ENA Soft FLOW

(EN) ENGLISH
Instructions for use

Description
Ena Soft Flow is a light-curing temporary dental filling material. Ena Soft Flow is an elastic material for dental temporary restorations. It has advantage of easy removal in one piece without damage to preparation. Ena Soft Flow is suitable also for long term temporaries because it perfectly maintains the shape of tooth. It can be used also for luting temporary veneers.

Intended purpose
Dental temporary restorations. Luting of temporary Veneers
Benefits:
- simple to apply: not sticky;
- easy to remove in one piece;
- suitable for temporary inlay & onlay;
- perfect for luting and sealing of temporary veneers.

Composition:
- Organic matrix: UDMA, HEMA
- Inorganic fillers: silicon dioxide
- Additives: Initiator, Catalyst, Stabilizer, Others

Indications
Patients that have been treated for pathogenic or aesthetic reason and need:
- temporary fillings especially for inlay & onlay
- temporary luting especially for veneers

Intended user
Dentists in dental office and hospitals
Patient target group and medical condition
Children 6 - 18 years, adults 19 - 64 years, elderly 65 – above, of any sex and condition.
Patients that have been treated, for pathogenic or aesthetic reasons, with a preparation for inlay/onlay or veneer.
Contra-indications: Uncured resin could cause skin allergy: If a patient has known hypersensitivities towards a component of this product, we recommend not to use it or to do so only under strict medical supervision.
Hazard statements: The product contains substances that may cause an allergic skin reaction.
Precautionary statements: To reduce the risk of all allergic response, minimize exposure to uncured materials. If allergic reaction occurs, seek medical attention as needed. Be careful not put in contact with eyes and use only in oral cavity. Use protective mask.
Avoid breathing dust/fume/gas/ mist/vapours/spray. Wear protective gloves. If skin irritation or rash occurs: Get medical advice/attention.
Side effects: With proper use of this medical device, unwanted side-effects are extremely rare. Reactions of the immune system (allergies) or local discomfort, however, cannot be ruled out completely. Should you learn about unwanted side-effects – even if it is doubtful that the side-effect has been caused by our product – please kindly contact us. Any serious incident relating to the device must be reported to the manufacturer (Micerium S.p.A.) and to the competent authority of the Member State in which the user and/or patient is established.
Materials to be avoided: Materials containing phenolics (like eugenol) could inhibit composite curing. Avoid the use of these materials as liners.

Instructions for use
1) Unscrew the cap and place a disposal application needle (minimum 1,2 mm diam.).
2) Prepare the cavity.
3) Clean the cavity and dry it.

Dental temporary restorations
- Apply sufficient amount of Ena Soft Flow, depending on size of restoration.
- Check occlusion and then remove excess material.
- Light-cure for 10 seconds, for a 4 mm thickness, and for 20 seconds, for a 8 mm thickness, using a led (like CLEDPLUS – Micerium) or halogen light-curing unit with more than 1000 mW/cm^2 power (if between 550 mW/cm^2 and 1000 mW/cm^2 double the time).
- The restoration can be removed with an instrument: it comes out in one piece.

Luting of temporary Veneers
- Application of Ena Bond inside the temporary veneers: blow away completely liquid excess and light cure for 40 sec.
- “Spot” etching, with a small ball of etching gel (Ena Etch – Micerium) only in the middle of the tooth.
- Application of Ena Seal on the tooth
- Application of Ena Soft flow inside the temporary veneers
- Temporary Veneers positioning in place and control

- Residual cement removal
- Light cure for 40 sec. each side (Buccal and palatal)
- Temporary veneers can be removed without any residue

Disinfection / Protection from cross-contamination
Place the syringe with attached delivery tip into a suitably shaped barrier sheath; pierce end of sheath with cannula, exposing the cannula for use. Using a barrier sheath facilitates cleaning and disinfection of the syringe between patients. After use of sheathed syringe, remove delivery tip and sheath by grasping on the hub of the delivery tip through the sheath; twist and remove tip along with sheath. Discard used tip and sheath in appropriate waste stream. Replace syringe storage cap.
Disinfection - After removing the application tip and the sheath, disinfect the syringe using an intermediate-level disinfection process (liquid contact) as recommended by the Centre for Disease Control and endorsed by the American Dental Association. Guidelines for Infection Control in Dental Health-Care Settings - 2003 (Vol.52; No. RR-17), Centre for Disease Control and Prevention (USA).

USE AND STORAGE
Do not store below 3°C/38°F and above 25°C/77°F. Shelf life at room temperature is 24 months. Ambient temperatures routinely higher than 25°C/77°F may reduce shelf life. Avoid direct exposure to sunlight. Do not use the product after the expiration date (see label on syringe). Use the material at room temperature. Avoid package contamination. Do not store materials in proximity to products containing Eugenol. Medical device, for professional dental use only: keep away from children. Pull the piston back after taking out the material, in order to stop the flow of the material, and close the container. After use, close container with cap and keep it closed.
Disposal: parts and accessories in direct contact with patient's mouth must be sterilised before disposal or disposed of as special waste. Disposal of the medical device must be carried out in accordance with local regulations. Contaminated packaging can be disposed of, after cleaning, in the separate collection of rubbish in accordance with the identification symbols, if applicable (97/129 EC).

Troubleshooting

Trouble	Cause	Remedy
Material does not cure	Luminous intensity of the polymerization unit insufficient	Check luminous intensity; replace light source, if necessary
	Emitted spectral range of the polymerization unit insufficient	40 sec. for temporary veneer luting 10-20 sec. for temporary inlay/onlay minimum 1000 mW/cm^2 depending on thickness Double time for 650 mW/cm^2
Material seems to be too hard/ firm inside the syringe	Material was stored at temperatures below 3°C/38°F for a longer period of time	
	Syringe was not closed tightly which caused part of the material to cure	Close syringe correctly with the cap after each use

MSDS available on website: www.micerium.com

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