

Sirona Dental Systems GmbH • 64625 Bensheim

To all CEREC user

04/15/2018

Important warning in the latest version of the directions for use for CEREC AC / AF / AI with Omnicam

Dear Mr. / Ms. (Dr.),

As part of our proactive approach to risk management, we have incorporated a new warning in the directions for use of the CEREC AC /AF / AI with Omnicam. Since your safety and that of your patients and staff is paramount when using our medical products, we are bringing this retroactive notice to the attention of all existing active users.

On the Dentsply Sirona Portal, there is an update to your directions for use at the address manuals.sirona.com, which has been expanded with a warning in section 7.3. As with lots of other optical impression systems, the CEREC Omnicam uses pulsating light. In rare cases, pulsating light from a CEREC Omnicam may trigger epileptic seizures. For this reason, persons diagnosed with epilepsy are strongly urged to refrain from using the Omnicam. This characteristic prompts us to formulate the warning as follows:

WARNING

Danger of injury in the case of diagnosed epilepsy

Patients who have been diagnosed with epilepsy cannot be treated with the CEREC Omnicam.

Dentists and dental assistants who have been diagnosed with epilepsy cannot work with the CEREC Omnicam.

Dentsply Sirona has installed thousands of CEREC systems on the market which have generated millions of scans and restorations. Given such high rates of use, such incidents are possible even if extremely rare. Rest assured that the CEREC system meets the latest safety standards for a medical product and will continue to do so.

Yours sincerely,

Stefan Leopold
CAD/CAM Quality Management Manager

Christian Schwarze
CAD/CAM Product Management