

U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

Cranial Perforators with an Automatic Clutch Mechanism, Failure to Disengage: FDA Safety Communication

Date Issued: September 28, 2015

Audiences: Neurological Surgeons

Device: Cranial perforators are bone cutting and drilling medical devices used to create a small hole (burr hole) in a patient's skull so that a neurosurgeon can access the brain during certain procedures. These devices often include a clutch mechanism that is designed to automatically disengage or stop the tip from drilling once it has penetrated the patient's skull to prevent damage to the brain.

Purpose: The FDA is issuing this communication to remind neurosurgeons about the techniques for the safe use of cranial perforators with an automatic clutch mechanism to reduce the risk that these devices will fail to disengage or stop drilling.

Summary of Problem and Scope:

Most cranial perforators are designed to automatically stop drilling after penetrating the skull to prevent the tip from unintentionally drilling or "plunging" into the brain. However, this clutch mechanism may fail to disengage if proper use, patient considerations, and device selection are not followed in accordance with the manufacturer's instructions for use. The clinical consequences of cranial perforators failing to disengage can be serious. From January 2005 through August 2015, FDA received over 300 medical device reports (MDRs) associated with the use of cranial perforators with an automatic clutch mechanism failing to disengage, resulting in over 200 injuries. These injury reports describe patient injuries including perforation of the brain's protective covering just beneath the skull (dura mater), bleeding (hemorrhage), brain contusion, cerebral tissue damage, and decreased function of the brain (neurological deficit). The outcomes from these injuries have included seizures, damage to the portion of the brain responsible for language (aphasia), delayed/prolonged hospital stays, and the need for additional procedures.

The FDA analysis of currently available data suggests that failure to disengage is not specific to any manufacturer or brand of devices. The risk of these devices failing to disengage can be mitigated through proper use, patient considerations, and device selection in accordance with the device's instructions for use. Failing to follow the manufacturer's instructions for use can lead to the device not performing as expected, potentially placing patients at risk.

Recommendations

For Neurosurgeons:

- Review and follow the device labeling instructions for use for cranial perforators with an automatic clutch mechanism.
- Utilize correct techniques for cranial perforators with an automatic clutch mechanism including:
 - Select the appropriate cutting accessories based on the patient's skull thickness.
 - Hold the perforator perpendicular to the inner table of the skull at the point of penetration throughout the entire drilling procedure.
 - Do not rock, rotate, or change the angle of the device during drilling.
 - Avoid using excessive pressure when nearing the point of perforation to prevent penetration into the brain.
- Be cautious when using a cranial perforator with an automatic clutch mechanism if you:

- Perforate areas of the skull that have variations in bone contours and thickness such as the posterior fossa.
- Perforate the skull of infants, children, or elderly patients because of varying skull consistency and thickness of bone.
- Perforate a patient's skull if there is diseased or fragile bone or the possibility of adherent underlying dura mater.
- **Report** any adverse events associated with the use of cranial perforators with an automatic clutch mechanism to the FDA and the manufacturer.

FDA Actions:

The FDA will continue to monitor this issue and keep the public informed if significant new information becomes available.

Reporting Problems to the FDA:

Prompt reporting of adverse events can help the FDA identify and better understand the risks related to the use of medical devices. If you suspect or experience a problem with a cranial perforator, we encourage you to file a voluntary report through **MedWatch, the FDA Safety Information and Adverse Event Reporting program** (</Safety/MedWatch/HowToReport/ucm2007306.htm>). Health care personnel employed by facilities that are subject to **FDA's user facility reporting requirements** (</MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/ucm2005737.htm>) should follow the reporting procedures established by their facilities.

Contact Information: If you have questions about this communication, please contact CDRH's Division of Industry Communication and Education (DICE) at DICE@fda.hhs.gov (<mailto:DICE@fda.hhs.gov>), 800-638-2041, or 301-796-7100.

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