



Standard Specification for Preformed Cranioplasty Plates¹

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1. Scope

1.1 This specification covers preformed cranioplasty plates which do not require further alteration for covering skull defects. This specification covers compositional and physical performance and packaging requirements, but does not cover toxicity nor biocompatibility of the materials.

2. Referenced Documents

2.1 *ASTM Standards:*²

F56 Specification for Stainless Steel Sheet and Strip for Surgical Implants (Withdrawn 1989)³

F75 Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Castings and Casting Alloy for Surgical Implants (UNS R30075)

F86 Practice for Surface Preparation and Marking of Metallic Surgical Implants

F139 Specification for Wrought 18Chromium-14Nickel-2.5Molybdenum Stainless Steel Sheet and Strip for Surgical Implants (UNS S31673)

2.2 *American Society for Quality (ASQ) Standard:*

ASQ C1 Specifications of General Requirements for a Quality Program⁴

3. Materials

3.1 Cranioplasty plates conforming to this specification shall be fabricated from materials described in the latest issue of Specifications **F56**, Grade 2, **F75**, or **F139**, Grade 2. The condition of the material (such as, annealed, cold finished, and so forth) should be specified in the purchase order.

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.

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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 The last approved version of this historical standard is referenced on www.astm.org.

⁴ Available from American Society for Quality (ASQ), 600 N. Plankinton Ave., Milwaukee, WI 53203, <http://www.asq.org>.

4. Dimensions and Tolerances

4.1 Cranioplasty plates conforming to this specification shall be fabricated in a variety of dimensions to accommodate, without further alteration, various sized skull defects.

4.2 Shape shall be contoured so as to re-establish the normal configuration and symmetry of the skull at various anticipated sites of defect such as the parietal bosses, theinion, the brow, the linea temporalis, and so forth.

4.3 Plates shall contain multiple perforations (see Fig. 1).

4.4 Thicknesses and individual shapes shall vary with need. Thickness tolerances shall be as follows:

Specified Thickness, in. (mm)	Thickness Tolerances, in. (mm)
0.005 (0.13) to 0.010 (0.25), incl	±10 %
0.010 (0.25) to 0.020 (0.51), incl	±0.0015 (0.04)
0.020 (0.51) to 0.035 (0.89), incl	±0.002 (0.05)
0.035 (0.89) to 0.050 (1.27), incl	±0.0025 (0.06)
0.050 (1.27) to 0.100 (2.54), incl	±0.003 (0.08)

5. Finish and Identification

5.1 Cranioplasty plates conforming to this specification shall have their surfaces prepared in accordance with the latest issue of Practice **F86**. Specific requirements of surface finish (if any) shall be stated in the purchase order.

5.2 The method of marking the plates shall be one of those specified in Practice **F86**.

6. Precautions

6.1 Cranioplasty plates covered by this specification shall *not* be reshaped in any manner after manufacture.

6.2 Material used to fasten the cranioplasty plates covered by this specification shall be the same alloy as the material used to make the specific plate being installed.

7. Packaging and Labeling

7.1 Cranioplasty plates conforming to this specification shall be supplied, packaged in accordance with the appropriate recommended practice being developed by ASTM Committee F04. Minimum packaging and labeling for cranioplasty plates shall include the following:

7.1.1 An insert shall be included in the package for the plate showing the material from which it was fabricated and include

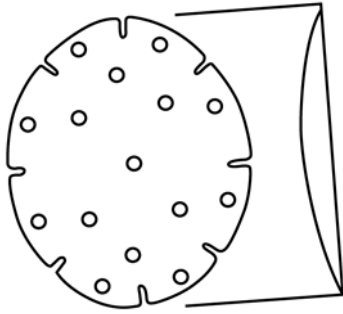


FIG. 1 Preformed Cranioplasty Plate

7.1.2 Labeling shall include the nominal thickness of the plate.

8. Quality Program Requirements

8.1 The manufacturer of cranioplasty plates covered by this specification shall maintain a quality program such as, for example, defined in ASQ C1.

9. Keywords

9.1 cranioplasty plates; neurosurgical medical devices/applications; orthopaedic medical devices; bone plates

a recommendation against using fasteners other than the same material or a recommended substitute to secure the plate when implanted.

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