CE 0482

Preparation Instructions
Adaption Set

MED CERT EN ISO 13485

Dr. Arabin GmbH & Co KG Alfred-Herrhausen-Str. 44, D-58455 Witten
Tel: +49 2302 189214 www.dr-arabin.de info@dr-arabin.de

The reprocessing, cleaning, disinfection and sterilization of the rings of the fitting set was performed by a certified laboratory (Hygcen) conforming to EN ISO 17664
(see "downloads" : www.dr-arabin.de)
Test No.: 2019-1205 2019-1206 2019-1207 dated 06.05.2019 Test product: Fitting ring set (4 rings without inner wire), SET R LARGE, batch: K 27/18/1 Fitting ring set (4 rings without inner wire), SET R MEDIUM, batch: K 32/19/1
Accordingly, we have presented the most important steps in conformity with Table B1 of the standard EN ISO 17665 - 2018

WARNINGS	After the end of a fitting, clean and disinfect all parts that have get into contact with a patient Store without direct contact with reactive media such as gas, ozone or mineral oil or radioactive radiation. Do not handle by force.
Limitation during reprocessing	Only use cleaning agents/disinfectants approved for reprocessing medical devices. Observe the manufacturer's instructions for the cleaning agents/disinfectants. Based on the manufacturer's current knowledge, the shelf life of the device might be limited primarily by the ability of the material to maintain its mechanical properties over time due to wear and sterilization cycles. There are no known product changes noted as a result of the reprocessing procedures listed below. Wear not excluded in case of very frequent use, do not use if damaged.
INSTRUCTIONS	
Initial local treatment	After removing the device from a patient, wipe the surface with gauze soaked in cleaning solution. Use a cleaning agent suitable for medical device reprocessing for this purpose.
Preparation for cleaning	The surface of the rings should be clean.

Mechanical cleaning and disinfection	Use an EN ISO 15883-1 and -2 compliant washer/disinfector (WD). For reprocessing in the WDG, the products can be placed in sieve trays. Follow the instructions for use provided by the equipment manufacturer of the washer/disinfector. The reprocessing was validated by the manufacturer in an EN ISO 15883 compliant washer-disinfector type Miele Professional PG8581 using program 2 Vario TD Dental with the following program parameters: Step 1 Pre-cleaning with cold tap water Step 2 Cleaning 0.5% detergent at 55°C for 5 minutes with demineralized water Step 3 Rinsing with demineralized water for 1 minute Step 4 Thermal disinfection with demineralized water at 93°C for 5 minutes The validation was carried out using the cleaner neodisher Medi® Clean Forte (Dr. Weigert).
Manual cleaning and disinfection	- Not scheduled
Drying	As part of the machine reprocessing program; if the products are not sufficiently dry after completion of the machine reprocessing, manual re-drying with a lint-free cloth or drying with medical compressed air is possible.
Maintenance, inspection and testing	Check for visible contamination and damage. If contamination is still visible, repeat the reprocessing.
Packaging	Within outpatient departments/clinics use packaging conforming to EN ISO11607 (e.g. paper-laminate film).
Sterilisation	It is recommended to use an EN ISO 17665 or EN 285 compliant sterilizer. Validation was performed using a fractionated pre-vacuum process at 134 °C with 5 minutes holding time. The sterilizer manufacturer's instructions for operation and load configuration should be followed explicitly. When sterilizing multiple instrument sets in one sterilization cycle, ensure that the maximum load of the sterilizer is not exceeded. When loading the sterilizer, ensure that steam can penetrate and come into direct contact with all surfaces.
Storage	Sterile, wrapped instruments should be stored in a designated, accessible area with limited access that provides protection from dust, insects, vermin, and extremes of temperature and humidity.
Additional Information	The above instructions are recommended by the medical device manufacturer as SUITABLE for preparing a medical device for reuse. It is the responsibility of the medical facility to ensure that the actual reprocessing performed with equipment, materials and trained reprocessing personnel in the reprocessing facility achieves the desired result.

	This requires validation and routine monitoring of the process. Similarly, any deviation by the reprocessor from recommendations should be properly evaluated for effectiveness and potential adverse consequences. Users must then establish an appropriate cleaning protocol for the reusable medical devices used at their sites according to the recommendations of the device manufacturer and the detergent/disinfectant manufacturer. Due to the many variables involved in sterilization/decontamination, each medical facility should validate the sterilization/decontamination process (e.g., temperature, times) used with their devices. It is the responsibility of the medical facility to ensure that the reprocessing is performed with the appropriate equipment and materials and that the personnel in the reprocessing facility have been adequately trained to achieve the desired result.
Contact to the manufactorer	See above.