CEREC® Omnicam Stainless Steel Sleeve
Proper Cleaning and Disinfection

Instructions For Use
with the CEREC Omnicam Stainless Steel Omnicam Sleeve ONLY. (Valid for USA Only)
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1.0 General Information

The CEREC® Omnicam is a very sensitive optical device and must therefore be handled with the utmost care. Protect the coated sapphire glass and the camera windows against scratches and clean them with a clean, lint-free cloth and ethanol (commercially available cleaning alcohol) whenever a film is noticed during imaging.

Dental healthcare providers are advised to select the cleaning and high-level disinfection process that complies with the proper reprocessing of a heat sensitive semi-critical device. An effective infection control program is practical, reasonable, and reproducible.

Dentsply Sirona has tested and recommends VoloWipes® Disinfecting/Deodorizing/Cleaning Wipes and Sporox® II Sterilizing & Disinfecting Solution for cleaning and high-level disinfection of the Omnicam stainless steel sleeve.

1.1 HLD (High-Level Disinfection) Kit Contents

Dentsply Sirona developed the PracticeProtect™ Care Kit for the CEREC Omnicam to assist the user in performing cleaning and high-level disinfection of the stainless steel sleeve. It is critical that the CEREC Omnicam user comply with proper federal and industry guidelines for the reprocessing of the device. The care kit contains VoloWipes Disinfecting/Deodorizing/Cleaning Wipes and Sporox II Sterilizing & Disinfecting Solution as well as a convenient soaking container system for the reprocessing of the stainless steel sleeve. Sporox II Solution should only be used on the stainless steel version of the sleeve. See General Information above.

1.2 Indications for Use

The Practice Protect Care kit for the CEREC Omnicam is intended for the manual cleaning and high-level disinfection of the stainless steel CEREC Omnicam sleeve only. The care kit is intended to be used by trained dental professionals only.

Stainless steel mirror sleeves are marked with the letters ST (see figure 1)

Never use Sporox II Sterilizing & Disinfecting Solution on the titanium-coated nickel silver sleeve.

1.3 Contraindications

Sporox II Solution should be used on the stainless steel sleeve only.

Visit the Dentsply Sirona online portal for Technical Documentation at www.sirona.com/manuals for additional information on dry heat sterilization, disposable sleeves and the high-level disinfection of the titanium-coated nickel silver sleeve.

1.4 Product Warnings

If the CEREC Omnicam is accidentally dropped, check to make sure that the camera windows and coated sapphire glass are not damaged. If the CEREC Omnicam has been damaged, it must not be used on patients. The CEREC Omnicam must be recalibrated.

NOTICE:

• DO NOT STERILIZE THE CEREC OMNICAM OR THE CAMERA CABLE!
• THE MIRROR SLEEVES ARE NOT STEAM STERILIZABLE!

1.5 Precautions

The PracticeProtect Care kit for the CEREC Omnicam is intended for the manual cleaning and high-level disinfection of the stainless steel Omnicam sleeve only. Sporox II Sterilizing & Disinfecting Solution cannot be used on the titanium-coated nickel silver alloy sleeve.

Before using this product, carefully read and follow all instructions and save them for future reference. Observe all precautions and warnings.

As with all dental procedures, use proper personal protection equipment (i.e. wear face mask, eyewear or face shield, gloves and protective gown.) Consult the reprocessing instructions for special recommendations.
1.6 Adverse Reactions
Keep out of reach of children
Sporox II Sterilizing & Disinfecting Solution is corrosive to eyes. Due to corrosive nature, Sporox II Sterilizing & Disinfecting Solution may be harmful or fatal if swallowed. Do not get in eyes, on skin or clothing. Consult the Instructions for Use for the Sporox II Sterilizing & Disinfecting Solution for complete information and instructions.

2.0 CEREC Omnicam Components

2.1 Removal and Refitting of the Stainless Steel Sleeve

Removal
If required to remove the mirror sleeve, do the following:
1. Press the mirror sleeve against the camera body.
2. With the end of your finger or thumb, press detent marked A above.

NOTICE: THERE IS A RISK OF DAMAGING THE CAMERA WINDOWS OR THE COATED SAPPHIRE GLASS IF THE MIRROR SLEEVE IS NOT PULL STRAIGHT TOWARD THE FRONT. PULL THE MIRROR SLEEVE STRAIGHT TOWARD THE FRONT – DO NOT TILT.
3. Pull off the mirror sleeve.

Refitting

NOTICE: THERE IS A RISK OF DAMAGING THE CAMERA WINDOWS OR THE COATED SAPPHIRE GLASS, IF THE MIRROR SLEEVE IS NOT PUSHED STRAIGHT TOWARD THE CAMERA BODY. THE MIRROR SLEEVE MUST NOT COME INTO CONTACT WITH THE CAMERA WINDOWS. PUSH THE MIRROR SLEEVE STRAIGHT TOWARD THE CAMERA BODY – DO NOT TILT.
1. Carefully refit the mirror sleeve until it locks in place.

