GC AMERICA REVOTEK LC Composite Resin for Temporary Restoration Instructions

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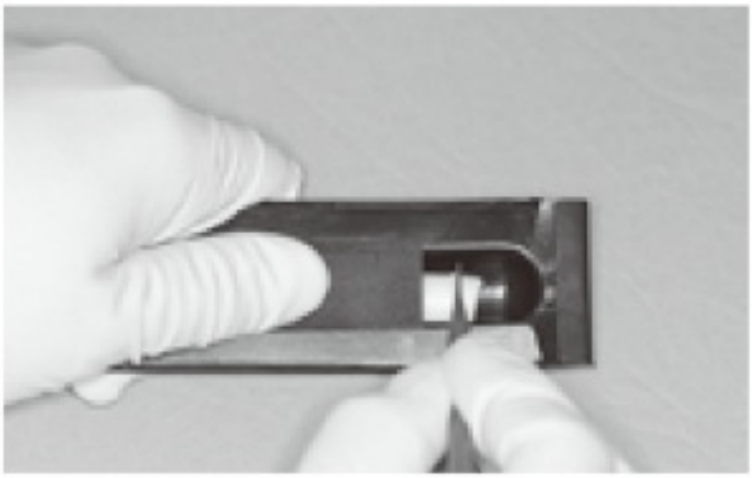
LIGHT-CURED RESIN FOR TEMPORARY CROWN, BRIDGE, INLAY & ONLAY
REVOTEK LC is a new light-cured single-component sculptable composite resin for temporary inlays, onlays, crowns and bridges.
For use only by a dental professional in the recommended indications.

Contents

DIRECT METHOD A

A-1



A-2

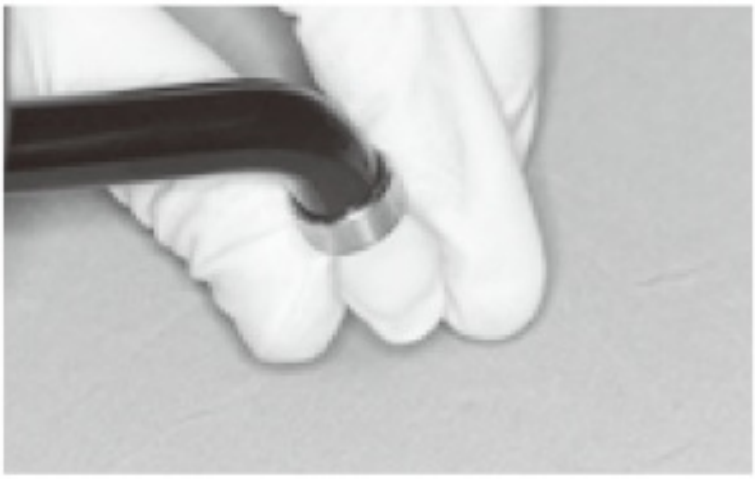
A-3a

A-3b

A-4

A-5

A-7



A-8

A-9

A-10

RECOMMENDED INDICATIONS

Fabrication of temporary crowns, bridges, inlays and onlays.

CONTRAINDICATIONS

Avoid use of this product in patients with known allergies to methacrylate monomer or methacrylate polymer.

DIRECTIONS FOR USE

DIRECT METHOD (in the patient's mouth)

A. Temporary Crowns & Bridges

1. Transfer of putty stick to the storage case Transfer putty stick from the aluminum foil pack into the storage case provided in the Introductory Set.
   Note:
   1) When putty stick is transferred to the storage case or is dispensed, handle with care in order to prevent contamination.
   2) If the storage case is used repeatedly, fine abrasion fragments may be produced from the lid because of the structure of the case. When paste is replaced, make sure that the inside of the case is clean. If it is dirty, clean

with cotton moistened with alcohol.

2. Dispensing material Dispense the required amount of material using the spatula. Adjust the shape of paste with gloved fingers to allow easy placement onto the abutment. To soften the material, lightly knead several times with the fingers.

   Note:

   1) Do not warm up before use. The material will become sticky, making it much more difficult to handle.

   2) Do not knead excessively, or the material will become sticky. 3) After dispensing, immediately close the storage case to protect the material from light.

3. Preparations for pressing material onto the abutment Make preparations in such a way as to ensure that the mass of material fits into the space between the abutment and the adjacent tooth. It is effective to shape the material in advance so that it goes into the space easily (Picture A-3a), or to put another paste in the space before the mass is pressed onto the abutment (Picture A-3b).

   Note:

   If any undercuts are present on the abutment, block out with wax before placing material.

4. Pressing material onto the abutment Press the material onto the abutment and roughly contour with the fingers or spatula.

   Note:

   Apply COCOA BUTTER or Vaseline to the fingers or spatula to help shape the material more easily and to make the surfaces glossier. For additional application of material, temporarily light cure and remove the coated surface using a laboratory carbide bur, etc.

