

# Composite Tip Dispenser

## Instructions for use

EN

Please read the Instructions for Use carefully before using the product.

### Product Description

The Composite Tip Dispenser is used to apply composite filling material from capsules (tips).

### Intended Use

- Application of composite filling material from tips directly into the cavity being treated
- Dispensing of composite filling material from tips onto a mixing block for application with an instrument

### Indications for Use

Is used in combination with medical devices.

### Safety Instructions

#### ⚠ WARNING

- There is a risk of infection if cleaning and sterilisation are not performed or are performed improperly. Please read the section on reprocessing carefully and follow the instructions.
- The use of this product in the patient's mouth may only be undertaken by specialist personnel such as dentists and dental assistants with appropriate qualifications.

#### ⚠ CAUTION

- The dispenser is designed for composite tips from COLTENE. Users are responsible for checking the compatibility of other products.
- There is a risk of injury due to squashing if handled improperly. See section "Proper Use".
- As small parts generally pose a risk of swallowing and aspiration, the use of a rubber dam is strongly recommended.

#### NOTICE

Follow the Instructions for Use for the composite filling material.

### Side effects and Interactions

No harmful reactions or secondary effects on patients and / or dental personnel are known.

### User / Patient Group

Application through specialist dental personnel. Suitable for all patient groups.

### Proper Use

1. Reprocess the dispenser (see section "Reprocessing").
2. Press the tip from below into the recess on the dispenser until it audibly clicks into place.
3. If necessary, turn the tip in the dispenser so that the end of the tip faces in the desired direction.
4. Remove the sealing cap.
5.  Dispense the material by smoothly pulling the trigger. Avoid applying too much pressure.
6. Slowly release the trigger until it has reached its starting position again. Remove the tip from the recess and discard along with any residual material.

### Reprocessing

 Reprocessing should be performed in accordance with EN ISO 17664. The user is responsible for ensuring that reprocessing is performed properly.

### Preparation

Remove any composite filling material that has not cured with a clean soft cloth. If cured composite filling material has adhered to the dispenser, place the dispenser in an alcohol-based cleaning fluid (e.g. 15 min in 0.5% neodisher Septo PreClean, Dr. Weigert, Hamburg). Then remove the material with a non-abrasive

tool (e.g. a plastic spatula or a nylon brush). Do not use metal brushes or similarly harsh cleaning tools.

#### Cleaning and disinfection in an ultrasonic bath

For cleaning in an ultrasonic bath, place the contaminated dispenser in a basket or use a cassette. Immerse the basket in the main tank filled with the cleaning fluid. Follow the dosing instructions for the cleaning solution. Start the ultrasonic cleaning process. Then remove the dispenser from the ultrasonic bath and rinse thoroughly under running water (preferably use deionised water). Dry the dispenser with compressed air.

#### Cleaning and disinfection in a washer/disinfector (validated in a Miele PG8535)

If a washer/disinfector is available, preference should be given to automated cleaning. Place the dispenser in the washer/disinfector in accordance with the recommendation of the equipment manufacturer. Select suitable cleaning fluids in accordance with the specifications of the product and equipment manufacturer and start the cleaning and disinfection process.

#### Example:

- Pre-rinse for 1 min. with cold water
- Drain
- Pre-rinse for 3 min. with cold water
- Drain
- Wash for 10 min. at 55 °C with 0.5 % alkaline detergent Neodisher Mediclean Dental, Dr. Weigert, Hamburg
- Drain
- 3 min. neutralisation with warm tap water (> 40 °C) and 0.1 % neutraliser Neodisher Z Dental, Dr. Weigert, Hamburg
- Drain
- 2 min. intermediate rinsing with warm tap water (> 40 °C)
- Drain
- Thermal disinfection with demineralised water, temperature 92 °C, for at least 5 minutes
- Automatic drying, 30 min. at approx. 90 °C

Remove the dispenser from the washer/disinfector and, if required, dry with compressed air.

#### Inspection

Inspect the dispenser for visible contamination. If required, repeat the cleaning process as described above.

#### Sterilisation (validated in a Tuttnauer EHS 3870 steam steriliser)

The dispenser should be steam sterilised in an autoclave with the following parameters:

- Unpackaged
- 3 × fractionated pre-vacuum to remove any air
- Hold time 3-5 min.
- Temperature 132-134 °C

### Shelf life & storage

- The dispenser should be stored dry at room temperature and protected from dust.
- Minimum shelf life: 8 years from date of manufacture.
- The service life of the dispenser is limited due to wear. A defective or worn dispenser must not continue to be used, particularly if the tip no longer audibly engages securely in the recess.

### Disposal

This product can be disposed of with the household waste. Special country-specific regulations may apply.

### Reporting obligation

All serious incidents occurring in conjunction with this product must be reported immediately to the manufacturer as well as to the competent authority.



## Glossary



Consult instructions for use



Marking of Conformity Europe



Sterilisation procedure



Identification for Russia



Identification for Ukraine



Legal Manufacturer



Expiry Date



Batch Code



RX only



Medical Device



Manufacturing Date



Unique Device Identifier



European Authorized Representative



Reference Number

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