Instructions for Use
Holder for occlusion test materials
BK 132, BK 133, BK 142, BK 143, BK 144, BK 145

Manufacturer
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1 General description and intended use of the medical device

The holder is an instrument made of stainless steel or plastic for the application of occlusion test materials in the oral cavity of the patient.
The holder is sterilizable.
For professional use only.

Indication
The holders serve as testing aids for the application of articulating papers and occlusion test foils. They can be used by dentists in the patient's mouth or on models, as well as by the dental technicians in the laboratory.

Contraindication
No known contraindications.

Side effects
Possible side effects may be specific allergic reactions. However, given the product's history, there has not been a verified documented report of allergic reactions. Side effects or interactions may occur if the products are used with new, unknown products or materials.

2 Notes

- Before each use the holder (instrument) has to be cleaned, disinfected and sterilized.
- The instrument can be steam-sterilized (humid heat, 134°C).
- The instrument can be used in combination with articulating paper or occlusion test foils, produced by Dr. Jean Bausch GmbH & Co. KG.
- The holders BK 132 BK 133, BK 142 und BK 144 can also be used together with the accessory BK 146 (Arti-Grip™).
- Disposal: The instrument should be disposed of with the usual contaminated practice waste.

3 Package content

- 1 Holder (clamping forceps BK 132, BK 133, BK 142, BK 144, BK 145) or
- 10 single holders and 5 connectors (Fix-Clip BK 143)
- Instructions for Use

4 Preparation

The Instrument must be cleaned, disinfected and sterilized before each use. This also applies in particular to the initial application after delivery, since the instrument is delivered non-sterile. Please refer to the detailed requirements for reprocessing, described in section 6 Reprocessing.

5 Application

- Remove the instrument from the packaging in accordance with standard practice hygiene (use of disposable gloves).
- Clamp the occlusion test material (e.g. paper or foil) into the holder so that it is buccally (between cheek and tooth) in the patient's mouth during use.
- Check that the occlusion test material is firmly seated in the holder.
- Use the holder to hold the occlusion test material buccally between the respective teeth of the upper and lower jaw.
- The static or dynamic occlusion test is being performed.
- After completion of the occlusion test, remove the holder with the occlusion test material from the mouth and dispose of the used material with the normal, contaminated practice waste.
- Prepare the holder for reprocessing.

6 Reprocessing

In principle, the following should be followed: "Hygiene requirements for 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)," Federal Health Bulletin 2012 • 55:1244-1310.

The instruments must be reprocessed immediately after each treatment (within a maximum of 2 hours):

- Thoroughly clean the instruments by hand, using an appropriate small brush with firm bristles.
- Note: The cleaning should be carried out in a water bath, without any additional cleaning agent, below the water surface, to achieve a sufficient cleaning of the instruments and to avoid protein fixation as well as to protect the environment against contamination with splashed water.
- Rinse the instruments with water (at least drinking water quality).
- Place the parts in a practice-customary cleaning and disinfecting bath. Examples:
  - Becht Bechtol Futura
  - Dürr Dental ID 213 instrument disinfection
  - Pluradent Pluline instrument bath
  - Schülke & Mayr gigasept® instru AF
  - Note: "List of disinfectants and disinfecting procedures tested and approved by the Robert Koch Institute" or the VAH list of disinfectants.
  - Note: To prevent protein fixation, formaldehyde-containing cleaning agents and disinfectants may be used only after adequate cleaning.
  - Note: Strictly follow the instructions provided by the manufacturer of the cleaning agent or disinfectant. In particular, always follow the required concentration and residence time!
  - Note: In case of automatic cleaning, the manufacturer's instructions have to be followed strictly!
- Final lavage of the instruments with water (at least drinking water quality, recommendable: demineralized water with microbiological quality equal to drinking water)
- Drying.
- Visual check for corrosion, damaged surfaces, chipping, damage to shape and contamination. Damaged instruments shall be discarded (limited number of reconditioning cycles see Section “Reusability”). In case of residual contamination, the entire cleaning procedure with all stages shall be repeated (cleaning, intermittent rinsing, disinfection, final rinsing and drying).
- The instrument and all parts must be free of any residue and dry before further preparation.
- The instrument does not require servicing.
- All parts of the instrument should be packed and sealed in adequately sized, single-use sterilization bags that comply with EN 868-2ff ISO 11607 (suitable for steam sterilization). Follow the instructions of the manufacturer of the sterilization bags and sealing machines and the current standard requirements.
- Sterilization must be completed in a validated procedure using moist heat in an autoclave in accordance with DIN EN 13060 Type B and DIN EN 285 and ANSI AAMI ST79. Follow the instructions for use of the autoclave manufacturer.
- Sterilize the instrument using moist heat (saturated steam) and a pre-vacuum procedure for **5 minutes at 134°C**.
- After completion of sterilization, the instrument parts must be stored dry and dust-free in the sealed sterilization packaging.
- The recommended storage period for sterile medical products is described in Standard DIN 58953-8 and depends on external influences and effects during storage, transport and handling.

7 Reusability

Frequent reconditioning does not have any effect or limit on the use of the instrument, as the end of the product lifetime is determined by wear and damage due to use.

The use of damaged or soiled instruments is the responsibility of the user.

In case of non-compliance, all liability is excluded.

8 Disposal Instructions

Before disposing of the instrument, it has to be to be sterilized or disposed of with the normal contaminated practice waste.

9 Notification of Incidents

Serious adverse events occurring in connection with the product must be reported to the manufacturer and the competent authority of the Member State.

10 Symbols

Manufacturer

Production Date

Steam sterilizable with saturated steam (autoclaving) at 134°C

„Follow manufacturers instructions“

Reference number

Unique Device Identifier

Conformity with the relevant EU regulations