

Instructions for use

XPLEX

COLD/ HOT-CURING HIGH IMPACT DENTURE BASE MATERIAL



ENGLISCH

XPLEX

POLYMER / MONOMER

1. INTRODUCTION

Dear customer,

You have acquired a medical device. Please ensure that you file the LOT number and product name in your administrative system on receipt of the product. For each piece of work that you produce, please make a note of all the materials used along with all the appropriate LOT numbers. For your own protection as well as for your patients and the environment, please also follow the important guidelines in these instructions for use.

The dual-purpose, cold/hot-curing high impact denture base material for XPLEX is characterized by its good pour and modeling properties. The set processing time has a positive effect when several saddles are filled. The high-impact modification (impact strength according to EN ISO 20795-1) improves the physical properties of the material and thus offers high fracture strength.

Various finishing processes are available to the dental technician for processing as a hot-curing denture base material.

The dental technician can choose between two different techniques for processing as a cold-curing denture base material – the pouring technique and the pressing technique.

Both processing procedures (hot and cold processing) are explained in more detail in the attachment in the section "Application".

The system consists of a polymer "XPLEX Polymer" for cold **AND** hot processing, a monomer "XPLEX Monomer Cold" for cold processing and a monomer "XPLEX Monomer Hot" for hot processing.

The XPLEX Polymer is available in the following CANDULOR shades: F1, F3, F5, F34, F53, F55 and F57.

2. INTENDED USE

Intended Purpose

Cold-/Hot-Curing High Impact Denture Base Material

Use

For dental use only!

Description

Cold processing	Hot processing
<ul style="list-style-type: none">• Full dentures• Partial dentures• Combined dentures• Implant prosthetics• Repairs	<ul style="list-style-type: none">• Full dentures• Partial dentures• Combined dentures• Implant prosthetics

Indication

Edentulism

Contraindication

In the event of allergy to one of the constituents of XPLEX.

Limitations in use

Avoid direct contact of unpolymerized material within the oral cavity.

Side effects

No systemic side effects have been reported to date. In individual cases, local allergic reactions to PMMA/MMA-based denture base materials have been reported.

Composition

Powder (polymer)

Polymethyl methacrylate, contains dibenzoyl peroxide

Liquid (monomer)

XPLEX Monomer Cold

Methyl methacrylate, butanediol-dimethacrylate

XPLEX Monomer Hot



Methyl methacrylate, ethylene glycol dimethacrylate

Physical properties

Properties	Unit	Guaranteed values	
		Hot curing	Cold curing
Flexural strength	MPa	≥ 65	≥ 60
Flexural modulus	MPa	≥ 2000	≥ 1500
Maximum stress intensity factor	MPa m ^{0.5}	≥ 1.9	
Total fracture work	J/m ²	≥ 900	
Residual amount MMA	%	≤ 2.2	≤ 4.5
Water absorption (7 days)	µg/mm ³	≤ 32	
Solubility (7 days)	µg/mm ³	≤ 1.6	≤ 8.0

3. APPLICATION

Mixing ratio

Cold processing	Hot processing
 <p>13 ml 20 g</p> <p>POURING TECHNIQUE PRESSING TECHNIQUE</p>	 <p>9 ml 23 g</p> <p>PRESSING TECHNIQUE</p>

Processing

Important

- The matrix and model must be well soaked in water.
- Apply two coats of ISO-K and allow to dry thoroughly.
- Roughen the teeth well and wet with monomer to ensure proper bonding with the denture base.

- The denture material should be thoroughly mixed with a suitable spatula (approx. 30 sec.).
- Avoid cooling quickly in cold water (causes stress cracks).
- Adhere to the recommended mixing ratio.
- Ideally, Candulor flasks should be used.
- Ensure compliance with the polymerization parameters.
- Condensation-curing silicones (K-silicones) can have a damaging effect on the prosthesis material.
- Varnishing dentures is not recommended.
- The use of solvents can damage the base of the prosthesis.

