



Standard Specification for Stainless Steel Suture Needle Holders-General Workmanship Requirements and Corresponding Test Methods¹

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^{ε 1} NOTE—Subsections 3.1.2 and 4.1 were editorially corrected in December 2008.

1. Scope

1.1 This specification covers general workmanship aspects of stainless steel suture needle holders intended for reuse in surgery.

2. Referenced Documents

2.1 ASTM Standards:²

E18 Test Methods for Rockwell Hardness of Metallic Materials

E92 Test Method for Vickers Hardness of Metallic Materials (Withdrawn 2010)³

E140 Hardness Conversion Tables for Metals Relationship Among Brinell Hardness, Vickers Hardness, Rockwell Hardness, Superficial Hardness, Knoop Hardness, Scleroscope Hardness, and Leeb Hardness

F899 Specification for Wrought Stainless Steels for Surgical Instruments

F921 Terminology Relating to Hemostatic Forceps

F1089 Test Method for Corrosion of Surgical Instruments

3. Terminology

3.1 Definitions:

3.1.1 *modified working end*—working surfaces possessing superior hardness characteristics which are either the result of depositing various materials on the base metal or the result of permanently securing an insert (such as by brazing) to the base metal.

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 F04.33 on Medical/Surgical Instruments.

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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 The last approved version of this historical standard is referenced on www.astm.org.

3.1.2 *Discussion*—The typical method of modifying the working end of the suture needle holder is to use jaw inserts or to plasma deposit (flame plate) materials with improved wear characteristics such as tungsten carbide or stellite (trade-marked). For the jaw insert method, the insert is brazed to the jaw face with a uniform deposit of silver solder which is free of crevices at all interfaces. For the flame plating method, a uniform layer of material is deposited which is 0.004 ± 0.001 in. thick.

3.2 Definitions applicable to stainless steel suture needle holders and the terms specified herein, shall be in accordance with Definitions of Terms F921.

4. Materials

4.1 All component parts of the instrument other than the modified working end shall be fabricated from martensitic stainless steel type 410, 410X, 416, 420A, 420B, 420C, 420F, 420F Mod, and 440B per Specification F899 (see Note 1). The modified working end may be made of stellite (trademarked), tungsten carbide, or other suitable material.

NOTE 1—Free-machining grades of stainless steel are inappropriate for use due to their lower corrosion resistance and toughness.

5. Requirements

5.1 Heat treatment and hardness for component parts.

5.1.1 Stainless steel component parts of the instrument shall be heat treated under conditions recommended for the material used.

5.1.2 The Rockwell hardness of an instrument with the working end not modified shall be 42 HRC to 52 HRC. Instruments where the working end has been modified shall have a modified working surface whose Rockwell hardness is A77 minimum.

5.2 *Corrosion Resistance*—Holders with working ends not modified shall be subjected to corrosion tests as specified in Test Method F1089. Holders with modified working ends shall be subject to corrosion tests as specified in Test Method F1089 except for the modifying material.

TABLE 1 Suture/Needle/Holder Relationship

Suture Needle Holder	Most Common Use	Recommended Teeth Per Square Inch	Compatible Suture Size Per USP ^A		Corresponding Wire Size (Diameter) of Needle
Debakey 7 thru 12 in.	vascular and valve replacement	2500	0	0.16 in.	0.035 in.
Hufnagel 8 thru 10 in.		2500	2-0	0.14	0.24
			3-0	0.010	0.024
			4-0	0.008	0.015
Webster	coronary bypass	3500 or smooth	5-0	0.006	0.015
Hegar-Mayo			6-0	0.004	0.009
Brown			7-0	0.003	0.009
Castrovieijo	microsurgery	smooth	8-0	0.002	0.006
Kalt			9-0	0.0015	0.006
			10-0	0.0008	0.006

^A Mean average of USP absorbable and non-absorbable and Suture size averages.

6. Performance Requirements

6.1 *Needle retention test*—From **Table 1**, select a needle, sized for use with the holder being tested. The suture needle, with its axis held perpendicularly to the axis of the jaw shall, upon engagement of the second ratchet of the suture needle holder, show no lateral, rotational, or longitudinal motion when subjected to a one-half pound pull and a one-inch-pound torsion.

7. Workmanship, Finish, and Appearance

7.1 Finish:

7.1.1 *Surfaces*—Surfaces of the instrument shall be uniformly finished and free from burrs, sharp edges, cracks, coarse marks, and processing materials.

7.1.2 *Type*—The finish shall be one of the types specified in Definitions of Terms **F921** or as specified by the purchaser.

7.2 Workmanship:

7.2.1 Finger rings—inside surfaces of the finger rings shall be well rounded and conform to the requirements of Section **7.1.1**.

7.2.2 The pivot screw or pin shall be permanently set peened, and flush.

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