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Standard Specification for Stainless Steels 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 steels used for the manufacture of surgical instruments.

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 480/A 480M Specification for General Requirements for Stainless and Heat-Resisting Steel Plate, Sheet, and Strip[3]

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 Standard:*

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

2.3 *American Society for Quality (ASQ) Standard:*

C1 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,

4.1.3 Type,

4.1.4 Form,

4.1.5 Condition,

4.1.6 Finish,

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, quench hardened and tempered, or as specified by the purchaser. (**Warning**—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.)

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

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

[4] Available from American National Standards Institute, 25 W. 43rd St., 4th Floor, New York, NY 10036.

[5] Available from American Society for Quality Control, 600 N. Plankinton Ave., Milwaukee, WI 53203.

***A Summary of Changes section appears at the end of this standard.**

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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

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 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 7153/1.

7. Chemical Requirements

7.1 The heat analysis shall conform to the requirements as to chemical composition specified in Tables 1-4.

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 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 Definitions A 751.

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
420 Mod	0.37–0.45	0.60	0.020	0.005 max	0.60	15.00–16.50	Mo 1.50–1.90 V 0.20–0.40 N 0.16–0.25
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.

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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
XM-13	0.05	0.10	0.01	0.008	0.10	12.25–13.25	7.50–8.50	...	...	Al 0.90–1.35 Mo 2.00–2.50 N 0.01 max
...[A]	0.02	0.25	0.015	0.010	0.25	11.00–12.50	10.75–11.25	...	...	Ti 1.50–1.80 Mo 0.75–1.25

[A] UNS S46500.

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. Hardness guidelines for selected Class 4 martensitic stainless steels in the annealed condition are listed in Table 5.

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
420 Mod	255
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 ASQ C1.

11.2 The manufacturer of surgical instruments may audit the producer'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

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