



Standard Specification for Preformed Cranioplasty Plates That Can Be Altered ¹

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1. Scope

1.1 This specification covers preformed cranioplasty plates that allow alteration for covering skull defects.

2. Referenced Documents

2.1 ASTM Standards:

F 67 Specification for Unalloyed Titanium (UNS R50250, UNS R50400, UNS R50550, R50700) for Surgical Implant Applications²

F 86 Practice for Surface Preparation and Marking of Metallic Surgical Implants²

F 90 Specification for Wrought Cobalt-20Chromium-15Tungsten-10Nickel Alloy for Surgical Implant Applications (UNS R30605)²

F 136 Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy (UNS R56401) for Surgical Implant Applications²

2.2 ASQC Standard:

C1-1968 Specifications of General Requirements for a Quality Program³

3. Terminology

3.1 Definition:

3.1.1 *cranioplasty plate*—an implanted prosthetic device used to repair or cover a skull defect or hole.

4. Materials

4.1 Cranioplasty plates conforming to this specification shall be fabricated from one of the materials covered by the following ASTM specifications or other such materials found acceptable for neurosurgical procedures only: F 67, F 90, and F 136.

5. Dimensions and Tolerances

5.1 Cranioplasty plates conforming to this specification shall be fabricated in a variety of dimensions to accommodate

various sized skull defects. These plates may be altered in the operating room by the neurosurgeon in order to fit a particular skull defect.

5.2 The shape of the plate shall be contoured so as to reestablish 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.

5.3 Plates shall contain multiple perforations.

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

Specified Thickness, in. (mm)	Tolerances, in. (mm)
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)

5.5 For plates that are cast or hand-wrought, the establishment of tolerances is not practical and is the responsibility of the implant manufacturer.

6. Finish and Identification

6.1 Cranioplasty plates conforming to this specification shall be finished in accordance with Practice F 86.

6.2 Cranioplasty plates conforming to this specification shall be identified as to the material used for fabrication, in a manner in accordance with Practice F 86.

6.3 Tantalum cranioplasty plates shall be cleaned using a tantalum etching solution.

6.3.1 Prepare the tantalum etching solution as follows:

Hydrofluoric acid (H ₂ F ₂)	48 vol %	4 parts
Sulfuric acid (H ₂ SO ₄)	98 vol %	6 parts
Nitric acid (HNO ₃)	70 vol %	3 parts
Water		13 parts

6.3.2 Use the tantalum etching solution at room temperature for a period of 15 min (Note 1). Wash with water immediately. (**Warning**—The use of this solution should be under a hood as the fumes are toxic.)

NOTE 1—The 15-min dip followed by a water bath is necessary to clean the tantalum cranioplasty plates.

7. Precautions

7.1 When metallic sutures or screws are used to fasten the

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² Annual Book of ASTM Standards, Vol 13.01.

³ Available from American Society for Quality (ASQ), 600 N. Plankinton Ave., Milwaukee, WI 53203.

cranioplasty plates covered by this specification, they shall be of the same metallic composition as the specific plate being installed.

8. Packaging and Labeling

8.1 Cranioplasty plates conforming to this specification shall be packaged in accordance with federal regulations appropriate for such devices.

8.1.1 An insert shall be included in the package for the plate identifying the material from which it was fabricated. A recommendation against the use of fasteners other than the same material to secure the plate shall also be included.

8.1.2 Labeling shall include the nominal thickness of the plate.

9. Quality Program Requirements

9.1 The manufacturer of cranioplasty plates covered by this specification shall maintain a quality program such as defined in ASQC C1-1968.

10. Keywords

10.1 cranioplasty plates; neurosurgical medical devices/ applications

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