This guidance was written prior to the February 27, 1997 implementation of FDA's Good Guidance Practices, GGP's. It does not create or confer rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both. This guidance will be updated in the next revision to include the standard elements of GGP's

DRAFT VERSION
CRANIAL PERFORATOR GUIDANCE

Prepared By:

Neurological Devices Branch
Division of Cardiovascular, Respiratory and Neurological Devices
Office of Device Evaluation

Draft - July 13, 1994
(reformatted 12/17/97)

(To be used in conjunction with Draft DCRND 510(k) Guidance)

This guidance document may contain references to addresses and telephone numbers that are now obsolete. The following contact information is to be used instead:

- **While this guidance document represents a final document, comments and suggestions may be submitted at any time for Agency consideration to the General Surgical Devices Branch, 9200 Corporate Blvd., HFZ-410, Rockville, MD 20850.**
- **For questions regarding the use or interpretation of this guidance, contact the General Surgical Devices Branch at 301- 594-1307.**
- **To contact the Division of Small Manufacturers Assistance (DSMA), call 800-638-2041 or 301-443-6597; fax 301-443-8818; email dsmo@cdrh.fda.gov; or write to DSMA (HFZ-200), Food and Drug Administration, 1350 Piccard Drive, Rockville, Maryland 20850-4307. FACTS-ON-DEMAND (800-899-0381 or 301-827-0111) and the World Wide Web (CDRH home page: http://www.fda.gov/cdrh/index.html) also provide easy access to the latest information and operating policies and procedures.**

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
Center for Devices and Radiological Health
Rockville, MD 20850

INTRODUCTION

This document is intended to be used in conjunction with the general information outlined in the "Draft - DCRND 510(k) Guidance." This document outlines specific information to be submitted for cranial perforators, craniotomies and motor drives.

OVERVIEW

Cranial perforators are described in the FDA regulations, 21 CFR 882.4305 as "Powered compound cranial drills, burrs, trephines and their accessories are bone cutting and drilling instruments used on a patient's skull. The instruments employ a clutch mechanism to disengage the tip of the instrument after penetrating the skull to prevent plunging of the tip into the brain. Hazards identified during initial classification of this device by the advisory panel included issues related to the potential for the device to penetrate into the brain during use. In particular, issues related to the potential failure of the clutch mechanism were identified. The advisory panel classified the device as a class II (special controls) device.

The information below is applicable to cranial perforators, craniotomies, motor drives and accessories.

SUGGESTED FORMAT - see DCRND 510(k) draft guidance and Content

- **General information** - see DCRND 510(k) draft guidance
  a. Trade name
  b. Common name
  c. Establishment registration Number
  d. Address of manufacturing facilities
  e. Classification
  f. Identification of predicate device
  g. Compliance with standards or guidelines

- **Summary and/or certification statement in accordance with SMDA** - see DCRND 510(k) draft guidance

- **Proposed labeling** - see DCRND 510(k) draft guidance.
  a. Intended use.
  b. Prescription labeling in accordance with 21 CFR 801.109 (b)(1).
  c. Identification labels, size of inner and outer cutters (perforators).
  d. Provide all labeling including advertisements, appropriate directions for re-processing/disinfection/sterilization, maintenance, etc. Include all cautions, warnings, precautions, contraindications or limitations.

     Provide warnings, contraindications etc. as appropriate which instructs the user that:
     (1) the perforator may nick or tear the dura with adherent dura, high ICP or with underlying abnormalities.
     (2) underlying bone may not support pressure of drilling and the perforator may penetrate the brain.
     (3) the perforator may not disengage and there is a possibility that the perforator could perforate the brain.

Reusable device

(1) Sterilization instructions. The repeated re-sterilization should not compromise the performance of the device.
(2) Provide the intervals for routine maintenance.
(3) Provide directions for determining deterioration of the motor drive and reusable perforator tip signaling the need to repair or replace the device.
(4) Detailed instructions must be provided in addition to sterilization including the following:
    * Assembly/disassembly
    * Detailed cleaning
(5) Recommended intervals for return to manufacturer for comprehensive maintenance.

Disposable devices.

(1) Date of sterilization and date of sterility expiration.

e. Provide all modes of operation
(1) Recommended rpm.
(2) Reversibility (bi-directional capability vs. forward only)
(3) Directions regarding adherent dura.

f. Modes of operation in which the perforator (and/or craniotome) may not protect against brain injury.
(1) Minimum thickness for designed function.
(2) Excessive load, penetration due to shelf fracture ("pushthrough").
(3) Drilling at an angle to the inner table of the skull surface.
(4) Maximum inward travel beyond the cortex during and after release.

