

INSTRUCTIONS FOR USE

DuraLay Inlay Pattern Resin

Inlay Resin Material

DESCRIPTION:

Inlay resin material consist of powder and liquid reagents used as direct technique for cast posts and cores, fabricating copings, connecting metal copings, transferring copings, connecting a metal casting to a removable partial denture, stationary dies, inlay impressions, bite registration, implant attachments, adhesion bridges, clasps, telescoping crowns, lingual and palatal bars, and certain pre-soldering techniques. The device is meant to last for 2-3 minutes in the mouth and is composed of powder reagents (Polymethyl Methacrylate, Benzoyl Peroxide) and liquid reagent (Methyl Methacrylate Monomer) blended in a certain ratio to produce a custom-made pattern. The device is supplied as non-sterile.

INTENDED PURPOSE:

The intended purpose of the device is to take an impression of the tooth after the dentist drills into it and accurately capture the structure and details of a patient's teeth. The device is then removed and sent for casting. It is also appropriate for connecting bars and transfer copings.

INDICATION FOR USE:

The device is indicated to use as direct technique for cast posts and cores, fabricating copings, connecting metal copings, transferring copings, connecting a metal casting to a removable partial denture, stationary dies, inlay impressions, bite registration, implant attachments, adhesion bridges, clasps, telescoping crowns, lingual and palatal bars, and certain pre-soldering techniques.

The device is indicated to be used in impression purpose for old, deteriorating dental fillings, especially when the existing filling is large or has become damaged.

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

Easy repair

Good shear bond strength

CONTRAINDICATIONS:

Not to be used in contact with damaged mucosa membrane.
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 molded to form Impressions.

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
2244 - DuraLay Standard package (56g powder/60mL liquid/lubricant/dropper)
2244-C - DuraLay Standard package (56g powder/60mL liquid/lubricant/dropper)
2249A - DuraLay Laboratory package (224g powder/240mL liquid/lubricant/dropper)

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.

INSTRUCTIONS FOR USE:**DURALAY BRUSH METHOD****DIRECT APPLICATION:**

1. Pour a small portion of DuraLay powder into one dappen dish and about 6 drops of DuraLay liquid into another.
2. Dry cavity of tooth with blast of air and coat with a thin film of DuraLay lubricant to facilitate removal of pattern. Brush off excess.
3. Dip small brush in liquid and then into center of powder (do not touch dish) to pick up a bead on tip of brush. Place in base of cavity. If mix is too thick to flow into place, dip brush into liquid again and touch it to the mix
4. After floor of cavity is covered, use large brush in same manner to pick up larger quantities and fill in remainder of preparation. Flow of DuraLay can be controlled and directed with brush to approximate shape of tooth.
5. When pattern is set (this will take an additional two minutes after last layer is applied), check bite, trim margins and carve as desired, in or out of the mouth, with bur, disk, or rubber wheel.

6. For casting, tack on sprue with wax, and invest and burn out in usual manner. The DuraLay patten will volatilize in 40 minutes at 800°F / 427°C leaving no residue.

INDIRECT APPLICATION:

The DuraLay Brush Method is equally fast and accurate for building patterns for inlays and bridges on stone, investment or amalgam casts. Rub DuraLay lubricant into model and apply DuraLay beads in same manner as for direct inlays.

MATRIX BANDS - On M.O.D.'s three-quarter crowns and full crowns, a metric is recommended. The matrix will separate easily from the hardened DuraLay. Trim pattern to desired shape, resetting in position to check; then add contract points.

PACKING METHOD - Make a very thin mix using approximately equal portions of DuraLay powder and liquid by spatulating on a cement slab or stirring in a dappen dish. Then pack into matrix-contained cavity with instrument. Cover with cellophane or tinfoil and have patient to occlusion to secure compression. Hold in position until pattern hardens. Remove from tooth; trim to desired shape.

USE OF WAX - Contact points and occlusal surfaces may be added with inlay wax after DuraLay vase or core has hardened. Wax may be used also for three-quarter and full crowns, linguals, occlusals, and to check margins.

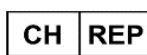
UNDERCUTS - If undercuts exist in the preparation, it will be necessary to disk or bur through the pattern, remove it, adjust preparation, and reconstruct pattern.

HANDLING - As DuraLay liquid evaporates during building process, the resin forms a dense, accurate, non-shrinking pattern that may be trimmed, handled, and invested without fear of breakage, chipping, distortion or temperature changes. A DuraLay pattern is almost indestructible.

PLASTIC TEETH - No separating foil is necessary except when bite is against plastic teeth or fillings, or when packing method is used.

UPPER TEETH - For upper teeth, it is best to place first bead of DuraLay in gingival portion of preparation. Enough of it will adhere to gingival section to form a base and permit building of additional layers.

EXPLANATION OF SYMBOLS:

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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

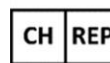


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