Information on processing

Process step	Description
Preparation on site	Only use products from unopened (intact seal) and original packed shipping boxes. Before clinical use, they must be sterilely prepared in the dental practice using a validated procedure in accordance with the guidelines of the RKI (www.rki.de). The legal requirements valid in the country of use must be observed.
Preparation prior to cleaning	The screws supplied must be separated from the abutments, gingiva formers or scan bodies before cleaning. It must be ensured that components cannot be confused with each other. We recommend the use of a fine-pored tea strainer made of stainless steel for this purpose. These should be marked to avoid product mix-ups. (batch traceability). One abutment and one screw can be prepared in each of the tea strainers. You can find illustrated instructions on wiki.abutments4life.de.
Cleaning	MEDTEOR's medical products are delivered in a pre-cleaned condition. They are free of visible dirt and invisible organic material to prevent colonisation by micro-organisms. If the adhesive bases are bonded or further processed with individual adhesive bodies in the dental laboratory, it can be assumed that the delivered Abutments are contaminated with wax or cement residues. As these prevent soft tissue from adhering to the Abutment, a thorough and multi-stage preliminary cleaning must be performed: 1. thorough evaporation with the steam jet to remove coarse wax residues 2. ultrasonic cleaning bath #1 with Elma tec clean A2 (5 %) 50°C - 5 min 3. drip off time 1 min 4. ultrasonic cleaning bath #2 with VIGON 1000CR (10 %) 50°C - 5 min 5. drip off time 1 min 6. flushing with city water at RT - 3 min 7. air drying 12h or drying with circulating air 80° - 10 min The washing media are renewed according to the degree of soiling and as required. The washing medium should turn milky white when used. Manual pre-cleaning with metal brushes should be avoided, as this can damage the surface. To monitor the cleaning process, we recommend the use of test inks for determining the surface energy of the company Geo-Reinigungstechnik in 48712 Gescher. Oily and contaminated surfaces have a value of 30 mN/m (milli-Newton per meter). Clean surfaces have a value of over 40 mN/m. If this value is not achieved, steps 2 and 3 must be repeated. The use of fully demineralized water may be indicated for step 6. Cleaning of screwdriver and contra-angle handpiece insert Coarse impurities must be removed immediately after use of the instruments in order to prevent sticking. In particular, dirt must be removed from the opening for the screw head. • The final cleaning of the instruments must be carried out according to the procedure validated in practice. • Depending on the degree of soiling, we recommend the following procedure: place the instruments in an ultrasonic bath with disinfectant solution. If the components are contaminated with blood, the disinfectant should be aldehyde-free (otherwise the blood contamination could solidify). It should also have a proven effectiveness (e.g. VAH/DGHM or FDA approval or CE marking), be suitable for disinfecting the instruments and be compatible with them. Cleaning should take 7 minutes at 55°C. Then the parts must be rinsed twice with water of drinking water quality and dried. • Use only a soft brush or a clean, soft cloth. • Under no circumstances should metal brushes or steel wool be used to remove impurities. • Rinse all instrument cavities several times with disinfectant solution using a disposable syringe. The instruments must be visually inspected for damage after each cleaning and replaced if necessary. Basic principles for the selection of cleaning agents for titanium components No oxidative components (H_2O_2) must be used in a cleaner or cleaner additive, otherwise a yellow-orange discoloration may occur (formation of titanium oxide). No active chlorine must be used, otherwise the surface topography and thus the bio adhesion changes. No phosphoric acid (neutralising agent) may be used, as this also changes the topography and leads to a reduction of foreign elements and thus to changes in biocompatibility. No caustic soda solution may be used, which can lead to an apatite layer (thin layer of minerals of the apatite-polymorphite group) on the surface. Strong alkaline cleaners must not be used, as they attack the titanium surface.

Disinfection	Disinfection is used to kill or inactivate pathogens to prevent infections in humans. It should be carried out in the RDG (thermal disinfector) using a validated procedure. Individual Hybrid-Abutments bonded in the laboratory do not have to be removed from the tea strainers after pre-cleaning but can be transferred directly into the thermal disinfector. Prefabricated Hybrid-Abutments and screws are transferred into marked tea strainers and also transferred to the RDG. Here too, correct batch traceability must be ensured. For cleaning we recommend DGHM-listed cleaners such as Thermosept X-Tra from the company Schülke & Mayr GmbH, 22840 Norderstedt, Germany, in 0.5% concentration. The product removes organic impurities such as blood, proteins, tissue residues as well as mucus and fatty soiling even at low dosages and is characterised by good material compatibility. The programme guide is to be adapted according to the manufacturer's specifications based on the RKI recommendation. (Min. 55°C - PH >10 - 10 min.) The methods or verifications required to determine the residual quantities of the process chemicals depend on the process chemicals used and must be provided by the manufacturer of the process chemicals. The test should be performed once a week. The thermal disinfection performance can be checked using the A0-value (DIN EN ISO 15883). According to the RKI, this should reach a value of at least 3000 for critical medical devices. This can be achieved by exposure to hot water (5 minutes at 90°C or 50 minutes at 80°C). The determination of the A0-value replaces testing with bio-indicators. Only softened water (demineralised water) should be used. The following values are recommended as minimum requirements: • Total hardness: < 3°dH (< 0.5 mmol CaO/l) • Evaporation residue: < 500 mg/l • Chloride content: < 100 mg/l • pH value: 5 - 8.
Drying	Drying takes place in the RDG according to validation. The drying performance can be checked using white indicator paper containing copper(II) sulphate. This turns blue if the drying performance - preferably in the screw channel of the abutment - is insufficient.
Inspection, maintenance and testing	The RDG used must be maintained according to the validation plan. The maintenance cycles must be observed. A final visual inspection is always recommended.
Sterilization and packaging	The Hybrid-Abutments can be steam sterilized using validated procedures according to DIN EN 13060. (Temp. 134°C - min. 5 min holding time - drying time min. 10 min) If adhesive bases have been combined with individual adhesive bodies, the suitability of the adhesive used must be ensured in the steam sterilisation process. Otherwise, the classification of the Abutments or gingiva formers changes from **Critical B** to **Critical C**. The sterilized containers and components should be delivered as directly as possible to the patient. If the components intended for clinical use are not immediately intraorally applicable, they must be removed from the tea strainer without contact into an approved and suitable sealing film and then sterilised in an autoclave using a validated procedure. To avoid confusion, the sealed components must be marked steam-proof for the sterilization process. After drying, peel off the multi-layer label of the packaging and stick it to the sealing film. Folded together, both can be stored in the original packaging.
Storage	The storage times are to be considered according to the sealing method used. It must be protected against dust and moisture. You can find illustrated instructions on wiki.abutments4life.de.

Literature

1. DIN EN ISO 17664 Manufacturer information on the reprocessing of resterilizable medical devices
2. Guideline of DGKH, DGSV and AKI for the validation and routine monitoring of automated cleaning and thermal disinfection processes for medical devices New publication October 2014 - 4th edition - Robert Eibl
3. DIN EN ISO 14971 Application of risk management to medical devices
4. DIN EN ISO 10993 parts 1-20 Series of standards for the biological evaluation of medical devices
5. Recommendation of the KRINKO/BfArM: “Hygiene requirements for the reprocessing of medical devices”

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These instructions for processing must be used in conjunction with the instructions for use.