, reamers	drills, retractors, raspatory, tongs
420 Mod	chisels, curettes, cutters, bone cutting forceps, knives, scissors, rongeurs, scalpels, skin punches, conchotomes, ostoetomes, 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 10.1)
[B] Types 420A, 420B, 420C, or UNS S42026 may be used depending on instrument design and application.
[C] Types 440A, 440A Mod, 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 ISO 9001, or other recognized program.

12. Keywords

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