PULSETEMP (AUTOMIX 10:1) **Instructions for Use**
Automix Temporary Crown & Bridge Material

Product description
PULSETEMP (AUTOMIX 10:1) is an automatically mixed two component material in AUTOMIX-cartridges based on multifunctional methacrylic esters. PULSETEMP is a very easy and comfortable material for creating short- and long-term temporary crowns or bridges, inlays, onlays and veneers. The material is especially suitable for longer bridge spans because of its flexibility. PULSETEMP (AUTOMIX 10:1) shows fluorescence in UV-light.

PULSETEMP (AUTOMIX 10:1) is free of methyl methacrylate. Its temperature derived while curing is lower than 40 °C / 104 °F. As a temporary crown or bridge it protects the prepared teeth against external influences and preserves the occlusion. It shows increasing transverse strength, good abrasion resistance and low polymerization shrinkage. It fits perfect. Showing good polishability, good color stability and fluorescence - it looks perfect.

And if PULSETEMP (AUTOMIX 10:1) breaks - which may happen with acrylics - it is easy to repair. Cured material can be repaired with any natural or light cure composite building up again a chemical link. In nearly every property PULSETEMP (AUTOMIX 10:1) is superior to the common materials based on monomer/polymer systems. It allows thin edges and production of longer bridge spans.

Indications/Intended use
• Fabrication of temporary crowns, bridges, inlays, onlays and veneers

Performance features
The performance features of the product meet the requirements of the intended use.

Contraindications
Do not use for patients with allergic reactions against acrylates. PULSETEMP (AUTOMIX 10:1) should not be used any more, if allergic reactions are observed.

Patient target group
Persons who are treated during a dental procedure.

Intended users
This medical device should only be used by a professionally trained dental practitioner.

APPLICATION
1. Impression taking
Before preparation of the crown or bridge or prior to extraction of a tooth, take an impression using silicone or alginate. For better stability of the temporary, carve out interdental areas. In molar areas with teeth absent, it may be necessary to cut a groove in the impression between the abutments to create a bridge-like connection between the tooth units.

Note: Block out undercuts and if necessary, cut grooves into the impression.

2. Preparing of the cartridge
Twist and pull out the cartridge cap and discard. Do not reuse. Attach one of the supplied mixing cannulas and turn the cannula 90° clockwise until it locks in position. The application gun is loaded with the prepared cartridge and is ready for application.

Note: Prior to each application, discard the initial extrusion (pea-size) from the mixing cannula. The following mix is ready to use.

Leave the used mixing cannula on the cartridge. It serves as a cap.

3. Application
PULSETEMP (AUTOMIX 10:1) is automatically mixed when dispensed with slight and even pressure directly into the impression. Fill the impression in the relevant spaces from bottom up to prevent voids.

4. Forming of the temporary crowns or bridges
a. Dispense PULSETEMP (AUTOMIX 10:1) into the impression.
b. Seat the impression within the working time (50 seconds at 23 °C/74 °F) onto the prepared teeth.

After 1-2 minutes (setting time in mouth at 37 °C/98 °F) the material shows a hardened but elastic condition and can be removed from the teeth together with the impression. (alternatively: 3-4 minutes setting time on the model)

Note: The setting reaction must be checked intra-orally (e.g. with a dental probe). The oral temperature has a significant effect on the setting reaction and the temporary can only be removed without destruction during the elastic state.

5. Post-curing and finishing
If possible, leave the temporary in the impression during post-cure.

For optimal results, the temporary is post-cured in warm water (45-55 °C/ 113-131 °F), e.g. in a hot cure polymerization device until reaching its final hardness (approx. 4:30 minutes from start of mix). Post-cure at room temperature is completed after about 6 minutes from start of mix.

After the temporary cured completely, remove excess material and proximal undercuts. If necessary, the temporary can be refined with rotary instruments and polished to high gloss.

Do not breathe polishing dust; use suitable mouth protective device and safety goggles!

Note: Before finishing, completely remove the smear layer on the surface formed by the oxygen in the air. It can easily be removed by alcohol or other suitable solvents.

6. Cementing of the temporary
For PULSETEMP (AUTOMIX 10:1) temporary crowns or bridges, use eugenol-free temporary cement. Eugenol may prevent and inhibit curing reaction. Leaves eugenol residue.

7. Repairs of the temporary
PULSETEMP (AUTOMIX 10:1) temporaries show high mechanical strength. In case a temporary breaks the following procedures are recommended:

a. Fracture shortly after production
Repair both ends of the fracture with freshly extruded PULSETEMP (AUTOMIX 10:1).

b. Fracture of longer existing temporary
Clean and roughen the fractured area to provide mechanical retentions. Apply freshly extruded PULSETEMP (AUTOMIX 10:1). To speed up curing time, the processed provisional can be placed in warm water for a few minutes.

8. Special Note
Non-hardened PULSETEMP (AUTOMIX 10:1) can easily be removed with alcohol or other suitable solvents.

9. Storage
Do not store above 25 °C / 77 °F. Do not use after expiry date.

10. Additional notes/Warnings
- PULSETEMP (AUTOMIX 10:1) is free of methyl methacrylate but contains other acrylates.
- Avoid contact with skin, mucous membrane and eyes.
- If the material comes into contact with skin, immediately wash with water and soap. If the material comes into contact with eyes, immediately rinse with copious amounts of water and seek medical advice if required.
- For sensitive skin, sensitization to the material cannot be excluded. If allergic reactions are observed, the material should not be used. Do not use for persons with allergic reactions to acrylates.
- Commercial medical gloves do not protect against the sensitizing effect of methacrylates.
- Keep away from children!

Composition
Unsaturated esters, multifunctional methacrylates, multifunctional acrylates, malonyl urea derivatives, dental glass, silicon dioxide, catalysts

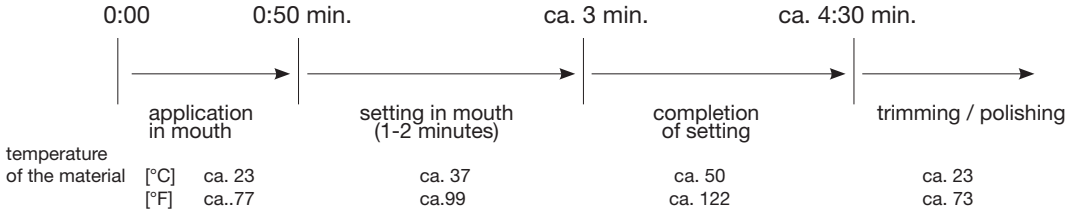
Disposal
Disposal of the product according to local authority regulations.

Warranty
Manufacturer warrants this product to be free from manufacturing defects for one year from date of purchase. Warranty is void if product is not used for intended purpose or not used as instructed.

Limitation of Liability
Except where prohibited by law. Lang Dental Mfg. Co., Inc. will not be liable for any loss or damage arising from this product, whether direct, indirect, special, incidental or consequential, regardless of the theory asserted, including warranty, contract, negligence or strict liability.

℞ Only

Time Table of application and curing of PULSETEMP (AUTOMIX 10:1)



If the completion of setting takes place at room temperature, the provisional can be trimmed and polished after 6 minutes from start of mix.

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