Instruction for use
Holder for occlusion test material
BK 132, BK 133, BK 142, BK 143, BK 144, BK 145

Manufacturer
Dr. Jean Bausch GmbH & Co. KG
Oskar-Schindler-Str. 4
50769 Cologne
Germany

Tel: +49 221 70936-0
Fax: +49 221 70936-66
E-mail: info@bauschdental.de
Internet: www.bauschdental.de

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1 General description and intended use of the medical device

The holder is an instrument used for applying occlusion test material within the oral cavity of patients.
The holder is sterilizable.

2 Notes

- The instrument can be sterilized with steam (moist heat, 134°C).
- The instrument must be disinfected, cleaned and sterilized prior to each use.
- Disposal: the instrument must be disposed of together with the normal contaminated practice waste.

3 Package contents

- 1 holder (self-locking tweezers BK 132, BK 133, BK 142, BK 144, BK 145) or
- 10 holders and 5 connectors (Fix-Clip BK 143)
- Instructions for use

4 Preparation

The instrument must be cleaned, disinfected and sterilized prior to each use; This applies particularly to the initial application after delivery, since the instrument is supplied non-sterile (cleaning and disinfecting after removal of the transport packaging. Sterilization after packaging). Please refer to the detailed specifications for reprocessing under point “6 Reconditioning”.

5 Use

- The instrument has to be removed from its sterile packaging in consideration of usual standards of practice hygiene (use of disposable gloves.)
- Clamp the occlusion test material (e.g., paper or film) into the holder so that it is located in the buccal area of the patient’s mouth (between cheek and teeth).
- Check the tight fit of the occlusion test material in the holder.
- With the holder in a buccal position, the occlusion test material is held between the relevant teeth of the upper and lower jaw.
- Perform the static or dynamic occlusion test.
- Subsequently remove the holder with the used occlusion test material from the mouth and dispose of together with the normal contaminated practice waste.
- Prepare the holder for reprocessing.

6 Reconditioning

Basically the following should be observed: "Requirements for hygiene in the processing of medical devices Recommendation of the Commission for hospital hygiene and infection prevention (KRINKO) at the Robert Koch Institute (RKI) and the Federal Institute for Drugs and Medical Devices (BfArM)". Bundesgesundheitsblatt 2012 -55: 1244-1310.

The Instrument must be reconditioned immediately after each treatment (within a maximum of 2 h):

- Thoroughly clean the holder by hand with a small brush with firm bristles.
- Note: The cleaning should be done in a water bowl without further additives below the water surface in order to achieve adequate cleaning of the Instrument parts whilst avoiding protein fixation as well as to protect the environment from contamination due to splash water.
- Intermediately rinse the holder with water (minimum drinking water quality).
- Place the parts in a standard cleaning and disinfecting bath. Examples:
  - Becht Premium Konzentrat
  - Dürr Dental ID 213 Instrumenten Desinfektion
  - Pluradent Instrumentenbad PluLine
  - Schülke & Mayr gigasept® instru AF
  - Quod vide: "List of disinfecting agents and methods tested and approved by the Robert Koch Institute" or disinfectant list VAH.
  - Note: Formaldehyde containing cleaning and disinfecting agents may only be used after sufficient cleaning in order to avoid protein fixation.
  - Note: The instructions for use of the manufacturer of the cleaning and disinfecting agent must be strictly observed. In particular, the concentrations to be used and the reaction times must be observed!
  - Note: For machine cleaning, the manufacturer's instructions for use must be followed carefully!
- Finally, rinse of the holder with water (minimum drinking water quality, recommended: demineralized water with microbiological quality according to drinking water).
- Dry.
- Visual inspection of corrosion, damaged surfaces, chipping, mold damage and impurities. Damaged Instruments must be discarded (For a limited restriction of reuse, see the chapter "Reusability"). If residual contamination still exists, the entire cleaning process must be repeated with all steps (Cleaning, intermediate rinsing, disinfection, final rinsing and drying).
- The holder must be free of any residue and dry before further processing.
- Maintenance of the holder is not required.

- The holder ha to be packed and sealed in a sufficiently large single sterilization bag according to EN 868-2 et seqq. ISO 11607 (suitable for steam sterilization). Observe the instructions of the manufacturers of the sterilization bags and the sealing machines and the current normative requirements.
- Sterilization must be carried out in a validated process with moist heat in an autoclave according to DIN EN 13060 Type B or DIN EN 285 resp. ANSI AAMI ST79. Observe the manufacturers operating instructions of the autoclave.
- Sterilize the holder with humid heat (saturated water vapor) using a pre-vacuum procedure for 5 minutes at 134°C.
- After sterilization the holder must be stored dry and dust-free in the closed sterilization package.
- The recommended storage life for sterile medical devices is described in standard DIN 58953-8 and depends on external influences and effects during storage, transport and handling.

7 Reusability

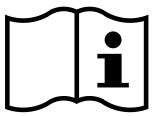
Frequent reconditioning has no effect or restriction on this instrument, since the end of the product life is determined by wear and damage caused by use.

The use of damaged and soiled instruments is the responsibility of the user.
In case of non-compliance with these instructions for use, any liability is excluded.

8 Symbols

Manufacturer

Sterilise in a steam steriliser with saturated steam (autoclave) at 134°C



Follow instructions for use