The Joint Commission

February 19, 2020

ALERT: IMMEDIATE ACTION REQUIRED

Re: Sterilization of Dental Instruments and Handpieces

ISSUE:
The ADA and CDC worked together in 2018 to clarify that dental healthcare personnel should only use FDA-cleared devices and should follow the validated device manufacturer's instructions for use for reprocessing (cleaning, lubricating, and/or sterilizing) these devices.

Despite this information, a review of Joint Commission survey data has identified either a lack of awareness of the requirements or misinterpretation of manufacturer's instructions — in addition to a lack of staff training and leadership oversight — related to the sterilization of dental devices. This has resulted in multiple declarations of an Immediate Threat to Health and Safety of patients.

Organizations have mistakenly used pre-programmed sterilization cycles (e.g., pouched, wrapped or handpiece cycles) that do not match the validated device sterilization parameters required by the manufacturer. For example, the handpiece cycle on the sterilizer was set for 132°C (270°F) for 6 minutes but the handpieces being sterilized require cycles of 270 °F for 15 minutes and 275°F for 10 minutes.

Even if the chemical indicator has changed, handpieces and instruments that have been processed using parameters that do not match the device manufacturer sterilizer parameters should not be considered sterile.

ACTION REQUIRED:
Organizations should immediately identify the handpiece manufacturer's sterilization parameters for *each* handpiece that is being reprocessed at their organization and compare it to the sterilizer cycle parameters that they are using to reprocess this device. This may require contacting each manufacturer to ensure that the organization had the most up-to-date information.

If cycle parameters do not match, the sterilizer may need to be reprogramed to match the necessary cycle parameters. If it is not possible to reprogram an existing sterilizer, organizations will need to either replace the handpiece to one with compatible parameters or replace the sterilizer to one that can achieve the required parameters.

Handpieces should not be used until they can be sterilized at the device manufacturer's validated parameters.

Health care organizations and providers that use dental handpieces should be aware that studies have demonstrated how internal components of air-driven low- and high-speed dental handpieces may become contaminated with patient material during use, and that retained patient material may then be expelled intraorally during subsequent uses. For this reason, if an organization has been improperly reprocessing dental handpieces or any other instruments requiring sterilization using sterilization parameters that do not match the device (e.g., handpiece) manufacturer instructions they should seek assistance from their local health department or state healthcare associated infection liaison for assistance in determining if any patient follow-up is indicated.