Manufactured in U.S.A. by:

SCI-PHARM®

Anterior/Posterior Restorative, Paste/Paste Type
Sci-Pharm Catalog No. 50-04

TECHNICAL BULLETIN
Instructions

Anterior/Posterior Composite Restorative, Paste/Paste Type with Bonding Agent

A Self-Cured Radio-Opaque Resin-Based Dental Restorative Material

INDICATIONS FOR USE:

For use in Class III, IV, and V restorations, and for limited use in posterior restorations where aesthetics are of primary importance.

CONTRAINDICATIONS:

This product should not be used where patients have known hypersensitivity to methacrylate monomers. Do not apply on very sensitive teeth or in contact with the pulp.

KIT CONTAINS:

- Cat. No. 50-041: Restorative Paste, Part A, 14g
- Cat. No. 50-042: Restorative Paste, Part B, 14g
- Cat. No. 50-013: Enamel Conditioner, 13cc
- Cat. No. 50-043: Bonding Agent, Part A, 3g
- Cat. No. 50-044: Bonding Agent, Part B, 3g
- Accessories & Instructions

Cat. No. 50-04

OUTSTANDING FEATURES OF THE MATERIAL

- High filler content
- High mechanical strength
- High wear resistance
- Long shelf-life
- Excellent marginal adaptation
- Low shrinkage
- Low pulp irritation potential
- Excellent x-ray opacity
- Good polishability
- Resistance to staining
- Excellent aesthetics
- Bonds to enamel

CAUTION

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

GENERAL INFORMATION

Among the different forms of self-cured composite restorative materials, the paste/paste type is the most popular because of its ease of handling and uniformity of mix consistencies. The paste/paste type materials are, however, known to have two major limitations:

1. They need to be stored under refrigeration.
2. Their use is usually limited to "non-bonding" type restorations where the geometry of the cavity provides conditions for mechanical retention.

Scientific Pharmaceuticals has developed a restorative that overcomes these limitations. Our material may be stored under room temperature, not exceeding 73°F (23°C), for eighteen months.

The Bonding Agent included in the kit contributes to improved marginal adaptation through bonding to conditioned (etched) enamel. It also allows so-called "adhesive restorations"; for example, Class IV incisal edge restorations, where retention is based on bonding to etched enamel. It may also be used for thinning the pastes, if desired for a particular application, without affecting the setting characteristics.

However, the most important advantage of the Sci-Pharm restorative results from its remarkable set of physical properties. Its high filler content contributes greatly to reduced shrinkage, low water sorption, increased mechanical strength and hardness, and improved wear resistance. The proprietary resin blend used in the Sci-Pharm restorative constitutes another important factor in achieving true and long-awaited progress in the properties of composite restoratives.

Until now, composite restoratives were limited in their use almost exclusively to anterior restorations. Their high polymerization shrinkage and, most importantly, inadequate wear resistance virtually precluded their use in posterior restorations. However, because of its advanced set of properties, Sci-Pharm's restorative can be judiciously used for these purposes.

PHYSICAL PROPERTIES

PHYSICAL PROPERTIES OF THE PRODUCT		
Property	**Specification**	**Sci-Pharm Results**
Flexural Strength	**Not less than 80 MPa	105.28 MPa
Compressive Strength	No specification	275 MPa (39,880 PSI)
Hardness (Barcol)	No specification	>80
Coefficient of Thermal Expansion	No specification	31 x 10^{-6} cm/°C
Opacity/Translucency Factor (C^{70})	*0.35 - 0.55	0.40
pH	No specification	Neutral
Water Sorption	**Not more than 40 µg/mm^3	13 µg/mm^3
X-ray Opacity	**Equivalent to the same thickness of aluminum	Complies
Color Stability	**No more than slight color change	Complies
Working Time at 23°C (73°F)	**Not less than 90 seconds	100 seconds
Setting Time 37°C (98.6°F)	**Not more than 5 minutes	2.5 minutes

NOTE: Table results are based on ADA (*) and ISO (**) testing and specifications.

CLINICAL PROCEDURES

Cavities are prepared in the conventional manner. In case of direct pulp exposure, the use of calcium hydroxide-type base is indicated. If pulp is not exposed, but the thickness of remaining dentin is less than 1mm, the use of a light-cured cavity liner, such as Sci-Pharm's *Fluoroseal*® (Cat. No. 75-03), is strongly recommended. In all other cases, the application of composite compatible dentin sealer over the exposed dentin surfaces, such as Sci-Pharm's *Universal Cavity Varnish* (Cat. No. 70-03), will alleviate post-operative sensitivity. Best marginal adaptation is achieved by etching the enamel surrounding the cavity and applying the Bonding Agent prior to inserting the restorative into the cavity.

