

RestorePLUS Bulk

Instruction For Use

Light curing, bulk fill composite. It is a radio-opaque polymer-based dental restorative material for posterior restorations, including occlusal surfaces. Radiopacity values (all shades) are $\geq 1\text{mm}$ if aluminium.

Product Name	RestorePLUS Bulk
Distributor	Perfection Plus Ltd
Address	6 Westwood Court, Brunel Road, Totton, Hampshire, SO40 3WX, UK
Phone No.	+44 (0) 2380 866 677

PRODUCT CODE - REF

PP010/1630 – RestorePLUS Bulk 4g Syringe A1 PP010/1640 RestorePLUS Bulk Capsules 20 x 0.25g A1
 PP010/1631 – RestorePLUS Bulk 4g Syringe A2 PP010/1641 RestorePLUS Bulk Capsules 20 x 0.25g A2
 PP010/1632 – RestorePLUS Bulk 4g Syringe A3 PP010/1642 RestorePLUS Bulk Capsules 20 x 0.25g A3

Classification (ISO 4049): Type 1, Class 2, Group 1

Intended Use: Dental restorative material

Use environment: Dental practice

Patient target group: People treated in the course of a dental procedure with no limitations in age or gender.

COMPOSITION

Methacrylate monomers (19% by wt.)

Inorganic fillers containing barium glass and mixed oxides (81% by wt. or 61.5% by vol.). Filler particle size: 0.02-2.5 μm with an average particle size of 1.0 μm .

Photo-initiators

Stabilizers

INDICATIONS

- Direct posterior restorations (Class I, II) including occlusal surfaces
- Cores build-ups
- Splinting
- Indirect restorations

SHADE SELECTION

Select the desired shade with Vita® shade guide in daylight conditions. For better shade determination, clean the teeth with pumice and water to remove surface stains. The shade should be selected with the tooth still moist.

APPLICATION

Prepare the cavity in the appropriate manner and following the requirements of the preferred technique. In case of pulp exposure, a calcium hydroxide lining should be applied. Avoid contamination of the treatment area from saliva or blood to produce optimal results. A rubber dam is recommended to keep the cavity area clean and dry. Conduct etching and bonding according to the chosen technique and following the corresponding instructions of use. RestorePLUS Bulk is compatible with all methacrylate dental adhesive systems.

• SYRINGE

(Take appropriate measures to avoid cross contamination between patients): Remove cap of syringe and using a suitable instrument place increments of up to 4mm into the preparation taking care to prevent voids. Replace cap immediately after use.

• UNIT DOSE (Single use)

Mount unit dose on appropriate applicator. Dispense directly onto the preparation or first onto a mixing pad and then manually insert on preparation. Place increments of up to 4mm taking care to prevent voids. Discard after use, do not re-use to avoid cross contamination.

Matrix strips may be used to minimize the amount of material used or for interdental wedges. Light cure keeping the tip of the light as close to the surface as possible, otherwise the curing depth may be reduced. Light cure each layer with a halogen, LED light ($\geq 400\text{mW}/\text{cm}^2$). Curing wavelength $470\pm 20\text{nm}$. Be aware that polymerization may be started by ambient lighting or the dental operating light.

Curing Times (Depth of cure: $\geq 4\text{mm}$)

-For lighter shades (e.g., A1, A2, A3): 20 seconds ($400\text{-}1000\text{mW}/\text{cm}^2$) / 10 seconds ($>1000\text{mW}/\text{cm}^2$)

-For darker shades (e.g., A3.5, B3): 40 seconds ($400\text{-}1000\text{mW}/\text{cm}^2$) / 20 seconds ($>1000\text{mW}/\text{cm}^2$)

Finishing

Contour with fine diamonds, stones or burs. Polish to high gloss with discs or rubber points. Inter-proximal finishing is accomplished by fine grit finishing strips.

PRECAUTIONS

- Use of protective gloves and a no-touch technique is recommended
- Do not use any resin to adjust viscosity of composite material
- Replace syringe cap immediately after use
- Neither store the composite material in proximity of eugenol containing products, nor let the composite come into contact with materials containing eugenol. Eugenol can impair the hardening of the composite and causes discoloration
- Avoid contact with skin and eyes. In case of contact, rinse immediately with plenty of water and consult a physician if necessary
- Seek immediate medical attention in case of ingestion
- Do not use after the use-by date

CONTRAINDICATIONS

Application of the above material is contraindicated:

- If a dry working field cannot be established
- If a patient is known to be hypersensitive or allergic to any of the ingredients

STORAGE

Store at 4-25°C (39-77°F). If temperature exceeds this, storing in refrigerator is recommended.

Caution: Do not freeze, do not expose to direct light or other heat sources. Return to room temperature before use. Keep material out of children's reach.

REPORTING OBLIGATIONS

Should a serious incident in relation to this product occur, it should be reported to the manufacturer and the competent authority.

LOT NUMBER AND EXPIRY DATE

The above are printed on each package and should be quoted in all correspondence which requires identification of the product.

DISPOSAL

Dispose of the product according to local regulations as applicable.

USERS/FOR PROFESSIONAL USE ONLY

These materials have been developed for use exclusively by dental professionals and must be handled according to the instructions of use. The recommendations included in the instructions correspond to the actual state of knowledge regarding dental techniques. This does not relieve the user from determining the suitability of the product for its intended purpose. The manufacturer cannot be held responsible for damages caused by other uses or incorrect handling.














REPORTING OBLIGATIONS

Should a serious incident in relation to this product occur, it should be reported to the manufacturer and the competent authority.

NOTE

The Summary of Safety and Clinical Performance (SSCP) can be found at the European Database on Medical Devices (EUDAMED) at <https://ec.europa.eu/tools/eudamed>. Basic UDI-DI: 5206569COMP425A

SYMBOLS GLOSSARY

	Medical device		Catalogue number
	Consult instructions for use		Batch code
	Caution		Use-by date
	Keep away from direct sunlight		Unique device identifier
	Temperature limit		Manufacturer
	Do not re-use		EU conformity mark
	Distributor		



DMP Dental Industry S.A.
Kalyvion Avenue, Markopoulo
Industrial Zone,
Attiki 190 03, Greece
Tel: +30 22990 23041,
www.dmpdental.com



Perfection Plus Ltd
6 Westwood Court
Brunel Road, Totton
Hampshire
SO40 3WX, UK
www.perfectionplus.com
Regulatory@perfectionplus.com

