



Standard Specification for 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 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 Shapes²

A 314 Specification for Stainless and Heat-Resisting Steel Billets and Bars for Forging²

A 480/A 480M Specification for General Requirements for Stainless and Heat-Resisting Steel Plate, Sheet, and Strip³

A 484/A 484M Specification for General Requirements for Stainless and Heat-Resisting Bars, Billets, and Forgings²

A 555/A 555M Specification for General Requirements for Stainless and Heat-Resisting Steel Wire and Wire Rods³

A 564 Specification for Hot-Rolled and Cold-Finished Age-Hardening Stainless and Heat-Resisting Steel Bars and Shapes²

A 582 Specification for Free-Machining Stainless and Heat-Resisting Steel Bars, Hot-Rolled or Cold-Finished²

A 751 Test Methods, Practices, and Terminology for Chemical Analysis of Steel Products³

2.2 ISO Standard:

ISO 7153/1 Instruments For Surgery—Metallic Materials—Part 1: Stainless Steel⁴

2.3 American Society for Quality (ASQ) Standard:

C1 Specification of General Requirements for a Quality Program⁵

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.