

EXACLEAR

CLEAR VINYL POLYSILOXANE FOR BITE REGISTRATION

Prior to use, carefully read the instructions for use.

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

RECOMMENDED INDICATIONS

To check bite registrations.

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, acrylates, glycerol and spray-type or ointment-type topical surface anesthesia (e.g. lidocaine).

DIRECTIONS FOR USE

CARTRIDGE LOADING AND DISPENSING

1. 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 that the V-shaped notch on the flange of the cartridge is facing down. Push the cartridge holder down to hold the cartridge firmly in place.
2. Lift the release lever and push the piston plunger forward until it engages into the cartridge.
3. Remove the cartridge cap by rotating 1/4 turn counter-clockwise. Tilt 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. Make sure that base and catalyst come out evenly.
4. Align the V-shaped notch on 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.
5. Squeeze the handle several times to extrude the material. 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. Tilt the mixing tip downward and peel it away from the cartridge.
6. Remove the old mixing tip prior to next use. Before attaching a new tip, gently extrude a small amount of material to ensure that base and catalyst are flowing evenly from both openings. If the materials should fail to extrude, remove any hardened materials from the end of the cartridge.
7. To 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.

BITE REGISTRATION

1. Apply the mixture on tooth surface being checked.
2. Wait for the material to set.
3. Remove the prosthesis from the mouth and assess contacts.
4. Rinse the impression under running tap water and disinfect with an appropriate disinfectant.

Working time (at 23°C) (sec.)	45 sec.
Minimum time in mouth (min.)	2 min.
Hardness (ShoreA)	60

COLOR

Clear

STORAGE

Recommended for optimal performance, store at room temperature away from direct sunlight (15-25°C, 59.0-77.0°F).
(Shelf life : 2 years from date of manufacture)

PACKAGE

EXACLEAR

Two cartridge package: Cartridge 51g (48mL) x 2,
MIXING TIP II L (green) x 6

CAUTION

1. In case of contact with oral tissue or skin, remove and flush with water.
2. In case of contact with eyes, flush immediately with water and seek medical attention.
3. Do not mix EXACLEAR with components of any other products.
4. Avoid getting material on clothing as it is difficult to remove.
5. Before attaching a new mixing tip, extrude a small amount of materials to ensure that base and catalyst are coming out evenly. Uneven extrusion may cause delayed setting.
6. Take care to avoid ingestion of the material.
7. 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 chemiclave.
8. Personal protective equipment (PPE) such as gloves, face masks and safety eyewear should always be worn.
9. 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 sheets available at:

<http://www.gcamerica.com>

They can also be obtained from your supplier.

CLEANING AND DISINFECTING

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 IMMERSE. 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.

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Rx Only

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