



Resin-Based Light-Cured Posterior Composite Restorative

KIT CONTAINS:

- 25 x .35g Single-Use Carpules

INDICATIONS FOR USE:

Composite restorative, light-cured, resin-based for use primarily in Class I and Class II restorations.

CONTRAINDICATIONS:

This product should not be used where patients have known hypersensitivity to methacrylate monomers.

| Shade | SHADE INFORMATION | | |
|--------------|-------------------|--------------|-----------------|
| | Catalog Number | Lumin/Vacuum | Trubyte/Bioform |
| Light | 50-501 CB | A1 | 51,59 |
| Universal | 50-502 CB | A2 | 65,66,67 |
| Gray/Brown | 50-503 CB | C3/D3 | 91,92,93 |
| Yellow/Brown | 50-504 CB | A3.5/B3 | 55,56,68 |

PROPERTIES OF THE CURED RESTORATIVE

(Technical information required by American Dental Association revised Specification No. 27):

- Principal organic component of material: bis-GMA and aliphatic dimethacrylate resin blend
- Particle size of inorganic filler: 100% below 20 microns, 90% below 10 microns, 50% below 2 microns
- Volume % of filler in the restorative material: 66%

OUTSTANDING FEATURES OF THE MATERIAL

- Exceeds the requirements of the newest ADA and ISO specifications for composite restoratives
- High filler content contributes to low shrinkage, low water sorption, low coefficient of thermal expansion and good wear resistance
- Excellent X-ray opacity for future diagnosis
- Very good polishability
- Optimized consistency for ease of handling
- Superior aesthetics due to a well-balanced opacity and availability of four shades
- Outstanding color stability
- Virtually non-existent oxygen inhibited layer

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



For technical information, call or write:

Quality Management System Certified to

ISO 13485:2016



SCIENTIFIC PHARMACEUTICALS, INC.

3221 PRODUCER WAY • POMONA, CALIFORNIA USA 91768

PHONE: (800) 634-3047 • (909) 595-9922

FAX: (909) 595-0331 • E-MAIL: scipharm@msn.com

WEBSITE: <http://www.scipharm.com>

6728 - P1/2

Printed in U.S.A.

092624

...chemistry working for medicine and dentistry...

CLINICAL PROCEDURES

Cavities are prepared in the conventional manner. In deep restorations, the use of calcium hydroxide base is recommended. Sealing of the dentin with cavity varnishes compatible with composite restoratives is recommended; best marginal integrity is achieved by etching the enamel surrounding the cavity and applying bonding agent prior to inserting the restorative paste.

Class I: Etch the enamel surrounding the cavity with Enamel Conditioner for one minute. Apply Bonding Agent over the enamel margins, and optionally, over the dentin and cure. Place restorative material with a tapping movement and cure in layers of 2-4mm deep, depending on the shade of the restorative and light intensity of the curing instrument.

A typical Class II restoration procedure consists of the following steps: (1) Tooth is pre-wedged on one or both sides depending on the eventual box form. The decayed dentin, as well as any previous restoration is removed; (2) The pulpal floor and axial walls are covered with base; (3) The margins are prepared by slightly beveling the occlusal surfaces and producing slight flares on interproximals. A 12-fluted finishing bur or fine finishing diamond is recommended; (4) The matrix band is placed (preferably 0.0015") followed by re-wedging. After the band is secured by the wedge, it should be loosened to allow for full contours when packing the restorative. The contact area is heavily burnished; (5) The enamel is etched, thoroughly rinsed and dried; (6) Bonding Agent is applied over the etched enamel and, optionally, over the dentin and cured; (7) The restorative is inserted in box form to the height of pulpal floor and cured for 20 seconds. A small amount of bonding agent on instrument may facilitate placement; (8) The material is applied to the remaining preparation and cures in a manner described above. (9) Matrix band and wedge are removed and each interproximal area is cured for 20 seconds; (10) The restoration is finished in the conventional way.

PHYSICAL PROPERTIES

| PHYSICAL PROPERTIES OF THE PRODUCT | | |
|------------------------------------|--|---|
| Test | ADA/ISO Requirement | CuRAY-II® Test Results |
| Ambient Light Sensitivity* | Material will show no signs of polymerization after exposure to 10,000 lux light for 60 sec. | Pass |
| Depth of Cure* | >4.5mm | 5.5mm |
| Flexural Strength* | S>N | S=120 MPa (17,400 PSI) N=91.6 MPa (13,300 PSI) |
| Water Sorption* | Not more than 40 µg/mm ³ | In-Process |
| Water Solubility* | Not more than 7.5 µg/mm ³ | In-Process |
| Shade* | Match color standard | Pass |
| Color Stability* | 1mm sample disk will show no more than slight discoloration. Virtually no discoloration after exposure to 5,000 K color, 10,000 lux light source | Complies |
| Radio Opacity* | Opacity of 1mm sample disk shall be greater than 2mm 99.5% pure aluminum plate. | Complies |
| Compressive Strength** | Not Specified | 273 MPa (39,600 PSI) |
| Tensile Strength** | Not Specified | 39.7 MPa (5,760 PSI) |

* Following ADA/ISO specifications for test procedures.

** Test not required for certification; no minimum requirement is set.

STORAGE AND SHELF-LIFE

When stored at temperatures not exceeding 75°F (24°C), the material has a shelf-life of 2 years.