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Standard Specification for General Workmanship and Performance Measurements of Hemostatic Forceps¹

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1. Scope

1.1 This specification covers general workmanship aspects of hemostatic forceps fabricated from stainless steel and 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

3. Terminology

3.1 Definitions applicable to hemostatic forceps shall be in accordance with Terminology **F921**.

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 **F899**.

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.

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 given in Specification **F899**.

5.1.2 The hardness of all opposing parts of the same instrument shall not vary in hardness by more than four units on the Rockwell Hardness C scale (HRC) or equivalent. (See Test Methods **E18**.)

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*—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 Terminology **F921**. 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 $90 \pm 5^\circ$ (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*—Ratchets 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

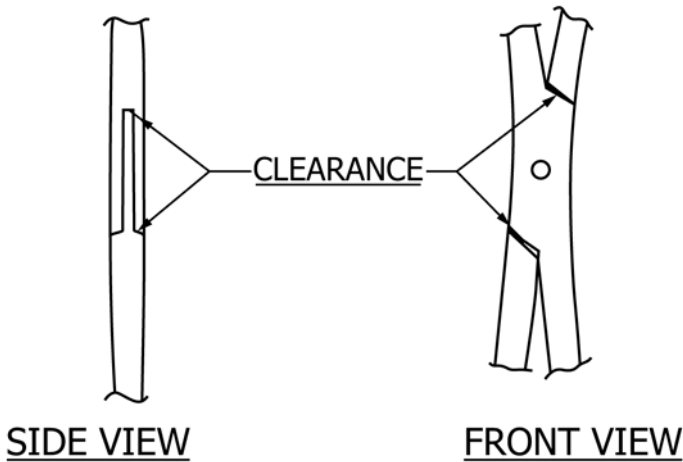


FIG. 1 Clearance of Forceps

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.

6.7 *Elasticity*—The instrument by design shall be capable of passing the test for elasticity as specified in 8.2. After completion of the test, no visible distortion, cracks, or other visible damage to the instrument shall be evident.

7. Workmanship, Finish, and Appearance

7.1 *Surfaces*—The surfaces of the instrument shall be uniformly finished and free of burrs, sharp edges, cracks, coarse marks, and manufacturing materials.

7.2 *Type*—The finish shall be one of the types defined in Terminology F921, or as required by the purchaser.

8. Test Methods

8.1 *Hardness*—Hardness shall be determined in accordance with Test Methods E18 or Test Methods E92. Conversion of Vickers hardness values to Rockwell values shall be in accordance with the Conversion Tables in E140.

8.2 *Elasticity*—The instrument shall have a segment of basswood, leather strap, or stainless steel wire test material placed between the jaws at the tip. The instrument shall be engaged in the last (tightest) ratchet position for 24 h at room temperature. The thickness of the test material shall be as listed in Table 1.

8.3 *Corrosion Resistance*—Instruments or instrument components shall be subject to the corrosion tests.

9. Marking and Labeling

9.1 All markings shall be legible.

9.2 The instrument shall bear: the manufacturer’s or contractor’s name or registered trademark; the country of origin, when the instrument is not manufactured in the United States; and other markings as required by the purchaser, manufacturer, or contractor.

9.3 The markings shall be located on a suitable surface of the instrument.

TABLE 1 Test Material Thickness and Instrument Length

Thickness or Diameter of Test Material, mm (in.)	Nominal Overall Length of Instrument, mm (in.)
1.98–2.00 (0.0781–0.0787)	Up to and including 127 (5)
3.00–3.18 (0.1181–0.1250)	Over 127 to 150 (5 to 5.906)
3.97–4.00 (0.1563–0.1575)	Over 150 to 177.8 (5.906 to 7.000)
4.76–5.00 (0.1875–0.1969)	Over 177.8 (7.000)

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