

INSTRUCTIONS FOR USE

DuraLay Temporary Crown & Bridge

Temporary Crown and Bridge resin material

DESCRIPTION:

Temporary Crown and Bridge resin material consist of powder and liquid reagents for making non-permanent tooth-colored acrylic crowns and bridges meant to last for 6 months in the mouth. Powder reagents (Polymethyl Methacrylate, Benzoyl Peroxide, and Titanium Dioxide) and liquid reagents (Methyl Methacrylate Monomer) are combined to form a custom-made temporary crown and bridges. The device is supplied as non-sterile.

INTENDED PURPOSE:

The intended use of the Temporary Crown and Bridge resin material is temporary repair and restoration of damaged or missing teeth prior to the insertion of permanent restorations. The materials contribute to oral health, stability, and long-term durability.

INDICATION FOR USE:

In individuals as preparation for receiving permanent crowns or bridges.

In individuals with large cavities or major structural tooth defects, for patients requiring interim protection for treated teeth or awaiting permanent restorations.

To protect prepared teeth or dental implants until permanent restorations are ready.

To serve as a temporary fix in dental emergencies, allowing patients to function and feel more comfortable until a comprehensive treatment plan is established.

INTENDED PATIENT POPULATION:

Intended to use in patients above 25 years of age.

INTENDED USER POPULATION:

The material is used by a dentist or a lab technician in a dental laboratory.

EXPECTED CLINICAL BENEFITS:

Metal-free aesthetic restorations to the patient

PERFORMANCE CHARACTERISTICS:

Good fracture strength

Color stability

Easy repair

Good shear bond strength

CONTRAINDICATIONS:

Not to be used in contact with damaged mucosa membrane.

Not to be used if the patient with Periodontal Disease/ Uncontrolled Gum Disease.

Not to be used in patients with Ongoing Dental Infection.

Not to be used in patients with hypersensitivity or allergy to materials.

LIMITATIONS:

The Material should not be used for purposes other than the identified intended purpose herein.

Do not use Off-labeled device.

MODE OF ACTION:

When a liquid monomer is mixed with a powder of polymer in a specified mixing ratio, the mixture undergoes polymerization through chemical curing activation. The polymerized resin is composed of numerous monomer units linked together to form a long-chain polymer. The polymerized resin is moulded to form temporary bridges, and crowns.

WARNING

The materials are combustible, Avoid sources of ignition. Store as per the storage instructions.

The materials are not supposed to be used beyond their shelf life.

Do not smoke in the presence of open containers.

Dispose of material in accordance with local, state, and country laws.

PRECAUTION

Liquid may cause skin irritation. Avoid contact with skin, eyes, and clothing.

Wash hands and exposed skin thoroughly after handling.

Seek medical advice/attention if there is any irritation to the skin/eyes.

Wear protective gloves and safety glasses with side shields or chemical splash goggles.

Avoid breathing dust/fumes/gas/vapors and use with adequate ventilation.

Surrounding gingival tissues should be protected from the material.

Exposed vital dentin should also be protected from the material.

In case of accidental contact, immediately remove the offending material and flush the surrounding area liberally with water.

An allergy test is recommended prior to use of monomers in the mouth.

NOTE: See Safety Data Sheet (SDS) for complete information. SDS is available at reliancedental.net or by contacting the manufacturer.

RESIDUAL RISKS/ UNDESIRABLE SIDE EFFECTS:

Materials may cause irritation or allergies to skin or mucous membranes due to residual monomers.

WARRANTY:

Manufacturer warrants this product to be free from manufacturing defects for four years from date of manufacture. Warranty is void if product is not used for intended purpose, not used as instructed, or not stored in the original container.

DISPOSAL:

Dispose of material in accordance with local, state, and federal regulations. When scrapped, the powder is not considered hazardous. Discarded liquid is a hazardous waste by the EPA under RCRA. It is the responsibility of the generator to determine at the time of disposal whether the product meets the criteria of a hazardous waste.

STORAGE CONDITIONS:

Close bottles tightly after use. Store in original container in a dry, well-ventilated location, away from sources of ignition and light, at room temperature.

SUPPLY:

This IFU is applicable for the following Packages

2503 - DuraLay Crown & Bridge package (4 x 56g powder/2 x 60mL liquid)

INSTRUCTION:

For an extended mixing and setting time, store powder and liquid in the refrigerator (4-7°C).

ATTENTION:

In order to avoid uncontrollable chemical reactions and contaminations, please use only mixing jars/dappen dishes and spatulas/brushes which do not get in contact with other resins.

MIXING INSTRUCTIONS:

1. Take an impression prior to doing any preparatory work, using alginate, rubber base, silicone or hydrocolloid. Lay aside and keep moist.
2. Complete all tooth preparations and then lubricate teeth with Vaseline or a silicone lubricant.

3. Dry impression thoroughly. Apply sufficient liquid directly to impression with medicine dropper and add powder. Dispense powder from plastic bottle by shaking lightly until liquid is absorbed. More liquid and powder can be added if needed. For temporary crown, using crown form, fill form half full of liquid and add powder until liquid is absorbed.
4. After impression or crown form is filled with DuraLay, wait one minute for dull appearance. Reset in mouth in proper position. Working time is 3 minutes from start of mix. The impression can then be removed from the mouth without distorting. Set impression on bench for complete hardening, which is approximately 5 minutes from the start of mix.
5. Remove DuraLay from impression or crown form and trim excess. The temporary crown or drive is finished and polished with stones or carbine burs and conventional composite polishing instruments, then cemented into place.

BASIC UDI-DI: ++D94725033Z

REPORTING:

In case of any adverse events related to the device, it must be reported to the manufacturer & Competent Authority.

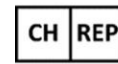
COMPETENT AUTHORITY DETAILS:

DE/CA37, Regierungspräsidium Stuttgart
Address: Ruppmannstraße, 21, Stuttgart, Germany
Email: abteilung9@rps.bwl.de

EXPLANATION OF SYMBOLS:

EXPLANATION OF SYMBOLS	
Symbol	Title
	CE Logo with Notified Body number
	Manufacturer
	Swiss Authorised Representative
	Authorized Representative in the European Community/ European Union

	Date of Manufacture
	Batch code
	Use-by Date
	Catalogue Number
	Caution
	Keep away from Sunlight
	Unique Device Identifier
	Upper limit of temperature
	Medical device
	Consult instructions for use or consult electronic instructions for use
	Importer
	Distributor
	Keep dry
	Country of Manufacture



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