JS-Gauge®
SleepLikeMe® Medical

PROCESSING METHOD

according to ISO 17664
for the medical device JS-Gauge®

2031-05-31 REF JS2.0 LOT 001 DE

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QTY: 1 EA JS-Gauge® https://js-gauge.com

MD 3D bite registration in dental sleep medicine

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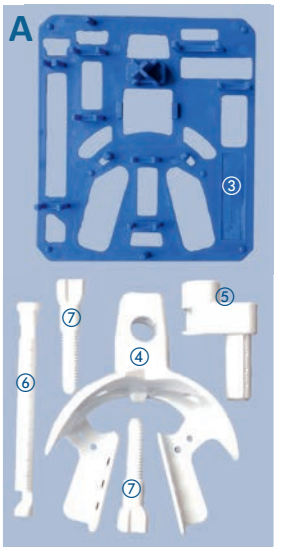
The medical device consists of a sterilisation-box (white), consisting of a lid (1) and base with perforation (2), washing-tray (3) (blue), and a bite fork consisting of 5 individual parts (4, 5, 6, 2 x 7).

Preparation at the point of use

WARNING! Hazard from non-sterile products. Max. 40 processings.

There is a risk of infection from contaminated medical devices.

- ➔ Take suitable personal protection measures.
- ➔ Disassemble the medical device into its individual parts (see Fig. A).
- ➔ Remove residues from the medical device, e.g. impression material or other contamination.



Cleaning: manual external cleaning

Required accessories:

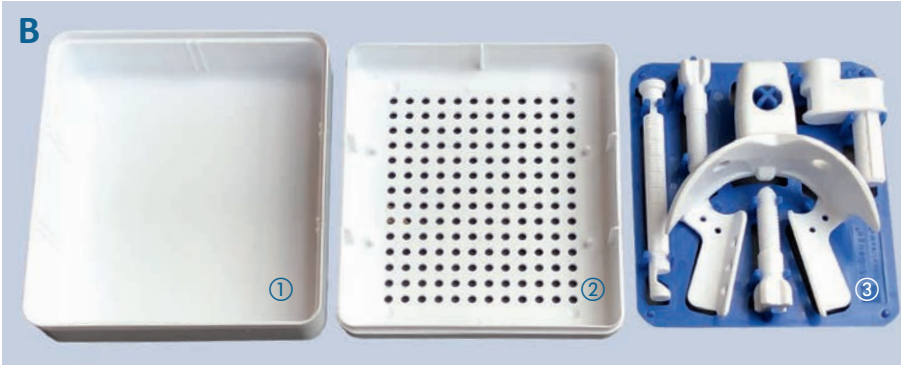
- ➔ drinking water 30 ° C ± 5 ° C (86 ° F ± 10 ° F),
- ➔ metal-free brush, e.g. medium-hard toothbrush,
- ➔ instrument, e.g. dental tweezers or comparable,
- ➔ cleaning cloth, e.g. Wet Wipes by Kleiser Medical.

Remove residues with instrument. Brush off under running drinking water. Remove markings with the cleaning cloth.

Cleaning: machine cleaning

The manufacturer (SleepLikeMe-medical GmbH & Co. KG) recommends thermal disinfection according to ISO 15883-1, eg Miele G 7781 / G 7881 (Validation was carried out with the “VARIO-TD” program, “ProCare Dent 10 MA” cleaning agent, “ProCare Dent 30 C „and rinse aid“ neodischer® Mielclear „and only refers to the material compatibility of the medical product).

- ➔ Refer to the thermal disinfectors instruction-manual for program settings, cleaning agents and disinfectants to be used.
- ➔ Position the five individual parts of the bite fork (4, 5, 6, two times 7) on the washing tray (3) (blue) (Fig. B). Arrange the medical device in an inclined position in the washing strainer in the thermal disinfector (Fig. C). The cover (1) and base (2) of the medical device point downwards.



Disinfection: machine disinfection

Attention! Malfunctions from using the disinfectant-bath or disinfectants containing chlorine. Defects in the product.

The manufacturer recommends thermal disinfectors in accordance with ISO 15883-1, eg Miele G 7781 / G 7881 (validation was carried out with the „VARIO-TD“ program, cleaning agent „ProCare Dent 10 MA“, neutralising agent „ProCare Dent 30 C“ and rinse aid „neodischer® Mielclear” and only relates to the material compatibility with the medical device).

- ➔ Refer to the thermal disinfector manual for program settings, cleaning agents and disinfectants to be used.

Drying: machine drying

As a general rule the drying process is part of the cleaning program of the thermal disinfector. Note: Please follow the instructions for use of the thermal disinfector.

maintenance

Functionality test: Assemble the bite fork from the 5 individual parts (see Fig. D), check the mobility and clamping ability of the two screws, check the mobility of the sliding and rotating connections. If necessary, replace non-functional individual parts and repeat the functionality test. Disassemble the functional bite fork into the five individual parts.

packaging

Note: The sterilisation-packaging must be large enough for the medical device so that the packaging is not under tension. The quality and application of the sterilisation-packaging must meet the applicable standards and be suitable for the sterilisation-process!

- ➔ Position the five individual parts of the bite fork on the washing tray, place the washing tray with the underside on the base of the sterilisation box, join the lid and base of the sterilisation box, and shrink-wrap it in sterile packaging (e.g. Euronda Sterilisation Roll Mat. No. 20410354) (see Fig. E).

sterilisation

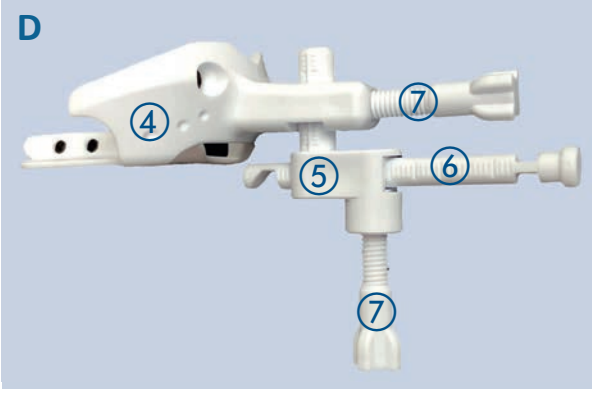
Sterilisation in a steam steriliser (autoclave) EN 13060 / ISO 17665-1. The medical device has a temperature resistance of at least-30 ° C (-22 ° F) to a maximum of 153 ° C (308 ° F). A suitable method (depending on the device) can be selected from the following gravitation methods.

- ➔ Autoclave with triple pre-vacuum, at least 4 minutes at 134 ° C ± 1 ° C (273 ° F ± 1.8 ° F).
- ➔ Autoclave with gravity method, at least 10 minutes at 134 ° C ± 1 ° C (273 ° F ± 1.8 ° F).
- ➔ Autoclave with gravitation process, at least 60 minutes at 121 ° C ± 1 ° C (250 ° F ± 1.8 ° F).

storage

Reconditioned medical device must be stored dust-proof in a dry room with as few germs as possible at-5 ° C (23 ° F) to a maximum of 40 ° C (104 ° F). Storage up to 6 months.

D



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