

BridgelT Temporary Crown and Bridge Material

Instruction for Use

BridgelT Temporary Crown and Bridge Material is a self-curing, radiopaque, polymer-based material, for the production of temporary crowns and bridges. A two-component material which is compatible with other commercially available self and light curing polymer-based materials.

SPECIALLY FORMULATED FOR USE IN DENTISTRY

IDENTIFICATION

Product Name	BridgelT Temporary Crown and Bridge Material
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

PP010/1610 – BridgelT Temporary Crown and Bridge Material 75g A2 & 6 Mixing Tips

PP010/1611 – BridgelT Temporary Crown and Bridge Material 75g A3 & 6 Mixing Tips

INTENDED USE

Dental temporary 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 resins

Inorganic fillers

Initiators

Stabilizers

INDICATIONS

- Temporary crowns and bridges
- Temporary inlays and onlays

Working and Setting Times

Working time (dispensing and insertion in the mouth)* (minutes)	0:40 – 1:00
Setting time (curing time in mouth) (minutes)	1:00 – 2:30
Trimming and finishing* (minutes)	4:00 – 6:00

Attention!

*Application is at 23°C ±2°C (73°F±4°F), 50± 5% relative humidity. Higher temperature reduces working and setting times and lower temperature prolongs working and setting times.

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.

DELIVERY SYSTEMS

BridgeIT Temporary Crown and Bridge 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. 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. Mixing tips are for single use only.

APPLICATION

Take a preliminary impression of the area with an appropriate impression material following the corresponding instructions of use. Trim interdental excess and remove undercuts from the impression. Prepare the impression accordingly and cut drainage channels. Remove the pontic area when constructing a temporary bridge. Clean and dry the impression.

Dry the prepared teeth and level out any undercuts in the preparation using appropriate material (e.g. wax). Then lubricate the prepared teeth and surrounding tissue, along with any linings or composite core build ups, with Vaseline or similar separating medium. Apply BridgeIT Temporary Crown and Bridge Material directly into the impression ensuring the tip of the mixer is immersed in the material to avoid the formation of bubbles. Do not overfill. Follow the working and setting times as indicated above.

After removal of the temporary from the impression carefully trim excess with scissors or diamond bur (after 4 to 5 minutes). Remove the oxygen inhibition layer from the temporary by wiping it with alcohol and polish if desired. Cement the temporary prosthesis with a non-eugenol temporary cement. Check occlusion and adjust accordingly.

CUSTOMIZING AND REPAIR OF TEMPORARIES

In case of immediate fracture of the temporary after manufacturing it, re-connect the fracture with freshly mixed BridgeIT Temporary Crown and Bridge Material.

In case of fracture of older temporaries, roughen the fracture with a bur and place undercuts. Apply a bonding agent on the prepared fracture and cure according to the corresponding instructions for use. Apply BridgeIT Temporary C&B Material to the prepared areas. Press parts together for approximately 3 minutes. If necessary, finish the appropriate points after 5 to 6 minutes. Alternatively, BridgeIT Temporary C&B Material temporaries can be repaired with flowable composites following the above technique.

PRECAUTIONS

- The material is adversely affected if the mixing ratio of 1:1 is not kept
- 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
- Wear face mask and goggles when finishing the temporary to avoid dust getting into the eyes and respiratory tract
- 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 patient is known to be hypersensitive or 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 children's reach.

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
















Caution:

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: 5206569COMP46SJ

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		