

INSTRUCTIONS FOR USE (IFU)

Information for the processing of resterilizable medical devices in accordance with EN ISO 17664:2017

Products: **SILICONE MOUTH PROPS, Sizes: Adult, Child, & Small Child**
Applicable to Items# SC-9040-7X, SC-9050-7X, SC-9060-7X

Indication For Use: It is a wedge shaped device used in dentistry for patients who have difficulty keeping their mouths wide open & steady during a dental procedure, esp. when patient is sedated. Silicone Mouth Props are autoclavable, chemiclavable, & can be “Quick” dry heat.

Warning Notice: No special requirements.

Limitation of Reprocessing: Repeated reprocessing has minimal effect on the performance, however, the end of a product’s service life is determined by wear & tear and damage due to going over the sterilization limit, or how the user uses it.

Storage and transport: No special requirements needed.

Packaging: 2 Pcs/Pk, 250 Boxes/Case.

Cleaning: Only use disinfecting solution suitable for synthetic/plastic material, carefully following the instructions of the respective manufacturer. Remove disinfecting solution thoroughly under running water. Don’t exceed 93°C for mechanical disinfection.

Sterilization for Silicone Mouth Props: The device may be sterilized by all cold sterilization techniques, Ethylene Oxide (ETO), steam autoclave or chemiclave up to 273°F or 134°C, chemiclave, and “Quick” dry heat up to 500°F or 260°C. Generally, these Mouth Props are capable of most normal infection method. However, since each machine unit varies, the exposure time and drying time for the disinfection procedure will vary. Therefore, the user should follow the instruction of the manufacturer that comes with the machine.

Control/Functional Check: Sight check on damages, wear, deformation.

The instructions have been validated as suitable for preparation of a medical device and its use by the medical device manufacturer. It is the processors’ responsibility that the process achieves the required result with the equipment and materials applied and personnel involved in the processing site. Furthermore, the processor should evaluate any deviation from the provided instructions regarding efficiency and possible adverse consequences.