JUELL™ Cure · SOFT SOFT RELINE MATERIAL

Carefully read instructions prior to use

JUELL CURE – Soft is a self curing, A-silicone-based and permanently soft relining material for removable dentures. Its autopolymerizing, cold-curing properties assure that JUELL CURE – Soft is simple and quick to use for direct as well as indirect soft relinings. JUELL CURE – Soft is suitable for all PMMA-based dentures.

The **JUELL CURE – Soft** kit contains the following: a bottle of adhesive liquid (a primer that ensures a strong bond between the prosthesis and the relining material), a double-chamber dispenser safety cartridge containing glazing base and catalyst for sealing and smoothing rough surfaces.

Indications:

JUELL CURE – Soft is intended for use as a permanent soft relining for total and partial dentures

- To relieve pressure from points
- To dam the palatal vibrating line
- In cases of flabby ridge and/or insufficient adhesion
- To cushion sharp-edged alveolar processes
- To support the healing process in implantology

Contraindications:

JUELL CURE – Soft contains silicone compounds and a platinum catalyst. **JUELL CURE – Soft** adhesive contains butanone and methacrylates.

Do not use in cases of known allergies to these ingredients.

Applications:

1. PREPARING AND COATING THE DENTURE

CLEAN THE DENTURE

Clean denture thoroughly with a brush and dry. Always remove any existing relining. Grind down all areas to be relined to at least 1mm to allow a later relining of at least 2mm. Prepare vestibular, lingual and dorsal rims e.g. in the form of a chamfer. Round off the rims of the denture. Clean denture and dry with air. Remove grinding dust with a brush or dry with oil-free air. Do not use water or a vapor jet. Then degrease the denture surface by wetting a dust-free cloth with isopro-panol or pure alcohol (90% or higher) and wiping the surface clean. Let aerate for 1 min. Humidity, additives (i.e. cavity cleaning agents), saliva, monomer-containing synthetic liquids or touching will diminish the adhesion of **JUELL CURE – Soft** to the denture.

APPLY ADHESIVE

- Remove the cap from the adhesive bottle and replace it with the cap-brush. Do not use the brush cap for the alcohol.
- Apply a thin, even and complete coat of adhesive to denture surfaces to be relined.
- Close the adhesive bottle immediately after use and store in an upright position.
- Allow the adhesive-coated surfaces to dry for 1 min.

APPLY THE JUELL CURE - Soft PASTE

Insert the JUELL CURE – Soft cartridge into the JUELL CURE – Soft Dispenser gun (SC-DISP) or any dispenser with a suitable plunger. Should differences in the filling level of the chambers occur, remove the transport cap from the safety cartridge and extrude material until the chambers deliver evenly. Then fix and lock the mixing tip (MIX-SC) with a clockwise 90° turn. The material is extruded and automatically mixed in the correct ratio by pressing the dispenser lever. After use, leave the mixing tip on the safety cartridge and replace or use the transport cap.

Apply the mixed material first to the lingual/dorsal rim, then to vestibular site. Finally, coat the base also. Make sure to cover all areas carrying adhesive with silicone. JUELL CURE – Soft should be applied at least 2mm thick on all surfaces to be relined. After mixing, JUELL CURE – Soft has a working time of 1 min and 45 s.

2a. DIRECT RELINING IN THE MOUTH:

- 1 min after coating with JUELL CURE Soft, the denture can be inserted in the patient's mouth.
- Have the patient gently bite in a normal occlusion and hold this position for about 1 min.
- Have the patient gently carry out chewing and swallowing motions for about 5 min.
 - CAUTION: Check for and remove any excess of JUELL CURE Soft to avoid inadvertent swallowing. Tell the patients to alert the dentist if, at any time, they feel relining material moving towards their throat.
- Remove the denture approximately 6 min from the time it was seated in the patient's mouth.

IMPORTANT: Strictly observe the above-stated time intervals

Finishing should be started 10 min after the relined denture is removed from the patient's mouth. Any earlier finishing must be carried out with extreme care.

CAUTION: JUELL CURE – Soft should not be aspirated or ingested. Care must be taken to ensure that excess material is quickly removed from the patient's

To ensure excellent soft relining, the working and the intra-oral setting time must be followed exactly. Should the temperature of material significantly deviate from 24°C (75° F), both times will be affected.

2b. INDIRECT RELINING IN THE LABORATORY:

When relining has to be carried out in the laboratory, prepare the denture and coat it with JUELL CURE – Soft. Then, isolate the plaster model with a formaldehyde-free separating agent for synthetic materials according to the instructions for use provided with the separating agent. Place the denture coated with JUELL CURE – Soft on the model and fix both in the relining jig or casting flask. Shape function rims with a metal spatula or a clean plaster knife. After shaping, let JUELL CURE – Soft set for 5 min, then place the relining jig (loaded with the denture and the model) into a pressure unit for 15 min at 104° F – 112° F (40° C – 45° C). Allow the relining setup to cool for 20 min. IMPORTANT: At no time should the denture, plaster model or relining device be worked on with stream jet.

