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Standard Specification for General Workmanship and Performance Measurements of Hemostatic Forceps[1]

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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 general workmanship aspects of hemostatic forceps fabricated from stainless steel and 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 Materials[2]

E 92 Test Method for Vickers Hardness of Metallic Materials[2]

E 140 Hardness Conversion Tables for Metals[2]

F 899 Specification for Stainless Steels for Surgical Instruments[3]

F 921 Definitions of Terms Relating to Hemostatic Forceps[3]

3. Terminology

3.1 Definitions applicable to hemostatic forceps shall be in accordance with Definitions F 921.

4. Material

4.1 All of the component parts of the instruments shall be made of martensitic stainless steel of Type 410, 410X, 416, 416MOD, 420A, or 420B of Specification F 899.

5. Physical Requirements

5.1 *Heat Treatment and Hardness for Component Parts*:

5.1.1 The component parts of the instruments shall be heat treated under conditions recommended for the material used. Typical heat treating guidelines and hardness values are shown in Specification F 899.

5.1.2 The hardness of all opposing parts of the same instrument shall not vary in hardness by more than 4 units on the Rockwell Hardness C scale (HRC) or equivalent.

5.2 *Passivation*—Instruments and instrument components shall be passivated after completion of all fabricating and finishing operations.

6. Performance Requirements

6.1 *Finger Rings*—Inside surfaces shall be well rounded and polished and shall comply with the requirements in 7.1.

6.2 *Jaw Serrations and Teeth*—Jaw serrations and teeth shall be of the types specified in Definitions F 921. The serrations and teeth shall be of uniform depth and height and well defined to provide effective gripping. The serrations and teeth shall interdigitate. The edges of the serrations shall be chamfered.

6.3 *Box Lock*—The hemostatic forceps shall be of box lock construction, as defined in Definitions F 921. The pin, or other fastening component, shall be permanently secured. The joint performance of the box lock shall be smooth, of equal resistance, and non-binding when opening or closing the forceps to an included angle of 90 ± 5° (the lock may be lubricated).

6.4 *Clearance*—The maximum clearance between the male and female members of the forceps in the lock area shall be 0.4 mm (0.015 in.). The clearance is the visible gap that exists when the instrument is viewed from both the front and side profile or end view of the instrument (excluding bevel) (see Fig. 1).

6.5 *Ratchets*—Ratchet and ratchet catch shall securely engage at each ratchet position in a smooth and progressive manner.

6.6 *Jaw and Ratchet Setting*—The jaw tips shall close and interdigitate when the first ratchet position is engaged, and there shall be no visible misalignment of the jaws. The jaws shall progressively tighten with each succeeding ratchet engagement. Each ratchet position shall hold firmly and release easily. The jaws shall be fully closed and the serrations interdigitated when the last ratchet is engaged. The jaws shall not open as the result of engaging any ratchet position.

[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] *Annual Book of ASTM Standards*, Vol 03.01.

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