

## Instructions for Use – EasyGum Composite Strips (for All-in-One Bond, see page 4)

### Indications

Harvest EasyGum™ is indicated for adding texture and color to the gingival area of a dental base for removable dentures. This composite is bondable to typical acrylic denture resins used for making bases, such as polymethylmethacrylate (PMMA), as well as metals and ceramics (zirconia). The EasyGum™ Strip is an alternative to the laborious method of using a shaded composite paste to manually build up and model visible gingival surfaces to look similar to natural gingival issues. Additional texturization and coloration can be added using various shades of EasyGum™ Modifiers. The Strip is bonded to the base utilizing EasyGum™ Bond, and after any final detailing is to be cured utilizing a typical light curing device. EasyGum™ is intended to be used by dental lab technicians and approved by licensed practitioners before being provided to the patient.

### Contraindications:

EasyGum™ may only be used for its intended purpose. Any other use is strictly prohibited, and sole responsibility lies with the user. This product must not be used in patients with known allergies to any of its ingredients.

### Composition:

EasyGum™ Strip: Urethane methacrylate, Di methacrylate, trimethacrylate, pyrogenic silica.

EasyGum™ Modifier: Urethane methacrylate, dimethacrylate, trimethacrylate, pyrogenic silica.

EasyGum™ Bond: Refer to Adhesive Instructions for Use.

### Hazard and Precautions:

#### Danger:

- Causes skin irritation
- May cause an allergic reaction
- Causes serious eye irritation
- Wear protective gloves, protective clothing, eye protection, face protection

#### First Aid:

- If on skin, wash with plenty of water
- If in eyes, rinse cautiously with water for several minutes. Remove contact lenses, if possible, and continue rinsing for several minutes
- If swallowed, immediately call poison center.

#### Caution:

Any unauthorized changes to the process, workflow, materials, equipment, parameters, or software may result in a device that is out of specification and is not recommended. Contact [harvest@harvestdental.com](mailto:harvest@harvestdental.com) for a current list of compatible components.

## Use Instructions

### A. Bonding Instructions for EasyGum™ Bond

- A. Sandblasting with aluminum oxide to enhance adhesion is required for long term bond strength.
- B. Thoroughly clean to remove any dust and debris, then Dry.
- C. Dispense a drop of EasyGum™ Bond into the cavity of the enclosed mixing well. Using a bristle brush applicator, apply 2 coats of EasyGum™ Bond to the entire preparation to be bound.
- D. DRY THE SURFACE THOROUGHLY - Do not blast the surface with air or use suction as this could remove material from the surface and lead to debonding.

**E. LIGHT ACTIVATE - CAUTION EasyGum™ BOND must be activated with a handheld dental activation light that is 430nm ~ 510nm in wavelength. Light-activate for 20 seconds.**

EasyGum BOND is a revolutionary (All-in-One) light cured bonding agent that bonds to Nano-Ceramics, PMMA, Metal and Zirconia, thus requiring a higher wavelength (430nm – 510nm) than other common light cure composite bonding agents.

**Note:** For the full EasyGum Bond IFU, see below Instructions for Use – All-in-One Bond

### C. EasyGum Application

Select EasyGum™ with the desired shading that, when cured, matches natural gingival issues. Cut the Strip to roughly the overall size needed and apply to the base with minor pressure to attain basic adhesion.

### D. EasyGum Trimming and Finishing

Trim the Strip to the desired shape, and finish with typical hand tools to include the appropriate features such as the gingival line and interdental papilla. EasyGum™ Modifiers can be applied and modelled for additional texture and enhanced coloration to closely resemble the natural gingiva.

### E. Light Curing EasyGum™ Strips, Pink Modifiers & Intense Modifiers

Light cure using a dental light curing unit according to the following table and the light manufacturer's instructions:

Light-Curing Unit	Halogen	LED Handheld	LED Cure Box*
Light-Curing Duration	40 Seconds	20 Seconds	40 ~ 120 Seconds
Wavelength	400-500nm	440-490nm	440-490nm
Light Intensity	≥ 500mW/cm2	≥ 1000mW/cm2	≥ 1000mW/cm2

**Note:**

- \*1. If you are curing with a dental cure box, the Light-curing duration will increase relative to the distance of the light source to the prosthetic.
- 2. When EasyGum is fully cured, it will not be sticky or tacky. The surface of EasyGum should be fully hardened. Press EasyGum with a metal instrument and check the surface for hardness.
- 3. In cases where the gingival area is large and using a directed light source, light-cure the Strip in segments.

