

Prior to use, carefully read the instructions for use. EN

Vor der Benutzung bitte die Gebrauchsanweisung gründlich lesen! DE

## EXACLEAR

CLEAR VINYL POLYSILOXANE

For use only by a dental professional in the recommended indications.

### INDICATIONS FOR USE

- Silicone matrix for the composite injection molding technique
- Silicone matrix for temporary crown and bridge work
- Silicone key for the composite layering technique
- Bite registration
- Fixation material for X-ray pellets used in implant planning
- Silicone matrix for the transfer of brackets or fibers from the model to the mouth

### CONTRAINDICATIONS

Avoid use of this product in patients with known allergies to silicone.

### PRECAUTIONS

When extruding or mixing EXACLEAR, care should be taken to avoid mixing or contact with the following materials which may delay or prevent setting: catalyst for condensation silicone impression materials, polysulfide impression materials, eugenol materials, sulfur, latex, oil, acrylics, glycerol, spray-type or ointment-type topical surface anesthesia (e.g. lidocaine).

### DIRECTIONS FOR USE

- Lift the release lever of CARTRIDGE DISPENSER II and pull the piston plunger all the way back into the dispenser. Lift the cartridge holder of the dispenser and load the cartridge, ensuring the V-shaped notch on the flange of the cartridge is facing down. Place the cartridge holder down to hold the cartridge firmly in place.
- Lift the release lever and push the piston plunger forward until it engages into the cartridge.
- Remove the cartridge cap by rotating 1/4 turn counter-clockwise. Till the cap downward and peel it away from the cartridge. Gently squeeze the dispenser handle to extrude a small amount of material from the two openings at the end of the cartridge.
- Align the V-shaped notch in the rim of the MIXING TIP II to the V-shaped notch between the cartridge barrels. Push firmly to attach the mixing tip. Then rotate the colored collar of the mixing tip 1/4 turn clockwise to the end of the cartridge. The dispenser is now ready for use.
- Dispensing of the material
  - Squeeze the handle several times to extrude the material.
  - Apply the mixed material in the mouth or on the model.
  - Wait until the material has set before adding the catalyst.
  - Remove the impression from the mouth or the model.
- After use, do not remove the MIXING TIP II as this will become the storage cap until next use. When replacing the MIXING TIP II, rotate the collar on the mixing tip 1/4 turn counter-clockwise to align the V-shaped notch on the cartridge. Till the mixing tip downward and peel it away from the cartridge.
- Replace the cartridge, lift the release lever and retract the piston plunger fully. Remove the empty cartridge by lifting the cartridge holder and load a new one into the dispenser.

### TECHNICAL DATA

Working time (at 23°C)	45 sec.
Minimum time in mouth	2 min.
Minimum time on a model (at 23°C)	Approx. 7 min.
Hardness (Shore A)	60

### COLOR

Clear

### STORAGE

Recommended for optimal performance, store at room temperature away from direct sunlight (15-25°C, 59.0-77.0°F).

### PACKAGE

Two cartridges package:  
Cartouche 51 g (48 mL) x 2  
MIXING TIP II L (green) x 6

### CAUTION

- In case of contact with oral tissue or skin, remove and flush with water.
- In case of contact with eyes, flush immediately with water and seek medical attention.
- Do not mix EXACLEAR with components of any other products.
- Avoid getting material on clothing as it is difficult to remove.
- Before attaching a new mixing tip, extrude a small amount of material to ensure that base and catalyst are coming out evenly. Uneven extrusion may cause delayed setting.
- Take care to avoid ingestion of the material.
- Mixing tips are for single use only. To prevent cross-contamination between patients, do not reuse the mixing tip. The mixing tip cannot be sterilized in an autoclave or chemostatic bath.
- Personal protective equipment (PPE) such as gloves, face masks and safety eyewear should always be worn.
- In rare cases, the product may cause sensitivity in some people. If any such reactions are experienced, discontinue the use of the product and refer to a physician.

Some products referenced in the present IFU may be classified as hazardous according to GHS. Always familiarize yourself with the safety data sheet (SDS) available at:

<http://www.gc-europe.com>

They can also be obtained from your supplier.

### CLEANING AND DISINFECTION

MULTI-USE DELIVERY SYSTEMS: to avoid cross-contamination between patients this device requires mid-level disinfection.

Immediately after use inspect device and label for deterioration. Discard device if damaged.

DO NOT IMMERSER. A thoroughly clean device to prevent drying and accumulation of contaminants. Disinfect with a mid-level registered healthcare-grade infection control product according to regional / national guidelines.