5. Shaping material: Step 1

   Let the patient bite softly to register the occlusal surface and adjust occlusion. Also adjust and contour the margin of the buccal surface.

6. Shaping material: Step 2

   Adjust the margin again as necessary, and contour the proximal and lingual surfaces. Using an appropriate instrument, remove any excess material, particularly from interproximal spaces.

   Note:

   1) If shaping the material takes a long time, it may become sticky. In this case, apply COCOA BUTTER or Vaseline to the fingers or instrument. In cases where additional application of material is needed, temporarily light cure and remove the coated surface using a laboratory carbide bur.

   2) Any material remaining after shaping should not be returned for storage because it has been exposed to ambient light. Dispose of it according to normal practice.

7. Temporary light curing Temporarily light cure the restoration in the patient's mouth in order to prevent possible deformation during removal from the mouth. Light cure all surfaces of the crown or unit for a combined total of 10 seconds with Halogen/LED (> 700 mW/cm2). **Note:**

   1) Make sure that no excess material remains in interproximal spaces before light curing. Any material remaining will make it difficult to remove the temporary restoration from the mouth.

   2) Remove and trial fit the temporarily light cured restoration perpendicular to the abutment.

8. Final light curing Perform final polymerization outside the patient's mouth. Light cure each of the buccal, proximal, occlusal and lingual surfaces for 20 seconds with Halogen/LED (> 700 mW/cm2). When using a tabletop fluorescent light curing unit (LABOLIGHT LV-III or equivalent), light cure for at least 3 minutes.

   Note:

   1) When using a hand held type of light curing unit, be sure to light cure the internal surface of each crown or

unit for the above designated time.

2) When using a hand held type of light curing unit*, the range of effective polymerization depends on the cross sectional area of the light guide. If the resin restoration is larger than that, light cure in sections for effective polymerization.

3) Too short an irradiation time will result in incomplete hardening and possible discolouration.

Irradiation time and Depth of cure

	1 mm	2mm	3mm	4mm
Halogen/LED (> 700 mW/cm2)	–	–	10 sec.	30 sec
High power LED (more than 1200 mW/ cm2)	–	5 sec	10 sec.	20 sec.
LABOLIGHT LV-ill	30 sec.	1 min.	3min.	15 min.

Note: 20 sec. with Halogen light – 3.5 mm

9. Correction of contour, finishing and polishing Correct the temporary restoration using a laboratory carbide bur or silicone point. For an external addition, use REVOTEK LC. For an internal addition, use a self-curing resin (UNIFAST Trad, ALIKE), a light-cured resin (UNIFAST LC) or a flowable composite according to its instructions for use. Polish with a felt or chamois wheel to provide a glossy and beautiful appearance.

   Note:

   1) It is recommended to use a laboratory carbide bur to grind the hardened restoration. When using a fine diamond bur such as GC SMOOTH CUT, or a steel bur, first remove the unpolymerized layer with a laboratory carbide bur or alcohol to prevent the diamond or steel bur from clogging.

   2) Before UNIFAST Trad, Alike or UNIFAST LC is additionally poured onto the inside of the restoration, drill a hole into the occlusal or buccal surface to allow discharge of excess resin so that the temporary restoration can be properly seated
10. Completion Cement the completed temporary restoration using FREEGENOL TEMPORARY PACK or equivalent temporary cement.
11. Repair If needed, the cemented temporary restoration can be repaired in the patient's mouth using REVOTEK LC or a self-curing resin (UNIFAST Trad, ALIKE), a light-cured resin (UNIFAST LC) or a flowable composite according to its instructions for use.

    a. Remove a layer of the surface to be repaired using a laboratory carbide bur. For optimal results, apply a resin bonding agent to the area and dry with an air syringe.

    b. Place material over the area, shape, cure and polish.

B. Temporary Inlays & Onlays

1. Transfer of putty stick to the storage case Follow instructions as described under A1 above.
2. Dispensing material Follow instructions as described under A2 above.
3. Preparations for applying material into the inlay cavity Block out undercuts with a (VLC) glass ionomer cement. Apply COCOA BUTTER or Vaseline to all surfaces of the preparation, including the (VLC) glass ionomers base / liner.
4. Pressing material into the inlay cavity Press the material into the cavity and roughly contour with the fingers or

spatula. Note: Apply COCOA BUTTER or Vaseline to the fingers or spatula to help shape the material more easily and to make the surface glossier. For additional application of material, temporarily light cure and remove the coated surface using a laboratory carbide bur, etc.

5. Shaping material : Step 1 Let the patient bite softly to register the occlusal surface and adjust occlusion.
6. Shaping material : Step 2 Adjust the margin as necessary. Using an appropriate instrument, remove any excess material.

