



Designation: F1831 – 17

Standard Specification for Cranial Traction Tongs and Halo External Spinal Immobilization Devices¹

This standard is issued under the fixed designation F1831; 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 designing, manufacturing, testing, labeling, and documenting of halo and tong external spinal immobilization devices, but it is not to be construed as production methods, quality control techniques, manufacturer's lot criteria, or clinical recommendations.

1.2 This specification represents the best currently available test procedures at this time and is a minimum safety and performance standard.

1.3 This specification covers only those halo and tong devices intended for use on humans for therapeutic purposes. This specification assumes the user is well-trained in the procedures and maintenance of halo and tong application and has the ability to determine if an abnormality is treatable by these procedures.

1.4 This specification describes those devices commonly known as halo external fixation devices and what is known as cranial traction tongs.

1.5 Cranial traction tongs and halo devices are used to achieve and maintain optimal spinal alignment, in order to enhance fusion and decrease neurological deficit.

1.6 Monitoring the progress of treatment after application of these devices is important, this should be done in accordance with the manufacturer's recommendation and guidelines pertaining to the specific device.

1.7 The values stated in both inch-pound and SI units are to be regarded separately as the standard. The values given in parentheses are for information only.

1.8 The following precautionary statement pertains only to the test method portions, Sections 10 – 13: *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 and health 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:²

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 Standard:

IEC 601-1 Medical Electrical Equipment³

3. Terminology

3.1 Definitions of Terms Specific to This Standard:

3.1.1 *cranial traction tong*—a device providing weighted cervical traction to a patient through invasive attachment to the skull. This traction instrument is indicated for closed reduction of a cervical spine injury (that is, fracture or dislocation).

3.1.1.1 *adjustable tong*—a cranial traction tong that adjusts for size, pin positioning, or pin pressure.

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 F04.31 on Neurosurgical Standards.

Current edition approved June 1, 2017. Published July 2017. Originally approved in 1997. Last previous edition approved in 2014 as F1831 – 97(2014). DOI: 10.1520/F1831-17.

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.

³ Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, <http://www.ansi.org>.

*A Summary of Changes section appears at the end of this standard