

RestorePLUS Core Build

Instruction For Use

RestorePLUS Core Build dual-curing flowable core build-up composite, is a radiopaque, two component (base-catalyst) polymer-based material. As it possesses dual-curing properties, the material self-cures therefore light curing is optional. Radiopacity values are ≥ 1 mm of aluminium.

SPECIALLY FORMULATED FOR USE IN DENTISTRY

IDENTIFICATION

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 2, Class 3

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 (40% by wt.)

Inorganic fillers containing barium glass and mixed oxides (60% by wt. or 49% by vol.). Filler particle size: 0.04-3.0 μ m

Photo-initiators

Benzoyl peroxide

Stabilizers

INDICATIONS

- Cores build-up
- Post cementation

WORKING AND SETTING TIMES

Working time* (minutes)	2:00
Total self-curing setting time* (minutes)	3:30

Attention!

Application is at 23°C \pm 2°C / 73°F \pm 4°F, 50 \pm 5% relative humidity. Higher temperature reduces working and setting times and lower temperature prolongs working and setting times.

Light cure keeping the tip of the light as close to the surface as possible. Light cure with a halogen, LED light (≥ 400 mW/cm²).

Curing wavelength 470±20nm.

Light curing time:

40 seconds (400-1000mW/cm²) / 20 seconds (>1000mW/cm²)

DELIVERY SYSTEMS

RestorePLUS Core Build Cartridge (automix -ratio 1:1)

Load the cartridge onto the appropriate handheld dispenser following the manufacturer's instructions. Once loaded remove cap and extrude material until it exits both chambers at the same rate and then mount the appropriate mixing tip. An intra-oral tip may be placed on the mixing tip. After use either leave the used mixing tip as a cap until the following application or carefully remove mixing tip and place cap immediately taking care not to cross contaminate the materials. Intra-oral tips and mixing tips are for single use only.

RestorePLUS Cor Build Syringe (automix ratio 1:1)

Remove cap of syringe and extrude material until it exits both chambers at the same rate and then mount the appropriate mixing tip. An intra-oral tip may be placed on the mixing tip. After use carefully remove mixing tip and place cap immediately taking care not to cross contaminate the materials. Intra-oral tips and mixing tips are for single use only.

APPLICATION

POST CEMENTATION: Select appropriate post and prepare root canal following the instructions of the manufacturer. Once preparation has been completed take care not to contaminate the surfaces. If core build up will follow, place appropriate bonding material on the tooth surfaces beyond the post following the corresponding instructions of use. Prepare the post according to the instructions of the manufacturer. Dispense RestorePLUS Core Build evenly and gradually directly into the root canal. In order to avoid air bubbles always keep tip of the mixing/intra-oral tip immersed in the material. Insert the post carefully and apply slight pressure until the post is steady. Light cure the surface. Core build up can commence once polymerization has taken place.

CORE BUILD UP: Prepare tooth by removing existing restorations and caries. In case of pulp exposure, a calcium hydroxide lining should be applied. Place a matrix strip around the prepared tooth to isolate. Conduct etching and bonding according to the chosen technique and following the corresponding instructions of use. Dispense RestorePLUS Core Build evenly and gradually placing an increment of 2-3mm taking care to prevent voids. Light cure the material and then place larger increment. If a crown form is used load directly into crown form and place the loaded crown on to prepared tooth. Allow the preparation to self-cure and remove matrix. It is advisable to light cure the surface.

PRECAUTIONS

- The material is adversely affected if the mixing ratio of 1:1 is not kept
- Carefully assess the use of the adhesive to be applied
- It is not recommended to use a lentulo spiral to place Bright Flow Core into the root canal
- Replace 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
- 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 allergic to any of the ingredients

STORAGE

Store at 4-25°C (39-77°F). Storing material in refrigerator is recommended. Storage conditions must be kept to guarantee material stability.

Caution: Do not freeze, do not expose to direct light or other heat sources. Return to room temperature before use.

Keep material out of reach of children.



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.

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: 5206569COMP42SA

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		

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