- **Detailed physical device description** - see DCRND 510(k) draft guidance. In addition provide the following:

a. Specifications -
(1) Diameter of inner and outer drill cutters.
(2) Length, (engaged and disengaged).
(3) Disengagement distance
(4) Materials
(5) Provide technical specifications including electrical and insulating safety features of the motor drive.
(6) Recommended rpm of use.
(7) Engagement force necessary to initiate cutting with the perforator.
(8) Operating force necessary to continue the drilling with the perforator.
(9) Self centering?
(10) Reversibility of the drill direction
(11) Provide the thickness of remaining bone pad if applicable.
(12) Description of depth stops or means of prevention of accidental plunging
(13) Description of shank type.
(14) If reusable describe how parts may be prevented from being interchanged with

other perforators. Describe if they can/not be interchanged and provide tolerances.

b. Detailed schematic, assembly, and engineering drawings.
   (1) Enlarged drawings and descriptions of all tip configurations should be provided indicating any limitations of use.
      - Drawings should indicate a cut-away view of the engagement mechanism and cams.
        Depict both the engaged and disengaged view of the device.
   (2) Provide the maximum extension of the inner cutter beyond the outer cutter in the engaged and extended unengaged position.

c. Testing
   (1) Type of material used (wood, plexiglass, human cadaver, animal bone, other)
   (2) Shelf adequacy - shelf fracture force?
   (3) Perforator, craniotome and motor drive
      - Design qualification protocol
        (*) Describe how the design qualification testing was performed.
        (*) Summarize the design testing and results which were performed on this device to assure the safety and effectiveness of the design. Include the number of holes drilled by each tested perforator?
        (*) Describe the conditions of the drill testing including operating force required to test the drill, the material utilized in the testing, rpm, high/low load conditions, angle of drilling (60^o to the exit surface of the material), direction of drilling, and the strength of the remaining shelf to assure safety from breakthrough of the drill once the hole was drilled.
        (*) Provide a statistical analysis justifying the number of devices tested and the number of holes drilled by each unit to assure safety and reliability of the device.
        (*) Provide a comparison of your device to other presently manufactured devices regarding operating force needed and characteristics of the holes drilled such as shelf strength, size of the hole, thickness of the shelf, etc.
        (*) Describe the design qualification protocol utilized to assess the potential for nicking, cutting, lacerating or tearing the dura and provide results of that testing. Provide a statistical analysis of this testing to validate the sample size. Such testing is different from breakthrough testing which would be used to demonstrate the strength of the created shelf and clutch release of the perforator. Compare results with an equivalent device tested under the same conditions to demonstrate equivalence.
      - Describe the protocol and actual life testing of the device and parts.
        (*) Provide a statistical analysis to support the design protocol testing performed.
        (*) Describe how the tested perforator bodies were cleaned and resterilized following a specific number of life cycle sterilization tests. Such testing would expose the perforator to situations more similar to actual realistic use. Cleaning, soaking and sterilizing of the perforators may expose the inner workings to bioburden and

gross material contamination that, over an extended period of time, may contribute to failure which may not be replicated in repeated use by drilling alone. This is especially of concern in a perforator body which can not be completely disassembled following use. The effects of heat and pressure of an autoclave may induce negative factors when combined with potential contamination in the processing of the device.

- Routine <u>production quality assurance testing</u>

(*) Provide the protocol for routine production quality assurance testing following final assembly prior to sterilization, packaging and shipment. Describe the percent of devices tested, what is tested, how tested, what parts are destroyed during testing and how replacement parts are assured to be functional.

d. Describe the protocol by which the perforator cutting tips were interchanged, reused, etc., during both life cycle and disengagement testing.

e. Motor drive - describe how the device is lubricated and testing to assure that air and/or lubrication is confined to the hose and motor drive. Describe the testing to assure that seals prevent contamination of the sterile tip. Describe the testing protocol. Describe how the lifetime of the motor drive was established before refurbishing is necessary.

- **Comparative information -** see DCRND 510(k) draft guidance

In addition the following must be provided in side by side tabular form:

a. Predicate device physical description comparison.
   (1) Identify predicate device with same intended use and make comparisons.
   (2) Provide side by side comparisons in chart form including similarities and differences.
   Explain the consequences and effects of changes or modifications and how the differences affect the use and safety of the device.
   (3) Comparisons in physical description, specifications, materials, dimensions, and other characteristics.
   (4) Comparisons in testing and operating parameters

- **Biocompatibility** - see DCRND 510(k) draft guidance

- **Sterilization Information** - see DCRND 510(k) draft guidance

a. Sterile devices
   (1) Method of sterilization used (ETO, RAD, Steam).
   (2) SAL level attained.

b. Reusable devices
   (1) Provide bench testing to document sterilizability of the device under conditions of use in an institutional setting.
   (2) Provide inoculation microbiological testing of a representative number of devices after subsequent decontamination, cleaning, and resterilization to document that the recommended institutional reprocessing techniques will be adequate.
   (3) Type of sterilization (ETO/Steam?)

- **Software validation** - not applicable

- **Standards**
  Document all standards with which your device is in compliance. Where the device deviates from the standards provide a summary of the implications of the deviation or a justification where the standard is not applicable.
  a. DIN standard
  b. ISO 9000 and 9001
  c. ASTM 701-81; Care and Handling of Neurologic Implants and Instruments.
  d. UL-544
  e. Draft ASTM F-04-05.12.
  f. CITECH certification?

References

1. Gurdihan ES. *Operative Neurosurgery*. Baltimore: Williams and Wilkens, 1964.

2. Heifetz MD. *A variable-depth motorized skull perforator*. J Neurosurgery 1984 Sep; 61:602-3.

3. Smith GW An automatic drill for craniotomy. *J Neurosurgery* 1950 Jan; 7:285-6.

4. ECRI, Product Comparison System, Perforators, Cranial, Automatic; June 1992, 1-6.