Cold processing

Pouring technique

1. Preparation

Isolate boiled out, well-watered plaster surfaces twice with ISO-K and allow to dry thoroughly. To ensure proper bonding with the denture base, roughen the teeth well with a milling cutter and wet with monomer.

2. Dosage

Ideal mixing ratio for dentures:

20 g polymer : 13 ml monomer

The specified powder/liquid ratio ensures optimum material properties.

3. Mixing

Mix the powder and liquid thoroughly in the mixing ratio or as required and blend thoroughly for 30 seconds using the spatula. Then allow to stand for 15 seconds so that any air bubbles can escape from the material.

4. Pouring phase

The pouring phase lasts approximately 1.5–3 minutes at 23°C / 73°F. During this period, allow the material to pour into the flask or matrix.

5. Modeling phase

After a transition phase of approx. 4 minutes, the material is stable and can still be modeled for approx. 5 minutes.

Attention: The higher the room temperature, the shorter the pouring and modeling phase! The resin must be placed in the pressure vessel after a total processing time of approx. 12 minutes at the latest.

6. Polymerization

Polymerization takes place in the pressure vessel for 15 minutes at a temperature of 50°C / 122°F and a pressure of 2–6 bar / 29–87 psi (check).

7. Finishing

After removing the pouring flask or matrix, finish in the usual manner.

Pressing technique

1. Preparation

Isolate boiled out, well-watered plaster surfaces twice with ISO-K and allow to dry thoroughly. To ensure proper bonding with the denture base, roughen the teeth well with a milling cutter and wet with monomer.

2. Dosage

Ideal mixing ratio for dentures:

20 g polymer : 13 ml monomer

The specified powder/liquid ratio ensures optimum material properties.

3. Mixing

Mix powder and liquid in the specified mixing ratio with the spatula and mix well for 30 seconds.

Put the lid on the mixing beaker and leave to stand for roughly 8–10 minutes. The resulting mixture is then workable for a period of approximately 4 minutes.

Attention: The higher the room temperature, the shorter the working and setting times!

4. Pressing

Place an ample amount of the mixture in one half of the flask which must be at body temperature and which you have previously wetted and isolated with ISO-K. Close the flask carefully, place it under the press and apply a pressure of 80 bar / 1160 psi.

5. Polymerization

Polymerization is performed in the press under constant pressure for 30 minutes at a room temperature of 23°C / 73°F.

6. Removal and finishing

Open the flask, remove the plaster and finish in the usual manner.

Repairs and corrections using XPLEX

Corrections and repairs can be performed with XPLEX Cold (cold-curing denture base material). The contact surfaces must be well roughened and wetted with XPLEX Cold Monomer.

Hot processing

Pressing technique

1. Preparation

Isolate boiled out, well-watered plaster surfaces twice with ISO-K and allow to dry thoroughly. To ensure proper bonding with the denture base, roughen the teeth well with a milling cutter and wet with monomer.

2. Dosage

Ideal mixing ratio for dentures:

23 g polymer : 9 ml monomer

The specified powder/liquid ratio ensures optimum material properties.

3. Mixing

Mix the powder and liquid thoroughly in the mixing ratio or as required and blend thoroughly for 30 seconds using the spatula. Put the lid on the mixing beaker and leave to stand for roughly 12–15 minutes (at a room temperature of 23°C / 73°F).

4. Processing time

As soon as the material no longer sticks after the maturing period, it can be processed for approx. 20 minutes at 23°C / 73°F.

5. Pressing

Place resin dough together with excess in the flask halves. Close the flask carefully, place it under the press and apply a pressure of 80 bar / 1160 psi.

Maintain pressing pressure!

6. Polymerization

Hot-curing can be performed according to various procedures:

Standard workflow

Place the closed flask in cold water, heat to 100°C / 212°F and allow to boil for 45 minutes.

