Designation: F1325 – 91 (Reapproved 2023)

Standard Specification for Stainless Steel Suture Needle Holders—General Workmanship Requirements and Corresponding Test Methods[1]

This standard is issued under the fixed designation F1325; 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.

1. Scope

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

1.2 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

2. Referenced Documents

2.1 *ASTM Standards:*[2]

E18 Test Methods for Rockwell Hardness of Metallic Materials

E92 Test Methods for Vickers Hardness and Knoop Hardness of Metallic Materials

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.

3.1.1.1 *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 (trademarked). 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 Terminology 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

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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.

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	2500	0	0.16 in.	0.035 in.
			2-0	0.14	0.24
Hufnagel 8 thru 10 in.	replacement	2500	3-0	0.010	0.024
			4-0	0.008	0.015
Webster	coronary	3500 or	5-0	0.006	0.015
Hegar-Mayo	bypass	smooth	6-0	0.004	0.009
Brown			7-0	0.003	0.009
Castrovieijo	microsurgery	smooth	8-0	0.002	0.006
			9-0	0.0015	0.006
Kalt		smooth	10-0	0.0008	0.006

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

be subject to corrosion tests as specified in Test Method F1089 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.

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 Terminology 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 7.1.1.

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