




**Important instruction for use  
and reprocessing of sterilisable  
medical devices :  
Silicone mouth props**

**CE**

Procedure	Mechanical, within the cleaning and disinfection apparatus (RDG)
Products	Silicone mouth props One-piece instrument without hinges, screws or rivets or disassemblable instruments
Intended use	Silicone mouth props may only be used for their intended purpose in specialist medical fields by properly trained, qualified personnel. The attending doctor or operator is responsible for the selection of the mouth prop.
WARNINGS	<p>Improper handling and care of the mouth props and their misuse or alteration may result in damage to or failure of the mouth props, which could result in serious injury or death to the patient. Upon receipt, check the mouth prop for possible transport damage and proper functioning.</p> <p>Silicone mouth props are non-sterile on delivery and must be cleaned and sterilised by the operator before use.</p> <p>Treat all instruments with the necessary care. Every instrument should be checked visually before each use. Check in particular for cracks, fractures and deformation.</p> <p>Mouth props must be secured by the user in such a way that swallowing or aspiration is ruled out.</p> <p>There is the possibility of a higher risk of infection if the products are used on patients suspected of having a prion disease (e.g. Creutzfeldt-Jakob disease). In such a case it is at the discretion of the doctor either to dispose of the product or reprocess it in accordance with the national regulations.</p>
Restriction of reprocessing	<p>Due to the product design and the used materials, no defined limit of maximal realizable cycles for the treatment can be settled. The durability of the medical devices will be defined by its function and a gentle handling.</p> <p>Defective products must have undergone the entire reprocessing process before being returned for repair.</p>

INSTRUCTIONS for the reprocessing	
Preparation on the place of action	<p>Immediately after use, remove visible residues from the instruments as completely as possible with a lint-free cloth or disposable cloth.</p> <p>Do not use metal brushes or other surface-damaging abrasives for cleaning.</p> <p>Do not use fixed solutions or hot water (&gt; 40°C), which can cause residues and influence the success of the cleaning.</p> <p>For further detailed information on hygienically safe and material-friendly/value-preserving reprocessing, see <a href="http://www.a-k-i.org">www.a-k-i.org</a>, publications section Red brochure - Reprocessing of instruments to retain value.</p>
Storage and transport	Standard-compliant packing of instruments for sterilization (recommendation)
Preparation for cleaning	Inspect the mouth props for damage (such as deformations, porous spots, cracks), sort out damaged mouth props.
Pre-cleaning	Immediately after application, remove abrasive dirt from the mouth props with a disposable cleaning cloth / paper towel. Do not use fixed solutions or hot water (>40°C), which can cause residues and influence the success of the cleaning.
Cleaning: automatically	Only use cleansers suitable for synthetic/plastic according to the instructions of the respective manufacturer. Remove cleanser thoroughly under running water. Do not exceed 93°C for mechanical cleaning.
Disinfection	Only use disinfecting solution suitable for synthetic material, carefully following the instructions of the respective manufacturer. Remove cleanser thoroughly under running water. Do not exceed 93°C for mechanical cleaning.

Drying	Drying of the outside of the instruments through the drying cycle of the washer-disinfector (Miele G 7736 CD). If necessary, manual drying can also be achieved using a lint-free cloth or disposable cloth. Cavities of instruments can be dehydrated with sterile blast.
Maintenance	No special measures needed
Control and functional check	Visual inspection and functional test (cleanliness, damage, no notches). Check mouth props for cleanliness. Worn, deformed, porous or otherwise damaged mouth props must be sorted out. If necessary, repeat the reprocessing process until the mouth prop is visually clean.
Packing	For the sterilisation you have to pack the instruments in packaging according to ISO 11607 and EN 868 standards.
Sterilisation	Silicone Mouth Props may be sterilized by all cold sterilization techniques, Ethylene OXIDE (ETO), steam autoclave or chemoclave, dry heat or "Quick" dry heat up to 500°F or 260°C.
Storage	Storage of the sterilised instruments in a dry, clean and dust-free environment, no storage nearby any chemical products. Avoid temperature fluctuations and direct sunlight. Storage at moderate temperatures from 5°C to 40°C.
Disposal	Observe your local and national laws, guidelines, standards and regulations for disposal and ensure that parts are not contaminated during disposal.
Exceptions	None
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We refer to our instructions which you can find in our catalogue respecting cleaning, sterilisation and care of the instruments. The instructions above have been validated by Kohler, based on the current version ISO 17664, for the preparation of a medical device for reuse as SUITABLE.

It is the responsibility of the processor to ensure that the treatment actually carried out with the equipment, materials and personnel used in the treatment facility achieves the desired results. This usually requires validation and routine monitoring of the process. Likewise, any deviation from the instructions provided by the preparer should be carefully evaluated for its effectiveness and possible adverse consequences.

Serious incidents related to the instrument must be reported to the manufacturer and authorities of the Member State where the user or the patient is established.