Manufacturer's information
For the processing of resterilizable medical devices according to EN 17664-1

Classification according to RKI-guidelines:	HAHNENKRATT Products:
semi-critical A	PROTECT Crowns PROVISA Shells Copperbands + ATR Impression Shells

CE

Stand 2021-11

⚠ Warnings

Observe the standard accident prevention regulations (UVV)
We are not aware of any warnings if the instructions for the devices and disinfection and cleaning agents to be used are followed.

To avoid cross-contamination, the product is intended for single use.

Limitation on reprocessing

Not for reprocessing
Crowns and Shells are intended **for single use only** and must not be reused or reprocessed

Instructions

The procedures described are well known and based on standard equipment and consumable materials.

Point of use

Carry out reprocessing only in the rooms/areas designated for this. Observe the effective hygiene measures in accordance with the country-specific guidelines.

Storage and transport

Storage and transport must carried out in the rooms and containers designated by the practice.

Preparation for decontamination

Observe the standard instructions for instruments in your practice. No other special requirements need to be followed for our HAHNENKRATT products.

Manual Preparation – Cleaning, disinfection and drying:

Equipment: Alcohol, e.g. ethanol 70% pure DAB

Procedure:

1. remove medical device from the packaging
2. **completely** soak in alcohol, e.g. ethanol 70% pure DAB, for cleaning and disinfecting for 10 minutes
3. if necessary, allow excess alcohol to evaporate until there is no more residual moisture

The disinfected medical device must be used immediately after disinfection. Packaging and storage is not intended.

Maintenance

The medical device does not require maintenance.

Inspection and functional check

Visual inspection of the product for intactness before use.

Packaging

Use standardized (DIN EN ISO 11607-1) and appropriate packaging material. The packaging must be large enough so that no stress is placed on the seal.

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Sterilization

If the medical device is used for restorative measures where it comes into contact with open wounds, sterilization is possible and specified as "Critical A".

According to RKI published in the Bundesgesundheitsblatt 2012-55:1244-1310 "Hygiene requirements for the reprocessing of medical devices" page 1248, Table 1 Risk assessment and classification of medical devices:

Semi critical A: Sterilization (X)= step is optional
Critical A: Sterilization X = Always sterilize with moist heat

Equipment: Steam sterilizer, according DIN EN ISO 17665 moist heat

Procedure:

Steam sterilization using a fractionated vacuum method at 134°C in a device in accordance with EN 13060:

1. Fractionated pre-vacuum method (at least 3-fold)
2. Sterilization temperature 134°C
3. Exposure time: 5 minutes (full cycle)
4. Drying time: 10 minutes

Observe standard EN 17655 for sterilization with moist heat.

Follow the operating instructions of the device manufacturer and the manufacturer of the sterile packaging.

Additional information

Any serious incidents that occur in connection with the product must be reported to the manufacturer and the competent authority of the member state in which the user and/or patient is established.

Make sure that the maximum load of the devices is observed.

Observe the national regulations for disposal.

Basis for this Manufacturer's Information are validations, which were carried out by the accredited laboratory Zwisler.

Validation report:
1910.3009-hahn_manual reprocess_matrix

Manufacturer contact

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Observe your country's applicable legal requirements for the reprocessing of medical devices. You can find information about this at www.rki.de

Also observe the standard German accident prevention regulations (UVV)

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The instructions provided above have been validated by the medical device manufacturer as being SUITABLE for the preparation of a medical device for reuse. It is the responsibility of the operator to ensure that the actual processing performed in the processing facility – including the equipment, materials and personnel used – achieves the desired result. This usually requires validation and routine monitoring of the procedure in the processing facility.

Any deviation from the instructions provided should be carefully evaluated for effectiveness and any possible negative consequences by the practice's safety officer.