



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

This standard is issued under the fixed designation F 1325; 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 general workmanship aspects of stainless steel suture needle holders intended for reuse in surgery.

2. Referenced Documents

2.1 ASTM Standards:

E 18 Test Methods for Rockwell Hardness and Rockwell Superficial Hardness of Metallic Materials²

E 92 Test Method for Vickers Hardness of Metallic Materials²

E 140 Hardness Conversion Tables for Metals²

F 899 Specification for Stainless Steels for Surgical Instruments³

F 921 Definitions of Terms Relating to Hemostatic Forceps³

F 1089 Test Method for Corrosion of Surgical Instruments³

3. Terminology

3.1 Definition:

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.

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. 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 F 921.

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 F 899 (see Note 1). The modified working end may be made of stellite, 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 F 1089. Holders with modified working ends shall be subject to corrosion tests as specified in Test Method F 1089 except for the modifying material.

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.

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.

Current edition approved April 15, 1991. Published June 1991.

² *Annual Book of ASTM Standards*, Vol 03.01.

³ *Annual Book of ASTM Standards*, Vol 13.01.

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 2-0 3-0 4-0	0.16 in. 0.14 0.010 0.008	0.035 in. 0.24 0.024 0.015
Hufnagel 8 thru 10 in.	coronary bypass	3500 or smooth	5-0 6-0 7-0	0.006 0.004 0.003	0.015 0.009 0.009
Webster Hegar-Mayo Brown	microsurgery	smooth	8-0 9-0	0.002 0.0015	0.006 0.006
Castrovieijo		smooth	10-0	0.0008	0.006
Kalt		smooth			

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

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 F 921 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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