Variants

- Place the flask in cold water, heat to 70°C / 158°F and leave for 30 minutes, then heat to 100°C / 212°F and allow to boil for 30 minutes.
- Place the flask in 70°C / 158°F warm water and leave for 60 minutes, then heat to 100°C / 212°F and allow to boil for 30 minutes.
- Place the flask directly in boiling water and boil the water again for 40 minutes. Only suitable for small and medium-sized dentures!

Note:

To obtain the lowest possible residual monomer content (<2.2%), the standard procedure is recommended.

7. Cooling

Allow the flask to air dry for at least 30 minutes, then cool completely in cold water. Allow the flask to cool completely before opening. Avoid cooling quickly in cold water!

8. Removal and finishing

Open the completely cooled flask and remove plaster. Finish in the usual manner after the occlusal check.

Repairs and corrections using XPLEX

Corrections and repairs can be performed with XPLEX Cold (cold-curing denture base material). The contact surfaces must be well roughened and wetted with XPLEX Cold Monomer.

4. SAFETY NOTES

Danger warnings

- The monomer contains methyl methacrylate (MMA).
- MMA is an irritant and easily flammable (flash point: + 10°C / 50°F).
- MMA and its vapors are irritating to the eyes, respiratory system and skin.
- May cause sensitization by skin contact.
- Do not inhale vapors.
- Keep away from sources of ignition – no smoking.
- Do not empty into drains.
- Avoid contact of the skin with monomer and uncured material. Many commercial gloves, e.g. those made of latex or vinyl, are not monomer-resistant and therefore do not provide protection against the sensitizing effect of methacrylates.
- Wear a mask when grinding and use a suction removal system.
- Always use a spatula when handling the mixture.
- Take precautionary measures against static discharges.
- Avoid direct contact of unpolymerized material within the oral cavity.

In the event of serious incidents that have occurred in connection with the product XPLEX, please contact the manufacturer CANDULOR AG, Boulevard Lilienthal 8, 8152 Glattpark (Opfikon), Switzerland, www.candulor.com and your local health authority.

Any residual XPLEX must be disposed of in accordance with national legal regulations.

Safety data sheets can be found on our website at www.candulor.com.

The current instructions for use are available on the CANDULOR AG website in the download area: www.eifu.candulor.com.

Please ensure that you always have the latest version available, which you can find in the download section of the Candulor website.

If you wish to receive the instructions for use in paper form, please contact the manufacturer CANDULOR AG. To do this, please use the telephone number or the e-mail address on the last page of these instructions for use. The instructions for use will be sent to you free of charge by post within seven days.

5. STORAGE INSTRUCTIONS

Store material in a dark, cool and well-ventilated place. Storage temperature: 2–28°C / 36–82°F. Do not use products after the expiry date. Expiry date – see instructions on packaging. Store out of reach of children.

6. NOTE

The denture resin has been developed solely for use in dentistry and must be handled strictly in accordance with the instructions for use. The manufacturer cannot be held liable for any damages arising as a result of failure to observe the instructions for use or the stated area of application. The same applies in the event that the product is mixed or processed with other manufacturers' products. The user shall be solely responsible for testing the material with respect to its suitability prior to use for any purpose other than those explicitly stated in the instructions for use.

EXPLANATION OF SYMBOLS



Catalogue number



Batch code



Use by date



Manufacturer



Mfg. date

Date of manufacture



Serial number



SEE INSTRUCTIONS
EIFU.CANDULOR.COM

Consult instructions for use on the website



Storage temperature



AVOID SUNLIGHT

Keep away from sunlight



MEDICAL DEVICE

Medical device



Do not re-use



Packaging consists of polyethylene



CONTAINS/ENTHÄLT
DIBENZOYL PEROXIDE

Attention! – Contains dibenzoyl peroxide!



Contains/Enthält: Methyl methacrylate
Flash point/Flammpunkt: 10 °C



Danger! – Contains methyl methacrylate!
Flash point is 10°C.



Authorized representative in the European
Community

CE 0123

Rx ONLY

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