Designation: F 622 – 79 (Reapproved 1998)

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 for Surgical Implant Applications[2]

F 86 Practice for Surface Preparation and Marking of Metallic Surgical Implants[2]

F 90 Specification for Wrought Cobalt-Chromium-Tungsten-Nickel Alloy for Surgical Implant Applications[2]

F 136 Specification for Wrought Titanium 6A1-4V ELI Alloy for Surgical Implant Applications[2]

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: 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, the inion, the brow, the linea temporalis, etc.

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_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.

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

6.3.3 **Warning**—The use of this solution should be under a hood as the fumes are toxic.

7. Precautions

7.1 When metallic sutures or screws are used to fasten the 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

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

[3] Available from American Society for Quality Control, 161 W. Wisconsin Ave., Milwaukee, WI 53203.