Undesired effects- Reporting: If you become aware of any kind of undesired effect, reaction or similar events experienced by use of this product, including those not mentioned in this document, report them directly through the relevant vigilance system, by selecting the proper authority of your country accessible through the following link:

<https://ec.europa.eu/growth/sectors/medical-devices/>

as well as to our internal vigilance system: vigilance@gc.dental In this way you will contribute to improve the safety of this product.

Last revised: 04/2020

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## EXACLEAR

KLARES VINYL-POLYSILOXAN

Nur von zahnmedizinischem Fachpersonal für die angegebenen Indikationen zu verwenden.

### INDIKATIONEN ZUR ANWENDUNG

- Silikonkern für die formgebende Composite-Injektionstechnik
- Silikonmatrix für temporäre Kronen- und Brückendarbeiten
- Bite Registration
- Fixation material for X-ray pellets used in implant planning
- Silikonmatrix für die Transferierung von Brackets oder Glasfasern vom Modell in den Mund

### KONTRAINDIKATIONEN

Vermeiden Sie die Anwendung dieses Produktes bei Patienten mit bekannter Allergie gegen Silikone.

### VORSICHTSMASSNAHMEN

Beim Ausdrücken oder Anmischen von EXACLEAR sollte das Vermischen oder ein Kontakt mit den folgenden Materialien vermieden werden, um eine Abbindungsverzögerung oder Verhindern der Kondensation von Silikon-Abformmaterialien, Polysulfid-Abformmaterialien, eugenolhaltige Materialien, Schweiß, Latex, Öl, Acrylate, Glycerol, Sprüh- oder Salben-Oberflächenanästhetika (bspw. Lidocain).

### GEBRÄUCHSANWEISUNG

- Heben Sie den Freigabehebel des CARTRIDGE DISPENSER II an und schieben den Kolben vollständig zurück in den Dispenser. Heben Sie den Kartuschenhalter des Dispensers an und legen die Kartusche hinein. Versichern Sie sich, dass die V-förmige Aussparung im Gehäuse der Kartusche nach unten zeigt. Drücken Sie den Kartuschenhalter nach unten, um die Kartusche zu fixieren.
- Lift the release lever and push the piston plunger forward until it engages into the cartridge.
- Remove the cartridge cap by rotating 1/4 turn counter-clockwise. Till the cap downward and peel it away from the cartridge. Gently squeeze the dispenser handle to extrude a small amount of material from the two openings at the end of the cartridge.
- Align the V-shaped notch in the rim of the MIXING TIP I to the V-shaped notch between the cartridge barrels. Push firmly to attach the mixing tip. Then rotate the colored collar of the mixing tip 1/4 turn clockwise to the end of the cartridge. The dispenser is now ready for use.

### DISPENSING OF THE MATERIAL

- Apply the mixed material in the mouth or on the model.
- Wait until the material has set before adding the catalyst.
- Rinse the impression from under running tap water and disinfect with an appropriate disinfectant.
- After use, do not remove the MIXING TIP II as this will become the storage cap until next use. When replacing the MIXING TIP II, rotate the collar on the mixing tip 1/4 turn counter-clockwise to align the V-shaped notch on the cartridge. Till the mixing tip downward and peel it away from the cartridge.
- Replace the cartridge, lift the release lever and retract the piston plunger fully. Remove the empty cartridge by lifting the cartridge holder and load a new one into the dispenser.

### TECHNICAL DATA

Working time (at 23°C)	45 sec.
Minimum time in mouth	2 min.
Minimum time on a model (at 23°C)	Approx. 7 min.

### COLOR

Clear

### STORAGE

Recommended for optimal performance, store at room

temperature away from direct sunlight (15-25°C, 59.0-77.0°F).

### PACKAGE

Two cartridges package:  
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MIXING TIP II L (green) x 6

### CAUTION

- In case of contact with oral tissue or skin, remove and flush with water.
- In case of contact with eyes, flush immediately with water and seek medical attention.
- Do not mix EXACLEAR with components of any other products.
- Avoid getting material on clothing as it is difficult to remove.
- Before attaching a new mixing tip, extrude a small amount of material to ensure that base and catalyst are coming out evenly. Uneven extrusion may cause delayed setting.
- Take care to avoid ingestion of the material.
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## EXACLEAR

VINYLSILIKON

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### INDIKATIONEN ZUR ANWENDUNG

- Silikonkern für die formgebende Composite-Injektionstechnik
- Silikonmatrix für temporäre Kronen- und Brückendarbeiten
- Bite Registration
- Fixierung von Röntgenpellets in der Implantatplanung
- Silikonkern für die Übertragung von Brackets oder Glasfasern vom Modell in den Mund

### KONTRAINDIKATIONEN

Vermeiden Sie die Anwendung dieses Produktes bei Patienten mit bekannter Allergie gegen Silikone.