   Note:

   1)If shaping the material takes a long time, it may become sticky. In this case, apply COCOA BUTTER or Vaseline to the fingers or instrument. In cases where additional application of material is needed, temporarily light cure and remove the coated surface using a laboratory carbide bur.

   2) Any material remaining after shaping should not be returned for storage because it has been exposed to ambient light. Dispose of it according to normal practice. 3)For ease of removal, you can insert a pin into the inlay.
7. Temporary light curing Temporarily light cure the restoration in the patient's mouth in order to prevent possible deformation during removal from the mouth. For curing time recommendations and notes see above under A7.
8. Final light curing Perform final polymerization outside the patient's mouth. For curing time recommendations and notes see above under A8.
9. Correction of contour, finishing and polishing For instructions and notes see above under A9.
10. Completion Cement the completed temporary restoration using FREEGENOL TEMPORARY PACK or equivalent temporary cement.
11. Repair For instructions see above under A11.
12. Removal from the mouth Cut the inlay with an appropriate bur.

INDIRECT METHOD (on the stone model)

1. When a REVOTEK LC restoration is made on the stone model, apply a small amount of COCOA BUTTER or Vaseline to the area which will come in contact with the product.
2. Follow instructions described in I. DIRECT METHOD.

COMBINED USE WITH READY-MADE PLASTIC AESTHETIC TEMPORARY CROWNS

1. When a plastic full temporary crown is used

   a. Apply a resin bonding agent to the internal surface of the plastic full temporary crown.

   Note:

   More stable adhesion can be obtained by roughening the internal surface of the full temporary crown with a paper cone shaped point or other instrument before application of the resin bonding agent.

   b. Fill the temporary crown with REVOTEK LC and press it onto the abutment.

   c. Apply light to the outside of the crown for temporary polymerization as described in I. DIRECT METHOD, A7 Temporary light curing.

   d. After removing the crown from the patient's mouth, follow instructions described in I. DIRECT METHOD, A concerning final light curing, correction of contour, finishing, polishing and completion.
2. When a plastic veneer-like partial temporary crown is used

   a. Apply a resin bonding agent to the internal surface of the plastic veneer-like partial temporary crown.

   Note:

More stable adhesion can be obtained by roughening the internal surface of the partial temporary crown with a paper cone shaped point or other instrument before application of resin bonding agent.

b. Press REVOTEK LC onto the abutment. Then, press the partial temporary crown over the material, shape it and for temporary polymerization apply light to the buccal and lingual surfaces in that order as described in I. DIRECT METHOD, A7 Temporary light curing.

c. After removing the crown from the patient's mouth, follow instructions described in I. DIRECT METHOD, A concerning final light curing, correction of contour, finishing, polishing and completion.

COMBINED USE WITH READY-MADE TRANSPARENT PLASTIC STRIP CROWN FORMS

1. Adjust the cervical area of the plastic strip crown form using crown scissors and burs, and make an escape hole in the occlusal or buccal surface. Trial fit it in the patient's mouth.
2. Lightly knead REVOTEK LC several times. Fill the strip crown form with material and press it to the abutment. Remove excess material.
3. For temporary polymerization, apply light to all surfaces of the crown form as described in I. DIRECT METHOD, A7 Temporary curing.
4. After removing the crown form from the patient's mouth, for final polymerization apply light to each surface as described in I. DIRECT METHOD, A8 Final light curing. Remove the crown form using a sharp instrument, and trim and finish the temporary restoration. Seat in the patient's mouth using the temporary cement.

STORAGE

Recommended for optimal performance, store in a cool and dark place away from high temperature and direct sunlight or intense ambient light (4-25°C)(39.2-77.0°F).

SHADE

B2 (based on Vita® shades)
Vita® is a registered trademark of Vita Zahnfabrik, Bad Säckingen, Germany.

PACKAGE

1. Introductory Set
   Pack of putty stick 16 g, storage case (1), plastic spatula No. 2 (1)
2. Refill
   3 packs of putty stick 16 g

CAUTION

1. In case of contact with eyes, flush immediately with water and refer to a physician.
2. Do not use or store near fire.
3. Take care not to swallow the paste.
4. Do not mix with other materials.
5. When using a light curing unit, wear eye protection glasses. Do not look directly into the light.
6. In rare cases the product may cause sensitivity in some people. If such any reactions are experienced,

discontinue the use of the product and refer to a physician.

7. Personal protective equipment (PPE) such as gloves, face masks and safety eyewear should always be worn.

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.gceurope.com** or for The Americas **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.

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 listed in this instruction for use, please 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/contacts_en** as well as to our internal vigilance system: **vigilance@gc.dental** In this way you will contribute to improve the safety of this product.

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Documents / Resources

	GC AMERICA REVOTEK LC Composite Resin for Temporary Restoration [pdf] Instructions REVOTEK LC, Composite Resin for Temporary Restoration, REVOTEK LC Composite Resin for Temporary Restoration, Temporary Restoration