Designation: F 899 – 95

Standard Specification for Stainless Steel Billet, Bar, and Wire for Surgical Instruments[1]

This standard is issued under the fixed designation F 899; 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 requirements for stainless steel billet, bar, and wire used for the manufacture of surgical instruments. Billet or bar intended for forging into special shapes may also be purchased in accordance with this specification.

2. Referenced Documents

2.1 *ASTM Standards:*

A 276 Specification for Stainless and Heat-Resisting Steel Bars and Shapes[2]

A 314 Specification for Stainless and Heat-Resisting Steel Billets and Bars for Forging[2]

A 484/A484M Specification for General Requirements for Stainless and Heat-Resisting Bars, Billets, and Forgings[2]

A 555/A555M Specification for General Requirements for Stainless and Heat-Resisting Steel Wire and Wire Rods[3]

A 564 Specification for Hot-Rolled and Cold-Finished Age-Hardening Stainless and Heat-Resisting Steel Bars and Shapes[2]

A 582 Specification for Free-Machining Stainless and Heat-Resisting Steel Bars, Hot-Rolled or Cold-Finished[2]

A 751 Test Methods, Practices, and Terminology for Chemical Analysis of Steel Products[3]

2.2 *ISO Draft International Standard:*

ISO/DIS 7153/1 Instruments For Surgery—Metallic Materials—Part 1: Stainless Steel[4]

2.3 *American Society for Quality Control (ASQC) Standard:*

C1-1985 Specification of General Requirements for a Quality Program[5]

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 1 and 2.

4. Ordering Information

4.1 Inquiries and orders for material under this specification shall include the following information:

4.1.1 Quantity (weight or number of pieces),

4.1.2 Classification, optional (see 3.1),

4.1.3 Type (see 3.2),

4.1.4 Form (billet, bar, wire),

4.1.5 Condition (see 5.1),

4.1.6 Finish (see 5.3),

4.1.7 Mechanical properties or hardness (see Section 8), and

4.1.8 Applicable dimensions including size, thickness, width, and length (exact, random, or multiples) or print number.

5. Manufacture

5.1 *Condition*—Billet, bar, and wire shall be furnished to the instrument manufacturer, as specified, in the hot finished, cold finished, annealed, solution treated, solution treated and aged, quench hardened, quench hardened and tempered, or as specified in the instrument manufacturer's purchase order.

Cautionary Note—Highly hardenable martensitic stainless billets and bars such as Types 420A, 420B, 420C, 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

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[2] *Annual Book of ASTM Standards*, Vol 01.05.

[3] *Annual Book of ASTM Standards*, Vol 01.03.

[4] Available from American National Standards Institute, 1430 Broadway, New York, NY 10018.

[5] Available from American Society for Quality Control, 161 West Wisconsin Avenue, Milwaukee, WI 53203.

TABLE 1 Composition of Class 3, Austenitic Stainless Steels, %

Type	Carbon, max	Manganese	Phosphorus, max	Sulfur	Silicon, max	Chromium	Nickel	Other Elements
301	0.15	2.00 max	0.045	0.030 max	1.00	16.00–18.00	6.00–8.00	—
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
303	0.12	2.00 max	0.060	0.15–0.35	1.00	17.00–19.00	8.00–10.00	Mo 0.70 max[A]
304	0.07	2.00 max	0.045	0.030 max	1.00	17.00–19.00	8.00–11.00	N 0.10 max
316	0.07	2.00 max	0.045	0.030 max	1.00	16.50–18.50	10.50–13.50	Mo 2.00–2.50 N 0.10 max
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
XM-7	0.10	2.00 max	0.045	0.030 max	1.00	17.00–19.00	8.00–10.00	Cu 3.00–4.00
—	0.15	17.00–19.00	0.040	0.040 max	1.00	17.00–19.00	—	Mo 0.75–1.25 Cu 0.75–1.25 N 0.40–0.60

[A]Optional.

TABLE 2 Composition of Class 6, Ferritic Stainless Steels, %

Type	Carbon, max	Manganese, max	Phosphorus, max	Sulfur	Silicon, Max	Chromium	Other Elements
430 F	0.08	1.50	0.060	0.15–0.35	1.00	16.00–18.00	Mo 0.60 max Ni 1.00 max
XM-34	0.08	2.50	0.040	0.28–0.41	1.00	17.50–19.50	Mo 1.50–2.50

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 instrument manufacturer's purchase order.

