

Designation: F899 - 12a F899 - 12b

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.
- 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.

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.

Current edition approved Nov. 1, 2012 Dec. 1, 2012. Published December 2012. Originally approved in 1984. Last previous edition approved in 2012 as F899 – 12a. DOI: 10.1520/F0899-12A.10.1520/F0899-12B.

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 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 | | |
| 440B | 285 | | |
| 440C | 285 | | |
| 440F | 285 | | |
| UNS S42026 | 260 | | |
| UNS S42010 | 235 | | |

A Excludes billets and bars for forging.

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),
 - 4.1.1 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.

^B Or equivalent Rockwell hardness.

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

| Туре | Typical Hardening ^A Heat Treatment | Typical Hardness at Indicated Tempering Temperature ⁸ | | | Туре | 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 | | | 800 ^D | 427 | 55 |
| 410 | Oil guench | 700 | 371 | 46/47 | 420F | 1900°F (1038°C) + | 300 | | 52 |
| | | 900 ^C | | | 4206 | | | 149 | |
| | or air cool | | 482 | 48 | | Warm oil quench | 400 | 204 | 52 |
| | | 1000 ^C | 538 | 44 | | | 500 | 260 | 50 |
| | | 1100 | 593 | 31 | | | 600 | 315 | 50 |
| 16 Mod | 1800°F (982°C) + | 300 | 149 | 38 | | | 700_ | 371 | 49 |
| | Oil quench | 500 | 260 | 37 | | | 800^{D} | 427 | 49 |
| | | 700 | 371 | 37 | 420F Mod | 1900°F (1038°C) + | 300 | 149 | 53 |
| | | 900 ^C | 482 | 35 | | Warm oil quench | 400 | 204 | 50 |
| | | 1000 ^C | 538 | 30 | | | 500 | 260 | 48 |
| | | 1100 | 593 | 22 | | | 600 | 315 | 48 |
| 416 | 1800°F (982°C) + | 300 | 149 | 41 | | | 700 | 371 | 48 |
| 410 | Oil quench | 500 | 260 | 39 | | | 800 ^D | 427 | 48 |
| | Oil quelloil | | | | LINIC | 4020°E | | | |
| | | 700 | 371 | 41 | UNS | 1920°F | 400 | 204 | 56 |
| | | | | | S42026 | (1050°C)+ | | | |
| | | 900 ^C | 482 | 36 | | oil quench or | 500 | 260 | 54/55 |
| | | 1000 ^C | 538 | 31 | | pressure gas | 600 | 315 | 53/54 |
| | | 1100 | 593 | 26 | 431 | 1900°F (1038°C) + | 500 | 260 | 42 |
| | | | | | | Oil quench | 700 | 371 | 42 |
| | | | | | | | 900 ^C | 482 | 45 |
| | | | | | | | 1100 ^C | 593 | 34 |
| 420A | 1850°F (1010°C) + | 300 | 149 | 53 | 440A | 1900°F (1038°C) + | 300 | 149 | 56/57 |
| 12071 | Warm oil quench | 400 | 204 | 50 | | Warm oil quench | 400 | 204 | 56 |
| | waiiii oli quelicii | 500 | 260 | 48 | al II (U al I | Walli oii quelicii | 500 | 260 | 54 |
| | | | | | | | 600 | | |
| | | 600 | 315 | 48 | 1 | | | 315 | 51/52 |
| | | 700 | 371 | 48 1 9 m | nards | | 700 | 371 | 51 |
| | | 800 ^D | 427 | 48 | dat an | | 800 ^D | 427 | 50 |
| 420B | 1900°F (1038°C) + | 300 | 149 | 52 | 440B | 1900°F (1038°C) + | 300 | 149 | 58/59 |
| | Warm oil quench | 400 | 204 | 52 | + Dwo | 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 |
| | | 800^{D} | 427 | 49 | | | 800^{D} | 427 | 54 |
| 420 Mod | 180°F (1010°C) | 350 | 177 | 56/57 | F899-12b | | | | |
| | + oil quench or | 400 | 204 | 55 | | | | | |
| | | 500 catalo | | 154 ist/c377c | :99b-a705-4 | | | | |
| | F 900 | 600 | 315 | 53 | | | | | |
| 420X | 1900°F (1038°C) + | 300 | 149 | 52 | 440C | 1900°F (1038°C) + | 300 | 149 | 60 |
| TLUM | Warm oil quench | 400 | 204 | 52 | 7700 | Warm oil quench | 400 | 204 | 59 |
| | wann on quench | | | | | vvaiiii oli quench | | | |
| | | 500 | 260 | 50 | | | 500 | 260 | 57 |
| | | 600 | 315 | 50 | | | 600 | 315 | 56 |
| | | 700 | 371 | 49 | | | 700 | 371 | 56 |
| | | 800 ^D | 427 | 49 | | | 800 ^D | 427 | 56 |
| S42010 | 1900°F | 400 | 204 | 50 | 440F | 1900°F (1038°C) + | 300 | 149 | 60 |
| | (1038°C) + Warm | 500 | 260 | 47 | | Warm oil quench | 400 | 204 | 59 |
| | Oil Quench | 600 ^E | 316 | 47 | | • | 500 | 260 | 57 |
| | • | 700 | 371 | 48 | | | 600 | 315 | 56 |
| | | 850 | 454 | 48 | | | 700 | 371 | 56 |
| | | 000 | 707 | 70 | | | 800 ^D | 427 | 56 |
| | | | | | 040007 | 10500 | | | |
| | | | | | S42027 | 1850°F | 300 | 149 | 58/59 |
| | | | | | | (1010°C) + | 400 | 204 | 57/58 |
| | | | | | | oil quench or | 500 | 260 | 57/58 |
| | | | | | | pressure gas | 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.

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.

^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

| | | - |
|---------|---|---|
| Туре | 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

| Туре | 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 |
| 304 | | strips, tongs, tunnelers, probes 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 |
| 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 XM-16 | tan reamers scissors iteh.ai/catalog/standards/sist/e377 | c9drills, needles 4c41-aff4-30ec4f520b2c/astm-f899-12b |
| 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.

- 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.

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