## F. Contouring and Polishing

After light-curing, contour, and polish EasyGum™ as needed using typical methods.

### Storage Conditions, Expiration Date and Reuse Material:

EasyGum™ Strip and Modifiers must be stored in their original containers between 41°F (5°C) and 86°F (30°C) and protected from direct sunlight. Keep containers closed when not in use.

The expiration date of the product is displayed on the container. Use after the expiration date is strictly prohibited and could lead to finished devices with inadequate properties.

### Disposal:

Dispose of EasyGum™ Strip and Modifiers according to local regulations. Materials should be fully cured/dried prior to disposal.

### Disinfection and Sterilization:

If necessary, finished devices made using EasyGum™ may be cleaned and disinfected using a 70% ethanol solution in water. Devices made using this product are not to be sterilized.

### Labeling:



**Rx Only**

Caution: Federal law restricts this device to sale by or on the order of a dentist



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(en) Instructions for Use – All-in-One Bond (for EasyGum Composite Strips, see page 1)

## Description

EasyGum<sup>™</sup> Bond is a single bottle bonding system for use in bonding light-cured composite (Harvest Dental EasyGum<sup>®</sup>) to polymethylmethacrylate (PMMA), metal and ceramic (zirconia) dental prostheses. EasyGum<sup>™</sup> Bond combines the etchant, primer and bonding resin into a single component. Through the elimination of components and steps within the application protocol, EasyGum<sup>™</sup> Bond is extremely easy to apply and has little to no technique sensitivity. EasyGum<sup>™</sup> Bond provides: easy application, consistent results, and best in class bonding in a single bottle.

## Indications for use:

Indirect Restorations: bonding light-cured composite (Harvest Dental EasyGum<sup>®</sup>) to polymethylmethacrylate (PMMA), metal and ceramic (zirconia) dental prostheses.

## Storage:

Protect from sunlight. Store between 2°C/36° F and 30°C/86° F. See individual component labels for specific expiration dates.

## Cautions:

Avoid contact with eyes. If the material comes into contact with the eyes, flush with copious amounts of water and seek medical attention. Unpolymerized resins may cause skin sensitization in susceptible persons, in case of contact with the skin, wash thoroughly with soap and water.

## General Instructions for EasyGum<sup>™</sup> Bond:

- A. Sandblasting with aluminum oxide to enhance adhesion is required for long term bond strength.
- B. Thoroughly clean to remove any dust and debris, then Dry.
- C. Dispense a drop of EasyGum<sup>™</sup> Bond into the cavity of the enclosed mixing well. Using a bristle brush applicator, apply 2 coats of EasyGum<sup>™</sup> Bond to the entire preparation to be bound.
- D. DRY THE SURFACE THOROUGHLY - Do not blast the surface with air or use suction as this could remove material from the surface and lead to debonding.
- E. **LIGHT ACTIVATE – CAUTION: EasyGum<sup>™</sup> BOND must be activated with a handheld dental activation light that is 430nm ~ 510nm in wavelength. Light-activate for 20 seconds.**
- F. EasyGum BOND is a revolutionary (All-in-One) light cured bonding agent that bonds to Nano-Ceramics, PMMA, Metal and Zirconia, thus requiring a higher wavelength (430nm – 510nm) than other common light cure composite bonding agents.
- G. Continue procedure with EasyGum<sup>™</sup> Strip and Modifiers following EasyGum<sup>™</sup> Instructions For Use.

## Notes:

1. EasyGum<sup>™</sup> Bond is always light-activated before placing EasyGum<sup>™</sup>. Please make sure to use a handheld dental activation light that is 430nm ~ 510nm in wavelength.
2. Visit [harvestdental.com](http://harvestdental.com) for SDS.

**Labeling:**



**Temperature limits**



**Keep away from sunlight**



**Consult Instructions for Use**



**Do not use if package is damaged**



**Caution: Consult Instructions for Use**

**Rx Only**

**Caution: Federal law restricts this device to sale by or on the order of a dentist**

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