6. General Requirements for Delivery

6.1 In addition to the requirements of this specification, all requirements of the current editions of Specification A 484/A 484M and A555/A 555M shall apply as applicable.

6.2 This ASTM specification compliments the ISO applicable document covering stainless steel for surgical instruments and, by reference, includes all of the stainless grades in ISO/DIS 7153/1.

7. Chemical Requirements

7.1 The heat analysis shall conform to the requirements as to chemical composition specified in Tables 1-2.

7.2 Restricted carbon and sulfur limits for certain Class 4 martensitic stainless steels are specified to ensure consistency in the materials used for the manufacture of surgical instruments.

7.3 The chemical composition requirements for Types 301, 303, 304, 316, 410, 420A, 420B, 420C, and 430F will meet the composition requirements in ISO/DIS 7153/1.

7.4 Methods and practices relating to chemical analysis required by this specification shall be in accordance with Test Methods, Practices, and Definitions 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 meet the mechanical property requirements specified in the instrument manufacturer's purchase order.

8.2 When desired, Brinell hardness number (HB), Rockwell hardness, B scale (HRB) or Rockwell hardness, C scale (HRC), limits may be specified. Hardness guidelines for selected Class 4 martensitic stainless steels in the annealed condition are listed in Table 5.

TABLE 3 Composition of Class 4, Martensitic Stainless Steels, %

Type	Carbon	Mn Max	P Max	Sulfur S	Silicon Max	Chromium	Other Elements
410	0.09–0.15	1.00	0.040	0.030 max	1.00	11.50–13.50	Ni 1.00 max
410X	0.16–0.21	1.00	0.040	0.030 max	1.00	11.50–13.50	Ni 1.00 max
416	0.09–0.15	1.25	0.060	0.15–0.27	1.00	12.00–14.00	—
416 Mod	0.09–0.15	1.25	0.060	0.28–0.41	1.00	12.00–14.00	—
420A	0.16–0.25	1.00	0.040	0.030 max	1.00	12.00–14.00	Ni 1.00 max
420B	0.26–0.35	1.00	0.040	0.030 max	1.00	12.00–14.00	Ni 1.00 max
420X	0.36–0.41	1.00	0.040	0.030 max	1.00	12.00–14.50	Ni 1.00 max
420C	0.42–0.50	1.00	0.040	0.030 max	1.00	12.50–14.50	Ni 1.00 max
420F	0.30–0.40	1.25	0.060	0.20–0.34	1.00	12.50–14.00	Cu 0.60 max[A] Ni 0.50 max[A]
420F Mod	0.20–0.26	2.00	0.040	0.15–0.27	1.00	12.50–14.00	Mo 1.10–1.50 Ni 0.75–1.50
431	0.20 max	1.00	0.040	0.030 max	1.00	15.00–17.00	Ni 1.25–2.50
440A	0.60–0.75	1.00	0.040	0.030 max	1.00	16.00–18.00	Mo 0.75 max
440B	0.75–0.95	1.00	0.040	0.030 max	1.00	16.00–18.00	Mo 0.75 max
440C	0.95–1.20	1.00	0.040	0.030 max	1.00	16.00–18.00	Mo 0.75 max
440F	0.95–1.20	1.25	0.060	0.15–0.27	1.00	16.00–18.00	Cu 0.60 max[A] Ni 0.50 max[A]

[A]Optional.

TABLE 4 Composition of Class 5, Precipitation Hardening Stainless Steels, %

Type	Carbon, max	Manganese, max	Phosphorus, max	Sulfur, max	Silicon, max	Chromium	Nickel	Copper	Columbiun + Tantalum	Other Elements
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	—
631	0.09	1.00	0.040	0.030	1.00	16.00–18.00	6.50–7.75	—	—	A1 0.75–1.50
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
XM-16	0.03	0.50	0.015	0.015	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

TABLE 5 Hardness Guidelines[A] for Selected Class 4 Martensitic Stainless Steels in The Annealed Condition

Type	Brinell Hardness,[B] max (HB)
410	210
410X	220
416	262
416 Mod	262
420A	220
420B	235
420X	262
420C	262
420F	262
420F Mod	262
431	285
440A	285
440B	285
440C	285
440F	285

[A] Excludes billets and bars for forging.
[B] Or equivalent Rockwell hardness.

9. Heat Treatment

9.1 Material shall be heat treated as applicable for the stainless composition involved.

9.2 Heat treating guidelines and typical hardness values for selected Class 4 martensitic stainless steels are listed in Table 6.

