

FOR THE USE OF DENTAL PROFESSIONALS

RestoFill®

Composite

Restorative Material - Light Cure Radio Opaque ISO 4049

MICROHYBRID

PRODUCT DESCRIPTION

RESTOFILL is a microhybrid, light cure, radio opaque composite. It offers both strength and aesthetics, & is designed to suit both anterior and posterior restorations. **RESTOFILL** is available in most widely used shades of A1, A2, A3, A3.5, B1 & B2 to match the different tooth colours. **RESTOFILL** is also available in universal opaque shade of OA2.

RESTOFILL is packed in a 4 g colour coded "twist syringe".

RESTOFILL composite contains Bis-GMA/TEGDMA matrix. **RESTOFILL** has barium glass fillers with fumed silica. The total filler content is 79% w/w, with an average particle size of about 0.7 micron.

RESTOFILL contains both the photo-initiator and the activator for polymerization to commence once exposed to visible light. Depth of cure of **RESTOFILL** is minimum 2 mm.

INTENDED USE / INDICATION FOR USE

Dental restorative material for direct and indirect restoration of cavities in teeth. Micro hybrid light cure radio opaque restorative composite for:

- Direct anterior and posterior restorations
- Core build-ups
- Indirect restorations (including inlays, onlays)

CONTRAINDICATIONS

Sensitivity: Some patients may experience sensitivity following restoration as the product contains acrylates.

The risk of sensitivity can be minimized by the following measures:

- Remove minimal tooth structure while preparing the cavity for restoration.
- Use rubber dam for isolation.
- Use a glass ionomer or calcium hydroxide cavity liner/base on dentine to avoid pulp irritation.
- Place restorative material in increments, curing each increment separately.
- Adjust occlusion carefully.

DIRECTIONS FOR USE

(For best results, use **RESTOFILL** composite with *Eazetch* and *Stedbond*)

- The ideal temperature for optimum handling property is between 18°C and 24°C. If refrigerated, make sure to bring the product to the above mentioned temperature atleast one hour before use.
- Isolate and prepare the tooth to be restored.
- For dentine conditioning, apply and expose *Eazetch* for 10 seconds; for etching the enamel, apply and expose for 30 seconds; for etching fluorosed enamel, apply and expose for 50-60 seconds.
- Rinse thoroughly for 1 minute and remove excess water. Do not dry the tooth completely.
- Apply *Stedbond* as per the Directions for use provided in the pack insert.
- Place appropriate base/liner in the cavity, if required.
- Fill the cavity with sufficient quantity of appropriate shade of **RESTOFILL** and light cure for 20 seconds at a wave length of 400-500 nm (blue light) and an intensity of 500 mW/cm². For bigger cavities, place **RESTOFILL** in increments of not more than 2 mm, curing each increment separately for 20 seconds at a wavelength of 400-500 nm (blue light) and an intensity of 500 mW/cm².
- Check for high points and polish at the end of the restorative procedure.

PRECAUTIONS

- It is advisable to wear an eyewear while using **RESTOFILL**. **RESTOFILL** contains acrylates which are found to cause allergic reactions in small percentage of population.
- To reduce the risk of allergic response, minimize exposure particularly to uncured resins.

- Use of protective gloves and no-touch technique is recommended. Acrylates may penetrate commonly used gloves. If restorative material contacts glove, remove and discard the glove, wash hand immediately with soap and water and then re-glove.
- Avoid contact with oral mucosa, eyes and skin. If accidental contact or irritation occurs, flush immediately with sufficient amount of water. In case of eye contact or irritation, please consult a physician.

STORAGE

- Do not expose **RESTOFILL** to elevated temperature or intense light.
- Do not store **RESTOFILL** near eugenol-containing products.
- **RESTOFILL** is to be stored between 10°C and 30°C. For maintaining the consistency of the product, it should be refrigerated when not in use.
- Make sure that **RESTOFILL** is always kept closed when not in use.

SHELF LIFE

When stored between 10°C and 30°C, the product has a shelf life of 24 months from the month of manufacturing.












PACKING / CONTENT

Each pack contains 1 syringe x 4 g (2 ml) and a pack insert.


NOTE

The material is for the use of dental professionals only. Processing should be carried out strictly according to the instructions for use. Liability cannot be accepted for damages resulting from misuse or failure to observe the instructions including storage conditions. The user is responsible for testing the product for its suitability and use for any other purpose that is not explicitly stated in the instructions.

SYMBOLS

	Medical Device		Caution
	Lot No.		Manufactured by
	Instruction for Use		Date of Manufacture
	Storage Temperature		Date of Expiry
	Keep away from sunlight		Do not use if package is damaged
			Non Sterile

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