

Essential Dental Systems, Inc.

Information for the processing of resterilizable medical devices in accordance with EN ISO 17664.

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Products: Mouth Mirrors as well as Handles made of stainless steel

WARNING NOTICE:	<p>The standard Accident Prevention Regulations, valid in your country must be observed</p> <p>No warnings are known to us if the instructions for use of the devices and the disinfection and cleaning solutions are followed.</p> <p>The mirror glass can break if used improperly, for example when excessive pressure is applied to the glass.</p> <p>Glass has another expansion coefficient as stainless steel. Therefore in case of unusual rapid and high changes in temperature in the sterilization device can result into pressure of the casing to the mirror, This pressure cause tension in the glass, which can make the glass crack. Therefore do not sterilize with "Quick Sterilization Programs"</p> <p>Pick out cracked mirror parts using suitable aids (possibly forceps, vacuum cleaner). Ensure suitable protection against pieces of broken glass – danger of injury and infection.</p> <p>Observe the point "Control and functional test" on page 3 also prior to first use.</p>
Limiting the number of reprocessing cycles:	<p>Repeated processing has minimal effect on the performance of these instruments. The end of a product's service life is therefore determined by wear and tear and by damage due to use, such as scratches caused by mechanical cleaning (e.g. by hard brushes), damage caused by rotating instruments and/or calciferous residues (e.g. if the decalcification of the thermal disinfectant is not correctly adjusted) impair the mirror quality. Thus end of a product's service life varies and is therefore to be determined by the user.</p>

INSTRUCTIONS

The methods described are of a general nature and are well known and are based on standard equipment and consumables.

Work station:	Instruments must be reprocessed only in the rooms/areas designated for this.
Storage + transport	Instruments must be stored and transported in the rooms and containers designated by the practice. The instruments should be processed as soon as possible after use.

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<p>Preparation for decontamination:</p>	<p>Observe the standard instructions for instruments in your practice. No special preparations are required for mouth mirrors and handles.</p> <p>Since our mouth mirrors are also mounted on handles of other manufacturers or our handles are used on the mouth mirrors of other manufacturers, we recommend that mouth mirrors and handles are disassembled for processing. However normally the unit (the mouth mirror mounted on the handle) is processed in the practice.</p>
<p>Cleaning: automatic</p>	<p>Washer (Thermo Disinfector)</p> <p><i>C-MOR mirror is a combination of Tantalpentoxid TaO5 and Siliciumdioxid SiO2 layers. C-MOR is also acid resistant, but during the high temperature of sterilization calciferous residues are bonded firmly into these layers.</i></p> <p>Use the treatment chemicals recommended by the manufacturer of the device. Select a cleaning program recommended by the manufacturer of the device for mouth mirrors.</p> <p>On completion of the cycle inspect the mouth mirror for visible contamination / residues. If necessary repeat the cleaning cycle and/or clean manually.</p> <p><i>NOTE: If the decalcification of the thermal disinfector is not correctly adjusted, calciferous residues impair the mirror quality. Calciferous residues on the instrument leave behind white deposits or watermarks.</i></p>
<p>Cleaning: manual</p>	<p>Disinfect instruments prior to manual cleaning. Cleaning aid: for example soft brushes Treatment chemicals: All cleaning solutions which recommend use for mouth mirrors in their instructions for use.</p> <p>Clean the mouth mirror in accordance with the instructions for use of the selected treatment chemical. On completion of cleaning, <i>rinse with fully demineralised (desalinated, deionised) water, to avoid for example calciferous residues on the instrument, which leave behind white deposits or watermarks.</i></p>
<p>Disinfection:</p>	<p>1. Washer (Thermo Disinfector): please see under "Cleaning automatic"</p> <p>2. The mouth mirror can be disinfected with all disinfectants which recommend use for mouth mirrors in their instructions for use. Also use the aids recommended therein. However, do not use and mechanical / abrasive aids, as these would scratch the mirror. On completion of disinfection, <i>rinse with fully demineralised (desalinated, deionised) water, to avoid for example calciferous residues on the instrument, which leave behind white deposits or watermarks.</i></p>

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	If tap water is used for rinsing, drying can leave white calciferous deposits and/or water spots on the mirror.
Drying:	Dry the mouth mirror with the aids and/or equipment provided for this in the practice. Only absolutely dry instruments must be placed in the sterilizer, in order to avoid for example calciferous deposits and/or water spots.
Servicing	The product does not have to be serviced.
Control and functional test:	<p>Visual examination for defects, damage and wear and tear. For better visual examination a device with optical magnification is recommended, for example a magnifying glass. Discard faulty and/or defective instruments, for example:</p> <p>instruments with</p> <ul style="list-style-type: none">- rough and/or protruding corners, edges- with defects in the mirror glass, e.g. cracks, nicks on the edge- weaken welding of stem to casing <p>Check that the mouth mirror is sitting firmly in the handle, twist to tighten if necessary.</p>
Packaging:	Use standardised suitable packaging material. The packaging must be large enough to ensure that there is no pressure on the seal.
Sterilisation:	<p>Equipment: Steam sterilizer</p> <p>Method: Steam sterilization using a fractionated vacuum process at 134° C in a device in accordance with EN 13060:</p> <p>Observe EN 17665 for moist heat sterilization.</p> <p>In order to prevent staining and corrosion, the steam must be free of particles. When several instruments are sterilized, the maximum capacity of the sterilizer must not be exceeded.</p> <p>Follow the instructions for use of the device manufacturer of the steam sterilizer.</p>
Storage:	The packaging of the sterile items in foils must protect from dust, moisture and recontamination during transport and storage.
Additional information:	Ensure that the maximum load of the devices is not exceeded.

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Manufacturer's contact details:	Essential Dental Systems, Inc. 89 Leuning Street South Hackensack, New Jersey 07606 USA Phone: 201-487-9090 Fax: 201-487-5120 Email: info@edsdental.com
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The instructions presented above have been validated as suitable by the manufacturer of the medical device for the reconditioning of that device for reuse. The person performing the reconditioning of the device is responsible for ensuring that the reconditioning, actually performed in the practice, produces the desired results using the above mentioned procedure. This normally requires validation and continuous monitoring of the process.

Any deviation from the instructions detailed above should be carefully evaluated by the practice safety officer to ensure effectiveness and prevent any potential adverse consequences.

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