Instructions for Use
Arti-Grip™ Silicone sleeves for Arti-Fol®-Forceps
BK 146

Manufacturer
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1 General description and purpose of the medical device

Sterilizable, flexible blue silicone sleeves of 45 mm length with an outer diameter of 4.5 mm.
For professional use only.

Indication
Arti-Grip™ sleeves are used to improve the clamping force of Arti-Fol® forceps („Miller"-forceps). The silicone sleeves, pre-cut in 45 mm length, are pulled over one or both clamping surfaces of "Miller" forceps. The slightly adhesive surface of the silicone sleeves results in a stronger clamping effect. Thin occlusion foils and Shimstock foils are thus held securely. Dentists can use the Arti-Grip™ -sleeves, in the patient´s mouth as well as on models. Arti-Grip™-sleeves can also be used 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 Arti-Grip™-sleeves must be removed from the clamping surfaces of the forceps and subsequently must be cleaned, disinfected and sterilized.
- The Arti-Grip™-sleeves can be steam-sterilized (humid heat, 134°C).
- Arti-Grip™-sleeves can be used together with Arti-Fol®-forceps BK 132, BK 133, BK 142 and BK 144 and Arti-Fol® metallic, Shimstock-film.
- Disposal: before disposing Arti-Grip™-Silicone sleeves, they either have to be sterilized or disposed of with the normal contaminated practice waste.

3 Package content

- 20 pieces Silicone sleeves Arti-Grip™ (non-sterile)
- Instructions for Use

4 Preparation

Arti-Grip™-Silicone sleeves 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

- The Arti-Grip™-sleeves are removed from the packaging in accordance with standard practice hygiene (use of disposable gloves).
- The sleeves should first be moistened with medical alcohol (ethanol or isopropyl alcohol, min. 70%), in order to facilitate to pull them more easily onto the clamping surfaces of the forceps.
- Subsequently, a strip of occlusion testing material (paper or foil) is clamped between the clamping surfaces of the forceps.
- The occlusion test material is inserted (buccal), with the aid of the forceps, between the respective teeth of the upper and lower jaw.
- The static or dynamic occlusion test is being performed.
- The occlusion test material is removed from the mouth and disposed of with the contaminated, normal practice waste.
- The silicone sleeves are removed from the clamping surfaces of the forceps.
- The forceps and the silicone sleeves are prepared 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 Arti-Grip™-Silicone sleeves must be reprocessed immediately after each treatment (within a maximum of 2 hours):

- Thoroughly clean the Silicone sleeves by hand, using an appropriate small brush with firm bristles. The Silicone sleeves „Arti-Grip“ must also be cleaned from the inside, using a suitable tool.
- 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 Arti-Grip™-Silicone sleeves 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 Arti-Grip™-Silicone sleeves 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 sleeves 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 Silicone sleeves must be free of any residue and dry before further preparation.
- Silicone sleeves do not require servicing.
- Silicone sleeves 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 Silicone sleeves 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 Arti-Grip™-Silicone sleeves, 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 Arti-Grip™-Silicone sleeves, they either have 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 manufacturer's instructions"

Reference number

Unique Device Identifier

Conformity with the relevant EU regulations