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Standard Specification and Test Methods for External Skeletal Fixation Devices[1]

This standard is issued under the fixed designation F 1541; 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 provides a characterization of the design and mechanical function of external skeletal fixation devices (ESFDs), test methods for characterization of ESFD mechanical properties, and identifies needs for further development of test methods and performance criteria. The ultimate goal is to develop a specification, which defines performance criteria and methods for measurement of performance-related mechanical characteristics of ESFDs and their fixation to bone. It is not the intention of this specification to define levels of performance or case-specific clinical performance of the devices, as insufficient knowledge is available to predict the consequences of the use of any of these devices in individual patients for specific activities of daily living. Furthermore, it is not the intention of this specification to describe or specify specific designs for ESFDs.

1.2 This specification describes ESFDs for surgical fixation of the skeletal system. It provides basic ESFD geometrical definitions, dimensions, classification, and terminology; material specifications; performance definitions; test methods; and characteristics determined to be important to the in-vivo performance of the device.

1.3 This specification includes a terminology and classification annex and five standard test method annexes as follows:

1.3.1 *Classification of External Fixators*—Annex A1.

1.3.2 *Test Method for External Skeletal Fixator Connectors*—Annex A2.

1.3.3 *Test Method for Determining In-Plane Compressive Properties of Circular Ring or Ring Segment Bridge Elements*—Annex A3.

1.3.4 *Test Method for External Skeletal Fixator Joints*—Annex A4.

1.3.5 *Test Method for External Skeletal Fixator Pin Anchorage Elements*—Annex A5.

1.3.6 *Test Method for External Skeletal Fixator Subassemblies*—Annex A6.

1.3.7 *Test Method for External Skeletal Fixator/Constructs Subassemblies*—Annex A7.

1.4 A rationale is given in Appendix X1.

1.5 The values stated in SI units are to be regarded as the standard.

1.6 The following safety hazards caveat pertains only to the test method portions (Annex A2-Annex A6):

1.7 *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:*

A 938 Test Method for Torsion Testing of Wire[2]

D 790 Test Methods for Flexural Properties of Unreinforced and Reinforced Plastics and Electrical Insulating Materials[3]

E 4 Practices for Force Verification of Testing Machines[4]

F 67 Specification for Unalloyed Titanium for Surgical Implant Applications[5]

F 90 Specification for Wrought Cobalt-20 Chromium-15 Tungsten-10 Nickel Alloy for Surgical Implant Applications (R30605)[5]

F 136 Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy (UNS R56401) for Surgical Implant Applications

F 138 Specification for Wrought 18 Chromium-14 Nickel-2.5 Molybdenum Stainless Steel Bar and Wire for Surgical Implants (UNS S31673)[5]

F 366 Specification for Fixation Pins and Wires[5]

F 543 Specification for Metallic Medical Bone Screws[5]

F 544 Reference Chart for Pictorial Cortical Bone Screw Classification[6]

F 1058 Specification for Wrought Cobalt-Chromium-Nickel Molybdenum-Iron Alloy for Surgical Implant Applications (UNS R30003 and UNS R30008)[5]

F 1264 Specification and Test Methods for Intramedullary Fixation Devices[5]

F 1472 Specification for Wrought Titanium-6 Aluminum-4 Vanadium Alloy for Surgical Implant Applications (UNS R56400)[5]

[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 F04.21 on Osteosynthesis.

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[2] *Annual Book of ASTM Standards*, Vol 01.03.

[3] *Annual Book of ASTM Standards*, Vol 08.01.

[4] *Annual Book of ASTM Standards*, Vol 03.01.

[5] *Annual Book of ASTM Standards*, Vol 13.01.

[6] Discontinued; see 1998 *Annual Book of ASTM Standards*, Vol 13.01.

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