Designation: F622 – 79 (Reapproved 2002)

Standard Specification for Preformed Cranioplasty Plates That Can Be Altered [1]

This standard is issued under the fixed designation F622; 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 that allow alteration for covering skull defects.

2. Referenced Documents

2.1 *ASTM Standards:*[2]

F67 Specification for Unalloyed Titanium, for Surgical Implant Applications (UNS R50250, UNS R50400, UNS R50550, UNS R50700)

F86 Practice for Surface Preparation and Marking of Metallic Surgical Implants

F90 Specification for Wrought Cobalt-20Chromium-15Tungsten-10Nickel Alloy for Surgical Implant Applications (UNS R30605)

F136 Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)

2.2 *ASQC Standard:*

C1-1968 Specifications of General Requirements for a Quality Program[3]

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: F67, F90, and F136.

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, the inion, 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 F86.

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 F86.

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_2F_2)	48 vol %	4 parts
Sulfuric acid (H_2SO_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.)

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