SPECIAL RECOMMENDATIONS

Class I: Slightly overfill the cavity. Place plastic strip over the restoration and instruct the patient to bite down for one minute. Remove excess restorative and trim the flash. The restoration will be ready to finish five minutes after inserting the paste into the cavity.

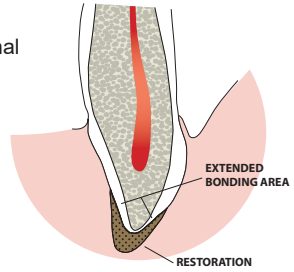
Class III: The use of a plastic strip is recommended for interproximal separation and as a matrix. Compress the restorative in the cavity with the strip. Hold the strip for three minutes until the restorative sets. Trim and finish after five minutes.

Class IV: Incisal edge restorations may be prepared with or without the use of crown forms. The use of the Bonding Agent over etched enamel is a necessary step in this kind of restoration. To provide adequate bonding strength, a relatively large area of enamel should be etched and primed with Bonding Agent. For this reason butt joints are generally not recommended. Greatly improved retention is achieved by extending the bonding area 2-3 mm around the fracture (see illustration).

Retention may also be increased by beveling or tapering the adjacent enamel, or by making small undercuts on the lingual side of the tooth. In some situations the use of pins placed in the dentin may be necessary. The use of crown forms is especially recommended in larger restorations. The crown form should be removed no sooner than five minutes after it is seated.

A typical Class IV restoration procedure consists of the following steps:

1. Prophylaxis of the tooth (or teeth) to be restored, followed, if necessary, by operational preparation of the enamel for better crown form acceptance.
2. Prefitting of the crown form.
3. Application of Enamel Conditioner to the area to be bonded, followed in two minutes by washing and drying.
4. Preparation of the Bonding Agent mix and application to the etched enamel.
5. Preparing the restorative mix and filling the crown form.
6. Seating the crown form on the tooth.
7. After at least five minutes, cutting and removing crown form.
8. Finishing.



Class V: After conventional cavity preparation, fill the cavity with restorative paste and place the cervical matrix. After four minutes, remove the matrix. Trim and finish after five minutes.

MIXING AND APPLICATION INSTRUCTIONS

Enamel Conditioner - Using a cotton pledget, apply Enamel Conditioner to enamel and wait 30-45 seconds. Rinse conditioner and evacuate. Dry with oil-free air or with any commercial dental drying agent.

CAUTION: Avoid contact with soft tissue or dentin. If accidental spill occurs, wash immediately.

After drying, the properly conditioned (etched) area should have a chalky-white appearance. Highly mineralized teeth may require an additional two minute etching to obtain this effect.

Bonding Agent - Dispense an equal number of drops of Part A and Part B liquids into a mixing well. Mix for five seconds with a disposable brush and apply a thin layer over the dry, etched enamel. After 90 seconds, the

material will set, leaving a very thin film of uncured liquid on the surface that will provide better adhesion to the restorative applied thereafter.

Restorative Material - Using opposite ends of a disposable spatula, dispense Part A and Part B pastes onto a mixing pad. Equal amounts of Part A and Part B pastes in the mix will result in a shade that gives a good match with the majority of teeth.

Spatulate about 20 seconds to obtain a mix of uniform color. Place the restorative with the spatula or with a composite syringe.

The working time from the start of mixing is approximately 100 seconds at 73°F (23°C). If longer working time is desired, mix the material when cold. For example, mix the pastes shortly after removal from the refrigerator, or mix on a cold mixing slab. If matrix bands have been used, they may be safely removed four minutes after placement of the restorative. Crown forms used in larger Class IV restorations should be removed no sooner than five minutes after placement. Restorations may normally be trimmed and finished five minutes after placement. Finishing is accomplished using conventional composite finishing tools, polishing wheels, or polishing pastes, such as Sci-Pharm's *Luster*® (Cat. No. 50-05).

STORAGE AND SHELF-LIFE

Store at temperatures not exceeding 73°F (23°C). When stored under such conditions, the shelf-life of the material is eighteen months. Refrigerate when the material is not in use (for example, overnight and on weekends). When cold, the material has a stiffer consistency. For easier handling, remove from the refrigerator at least 15 minutes prior to use.

50-04 KIT: REORDER COMPONENTS AVAILABLE

ITEM	CATALOG NO.
Restorative, Part A, 14g	50-041
Restorative, Part B, 14g	50-042
Bonding Agent, Part A, 3g	50-043
Bonding Agent, Part B, 3g	50-044
Enamel Conditioner, 13cc	50-013
Disposable Spatulas, 100 Count	30-10
Disposable Brushes, 80 Brushes and Handle	30-30
Mixing Pads, 5 Pads/80 Sheets Each	30-70

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Quality Management System Certified to
ISO 13485:2016

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