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roeko ADAPTER, DOUBLE ADAPTER

Instructions for use **EN**

Carefully read the instructions prior to use.

1. PRODUCT DESCRIPTION
Round plastic parts with a centered hole for connection of aspirator tips with either 6,5 mm or 11 mm end opening to suction machines of either 11 mm or 16 mm connection. Adapter and Double Adapter can be reprocessed.

2. INTENDED USE
Adapters are intended to connect aspiration cannulas to the suction machine of the dental unit.

3. COMPOSITION
The adapters are made of polypropylene.

4. INDICATION
Liquid control through aspiration during dental treatments.

5. CONTRAINDICATIONS
N/A

6. SAFETY INSTRUCTIONS
N/A

7. SIDE EFFECTS/INTERACTIONS
No reciprocal or side effects for this device.

8. USER/PATIENT GROUP
The user group are dentists and dental assistants. The adapters are suitable for all patient groups.

9. PREPARATION
The Adapters must be reprocessed before any application according to the reprocessing instructions (see paragraph 12). The Double Adapter must always be disassembled into the two single adapters for reprocessing.

10. PROPER USE
The device enables the connection of aspiration cannulas with the suction machine of the dental unit.

11. TEST METHOD FOR CORRECT APPLICATION
N/A

12. REPROCESSING, CLEANING, DISINFECTION, MAINTENANCE

Risk assessment/classification recommendation:
As there is only contact with intact skin, it is recommended that the adapters or double adapters be classified as non-critical medical devices.

The following reprocessing measures are recommended: mechanical cleaning in combination with thermal disinfection (WD) and steam sterilisation before use.

Warnings:
During reprocessing, there is a risk of transmitting pathogens via blood and tissue residues. Suitable protective equipment (gloves, face mask, goggles) is absolutely essential.

Processing limitations
Due to the product design and the materials used, no definite limit to the maximum number of performable reprocessing cycles can be specified. The service life of the medical devices is determined by their function and careful handling. If the products show visible changes in material or shape after reprocessing or if their functionality is restricted, the products may no longer be used. The number of times a product can be reused depends on its reprocessing and handling. The condition of the products should always be verified before and after every use.

Pretreatment on site:
Remove general soiling from the products directly after application. Do not use fixating agents or hot water (>40°C), as this causes fixation of residues and can impair successful cleaning. In order to avoid contamination drying on, soak the used products in a disinfectant bath.

Transport:
Safe storage in a closed container and transport of the products to the processing location, in order to avoid damage to the products and environmental contamination.

Preparation before cleaning:
No particular requirements.

Mechanical cleaning and disinfection in the washer/disinfector Machine:
Use of a washer-disinfector (WD) in accordance with ISO 15883-1 and -2 (medical device Class II B according to 93/42/EEC).

Carrier for items to be washed:
The single adapters need to be placed on injector nozzles for cleaning hollow instruments. The use of a cover net is recommended so that the products do not fall off the injector nozzle during cleaning.

Process chemicals:
Alkaline detergent (medical device according to Directive 93/42/EEC).

Cycle:
Cycle parameters as specified by the device manufacturer. A typical cycle consists of
- Rinsing stage (< 45 °C to avoid protein coagulation)
- Cleaning stage (e.g. 55 °C - according to instructions for the detergent)
- Rinsing stage (if required)
- Thermal disinfection
- Drying

Manual cleaning and disinfection in an ultrasonic apparatus:
For cleaning the products in the ultrasonic apparatus, put the products in a beaker filled with the cleaning liquid, place in the ultrasonic apparatus filled with a suitable contact liquid and start the ultrasonic cleaning process.
1. Main cleaning process at 25 °C with an alkaline disinfectant cleaner (medical device according to Directive 93/42/EEC; concentration and application according to manufacturer's specifications)
2. Generous manual rinsing under running water (reverse osmosis water)

Manual disinfection:
If a disinfectant cleaner is not available for manual cleaning, separate disinfection must be performed after cleaning by placing in a suitable disinfectant (observe the instructions for use of the disinfectant with regard to effective concentration and exposure time). Then rinse thoroughly with reverse osmosis water and dry.

Manual drying:
Drying with low-germ / sterile filtered compressed air.

Inspection and maintenance:
Cleaning inspection:
Visual inspection for cleanliness. If necessary, repeat the reprocessing procedure until the product is visually clean.
Functional inspection:
No particular requirements

Packaging:
Standardised packaging of products for sterilisation according to ISO 11607 and EN 868.

Sterilisation:
Equipment: Steam steriliser according to EN 285 or EN 13060; Cycle B (Declaration of conformity as a medical device according to 93/42/EEC). Fractionated vacuum process; at least 3 minutes at 134 °C and subsequent drying.

Storage:
The above instructions were validated by the manufacturer of the medical device as being suitable for the preparation of a medical device for its reprocessing. The reprocessor is responsible for ensuring that the actual reprocessing with the equipment, materials and personnel employed in the reprocessing plant delivers the desired results. This re-quires verification and/or validation and routine monitoring of the process.

13. SINGLE USE DEVICE
N/A

14. SHELF LIFE AND STORAGE
See storage symbols on the packaging.

15. DISPOSAL
The Adapter/ Double Adapter can be disposed with the practice waste unless local requirements define otherwise.

16. TECHNICAL DATA
N/A

17. REPORTING OBLIGATION
All serious incidents occurring in conjunction with the product must be reported to the manufacturer and to the competent authority of the member state where the user and/or patient is registered.

Glossary


Consult instructions for use


Conformity mark Ukraine


Manufacturer

Batch Code

Restricted device for professional use only

Medical Device


Date of manufcature

Non-sterile

Catalogue Number

Made in Germany

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