Designation: F 452 – 76 (Reapproved 2002)

Standard Specification for Preformed Cranioplasty Plates[1]

This standard is issued under the fixed designation F 452; 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 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:*

F 56 Specification for Stainless Steel Sheet and Strip for Surgical Implants[2]

F 75 Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Castings and Casting Alloy for Surgical Implants (UNS R30075)[3]

F 86 Practice for Surface Preparation and Marking of Metallic Surgical Implants[3]

F 139 Specification for Wrought-18 Chromium-14 Nickel-2.5 Molybdenum Stainless Steel Sheet and Strip for Surgical Implants (UNS S31673)[3]

2.2 *American Society for Quality Control (ASQC) Standard:*

C1-1968 Specifications of General Requirements for a Quality Program[4]

3. Materials

3.1 Cranioplasty plates conforming to this specification shall be fabricated from materials described in the latest issue of Specifications F 56, Grade 2, F 75, or F 139, Grade 2. The condition of the material (such as, annealed, cold finished, and so forth) should be specified in the purchase order.

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, the inion, the brow, the linea temporalis, and so forth.

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

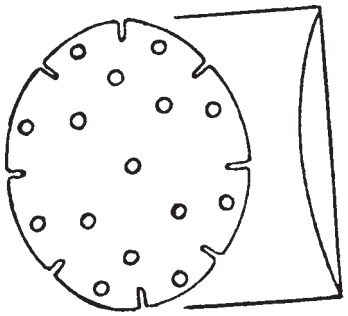

FIG. 1 Preformed Cranioplasty Plate

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 F 86. 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 F 86.

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[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] Discontinued—See 1991 *Annual Book of ASTM Standards*, Vol 13.01.

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

[4] Available from American Society for Quality (ASQ), 600 N. Plankinton Ave., Milwaukee, WI 53203.

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

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 ASQC Specifications C 1-1968.

9. Keywords

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