2.2 HLD Kit Set-up

Before you fill the HLD Soaking Container, take the supplied expiration label and note the date the Sporox II Solution was added to the container. Write the expiration date on the second line which is 21 days after the solution was added. Affix the removable label to the base of the HLD Soaking Container supplied with the PracticeProtect Care Kit for the CEREC Omnicam. Don utility gloves and fill the container with Sporox II Solution to the max fill line. To assemble the sleeve holder, gently slide the rubber stopper into the base of the sleeve holder.

• It is recommended that the stainless steel sleeve and camera be reprocessed as soon as it is reasonably practical following use.
• Replace the label with a new label each time the Sporox II Solution is changed.
• Prior to each use, you should test the Sporox II Solution to ensure the concentration of the active ingredient - Hydrogen Peroxide - is above the minimum effective concentration by using the Sporox II Test Vials. Consult the quick start guide that comes with the test vials for proper use. (Dentsply Sirona Part #75195).
• One 8 fl. oz. bottle of Sporox II Solution will fill the HLD container to just below the max fill line. This is acceptable.
## 3.0 Instructions for Reprocessing of the CEREC Omnicam Stainless Steel Sleeve

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| **Cleaning; Manual** | • Immediately after use, and prior to removing the sleeve from the camera, don utility gloves, and remove all visible soil by wiping the entire surface of the sleeve using fresh VoloWipes Disinfecting/Deodorizing/Cleaning Wipes. Pay special attention to all seams and crevices.  
• Using a lint-free cloth dampened with water of drinking quality, wipe down the sleeve for 30 seconds to remove any residual cleaning agent.  
• Take a new dry lint-free cloth and dry the sleeve  
• If visible soil remains, repeat the above three steps.  
• Remove the sleeve from the camera by pressing your thumb into the slot on the underside of the sleeve and gently pulling on the sleeve until it is free of the camera body.  
• Place the supplied protective cap over the end of the Omnicam Camera body and place the camera in its cradle to prevent damage. | • Never use a brush to remove debris as this may damage the sapphire glass.  
• Never allow liquid to enter the inside of the sleeve.  
• Dentsply Sirona recommends the use of VoloWipes Disinfecting Wipes which have been tested for use on the CEREC Omnicam Stainless Steel Sleeve. |
| **Cleaning; Automated** | Not applicable. | The CEREC Omnicam Stainless Steel Sleeve cannot be cleaned with an automated method. |
| **High-Level Disinfection** | • Press the stainless steel sleeve onto the rubber stopper attached to the sleeve holder until it is firmly seated.  
• Using utility gloves, wipe the upper handle portion of the sleeve holder with a VoloWipes Disinfecting Wipe.  
• Lower the sleeve and holder into the HLD soaking container filled with Sporox II Solution making sure the sleeve is completely submerged in the Sporox II Solution.  
• Place cap on container and wipe the cap with a VoloWipes Disinfecting Wipe.  
• Allow the mirror sleeve to remain submerged for 30 minutes to high-level disinfect.  
• After 30 minutes, remove the cap and lift the sleeve holder from the Sporox II Solution.  
• Replace the lid.  
• Holding the sleeve holder handle, rinse the sleeve under running water of drinking quality for 30 seconds.  
• Once fully rinsed, remove the sleeve from the holder by pressing down on the handle of the sleeve holder and gently pulling up on the sleeve.  
• Dry the external surface and lower part of the inner surface of the sleeve using a clean, lint-free cloth.  
• Store the mirror sleeve in a manner to protect it from contamination until time of use. | • Prior to each use, you should test the Sporox II Solution to ensure the concentration of the active ingredient – hydrogen peroxide – is above the minimum effective concentration by using the Sporox II Test Vials. Consult the quick start guide that comes with the test vials for proper use  
• Use Sporox II Solution only on the stainless steel sleeve. Look for “ST” on base of sleeve indicating a stainless steel version.  
• Always keep the HLD soaking container, which contains Sporox II Solution, covered when not in use.  
• Keep the sleeve vertical. Take care that the liquid does not get into the inside of the sleeve.  
• Consult the Sporox II Solution Instructions for Use for detailed information on the Sporox II Solution. |
| **Sterilization** | Not required. As a semi-critical device, sterilization is not applicable if manual cleaning is followed by high-level disinfection using Sporox II Solution. | • Never steam sterilize the CEREC Omnicam Stainless Steel Sleeve.  
• Consult the CEREC Acquisition Center manual for instructions on the use of dry heat sterilization. |