Designation: F3395/F3395M – 24

Standard Specification for Neurosurgical Head Holder Devices[1]

This standard is issued under the fixed designation F3395/F3395M; 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 standards a manufacturer shall meet in the performance testing of neurosurgical head holder devices (skull clamps).

1.2 This specification covers neurosurgical head holder devices (skull clamps) made of metal (nonradiolucent) as well as neurosurgical head holder devices (skull clamps) made of plastic material (radiolucent).

1.3 This specification represents the best currently available test procedures and is a minimum safety and performance standard.

1.4 This specification covers only those neurosurgical head holders (skull clamps) intended for use on humans for neurosurgical and spinal clinical applications. This specification assumes the user is well trained in the procedures and use of these devices including selection of the correct device type and accessories.

1.5 This specification describes those devices commonly known as skull clamps and accessories, such as skull pins, attachments, and various adaptors.

1.6 This specification only describes head holder devices that provide rigid skeletal fixation of the skull by means of three skull pins that penetrate the outer surface or outer layers of the patient's head during neurosurgical or spinal procedures (compare with Ref (**1**)).[2] Two pins are typically located in a two-pin rocker, whereas the force delivery component is equipped with a single pin.

1.7 The values stated in either SI units or inch-pound units are to be regarded separately as standard. The values stated in each system are not necessarily exact equivalents; therefore, to ensure conformance with the standard, each system shall be used independently of the other, and values from the two systems shall not be combined. The values given in parentheses are for information only.

1.8 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety, health, and environmental practices and determine the applicability of regulatory limitations prior to use.*

1.9 *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:*[3]

D638 Test Method for Tensile Properties of Plastics

D695 Test Method for Compressive Properties of Rigid Plastics

D792 Test Methods for Density and Specific Gravity (Relative Density) of Plastics by Displacement

F2052 Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment

F2119 Test Method for Evaluation of MR Image Artifacts from Passive Implants

F2182 Test Method for Measurement of Radio Frequency Induced Heating On or Near Passive Implants During Magnetic Resonance Imaging

F2213 Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment

F2503 Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment

2.2 *IEC Standards:*[4]

IEC 60601-1 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance

IEC 60601-2-46 Medical electrical equipment – Part 2-46: Particular requirements for the basic safety and essential

[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 F04.25 on Spinal Devices.

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[2] The boldface numbers in parentheses refer to a list of references at the end of this standard.

[3] For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at www.astm.org/contact. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

[4] Available from International Electrotechnical Commission (IEC), 3, rue de Varembé, 1st floor, P.O. Box 131, CH-1211, Geneva 20, Switzerland, https://www.iec.ch.

performance of operating tables

3. Terminology

3.1 *Definitions of Terms Specific to This Standard:*

3.1.1 *base handle*—component of the table adaptor (*base unit*) system that facilitates locking and unlocking of the head rest support and/or table adaptor system.

3.1.2 *base unit*—see 3.1.9, *table adaptor*.

3.1.3 *force delivery component*—component of the neurosurgical head holder that supplies a user-defined clamping force to impinge the patient's head (also referred to as a *torque bolt*, *torque screw*, or *force applicator*).

3.1.4 *neurosurgical head holder*—commonly referred to as *skull clamp*, device used to clamp the patient's skull to hold the head and neck in a specific position (known as rigid fixation) during surgical procedures.

3.1.4.1 *Discussion*—To avoid confusion, this specification will refer to the *neurosurgical head holder* as the *skull clamp*. See Fig. 1 for visual of a typical skull clamp device achieving rigid fixation.

3.1.5 *neurosurgical head holder (skull clamp) system*—typically, a complete neurosurgical head holder (skull clamp) system consists of a skull support device such as a skull clamp or head rest, a base unit, skull pins, and various types of skull clamp adaptors. See Fig. 2 for a visual (with high level terminology) of a typical skull clamp system.

3.1.6 *skull clamp*—see 3.1.4, *neurosurgical head holder*.

