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Standard Guide for Characteristics for Adjunct Cervical Spine Immobilization Devices (ACSID)[1]

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INTRODUCTION

The objective of this guide is to begin to address the recognized need to support and immobilize the components of the spine or spinal cord. Although this guide does not quantitatively address performance standards for this device, it does address the characteristics of the device(s) used to provide support and immobilization of the components of the central nervous system for the patient suspected of receiving trauma to that body system.

1. Scope

1.1 This guide establishes minimum standards for devices designated here as adjunct cervical spine immobilization device (ACSID); a lateral stabilizer for the head is an example of this type of device. The ACSID is designed to be used to assist in the immobilization of the cervical spine, by emergency medical services personnel.

1.2 This guide does not identify specific degrees of limitation of motion achieved by placement of an ACSID on a patient. Definitive requirements for immobilization of the spine, and, in particular, the degree of limitation associated with the use of an ACSID, have not been established in the medical literature.

1.3 *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.*

2. Referenced Documents

2.1 *ASTM Standards:*

F 1177 Terminology Relating to Emergency Medical Services[2]

2.2 *OSHA Standard:*

20 CFR 1910.1030 Occupational Exposure to Bloodborne Pathogens; Final Rule[3]

2.3 *Centers for Disease Control Standard:*

Guidelines for Prevention of Transmission of HIV and HBV to Healthcare and Public Safety Workers[4]

3. Terminology

3.1 *Definitions:*

3.1.1 *retention system*—an adjunct to or an integral part of the primary platform that allows the patient to be securely attached to that platform used in whatever configuration and size necessary to accomplish the goal while still allowing reasonable and necessary access to the patient.

3.1.2 *spinal immobilization*—immobilization of the entire spine and its contiguous structures, the pelvis and skull.

3.1.3 *spine*—the spine shall include the cervical, thoracic, lumbar, and sacral vertebrae.

3.2 *Definitions of Terms Specific to This Standard:*

3.2.1 *directions of movement*—directions include flexion, extension, rotation, distraction, lateral motion, and axial compression motion.

3.2.2 *immobilization*—limitation of motion.

3.3 For definitions of other terms used in this guide, refer to Terminology F 1177.

4. Significance and Use

4.1 The intent of this guide is to identify characteristics that an ACSID shall possess.

4.2 It is not expected that the ACSID will be used alone to provide the entire scope of required immobilization. Clinical situations may require differing combinations of devices for adequate total spinal immobilization. An ACSID may be one of the devices.

4.3 An ACSID is intended to provide stabilization and/or support in addition to other immobilization devices in one or more of the planes of motion mentioned in 3.2.1 (see 4.2).

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[1] This guide is under the jurisdiction of ASTM Committee F30 on Emergency Medical Services and is the direct responsibility of Subcommittee F30.01 on EMS Equipment.

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[2] *Annual Book of ASTM Standards*, Vol 13.02.

[3] Available from Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402.

[4] Available from Centers for Disease Control and Prevention (CDC), 1600 Clifton Rd., Atlanta, GA 30333.

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5. Characteristics

5.1 Placement or use of the ACSID shall not require or cause movement of the head or neck, or both, during treatment or transport of patient.

5.2 Once in place, the ACSID shall assist in the immobilization of the cervical spine.

5.3 It shall not cause vascular compression or airway compromise.

5.4 It shall provide access to see the ears once applied.

5.5 It shall provide for continued evaluation of cervical soft tissue or jugular vein distention, or tracheal deviation, or combination thereof.

5.6 It shall be capable of being applied without movement of the cervical spine.

5.7 It shall provide for the performance of normally accepted techniques of airway management/maintenance.

5.8 It shall allow X-ray to be taken through it and be MRI compatible.

5.9 It shall be compatible with other devices used in the complete immobilization of the cervical spine.

6. Durability

6.1 The ACSID shall maintain stated characteristics throughout its lifetime as indicated by manufacturer's recommendations.

7. Maintenance

7.1 The ACSID shall be disposable or easily cleaned consistent with CDC and OSHA decontamination procedures, without deterioration of the product or the retention of cleaning agents that may be harmful to the patient.

7.2 The cleaning/decontamination procedure shall be explained in the manufacturer's product information.

8. Capability

8.1 This guide does not presently quantify the limitation of motion expected to be imposed upon a patient as a result of the application of a SPINE device. This capability has not been omitted due to a lack of need, but as a result of the fact that such quantitative requirements have not been identified in the medical literature. It is hoped that such requirements can be developed, and included in this guide at its next review.

9. Keywords

9.1 cervical spine immobilization device; spinal cord; spine

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