MANUFACTURER: EVE ERNST VETTER GMBH
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75210 KELTERN, GERMANY

REV. STATUS: 002

PRINT DATE: 2018-01-01

// FOR THE USE OF EVE STRIPS

Unless described otherwise, the following notes apply to the proper use of the following product groups offered by EVE Ernst Vetter GmbH: Carbostrips, Diastrips.

// INTENDED USE / PROPER USE

- All the above mentioned instrument groups are intended for multiple use as part of dental medical treatment. They are used for the reduction, excavation and cutting or surface conditioning of dental tissue such as bone, dentine and enamel, as well as dental materials such as composites, metal alloys, ceramics and dental resins.
- The product groups are intended for use by trained qualified personnel and dentists.
- Separating strips are operated by hand.

// TRANSPORT, STORAGE AND TREATMENT OF NEW INSTRUMENTS PRIOR TO FIRST USE

- There are no specific conditions for transport. Store all instruments in their original packaging in clean, dry conditions at room temperature.
- New instruments are not packaged sterile and must be cleaned, disinfected and sterilised prior to every use according to the processing instructions.
- When unpacking longer, thinner instruments and discs ensure that these are not bent.

// DISPOSAL

- All instruments are free of hazardous materials ex works. Only infection and contamination precautions must be taken into account for disposal.

// INSTRUCTIONS FOR USE

**All our instruments have been developed and manufactured with care for their intended use.
Improper use can represent a hazard for both users, patients and, if applicable, third parties.
Please observe prior to use:**

- As infectious particles can be distributed in the environment, users and assistants are to wear mouth protection, goggles and gloves and to disinfect the environment (treatment unit, etc.) accordingly.
- Ensure adequate air-/water cooling.
- When processing exogenous materials, aspiration and, if applicable, further safety measures such as cofferdams are recommended.
- Operate with as little pressure as possible (approx. 50 g, corresponds to writing pressure) and avoid canting the instrument. Greater pressure only leads to more heat development, faster wear and poorer working results. If the instrument is jammed, carefully remove the instrument without canting and check for damage before reusing.
- Blunt and damaged instruments may not continue to be used! Check instruments prior to every use!

Non-compliance with the safety warnings can lead to damage of the tooth and surrounding tissue or to the workpiece and possibly be a hazard to the user, patient and third parties.

// INSTRUCTIONS FOR USE

- **Note on notification requirements:**
  According to the applicable legal requirements, serious incidents occurring in conjunction with an EVE product must be notified to us (see address above) and the competent authorities of the country in which the user works. In the meaning of the law, incidents must be notified if the use of the instrument led or could lead directly or indirectly to the death or a severe worsening of the health status of the patient, the user or a third party (Source: Safety Plan Directive Medical Devices §2).

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// NOTES ON PREPARATION

The following processing instructions include the minimum requirements for processing for which safe processing has been validated. In addition, there are process steps marked as recommendations which may improve the results of the checks, in particular after cleaning and disinfection. Furthermore, a validated manual method is also offered for cleaning and disinfection. This is intended as an alternative for regions with a poor infrastructure or in case of breakdown of technical equipment.
All devices used must comply with the applicable standards and regulations and be in perfect technical and hygienic condition as a matter of principle.

Legal and regulatory principles
These notes on processing were prepared according to: EU Medical Device Directive (MDR/2017), DIN EN ISO 17664: 2004 and the recommendations of the Commission for Hospital Hygiene and Infection Prevention of the Robert-Koch Institute (RKI): "Infection prevention in dentistry – Hygiene requirements“ (2006) and "Hygiene requirements for the processing of medical devices" (2012).

Scope of application of these notes
Unless described otherwise, the following notes apply to the proper use of the following product groups offered by us: Carbostrips, Diastrips.

Risk assessment and classification of the product groups according to the above mentioned RKI guideline
Due to their field of application and because of the abrasive surface of the separating strips they are to be classified as semi-critical B with special requirements for processing. Technically they are suited for processing in most types of ultrasonic baths, cleaning and disinfection devices as well as autoclaves. Cleaning and disinfection devices alone may possibly provide insufficient cleaning performance due to the above described specifics (see also critical process steps).
Our instruments are not suited for chemiclav or hot air sterilisation.

Critical process steps
Inspection after cleaning is regarded as a critical control point. Due to the "rough" surfaces of the instruments through diamonding or interlocking, there is a risk that tissue residues and other types of contamination may not be removed fully. This can have a negative effect on disinfection and sterilisation. Therefore the drying on of contamination is to be avoided and inspection after cleaning is to be carried out with special care with aids such as a magnifying glass or microscope.

Specialist knowledge and protection of the person performing processing
The above mentioned product groups may only be processed by persons with the required specialist knowledge. The requirements are defined in the applicable regulations and laws. To avoid contact with potentially infectious material, gloves, mouth protection and protective goggles including protective clothing are to be worn.

Suitable cleaning and disinfectant agents
Use only certified agents manufactured according to the applicable standards. As a matter of principle, the manufacturers of these cleaning and disinfectant agents test whether a product is suitable for rotating instruments. Therefore, all agents released for use with rotating instruments in the instructions by the manufacturer, can be used.
Important: they should contain anti-corrosion protection. Cleaning and disinfectant agents containing strong acids and alkalis as well as hydrogen peroxide and sodium hypochlorite are not suitable.

Storage and processing of new instruments
Store all instruments in their original packaging clean and dry and at room temperature. New instruments are packaged non-sterile and must be cleaned, disinfected and sterilised prior to use according to the following instructions.

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// PROCESS STEPS

All product groups must be processed prior to every use according to the following steps:

PREPARATION FOR CLEANING:	▸ *Cleaning commences immediately after use to avoid difficult to remove dried matter. Occupational safety (risk of infection and contamination) must be observed when storing used instruments.*
	Recommendation: *Pre-cleaning in an ultrasonic bath can significantly improve the result of visual inspection. Please observe the manufacturer's information.*
A) AUTOMATIC CLEANING AND DISINFECTION:	▸ *Cleaning and disinfection in the cleaning and disinfection device according to the manufacturer's information. Attention should be paid to fixating the instruments such, that they cannot rub against anything.*
B) MANUAL CLEANING AND DISINFECTION:	▸ *Place the instruments in cold water for at least 5 minutes, rinse under running water and remove any tissue residue with a brush and rinse again.* ▸ *After inspection under a magnifying glass repeat brushing and rinsing if required.* ▸ *Then chemically disinfect the strip in a disinfection bath. Use disinfectants with anti-corrosion protection exclusively and adhere to the exposure times and concentrations prescribed by the manufacturer.* ***All instruments must be rinsed after disinfection with microbiologically and chemically pure water and dried thoroughly, for example, with medical compressed air.***
FOLLOW-UP INSPECTION:	▸ *Prior to sterilisation all instruments must be checked for cleanliness and functionality. It is recommended using a magnifying glass or microscope for this purpose. In case of any contamination, particularly in the diamonded or interlocking areas, the cleaning and disinfection process must be repeated or the instrument disposed of. Worn, bent or damaged instruments must be sorted out.*
STERILISATION:	▸ *Critical (surgically) used instruments must be sterilised in autoclaves, packaged and labelled in accordance with the guidelines. As a rule, a fractionated pre-vacuum and hold time of 5 minutes at 134 °C and approx. 2 bar pressure is applied. Decisive is the information of the device manufacturers.*
STORAGE:	▸ *Processed and packaged instruments are to be stored protected from dust, clean and dry at room temperature.*