



Designation: F 1325 – 91 (Reapproved 2008)

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:²

E 18 Test Methods for Rockwell Hardness of Metallic Materials

E 92 Test Method for Vickers Hardness of Metallic Materials

E 140 Hardness Conversion Tables for Metals Relationship Among Brinell Hardness, Vickers Hardness, Rockwell Hardness, Superficial Hardness, Knoop Hardness, and Scleroscope Hardness

F 899 Specification for Wrought Stainless Steels for Surgical Instruments

F 921 Terminology Relating to Hemostatic Forceps

F 1089 Test Method for Corrosion of Surgical Instruments

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,

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 Feb. 1, 2008. Published March 2008. Originally approved in 1991. Last previous edition approved in 2002 as F 1325 – 91 (2002).

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.