

RISK ALERT

Dental Electric Handpieces: Dangerous Overheating

The U.S. Food and Drug Administration (FDA) has re-issued the agency's Public Health Notification regarding the potential for harm to patients as a result of overheating of dental electric handpieces. The FDA references an increasing number of complaints received since the first alert was published in December, 2007 as its reason for re-issuing the notice in September, 2010.

The issue

AC-powered handpieces, such as those used for drilling and cleaning teeth, have a tendency to overheat. The housing around the handpiece insulates the dentist from feeling any heat build-up generated by the equipment. Compounding the issue is patient numbness – the area of the patient's mouth being treated has been anesthetized. Complaints received by the FDA provide evidence of tissue injury/damage of which neither the dentist nor the patient was aware at the time of treatment. Injuries range from first-degree to third-degree burns (requiring reconstructive/plastic surgery, according to the FDA alert).

Unlike air-driven equipment that begins to operate "sluggishly" – a signal to the dentist that a burr has become dull or gears or bearings have become worn or clogged – electric handpieces deliver additional power to compensate for these deteriorating conditions. The harder the handpiece has to work, the greater the amount of heat that is generated due to this resistance.

The FDA has requested manufacturers of electric handpieces to "identify the root causes of the overheating hazard; determine if the handpiece labeling is understood by users and... consider risk mitigation steps such as design modification, the addition of an overheating alarm, warning labels, operator training to avoid overheating, or modified use of the handpieces."

Recommendations

In his 12/12/2007 notice to dentists, Daniel G. Schultz, MD, Director of the Center for Devices and Radiological Health at the FDA, outlined the following recommendations:

- Be vigilant about maintaining electric dental handpieces according to manufacturer's instructions.
- Verify with the manufacturer the appropriate routine service interval for your dental practice based on the actual use of your handpieces.
- Train personnel to properly clean and maintain the electric dental handpieces and to follow specific device maintenance requirements.
- Develop a method for tracking maintenance and routine service for each handpiece used.
- Do not use poorly maintained electric dental handpieces. ❖

This material is not to be construed as establishing professional practice standards or providing legal advice. Compliance with any of the recommendations contained herein in no way guarantees the fulfillment of your obligations as may be required by any local, state or federal laws, regulations or other requirements. Readers are advised to consult a qualified attorney or other professional regarding the information and issues discussed herein, and for advice pertaining to a specific situation. ❖

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