

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.



Dental Handpiece Sterilization

September 28, 1992

Dear Doctor:

This is to notify you that the Food and Drug Administration (FDA) recommends that reusable dental handpieces and related instruments (such as air/water syringes and ultrasonic scalers) be heat sterilized between each patient use. Handpieces that cannot be heat sterilized should be retrofitted to attain heat tolerance. Handpieces that cannot be retrofitted and thus not heat sterilized should not be used. Chemical disinfection is not recommended.

The Centers For Disease Control (CDC) fact sheet entitled "HIV Transmission in Dental Settings," issued May 15, 1992, states "CDC and the American Dental Association have always recommended that dental handpieces be autoclaved between each patient, but in the 1980's not all handpieces could physically withstand heat sterilization. Since 1989 CDC has recommended that those dental handpieces that cannot be autoclaved only be used until the practitioner can replace them with a handpiece that can be autoclaved. Components of all dental handpieces currently made in the U.S. are either heat-stable or can be replaced with components that are heat-stable."

The American Dental Association document entitled "Infection Control Recommendations for the Dental Office and the Dental Laboratory" published in a supplement to the August 1992 issue of *The Journal of the American Dental Association* states, "Although no documented cases of disease transmission have been associated with contaminated dental handpieces or prophylaxis angles, sterilization between patients with acceptable methods which assure internal as well as external sterility is recommended for these instruments." For the complete text of this document, refer to the supplement to the August 1992 issue of *The Journal of the American Dental Association*.

Sincerely yours,

A handwritten signature in cursive script that reads "James S. Benson".

James S. Benson
Director
Center for Devices and
Radiological Health