9.3 Heat treating guidelines for Class 5 precipitation hardening stainless steels are included in Specification A 564.

10. Special Information

10.1 Some examples of selected stainless steels that have been used for various surgical instrument applications are listed in Table 7 and Table 8 for information purposes.

11. Quality Program Requirements

11.1 The producer shall maintain a quality program, such as defined in ASQC C1-1985.

11.2 The manufacturer of surgical instruments may audit the producer's quality program for conformance to the intent of ASQC C-1985, or other recognized program.

12. Keywords

12.1 instruments; stainless steel—bar; billets; wire

TABLE 6 Heat Treating Guidelines and Typical Hardness Values for Selected Class 4 Martensitic Stainless Steels

Type	Typical Hardening[A] Heat Treatment	Typical Hardness at Indicated Tempering Temperature[B]		
		°F	°C	Hardness (HRC)
410	1850°F (1010°C) + Oil quench or air cool	500	260	43
		700	371	43
		900[C]	482	42
		1000[C]	538	30
		1100	593	24
410X	1875°F (1024°C) + Oil quench or air cool	500	260	46
		700	371	46/47
		900[C]	482	48
		1000[C]	538	44
		1100	593	31
416 Mod	1800°F (982°C) + Oil quench	300	149	38
		500	260	37
		700	371	37
		900[C]	482	35
		1000[C]	538	30
		1100	593	22
416	1800°F (982°C) + Oil quench	300	149	41
		500	260	39
		700	371	41
		900[C]	482	36
		1000[C]	538	31
		1100	593	26
420A	1850°F (1010°C) + Warm oil quench	300	149	53
		400	204	50
		500	260	48
		600	315	48
		700	371	48
		800[D]	427	48
420B	1900°F (1038°C) + Warm oil quench	300	149	52
		400	204	52
		500	260	50
		600	315	50
		700	371	49
		800[D]	427	49
420X	1900°F (1038°C) + Warm oil quench	300	149	52
		400	204	52
		500	260	50
		600	315	50
		700	371	49
		800[D]	427	49
420C	1900°F (1038°C) + Warm oil quench	300	149	58
		400	204	55/56
		500	260	53/54
		600	315	53/54
		700	371	54/55
		800[D]	427	55
420F	1900°F (1038°C) + Warm oil quench	300	149	52
		400	204	52
		500	260	50
		600	315	50
		700	371	49
		800[D]	427	49
420F Mod	1900°F (1038°C) + Warm oil quench	300	149	53
		400	204	50
		500	260	48
		600	315	48
		700	371	48
		800[D]	427	48
431	1900°F (1038°C) + Oil quench	500	260	42
		700	371	42
		900[C]	482	45
		1100[C]	593	34
440A Mod	1900°F (1038°C) + Warm oil quench	300	149	56/57
		400	204	23
		500	260	54
		600	315	51/52
		700	371	51
		800[D]	427	50
440B	1900°F (1038°C) + Warm oil quench	300	149	58/59
		400	204	56/57
		500	260	53/54
		600	315	53
		700	371	54
		800[D]	427	54
440C	1900°F (1038°C) + Warm oil quench	300	149	60
		400	204	59
		500	260	57
		600	315	56
		700	371	56
		800[D]	427	56
440F	1900°F (1038°C) + Warm oil quench	300	149	60
		400	204	59
		500	260	57
		600	315	56
		700	371	56
		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 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.

TABLE 7 Examples of Selected Stainless Steels That Have Been Used for Surgical Instruments in Accordance with ISO/DIS 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	

TABLE 8 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		cheak retractors, insertion wrenches, orthopeadic instruments
440[C]	chisels, knives, osteotomes, scalpels	drills, retractors, spreaders, tongs
630	reamers	
XM-16	scissors	drills, needles

[A] It is not recommended that free-machining grades be used for critical portions of surgical instruments.
[B] Types 420A, 420B, or 420C may be used depending on instrument design and application.
[C] Types 440A, 440B, or 440C may be used depending on instrument design and application.

APPENDIX

(Nonmandatory Information)

X1. STATEMENT OF RATIONALE FOR SPECIFICATION F 899

X1.1 The primary reason for this standard is to characterize composition and mechanical requirements to assure consistency in wrought materials used, directly or modified by forging in the manufacture of stainless steel surgical instruments.

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 Draft International 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, quench hardened, 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 Hardness and heat-treating guidelines for selected Class 4 stainless steels are included in this specification since the martensitic grades are the predominant class of stainless steel used for surgical instruments.

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