3. FINISHING THE RELINING:

Any excess material can be removed with a fine, sharp pair of scissors or a scalpel. Finish the denture with a finishing bur that is suitable for use on flexible materials. Polish with the enclosed polishing disk or other suitable disk.

4. CORRECTIONS:

Immediately correcting the relining is possible. Rinse the relining with water and dry, apply fresh **JUELL CURE – Soft** paste, shape and let it set in the mouth for 7 min or in the pressure unit for 5 min.

Any later correction of the relining (within 2 weeks) can be carried out after removing the top layer of the **JUELL CURE – Soft**.

5. SEALING (GLAZING)

Glazing is used to seal and smooth surfaces treated in step 3. It is important that rough areas (e.g. surfaces left after trimming excess material) be glazed in order to prevent accumulation of food particles or discoloration. Glazing is prepared by mixing equal amounts of base and catalyst.

For better dosing, hold each bottle vertically with the dropper pointing down and let air bubbles rise to the top. Apply an equal number of drops of glazing base and glazing catalyst onto a mixing slab. Mix to homogeneity with a disposable applicator brush. Brush a thin coat of the mixture onto the finished relining surfaces. The working time of JUELL CURE – Soft is 2 min. The setting time is 10 min at room temperature. Cooler conditions prolong the setting time. The setting time can be shortened to 3 min by using a pressure unit with a temperature of 104° F – 113° F (40° C).

Close bottles immediately after use.

Attention: Keep the correct cap on each bottle.

Glazing Base = white cap Glazing Catalyst = red cap

Additional Information:

- Sandblasting can be used for roughening the surface during denture
 - preparation. Afterwards, carefully clean with pure alcohol. Refrigerating **JUELL CURE Soft** will prolong working
- and setting times and cannot be changed by altering quantities of the catalyst paste.
- Always adhere to the indicated setting times to achieve an optimal adhesive bond between denture and relining.

Storage:

Keep containers tightly closed and store below 75° F (24° C). Do not use after expiration date. Shelf life of the components is stated on the package.

Clinical Precautions:

- Process JUELL CURE Soft at room temperature.
- If the patient is uncertain about allergies, a patch test should be performed by extruding a small amount of JUELL CURE – Soft, allowing it to set and applying it to the patient's arm under a piece of dressing tape or bandaid for 24 hours. DO NOT apply uncured JUELL CURE – Soft to the skin.
- Advise patients of the possibility and signs of silicone sensitivity. Instruct them that if signs of sensitivity occur, they should immediately remove the denture and contact their dentist.
- Avoid contact of JUELL CURE Soft components with the eyes. Should contact occur, flush thoroughly with water and contact a physician.
- Avoid skin contact with uncured components of the JUELL CURE –Soft. Should contact occur, immediately clean with alcohol and flush thoroughly with water.
- Avoid contamination after denture fabrication. Contamination may lead to incomplete curing of JUELL CURE Soft / glazing and an irritating taste in the mouth.

- For finishing, use the enclosed polishing disc or other suitable burs or polishing discs for flexible materials.
 Do not inhale silicone or synthetic dust when finishing the denture or the relining. Wearing a protective mask is recommended.
- Seal only the rough, finished surfaces (functional rim) with glazing to prevent accumulation of food residue or discoloration.
- Severe injury can result if uncured material is ingested or aspirated. During direct relining, be sure to remove excess material from the palatal area and ensure that no excess material moves towards the throat or esophagus.

Additional Instructions:

The **JUELL CURE – Soft** relining can last 1-2 years. The period varies on the patient's intra-oral conditions. Avoid spilling uncured materials on clothes. Patients should be advised that the relined denture: Should only be cleaned using a special soft denture brush or a toothbrush with abrasive-free cleanser (e.g. neutral soap) and after cleaning, should be thoroughly rinsed with water.

- Should be stored in water, not be exposed to strong bleach and be routinely examined as well as treated for plaque accumulation.
- Should be inspected once every 3 months by the dentist

Product Order Numbers:

COMPLETE JUELL SOFT CURE KIT	JCS-1
10 ml each of glazing base/catalyst	SCAT-1
Refill 50 ml safety cartridge, mixing tips type 8	SCAR-1
Refill 10 ml adhesive	SADH-1
Refill 20 ml glazing	SBAS-1
Mixing tips type 8, 50 pieces	JMIX-1

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CAUTION: U.S. Federal Laws restrict this device to sale by or on the order of a dentist.

No person is authorized to provide any information which deviates from the information provided in the instruction for use.

For questions or comments, please call 1-800-243-7372

Keep this material out of reach of children. For dental use only.



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