EN ISO 17664-1 Manufacturer's instructions for preparing medical devices

Classification under Robert Koch Institut (RKI) guidelines:	HAHNENKRATT Products:
Semi-critical A / Critical A	Matrices and matrix bands

CE

⚠ Warning

Observe standard accident prevention regulations
We are not aware of any warnings if the devices in question are used in compliance with the instructions for use, and the proper disinfection and cleaning solutions are used.

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

Risk of injury through cuts!
Matrix bands have to be very thin, yet stable and tear-resistant. Our matrix bands are micro-thin, at just 0.03, 0.04 or 0.05 mm thick. This minimal thickness combined with the stability of the material means that simply pressing or applying pressure to the edge can result in a cut. Even paper has the potential to damage or cut the skin.

Dentists and dental staff are generally aware of the potential risk of injury:

The product must generally be handled with care, and appropriate care must be taken when fitting it to a matrix retainer or when using it on a patient to avoid injuries from cutting.

If there is a protective area, the ends of the matrix band must not extend beyond the the protective area of the matrix retainer.

Appropriate and careful use on the patient is necessary to prevent injuries from cutting.

Restrictions on re-use

Not for re-use
Matrices and matrix bands and designed for **single use** and are not intended for re-use.

Instructions

The procedures described here are well known and are based on standard equipment and consumables.

Place of use

The product may only be processed in designated rooms/areas. Observe hygiene measures, in accordance with country-specific guidelines.

Storage and transport

The product must be stored in the rooms and transported in the containers provided for this purpose.

Preparing for decontamination

Follow the standard instructions for instruments in your practice. There are no specific requirements to follow for our HAHNENKRATT instruments.

Cleaning, disinfection and drying

Mechanical preparation

Not applicable

Cleaning, disinfection and drying

Approved manual preparation

Treatment agent: 70% ethanol/water mix as per the German Pharmacopoeia (DAB, Deutsches Arzneibuch)

Procedure, approved:

1. Remove matrices / matrix bands from packaging;
2. clean and disinfect by placing in a 70% ethanol/water mix, as per the German Pharmacopoeia (DAB), for 10 minutes
3. – ensure that the whole device is submerged.
4. If necessary, allow excess alcohol to evaporate until there is no more residual moisture.

The disinfected medical device must be sterilised immediately after disinfection if the matrix comes into contact with open mucous membrane. (Critical A)

Maintenance

The medical device does not require maintenance.

Inspection and functional checks

Carry out a visual inspection of the product for integrity and cleanliness before use. 8x magnification should allow visual inspection. Dispose of any damaged matrices or matrix bands.

Packaging

Suitable individual packaging in a sterile film, pursuant to standard DIN EN ISO 11607-1. The packaging must be large enough to prevent the seal from being under any tension.

Sterilisation

The disinfected medical device must be sterilised immediately after disinfection if the matrix comes into contact with open mucous membrane. (Critical A)

Pursuant to RKI, published in Federal Health Bulletin (Bundesgesundheitsblatt) 2012-55:1244-1310 "Hygiene requirements for the preparation of medical devices" page 1248, Table 1 "Risk assessment and classification of medical devices":

Semi-critical A: Sterilisation (X)= optional procedure
Critical A: Sterilisation X = Always sterilize with moist heat

Equipment: Steam sterilizer, pursuant to DIN EN ISO 17665 moist heat

Procedure:

Steam sterilization using a fractional vacuum process at 134°C in a device pursuant to DIN EN 13060:

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

Observe standard DIN EN ISO 17665 on sterilisation with moist heat.

Follow the instructions for use from the device manufacturer and the sterile packaging manufacturer.

Insert the matrix into a matrix retainer you have already prepared.

If necessary, mount the sterile matrix on a sterile matrix retainer, and then repeat the sterilisation process to prepare a ready-to-use instrument.

Storage

Packaged sterile materials must be transported and stored so that they are protected from dust, moisture and (re)contamination.

Additional information

All serious events that occur in connection to the product must be reported to the manufacturer and to the competent authority of the Member State where the user and/or patient are based.

Observe the instructions for use from the device manufacturer, and do not exceed the maximum load for the device.

Observe national regulations concerning disposal.

Observe the statutory requirements concerning the reprocessing of medical devices in your country. For more information, visit www.rki.de

The above instructions have been validated by the medical device manufacturer as SUITABLE for preparing a medical device for reuse. It is the responsibility of the processor to ensure that the actual treatment carried out in the preparation area – including the equipment, materials used and personnel – achieves the desired results. This usually requires validation and routine monitoring of the process in the preparation area.

Any deviation from the instructions provided should be assessed with care by the practice Safety Officer for its effectiveness and any potential adverse effects.

These manufacturer's instructions are based on validations carried out by the accredited laboratory Zwisler.

Validation report:
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