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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 2-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

[1] This test method 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 service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

FIG. 1 Skull Clamp Device Achieving 3-Pin Rigid Fixation

FIG. 2 Skull Clamp System (Skull Clamp, Base Unit, Adaptor, and Skull Pins)

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 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

[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.

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*—rigid pin point devices used in conjunction with skull clamping devices which, when properly applied, impinge the skull. Skull pins are intended to be sterile at the time of use.

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.

6. Conformance

6.1 Presently, this specification is voluntary and not required by law. A manufacturer may label a product as conforming to this specification only if the product meets all the requirements of this specification.

7. Classification

7.1 *Intraoperative 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 system adaptors. The uniqueness of these systems is their ability to provide surgeons with numerous degrees of freedom and patient position options.

8. Magnetic Resonance Imaging (MRI) Compatibility Requirements

8.1 For neurosurgical head holders (skull clamps) to be used with intraoperative MRI imaging only:

8.1.1 These neurosurgical head holder device (skull clamp) MRI compatibility requirements are intended to protect the patient and users from harm in the MR environment.

8.1.2 Manufacturers shall be responsible for testing the MRI safety and efficacy of the device.

8.1.3 *Test Methods*

8.1.3.1 For neurosurgical head holders (skull clamps) designed for use in the MR environment, the manufacturer shall ensure that its construction uses a minimum amount of metallic and/or conductive components.

8.1.3.2 Where metallic components are present and cannot be avoided, the materials used shall be non-magnetic and non-conductive to the greatest extent possible.

8.1.3.3 Perform testing and analyses referenced in Practice F2503 to evaluate the safety of the device in the MR environment. Label the device MR Safe, MR Unsafe, or MR Conditional as defined in Practice F2503.

8.1.3.4 The worst-case configuration shall be determined for each evaluation, and the tests shall be conducted on the identified worst-case configurations.

8.1.3.5 Evaluate the magnetically induced displacement produced by the device. Perform testing and analyses outlined in Test Method F2052.

8.1.3.6 Evaluate the magnetically induced torque produced by the device. Perform testing and analyses outlined in Test Method F2213.

8.1.3.7 Assessment of radio frequency (RF)-induced heating for these devices is complex. While Test Method F2182 is limited to devices entirely implanted inside the body, RF-induced heating can be evaluated experimentally and/or computationally using a method similar to that described in Test Method F2182, with modifications for head holder devices. The components that are in contact with the patient need to be monitored, and particular attention needs to be paid to determining the worst-case configuration (**4**). In addition to the possibility of antenna resonant effects, these devices may create conductive loops that may result in heating.

8.1.3.8 Evaluate the MR image artifact produced by the device. Perform testing and analyses outlined in Test Method F2119.

8.1.3.9 Testing shall encompass the entirety of the cranial stabilization system exposed to the MR environment including accessories and ancillary devices.

9. Mechanical Testing

9.1 *Static Load Test*

9.1.1 To ensure mechanical integrity of the skull clamp under load, the skull clamp is tested to withstand static loading.

9.1.2 To ensure that the device is free from deformation under load, the minimum applied force shall be equal to the maximum force able to be exerted by the device's force delivery component for a period of 24 h. A typical surgical procedure involving these devices could range from 8 to 12 h, with 24 h representing a worst-case duration to account for extensive surgical procedures. Because mechanical failure of the device could lead to a sudden loss of functionality and/or patient support, the system shall be tested at this maximum force (simulating the maximum clamping force of the force delivery component) for 24 h.

9.1.3 The test method is defined in Section 11.

9.2 *Creep Test (Load Loss)*

9.2.1 The skull clamp must be able to achieve and maintain a user-defined force for a specified period of time during utilization.

9.2.2 Extensive surgical procedures for which this device will be used may be up to 12 h in duration. To account for extensive surgical procedures, this test method represents a worst-case duration of 24 h. It is important that the skull clamp maintains its support throughout clinical use.

9.2.3 The test method is defined in Section 12.

9.3 *Torque Load Resistance Test*

9.3.1 A skull clamp is designed to allow proper positioning and locking by the surgeon to achieve rigid fixation. This locking is critical as the patient's head must be restricted from unintentional movement.

9.3.2 The torque load test is intended to ensure the skull clamp can withstand rotational movement when in use without impacting the locking mechanism.

9.3.3 The test method is defined in Section 13.

9.4 *System Test*

9.4.1 The skull clamp system, which consists of the skull clamp and the table adaptor, is intended to ensure rigidity of the system. The test verifies that the system is capable of resisting forces imposed by the patient and the surgeon when in use and in the locked position.

9.4.2 The table adaptor system is an assembly of various components (table adaptor, skull clamp adapter). As such, the totality of the finished assembly including the skull clamp shall be verified to ensure its capability to resist movement when locked and in use.

9.4.3 Taking into account the average weight of a human head and corresponding applied loads detailed in 9.4.1, the device could see static loads as high as 9.1 to 11.3 kg (20.0 to 25.0 lb). With a 2× safety factor, the skull clamp shall be tested to hold a minimum vertical shear force of at least 222.4 N (50.0 lbf).

9.4.4 The load requirements may vary due to its intended use. IEC 60601-1 may be consulted for load distributions for normal patients. IEC 60601-2-46 may also be consulted for weight distributions of larger patients.

9.4.5 The test method is defined in Section 14.

9.5 *Force Delivery Accuracy Verification*

9.5.1 The skull clamp force delivery component is used to apply a user-defined force to the patient's head.

9.5.2 The force delivery component is typically an assembly of various components. As such, the totality of the finished assembly shall be verified to ensure delivery of the prescribed force (e.g., not only a compression spring).

9.5.3 The test method is defined in Section 15.

9.6 *Skull Pin Shear Test*

9.6.1 The skull pin must be capable of resisting shear force arising out of the weight of the patient's head, and surgical activities without breaking, and without skull pin locomotion perpendicular to the pinned skull bone surface. Potential vibrations of the patient's head occurring during surgery are not considered in this skull pin test, as vibrations may occur although the mechanical integrity of the skull pin is given.

9.6.2 A human head weighs approximately 3.6 to 5.4 kg (8.0 to 11.9 lb). Considering additional loads applied by the surgeon and instruments the skull pins must sustain loads as high as 9.1 to 11.3 kg (20.0 to 25.0 lb). During surgical application, this load is distributed between all utilized skull pins. The theoretical maximum load a skull pin is exposed to occurs on the single pin side in a 3-pin rigid cranial fixation system. Including a 2× safety factor, this load reaches 9.1 to 11.3 kg (20.0 to 25.0 lb). Therefore, a skull pin shall be tested to withstand a perpendicular tensile force of 111.0 N (25.0 lbf).

9.6.3 The test method is defined in Section 16.

10. Performance Requirements

10.1 The purpose of these requirements is to ensure that the skull clamp devices meet the minimum performance requirements as originally designed. The skull clamp device requirements should not vary from procedure to procedure provided they are used and maintained according to the manufacturer's recommendation.

10.2 *Performance Requirement*

10.2.1 All mechanical fixation components shall be manufactured out of corrosion resistant materials.

10.2.2 All components shall be manufactured from materials capable of providing functional integrity over the useful life of the device.

10.2.3 The manufacturer shall be responsible for maintaining adequate mechanical test data or equivalent clinical data regarding the suitability of design, useful life, and diagnostic imaging compatibility of the system.

10.2.4 The manufacturer shall be responsible for supplying materials that are suitable to be reprocessed by the manufacturer's recommended reprocessing techniques.

10.3 *Maintenance Requirement*