IFU Size: 161 H x 104 W

GINGIVA SHIELD VLC



Light Curing Gingival Resin Barrier, Blue

Product Description: Gingiva Shield VLC is a light curing resin based gingival barrier in syringe applicator. It quickly and easily seals the margins to protect soft tissues during whitening treatment and other procedures.

Composition: Urethane Dimethacrylate, Triethylene Glycol Dimethacrylate, Fillers, Radiopacifiers, Pigments, Curing Agents and Stabilizers.

Intended Purpose / Intended use: It is used to seal the margins to protect soft tissues during dental/teeth whitening treatment.

Indications for Use:

- 1. Protects the gingiva during teeth whitening or bleaching treatment.
- 2. Protects the teeth whitening material from blood or saliva contamination during the treatment.
- 3. Also, used to protect hard and soft tissues in procedures such as sand blasting or etching with strong acids.

Instructions for Use:

- 1. Place self-supporting lip/cheek retractors.
- 2. Remove lock cap and attach applicator tip provided with the product.
- 3. Rinse and air dry the teeth.
- 4. Build a resin barrier along the gingival margin about 1.5-2.0 mm thick. Continue building the barrier apically until approx 6 mm of the tissue is covered and extend the resin beyond the last tooth to be bleached.
- 5. Light cure the resin by fanning movement over the entire surface for 20-30 sec.
- 6. After completion of whitening procedure, suction of the whitening gel, rinse teeth with water/air syringe. Lift Gingiva Shield Barrier from the surface using an explorer or instrument.
- 7. The dispensed material shall not be placed back in container and the dose once applied.

Warnings: Avoid prolonged or repeated contact with skin (allergic contact dermatitis), and eyes. Avoid prolonged inhalation. Do not take internally. Contact with the skin may cause irritation, burns of hypersensitivity. If contact with skin occurs immediately wipe off thoroughly with cotton and alcohol and then wash well with soap and water. If skin rash and sensitization or other allergic reaction occurs discontinue use and seek medical attention. If the product comes into contact with the eyes, rinse thoroughly with fresh water and consult a physician. It should not be used with patients who have a history of severe allergic reaction to any of the components and shall not be reused.

Precautions:

- 1. For professional use only.
- 2. Do not use on patients with known sensitivity to resins, especially methacrylates.
- 3. Material is not to be injected.
- 4. Check material flow on an inert surface (e.g. mixing pad) to ensure evenness of flow before using intraorally.
- 5. Gingival and oral health should be confirmed before using this product.

Contraindications: Contraindicated for patients with known allergies to polymerizable resins.

Storage conditions: Store at temperature between 10°C(50°F) to 24°C(75°F). Close the cap carefully after use. Keep away from moisture. Shelf life not affected after opening if stored in a cool dry place.

Shelf Life: 3 years from the date of Manufacturing.

Presentation:

Ref. 90010

Intro Pack: 2 x 1.2ml Syringe, 2 x Applicator tips.

Trial Pack: 1 x 1.2ml Syringe, 2 x Applicator tips.

Ref. 90011

Economy Pack: 4 x 1.2ml Syringe, 4 x Applicator tips.

Disposal conditions: To be disposed off based on the prevailing rules of the country in which it is used.

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UDI Symbol for "UNIQUE DEVICE IDENTIFIER"

LOT Symbol for "BATCH CODE" Symbol for "USE-BY DATE" Symbol for "NON STERILE" Symbol for "KEEP DRY" \Lambda Symbol for "CAUTION" 🔃 Symbol for "CONSULT INSTRUCTION FOR USE" 🔃 REF Symbol for "CATALOGUE NUMBER" ECIREP Symbol for "AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY/EUROPEAN UNION"

Symbol for "DO NOT USE IF PACKAGE IS DAMAGE" "Symbol for "KEEP OUT OF THE REACH OF CHILDREN" MI Symbol for "MANUFACTURER"

Symbol for "TEMPERATURE LIMIT" 🌋 Symbol for "KEEP AWAY FROM SUNLIGHT" MD Symbol for "MEDICAL DEVICE"

The material has been developed solely for professional dental use. Application should be carried out strictly according to the instruction for use. Liability cannot be accepted for damages resulting from failure to observe the instructions of the stipulated area of applications. The user is responsible for testing the material for its suitability and use for any purpose not explicitly stated in this instruction sheet. Description and data constitute no warranty of attributes and are not binding. For feedback, complaints and reporting of unexpected events contact customer care.