3.1.7 *skull clamp adaptor*—accessory of the neurosurgical head holder (skull clamp) system that allows connection of various components to the table adaptor.

3.1.8 *skull pin*—a rigid pinpoint device used in conjunction with skull clamps, halo rings, and/or cranial traction tongs, which when properly applied, invasively anchors and impinges the skull.

3.1.9 *table adaptor (base assembly)*—commonly referred to as *base unit*, device used to provide attachment from the operating room table to a skull clamp or other neurosurgical device.

3.1.9.1 *Discussion*—To avoid confusion, this specification will refer to the *table adaptor* as the *base unit*.

3.1.10 *torque screw*—(sometimes referred to as *torque bolt* or *force applicator*) supplies a user-defined clamping force to impinge the patients head.

3.1.10.1 *Discussion*—To avoid confusion, this specification will refer to the *torque screw* as the *force delivery component* (see 3.1.3, *force delivery component*).

4. Recommended Auxiliary Materials

4.1 *Definitions of Auxiliary Materials for this Specification:*

4.1.1 *Analogue Cortical Bone*—Material that mimics a human cortical skull bone and features the following properties:

4.1.1.1 *Density,* 1.7 ± 0.2 g cm^{-3} (Test Methods D792).

4.1.1.2 *Compression Modulus,* 15.0 ± 3.0 GPa (Test Method D695).

4.1.1.3 *Transverse Tension Modulus,* 10.4 ± 3.0 GPa (Test Method D638).

4.1.1.4 These properties are in line with values of a human cortical skull bone given in the literature **(2, 3)**.

4.1.2 *Rigid Non-Creeping Material*—Materials with a Young's modulus (*E*) > 2.5 GPa. Effective materials include the following:

4.1.2.1 *Stainless Steel, E* ≈ 203.0 GPa.

4.1.2.2 *Polyoxymethylene (POM), E* ≈ 2.6 to 3.1 GPa.

4.1.2.3 *Aluminum 6061-T6, E* ≈ 68.9 GPa.

4.1.2.4 *Garolite (G-10 Fiberglass Epoxy Laminate), E* ≈ 18.6 GPa).

4.1.2.5 *Phenolic Laminate, E* ≈ 9.65 GPa.

4.1.2.6 *Oak Wood, E* ≈ 8.6 to 11.0 GPa.

4.1.2.7 *Solid Polyurethane Foam, E* ≈ 10 to 16 GPa.

5. Recommended Tolerances

5.1 *Force Tolerance*—The recommended tolerances for the force values listed throughout this specification are ±8.9 N (±2.0 lbf) unless otherwise specified.

5.2 *Mass Tolerance*—The recommended tolerances for the mass values listed throughout this specification are ±1.0 kg (±2.2 lb) unless otherwise specified.

5.3 *Time Tolerance*—The recommended tolerances for the time values listed throughout this specification are ±1.0 s unless otherwise specified.

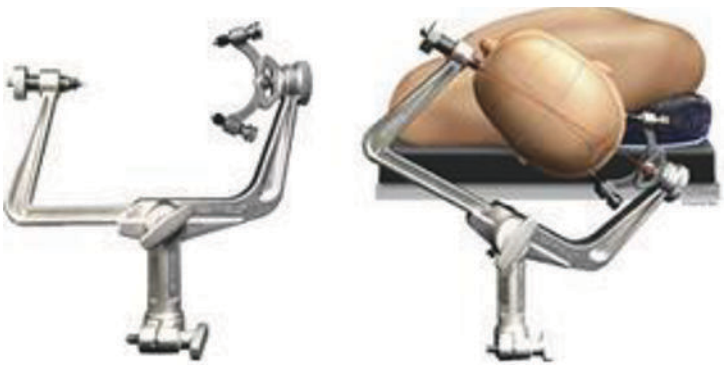

FIG. 1 Skull Clamp Device Achieving Three-Pin Rigid Fixation