### VORSICHTSMASSNAHMEN

Bei dem Ausdrucken oder Anmischen von EXACLEAR sollte das Vermischen oder ein Kontakt mit den folgenden Materialien vermieden werden, um eine Abbindungsverzögerung oder Verhindern der Kondensation von Silikon-Abformmaterialien, Polysulfid-Abformmaterialien, eugenolhaltige Materialien, Schweiß, Latex, Öl, Acrylate, Glycerol, Sprüh- oder Salben-Oberflächenanästhetika (bspw. Lidocain).

### GEBRÄUCHSANWEISUNG

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### TECHNICAL DATA

Working time (at 23°C)	45 sec.
Minimum time in mouth	2 min.
Minimum time on a model (at 23°C)	Approx. 7 min.

### COLOR

Clear

### STORAGE

Recommended for optimal performance, store at room

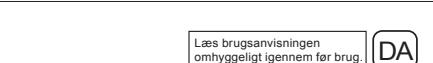
temperature away from direct sunlight (15-25°C, 59.0-77.0°F).

### PACKAGE

Two cartridges package:  
Cartouche 51 g (48 mL) x 2  
MIXING TIP II L (green) x 6

### CAUTION

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- In case of contact with eyes, flush immediately with water and seek medical attention.
- Do not mix EXACLEAR with components of any other products.
- Avoid getting material on clothing as it is difficult to remove.
- Before attaching a new mixing tip, extrude a small amount of material to ensure that base and catalyst are coming out evenly. Uneven extrusion may cause delayed setting.
- Take care to avoid ingestion of the material.
- Mixing tips are for single use only. To prevent cross-contamination between patients, do not reuse the mixing tip. The mixing tip cannot be sterilized in an autoclave or chemostatic bath.
- Personal protective equipment (

**EXACLEAR**

KLAR VINYLPOLYSILOXAN

Må kun benyttes af professionelt tandlægepersonale til de anbefaede indikationer.

- INDIKATIONER TIL ANVENDELSE**
- Silikonmatrix til komposit sprøjtebindingsteknik
  - Silikonmatrix til provisoriske kroner og broer
  - Silikonform til komposit lagteknik
  - Bidregistrering
  - Fixeringsmateriale til røntgenkugler anvendt ved implantatplanlægning
  - Silikonmatrix til flytning af brackets eller fibre fra model til mund

**KONTRAINDIKATIONER**  
Undgå brugen af dette produkt til personer med kendte allergier mod silikone.

**FORHOLDSSREGLER**  
Når man skal blande eller ekstrudere EXACLEAR, bør man være opmærksom på at undgå at blande med andre materialer med følgende risiko for at få teknisk fejl i formen eller tekniske afbindninger: katalysator for kompositoligoforpolymersens, silikonatrykermaterialer, polyulfid atrykermaterialer, eugenolholdige materialer, sulfur, latex, olie, acrylat, glycerol og topik anæstesi (f.eks. lidokain) af sprøjte type eller salve.

**BRUGSEGLING**  
1. Styk atterlykkelen på CARTRIDGE DISPENSER II. Løft stempelstiftet og træk stemplet helt tilbage på dispenseren. Laag med eneste hånd og hæld den ønskede indskæring på magasinet flange vendt nedad. Skub patronholderen ned igen for at holde magasinet fast på plads.

2. Loft stempelstiftet og skub stemplet frem, indtil det får greb i magasinet.

3. Fjern låget på magasinet ved at dreje det 1/4 omgang mod uret. Vip låget nedad og vrid det væk fra magasinet. Tryk forsigtigt på dispenseren for at ekstrudere en lille smule materiale fra de to åbninger på magasinet. Sej af både base og katalysator til at undgå at få magasinet abninger.

4. Tilpas den V-formede indskæring på kanten af MIXING TIP II til den V-formede indskæring på kanten af MUXING TIP I mot den V-formede indskæring i midten af MUXING TIP II.

5. Drej den V-formede indskæring i midten af MUXING TIP II til den V-formede indskæring i midten af MUXING TIP I.

6. Dispenseren er klar til bruk.

7. Dispenseren af materialet:

- Tryk flere gange på håndtaget for at ekstrudere materialet.
- Applicér det blandede materialet enten i munden eller på modellen.
- Vent på materialet at afbindre.
- Fjern atrykermaterialet fra munden eller modellen.
- Skyl atrykretet under rendende vand fra hanen og desinficer med et passende desinfektionsmidde.

8. Efter brug, efterlades MIXING TIP II som opbevaringsstål til næsteibrugning. Når MIXING TIP II skal udskiftes, drejes kraven på blandespidsen 1/4 omgang mod uret for at tilpasse den V-formede indskæringen på kanten af MUXING TIP II til den V-formede indskæringen på kanten af MUXING TIP II.

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